DOCTORAL THESIS

Understanding Failure in Digital Health Implementation – A Case Study of Implementing Computerised Cognitive Behaviour Therapy (cCBT) in Estonia

Melita Sogomonjan

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Declaration:
Hereby I declare that this doctoral thesis, my original investigation and achievement, submitted for the doctoral degree at Tallinn University of Technology, has not been submitted for any academic degree elsewhere.

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signature

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Contents

List of Publications

The present Ph.D. thesis is based on the following publications that are referred to in the text by Roman numbers:

I Sogomonjan, M. (2020). Challenges and Opportunities for e-Mental Health Policy: an Estonian Case Study. *Contemporary Social Science, 16*(2): 185–198.

II Sogomonjan, M., Kerikmäe, T., Ööpik, P. and Ross, P. (2019). A Report on the Survey. Attitudes of Estonian Healthcare Professionals to Internet-delivered Cognitive Behavioural Therapy. *Cogent Psychology, 6*(1).

III Hantrais, L., Allin, P., Kritikos, M., Sogomonjan, M., Anand, P., B., Livingstone, S., Williams, M. and Innes, M. (2020). Covid-19 and the Digital Revolution. *Contemporary Social Science, 16*(2): 256–270.

IV Txarramendieta, J., Fullaondo, A., Keenoy, E. M., Vis, C., Etzelmuller, A., Pinto, A. G., Sierra, M., Piera, J., Fernandez, S., Cavallo, M., Carniato, S., Williams, B., Gokay, D., Sogomonjan, M. and Vallejo, L. (2017). Final Trial Report 2nd Wave (cCBT). MasterMind Project. Final Trial Evaluation, Deliverable 6.5, WP6 - Internet Based Guided cCBT for Treatment of Depression, V2.0. EU Commission.

V Sogomonjan, M., Kerikmäe, T. and Ööpik, P. (2018). A Review Article on Internet-based Psychological Interventions in Primary Care. What is the Global Experience? How Reliable Are Results from RCTs? Lessons Learned from the European, US and Australia Case Studies. *Baltic Journal of European Studies, 8*(2): 146–163.

Author's Contribution to the Publications

I The author of this dissertation is the sole author of the article.

II The author is the lead author. She conceived and designed the analysis of research. The author conducted the case study on physicians' attitudes towards using Internet-delivered cognitive behaviour therapies and developed the content, including the introduction, empirical analysis and discussion. She participated in collecting the underlying data in her role as a project manager at TalTech.

III The author analysed both the opportunities for implementing cCBT services and the barriers to successfully doing so.

IV The author was involved in conducting the research and contributed by writing on the impact of the Covid-19 pandemic on e-mental health policy in Estonia. The author analysed how the current pandemic accelerated the use of digital mental healthcare services.

V The author is the lead author. She performed a deep literature review of randomised clinical trials and investigated the effectiveness of guided versus unguided Internet-delivered cognitive behavioural therapies in primary care in the EU, USA, and Australia. She conducted the research and developed the content, including the introduction, methodology analysis, discussion and conclusions.

Abbreviations

AI	Artificial Intelligence
CBT	Cognitive Behaviour Therapy
cCBT	computerised Cognitive Behaviour Therapy
ccVC	Video Conferencing for Collaborative Care
EAAD	European Alliance Against Depression
EC	European Commission
EU	European Union
HCIT	Healthcare Information Technology
ICT	Information Communication Technology
IS	Information System(s)
IT	Information Technology
MasterMind	Management of Mental Health Disorders Through Advanced Technology and Services – Telehealth for the Mind
NHS	National Health Service
NSRF	National Suicide Research Foundation
PREDI-NU	Preventing Depression and Improving Awareness Through Networking in the EU
TalTech	Tallinn University of Technology

Terms

Healthcare	Refers to systems through which medical services are provided.
Health care	Refers to services provided by healthcare professionals by dint of the healthcare system.
e-Health	e-Health refers to: (1) services provided by the healthcare professionals delivered digitally, online and/or by computer; (2) a healthcare system through which digital health services are provided.

1 Introduction

"Orandum est ut sit mens sana in corpore sano"
(One must pray for a healthy mind in a healthy body)
Decimus Junius Juvenalis, Satire X,
End of the 1st century CE

This thesis aims to understand implementation failures in digital health services. It focuses on the of implementation failure of a computerised Cognitive Behaviour Therapy (cCBT) in Estonia. The failure of cCBT in Estonia is case study. Nevertheless, this research helps to identify the factors that led to failure in ways that address pitfalls of similar initiatives. Most importantly, this study offers guidance information for future decision making and implementation strategies.

Cognitive Behaviour Therapy (CBT) is the most widely practiced and researched form of problem-focused psychotherapy (often called "talk therapy") in the world (David et al., 2018; Knapp et al., 2015; Hofmann et al., 2012). It is used to treat specific problems associated with diagnosed psychological disorders (Beck et al., 2021). CBT has been labelled as a gold standard in psychological treatment (David et al., 2018).

The goal of treatment is to allay symptoms and achieve specific, predefined objectives. CBT has been recognised by the American Psychological Association as an evidence-based and effective treatment for depression. It has been included in the practice guideline for the managing patients with major depressive disorders (Gelenberg et al., 2010). It is also considered as a first-line therapy in many complex disorders of childhood, adolescence and adulthood, in particular when combined with psychopharmacological measures (Big Health, 2021; Gelenberg et al., 2010). CBT has been included in the Estonian guidelines for treatment of depression (Kleinberg et al., 2011).

While there are many discussions about the use of CBT in combination with psychopharmacological interventions (and suggestions that it is most effective when used in this manner), there have been many reports indicating that CBT alone is effective for mild to moderate depression, anxiety and post-traumatic stress disorders (Todd et al., 2022). It may also be combined with other forms of psychotherapy and with additional psychosocial interventions (Goodyer et al., 2016). The idea that CBT could be effective in the online treatment of depression was well supported.

Based on analogous principles emanating from CBT, cCBT has been deployed to treat common mental health disorders (Rosenberg et al., 2023; Health Quality Ontario, 2019) remotely through online software programmes or through a specific mobile application (Gratzer et al., 2016).

Some of the sentinel studies that demonstrated both the clinical efficacy and the cost effectiveness of cCBT were undertaken in Great Britain more than twenty years ago (Proudfoot et al., 2004; McCrone et al., 2004). The data suggested that cCBT improved the outcomes of patients in a general practice setting independently of age, gender, duration of pre-existing illness, or concomitant drug therapy. These conclusions were based on trials involving cCBT in the remote treatment of common mental health problems in primary care.

Following the publication of these studies, the deployment of cCBT and other therapeutic techniques based in emerging digital healthcare information technologies (HCIT) accelerated. The increasing demand for HCIT-based therapy can be linked to (i)

increased awareness of the problem; (ii) an increase in the number of channels offering information about treatment options; (iii) the availability of technology; (iv) the impact of mental health disorders (Rehm et al., 2019) on the global economy[1] (OECD/EU, 2018; Patel et al., 2018); (v) the opportunity for patients to manage their own care (Bucci et al., 2019); and finally (vi) the challenges associated with the treatment of psychological disorders during the covid-19 pandemic and lockdown measures set up by the governments (Liu et al., 2021; Prati et al., 2021; Serafini et al., 2020; Rossi et al., 2020; Van Mulukom et al., 2021).

Currently, various examples and embodiments of cCBT programmes are in use. They are categorised according to their duration (short- vs long-term), whether they are patient-guided or unguided, and whether or not they are goal-oriented (Gratzer et al., 2016; Health Quality Ontario, 2019). Usually, cCBT programmes consist of six to twelve modules. Content may differ according to the condition being treated (Gratzer et al., 2016). To start using any of cCBT programmes, individuals must possess some familiarity with computers and at least some limited digital skills, Internet access, smartphones, and a tablet or a computer.

Research on cCBT or other patient facing HCIT software deployment, implementation and impact reflects many different perspectives on this topic. A partial list of perspectives includes information technology (IT), medicine, psychology, law, public administration, operations research and management sciences. Because the research draws upon a wide range of disciplines, the different scholars engaged in HCIT digital or (e-)health, and healthcare systems research have predictably approached their studies from several different points of view.

Information Technology (IT), for example, has focused on the development of digital mental health technologies (Garrido et al., 2019; Hill et al., 2018). Medicine and psychology have focused on the potential for new modes of therapy and their clinical effectiveness (Berger et al., 2017; Johansson et al., 2019). Legal scholars have focused on the regulation of digital mental health and in particular, on the protection of personal information (privacy) processed by digital mental health information technologies (Bhugra et al., 2017; Gooding, 2019; Huckvale et al., 2019). Social scientists in general, and particularly scholars of public administration and public health, have focused on the user experience, user satisfaction, the regulation of digital mental health, and population-facing outcome assessment including cost-effectiveness, and access (Iyamu et al., 2021; Linos et al., 2021, James et al., 2017; Simonet, 2015). Therefore, a matrixed perspective to address cCBT implementation and deployment in a comprehensive and holistic way is required. Any comprehensive approach to the study of cCBT must be interdisciplinary.

The challenges and risks associated with the implementation of digital mental health information technologies are legion. New interventions in the healthcare sector need to be tested for safety and effectiveness. This is a time-consuming process (Murphy et al., 2020). Because IT is a fast-paced and quickly changing sector, a particular

[1] The global burden of mental health disorders is a major public health concern accounting for 32.4% of years lived with disability and 13% of DALYs (Disability-Adjusted Life-Years) (Mathers et al., 2008; Vigo et al., 2016). Between 2010–2030, the increasing prevalence of mental disorders worldwide was projected to incur a cost of over US$16 trillion to the global economy (Patel et al., 2018). Across the EU countries, the total costs of mental health problems are estimated to amount to more than 4% of the GDP, which is equivalent to over 600 billion EUR per year (OECD/EU, 2018).

technology in healthcare may be altogether outdated by the time it is validated and verified (Mohr et al., 2017; Mohr et al., 2017).

Indeed, the pace of progress and the replacement of applications by new versions may cause concerns among patients and professionals alike (Bertl et al., 2022; Torous et al., 2020; Bhugra et al., 2017; Torous et al., 2017). The centrality of technology to digital mental health means that the characteristics of a specific user interface may influence the therapeutic relationship[2] and the outcomes of intervention (Bertl et al., 2023; Berry et al., 2017). The effects of these characteristics may not be linear. Thus, small changes may have daunting and unforeseen effects. In addition, should breaches of privacy occur, they may result in data corruption or data falsification, possible discrimination, and other problems related to outcome assessment and the legality of the data for use. The social repercussion may be equally non-linear (Bhugra et al., 2017; Gooding, 2019; McKee et al., 2019).

Estonia seems to be the ideal test case to study the introduction of cCBT. Estonia is considered to be one of the most digitally advanced countries in the European Union (Randma-Liiv et al., 2017) and has one of most comprehensive digital ecosystems in the world (European Commission, 2021). The country is widely recognised as a leader in the digitalisation of public services (Ronzaud, 2020; Toots et al., 2017). It is often called e-Estonia because of its many e-services (Ronzaud, 2020) well-developed e-governance system (Kerikmäe et al., 2021), and its excellent and widely disseminated e-health capacity (Ćwiklicki et al., 2020; Metsallik et al., 2019; Zilgalvis et al., 2015).

Nevertheless, in the area of digital mental health solutions, Estonia has lagged behind a number of ostensively less digitally advanced nations including, for example, Denmark, the Netherlands, Sweden, Canada and Australia. The introduction and implementation of digital mental health initiatives has been successful. In these countries, success has been ascribed to a robust combination of local and national policy initiatives, and of regulatory and funding mechanisms that have been put in place. As a result, digital mental health solutions are widely available (Burns et al., 2014; McGrath et al., 2018).

In Estonia, even though there are no particular impediments ensconced in public policy, and the digital ecosystem supports the introduction and further deployment of cCBT on its surface, the lack of public investment in digital mental health information technologies and the reluctance of relevant professionals to engage with these technologies have prevented digital mental health initiatives from reaching their goals (Thiel et al., 2018).

Thus, when the European Commission announced the financing of two funded projects to contend with the mental health needs of the population in Estonia, it was widely anticipated that both projects would be implemented successfully and adopted rapidly. The two projects centred around a computerised form of CBT. One of the projects was called Preventing Depression and Improving Awareness through Networking in the EU (PREDI-NU) (EAAD, 2022). The second was called Management of Mental Health Disorders through Advanced Technology and Services – Telehealth for the Mind (MasterMind, 2018). The latter became known as the MasterMind project[3].

[2] The level of therapeutic support means the extent of involvement by a therapist to support patients enrolled in a cCBT program (usually depends on the therapist). Therefore, therapeutic support may be low (for example, patients are introduced to cCBT programmes only), medium (patients are given self-directed exercises with some follow-up) or high (cCBT is included in the treatment plan, with Internet-assisted follow-up and discussion) (Gratzer et al., 2016; Andersson et al., 2014).

[3] Further information about MasterMind project is available at:

The author of this thesis was appointed to serve as the project manager of the MasterMind project in 2014. She participated in the introduction and deployment of MasterMind project and this experience prompted an abiding interest in the study of mental health services delivered through information technologies and the assessment of their deployment, implementation and impact. This counter-intuitive outcome prompted a number of questions about digital or (e-)health services and ultimately led the author of this study to seek to position and understand this failure in a wider context.

The MasterMind project was intended to study the management of depression using information technology (then called as information communication technology or ICT). The primary goal of the project was to assess the impact of two technologies on depression. The first technology was cCBT. The second was the use of video conferencing for collaborative care and treatment for depression (ccVC). The second goal was to recruit a cohort of at least 5,000 patients across 9 EU and Associated Countries. ccVC was not piloted in Estonia.

Notwithstanding the wide availability of a variety of existing cCBT software programmes, Estonia piloted additionally a CBT Basic App mobile application developed specifically and uniquely for use in Estonia. Thus, Estonia piloted two cCBT programmes in sequence: first, an iFightDepression software program between 2014–2017, and second, a CBT Basic App mobile application between 2016–2017. The iFightDepression software program was deployed because it had already been translated into Estonian and had been introduced in conjunction with the PREDI-NU project between 2011–2014. The CBT Basic App mobile application was deployed for its ease of use, modern design and availability in Russian.

With an advanced digital eco-system already in place, Estonia should seemingly have offered a fertile field for the implementation of comprehensive digital mental health services to complement other aspects of digital or (e-)health systems already in place. Surprisingly, and in the face of all expectations to the contrary, the implementation of both projects in Estonia (PREDI-NU and MasterMind) failed. The failure of MasterMind project to deploy cCBT was rather unexpected and disconcerting.

These circumstances provided an ideal setting in which to study the reasons for the failure of implementing cCBT in Estonia, as well as to a failure analysis of digital health services more broadly. As a consequence of this analysis, this research offers recommendations on how to improve patient-facing digital mental health services and effectively integrate the advancements in HCIT into digital health systems in a more comprehensive and effective manner.

1.1 Focus of the Thesis

This thesis examines the characteristics of the programmes piloted in Estonia to highlight and study the flaws in deployment of the MasterMind project that impeded the successful implementation of cCBT. It is focused on the matters of, and the circumstances around introduction, deployment and adoption. It does not focus on the technology underlying the cCBT program.

(i) https://cordis.europa.eu/project/id/621000 and
(ii) https://web.archive.org/web/20160324223018/http://mastermind-project.eu/

The investigations conducted during this study examine the way MasterMind project was ushered in between March 2014 and March 2017. The thesis applies a failure analysis methodology for digital health services. While a variety of technology-based frameworks have emerged, they have not been consistently applied nor demonstrated adequacy in assessing failure of digital health services.

The first question that must addressed is whether we can be sure that the implementation of cCBT in Estonia really failed, and the basis on which we can reach that conclusion.

cCBT programmes were implemented initially as part of the broad MasterMind project initiative across 9 EU and Associated Countries: Denmark, Scotland, Wales, the Netherlands, Spain, Italy, Turkey, Germany, Norway, Estonia and Greenland. Of the countries listed, cCBT programmes were successfully implemented in Scotland, the Netherlands, Germany, Aragon and Barcelona (specific regions of Spain), Veneto (a specific region in Italy) and Turkey (MasterMind, 2018). Successful implementation throughout the EU was defined in terms of the number of patients recruited relative to a target recruitment figure to be achieved as of February 1st, 2017. Thus, successful recruitment was achieved in 7/11 regions, or 64%. The Estonian deployment of cCBT, however and therefore the implementation of MasterMind project (in Estonia), failed.

The second overarching question is what we can extract managerially, socially and medically from studying a project of this importance. There is ample potential for meaningful impact and social benefit. With this on background, an appropriately critical, but also comprehensive and ultimately constructive approach to failure analysis is of the highest priority (Heeks, 2003). The development of such an approach has been the key motivation for this study.

A framework for defining success and failure in project implementation has been applied. A conceptual framework of cCBT failure in a digitalised context is then provided.

The overarching aim of this research, therefore, extends beyond the examination of the specifics of the failed implementation of cCBT program in Estonia as part of the MasterMind project. It is imperative to elicit insights into its failure, to induce hypotheses of causation, to generate recommendations for enhancing patient-facing digital mental health services and to learn how to integrate advancements in HCIT into digital health systems generally.

Given the background of the case study under analysis, the following are the salient research questions:

1. How was cCBT implemented in Estonia? (RQ1)
2. What were the reasons and factors that contributed to the failure of cCBT implementation in Estonia? (RQ2)
3. What lessons can be learnt from cCBT implementation failure in Estonia to prevent failures of implementing other but similar digital health initiatives in future? (RQ3)

To answer these research questions, it is useful to begin by probing the content and context of digital mental health initiative in Estonia and compare this initiative to other relevant experience in the field. For this purpose, the thesis utilised the case study methodology.

The critical element, perhaps even the decisive factor contributing to the failure of the cCBT implementation in Estonia was a failure to recruit[4] practitioners and patients effectively. Both groups must be engaged.

The numbers are telling. In a pilot survey of Estonian healthcare professionals (n = 20) more than half expected that patients would benefit from cCBT (**II**). Fifteen respondents, for example, believed cCBT ought to be an integral and necessary part of psychiatric care that ought to be available for the population at large (**II**). Nevertheless, only 56 (18.7%) patients were successfully recruited from a very modest target number of 300 patients (**IV**). The failure to recruit professionals and patients could be viewed as the downfall of the project and the key factor leading to its failure.

The failure to recruit can be ascribed to a number of factors and biases. First, despite their assurances to the contrary, many practitioners may not have actually supported the dissemination of cCBT because of a belief that the lack of face-to-face doctor-patient communication would render it less effective than traditional psychotherapy (**II**). Second, even though cCBT seemed effective in mild to moderate depression, the community of practitioners had mixed reactions to use of cCBT for severe mental disorders. Finally, therapists were concerned that cCBT would increase their workload to the extent and in ways that it lowered the quality of patient care (**II**). Unfortunately, there were insufficient data to determine more specifically the basis on which practitioners formulated these opinions.

The failure to recruit was the critical element both because recruitment as an endpoint was both hard and measurable, and because it was the *sine qua non* to the success of the project. Had recruitment proved successful, studies around other critical measures, including effectiveness, cost-effectiveness, cost efficiency and public policy related to these measures would have followed. In the absence of adequate recruitment, however, such underlying data were not present.

The exercise of studying the failure of cCBT introduction in Estonia is more beneficial and revealing than the studying success stories around digital health incentives elsewhere. As noted by Karl Popper (1959), the success or failure of predictions is to be attributed not to the laws from which they are derived, but rather to the alignment or misalignment of these laws with the actual constitution of nature. Hence the impetus to review and analyse the causes of failure systematically.

Among the various theoretical and analytical frameworks that have been applied to the study of failure analysis, the most pertinent to this research is the context-oriented framework developed by Sauer (1993) to study failures in information systems (IS). Sauer (1993) relates IS failure to the organisational context (Kim et al., 2005). He construes IS failure, moreover, as failure of innovation process in an uncertain and constantly changeable environment (Toots, 2019).

Failure, he concludes, results in a "system abandonment due to stakeholder dissatisfaction" (Sauer, 1993; Toots, 2019, p. 548), to an extent that, "there is no longer enough support to sustain it" (Fitzgerald et al., 2005, p. 245). Whether the lack of support merely reflects failure or whether it results in failure is a question that will not be addressed here. Nevertheless, according to Sauer (1993), projects will ultimately, and perhaps even inevitably fail irretrievably if a project organisation lacks support and fails to manage the system (Dwivedi et al., 2015).

[4] Whether failure to recruit inevitably defines or results in overall project failure is an important question that merits further discussion. The answer is not as cut and dried as might be expected.

Sauer's (1993) framework draws upon on three main components that constitute what he called a triangle of dependencies: (i) an IS; (ii) project organisation and (iii) supporters. The triangle of dependencies, he described, function within the context of an environment (Kim et al., 2005). He considers the environment to be the forth element (Fitzgerald et al., 2005). These four elements are often called as contextual or termination factors (Mukherjee, 2008; Dwivedi et al., 2015).

The HCIT domain is inherently complex. Failures in HCIT not only involve the commonly mentioned determinants but also encompass failures in innovation. Sauer's framework does not adequately incorporate the role of innovation. For this reason, the author of this dissertation drew on an additional model in rounding out an explanation of the failure of cCBT deployment. This model was developed from Regina Herzlinger's model of innovation and impairments of innovation in health care (Herzlinger, 2006).

1.2 The Structure of the Thesis

This thesis investigates cCBT implementation failure in Estonia. It comprises original articles, co-authored by colleagues with diverse competencies and disciplines, as presented on the page 7. In the absence of multidisciplinary collaboration, this research endeavour would not have been feasible. The author specifically focused on perceived usefulness[5] and satisfaction of healthcare professionals when applying cCBT in their daily routine practice (**II**, **IV**) and public administration of mental health policy (**I**, **III**). Noteworthy, the earliest technology acceptance model used to explain the individuals' decision to accept, use or reject technological innovations and linked new technology adoption and acceptance to two basic measures: (i) perceived usefulness (utility) by the user and perceived ease of use (simplicity) by the user (Davis, 1989). The balance between the perceived usefulness and ease of use influences user motivation (Safi et al., 2018). Concomitantly, individual's motivation is higher if the technology is easy to use in terms of understanding how to use it, and in terms of the benefits the technology may provide.

Additionally, paper **V** is a comparative study investigating the effectiveness of guided cCBT programmes in different healthcare systems where such programmes have been successfully implemented. The case study of this research is based on these research articles. The results of these research articles provide an historical and psychosocial context for the case analysis. The contribution of the articles to answer the three research questions is provided below.

The first two research questions (1. How was cCBT implemented in Estonia? 2. What were the reasons and factors that contributed to the failure of cCBT implementation in Estonia?) are analysed in the articles **I**, **II** and **III**. The analysis reveals that the lack of public investment in, and governmental support for e-mental health interventions (comprehensive online diagnosis and treatment for mental illness) have hindered the comprehensive implementation of e-mental health initiatives in the public mental health sector in Estonia. The research papers present and discuss the factors that interfered with the adoption of e-mental health solutions and impeded its further implementation in Estonia. Additionally, the articles pose questions about the benefits and risks that emerge when comparing cCBT to face-to-face care and how funding and delivery mechanisms as well as the legal framework can reduce the burden and cost of care and

[5] Perceived usefulness is defined as user's subjective evaluation on how a new technology (here software) can improve the workflow and job performance (Safi et al., 2018).

improve the delivery of mental health services and mental health outcomes. Furthermore, article **III** addresses the proliferation of e-mental health in Estonia during the Covid-19 pandemic and elucidates the ways in which seemingly insuperable obstacles to the implementation of e-mental health were largely overcome. The opportunities and benefits that e-mental health provides are further analysed.

Lastly, article **II** and report **IV** provide insights and help to analyse the perceived usefulness and satisfaction of healthcare professionals when applying cCBT in their daily routine practice. The results showed that healthcare professionals were, in general, in favour of broadening the options available to improve the well-being of patients, however, they also expressed concerns around the suitability of cCBT for patients with more severe psychiatric conditions.

As noted earlier, some healthcare professionals considered cCBT less effective than traditional psychotherapy because of the lack of a direct physician-patient therapeutic relationship. They also were worried about increases in their own workload as a consequence of cCBT and feared that an increased workload might result in a lowered standard of care and increases in potential medical liability. Finally, healthcare professionals were often put off by a combination of the inherent limitations of the program and were dissuaded by lack of adequate technical support.

Finally, the answer to third research question is provided in this thesis (section 6) and supported by the international experience gained from other countries as analysed in the article **V** and report **IV**. The results from this analysis showed that guided cCBT is more effective in combination with other methods of care delivery (*i.e.*, cCBT plus standard of care, which may entail combinations of medications, psychotherapy and other modalities) for treatment purposes. Furthermore, the analysis revealed that while guided cCBT can be shown to offer some improvement in the control of mental disorders, it fails to demonstrate consistent improvement or to replace face-to-face therapy.

This thesis provides a comprehensive overview of the research conducted in these articles and is organised along the lines of these three topics. The research articles are presented in the form of a case study and contribute to answering the research questions in the following 6 sections.

Section 2 starts out with the methodology of the thesis in which the underlying articles are described. In the following section (3) the theoretical background of the study of failure analysis including frameworks for failure analysis in HCIT is presented. Section 4 starts out with the background of the case study. It examines Estonia as a valid testing ground for digital health services and sets out the failure analysis of cCBT implementation in Estonia using the contextual framework of Sauer (1993) and the operational framework of Herzlinger (2006). In section 5, the thesis provides a comprehensive discussion of the results of the analysis including the reasons of the failure of cCBT implementation in Estonia and limitations of the current study. The thesis concludes (chapter 6) with a summary of answers to research questions and recommendations that shall be considered.

2 Research Methodology

This thesis applies an explanatory case study approach as the main research methodology.

2.1 Case Study Research

From an academic perspective, the case study methodology represents a respected and notably well-established approach to information technology research (Benbasat et al., 1987). In particular, as emphasised by Recker (2013) and Walsham (1995), case study facilitates the explanation of complex interactive dynamics amongst information systems on the one hand, and of technology on the other. Additionally, case study methodology guides the understanding of key characteristics, meanings, and implications of the matters under consideration (McCombes, 2023). Finally, this methodology can also provide new insights for decision-making, policy development, and the establishment of best practices across various disciplines (Blatter et al., 2012; Hassan, 2022). Thus, the study of the MasterMind project was developed as an explanatory case study which focused on a single phenomenon in a real-life context (Yin, 2018). The single phenomenon was the failure to recruit practitioners and patients. Some additional observations might be in order.

First, the deployment of cCBT in Estonia was selected as an explanatory case study for several reasons. This is due to access to available data. A case study methodology is instrumental in elucidating an original issue within a specific context, drawing upon a range of data sources (Baxter et al., 2008). Overall, a case study delves into a specific problem rooted in a real-world situation applying original information as methodological instrument (Herrera et al., 2016).

Case studies are commonly used to gain contextual, in-depth knowledge about a specific real-world subject. As mentioned earlier, the author of this thesis was involved in the MasterMind project and had an opportunity to do observation and collect data. Given that Estonia possesses an effective and widely disseminated e-health system, the context in which the cCBT was introduced and deployed seemed highly conducive to successful recruitment. Hence, cCBT implementation in Estonia served as a suitable case for this study.

Second, a case study offers rich contextual information and a nuanced understanding of a specific phenomenon, thereby contributing to the development and refinement of theoretical frameworks (Robson et al., 2020). Contextualising failure opens a window on its components (Sauer, 1993; Van Der Blonk, 2003). While it is well understood that single case studies are unable to reveal generalisable statistical insights, they are still capable of informing theory providing useful guidance.

Third, the explanatory case study approach is selected because it is particularly useful for discovering and analysing the reasons of cCBT implementation failure in Estonia in-depth and why the expected outcomes were not reached.

Yin (2018) explained that the explanatory case study methodology is particularly effective due to its contemporary focus on phenomena within real-life situations, where the researcher has limited control over the occurrence of events. This approach enables the researcher to minimise potential biases that may arise during observations.

Yin (2018) also argued that a properly designed and executed explanatory case study has the potential to generate highly credible and generalisable conclusions. Therefore, while the analysis of a cCBT implementation failure in a highly digitised country like

Estonia may not directly produce externally valid statements applicable to the implementation of digital health services worldwide, it can serve as a basis for analytical generalisation (George et al., 2005; Miles et al., 2014; Yin, 2018).

The primary goal of this case study is to expand and further generalise existing concepts and theories rather than to extrapolate probabilities through statistical generalisation or serving design purposes (Yin, 2018, p. 21). This study is intended to serve as a starting point for future research, including the validation and discussion of the findings related to cCBT implementation.

Fourth, this study employs Sauer's (1993) theory of failure analysis as its framework. According to Sauer, failure results from the interaction of internal and external processes. Therefore, Sauer's theory is well-suited to explain the causal interactions between internal and external processes in the case. According to Sauer (1996), failure analysis cases are based on three criteria. The first criterium emphasises on stakeholders' perception of system failure. The second criteria underline sufficient historical data for tracking system evolution. Lastly, the third criteria focus on access to contextual information for comprehensive analysis of the case. The cCBT case meets these three criteria.

Fifth, to conduct this research, four primary sources of data were utilised: (i) the pertinent literature accessed through the scientific search engines; (ii) interviews with health care professionals to gather insights and perspectives on the subject matter; (iii) online survey of stakeholders involved in the research area; and (iv) participant observation to gain first-hand understanding and gather relevant data. By employing these multiple data sources, a comprehensive and multi-dimensional view of the research topic was obtained.

Given the explanation of case study selection above and considering that Estonia has an effective and widely disseminated e-health system, the context underlying cCBT introduction, deployment and adoption would appear to have been eminently suited to the purpose of recruitment. Thus, the MasterMind project, a cCBT initiative with a three-year history in Estonia, was a suitable case.

2.2 Methods of Data Collection and Analysis

Data for the case study were elicited through document analysis including project reports from 2014–2017 (MasterMind, 2018), project notes, meeting notes, emails, personal notes and working papers beginning in 2014 and extending through the duration of the project. Access to and collection of data for the case study was facilitated by the thesis author's appointment as project manager for MasterMind at TalTech in 2014. Policy documents, project reports papers and newspaper articles relevant to the study and healthcare statistical data were referenced and incorporated. The project notes included comprehensive statistics on data utilisation. Finally, personal and group interviews with participating health care professionals were conducted in September of 2016, and online survey was conducted in April of 2017. During the project lifetime, demographic data of healthcare professionals and patients as well as their perceived satisfaction and usability with the cCBT were assessed through a variety of questionnaires. A small number of patients were interviewed casually in 2016 but the number of patients was insufficient to support useful conclusions. Nevertheless, these conversations successfully provided a non-statistical signal reflecting patient attitudes towards the platform.

The following paragraphs provide additional details on the methods applied in the publications. This thesis utilises multiple methods to gather data on subject. The triangulation is needed to develop better understanding of the case study. Table 1 provides a concise summary of the methodologies applied in the research articles contributing to the development of this doctoral thesis.

Systematic literature reviews are applied to synthesise research findings in a systematic, transparent, and reproducible way (Davis et al., 2014). This method has been widely implemented in software engineering to evaluate research topic trustworthiness and severity (Kitchenham et al., 2007; Kitchenham et al., 2009). Furthermore, systematic literature reviews add value to the development and maintenance of software by integrating research evidence with practical experience and human values in the decision making process (Kitchenham et al., 2005).

This thesis incorporates research publications and conducts an analysis of the pertinent literature to identify, compile, critically appraise previous research and summarise the available empirical evidence to answer research questions in the articles **I–III** and **V** (Liberati et al., 2009; Higgins et al., 2022). A literature review has the power to address research questions by integrating findings and perspectives from multiple empirical studies, surpassing the capabilities of any single study alone (Snyder, 2019). Although, systematic literature reviews are prone to biases (Jackson et al., 2017), the method of reviewing articles in a transparent way lead to the objective evaluation and analysis of the available empirical data, minimising bias and facilitating the generalisation of research findings (Snyder, 2019; Delios et al., 2022). Therefore, in the areas where research is needed, effective and properly conducted systematic literature reviews contribute to the advancement of knowledge and the development of theoretical frameworks and conceptual models (Snyder, 2019; Webster et al., 2002).

Given that introduction, deployment, adoption and support of cCBT are approached from a variety of perspectives, the systematic literature reviews provided an overview of studies on effectiveness, satisfaction, adoption and implementation in healthcare settings, as well as on regulation and governance level. The results of the literature reviews are presented in publications **I–V**. The pertinent literature was retrieved using search terms extracted from academic research publications, reports and policy documents related to the topic. The information was collected through generic databases in English (Science Direct, PUBMED, SCOPUS, Web of Science) as well as specific databases for guidelines and standards. The selection of the results was based on the following criteria: (i) relevance to the objective, (ii) recency, and (iii) provenance.

The results from the desk research were verified and validated through the interviews, online surveys, and participant observation.

The qualitative methods used in the publications (**II**, **IV**) were aimed at in-depth and extensive understanding of the research theme primarily through the interviews and surveys with health care professionals, and participant observation. According to Bertrand and Hughes (2017) interviews are a useful method for data collection for at least three reasons: (i) interviews provide interviewees opportunity to respond to questions by their own terms, (ii) verbal answers are more informative compared to written answers, and (iii) interviews help to clarify from the participants what has been observed. The interviews conducted with health care professionals were semi-structured focus group interviews, lasted for 90 minutes. These interviews were conducted in a face-to-face context except for one individual interview that was conducted online. The focus

group interviews were time efficient, providing participants with an opportunity to be actively involved in the discussion (George, 2012; Morgan, 1996).

Lastly, in-person interviews are considered to be the gold standard in qualitative research in regard to validity and quality of response (Rahman, 2015). Nevertheless, the quality of the interviews, as well as technical difficulties that might arise (*e.g.*, training and skills of moderator in generating the data and the group itself) may impact the value of the results (Creswell et al., 2016; Morgan, 1996).

In this study, the interviews with clinical personnel were intended primarily to elicit impressions of needs of patients, the needs of professionals during the project implementation, the nature, quality and safety of cCBT in daily practice, the circumstances under which patients dropped out of the study, professional satisfaction with the services and program usability, factors facilitating and inhibiting adoption, and ideas around ideal implementation (**II**, **IV**). The output from the interviews was transcribed and systematically analysed across various thematic areas. This approach allowed for a comprehensive understanding of the data collected during the interviews. As most healthcare professionals who participated in the interviews held positions as heads of primary care centres, questions pertaining to the implementation of cCBT at the organisational level were directed towards them.

In addition to the qualitative methods of data collection introduced above, a qualitative survey was conducted to complete the interviews with health care professionals since the knowledge gained from the interviews and observation could have been misunderstood or misinterpreted and insufficiently discussed due to time limitations. Qualitative surveys aim to determine the heterogeneity of the research field within a given population (Jansen, 2010) and can elicit information about the attitudes of the participants that are difficult to measure using observational techniques (Glasow, 2005; McIntyre, 1999). Therefore, qualitative surveys allow to analyse the meanings and experiences of that population (Jansen, 2010).

For the purposes of this study, the online survey consisting of self-administered questionnaire directed at selected target group of participants having had experience with cCBT (**II**). Given the workload of the health care professionals, the survey was considered as one of the cost-efficient research methods requiring minimum resources (time). The survey aimed to identify the attitudes of health care professionals to cCBT including the needs, practical (technical), organisational, financial and legal limitations and opportunities in integrating cCBT into clinical and primary care practice (**II**). In present study (article **II**), the sample consisted of 22 health care professionals, and even though the sample might be criticised as small and inadequate representation, it is still adequate and of sufficient size given the time period when cCBT was introduced and piloted in Estonia. The survey included twenty-four open-ended and seven multiple choice questions covering three thematic areas. Health care professionals' views served to guide the recommendations around implementation strategies summarised in article **II**.

For the purposes of studying perceived satisfaction and usability with the cCBT programmes among health care professionals, two questionnaires were addressed. First, data were collected through the Client Satisfaction Questionnaire (CSQ-3), containing items 3, 7 and 8 of the CSQ-8 (**IV**). Empirically, these items are the most salient for the measurement of satisfaction with service and are used to provide a maximum amount of efficiency in obtaining data. The health care professional's perception of usability was measured with the System Usability Scale (SUS) (**IV**). These questionnaires are the most frequently used and referenced in measuring usability in European studies.

Observation is recognised as one of the four core and essential research methods to gain knowledge about a specific environment (Adler et al., 1994). Its value lies in providing researchers with systematic means to gain insights into organisations and understand phenomena or group perspectives within their natural settings (Baker, 2006; Iacono et al., 2009; Gorman et al., 2005). Observation as a scientific method for data collection is considered either as supplemental qualitative method to corroborate research findings systematically or as the main method focusing on specific research questions (Jamshed, 2014; Ciesielska et al., 2018).

In this study, participant observation was undertaken by the author of this thesis as she was appointed as project manager for MasterMind at TalTech in 2014. The observed environment consisted of primary health care settings and the population observed – health care professionals. While the results of observation is a function of the knowledge, expectations and previous experiences of the observer (Kraus, 2023), the criticisms refer to the risk of personal bias of the researcher possibly affecting the results of interpretation (Grinnell, 2013; Kraus, 2023).

Table 1. Data Collection Methods of the Publications (Source: Author)

Article	**Research questions**	**Data collection methods**
I	Why have e-mental health innovations not been readily embraced? What are the benefits and risks of cCBTs compared to face-to-face care? What are the funding and delivery mechanisms supporting the use of cCBT in Estonia? What regulatory framework is required if the e-mental health solutions adopted in Estonia are to reduce the burden and cost of care and improve the sustainability of health services and mental health outcomes?	Systematic literature review, observation
II	What are the limitations and barriers for the implementation of cCBT in primary care in Estonia? What are the experiences and attitudes of healthcare professionals regarding cCBT and its legalization?	Systematic literature review, qualitative self-administered online survey
III	How has the pandemic supported changes to the implementation of e-mental health treatments?	Systematic literature review
IV	What is the perceived usefulness and satisfaction of healthcare professionals when applying cCBT?	Interviews, questionnaires (CSQ-3, SUS), observation
V	What is the global experience of cCBT in primary care? Does cCBT work in the 'real world' in general practice? How reliable are the results from randomised control trials?	Systematic literature review

3 Theoretical Background

Failure analysis is designed to test against rigorous real-world standards of use. This is important because critical projects and products should be designed optimally to withstand any worst-case scenario. The latter, however, may vary in different environments.

Best practice in failure analysis requires specifying a standard of certainty. Explanations can be characterised as possible, likely, or definitive. The greatest advantage of objective failure analysis is that it does not judge the failure, the extent of failure or the causes of failure in advance. It focuses on a chain of causation rather than a single necessary cause (see Sauer framework, Figure 1).

One form of failure analysis is a matter of phased quality control – an important operational feature of software development (Booch, 2018; Campbell-Kelly, 2007; Lehr, 1984). Initially, failure analysis was focused on technical matters such as programming and software routines. Therefore, there is yet a tendency to think of HCIT failures in terms of technology alone (Kaplan et al., 2009).

In this study, the term failure analysis is a process that seeks to explain how and why project failed. It aims to understand both the events implicated in the failure, and to forestall similar events from happening in the future. It also seeks to uncover vulnerabilities in project planning and implementation, and errors in the innovation itself, communication and promotion processes. Therefore, in this section the author of this dissertation seeks to enrich the discourse on digital health services by introducing the concept of failure analysis. Given that digital health technologies form an integral part of the intricate health system, the application of failure analysis in this domain offers valuable perspectives for enhancing the delivery of digital or e-health services. Therefore, a thorough investigation of the causative factors behind the failure of digital health implementation is necessary. These factors encompass resource scarcity and stakeholder engagement (Föhn et al., 2023; Amirkhanyan, 2006), resistance to change and workflow disruptions (Zhu, 2017; Armbruster et al., 2013), inadequate political commitment, evaluation and monitoring (Frieden, 2014), limited user acceptance and engagement (Moynihan et al., 2012), and legal and regulatory obstacles (Gostin, 2000).

The focus of this thesis is to interpret the unsuccessful deployment of health technologies as a project implementation failure. To this end, this section initially offers a background on failure analysis, followed by defining what constitutes success and failure in project implementation. Subsequently, it presents a detailed overview of failure analysis in the deployment of digital health technologies, specifically highlighting why the healthcare sector experiences a significantly higher failure rate compared to projects involving only information systems. It is crucial to understand the failure in deploying health technologies, especially in the context of patient-facing therapeutic programs like cCBT, given that this area of research is currently underdeveloped. To delve deeper into this, the fifth part of this section introduces two frameworks that can be used to study the failure of digital health technologies: Sauer's Triangle of Dependencies (Sauer, 1993) and Herzlinger's Six Factor Framework (Herzlinger, 2006). These frameworks serve as valuable tools for understanding the failure process of information systems and identifying the key factors that contribute to successful deployment or, in other words, failure prevention. Finally, a summary of the frameworks used for failure analysis is presented at the conclusion of this section.

3.1 Failure Analysis of Digital Health Implementation

In this study, the term failure analysis refers to a process that seeks to explain how and why project failed. It aims to understand both the events implicated in the failure, and how to forestall failure of implementing digital health technologies in the future. It also seeks to uncover vulnerabilities in project planning and implementation, and errors in the innovation itself, communication and promotion processes.

Failure analysis is applied across various domains, such as innovation (Bleda et al., 2013), strategic planning (Lauenstein, 1986; Mintzberg, 1994; Mendenhall, 2023), change management (Decker et al., 2012) and governance (White, 2022; Howlett et al., 2017). Over time, failure analysis expanded its focus beyond technical aspects to include vulnerability prevention, response and detection[6] (Martinez, 2019; Revdebug, 2020). Failure analysis became instrumental in optimising performance, enhancing interactions, ensuring data security, and improving user-friendliness (Martinez, 2019). This shifted the framework from reactive failure analysis to failure avoidance, product optimisation, integration and service innovation. The progress of this evolution has impacted various research fields, including psychology, anthropology, sociology, semiotics, pedagogy, and marketing. In healthcare, particularly, the significance of this evolution cannot be overstated (Moore, 1991; Tabbaa, 2018).

One of the roles of failure analysis, therefore, is to elucidate, to the extent possible, the likely chain of causation. Causation may not always emerge as a categorical result from the expedient of failure analysis, but if done well, the failure analysis will yield a likely and plausible set of relevant explanations (Brender et al., 2006). Good failure analysis avoids the fallacy of causal reductionism. Causal reductionism is the assumption that there is only one, unitary and simple cause of a failed outcome when, in fact, the outcome may be more logically be attributable to a number of sufficient causes that acted together (Brender et al., 2006).

The insights derived from analysing failures can shape evidence-based decision-making and inform policy formulation. Failure analysis can facilitate knowledge sharing, best practices dissemination, and the identification of emerging trends and technologies that can drive positive change in the digital health sector. By understanding the factors that lead to failure, policymakers can develop more robust frameworks, regulations, and guidelines to mitigate risks and improve the effectiveness of digital health services (Sogomonjan et al., 2017). Lastly, lessons learned from failures can serve as a valuable resource for future planning and implementation, helping to avoid similar pitfalls and optimise resource allocation. As a result, more efficient and user-centred digital health services can be effectively shared to meet the needs of individuals and communities.

Because of the practical importance of context, the field of failure analysis has been criticised for a lack of adequate theoretical models to explain the influence of contextual factors on project failure (Toots, 2019). It is likely that the factors that truly and aptly explain failure will differ in different domains. Two decades ago, Kukafka and others (2003, p. 218) noted that “a gap exists between the implementation of IT and the integration of theories and models that can be utilized to develop multi-level approaches to identify factors that impede usage behaviour”. This gap has yet to be closed. Its continued existence inspired this thesis to add to the understanding of failure analysis in HCIT domain.

[6] Over time, cybersecurity took precedence over other factors in vulnerability assessment, prevention and response.

3.2 Defining Success and Failure in Project Implementation

Any discussion of the success and failure of HCIT are likely to begin with a definition of its terms. To do so, the author of this thesis first analyses the definitions of success and failure in project implementation prior analysing failure in the deployment of digital health technologies.

Success in project implementation is best defined operationally, in terms of an endpoint that embodies what the implementation was intended to accomplish and its goals and objectives. Operational aspects of an IS implementation generally fall under the heading of project management. The components of project management include project initiation, planning, execution or implementation, monitoring and control and closure. This rubric should also include on-time and on-budget delivery before project initiation, and the fulfilment of functional expectations after it (Thomas et al., 2013). Scoping the project – defining its extent – is generally assimilated into the planning phase. Questions around whose functional expectations should matter in association with determinations of project success or failure are rarely necessarily considered even though they should be.

Other factors that indicate success, or at least the extent of successful implementation include the quality of the system, the information content, user support, usage level, user retention, platform dwell time, user satisfaction and overall benefit. The latter, of course, comprehends both subjective and objective criteria, and may be difficult to measure objectively (Delone et al., 2003; Ojo, 2017).

Failure is more difficult to define. Lyytinen and Hirschheim (1988) identified four types of failure: (i) correspondence failure, (ii) process failure, (iii) interaction failure, and (iv) expectation failure. Correspondence failure refers to information system's inability to meet the requirements for which the system was developed. Process failure refers to paucity of time, budget constraints and poor project management. Interaction failure refers to poor and inadequate use of the system as a result of high dissatisfaction by the users. Lastly, expectation failure encompasses the three preceding categories of failure and refers to the inability of the information system to meet stakeholders' expectations in terms of correspondence, process and interaction. Sauer (1993) criticised expectation failure definition since it does not meet specific stakeholders' expectations.

Thus, failure can be defined as lack of success, as defeat, as the absence (or omission) of an expected or anticipated result, or as the inability to meet a desired objective. The generic criteria often associated with failure in innovation include failure to initiate, materially flawed functionality after initiation, user dissatisfaction sufficient to impair meaningful or projected adoption at any time, and the inability to scale. Failure to scale can arise from inadequate user support, from platform inadequacy (*e.g.*, how many simultaneous operations the platform can support without crashing), or, simply, user disinterest. A looser, but at the same time, perhaps more useful definition positions failure simply in terms of the gap between actual and required performance. (Toots, 2019; Dwivedi et al., 2015). Projected user disinterest in the context of failed clinical trials, as opposed to more complicated situations, may be a function of poor marketing or inadequate capital, even in the context of failed clinical trials (Briel et al., 2021). The term projected user is intended to capture the fact that most successful software programs and platforms are written with a specific user audience in mind.

It is important to add that failure may be characterised by a violation of rules, however, it is not defined by a violation of rules. Correlation is not causation. The violation of inferred rules does not necessarily entail a failure. The determination that a failure has occurred is a matter separate from an analysis of what precipitated the events defined as a failure.

These criteria for failure differ decidedly from the failure of ammunition manufacturing or the failure of a construction project. In this study the analysis is restricted to health care technology project implementation. To proceed with, Sauer's exchange framework (1993) and Herzlinger's six factors framework (2006) are applied for failure analysis in HCIT below. The differences between the Sauer's (1993) and Herzlinger's (2006) ideas are important in this study to analyse the key determinants of cCBT failure. Sauer's exchange framework (Sauer, 1993) focuses on IS failure, while Herzlinger's (2006) framework is aimed at identifying the impact of six factors on innovation success or failure prevention. In this study, both frameworks are important from different perspectives. The strengths and weaknesses of each framework are discussed accordingly.

3.3 Failure Analysis in the Deployment of Digital Health Technologies

Failure analysis in the deployment of digital health technologies and applications has not received much attention. While failure analysis has developed into a fully-fledged and recognised area of research in IS domains (Toots, 2019), the application of failure analysis to the deployment of healthcare IS remains relatively undeveloped. This statement is especially true with reference to patient-facing therapeutic programs such as the example of cCBT studied in this thesis.

Failure rates in projects involving IS are high. Estimates around 85% have been offered (Dwivedi et al., 2015; Goldfinch, 2007; Thomas et al., 2013). In the United States, 94% of large federal information technology projects were unsuccessful, more than 50% were delayed, overbudget, or didn't meet expectations and a total of 41.4% were judged to be complete failures (Johnson et al., 2013).

In the health care sector, IS failure rates exceeding 90% have been reported. Notably, this estimate includes the pharmaceutical industry, which has robust IT and IS capabilities. The true failure rates in purely clinical HCIT applications are more elusive (Opperman, 2020; De la Boutetière et al., 2018).

High failure rates in healthcare industry are partly due to the complexity of the industry and its fundamental differences compared to other industries irrespective of whether they belong to the public or private sector (Jane et al., 2017; Avison et al., 2007). Failure rate estimates are also complicated because innovations are rarely simple and straight forward: they usually involve complex initiatives in large healthcare organisations (Jacobs et al., 2015). The client population in healthcare is necessarily broad and diverse. There is a wide variety of treatments available in different markets (Weeks et al., 2013). Failure rates are related to increasing costs associated with new digital health technologies, as well as other sources of resistance (Safi et al., 2018).

As with other socially significant projects in IS, a critical approach to failure analysis in HCIT and healthcare IS is of high priority (Heeks, 2003). The salient triad of industry needs encompasses strategic, operational and implementational components. The term strategic refers to planning – what to plan for and how. The term operational refers to the creation and introduction of a functional product. The term implementational refers to marketing a product and driving adoption.

Above all it is critical to anticipate and pre-empt failure before it occurs (Bannister et al., 2012; Sauer, 1993). Pre-emption of failure is particularly important in the clinical domain, where many stakeholders remain sceptical of benefit and resent the changes in workflow and the limitations on autonomy, among other things, that the

introduction of new healthcare IS initiatives seems inevitably to entail. These issues – strategy, operations and implementation moreover, only three of the contextual factors that appear to matter most.

It is often the case that the introduction of a new technology takes time. It is rarely immediate. Successful introduction requires education, marketing and effort against competitive forces (Porter, 1979). The introduction of a new medical technology is subject to the same rules as the introduction of other technologies. Patients do not always behave as fully independent consumers of new technology. Neither can their behaviour necessarily be predicted by the behaviour of clinicians. Therefore, there is no objective reason to expect that, in the short-run, patients will necessarily adopt a new technology (Boeldt et al., 2015; Safi et al., 2018). This observation is of great importance in recruitment for clinical trials. Trial recruitment is subject to many variables: only about one third of clinical trials meet their objectives (Laaksonen et al., 2022; Man et al., 2015; White et al., 2015).

Whether for therapeutic uses of HCIT or for other forms of medical intervention, trials may fail to recruit because of a number of remediable causes including: (i) over-optimistic recruitment estimates; (ii) narrow eligibility criteria; (iii) lack of engagement on the part of recruiters and the trial team; (iv) lack of competence or training or experience on the part of recruiters; (v) insufficient initial funding, and (vi) high burden for trial participants (Fogel, 2018; Sun et al., 2022). Recruitment is only one objective in the course of project implementation, and failure to meet the recruiting objective was only one part of the problem surrounding the case in this thesis. In fact, underlying contextual issues were probably critical causes of the failure to recruit.

In addition to contextual factors, fragmentation of the healthcare system has been noted as one of the most significant factors resulting in failure of implementation: first, limiting the adoption and second the diffusion of the medical or healthcare technology in National Health Service (NHS) in UK (Asthana et al., 2019). Castle-Clarke and others (2017) emphasised on structural factors that obstruct NHS due to its structure based on a supply-driven and top-down approach to innovation. As opposed to this approach, they argued that supply-driven and top-down approaches have to be shifted toward co-production of health care professionals and industry to find out best solutions for adopting medical technology. Other structural factors are related to the strategic planning of organisations such as the focus on the short funding rounds rather than the innovation impact (Elmansy, 2021).

Challenges around implementation of technology in healthcare are not, however, limited to the medical equipment only. Petersson and others (2022) analysed implementation challenges of artificial intelligence (AI) in Swedish healthcare system. Surprisingly, but regardless of implementation difficulties, data-driven AI is increasingly used in digital mental health field as a serious, complementary system to improve existing decision support systems (Balcombe et al., 2021; Tiffin et al., 2018). While data-driven AI has the potential to enhance patients' experiences, predict, detect and improve health outcomes (Bertl et al., 2021) and advance person-centred mental health care (Rosenfeld et al., 2021; Balcombe et al., 2021; D'Alfonso, 2020) researchers' opinions are divided on this matter.

On one hand, researchers argue that data-driven AI methods, including machine learning, can bring more clarity in diagnosing depression and cognitive declines (Shatte et al., 2019; Eichstaedt et al., 2018; Reece et al., 2017; Schnyer et al., 2017; Wager et al., 2017), psychosis in schizophrenics (Chung et al., 2018; Bedi et al., 2015)

and even suicide or suicidal ideation (D'Hotman et al., 2020; Shatte et al., 2019; Walsh et al., 2018; Just et al., 2017). They can also add value in predicting successful antidepressant medication (Chekroud et al., 2016). On the other hand, scholars point out that unlike in physical health, the real impact of data-driven AI in mental health is insufficient due to "the impossibility of predicting individual risk accurately" (Mulder et al., 2016, p. 272), lack of information and limited usefulness in the real-world settings (Shatte et al., 2019; Graham et al., 2019; Tiffin et al., 2018). Researchers warn that relying on AI-enabled risk categorisation may be of limited value and may even include potential harms for patients if the system inappropriately identifies people in a low-risk group as being in a high risk group and *vice versa* (Mulder et al., 2016). As a result, people in danger of committing suicide can be left without proper and intensive supervision, while patients belonging to a high risk group are, in most cases, false positives and may needlessly receive more restrictive treatment (Mulder et al., 2016).

These different opinions derive from the fact that AI-enabled risk categorisation does not reduce morbidity outcomes but rather helps with earlier intervention to prevent deterioration of diseases and early mortality outcomes (Bertl et al., 2023; Paton et al., 2014). In this regard, researchers emphasise that the need to identify the causal factors for mental health outcomes is a priority rather than looking for conventional statistical predictors (Franklin et al., 2017; Mulder et al., 2016; Chan et al., 2016).

Despite its potential benefits and expectations of researchers supporting implementation of data-driven AI in the field of mental healthcare, the international experience shows that the use of data-driven AI in healthcare may pose harms to patients' safety if real data used for treatment are limited or inappropriate, and thus, it may lead to medical malpractice (Bertl et al., 2022; Topol, 2019; Ross et al., 2018). It has been also noted that the accuracy of algorithms cannot be considered equal to treatment success since they do not account for all the issues that need to be taken into consideration for optimal clinical treatment (Keane et al., 2018). Subsequently, the application of data-driven AI in healthcare can only be considered as a supportive tool but not (yet) a replacement for clinical decision making by humans (Topol, 2019) due to lack of its clinical representativeness (Balcombe et al., 2021; Briganti et al., 2020; Dagi, 2017). Thus, the use of data-driven AI promises to address important diagnostic and clinical decision-making issues in digital mental health rather than having a real impact on improving mental health outcomes and patients' satisfaction.

In the following paragraphs, the author of this dissertation presents Sauer's exchange framework (1993) and Herzlinger's six factors framework (2006) for further analysis of failure in HCIT domain.

3.4 Frameworks for Failure Analysis in HCIT

As mentioned above, the frameworks applied for failure analysis in HCIT in this thesis include Sauer's exchange framework (1993) and Herzlinger's six factors framework (2006). Sauer's Triangle of Dependencies (1993) is useful to understand the process of failure of information systems. Herzlinger's Six Factor Framework (2006) highlights the key determinants of successful deployment, or in other words, failure prevention.

3.4.1 Sauer's Triangle of Dependencies

Sauer's Triangle of Dependencies model has served as a common framework for failure analysis in information systems generally and in HCIT in particular (Bomba et al., 2006; Kaplan et al., 2009). Sauer's model links success and failure to an organisational context that involves three key actors, or parties to the process: (i) the project organisation; (ii) the system; and (iii) the supporters.

The term project organisation refers to the group of individuals who initiate, develop, implement, operate or maintain an information system (Sauer, 1993). The term system refers to the information system in questions. The supporters invest in, support and sustain the project organisation. They may provide funding, information or other assets and resources, including information. They expect a return from the system. These three elements constitute the Triangle of Dependencies (see Figure 1).

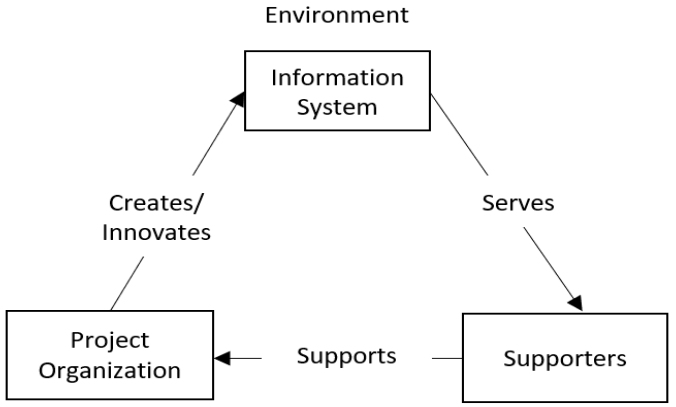

Figure 1. Sauer's Model of IS Development (Source: Sauer, 1993)

In addition to internal organisational processes, *i.e.*, the interaction between the IS, project organisation and supporters, the failure of IS project results from external, even broader organisational processes. Sauer identified six exogenous factors that modulate the Triangle of Dependencies. Taken together, they describe an information systems context. The information system context consists of (i) cognitive limits; (ii) technical process; (iii) environment; (iv) politics; (v) structure; and (vi) history.

Contextual factors figure more prominently in Sauer than might initially thought. In Sauer's scheme, the term cognitive limits refers to the intellectual and cognitive capacities of the individuals involved with the project. They allude to executive functions including problem-solving and decision-making. They include memory, attention, logical reasoning, and the faculties of abstraction and conceptualisation (Sauer, 1993). This contextual factor is often difficult to apply.

The Sauer's framework is by its very nature explanatory and particularly useful in understanding political, technical and social factors of information system failure. As noted by Kim and Iijima (2005, p. 216) "Sauer's framework is useful in proposing that it is only when relationships between crucial elements of an information systems project break down irrevocably that the project can be seen as having failed".

Thus, Sauer (1993) perceives the causes of failure as originating from or within the connections or relationships that exist within the system itself, its supporters, and the

project organisation. Flaws occurred in any of these components are prone to exerting a negative impact on the IS development project, and to lead to failure or to project termination (Fitzgerald et al., 2005).

Structural and cultural factors are also important in seeking to comprehend the potential causes of IS failure. These factors help in projecting the benefits, motivations and rationales of project supporters as they drive the advancement of the project.

The designation of factors as either structural or cultural depends on whether the support was provided directly by the supporter or influenced by the shared values within the supporter' community (Sauer, 1993). Furthermore, Sauer (1993a, p. 73) observes that "even where a potential supporter sees benefits from giving support there may be external factors which discourage or prevent this from being converted into something usable". The factors influencing the failure of the IS and its termination might be external or environmental, or internal, or both.

Nevertheless, the Sauers' framework has been criticised for being general when addressing the specific contextual details and intricacies of IS projects in organisational, cultural, social and historical contexts (Baghizadeh et al., 2019). For example, the interaction of crucial elements in Sauer model is prone to various flaws that may snowball if not identified and dealt with promptly (Baghizadeh et al., 2019). When IS project supporters are not supported and consider an IS is less likely serving their needs, expectations and interests, they likely terminate the project, using project flaws as justification. Sauer's (1993) process model makes a distinction between flaws and failures. Flaws are objective internal project problems while failures result from decision-making and organisational processes and tend to be politically and socially defined (Fincham, 2002; Sauer, 1993).

3.4.2 Herzlinger's Six Factor Framework

Regina Herzlinger studied the process of innovation and barriers to innovation to answer the question "Why is innovation so often unsuccessful in health care?". She chose this approach in preference to focusing primarily on the context of information systems. A framework of six factors emerged.

The six factors framework (see Figure 2 and 4) was actually designed more ambitiously, as framework to examine innovative ventures generally. Nevertheless, Herzlinger's framework is compatible with HCIT without being restricted to it. In that sense, she departs from Sauer. She focuses on innovation and the environments that facilitate innovation. She takes into consideration the roles of consumers, market structures, financing mechanisms, regulatory conditions, and the inherent nature of the technology. *Pari passu*, she expands on the factors that can result in the success or failure of an innovation. Herzlinger's concept of innovation includes innovation in health care services.

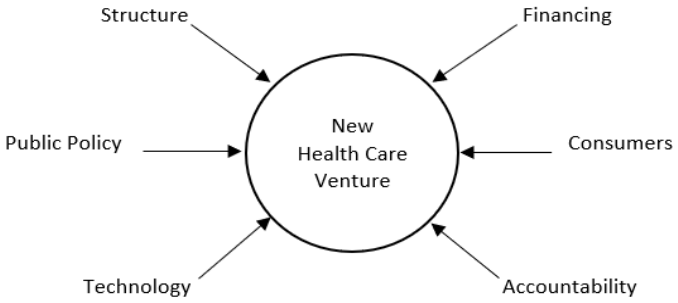

Figure 2. The Six Factors Framework That Affect New Health Care Ventures (Source: Herzlinger, 2013)

Herzlinger introduced six factors to guide innovation in healthcare and overcome structural impediments to change: (i) structure; (ii) financing; (iii) technology; (iv) accountability; (v) consumers, and (vi) public policy (Herzlinger, 2006). Successful companies, moreover, will tend to focus on one of three opportunities: consumer-facing activity, system integration, or technical advances (Herzlinger et al., 2017).

Herzlinger (2006) focuses on innovation as one of the major factors in gaining and retaining market share, and the environments that facilitate innovation. The six factors framework was designed to examine the structure and dynamics of innovative ventures. The technology component may be central to the analysis, but not necessarily to the dynamics of success and failure.

Herzlinger (2006) argues that improvement in health care can be characterised by improvements in quality and cost: better and cheaper. She suggests that useful change is driven by (i) process affecting the ways consumers buy and use health care; (ii) tapping into new technologies in health care; and (iii) generating new business models in health care (Herzlinger, 2006). HCIT is ultimately one of the key factors influencing the way healthcare can be improved and delivered.

Thus, unlike Sauer (1993), Herzlinger's (2006) six factors framework does not focus on the relationships between the factors: rather the analysis of the barriers to innovation in health care relates to the impact of the six factors on innovation or technology *per se*. Nevertheless, these three elements are not universally applicable – new business models in health care may not be attainable everywhere – but the principles remain valid.

Barriers to each type of innovation may be erected by the healthcare system – inevitably, in Herzlinger's view. They can, however, be managed. The barriers can be described by reference to her six forces. The six forces are: (i) the players, friends and foes of an enterprise or project who can bolster or destroy innovations; (ii) funding, the revenue-generation and capital-acquisition processes, which differ from those in industries other than health care; (iii) policy, the regulations that pervade the industry and to which the industry must accord; (iv) technology, the foundation for many of the innovations that can make health care delivery more efficient and convenient; (v) customers (clients), the empowered and engaged consumers of health care; and (vi) accountability, the demand that emerges from consumers, payers, and regulators around the safety, effectiveness and cost-effectiveness of innovations in health care.

As a general rule, companies can utilise these six forces to their advantage. While the details may differ in different markets, market structure, financing mechanisms,

regulatory conditions, new technologies and consumer behaviour are factors that can influence the success or failure of an innovation or an innovative project.

Notably, Herzlinger (2006) focuses on the consumer as a factor rather than the supporter. The needs of consumers and supporters may differ significantly (see Figure 2 and 4). While supporters may agree to support the entire project organisation for a variety of implicit or explicit reasons (Sauer, 1993), the consumers have no objective reason to support unless they are benefitted financially or otherwise (**I, V**). This point was noted also by Herzlinger (2013): none of the key stakeholders including those in charge of commercialisation of medical technology will change unless they are provided with powerful, easy-to-follow incentives to alter their habits.

Based on the author's knowledge at the time of writing this thesis, no publication criticising Herzlinger's six factors framework was found.

3.5 Summary

A failure analysis tries to determine what happened that resulted in failure or failures in a given situation. A failure analysis does not, *ipso facto*, determine that an event or a series of events constituted a failure or that a failure took place. That judgement may be complicated and include a component of subjectivity.

Thus, the judgement of what constitutes failure and what qualifies as success must precede and be fairly well established prior to commencing the failure analysis. A failure analysis cannot be carried out in a vacuum. A failure analysis can only proceed in the context of a failed ambit. There has to be agreement around the fact that a failure has taken place for a failure analysis to be useful, much less relevant.

Among the various theoretical and analytical frameworks that have been applied to the study of failure analysis, the most pertinent to this research is the context-oriented framework developed by Sauer (1993) to study failures in information systems (IS) and Herzlinger's framework on innovating in healthcare to study failure analysis in HCIT.

The thesis applies both Sauer's exchange framework (1993) and Herzlinger's six factors framework (2006) for failure analysis of cCBT in Estonia. Sauer's Triangle of Dependencies model identifies three key actors in the failure process: the project organisation, the system, and the supporters. It also considers six contextual factors that influence failure. Herzlinger's framework focuses on innovation and identifies six factors for assessing failure in healthcare innovation: structure, financing, technology, accountability, consumers, and public policy. While Sauer's framework emphasises relationships between key actors, Herzlinger's framework emphasises the impact of factors on innovation. Understanding the needs and incentives of consumers and supporters is crucial for failure prevention in healthcare.

These frameworks are tested on the cCBT case of implementation not only because of the nature of the case and for the purposes of understanding the Estonian context and experience, but also because it provides insights into the deployment of patient-facing health care software and digital health more generally.

In the next section, the author of this thesis first presents the case study and then analyses the case study through the conceptual models of both Sauer (1993) and Herzlinger (2006).

4 The Case Study

This section aims to provide insights about the specific case study, its failure and the results in-depth.

4.1 Background

Estonia is a country with highly digitised economy, and from the perspective of digital health, Estonia might well qualify as an ideal place to launch an e-platform (e-Estonia, not dated). It has created a carefully crafted position around e-competence (Toots, 2019; Drechsler, 2018; Toots et al., 2016). Digital services are familiar, widely deployed, and frequently utilised. Currently, 99% of Estonian state services, *e.g.*, voting and declaring taxes, are online (Tuula et al., 2022). Furthermore, wide availability of public e-services has turned the country into a service platform allowing citizens of foreign countries to launch and run their businesses fully online (Drechsler, 2018).

From a market, but also from a policy perspective, there is every reason to expect that digital or (e-)health platforms would succeed (Ross, 2019; Ross, 2021; Zilgalvis et al., 2015; Petrone, 2022; SCOOP4C, 2023; Schmidt et al., 2022). Electronic medical records are ubiquitous (Stewart, 2023; e-Estonia, not dated): 99,9% of medical prescriptions[7] are digital (Tuula et al., 2022). By 2022, patients' genetic data were supposed to be integrated with the e-prescription system to provide more precise and, perhaps, personalised medical care (Kõnd et al., 2019). In the field of mental health care, a clinical decision support system – DocuMental – has been implemented to increase accuracy in diagnostics, treatment and assessment (Maron et al., 2019).

Digital Health Index ranked Estonia first in comparison to other digitally advanced European Union and OECD countries such as Denmark and Canada (Thiel et al., 2018). In 2015, the Estonian Government adopted the national e-Health strategy 2020 (called then as Estonian eHealth Strategic Development Plan 2020) that became an integral part of general national health policy plan and established a clear vision of a variety of digital or (e-)health initiatives including digital health solutions to be developed until 2025 (Government of the Republic of Estonia 2015, 2019). In 2021, the Government approved the Green Paper on Mental Health (*Vaimse tervise roheline raamat* in Estonian) prioritising prevention and early detection of mental and behavioural disorders through digital health solutions including e-counselling (*e.g.*, MinuDoc) and online psychotherapies (*e.g.*, online guided self-help programmes) (Sotsiaalministeerium, 2020).

According to a 2018 Empirica report entitled *SmartHealthSystems*, digital health policies and regulations in Estonia provide financial incentives for health care providers to take-up digital health apps and services (Thiel et al., 2018). Nevertheless, there is no oversight for mobile health applications (Thiel et al., 2018, p. 97). Delivery of health care at a regular basis using mobile health applications is deployed only to some extent. Also, the deployment of patient facing HCIT is only partially ready to actively contribute to patient empowerment and patient-centred care (Stein et al., 2013; Thiel et al., 2018).

This can be explained since financing of implementation and operation of digital health applications and services at national and regional-levels are mostly project-based (Tiik, 2021; Oja, 2021). Lack of financial sustainability, support and active

[7] Medical prescriptions include both medications and medical devices.

involvement from government agencies slow down the implementation process and make it ineffective (Tuula et al., 2022; Thiel et al., 2018; Värnik et al., 2016; Praxis, 2002). Therefore, regardless of having an outstanding digital health profile with successful history of nationwide health information system, the uptake and sustainable implementation of digital health applications and services in Estonia are not yet mature. The failure to deploy cCBT provides support for that contention. The factors that contributed to the failure of cCBT in Estonia are multiple and reviewed in the sections below.

4.2 The Case: Deployment of cCBT in Estonia

Before delving deeper into the Estonian case, let us look at the two deployed solutions. The cCBT programmes piloted in Estonia did not differ significantly from other forms of cCBT programmes available in the HealthIT market. Two programmes – iFightDepression software program and CBT Basic App mobile application – were aimed to be supplemental treatment methods featuring a self-managed approach to treatment. These two programmes included various cCBT exercises and recorded patients' notes directly in the program. In the following they are briefly introduced.

First, the iFightDepression program is a multilingual, Internet-delivered self-help tool. It is designed as an adjunctive intervention to standard care practices, aimed at enhancing the well-being of individuals experiencing mild to moderate depressive symptoms (Hegerl et al., 2020; Justicia et al., 2017). As noted earlier in this study, the program was first developed as part of the PREDI-NU project in 2011–2014 and was piloted and tested for effectiveness at a large scale in several research projects including MasterMind, MoodFood and Joint Action for Mental Health and Wellbeing. The iFightDepression software program was co-founded by the Health Programme of the European Union and implemented by the National Suicide Research Foundation (NSRF), the University of Stirling (iFightDepression, 2023) and international non-profit organisation European Alliance Against Depression (EAAD) aimed to improve care and optimise treatment for patients with depressive disorders and to prevent suicidal behaviour (EAAD, 2022). In 2019, the iFightDepression software program was recognised as a mental health best practice by representatives of the EU Member States at the European Commission's Joint Research Centre (European Commission, 2021).

The iFightDepression software program had been evaluated in outpatient and inpatient treatments in different European countries, and the results had indicated positive treatment outcomes (Schwarz et al., 2022; Oehler et al., 2021; Justicia et al., 2017). Several researchers provided evidence that broad implementation of the iFightDepression software program in the public health care system could reach a large number of patients, thus avoiding long waiting lists (Weih, 2021; Justicia et al., 2017). In addition, a mildly above-average level of satisfaction and willingness to continue after discharge had been noted among active patients in inpatient treatment (Schwarz et al., 2022).

Nevertheless, and irrespective of studies supporting the evidence for iFightDepression software program use, findings from a study by Vereenooghe and others (2021) warrant a critical appraisal in relation to the previous research. Specifically, the study notes that for the most participants encountered difficulties in understanding or using the program and that the perceived usefulness and potential personal benefit of the iFightDepression software program were not obvious

(Vereenooghe et al., 2021). Hence, a low ease-of-use and limited utility resulted in a negative perception, lower general accessibility and even reduced motivation to continue using the program (Vereenooghe et al., 2021). Similar findings were observed in Estonia.

The second implementation is the CBT Basic App mobile application, which is a multilingual Estonian cCBT program developed by private company providing psychological services – Noviti OÜ. Like other cCBT programmes, CBT Basic App mobile application aimed to support patients in self-care and self-management of mild to moderate levels of depression. An app allowed users to continue the online program on the go and easily create the right activity based on user own inputs or in cooperation with a CBT therapist (Lust-Paal, 2015; Fullaondo et al., 2016). The program was partially commissioned by private e-health company Cognuse OÜ and limited to local context. To the date, there are no data published on CBT Basic App effectiveness in treating patients. The app is no longer available in Apple and Google Store.

Having gained an understanding of the two deployed applications, let us look at the implementation. The first initiative to pilot cCBT in Estonia was led by the Estonian-Swedish Mental Health and Suicidology Institute (the Institute) during the EU research project PREDI-NU in 2011–2014. This project aimed to develop an Internet-delivered guided self-management tool for mild to moderate depression to contribute to the promotion of mental health and the prevention of depression and suicidality (EAAD, 2022). Between 2011–2014, a cCBT program iFightDepression was developed and translated into Estonian. Several training sessions were organised to introduce the program and increase awareness among health care professionals and policy makers.

In 2014, Tallinn University of Technology (TalTech) was invited to take part in an EU research project MasterMind (MasterMind, 2018). The project aimed to make high quality treatment for depression more widely available for adults suffering from the mild to moderate depression level by the use of cCBT programmes (MasterMind, 2018). While it succeeded in some regions, it did not enjoy success in Estonia.

The ambit of the MasterMind project was to provide recommendations for successfully implementing both cCBT and ccVC in different settings (MasterMind, 2018). One of the central themes of the initiative was centred around the idea of increasing the autonomy of individuals with depression: “All citizens suffering from depression, who are able to, and who would benefit from it, should have the opportunity of managing their own mental health.” (MasterMind, 2018). The project developers believed that the use of ICT for depression would encourage depressed individuals “to master their own treatment and thereby their own mind, with minimal involvement of mental health professional [sic].” (MasterMind, 2018). The work was overseen by a renowned international Scientific Committee.

The justification for this project was based on the global prevalence of mental health disorders and as mentioned earlier on their impact on the economy as well as on earlier experiences with the implementations of digital health services in the EU. Nearly one billion people are affected by psychological disorders, including substance use disorders, globally (Elflein, 2021). Mental health disorders are one of the most significant public health challenges in Estonia and the EU, being the leading cause of disability (19% of all years lived with disability) and the third leading cause of overall disease burden (the burden of mental disorders is measured in DALY to be 7% of the total global disease burden) (Rehm and Shield, 2019). In 2021 and 2022, around half of young people in EU have faced unmet needs for mental health care (OECD/EU, 2022).

Several studies have indicated that digital mental health services are cost-efficient and resource sparing (Schueller et al., 2020; Mohr et al., 2017). Lastly, depression was selected as a target due to its high incidence, social cost and the proven clinical effectiveness of ICT in its treatment (MasterMind, 2018). At the time of cCBT pilot, the prevalence of depression in Estonia was the highest in Europe (World Health Organisation, 2017).

Today, various estimates of the prevalence of depression have been published. The Estonian National Mental Health Study of 1 September 2020 to 28 February 2022 reported a depression prevalence of 12.4% and a prevalence of anxiety of 9.8% (Konstabel et al., 2022). Furthermore, based on self-assessments, the study data show that 28% of Estonians are at risk of depression and 20% suffer some degree of anxiety (Konstabel et al., 2022). The World Health Organisation (2017) and World Population Review (2024), however, assert that the highest rate of depression in Estonia is 5.9%, that is to say 75 667 cases per 1 326 062 population (World Health Organisation, 2017; World Population Review, 2024). These figures represent a significant burden of emotional distress, and a challenge to both the medical profession and the public health and social policies.

Inasmuch as TalTech had no prior experience with cCBTs, the university contracted with an e-health company Cognuse OÜ to provide support for iFightDepression delivery. Cognuse OÜ had a portal which became controversial when the EAAD argued that it did not provide adequate security and data protection and claimed that certain of its intellectual property rights were at risk.

TalTech and Cognuse OÜ attempted to organise several trials in collaboration with the Estonian Association for Cognitive Behaviour Therapy (the Association) and the the Institute. TalTech and Cognuse OÜ had hoped to pilot the cCBT program in Estonia. The attempt at collaboration failed in part because the Association asked for data supporting the clinical effectiveness of the iFightDepression program in Estonia before initiating patients' recruitment process. These data did not exist. Studies proving the effectiveness of other, similar cCBT programmes instantiated in other countries (*e.g.*, Sweden, the Netherlands, Belgium, UK, USA, Canada and Australia) were simply not accepted by the Association.

In an attempt to circumvent the problem, the EAAD then advised TalTech to collaborate with the Institute to get access to the iFightDepression program and to organise training sessions for healthcare professionals. By the end of 2014, a formal agreement with the Institute had been concluded. At the same time, an approval from medical research ethics committee[8] was received that was supposed to support patients' recruitment. Nevertheless, recruitment of both professionals and patients lagged. There appeared to be little interest in using the program and the problem of slow recruitment continued. The patient data needed to promote confidence in iFightDepression remained elusive.

Around 2016, the university piloted an Estonian cCBT program called CBT Basic App. Patients' recruitment improved, but data remained biased.

The MasterMind project ended officially in March of 2017. While official patient recruitment was to have ended then as well, cCBT programmes may have remained in

[8] Decision nr 816 of the Tallinn Ethics Committee on Medical Research of the National Institute for Health Development.

scattered use. In any event, documentation on the continued deployment of the iFightDepression program and CBT Basic App after February 1st 2017 was unreliable.

Indeed, the first mention of cCBT program iFightDepression in Estonian mental health policy document only came in 2016, towards the end of the MasterMind project. Even then, it was only portrayed in general terms as a digital mental health service for the treatment and rehabilitation of adults (Värnik et al., 2016). It is noteworthy that the pilot implementation began prior to the formal introduction of cCBT to the Estonian mental health system. Digitalisation of healthcare has never been a matter of public discussion, nor has it been particularly promoted by individual politicians (Thiel et al., 2018, p. 97). That meant that the pilot implementation was introduced outside of any comprehensive social or professional preparation, without full analysis of the context for use or adoption, and in advance of socialisation (formal and informal discussions with stakeholders to prepare them for the introduction).

Given the background of the case, one might be forgiven for surmising that clinicians would greet the introduction and following implementation of patient facing HCIT with alacrity, if not with outright enthusiasm. One might also surmise that individuals seeking treatment for anxiety and depression would be open to online therapy and eager to receive it. By the same logic, the recruitment goal of 300 individuals out of several hundred thousand potentially eligible patients would seem eminently reasonable. Thus, if one were to project the objectives and the conditions for the successful implementation of an e-health initiative, it would be reasonable to look to Estonia and anticipate: (i) interest and acceptance by clinicians; (ii) interest and adoption by patients; and (iii) rapid recruitment of the target patient cohort.

These objectives, however, were not realised. Clinicians did not fully embrace cCBT (**II, IV**). Patients did not flock to the program (**II**, **IV**). Only 56 patients were recruited (**IV**). It seems evident that none of the three key indexing end goals was reached.

4.3 Failure Analysis of cCBT Implementation in Estonia

In this section, the failure of cCBT implementation in Estonia is analysed through the Sauer (1993) context-oriented information system failure framework and Herzlinger's (2006) six factors framework on innovating in health care. Based on these frameworks, an explanation for the failure of cCBT is provided along the lines presented below.

From the perspective of the Sauer's (1993) Triangle of Dependencies (project organisation, system and supporters), the system (the cCBT technology) was the least problematic (see Figure 3). For the sake of clarity, when Sauer uses terms such as project organisation, he refers to the development of information systems rather than their application. Here, the term is used instead to refer to the organisation and implementation of the cCBT program.

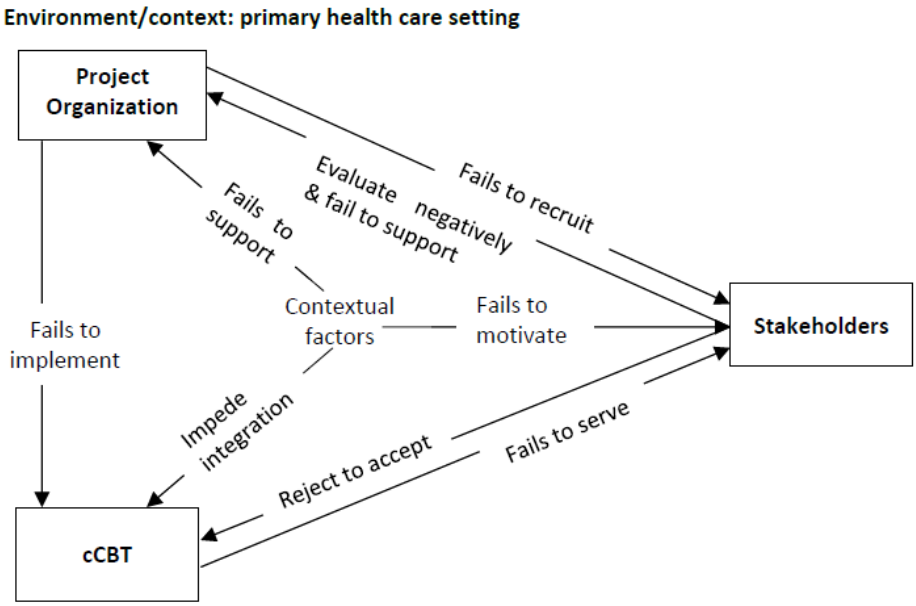

Figure 3. Failure of cCBT Implementation Based on Sauer (1993) and Adapted from Toots (2019)

The project organisers were the group of individuals who initiated, developed, implemented, operated and maintained the cCBT program and the application that was eventually launched on the Cognuse OÜ platform. The information system was a key part of the project. Any critical reference to the information system must not be taken to suggest that had the information system *per se* been better adapted or better written, the project would not have failed. The evidence does not support this interpretation.

The term environment is used with reference to both the internal and external environments of the organisation. Since Sauer used this term in 1993, its meaning and its significance have both enlarged substantially. Employees, values, leadership philosophy, and corporate culture all contribute to the internal environment of an organisation. The external environment encompasses political and economic issues, the legal environment, demographics, the competitive landscape, global considerations, social factors, and of course technological factors. All of these have the ability to affect the implementation of an information system. Therefore, politics as a key factor affecting the environment and interaction between Sauer's actors is different in each health care setting. Politics in primary care might be different from the politics in psychological and psychiatric centres or politics of healthcare system in general. Therefore, when implementing cCBT in a specific healthcare setting one must consider the specifics of the environment of that organisation but also the needs and expectations of actors working in that organisation.

The influence of politics incorporates governance and the pursuit, distribution and exercise of power. The distribution of power may affect funding or speed of implementation. It may affect the competitive environment. It may create regulatory constraints and affect reimbursement for HCIT. It may create technological stumbling blocks, particularly in environments where high-speed Internet is not always present. Privacy may also be a relevant issue. Most importantly, politics can also create

impediments to project success that are entirely unrelated to technological issues or projected benefit.

Sauer postulated that organisational structure influences the flow of information within an organisation. The structure of an organisation, in his paradigm, is linked to the dissemination of information about any information systems that might be involved to users and decision makers (Southon et al., 1997; Köpke et al., 2019). In retrospect, one may legitimately contend that information about cCBT was not disseminated in the organisation. Nevertheless, this has to be proven better.

The importance of optimised outbound information flow cannot be overestimated. Arguably, communications management inside the organisation and outside the organisation, including promotion, are equally important. It has been argued that the evolution of marketing and communication in the digital age has precipitated relevant changes in the perception of information and the promotion of new products (Ogilvy, 1983; Young, 2018). In Estonia, the lack of adequate information management was very likely an important factor in the MasterMind project failure and as a result failure of cCBT further deployment.

The friends and foes of cCBT tremendously affected its introduction to a wide community of health care professionals. The attempts to find friends for cCBT pilot, however, failed since the importance of friends and foes of an innovation was not appreciated. The approach to this group was ineptly negotiated (see Figure 4).

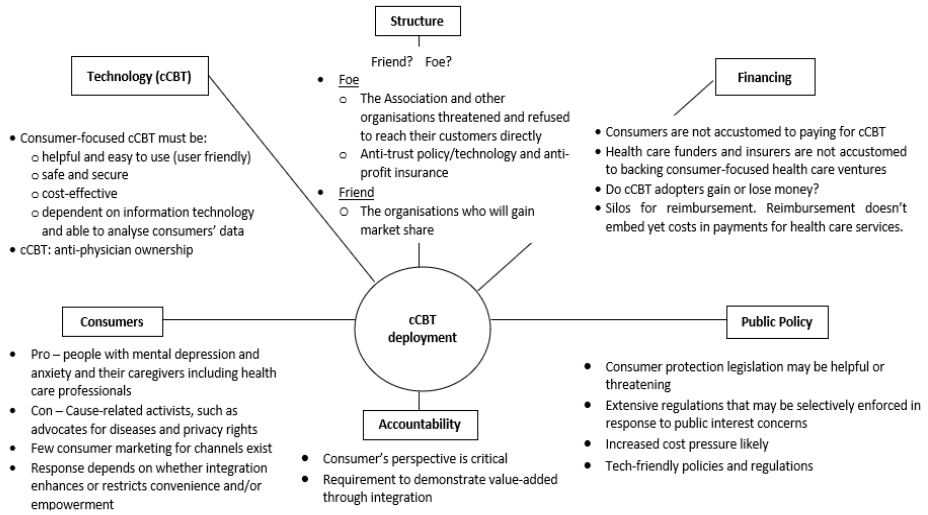

Figure 4. Description of the cCBT Case Using the Six Factors Framework. Adapted from Herzlinger (2013)

When TalTech received the funds from the EU to implement cCBT during MasterMind project, Cognuse OÜ and other, including the author of this dissertation, initiated negotiations with several organisations to introduce and deploy cCBT in Estonia. As a first partner in cCBT pilot, the Association was addressed to deploy cCBT by recruiting therapists who were members of the Association and their patients. Nevertheless, members of the Association rejected this request on the grounds that there were insufficient data to justify deployment. The Association demanded the results of randomised trials. Such trials had not been carried out. Among other weaknesses were noted lack of mental health specialists involved into the project to spearhead the

project. Though the leader of the project was not an expert in the mental health field, he tried to persuade the Association that the data from deployments elsewhere in Europe constituted sufficient warrant for initiating the trial in Estonia. This effort was not successful.

The second attempt to find a partner in piloting cCBT was the Institute as suggested by the EAAD, who were the developers of the iFightDepression software. It turned out, that the Institute had previous experience with the iFightDepression program and had also been involved in deploying the software prior MasterMind project. The Institute agreed to participate and to recruit the practitioners through whom patients would be recruited on condition that the Institute receive compensation and that it be included in any publications arising from MasterMind project.

Compensation was arranged through TalTech University. The Institute was only compensated for recruiting therapists, however, and not patients. Patients were to be recruited by the therapists. The Institute also undertook responsibility for the secure sign-on for iFightDepression program.

The Institute approached hospitals and outpatient clinics to recruit therapists. The therapists who were recruited came from general practice, psychiatry, psychology, neurology and paediatrics. Their role included recruiting the patients. It is important to note, that at the time of cCBT introduction in Estonia almost half of therapists were either of retirement age or were to retire in near future (National Audit Office, 2020). The problem with aging health care professionals was followed *inter alia* by shortages of family physicians, psychologists and psychiatrists.

Furthermore, at the time of cCBT pilot, health care professionals were broadly defined as "any category of healthcare professional involved in the provision of depression treatment" (Prieto et al., 2015, p. 10). It turned out that this definition of health care professionals conflicted with the national requirements applicable for health care professionals to provide cCBT. The professional competence required to provide cCBT was strictly devoted to psychologists registered with the Estonian Qualifications Authority (2019) or psychiatrists registered with Health Board, who have passed the intermediate training for CBT therapists (**I**).

Health care professionals who had not undergone cCBT training were not considered to be fully equipped to provide cCBT service (Pederson et al., 2017). In retrospect, it is obvious that health care professionals did not receive continuous and intensive trainings. The organisation responsible for trainings of health care professionals – the Institute – was independent institution with no relation to internal processes of the healthcare organisation itself. cCBT was primarily piloted in primary care settings, where the primary care physicians were the head of the primary care settings. The solo primary care settings in Estonia in general included one primary care physician and one nurse.

Therapists were not compensated for offering the new service involving the iFightDepression program. From a work-flow perspective, they were asked to produce confidential sign-on credentials and oversee the patients' use of the iFightDepression program in addition to their on-going clinical interactions with the same patients. The administrative burden of the program had not been considered and would not be. The administrative burden entailed several steps and was projected to require 20 minutes additional work per patient therapeutic session.

The therapists were instructed in the program by the author of this thesis and by Institute. Each therapist was provided 30 minutes to an hour instruction in the use of the

software. Additional contact time was available but only approximately 5 of the 18 therapists recruited (the relevant data do not appear to have been preserved) returned with questions or for further instructions.

The results of patient recruitment showed the slow process of their integration with technology (**IV**). In summary, 72 800 patients out of a population of patients were eligible because of a statistical diagnosis of depression available in 2015. Of these 3500 patients were potentially eligible to receive services while 101 patients were targeted through the recruitment strategies and 72 patients were offered services (**IV**). Lastly, 56 patients were recruited and 15 completed treatment (**IV**). The Final Trial Evaluation document makes note that not all types of depression were eligible for the study, and the number of patients available in Estonia was lower than in Wales, Aragon, Galicia, Turkey and Badalona, other areas in which cCBT trial was successfully implemented.

The salient error was in lack of project positioning, marketing and networking. Several stakeholders should have been identified, pursued and included early on: TalTech, the university; The Estonian Association for Cognitive Behaviour Therapy; The Estonian-Swedish Mental Health and Suicidology Institute; professional organisations directed at psychologists, psychiatrists, neurologists, and primary care practitioners (rather than those directed at a specific diagnosis such as depression); patient representatives; and possibly the Ministry of Social Affairs.

The third attempt to get support and continue with cCBT initiative was the Ministry of Social Affairs. The Ministry, however, did not respond and this attempt failed without objective reasoning. cCBT pilot had no political support either.

The Principal Investigator was a highly respected academic but not a mental health knowledge leader or specialist. Three individuals were hired to instruct the mental health professionals. They too came from outside the mental health therapists' professions.

Aside from the therapists, there was no one to communicate regularly with the patients. The challenge of every therapeutic trial is patient recruitment and retention. It may have been assumed that personal communication would not be needed in a highly digitised country. Nevertheless, continued patient relationship management is an important tenet in patient retention. In the cCBT case particularly, it should have been considered because of the nature of supporters or consumers as mentioned by Sauer and Herzlinger, respectively.

It is worthwhile noting that the key supporters in cCBT case were depressed patients and therapists. Depressed patients do not make for good supporters because they suffer the somatic effects of depression, including loss of interest, increased fatigue and lack of energy, and, often, high levels of irritability (Kennedy, 2008; Targum et al., 2011; Vidal-Ribas et al., 2021). It is unlikely that such patients adopt something new, particularly if the technology involved lacked user-friendliness. Health care professionals are considered some of the most conservative individuals when it comes to new technology adoption. The implementation of digital health technologies often fails because of high expectations and the high costs of change (Herzlinger, 2006). The specific supporting culture thus plays an important role in the introduction of innovation and the process of implementation.

Sauer's comment on the importance of organisational structure influenced to flow of information within an organisation and to stakeholders is critical here (see Figure 3). There was no strong central entity to manage information flow to stakeholders. Any potential benefit that could have been obtained from involving therapists and patients, government officials and partner organisations was lost (Southon et al., 1997; Köpke

et al., 2019). The failed MasterMind project implementation underscores the importance of communication management, focusing not only on informing, but also on persuasion and promotion.

In retrospect, the clear distinction between friends and foes of cCBT pilot in Estonia is blurred. Indifference or frank opposition of the organisations the university approached to continue with cCBT pilot sank the project completely. Even though the Institute was interested in recruiting health care professionals, the motivation behind that was purely financial. Given this, one may legitimately consider that so called friends of cCBT were supporting its implementation passively. The reason behind that could be lack of policies and gaps in laws to promote implementation, inefficient funding and lack of interest and policy support (**I, II**).

Funding, the second of Herzlinger's Six Forces, was also poorly managed (see Figure 4). Funding plans need to be comprehensive, meaning that adequate funds need to be available for the duration of the project to be introduced, contemplate all the costs that might reasonably be anticipated and allow for an overage buffer. Otherwise, the possibility that the project may be financially strangled cannot be ruled out. Funding also affects employee dynamics.

Therapists asked for additional compensation for participating in the MasterMind project trial. It is difficult at this point to assess whether the request for compensation was aspirational, whether it reflected undocumented market perceptions, whether it foreshadowed a change in patterns of professional competition, whether it represented one of the ways underpaid health care professionals in Estonia could legitimately increase their income, or whether it was a mere political gesture.

In any case, unless there were legally, professionally or strong sociologically received objections to fees for clinical trial participation, or legitimate ethical concerns about conflicts of interest and other related issues, it might have been reasonable to negotiate payment before recruiting therapists. Not doing so could be read as personal disparagement, as well as professional exploitation. The fully burdened costs of a failed trial are very likely to measurably exceed the costs of additional compensation to the therapists. Thus, the possibility of additional compensation to the therapists should have been explored and planned for, to the extent allowable.

Should the payment of additional compensation been possible, it might also have made sense to incorporate this step as a matter of public policy, to preclude misunderstandings or conflict in the future and reduce the risks associated with recruitment for clinical trials in Estonia. In the cCBT example, good health IT policy with adequate funding mechanism and legal framework could accelerate the uptake of new digital health technologies among health care professionals.

A relatively focused technological issue regarding user authentication and sign-on procedures became a touchpoint during implementation. The responsibilities imposed upon the therapists included the implementation of an awkward authentication and sign-on system based on the Cognuse OÜ platform. The Cognuse OÜ platform worked to the advantage of Cognuse OÜ, who had an interest in acquiring certain health data but was unnecessary for the iFightDepression program. The sign-in routine conferred needless complexity on the therapists, which interfered with software platform adoption and the implementation of cCBT.

Rather than simplifying and enabling the trial, the sign-on technology encumbered the interface for the therapists and the patients. This problem could have been pre-empted by thoroughly evaluating the user experience before and during implementation and

putting in place procedures to improve the interface as problems emerged. This could and should have been of the validation process prior to launching the program in Estonia.

As seen, the system and technical processes of an innovation itself play a tremendous role in its success or failure. The technical process factor encompasses the constraints inherent in the hardware and software deployed and reflects the limitations of computer-based systems. It is more intuitive and easier to explore, but there still are subtleties that might be lost. In the cCBT example, patients with severe anxiety or complex psychological disorders may be put off by computer use. One might legitimately argue that depressed individuals would have a more difficult time integrating new technologies into their lives than individuals without depression, but this assertion would have to be studied carefully and proven to be true to be held out as a truth. Likely, depressed people might need more assistance and support when integrating with the technology similarly as younger generation is likely to adopt new technologies easier and faster compared to older generation.

In the recent study, Simblett and others (2023) have investigated factors that support usage of digital health technologies among depressed individuals. These factors are the accuracy in detection of symptoms, privacy and clear, proven and practical benefit of the technology (Simblett et al., 2023). In Estonia, on the contrary, patients main concern was associated with difficulties to manage online treatment (**IV**) since professionals' interaction with the interface of cCBT was very minimal due to the reasons mentioned above (Mol et al., 2020; **II, IV**).

In the example of cCBT, it turned out that iFightDepression program did not provide support or person-specific information to health care professionals regarding patient care management. In contrast, the technical aspects of how to access to the program and the design of the content of the cCBT resulted in failure to recruit professionals and patients. Furthermore, despite the literature and trial protocols suggesting guided cCBT as effective complementary tool for the improvement of minor mental health disorders, health care professionals reported lack of direct association between health outcomes and cCBT program. This can be explained due to either insufficient guidance by local professionals, low level motivation among patients and professionals or biased results of the previous studies (**II, V**). Thus, user satisfaction with technology and its acceptance matter and influence organisation to take steps towards its implementation or rejection.

Finally, Sauer includes history as a factor. History refers not only to near history, *e.g.*, factors like the ideas behind the development of a system such as iFightDepression program, but also the past experiences of users and decision makers. Relevant experiences might include the success and failure of legacy systems, previously failed IS, and other, similar conditions (Sauer, 1993; Kaplan, 1995).

Thus, failure of cCBT deployment was partially similar to failure of Estonian national e-booking system or Digital Registration in 2008 due to opposition from health care service providers (National Audit Office, 2015). Though state e-health solutions are likely to be implemented with time, failure to implement them in time is associated with lack of sufficiently detailed document standards; opposition of health care service providers associated with massive workload, lack of time and knowledge how to start to use the system; changes in the organisation and management and among staff members; lack of investments and emerging unexpected costs; and other technical reasons (National Audit Office, 2015). These reasons to which the failure of state e-health services was attributed deemed similar to the present case. Nevertheless, implementation of state e-health solutions is likely to be sustainable, goal-oriented, supported and supervised

by state actors. In the current case of cCBT implementation, however, support from state actors was not received. Even though CBT as a treatment option was already included in the treatment guidelines for depression, its alternative version of delivery, *i.e.*, through online channels, was in practice disregarded. Furthermore, cCBT as remote mental health service was not aimed to be a national project to fight against mental health disorders more broadly at national level. It was never included in the Estonian mental health policy document prior 2016.

In retrospect, slow acceptance of digital health technologies in Estonia is not at all, surprising. The healthcare sector remains very traditional and conservative in its perspective both in Estonia and beyond (Paré et al., 2008). Therefore implementation of new digital health technologies requires more time and patience to identify the possible risks and impediments for adoption and use.

The need to retain, as well as to recruit volunteers for the trial has already been noted. The size of the staff assigned to patients was insufficient and the time they could devote to optimising the patient experience was inadequate. As a result, if patients disengaged or dropped off, or were put off by the technology or the trial, there was nothing positioned to help them. The principles of customer relations management are applicable to patients in trials, even in a small pilot study.

Finally, the need for accountability – the demand from stakeholders for reassurance and proof that the health care innovation is safe and effective – was not explicitly satisfied. This need was complicated by the number of stakeholders and the fact they were layered – the European Commission, professional organisations, practitioners, patients and others rather than strongly networked.

It may be reasonable to add one more observation to the mix to explain the failure of cCBT implementation in Estonia. Clinical trials generally do best when the distribution of benefits across the stakeholders is well understood and openly articulated. This is especially the case when the trial involves therapeutic services. That articulation bears repetition at multiple points in the process, beginning with when it is conceived. In the case of MasterMind project implementation in Estonia, even though iFightDepression program had already been deployed elsewhere in Europe and piloted during PREDI-NU project between 2011–2014, data obtained, and proof of concept obtained, the local aspects of project development, initiation and implementation were not adequately nurtured.

4.4 Reflections on Frameworks for Failure Analysis in HCIT

The frameworks summarised above are directed at technology acceptance and adoption, which constitute only one part of the integration of new technologies into the health IT market. Technology adoption has been the object of a great deal of research work. One reason technology adoption has garnered so much attention is that is so difficult and, statistically, relatively elusive: many technologies are introduced, but few are adopted, and fewer persist to become market leaders. Therefore, successful technology adoption is fascinating. Therefore too, it is highly appealing to try and model the characteristics of successful technology adoption to improve the likelihood of success.

As tempting as it may be to simply anticipate and synoptically designate failure of technology adoption as the all-purpose outcome of failure analysis in HCIT, it would ultimately be unreasonable. Adoption might be the first gating function in the successful introduction of a new technology, but it is not the only gating function.

Technologies are inevitably subject to market dynamics that may result in eventual failure or success prior initial introduction. Introduction, however, does not entail adoption.

Whether the term adoption can be used equivalently to the idea of widespread utilisation is debatable. It probably cannot. The meaning and implications of adoption need to be addressed specifically for each and every case under discussion. Neither initial technological success nor initial market entry (introduction) guaranty early adoption, successful implementation, widespread utilisation or lasting market success. Introduction precedes adoption. Implementation and adoption are closely timed. Utilisation is the third step. Market success can be assessed only over time.

One potentially important distinction that has not been adequately pursued, is the differences to be found amongst adopters between large and small, or between developed and emerging economies. In certain domains of technology, medicine and the life sciences, the adoption of particular forms of diagnosis and treatment may be heavily influenced by sets of cultural factors and perceptions of risk that need to be more methodically explored (Lee, 2000; Lee, 2004; Rycroft-Malone, 2004).

In conclusion, the failure in the present study can be characterised by a failure of implementation that comprises breakdowns and malfunctions of preparation, initiation, and adoption. These are examples of the way failure analysis has been undertaken and in which failure in HCIT has been analysed. Nevertheless, these methods are inadequate because of biases based in part on the sources of research funding, lack of generalisability, inappropriate validation of quantitative and qualitative methods; and in part on the risks of reductionism, subjectivism and too narrow focus on a specific technological solution.

Furthermore, the adoption of the new technological innovation largely depends on the interaction of subjective[9], objective[10] and sociodemographic[11] acceptance factors as well as the context in which acceptance occurs (Safi et al., 2018). Thus, acceptance or adoption of a technology in a very complexed environment cannot be predicted categorically because of the variety of perceptions of individuals who will be involved in evaluating the risks associated with using the technology for the purpose of delivering safe, secure, reliable and effective care. The conditions under which these individuals are required to use the technology may either encourage individuals' motivation or discourage and prevent them from using the technology in equal measure.

Lastly, the decision to accept or reject the use of the technology may also depend on outside factors such as financial impact, adequate legal frameworks, political climate of the organisation where the technology is expected to be implemented, cost-benefit analysis, acquisition of necessary skills and participation cultures, or opportunities for work facilitation (Safi et al., 2018).

4.5 Results

The initiative to introduce and deploy cCBT in Estonia between 2014 and 2017 took the form of a pilot trial. It was highly expected that introduction of cCBT in Estonia would be successful due to highly digitalised infrastructure. Nevertheless, the predictions fail. While the initiative recruited a sufficient number of patients elsewhere in Europe to

[9] *E.g.*, attitudes and cultural and religious beliefs.
[10] *E.g.*, functionality and advantages of using technology.
[11] *E.g.*, age and educational level.

continue and complete the study (Vis et al., 2022), the dynamics in Estonia were not systematic. The recruitment goal was 300 patients but only 56 patients were recruited. At the time it was abandoned, the trial in Estonia was deemed to have failed (**IV**). Implementation of cCBT in Estonia was considered to have failed by the EC and those responsible for implementing the cCBT study. Failure of cCBT in Estonia met the following criteria (Toots, 2019; Dwivedi et al 2015):

1. Perception of stakeholders that the system failed;
2. A sufficient history to permit following the system's evolution over time;
3. Access to information about its context;
4. Failure to launch according to plan;
5. Materially flawed functionality after launch;
6. User dissatisfaction sufficient to impair meaningful or projected adoption.

It seems clear that at the time of cCBT implementation, the Estonian situation was not fully comprehended or managed by the project organisers. Having digital health infrastructure and public services did not guarantee nor suffice the effective implementation of cCBT. This thesis has proved that even in the digital friendly country such as Estonia, failure of cCBT implementation is not a phenomenon.

Although the cCBT implementation was construed as a trial, the dimensions of the trial were not adequately thought through. The endpoint of the trial was planned as a trial of the effectiveness of cCBT. In effect, it assumed the infrastructure necessary to implement cCBT was in place. The assumptions behind the trial were not correct.

In reality, this project should have been construed as the trial of multi-tiered, but better coordinated project with a number of arms, involving and including:

1. The introduction of cCBT to both general and mental health care professionals in Estonia;
2. A detailed demographic analysis of the population of people with depression and anxiety in Estonia;
3. The development of a number of organisational partnerships to facilitate and strengthen a clinical trial implemented by only loosely connected professionals;
4. A detailed analysis of the individuals within this population who might be eligible for CBT together with how they might be approached (important to note that some individuals may not have sought treatment yet and may not yet be patients);
5. An assessment of patients in this group who have the necessary infrastructure capabilities (*e.g.*, computer access, bandwidth, relationship with therapists who might be inclined to participate);
6. An assessment of therapists who might be capable and willing to participate in the trial, alongside of an assessment of their requirements for participation;
7. An assessment of the broader context for the introduction of a new therapeutic modality to include government and regulatory bodies and professional organisations;
8. Obtaining commitments from professionals who would participate in the trial;
9. Involving the therapists personally in the trial so that they would have a stake in the outcome;
10. Creating a software testing strategy with specific performance objectives;

11. Examining the software proposed, and subjecting the software to standard tests of suitability specifically for the users who would be involved in the trial in Estonia, rather than the EU generally;
12. Appointing separate teams for functional and non-functional testing;
13. Simulating the appropriate testing environment for testing the software, including end users and developers;
14. Soliciting user (client) feedback and establishing a response mechanisms;
15. Subjecting the software to standard tests of verification, validity, scalability;
16. Undertaking significant changes and planning for future version changes based on continuing feedback in use;
17. Establishing and incorporating user groups;
18. Establishing and empowering rapid response assets to deal nimbly with all aspects of the trial including the software issues as they came to pass;
19. Providing for interim looks over the term of the trial to identify and address remediable problems.

To conclude, the healthcare sector today involves a wide range of stakeholders with different interests, needs and expectations, perspectives, power and policies. To meet all demands is unrealistic. Therefore, it is highly likely that implementation of new digital health technologies in healthcare sector, even though proved to be clinical and cost-effective, results in failure.

The key element in preventing failure is organisation. Implementation failure of new digital health technologies depends on interaction between healthcare organisation with internal and external stakeholders as well as consistency between internal and external policies regarding reimbursement, legal and regulatory issues. The weaker is the role of organisation (*e.g.*, management board of health care setting), the higher is the risk of failure to introduce and deploy a new health care technology. Implementation failure in the organisation can be prevented through careful and transparent planning and transparent decision making as well as involvement of targeted stakeholders at the early stage of introducing the digital health technology (Vis et al., 2022). No less important is to have available technical support, data collection and analytical tools (Vis et al., 2022).

Organisation is also a central element in employing skilful health care professionals with experience and relevant expertise, and additionally organising the specific trainings when necessary. Continuous staff development, education and trainings provided by technology developers and health care professionals involved in the implementation work as well as professionals' enablement in the context of collaborative team-based approaches can facilitate knowledge exchange (Vis et al., 2022) and change the practice of health care professionals (Chauhan et al., 2017). Professionalism of health care professionals, in turn, influence on the attitudes of patients and trust towards health care services (Birkhäuer et al., 2017).

The size of an organisation also plays an enormous role in preventing implementation failure. In a small organisation, implementation of new technologies might be resistant due to lack of collaboration between professionals.

The role of an organisation is no less important outside of an organisation itself. Its active participation with the technology developers, administrative bodies and insurance companies optimises implementation strategies of new digital health technologies and

lead to optimisation of costs for public healthcare services, reimbursement, and legal clarity around privacy issues.

The technology itself is no less important for analysis prior its implementation. The process of introducing something new to health care professionals or implementing it in the healthcare organisation must meet certain criteria. Those include safety, effectiveness and ease of use. If technology is effective but too complicated to proceed with, or the technology is safe but there is no objective positive effect on health outcomes, the risk of failure to implement that particular technology is high. Technology must be a facilitator not a barrier. It must be easily integrated into day-to-day workload, clearly define benefits for improving practice and patient outcomes (Keyworth et al., 2018). Therefore, to enhance motivation of stakeholders, the technology must be user friendly, easy in use and focus on providing decision support for clinical practice and person-specific information to assist with patient management (Keyworth et al., 2018).

Digital health technologies have promising results in addressing barriers in work environment such as time and workload pressure resulting in change of professional practice and greater impact on patient outcomes (Ross et al., 2013). It has been also noted that positive and proactive attitude towards new health care technologies and information systems may improve work experience and well-being of health care professionals (Mansour et al., 2022). Nevertheless, using rigid digital health technologies as part of everyday practice may in contrary increase workload, cause time pressure and thus disrupt the workflow of health care professionals, primarily working in primary care settings (Keyworth et al., 2018; **II**). These barriers are influencing the effectiveness of technology-based interventions and likelihood of health care professionals using technology (Keyworth et al., 2018). In retrospect, one may legitimately claim that the piloted cCBT program iFightDepression caused additional time and work pressure.

Time management is critical for implementation of digital health technology in the healthcare organisation. It can both accelerate and impede the uptake of technology, if introduced at the right time or at the wrong time. It can also apply to technology whether access to technology is time-limited or whether the use of the technology is time-consuming. Given the workload of health care professionals, a typical issue in implementing new health technology is a lack of time to concentrate on benefits the health technology can provide. The cCBT pilot was estimated to conduct in three years. In reality, however, the cCBT introduction to health care professionals and deployment in the organisation started since the approval from ethics committee was received. By saying this, the real time for professionals' and patients' recruitment was left less than two years. Lastly, the endorsement of cCBT at national level required evidence of clinical- and cost-effectiveness of the program.

Implementation failure in new health care technologies is facilitated by financial incentives too. For example, reimbursement, transparent and fair payment as a way of engaging health care professionals may accelerate the uptake with technology (Keyworth et al., 2018; Vis et al., 2022). Compared to other pilots in different regions (**IV**), at the time of the cCBT pilot in Estonia, no financial support was offered to health care professionals nor patients to complete with cCBT program. Important to note, that financial incentives may attract health care professionals at the beginning, in a long-term perspectives, reimbursement does not influence practice change (Chauhan et al., 2017).

Failure to implement cCBT in Estonia was also related to a level of public policy support and the priorities set up by the Government. In general, mental health policies in Estonia include prevention of psychiatric and behavioural disorders, early and timely access to mental healthcare facilities and the promotion of mental health in society *inter alia* through self-help tools. The activities and interventions, however, continue to reflect fragmented mental health policy insofar as those are not strategically planned with cross-cutting clearly delineated responsibilities between health care professionals in mental and primary healthcare.

5 Discussion

Digital mental health services, including cCBTs have been introduced and successfully implemented in many European countries. Many of those countries successfully implemented, however, are less digitally advanced than Estonia. This study addresses the failure of deployment of cCBT in Estonia and the reasons of failure through the conceptual analytic frameworks following Sauer (1993) and Herzlinger (2006). The framework is tested on the cCBT case of implementation, which was selected not only because of the nature of the case and for the purposes of understanding the Estonian context and experience, but also because it provides insights into the deployment of patient facing HCIT and digital health incentives more generally. This thesis, therefore, adds an explicit analysis of the dynamics of health care innovation and its significance. Although innovation holds a respected place in healthcare and, of course, in software development and computing, the analysis of a failed HCIT project simultaneously from both the software implementation and the healthcare innovation perspective does not seem to have been fully developed previously (Greenhalgh et al., 2020; Greenhalgh et al., 2019; Greenhalgh et al., 2017). This thesis also showed that having e-competence and highly digital ecosystem does not suffice to implement cCBT or any other patient-facing HCIT. Therefore, this thesis aimed to study how and why implementation of cCBT in Estonia failed and what needs to be done to make it success.

5.1 Reasons for Failure of cCBT Implementation in Estonia

To understand and explain the pertinent aspects of the failure on the introduction and deployment of cCBT in Estonia, the reasons for cCBT failure must be outlined.

The key important observation demonstrated that e-mental health technology has to function in a matrix structure that includes, but is not limited to (i) national and local regulatory considerations and health policies; (ii) pertinent workflow preferences; (iii) reimbursement; (iv) computer availability and literacy, including access to and speed of Internet; (v) models of acceptable physician-patient relationships; (vi) infrastructure for the social and psychological support of patients; (vii) familiarity with and acceptability of remote care; (viii) family and social structure; (ix) community fabric; (x) diagnostic conventions (*e.g.*, what is depression?); (xi) demographic considerations (*e.g.*, who is depressed?) and (xii) therapeutic protocols. This structure also touches on more difficult questions around the sociology of depression including the question of what degree of depression is deemed acceptable or tolerable in the patient's community.

The second observation pertains to the process and organisation of recruitment. This thesis demonstrated that failure to recruit was itself the result of other contributory factors and biases that need to be understood.

One of the main factors included the failure of coordination of the cCBT program, poor preparation and promotion prior to initiate, and failure of deployment at the local level. Health care professionals referred that cCBT does not provide direct contact with patient and that may result in poor quality of self-management and care in general (**II**). Second, they emphasised that patients with severe mental disorders need more careful attention and cCBT may not be suitable for them considering the nature and severity of their illness (**II**). Finally, they concluded that cCBT if not integrated with their day-to-day practice and information system may unnecessarily increase workload and result in poor management and quality they would offer to patients (**II**).

In retrospect, this can be partially explained since lack of eligible professionals to conduct a trial resulted in recruitment of professionals without adequate education and familiarisation. Due to this limitation, a detailed understanding of the specific factors influencing their perspectives could not be fully established.

In general, however, e-mental health initiatives have been positioned as saving time for the practitioners (Parisi et al., 2021; Donaghy et al., 2019). This thesis showed, that in Estonia, practitioners have remained sceptical (**II**, **IV**). New therapies, in general, are often perceived to be time-sinks. Physicians have expressed the desire to be reimbursed for the administrative and clinical responsibilities that might become incumbent upon them with the introduction of new technologies and protocols. This represents both an economic concern and a personal, work-flow anxiety. At the very least, they often ask to be reimbursed separately and explicitly for online consultations. The introduction of e-mental health initiatives must, therefore, contend with the economic demands of practitioners.

Another reason observed was related to the potential fearfulness of online therapy for patients with emotional distress (Di Giacomo et al., 2019; Meier, 1985; Olavarria, 2014) and their ability level to adhere and comprehend the new method of depression treatment. Although patients' fearfulness towards digital mental health interventions cannot be addressed adequately in this thesis, a particular somatic symptom in depression is loss of energy (Vreijling et al., 2023). That makes it difficult for patients with depression to make decisions or adopt changes in technology (Simblett et al., 2023; Biagianti et al., 2023). Even if patients were to agree, or decide to make a change or attempt something new, the motivation to actually engage in change may be sorely lacking (Titov et al., 2010). As a result, the effort to introduce new modes of therapy, including e-mental health to depressed individuals, needs considerably more than just the education of the practitioners and the prescription of a new protocol for the patient. The introductory effort must include a component of advertising and marketing to the patient, not dissimilar to the strategy described and promoted by the advertising genius David Ogilvy (Ogilvy, 1983; Young, 2018).

5.2 Limitations of the Study

The limitations of this study include the following. First, the interpretation of the research findings can be criticised due to the limited generalisability of case studies overall, including this one (Yin, 2017; Price et al., 2004).

Second, the generalisability of this study may be limited to be the very setting that enabled it, *i.e.*, the unique setting of the research in Estonia, a country with a strong digital ecosystem and health-IT infrastructure. Were the same efforts to have been studied in a different setting, other, and potentially different details might have become more salient, and the conclusion might have required modulation.

Third, this study is subject to criticism for its potential lack of objectivity due to intensive participant observation and the personal involvement of the author as project manager (Iacono et al., 2009). Limitations on observer involvement can also impede a researcher from fully understanding the context being studied and bias data interpretation (Takyi, 2015). On the other hand, the personal understanding and interpretation of a case through observation and participation is unique (Iacono et al., 2009) and has been recognised as potentially providing unique and valuable insights (Myers, 2000).

Fourth, this study would benefit hugely from more data, in particular, analysing more patients' experiences in using the iFightDepression program in Estonia. Low awareness among the general population on cCBT and e-mental health programmes in Estonia in general contributed to difficulties with patient recruitment. While the author of this dissertation does not expect that the conclusions would have differed with a larger cohort, this study may still suffer from sampling errors and small numbers.

These limitations have been mitigated by comparison of the pilot cCBT case with the academic literature.

6 Conclusion

This thesis studied an example of the introduction of e-mental health services in Estonia. Despite the robust e-health infrastructure, only 56 patients were recruited of the 300 that were targeted, and only a handful of physicians and mental-health practitioners.

Initially, the EU hoped to obtain data on the clinical, real-time, clinical efficacy and effectiveness[12] of e-mental health in cases of mild to moderate depression – one of the most prevalent emotional disorders. While clinically useful and statistically significant data emerged elsewhere in the EU, they were not forthcoming in Estonia. Some indications of effectiveness, *i.e.*, how cCBT helped symptomatic depressed and anxious individuals in Estonia, could be inferred from information signalled by the data, but clinically significant data were elusive. Therefore, the lack of conclusive data was disappointing and the circumstances of the pilot introduction to e-mental health still generated very interesting information regarding the steps required to improve the implementation of e-mental health services and, by implication, to improve the introduction of new e-health services more broadly.

The purpose of this thesis was to examine the reasons behind the unsuccessful implementation of cCBT in Estonia and to propose recommendations that can be considered from this failure for future implementations. The research questions that guided this study were as follows:

1. How was cCBT implemented in Estonia? (RQ1)
2. What were the reasons and factors that contributed to the failure of cCBT implementation in Estonia? (RQ2)
3. What lessons can be learnt from cCBT implementation failure in Estonia to prevent failures of implementing other but similar digital health initiatives in future? (RQ3)

To answer these research questions, a case study methodology was employed, which involved conducting interviews with stakeholders, analysing relevant literature and documents, and observing meetings related to cCBT implementation.

The findings of this case study indicate that several factors played a role in the failure of cCBT implementation in Estonia. These factors can be summarised as follows: (i) lack of skilful stakeholders' engagement within the project from its initiation, (ii) inadequate funding mechanisms to support stakeholders for long-term use of cCBT, *i.e.*, after the project end; (iii) insufficient project organisation and communication between organisers and end-users, (iv) technical issues with the platform used for delivering cCBT and (v) lack of policy support with supportive tech-friendly legal framework.

This case study offers important insights for the future implementation of patient-facing digital mental health initiatives, highlighting the need to overcome the challenges and influential factors mentioned above that lead to the failure of cCBT implementation in Estonia. It is anticipated that these findings will inform and prevent future implementation failures, thereby enhancing the global access to digital health services.

Addressing the first research question (RQ1), it was observed that implementation of cCBT in Estonia was marred by organisational inadequacies. A limited engagement of key stakeholders during the planning and execution phases resulted in resistance to change.

[12] When referring to therapeutics, efficacy refers to the statistical likelihood that a desired effect is achieved. In theory, under ideal circumstances, effectiveness refers to clinical effect that can be documented under real world circumstances.

In response to the second research question (RQ2), it was determined that the success of digital health initiatives hinges on a robust infrastructure, one which includes reliable and ample financial resources. Budgetary limitations can obstruct the implementation process, leading to incomplete or poorly executed initiatives. There is very little written about economic incentives and reimbursement associated with the introduction of e-mental health services in Estonia specifically. Nevertheless, there is much to be learned from the positions assumed by mental health practitioners elsewhere and with professional organisations associated with mental health in other locales, even if the medical practice and reimbursement models of mental health services are substantially different across different countries (Wykes et al., 2015; American Psychiatric Association, 2023; American Academy of Child and Adolescent Psychiatry, 2023; Titzler et al., 2018).

Other factors that contributed to the failure of implementation of cCBT in Estonia included the difficulties encountered in integrating the program with the e-health platform. These difficulties impeded information exchange, thereby necessitating additional efforts and responsibilities for the delivery of cCBT. The most significant challenges were the inability to recruit trained professionals who could effectively recruit patients, resistance to changes in workflow, and a lack of financial incentives to motivate key stakeholders and ensure the project's sustainability after its completion. Furthermore, the technology lacked a user-friendly or user-centred design, which deterred many users from continuing with cCBT. For digital health initiatives to be successful, it is crucial that end-users find value in the technology and actively engage with it. If aspects such as usability, accessibility, and user experience of digital health solutions are not prioritised, it can lead to low adoption rates, limited usage, and ultimately, implementation failure.

In response to the third research question (RQ3), it is evident that further research is imperative for the successful introduction and promotion of digital or (e-)mental health services in Estonia.

This case study serves as an example of a situation in which the failure analysis points to contextual reasons for failure, but the forces resisting innovation in health care reinforced the failure. The putative virtues and benefits did not suffice to overcome the forces or the contexts in which they function. As seen, the results of this thesis are specific to the failure of cCBT implementation in Estonia. Nevertheless, the recommendations provided below have broad applicability and can be used to prevent similar failures in implementing other digital health services in future.

First, the research conducted and reported upon in this thesis emphasises the need for coordinated efforts around both public policy and professional education to implement digital or (e-)mental health services and include them in routine care (**I**, **III**). The recommendations are restricted to digital or (e-)mental health applications because the psychosocial milieu for and determinants of other digital or (e-)health applications and in other domains may turn on factors that are not in play in Estonia and that have not been considered here (Ross et al., 2016; Vitacca et al., 2009). Promotion of e-mental health among the public in general and capacity building among health care professionals are required to improve access to, coordination and continuity of mental care (**I**-**III**). Also, no less important is to implement appropriate regulatory and funding mechanisms to maintain the sustainable use of e-mental health (**II**, **III**).

Second, the purpose of education is to establish credentialed competence in the use of digital or (e-)mental health technology but also to provide a workable context for the technology's use. The aphorism – all healthcare is local – is an oft-repeated truism but it

is especially true in this setting (Clyde et al., 2008). The issues are: (i) just how local and (ii) what, exactly does local mean (Clinton Foundation, 2013). In some locations, local can be defined by distance. In others, it is a matter of culture, language, history, race or other influencers. In any event, locality affects the choice of medical treatment for both the treating health care professional and the individual treated (McCarthy et al., 2017). Breakdowns in the introduction of change can be ascribed to remarkably small things. This phenomenon is well described in the literature of change management generally, and change management associated with digital health in particular (Kho et al., 2020).

Third, implementation of any e-health system and health care technology qualifies as innovation process. It is subject to predictable uncertainties, vulnerabilities and changes in context. The experience in Estonia demonstrated that the achievement of professional competence does not necessarily lead to openness to change or to the introduction of new technologies. Some of that may be due to what is locally accepted and expected in healthcare. Some may be due to a theory of good enough – why change? Some may be due to the perception that change from what seems to work well enough entails extra work for the health care professional, either during the immediate process of new technology adoption or in its wake. And especially when the full implications of workflow alterations after changes in medical protocol are unfamiliar, there will be resistance to change (Kho et al., 2020; Vitacca et al., 2009).

Fourth, the innovation in cCBT was the computerised part rather than the cognitive behavioural therapy aspect. Nevertheless, it was the launch that failed because it did not inspire confidence or adequate interest on the part of the therapists or the patients. It would be incorrect and myopic to suggest that the failure of cCBT in Estonia was a technological failure, although it was, actually, a product failure. The failure of the product launch involved a complex set of decisions and manoeuvres and therefore could not really be separated from the process of introduction. Within Estonia, the process was intended to introduce the new method of e-therapy for depression and anxiety. The method included the technology; the process to implement started with introduction. So long as the process resulting in adoption had worked, and so long as cCBT would resulted in improved access, convenience and good or better clinical outcomes, the ministry, the European Commission, the therapists and probably the patients would have been satisfied. It was only as the process of introduction failed, that the introduction itself became the critical gate to the use of the product to treat depression.

Lastly, failure of cCBT implementation might have been avoided had the local stakeholders in Estonia been empowered successfully and effectively networked into the project. An unanswered question in this analysis is the effect of time scales. The failure reflected the typical vulnerabilities of patient-facing health care, and especially of patient-facing software trials in digital health. It is prudent always to construe health care as local care, even when it is an extension or an expression of a larger entity, process or initiative (Flyvbjerg, 2006; Kratochwill et al., 1992; Miller, 2018).

The experience in Estonia also demonstrated the wariness of patients to adopt a change in technology and treatment protocol. From a theoretical and arguably a near-ideological perspective around ideal healthcare, the improvement of patient autonomy and self-help is highly desirable in many cases. From a clinical perspective, however, two of the salient characteristics of depression is the loss of self-worth and fear of abandonment (National Institute of Mental Health, 2022; Kennedy, 2008; Taylor, 2008). One can readily imagine that patients suffering from depression might be fearful of the shift to self-care and terrified that they might be abandoned by their therapist.

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Abstract

Understanding Failure in Digital Health Implementation – A Case Study of Implementing Computerised Cognitive Behaviour Therapy (cCBT) in Estonia

Computerised Cognitive Behaviour Therapy (cCBT) is a cost-effective and evidence-based method for treating common mental health disorders, such as depression and anxiety. cCBT was introduced in Estonia to support traditional face-to-face therapy, increase awarenness about mental health self-help tools for management of mild to moderate level of depression and anxiety and reduce the burden of primary care physicians. Estonia seemed to be ideal place to ipleemnt cCBT due to it high capacity in implementing several e-health projects and advanced e-health ecosystem. Contrary to expectations, implementation of cCBT failed with numerous challenges. This thesis, therefore analysed the implementation failure of cCBT in Estonia and proposes recommendations to prevent failures of other but similar digital health projects in future. It also provides insights to advance the understanding of the utilisation of failure analysis frameworks.

The thesis starts with an introduction that provides background information on digital mental health initiatives and their potential benefits. The introduction also outlines the research questions that guide the thesis, including how cCBT was implemented in Estonia, why the implementation of cCBT in Estonia failed, what factors contributed to its failure, and what recommendations can be considered to avoid similar failures in other contexts.

The second chapter introduces the case study methodology used to investigate the implementation process of cCBT in Estonia. It describes how empirical data were collected through interviews and online survey with stakeholders, document analysis, and observation of meetings related to cCBT implementation.

The third chapter provides background of the theory of failure analysis. It presents a literature review on implementation challenges of health care information technologies and investigates the definition of failure and success in implementation project. Lastly, the chapter presents frameworks for failure analysis.

The fourth chapter provides insights into the case study and presents its findings. The chapter starts with an overview of the Estonian healthcare system and its digitalisation efforts. Next, it describes how cCBT was introduced as part of a larger initiative to improve access to mental health services in Estonia. The chapter includes analysis of the stakeholders involved in the implementation process, their roles and the key factors that contributed to the failure of cCBT implementation in Estonia.

The fifth chapter discusses the results of the case study. The reasons for failure of cCBT in Estonia and limitations of the study are thoroughly considered.

The last chapter of the thesis concludes with an answer to the research questions emphasising main findings and contributions and highlights the need for more research on implementation challenges in digital health initiatives.

To conclude, this thesis contributes to the understanding and analysis of innovation failure in healthcare and provides recommendations for failure prevention and implementation of patient-facing digital mental health services.

Kokkuvõte

Mõtestades e-Tervise rakendamise ebaõnnestumist – arvutipõhise kognitiivse käitumisteraapia (KKT) rakendamise juhtumiuuring Eestis

Arvutipõhine kognitiivne käitumisteraapia (KKT) on kulutõhus ja tõenduspõhine meetod enamlevinud vaimse tervise häirete ravimiseks, eelkõige depressiooni ja ärevuse puhul. KKT tutvustati Eestis eesmärgiga suurendada teadlikkust vaimse tervise eneseabivahenditest, aidata juhtida mõõdukat depressiooni ja ärevust ning vähendada esmatasandi arstide koormust. Eesti tundus ideaalne koht arvutipõhise KKT rakendamiseks tänu selle suurele võimekusele mitmete e-tervise projektide elluviimisel ja arenenud e-tervise ökosüsteemile. Vastupidiselt ootustele ebaõnnestus KKT rakendamine mitmete väljakutsete tõttu. Käesolev lõputöö analüüsib arvutipõhise KKT rakendamise ebaõnnestumist Eestis ja pakub soovitusi, kuidas vältida sarnaste digitaalsete terviseprojektide ebaõnnestumist tulevikus. Samuti pakub töö teadmisi ebaõnnestumise analüüsi raamistikest, et edendada paremat arusaamist.

Doktoritöö sissejuhatuses annab autor ülevaate digitaalsete vaimse tervise rakendustest ja nende potentsiaalsetest kasudest. Sissejuhatuses toob autor välja uurimisküsimused, millest käesolev uurimistöö lähtub sh kuidas arvutipõhist KKT-d on Eestis rakendatud, miks see rakendamine ebaõnnestus ning mis olid selle peamised põhjused. Sissejuhatuses antakse ka soovitusi, mida teiste digitaalsete või e-Tervise rakenduste ebaõnnestumiste vältimiseks tuleks arvestada.

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Neljandas peatükis annab autor ülevaate juhtumiuuringust ning toob välja uuringu tulemused.

Viiendas peatükis analüüsib autor juhtumiuuringu tulemusi, selgitades täpsemalt, mis olid peamised tegurid, mis põhjustasid arvutipõhise KKT rakendamise ebaõnnestumise Eestis ja doktoritöö uuringu läbiviimise piirangud.

Doktoritöö viimases peatükis annab autor vastused uurimisküsimustele tuues välja olulisemad järeldused ning soovitused. Peatükis rõhutatakse suurema uurimistöö vajaduse järele tervisetehnoloogiate rakendamisel.

Käesoleva doktoritöö uurimus panustab teadmistega arvutipõhise KKT ja muu tervisetehnoloogiate rakendamise ebaõnnestumiste ärahoidmiseks ning vaimse tervise innovatsiooni elluviimise optimeerimisele e-tervise teenuste kontekstis. Lisaks annab uurimus soovitusi patsiendile suunatud digitaalse vaimse tervise teenuse optimeerimiseks ning üldisemalt kogu tervishoiu infotehnoloogia integreerimisele digitaalsetesse tervisesüsteemidesse.

Kokkuvõttes annavad käesoleva doktoritöö tulemused erinevaid võimalusi mõista ja analüüsida digitaalsete tervisetehnoloogiate rakendamiste ebaõnnestumisi toob välja soovitusi ebaõnnestumiste ärahoidmiseks.

Appendix 1

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Challenges and opportunities for e-mental health policy: an Estonian case study

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ABSTRACT

Public administration of mental health policy is an area that raises issues about human rights and dignity, equality of access to high-quality mental health services and the adequacy of financial resources. Globally, most people with mental health problems lack access to care services due mainly to the limited number of trained specialists, the stigma and discrimination associated with mental illnesses, and fragmented service delivery models. A widespread response to the growing demand for integrated care is the establishment of e-mental health services engaging primary and secondary healthcare specialists from different disciplines. In Estonia, evidence-based e-mental health solutions are being introduced to improve access to mental healthcare and to reduce the costs associated with treatment. However, awareness of the benefits of e-mental health solutions remains limited among healthcare professionals and the wider population. This article draws on findings from EU-funded research projects to examine the challenges Estonia faces in adopting e-mental health solutions. The author shows how the lack of public investment in evidence-based e-mental health interventions and the reluctance of relevant professionals to engage with e-mental health technologies have resulted in legal uncertainty, hindering full implementation of e-mental health policy in mental health services.

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e-Mental health policy; internet delivered cognitive behavioural therapy (CBT); integrated mental healthcare; digital awareness

Introduction

Health policy is evolving globally due to the rapid application of technological innovations. Change is needed not only to improve the quality of health services, avoid inaccurate diagnoses, errors in prescribing medication, unnecessary treatment and unsafe clinical facilities, but also to remedy the shortage of high-skilled healthcare professionals (Kieny et al., 2018). According to the World Health Organisation (WHO, 2016b), the global shortfall of healthcare professionals has contributed to the inadequate provision of even basic healthcare. Arguably, the unequal distribution of healthcare resources and the poor quality of healthcare are exacerbated by problems of access and acceptability of effective treatments, making quality teamwork and supportive environments difficult to establish (Kieny et al., 2018). All these problems are especially acute in mental healthcare.

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For WHO (2018), depression is one of the most common mental disorders among the population in general. According to a UK psychopharmacologist of depression, Philip Cowen (2017, p. 17), 'the central diagnostic features of an episode of clinical depression are regarded as low mood, lack of enjoyment in most or all aspects of life, and lowered energy'. At least two of these three features and a number of other symptoms such as reduced concentration, self-esteem and confidence, ideas of self-harm, disturbed sleep and diminished appetite need to be present for 'at least two weeks' to fulfil a diagnosis for a 'depressive episode' in the International Classification of Diseases 10th Revision (ICD-10) criteria.

In 2015, the 'prevalence of depression', as diagnosed among 322 million people worldwide, was estimated to be 4.4% of the global population and 5.9% of the Estonian population (WHO, 2017). The proportion of people in the EU suffering from 'chronic depression' in 2014 was estimated to be 7.1% and 4.8% in Estonia (Eurostat, 2018). Untreated depression is known to lead to self-harm and suicide. Globally, nearly 800,000 deaths per year are suicide cases (WHO, 2017). Half of all 'completed' suicide cases have been found to be associated with depressive and other mood disorders (Bachmann, 2018). In the EU, the average standardised death rate for intentional self-harm incidents was 10.9 per 100,000 residents (Eurostat, 2018). Estonia is among the top 20 countries in the world reporting high suicide rates (WHO, 2018). With 17.8 suicides per 100,000 residents, it is in sixth place in the EU (WHO, 2018). Of the two other EU Baltic states, Lithuania records the highest suicide rate in the world with 31.9 suicides per 100,000 residents, followed by Latvia with 21.2 suicides per 100,000 residents (WHO, 2018). Despite being very different from Estonia in many respects, Switzerland records similarly high rates to Estonia for suicides (17.2 per 100,000) and depression (5.0%). In 2017, Switzerland also reported the highest number of psychiatrists in the European region: 51.7 psychiatrists per 100,000 residents, compared to only 18.4 psychiatrists in Estonia, 14.7 in Latvia and 23.7 in Lithuania (Eurostat, 2019).

In recognition of the high incidence of untreated depression and high suicide rates, governments at national level, for example, in Australia, Canada, the Netherlands, Sweden, the UK and USA, have recognised the urgent need to improve timely and fair access to mental health services, justifying the use of technological innovations. In this article, 'e-mental health' refers to a broad concept encompassing digital mental health programmes, e-prescription and online documentation, as well as e-consultations and the use of Artificial Intelligence (AI) and various electronic devices in the provision of mental health services. Evidence from evaluations of e-mental health therapies blended with traditional guided mental health interventions, already in use in the EU, Australia and the USA, has shown how they can facilitate and increase access to treatment (Berger et al., 2017; Hickie et al., 2010; Høifødt et al., 2013; Rollman et al., 2017). In addition, the development of AI has resulted in more advanced automated or semi-automated therapeutic tools (Foley & Woollard, 2019). These different technological advances are changing mental healthcare in ways that are found to provide more person-centred care, which is becoming an increasingly important objective for all health services.

This article focusses specifically on the challenges faced in Estonia in developing and implementing computerised Cognitive Behavioural Therapies (cCBTs) for the treatment of mild forms of depression, delivered on-line, guided and/or unguided. Whereas CBTs

are widely accepted for the treatment of mild depression, the use of cCBTs is frequently contested. The piloting phase of two EU-funded research projects (PREDI-NU and MasterMIND) in which Estonia participated between 2011 and 2017, identified various factors that are hindering the development of a fully integrated mental health strategy. These factors are analysed with reference to the Estonian case. Given that, in many areas of healthcare, Estonia is considered to be one of the most digitally advanced countries in the EU, and the adoption of new technologies by patients, healthcare providers and funders is seen as the key to the success of Estonia's e-health policy (Saluse et al., 2010), the interest here is in understanding why e-mental health innovations have not been more readily embraced.

The first section of the article situates Estonian e-mental health services in relation to the EU Digital Single Market and introduces the analytical approach underpinning the study. The second and third sections consider the funding and delivery mechanisms supporting the use of cCBTs in Estonia, as well as the regulatory framework required if the e-mental health solutions adopted in Estonia are to reduce the burden and cost of care, and improve the sustainability of health services and mental health outcomes. The fourth section considers the benefits and risks of delivering cCBTs compared to face-to-face care. The conclusion assesses the remaining challenges for Estonian health services if a significant impact is to be made on equality of access and wider availability of e-mental health services.

Towards an EU digital mental healthcare strategy

Estonia participated in two EU projects carried out between 2011–2014 and 2014–2017: Preventing Depression and Improving Awareness through Networking in the EU (PREDI-NU), and MAnagement of mental health diSorders Through advancEd technology and seRvices – telehealth for the MIND (MasterMIND). The projects were designed to identify ways of preventing mild and moderate depression and suicidal thoughts, and of making access to high-quality treatment for depression more widely available through internet-delivered services. Participants analysed the reasons for the lack of a harmonised mental health policy across the EU and sought to explain why it has been difficult to incorporate e-mental health services in integrated primary and secondary mental healthcare in an attempt to prevent serious mental health disorders, rehabilitate patients, promote self-help and reduce stigmatisation.

An important goal of the MasterMIND project was to use the findings from an initial pilot study to develop a widely applicable internet-based guided self-management tool for mild to moderate depression. This second project focussed on the role of healthcare professionals 'defined broadly as any category of healthcare professional involved in the provision of depression treatment' (Prieto, Fullaondo, & Erreguerena, 2015, p. 10). The main inclusion criteria for healthcare professionals in the pilot were professional experience of at least three years, digital literacy and professional competence to provide cCBT. Those who had not undergone cCBT training were not considered to be fully equipped to provide the service (Pederson, Craggs, Skjøth, & Thomsen, 2017). Project participants were asked to analyse clinical and cost-efficiency of the service using interviews with physicians and heads of organisations where cCBT was being piloted.

The theory developed by Rogers (2003) in his work on the diffusion of innovations provided a useful framework for the author's analysis of the role of healthcare professionals in the Estonian contribution to the EU projects. Rogers' theory describes how, why and at what rate an innovation gets adopted and spreads in a specific group of participants within a social system. He argues that the rate of adoption of innovations is influenced by four main determining variables: type of innovation decision, communication channels, nature of the social system and extent of the promotion efforts by change agents (Rogers, 1995, p. 206).

The iFightDepression cCBT programme produced initially in Germany by the European Alliance Against Depression (EAAD) was translated during the PREDI-NU project, and an attempt was made to implement it in Estonia. When the EU pilot was being conducted, the promotion of cCBTs by healthcare professionals could not be successfully implemented in Estonia. The programme failed, among other reasons, because 'a critical mass of adopters' was not achieved. The healthcare professionals were not 'engaged in joint problem solving to accomplish a common goal', as recommended by Rogers (2003, p. 23). The reluctance of primary care physicians and psychologists to adopt the programme was due not only to the lack of evidence about clinical effectiveness, but also to the absence of support from policymakers. Obstacles were raised concerning public procurement, financial mechanisms and the integration of the programme into the software that primary care physicians are using daily in their practice in the absence of appropriate training. These issues, among others, are considered in more detail in a contextualised analysis of the Estonian case.

Delivering e-mental healthcare policy in Estonia

According to WHO (2015, p. 2), 'mental health policies need to combine structural reform of services with a focus on quality, ensuring the delivery of safe, effective and acceptable treatments by a competent workforce'. The OECD/EU (2018, p. 26) reported that 'in 2015, the overall costs associated with mental ill-health are estimated to have exceeded 4% of GDP across the 28 EU countries', whereas they reached only 2.8% in Estonia, which places it below the EU28 average. This section analyses both the system adopted for funding and delivering e-mental healthcare in Estonia, and the legal framework governing the provision of e-mental health services. It identifies the shortcomings that help to explain why technological innovations have not been diffused more extensively in Estonia.

Developing Estonian e-mental health services

The development of Estonian national mental health policy was initiated in the Eesti Vaimse Tervise Poliitika Alusdokument (the basic document of Estonian mental health policy), which identified the problems and main lines of action for solving problems in mental healthcare (Poliitikauuringute Keskus PRAXIS, 2002). The overall objective of Estonia's Mental Health Strategy 2016–2025 reflects the EU's strategic goals in that it includes the prevention of psychiatric and behavioural disorders, early and timely access to mental healthcare facilities and the promotion of mental health in society (Sotsiaalministeerium, 2016).

The Estonian Health Insurance Fund is the public administration responsible for funding health services. All specialised medical care costs are reimbursed by the Health Insurance Fund. Since 2002, the share of funds allocated to outpatient psychiatric services has gradually been increasing. By 2007, 25% of funds allocated to mental healthcare were spent on outpatient services (Lai, 2013, p. 166).

The structure of the primary care budget includes a capitation payment, a fee for service, a performance-related payment and an allowance to cover overheads associated with premises, transport and additional services in remote areas (Health Insurance Fund, 2019). Under the 'therapeutic fund', however, only 3% of the budget dedicated to the capitation payment is spent on combined psychological consultations, speech and language pathologists and physiotherapists, which means that only two to three patients on a practice list of a family physician can hope to benefit from the full therapy sessions offered by these services. To ensure relatively timely access to a clinical psychologist's consultation for at least ten patients on a practice list, a family physician is able to refer patients for one, two or a maximum of three sessions. Insured people, including the registered unemployed, in theory have access to mental health services on an equal basis, either through the state-financed health services or by making an out-of-pocket payment. In practice, even if patients are referred by a family physician for a consultation with a clinical psychologist within the 'therapeutic fund', they have to cover around half of the total price.

Access to psychiatric care does not require a referral from a family physician, but queues for an appointment with a psychiatrist are long, especially in the capital region. Whereas primary care settings are located close to or in the community, specialised psychiatric out-patient care is concentrated in regional centres, and acute psychiatric in-patient care is available only in two central hospitals. Transport problems have been found to exacerbate inequalities in access to specialised psychiatric care, including specialist counselling (Lai, 2013, p. 165). Within the EU, Estonia reported the highest level of unmet need for specialist care due not only to long waiting lists but also to cost and the long distances that need to be travelled for treatment (OECD, 2017). Whereas the poor provision of state-funded psychotherapies may have fostered growth and competition between mental health professionals in private practice, and appointments with a psychiatrist or clinical psychologist in private health centres are easier to obtain than in the state system, the cost of private medicine remains prohibitive for patients on low incomes.

Estonia's mental health strategy 2016–2025 can be said to contain only a fragmented mental health policy insofar as activities and interventions are not strategically planned with cross-cutting clearly-delineated responsibilities between healthcare professionals in mental healthcare and primary healthcare, with the result that the quality of provision of mental health services is also uneven. Low availability, combined with regional inequalities in access to mental health services, a lack of coordination, underfunding, inadequate resources and system-centred services, as well poor awareness of the extent of mental and behavioural disorders among the Estonian population, have all been identified as issues preventing timely access for those in need of support (Kleinberg, 2014).

In line with the Mental Health Strategy, the e-Health Strategic Development Plan for 2025 focusses on the integration of health, labour and welfare services through the sharing of data between primary care physicians and social workers (Sotsiaalministeerium, 2015). Although the development of telemedicine is a priority in the overall eHealth

Strategic Plan, which focusses on real-time communication, connection with professionals and supporting technologies, it is unclear at the time of writing what kind of health services will be provided through telemedicine as a first point of call. Both strategic plans emphasise the importance of data sharing between different sectors as a means of solving the growing demand for mental health services and offsetting the increasing costs for society in responding to the challenges posed by economic, technological and societal change. However, the absence of a well-structured operational plan for delivering e-mental health services, combined with the shortage of qualified and engaged professionals to implement it, would seem to be preventing both full integration between sectors and effective access to mental healthcare. The integration of e-mental health technologies in Estonia thus remains a particular challenge for primary and secondary mental healthcare, further complicated by incomplete regulatory provisions.

The legal framework for delivering e-mental health services

To comply with the European Economic Area (EEA), national policymakers are required to meet health, safety, and environmental protection standards and certification requirements. In addition, they must ensure reimbursement of costs for users, and training and curricula development of providers.

According to WHO (2016a, p. 108): 'data quality and integrity [are needed] as a basis for clinical and patient decision-making, and [to] provide for the adaptation of professional liability rules to accommodate care provided remotely or virtually'. Unlike some other EU countries, the provision and reimbursement of e-mental health services in Estonia are not regulated by the State. There is no legislation specific to the provision of telehealth services focussing on e-mental healthcare, which means that litigation is needed to establish the concept of 'standard of care' in these services.

Effective services require a robust legal framework to enable the transfer and use of data and information between healthcare professionals and patients. Even though Estonia has developed good e-health infrastructures enabling the collection of patient health data, no formal e-health service has, as yet, been established focussing on direct patient-physician communication. Government Decree nr 54 (in force from 01.07.2019), regarding the 'Estonian Health Insurance Fund list of health services', makes provision for 'e-consultation through the health information system'. It thereby opens a communication channel between general practitioners and specialists for patient treatment plans in 21 specialisms, including psychiatry (Government of the Republic of Estonia, 2019). The nation-wide health information system does not, however, provide the opportunity for video-conferencing with patients; nor can it refer patients to guided and self-help e-mental health therapies. The absence of such provision has proved to be an obstacle to the integration of e-mental health into primary and secondary care, and to inhibit access to further specialist care.

Nor have standards of care for the provision of e-mental health services been formally established in Estonia within the existing legal framework. Guided cCBT is indirectly regulated insofar as the health service is a part of psychiatric care and intended for the prevention of mental disorders. Healthcare professionals providing e-mental health services are required to have formal certification and undergo regular competency assessments as new technologies and more cCBTs become available. Implementation of cCBT services

must be negotiated with the Association of Family Physicians, the Estonian Association for Cognitive Behaviour Therapy involving the Health Insurance Fund, Health Board and Health and Welfare Information System Centre, among others.

Although primary care physicians ought to be best placed to provide cCBT, in practice they are not authorised to provide either face-to-face CBT or cCBT. Instead, the provision of internet-delivered CBT has to rely on psychologists registered with the Estonian Qualifications Authority (2019) or psychiatrists registered with Health Board, who have passed the intermediate training for CBT therapists. These requirements limit the number of cCBT activity licenses issued and, therefore, the extension of e-mental health services to a wider population. In effect, because out-patient mental health services are mainly provided by family physicians in primary care settings and by mental health specialists in secondary care settings, the remit of family physicians is confined to referring patients to the limited number of clinical psychologists authorised to provide cCBTs.

Healthcare professionals are obliged by law to maintain and protect patients. The professional liability of primary care physicians includes the obligation to inform patients and obtain their consent for the provision of e-mental health services. Although healthcare professionals and providers are 'liable only for the wrongful violation of their own obligations, particularly for errors in diagnosis and treatment and for violation of the obligation to inform patients and obtain their consent', they must inform the patient *inter alia* about 'the risks and consequences associated with the provision of such health care services and of other available health care services' (Law of Obligations Act § 770 chapter 1, § 766 chapter 1, in force from 02.03.2019). This duty to inform patients of the risks and consequences associated with cCBT implies that patients should be made aware of the privacy risks involved.

However, healthcare professionals cannot be held liable for the data security and data protection of the software to which the patient was referred since they have been trained only to provide effective health services and are not required to study cybersecurity. It can also be argued that, given cCBT is a preventative tool for enabling patients to gain easy and quick access to a light psychotherapy, healthcare professionals need to be sufficiently informed about tool privacy issues so that they recommend only secure health services to patients.

Under the Mental Health Act §3 chapter 1 (in force from 01.01.2019), psychiatric care in Estonia is provided on a voluntary basis. Except in the case of an involuntary emergency psychiatric care, a request or 'informed consent' must be provided by the patient. Informed consent means 'consent given where the person is capable of understanding the meaning of consent and the consequences of granting or refusing consent' (Mental Health Act §2, p. 5). Informed consent given by a patient includes the risks associated with data disclosure to defend healthcare professionals from patients' potential arguments about the security of information. In the case of cCBTs, patients must be informed that data inserted in a specific programme might be accessible to the owners of the programme for statistical and research purposes. Patients find it difficult to understand these requirements since they often do not know the third parties involved in their care plan. Although no personal identity data are required for statistical purposes, the risks involved in using any new method of care delivery and the final decision must be the patients' responsibility. In cases of involuntary in-patient mental health provision, psychiatrists

may have to decide on behalf of a patient based on their understanding of his/her health interests.

Another ethical issue preventing more extensive uptake of cCBTs is related to the identification and authentication of the patient receiving the treatment and to the healthcare professionals providing it. No guarantee can be given against cyber-attacks insofar as access to the system is not provided through the identification of biometrical data. The liability of healthcare professionals for ensuring that treatment is prescribed to the right patient can only be ensured if they are certain that another person has not been given access to the programme using the patient's login credentials, just as with pharmacological treatments where it is difficult to ensure that a patient is taking the medicine as prescribed by the physician.

EU standards on health and safety protection, EEA certification requirements and the guarantee of the reimbursement of costs for users, as well as the training and curricula development of providers, play an important part in enabling the implementation of cCBTs at national and EU levels. The analysis carried out for the EU project showed that it is important to start with public procurement and the licensing of programmes for primary care physicians to use when referring patients to cCBTs before they obtain the first appointment with a mental healthcare specialist. The EU projects also highlighted the need for governments to invest in the training of primary care physicians to prepare them for work with internet-delivered CBTs.

In a survey conducted in Estonia in 2017, 15 out of the 20 of the primary care physicians interviewed stated that they consider cCBT as a part of psychiatric care. They concurred that targeted government funding would increase access to psychotherapy (Sogomonjan, Kerikmäe, Ööpik, & Ross, 2019). Legally, primary care physicians can involve clinical psychologists in the treatment of the patient, whereas, in practice, patients are not referred for cCBT before they are given an appointment with a clinical psychologist. This lack of competence enabling primary care physicians to guide patients through internet-delivered CBT, combined with restrictions on access to training and qualifications, is found to prevent the integration of access to state-funded e-mental health services in primary care settings.

Concerns about the competence of physicians and standards of care provision raise issues about who, in the future, will perform guided cCBT if primary care physicians have not received appropriate training, and if the number of suitably qualified clinical psychologists and psychiatrists on the market is limited. AI could help to offset the lack of skilled and trained specialists. However, the absence of legislation regulating the use of AI in health services, in particular, in the delivery of psychotherapies, presents challenges regarding the automatic processing of health data and concomitantly professional liability for making clinical decisions.

Maximising the benefits of cCBTs

Arguably, in combination with the shortcomings in the funding and delivery mechanisms, the many gaps in legal texts regulating e-mental healthcare provision have hindered the potential use and integration of e-mental health services into routine care. The relatively poor provision of high-quality mental health services in Estonia has meant that the needs of the increasingly large numbers of patients suffering from psychiatric and addiction

disorders are not being met, contributing to rising suicide rates among children and young people (Sotsiaalministeerium, 2016). In addition to the negative impact on individual well-being, morbidity and mortality rates, these shortcomings mean that the economic burden of mental disorders on the wider population should not be underestimated.

While many obstacles have been hampering greater diffusion of e-mental health services in Estonia, international studies have shown that cCBTs can be effective both as intervention and prevention tools for mild forms of depression. They suggest that the integration of technological solutions in clinical practice can offer a relatively low-cost opportunity to increase access and awareness of the population about mental illness, and promote prevention, early detection and remote monitoring. Observations made by Gratzer and Khalid-Khan (2016) in Australia and the UK have demonstrated, for example, that cCBT has two principal advantages: patient empowerment and increased clinical efficiency. The authors found that patients benefit most from the 'geographic independence the therapy provides', and the ability to schedule the care and therapy they receive at a distance. From a clinical efficiency perspective, clinicians are found to treat more patients effectively in less time. Compared to traditional CBT, cCBT require fewer resources and is less time–consuming even if therapist support is intermittent. In cases where cCBTs require a high level of therapist involvement, the physician does not spend less time and the cost of providing the service may not be lower, but patients may still benefit by avoiding the cost and time of travel. Although similar studies have not been conducted in Estonia, surveys comparing a wait-list control groups with and without cCBT in Australia, Germany, the Netherlands, Sweden, Switzerland, the UK and USA have estimated the cost-effectiveness of cCBT having a probability level ranging from of 57% to 70%, 79.5% and even 95%, depending on the approaches used (Arnberg, Linton, Hultcrantz, Heintz, & Jonsson, 2014; Dear et al., 2015; Hedman, Ljotsson, & Lindefors, 2014; Titov et al., 2015).

Moving towards a more person-centred approach in healthcare means not only empowering patients in the decision-making process but also providing an opportunity to access a service at a freely chosen location and time. These international studies confirm that the implementation and regulation of cCBTs in primary mental healthcare can reduce the workload of primary care physicians and increase data accuracy and analysis. The findings from the 2017 Estonian survey suggested that guiding patients through cCBT requires specialist skills to deliver effective patient-physician communication (Sogomonjan et al., 2019). Analysis of the attitudes of Estonian family physicians towards cCBTs revealed that they believed e-mental health therapies to be useful for keeping in touch with patients and for monitoring their activities before they move into secondary care.

Arguably, regular and structured monitoring of patients' behaviour patterns when using automated therapeutic tools has the potential to reduce the workload of mental health professionals by analysing data reported from the patients themselves online. Algorithms for identifying the person and analysing structured biological data are unlimited: they can include the patient's behavioural patterns, their body language and eye movements. Advanced technology can help to reduce medical errors by pre-screening patients at their first visit to their general practitioner, while the decision regarding the treatment options – internet-delivered CBT, face-to-face psychotherapy, pharmacology or a combination of several therapies – together with further examinations remains the responsibility of a physician. Analysis of the raw data received from the patient and

screening for the presence and level of mental disorders using AI are found to be useful in supporting physicians as they decide on the most appropriate treatment.

As elsewhere, the Estonian governments is seeking cost-effective ways of maintaining public health, containing the state budget allocated to the healthcare sector, and sustaining the capacity of the workforce by investing in disease prevention and health promotion. The funding of remote health services in Estonia has to be justified according to two main criteria: first, e-health services must be clinically effective or outperform traditional face-to-face services; and second, they must be significantly cheaper than traditional services. In a systematic review of cCBTs carried out in Estonia in 2018, it was evident that online therapies alone were less effective than when they are supported by, or in combination, with pharmacological treatments, since cCBTs cannot achieve the same effects as prescribed drugs. The review also found that depressed people are not always able to complete sessions without guidance from a therapist, since they need more time to concentrate and self-motivate (Sogomonjan, Kerikmäe, & Ööpik, 2018). The findings from the 2017 Estonian survey suggested that a possible solution to problems of access to mental healthcare for patients with mild to moderate depression would be to provide self-help e-mental health therapeutic tools intended for common mental disorders supervised by a family physician before the first appointment with a clinical psychologist (Sogomonjan et al., 2019). However, psychiatrists in Estonia remain very sceptical about the benefits of cCBTs. As one psychiatrist commented in the 2017 survey: 'Depression cannot be treated through the internet just as children cannot be educated on-line. You need live communication, eye contact, etc'.

Conclusion

Mental health is a recognised public health issue that requires careful attention to prevention, early detection of diseases and equality of access to treatment. In a context where e-mental health is a rapidly growing area with the potential to improve access to health services for large numbers of patients, and appropriate and timely assistance for the prevention of mental disorders, this article suggests how the use of e-mental health services could be more widely integrated into primary care and could increase the demand for primary care physicians to provide cCBTs.

With the shift towards more fully integrated and coordinated care with personal value and patient-centred clinical interventions, e-mental health services need to address three common problems: communication and information sharing between patients, professionals and organisations; support for decision-making based on analyses by AI; and the adoption of organisational change. The evidence presented in this article confirms that e-mental health needs to be an integral part of mental health and e-health strategies in the future if they are to help solve issues related to mental health promotion, prevention and access to healthcare. If precise information about mental health status has been recorded in the database, e-health infrastructures enable it to be captured and monitored remotely. AI, if implemented, can be used to assist with these processes, to analyse data available in both systems and to maximise the potential benefit for healthcare professionals and patients.

However, several concerns regarding e-mental health are found to prevent more effective use of AI in conjunction with cCBTs in mental healthcare. They relate to privacy,

professional liability, the competence of healthcare professionals, licensure to provide e-mental health services and patients' informed consent. Effective regulation of these issues is required to improve the transparency of care delivery, adequacy of funding and the division of responsibilities between state, healthcare professionals and patients.

Challenges for e-mental health policy remain due to the shortage of high-skilled professionals, legal uncertainty about the procedures for providing e-mental healthcare and the lack of financial investment for implementing cCBTs. Arguably, in this situation, provision of guided cCBT in all primary care settings might reduce the risks associated with the limitations of the activity license. Although cCBT may not resolve all the issues associated with the lack of human and financial resources causing long waiting lists, the available evidence suggests that they can be used by patients while they are waiting for specialist care and can be supervised by primary care professionals, thereby freeing up resources to treat larger numbers of mental health patients with diagnosed conditions. Filling the time gap when patients are waiting for specialist care with guided cCBT has been shown to increase the probability of a reduction in symptoms, provide immediate access to mental healthcare and medical consultations and maintain the sustainability of health services in general. If implemented appropriately, cCBT may reduce the workload of primary care physicians allowing them direct access to analysed data. Additional training and technical assistance would be needed, however, to prepare primary care physicians to deliver cCBTs to patients. Limited funding in healthcare is likely to remain a common challenge globally. With time and political will, the redistribution of financial resources towards support for cCBT might be expected to reduce unmet need and increase the public health awareness of how to deal with mood disorders.

The available evidence from the Estonian case suggests that, as elsewhere in the countries participating in the two EU pilot projects underpinning this article, the model of delivery of e-mental healthcare reported affords a valuable option for the prevention of mild to moderate common mental health disorders. cCBTs can reduce the time spent waiting or the first face-to-face assessment with a clinical psychologist. Timely assessments and treatment can help prevent the exacerbation of the mental disorders, while also further reducing the costs of treatment. Agreement at EU level about the regulatory framework for cCBTs should not, however, eliminate the need to consider the different contexts in which innovatory technologies are being introduced. The Estonian case shows how serious obstacles remain to be overcome in diffusing cCBTs to larger numbers of mental health patients, even in a country that has been a trail blazer in adopting digital practices in healthcare more generally.

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No potential conflict of interest was reported by the author(s).

Notes on contributor

Melita Sogomonjan was a PhD student in the Faculty of Business and Governance, Ragnar Nurkse Department of Innovation and Governance, Tallinn University of Technology between 2016 and 2020. Her research is interdisciplinary and related to digital healthcare and governance, with a particular focus on mental health, data protection and the legal framework of e-health policy. She has worked with the Asian Development Bank as a health information system expert, and she gained practical experience at the Health Board and in the Ministry of Social Affairs in Estonia.

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Appendix 2

II

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HEALTH PSYCHOLOGY | RESEARCH ARTICLE

A report on the survey. Attitudes of Estonian healthcare professionals to internet-delivered cognitive behavioural therapy

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Abstract: Internet-delivered cognitive behavioral therapy (iCBT) could be useful for early detection of mental disorders. The purpose of the study is to explore the attitudes of healthcare professionals within adults psychiatry towards iCBT in Estonia. A survey study was conducted by 20 healthcare professionals participated in the PREDI-NU and MasterMind projects. A semi-structured questionnaire was used for data collection. All statistical analyses were conducted with IBM SPSS Statistics 22. More than half of healthcare professionals surveyed concluded that patients need to receive iCBT for more rapid recovery. Fifteen respondents deemed iCBT an integral and necessary part of psychiatric care that ought to be available for the population at large. Nevertheless, some physicians saw it as less effective than traditional psychotherapy because of a lack of a direct relationship with the patient and its inability to cope with severe mental disorders. Although iCBT creates the opportunity for remote intervention and increase the liability of physicians, it also increases workload in such a way as to lead to inattention. Limitations of the program often demotivate healthcare professionals to provide service widely.

Melita Sogomonjan

ABOUT THE AUTHOR

Melita Sogomonjan is a Ph.D. student at faculty of Business and Governance, Tallinn University of Technology. She has been responsible for the testing iFightDepression program in Estonia when EU funded research project MasterMIND was piloting. She also had practical experiences in the Health Board and the Ministry of Social Affairs. Her area of research is interdisciplinary and related to the development and regulation of eHealth policy and public health administration.

PUBLIC INTEREST STATEMENT

Depression is a growing problem for the socio-economic environment today. Digital era enables Internet-based programs to alleviate the rising demand for effective and coordinated treatment of common mental health issues. So-called Internet-delivered Cognitive Behavior Therapy programs are aimed at the improvement of mental health care and directed in particular at early intervention and the delivery of psychiatric assessment and care online. Most of the research on prevention measures have focused on clinical effectiveness and cost-effectiveness. However, a little attention has been devoted to the limitations and barriers of the implementation process in the context of experiences and attitudes of healthcare professionals e.g. legalisation in primary care. The current research explored the attitudes of healthcare professionals towards the implementation of "iFightDepression" program to identify the main reasons related to willingness and reluctance of using Internet-delivered Cognitive Behavioural Therapy in general to prepare the healthcare professionals to use the modern technologies.

Nevertheless, on balance, iCBT is probably more helpful rather than less in population terms.

Subjects: Medical & Healthcare Law; Psychological Science; Evidence-based Mental Health; Mental Health Research; Mental Health Services & Policy; Mood Disorders in Adults - Depression,Mania, Bi-polar; Ethics & Legal issues in Mental Health; Health andSocial Care; Assistive Technology; Mental Health

Keywords: Internet-delivered cognitive behavioral therapy; primary care; attitudes; adults; depression

1. Introduction

Depression is the leading cause of disability, morbidity, and mortality globally (Ferrari et al., 2013; Marcus et al., 2012, World Health Organization, 2018). World Health Organization emphasizes the importance of integrating mental health into primary care in order to increase access to effective and reliable care (Brown, 2001; WHO, 2013, 2008). Around 10% of primary care patients worldwide have diagnosed with clinical depression (Brown, 2001; Kivi et al., 2015). From the economic perspective treating depression in primary care is feasible, affordable and cost-effective (Araya et al., 2006).

Studies on Internet-delivered cognitive behavioral therapy (iCBT) have been demonstrated to be an effective and efficient method of mental health care delivery under strictly controlled conditions where patients were allowed to take additional medication (Berger et al., 2017; Newby et al., 2013; Bergstrom et al., 2010; Nordgren et al., 2014; Perini et al., 2009; Ruwaard et al., 2009; Andersson et al., 2005; Berger et al., 2011; Johansson et al., 2012; Kay-Lambkin et al., 2011; Proudfoot et al., 2004; Salomonsson et al., 2017; Kivi et al., 2015; Høifødt et al., 2013; Rollman et al., 2017; de Graaf et al., 2009, 2011; Kessler et al., 2009; Gilbody et al., 2015; Roy-Byrne et al., 2010). These studies have been mainly focused on treatment outcomes, acceptability and research participants' satisfaction where data have been collected mainly from patients' self-reported questionnaires. Our recent systematic review and analysis of the effectiveness and efficiency in primary care setting found that iCBT cannot be offered for each patient and therefore replace either outperform the traditional treatment method in real-world practice under routine conditions mainly due to the absence of structured monitoring and motivational support (Sogomonjan et al., 2018) The current availability fails to reflect current needs for the effective mental health treatment. All this anticipate that iCBT implementation in the primary care setting can be complicated.

The attitudes and practices of clinicians towards iCBT interventions vary tremendously worldwide. Stallard et al. (2010), Whitfield and Williams (2004) and Vigerland et al. (2014) found clinicians' positive attitude towards Internet-delivered psychological interventions in the United Kingdom and Sweden even though only a few clinicians used such interventions in their routine clinical practice. Wangberg et al. (2007) found that the attitudes of the Norwegian psychologists towards e-therapy were neutral, even though 3% of the psychologists felt using e-therapy with patients is unacceptable. A negative experience, however, has been appeared among North American psychotherapists as the main barrier to uptake new psychological treatments due to concerns around the efficiency of the new method introduced, lack of interest and clinician's beliefs (Cook et al., 2009). Psychologists and psychotherapists concluded that iCBT could be suggested only for some primary care patients in conjunction with face to face therapy (Kivi et al., 2014). Lack of knowledge about Internet-delivered psychotherapies is existing yet in primary care and set a barrier to expanding the use of iCBT by general physicians (Kivi et al., 2015). Kivi et al., (2015) reported that iCBT has been seen by general physicians as relatively new care model that is not yet integrated into the primary care.

The present study focuses on experiences and attitudes of Estonian healthcare professionals participated in the PREDI-NU (Preventing depression and improving awareness through networking in the EU (http://www.predi-nu.eu/)) and MasterMind (Management of mental health disorders through advanced technology and services—telehealth for the mind (http://mastermind-project.eu/)) projects aimed at the implementation of iCBT in the primary care. Researchers are interested to explore:

(1) Limitations and barriers for iCBT implementation in primary care in Estonia;
(2) Experience and attitudes of healthcare professionals to iCBT and its legalization.

2. Methods

2.1. Study design

This study was an explorative survey study. Participants were fully informed about the purposes of the study and completed the questionnaire voluntary. In the period of preparing a semi-structured questionnaire in February-March 2017, authors consulted with six experienced general physicians from different Estonian primary care settings to adjust the methodology according to their empirical experience.

A semi-structured questionnaire was developed on the basis of A Model for Assessment of Telemedicine applications (MAST) (Kidholm et al., 2012) and systematic literature review, and modified according to the specific Internet-delivered Cognitive Behavior Therapy program (iFigtDepression).

2.2. Data collection and analysis

Data were collected from the semi-structured questionnaire and additional discussions with healthcare professionals. Collected data were analyzed using a combination of qualitative and quantitative analyses. Results were separated according to four main themes. All statistical analyses were conducted with IBM SPSS Statistics 22. Multiple response analysis was used to interpret healthcare professionals' responses.

The semi-structured questionnaire consisted of 41 questions: 24 open-ended and 7 multiple-choice questions. The survey covered three thematic areas. The first part was directed at identifying the need of iCBT at the primary care level. The second part focused on limitations and barriers impeding iCBT integration within a primary care setting. The third part was aimed to explore healthcare professionals' attitude towards legalization of iCBT. The semi-structured questionnaire is presented in Table 1. The questionnaire was sent in April 2017 to healthcare professionals and was followed by two reminders in May 2017. Data were analysed in June 2017. Additional consultations with participants to specify the terminology matters and narrow down the answers to open-ended questions were performed during the data analysis via emails and telephone calls.

2.3. Participants

Altogether, 41 family doctors, 3 psychiatrists, and 11 psychologists participated in the PREDI-NU and MasterMind projects (the period of PREDI-NU project was 2011–2014 and the period of MasterMind project was 2014–2017) were asked to complete the survey. Participants were selected for the following main inclusion criteria: (1) participation in the MasterMind and PREDI-NU projects and familiarity with iFightDepression programme, (2) healthcare professionals' education level and professional skills in providing iCBT, (3) healthcare professionals who have recruited patients into the study; and (4) digital literacy. The survey was completed during 7 weeks by 20 participants: 18 family physicians (from them 2 general physicians had specialization in other medical disciplines), 1 psychologist and 1 psychiatrist.

2.4. iFightDepression—an internet-delivered cognitive behavioural therapy tool for prevention of depression

The iFightDepression tool is a guided, Internet-delivered Cognitive Behavior Therapy program for individuals experiencing mild to moderate depression (Final Trial Report 2nd Wave (cCBT), 2017).

Table 1. The semi-structured questionnaire

Questions:	Answers:
Theme 1. Identifying the need of iCBT in the primary care in Estonia.	
1. Do you think patients need Internet-based cognitive-behavioral therapy (iCBT)?	1. Yes 2. No
2. In the case of a positive answer, please specify how many patients need iCBT?	1. Quite a lot 2. A lot 3. Few
3. Should iCBT be available for anyone to access?	1. Yes 2. No
4. Should iCBT allow you to track the patients treatment results?	1. Yes 2. No
5. Please explain your answer briefly.	
6. What are the positive aspects of iCBT?	
7. What are the negative aspects of iCBT?	
8. What are the positive aspects of iCBT from patients perspectives?	
9. What are the negative aspects of iCBT from patients perspectives?	
10. What resources do you need to implement iCBT in your daily practice?	
11. How often did you recommend iCBT to your patients (how many patients within one month)?	
12. Did you continue to recommend iCBT to your patients?	1. Yes 2. No
13. How many patients refused to use iCBT?	1. Quite a lot 2. A lot 3. Few 4. No one
Theme 2. Limitations and barriers for iCBT implementation in primary care in Estonia.	
1. Why patients refused to use iCBT?	
2. How many patients did not complete iCBT?	1. Quite a lot 2. A lot 3. Few 4. No one
3. Why patients did not omplete iCBT as intended?	
4. What motivates you to use iCBT in your daily practice?	
5. What prevents you from using iCBT?	
6. How satisfied are you with the opportunity to provide iCBT?	
7. Have you explored patients satisfaction with the use of iCBT?	1. Yes, during the appointment 2. Yes, by e-mail/telephone 3. Yes, I used the client satisfaction uestionnaire 4. No
8. Would you like to add more?	
Theme 3. The attitudes of Estonian healthcare professionals to iCBT legalisation.	
1. In your opinion, must the clinical psychologist be registered in the State Register of health professionals?	1. Yes 2. No
2. In your opinion, is iCBT a health care service?	1. Yes 2. No
3. Please explain your answers briefly.	
4. In your opinion, is iCBT a part of psychiatric help?	1. Yes 2. No

(*Continued*)

Questions:	Answers:
5. Should the concept of „psychological help" be set out separately in the Health Services Organisation Act and Mental Health Act?	1. Yes 2. No
6. Will iCBT improve the availability of psychotherapy in the treatment of depression, if financed from the State budget?	1. Yes 2. No
7. Please explain your answers briefly.	
8. In your opinion, is the doctor or the clinical psychologist responsible for iCBT mistakes while he/she is offering it to a patient?	1. Yes 2. No
9. Who is responsible for complications encountered while providing iCBT?	
10. Please explain your answers briefly.	
11. What kind of key legal aspects must be taken into account at all for the future development and implementation of Internet-based psychotherapies in Estonia?	
12. How the use of iCBT may affect on the development of Estonian health care system?	
13. What are the most significant obstacles (legal/ethical) that interfere with the implementation of all Internet-based psychotherapies in providing medical care?	
14. In your opinion, are Internet-based psychotherapies sufficiently secure environment for processing patients special categories of data for therapeutic purposes?	1. Yes 2. No 3. Hard to say
15. Do you have any other suggestions?	

The iFightDepression program supports online learning and increases the awareness of suicidal behavior and depression (Anifowoshe, 2017). The tool is intended to help individuals to self-manage their symptoms of depression and to promote recovery, with support from a trained GP or mental health professional (Final Trial Report 2nd Wave (cCBT), 2017). The tool is based on the principles of CBT: it consists of six core modules and three additional modules that can be performed by patients, according to their clinical needs (Final Trial Report 2nd Wave (cCBT), 2017). More precisely, the iFightDepression program consists of informative modules that focus on increasing daily activity, identifying and challenging unhelpful thought patterns, monitoring mood, adopting healthy sleeping patterns, and maintaining a healthy lifestyle (Final Trial Report 2nd Wave (cCBT), 2017). Associated worksheets and exercises encourage users of the tool to practice and consolidate new skills and to promote self-monitoring (Final Trial Report 2nd Wave (cCBT), 2017).

3. Results

Healthcare professionals had both positive and negative experiences with the using of iFightDepression during PREDI-NU and MasterMind projects. Results reflected several of the problems involved with introducing and potential implementation of new technology in primary care settings. Challenges during the pilot study included lack of time for face to face consultations, patients' eligibility including the presence of co-morbidities, language, age, the lack of digital skills, technical problems with the access to the program, the quality and the proof of the program. From the positive aspects, iCBT has been seen by most of the participating healthcare professionals as a good alternative for young and economically vulnerable patients giving the opportunity to self-monitor records.

3.1. Theme one—the need of iCBT in primary care

The awareness of iCBT interventions in primary care in Estonia has been increased with the piloting PREDI-NU and MasterMind projects. Although, most health care professionals are enthusiastic and open about receiving new tool results reflected that professionals need to be trained with iCBT treatment delivery further.

A specialist who prescribes the treatment method should be well-informed about the treatment outcome and the effect of that. (GP18)

Three-quarters of the respondents concluded that the iCBT had to be made as accessible as appropriate for patients with depression and anxiety, inasmuch as the number of patients in need is growing. Additionally, iCBT has the potential to empower patients with knowledge about their diseases. Patients who have difficulties seeing their physician or clinical psychologist during normal appointment hours are able to use online services at their convenience without additional payment for the service.

Psychotherapy is not available for many patients due to economic reasons and it would be good if in some way it could be afforded to people. (GP8)

Internet-delivered psychotherapies are available to anyone. No need to pay for the service. Therapy fund has limited resources and does not end up for all patients who need treatment. Patients can have a couple of cognitive behavioral therapy sessions and then must continue to pay for that, which is why face to face service often remains incomplete due to financial insufficiency. (GP9)

Forty-four percent (n = 8) of general physicians emphasized that availability, accessibility, and flexibility of the program are the most common iCBT positive aspects. Five general physicians reported that iCBT allows for patients to monitor their own treatment outcomes (records), four concluded that iCBT is cheap and one emphasized that iCBT saves healthcare professionals' time. Overall, 75% (n = 15) of healthcare professionals concluded that patients need iCBT and 65% (n = 13) have suggested iCBT for patients. Fifty percent (n = 10) of healthcare professionals have suggested less than 10 patients per month. Almost 85% (n = 17) reported that iCBT should be available for everyone to access and 80% (n = 16) emphasized the importance of follow-up patients records. Twenty-eight percent (n = 5) of general physicians concluded that iCBT is needed for a lot of patients and 28% (n = 5) reported that iCBT is required by many patients, 22% (n = 4) of GPs indicated that only a few patients may need iCBT. Data from four general physicians, 1 psychiatrist, and 1 psychologist have not been provided.

3.1.1. Theme two—limitations and barriers to iCBT implementation in primary care

Eighty percent (n = 16) of healthcare professionals found that iCBT implementation into primary care unit and its further dissemination among patients require additional training, time, technical support and integration within a software used by general physicians at their daily work.

It should be integrated with our software. In my case, there was a lack of time: I have a tremendous amount of work, I have to think about a lot at the same time and know a lot about. If I direct a patient to iCBT, then I would not want to be the one who registers the patient, learns about another new web environment. It was precisely behind this that I was passing my patients. The patients were interested, but I did not have the strength and time to start registering them. I guess I even registered it, but patients probably did not start using it. If patients registration is automatic or integrated into our software we use every day, for example, I should target 1–2 clicks, then all patients will be forwarded. (GP7)

Healthcare professionals concluded that iCBT has to be easy, user-friendly, interactive and should allow monitoring patients records.

iFightDepression had not been user-friendly. Many patients refused to continue treatment due to lack of personalization. (GP4)

iCBT should be easy to use. The program I suggested for patients—iFightDepression—was complicated. I had no opportunity to see patients' records and monitor his/her health outcomes. (GP12, GP16, GP17)

Even though iCBT provides easy access to the treatment, healthcare professionals found that the direct face to face contact with a patient is crucial in continuing treatment effectively. Sixty percent (n = 12) of participated healthcare professionals concluded that iCBT requires motivation, concentration, digital literacy, interpersonal contact, and direct feedback. For these reasons, patients drop-out has been high and many patients have refused from using iCBT. Twenty-two percent (n = 4) of general physicians reported that quite a lot of patients refused to use iCBT, 45% (n = 9) answered that only a few patients refused to continue with iCBT and 25% (n = 5) of physicians reported that they have not referred patients to iCBT at al. Although, 85% (n = 17) of healthcare professionals found significant limitations in iCBT, 15% (n = 3) reported that iCBT has no negative aspects.

The Internet-delivered program might be cumbersome to sign in and requires very good commitment and self-control skills. People are not used to treating themselves using for that purposes of digital therapies, especially older people. A depressed patient often is demotivated and has difficulties with his/her daily routine. Additional tasks might seem to be as an excessive burden and an additional stressor too. (GP9, GP10, GP11, GP15)

Therapy could be performed only through eye contact. It is the same issue to educate children through the Internet which is impossible. The relation treats, the relationship is what we need. No relation—no treatment. (GP7)

iCBT treatment effect is based on personal human relationships. I do not see currently this kind of treatment (Internet-delivered psychotherapy) relevant to patients. (GP20)

Psychotherapy is based on face to face personal interaction. Psychotherapy could not be delivered remotely. (GP3)

Overall, 80% felt iCBT should be allowed assuming patients responded even though the implementation of it results in extra clinical work for healthcare professionals and an additional burden with respect to documentation.

3.1.2. Theme three—the attitude of healthcare professionals towards legalization of iCBT

Healthcare professionals explained their concerns very differently. Eighty-five percent (n = 17) of participants considered iCBT as a healthcare service. Twenty-five percent were opposed to registering a clinical psychologist in the national register of healthcare professionals, even though, in point of fact, clinical psychologists participate actively in the treatment process as they treat patients with psychological and cognitive behavioral problems, and also participate in prevention.

Psychotherapists and clinical psychologists are different specialists. The clinical psychologist is a part of the psychiatric team. Therapy cannot be performed web-based. It is an uncontrollable activity. (GP7)

National register of healthcare professionals does not need to include all the people with whom the patient is exposed to their health troubles. Internet-delivered psychotherapy is not sufficiently effective and is not reliable to count it as a health service. (GP10)

iCBT must be developed in accordance with evidence-based guidelines and could be overseen by the Health Insurance Fund's Board of Directors inasmuch as the issue of reimbursement of e-Mental health services need to be solved. (GP11)

Eighty percent (n = 16) of healthcare professionals concluded that the term *"psychological help"* should be separately defined in the Health Services Organisation and Mental Health Acts and the educational standards for psychologists are needed to be improved.

A clinical psychologist is a specialist with pedagogical education. Even though a clinical psychologist needs to be registered then it is supposed to have a longer educational program that will include the basic medical subjects such as anatomy, physiology, chemistry. Otherwise no need to be registered as a health care professional. (GP14, GP17)

Healthcare professionals have also mentioned the apparent weakness and deficiency of the existing healthcare system that increases the workload of primary care physicians.

It is important to send a bill for a clinical psychologist. This could be well-performed through a health information system. For this person, a clinical psychologist needs to have access to the health information system as far as a general practitioner needs feedback about what has been done with a patient. Currently, all such things are encrypted and sent by emails. This is not the right way of information delivery between colleagues and moreover creates additional work. (GP12)

Clinical psychologists are working with diagnosed patients and have to have an opportunity to send the patients summary to the health information system and maybe to be informed with the medication that is prescribed for a patient. (GP20)

Healthcare professionals drew the attention to the patient identification, protection of patients' personal data, confidentiality, medical prescription writing, and the safety of patients' medical records as the main legal and ethical prerequisites for the legalization of telepsychiatry in Estonia. For instance, iCBT sessions could be easily implemented by third parties inasmuch as the only requirement for signing remains the availability of login credentials. No guarantee exists that sessions involved by the right patient. Thus, individual patient identification is key.

Forty-five percent (n = 9) of healthcare professionals considered patient safety, confidentiality and data protection as important legal aspects for the further implementation in primary care. Twenty percent of healthcare providers (n = 4) deemed that iCBT is a sufficiently secure environment for purposes of special categories of personal data according to the standards for the transfer of personal data.

Data, concerning patients health are not enough protected. (GP8)

All data must be protected and delivered in an encrypted way. (GP12)

All this is directly related to the liability issues. According to the survey, 70% (n = 14) of healthcare professionals emphasized that the healthcare service provider should be held responsible for treatment outcomes and possible complications.

4. Discussion

The present study investigated limitations and barriers for iCBT implementation in primary care in Estonia and attitudes of healthcare professionals to iCBT and its legalization. Results revealed that the majority of healthcare professionals were in favor to provide iCBT for a younger population with mild depression mainly for two reasons: as additional therapy iCBT allows patients to monitor their behavior patterns at any time patients are able to complete and it does not require additional costs for patients. Most healthcare professionals believed that iCBT implementation in primary care will improve the accessibility to receive mental health care and increase therapy efficiency and sustainability resulting in treatment outcomes. All this leads to the improvement of the quality of life insofar as people with mental disorders become more independent and recover self-esteem. However, healthcare professionals mentioned that iCBT

development should be in accordance with evidence-based guidelines and cannot be delivered freely online without technical and professional support for each patient. They agreed, that iCBT cannot replace face-to-face therapy and direct communication with depressed patients is crucial for proceeding with better treatment outcomes. Unlike in Vigerland et al. (2014) in our study healthcare professionals reported "lack of direct communication and feedback with patient" as leading disadvantages of the iCBT intervention. The program, a complex of sessions directed at self-analysis, proved inadequate for depressed individuals with concentration and motivation problems. Healthcare professionals reported that iFightDepression was not user-friendly. Moreover, they emphasized that iCBT is not suitable for everyone, but iCBT should be available for everyone. Healthcare professionals concluded that implementation of iCBT in Estonia has the potential to reduce the rate of depression in the population and prevent it from the forthcoming emergence and evolution. In view of the ratio of the regional average of the population suffering depression in Estonia is 5% (Kleinberg, 2014). Considering the number of patients who need inpatient care in proportion to the average number of hospital beds in a whole country, researchers are inclined to conclude that access to direct care should be ensured as well. iCBT has the potential to improve access to mental health care, but can never guarantee the quality and is complicated to measure the outcome of the treatment. Patients treated with iCBT need to be informed about its clinical value. All the important information that could be retrieved from the patient facial expression, eye contact, voice tone, gestures, and body positioning during the psychotherapy may make it difficult for the healthcare professional to arrive at the right diagnosis. The therapeutic relationship affects both the quality of the treatment and general well-being too. In addition, technical malfunctions may cause difficulties in the clinical examination and increase suicide risk because of reduced effectiveness.

Despite on limitations existing in the legal framework of mental health policy in Estonia, many healthcare professionals believed that iCBT is a healthcare service and is a part of psychiatric care. Most of them found that healthcare professional is responsible for iCBT mistakes and complications, although iCBT has been considered as an alternative way of psychotherapy delivery. Even though a healthcare professional cannot be held liable either for the direct patient impact of treatment, treatment protocol or prescribed medicine, he/she is liable for the selection of the right treatment method. Evidence-based treatment is the basis for most of the treatment guidelines and might cause a variety of complications and even the risk of mortality among vulnerable patients. Therefore, the treatment process has to be personalized with regard to the selection of the right personalized treatment process and the liability of healthcare professionals must be addressed in this context.

Healthcare professionals noted that personal data protection and secure access to Internet-delivered therapies is important to avoid potential misuse of patients' sensitive data as well as to ensure their confidentiality. So far, access to the iFightDepression has involved login credentials such as using e-mail addresses and passwords to enter the system. Wang et al., (2014) stated that encoding and decoding the audio and video conversation or providing other e-Mental health services via a virtual private network (VPN) decreases the risks of security breaches. Insofar as patients' identification is not based on the authorization of the biometric data such as fingerprint, eye-based authentication, voice and face recognition, the identification will remain unsafe despite potential lapses in the system. The marginal benefits of multimodal authentication systems, i.e. fingerprint and face recognition, voice and eye recognition, fingerprint and eye recognition or voice and face recognition remain to be quantified.

Authors found iCBT negative aspects as very important factors hindering the sustainable use of the program. Researchers agree that it is important to deal with leading obstacles insofar as the lack of mental healthcare professionals is apparent. To our knowledge, this study is first exploring limitations and barriers for iCBT implementation in primary care in Estonia and attitudes of healthcare professionals to iCBT and its legalization.

5. Limitations

This study lacks deep research on legal aspects around psychiatry in Estonia. Further research is needed to explore why Estonia should consider telepsychiatry and what legal infrastructure is required.

6. Conclusions

The present study assessed the views of healthcare professionals. The emerging picture reflected both positive and negative attitudes. The positive attitude was mainly associated with access to the service, prevention, and treatment of mild depression among young population. The negative attitude was related with lack of legal framework around e-Mental health services, time and technical resources, including program content, lack of evidence of the specific program and inability to provide iCBT for a wider population with severe symptoms of depression. In summary, the results of the present study suggest that iCBT is probably more helpful rather than less in population terms.

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Appendix 3

III

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Covid-19 and the digital revolution

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ABSTRACT

Since the 1980s, the digital revolution has been both a negative and positive force. Within a few weeks of the Covid-19 outbreak, lockdown accelerated the adoption of digital solutions at an unprecedented pace, creating unforeseen opportunities for scaling up alternative approaches to social and economic life. But it also brought digital risks and threats that placed new demands on policymakers. This article assembles evidence from different areas of social science expertise about the impacts of Covid-19 in digitised societies and policy responses. The authors show how the pandemic supported changes in data collection techniques and dissemination practices for official statistics, and how seemingly insuperable obstacles to the implementation of e-health treatments were largely overcome. They demonstrate how the ethics of artificial intelligence became a primary concern for government legislation at national and international levels, and how the features enabling smart cities to act as drivers of productivity did not necessarily give them an advantage during the pandemic. At the micro-level, families are shown to have become 'digital by default', as children were exposed to online risks and opportunities. Globally, the spread of the pandemic provided a fertile ground for cybercrime, while digital disinformation and influencing risked becoming normalised and domesticated.

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Introduction

Schwab (2015), the Founder and Executive Chairman of the World Economic Forum, argued that, building on the third 'digital revolution', the Fourth Industrial Revolution was distinguished from previous industrial revolutions by its 'velocity, scope, and systems impact'. He anticipated that this Fourth Industrial Revolution would develop exponentially rather than linearly and would 'fundamentally alter the way we live, work, and relate to one another'. Five years later, Schwab and Malleret (2020)

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acknowledged that the world was facing a 'defining moment' as the pandemic precipitated the fusion of technologies, enabling digital technologies to extend their reach, almost uncontrolled, into every aspect of life.

In 2018, *Nature* devoted a supplement to 'Digital revolution', recognising that the digital world had become 'crucial' to the functioning of society but conceding that more needed to be done to realise its democratising potential (Hodson, 2018). Two years later in the same journal, Budd et al. (2020) portrayed digital technologies being harnessed to support public health responses to Covid-19 worldwide. For the same authors, while the emergency was depicted as a positive force driving the development and adoption of new digital technologies at scale and speed, their uninhibited implementation in some areas raised legal, ethical and privacy concerns, as well as intensifying risks for disadvantaged communities.

These concerns were not new. An OECD (2016) report had alerted researchers to variations in 'what is legal' and 'what is ethical' in the interests of data subjects from one national legislature to another. The European Commission had tracked the growth of internet usage across EU member states mindful of the need to ensure that digitisation would benefit the majority of the population by tackling global challenges, while avoiding risks to privacy and the worsening of digital exclusion (Eurostat, 2018).

By mid-2020, 58% of the world population was estimated to be internet users, compared to almost 90% in the European Union (Internet World Stats, 2020). Within the EU, the same study showed that usage ranged from nearly 98% in Denmark to less than 70% in Bulgaria. Studies within countries revealed that the pandemic had widened the digital divide. Pre-existing digital exclusion, associated with socio-economic, gender, age and ethnic differences in access to online learning, teleworking and purchasing of goods and services, was compounded during lockdown (Allmann, 2020; Eurydice, 2020; Holmes & Burgess, 2020). The pandemic amplified the need for policymakers to address the fault lines that it had exposed in contemporary societies.

The social science contributors to this article provide evidence from their different areas of expertise about the positive and negative impacts of Covid-19 for digital society. They show how the pandemic accelerated the uptake of digital solutions, for example in data collection techniques; how it helped overcome what seemed hitherto insuperable obstacles to the implementation of e-health treatments; and how smart cities used or squandered their potential digital advantage. They consider the ethical, political and legal issues raised by the use of artificial intelligence, for example in surveillance, and the many risks associated with online opportunities, whether for children in social media, for the policing of cybercrime or for digital influencing and disinformation.

Official statistics in the time of Covid-19

Before the coronavirus pandemic, digitisation of data collection for official statistics was presented as having a major potential impact on society. Governments were gradually making greater use of administrative data while exploring and trialling new data sources to enhance the big data evidence-to-policy process (Allin, 2021).

While societies were under lockdown and with no understanding of what the 'new normal' would be, official statistical systems were called upon to live up to their function of serving government and society. Despite the challenges of the pandemic, official statistics continued to be published and developed. As across the rest of government, contingency plans were implemented and used to respond to new requirements for information about how people, households and businesses were being affected by the pandemic.

The UK's national statistician appeared alongside government ministers (occasionally making solo media appearances) in his role as a member of the group providing scientific and technical advice to support government decision-makers during emergencies. The Office for National Statistics (ONS, 2020a) addressed wider needs through a range of new material on its website. Some 150 new products were made available, including detailed reports, blogs and daily roundups. In the short term, face-to-face survey interviews were replaced by more telephone and online interviewing, and by turning to other data sources. This direction of travel had to be abruptly scaled up as it became the 'new normal' for data collection and dissemination.

The need to exploit new data sources in reporting on the pandemic also revealed a latent tension between official statistics, as formally defined, and other official figures. The numbers of deaths linked with Covid-19 came from two sources. Figures for the number of deaths of people who had tested positive for Covid-19, along with the number of new cases of Covid-19 over a 24-hour period, were collated and released the following day by the government departments responsible for health and social care. These data were presented as official figures, rather than as official statistics. They were stated to be incomplete, they were inconsistent between different parts of the country, and changes were made in their coverage during the course of the pandemic. Their value lay in their timeliness: they gave an account of what was happening day-by-day in the health and care system.

The official statistics produced by the ONS were full, weekly counts of all deaths involving Covid-19, that is all deaths where Covid-19 was mentioned on the death certificate. A doctor could certify the involvement of Covid-19 as a contributory factor, based on symptoms and clinical findings, even if this was not the main cause of death; a positive test result was not required (ONS, 2020b, Sections 5 & 6). These statistics were widely recognised to be of high quality because they were drawn from a long-established system of death registration. They also supported analyses of patterns over time, especially in how deaths exceeded or fell short of the average for the time of year. They were published eleven days after the end of the week to which they related.

The two sets were generally seen as contributing to a single picture of what was happening, thus putting a premium on statistical outputs that drew on both sources, enabling them to be compared and contrasted (ONS, 2020b, Section 3). Producing a global picture of Covid-19 deaths was even more challenging. The international comparability of Covid-19 data emerged as a contentious issue, both in terms of the compatibility of definitions and sources, and in interpreting the statistics in relation to different health and social care systems, and government responses to the pandemic.

This observation also chimes with increasing scrutiny of the approach whereby official statistics are usually considered to be only those derived from data generated within the official statistics system or imported into it. In practice, the boundary around official

statistics has been tweaked to include statistics produced by other organisations that commit to the Code of Practice for Statistics on a voluntary basis (Allin, 2019[2021]). The intention is to enable users to assess whether to trust figures as they come across them, rather than having to turn to a limited number of official outlets to find the figures. MacFeely and Nastava (2019, p. 311) proposed that 'official statistics switch from a purely production or manufacturing based model to a mixed business model: one combining the manufacture of official statistics with the franchising of production under license'. They made the proposal in the context of the search for data to help track progress towards the UN's 2030 sustainable development goals. But it suggests a more widely applicable model of licensing or accreditation based on compliance with codes of practice that support the fundamental principles for official statistics.

Could part of the 'new normal' accelerated by Covid-19 for official statistics mean that they serve as the bedrock but not the full extent of public statistics? Should we be moving to include producers currently outside the formal official statistics system, if all these statistics can be curated together and underpinned with reference to common standards for quality and trustworthiness?

Artificial intelligence and research ethics in the Covid-19 context

Social scientists have long been aware of the problem of balancing the efficient management of information and intellectual freedom – the fundamental dilemma of moral agency in cyberspace – which has given rise to the need for regulatory policies governing artificial intelligence (AI) (Iphofen, 2017). UNESCO (2020) was not alone in attempting to set global standards for the ethics of AI, supporting the argument that more policymakers should urgently consider regulations addressing advances made in AI and robotics, as well as issues of ownership, management and control (Iphofen & Kritikos, 2021). The Covid-19 epidemic made these concerns more pressing, as AI came to be seen as part of the solution to lockdown (Kritikos, 2020a).

A health monitoring start-up, using natural-language processing and machine learning, correctly predicted the spread of Covid-19 before anybody else (Niiler, 2020). AI was used extensively and in various forms in the context of Covid-19 (Council of Europe, 2020). AI applications were introduced to track the pandemic in real time, to predict accurately where the virus might appear next, and to facilitate the development of an effective vaccine. AI helped to detect whether people had novel coronavirus from visual signs of Covid-19 on images on lung CT scans, to monitor in real time changes in body temperature through the use of wearable sensors, and to provide an open-source data platform to track the spread of the disease. AI was capable of processing vast amounts of unstructured text data to predict the number of potential new cases by area, and to forecast which types of populations would be most at risk, while also assessing, evaluating and optimising strategies for controlling the spread of the epidemic (Kritikos, 2020c).

AI technologies were harnessed to produce new molecules that could serve as potential medications, or even accelerate the time taken to predict the virus's RNA secondary structure. The capacity of AI to search large databases quickly, scan approved drug databases (for other illnesses) and process vast amounts of medical data helped to accelerate the development of a drug that could fight Covid-19 (Mohanty, Harun AI Rashid, Mridul, Mohanty, & Swayamsiddha, 2020; Wakefield, 2020).

Other AI applications were used to deliver medical supplies by drone and disinfect patient rooms. They contributed to draconian enforcement of restraining measures for the confinement of the outbreak for unspecified durations: for example the use of facial recognition to track people not wearing masks in public; AI based fever detection systems; and the processing of data collected on digital platforms and mobile networks to track a person's recent movements. Certain AI applications could also detect fake news about the disease by applying machine-learning techniques for mining social media information and tracking down words that are sensational or alarming (Kritikos, 2020b).

AI not only created opportunities but also risks. It raised questions about the criteria used for the selection of relevant datasets and possible algorithmic bias. Not all public health systems have the capacity to collect the data needed to train algorithms that would be reflective of the needs of local populations, take local practice patterns into account, and ensure equity and fairness.

Arguably, the massive use of AI tracking and surveillance tools in the context of the Covid-19 outbreak, combined with the fragmentation in the ethical governance of AI, might have paved the way for a wider and more permanent use of surveillance technologies, leading to a situation known as 'mission creep', with state authorities extending the use of these technologies for surveillance purposes other than public health long after the end of the pandemic (Kritikos, 2020c). To prevent AI from contributing to the establishment of new forms of automated social control after the epidemic subsided, governments were called upon to address these ethical issues in ongoing legislative initiatives on AI such as those assumed by the European Commission (2020b) and the OECD.AI Policy Observatory (2019).

The impact of Covid-19 pandemic on e-mental health policy in Estonia

In many areas of healthcare, Estonia is considered to be one of the most digitally advanced countries in the EU and is recognised internationally for its innovations in e-health (OECD/European Observatory on Health Systems and Policies, 2017, p. 14–15). Before the pandemic, Estonian health professionals and the public at large had been reluctant to embrace innovations in e-mental health (Sogomonjan, 2021). The Covid-19 pandemic had negative effects for both individuals and societies, especially for people with common mental health disorders. An unanticipated consequence of the Covid-19 pandemic was that governments everywhere had to rethink the role of digital technology in healthcare (Green, 2020). This section considers how Covid-19 changed attitudes and practices in e-mental health in Estonian society.

The first Covid-19 case was identified on 27 February 2020. The Government of Estonia officially declared a state of emergency on 12 March. Restrictions were implemented on the movements of foreigners arriving in the country and on internal travel. All public gatherings were banned, playgrounds and sports areas were closed, and most planned appointments in healthcare institutions were cancelled. Although the spread of the virus was largely contained, the strict preventative measures imposed during lockdown resulted in an increase in unemployment and domestic violence (Republic of Estonia Social Insurance Board, 2020). The pandemic exacerbated underlying health conditions

among vulnerable people by increasing the risk of depression and anxiety for those forced to self-isolate from friends and family (Santini et al., 2020).

Already in early 2020, the Estonian Health Insurance Fund (2020a) had been planning to make available remote appointments with healthcare specialists. Covid-19 precipitated the need for telemedicine to prevent the spread of the virus and mitigate other impacts on society. The state intervened to enable mental healthcare services to be delivered online to reduce pressure on the overburdened healthcare system. During the emergency, 76% of all remote appointments were made in the field of psychiatry (Estonian Health Insurance Fund, 2020b). Psychological first aid was also made available through the national crisis hotline (1247 and 116 111), and on websites (www.palunabi.ee, www.peaasi.ee and www.lasteabi.ee), where questions from the public could be answered by specialists.

Arguably, 'the Covid-19 crisis and global pandemic served as a defining moment for digital mental health' (Torous, Myrick, Rauseo-Ricupero, & Firth, 2020). Previously, the introduction of telemedicine mental health services in Estonia had been hampered by legal debates regarding personal health data privacy, limited financial resources and policy priorities (Sogomonjan, 2021). General data protection regulation and national law on personal data protection allowed access to special categories of personal data in the case of public health emergencies, making it possible to overcome some of the legal barriers preventing greater take-up of digital mental health solutions during the pandemic. Scheduled outpatient appointments were replaced by virtual appointments, and online counselling and therapies were more readily accepted.

By accelerating the uptake of digital healthcare services and investment in personal health data tracing capacity, Covid-19 undoubtedly brought opportunities to extend access to e-mental health therapies, thereby facilitating teleworking for health professionals and helping to prevent overburdening and collapse of the healthcare system (Järviste, 2020). But the pandemic also created challenges and risks for mental healthcare. Fear of contracting the disease and social isolation caused additional anxiety and stress among people with underlying mental health conditions. Vulnerable patients, particularly older people living alone or in abusive relationships, with poor digital literacy skills or no access to basic technology were unlikely to use online services, exacerbating health inequalities and requiring action by policymakers.

Online risks and opportunities for families living under COVID-19

Research on children's experiences in a digital society has grown apace around the world, responding to the multiple challenges to their well-being posed by socio-technological transformation (Livingstone & Stoilova, 2021). Before lockdown, children went to school and saw their friends outside the home. While parents worried about their screen time, the digital future was the stuff of science fiction (Livingstone, 2018; Stoilova, Nandagiri, & Livingstone, 2019).

Under Covid-19, schooling suddenly went online, and life became digital by default. Technology became the way that children habitually interacted with the world: playing, seeing family, doing schoolwork, connecting with friends. Much of the infrastructure of childhood – education, social services, entertainment, civic and cultural institutions – moved online, including child activism (Cuevas-Parra & Stephano, 2020). More online

risks were created for children's safety, as bullies, scammers, groomers, fake news manufacturers and manipulators scaled up their activities online (End Violence Against Children, 2020).

When parents compared their own childhoods to those of their children, digital technologies often seemed to crystallise the difference. Pre-Covid-19, parents had time to think through steps they could take to balance family conflicts and shared togetherness (Livingstone & Blum-Ross, 2020). Under Covid-19, their previous coping strategies were no longer available to them. Disconcerting media headlines about screen time, gaming addiction, online sexual abuse and other cybercrimes demanded that parents address the very real challenges posed by Covid-19 in managing the technology (Staufenberg, 2020).

The focus in public discourse on digital technology risks under Covid-19 obscured the influence of other important changes on family life: transformations in family structure, job security, welfare provision, migration and identity politics, among others (Chambers, 2012). Arguably, it was these changes that played a dominant role in shaping parental expectations and fuelling their anxieties during the pandemic, since they imbued everyday technological decisions and conflicts with emotional intensity. More than screen time or social media habits, they accounted for most of the problems that children and young people were experiencing (Livingstone, 2018).

Families were unequally positioned when faced with the technological challenges of being locked down. Some families struggled to find reliable health information or effective ways of working online, or to stay in touch with distant relatives, while others enjoyed the greater time for hobbies or for spending as a family, both online and offline. These inequalities were most evident in the public policy row over the unfair consequences of moving from school attendance to online learning, given that many households lacked adequate technology and connectivity to support home-schooling (Eurydice, 2020). Children with special educational or other needs could not be reached online by the systems of care that previously supported them offline.

The new normal of a digital-by-default society did not only involve a changed lived experience; it was also government policy. In the planned shift away from (expensive) in-person state provision, Covid-19 occasioned a step-change in increased reliance on the national digital infrastructure. The result went further than digital inequalities to include a seeming mandate for increased datafication, commodification and digital surveillance of family life by both state and commerce (Lupton & Williamson, 2017).

Open questions for post-Covid research are whether the well-meaning efforts of families to find ways for children to play, see family, do schoolwork and interact with friends online under lockdown will have hastened a digital future in which people's lives are tracked and monetised in ways that few fully understand (Stoilova et al., 2019). Or will families have become more resistant to all things digital, more aware of the value of alternative ways of living, more determined to find their own balance and have their voices heard?

Smart cities and Covid-19

Smart cities aim to apply digital technologies to advance well-being of their citizens. A wide spectrum exists: at one end are cities using digital technologies and information

very effectively to improve public services; at the other are cities that are merely 'smart washing' and adopting superficial technological solutions that chase the symptoms rather than causes of complex urban issues (Anand, 2021). Since cities depend on social connections, the agglomeration effects that drive the productivity advantage of cities became the main source of risk during the Covid-19 pandemic. As the pandemic swept through the world, cities were at the forefront due to their global connections, social interactions and population density. Social distancing and other lockdown measures had a direct effect on cities as services, transport, hospitality and leisure industries took the biggest hit in the economic downturn (OECD, 2020b).

Did smart cities manage the pandemic in a smart way? As the 'track and trace' approach to containing the infection was being trialled, smart cities might have been expected to have an advantageous starting point. Preliminary analysis of the top and bottom 10 in the 102 cities in the IMD (2019) Smart City Index suggests that the number of cases and deaths in the cities concerned were influenced more by national-level policies and actions than by city-level actions. Many smart cities seemed to have been caught as much unprepared for the pandemic as other cities without a smart-city platform. Whatever data advantage smart cities were supposed to have, their status did not appear to have helped them in coping with the virus.

The limited evidence available (author's analysis) confirmed the pre-Covid-19 findings that cities with robust governance and participation mechanisms were likely to be resilient and manage crises better than those using isomorphic mimicry to look like a smart city (OECD, 2020a). Real smartness lay in adaptability, agility and delivering public services in innovative ways. According to this definition, many cities that were not on lists such as that of the Smart Cities Index performed well. Analysis of the policy responses from cities that tended to manage the pandemic most effectively identified several factors that may have contributed to their relative success: they had open, transparent and accountable leadership, and a partnership environment in which public, private and civic organisations, and social networks could all work to deliver different types of services to a range of stakeholders. The role of reliable information provided in a manner that reduced confusion, together with the level of public trust in institutions was also paramount (Devine, Gaskell, Jennings, & Stoker, 2020; Henderson et al., 2020).

On the negative side, where trust in public authorities was weak, militias, gangs and neighbourhood associations used lockdown to legitimise their control. Despite guidance from the United Nations Office on Drugs and Crime (UNODC, 2020) to improve accountability of emergency relief measures, we can conjecture that lockdown also increased corruption and diversion of funds and relief equipment, manipulation of information for advantage and worsening of existing inequalities. In preparation for future pandemics, smart cities could learn from those that were most successful in containing the virus; they could protect their economies by adapting the inclusive policies introduced elsewhere, as well as their data quality and transparency tools, to enable them to play an important role in 'building back better'.

Viral misinformation: Covid-19 and social media

Not only did the rise of social media in the early twenty-first century revolutionise public communication, but it also transformed the potential reach of criminal behaviour, raising

concerns about its use to spread hate crime, extremism and disinformation, as well as abusive, threatening and offensive content. Before the pandemic struck, police forces globally were under pressure to do more to regulate and control social media (Williams, Butler, Jurek-Loughrey, & Sezer, 2021).

To navigate the fear and uncertainty of the Covid-19 pandemic, people turned increasingly to social media to gather information and to engage in social learning. While this reaction could be empowering as a means of risk assessment and mitigation in the light of, at times, conflicting, ambiguous, and partial information, it also left people vulnerable to those adept at exploiting and capitalising on the fears, uncertainties and anxieties caused by the pandemic. Unsurprisingly, a dramatic increase was reported in cybercrime: socially engineered phishing and ransomware campaigns, malware distribution, fraud, hate speech, the online sexual exploitation of children, and the distribution of illicit and illegal commodities (Europol, 2020).

The pandemic also proved to be an efficient vehicle for misinformation, disinformation, and rumour which, among other things, hampered public health responses and effective crisis communication by sowing confusion and distrust in official and medical guidance (Allington, Duffy, Wessely, Dhavan, & Rubin, 2020). As a result, the Director-General of the World Health Organisation (WHO) stated that the world was fighting not only the Covid-19 pandemic but an 'infodemic', that is an overabundance of information that obfuscates reliable guidance (European Commission, 2020a). Social media amplified the potential reach and impact of this phenomenon: approximately one third of social media users surveyed across six countries were found to encounter false or misleading information about the coronavirus (Nielsen, Fletcher, Newman, Scott Brennen, & Howard, 2020).

Traditional investigative and prosecution procedures remain outdated and ill-suited for policing this type of criminality. However, signs were found that transnational organisations, national governments, and platforms increasingly worked together to police social media communications during the pandemic. They adopted a more holistic approach by taking concerted steps to counter, remove and deprioritise misinformation. In the UK, the government created a centralised Rapid Response Unit to coordinate responses to false information related to Covid-19. Their actions included ensuring platforms removed content, provided direct rebuttals to false narratives and promoted accurate medical information (Cabinet Office, 2020). The Rapid Response Unit also engaged directly with social media platforms, academics, technologists, and other experts to ensure that the extent, scope and impact of misinformation during the pandemic was fully understood and responded to.

This approach moved away from traditional investigation and prosecution procedures. The greater involvement of social media companies and experts reflected the evolution of thinking on the topic as outlined in the Online Harms White Paper (UK Government, 2020), specifically in the acknowledgment by government that they were unable to mitigate the harms of online communications offenses alone. This new approach was welcomed, since it potentially ensured the greater use of evidence to inform policy and practice, especially in the light of the three major challenges of policing online harm: scale, the global nature of social media and the principle of proportionality in light of communications, such as misinformation, that may be harmful but not necessarily illegal.

Significant challenges remained. The pandemic highlighted the fundamental problem with the information ecosystem, namely the erosion of factual authority associated with ease of access to polarising information. To counter this situation, cooperation was essential to ensure the reframing of how information is accessed, labelled, prioritised and shared, especially in times when falsehoods can literally be fatal.

Covid-19 and the domestication and normalisation of digital disinformation

The archetype for studying digital disinformation has become the US Presidential election in 2016. The discovery that operators working for the St Petersburg based Internet Research Agency, engaged across social media platforms such as Twitter, Facebook and Instagram, to amplify distrust and discord in the lead-up to the 2016 vote, became an inflection point in how the dynamics and pathologies of the contemporary media ecosystem are understood. All the principal academic studies of disinformation published since 2016 pivoted around this episode. Some concluded that the Russian interventions probably did have a material effect on the outcome (Jamieson, 2018). Others though have urged caution, arguing the current methodological state-of-the-art in terms of measuring influence and impact, especially where it pertains to complex messaging, is relatively immature (Benkler, Faris, & Roberts, 2018).

The study of digital disinformation during the pandemic and policy responses developed to it suggested that our conceptual and empirical paradigm was over-dependent on the known features of the 2016 US case (Innes, Dobreva, & Innes, 2021). This over-reliance became clear when we examined the role of misinformation and disinformation in manipulating public perceptions of Covid-19. One of our drivers for analysing disinformation and digital influencing after terrorism was to foreground how particular techniques for constructing and communicating distorting and disinforming messages could be detected in situations and settings other than democratic events.

Considerable public and political concern was expressed about multiple attempts to manipulate public perceptions of the causes and consequences of Covid-19, as well as the adequacy of policy responses to it. Areas raising concern included: conspiracy theories linking 5G mobile phone technologies; claims that coronavirus emerged from Chinese and American bio-weapon programmes (Kaszeta, 2020); and assertions that some drugs and substances provided effective treatments in the absence of supporting evidence (Freeman, Waite, Rosebrock, & Petit, 2020).

The global health pandemic confirmed and accelerated an extant trend in the causal dynamics of disinformation, and its normalisation and domestication. 'Normalisation' highlighted how misleading information became an almost expected and routine feature of the ways in which a profoundly polluted media ecosystem responds to public crises. Inspired in part by Vaughan's (1996) conceptualisation of the 'normalisation of deviance', in her seminal analysis of the Challenger space shuttle disaster, the key dynamic is how what was previously seen as aberrant and deviant was progressively accepted and tolerated. This is an apposite description of what was observed to be happening in terms of attitudes to misinformation and disinformation about Covid-19, where such reporting became so commonplace and prevalent that it was almost unremarkable. 'Domestication' conveys how, rather than emanating from the deliberate actions of

foreign governments, disinforming and misinforming content was increasingly authored and amplified by domestic citizens for a variety of motives.

Equally, however, this trajectory of development had a looping effect on the tactics and techniques utilised in (dis)information operations run by hostile states. Multiple allegations and claims swirled around that Russia, China and Iran, amongst others, were propagating a series of rumours and conspiracies about the causes and consequences of coronavirus. Significantly though, in many such instances they were just amplifying content originating within more domestic sources, rather than authoring such material themselves. If so, this represents an important new dynamic in the flow of misinforming and disinforming digital communications, and how public perceptions and political agendas associated with high-profile social problems were at risk of being manipulated. Such complexities present new challenges for constructing effective policy responses, given how governments deliberately tended to firewall agencies and departments focussed upon domestic issues and citizens from those engaged with foreign relations and external threats. In terms of how (dis)information flows and travels, it is not bound by any such considerations and conventions.

Conclusions

The examples provided in this article illustrate how the pandemic accelerated the adoption of digital technologies in some areas where uptake had been stalled or was only slowly progressing, such as data collection techniques, e-health online appointments and therapies, online working, learning, and social interconnectedness. New challenges were created, requiring the scaling up of production, fast-tracking of digital supplies, construction of online platforms and video-conferencing products. These transformations did not come without a cost: the pandemic exacerbated existing challenges, demanding government interventions to prevent harm and social exclusion associated with teleworking and social networking on an unprecedented scale.

Even before the pandemic, social scientists recognised that technological development and economic growth did not necessarily result in social progress (Hantrais & Thomas Lenihan, 2021). Their analyses and the questions they raise in this article reveal how the innovative digital solutions embraced during the pandemic to stop the spread of the virus and avoid economic meltdown may also have been used to justify restrictions on personal freedom and forms of surveillance that risk being difficult to reverse.

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Appendix 4

IV

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MasterMind

Deliverable D6.5

Final Trial Report 2nd Wave (cCBT)

MASTERMIND

"MAnagement of mental health diSorders Through advancEd technology and seRvices – telehealth for the MIND"

GA no. 621000

European Commission

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Executive Summary

This document contains the final trial evaluation report for WP6 computerised Cognitive Behavioural Therapy (cCBT) for the treatment of depression. It reports the detailed outcomes of the final evaluation, which is based on the MAST domains, of the cCBT service implementation in second wavers (Wales, Aragón, Basque Country, Badalona, Galicia, Piemonte, Treviso, Turkey, and Estonia). It concludes with the lessons learned collected by the second wavers during the deployment of the service.

The data analysis is based on both quantitative and qualitative information. The data gathered provides the possibility of an understanding of the meaning (qualitative) of the facts (quantitative) for all stakeholders (patients, healthcare professionals and organisations) and their interplay.

Overall, 1.550 patients have received cCBT treatment, and have been included in the analysis. 281 healthcare professionals have been enrolled, while 14 healthcare organisations were involved.

The cCBT solutions implemented are different between sites, but not the therapeutic support given. Some sites have localised existing cCBT programmes while others have created new ones, such as the “Supera tu depresión” tool designed by the Spanish cluster, or the CBT basic app developed by the Estonian pilot.

Similarly to first wave pilots, the recruitment target has not been met mainly due to slow progression in patient recruitment. The reasons are related to delays in development of cCBT platforms, technical problems during deployment, difficulties in professional engagement, and long procurement processes. However, all sites defined and set up corrective actions to overcome these obstacles.

Regarding the clinical effectiveness, 58% of patients were reported to experience a reduction in depressive symptoms, meaning that the cCBT treatment reached one of its major objectives.

The patients' satisfaction is different between sites, but positive in overall. 76,4% of patients reported to have been satisfied with the treatment. However, the overall perceived satisfaction by healthcare professionals with the treatment varies between regions: 17% in Estonia, 25% in Basque Country and Wales and 87% in Treviso. 67% of Wales’ professionals would use these services again, but in Aragón, Treviso and Turkey this is 100%.

The qualitative data derived from semi-structured interviews and focus groups with healthcare professionals and organisation representatives collected information on implementation strategies, the commitment of parties involved, as well as decision making processes. The analysis concluded that the deployment of the cCBT service has been a challenge for the second wave pilots, but valuable lessons for the future implementation and key factors to ensure the sustainability of the service have been raised.

In conclusion, the experience of the second wave pilot sites provides findings to demonstrate the benefits of eHealth solutions in the treatment of depression to facilitate the uptake of the service into routine practice.

Table of Contents

1. Introduction

1.1 Purpose of this document

This document contains the final trial evaluation report for WP6 Internet based guided cCBT for treatment of depression - 2nd wave in the MasterMind project. It uses the approach based on the MAST methodology.

The 2nd wave sites are:

- Powys teaching Local Health Board (PtHB), Wales.
- Azienda Unita Locale Socio Sanitaria N9 di Treviso (LHA N.9), Veneto, Italy.
- Azienda Sanitaria Locale TO3 (ASLTO3), Piemonte, Italy.
- Tallinna Tehnikaülikool (TUT), Estonia.
- Middle East Technical University (METU), Turkey.
- Servicio Aragonés de Salud (SALUD), Spain.
- Badalona Serveis Assistencials SA (BSA), Spain.
- Conselleria de Sanidade de Galicia (SERGAS), Spain.
- Servicio Vasco de Salud (OSAKIDETZA), Spain.

The MasterMind project aims to make high quality treatment for depression more widely available for adults suffering from the illness through the use of ICT. A major cause of morbidity worldwide, depression is characterised by its high incidence, social cost and the proven clinical effectiveness of ICT in its treatment.

The goal is to assess through implementation at scale (more than 5.000 patient overall, 2.300 patients in WP6) the impact of cCBT (computerised Cognitive Behavioural Therapy) on the treatment for depression across nine EU and Associated Countries (nine WP6 partners).

WP6 aims to:

1. Deploy at scale cCBT services for depressed adults across a number of EU and associated countries in regions where cCBT has been already piloted.
2. Collect the values of the indicators specified by the trial protocol before, during and after the trials (see deliverable D3.1).
3. Identify issues that can impede and enable implementation.
4. Devise ways to overcome the impeding factors and exploit the enabling factors.

The Final Trial Evaluation Report for WP6 reports quantitative and qualitative results of the 2nd wavers who deployed cCBT.

The three Final Trial Reports, D5.5, D6.5 and D7.6, adopt the same structure and share part of the descriptive content, some of which has been included in other deliverables, e.g. D3.1 Scientific Trial Protocol. This approach has been chosen to ensure both readability (avoiding too many references to other documents) and that the deliverables can be read independently from each other.

1.2 Structure of document

Section 2 contains a description of the organisation of the project and the analysis done.

Section 3 describes the data used for the analysis regarding recruitment, patients that finalised the treatment, and drop-outs.

Section 4 contains information for MAST Domain 1: Health problem and characteristics of the application.

Section 5 contains information for MAST Domain 2 and 3: Safety and clinical effectiveness.

Section 6 contains information for MAST Domain 4: Patient and healthcare professional perspectives.

Section 7 contains includes information for MAST Domain 5: Economic aspects.

Section 8 contains information for MAST Domain 6: Organisational aspects.

Section 9 contains information for MAST Domain 7: Socio-cultural, ethical and legal aspects.

Section 10 contains information on transferability assessment.

Section 11 contains information on lessons learned and recommendations.

Section 12 contains information on conclusions.

Appendix A gives the project objectives.

1.3 Glossary

ASLTO3	Azienda Sanitaria Locale TO3
BDI	Beck Depression Inventory
BMP	Business Process Modelling
BSA	Badalona
BTB	Beating The Blues
cCBT	Computerised Cognitive Behavioural Therapy
ccVC	Collaborative care Videoconference
CSM	Centro di Salute Mentale
DSM	Diagnostic and Statistical Manual of Mental Disorders
EHR	Electronic Health Record
FTE	Full Time Equivalent
GP	General Practitioner
GPS	Global Positioning System
HIE	Health Information Exchange

HIS	Hospital Information System
IBM	International Business Machines
ICT	Information and Communication Technology
IMSP	Institut Municipal de Serveis Personals
LHA	Local Health Authority
LHA N.9	Unitá Locale Socio Sanitaria
MAST	Model for ASsessment of Telemedicine
METU	Middle East technical University
MHCE	Mental Health Care Environment
MHCU	Mental Health Care Unit
MHD	Mental Health Department
OMI	Oficina Médica Informatizada
PACS	Picture Archiving and Communication System
PTHB	Powys teaching Health Board
PHQ	Patient Health Questionnaire
RIS	Radiology Information System
TUT	Tallinna Tehnikaülikool (Tallinn Technical University)
WHO	World Health Organisation

2. Methodology

The methodology is described in detail in deliverable D3.1 Scientific Study Protocol. An overview of the study design and data analysis plan is provided below.

2.1 Study design

To evaluate the 15 implementation sites, a multi-level and mixed-methods was undertaken using a process and pre-test-post-test study design. The evaluation assessed the viewpoints of three levels of stakeholders involved in the implementation projects: 1) patients, 2) healthcare professionals and 3) mental healthcare organisations. A mixed-methods approach was employed which provided a good understanding of what the implementation projects have achieved (quantitative results), and how or why these outcomes occurred (qualitative results). Using qualitative methods of data collection also provided a good insight into unintended consequences, and provided lessons for improvement of both interventions, and the implementation and up scaling of future interventions in routine practice.

The evaluation was structured according to the Model for ASsessment of Telemedicine (MAST) in which seven highly interrelated domains were assessed:

- Client and care profiles.
- Safety of patients.
- Clinical change in depressive symptoms.
- Implementation related costs.
- Patient and professional perspectives towards cCBT.
- Organisational aspects and the broader
- Social, legal and ethical issues related to employing cCBT in routine practice.

For these seven MAST domains, the following seven objectives can be derived:

1. To identify the factors which promote or hinder the implementation of cCBT for treating depression in routine practice.
2. To assess changes in patients' depressive symptoms when treated with cCBT in routine practice.
3. To assess the costs associated with implementation and large-scale uptake of cCBT for treating depression in routine practice.
4. To assess patients' safety in terms of their mental health when provided with cCBT in routine practice.
5. To assess the perceived satisfaction and perceived usability of cCBT in:
   - Patients when treated for depression.
   - Healthcare professionals when treating patients suffering from depression.
   - Healthcare professionals when using ccVC in a collaborative care setting.
6. To identify the reach of cCBT in routine practice through assessing general patient characteristics.
7. To identify how to implement cCBT at a large scale in routine practice in different care contexts.

Routine practice is our laboratory, thus the measurements should not interfere with the object of our study. Therefore, the study outcomes were based on data already available in routine care, such as information on the reduction of depressive symptoms. In addition, short self-report questionnaires were used to measure satisfaction with and usability of cCBT, as this information is not available in routine focus group interviews with a limited group of healthcare professionals; structured interviews with representatives from the involved healthcare organisations were undertaken to gain a better understanding of the process that leads to implementation success or failure.

The primary focal points of interest were reach, clinical effect, acceptability, appropriateness, implementation costs, and sustainability of the interventions in practice.

The resulting summative evaluation provided valuable insights into the factors that influence the implementation and up-scaling of cCBT in a variety of real political, social, economic and clinical contexts. It provided insight into the perspectives of involved stakeholders, and resulted in concrete recommendations for implementing and up-scaling cCBT for depression in different mental healthcare contexts.

2.2 Data management

To ensure a proper and timely statistical analysis of the collected data, it was essential that, previously, each pilot site in the study assured the correct entry of all requested data, including all relevant quality controls. That way we were able to fulfil the data analysis as described in the next section within the time schedule and deadlines established in the project and by the European Commission.

Each pilot site in the study ensured the quality of the data collected and its completeness, with sufficient controls to prevent the introduction of erroneous data and to totally ensure the confidentiality of patient information entered into the database. To do so, each pilot site nominated a data manager.

Each pilot site had to upload or export the data to the central database (depending on the tool chosen) on a monthly basis. Every month, pilot sites had the opportunity to correct any mistakes introduced in the previous months. The most relevant aspects to be checked were:

- The number of valid participants included in the database.
- The quality of the information entered: completeness, no missing data or erroneous data, mainly in relation to the most relevant variables of the study.
- Detect possible adverse effects of the intervention, mainly suicide attempts or worsening of the patient's condition.

If any important mistake occurs, pilot sites communicated with the coordination team.

In addition to the quality assurance carried out by pilot sites, Arsenal.IT (which was responsible for the central database) checked if the data uploaded were in the correct format according to the codebook, i.e. all mandatory indicators were entered, no incorrect symbols were introduced, ranges of the indicators were respected, etc.

As a third layer of quality assurance, the evaluation team led by the scientific coordinators was in charge of monitoring whether the data was of good scientific quality, e.g. the option

of "missing answer" was used as little as possible, and instruments were monitored to measure and provide data as intended.

Once data capture was completed, each pilot site fully rechecked the quality of the information entered; if any errors were detected in the data entry or data was found missing, they corrected it prior to the statistical analysis.

2.3 Analysis plan

The analyses underwent the following three steps:

- **Step 1**: Due to the strong heterogeneity amongst the participating sites in terms of cCBT solutions, recruitment procedures, and healthcare systems, the analyses of the quantitative data were of a descriptive nature. This was expected and fits the study design: summative evaluation. Frequency tables and scoring were used to observe trends in the data. Univariate analysis was used to investigate potential associations between variables.
- **Step 2**: Through thematic content analysis, semantic units of meaning related to the study objectives were identified inductively within the qualitative data, and then coded and summarised in aggregated narrative tables.
- **Step 3**: The results from step 1 and 2 were combined and observed for trends. Quantitative data were confronted with the qualitative results, and remarkable observations described. The interpretation was of a descriptive nature in order to preserve heterogeneity between levels and contexts of sites. Additionally, and where possible, explorative statistical methods were employed to investigate cross-sectional relationships between levels (patients, healthcare professionals and organisations), care settings and, if possible, specific intervention characteristics.

Presentation of results and interpretations was structured in accordance with the MAST domains. At patient level, data of all participants were included in the analyses when they were eligible and agreed to receive treatment, regardless of whether the participant ended their participation as intended. The reason for this is that information on e.g. complete discontinuation of treatment or parts of the treatment provides valuable information on the effectiveness of the implementation programme. As the focus of this study was on implementation effectiveness, no data, or parts of the data missing, was core information for the outcomes. Therefore, no imputation techniques were applied.

2.3.1 Descriptive statistics

Data cleaning for the depicted analysis included the filtering of patients that were a) eligible for treatment offered, b) recruited and gave consent for the use of their data in the project, and c) of adult age. In general, no other exclusion criteria from data analysis have been used. For post treatment analysis, patients have been excluded who did not provide pre-treatment data. For the clinical effectiveness and change analyses, cases have not been filtered by the number of sessions completed; all provided cases have been used.

We used SPSS 24 for the data analysis. The data has been divided into a core and sub-data sets. The core data sets include all available data on patients, professionals and organisations in order to report a maximum data on the demographics with regard to the inclusion criteria mentioned above. Additionally, for each analysis, a sub-set demographics

table is reported in order to indicate the differences in these sub-datasets from the core data set.

For the clinical effectiveness measure, pre- and post-treatment total numbers and percentages are depicted within pre-set categories (no symptoms, mild, moderate, severe or very severe symptoms). For clinical change, the difference scores between these categories have been calculated indicating the degree of change in the pre-set categories. “Reduction in one category” means that the patient symptoms were reduced by one severity category, e.g. from very severe to severe depressive symptoms, severe to moderate, moderate to mild or mild to no symptoms. Similarly, “reduction in two categories” depicts patients whose depressive symptom severity was reduced either from very severe to moderate, severe to mild or moderate to no symptoms. Under “deterioration”, the number of patients is shown who experienced a higher level of depressive symptom severity after treatment than before.

Patient’s perceived satisfaction was measured with the Client Satisfaction Questionnaire (CSQ-8[1]). This version of the CSQ contains eight questions on consumers’ satisfaction; it is easily scored by summing the individual item scores to produce a range of 8 to 32, with high scores indicating greater satisfaction. The answer options on the Likert scale linked to approval have been combined as indicating “approval”, and the disapproving options in the category “disapproval”. Item selection for the CSQ-8 has been done by expert ratings and factor analysis. Being one-dimensional, the measurement is equipped to provide a homogeneous estimate of general satisfaction with services. In numerous studies, the CSQ-8 has proven to extract patients' perspectives of the value brought by the service, and not so much the gain from treatment or outcome. Similarly, the healthcare professionals' perceived satisfaction was assessed with the Client Satisfaction Questionnaire (CSQ-3), containing items 3, 7, and 8 of the CSQ-8. These items are the empirically the most salient ones, and are used to provide the maximum efficiency in obtaining data. For the reader’s convenience, we chose to show the percentage of approval.

Patients' and health care professionals' perceived usability was measured with the System Usability Scale (SUS[2]) consisting of ten items to facilitate the evaluation of products such as software and applications. The questionnaire was chosen because it represents the gold standard in the field of measuring system usability, it can easily be administered, is realisable in small sample sized, and has been proven to be a valid instrument. Interpretation can be complicated, as the scoring of the SUS items can be positive or negative[3]. To calculate the score, each participant's scores for each question are converted individually, added together and then multiplied by 2.5 to convert the original scores of 0-40 to 0-100. Though the scores are 0-100, these are not percentages and should be considered only in terms of their percentile ranking. Based on research, a SUS score equal to or above a 68 would be considered above average and anything below 68 is below average.

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Bangor, A., Kortum, P. T., & Miller, J. T. (2008). An empirical evaluation of the system usability scale. Intl. Journal of Human–Computer Interaction, 24(6), 574-594.

[3] https://www.usability.gov/how-to-and-tools/methods/system-usability-scale.html

The data has been converted into table format with the help of the "ctable" command in SPSS, and laid out by the MasterMind partner Kronikgune.

2.3.2 Cost analysis: budget impact analyses

An economic evaluation, sometimes referred to as cost-effectiveness analysis, is defined as "the comparative analysis of alternative courses of action in terms of both their costs and their consequences"[4]. Therefore, an economic evaluation requires a comparison of two or more treatment alternatives, and the consideration of both costs and health outcomes in the analysis.

MasterMind does not include a control group, as this is out of the scope of the evaluative framework design of the project. This precludes a comparison between the interventions under study and other treatment alternatives; this prevents a full assessment of the cost-effectiveness of these interventions. The scope of the economic analysis is thus focused on the implementation costs, the recurring costs of the implemented cCBT service, and potential savings derived from the use of the technologies under evaluation.

The economic analysis, or budget impact analyses, is based on responses to the questionnaires preceding the semi-structured interviews with healthcare organisations, which include a series of questions regarding implementation and maintenance costs. The semi-structure interviews collected relevant views in terms of potential savings and a potential business case for initiating and retaining the interventions according to directors / or owners of the healthcare organisations participating in MasterMind.

The budget impact analyses contained the following two steps:

1. Estimate costs of implementing interventions:

   The overall implementation cost to the healthcare organisation is estimated based on information on investment (§6.2.2) and recurring costs (§6.2.3), as well as reimbursement modalities (§6.2.4) and external information on unit costs for staff time.

2. Estimate cost of providing interventions:

   Based on questionnaires preceding the interviews with organisations and information from questionnaires preceding healthcare professionals' focus groups, the (recurring) cost of providing cCBT service in practice are estimated.

2.3.3 Qualitative analysis

The qualitative analysis aligned to a constructivist understanding of the factors that facilitate or hinder implementation by focusing on the opinions that groups of healthcare professionals and individuals in managerial positions hold towards implementing cCBT. We did not set out to answer a specific hypothesis. In that sense, the aim was to describe the participants' experiences of a certain event, which allows presenting the participants' point of view and staying close to data[5].

[4] Ref. Drummond, M.F. et al., 2005. Methods for the Economic Evaluation of Health Care Programmes, Oxford University Press.

[5] Neergaard, M.A., Olesen, F., Andersen, R.S., Sondergaard J.,2009. Qualitative description - the poor cousin of health research?, BMC Med Res Methodol. Jul 16;9:52. doi: 10.1186/1471-2288-9-52.

Full details on the qualitative studies can be found in the deliverable D3.1 Scientific study protocols[6].Below is an overview of the various components of analysis of the qualitative data in MasterMind.

The qualitative study addressed the perspective of healthcare professionals and healthcare organisations for the following MAST domains:

- Domain 2: Client Safety: reasons for stopping treatment.
- Domain 4: Economic aspects: expected cost savings, business cases, and sustainability.
- Domain 5: Perspectives towards cCBT and ccCV: needs of the patient and professionals.
- Domain 6: Organisational aspects: leadership and factors promoting or inhibiting implementation.
- Domain 7: Social, legal and ethical aspects: issues with liability, benchmarking, and public image.

The qualitative study followed a two-stepped emerging design that steered the contents of the structuring themes. Focus group discussions were conducted with healthcare professionals (both therapists and clinician referrers) to obtain collective views on the identified themes for cCBT. The interviews were aimed at obtaining the opinions of individuals representing the services organisations related to the context they are operating in.

For the data collection and analysis, a combination of inductive and deductive methods was applied. The MAST framework[7], Consolidated Framework for Implementation Research (CFIR)[8], Measurements for Determining Innovation (MIDI)[9], RE-AIM[10] and the Normalisation Process Theory (NPT) were used to deductively inform the initial themes. These frameworks (MAST, CFIR, MIDI, RE-AIM) and theory (NPT) describe items and issues one should take into account when considering, planning, executing and evaluating an implementation project. Through iterative testing of the items in a pilot study, saturation of themes was achieved inductively. Purposive sampling was applied. The composition of the focus groups and interviews is listed in the tables below.

Table 1: Wave 2: Focus group discussions

Site	Service discussed	Participants
Aragón	Guided cCBT	Primary care practitioners, nurses, and specialist therapists (n=7)
Badalona	Guided cCBT	GP, nurse, psychologist, MD, director, psychiatrist (n=6)

[6] Vis, C. et all. Implementing and up-scaling evidence-based eMental health in Europe: The study protocol for the MasterMind project. Internet Interventions 2 (2015) 399–409

[7] Kidholm, K et all. A model for assessment of telemedicine applications: mast. Int J Technol Assess Health Care. 2012 Jan;28(1):44-51. doi: 10.1017/S0266462311000638.

[8] Damschroder, L.J. et all. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009 Aug 7;4:50. doi: 10.1186/1748-5908-4-50.

[9] Fleuren, M.A. et all. Towards a measurement instrument for determinants of innovations. Int J Qual Health Care. 2014 Oct;26(5):501-10. doi: 10.1093/intqhc/mzu060. Epub 2014 Jun 20.

[10] Glasgow, R.E. et all. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. Am J Public Health. 1999 Sep;89(9):1322-7.

Site	Service discussed	Participants
Basque Country	Guided cCBT	Primary care practitioners (n=5)
	Guided cCBT	Primary care practitioners (n=7)
Estonia	cCBT min. guidance	Primary care practitioners (n=9)
Galicia	Guided cCBT	Primary care practitioners, nurses, therapists (n=6)
Piemonte	Guided cCBT + ccVC	Primary care practitioners, specialist therapists (n=11)
Treviso, Veneto	Guided cCBT + ccVC	Primary care practitioners, specialist therapists (n=5)
	Guided cCBT + ccVC	Primary care practitioners, specialist therapists (n=7)
Turkey	cCBT min. guidance	Specialist therapists (n=3)
Wales	Unguided cCBT	Primary care practitioners (n=5)

Table 2: Wave 2: Semi-structured interviews

Site	Service discussed	Participants
Aragón	Guided cCBT	Coordinator mental healthcare unit
Badalona	Guided cCBT + ccVC	Director Innovation, research, and ICT
	Guided cCBT + ccVC	Medical officer
Basque Country	Guided cCBT	Regional Director of integration
	Guided cCBT	Regional Director of integration (different region)
Estonia	Guided cCBT	Head of GPs and psychologist centre
Galicia	Not available; corrupt data file	
Piemonte	Guided cCBT + ccVC	Director of mental health department
	Guided cCBT + ccVC	Director of mental health unit
Treviso, Veneto	Guided cCBT	Director of department of mental health
	Guided cCBT	Director of social services
Turkey	cCBT min. guidance	Project manager
Wales	Guided cCBT	Chief Executive Officer
	Guided cCBT	Assistant director mental health services

Credibility and validity was ensured through cross verification (i.e. triangulation) of the outcomes of the various methods. This took place in three ways:

- For healthcare professionals - therapists / referrers: confirmative research of the CSQ-3 and SUS questionnaires that were administered to healthcare professionals.
- For healthcare professionals - team leaders: confirmative research of the CSQ-3 and SUS questionnaires that were administered to healthcare professionals.
- Between healthcare professionals and healthcare organisations upper-level management: confirmative research of the focus groups with professionals and team leaders.

Preceding the focus-group discussions and semi-structured interviews, participants were asked to fill out a short questionnaire to obtain general information about the interviewees and to prepare them for the interviews.

A detailed field guide and reporting template was developed, and interviewers and focus group facilitators were trained in a two-day workshop. Please refer to the generic study protocol (D3.1 version 1.2) for more information on the data collection procedures.

The analysis consisted of two distinct steps:

- Step 1: Thematic content analysis.
- Step 2: Thematic analysis.

2.3.3.1 Step 1: Thematic content analysis

Through thematic content analysis, semantic units of meaning related to the initially defined themes were identified within the qualitative data, and then coded and summarised in tables corresponding the MAST domains. The reports delivered by the sites were split, and categorised in accordance with the wave the sites were active in, in combination with the service evaluated (i.e. cCBT + ccVC or ccVC only). The reports contained summary statements from the interviewer, together with transcribed and translated (to English) quotes from the audio tapes supporting the summary statements.

The process of coding and categorisation of data was structured according to the following four steps:

1. The reports were read to obtain an overview of data and to identify recurrent themes.
2. The reports were reread and coded according to the themes identified in the first step.
3. All text sections that were coded similarly were categorised into general themes.
4. To ensure correct coding and categorisation, the data was reviewed for coherence and reallocated if discrepancies were found.

Coding and categorisation was using the qualitative data analysis application ATLAS.ti.

2.3.3.2 Step 2: Thematic analysis

Analysis of combined data was of a descriptive nature in order to preserve heterogeneity between the levels and contexts of sites. For each (type of) interview, a table was constructed with the final categorisations from step 1, a summary description of the findings, and a description of the sources (site, focus group or interview, participants), was prepared and included in the results sections.

The descriptions of findings, data collection processes and participants were created by using narrative summaries in the form of simple descriptions of disaggregated data in tabular format [11]. These narrative summaries are included in the presentation of the results for the corresponding MAST domains, after are included the interpretative step described in step 3 of the overall analyses plan.

[11] Dixon-Woods, M., Agarwal, S., Jones, D., Young, B., Sutton, A., 2005. Synthesising qualitative and quantitative evidence: a review of possible methods. J Health Serv Res Policy;10(1):45-53.

3. Domain 1: Health problem and characteristics of the application

3.1 Introduction

Domain 1 addresses the health problem and general characteristics of the patients, healthcare professionals, and organisations involved. It results in a profile of the average patient, average healthcare professional, and organisation providing the services. The patient profiles contain information on basic demographics (age, gender, education, employment, etc) and health status. The profiles of the healthcare professionals include demographic information, as well as professional experience in the field of mental healthcare and with the services. The organisational profiles include information in terms of age and size.

Data for this domain is mainly of a quantitative nature, and is used to answer the following questions from the project objectives:

- Objective #1: To identify barriers and facilitators that influences the implementation of cCBT for treating depression in routine practice.
- Objective #6: To assess who receives cCBT in routine practice.
- Objective #7: To assess the transferability of implementation and up-scaling of cCBT in routine practice in different care contexts.

The instruments used to collect the data include Routine Outcome Measurements (ROM), the treatment platforms, and online questionnaires.

The quantitative data retrieved from the trial sites has been enriched with qualitative descriptions of the epidemiological health problem in the regions and an overview of the mental health systems currently active. This enables drawing conclusions in terms of the reach of the implemented intervention for the given healthcare context.

3.2 The setting

3.2.1 Prevalence of depressive disorder

Unipolar depressive disorder is currently one of the most prevalent mental disorders worldwide, and is predicted to be the number one overall cause of disability by 2030 for citizens of higher income countries[12]. Depressive disorders can lead to reduced quality of life, impaired social and personal relationships, and disturbed professional life. They are often accompanied by other psychiatric disorders (e.g. anxiety disorders, substance abuse), and a variety of physical health problems. A depressive disorder may start early in life, and the course is often recurrent[13,14]. Therefore, depressive disorders are associated with

[12] Mathers, C.D., Loncar, D..2006. Projections of global mortality and burden of disease from 2002 to 2030. PLoS Med;3(11):e442.

[13] Bijl, R.V., Ravelli, A.. 2000. Psychiatric morbidity, service use, and need for care in the general population: results of The Netherlands Mental Health Survey and Incidence Study. Am J Public Health;90(4):602-7.

[14] Barney, L.J. et all. Stigma about depression and its impact on help-seeking intentions. Aust N Z J Psychiatry. 2006 Jan;40(1):51-4.

substantial economic and societal costs, such as cost of treatment, loss of work productivity, absenteeism, early retirement, and premature death.

Despite the availability of effective treatments, the number of people that actually receive treatment for depressive disorders is not optimal. Care utilisation rates for adults with depression range from 35% to 45% in higher income countries. Suggested barriers that contribute to these low rates include: fear of or perceived stigmatisation; lack of adequately trained therapists; and the costs associated with healthcare delivery. Also, the often mono-diagnostic nature of interventions available might limit treatment options for patients with mixed symptoms, the relatively high comorbidity among psychological disorders, or interpersonal differences in patients.

The table below provides an estimate of the eligible patients for each region. This number is based on the local or national prevalence for depression, and the population of the region.

Table 3: Estimation of eligible patients for each region

Region	Number of eligible patients	Applicable (local) eligibility criteria for cCBT
PtHB-IRH (Wales)	10,614	Gathered through Mental Health Team needs assessments with the HB (linked to their IMTP)
SALUD (Aragon)	3,697	Adults with depression in the area of intervention
Osakidetza (Basque Country)	39,404	10% of the depressed inhabitants of the Basque Country, with mid or moderate symptoms. The depressed inhabitants are 18% of the total.
BSA (Catalonia)	25,105	Depressed population that go to their centres
SERGAS (Galicia)	101,424	Patients meeting inclusion criteria
ASLTO3 (Piemonte)	21,600	Population reached by the 18 GPs trained and involved in MM (18 * 1,200patients/GP)
LHA N.9 (Treviso, Veneto)	88,000	Calculation is estimated on the prevalence of the inhabitants of the Veneto region (5.000.000) in relation to the intended users of Mental Health Services in Veneto region LHA N.9
METU (Turkey)	8,450	5750 students (prevalence: 0.25) 2700 staff (prevalence: 0.1)
TUT (Estonia)	100	Applicable (local) eligibility criteria for cCBT: - Mild to moderate depressed patients, adults (18+). - Motivated and interested in using CBT BASIC app and iFightDepression programme. - Involved through GPs and psychologists over country. - No serious morbidities that affect further usability of programmes.

3.2.2 Current mental healthcare settings targeting depression

The majority of persons with a mild or moderate depressive disorder receive treatment in primary care settings, mostly by GPs, by means of antidepressants and less by brief psychotherapeutic interventions. Patients suffering from more severe depressive disorders are often referred to specialised mental health care services where treatment consists of medication, psychotherapy or a combination of both[15,16]. For specialised care, there is an overall trend in Europe to replace inpatient by outpatient care in specialised mental health centres, and treat depression if appropriate in the community in primary care settings. However, the rates differ considerably between EU countries.

3.2.2.1 PtHB-IRH (Wales)

Powys covers ¼ landmass of Wales, but only has 4.5% of the population (132,000 people approximately) making it the most sparsely populated region in Wales. PtHB is part of the National Health Service within the United Kingdom. Travel between some of the different Health Board sites can take three hours plus.

The majority of the persons suffering with mild / moderate depression first contact their GP; the GP would usually undertake watchful waiting, or possible treatment with antidepressants. If this was not successful, then the GP would refer the patient into the Local Primary Mental Health Support Service (LPMHSS) for further assessment and psychological therapy.

3.2.2.2 SALUD (Aragon)

The primary care professionals at the Primary Care Centres have the first and closest contact with the patients. They do the first diagnosis, and normally treat mild to moderate depression. This treatment might include an anti-depressants prescription. When there is a patient profile with more complex needs and/or the symptoms are more severe, the GP might decide whether to contact the Mental HealthCare Unit at the main general hospital or not. The frequency and the type of interaction depends very much on the GP's workload and on his/her training and experience in the treatment of mental health disorders. These contacts with the Mental Healthcare Unit can be of two types:

- Consultations. This kind of contact normally consists of a description of a case with specific questions about diagnosis or therapeutic treatment.
- Direct referral, when the severity or the complexity of the patient profile indicates specialised treatment.

3.2.2.3 Osakidetza (Basque Country)

The Basque Health System includes 15 hospitals, more than 100 primary care clinics organised through three different geographical areas, apart from the Mental Health Centres, Emergencies and Basque Transfusions and Human Tissue Centre. More than 32,000 professionals work for Osakidetza, which could be considered the biggest organisation of the Basque Country.

[15] Cuijpers, P. et all. Personalized treatment of adult depression: medication, psychotherapy, or both? A systematic review. Depress Anxiety. 2012 Oct;29(10):855-64. doi: 10.1002/da.21985. Epub 2012 Jul 19.

[16] Cuijpers, P., van Straten, A., Andersson, G., van Oppen, P. Psychotherapy for depression in adults: a meta-analysis of comparative outcome studies. J Consult Clin Psychol. 2008 Dec;76(6):909-22. doi: 10.1037/a0013075.

Mental health services in the Basque Country are based on the community care model which:

(i) promotes integration and standardisation of mental health care services;

(ii) gives support and facilitates social integration and normalisation of the affected population; and

(iii) endorses coordination of social and health care.

Mental health services consist of three regional networks with four psychiatric hospitals (777 beds), two contracted long-term mental hospitals, and several mental health centres in close collaboration with primary care. Mental health services in the Basque Country consist of departments and functions across the three provinces of the Autonomous Basque Community.

Service deployment in the Basque Country includes different actors with specific tasks: GPs from primary care, psychologists and psychiatrists from Mental Health Centres and/hospitals, managers and patients. Healthcare professionals belong to distinct organisations of the three provinces of the Basque Country. According to the organisational model defined, GPs are the main actors responsible for patient recruitment. They invite candidate patients, who meet the inclusion criteria defined in the general scientific trial protocol, to participate in MasterMind project. In addition to these criteria, GPs ensure that the patient is able to handle the online cCBT tool.

3.2.2.4 BSA (Catalonia)

Badalona Serveis Assistencials (BSA) is a consortium that manages seven Primary Care Centres, an acute care hospital (Hospital Municipal de Badalona), an intermediate care hospital (Centre Sociosanitari El Carme), an integrated homecare service, and a Centre for Sexual and Reproductive Health. BSA provides care to a total population of 234,000 inhabitants in the most populated suburban area of Barcelona. BSA employs more than 1,200 staff.

One of the most significant characteristics is the strategy based on the coordination of the different levels of care: from primary and home care to hospital care, all the interventions are well coordinated and globally supervised. This integrated model of care ensures the best service for citizens when and where needed, optimising the use of resources to guarantee the best overall care. The possibility of sharing the EHCR among the different healthcare levels allows the development of new models of care to improve the access of patients to secondary care, without generating duplications or delays in lab tests or other diagnostic procedures. This allows specialists to consult patient both at their home and in the Primary Care Centres.

We also work very closely with IMSP (in Catalan, Institut Municipal de Serveis Personals). It is a public organisation operating in Badalona region which is in charge of providing the most specialised mental care support. It is also owned by the City Council of Badalona.

3.2.2.5 SERGAS (Galicia)

Galicia is a territory with a significant demographic dispersion. The mental health services are designed from a community perspective in order to provide resources for the whole population.

Any health problem is evaluated first by a GP. In the case of mental illnesses, GPs treat the most prevalent and mild diseases such as adaptation problems or mild depression. GPs can refer to secondary care any case that he/she considers specifically psychosis or severe affective disorders. Mild and moderate depression cases are usually treated by the GP.

Secondary care provides psychiatric services. There are seven psychiatric services in Galicia. Each of them has community based resources and hospital care units. The basic unit for community based approach is the Mental Health Unit (USM). Each of them is composed of a team of psychiatrist, psychologist and a nurse, plus a social worker. We also have continuity care teams, in order to treat the most isolated cases at their home. Chronic cases could be treated in Units for Psychosocial Rehabilitation or supervised flats.

There are also units in general hospitals for treating severe acute patients. We have two psychiatric hospitals for admissions of patients with very severe chronic conditions.

There are 52 Mental Health Units in Galicia. They are in general health centres or in hospitals. We are recruiting patients in three of the seven health areas of our region; all of them are part of a single health service (SERGAS). Six Mental Health Units have been selected to pilot the MMIND cCBT programme.

3.2.2.6 ASLTO3 (Piemonte)

ASLTO3, partner of the MasterMind project, is located in Piedmont, and covers the widest part of the regional territory, as compared to the other ASL. Overall, the psychiatric services of ASLTO3 treat about 9,000 cases per year. They receive about 3,000 new cases every year, with an estimated proportion of depressive disorders of around 20%. Over the years, a specific pathway has been developed for the assessment and treatment of people suffering from depression. This pathway encompasses an assessment stage of the patients in the Mental Health Outpatient Services (11 distributed in the territory of the ASLTO3); when appropriate, this is followed by referral to a therapeutic treatment of low, medium or high intensity, depending on the clinical needs of the patients. Patients can be treated in three hospitals (with 10 beds each for psychiatric emergencies, and an average length of stay of around 12 days), or in two private accredited facilities (with 140 beds in total, and an average length of stay of around 36 days).

In addition, in the territory covered by ASLTO3 there are currently more than 400 GPs who represent a precious resource. In the last few years, collaboration of the GPs has increased the capacity for early detection of those who are suffering (or at risk of suffering) from depression. However, it is currently difficult to provide adequate therapeutic treatment to such a large number of patients with traditional approaches (e.g. face-to-face psychotherapy), especially as the number of patients with depressive disorders will increase significantly in the next decades (World Health Organisation, 2001). Thus, the introduction in ASLTO3 of a cCBT service, and the increased use of video-conference system for clinical monitoring (as implied by the MasterMind pilot) would probably allow a significant proportion of patients with mild to moderate depression to benefit from a treatment of their disorder.

3.2.2.7 LHA n.9 (Treviso, Veneto)

The Mental Health Department in Treviso comprises two psychiatric services, one for 200,000 people which has two psychiatric wards and four Mental Health Centres, and one for 100,000 people. Patients suffering from severe mental health disorders are often referred to these mental healthcare services where treatment consists of medication,

psychotherapy, or a combination of both. The majority of persons with a mild or moderate mental disorder, depressive disorders included, receive treatment in primary care settings from GPs, mostly medication.

During the follow-up, the specialists (MasterMind psychologist and psychiatrist) meet the patient at the Mental Health Centre for evaluation, and consider the possibility of assigning to cCBT treatment, in collaboration with the GP by collaborative care through videoconference or phone. At the Mental Health Centre, depending on the clinical situation presented, the patient is invited to start cCBT treatment or to start an adequate treatment for his condition, with or without medication. In both cases, the GP has the opportunity to share the patient status with the specialist, at any time, through videoconferencing with the specialist and in the shared electronic MasterMind folder. The patient, who agrees to undergo cCBT treatment, will be adequately informed and invited to carry out the treatment activities, under the supervision of a psychiatrist mental health specialist or a case manager (MHC workers).

3.2.2.8 METU (Turkey)

The prevalence of depression in the general Turkish population is of the order of 13% in women and 8% in men according to Turkish psychiatry association. However, the prevalence is much higher among university students (25% according to Binbay et.al 2013). The target population of MasterMind in Turkey has been university students. For this purpose, several customisation procedures have been implemented. First of all, the language used in the cCBT modules is tilted towards the jargon common to youth; also the respect code in the language is tilted towards addressing younger people. Secondly, the therapists are chosen from among specialists closer to the patient populations; the therapists are graduates of psychology departments with MS degrees, they are licensed in CBT, and they are students themselves, pursuing PhD. Finally, the delivery of services is entirely free. The online service is based on the educational LMS platform offered by METU. The modules are entered as a part of a regular online class. If the service is licensed in the future, this can easily be done through METU.

Local patient recruitment was initially planned to be done only from the METU student counselling services, AYNA. But later, after a few encounters with other universities, Bogazici University's BUREM also joined. Both of these services are overcrowded with student patients. Usually, the time spent in the waiting list is around 5-6 months. The recruitment strategy takes patients from the waiting list, but keeps their place on the list, so that if the patients wish to continue with face-to-face therapy after cCBT, this is still available. One problem seems to be the creativity of students to have thoughts of suicide. This is an exclusion criteria, and it appears that quite a few students indicate that they have developed a suicidal plan after they gave consent to participate. In these cases, they have to be immediately referred to face-to-face therapy, so they have to be dropped out of Top Sende. Currently remedies are being sought for this issue.

3.2.2.9 TUT (Estonia)

In Estonia, patients have an opportunity to choose whether they like to visit their GP in the primary healthcare setting, or to visit a psychologist / psychotherapist / psychiatrist in the mental healthcare centre without any referral letter; mental healthcare service is also available in private healthcare centres. The psychiatric services in the Register of Activity Licences of the Health Board are classified as follows:

- Outpatient psychiatric services.

- Outpatient children's psychiatry services.
- Outpatient psychiatric services (including children's psychiatry).
- Children's psychiatry services.
- Psychiatric services of day medical treatment.
- Psychiatric services (including children's psychiatry) inpatient psychiatric services.
- Auxiliary psychotherapy services.
- Out-patient psychotherapy.

74 natural or legal persons, providing health services, hold a valid activity licence for the provision of psychiatric services. Some of them provide services to mainly or only a certain target group (e.g. people suffering from mental disorders caused by the consumption of psychoactive substances, and to those suffering from sexual dysfunctions).

Social services, with reference to people with severe and long-lasting mental special needs, are provided by 86 service providers who provide the following services:

- Supported living.
- Living in a community.
- Supported employment.
- Supporting everyday life.
- 24-hour care.
- 24-hour care with intensified monitoring

3.2.3 Interventions implemented in MasterMind WP6

Within MasterMind, the participating healthcare organisations implement evidence-based cCBT interventions in routine mental healthcare practice. The cCBT interventions are evidence-based, in that there is clinical evidence from randomised controlled trials demonstrating that the underlying therapeutic principles contribute to improvement of depressive symptoms and health related client outcomes.

The exact treatment and service modalities depend on the type and structure of the technical cCBT platform used, the individual needs of patients, and the care setting. For all implementation sites, the treatment protocols and technological solutions adhere to the multidisciplinary NICE clinical guidelines for depression developed by the National Institute for Care and Excellence in the UK[17]. The core components of all cCBT treatments are: (1) psycho-education, (2) cognitive restructuring, (3) behavioural activation, and (4) relapse prevention. These components are delivered over a number of sessions, either online (with minimal guidance), or via a combination of face-to-face sessions with a mental healthcare professional, alternating with online sessions in which the CBT components are described and practised.

Patients for whom CBT treatment is indicated and have for example difficulty visiting the clinic will be offered a video supported cCBT treatment. The online sessions are delivered through a secure web-based online treatment platform. The internet platforms include a web-based interface providing patients with access to cCBT therapy modules, a digital workbook, and a secure communication channel for both therapists and patients.

The cCBT solutions adopted by 2nd wavers have followed a similar procedure in order to decide the cCBT programme used. In this way, some of the aspects that have been

[17] NICE. Depression: the Treatment and Management of Depression in Adults. 2009.

considered are in relation to the collection of information on the different characteristics of the programmes such as structure and clinical content of the online therapy, costs, or privacy and confidentiality.

The following table shows the cCBT programmes chosen by 2nd wavers.

Table 4: cCBT programmes chosen by 2nd wavers

Pilot site	cCBT programme
Wales	Beating the Blues
Piemonte	iFight Depression
Treviso, Veneto	iFight Depression
Estonia	iFight Depression and CBT Basic app
Turkey	Top Sende (a brand new programme in Turkish)
Badalona	"Supera tu depresión" (adapted by Spanish cluster)
Aragón	
Galicia	
Basque Country	

3.2.3.1 PtHB-IRH (Wales)

Powys had adopted the 'Beating the Blues' system of online CBT developed by Ultrasis (but now owned by 365 Health & Wellbeing). Beating the Blues is a cCBT programme for depression and anxiety. It is a clinically proven drug-free treatment that is cost effective and time efficient, which integrates best practice in psychological therapies with advanced multimedia software. The programme was developed and evaluated by Ultrasis in collaboration with a research team from the Institute of Psychiatry, Kings College, London, led by Dr Judy Proudfoot. Beating the Blues has been evaluated through independent clinical trials; the results have been published by the British Journal of Psychiatry.

The eight sessions enable users to identify specific problems and realistic treatment goals. Users work through cognitive modules to identify and challenge automatic thoughts, thinking errors, distractions, core beliefs and attributional styles. Problem directed behavioural components are interlinked with these cognitive elements, enabling users to work on activity scheduling, problem solving, graded exposure, task breakdown, or sleep management, according to their specific problems. The final session looks at action planning and relapse prevention.

Beating the Blues uses interactive modules, animations and voice-overs to motivate and engage the user. A major feature is a series of filmed case studies of fictional patients who model the symptoms of anxiety and depression, and help demonstrate the treatment by CBT.

The programme offers clinicians a remote monitoring tool whereby users complete modules from any computer, whilst their clinical helper can print off reports from their own system. The programme has integrated assessment tools PHQ9 and GAD 7 in line with IAPT requirements. Suicide risk alert emails are generated, and regular encouragement is fed back to users.

3.2.3.2 SALUD, Osakidetza, BSA and SERGAS (Spain)

The four Spanish organisations participating in MasterMind agreed to adapt existing evidence-based cCBT programmes to their local cultural context. For this purpose, a group of healthcare professionals (psychiatrists and psychologists) from these regions, with expertise in CBT interventions and online therapies directed to other pathologies, have worked together to define the clinical content of the cCBT programme to be implemented.

The adapted cCBT programme is called “Supera tu depresión" (Overcome your depression) and consists of eight modules:

1. What is depression?

   Description of depression, its main symptoms, and guidelines to face depression are stated. In addition, how to manage anxiety and relaxation techniques are explained.

2. How different activities affect our mood.

   Relationship between behaviour and emotions is explained, and how changing our daily activities can influence our mood.

3. Increasing pleasant activities. Additional information on healthy habits.

   Guidelines to plan and perform pleasant activities are given.

4. How our thoughts affect our mood.

   Relationship between thoughts and mood is defined, and different types of thoughts that boost the appearance of the depression are listed and illustrated with examples. In addition, guidelines to detect negative thoughts are given.

5. Learning to change our negative thoughts.

   Benefits of being optimistic are explained and how to reverse a negative thought into a more reasonable and positive idea.

6. Learning to change our negative thoughts. Special situations.

   Different techniques to boost positive thoughts are given, such as distraction, and a set of exercises is proposed.

7. Problem solving.

   Steps to problem solving are explained: 1) identification of the problem, 2) specification of the response that usually occurs, 3) listing alternative solutions, 4) assessment of consequences of each alternative solution, 5) analysis of the results.

8. Looking to the future.

Salud

The strategy in MasterMind also includes a "stepped approach", as there was no previous experience in the area / organisation in the use of cCBT, nor in mental health technology-related projects. This stepped approach is composed of two routes of incremental activity:

- Beginning at the Mental Healthcare Unit with a few patients, and after that small intervention, inclusion of recruitment by a few GPs at some Healthcare Centres.
- The initial approach was to try a "self / auto-guided" intervention with a minimum follow-up. Monitoring would be increased / tailored depending on the effectiveness of the intervention and on the adherence to treatment from users.

The plan includes:

- A first phase with a few patients, in which psychiatrists from the Mental Health Care Unit would put the final touches to the intervention. This initial phase started in October 2015, and included a few patients recruited from the Mental Health Care Unit. The initial results of this small experience led to a redesign of the intervention due to the lack of adherence to treatment by patients, including more training materials, more technical support, and the inclusion of training sessions. Also, the complex profiles of patients at the Mental HealthCare Unit caused some changes in the recruitment strategies.
- A second phase focused on recruitment at the Primary Care Centres. This phase started in February 2016 with the intervention of GPs to do the recruitment, and nurses from primary care to do the follow-up. Recruitment at the Mental Health Care Unit also continues, but with a few changes from the initial approach (more collaboration with the Mental Health Care nurses and a more intensive monitoring of patients).

Once the solution and the protocol have been assessed and validated at these centres, further deployments are foreseen.

Osakidetza

Once the patient has accepted to participate in the intervention, the GP or the GP nurse is in charge of explaining how the online cCBT tools works. After the demo, the patient is given a username and a password, and he/she can start with the first session scheduled in the cCBT programme. Before starting the session, the patient has to complete some questionnaires online (MANSA-2, PHQ-9, BDI and EuroQoL).

The MasterMind platform is a web application developed in HTML5. Access to this application is possible by mobile, tablet or PC. It is composed of two parts or "consoles":

- Patient console: accessible by a link in the personal health folder, this console is used by two roles (patient and caregiver). Authentication in this console is supported by personal certificate or Barcode – Advanced electronic signature.

  The most important functionalities provided are:
  - Empowerment of patients in your activities to check your disease.
  - Education about your disease.
  - To answer questionnaires about your health status or disease status.
  - To send messages to clinicians.

- Clinical Console: accessible by URL deployed in the internal environment of the public health service (Osakideza). It is accessible only by clinicians. The method for authentication is SSO (Single Sign On) using the user and password introduced by user in Osakidetza environment.

  The most important functionalities are:
  - Management of the clinical contents of app (movies, questionnaires, educational documents…).
  - Monitoring patients' status.
  - Check alarms.

BSA

A platform recently developed through a joint venture with Arvato-Bertelsmann is used to deploy the cCBT service. The platform has now been integrated within BSA information systems. A positive aspect of the platform is that it has been designed to be able to change / tune the interventions to be deployed very easily by a non-programmer.

The platform is designed to be able to deploy any internet intervention, and has the following main components:

- Workflow engine: This defines and manages the flow of the intervention according to roles, tasks and time.
- Content management system: This manages the content which is shown by the intervention. The content can be: enriched text integrated in the web page; files to download; and external content including videos.
- Communication system: This manages the communication channels and messages between the different roles involved within the interventions. The communication channels can be: internal messaging system, SMS and email.
- Form / questionnaire tool: This manages every questionnaire or form within the platform. The questionnaires can be fully tuned according to the needs of the intervention.

SERGAS

The IT department has integrated the CBT programme in our electronic clinic report, and ensured that the online sessions are delivered through a secure web-based online treatment platform. The internet platforms include a web-based interface providing patients with access to cCBT therapy modules, a digital workbook, and a secure communication channel for both therapists and patients. The programme would be included in a computer-based clinical process that guides professionals in treating depression. In that process, professionals could assign this therapy to any patient they consider.

All the interventions are registered in the electronic clinical report. This electronic clinical report has a special security profile in order to protect clinical data in accordance with Spanish legislation.

During 2016, other healthcare centres have been enrolled in the MasterMind project. We try to offer a very helpful programme in order to provide better management of mild and moderate patients. We have been able to enrol 49 GPs during this time. Once we have the final cCBT programme integrated in our clinic history tool, we will start new courses in order to explain to participants the specific aspects of the protocol.

3.2.3.3 ASLTO3 and LHA N.9 (Italy)

Both Italian partners have adopted the iFightDepression© system for online CBT. iFightDepression was developed within the Predi-NU project, Preventing depression and improving awareness through networking in the EU (http: // www.predi-nu.eu/).

The iFightDepression tool is a guided, internet-based self-management programme for individuals experiencing mild to moderate depression; it was developed based on existing evidence, best practice recommendations, and user and expert consensus. The tool is free

to use, and is intended to help individuals to self-manage their symptoms of depression and to promote recovery, with support from a trained GP or mental health professional. The tool is based on the principles of CBT; it consists of six core modules, and three additional modules that can be performed by patients, according to their clinical needs. More precisely, iFightDepression consists of informative modules that focus on increasing daily activity, identifying and challenging unhelpful thought patterns, monitoring mood, adopting healthy sleeping patterns, and maintaining a healthy lifestyle. Associated worksheets and exercises encourage users of the tool to practise and consolidate new skills and to promote self-monitoring.

ASLTO3

After the inclusion of patients in the pilot, the MasterMind team contacts patients to provide the username to access the iFightDepression website, and to explain in more detail how to go through the website. The aim is to ensure that the patient gets the greatest possible benefits from the clinical tool. In addition, a guide on how to use the tool is included within the cCBT tool itself.

Patients receive support from the MasterMind team for the entire duration of the pilot. The team is available via VC, email or phone to support patients, and is also in contact with patients' GPs, to solve possible problems related to the clinical use of the tool. For technical needs, our technical MasterMind partner (CSI Piemonte) is the first line of support. In addition, help lines and contact details of emergency services are provided to all patients; they are also included in the appropriate contact section of the cCBT tool.

Our cCBT programme is mainly delivered at patient's home. GPs, psychologists and psychiatrists are eligible to refer to the service. Health professionals are required to possess a PC, laptop or tablet to be able to use the tool and supervise patients' treatment. If professionals are willing to participate, but do not have an electronic device available, it was provided by our MasterMind team. A specific email account has been created through which health professionals can contact project staff, and through which information about the cCBT tool is sent.

3.2.3.4 METU (Turkey)

Metu has developed a new programme, Top Sende, based on two first wave CBT programmes, Alles under Controle and GetOn. This new programme contains six modules described in the table below.

Table 5: Top Sende modules

Module	Description	Exercise
1	Identification of important things and classification of problems	- List of important things. - List of problems and worries.
2	Behavioural activation	- List of enjoyable activities. - Planning of daily activities. - Diary.
3	Working on important and solvable problems	- Book keeping for an attempt to solve a single important problem.

Module	Description	Exercise
4	Working on unimportant worries	- Pursuing a suggested technique for getting rid of unimportant worries. - Pursuing a technique for summoning positive thoughts.
5	Working on important but unsolvable problems	- Emotional appraisal. - Sharing thoughts with others.
6	Getting ready for the future	- Updating the list of important things, problems and worries. - Noting new directions for life in the future. - Listing probable stressful events. - Listing personal signals for awareness.

This is an approach rooted in problem solving therapy, augmented with behavioural activation. The ICT backbone is the learning management system used in METU for online course management. It requires PC access and internet connection.

3.2.3.5 TUT (Estonia)

Estonia is also using iFightDepression programme, similarly to the Italian pilot sites. But in Estonia, additionally, a CBT Basic App has been created by clinical psychologist Mrs. Kärt Lust-Paal from Estonia, which is available as iOS version in the App Store, and as Android version in the Play Store. The modern design of this cCBT app makes the CBT process simpler, more patient-friendly, paperless and modern. The app consists of basic CBT elements such as basic cognitive model, jotting down automatic thoughts, planning behavioural experiments, compiling coping cards, and most importantly, it helps to easily construct your own tables for therapy or to make notes in cooperation with your CBT therapist. The various functions are:

- Cognitive model: at the beginning of the CBT process, the basic cognitive model is explained. According to this, thoughts, feelings and behaviour are all connected, and individuals can move towards, overcoming difficulties and meeting their goals by identifying and changing unhelpful or inaccurate thinking, problematic behaviour, and distressing emotional responses. The purpose of this function is to have the cognitive model as a reminder for the app users.
- Start your thought diary: this diary is a commonly used tool in CBT for monitoring thoughts, feelings and behaviours, as well as noticing problematic situations. The function has three levels: noticing the mentioned elements, answering or finding alternative ways of thinking, and re-evaluating thoughts, feelings and behaviours. The therapist chooses the required levels and the number of sessions that are necessary for the patient. The patient can choose individually whether to continue using the function after the task has been completed.
- Make your own table: as the app is not diagnosis specific, there are numerous tables / worksheets in CBT that can help the patient to notice and change dysfunctional thoughts and/or behaviours. The therapist decides what task to fill in, and the app creates the corresponding worksheet(s). This is one function that separates the app from any other existing cCBT solutions, as it flexibly gives the therapist an opportunity to choose the ways that patient jots down homework.
- My coping cards: during the therapy procedure, patients learn to change unhelpful thoughts for more balanced thinking; however, people still tend to forget the strong

and useful arguments and new core beliefs when they are in difficult situations. This is when they can use coping cards that are prepared in therapy or on their own.

- Behavioural experiment: this function in the CBT Basic app gives structure to behavioural experiments; these are planned activities, based on experimentation or observation, undertaken by clients in sessions or in between sessions. The premade form in the app helps to test existing beliefs and/or help to test more adaptive beliefs by jotting them down and making conclusions. The therapist guides the patient how, why and when to fill in the forms.

Section 5 of the Generic Protocol (D3.1) provides more information on the included cCBT intervention services.

3.2.4 Recruitment and reach of MasterMind services

Reach is defined as the absolute number, proportion, and representativeness of individuals who are willing to participate in a given intervention. In this document, reach is reported by:

a. Prevalence of depression in target region;
b. Potentially eligible patients to receive services;
c. Patients whom are targeted by recruitment strategy;
d. Patients to whom the services are offered;
e. Patients who are recruited;
f. Patients who completed treatment, and reach (% participating, e. divided by b.).

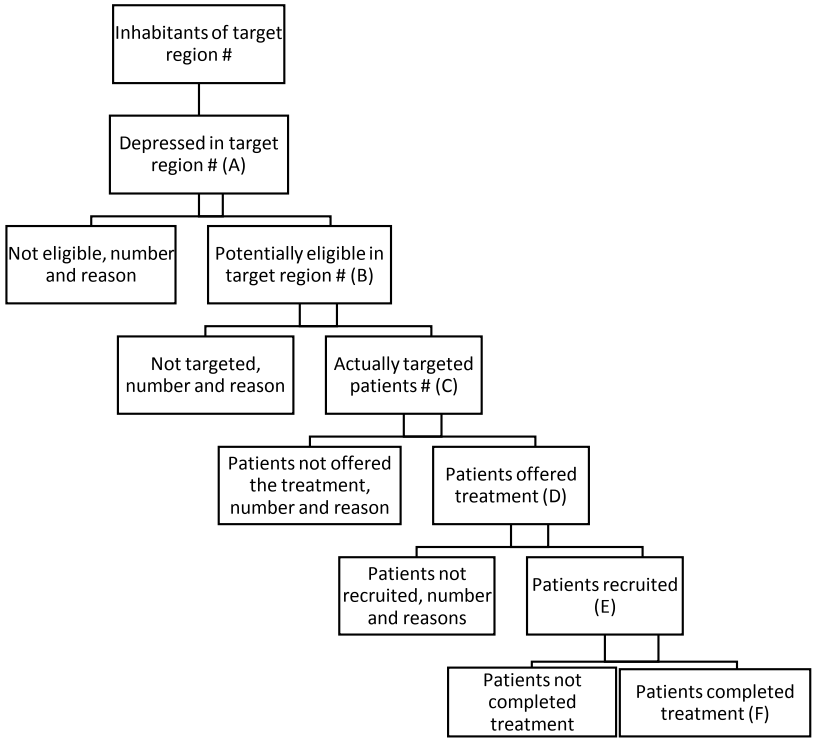


Table 6: Recruitment and reach of MasterMind services

	Region								
	PtHB-IRH (Wales)	**SALUD (Aragon)**	**Osakidetza (Basque Country)**	**BSA (Badalona)**	**SERGAS (Galicia)**	**ASLTO3 (Piemonte)**	**LHA N.9 (Treviso, Veneto)**	**METU (Turkey)**	**TUT (Estonia)**
Prevalence of depression in target region (A)	10614	4297	394036	25105	109293	60000	156000	8450	72800
Potentially eligible patients to receive services (B)	10614	4297	39404	25105	101424	21600	88000	8450	3500
Patients whom are targeted by recruitment strategy (C)	10614	3697	1107	8000	1334	1188	200	390	101
Patients to whom the services are offered (D)	355	135	234	1549	141	401	220	240	72
Patients who are recruited (E)	355	129	216	253	110	161	150	120	56
Patients who completed treatment (F)	31	35	66	54	14	72	29	19	15
Reach (E:B)	355/10614 = 0.03%	129/4297 = 0.03%	216/39404 = 0.005%	253/25105 = 0.01%	110/101424 = 0.001%	161/21600 = 0.007%	150/88000 = 0.0017%	120/8450 = 0.014%	56/3500 = 0.017%

Most patients, if not all, who suffer from depression are potentially eligible patients to receive cCBT in Wales, Aragón, Badalona, Galicia and Turkey; however, the number of patients who are eligible in Basque Country, both Italian regions and Estonia is significantly lower. Reasons can vary: not all types of depressions are included (severe symptoms are excluded), not the whole the geographical area participates in the project, or only a certain number of healthcare professionals are involved in the study. As expected, from the targeted patients a smaller percentage is approached and invited to participate in the study. In all sites, with the exception of Wales and Turkey, some patients declined to receive cCBT. It is remarkable that in Badalona only the 16% of the patients approached accepted.

3.3 Results

3.3.1 Demographic characteristics of patients

With respect to demographic characteristics, the number of patients who met the inclusion criteria was 1550, differently distributed across the nine cCBT trial sites. The sample size differs significantly from site to site, ranging from 56 (Estonia) to 355 (Wales). The average age of participants is around 45 in most sites, with the exception of Turkey, Estonia and Wales, where patients are considerably younger, 25, 33 and 38 respectively. The proportion of females is considerably higher in all sites, and the educational level is primarily university, except for Aragón and Badalona where there is a greater number of patients with secondary studies. Immigrants represent a very low percentage of the sample. Employees are more than 60% of the total. Most of the patients (53,7%) are referred to the cCBT service by GPs; however, other healthcare professionals are responsible of referrals in Wales, Aragón and Turkey (other mental health professionals, psychologists and self-referral, respectively). Anti-depressant medication use is highly variable, having a significant number of patients taking drugs for more than two months and others without medication.

See Table 7 for more details of patient demographics.

Table 7: The demographic characteristics of patients

	Region									
	Basque Country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Sample: *n*	216	355	129	253	110	161	150	120	56	1550
Age years: mean (SD)	44 (12)	38 (14)	46 (12)	47 (13)	44 (12)	47 (14)	44 (13)	25 (7)	33 (10)	42 (14)
Gender: *n* (%)										
Male	54 (25%)	122 (34,4%)	35 (27,1%)	83 (32,8%)	25 (22,7%)	57 (35,4%)	55 (36,7%)	40 (33,3%)	16 (28,6%)	487 (31,4%)
Female	162 (75%)	233 (65,6%)	94 (72,9%)	170 (67,2%)	85 (77,3%)	104 (64,6%)	95 (63,3%)	80 (66,7%)	40 (71,4%)	1063 (68,6%)
Education: *n* (%)										
Primary	36 (19,3%)	4 (1,2%)	45 (35,7%)	47 (18,7%)	14 (14,6%)	3 (1,9%)	5 (3,3%)	0 (0%)	4 (7,3%)	158 (10,7%)
Secondary	44 (23,5%)	146 (42,7%)	52 (41,3%)	112 (44,4%)	42 (43,8%)	48 (30%)	41 (27,3%)	0 (0%)	14 (25,5%)	499 (33,9%)
Higher / University	107 (57,2%)	192 (56,1%)	29 (23%)	81 (32,1%)	40 (41,7%)	109 (68,1%)	103 (68,7%)	104 (100%)	37 (67,3%)	802 (54,5%)
Other	0 (0%)	0 (0%)	0 (0%)	12 (4,8%)	0 (0%)	0 (0%)	1 (0,7%)	0 (0%)	0 (0%)	13 (0,9%)

	Region									
	Basque Country	Wales	Aragón	Badalona	Galicia	Piemonte	Treviso, Veneto	Turkey	Estonia	Total
Immigrated: *n* (%)	19 (8,8%)	0 (0%)	1 (0,8%)	4 (1,6%)	3 (2,7%)	27 (16,9%)	10 (17,5%)	8 (6,7%)	7 (12,5%)	79 (7,2%)
Employed: *n* (%)	156 (75%)	196 (55,5%)	66 (52,4%)	180 (71,4%)	76 (70,4%)	88 (54,7%)	97 (65,1%)	39 (40,2%)	33 (64,7%)	931 (61,9%)
Service referral: *n (%)*										
General practitioner	144 (66,7%)	91 (25,7%)	27 (20,9%)	231 (91,3%)	109 (99,1%)	110 (68,3%)	0 (0%)	0 (0%)	38 (70,4%)	750 (53,7%)
Psychiatrist	48 (22,2%)	4 (1,1%)	14 (10,9%)	15 (5,9%)	1 (0,9%)	24 (14,9%)	0 (0%)	0 (0%)	2 (3,7%)	108 (7,7%)
Psychologist	24 (11,1%)	12 (3,4%)	87 (67,4%)	7 (2,8%)	0 (0%)	1 (0,6%)	0 (0%)	1 (0,8%)	8 (14,8%)	140 (10%)
Other mental health professional	0 (0%)	209 (59%)	0 (0%)	0 (0%)	0 (0%)	1 (0,6%)	0 (0%)	1 (0,8%)	0 (0%)	211 (15,1%)
Self-referral	0 (0%)	0 (0%)	1 (0,8%)	0 (0%)	0 (0%)	24 (14,9%)	0 (0%)	40 (33,3%)	2 (3,7%)	67 (4,8%)
Anti-depressant medication use: *n (%)*										
Yes, for less than one month	37 (17,1%)	14 (4%)	3 (2,4%)	7 (2,8%)	19 (17,3%)	12 (7,5%)	21 (14,1%)	2 (2%)	17 (32,1%)	132 (8,7%)
Yes, for less than 2 months	23 (10,6%)	18 (5,1%)	5 (4%)	49 (19,4%)	5 (4,5%)	7 (4,3%)	11 (7,4%)	3 (3,1%)	9 (17%)	130 (8,6%)
Yes, for more than 2 months	66 (30,6%)	173 (48,9%)	92 (73%)	91 (36%)	63 (57,3%)	64 (39,8%)	59 (39,6%)	13 (13,3%)	7 (13,2%)	628 (41,3%)
No	90 (41,7%)	149 (42,1%)	26 (20,6%)	106 (41,9%)	23 (20,9%)	78 (48,4%)	58 (38,9%)	80 (81,6%)	20 (37,7%)	630 (41,4%)

3.3.2 Demographic characteristics of healthcare professionals

Information on 281 healthcare professionals has been gathered in the 2nd wave sites. The demographic characteristics of healthcare professionals show that most are women (71,5%) and GPs (54,5%). A high percentage of the professionals are experienced in mental health field, most of them with more than 10 years (47,3%) or less than 3 years (23,4%). Additionally, the experience in providing cCBT service is less than five times (53,9%). This makes sense, because the second wavers were regions with no previous experience in the provision of cCBT services.

Table 8: Demographic characteristics of healthcare professionals

	Region									
	Basque Country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Sample: *n*	53	27	12	114	11	21	22	3	18	281
Gender: *n* (%)										
Male	16 (30,2%)	6 (22,2%)	3 (25%)	27 (23,7%)	4 (36,4%)	13 (61,9%)	11 (50%)	0 (0%)	0 (0%)	80 (28,5%)
Female	37 (69,8%)	21 (77,8%)	9 (75%)	87 (76,3%)	7 (63,6%)	8 (38,1%)	11 (50%)	3 (100%)	18 (100%)	201 (71,5%)
Profession: *n (%)*										
General practitioner	41 (77,4%)	5 (18,5%)	4 (33,3%)	59 (51,8%)	11 (100%)	17 (81%)	4 (19%)	0 (0%)	11 (64,7%)	152 (54,5%)
Licensed psychologist	2 (3,8%)	0 (0%)	2 (16,7%)	3 (2,6%)	0	1 (4,8%)	5 (23,8%)	3 (100%)	3 (17,6%)	19 (6,8%)
Psychologist (in training)	0	0	0	0	0	0	0	0	0	0
Psychologist (basic training)	1 (1,9%)	0	0	0	0	0	1 (4,8%)	0	0	2 (0,7%)
Licensed psychiatrist	0	1 (3,7%)	2 (16,7%)	2 (1,8%)	0	3 (14,3%)	2 (9,5%)	0	0	10 (3,6%)
Psychiatrist (in CBT training)	1 (1,9%)	0	0	0	0	0	6 (28,6%)	0	0	7 (2,5%)
Psychiatrist (diploma in CBT)	0	1 (3,7%)	0	0	0	0	1 (4,8%)	0	0	2 (0,7%)
Psychiatrist (master)	0	0	1 (8,3%)	1 (0,9%)	0	0	2 (9,5%)	0	0	4 (1,4%)
Psychiatrist (doctorate)	3 (5,7%)	0	0	0	0	0	0	0	1 (5,9%)	4 (1,4%)
MH / community worker	0	14 (51,9%)	0	0	0	0	0	0	1 (5,9%)	15 (5,4%)
Central administrator	0	0	0	2 (1,8%)	0	0	0	0	0	2 (0,7%)
Other	5 (9,4%)	6 (22,2%)	3 (25%)	47 (41,2%)	0	0	0	0	1 (5,9%)	62 (22,2%)
Training in cCBT: *n (%)*	44 (83%)	13 (50%)	12 (100%)	109 (96,5%)	0	18 (85,7%)	14 (82,4%)	2 (66,7%)	2 (11,1%)	214 (78,1%)

	Region									
	Basque Country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Field experience: *n (%)*										
Less than 3 years	6 (11,3%)	0	4 (36,4%)	46 (40,4%)	2 (18,2%)	2 (10%)	0	2 (66,7%)	2 (11,8%)	64 (23,4%)
Between 3 and 5 years	2 (3,8%)	0	0	16 (14%)	2 (18,2%)	1 (5%)	0	1 (33,3%)	3 (17,6%)	25 (9,2%)
Between 5 and 10 years	6 (11,3%)	4 (14,8%)	2 (18,2%)	11 (9,6%)	0	4 (20%)	0	0	5 (29,4%)	32 (11,7%)
10 years or more	39 (73,6%)	0	5 (45,5%)	41 (36%)	7 (63,6%)	13 (65%)	17 (100%)	0	7 (41,2%)	129 (47,3%)
Experience with providing cCBT: *n (%)*										
Less than 5 times	43 (89,6%)	14 (53,8%)	12 (100%)	22 (19,5%)	8 (72,7%)	19 (90,5%)	17 (100%)	3 (100%)	6 (37,5%)	144 (53,9%)
Between 5 and 10 times	1 (2,1%)	5 (19,2%)	0	31 (27,4%)	2 (18,2%)	1 (4,8%)	0	0	0	40 (15%)
Between 10 and 15 times	0	3 (11,5%)	0	12 (10,6%)	1 (9,1%)	0	0	0	2 (12,5%)	18 (6,7%)
Between 15 and 19 times	1 (2,1%)	2 (7,7%)	0	22 (19,5%)	0	0	0	0	1 (6,3%)	26 (9,7%)
More than 20 times	3 (6,3%)	2 (7,7%)	0	26 (23%)	0	1 (4,8%)	0	0	7 (43,8%)	39 (14,6%)

3.3.3 Characteristics of mental healthcare organisations

14 organisations belonging to the cCBT trial sites provided information on their characteristics. The age, size and composition of the healthcare organisations involved are considerably different, and consist of a varying number of units, between one to 1.250 units. The staff full-time equivalents are 3.976 on average, and turnover varies significantly between less than 2 million euro (28,57%) and over 50 million euro (57,14%).

Table 9: Characteristics of mental healthcare organisations

	Region									
	Basque Country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Sample: *n*	2	2	1	2	1	1	1	1	3	14
Age (year of establishment)	1983	1948	1989	1932	1990	2008	2000	1956	2000	1976
Number of units / departments: *mean (range)*	49 (2)	6 (6)	17 (.)	30 (0)	1250 (.)	14 (.)	2 (.)	36 (.)	1 (0)	106 (330)
Number of FTE employed: *mean (range)*	3.679 (1.869)	742 (915)	900 (.)	1.000 (0)	36.000 (.)	3922 (.)	200 (.)	3800 (.)	2 (1)	3.976 (9.364)
Turnover: *categorical*										
equal or less than 2 million Euro	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)	3 (100%)	4 (28,57%)
between 2 and 10 million Euro	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
between 10 and 50 million euro	0 (0%)	1 (50%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	0 (0%)	2 (14,28%)
over 50 million	2 (100%)	1 (50%)	1 (100%)	2 (100%)	1 (100%)	1 (100%)	0 (0%)	0 (0%)	0 (0%)	8 (57,14%)
Waiting list: categorical										
less than a week	2 (100%)	0 (0%)	0 (0%)	2 (100%)	1 (100%)	0 (0%)	0 (0%)	0 (0%)	3 (100%)	8 (57,1%)
between 1 and 4 weeks	0 (0%)	1 (50%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)	1 (100%)	0 (0%)	0 (0%)	3 (21,4%)
1 and 2 months	0 (0%)	0 (0%)	1 (100%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (7,1%)
between 2 and 6 months	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)	0 (0%)	1 (7,1%)
more than 6 months	0 (0%)	1 (50%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (7,1%)

3.4 Summary

Patients

Data from 1. patients has been considered from the pilots of the 2nd wave. 68,6% are female and the mean age of participating patients is 42 years (SD=14). 54,5% of patients received high education, and the 61,9% of them are employed, which indicates a highly educated data set in comparison to the general population. 41,3% of them have been using anti-depressant for more than two months, while 41,4% do not use them at all.

Overall, the profile of the depressive patients (including age and gender distribution) is considerably similar in all sites, with no unexpected characteristics. There is one exception, Turkey, that presents patients much younger, all of them with university degree, with a decreased use of medication and mainly provided with cCBT by self-referral; this is because the service is only offered to university students.

With regard to the cCBT service referral, although the 53,7% of patients have been referred to the cCBT service by GPs, three differentiated groups can be seen. GPs are the main referrers in Basque Country, Badalona, Galicia, Piemonte and Estonia, whereas mental health professionals provide cCBT in Wales and Aragón; as previously mentioned, patients in Turkey are self-referred to the service. These differences can influence the results, as one can expect that a mental healthcare professional might provide a better support to patients in the use of the cCBT tool.

Biases in the selection of patients might have happened at distinct points, and have to be considered:

a) Inclusion criteria in the project scientific protocol are wide: patients suffering from depression are eligible. In addition, each pilot site might have tailored not only the inclusion criteria, but also the exclusion criteria, to local needs and context. For example, patients included in each site might differ in the severity of their depression, which might affect the clinical results.
b) Professionals might have invited patients who are more likely to fill out questionnaires and exercises. Therefore, data collection might come from those patients whose cCBT programme worked better.
c) Professionals tend to select and recruit patients who already have a certain belief or trust in eHealth approaches.

Healthcare professionals

In total, information on 281 healthcare professionals has been gathered within the cCBT 2nd wave sites. Within the reported sample, 71,5% are women, and 54,5% are GPs. It is observable that most healthcare professionals show remarkable clinical experience (more than 60% with more than five years of experience) and have received specific training in cCBT. This is completely aligned with 2nd wavers' reality since they do not have experience in providing cCBT service in contrast to 1st wavers. As an exception, psychologists in Turkey have less clinical experience.

The engagement of the healthcare professionals has been difficult. A lack of motivation among the healthcare professionals has been experienced, due to different reasons; daily

work routines, lack of time for face-to-face consultations, the lack of ICT skills, and technical problems with the cCBT, have been a great challenge. The poor engagement of healthcare professionals at some point has affected the recruitment rate of patients. However, several corrective actions were developed and implemented during the pilots to improve professionals' motivation and, as a consequence, to increase the inclusion numbers of patients.

Organisations

14 organisations provided information on their characteristics within the cCBT trial sites. The organisations differ significantly in the age and the number of units. Most trial sites combined information on multiple clinics working under one head organisation, with the exception of Estonia who provided implementation site specific information.

4. Domain 2 and 3: Safety and clinical effectiveness

4.1 Introduction

The analysis within the context of domains 2 and 3 establish the clinical effectiveness of the services in real world settings. The analysis for safety focused on suicidality, drop-outs, and treatment attrition, together with safety issues as perceived by the healthcare professionals. In terms of clinical effectiveness, the variables included address the symptoms and methods for establishing symptoms, referral modalities, quality of life, access to the systems, and reasons for drop-outs and attrition rates.

Data for these domains are quantitative, and are used to answer these project objectives:

- objective #1: to identify barriers and facilitators that influences the implementation of cCBT for treating depression in routine practice;
- objective #2: to assess clinical change of patients' depressive symptoms when treated with cCBT in routine practice;
- objective #4: to assess patients' safety in terms of their health when provided with cCBT in routine practice; and
- objective #7: to assess the transferability of implementation and up-scaling of cCBT in routine practice in different care contexts.

The instruments used to collect the data include Routine Outcome Measurements (ROM), the treatment platforms, and online questionnaires.

These results enable drawing conclusions in terms of the acceptability and appropriateness of the services in alleviating depressive symptoms. Acceptability is the perception among patients that the received treatment is agreeable, palatable, or satisfactory[18]. Appropriateness is the perceived fit, relevance, or compatibility of the treatment for the patient in addressing his/her mental disorder[19]. Acceptability and appropriateness are measured through:

a) establishing changes in depressive symptoms and quality of life (domain 3);
b) establishing perceived satisfaction with the treatment (domain 4);
c) establishing the perceived usability of the treatment (domain 4); and
d) treatment attrition (domain 2 and 3).

The methods for measuring the symptoms of depression adhere to routine practice, and are registered in terms of: clinical interview; professional clinical judgement; or a symptom questionnaire. Symptoms are recorded in terms of no, mild, moderate or severe symptoms according to routine practice diagnostic procedures (e.g. PHQ-9, BDI, etc.) using appropriate transformation scales if needed.

[18] Proctor E. et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Springer US, 2011

[19] Proctor E. et al. Administration and policy in mental health. Springer US, 2011

4.2 Results

4.2.1 Clinical safety

This topic relates to concerns about to the clinical safety of the patient and the confidentiality of their data. Qualitative and quantitative data has been assessed to answer the questions on patient's safety in a whole and will be discussed jointly in the discussion of this chapter. Quantitative data on clinical safety and suicidal ideation has been provided by eight of the nine WP6 partners.

The number of patients who have been included in the analysis of safety and clinical effectiveness domains is 1.162, differently distributed across the nine sites.

The idea of suicide is very infrequent among patients: the Basque Country is the site with the highest percentage (10,7%). The number of patients who attempted to commit suicide is very low (Badalona 4%; Basque Country 0,5% and Treviso 1%). Although the number of ideations is clearly higher in the Basque Country, the attempts are less.

Table 10: Clinical safety: suicidal ideation

	Region									
	Basque Country	Wales	Aragón	Badalona	Galicia	Piemonte	Treviso, Veneto	Turkey	Estonia	Total
Sample: n	215	208	103	253	46	125	100	112		1162
Has the patient being thinking lately to end his/her life?										
Yes: n (%)	23 (10,7%)	8 (3,8%)	1 (1%)	25 (9,9%)	2 (4,3%)	0 (0%)	6 (6%)	1 (0,9%)		66 (5,7%)
No: n (%)	192 (89,3%)	200 (96,2%)	101 (99%)	228 (90,1%)	44 (95,7%)	125 (100%)	94 (94%)	111 (99,1%)		1095 (94,3%)
During the treatment, has the patient attempted to commit suicide?										
Yes: n (%)	1 (0,5%)	0 (0%)	0 (0%)	10 (4%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)		12 (1%)
No: n (%)	214 (99,5%)	208 (100%)	103 (100%)	243 (96%)	46 (100%)	125 (100%)	99 (99%)	112 (100%)		1150 (99%)

Qualitative data

The main findings coming from the qualitative analysis are:

- Clinical risks were reported mainly regarding seriously ill patients and patients with a history of suicidal ideation and self-harm.
- Monitoring was stated to protect against dropout, to ensure the efficacy, and safety of the intervention. Finally, it was underlined to be an important factor for the relational aspect of treatment.
- Technical and confidential security related to the transmission of privacy sensitive information. The majority of patients seemed to not worry about privacy issues. The others were relatively easily assured after a discussion by their doctor.

Appendix A.1 contains more details on the findings from the focus group interviews, which substantiate the factors that relate to concerns about to the clinical safety of the patient and the confidentiality their data.

4.2.2 Clinical effectiveness in symptom reduction

The subset of patients analysed is 679. Data from patients with pre and post questionaires has been analysed.Most of the patients suffer from mild, moderate or severe symptoms; no symptoms or very severe symptoms are practically not present. The results show that symptoms are improved after treatment, with an increase in the percentage of patients with better symptomatology. Before treatment, the percentage of patients with no symptoms is near zero; however this proportion is increased in all sites (by 5,3% up to 71,8%, Turkey and Aragón respectively). How this percentage fluctuates in each site, depending very much on the starting symptomatology of patients. The duration of depressive episodes has been decreased by a significant proportion, 3-6 months and 1-3 years are more represented. Concerning the change in depressive symptom severity, most cases show a reduction of one category or no change at all. However, Aragón, Galicia and Treviso present a reduction of significance in two or more categories.

Table 11: Clinical effectiveness in symptom reduction

	Region																			
	Basque Country		**Wales**		**Aragón**		**Badalona**		**Galicia**		**Piemonte**		**Treviso, Veneto**		**Turkey**		**Estonia**		**Total**	
	B/line	**End**	**B/line**	**End**	**B/line**	**End**	**B/line**	**End**	**B/line**	**End**	**B/line**	**End**	**B/line**	**End**	**B/line**	**End**	**B/line**	**End**	**B/line**	**End**
Sample: *n*	161		64		39		84		41		121		112		19		38		679	
Symptoms of depressive disorder: *n (%)*																				
No symptoms are experienced	0 (0%)	35 (21,7%)	1 (1,6%)	6 (9,4%)	1 (2,6%)	28 (71,8%)	0 (0%)	37 (44%)	0 (0%)	17 (41,5%)	0 (0%)	33 (27,3%)	0 (0%)	49 (43,8%)	0 (0%)	1 (5,3%)	1 (2,6%)	12 (31,6%)	3 (0,4%)	218 (32,1%)
Symptoms are mild	42 (26,1%)	52 (32,3%)	12 (18,8%)	26 (40,6%)	20 (51,3%)	8 (20,5%)	58 (69%)	38 (45,2%)	11 (26,8%)	12 (29,3%)	47 (38,8%)	47 (38,8%)	32 (28,6%)	39 (34,8%)	12 (63,2%)	14 (73,7%)	15 (39,5%)	15 (39,5%)	249 (36,7%)	251 (37%)
Symptoms are moderate	103 (64%)	64 (39,8%)	51 (79,7%)	32 (50%)	13 (33,3%)	1 (2,6%)	18 (21,4%)	5 (6%)	6 (14,6%)	10 (24,4%)	33 (27,3%)	27 (22,3%)	54 (48,2%)	13 (11,6%)	7 (36,8%)	4 (21,1%)	21 (55,3%)	9 (23,7%)	306 (45,1%)	165 (24,3%)
Symptoms are severe	14 (8,7%)	8 (5%)	0 (0%)	0 (0%)	5 (12,8%)	2 (5,1%)	8 (9,5%)	3 (3,6%)	24 (58,5%)	2 (4,9%)	31 (25,6%)	12 (9,9%)	19 (17%)	9 (8%)	0 (0%)	0 (0%)	1 (2,6%)	2 (5,3%)	102 (15%)	38 (5,6%)

	Region																			
	Basque Country		Wales		Aragón		Badalona		Galicia		Piemonte		Treviso, Veneto		Turkey		Estonia		Total	
	B/line	End	B/line	End	B/line	End	B/line	End	B/line	End	B/line	End	B/line	End	B/line	End	B/line	End	B/line	End
Symptoms are very severe	2 (1,2%)	2 (1,2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (1,2%)	0 (0%)	0 (0%)	10 (8,3%)	2 (1,7%)	7 (6,3%)	2 (1,8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	19 (2,8%)	7 (1%)
Current depressive episodes: *n (%)*																				
Less than 4 weeks	7 (4,6%)		0 (0%)		0 (0%)		2 (2,4%)		0 (0%)		9 (7,6%)		2 (1,8%)		4 (21,1%)		10 (27%)		34 (5,2%)	
Between 4 and 8 weeks	19 (12,6%)		1 (1,6%)		1 (2,6%)		11 (13,1%)		6 (17,6%)		14 (11,8%)		3 (2,7%)		4 (21,1%)		9 (24,3%)		68 (10,3%)	
Between 8 and 12 weeks	17 (11,3%)		2 (3,1%)		2 (5,1%)		17 (20,2%)		4 (11,8%)		21 (17,6%)		6 (5,4%)		1 (5,3%)		1 (2,7%)		71 (10,8%)	
Between 3 and 6 months	39 (25,8%)		3 (4,7%)		7 (17,9%)		22 (26,2%)		8 (23,5%)		28 (23,5%)		12 (10,8%)		3 (15,8%)		6 (16,2%)		128 (19,5%)	
Between 6 month to a year	25 (16,6%)		10 (15,6%)		7 (17,9%)		14 (16,7%)		7 (20,6%)		20 (16,8%)		11 (9,9%)		1 (5,3%)		9 (24,3%)		104 (15,8%)	
Between 1 year and 3 years	26 (17,2%)		11 (17,2%)		9 (23,1%)		12 (14,3%)		8 (23,5%)		15 (12,6%)		24 (21,6%)		5 (26,3%)		2 (5,4%)		112 (17%)	
3 to 5 years	8 (5,3%)		8 (12,5%)		12 (30,8%)		0 (0%)		0 (0%)		4 (3,4%)		12 (10,8%)		1 (5,3%)		0 (0%)		45 (6,8%)	
5 to 10 years	7 (4,6%)		10 (15,6%)		1 (2,6%)		2 (2,4%)		0 (0%)		5 (4,2%)		21 (18,9%)		0 (0%)		0 (0%)		46 (7%)	
More than 10 years	3 (2%)		19 (29,7%)		0 (0%)		4 (4,8%)		1 (2,9%)		3 (2,5%)		20 (18%)		0 (0%)		0 (0%)		50 (7,6%)	

4.2.3 Clinical change

In order to depict the change in symptom severity further, difference scores have been calculated between the symptom severity before and after treatment. “Reduction in one category” means that the patient symptoms were reduced by one severity category, i.e. from very severe to severe depressive symptoms, severe to moderate, moderate to mild or mild to no symptoms. Similarly, “reduction in two categories” means that the patient depressive symptoms were reduced either from very severe to moderate, severe to mild or moderate to no symptoms. Under “deterioration” the number of patients are shown who experienced a higher level of depressive symptom severity after treatment than before.

Within the reported sub data set, in total 58% of patients were reported to experience a reduction in depressive symptoms, 38,7% by one and 19,3% by two categories. 4,6% deteriorated and 37,4% showed no change between the start and the end of cCBT treatment. Huge differences can be seen between the trial sites. Aragón report 82,1% of patients improving between the beginning and end of cCBT treatment, 78,5% for Treviso, and 59,5% for Badalona’s patients, whereas only 31,6% of Turkish patients reported a reduction in depressive symptom severity. 57,9% of the Turkish patients deteriorated between the start and the end of cCBT treatment. 64,6% of Basque patients, 54,7% of Wales patients and 10,5% of Turkish patients experienced no change in symptoms between the beginning and end of the cCBT treatment.

It has to be noted that clinical effectiveness is biased since patients who never initiated the cCBT or did not complete any session were included in the analysis (80 in the Basque Country, 2 in Aragón, 22 in Galicia, 2 in Piemonte, 40 in Treviso, and 1 in Estonia). This number is the 57.4% of all drop outs (146 from 254) . These patients abandoned the treatment and the study due to diverse reasons. Therefore, the real clinical effectiveness of the therapy is underestimated.

Table 12: Clinical change

	Region									
	Basque Country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Change in depressive symptom severity: *n (%)*										
Reduction in one category	28 (17,4%)	25 (39,1%)	20 (51,3%)	37 (44%)	18 (43,9%)	57 (47,1%)	50 (44,6%)	6 (31,6%)	22 (57,9%)	263 (38,7%)
Reduction in two or more categories	28 (17,4%)	1 (1,6%)	12 (30,8%)	13 (15,5%)	16 (39%)	22 (18,2%)	38 (33,9%)	0 (0%)	1 (2,6%)	131 (19,3%)
Deterioration:	1 (0,6%)	3 (4,7%)	1 (2,6%)	6 (7,1%)	1 (2,4%)	7 (5,8%)	7 (6,3%)	2 (10,5%)	3 (7,9%)	31 (4,6%)
No change:	104 (64,6%)	35 (54,7%)	6 (15,4%)	28 (33,3%)	6 (14,6%)	35 (28,9%)	17 (15,2%)	11 (57,9%)	12 (31,6%)	254 (37,4%)

4.2.4 Quality of life

The table below shows the results obtained with the MANSA questionnaire to assess the patient´s perception regarding their quality of life. Overall, the satisfaction with life is poor; those categories reflecting dissatisfaction present the highest percentages. However, this unhappiness is slightly decreased after treatment, having a great number of patients mostly satisfied. On average, an improvement in the results of all categories between pre- and post-treatment is observed.

Concerning the satisfaction with their mental health, there is a generalised improvement which is observed with a clear increase in the "mostly satisfied" category (31.2%). In both satisfaction measures, the most negative categories present a more dramatic decrease after treatment.

Table 13: Quality of life

			Region																	
	Basque Country		Wales		Aragón		Badalona		Galicia		Piemonte		Treviso, Veneto		Turkey		Estonia		Total	
	B/line	End	B/line	End	B/line	End	B/line	End	B/line	End	B/line	End	B/line	End	B/line	End	B/line	End	B/line	End
Satisfaction with life: *n (%)*																				
Couldn´t be worse	3 (3,4%)	3 (3,3%)	3 (4,8%)	3 (4,7%)	2 (5,1%)	0 (0%)	4 (4,8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (1,8%)	2 (1,8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	14 (2,3%)	8 (1,4%)
Displeased	12 (13,6%)	5 (5,4%)	8 (12,7%)	9 (14,1%)	7 (17,9%)	3 (7,9%)	15 (17,9%)	1 (1,6%)	6 (15%)	1 (2,7%)	25 (20,7%)	10 (8,3%)	15 (13,4%)	10 (8,9%)	0 (0%)	0 (0%)	5 (13,2%)	3 (7,9%)	93 (15,4%)	42 (7,2%)
Mostly dissatisfied	32 (36,4%)	20 (21,7%)	12 (19%)	4 (6,3%)	12 (30,8%)	13 (34,2%)	25 (29,8%)	3 (4,8%)	18 (45%)	5 (13,5%)	21 (17,4%)	7 (5,8%)	42 (37,5%)	12 (10,7%)	6 (31,6%)	3 (15,8%)	15 (39,5%)	5 (13,2%)	183 (30,3%)	72 (12,3%)
Mixed	16 (18,2%)	10 (10,9%)	26 (41,3%)	22 (34,4%)	11 (28,2%)	7 (18,4%)	33 (39,3%)	19 (30,2%)	6 (15%)	8 (21,6%)	39 (32,2%)	35 (28,9%)	25 (22,3%)	32 (28,6%)	6 (31,6%)	4 (21,1%)	12 (31,6%)	5 (13,2%)	174 (28,8%)	142 (24,3%)
Mostly satisfied	17 (19,3%)	15 (16,3%)	14 (22,2%)	22 (34,4%)	7 (17,9%)	9 (23,7%)	4 (4,8%)	22 (34,9%)	6 (15%)	17 (45,9%)	24 (19,8%)	35 (28,9%)	25 (22,3%)	46 (41,1%)	6 (31,6%)	7 (36,8%)	3 (7,9%)	9 (23,7%)	106 (17,5%)	182 (31,2%)
Pleased	7 (8%)	24 (26,1%)	0 (0%)	3 (4,7%)	0 (0%)	6 (15,8%)	3 (3,6%)	13 (20,6%)	4 (10%)	6 (16,2%)	12 (9,9%)	31 (25,6%)	2 (1,8%)	8 (7,1%)	1 (5,3%)	5 (26,3%)	1 (2,6%)	12 (31,6%)	30 (5%)	108 (18,5%)

Couldn´t be better	1 (1,1%)	15 (16,3%)	0 (0%)	1 (1,6%)	0 (0%)	0 (0%)	0 (0%)	5 (7,9%)	0 (0%)	0 (0%)	0 (0%)	3 (2,5%)	1 (0,9%)	2 (1,8%)	0 (0%)	0 (0%)	2 (5,3%)	4 (10,5%)	4 (0,7%)	30 (5,1%)
Satisfaction with mental health: n (%)																				
Couldn´t be worse	4 (4,5%)	5 (5,4%)	2 (3,2%)	5 (7,8%)	4 (10,3%)	1 (2,6%)	2 (2,4%)	0 (0%)	1 (2,5%)	0 (0%)	0 (0%)	1 (0,8%)	2 (1,8%)	3 (2,7%)	0 (0%)	0 (0%)	1 (2,6%)	0 (0%)	16 (2,6%)	15 (2,6%)
Displeased	24 (27,3%)	9 (9,8%)	20 (31,7%)	11 (17,2%)	10 (25,6%)	5 (13,2%)	17 (20,2%)	2 (3,2%)	12 (30%)	1 (2,7%)	41 (33,9%)	12 (9,9%)	18 (16,1%)	5 (4,5%)	7 (36,8%)	2 (10,5%)	6 (15,8%)	3 (7,9%)	155 (25,7%)	50 (8,6%)
Mostly dissatisfied	34 (38,6%)	28 (30,4%)	11 (17,5%)	6 (9,4%)	15 (38,5%)	7 (18,4%)	29 (34,5%)	6 (9,5%)	18 (45%)	9 (24,3%)	28 (23,1%)	15 (12,4%)	44 (39,3%)	15 (13,5%)	4 (21,1%)	0 (0%)	17 (44,7%)	7 (18,4%)	200 (33,1%)	93 (16%)
Mixed	12 (13,6%)	2 (2,2%)	21 (33,3%)	23 (35,9%)	7 (17,9%)	7 (18,4%)	30 (35,7%)	13 (20,6%)	3 (7,5%)	11 (29,7%)	27 (22,3%)	32 (26,4%)	23 (20,5%)	27 (24,3%)	6 (31,6%)	5 (26,3%)	9 (23,7%)	4 (10,5%)	138 (22,8%)	124 (21,3%)
Mostly satisfied	6 (6,8%)	11 (12%)	6 (9,5%)	15 (23,4%)	3 (7,7%)	12 (31,6%)	6 (7,1%)	27 (42,9%)	5 (12,5%)	10 (27%)	21 (17,4%)	34 (28,1%)	24 (21,4%)	49 (44,1%)	2 (10,5%)	8 (42,1%)	2 (5,3%)	8 (21,1%)	75 (12,4%)	174 (29,8%)
Pleased	7 (8,0%)	25 (27,2%)	2 (3,2%)	2 (3,1%)	0 (0%)	6 (15,8%)	0 (0%)	6 (9,5%)	1 (2,5%)	6 (16,2%)	4 (3,3%)	26 (21,5%)	1 (0,9%)	12 (10,8%)	0 (0%)	3 (15,8%)	1 (2,6%)	10 (26,3%)	16 (2,6%)	96 (16,5%)
Couldn´t be better	1 (1,1%)	12 (13%)	1 (1,6%)	2 (3,1%)	0 (0%)	0 (0%)	0 (0%)	9 (14,3%)	0 (0%)	0 (0%)	0 (0%)	1 (0,8%)	0 (0%)	0 (0%)	0 (0%)	1 (5,3%)	2 (5,3%)	6 (15,8%)	4 (0,7%)	31 (5,3%)

4.2.5 Appropriateness of MasterMind services in alleviating depressive disorder in routine practice

With respect to the appropriateness of the treatment that patients received, information on 786 patients has been reported. The differences in term of contribution between the trial sites are large: Basque Country reported 74,8% of participants of its whole sample size at the post assessment, Wales 18,3%, Aragón 51,16%, Badalona 33,2%, Galicia 61,8%, Piemonte 75,1%, Treviso 100%, Turkey 15,8%, and Estonia 69,6%. The differences in reported post-treatment data derive mainly from patients that are still under treatment (on-going), and difficulties in the data collection process under routine care conditions, and should be considered a limitation factor in the interpretation of the post-treatment data.

The average age is around 44. The other parameters remain similar to the demographic characteristics reported above: a high representation of women; most patients with university degrees; immigrants are poorly represented; most patients are referred by GPs; and most patients either do not take drugs or take anti-depressants for more than two months.

Table 14: Appropriateness of treatment

		Region								
	Basque Country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Access to service: *n (%)*										
Individual, personal location (e.g. at home)	161 (100%)	64 (98,5%)	66 (100%)	84 (100%)	55 (67,9%)	120 (99,2%)	99 (66%)	18 (94,7%)	36 (92,3%)	703 (89,4%)
Community location	0 (0%)	1 (1,5%)	0 (0%)	0 (0%)	1 (1,2%)	0 (0%)	1 (0,7%)	1 (5,3%)	0 (0%)	4 (0,5%)
At care institution	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0,8%)	11 (7,3%)	0 (0%)	1 (2,6%)	13 (1,7%)
Number of sessions completed in total: *mean (sd)*	3,61 (3,84)	5,25 (2,91)	5,91 (3,58)	5,24 (1,26)	3,23 (3,7)	5,5 (2,15)	5,14 (3,99)	6,16 (0,69)	13,9 (24,99)	5,23 (6,71)
Number of sessions completed online: *mean (sd)*	3,61 (3,84)	5,25 (2,91)	4,95 (3,51)	4,24 (1,26)	2,64 (2,76)	5,4 (2,16)	3,29 (3,15)	6 (0)	13,62 (29,28)	4,6 (7,41)
Reasons for ending the treatment: *n (%)*										
I completed all sessions that were planned	66 (41%)	31 (47,7%)	35 (53%)	54 (64,3%)	14 (17,3%)	72 (59,5%)	29 (19,3%)	19 (100%)	15 (38,5%)	335 (42,6%)
I had problems with my internet connection and/or my computer was not functioning..	7 (4,3%)	5 (7,7%)	1 (1,5%)	4 (4,8%)	7 (8,6%)	3 (2,5%)	10 (6,7%)	0 (0%)	0 (0%)	37 (4,7%)
I don´t have a computer	0 (0%)	2 (3,1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0,7%)	0 (0%)	0 (0%)	3 (0,4%)

I don´t trust the online sessions are secure	1 (0,6%)	1 (1,5%)	1 (1,5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (0,4%)
I don´t have enough skills to follow the online sessions	1 (0,6%)	1 (1,5%)	1 (1,5%)	2 (2,4%)	0 (0%)	9 (7,4%)	4 (2,7%)	0 (0%)	0 (0%)	18 (2,3%)
I forgot to attend the online sessions	3 (1,9%)	0 (0%)	3 (4,5%)	3 (3,6%)	0 (0%)	2 (1,7%)	4 (2,7%)	0 (0%)	2 (5,1%)	17 (2,2%)
I ran out of time	0 (0%)	0 (0%)	1 (1,5%)	0 (0%)	19 (23,5%)	2 (1,7%)	19 (12,7%)	0 (0%)	1 (2,6%)	42 (5,3%)
I was ill	0 (0%)	0 (0%)	1 (1,5%)	3 (3,6%)	4 (4,9%)	2 (1,7%)	1 (0,7%)	0 (0%)	0 (0%)	11 (1,4%)
I had to work	0 (0%)	0 (0%)	0 (0%)	1 (1,2%)	3 (3,7%)	6 (5%)	0 (0%)	0 (0%)	1 (2,6%)	11 (1,4%)
My family did not support me	1 (0,6%)	0 (0%)	0 (0%)	1 (1,2%)	2 (2,5%)	0 (0%)	1 (0,7%)	0 (0%)	1 (2,6%)	6 (0,8%)
I did not want to share my personal information through internet	0 (0%)	0 (0%)	1 (1,5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (0,1%)
For other therapeutic reasons	12 (7,5%)	0 (0%)	2 (3%)	1 (1,2%)	1 (1,2%)	0 (0%)	0 (0%)	0 (0%)	2 (5,1%)	18 (2,3%)
I am not convinced that the therapy solves my problems	1 (0,6%)	0 (0%)	1 (1,5%)	1 (1,2%)	13 (16%)	23 (19%)	2 (1,3%)	0 (0%)	3 (7,7%)	44 (5,6%)
The therapist and I concluded that it had no use to continue treatment	4 (2,5%)	0 (0%)	3 (4,5%)	1 (1,2%)	4 (4,9%)	0 (0%)	0 (0%)	0 (0%)	3 (7,7%)	15 (1,9%)
My mental problems are alleviated	8 (5%)	18 (27,7%)	1 (1,5%)	10 (11,9%)	1 (1,2%)	2 (1,7%)	2 (1,3%)	0 (0%)	5 (12,8%)	47 (6%)
Other reasons	0 (0%)	0 (0%)	3 (4,5%)	3 (3,6%)	0 (0%)	0 (0%)	34 (22,7%)	0 (0%)	1 (2,6%)	41 (5,2%)

The analysis shows that the large majority of patients access the service from their own computer (89,4%), and very rarely from community and care organisations locations. The average number of sessions completed was: 3,61 in the Basque Country, 3,23 in Galicia, higher than five in the rest of regions and up to six in Turkey and Estonia. The number of online sessions slightly decreases on average in Badalona, Galicia, Piemonte, Treviso, Turkey and Estonia, leaving an average of 4,6 in total; Wales and Basque Country remain equal.

For the interpretation of treatment drop-out, patients were offered different options to choose from. As of now, the drop-outs number 314 (20,25% of the patients included). There is a huge variability by region in relation with the reasons for ending the treatment. 37 patients stated that they dropped out of treatment because they had problems with the internet connection or that their computer was not functioning. 18 patients stated to have stopped the treatment for therapeutic reasons, 17 forgot to attend the online sessions, and 18 stated that they did not have the skills to follow the online treatment.

4.2.6 Appropriateness of MasterMind services based on focus group interviews

Besides access to service, completion numbers, and reasons presented above, all trial sites engaged in obtaining a rich patient profile of those for whom the cCBT service is most appropriate. This was done by performing in total 11 focus group discussions with healthcare professionals in the five 1st wave trial sites reflecting on the patients they see in their daily practices. From these focus groups, it appeared that various factors are relevant to:

a) the appropriateness of the service in alleviating the needs of the patients;

b) the decision to engage with the cCBT service;

c) adherence to cCBT treatment; and

d) safety of the service.

In summary, the focus groups indicated the following factors as relevant:

- **Appropriateness**
  - **Clinical symptoms**: It seems that cCBT is most likely appropriate for mild to moderate depression. Patients should be monitored, especially when they have suicidal tendencies or display self-harming behaviour.
  - **Contextual factors**: Patients need professional support and are more likely to drop out if they are not supported.
  - **Skills, personality traits, and attitude**: The intervention seems to be not equally effective for all type of patients. Certain factors, such as age, educational level or ICT skills seem to be important when considering who should be referred for cCBT.
  - **Treatment delivery**: The programme was appreciated as an additional type of support that was at any time freely available. However, some patients preferred face-to-face contact, and did not wanted to be involved with technology in their treatment.
- **Decision to engage**
  - **Access to treatment**: Not every patient owns a computer at home. The idea of providing computers at the facility and making the tool available for smartphones and tablets received much attention.
  - **Awareness of treatment**: Many patients are not aware of this type of treatment. Increasing the knowledge of the general population about e-health technology might increase recruitment. Furthermore, professionals seem to be very eager at first to include a lot of patients in the new intervention, but after a while seem to forget about its existence.
  - **Consent and referral**: Not every patient seems to be suitable for this type of therapy. Early support seems to increase the chances of people accepting the treatment. The way professionals advertise the intervention to their patients also seems to be a crucial factor.
  - **Expectations and needs**: Patients require a clear introduction to cCBT to start with realistic expectation of the therapy. Otherwise, patients might be at risk of dropping out.

- **Adherence to treatment**
  - **Applicability of content**: The intervention does not fit every patient to the same extent. The need for carefully screening of patients was mentioned to identify patients who can be considered eligible.
  - **Attractiveness of content and design of treatment platform**: There is room for improvement regarding the design of the platform, but also for the content. Patients who already had experience with CBT seem to find the intervention repetitive and might drop out due to this.
  - **Clinical changes**: It was stated that the tool has the capacity to elicit a change in clinical symptoms, but also decreases the amount of GP visits. However, it seems that seriously ill patients should be excluded due to the risk of getting worse.
  - **Motivational aspects**: The importance of motivation was mentioned to keep patients doing the exercises. Incentives were mentioned as a possible approach to increase motivation.
  - **Practical arrangements**: Certain practical arrangements might increase adherence. Some of those are mentioned are: follow-ups; forms describing technical features; additional human resources; support; basic ICT courses; alarm functions for practitioners; review appointments; having a computer at the centre.
  - **Technical aspects and user-friendliness**: It seems as some patients had technical issues with the application, and the support could not always immediately help these patients. As a consequence, some patients might not have adhered to the treatment; whereas others thought the technical support to be relatively good with a fast response rate. In the same way, some patients criticised the tool as too complicated and unstable, while others seemed to like the design and described the tool as stable.

Appendix A.2 contains more details on the findings from the focus group interviews, which substantiate the factors related to the appropriateness of the service.

4.2.7 Summary

This section presents data on safety and clinical effectiveness from the 2nd wave pilots. 1167 patients have been included in the analysis of the safety and clinical effectiveness domains, differently distributed across the nine sites. The sample size differs significantly from site to site.

Safety

The percentages in terms of suicide ideation and attempts are not high, which reflects that the cCBT service provided is considered safe. In fact, the numbers are more favourable than the literature describes. For example, in Spain, the percentages are 8,26% and 1,78%, for ideation and attempts respectively, which are higher than our results. There are differences between regions; the Basque Country and Badalona are especially noteworthy. Yet, it has to be noted that the assessment for suicide ideation and attempts is different from site to site. Differences in the severity of the initial symptoms, which is a fact, can clearly be another reason of such contrasts. Additionally, it has to be highlighted that distinct methods or approaches have been used for diagnostic assessment, which can hinder the comparability of the results.

A qualitative analysis has been conducted through interviews and focus groups with the healthcare professionals involved in the study. Interviewees were questioned about the efficacy and safety of the intervention provided. At the beginning of the process, some patients needed to be reassured by the doctors about the safety of the tool. After this reassurance, no patient expressed any concern regarding clinical safety. Even more, the majority of patients seemed not to be worried about privacy issues.

Clinical effectiveness

Pre-treatment and post-treatment data have been taken into account in this analysis. To this end, data from 679 patients has been analysed, differently distributed between pilots. On average, patients are around 44 years old, though two pilots present opposite tendencies: Turkey drops to 28 years old and Aragón goes up to 50 years old. The other parameters of the demographic characteristics (gender, education, employment status) remain similar.

Most of the patients represented in pre-treatment data suffered from mild (36,7%), moderate (45,1%) or severe symptoms (15%). No symptoms, or very severe symptoms, were almost non-existent. Approximately 58% of patients improved after receiving cCBT; this is a positive result, taking into account that 50% of remissions are described with antidepressant use. Approximately 63% of patients with severe or very severe symptoms improved their mental health status, and the number with moderate depression was significantly decreased. The results show that symptoms are improved after the treatment, with an increase in the percentage of patients with better symptomatology. Before treatment, the percentage of patients with no symptoms was zero; however this proportion is increased in all sites, from 5,3% (Turkey) up to 71,8% (Aragón). How this percentage varies in each site depends very much on the starting symptomatology of patients. The duration of depressive episodes has decreased by a significant proportion, being 3-6 months and 1-3 years more represented.

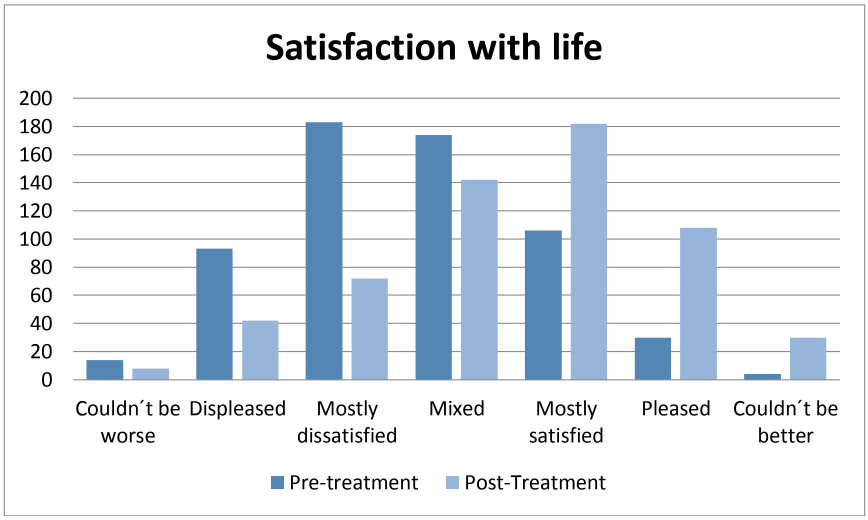
Looking at the change during the treatment, by calculating score differences between the symptom severity before and after treatment, in total 58% of patients were reported to experience a reduction in depressive symptoms, 38,7% by one and 19,3% by two categories. Large differences can be seen between the trial sites: Galicia reported 82,9% of patients with improved symptomatology, 82,1% in Aragón and 78,5% in Treviso; on the other hand, 31,6% of the Turkish patients deteriorated between the start and the end of cCBT treatment.

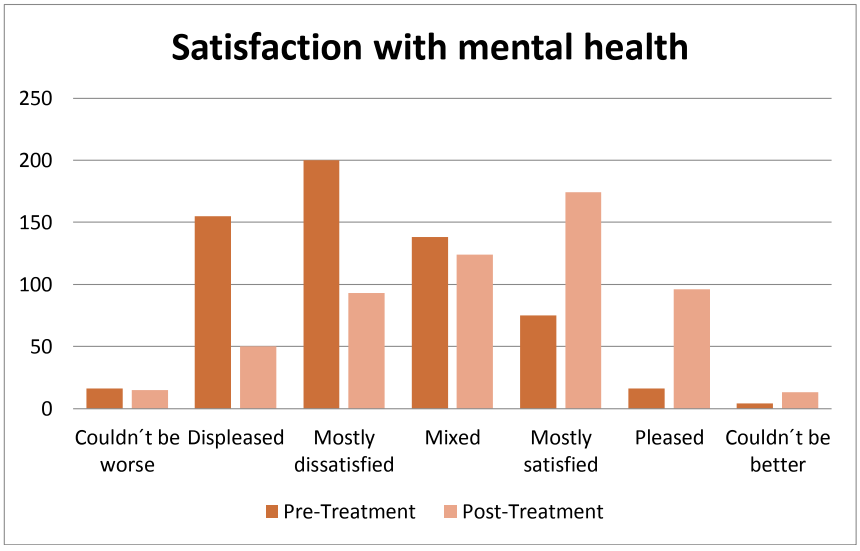
64,6% of the Basque patients, 57,9% of the Turkish patients and 4,70% of the Welsh patients experienced no change in symptoms between the beginning and the end of the cCBT treatment. As mentioned before, it has to be noted that clinical effectiveness is biased since patients who never initiated the cCBT or did not complete any session were included in the analysis. This number is the 57.4% of all drop outs (146 from 254), therefore, the real clinical effectiveness of the therapy is underestimated.

It has to be highlighted that the proportion of chronic patients is high, which can affect the clinical responsiveness, since this type of depression is often resistant to treatment. This is even more true when the treatment is online, since the patients are in charge of the treatment, and they can abandon it whenever they want. In the qualitative analysis, the importance of proper supervision was underlined. It was also reported that patients who do not feel that they receive enough professional support are likely to drop out. Doing online

therapy needs a lot of motivation from the patient, since it is an active treatment compared to pharmacological interventions. Possible ideas to motivate and encourage patients were focused mainly on providing the service in a more continuous and constant way, for example, with the use of supportive therapy through telephone or explanatory videos.

Regarding quality of life and satisfaction with mental health, an improvement can be seen between pre-treatment and post-treatment assessment. The following graphs show the improvement of the quality of life and satisfaction with mental health between pre-treatment and post-treatment assessment:





Based on the results on access to the service, the use of personal location is predominant (89,4%). It could be interesting to promote the use of public or community settings, which might improve the access rate.

The number of sessions completed (in total, which could be a combination of face-to face and online sessions) and the number of sessions completed online is 5,23 and 4,6 respectively, varying between sites. 42,6% of patients completed the treatment as planned. It can be concluded that most patients drop-out due to poor skills in managing technology, problems with limited connectivity, or problems with the computers. In the case of Galicia and Piemonte, the main drop-out reason is that patients are not convinced that the therapy could solve their problems, with 13 and 23 drop-out cases respectively. Strategies to boost patients completing the treatment are clearly needed, which will probably result in better clinical effectiveness.

Appropriateness of the service

The appropriateness of the treatment was discussed in the qualitative analysis' focus groups. The positive aspects of MasterMind mentioned were: free of costs for the patient; only requires basic informatics competencies; user-friendliness; accessible at any time. It was stated that family doctors liked cCBT for patients that live far away, and for foreign patients with language barriers. Also, the further the patients lived from the mental health centre, the more they appreciated the programme. It was also stated that healthcare professionals should offer this kind of therapy to patients more scientifically (evidence, information, explanations) in order to make the patient more confident that this is a proven and reliable treatment.

5. Domain 4: Patient and healthcare professional perspectives

5.1 Introduction

Domain 4 addresses the perceived satisfaction of both patients and healthcare professionals, and the usability of the programmes. The perspectives are measured through validated self-reported measures (CSQ-8/3 and SUS), and provide an indication of the acceptance and appropriateness of the services in addressing the depressive disorder. The data on satisfaction includes variables on quality, type, needs, complexity and overall satisfaction. Data on usability describe usage, complexity, consistency, confidence, and level of integration.

Domain 4 aims to answer research objectives:

- objective #1: to identify barriers and facilitators that influence the implementation of cCBT for treating depression in routine practice;
- objective #5: to assess the perceived satisfaction and usability of cCBT; and
- objective #7: to assess the transferability of implementation and up-scaling of cCBT into routine practice in different care contexts.

Together with domains 1, 2, 3, and 5, these results enable drawing conclusions in terms of the acceptability and appropriateness of the services in alleviating depressive symptoms. The results have been triangulated (mixed-methods) with the focus group discussions with the healthcare professionals (domain 4) and organisations (domain 5). This triangulation provides an understanding of the meaning (qualitative) of the facts (quantitative) for the healthcare professionals and organisations, and the interplay of both stakeholders.

More specifically, data provide information on patients' perspectives towards the services implemented within the MasterMind project, and the healthcare professional perspective towards these services, by analysing and interpreting data retrieved from focus group interviews and structured interviews.

5.2 Results – Patient perspectives

5.2.1 Patient's perceived satisfaction

Information for 576 patients has been reported, representing 37,16% of the core dataset. The differences between the trial sites are large: Turkey reports 15,8% of participants at post-self-assessment, Wales 19,4%, the Basque Country 25,4%, Estonia 26,78%, Aragón 27,13%, Galicia 30,9%, Badalona 33,99%, Piemonte 74,56% and Treviso 95,33%. All the data available was included in the analysis of the dimension "patient's perceived satisfaction".

The average age is around 45, except Turkey and Estonia (28 and 30 years old respectively). The other parameters remain similar to the overall demographic characteristics reported above: high representation of women; most patient with university degrees (except Aragón); immigrants are poorly represented; most patients are referred by GPs (except

Wales and Turkey); and most patients either do not take drugs or take anti-depressants for more than two months.

Patient's perceived satisfaction was assessed with the Client Satisfaction Questionnaire (CSQ-8). This version of the CSQ contains eight questions on consumers' satisfaction, and is easily scored by summing the individual item scores to produce a range of 8 to 32, with high scores indicating greater satisfaction. For the reader's convenience, we chose to depict the results as percentage of approval in Table 15 below. The answer options on the Likert scale linked to approval have been combined as indicating "approval", and the disapproving options in the category "disapproval".

In total, across all items, 76,4% of patients reported to have been satisfied with the treatment; Badalona with 98,3% of patients satisfied, and Wales with only 49,3% satisfied, show the differences. On the question if it was the desired type of treatment, it goes from 35,3% satisfaction in Galicia to 100% in Aragón and Basque Country. The percentage of satisfaction as to whether the treatment meets the needs of the patient, it goes to the 54,5% in general. Again, there are huge differences between sites; with a 26,5% in Galicia, and 90,9% in the Basque Country. The treatment recommendation is quite good (79,5%), except in Galicia where the satisfaction is 14.7%. The amount of aid received lowers the percentage of overall satisfaction. There is a big difference between regions regarding the satisfaction to effectively treat problems with treatment; it is 40% in Estonia, but 100% in Basque Country or Turkey. Regarding the satisfaction to reuse the treatment in case of need it again, it is very low in Galicia (17,6%), but much higher in the Basque Country, Aragon and Badalona (it surpasses 90%)..

Table 15: Patient's perceived satisfaction

	Region									
	Basque Country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Sample: *n*										
1. Quality of the treatment you have received? *% approval*	54 (98,2%)	38 (55,1%)	33 (94,3%)	59 (98,3%)	30 (88,2%)	76 (63,3%)	79 (79%)	15 (78,9%)	10 (66,7%)	394 (77,7%)
2. Did you get the kind of treatment you wanted? *% approval*	54 (100%)	37 (55,2%)	35 (100%)	59 (98,3%)	12 (35,3%)	68 (56,7%)	55 (79,7%)	15 (78,9%)	10 (66,7%)	345 (72,9%)
3. To what extent has the treatment met your needs? *% approval*	50 (90,9%)	25 (36,2%)	23 (65,7%)	54 (90%)	9 (26,5%)	41 (34,2%)	37 (54,4%)	12 (63,2%)	8 (53,3%)	259 (54,5%)
4. If a friend were in need of similar help, would you recommend this treatment to him or her? *% approval*	54 (98,2%)	47 (68,1%)	34 (100%)	59 (100%)	5 (14,7%)	91 (75,8%)	59 (85,5%)	17 (89,5%)	11 (73,3%)	377 (79,5%)
5. How satisfied are you with the amount of help you have received? *% approval*	54 (100%)	30 (43,5%)	33 (94,3%)	57 (95%)	8 (23,5%)	71 (59,2%)	56 (82,4%)	17 (89,5%)	10 (66,7%)	336 (70,9%)
6. Has the treatment you received helped you to deal more effectively with your problems? *% approval*	55 (100%)	38 (55,1%)	33 (94,3%)	57 (95%)	25 (73,5%)	70 (58,3%)	50 (74,6%)	19 (100%)	6 (40%)	353 (74,5%)
7. In an overall, general senses, how satisfied are you with the treatment you have received? *% approval*	54 (98,2%)	34 (49,3%)	33 (94,3%)	59 (98,3%)	28 (82,4%)	71 (59,2%)	85 (84,2%)	14 (73,7%)	10 (66,7%)	388 (76,4%)
8. If you were to seek help again, would you make use of this treatment again? *% approval*	54 (98,2%)	39 (56,5%)	34 (97,1%)	54 (96,4%)	6 (17,6%)	67 (55,8%)	91 (89,2%)	15 (78,9%)	9 (60%)	369 (73,1%)

5.2.2 Patient's perceived usability

Information on 577 patients has been reported, representing 37,2% of the core dataset. Treviso provided 94% of its whole participants sample at post assessment, and Piemonte 74,53%. The other sites' numbers are much lower.

The average age is around 45, except Turkey and Estonia (28 and 31 years old, respectively), and Aragón (50 years old). The other parameters remain similar to the demographic characteristics reported above: high representation of women; most patient with university degrees (except Aragón); immigrants are poorly represented; most patients are referred by GPs (except Wales and Turkey); and most patients either do not take drugs or take anti-depressants for more than two months.

Patient's perceived usability was measured with the System Usability Scale (SUS; cite), consisting of ten items to facilitate the evaluation of products such as software and applications. The questionnaire was chosen because it depicts the gold standard in the field of measuring system usability, it can be administered easily, is realisable in small sample sized, and has been proven to be a valid instrument (cite). The interpretation can be complicated. For the reader's convenience, we provide below a table showing the percentage of approval within the specific SUS category as well as the mean score. Though the scores are 0-100, these are not percentages and should be considered only in terms of their percentile ranking. A SUS score above a 68 would be considered above average and anything below 68 is below average.

More than 66% of patients would use the cCBT service again if needed, with the exception of Wales and Piemonte which present lower percentages. Most of the patients asked (84,3%) believe that the platform is not complex to use, and many of them (more than 69,6%) believe the treatment is easy to use and apply; the maximum rate was obtained in Turkey (89,5%). On the contrary, patients in Estonia mainly consider that the treatment is difficult to manage.

Less than 22% of patients in all sites required the support of a technician to use the cCBT platform, except Treviso where the proportion is slightly higher (41%). Satisfaction with regard to the integration of functionalities is around 50% in Estonia, while the rest of sites show higher numbers. Inconsistencies in the therapy are not a major issue for patients of most sites. Piemonte and Treviso,both Italian regions, present the highest percentages; 34,2% and 20,4% respectively.

The perception of how rapidly people would learn using the cCBT platform varies widely from site to site. Patients from Wales consider that only 47,8% of the people would get the skills to handle the treatment quickly, whereas all Turkish patients agree on the ease of use. Most patients do not describe the treatment as cumbersome; the percentage only surpasses 15% in Wales and Treviso.

In terms of feeling confident when handling the platform, sites show very variable results, from 39,2% in Piemonte to a 97,1% in Aragón. The majority of patients interviewed do not think that lots of things have to be learned before starting treatment; the highest proportion is Badalona (26,7%).

The final score obtained in the SUS questionnaire reflects that patients of most sites consider the cCBT service of high usability (score > 68). There are two sites with diametrically opposed results: Treviso shows a very low score, while Estonia presents a considerably high score.

Table 16: Patient's perceived usability

	Region									
	Basque Country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Sample: *n*										
1. I think that I would like to use [cCBT/ccVC] treatment frequently when needed. *% approval**	46 (82,1%)	34 (49,3%)	33 (97,1%)	51 (87,9%)	25 (71,4%)	51 (42,5%)	69 (69,7%)	15 (78,9%)	10 (66,7%)	334 (66,1%)
2. I found the [cCBT/ccVC] platform unnecessarily complex. *% approval**	8 (14,3%)	14 (20,3%)	5 (14,3%)	4 (6,7%)	5 (14,3%)	20 (16,7%)	24 (24,2%)	0 (0%)	0 (0%)	80 (15,7%)
3. I thought the [cCBT/ccVC] treatment was easy to use and apply. *% approval**	50 (89,3%)	38 (55,1%)	30 (85,7%)	46 (76,7%)	28 (80%)	68 (56,7%)	71 (72,4%)	17 (89,5%)	4 (28,6%)	352 (69,6%)
4. I think that I would need the support of a technical person to be able to use [cCBT/ccVC] treatment more often. *% approval*)*	9 (16,1%)	13 (18,8%)	9 (26,5%)	4 (6,7%)	5 (14,3%)	22 (18,3%)	41 (41%)	1 (5,3%)	4 (26,7%)	108 (21,3%)
5. I found the various functions in the [cCBT/ccVC] treatment were well integrated. *% approval**	52 (92,9%)	37 (53,6%)	32 (91,4%)	45 (75%)	21 (60%)	78 (65%)	78 (78,8%)	13 (68,4%)	7 (50%)	363 (71,6%)
6. I thought there was too much inconsistency in the [cCBT/ccVC] treatment. *% approval**	2 (3,6%)	9 (13%)	1 (2,9%)	2 (3,4%)	2 (5,7%)	41 (34,2%)	20 (20,4%)	0 (0%)	2 (13,3%)	79 (15,6%)
7. I would imagine that most people would learn to use and apply the [cCBT/ccVC] treatment very quickly. *% approval**	45 (80,4%)	33 (47,8%)	29 (82,9%)	35 (60,3%)	21 (60%)	60 (50%)	63 (63,6%)	17 (89,5%)	10 (66,7%)	313 (61,9%)
8. I found the [cCBT/ccVC] treatment very cumbersome to use and apply. *% approval**	3 (5,4%)	17 (24,6%)	0 (0%)	6 (10,3%)	3 (8,6%)	17 (14,2%)	20 (20,2%)	0 (0%)	1 (6,7%)	67 (13,3%)
9. I felt very confident using and applying the [cCBT/ccVC] treatment. *% approval**	45 (80,4%)	29 (42,6%)	34 (97,1%)	51 (86,4%)	27 (77,1%)	47 (39,2%)	68 (68,7%)	15 (78,9%)	8 (57,1%)	324 (64,2%)
10. I needed to learn a lot of things before I could get going with the [cCBT/ccVC] treatment. *% approval**	6 (10,7%)	10 (14,5%)	1 (2,9%)	16 (26,7%)	4 (11,4%)	12 (10%)	13 (16%)	3 (15,8%)	2 (13,3%)	67 (13,7%)
System Usability Scale (SUS): total *(>68 is high)*	78,79 (15,42)	63,19 (32,53)	77,64 (10,78)	67,65 (63,82)	76,21 (19,66)	60,54 (15,15)	27,18 (111,03)	78,29 (9,72)	110,67 (136,78)	60,75 (65,92)

5.3 Results – Healthcare professional's perspectives

5.3.1 Healthcare professional's perceived satisfaction

The professionals are mostly women (71%), except Piemonte, where the proportion of men is greater. Professionals are mainly represented by GPs, except Wales where MH / community workers are main actors. Most professionals questioned have had training in cCBT (77,4%), with the exception of Galicia (0%). Their field experience is 10 years or more (43,4%); however, their experience in using cCBT is less than five times (43,9%).

The healthcare professional's perceived satisfaction was assessed with the Client Satisfaction Questionnaire (CSQ-3), containing items 3, 7 and 8 of the CSQ-8 (as described in section 5.2.2). Empirically, these items are the most salient ones, and are used to provide a maximum amount of efficiency in obtaining data. For the reader's convenience, we chose to show the percentage of approval in Table 17 below.

The overall perceived satisfaction with the treatment varies between regions; 17% in Estonia, 25% in Basque Country and Wales, and 87% in Treviso. The satisfaction with patient treatment varies as well, from the 23% in Wales, to the 100% in Aragón. 67% of Wales' professionals would use these services again, but in Aragón, Treviso and Turkey this is 100%.

Table 17: Healthcare professional's perceived satisfaction

	Region									
	Basque Country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Sample: *n*	11	13	12	114	11	17	22	3	18	221
1. To what extent have these services met your needs in treating patients? *% approval**	1 (25%)	3 (25%)	10 (83,3%)	84 (76,4%)	5 (45,5%)	12 (70,6%)	7 (87,5%)	1 (33,3%)	3 (16,7%)	126 (64,6%)
2. In an overall general sense, how satisfied are you with the services in treating your clients? *% approval**	2 (50%)	3 (23,1%)	12 (100%)	93 (83,8%)	7 (63,6%)	12 (70,6%)	7 (31,8%)	1 (33,3%)	9 (50%)	146 (69,2%)
3. If you were to provide CBT treatment, would you use these services again? *% approval**	3 (75%)	8 (66,7%)	12 (100%)	93 (84,5%)	8 (72,7%)	15 (88,2%)	7 (100%)	3 (100%)	9 (50%)	158 (81,4%)

5.3.2 Healthcare professional's perceived usability

The healthcare professional's perceived usability was also measured with the System Usability Scale (SUS).

222 healthcare professionals (79% of the core dataset) reported information on perceived usability of the treatment. The proportion of professionals who answered the questionnaire on usability compared to those involved in the cCBT service varied significantly: Basque Country 22,6%, Wales 48,18%, Piemonte 80,95%, and Aragón, Badalona, Galicia, Treviso, Turkey, and Estonia all 100% . All data available was included in the analysis of the dimension "health care professional's perceived usability".

As in the previous analysis, women are more represented (70.7% in average). The professionals who refer patients to the cCBT treatment are mainly GPs, with the exception of Wales where MH / community worker are principal referrers. Most of the professionals received specific training in cCBT in all sites, but with a significant lower percentage in Galicia (0%) and Estonia (11%).

Professionals at most sites were willing to provide the cCBT treatment frequently, reaching 80% of professionals in Aragón. Yet, lower percentages can be observed in Wales (15.4%) and Piemonte (13.3%). There is a wide variability with respect to the complexity of the treatment; some regions consider that the treatment is not complex at all (Wales, Aragón, Treviso and Turkey), while others find it very difficult to handle (81%). Overall, 60% of professionals believe that the platform is easy to use; however, there are opposite perceptions depending on the site analysed: 18% in Galicia and 100% in Aragón.

The need for a technician to support the management of the cCBT platform differed considerably across sites (0% in Wales and 100% Estonia). The same tendency is observed (great variability) when integration of the functionalities into the platform is assessed, or the degree of inconsistencies in the treatment is investigated.

Ample differences are shown across sites in terms of need for learning to provide the cCBT service. Professional from the Basque Country, Wales, Piemonte, and Estonia mostly consider that learning to use the platform is not a straightforward and rapid process, while Aragón, Badalona, Galicia, Treviso and Turkey believe that providing the treatment is easy (54.5%-90%). Overall, most professionals do not think that the intervention is cumbersome to use; however, three sites (Wales, Galicia and Estonia) present some discrepancies in this matter.

Similarly, professionals of distinct regions do not completely agree when asked about their confidence is using the cCBT platform. None of the professionals in the Basque Country are confident, whereas others appear to be very confident (50%-80%).

In contrast to patients' perception on usability, the scores obtained by the survey of professionals is much lower. Only professionals of two sites (Aragón and Badalona) feel that the cCBT intervention is useable enough (score > 68). The other regions present values between 31.92 and 72.68 (Wales and Badalona, respectively).

Table 18: Healthcare professionals' perceived usability

	Region									
	Basque Country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Sample: *n*	12	13	12	114	11	17	22	3	18	222
1. I think that I would like to provide the [cCBT/ccVC] treatment frequently. *% approval**	1 (20%)	2 (15,4%)	8 (80%)	59 (53,6%)	6 (54,5%)	2 (13,3%)	4 (50%)	2 (66,7%)	8 (44,4%)	92 (47,7%)
2. I found the [cCBT/ccVC] treatment unnecessarily complex. *% approval**	2 (40%)	0	0	10 (9,1%)	6 (54,5%)	13 (81,3%)	0	0	9 (50%)	40 (20,6%)
3. I thought the [cCBT/ccVC] treatment was easy to use and provide to my clients. *% approval**	1 (20%)	6 (46,2%)	10 (100%)	75 (68,2%)	2 (18,2%)	8 (50%)	5 (62,5%)	1 (33,3%)	8 (44,4%)	116 (59,8%)
4. I think that I would need the support of a technical person to be able to use and provide the [cCBT/ccVC] treatment to my clients. *% approval**	3 (60%)	0	7 (70%)	9 (8,2%)	4 (36,4%)	11 (68,8%)	2 (28,6%)	2 (66,7%)	18 (100%)	56 (31,1%)
5. I found the various functions in the [cCBT/ccVC] intervention were well integrated. *% approval**	4 (80%)	0	9 (90%)	75 (68,8%)	4 (36,4%)	1 (7,1%)	6 (85,7%)	1 (33,3%)	2 (11,1%)	102 (57,6%)
6. I thought there was too much inconsistency in the [cCBT/ccVC] intervention. *% approval**	2 (40%)	0	0	3 (2,8%)	4 (36,4%)	12 (75%)	0	0	9 (50%)	30 (16,8%)
7. I would imagine that most healthcare professionals would learn to use and provide the [cCBT/ccVC] intervention very quickly. *% approval**	1 (20%)	1 (7,7%)	9 (90%)	76 (69,1%)	6 (54,5%)	2 (12,5%)	4 (57,1%)	2 (66,7%)	5 (27,8%)	106 (54,9%)
8. I found the [cCBT/ccVC] intervention very cumbersome to use and provide to my clients. *% approval**	1 (20%)	5 (38,5%)	0	9 (8,2%)	7 (63,6%)	2 (12,5%)	1 (12,5%)	0	7 (38,9%)	32 (16,5%)
9. I felt very confident using and providing the [cCBT/ccVC] intervention to my clients. *% approval**	0	2 (15,4%)	8 (80%)	77 (70%)	6 (54,5%)	11 (68,8%)	4 (50%)	2 (66,7%)	8 (44,4%)	118 (60,8%)
10. I needed to learn a lot of things before I could get going with using and providing the [cCBT/ccVC] intervention to my clients. *% approval**	2 (40%)	9 (69,2%)	8 (80%)	8 (7,3%)	7 (63,6%)	3 (18,8%)	4 (50%)	1 (33,3%)	8 (44,4%)	50 (25,8%)
System Usability Scale (SUS): *total (>68 = high)*	52 (19,56)	31,92 (3,41)	68,25 (7,64)	72,68 (17,36)	47,05 (16,39)	44,53 (6,66)	60,31 (13,79)	63,33 (11,81)	43,19 (13,2)	62,02 (20,6)

5.3.3 Healthcare professionals' perceived acceptability of MasterMind services in routine practice

Besides access to service, completion numbers and reasons presented above, all trial sites engaged in obtaining a rich professional profile of those for whom the cCBT service might be acceptable. This was done by carrying out focus group discussions with healthcare professionals reflecting on the patients they see in their daily practices. From these focus groups, it appeared that various factors are relevant to:

- the appropriateness of the service in alleviating the needs of the patients;
- the decision to engage with the cCBT service; and
- the satisfaction and usability of the services in routine practice.

In summary, the focus groups indicated the following factors as relevant:

- **Appropriateness of and adherence to treatment**
  - **Skills and knowledge:** The need of having knowledge of CBT as modality and understanding how the application works were underlined.
  - **Service delivery:** Professionals need to be trained how to deliver the tool. The use of the tool should be shortly after this training. Although cCBT does not safe professionals much time and many professionals are yet unfamiliar with this type of treatment delivery, potentials of the tool were recognized.
- **Engaging in treatment**
  - **Awareness and knowledge:** Professionals seem to be enthusiastic about receiving a new tool. Unfortunately, many professionals tend to forget about the tool after some time. Furthermore, patients need to be made aware of its existence.
  - **Expectations and needs:** It seems that professionals might have been pressured from their organization to use the tool. In order for professionals to be able to adopt to cCBT they need to be able to integrate it into their daily work.
  - **Support:** It was stressed that healthcare professionals need more resources and support (also technical) to being able to implement these services.
  - **Training and education:** Professionals cannot recommend something of which they don't have knowledge of. Specific learning courses for professionals were suggested.
  - **Technical and confidential security:** Professionals do not see any security issues with the tool. Contrary, it was stated that they perceive it as more safe compared to written notes.
- **Satisfaction and usability from the perspective of the healthcare professional**
  - **Satisfaction:** No major problems were reported regarding usage. Many individuals seemed to be grateful for the tool:
  - **Usability:** The professionals stated mostly that there were no major issues working with the tool and mentioned certain positive aspects of the tool, such as its value in monitoring patients.

Appendix A.3 contains more details on the findings from the focus group interviews, which substantiate the factors described above.

5.4 Summary

With regard to the patient's perceived satisfaction, information for 576 patients has been reported, which represents 37,16% of the core dataset, with differences between trial sites. Turkey reports 15,8% of participants at post-self-assessment, Wales 19,4%, the Basque Country 25,4%, Estonia 26,78%, Aragón 27,13%, Galicia 30,9%, Badalona 33,99%, Piemonte 74,56% and Treviso 95,33%.Patient's perceived satisfaction was assessed; the majority of the patients approved the quality of the treatment received (77,7%). 79,5% of them would recommend the treatment to patients with similar needs, and 76,4% of the patients were satisfied with the treatment that they received.

Healthcare professionals, mainly represented by GPs, are mostly satisfied with the services (69,2%), and believe that the cCBT service can be a useful solution to treat depression. In addition, 81,4% of healthcare professionals would use these services again, and 64,6% think that the services meet their needs in treating patients.

With respect to the patient's perceived usability of the treatment, more than 66% of patients will use the cCBT service again if needed, with the exception of Wales and Piemonte, which present lower percentages. Less than 22% of patients in all sites required the support of a technician to use the platform. Satisfaction with regard to the integration of functionalities is around 50% in Wales and Estonia, while the rest of sites show much higher numbers. In addition, most patients do not describe the treatment as cumbersome, addressing the high usability of the service.

In terms of the appropriateness of the cCBT service, focus groups reported primarily factors that can be categorised under treatment delivery processes. Professionals in most sites are willing to provide the cCBT treatment, reaching 80% of professionals in Aragón. In the qualitative analysis, not only was the need for professionals to have CBT skills stated, but also the need for increased knowledge of how the application works, and the support received to implement the services (in terms of resources). They stated that there were no major issues working with the tool, and mentioned certain positive aspects, such as its value in monitoring patients.

Although cCBT does not save professionals much time, and many professionals are as yet unfamiliar with this type of treatment delivery, the potential of the tool was recognised.

6. Domain 5: Economic aspects

6.1 Introduction

The analysis of the economic aspect of the implementation of the services is based on responses to the questionnaires preceding the semi-structured interviews with healthcare organisations. These questionnaires include a series of questions regarding implementation and maintenance costs. The semi-structure interviews collected relevant views in terms of potential savings, and a potential business case for initiating and retaining the interventions according to directors and/or owners of the healthcare organisations participating in MasterMind. These are also summarised in this section.

6.2 Results

6.2.1 Demographic characteristics of mental healthcare organisations (subset)

This table provides a summary of demographic characteristics of healthcare organisations in MasterMind.

Table 19: Demographic characteristics of mental healthcare organisations (subset)

	Region									
	Basque country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Sample: *n*	2	3	1	2	2	1	1	1	3	17
Year of establishment: *mean (SD)*	1983 (0)	1948 (0)	1989 (0)	1932 (0)	1990 (0)	2008 (0)	2000 (0)	1956 (0)	2000 (6)	1976 (26)
Number of units / departments: *mean (SD)*	49 (2)	7 (5)	17 (0)	30 (0)	1250 (0)	14 (0)	2 (0)	36 (0)	1 (0)	163 (410)
Number of FTE employed: *mean (SD)*	3.679 (1.869)	958 (747)	900 (0)	1000 (0)	36000 (0)	3922 (0)	200 (0)	3800 (0)	2 (1)	5.527 (11.567)
Turnover: *count (%)*										
Less than 2 million €	0	0	0	0	0	0	0	1	3	4 (24%)
Between 2 - 10 million €	0	0	0	0	0	0	0	0	0	0
Between 10 - 50 million €	0	1	0	0	0	0	1	0	0	2 (12%)
Over 50 million.	2	2	1	2	2	1	0	0	0	11 (65%)
Waiting time: *count (%)*										
Less than a week	2	0	0	2	2	0	0	0	3	9 (53%)
Between 1 and 4 weeks	0	2 (	0	0	0	1	1	0	0	4 (24%)
1 and 2 months	0	0	1	0	0	0	0	0	0	2 (12%)
Between 2 and 6 months	0	0	0	0	0	0	0	1	0	1 (6%)
More than 6 months	0	1	0	0	0	0	0	0	0	1 (6%)

6.2.2 Investments

The table below presents the initial investment in materials, ICT infrastructure and staff training required to implement the services in each region.

Table 20: Investments

	Region									
	Basque Country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Investments in materials and ICT infrastructure (€): *mean (SD)*	0	0	70.000 (49.497)	24.000 (0)	38.386 (43.254)	21.500 (0)	50.000 (0)	440 (0)	833 (416)	15.836 (24.459)
Efforts (time) needed of support staff to implement the services (FTEs): *mean (SD)*	0	0	0	1 (0)	5 (4)	3 (0)	2 (0)	1 (0)	2 (1)	1 (2)
Initial training and supervision: count (proportion)										
Yes	1 (1)	1 (0.5)	1 (1)	2 (1)	2 (1)	1 (1)	1 (1)	0 (0)	3 (1)	13 (0.87)
No	0	1 (0.5)	0	0	0	0	0	1 (1)	0	2 (0.13)
Training type: *count (%)*										
Technical aspects and how to use of the platform	0	0	0	0	1	0	0	-	3	5 (33%)
Therapeutic elements that are included in the platform (e.g. CBT)	0	0	0	0	0	0	0	-	0	0
Technical aspects and how to use the platform, and therapeutic elements that are included in the platform (e.g. CBT)	2	2	1	2	1	1	1	-	0	10 (67%)
Other aspects related to the service.	0	0	0	0	0	0	0	-	0	0

6.2.3 Recurring operational costs

The recurring operational costs, estimated by the direct and indirect costs per session, are summarised in the following table.

Table 21: Recurrent operational costs

	Region									
	Basque Country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Direct costs of for one cCBT session (€) ***mean (SD)***	0	0	100 (0)	238 (18)	348 (0)	50 (0)	20 (0)	100 (0)	25 (0)	78 (110)
Indirect costs spend on overheads for one cCBT/ccVC session (€) ***mean (SD)***	0	0	30 (0)	33 (4)	56 (0)	11 (0)	15 (0)	10 (0)	20 (0)	20 (18)

6.2.4 Reimbursement modalities

We present the reimbursement modalities reported by each organisation in each region.

Table 22: Reimbursement modalities

	Region									
	Basque Country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Main sources of reimbursement										
Public healthcare system (i.e. Ministry of Health)	-	2			1					3 (23%)
Health care insurers	-								3	3 (23%)
Patients	-							0		0
Other	-							1		1 (8%)
The service is not reimbursed structurally	-		1	2		1	1			6 (46%)
Unknown	-									0

6.2.5 Cost savings

This topic relates to the cost of the implementation. Resource utilisation was reported by the interviews on theme 1: Factors hindering and fostering implementation. Nevertheless, not all interviews addressed this issue.

Main topics emergent from the interviews included:

- The need of more economic evaluation.
- Potential savings.
- An overall perception of lack of resources in mental health services.

Appendix A.4.1 contains more details on these findings from these interviews.

6.2.6 Budget Impact Analyses

The table below summarises the main sources of costs identified in the questionnaires preceding the interviews. Savings could not be quantified monetarily, as this was not included in the questionnaire.

Table 23: Budget impact analyses

	Region									
	Basque country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Investments in materials and ICT infrastructure (€) ***mean (SD)***	0	0	70.000 (49.497)	24.000 (0)	38.386 (43.254)	21500 (0)	50.000 (0)	440 (0)	833 (416)	15.836 (24.459)
Effort (time) needed for support staff to implement the services. (FTEs) ***mean (SD)***	0	0	0	1 (0)	5 (4)	3 (0)	2 (0)	1 (0)	2 (1)	1 (2)
Direct costs for one cCBT session (€) ***mean (SD)***	0	0	100 (0)	238 (18)	348 (0)	50 (0)	20 (0)	100 (0)	25 (0)	78 (110)
Direct costs for one ccVC session (€)*mean (SD)*	0	0	20 (0)	95 (7)	374 (0)	50 (0)	50 (0)	-	-	62 (110)

The views in terms of potential savings and a potential business case for initiating and retaining the interventions are evaluated with the information provided by the semi-structure interviews:

- Reasons for maintaining the services
  - Services could be efficient and would not need many additional resources.
  - Quality of the programme.
  - Services are effective and able to treat previously untreated patients.
- Issues to be addressed to maintain the service
  - Programmes need to prove their efficiency.
  - Future funding.
  - Lack of human and technological resources.

Appendix A.4.2 contains more details on these findings from these interviews.

6.2.7 Economic sustainability of services in routine practice

Economic sustainability of services in routine practice relates to two topics that were collected through interviews:

- Perspective on maintaining the services in place.

  Regarding the perspective on maintaining the services in place, two main reasons emerged during the interviews:
  - Reasons for maintaining the services.
  - Improvements needed to maintain the service.
- Business case.

  Regarding business case, some participants mentioned some economic reasons that could build a business case, while others doubted it could be built due to lack of data and uncertainty regarding funding.

Appendix A.4.3 contains more details on these findings from these interviews.

6.3 Summary

There is a wide variation in the responses regarding the economic aspects of the implementation of the services. Initial investment in material and ICT infrastructure varied from 0€ to 70,000€ in Wales / Basque Country and Aragón respectively. Most regions required support staff to implement the services, with a mean FTE of one person. Almost every region required initial training and supervision for staff, which in most cases involved technical aspects on how to use the platform, and on the therapeutic elements that are included in the platform. The direct cost for one session is not provided in a number of regions; among those that provided this information, the cost varied from 0€ to 348€ for cCBT. Most regions reported that the service is not reimbursed structurally, with the exception of two organisations: one in Galicia and one in Wales recording a public health system reimbursement, and Turkey recording “other” type of reimbursement modality.

Regarding qualitative analysis, the economic aspects of the implementation of cCBT were analysed taking into account the reports of interviews from Aragón, Badalona, Basque

Country, Estonia, Galicia, Piemonte, Treviso, Turkey and Wales. Data from Estonia and Galicia were not available for analysis.

Qualitative reports were highly variable in the quantity and quality of the information included. In this sense, the number of quotations may not be representative of the interest in the topics. Both direct quotations from the interviews, and summary statements, were used as primary data and are cited in this analysis.

7. Domain 6: Organisational aspects

7.1 Introduction

Domain 6 aims to provide insights into organisational aspects and perspectives in implementing and up-scaling the cCBT services in routine practice. Variables include quantitative information on the organisational profile (as part of domain 1) and estimates of case load, and qualitative information retrieved via focus group discussions and semi-structured interviews on issues of leadership engagement (in terms of commitment and implementation strategies), resources (time and savings), perceived factors for implementation success, and innovation climate (including information on knowledge and beliefs about the services, self-efficacy in using the services, individual state of change, identification with the organisation, support and awards, and relative priority). Findings are triangulated between quantitative data and qualitative data, and between healthcare professionals and organisational perspectives (organisations).

The analyses will enable drawing answers to the research questions:

- To identify barriers and facilitators that influence the implementation of cCBT to treat depression in routine practice.
- To assess the costs associated with implementing and large-scale uptake of cCBT to treat depression in routine practice.
- To assess the perceived satisfaction and perceived usability with cCBT.
- To assess the transferability of implementation and up-scaling of cCBT in routine practice in different care contexts.

Findings from domain 6, together with domains 1-5 and 7, provides insights into the acceptability and appropriateness from the perspective of healthcare professionals, and the sustainability of the services in routine practice as seen from the viewpoint of the organisations.

7.2 Results – Healthcare professionals

7.2.1 Productivity, caseload and resources

Regarding the demographic characteristics, 92 professionals have reported information, which represents 32,74% of the core dataset: 48,9% were GPs, 5,2% licensed psychologists, and 10,9% licensed psychiatrists. 91% of professionals had been trained in cCBT, and 63,3% had 10 or more years of field experience in the provision of healthcare. 19.8% of the professionals analysed had offered cCBT more than 20 times, 7,7% between 15 and 19 times, 14,3% between 10 and 15 times, and 29,7% between 5 and 10 times. This means that only 28,6% of the professionals have offered the treatment less than 5 times.

In terms of productivity, caseload and resources, it is evident that the professionals in most sites have a high number of consultations per week; the Basque Country and Galicia are the ones with the highest numbers (103 and 173 respectively), although Piemonte, Aragón, Treviso and Badalona show considerable values (40-84), Wales, Turkey and Estonia present significantly lower numbers of consultations. Concerning the availability of time to provide cCBT service, 27,3% of professionals believe that they have enough time to make the

service part of their daily care practice (25% agree, and 2.3% strongly agree); on the other hand, 43% of professionals disagree (38,60%) or strongly disagree (4,45%). Regarding efficiency, 69,4% of professionals questioned consider that patients are more efficiently treated thanks to the cCBT intervention compared to the usual care(61.2% agree, and 8.2% strongly agree).

Table 24: Productivity, caseload and resources

	Region									
	Basque Country	**Wales**	**Aragón**	**Badalona**	**Galicia**	**Piemonte**	**Treviso, Veneto**	**Turkey**	**Estonia**	**Total**
Sample: *n*	12	5	12	12	6	20	13	3	9	92
Clients per week: *mean (SD)*	103 (74)	16 (4)	84 (4)	40 (38)	173 (46)	84 (56)	73 (63)	7 (4)	10 (6)	72 (63)
Availability of time: there is enough time to make the service part of daily care practice: *categorical*										
I strongly disagree	0	0	1 (9,1%)	0	0	1 (5%)	1 (7,7%)	0	1 (11,1%)	4 (4,5%)
I disagree	5 (41,7%)	2 (40%)	3 (27,3%)	4 (44,4%)	5 (83,3%)	9 (45%)	1 (7,7%)	0	5 (55,6%)	34 (38,6%)
I neither disagree nor agree	2 (16,7%)	0	2 (18,2%)	5 (55,6%)	1 (16,7%)	4 (20%)	9 (69,2%)	3 (100%)	0	26 (29,5%)
I agree	4 (33,3%)	3 (60%)	5 (45,5%)	0	0	5 (25%)	2 (15,4%)	0	3 (33,3%)	22 (25%)
I strongly agree	1 (8,3%)	0	0	0	0	1 (5%)	0	0	0	2 (2,3%)
Efficiency: patients are treated more efficiently: *categorical*										
I strongly disagree	0	0	0	2 (22,2%)	0	0	0	0	0	2 (2,4%)
I disagree	0	2 (40%)	0	3 (33,3%)	0	0	0	0	0	5 (5,9%)
I neither disagree nor agree	2 (18,2%)	0	2 (16,7%)	1 (11,1%)	0	4 (20%)	4 (30,8%)	0	6 (66,7%)	19 (22,4%)
I agree	7 (63,6%)	3 (60%)	8 (66,7%)	3 (33,3%)	6 (100%)	13 (65%)	9 (69,2%)	0	3 (33,3%)	52 (61,2%)
I strongly agree	2 (18,2%)	0	2 (16,7%)	0	0	3 (15%)	0	0	0	7 (8,2%)

7.2.2 Leadership engagement

From the 281 professionals surveyed, 71,3% characterise the decision making in their organisation as a participatory process; on the other hand, 27,6% describe the process as a top-down approach. Most of the professionals (62.8%) feel that supervisors are highly engaged in promoting the use of cCBT services. 52,3% of professionals recognise that there is a visible and accessible strategy for the implementation of the service. However, a third of the professionals do not have a clear position on this matter.

With respect to the availability of qualified staff to provide cCBT services, most professionals (51.7%) agree with this statement. On the other hand, only 47,3% of the professionals think that there is an adequate number of resources available to provide the service.

Table 25: Leadership engagement

	Region									
	Basque Country	Wales	Aragón	Badalona	Galicia	Piemonte	Treviso, Veneto	Turkey	Estonia	Total
How would you characterize the decision making process in your Organisation? *categorical; mean (SD)*										
Top-down	6 (50%)	3 (60%)	1 (9,1%)	3 (27,3%)	5 (83,3%)	4 (20%)	2 (15,4%)	0	0	24 (27,6%)
Bottom-up	0	1 (20%)	0	0	0	0	0	0	0	1 (1,1%)
Participatory	6 (50%)	1 (20%)	10 (90,9%)	8 (72,7%)	1 (16,7%)	16 (80%)	11 (84,6%)	0	9 (100%)	62 (71,3%)
Leadership engagement (Supervisors are highly engaged in using the cCBT and/or ccVC services in the clinical practice): *categorical; mean (SD)*										
I strongly disagree	0	0	0	1 (9,1%)	0	0	0	0	0	1 (1,2%)
I disagree	1 (8,3%)	2 (40%)	1 (10%)	0 (0%)	1 (16,7%)	2 (10%)	2 (15,4%)	0 (0%)	6 (66,7%)	15 (17,4%)
I neither disagree nor agree	3 (25%)	0	4 (40%)	2 (18,2%)	0 (0%)	5 (25%)	2 (15,4%)	0	0	16 (18,6%)
I agree	5 (41,7%)	3 (60%)	3 (30%)	3 (27,3%)	1 (16,7%)	10 (50%)	8 (61,5%)	0	3 (33,3%)	36 (41,9%)
I strongly agree	3 (25%)	0	2 (20%)	5 (45,5%)	4 (66,7%)	3 (15%)	1 (7,7%)	0	0	18 (20,9%)
Implementation strategy (A visible and recognisable strategy is used for implementing the services) *categorical; mean (SD)*										
I strongly disagree	2 (16,7%)	0	0	0	0	0	0	0	0	2 (2,2%)
I disagree	4 (33,3%)	2 (40%)	1 (10%)	1 (8,3%)	1 (16,7%)	3 (15%)	1 (7,7%)	0	1 (11,1%)	14 (15,6%)
I neither disagree nor agree	2 (16,7%)	0 (0%)	4 (40%)	1 (8,3%)	0 (0%)	5 (25%)	8 (61,5%)	3 (100%)	4 (44,4%)	27 (30%)
I agree	2 (16,7%)	3 (60%)	5 (50%)	8 (66,7%)	5 (83,3%)	11 (55%)	4 (30,8%)	0 (0%)	4 (44,4%)	42 (46,7%)
I strongly agree	2 (16,7%)	0	0	2 (16,7%)	0	1 (5%)	0 (0%)	0 (0%)	0 (0%)	5 (5,6%)
Staff availability (Enough qualified staff is available to provide the services) *categorical; mean (SD)*										
I strongly disagree	1 (9,1%)	0	0	0	0	0	0	0	0	1 (1,1%)
I disagree	0	2 (40%)	0	0	1 (16,7%)	3 (15%)	2 (15,4%)	0	7 (77,8%)	15 (16,5%)
I neither disagree nor agree	2 (18,2%)	0	1 (8,3%)	2 (16,7%)	3 (50%)	7 (35%)	11 (84,6%)	0	2 (22,2%)	28 (30,8%)
I agree	5 (45,5%)	3 (60%)	7 (58,3%)	9 (75%)	2 (33,3%)	8 (40%)	0	0	0	34 (37,4%)
I strongly agree	3 (27,3%)	0	4 (33,3%)	1 (8,3%)	0 (0%)	2 (10%)	0	3 (100%)	0	13 (14,3%)

	Region									
	Basque Country	Wales	Aragón	Badalona	Galicia	Piemonte	Treviso, Veneto	Turkey	Estonia	Total
An adequate number of resources are made available to offer the services. *categorical; mean (SD)*										
I strongly disagree	1 (8,3%)	0	0	0	0	1 (5%)	0	0	1 (11,1%)	3 (3,3%)
I disagree	4 (33,3%)	2 (40%)	4 (36,4%)	1 (8,3%)	1 (16,7%)	5 (25%)	7 (53,8%)	0	2 (22,2%)	26 (28,6%)
I neither disagree nor agree	0	0	4 (36,4%)	2 (16,7%)	1 (16,7%)	6 (30%)	6 (46,2%)	0	0	19 (20,9%)
I agree	4 (33,3%)	3 (60%)	3 (27,3%)	8 (66,7%)	4 (66,7%)	7 (35%)	0	3 (100%)	6 (66,7%)	38 (41,8%)
I strongly agree	3 (25%)	0	0	1 (8,3%)	0	1 (5%)	0	0	0	5 (5,5%)

7.2.3 Innovation climate

It is observed that a large majority of the professionals surveyed are committed to the goals of the organisation they work for (85,1%) and are loyal to their organisation (82%). 71,2% of professionals feel confident in their ability to use the cCBT service in treating their patients, and 60% feel they are supported by their organisation. 61% of professionals feel that their organisation appreciates their work when applying and using new ways of working such as cCBT in their daily practice.

Although 66,7% of professionals feel enthusiastic about using the therapy in their day-to-day practice, only the 29,1% give a high priority to its implementation.

Table 26: Innovation climate

	Region									
	Basque Country	Wales	Aragón	Badalona	Galicia	Piemonte	Treviso, Veneto	Turkey	Estonia	Total
Commitment: I am committed to the goals of the organisation I work for. *categorical; mean (SD)**										
I strongly disagree	0	0	0	0	0	0	0	0	0	0
I disagree	0	0	0	0	0	1 (5,6%)	0	0	0	1 (1,1%)
I neither disagree nor agree	1 (8,3%)	1 (20%)	1 (9,1%)	1 (9,1%)	0	3 (16,7%)	2 (16,7%)	3 (100%)	0	12 (13,8%)
I agree	5 (41,7%)	2 (40%)	9 (81,8%)	6 (54,5%)	6 (100%)	14 (77,8%)	9 (75%)	0	7 (77,8%)	58 (66,7%)
I strongly agree	6 (50%)	2 (40%)	1 (9,1%)	4 (36,4%)	0	0	1 (8,3%)	0	2 (22,2%)	16 (18,4%)
Loyalty: I see myself as being loyal to the organisation I work for. *categorical; mean (SD)**										
I strongly disagree	0	0	0	0	0	0	0	0	0	0
I disagree	0	0	0	0	0	0	1 (8,3%)	0	0	1 (1,1%)
I neither disagree nor agree	2 (16,7%)	1 (20%)	0	1 (9,1%)	2 (33,3%)	2 (10,5%)	4 (33,3%)	3 (100%)	0	15 (16,9%)
I agree	7 (58,3%)	2 (40%)	9 (75%)	5 (45,5%)	4 (66,7%)	15 (78,9%)	7 (58,3%)	0	5 (55,6%)	54 (60,7%)
I strongly agree	3 (25%)	2 (40%)	3 (25%)	5 (45,5%)	0	2 (10,5%)	0	0	4 (44,4%)	19 (21,3%)

	Region									
	Basque Country	Wales	Aragón	Badalona	Galicia	Piemonte	Treviso, Veneto	Turkey	Estonia	Total
Confidence: I feel confident in my ability to use the cCBT and ccVC services in treating clients. ***categorical; mean (SD)****										
I strongly disagree	0	0	0	0	0	0	2 (16,7%)	0	1 (11,1%)	3 (3,4%)
I disagree	1 (8,3%)	1 (20%)	0	0	0	0	0	0	2 (22,2%)	4 (4,6%)
I neither disagree nor agree	0	0	2 (16,7%)	0	0	7 (36,8%)	5 (41,7%)	0	4 (44,4%)	18 (20,7%)
I agree	9 (75%)	3 (60%)	8 (66,7%)	6 (66,7%)	6 (100%)	10 (52,6%)	4 (33,3%)	0	1 (11,1%)	47 (54%)
I strongly agree	2 (16,7%)	1 (20%)	2 (16,7%)	3 (33,3%)	0	2 (10,5%)	1 (8,3%)	3 (100%)	1 (11,1%)	15 (17,2%)
State of change: On the continuum of change, where are you currently in using and offering cCBT and/or ccVC services regularly to your clients? ***categorical; mean (SD)****										
I am currently orienting myself in using cCBT or ccVC	0	0	0	0	0	3 (17,6%)	2 (15,4%)	0 (0%)	1 (11,1%)	6 (7,3%)
I have some insight and understand how I can use cCBT or ccVC	4 (33,3%)	1 (25%)	0	2 (22,2%)	0	5 (29,4%)	3 (23,1%)	3 (100%)	2 (22,2%)	20 (24,4%)
I have decided to change my routine and start using cCBT or ccVC	0	0	0	0	1 (16,7%)	2 (11,8%)	3 (23,1%)	0	0	6 (7,3%)
I am currently testing usage of cCBT or ccVC in my daily routine	6 (50%)	0 (0%)	8 (88,9%)	4 (44,4%)	5 (83,3%)	5 (29,4%)	3 (23,1%)	0	6 (66,7%)	37 (45,1%)
I have integrated cCBT or ccVC in my routine in treating clients	2 (16,7%)	3 (75%)	1 (11,1%)	3 (33,3%)	0	2 (11,8%)	2 (15,4%)	0	0	13 (15,9%)
Support: I feel supported by my organisation in applying and using new ways of working such as cCBT and/or ccVC in my daily practice. ***categorical; mean (SD)***										
I strongly disagree	0	0	0	0	0	0	0	0	0	0
I disagree	2 (16,7%)	0 (0%)	1 (9,1%)	0	0	1 (5%)	1 (8,3%)	3 (100%)	1 (11,1%)	9 (10,3%)
I neither disagree nor agree	5 (41,7%)	2 (40%)	1 (9,1%)	0	2 (33,3%)	7 (35%)	3 (25%)	0	0	20 (23%)
I agree	3 (25%)	2 (40%)	5 (45,5%)	9 (100%)	0 (0%)	10 (50%)	8 (66,7%)	0	8 (88,9%)	45 (51,7%)
I strongly agree	2 (16,7%)	1 (20%)	4 (36,4%)	0	4 (66,7%)	2 (10%)	0	0	0	13 (14,9%)

	Region									
	Basque Country	Wales	Aragón	Badalona	Galicia	Piemonte	Treviso, Veneto	Turkey	Estonia	Total
Recognition: I feel recognised by the organisation I work for when incorporating a new intervention in my daily practice. ***categorical***										
I strongly disagree	0	0	0	0	0	0	1 (7,7%)	0	0	1 (1,1%)
I disagree	4 (33,3%)	1 (20%)	1 (8,3%)	0	1 (16,7%)	3 (15%)	2 (15,4%)	3 (100%)	1 (11,1%)	16 (17,8%)
I neither disagree nor agree	4 (33,3%)	0	2 (16,7%)	4 (40%)	1 (16,7%)	5 (25%)	2 (15,4%)	0	1 (11,1%)	19 (21,1%)
I agree	2 (16,7%)	4 (80%)	8 (66,7%)	6 (60%)	3 (50%)	11 (55%)	8 (61,5%)	0	7 (77,8%)	49 (54,4%)
I strongly agree	2 (16,7%)	0 (0%)	1 (8,3%)	0	1 (16,7%)	1 (5%)	0	0	0	5 (5,6%)
Appreciation: I feel appreciated by the organisation I work for when incorporating a new intervention in my daily practice. ***categorical; mean (SD)***										
I strongly disagree	0	0	0	0	0	0	1 (7,7%)	0	0	1 (1,2%)
I disagree	3 (25%)	1 (20%)	1 (8,3%)	0	1 (16,7%)	2 (10%)	2 (15,4%)	0	0	10 (11,8%)
I neither disagree nor agree	4 (33,3%)	0	2 (16,7%)	3 (60%)	1 (16,7%)	5 (25%)	3 (23,1%)	3 (100%)	1 (11,1%)	22 (25,9%)
I agree	2 (16,7%)	3 (60%)	8 (66,7%)	1 (20%)	1 (16,7%)	12 (60%)	7 (53,8%)	0	7 (77,8%)	41 (48,2%)
I strongly agree	3 (25%)	1 (20%)	1 (8,3%)	1 (20%)	3 (50%)	1 (5%)	0	0	1 (11,1%)	11 (12,9%)
Enthusiasm: I am enthusiastic about using cCBT in treating clients. ***categorical; mean (SD)***										
I strongly disagree	0	0	0	0	0	0	0	0	0	0
I disagree	2 (16,7%)	2 (40%)	0 (0%)	1 (11,1%)	0 (0%)	1 (5,3%)	0 (0%)	0	1 (11,1%)	7 (8%)
I neither disagree nor agree	5 (41,7%)	0	2 (18,2%)	0	1 (16,7%)	8 (42,1%)	6 (46,2%)	0	0 (0%)	22 (25,3%)
I agree	2 (16,7%)	3 (60%)	7 (63,6%)	8 (88,9%)	5 (83,3%)	9 (47,4%)	6 (46,2%)	0	8 (88,9%)	48 (55,2%)
I strongly agree	3 (25%)	0	2 (18,2%)	0 (0%)	0 (0%)	1 (5,3%)	1 (7,7%)	3 (100%)	0	10 (11,5%)
Priority: I give high priority to implementing the cCBT and/or ccVC services in my daily work. ***categorical; mean (SD)***										
I strongly disagree	0	1 (20%)	0	0	0	1 (5,3%)	2 (15,4%)	0	0	4 (4,7%)
I disagree	6 (50%)	1 (20%)	1 (10%)	0	0	6 (31,6%)	1 (7,7%)	0	1 (11,1%)	16 (18,6%)
I neither disagree nor agree	1 (8,3%)	1 (20%)	7 (70%)	4 (44,4%)	6 (100%)	8 (42,1%)	8 (61,5%)	3 (100%)	3 (33,3%)	41 (47,7%)
I agree	4 (33,3%)	2 (40%)	2 (20%)	5 (55,6%)	0	4 (21,1%)	2 (15,4%)	0	5 (55,6%)	24 (27,9%)
I strongly agree	1 (8,3%)	0	0	0	0	0	0	0	0	1 (1,2%)

7.2.4 Perspective on implementation (professional)

When asked about experience with and perspectives on the concrete implementation of the various cCBT services in practice, participants of the focus groups discussed various

factors that are to be taken into account. Topics discussed included factors related to access, referral, and the actual provision of the services. Also, aspects of the technology applied and the evidence base of the cCBT service emerged from the focus groups as aspects carrying the potential to either facilitate or hamper implementation processes. Information about, and training and education in, the service and therapeutic principles were noted as relevant, as well as collaboration and support by colleagues and others. In addition, the factors related to the process of implementation were discussed.

- **Access, referral, and treatment processes:** First of all, healthcare professionals struggle with a lack of time and resources. Professionals asked for the tool to be easily accessible at all times, and underlined the importance of face-to-face support.
- **Technology:** Some professionals mentioned that they worry about being slowly replaced by technology. However, others reported being already familiar with technology in their workplace, and welcomed cCBT as a new tool.
- **Evidence base and accreditation:** Professionals requested more scientific evidence regarding effectiveness in symptom reduction and cost-effectiveness. Evidence of how to present the tool to patients was also requested.
- **Information, training and education:** Healthcare professionals first often need to be trained, since not everyone has knowledge of CBT principles.
- **Collaboration and support:** Professionals are in need of technical support, technical equipment, previous training, and more healthcare workers to perform additional follow-ups.
- **Rationale and the implementation process:** Government regulations are needed that support the implementation process. Local institutions might prove valuable in promoting the tool.

Appendix A.5.1 contains more details on these findings from these focus groups.

7.3 Results – healthcare organisations

7.3.1 Leadership engagement

All trial sites held semi-structured interviews with representatives of the organisations that implemented the cCBT services in routine practice. The representatives that were interviewed had a certain level of decision making power in the organisation and/or a leading role in the implementation processes involved.

- **Commitment:** It seems that the majority were very committed and enthusiastic about the project, despite certain problems involving tools and lack of resources.
- **Decision making processes and rationale:** The decision making process regarding the adoption of the tool varied according to the study site. Certain organisations implemented the project based on the decision of the management, while others adopted a shared decision making process, and sought the professionals' approval.
- **Implementation strategies:** Various implementation strategies were mentioned by the different sites. Barriers hindering implementation were mentioned as well.

Appendix A.5.2 contains more details on these findings from these interviews

7.3.2 Perspective on implementation

Participants in the semi-structured interviews identified various factors that should be taken into account from an organisational view point when implementing cCBT in routine practice:

- **Needs and perspectives:** Different sites reported distinct needs and perspectives. This included various facilitators and barriers regarding the implementation of the programme.
- **Implementation success:** Mainly reasons that might have hindered the success of the tool were reported at the various study sites, such as the application not working, insufficient technical assistance, not enough professionals.
- **Strategy, policy and priorities:** Different obstacles were mentioned regarding policy details in the various countries included. The inclusion of the tool in depression guidelines was also mentioned.
- **Commitment:** Professionals who perceive themselves as part of the project seem to work more eagerly towards the goal of the project. The involvement of stakeholders, directors and management staff is also very important to achieve implementation goals.
- **Guidelines and professional development:** Various incentives to support personal and institutional development were offered by MasterMind.
- **Concrete activities:** Certain concrete activities were mentioned to improve the service provided, such as incentives, coordinated work, and developing specific programmes.
- **Technology:** The use of technology eases work and ideally saves time. Challenges include fitting the new service into routine care.
- **Resources:** Resources are sparse, but needed to improve implementation. These resources include: time, human resources, and technological resources. In order to save resources via cCBT, investments first need to be made to create an infrastructure. Then at a later stage when the infrastructure exists, the organisation can expect to save resources via e.g. fewer appointments for GPs and community psychiatric nurses.

Appendix A.5.3 contains more details the factors hindering and fostering implementation from an organisational view point.

7.4 Summary

Data from both healthcare professionals and organisations' representatives has been gathered, regarding the organisational aspects and the implementation process. A qualitative (semi-structured interviews and focus group) and a quantitative analysis approach have been carried out. Data has been analysed separately in the results section above.

Healthcare professionals

In total, 92 professionals have reported information, most of them represented by GPs. The information was gathered in focus groups. 27,3% of them believe that they have enough

time to make their service part of daily care practice. The number does not seem to be very promising, however it is necessary to take into account that the professionals of most sites have a very high number of consultations per week (103 Basque Country, 173 Galicia), making the uptake of new care processes more complex.

Most of the professionals (62.8%) feel that supervisors are highly engaged in promoting the use the cCBT services. 52,3% of professionals recognise that there is a visible and accessible strategy for the implementation of the service. The majority of them feel confident in their ability to use the service in treating patients; most of them feel supported by their organisation. Although 66,7% of professionals feel enthusiastic about using the therapy in their day to day practice, only the 29,1% gives high priority to its implementation.

When asked about experience with and perspectives on the concrete implementation of the various services in practice, focus groups participants discussed various factors that need to be taken into account. Topics discussed included factors related to access, referral, and the actual provision of the services. Healthcare professionals struggle with a lack of time and resources. Professionals asked for the tool to be easily accessible at all times, and underlined the importance of face-to-face support.

Healthcare organisations

A series of semi-structured interviews were carried out with organisational representatives who had a certain level of decision making power in the organisation and/or a leading role in the implementation processes involved. Despite the problems involving tools, lack of time and resources, the majority were very committed and enthusiastic about the project.

The main reasons that might have hindered the success of the tool were reported at the various study sites, such as the application not working, insufficient technical assistance, not enough professionals. Professionals who perceive themselves as part of the project seem to work more eagerly to the goal of the project. The involvement of stakeholders, director and management staff is also mentioned as a key to achieve implementation goals.

8. Domain 7: Socio-cultural, ethical and legal aspects

Domain 7 is concerned with the broader context of the implementation. In MasterMind, it is concerned with one issue: public image and benchmarking. Although more topics were identified in the design phase to discuss with both professionals in the focus groups and with organisations' representatives in the interviews, none of these raised the issue of professional liability when delivering computerised mental health services, nor on using ICT for benchmarking purposes. These topics thus seem not to be important at this moment. Only one interviewee replied in relation to guidelines that it would be beneficial to include cCBT services in clinical guidelines for depression, as was being done in other countries such as the UK and the Netherlands.

Concerning the topic of public image, Interviewees clearly indicated that it is expected that the MasterMind services contribute to a positive image of psychiatry in general, and the service provider specifically. It was stated that organisations aim to showcase the achievements of MasterMind to stimulate further deployment and up-scaling in their respective regions, and possibly even beyond.

Appendix A.6 contains more details on the findings on the factors described above.

9. Transferability assessment

In the MasterMind project, a large amount of data and knowledge has been collected, and is made available for other European regions in their work with implementation and up-scaling of eMental health services. As part of the reporting of the results, the MasterMind project provides two approaches to transferability assessment:

- The first is the transfer of knowledge of the implementation process and organisation of services. This information is primarily made available in the evaluation of domain 6 (Organisation) in the MAST model, the tools and process applied in the Market place concept described in deliverable D5.6, and in the deployment plans in deliverable D3.6. Process, experiences, and methods from this work have been validated by the Advisory Boards and external experts, and can be transferred by other regions.
- The second approach to transferability is to look at the specific outcomes of the domains in the MAST model based on the demographic characteristics of a specific region wanting to transfer the service.

It is possible to assess the transferability of results, i.e. determining whether particular demographics, clinical, organisational or economic issues have affected the outcome, and to what extent the results can be transferred to e.g. a larger patient group or other organisations. This could include an assessment of:

- Comparison of demographic characteristics with national data.
- Widening of inclusion criteria and the inclusion of other types of patients.
- What would it take to scale up the intervention to other areas?

This should be based on the MAST model, and include the assessment of scalability and generalisability of the domains in the MAST model.

This section has not been completed within the final report due to variation in data from each individual site. Instead, it has been decided that each individual site will perform transferability assessment and to scale up the results where appropriate.

10. Problems encountered and lessons learned

This chapter lists some of the preliminary lessons learned and recommendations from the pilots of the 2nd wave.

10.1 Basque Country

What are the main lessons learned regarding implementation, and organisation of the pilot (including facilitators and barriers for implementation)?

During the implementation of the cCBT service, we have noted that having a field trial coordinator responsible for the detection of incidents, application of corrective actions to ensure that the validated protocol is carried out, technical and clinical support to professionals, and coordination and monitoring of the whole process is crucial. The role of this actor appears to be a facilitator, since he/she provides rapid and appropriate solutions to issues that arise during the deployment of the service.

In addition to the field trial coordinator, a well-coordinated and accessible technical support team is very relevant in order to ensure that problems related to the online application can be solved properly and quickly. If the technical support is decisive, healthcare professionals feel more confident with the online treatment, and, as a consequence, they are more motivated and committed. Similarly, the patients' treatment adherence is significantly higher if the application responds correctly, meaning that they are not stopped in any given session during the therapy.

Another facilitator that needs to be highlighted is the commitment of the managerial teams of the healthcare organisations involved, which boosts the implementation process thanks to their decision-making capacity. These managers not only allow professionals to be excused from some daily tasks to attend training sessions, but also reward them in different non-financial ways (participation certificate, attendance to conferences and meetings, etc.).

Healthcare professionals who have similar profile of the attendees have led the training sessions, so this creates an empathy atmosphere favouring the positive impact of the session: professionals feel more comfortable and receptive if the trainers are their peers rather than their managers or supervisors.

Regarding barriers, we have to remark how detrimental incidents with the application have been to the success of service deployment. The online platform we have used was an existing one, but several improvements were made to enrich its functionality. The use of the newly developed functions resulted in several technical issues during the first few months after the inclusion of patients. These problems blocked both professionals and patients in the progress and follow-up of the therapy, respectively, which caused demotivation and drop-outs. The acceptance of the cCBT became lower than expected due to technical issues; professionals were not completely convinced of the benefit of the online therapy.

Additionally, the period between the training sessions (Nov 2015) and access to the final version of the online application (due to technical problems) and subsequent inclusion of patients (Feb 2016) was too long, so that many professionals who were excited about the therapy lost interest.

Finally, it is worth commenting that the work overload of those GPs who recruited and monitored patients was high. The first visit of the patient was especially long, three times longer than a routine consultation, since the project was explained, the application shown and the informed consent presented. This first consultation generated pressure on the professionals' schedule.

Engaging healthcare professionals and providers, setting up the technical services, patient recruitment, organisational issues and finance

As mentioned before, the initial engagement of the healthcare professionals, both specialists and GPs, was extremely high. A significant number of professionals were excited about providing the online therapy. This remarkable attitude was mainly due to: i) healthcare professionals recognised the need to empower GPs by providing tools (cCBT) to treat patients with mild or moderate depression; ii) specialists demanded more time to focus on severe cases, and consequently the urgency to refer mild/moderate depression patients to primary care; and iii) enhancing patients' self-management capacity and treatment adherence by offering an attractive, accessible and user friendly online tool to tackle their disease.

Besides that, managers of the healthcare organisations supported the implementation of the cCBT service, which reflected the commitment of the organisation and its interest, avoiding the feeling of a satellite project not aligned with the corporative strategy.

In summary, both bottom-up and top-down initiatives were completely in line, which created a perfect ground for the deployment.

However all this initial engagement slowly weakened due to the technical issues of the online platform. As described before, the existing platform was upgraded in order to provide new functionalities. In order to meet MasterMind project deadlines, professionals started using the application before it was completely tested and fine-tuned, and several incidents occurred regularly. This situation pushed professionals not to prescribe the cCBT because they were worried about providing a defective service to their patients, especially taking into account the profile of these types of patients.

On the other hand, patients who started the treatment abandoned the therapy once the problems started, though they feet motivated at the beginning.

The coordination between the technical staff from Osakidetza and the developers of the online application was not effective at the beginning, so the problems were not solved as fast as expected. This lack contributed to the demotivation of both professionals and patients.

Today, this situation has changed dramatically: technical incidents are anecdotal, and the problem solving capacity is much greater. Therefore, a re-engagement strategy has been launched to push professionals to recruit more patients, and to motivate those patients who stopped the online therapy to restart.

A significant number of the patients with depression of the Basque Country who were offered the cCBT were elderly people with no technological skills. Although these patients accepted to follow the online therapy, they also wanted to continue with the routine visits (face-to-face), which resulted in a work overload for GPs, so that blended therapy (cCBt plus face-to-face visits) was not possible.

What main problems did you experience, and how did you solve them?

The poor performance on the online platform was the main barrier for the successful deployment of the cCBT service.

Fitting all the pieces together (roles of all actors involved) has been complex and time-consuming. The coordination team of the project (Kronikgune and the field trial coordinator) made huge efforts to solve these issues and ease the workflow.

The deployment plan of the Basque Country, if the cCBT demonstrates its benefit to some extent, includes the incorporation of the functionalities of the online application into the Personal Health Folder. This approach will facilitate problem solving, since the technical staff from Osakidetza will be solely responsible for the platform.

What are the experiences of the healthcare workers?

Those GPs that overcame the technical problems have recruited more patients than expected, since they believe in the benefit of the online therapy. Although they have recommended some changes in terms of organisational workflows, they are convinced of the relevance of the treatment.

What are the experiences of the patients?

Those patients who finished the cCBT agreed on the positive impact of the therapy. In general, these patients were highly committed to the treatment, and presented sufficient skills to manage the technology. In other cases, the problems with the platform have caused some anxiety in some patients.

The cCBT solution of the Basque Country forces patients to complete (questionnaires, exercise etc.) one session before accessing the next one. This has caused a feeling of frustration and demotivation to those patients who were curious, or who had difficulties completing the exercises.

What recommendations do you have for others to start ICT based services in this area?

The technological platform has to be ready to be used in the real setting, meaning that technical issues have to be completely resolved. If any problem does occur, a responsive technical support team has to be accessible to solve them rapidly and effectively.

The training of professionals and patients is of great relevance, it becomes a key point in terms of success. Regular training sessions have to be organised for professionals, at least at the beginning, so they feel confident with the online therapy. These well trained professionals will be able to support the patients at any point in the therapy.

What are your comments on your numbers of patients / participants reached in MasterMind and completed treatment?

As above, the inclusion of the patients in the cCBT service has been lower than expected, due mainly to demotivation of professionals due to technical problems with the online platform. On the other hand, lots of patients abandoned the therapy because:

i) lack of support from their GP, since he/she was demotivated;
ii) constant technical problems dissuaded patients to continue, and

iii) this type of patients often feel they are recovered (symptoms have ameliorated), and do not see the point of continuing the treatment.

10.2 Wales

What are the main lessons learned regarding implementation, and organisation of the pilot (including facilitators and barriers for implementation)?

- **Engaging Health care professionals and providers:** The variation in willingness to engage within the healthcare professionals and the different teams has been surprising. There was a reluctance from some to work with platforms that they were not familiar with, and some distrust of CBT as a therapy as a whole, not just computerised CBT.
- **Setting up the technical services:** One of our main issues was relating to access to broadband or super-fast broadband; this caused issues for patients, in some areas, in accessing the programme. Also, the cCBT platform we opted for (Beating the Blues) is not currently compatible with iPads, tablets & smart phones; it therefore restricted patients' access to the programme. For those who did not have access to a computer or laptop, the option was given to use a community site; however, not all patients felt comfortable with this option.
- **Patient recruitment:** There are a considerable number of patients who feel uncomfortable talking about problems, and so do not want face-to-face therapy; therefore offering a computerised therapy is a welcome option.
- **Organisational issues:** On the whole, our organisation has been very positive and engaged in the implementation of cCBT, especially as it can have a positive impact on the achievement of our targets and objectives set by the Welsh Government with regards to waiting times, etc.
- **Finance:** This has been quite a complex issue for us, in that it has been difficult to predict spend, and a lot of work and detail goes into the collection of data with regards to staff time.

What main problems did you experience, and how did you solve them?

Our cCBT platform Beating the Blues does not currently work on iPads, tablets or Smartphones; we therefore set up community sites, i.e. libraries, where patients could access a laptop / computer and printer free of charge in order to complete the programme. Equipment such as headphones and privacy screens were provided in the community sites to ensure patients had adequate privacy to complete the programme at ease.

We had a high number of drop outs which caused the healthcare professionals to lose faith in the service. On reflection, and after receiving patient feedback, it was learned that it was not necessarily that patients were dropping out, but that they felt better after completing 4-5 sessions, so did not feel the need the continue to session 8.

We had a few issues with access to broadband which is a Powys-wide issue. This is not an issue that can be resolved by PtHB, but it is hoped that all of Powys will have super-fast broadband by the end of 2017.

What are the experiences of the healthcare workers?

There were mixed reviews within our healthcare professionals; many felt that this was an additional service / therapy that could be offered to patients, whilst others were more inclined to continue with offering only face-to-face therapies, rather than promoting the cCBT option. Some healthcare professionals had little faith in this mode of delivery, even though there is evidence to show its effectiveness. Some healthcare professionals felt threatened that this sort of therapy could reduce their workload, and therefore threaten their jobs.

What are the experiences of the patients?

Some patients preferred to continue with or opt for face-to-face therapy; it was a felt that there was a large element of self-motivation required to complete online sessions. However, it was welcomed by and beneficial to those patients who feel too uncomfortable to talk about their issues face-to-face. Some found the computerised platform dated and impersonal, whilst others reported that they found it a flexible form of therapy with relevant and helpful techniques, and information on how to use them, as well as being easily and readily accessible.

What recommendations do you have for others to start ICT based services in this area?

- Consider software carefully, ensure the software providers have development plans in place to stay on trend with new technologies. Ensure the software can be accessed and is compatible with all devices on standard computers, not just on specialist programs i.e. specific versions of Flash?
- Ensure professionals have a good understanding of the technology before implementing it in order for them to be able to assist / support patients.
- Research what technological issues could be a risk to your service, which are out of your control, i.e. broadband access in your area.
- Pilot the service within one team first, make them the pioneers of the service, and get good evidence of benefits before rolling out further.
- Invest sufficient time and effort into giving information to the necessary departments and injecting enthusiasm for the service

What are your comments on your numbers of patients / participants reached in MasterMind and completed treatment?

We did not have as many patient referrals as we would have liked, but our service was still deemed successful. Our number of completed patients is low in comparison to the number of patients referred.

Currently, the way our statistics are reported, the service is only deemed to be a success if the patient completes all eight sessions of the programme; it does not take into consideration those patients that feel better after session 5, so do not feel the need to continue to session 8. It is felt that if a patient does not complete all eight sessions, but ends the programme as they feels better, then this should also be considered as a completion and/or success.

It is felt that we may have achieved our patient target if we had engaged with our GPs sooner; we went down the incorrect route of engaging with the LPMHSS teams first.

10.3 Aragón

What main problems did you experience, and how did you solve them?

Problem	Proposed solution(s)	Specific action(s)
Recruitment of professionals	Highlight the added value for them and for the patients: better quality of the service; new, up to date and objective information from patients; the patients receive support between consultations.	Presentations in the regular GPs and clinicians meetings with specific materials (leaflets and video).
Low patient adherence	To increase the self-confidence of the patient in the use of technology. Transition from an unguided treatment to a blended treatment.	Inclusion of an initial training session with a nurse. Periodic telephone follow-up performed by a nurse.

What are the experiences of the healthcare workers?

The initial attitude towards the cCBT service can be classified into two very different groups: professionals highly interested in innovation and new services, and professionals who show reluctance to change due to different reasons: lack of time; fear of technology; lack of motivation because of previous experiences.

Each professional profile that has participated in the project plays a different role and has a different perspective:

- Recruitment of patients has been performed by psychiatrist, psychologists, and GPs.
  - Psychologists have recruited patients into ccBT, and have dealt with any specific severe problems (alarms). They consider the ccBT tool as a very useful complement to their treatment for patients, but they do not see the service as one solution that can replace face-to-face treatment.
  - The GPs have a positive opinion about ccBT as an effective intervention for a specific group of patients.
- Training and generic follow-up of patients in ccBT have been performed by (mental health and specifically trained) nurses. They consider that these services increase the quality of the service provided to patients, as they give the patient the idea of continuous follow-up and support from the healthcare organisations. Nurses have played a very important role in the treatment, and this change of roles has been well accepted by them, even though they admit that it implies more workload, because it gives them a more active role in the patient treatment.
- Professionals from the technical contact centre consider that recruiters must be very aware that only patients with enough digital skills should be included in the cCBT services, because otherwise their request for help & support could not be handled with the level of dedication required; this might lead to an overload of the technical resources, and also to patient frustration.

What are the experiences of the patients?

Most patients who have not finished their treatment have claimed that they wanted to follow it because it is effective for them, but they do not have the time, technological infrastructure or other specific situations (holidays, lack of internet access, problems with

the computer) that, once solved, would allow them to continue. The healthcare professionals believe that most of them will not continue, but they do not want to accept it, or they feel guilty and they do not want to report it.

Only a few patients have clearly specified that they were not going to continue the treatment for various reasons, mainly lack of time.

The results from the questionnaires show that patients who ended treatment are clearly satisfied with the service received. We have also received several positive inputs (comments, emails) from patients showing their gratitude and their support for the treatment.

What recommendations do you have for others to start ICT based services in this area?

There must be technical support available for professionals and users. There must be a previous evaluation of the level of digital literacy and aptitude of the patients, so as to avoid a high workload fo the technical support contact centre, and frustration for patients.

It is mandatory to make a specific effort to improve the usability of the tools for both professionals and patients. The maintenance, redesign and continuous improvement of the interface must be taken into account.

What are your comments on your numbers of patients / participants reached in MasterMind and completed treatment?

Aragón has reached its recruitment target. The initial design of the cCBT protocol (based on self-guided treatment) had bad results, so a blended protocol was designed, especially to meet the deadlines and the recruitment target of the project.

This redesign led to much better results, but some of the resources invested (training session with a nurse and telephone follow up) should be reoriented for routine practice, otherwise they might lead to an unsustainable service in the long term.

The figures about performance in the Aragón pilot show that the holiday periods have a clear impact on the adherence to treatment. Vacations cause treatment discontinuation, and finally lead to drop-out. This might be due to the positive effect of the holidays on patients, but it might also be caused by the change in the patient's daily habits that might hinder the continuation of treatment. Recruitment should be made during those periods in which it is not expected that any external circumstance might interfere with the patient's personal situation and daily habits.

10.4 Badalona

What are the main lessons learned regarding implementation, and organisation of the pilot (including facilitators and barriers for implementation)?

- **Engaging healthcare professionals and providers**

One of the most important facilitators has been that the organisation and especially the medical management are convinced about the benefits of Get Over your Depression and the video conference for collaborative care and treatment of depression in order to optimise care for patients with depression.

The training and the dissemination materials to engage our healthcare professionals has also been a key factor for success within the project: having the recruiters on board. We did an initial and strong campaign called "recruiting the recruiter", and we did a lot of dissemination activities in different phases of the pilot. In addition, most of our professionals had experience with cCBT treatment, because BSA previously implemented Caring me, another cCBT treatment to care for our users with depression.

Of course, there was a group of professionals who needed extra information and engagement to move from something to what they were used to, to something new. This process took a lot of effort.

- **Setting up the technical services**

The problems to extract data from our EHR, with our servers and some technical issues, have created a barrier or difficulty in implementation, especially our cCBT tool. To solve it, our ICT team had to make an important effort. In addition, the internal management team did some corrective actions after studying all the incidents. Examples:

  - Users' email (Hotmail) made recruitment difficult. We detected some cases in which users had not received the user and password because the first email was sent to Spam. For this reason, we carried out a specific "campaign" with all the steps that users needed to check if they did not receive the first email.

- **Patient recruitment**

Recruitment is influenced by the seasonal incidence of depression. Previous professional engagement is another factor to take into account. There were several differences between the different Primary Care Centres that BSA manages.

- **Organisational issues**

In BSA, the most important advantage for the implementation of collaborative care was that it was put in place some years ago. But, in fact, the experience with MasterMind has opened a new work group to improve the videoconference connection in order to do multicenter videoconferences. In addition, BSA had experience with cCBT treatments because of a previous programme called Caring me.

- **Finance**

During the pilot, the facilitator was that Get Over your Depression could be used free of charge within BSA. On the other hand, the collaborative care system used within the pilot was a free tool. The investment to take into account, especially after the pilot, will be the infrastructure and personal required.

What main problems did you experience, and how did you solve them?

We lost engagement (from professionals and users) with some technical problems with the cCBT tool; also, there was pressure of time in our healthcare system and, in some cases, deep-rooted beliefs that were difficult to change. To solve these issues, we activated a contingency plan, with the staff required to solve the problems, and encourage professionals to continue with Get Over your Depression. Now they have shown that they are quite satisfied with the potential of the service. Most of them thought and think that we should continue working on these projects to make them more compatible with

everyday tasks; they realised that they have to make an effort to get out of the comfort zone in order not to lag behind regarding the news things that emerge.

As previously mentioned, another problem was that, at some times, ours GPs were overloaded. Therefore some nurses were enrolled in order to help with the intervention (Get Over your depression), and we allocated financial resources for those who recruited patients; the Primary Care Centre is in charge of administrating this, but it only can be used for mentoring purposes.

What are the experiences of the healthcare workers?

In general, most of them trust in the potential capacity of online therapy; most of them are convinced that cCBT could be adequate for the treatment of patients with depression as an additional source of support, as long as it meets the clinical guidelines for the treatment of depression. Also it is considered as a tool to support patients in their recovery process, but not always as essential / compulsory. However, this depends on the characteristics of the patient; therefore we should respect this heterogeneity. They would need support during the initial stages of the online treatment. They also think that support from health professionals is very important, and they need to be well-informed to transmit this information to patients.

What are the experiences of the patients?

The videos, the time and the follow up from their professionals are the most important points for the users. The platform was developed through an iterative co-design process involving user interface designers and end users. As a result, and the assessment conducted on the usability of the platform, it has been demonstrated that patients find it very easy to use. In addition, patients are actively involved in the treatment of his/her pathology, and they show their satisfaction when they progress in the treatment.

On the other hand, we had to fight with some technical issues that damaged their trust, but we were able to overcome this with corrective actions, as noted above. Finally, they have not identified any confidentiality issues. No cases have emerged of users worried about the fact that others may have access to their personal information and discover about their condition.

What recommendations do you have for others to start ICT based services in this area?

- It’s important to visualise (from a professional's and user’s perspective) the benefits of this kind of service. Usability would be enhanced with scientific evidence for the clinical efficacy of the online treatment.
- A key factor is the motivation, not only at individual level, but also for groups, for professionals and patients. For those professionals who have to change their “mind”, it is important they do not feel alone in the change process; that is why the group training sessions can be useful. On the other hand, there must be an incentive during the early stages of their change process for both professionals and also users.
- There should be contingency plans to avoid organisational or technical problems, or issues that can arise during implementation. For example, they should foresee some barriers: lack of ICT literacy on the patient's side, which may cause a lot of drop outs in the recruitment process; lack of access to technology and internet, etc. In fact, an important inclusion criterion is the minimum capacity to manage with ICT solutions.

- They should have a contact centre or a clear system to manage all the incidents with all the stakeholders involved. The channels (emails, phones…), the kind of answer, the time for answering, etc., are also important.

What are your comments on your numbers of patients / participants reached in MasterMind and completed treatment?

The results are provisional, as professionals will continue using Get Over your Depression until the end of the year. After that, and with the results of the study, BSA will adapt the platform to improve it, but it will become a new tool within the health and social services portfolio.

10.5 Galicia

What are the main lessons learned regarding implementation, and organisation of the pilot (including facilitators and barriers for implementation)?

We regard the following as the most relevant aspects for a proper implementation of the project:

- Making a firm commitment on the part of the organisation in order to implement MasterMind.
- The continuity of the team in charge, as well as having well-defined responsibilities throughout the whole study.
- A fluent, fast coordination between collaborators and the organisation so as to be able to give an efficient response to the feedback provided by those participating in the project.

The facilitators for its implementation in our Autonomous Community include the pre-existence of such computer tools in the daily practice of professionals as the computerised medical record, where the MasterMind project has been included.

And among the most remarkable barriers that have hampered its implementation are the lack of time and the work overload borne by professionals and well as the slowness of the technical support.

Engaging Health care professionals and providers

Following an initial general training on computer-based behavioural cognitive interventions, the professionals participating in this project have required individualised training and support via email or telephone from the research team on technical issues.

Individual support to professionals has been essential for their involvement in the project.

Setting up the technical services

In our region, the decision to introduce the MasterMind project in the new computerised medical record has been a commitment to the future, but it has brought about the usual difficulties resulting from project overlap and coordination.

Patient recruitment

Experience so far on this project has provided us with information on the profile of the patients that most benefit from these interventions. Patients with mild or asymptomatic depressive disorder are those who benefit most from these programmes as preventive interventions.

Organisational issues

The proper coordination between the different participants in the project, and including these programmes in the regular services portfolio offered by professionals, are indispensable for the successful implementation of the project.

Financing

In Galicia, financing is public, and these programmes are part of the regular mental health care, so they do not entail additional costs to patients.

What main problems did you experience, and how did you solve them?

The main problem is the workload of GPs, which makes it difficult to organise the project more effectively. We have tried to solve this problem by asking the organisation for more time and means to implement the new tools.

We have had difficulties in the means used to inform stakeholders; information via email in some cases has not been useful. We have changed the procedure, and we now give the information in person; the result has been that professionals have considered this information more effective.

Prior distrust of new technologies due to bad experiences (bad connection, delays...) has been solved by checking the proper functioning of the new tool.

GPs describe the experience as positive, as a closer collaboration with specialists is a frequent demand from GPs.

In those centres where face-to-face consultation (GP - psychiatrist) had been established, a greater reluctance for new technologies was found, despite the fact that they allow an increase in the frequency of the sessions and facilitate access to more professionals.

What are the experiences of the patients?

With the data available so far, the impression patients have regarding the cCBT is that it is a useful programme that supplements their regular therapy, but they need more time and greater supervision.

What recommendations do you have for others starting ICT based services in this area?

The main recommendation is to have a detailed knowledge of the daily practice of professionals, so as to be able to adapt the new technologies to their real needs and implement a good coordination to effectively respond to their suggestions or the difficulties they encounter.

What are your comments on the numbers of patients / participants that have been reached by MasterMind and have completed treatment?

The number of patients who completed the full course is the 21%; this is in line with similar projects. We believe that patients need more time to complete the programme, and greater supervision to motivate them due to the characteristics of depressive symptomatology.

10.6 Piemonte

Engaging Healthcare professionals and providers, setting up the technical services, patient recruitment, organisational issues and finance

Regarding the cCBT service, realised in our unit (ASLTO3) with the tool IFightDepression© licensed by EAAD, in our experience various factors should be considered carefully:

- The clinical target of these services, i.e. patients affected by mild to moderate depression, typically refer primarily to GPs. Thus the first important thing is to foster the collaboration with a larger number of GPs and try to motivate them.
- In addition, it is relevant to involve a wider spectrum of health professionals in our unit: not only psychiatrists, psychologists and GPs, but also psychiatric nurses and professional educators.
- The role of the two dedicated figures of the MasterMind team was crucial to health professionals who can ask for support constantly.

Regarding the economic and financial aspects, in Italy the healthcare services provided by the Local Health Authorities receive a partial or total reimbursement from the regional government following the guidelines and rules established by the NHS. The main criteria of reimbursement of healthcare is represented by providing to patients public healthcare services included in the LEA[20] which are the common and official basic level of assistance for covering health needs of the population. Telemedicine services are basically not included in LEA, so they do not receive any form of reimbursement, except for several specialist disciplines[21] which do not include psychiatry.

On this basis, as there is not a fixed reimbursement model at national level the tele psychiatry tools can be maintained only through access to external resources, such as innovation funding by regional and EU programmes, support of local foundation, and continuing with the effort of the health professionals already involved in MasterMind to be considered subject to further availability of local resources.

What main problems did you experience, and how did you solve them?

- **Patients' recruitment, and their degree of acceptance of the innovative cCBT service:** we made a major activity of dissemination of the project, to attract both doctors and patients, and show the feasibility of this innovative service.

[20] The essential levels of care (LEA), are the facilities and services that the NHS has to provide to all citizens free of charge or on payment of a fee (ticket); these services have been defined by the Decree of President of the Council of Ministers of 29 November 2001, entered into force 23 February 2002.

[21] cardiology, diagnostic imaging, ophthalmology, clinical diagnostics

- **Significant collaboration of health professionals throughout the entire pilot:** we did not really solve this, as both GPs and psychiatrists needed to be continuously reminded of the pilot, and supported in all their activities related to the project. As a result, only a small group of GPs and psychiatrists cooperated with us for the entire duration of the pilot, while the majority of them did not collaborate significantly.
- **Adequate Internet coverage throughout the territory of our unit:** this was not a factor under our control. However, as far as our unit is concerned, we implemented technical equipment especially in mental health centres in which the internet connection was more stable and reliable.

What are the experiences of the healthcare workers?

Doctors (GPs, psychiatrists and psychologists) who cooperated throughout the entire duration of the project acknowledged the innovative and potentially very useful nature of these innovative services. However, they also underlined the difficulty to integrate this kind of project, and the associated monitoring of patients' use of services, into their already busy clinical routine. In other words, significant case-load for both GPs and psychiatrists emerged as the main issue that slowed down and hindered a full cooperation and satisfaction of healthcare workers towards this project.

What are the experiences of the patients?

We eventually recruited two types of patients: patients with informatics skills, high motivation to treat themselves, and availability to work overtime with the tools; and patients with a lack of skills and motivation. Patients belonging to the first group had a very good experience of these innovative services, clarified their symptoms, and had benefited from the treatment path. Patients of the second group did not get benefit, tended to drop out easily, and as a result did not provide positive feedbacks about these services.

What recommendations do you have for others to start ICT based services in this area?

Generally speaking, ad hoc training sessions and continuous monitoring of the study are key aspects facilitating adherence to the project. To realise this, it is necessary to have resources, adequate technical equipment, and the permission of all stakeholders involved.

What are your comments on your numbers of patients / participants reached in MasterMind and completed treatment?

We were not able to reach the declared target (N=300), mainly due to the difficulty of GPs in recruiting patients. However, the drop-out rate was significantly lower than "standard" drop-out rates reported in scientific literature about compliance to pharmacotherapy for depression[22], so our general comment is that it is not so easy to attract patients to these services, but once they have been recruited and informed, this kind of service may provide benefits and positive effects to a significant proportion of them.

[22] Pampallona et al., 2002; Reimherr et al., 1998

10.7 Treviso, Veneto

What are the main lessons learned regarding implementation and organisation of the pilot (including facilitators and barriers for implementation)?

- **Engaging healthcare professionals and providers:** Engage specialists and GPs, more communication and sharing of NICE guidelines and user-friendly tools.
- **Setting up the technical services:** User-friendly tools are important, at different level: users, GPs and specialists.
- **Patient recruitment:** Help GPs with psychologists at their office for screening of common mental health disorders.
- **Organisational issues**: Every change in the organisational needs reinforcement and time to be accepted by people.
- **Finance:** Financial support for implementation!

What main problems did you experience, and how did you solve them?

A major difficulty concerned the involvement of GPs who have perceived, especially at the beginning of the project, MasterMind as add a chore rather than as a resource and a prevention and education tool which can reduce accesses to doctors' offices.

It was solved by a greater commitment and involvement of mental health specialists, in particular in the enrolment phase, but the number of specialists who have participated in the project was limited compared to what was expected.

To involve more professionals at the Mental Health Centre, nurses have been involved for the follow up phase, with the aim to follow patients with difficulty in the use of ICT tools. In particular, the cCBT tool, iFightDepression, has showed big usability limitations rather than any technical aspects, creating difficulties for many patients. To limit these difficulties, we have printed worksheets.

What are the experiences of the healthcare workers?

Healthcare workers, who have been involved in the MasterMind project in different level, have verified the usefulness of the tool, which acts primarily as an important tool of psyco-education and prevention, and as an interesting resource in the relationship between the specialist and patient, and could help communication with the GP.

What recommendations do you have for others to start ICT based services in this area?

MasterMind is an important and innovative tool to introduce in Italy the stepped care vision and evidence-based treatment for low and moderate depression, as promoted by NICE guideline, at different level: citizens, GPs and mental health specialists.

What are your comments on your numbers of patients / participants reached in MasterMind and completed treatment?

The number of patients who finished the treatment is in line with that of similar projects, highlighting a number of dropouts. We also have to consider the not usable version of the cCBT tool that has discouraged the continuation of cCBT.

The satisfaction of those who have concluded the cCBT is widespread and evident. This gave them the opportunity to begin to cope with the initial and critical phase of mental problems, with an evidence-based instrument and guided support from specialists.

10.8 Turkey

Please elaborate on any issues that have been of importance related to the following categories:

- **Engaging healthcare professionals and providers**

This was extremely difficult for us. The professionals have limited time. They did not want to spend extra effort.

- **Setting up the technical services**

This was easier for us since the LMS system of METU was already up and running. After implementing modules, we needed a lot of training for its use by therapists. We did not expect that its use would require so much training.

- **Organisational issues**

METU bureaucracy was quite overwhelming. Even for reimbursement of travel we had to file several sheets of documents. Also, time sheets for the personnel were extremely hard to obtain and calculate. These administrative steps stole time from actual project implementation, and made it hard to focus.

- **Finance**

Our resources were very limited. We were very tight on budget. We could pay limited fees for referrals, therapists and technical support.

What are the experiences of the healthcare workers?

Our main resource is the therapists. They developed a good sense of service delivery only after 50 patients were admitted. Until then, they had to receive very close supervision to be able to guide the patients correctly. Because of that, they were devoting time that is close to face to face therapy. Now they are more comfortable, since they can help the patients much faster.

What are the experiences of the patients?

It seems that there is a specific kind of patient for whom cCBT can be helpful. These are the type of people with higher self-confidence and equipped with more auto-control. Of course, this is just a feeling, we do not have adequate statistics to back up this claim yet.

What recommendations do you have for others to start ICT based services in this area?

Before doing it, consult with other service providers, make a requirements analysis at your own site, and tailor your local needs and facilities accordingly.

What are your comments on your numbers of patients / participants reached in MasterMind and completed treatment?

Our drop-out rate is high, because we have a lot of patients in the study outside the university student group. Our target was university students, but the population referred to us by AYNA was quite heterogeneous. So we need to do more data collection on our actual target population before commenting on this.

10.9 Estonia

Please elaborate on any issues that have been of importance related to the following categories:

- **Engaging healthcare professionals and providers**

Lack of interest among the majority of healthcare providers to implement eHealth service into daily routine care, as it takes additional time for them to explore, and then explain the usefulness for patients. Many of healthcare professionals do additional appointments at the end of official working day if a depressed patient has a need to express his/her emotions and thoughts; time limits during official appointments (mean c. 20 minutes) do not allow to provide full therapy.

- **Setting up the technical services**

Technical issues were related to login access and further monitoring of patients status. However, monitoring patients' activities was complicated due to program functionality. Unfortunately, the programme could not engage patients with their healthcare providers. Moreover, the programme had no additional functionalities, such as automatic reminders for patients and healthcare providers to foster and motivate usability.

- **Patient recruitment**

Patients' recruitment depends on several factors. The most prevalent were:

  - Clinical diagnosis according to ICD-10 and their health condition to perform cCBT modules independently.
  - Willingness to contribute to the study.
  - Lack of time resources.
  - Lack of computer skills.
  - Language difficulties.
  - Accessibility and engagement with healthcare provider.

- **Organisational issues**

Data extracted from the semi-structured interview showed that the GP centres and psychological practices were open for innovative technological solutions intended as a treatment for mild to moderate depressed patients.

- **Finance**

During MasterMind project, healthcare providers were employed as long as they were providing cCBT for patients who had completed at least three modules (with or without healthcare provider supervision). During the project, patients used the programme for free.

From the reimbursement point of view, eHealth service is a part of a whole healthcare system. Patients might pay for a licence, for example downloading a program on their smartphones.

What main problems did you experience, and how did you solve them?

During the MasterMind project, TUT has been faced with several problems, from the technical solution of iFightDepression to professionals' engagement. The main problem issue was related to difficulties in providing seamless login access to the program from Cognuse platform. The remote authentication capability still does not work in a way to sign-in once. Furthermore, patients' data cannot be downloaded from the service.

What are the experiences of the healthcare workers?

Healthcare providers are interested in a solution which will help patients to recover faster. However, healthcare providers such as GPs have no experience in providing CBT or cCBT. Psychologists who have experience in that field are unfortunately not healthcare providers according to Health Services Organisation Act § 3 Chapter 1. This means that a psychiatrist has to be in the team providing cCBT service as it is recognised as evidence-based therapy.

What are the experiences of the patients?

The majority of patients have not completed treatment for the following reasons:

- Lack of time.
- Technical problems.
- Misunderstandings when performing modules.
- Low motivation, no interest (often patients forgot to complete modules).
- Become healthier before starting to use programme (direct effect of antidepressants).

What recommendations do you have for others to start ICT based services in this area?

GPs have concluded that they have not been educated or trained with a minimum 2-year specialised training programme for CBT. This makes difficulty to provide patients cCBT.

Recommendations:

- Any eHealth service must have a user-friendly interface.
- eHealth service has to be provided by experienced people in the specialist field.
- Any eHealth service has to be adapted by the clinical healthcare provider.
- Most psychiatrists did not agree to provide cCBT for depressed patients.

- Any eHealth service intended for patient treatment has to be addressed as a medical device according to Directive 93/42/EEC, and thus be clinically evaluated (Directive 2007/47/EC).

What are your comments on your numbers of patients / participants reached in MasterMind and completed treatment?

Target number of patients could not be achieved during MasterMind project time for several reasons:

- Provision of cCBT needs extra preparedness from healthcare providers, which requires a 2-year training programme.
- Guidelines for using cCBT programme are not enough.
- Psychologists need a proof of specific cCBT programme before they could offer it to depressed patients; in the case of iFD, this was a huge problem.

Only few patients completed the intended number of modules.

Appendix A: Qualitative data from focus groups and interviews

A.1 Domain 2: Clinical safety

Emerging topic and sources	**Description** *(quotes are in italics)*
Clinical safety	
Reported in 11 quotations by 8 out of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists (n=5,7); • Piemonte: doctors (n=11); • Treviso: psychologists (n=5,7); • Turkey: therapists (n=3); • Wales: therapists (n=5).	It was stated that at the beginning of the process, some patients needed to be reassured by the doctors about the safety of the tool. After this reassurance, no patient expressed any concern regarding clinical safety. *"They never told me they didn't feel safe." (2nd focus group Basque Guided cCBT)* *"It was so safe, so safe, that it probably failed due to safety." (2nd focus group Basque Guided cCBT)* *"I don't think that this service worsens the depressed state of the patient" (1st focus group Treviso Guided cCBT)* It was stated that cCBT was considered safe for patients likely to be included for this service, whereas seriously ill patients or patients with suicidal ideation and a history of self-harm should receive more intensive care. *"One of the reasons why seriously ill patients are excluded is the risk of getting worse."* *(1st focus group Basque Guided cCBT)*
Monitoring	
Reported in 7 quotations by 4 out of 11 focus groups in: • Estonia (physicians n=9; • Piemonte (doctors n=11); • Treviso (psychologists n=5, 7).	It was stated that the specialists agreed about the importance of monitoring patients' health that might feel increased sensitivity and vulnerability due to their condition. It was stated that properly conducted monitoring could also protect against dropout, ensure the safety and efficacy of the therapy, and finally, was seen as the relational aspect of the cCBT intervention. *"Being in touch with the patient to monitor their clinical status is important."* *(1st focus group Treviso, guided cCBT)*

Emerging topic and sources	**Description** *(quotes are in italics)*
Technical and confidential security	
Reported in 10 quotations by 7 out of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists/psychiatrists (n=7); • Piemonte: doctors (n=11); • Treviso: psychologists (n=7); • Wales: therapists (n=5); • Turkey: therapists (n=3); • Estonia: physicians (n=9).	It was stated that the vast majority of patients expressed no concern about privacy issues related to their condition. Others who expressed concerns were easily reassured after a discussion with their doctor. In fact, only a minority of patients considered the therapy insecure and inadequate to protect their privacy. *"During the proposal of the service, some patients were in two minds about it: 'then they know who I am…'."* *(1st focus group Piemonte, guided cCBT)* It was stated that for patients who do not want to start face to face therapy, cCBT is a discreet and private alternative therapy.

A.2 Domain 3: Effectiveness of the cCBT service

A.2.1 Appropriateness of the cCBT service

This relates to the extent to which the service alleviates and addresses the patient's needs.

Emerging topic and sources	**Description** *(quotes are in italics)*
Clinical symptoms	
Reported in 30 quotations by 11 out of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists	The majority of participants were convinced that the cCBT is adequate for the treatment of patients with mild to moderate depression as an additional source of support. *"I think that the inclusion and exclusion criteria have been selected correctly." (1st focus group Aragón Guided cCBT)* However, comorbidities are a common thing in daily practice. *"'Pure' profiles of depression (without other mental co-morbidities) are not common, especially in the Mental Healthcare Unit patients." (1st focus group Aragón Guided cCBT)* Depressed patients should be monitored because of the risk of low motivation to adhere to the treatment.

Emerging topic and sources	**Description** *(quotes are in italics)*
(n=5,7); • Estonia: (physicians (n=9); • Galicia: healthcare professionals (n=6); • Piemonte (doctors n=11); • Treviso: psychologists (n=5,7); • Turkey: therapists (n=3), • Wales: therapists (n=5)	*"I think that the state of depression shouldn't be severe, otherwise they don't have enough motivation."* *(1st focus group Treviso Guided cCBT)* Patients should receive relevant information and support to understand not just the subject of the modules, but also the technical skills to complete the modules on time. *"I think there are two categories of patients with mild to moderate depression: patients who need information, and patients who need an interpersonal relationship, for whom this service is not appropriate."* *(1st focus group Piemonte Guided cCBT)* It was stated that drop-out is part of every study, and the reasons are mostly because: patients feel better; co-morbidities; major depressive disorder; time deficiency to focus on tasks and worksheets; suicidal thoughts and attempts. However, there were some patients who did not like to share their personal data on the platform. The opinion of the professional was that cCBT should not be aimed at patients who are likely to have any suicidal self-harm or ideation. It was also observed that patients that avoid social situations prefer this type of intervention, whereas other patients, for example with anxiety issues, prefer face-to-face therapy. *"I think it targets a very specific group of patients." (1st focus groups Basque, Guided cCBT)* *"Seeing that the patient improves, that they make progress in the treatment, is what makes you feel good."* *(1st focus group Galicia, Guided cCBT)*
Contextual factors	
Reported in 6 quotations by 5 out of 11 focus groups in: • Aragón: healthcare professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists,(n=7); • Estonia: physicians (n=9; • Turkey: therapists (n=3).	The importance of proper supervision was underlined. The intervention also assists family members of the patients, which in turn ensures continuity of care. Also, group therapy via this intervention was proposed in order to fight feelings of loneliness. *"My patients need to have a contact, I mean, continuous staff." (2nd focus group Basque Country, guided cCBT)* *"I think what matters most is for patients here today to have an appointment and contact with the person."* *(2nd focus group Basque Country, Guided cCBT)* Another important issue reported by the focus groups was that patients that do not feel that they receive enough professional support are likely to drop out.

Emerging topic and sources	**Description** *(quotes are in italics)*
Skills, personality traits, and attitude	
Reported in 13 quotations by 5 out of 11 focus groups i: • Aragón: healthcare professional (n=7); • Estonia: physicians (n=9; • Piemonte: doctors (n=11); • Treviso: psychologists (n=5,7); • Wales: therapists (n=5).	What was very often mentioned was that it is important to verify the level of digital literacy of patients. Patients are in need of technical support, and need to have available resources such as a computer at home. *"Basic informatics skills and informatics resources available (e.g. computers, tablet, smartphone, etc…" (1st focus group Piemonte, Guided cCBT)* The intervention does not seem suitable for elderly patients with little experience in using computerized technology, nor for subjects characterised by too high or low depression levels or low education. *"Patients are different from one another, need to have a specific profile to appreciate this service: basic informatics skills; young age; medium to high level of formal education." (1st focus group Piemonte, Guided cCBT)* *"I've come across a few people who … through their lack of education, just the minute you mention computer … they just say no." (1st focus group Wales, Unguided cCBT)* *"Not all patients with depression were recruited, it depends on their competence with the computerised systems." (1st focus group Treviso, Guided cCBT)* *"Technical and skills issues in starting to use this kind of services." (1st focus group Piemonte, Guided cCBT)*
Treatment delivery	
Reported in 31 quotations by 11 out of 11 focus groups i: • Aragón: healthcare professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Basque Country psychologists (n=5,7); • Estonia: physicians (n=9; • Galicia (healthcare professionals n=6; • Piemonte: doctors (n=11);	Although older patients have more obstacles to access the ICT resources, they have higher commitment compared to younger patients. *"Geographical location is a big issue: the more the distance between patient's place and the mental health centre, the higher the appreciation of this kind of service." (1st focus group Piemonte, guided cCBT)* MasterMind was especially praised for the fact that it was freely available to patients, its user-friendliness, that it is standardised, and the fact that it was available at any time to the patients. Doing online therapy does need a lot of motivation from the patient, since it is an active treatment compared to pharmacological interventions. Possible ideas to motivate patients were that the service should be offered in a more continuous and constant way, for example, with the use of supportive therapy through telephone or explanatory videos. *"This service guarantees the care continuity and it gives the patients relief as they feel that there is somebody behind who can support them." (1st focus group Aragón, Guided cCBT)* Some patients did not want to be involved with technological-based therapy. They preferred human contact.

Emerging topic and sources	**Description** *(quotes are in italics)*
• Treviso: psychologists (n=5,7); • Turkey: therapists (n=3); • Wales: therapists (n=5).	*"For some patients, the negative feeling not to be followed by people, but by a computer."* *(1st focus group Piemonte, Guided cCBT)* *"I think they need a human contact."* *(1st focus group Piemonte, Guided cCBT)* *"There are still patients who do not link technology and health."* *(1st focus group Aragón, Guided cCBT)* *"All patients I supervised…they are not so many…agreed to begin traditional psychotherapy afterwards."* *(1st focus group Piemonte, Guided cCBT)* However, other statements show that some patients appreciated this form of delivery. *"…some of my patients have felt it's important for them to be able to do it without having to go and see somebody because sometimes they so much do, not want to come and see somebody."* *(1st focus group Wales, unguided cCBT)*

A.2.2 Engaging in treatment

Aspects that are related to the decision of a patient and professional to consume or deliver the cCBT service.

Emerging topic and sources	**Description** *(quotes are in italics)*
Access to treatment	
Reported in 15 quotations by 7 out of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Basque Country psychologists (n=5,7); • Estonia: physicians (n=9; • Piemonte: doctors (n=11); • Wales: therapists (n=5).	Certain access problems, such as not being able to register immediately, might have dampened the initial motivation. Many patients did not have a computer at home, but have a smartphone or a tablet. Therefore, practitioners are interested to know whether the programme will be updated in the near future to function on such devices. *"All accessibility issues and having … a much easier programme to access."* *(1st focus group Basque Country, guided cCBT)* Another interesting idea that was mentioned was to provide the patient an extra instrument to work at home and/or between consultations. *"I think a lot more people would have been keen to sign up if they could use it on tablets."* *(1st focus group Wales, unguided cCBT)* The positive aspects that were mentioned of MasterMind were: free of costs for the patient; only requires basic informatics competencies; user-friendliness; accessible at any time. Family doctors very much liked cCBT for patients that live far away, and for foreign patients with language barriers. Also, the further the patients lived from the mental health centre, the more they appreciated the programme.

Emerging topic and sources	**Description** *(quotes are in italics)*
	"Geographical location is a big issue: the greater the distance between patient's place and the mental health centre, the higher the appreciation of this kind of service." (1st focus group Piemonte, guided cCBT) *"I believe this kind of therapy is adequate as long as it meets technological requirements … it allows to reach a lot of people, giving more time for the traditional therapy (face-to-face treatment) with those that cannot access cCBT (i.e. illiterate), also giving more opportunities to them." (1st focus group Badalona, guided cCBT)* *"…people who I've had most success with have been people who … haven't always been able to book appointments, so they've wanted to go and try this at home, and it's worked for them … I think there is a group of people out there who don't have a computer who, if they could access it a bit more easily on tablets or mobiles, then they'd be more likely to at least give it a go and see how it went." (1st focus group Wales, unguided cCBT)* However, time limitations and increased workload were also mentioned. *"I think being part of the pilot has ensured that we (Primary Care) were the gatekeepers then added to the workload … GPs could be referring to this direct … it's about getting them to do the paperwork." (1st focus group Wales, unguided cCBT)*
Reported in 12 quotations by 9 out of 11 focus groups in: • Aragón (health care professional, n=7); • Badalona (psychologists / psychiatrists, n=7); • Basque Country psychologists, n=5); • Estonia (physicians n=9; • Piemonte (doctors n=11); • Treviso (psychologists n=5,7); • Turkey (therapists n=3); • Wales (therapists n=5).	The tool should be presented differently than it is now. Many patients are not aware of this programme. Therefore, presenting information about the tool to the general population might be a good solution. Healthcare professionals should offer this kind of therapy to patients more scientifically (evidence, information, explanations) in order to make the patient more confident that this is a proven and reliable treatment. *"We need to involve general population (…) some patients are not recruited because they don't go to the doctor's office o they are not called at all." (1st focus group Treviso, guided cCBT)* *"Some patients are not recruited because they don't go to the doctor's office o they are not called at all." (1st focus group Treviso, Guided cCBT)* Doctors recruited a lot of patients for the project at its beginning, and then tended to forget the existence of this project; as a result, recruitment slowed down later. *"As it was an innovative thing, what happened was more or less what usually happens with new drugs: we recruited patients for the project at the beginning, and then tended to forget the existence of this project." (1st focus group Piemonte, guided cCBT)* *"First of all, enthusiasm … and the conviction that it's going to be useful, and the possibility, I found very innovative the possibility of applying a new therapy; a tool we don't have in primary health care; i.e. something new which may continue and for which there was nothing structured in this way until now." (1st focus group Basque Country, guided cCBT)* Practitioners should be consulted prior to the implementation of the services. This would facilitate the incorporation of the

Emerging topic and sources	**Description** *(quotes are in italics)*
	services into routine practice. *"…it's an additional resource that's being funded centrally that doesn't impact on staffing levels."* *(1st focus group Wales, unguided cCBT)*
Consent and referral	
Reported in 13 quotations by 6 out of 11 focus groups in: • Badalona: psychologists / psychiatrists (n=7); • Galicia: healthcare professionals (n=6); • Piemonte: doctors (n=11); • Treviso: psychologists (n=5,7); • Wales: therapists (n=5).	There is a great heterogeneity of patients, some being more resistant to online therapy than others. A therapist concluded that we should respect this heterogeneity, and offer online therapy to patients who can accept new technology as a way of treatment. *"Not all patients with depression were recruited; it depends on the competence with the computerised systems."* *(1st focus group Treviso, guided cCBT)* The first contact of the patient with the system and the support he/she received was very helpful for the start of the treatment. *"The people I've had most success with Beating the Blues tend to be people that I've referred to the service and offered a sort of review part way through; I've noticed that's more helpful." (1st focus group Wales, unguided cCBT)* *"Yes consultation is key, absolutely." (1st focus group Wales, unguided cCBT)* However, the screening procedure for an online intervention takes much time of daily practice. Practitioners who are not familiar with CBT have less confidence referring patients to cCBT. Many primary Mental Health Care Practitioners felt strongly that cCBT is a service suited for GPs to refer patients directly into.
Expectations and needs	
Reported in 16 quotations by 8 out of 11 focus groups in: • Aragón (health care professional, n=7): • Badalona: psychologists / psychiatrists, n=7); • Basque Country psychologists, n=7); • Piemonte (doctors n=11);	The participants generally interacted with interest, and appreciated the extra up to date information that this kind of service provides. It was also stated that patients demand an immediate response to their problems. Patients can see from this service that they are not alone, and that worldwide a lot of people suffer from depression. However, geriatric patients, the majority of whom are functional illiterates, cannot be asked to follow an online computerised psychological treatment. *"Patients who refused the treatment said 'this has a lot to do with a machine, I need a person listening to me'"* *(1st focus group Piemonte, Guided cCBT)* *"I think they need a human contact (…) I think there are two categories of patients with mild to moderate depression: patients who need information, and patients who need an interpersonal relationship, for whom this service is not*

Emerging topic and sources	**Description** *(quotes are in italics)*
• Turkey (therapists n=3); • Wales (therapists n=5).	*appropriate." (1st focus group Piemonte, guided cCBT)* Patients require a clear explanation of cCBT along with realistic expectations of the therapy. *"…clarity of what it is, realistic expectations." (1st focus group Wales, unguided cCBT)* *"Yes, and I explain it a bit, I mean, how to do the exercise because if it's not complex —I think it's very important for a patient with this profile; otherwise he/she is going to give up because they get frustrated."* *(2nd focus group Basque Country, guided cCBT)*

A.2.3 Adherence to treatment

Aspects that are related to the adherence of a patient to the cCBT treatment. This includes reasons for 'no-show' or 'treatment drop-out' from the perspective of the healthcare professional.

Emerging topic and sources	**Description** *(quotes are in italics)*
Applicability of content	
Reported in 24 quotations by 10 out of 11 focus groups in: • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists (n=5); • Estonia: physicians (n=9; • Galicia: healthcare professionals (n=6); • Piemonte: doctors (n=11); • Treviso (psychologists n=5,7); • Turkey: therapists (n=3); • Wales: therapists (n=5).	Professionals need to select patients based on their profiles and needs for this treatment; e.g. high self-control, education, young age, and the existence of comorbidities were mentioned as relevant factors. Greater interest in the cCBT service was observed in patients that are young-middle aged and medium or highly educated. *"Patient's needs, that's the main thing, … needs… they have to be at least addressed."* *(4th focus group Basque Country, guided cCBT)* *"Doctors have to identify the patients who can be considered eligible and appropriate for this service, or not (…) younger patients are a reasonable target for this kind of services (with exceptions)."* *(1st focus group Piemonte, guided cCBT)* *"I think it targets a very specific group of patients." (1st focus group Basque Country, guided cCBT)* The idea of the possibility to offer more individualised / personalised treatment with some specific features for those who can use it as an additional supportive therapy, or for those who are less familiar with technology. Offering the service in a more continuous way, for example, with the use of supportive therapy through telephone or explanatory videos, was also mentioned. It was also stated that not every patient seemed to adhere to the therapy. *"When I look at my figures, 36 – 37 people I put on it? 7 or 8 have completed. Large numbers … stopped at session 2, and*

Emerging topic and sources	**Description** *(quotes are in italics)*
	as I say, it's not for the want of me saying, explained to them that the meat of it is in session 4 or 5, and just get through until then …you know you've got me to come and speak to. I've only put three people on it as a stand-alone, all of the others have been face-to-face as well, and they still drop out. What does that say about me? Or what does it say about cCBT? Or what does it say about the population that this is being aimed at? I think these are the big questions that we need to look at." (1st focus group Wales, unguided cCBT) *"The patient could drop out because he/she doesn't find the service useful." (1st focus group Treviso, guided cCBT)* *"I think there's an element of self-recovery as well, enduring the process, and often I've found that by the time patients have gotten to maybe sessions 4, 5, 6 they don't need it anymore." (1st focus group Wales, unguided cCBT)*
Attractiveness of content and design of treatment platform	
Reported in 19 quotations by 9 out of 11 focus groups in: • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists (n=5,7); • Estonia: physicians (n=9; • Galicia (healthcare professionals (n=6); • Piemonte: doctors (n=11); • Treviso: psychologists (n=5); • Turkey: therapists (n=3); • Wales: therapists (n=5).	Some professionals reported that their experience with the service was preliminary, and that they could not evaluate its utility yet. From the data that they had received until then, it seemed that some patients did not want to participate from the beginning, others agreed to participate but abandoned after the second or third session. Also, professionals are convinced that internet based CBT provides an opportunity for more secure note taking – notes could not be lost or seen by third parties. The professionals suggested improving the user interface to be more user-friendly and interactive, and easy in use. *"Upgrading it. Graphics and platforms." (1st focus group Wales, unguided cCBT)* Some patients who have previously undertaken CBT found the cCBT to be repetitive. *"I've only met with one (patient) who's sort of given me some feedback of why they dropped out, and that's because she doesn't like CBT; (it was) previously repeating on stuff she's done." (1st focus group Wales, unguided cCBT)* *"The patient could have dropped out because he/she doesn't find the service useful." (1st focus group Treviso, guided cCBT)* *"Importance of tailoring the 'right' treatment for the 'right' patient." (1st focus group Piemonte, guided cCBT)*
Clinical changes	
Reported in 28 quotations by 11 out of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists /	Professionals stated that due to the nature of depression, patients are often resistant to adhere to the treatment. This is even more true when the treatment is online, since the patients are in charge of the treatment, and they can abandon it whenever they want. Therefore, they should be accompanied by professionals in the initial stages as they need more support when accessing the treatment at home. *"These are patients who need phone or physical monitoring… otherwise I believe they feel a bit abandoned."*

Emerging topic and sources	**Description** *(quotes are in italics)*
psychiatrists (n=7); • Basque Country: psychologists (n=5,7); • Estonia (physicians n=9; • Galicia: healthcare professionals (n=6); • Piemonte: doctors (n=11); • Treviso: psychologists (n=5,7); • Turkey: therapists (n=3); • Wales: therapists (n=5)	*(1st focus group Basque Country, guided cCBT)* Doctors stated that this tool might have the capacity to change patients' perspective on their health, to increase personal awareness: supporting people in seeing that for example the physical symptoms they frequently report to the GPs are actually part of a depressive syndrome. Also possible are reduced frequency of access to the GP by the patients, and increased level of wellness reported by patients who used it. *"If treatment works, we should show reduced frequency of access to the GP by the patients."* *(1st focus group Piemonte, Guided cCBT)* *"Increased level of wellness reported by patients who used it."* *(1st focus group Piemonte, Guided cCBT)* *"Change patients' perspective: supporting people in seeing that for example the physical symptoms he/she frequently reports to the GPs are actually part of a depressive syndrome."* *(1st focus group Piemonte, Guided cCBT)* *"This service allows the patient not to consider him/herself as abnormal; … that it is a problem of many people … and at any rate I can get out of it somehow."* *(1st focus group Piemonte, Guided cCBT)* *"The initial assessment helps people to become aware, and then the cCBT tool reinforces their autonomy … they are not destined to lose against these difficulties."* *(1st focus group Piemonte, Guided cCBT)* Some patients get worse because it does not work as they expect, and they start seeing a therapist after that, while others have stopped the treatment because as a result of the treatment they started to recover. *"…some of mine have gone into crisis and they've been taken over by secondary services."* *(1st focus group Wales, unguided cCBT)* *"One of the reasons why seriously ill patients are excluded is the risk of getting worse."* *(1st focus group Basque Country, guided cCBT)* *"All patients I supervised … they are not so many … agreed to begin a traditional psychotherapy afterwards."* *(1st focus group Piemonte, guided cCBT)* Patients that drop-out do not provide sufficient data. Therefore, practitioners suggested an "I've completed the programme as far as is required" button to be incorporated into the programme.
Motivational aspects	
Reported in 37 quotations by 10 out of 11 focus groups in: • Aragón: health care professional	Young people, although initially more motivated, show less engagement later. Holiday periods have a negative impact on the adherence to treatment. Possible rewards were mentioned to increase motivation both for professionals and patients, e.g.: extra training for professionals; individualised treatment for patients.

Emerging topic and sources	**Description** *(quotes are in italics)*
(n=7); • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists (n=5,7); • Estonia: physicians (n=9; • Galicia: healthcare professionals (n=6; • Piemonte: doctors (n=11); • Treviso: psychologists (n=5,7); • Wales: therapists (n=5).	*"There must be an incentive for both the patient and the professional in the early stages of their changing process."* *(1st focus group Badalona, guided cCBT)* Patients and professionals need to be motivated, and to understand the utility of this kind of therapy. It was stated that the procedure of the system (to register a new patient or any other issues) should be more immediate, because the patient can lose motivation if this process takes too long. Supporting patients to help them with the treatment is crucial to keep them motivated and actively performing the programme. *"…follow-up by professionals, because many of them have fallen behind … because it stopped motivating them."* *(1st focus group Basque, Guided cCBT)* *"It's difficult to work with therapy like that on-line if you have no outside support from someone who structures and encourages you to continue."* *(1st focus group Basque, Guided cCBT)* Some professionals reported that patients with major depression are not well suited for online therapy due to low motivation, while others reported that they should receive the online component since it's an adjuvant therapy. The "faith" the doctor has in the treatment plays a crucial role. The support and coaching from the professionals seems to foster motivation in the clients. *"In proposing the service, the enthusiasm of the doctor is relevant in this kind of experience."* *(1st focus group Piemonte, Guided cCBT)* *"An attractive proposal of the service to the patient."* *(1st focus group Piemonte, Guided cCBT)* *"According to me, the support of a consultant who motivates the patient is crucial."* *(1st focus group Treviso, Guided cCBT)* Patients with motivation and self-interest seem to be more suited for cCBT.
Practical arrangements	
Reported in 11 quotations by 8 out of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists	Professionals stated that telephone follow-ups are a positive factor for adherence. Helpful practical arrangements would be: recruitment by primary care and Mental Health Units (psychology and psychiatry); training and follow up by nurses. Alarms management by nurses who check the validity of the alarm and who refer to the physicians if needed. *"As well as the nurses who do a great job, we probably need mental health care professionals more closely, going to Primary Care every now and then, to deal with the patient avalanche they have with those or other tools."* *(1st focus group Basque Country, guided cCBT)* Professionals stated that they would appreciate an easy and clear way to provide instruction about using the device.

Emerging topic and sources	**Description** *(quotes are in italics)*
(n=5,7); • Piemonte: doctors (n=11); • Treviso: psychologists (n=5,7); • Turkey: therapists (n=3); • Wales: therapists (n=5).	Another professional added that within the MasterMind project, an alternative solution is to give written information to the patients. The MasterMind project also offers a video on YouTube with a tutorial about how to use the device. *"A form reporting technical features of the service … to illustrate this service to patients with more details…"* *(1st focus group Piemonte, guided cCBT)* An additional human resource with medical education could be beneficial in terms of monitoring and consulting patients to complete modules and fulfil worksheets. *"According to me, the support of a consultant who motivates the patient is crucial." (1st focus group Treviso, guided cCBT)* Possible facilitators include: the development of paper materials to support the online programme; the possibility to involve local institutions in order to facilitate the diffusion and promotion of the programme (e.g. municipalities, local authorities, associations); having a standardised method, so the patient can understand where to start and where to go. Having specific courses for people who do not use computers was also suggested. A professional suggested that someone should develop a monitoring system for patients that drop out, perhaps via the GP. Having an alarm function if patients do not do their exercises would take less of the practitioner's time. *"We cannot spend all the time accessing the program to see whether patients have done their exercises or not… that would be ideal, a warning popping up and telling you if you have to correct exercises or not."* *(2nd focus group Basque Country, guided cCBT)* Practitioners reported that offering a review appointment with the patient part way through their course of cCBT therapy has encouraged them to complete the programme. *"The people I've had most success with Beating the Blues tend to be people that I've referred to the service and offered a sort of review part way through, I've noticed that's more helpful." (4th focus group Wales, guided cCBT)* Some patients need more supervision; a solution that was proposed was to offer them a place in the primary care centre to do the treatment. *"I think more phone contact with them is probably required to see how they're doing. I believe there was a large majority who were a bit disorganised, therefore maybe phone calls should be implemented weekly at the beginning, to prevent that disconnection." (1st focus group Basque Country, guided cCBT)* *"To have a computer available for patients, to have someone there, who I think could be an office clerk with computer skills." (2nd focus group Basque Country, guided cCBT)* *"I believe having a computer at the centre also helps, would help." (2nd focus group Basque Country, guided cCBT)*

Emerging topic and sources	**Description** *(quotes are in italics)*
Technical aspects and user-friendliness	
Reported in 35 quotations by 10 out of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists (n=5,7); • Estonia: physicians (n=9; • Galicia: healthcare professionals (n=6; • Piemonte: doctors (n=11); • Treviso: psychologists (n=5); • Wales: therapists (n=5).	Professionals and patients agreed to a great extent regarding the technical issues of the application. Specifically, certain patients highlighted that the technology was not always user-friendly, while others complimented its user-friendliness. The professionals agreed that the level of access to technology (internet, IT devices) has a high impact on the degree of adherence to treatment by patients. Professionals often stated that they would like to prevent patients sending them mails of complaints regarding technical problems. Patients need technical support for the application; its lack may have had an influence on the high drop-out rate. *"Apart from all the technical details, in particular ICT and technical details, etc., well, as everything that has been said before, it was extremely complicated." (1st focus group Basque Country, guided cCBT)* *"Only a few patients dropped out because of computer difficulties." (2nd focus group Treviso, guided cCBT)* *"Some patients abandoned at the beginning due to technical problems." (1st focus group Aragón, guided cCBT)* Some professionals complained that the technicians have not solved the problems on time, while others felt the support provided by the Beating the Blues Co-ordinator was good, with many of the practitioners contacting the Co-ordinator to assist with any technical issues that arose and received a prompt response. *"There have been continuous IT hurdles." (2nd focus group Basque, Guided cCBT)* *"There were patients who gave up because in session five it jammed and we received a response from IT two months later." (2nd focus group Basque, Guided cCBT)* *"It needs to be easy to access and use, work well, be agile and you need to know it well." (1st focus group Basque, Guided cCBT)* Poor usability and problems accessing the tool was one of the main problems of the treatment, while other reported that the platform could be improved, but that it is stable and decisive. *"I think the IT elements of updating the format and the platform as well as consultation I think are the main…" (1st focus group Wales, Unguided cCBT)* *"And yes, as you were saying, when they get better and are not on sick leave, they don't have so much time and as they also find IT problems…" (2nd focus group Basque, Guided cCBT)* *"It's not usable, I mean, maybe usable but easy _____, isn't it?" (2nd focus group Basque, Guided cCBT)* *"It is not usable for most, due to IT problems, of course." (2nd focus group Basque, Guided cCBT)* *"There are many problems with the Internet connection, especially in the rural areas."*

Emerging topic and sources	**Description** *(quotes are in italics)*
	(1st focus group Aragón, Guided cCBT) *"Not excellent internet connection throughout our territory." (1st focus group Piemonte, Guided cCBT)* *"Difficulty to access IT." (2nd focus group Basque, Guided cCBT)*

A.3 Domain 4: Healthcare professionals' perceived acceptability of MasterMind services in routine practice

A.3.1 Appropriateness of and adherence to treatment

Emerging topic and sources	**Description** *(quotes are in italics)*
Skills and knowledge	
Reported in 9 quotations by 6 out of 11 focus groups in: • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists (n=5); • Estonia: physicians (n=9; • Galicia: healthcare professionals (n=6); • Treviso: psychologists (n=7); • Wales: therapists (n=5).	The need for professionals to have CBT skills is required to be able to further inform the patients. This would assist the professionals to refer clients to cCBT, which is currently something new and unknown to many. Knowing how the application works was also underlined. *"I think if you believe and you're trained and believe in CBT as a modality, then you're going to have … a better understanding of what the resource is. I think those in our team who are less comfortable with that … may refer less as a consequence." (1st focus group Wales, Unguided cCBT)* *"…whether it was clinician's modality or you know they've got the understanding of CBT in the first instance, it's a major factor. I think that's been one of the major barriers to this." (1st focus group Wales, Unguided cCBT)*
Service delivery	
Reported in 17 quotations by 8 out of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists /	Professionals stated that they are in need of previous training, more time and the inclusion of the service in routine practice to deliver a quality service. The start of the intervention should be shortly after this training. *"They must have a belief in cCBT in the first place, and be trained in CBT and using it as their modality … a lot of the professionals are not trained in CBT, and therefore you're asking them to deliver something that they don't feel confident in." (1st focus group Wales, guided cCBT)*

psychiatrists (n=7); • Basque Country: psychologists (n=5); • Estonia: physicians (n=9); • Piemonte: doctors (n=11); • Treviso: psychologists (n=7); • Turkey: therapists (n=3); • Wales: therapists (n=5).	One of the professionals stated the immense potential of internet-based therapies, and used as an example the impact smartphones had. He concluded that professionals should be less sceptical of new technology. Professionals often feel more comfortable delivering traditional methods. Moving from something familiar to something uncertain takes a lot of effort, and it's about getting out of the comfort zone. Long-term benefits should be prioritised. An idea stated by the professionals was to offer individualised / personalised treatment according to the patient's profile: the service should include some specific features for those who can use it as an additional supportive therapy, and other features for those who are not willing to use it and consider it an excess of technology. Professionals should deliver this type of therapy through more scientific evidence, general information and explanations to transmit more prestige and reliability in the treatment. Professionals stated that there is no difference in time between traditional therapy and guided cCBT. The importance of making the patients feel in charge was highlighted. Finally, the problem of not having enough venues was mentioned. *"…the problem is we don't have enough venues where we can do this." (1st focus group Wales, guided cCBT)*

A.3.2 Engaging in treatment

Engaging in treatment relates to the decision of a professional to deliver the cCBT facilitated mental health service.

Emerging topic and sources	**Description** *(quotes are in italics)*
Awareness and knowledge	
Reported in 9 quotations by 7 out of 11 focus groups in: • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists (n=5); • Estonia: physicians (n=9); • Piemonte: doctors (n=11); • Treviso: psychologists (n=5); • Turkey: therapists (n=3);	Professionals stated that they are enthusiastic about the existence of a new tool. *"First of all, enthusiasm … and the conviction that it's going to be useful, and the possibility, I found very innovative the possibility of applying a new therapy; a tool we don't have in primary health care; i.e. something new which may continue and for which there was nothing structured in this way until now."* *(1st focus group Basque Country, guided cCBT)* GPs seem to be already very confident that cCBT might be very helpful for their practice. Especially for patients who live far away or have language barriers. Doctors after the initial waves of recruitment tend to forget the existence of this project and recruitment slows down. *"As it was an innovative thing, what happened was more or less what usually happens with new drugs: we recruited patients for the project at the beginning, and then tended to forget its existence."* *(1st focus group Piemonte, guided cCBT)*

Emerging topic and sources	**Description** *(quotes are in italics)*
• Wales: therapists (n=5).	More professionals should be made aware of this project, and networks should be created. Professionals should make patients aware of cCBT by providing them sufficient information. Practitioners should be made aware before implementation to facilitate the incorporation of the services into routine practice.
Expectations and needs	
Reported in 12 quotations by 6 out of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Galicia: healthcare professionals (n=6); • Piemonte: doctors (n=11); • Treviso: psychologists (n=5); • Wales: therapists (n=5).	Practitioners felt strongly about the need to be included in the decision making process before a new service such as cCBT is introduced. Statements about pressure referring patients to the service were mentioned. *"…we need to be left to make our own clinical judgements, free from any managerial interruptions, so you know we chose what's right for the patients." (1st focus group Wales, Unguided cCBT)* *"I suppose to reiterate something I said earlier, it's not being pressurised to have to refer to the service but to use the service by clinical judgement." (1st focus group Wales, Unguided cCBT)* Certain negative aspects are worries that new technologies might replace professionals some day. However, these tools might positively affect the caseload of the professionals, which can facilitate the adoption of these tools. *"It's adequate resourcing, and it's about raising the quality as well." (1st focus group Wales, Unguided cCBT)* Practitioners need to be trained in CBT and the online tool to easily integrate it in their daily work. *"I will be able to use it if I can easily integrate into my daily life." (1st focus group Galicia, Guided cCBT)* The need for monitoring patients via this tool was mentioned. *"This service is even more usable if maintenance sessions could be planned every now and then, in order to continue to monitor patients' condition over time and detect early possible relapses."* *(1st focus group Piemonte, Guided cCBT)*
Support	
Reported in 35 quotations by 11 out of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists	Healthcare professionals need more resources and support (also technical) to being able to implement these services. Health professionals need to be well-informed to transmit information to patients. However, not every professional is well informed about cCBT, therefore, more support should target health professionals. *"Training was insufficient, and very far away in terms of time." (1st focus group Basque, Guided cCBT)* *"In my opinion, I don't think it was supported at all, I mean not at all, in working hours, nor at meetings." (2nd focus group Basque, Guided cCBT)* *"You have spelled these three things out very clearly: time; ensure line managers are aware; and then if at least one*

Emerging topic and sources	**Description** *(quotes are in italics)*
(n=5,7); • Estonia: physicians (n=9); • Galicia: healthcare professionals (n=6); • Piemonte: doctors (n=11); • Treviso: psychologists (n=7); • Turkey: therapists (n=3); • Wales: therapists (n=5).	*meeting is required … so if there is financial remuneration, at least travelling expenses are considered, I think. And above all, above all, above all, time." (2nd focus group Basque, Guided cCBT)* *"…it's just knowing that … you've got somebody to contact, just that reassurance that if there's a problem." (1st focus group Wales, Unguided cCBT)* *"A nurse should have come here, in the same way physicians have been invited; volunteer nurses should have been invited, because nursing work is very important, crucial." (2nd focus group Basque, Guided cCBT)* *"The role of the nurses is essential." (1st focus group Aragón, Guided cCBT)* *"Support from other health professionals (e.g. nurses) to share with them some basic activities, and save time for innovative services like this one." (1st focus group Piemonte, Guided cCBT)* *"Adequate resources to service needs…" (1st focus group Wales, Unguided cCBT)* *"…the support has been good, and all the stats that the co-ordinator sends out are very good, they're quite detailed." (1st focus group Wales, Unguided cCBT)* *"There was no support service ... we were not given solutions for problems." (1st focus group Basque, Guided cCBT)* The idea to create a network of professionals open and interested in the topic was mentioned. Also to consult with other therapists. Satisfaction was linked to the opportunity of sharing practices, knowledge and information with other professionals. Satisfaction was tied to the possibility of extending expertise. *"The involvement of other professionals and team work is essential." (1st focus group Galicia, Guided cCBT)* *"Greater collaboration between professionals is necessary." (1st focus group Treviso, Guided cCBT)* Professionals need time to perform this treatment with their patients, time and financial compensations for the meetings and training. *"The screening part takes time. Data entry takes more time, and this is also true for the ccVC; this could lead the doctor to delegate these activities." (1st focus group Treviso, Guided cCBT)* cCBT does support professionals in their work. *"It also gives relief to the professionals." (1st focus group Aragón, Guided cCBT)*
Training and education	
Reported in 17 quotations by 8 out	Training is necessary to understand the functioning of the programme, and the time between this training and starting the

Emerging topic and sources	**Description** *(quotes are in italics)*
of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists (n=5); • Estonia: physicians (n=9); • Treviso: psychologists (n=5,7); • Turkey: therapists (n=3); • Wales: therapists (n=5).	treatment has to be short, because professionals cannot recommend something which they do not know about. Specific learning courses for professionals were suggested. *"In this project, we had some difficulties in implementing the programme in clinical practice because it involves changing our habits, habits that are like rituals … ding things without thinking is easier … in our everyday consultations it is the same when you have to change the way in which you treat your patients. In these first moments of change, we have to get some help, to receive some benefit (for example, we have agreed that the centres that recruit patients more easily, can receive a special training to facilitate their changing process)."* *(1st focus group Badalona, Guided cCBT)* *"Training was insufficient and very far away in terms of time." (1st focus group Basque, Guided cCBT)* *"The tool and the service fail because the tool is faulty, but the service provided to us until now, until it was changed, has been worse than bad, awful." (1st focus group Basque, Guided cCBT)* *"I believe it's programme and technical knowledge … because the therapy has only been addressed on the surface; I'm not saying you've got to do 300 hours, but a couple of sessions to explain what the therapy is." (1st focus group Basque, Guided cCBT)*
Technical and confidential security	
Reported in 3 quotations by 3 out of 11 focus groups in: • Badalona: psychologists / psychiatrists (n=7); • Estonia: physicians (n=9); • Turkey: therapists (n=3).	The professionals generally agreed on the security of the system and stressed that they had always kept patient information with the goal to help patients not to harm them. The fact that patients do not need to write e.g. their thoughts and emotions on paper, was received as more secure note taking, since they cannot be lost or seen by third parties.

A.3.3 Satisfaction and usability from the perspective of the healthcare professional

These are aspects that relate to the meaning of delivering the services in routine practice, in terms of the extent to which the cCBT services are usable and satisfying expectations, roles, and responsibilities.

Emerging topic and sources	**Description** *(quotes are in italics)*
Satisfaction	
Reported in 14 quotations by 7 out of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists (n=5,7); • Treviso: psychologists (n=5,7); • Wales: therapists (n=5).	During the study, many professionals and patients, but also their relatives, expressed their satisfaction with the treatment. *"Two patients came to me in the street and told me that the treatment had been very positive for them."* *(1st focus group Aragón, Guided cCBT)* *"Because it has improved." (1st focus group Basque, Guided cCBT)* *"Positive feedback from the patients … regular feedback, and that it's being helpful is how I would be satisfied."* *(1st focus group Wales, Unguided cCBT)* Satisfaction with care continuity was expressed. *"This service guarantees the care continuity, and gives the patients relief as they feel that there is somebody behind who can support them." (1st focus group Aragón, Guided cCBT)* A professional mentioned that he could only evaluate the satisfaction of patients that finished the training, and not those who did not. He considered this biased the results.
Usability	
Reported in 30 quotations by 7 out of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists (n=5); • Estonia: physicians (n=9); • Galicia (healthcare professionals n=6), • Treviso: psychologists (n=5,7); • Turkey: therapists (n=3); • Wales: therapists (n=5).	The professionals stated mostly that there were no major issues working with the tool; positive aspects include alarms and the information recorded in the tool, that help the professionals to perform a better follow up, to detect risky situations, and to schedule consultations with objective information. However, certain problems included: problems signing into the system; program design (less attractive); functionality (not interactive nor connecting patients with professionals); patients had to work on PC; complicated (but stable) platform, *"The tool and the service fail because the tool is faulty but the service provided to us until now, until it was changed, has been worse than bad, awful." (1st focus group Basque, Guided cCBT)* *"We already handle electronic medical records, it is not something completely new."* *(1st focus group Galicia, Guided cCBT)*

A.4 Domain 5: Economic aspects

A.4.1 Cost savings

Emerging topic and sources	**Description** *(quotes are in italics)*
More evaluation needed	
Reported in quotations in 6 locations: Aragón, Basque country, Piemonte, Treviso, Turkey, Wales.	More evaluation was needed to analyse whether the implementation of the interventions had produce savings. Respondents stated that evaluation in this sense was not possible for the moment, as costs have not been assessed. *"We don't have data to … I know how much it cost us, but I still don't know the benefits we have gained, what we have saved in appointments, I have no data to offer an opinion." (Basque Country_2)* *"I do not have such an observation. We did not have the opportunity to compare this to any other therapy service." (Turkey_1_ccbt)* Some participants had the perception that the implementation of these services could imply savings. *"The economic savings of the project are not immediately quantifiable, but it can definitely have an impact on the social spending. The MasterMind project might be able to invest the available financial resources better." (Treviso)* *"Early information will indicate there have been some savings such as fewer appointments for GPs and community psychiatric nurses." (Wales_2_ccbt)* Nevertheless, this perception was not unanimous.
Potential savings	
Reported in quotations from three locations: Aragón, Piemonte, Wales.	Participants stated that innovation contributes to ease work and to save time. And that they had appreciated some savings in indirect costs. *"…fewer appointments at GPs, etc. Fewer follow ups with the CPN, so I haven't physically seen the evidence of that, but the early information that I saw would certainly indicate that there has been some savings." (Wales_2_ccbt)* *"Anyway we can appreciate savings in terms of indirect costs." (Piemonte_2_ccbt+ccvc)*

Emerging topic and sources	**Description** *(quotes are in italics)*
Lack of resources	
Reported in quotations in two locations: Aragón, Wales.	Lack of resources in mental health services was mentioned as a factor hindering the implementation of the interventions. Human resources not only for this initiative, but for the whole mental health services, were scarce. Some human resources were needed to give support and help to patients. *"In Mental Health, we do not have many resources, neither professionals." (Aragón1)* Technology resources and infrastructure were also needed. Participants stated that in some cases practical issues such as room availability and Wi-Fi were an obstacle to implementation. Issues with Wi-Fi and room availability sometimes meant it was easier for face-to-face therapy. *"We always had issues with the rooms where we didn't have internet or broadband, or trying to book a room." (Wales_1)* Also some patients lacked technological resources.

A.4.2 Budget impact analyses

Emerging topic and sources	**Description** *(quotes are in italics)*
Reasons for maintaining the services	
Reported in 24 quotations in 6 locations: Aragón, Badalona, Piemonte, Treviso, Turkey, Wales.	The most mentioned reason for maintaining the services was that it could be efficient and did not need many additional resources. *"The organisation of the service does not require too many additional resources." (Aragón_1_ccbt1)* *"Moreover, the costs are not high." (Badalona_1_ccbt)* *"Using this programme should not require more time than the time the professionals usually employ treating these patients, so it could be incorporated naturally in everyday practice." (Basque_Country_1_ccbt)* Quality of the programme was also signalled as a reason for maintenance. Quality referred to technology, transportation, organisational issues or, avoiding external referrals. *"This kind of service is a good tool to perform follow up of mild mental disorders from primary care and to avoid referral to Mental Healthcare Units." (Aragón_1_ccbt1)* *"The implementation of cCBT helps the organisation." (Badalona_1_ccbt)* *"The most important reason for the maintenance of the MasterMind protocol is linked to satisfaction and functionality for both*

Emerging topic and sources	**Description** *(quotes are in italics)*
	professionals and patients (must be useful to both)." (Treviso_2_ccbt) *"Well defined roles and tasks and collaboration make everything easier." (Aragón_1_ccbt1)* *"I think it provides a tool … with mild depression what do you do? Well what you have learnt throughout your life and listen, as well as you can, and initially you don't refer it to mental health care. With a moderate depression you wonder whether to prescribe an anti-depressant ... now you have another tool." (Basque_Country_1_ccbt)* Some also stated that the services are effective and able to treat previously untreated patients. *"The most important reason for keeping it will be that it works." (Wales_2_ccbt)* *"For us, the main important reason for keeping cCBT is that we think and we are sure that it's a tool that helps better treat these patients that up till now we felt they were undertreated." (Badalona_1_ccbt)* A variety of other reasons were also mentioned; including the improvement of public image, the attraction of anew public, the alignment with regional needs. *"Main reason for keeping cCBT/ccVC services implemented in ASLTO3 catchment area: wide-spread depression." (Piemonte_1_ccbt+ccvc)* *"Positive impact of cCBT/ccVC services on the ASLTO3's public image." (Piemonte_1_ccbt)* *"…it will start to say about us that we're a forward thinking organisation which embraces technology." (Wales_2_ccbt)* *"…in terms of benchmarking in the healthcare market, for example, if we don't do these sorts of things we'll soon find that we're behind the curve, and other people will have done them and we'll be seen as traditional and sort of stuck in the mud." (Wales_2_ccbt)*
Issues to be addressed to maintain the service	
Reported in 13 quotations in 5 locations: Aragón, Basque Country, Treviso, Turkey, Wales.	Participants mentioned many issues that could hinder the maintenance of the services. For example, interviewees stated that the programmes needed to prove their efficiency. *"To be efficient and sustainable, not entailing any expense and to be externalised as part of what we do, from our usual practice, that doesn't add extra costs, but that we can develop with what we have." (Basque_Country_2_ccbt)* Future funding was unclear, so the maintenance of services depended on the possibility of sustaining it with the available resources or other financial sources. *"The programme would be sustainable, and it could be added to the everyday practice if it could be developed with current resources, with no need of new economic investments." (Basque_Country_2_ccbt)*

Emerging topic and sources	**Description** *(quotes are in italics)*
	"There are two funding streams: one option would be to apply externally for WG funding, the second option would be to apply for internal funding through the form of a business case, and to see if we could release resources from a different part of the system." (Wales_2_ccbt) *"A bid for additional resources to maintain this going forward is being submitted to the integrated medium term plan for the health board." (Wales_3_ccbt)* *"With a minimum set of resources and with time slots organised and scheduled in the agenda, it is feasible to continue with a project like this." (Aragón_1_ccbt1)* Lack of human and technological resources needed also to be taken into account. *"It would be necessary to get more professionals involved from the beginning of the project, even in the design of the whole study, to also get more patients to participate." (Basque_Country_2_ccbt)* *"The involvement of GPs is important for the early detection of diseases and good care. It is possible to cure better if the GP is fully part of the system of care." (Treviso_1_ccbt)* *"In order to have sustainable service, the main resource, the therapists, must be paid well. Because the therapists are responding one-on-one to patients. So they must be paid well." (Turkey_1_ccbt)* *"The technical infrastructure of our system should be improved." (Turkey_1_ccbt)*

A.4.3 Economic sustainability

Emerging topic	**Description** *(quotes are in italics)*
Building a business case	
Reported in 22 quotations in 6 locations: Aragón, Badalona, Basque Country Piemonte, Treviso, Wales.	Participants mentioned some economic reasons that built a business case. They stated that the interventions had not been expensive, seemed efficient, and could be absorbed in the daily wok of the institution. *"We do not have other tools. The tools we have used are not expensive, they are sustainable, and they do not overload the system." (Aragón_1_ccbt)* *"The infrastructure is very cheap to maintain because cCBT is a web-service." (Badalona_1_ccbt)* *"There is no need to add extra resources besides those that already exist to maintain this programme." (Basque_Country_1_ccbt)* *"I believe it can be perfectly absorbed in your daily agenda, you don't need more time with the patient ..., no, I believe in this*

Emerging topic	Description *(quotes are in italics)*
	regard nothing entailing more expenses has to be rescheduled." (Basque_Country_1_ccbt) Some participants considered that the continuity of services was guaranteed in their sites. *"Funding strategies are currently in place for sustaining cCBT service in practice." (Piemonte_1_ccbt)* *"There is a business case for the continuation of cCBT as the Health Board is keen to maintain the momentum already made by the project, and have since invested in a specialist CBT practitioner." (Wales_3_ccbt)* *"Yes, we're very keen to maintain the momentum made so far in this project." (Wales_3_ccbt)*
No business case	
Reported in 5 quotations in 3 locations: Aragón, Basque Country, Treviso.	Some participants expressed doubts regarding the viability of building a business case at the moment due to lack of funding or data. Specifically, data about effectiveness and acceptability by users and professionals were demanded. *"There are not enough data to be able to evaluate if there is a business case." (Basque_Country_1_ccbt)* *"I think we have very few patients and very few people involved." (Basque_Country_1_ccbt)* *"Maintaining the MasterMind protocol is not due to the direct resources to allocate, but rather how much it can become effective, and how much this can be evident to the resource decision makers." (Treviso_1_ccbt)* *"Deciding to keep or not the MasterMind protocol is not a matter of cost, but is linked to the acceptability by users and professionals." (Treviso_2_ccbt)* *"There are no funding instruments within the organisation. Some years ago, there was funding to facilitate some initiatives." (Aragón_1_ccbt)*

A.5 Domain 6: Organisational aspects

A.5.1 Perspectives on implementation (professionals)

Emerging topic	Description *(quotes are in italics)*
Access, referral, and treatment processes	
Reported in 22 quotations by 10 out of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists (n=5,7); • Estonia: physicians (n=9); • Galicia: healthcare professionals (n=6); • Piemonte: doctors (n=11); • Treviso: psychologists (n=5); • Turkey: therapists (n=3); • Wales: therapists (n=5).	Lack of time for professionals, need for resources. *"Lack of time is the key word."* *(1st focus group Galicia, Guided cCBT)* *"From the primary care point of view, I think the tool is very good, I'm certain about this, but the treatment of these patient profiles implies time dedicated to them."* *(1st focus group Aragón, Guided cCBT)* *"There must be an incentive for both the patient and the professional in the early stages of the changing process."* *(1st focus group Badalona, Guided cCBT)* *"If these services impact positively on doctor's case-load, this will facilitate hugely their adoption.".* *(1st focus group Piemonte, Guided cCBT)* Professionals stated that treatment should be initiated with face-to-face bonding, and then continue online. Follow-ups should be performed with the information recorded from the tool. *"It's difficult to work with therapy like that on-line if you have no outside support from someone who structures, encourages you to continue". (1st focus group Basque, Guided cCBT)* *"The goal is to use the programme as a support, and to have longer intervals of time between consultations"* *(1st focus group Aragón, Guided cCBT)* The application must work correctly, and must be accessible immediately 24/7. *"It took us a long time to start, until passwords started and all that, and it's very frustrating".* *(2nd focus group Basque, Guided cCBT)* *"All accessibility issues and having … a much easier access to programme." (1st focus group Basque, Guided cCBT)* The lack of any face-to-face supervision was mentioned. Professionals demanded that the tool should be accessible via tablet and phones. *"…I'd be really interested to know how the company itself have been in terms of is it upgraded? At what point will it be*

Emerging topic	Description *(quotes are in italics)*
	upgraded? At what point would it be on a tablet" *(1st focus group Wales, Unguided cCBT)*
Technology	
Reported in 9 quotations by 5 out of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists (n=7); • Galicia: healthcare professionals (n=6); • Treviso: psychologists (n=5).	Some professionals expressed the fear that they might start being replaced by technology. cCBT is seen as another technological tool for health purposes, as they already use in daily work, such as computerised medical history and electronic prescription. However, professionals often asked for ICT support due to access problems. *"Difficulty to access ICT." (2nd focus group Basque, Guided cCBT)*
Information, training and education	
Reported in 5 quotations by 3 out of 11 focus groups in: • Badalona: psychologists / psychiatrists (n=7); • Estonia: physicians (n=9); • Wales: therapists (n=5).	Not all professionals have knowledge of CBT, and need therefore training. *"I have no sufficient skills as I could not find time to pass a full training." (1st focus group Estonia, Guided cCBT)* *"…whether it was clinician's modality or you know they've got the understanding of CBT in the first instance, it's a major factor. I think that's been one of the major barriers to this."* *(1st focus group Wales, Unguided cCBT)*

Emerging topic	Description *(quotes are in italics)*
Collaboration and support	
Reported in 7 quotations by 5 out of 11 focus groups in; • Aragón: health care professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Basque Country: psychologists (n=5); • Piemonte: doctors (n=11).	Probable facilitators that were mentioned were technical support, technical equipment, previous training, and healthcare professionals to perform additional follow-ups. *"Providing significant resources, in terms of money, rooms, number of health professionals."* *(1st focus group Piemonte, Guided cCBT)* *"As well as the nurses who do a great job, we probably need mental healthcare professionals more closely, going to primary care every now and then, to deal with the patient avalanche they have with these or other tools."* *(1st focus group Basque, Guided cCBT)*
Rationales and the implementation process	
Reported in 12 quotations by 7 out of 11 focus groups in: • Aragón: health care professional (n=7); • Badalona: psychologists / psychiatrists (n=7); • Estonia: physicians (n=9); • Piemonte: doctors (n=11); • Treviso: psychologists (n=5,7); • Wales: therapists (n=5).	Government regulations are needed that support the implementation process. cCBT should be provided by registered healthcare providers. The process needs to be affordable, in terms of money, rooms, number of health professionals. One of the suggestions was to implement incentives to assist the implementation process. *"There must be an incentive for both the patient and the professional in the early stages of their changing process. "* *(1st focus group Badalona, Guided cCBT)* Practitioners should be consulted prior to the implementation of the services. It was suggested that local institutions might be able to promote the programme (e.g. municipalities, local authorities, associations). Also, meetings with the general population to present the tool were suggested. Finally, stakeholders need to be introduced to the tool. *"Apart from the ICT, it's important to involve the Municipality as well. It's important to introduce the service, because this help to become aware of it."* *(1st focus group Treviso, Guided cCBT)*

A.5.2 Leadership engagement (organisation)

Emerging topic	Description *(quotes are in italics)*
Commitment	
Reported in 25 quotations in 10 out 13 interviews in: • Aragón (n=1); • Badalona (n=1); • Basque Country (n=2); • Estonia (n=1); • Piemonte (n=1); • Treviso (n=2); • Wales (n=2).	First, the leaders acknowledged the importance of the programme; they involved and motivated the professionals to participate, given the wide use of technology and the innovativeness of the study. *"We are very happy with this project because it is very innovative and we think it can help us a lot in care practice." (1st interview Aragón, Guided cCBT)* *"We wish that this and other innovation projects continue, because it is very important to offer the patients any tool that might be useful for them." (1st interview Aragón, Guided cCBT)* *"Leadership engagement is essential." (1st interview Aragón, Guided cCBT)* *"I spent quite a large amount of time and energy in encouraging my colleagues, I mentioned it at the meeting of unit managers, and then we also went to several units to explain it." (1st interview Basque, Guided cCBT)* Despite this, certain sites experienced certain problems. *"It is also true that at this time in our organisation, specifically when the project was proposed in 2015, we had just come about as an integrated health care organisation, so maybe the timing wasn't the best for us to be on top of the project but, well ... that was also a barrier for us in some way, because we were caught in the middle of many projects and situations, not as much for the management but more for primary health care teams." (Basque2)* Clinical and cost-effectiveness must be supported by scientific studies to keep up the commitment. However, not every practitioner was happy to work with cCBT, since they did not have any experience with it before. *"The project can be seen as a possibility to create mutual interest, cultural habit in the relationship between general practitioners and the Mental Health Care Department." (1st interview Treviso, Guided cCBT)* *"Overcoming the lone working method of general Practitioners. " (2nd interview Treviso, Guided cCBT)* *"… some practitioners out in the field who practice CBT face-to-face and (are) quite traditional have been quite reluctant to adopt cCBT ,and what we've had is something of a culture." (2nd interview Wales, Unguided cCBT)* *"…it's that culture change in the teams that in some parts of the county have been quite difficult." (2nd interview Wales, Unguided cCBT)*

Emerging topic	Description *(quotes are in italics)*
	cCBT has many potentials, such as reducing participants on the waiting list. *"As managers within the directorate, we are very supportive of cCBT because we can see the benefits for waiting list reduction, for accessing patients who wouldn't normally wish to attend face-to-face CBT or group work." (2nd interview Wales, Unguided cCBT)* It seems that a key aspect of commitment is to involve professionals from the very beginning, and provide sufficient training. *"Once you involve professionals from the very beginning of the process, they feel the project is theirs, so this greatly improves the change management process and the adoption of new technology."* *(1st interview Badalona, Guided cCBT + ccVC)* *"Training courses, update and return sessions were organised, in particular for health professionals, during the entire life-cycle of the project." (1st interview Piemonte, Guided cCBT + ccVC)* *"…they can see the benefit, we can see that it's cost effective, that the clinical trials of it has been good." (2nd interview Wales, Unguided cCBT)*
Decision making processes and rationale	
Reported in 22 quotations in 10 out 13 interviews in: • Aragón (n=1); • Badalona (n=2); • Basque (n=1); • Estonia (n=1); • Piemonte (n=2); • Turkey (n=1); • Wales (n=2).	*"In this case it was top-down… it was Kronikgune who got in touch with management, and from management we encouraged it until it was implemented." (1st interview Basque, Guided cCBT)* Others reported a shared decision making process in which dialogue with the professionals was sought, and the approval of the healthcare setting was needed to implement the new tool. *"We were involved in order to start the project, to explain it, to choose the people that have to implement it, to supervise its implementation and evolution, and to provide support for any problem that could arise in the implementation." (2nd interview Badalona, Guided cCBT + ccVC)* *"Well, the decision was mine to make, when we were introduced to the project, we made the managerial decision, but we had professionals involved, i.e. we said 'we are interested in this project, are you ready to take part or not? Because if there is no involvement ,we are not going to launch it'. This was more or less the dynamics we followed. We started with volunteers, this wasn't a decision due to legal obligation."* *(2nd interview Basque, Guided cCBT)* However, in both cases, the early involvement of relevant stakeholders was reported to be key to facilitate implementation. *"These strategies are new for us, we see that they have a good future projection to be implemented … leadership support will depend on the cost." (1st interview Aragón, Guided cCBT)*

Emerging topic	Description *(quotes are in italics)*
Implementation strategies	
Reported in 22 quotations in 11 out 13 interviews in: • Aragón (n=1); • Badalona (n=1); • Basque (n=2); • Piemonte (n=2); • Treviso (2); • Turkey (n=1); • Wales (n=2)	Various implementation strategies were mentioned by the different sites, such as an implementation group that periodically met to report the results, and to analyse the problems and potential solutions. Further implementation strategies included: training, dissemination; motivation and including this project in the strategy of the local Health Service to improve the coordination with mental health services; giving professionals free hours; training, replacements when they had to attend meetings; involving management staff, etc. *"It is important to organise specific training sessions, and especially to encourage people to be open to different cultural models and to innovation." (1st interview Piemonte, Guided cCBT + ccVC)* *"Involve health professionals in the various phases of the project, providing them a regular update on the progress." (2nd interview Piemonte, Guided cCBT + ccVC)* *"….we've used the mental health partnership, mental health committee of the board, it's within our integrated medium term plan." (2nd interview Wales, Guided cCBT + ccVC)* *"The strategy we followed was to go and tell all unit managers; one of the targets of our strategy for 2016 was to improve coordination with mental healthcare, and within that mental coordination we had included MasterMind as another job to be done. Then we tried to have a professional in the project in all units, who would be involved and try to push it forward." (1st interview Basque, Guided cCBT)* *"Professionals have been acknowledged, i.e, they received incentives to take part in the programme, recognising work, facilitating training, facilitating replacement so they could attend training; and in this regard management was involved." (2nd interview Basque, Guided cCBT)* Raising awareness among health professionals to be part of a wide and innovative European project also seemed to be used to motivate professionals. *"Raise awareness among health professionals to be part of a pilot project with European scope, funded by the EU and then with the presence of other European countries. The project is innovative and ICT advanced from a technological point of view, and thus it contributes to innovate also the organisation of the treatment." (1st interview Piemonte, Guided cCBT + ccVC)* However, certain barriers to implementation included: restricted time, resistance from GPs who are used to working independently, and not by using tools such as cCBT. *"Healthcare professionals use the tools in their own time regular employment, extra time has not been provided for the*

Emerging topic	Description *(quotes are in italics)*
	treatment of patients with the services cCBT / ccVC." *(2nd interview Piemonte, Guided cCBT + ccVC)* Finally, the importance of adequate support and advertisement was mentioned. *"The new projects and new services should be adequately supported and advertised." (2nd interview Treviso, Guided cCBT)*

A.5.3 Perspective on implementation (organisation)

(Emerging) Topics	Description
Needs and perspectives	
Reported in 21 quotations in 8 out 13 interviews in: • Aragón (n=1); • Badalona (n=2); • Basque Country (n=2); • Piemonte (n=1); • Turkey (n=1); • Wales (n=1).	Different sites reported distinct needs and perspectives. Some reported having made no previous experience regarding innovation in mental health. *"We are starting, in mental health we still have a long way to go."* *(1st interview Aragón, Guided cCBT)* Professionals expected at first an increase in resources, because professionals need to spend extra time for training, but also for the delivery itself. cCBT is expected to bring societal benefits in the long-term (less prevalence of depression), rather than benefits for the organisation in the short term. Facilitators that were reported are: support, training, constant information, extra time for new responsibilities. cCBT must be seen as service that is delivered as standard at the clinic and not as something different. *"One barrier is how to fit the new technology into the daily routine. That's why the clinical transformation office is so important, because from there we are able to analyse indicators and measures objectives, and the performance before and after deployment of the new solution; then we are able to better tailor or adapt our service provision."* *(1st interview Badalona, Guided cCBT + ccVC)* *"We've made that flexible for the practitioner in the field, they have discretion within their job plans and within their clinics to spend the time that's necessary with the patient to support them with their cCBT."* *(2nd interview Wales, Unguided cCBT)* *"First, it is the cultural (barrier), to use treatments and techniques that are unfamiliar, this is the most important barrier."* *(2nd interview Badalona, Guided cCBT + ccVC)* *"Professionals have full-time dedication, and then they work those hours with some tools or others; it's true that they had all the*

(Emerging) Topics	Description
	training and all that, and they were given time to attend. But no, there was no extra time to apply the tool." (1st interview Basque, Guided cCBT) *"And as facilitators, we also had the support of Kronikgune whenever we had to call them for training, they've always been there."* *(2nd interview Basque, Guided cCBT)* Another issue that was mentioned was that some patients abandon the programme before finishing it, because they already feel better. *"… and then I believe there is another factor that maybe hasn't been taken into account, that they are patients who when they get a bit better, stop their appointments with the psychiatrist, the psychologist, and I think they also abandon these tools." (1st interview Basque, Guided cCBT)* Professionals seemed generally enthusiastic about the new tool. *"This study opens up new cultural and technological horizons."* *(2nd interview Piemonte, Guided cCBT + ccVC)* *"While recognising a potential benefit, we have not yet a priority, but we believe in the future to broaden the experience and continue the study."* *(2nd interview Piemonte, Guided cCBT + ccVC)* However, certain barriers might include: rurality, connectivity, lack of practitioner confidence in this format, cultural resistance, and the restrictive compatibility of the programme on handheld devices such as iPads. *"…rurality of Powys and the ICT connectivity we have within the county, another is the platform – more and more people using smart phones, iPads etc." (2nd interview Wales, Unguided cCBT)*
Implementation success	
Reported in 26 quotations in 10 out 13 interviews in: • Aragón (n=1); • Badalona (n=1); • Basque (n=2); • Estonia (n=1)	Mainly reasons for the failure or success, and their characteristics, were reported at the various study sites, such as the application not working, insufficient technical assistance, not enough professionals. *"From what they told me, the main difficulty was the tool. Therefore I believe it can't be like a contribution. I also think that this is something we should at least learn that ICT tools, applications frequently fail."* *(1st interview Basque, Guided cCBT)* *"Then they also told me that apart from the tool, they also find it difficult to contact the IT technician who had to respond to the problems, and was also very poor." (1st interview Basque, Guided cCBT)*

(Emerging) Topics	Description
• Piemonte (n=1); • Treviso (1); • Turkey (n=1); • Wales (n=2).	*"Implementation wasn't completed satisfactorily due to all the problems we had." (2nd interview Basque, Guided cCBT)* *"We had a problem because the person leading this project who was most involved had a major family problem, and was forced to step back for a while. This meant that the person who was going to facilitate the programme at the beginning turned this into a barrier by not being available at the time." (2nd interview Basque, Guided cCBT)* *"Barriers were availability regarding the ICT program, the problems we've had have been a major hurdle, and that was the greatest barrier which led to people abandoning the project. Another barrier is our situation, lack of substitutes, which made it difficult to get organised. In the end it has meant work overload for centres providing patients, because we didn't have substitutes to do it." (2nd interview Basque, Guided cCBT)* Economic savings were not observed yet, since it is too early for such an observation, the professionals stated. However, the professionals seemed certain that future savings will start as soon as cCBT is more universally implemented. Another professional stated that he would not expect economic savings, but a better care for patients in need. *"…fewer appointments at the GPs etc. Fewer follow ups with the CPN, so I haven't physically seen the evidence of that, but the early information that I saw would certainly indicate that there has been some savings." (1st interview Wales, Unguided cCBT)* *"I don't see us making any savings in cCBT… I'd see us actually investing in cCBT as a preventative measure to stop peoples' challenges escalating." (2nd interview Wales, Unguided cCBT)* However, the will to further try succeeding in the implementation is there. *"…the same would have happened to me, I would have approved it because I loved it, and as soon as I had any difficulties I would have said look, improve it and then I'll try it." (1st interview Basque, Guided cCBT)*
Strategy, policy and priorities	
Reported in 5 quotations in 4 out 13 interviews in: • Basque (n=1); • Estonia (n=1); • Piemonte (n=1); • Turkey (n=1).	Studies involving various countries face different obstacles regarding policy details, such as not being able to spend extra time to treat patients with cCBT/VC as it is considered a pilot study. Professionals stated that it could be included in the guidelines for the treatment of depression as in other European countries (NICE). Finally, one of the sites reported their plans to make cCBT an entry level class offered to all students through the student counselling centre with the aim of increasing quality of life.

(Emerging) Topics	Description
Commitment	
Reported in 25 quotations in 5 out 13 interviews in: • Badalona (n=1); • Basque (n=1); • Piemonte (n=1) • Wales (n=2).	Commitment to the project is very important. When professionals perceive themselves as part of the project, they work better as they reported. Involvement of stakeholders, support from the director and management staff, is very important as well. *"Then we made an effort to train quite a few professionals who had to be given days off work; the organisation made an effort because we believe in the project." (1st interview Basque, Guided cCBT)* *"We have provided all kind of facilities, in fact the data manager came from our organisation, and I believe it worked; she has been dedicating at least one day a week to this and to facilitate the organisation, but the organisation was 100% committed because we also believe in the project, although sometimes reality prevails." (1st interview Basque, Guided cCBT)* *"I see myself as taking a lead for this across Wales NHS … raising the profile and championing it, being clear about the priorities, making sure we become more focused on the evidence and the understanding oo what makes a difference." (2nd interview Wales, Unguided cCBT)* Certain barriers for professionals committing to the tool were mentioned. *"During the study, there were some difficulties of a cultural nature (such as resistance to innovation) and of technological nature for both the territorial coverage of the network (in the case of the ccVC) and for usability and limitations of the cCBT tool." (1st interview Piemonte, Guided cCBT + ccVC)* Some teams seem to be more committed to implement cCBT compared to others. *"It's a key priority … at a team level … we've seen two similar teams, one embrace cCBT very enthusiastically, and another team … has been much more reticent to take it on." (2nd interview Wales, Unguided cCBT)* *"….we're still trying to change the culture of some of the teams to embrace new technologies." (2nd interview Wales, Unguided cCBT)*
Guidelines and professional development	
Reported in 3 quotations in 10 out 13 interviews in: • Badalona (n=1); • Wales (n=1).	The MasterMind project offers professionals and study sites various incentives to support their development. For example: being able to participate in an international project and gain new professional capacities, primary care centres receive economic incentives depending on the recruitment targets achieved. This money has to be spent on research or learning purposes, such as attending conferences or diplomas.

(Emerging) Topics	Description
Concrete activities	
Reported in 9 quotations in 3 out 13 interviews in: • Aragón (n=1); • Basque (n=1); • Piemonte (n=2).	The implementation must include coordinated work involving the whole team (GPs, psychologists, psychiatrists and nurses, interchange of information, and transference of tasks). *"Our experience tells us that we have worked better once we have started to work collaboratively (in team)."* *(1st interview Aragón, Guided cCBT)* The professionals received various incentives to participate: they were reinforced with free hours for compensation purposes, they received training if needed. *"They were allowed to have the time off counted as labour deficit hours, I mean to say we worked out an estimate with them to see how much this might entail and that was compensated."* *(2nd interview Basque, Guided cCBT)* *"Regarding facilitators … we have facilitated their travelling to receive training, we have always provided substitutes so they could undergo that training as much as we could, we have compensated them, we have estimated the work hours which may be involved to compensate professionals."* *(2nd interview Basque, Guided cCBT)* Concrete activities that were suggested were increasing the actions to prevent mental disorders in the future. *"Ideally the treatment of mental disorders should be structured to be able to intercept the mental disorder onset before it determines important relational distortions that lead to marginalisation of the patient. Therefore intercepting the first symptoms of mental illness before it becomes disorder."* *(1st interview Piemonte, Guided cCBT + ccVC)* *"Development of specific programmes, based on epidemiological data, in order to understand adequately the mental disorder onset (age range 16-25 years, e.g. as it regards the psychosis."* *(1st interview Piemonte, Guided cCBT + ccVC)* *"Study and research programmes to better understand the causes of discomfort from not only a biological point of view, but also for example from a social perspective: migration, ethnic-cultural integration, etc."* *(2nd interview Piemonte, Guided cCBT + ccVC)*

(Emerging) Topics	Description
Technology	
Reported in 13 quotations in 10 out 13 interviews in: • Aragón (n=1); • Badalona (n=1); • Estonia (n=1) • Treviso (2); • Wales (n=2)	Technology contributes to ease work and therefore saves time. *"The need of technological resources that could make things less difficult." (1st interview Aragón, Guided cCBT)* One of the challenges includes fitting the new services into clinicians' daily routine. *"I would like to have online the psychotherapy programme in my clinic. Patients could be empowered, as they may choose what therapy they want to receive. " (1st interview Estonia, Guided cCBT)* The MasterMind project offers more treatment possibilities to patients. Also patients that are not willing to pay for psychotherapy receive a possible alternative. Facilitators are linked to the strong points of the protocol which stimulates the exchange between medical practitioners and specialists, resulting in an increase in the GPs' competence as well as the collaboration. The MasterMind project, facilitating, simplifying and developing competences, improves the possibilities of care. Another facilitator is the one linked to the use of computer as a tool for both communication and support for appropriate routes (tutoring). *"MasterMind accelerates the possibility of shared information systems."* *(1st interview Treviso, Guided cCBT)* *"In an ideal world healthcare will be widely computerised, perhaps with the risk of losing human contact." (2nd interview Treviso, Guided cCBT)* Finally, some of the barriers identified have been that some staff have been working in the health service a long time, and working in a traditional way, and new modes of service can be challenging to adopt. Practitioners question whether it is safe, effective, and whether service users will engage. Service users will need to be self-motivated, have choice, and find that mode of treatment acceptable. *"in terms of many of us who have been working in healthcare services for a long time, have worked in a sort of traditional way … new modes of service delivery are quite challenging at times for HCPs to adopt."* *(1st interview Wales, Unguided cCBT)* *"…some of us old folk will go 'Oh I'm not sure about that' and this may be another one where we go 'Is it safe?', 'Does it work?', 'What if they don't engage?'." (1st interview Wales, Unguided cCBT)* *"…So I think it's really the HCP motivation and grasp of it … the final thing would be about user acceptability, whether people who are in need of support feel confident enough to use the computer."* *(1st interview Wales, Unguided cCBT)*

(Emerging) Topics	Description
Resources	
Reported in 14 quotations in 7 out 13 interviews in: • Aragón (n=1); • Basque (n=2); • Estonia (n=1); • Piemonte (n=1); • Treviso (1); • Wales (n=1).	Resources are sparse, and an increase in resources would assist in the implementation of cCBT. These resources include: time, human resources, and technological resources. *"Some patients lack technological resources."* *(1st interview Aragón, Guided cCBT)* *"We do not have resources now to give that support."* *(1st interview Aragón, Guided cCBT)* *"In mental health, we do not have many resources nor professionals."* *(1st interview Aragón, Guided cCBT)* *"What can be done to simplify work and save time?"* *(1st interview Aragón, Guided cCBT)* *"Healthcare professionals are supported by dedicated personnel (two psychologists of MasterMind team) during the recruitment and treatment. So the time to be reserved for healthcare is limited to the prescription stage." (1st interview Piemonte, Guided cCBT + ccVC)* *"So if we can help people to think it's a different delivery mode rather than an outpatient appointment, then we should be allowing and seeing and enabling the healthcare professional to spend the time they need with that individual to encourage them." (1st interview Wales, Unguided cCBT)* In order to save resources from cCBT, the organisation first has to make an investment in it. At a later stage, when the infrastructure exists, the organisation can expect fewer appointments for GPs and community psychiatric nurses. *"There's a certain level of infrastructure you have to put in to get the internet CBT up and running." (1st interview Wales, Unguided cCBT)*

A.6 Domain 7: Socio-cultural, ethical and legal aspects

Emerging topic	**Description** *(quotes are in italics)*
Public image	
Reported in 10 quotations in 7 interviews in: • Badalona (n=2); • Basque Country (n=2); • Piemonte (n=3); • Turkey (n=1); • Wales (n=2).	In general, interviewees indicated that implementing cCBT in routine care positively impacts the organisation and how the public perceives the service provider. Internally, staff also indicated to be proud of being part of a leading organisation in the deployment of these kinds of services in their respective regions. *"I think this is another further improvement, and I think this will improve the image." (1st interview Basque Country, guided cCBT)* *"Telemedicine in psychiatry demonstrates an ambition to innovate the healthcare practices, also with the support of advanced equipment, particularly at a time with resources constraints due to the economic crisis of the western society." (1st interview Piemonte, guided cCBT)* Interviewees also indicated using the implementation outcomes to position themselves as leaders in the European market and can act as a reference to other players. *"The implementation of cCBT helps the organisation, which is very proud of being one of the leaders in the deployment of this kind of service in Catalonia, and wants to position itself as forerunner in the EU market." (1st interview Badalona, guided cCBT)* *"[…] then METU, as the first institution to establish this service, would have a stronger perception as a leader." (1st interview Turkey, guided cCBT)* *"Any innovative project in mental health in Aragón is an important reference for the others." (1st interview Basque Country, guided cCBT)* One of the major reasons for the services' contribution to the public image is to be able to provide more responsive services. *"Where we can have packages or episodes of care starting as close to possible after diagnosis ... that will help build the public image of the Health Board as a responsive mental health provider." (3rd interview Wales, unguided cCBT)*

Appendix 5

V

Sogomonjan, M., Kerikmäe, T. and Ööpik, P. A review Article on Internet-based Psychological Interventions in Primary Care. What is the Global Experience? How Reliable Are Results from RCTs? Lessons Learned from the European, US and Australia Case Studies. *Baltic Journal of European Studies, 8*(2): 146–163, 2018.

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A Review Article on Internet-based Psychological Interventions in Primary Care. What Is the Global Experience? How Reliable Are Results from RCTs? Lessons Learned from the European, US and Australian Case Studies[1]

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Abstract: *In the context of the EU's Digital Single Market (eHealth) Strategy, the deployment of digital tools for patients' empowerment and person-centred care is of high demand and importance. Shifting from treatment to health promotion and disease prevention, a variety of internet-based cognitive behavioural therapy programmes have been proven to be effective for managing common mental health disorders in secondary care even hough the effectiveness and the clinical use of internet-based cognitive behavioural therapy programmes alone in primary care have not been approved yet. Additionally, such interventions are neither included in the international clinical guidelines for treating common mental health disorders nor regulated by Member States as a*

[1] This work was supported by the Estonian Research Council grant PUT 1628.

healthcare service. Despite that, the UK National Health Service and the Swedish National Board of Health and Welfare endorse the use of internet-based cognitive behavioural therapy as a first treatment option. The aim of this research is to investigate the global experience of internet-based cognitive behavioural therapy programmes in controlled and real-life conditions in general practice and to evaluate the reliability of the results and concomitantly their compliance with the European Commission's eHealth Strategy. A systematic review of quantitative studies was conducted from January 2007 to December 2017. The results indicated that unsupported internet-based cognitive behavioural therapy programmes alone are less effective than combined therapy options for treatment purposes, if no additional therapy is prescribed. Guided internet-based cognitive behavioural therapy may supplement traditional treatment methods resulting in improving the control of mental disorders, but are unable to demonstrate consistent quality or replace face-to-face therapy.

Keywords: *anxiety, depression, digital single market, effectiveness, general practice, internet-based cognitive behavioural therapy, randomized control trial*

1. Introduction

Common mental health disorders have significant adverse impacts on the societal and emotional functioning of individuals (Collins *et al*., 2018). At a global level, in 2015 the prevalence of depression was estimated to be 4.4%, while 3.6% of people suffered from anxiety disorders (WHO, 2017). Access to healthcare for people experiencing these common mental disorders is a challenge mainly due to lack of resources reflected in the limited number of qualified therapists and the health system financing (NICE, 2011; WHO, 2017; Layard & Clark, 2014). Given that, the digital single market sets a priority to empower citizens with digital health solutions in order to foster the integration of health promotion and prevention into primary care. Digital transformation of healthcare services is aimed to develop new care models that will pursue with the delivery of efficient and cost-effective care. (Communication COM(2018) 233 final)

According to Berger *et al*. (2016) one way to increase access to evidence-based psychological treatment in primary care is to provide internet- or computer-based cognitive-behavioural treatment (iCBT/cCBT). iCBT or cCBT is a low-intensity

non-pharmacological intervention that includes internet-delivered psychological therapies or any downloadable software, online multimedia programme or smartphone application designed to teach users the basic concepts of cognitive behavioural therapy and the skills for managing their mental health symptoms (Jonassaint *et al*., 2017; Pennant *et al*., 2015; Marks *et al*., 2007). Despite the variety of iCBT interventions available on the global market, the most widely known internet-based psychotherapies used so far include the Beating the Blues, MoodGYM and Colour Your Life programmes. iCBT has the potential to increase access to high-quality mental health treatment for minority populations Jonassaint *et al*., 2017). Large-scale randomized control trials (RCTs) have investigated the high level of adherence and significant outcomes in reducing symptoms of depression considering guided therapist-assisted computerized cognitive behavioural therapies in routine clinical practice (Jonassaint *et al*., 2017; Richards & Richardson, 2012; Perini *et al*., 2009; Ruwaard *et al*., 2009; Andersson *et al*., 2005; Berger *et al*., 2011; Johansson *et al*., 2012; Knowles *et al*., 2014; Andersson & Cuijpers, 2009; Kay-Lambkin *et al*., 2011).

The efficacy of iCBT for depression in primary care so far has been investigated by only one study, wherein iCBT has been shown to be more effective than treatment-as-usual (Proudfoot *et al*., 2004). Salomonsson *et al*. (2017) have argued that using a stepped-care model[2] is an effective and efficient way to achieve improvements for nearly two thirds of primary care patients with common mental disorders while using fewer therapist resources.

Concerns about the clinical effectiveness of mental health services provided through internet-based interventions incited controversy among health care professionals worldwide (Montero-Marín *et al*., 2015; Du *et al*., 2013). The ambiguity regarding the effectiveness of iCBT programmes in treating depression and anxiety is apparent. If iCBT programmes are effective for use in real-life conditions in general practice, such programmes should not meet barriers to uptake or demonstrate high attrition rate.

Therefore, the aim of this review is to evaluate the effects and adherence of iCBT for adults with depression and anxiety disorders in general practice. The following main questions are addressed to complete this review:

1. What is the global experience of iCBT in primary care?
2. Does iCBT work in the 'real world' in general practice?
3. How reliable are the results from RCTs?

[2] Stepped care model: *(Step I = guided self-help CBT + Step II = face-to-face CBT or continued guided self-help treatment)*

2. Methods

2.1 Search strategy and study selection

A comprehensive search was carried out on Scopus, the Web of Science, PubMed and Psychology Medicine electronic databases from January 2007 to December 2017 in order to retrieve the most relevant data for current versions of iCBT. The search terms were 'internet- or computer-based cognitive-behavioural therapy', 'primary care', 'randomized control trials', 'efficacy', 'depression' and 'anxiety'. Articles were selected by title, by abstract or by reading the full original paper. Only articles in English were included.

2.2 Eligibility criteria

For the purpose of this study we selected RCTs evaluating the efficacy and, where possible, the effectiveness of iCBT for depression and anxiety disorders in primary care. Studies were eligible for inclusion if RCTs were performed in the primary care setting to investigate the comparison between:

(1) guided iCBT with minimum therapist contact with the control group or a wait-list control (WLC) group and

(2) unguided self-help programmes with face-to-face therapy.

The exclusion criteria were non-randomized control trials or studies that recruited children and adolescents or patients with severe mental health disorders including psychiatric co-morbidity, psychosis, bipolar disorder, personality disorders, alcohol or drug dependence or suicidal tendencies. Studies with an economic evaluation, including those evaluating the cost-effectiveness and efficiency of iCBT, were excluded from the analysis; however, they are considered important for further research.

2.3 Quality assessment

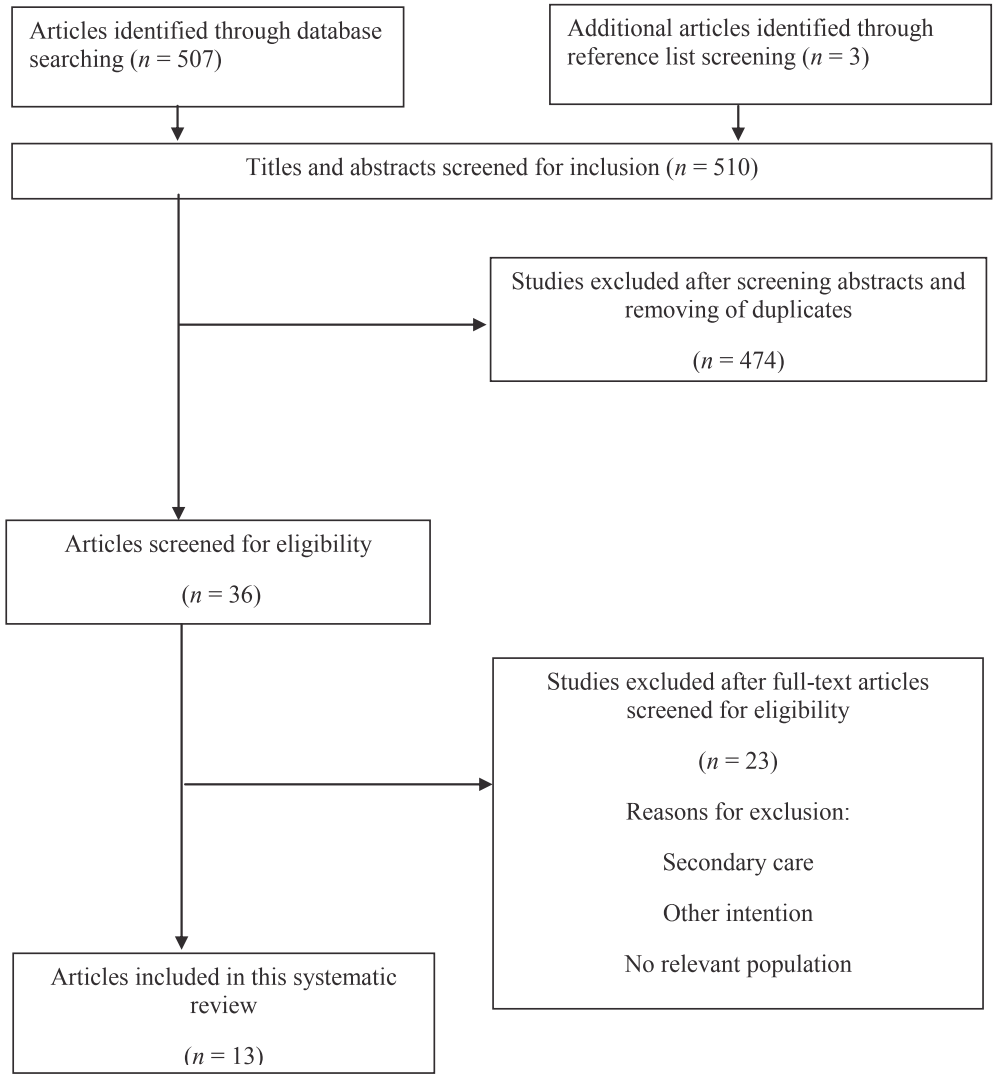
The methodological quality of studies has been evaluated, including criteria for intervention trials. No formal assessment of quality was performed as the main search strategy focused on whether the trial was randomized and performed in a primary care setting.

3. Results

3.1 Description of studies

A systematic review of 510 research articles were retrieved from the PubMed (n = 37), Scopus (n = 37), Web of Science (n = 53) and Psychological Medicine (n = 383) databases. As shown in Figure 1, the literature search identified 64 duplicate studies, and 410 further studies were removed for the reason that they did not address the scope of the current research. For more detailed evaluation 36 studies were considered. Only 14 studies met the inclusion criteria. Of those 14 studies,

Figure 1. Identification of studies for review



one study was removed due to insufficient data. All 13 studies were quantitative and conducted in Europe (69.2%), USA (15.4%) and Australia (15.4%).

3.2 Participants

Participants included in the studies were prescribed iCBT by their general physicians (GP) or licensed psychologists. The participants' mean age in the studies varied from 33.7 to 45.2, except in the study by Hickie *et al.* (2010) where patients were recruited starting from age 16. In all studies female participants constituted the overwhelming majority.

Of the 4,265 adult primary care patients, depression was estimated among 1,589 patients. The majority of patients participating in RCTs experienced several types of anxiety disorders (n = 2,676), including generalized anxiety disorder (n = 1,129), social anxiety disorder (n = 75), post-traumatic stress-disorder (n = 181), panic disorder with or without agoraphobia (n = 715) and other anxiety-related conditions (n = 575). Out of 8,401 participants assessed for eligibility, 3,134 patients remained until post-treatment. All in all, 2,717 patients received internet-based psychological therapy (both guided and unguided iCBT). Additionally, 264 patients were enrolled in the iCBT course after the treatment group had completed the programme. Treatment and control groups were followed up with at three, four, six, eight and twelve months post-treatment, depending on the study design. A variety of measurement tools were used to assess patients at baseline and post-treatment and during the follow-up period.

3.3 The global experience of iCBT in primary care

A literature review of randomized controlled trials of iCBT in primary care in Europe, the USA and Australia proved that additional professional support is required to engage depressed patients with self-help internet-based psychotherapies. At present, computerized CBT is offered by many healthcare systems as a minimally supported low-intensity psychological intervention and as part of a stepped-care framework (Salomonsson *et al*., 2017; Høifødt *et al*., 2013). The level of support for each patient is different and it varies mainly in severity of depression and the patient's ability to perform tasks online. Even though enhancement in the level of support and guidance increase uptake and effectiveness (Andersson & Cuijpers, 2009; Baumeister *et al*., 2014), evidence has accumulated to indicate that a low-intensity form of support such as technical telephone support had no additional clinical benefits when iCBT was added to usual primary care (Gilbody *et al*., 2017).

3.4 Drop-out and participants' adherence to iCBT throughout selected studies

In the included studies, iCBT modules aimed to help patients gain mastery over their symptoms using CBT techniques. Out of 3,134 patients remaining at post-treatment, 484 patients completed all sessions. The mean number of completed sessions varies from 1.1 to 7.2 with an estimated number of 4.1. Participants in the intervention group had a relatively higher drop-out rate relative to participants in the wait-list control group (Høifødt *et al*., 2013). Even though the drop-out rate was related to improvement attributed to other concurrent treatments (Newby *et al*., 2013), a variety of adverse events was also reported during treatment. As a consequence of commencing iCBT, the patients experienced a negative impact on their general wellbeing and reported slightly worse mood and more anxiety (Salomonsson *et al*., 2017; Rollman *et al*., 2017; Simblett *et al*., 2017).

In the studies conducted by de Graaf *et al*., in 2009 and in 2011, participants completed the mean of 3.4 sessions of Colour Your Life in the iCBT group and 4.0 in the iCBT plus treatment-as-usual group (de Graaf *et al*., 2009; de Graaf *et al*., 2011).

Altogether, 1,507 participants were allocated to participate in the Beating the Blues programme. In the study by Kessler *et al*. (2009) in the iCBT group, at the four-month follow-up 90 participants completed five sessions, while at the eight-month follow-up 70 participants completed eight sessions (Kessler *et al*., 2009). In the study by Gilbody *et al*. (2015), 18% (31 of 175) of participants completed all eight sessions. Moreover, 44% (93 of 210) of participants reported non-serious adverse events and 7% (15 of 210) reported serious adverse events (Gilbody *et al*., 2015). In the study by Rollman *et al*. (2017), at the six-month follow-up, 36.7% (221 of 603) of participants completed all eight sessions of the programme. The mean of 6.3 sessions of the BtB programme (40%) in the iCBT group and the mean of 7.2 sessions (32%) in the computerized cognitive remediation therapy (cCRT) group were completed in the study by Simblett *et al*. (2017). In the study by Hickie *et al*. (2010), 41% (12 of 29) participants did not complete MoodGYM programme. In the study by Gilbody *et al*. (2015), trained technicians made weekly telephone calls to 242 patients using MoodGYM. Only 16% (29 of 186) of participants completed all six sessions of the MoodGYM programme. In addition, 45% of participants reported adverse events (93 participants demonstrated non-serious adverse events and 15 participants reported serious adverse events). In the minimally supported group, 10.4% of participants completed all five sessions of MoodGYM and 19.4% of participants completed the telephone-facilitated iCBT. (Gilbody *et al*., 2017) In

the study by Høifødt *et al*., 2013 out of 52 participants in the intervention group, 31 participants (60%) adhered to the MoodGYM programme and attended 7 sessions. A mean of 3.8 of the 5 modules was completed during the treatment period by 50 patients. A mean of 7.2 sessions were attended. At seven weeks post-treatment, 15% participants (n = 8) had completed the treatment. However, 45% of participants (n = 19) in the intervention group received additional treatment during the six-month follow-up period. (Høifødt *et al*., 2013)

In the first study by Newby *et al*. (2013), 89% (41 of 46) of participants in the iCBT group completed all sessions of the Worry and Sadness Program. In the second study 41.2% (56 of 136) of participants completed all six lessons. (Newby *et al*., 2013)

In the study by Kivi *et al*. (2014), the supported iCBT Depressionshjälpen programme was provided for 44 depressed patients. In twelve weeks, 20 of 36 (56%) participants completed all seven modules and the average number of completed sessions was 5.1. Only 10% of participants reported adverse events. (Kivi *et al*., 2014)

In addition to treatment-as-usual, a supported Wellness Workshop CD-ROM programme was provided for 100 participants in the study by Levin *et al*. (2011). After two weeks, participants received a brief telephone call from the psychologist, but 27 participants did not start the program. The programme was used by 72 participants for an average of 2.9 weeks. (Levin *et al*., 2011)

In the study by Berger *et al*. (2017), the mean number of completed modules of the Velibra programme was 3.9. Thirty-two participants (45.7%) completed all six modules of the programme. Eight participants (11.4%) did not start the programme at all. (Berger *et al*., 2017)

3.5 Effects of the internet-based interventions

The results showed no clinically or statistically significant changes before treatment and immediately after treatment between treatment groups in all studies (Berger *et al*., 2017; Høifødt *et al*., 2013; Newby *et al*., 2013; Rollman *et al*., 2017; Simblett *et al*., 2017; Gilbody *et al*., 2017; de Graaf *et al*., 2009; Levin *et al*., 2011; de Graaf *et al*., 2011; Hickie *et al*., 2010; Kessler *et al*., 2009; Gilbody *et al*., 2015). Less than half of the patients recovered at post-treatment. Results from the studies by Høifødt *et al*. (2013) and Rollman *et al*. (2017) demonstrated that mean scores for the face-to-face group and WLC group were lower compared with scores for the intervention group for the depressive and

anxiety subscales at post-treatment and at the six-month follow-up. Kivi *et al*. (2014) found no significant differences between the reduction in scores for the iCBT and TAU groups during treatment or post-treatment. Berger *et al*. (2017) emphasized in their results that, at post-treatment, the participants benefited significantly in the TAU group plus unguided iCBT more, compared with the TAU group only. In the study by Simblett *et al*. (2014), participants in all groups demonstrated a decrease in symptoms of distress across time, but there was very little difference in terms of functional ability at post-treatment. Clinically significant improvement was noted in the study by de Graaf *et al.* (2009) for 26 patients in the iCBT group from 91 patients available at post-treatment. At the twelve-month follow-up, 36 patients in the intervention group were determined to be in remission (de Graaf *et al*., 2009). Statistically significant differences on recovery were found in the studies by Hickie *et al*. (2010) and Levin *et al*. (2011). Participants in the intervention group demonstrated significant decreases in dysfunctional attitudes and were more likely to go into remission than participants in the TAU group (Levin *et al*., 2011). A small, clinically meaningful difference was found immediately after treatment in favour of enhanced GP care plus the MoodGYM group (Hickie *et al*., 2010). A reliable improvement in reducing depression and anxiety disorders were demonstrated in the studies by Hickie *et al*. (2010) and Newby *et al*. (2013). A small difference was found in favour of the MoodGYM programme vs usual GP care at the twelve-month follow-up (Gilbody *et al*., 2015). A significant between-group difference was found in the study by Gilbody *et al*. (2017) in anxiety scores in favour of telephone-facilitated iCBT.

3.6 The impact of iCBT work in a 'real-world' general practice

A 'real-world' general practice significantly differs from develop-led trials, where additional professional support was included and the effects of the internet-based psychotherapies were measured under strictly controlled conditions. Studies delivering iCBT in real-life conditions in primary care are limited and have been absent for a long time. The impact of iCBT work on depression outcome in real-life conditions was evaluated in our review only in the 2014 study by Kivi *et al*. Licensed psychologists and psychotherapists (n = 12) were involved to support patients randomized for iCBT. Even though the proportion of recovered patients between treatment groups was similar (n = 15, BDI-II $\leq$ 13), eight patients in the iCBT group at post-treatment were undergoing pharmacological therapy and three patients deteriorated. (Kivi *et al*., 2014)

3.7 Therapist time

This review includes five trials in which therapist support time has been measured. Therapist time varies from two minutes to 30 minutes depending on the study design. Kessler *et al*. (2009) found that the quality of care was higher when CBT was facilitated by a therapist in real-time monitoring. Furthermore, real-time online CBT was suggested for patients with severe symptoms (Kivi *et al*., 2014).

In the study by Gilbody *et al*. (2015), patients allocated to the BtB programme received on average 6.2 minutes of support calls from a technician and those in the MoodGYM group received 6.5 minutes. In the study by Newby *et al*. (2013), a clinician and therapist regularly spent on average 23.37 minutes per patient on email and telephone contact during the trial. After each module, in the study by Høifødt *et al*. (2013), participants received face-to-face support (a range of 15–30 minutes). In the study by Kivi *et al*. (2014), therapists spent an average of 15 minutes on emails or telephone calls with each patient during each week. Every two weeks participants received telephone calls lasting from 15 to 30 minutes or an email from care managers in the study by Rollman *et al*. (2017).

3.8 Reliability of RCT results

Even though a small dosage of iCBT was associated with lower antidepressant medication use (de Graaf *et al*., 2011), it is difficult to determine the effectiveness of iCBT insofar as patients were financially compensated and allowed to undergo other treatment.

3.8.1 Financial compensation

To minimize the attrition rate and the number of drop-outs, participants in the study by de Graaf *et al.* (2009) were compensated €25 for internet use. In the study by Levin *et al*. (2011), each participant received $75 at each data point for completing the questionnaire and interview assessments. Finally, in the study by Rollman *et al*. (2013), after each completed assessment at three, six and twelve months, patients received from $15 to $60.

3.8.2 Psychotropic medication

No additional data have been collected about the impact of medication on patient outcomes while other interventions have been employed. In this review participants in all studies were equally likely to receive pharmacotherapy. In the 2010 study by Hickie *et al*., participants did not receive pharmacological

care at the time of study participation. Results from studies demonstrated that participants in the iCBT group were more likely to receive antidepressants compared with patients in the usual care group or in the treatment plus usual care group. It is difficult to evaluate the size of effect and relation between medication, face-to-face treatment or iCBT as long as data about the use of pharmacotherapy pre- and post-treatment and during the follow-up period are not available, which is true for the studies by Gilbody *et al*. (2017), Simblett *et al*. (2017), Levin *et al*. (2011), Newby *et al*. (2013) and Berger *et al*. (2017). Moreover, no study has yet analysed the outperformance of unsupported iCBT or guided iCBT as compared to pharmacological treatment.

4. Discussion

4.1 Main findings

This review includes both primary and secondary outcomes on depressed patients in the intervention trials for internet-based psychotherapies. Within the last ten years, more than 500 studies have been published examining telepsychiatry. The results from recent trials demonstrated reduction of symptoms of depression and anxiety even though participants were more likely to continue the use of antipsychotic medication and usual care. It is obvious that additional therapy and regular guidance result in improved outcomes and control of mental disorders. It has been noted that treatment outcomes from supported iCBT immediately at post-treatment are more efficacious than in wait-list control conditions. However, the effectiveness of iCBT in such trials is diminished at follow-up. Although iCBT is aimed at treatment of mild to moderate symptoms of depression and anxiety, six studies in this review included participants with more severe symptoms. Participants recruited within the primary care setting by health care providers with experience in CBT were more likely to complete iCBT modules compared with self-referred participants and those recruited through media. As long as therapist input has been considered important in terms of participant engagement, our findings underline that a minimum of 30 minutes per week is required either face-to-face or through telephone calls. In the methodologically stronger studies, participants demonstrated a high attrition rate and low adherence to iCBT intervention. In those studies, the secondary outcome at follow-up was considered at least a six-month rather than at a three-month follow-up or immediately at post-treatment. Our findings emphasize that the effectiveness of iCBT interventions in the primary care setting as an effective option for non-pharmacological therapy cannot be confirmed for

several reasons. First, the secondary outcome of the trials has not been measured with a clinical interview to establish the presence of depression according to accepted classification systems. The 'effectiveness' and 'efficacy' of iCBT were evaluated on participants' self-reported measures (questionnaires/assessments). Second, participants were free to use medication prior to the beginning of the study, during the trial, post-treatment and at follow-up. Thirdly, unemployed participants in three studies received financial compensation. Eventually, high drop-out and attrition rates are presented in all studies where financial compensation was not offered. Even though participants underwent an informed consent that was approved by the Review Board, information about the approval from the medical ethics committee is missing, especially in the studies where patients were provided with financial compensation. In two studies, participants reported reasons for dropping out. Only a small number of participants in our review completed all sessions of iCBT (Berger *et al*., 2017; Høifødt *et al*., 2013; Newby *et al*., 2013; Rollman *et al*., 2017; Simblett *et al*., 2017; Gilbody *et al*., 2017; Kivi *et al*., 2014; de Graaf *et al*., 2009; Levin *et al*., 2011; de Graaf *et al*., 2011; Hickie *et al*., 2010; Kessler *et al*., 2009; Gilbody *et al*., 2015; Waller & Gilbody, 2009). This, however, could not prove that the use of iCBT was effective in the reduction of depression and anxiety disorders insofar as data concerning reasons for drop-out are missing in most of the studies. In the end, information according to treatment fidelity (i.e. whether therapists who provided iCBT were supervised and treatment was provided by designed protocol) and security issues (the manner of treatment delivery) are absent in many studies.

4.2 Strengths and limitations

The current research was restricted to articles published in English within the last ten years. Researchers confirm that a risk of bias assessment could not be undertaken. Studies eligible for inclusion were primarily efficacy studies with lack of comparison groups evaluating the evidence for effectiveness of iCBT alone or for the added benefit of iCBT. In most studies, patients were recruited through primary care by licensed psychologists or neuropsychologists rather than by general physicians. In addition, programmes commercially available for a wider population are not tailored specifically for minority patients. Data about the cultural diversity of the populations studied have not been considered in most studies.

4.3 The interpretation of the study results in relation to existing literature

A previous review found iCBT to be no less effective than face-to-face cognitive-behavioural therapy (Kaltenthaler *et al*., 2002; Kaltenthaler *et al*., 2004; Kaltenthaler *et al*., 2006) and to reduce therapist time (Kaltenthaler *et al*., 2002; Kaltenthaler *et al*., 2006). At present, the results demonstrated reduction of symptoms of depression and anxiety even though participants were more likely to continue the use of antipsychotic medication and usual care. Treatment outcomes from supported iCBT immediately at post-treatment are more efficacious than in WLC conditions. The effectiveness of iCBT in trials is diminished at follow-up.

4.4 Compliance with digital single market strategy

In the context of digital single market, integrated eMental Health applications into primary care increase the collaborative economy of Member States, in particular improving the complementarity of cross-border healthcare services. Data collected from internet-based psychological interventions help us achieve the second priority of the European Strategy—personalized medicine through shared European data infrastructure. Although it seems that the European Strategy interests are more directed at protecting economic interests rather than human rights to receive qualified health and care (see also Uusitalo, 2018). In fact, EU legislation on medical devices, data protection, electronic identification and security of network give a legal framework for the eHealth infrastructure. However, digital solutions for health prevention and control of disease are not yet legally defined as healthcare services either in the regulation of Member States or in the EU legislation. All this leads us to think how to evaluate state capacity to handle healthcare services in the context of human dignity (see also Kerikmäe & Joamets, 2018; Kerikmäe *et al*., 2016).

5. Conclusion

Researchers are inclined to affirm that iCBT is used to control common mental health disorders enabling easy access to rather than providing quality of treatment. Reduced symptoms are likely to be an outcome due to reasons not considered in the studies. Engagement of patients with common mental health disorders with iCBT might show an effect but only if offered alongside a high level of facilitation and support or delivered online (Gilbody *et al*.,

2017; Kessler *et al*., 2009). The studies included in this review underlined the importance of additional resources in general practice. The specific impact of iCBT is difficult to determine without having care coach support and if data about the time therapists spent on each patient are not available. Instead, it makes it more complicated to evaluate which treatment option or a combination of therapeutic options resulted in the improved outcomes. Given the difficulty in assessing the clinical efficacy and effectiveness of iCBT, no study has revealed a drop-out rate between unemployed and employed participants or between participants on pharmacological therapy and those who did not take medication therapy. Researchers are inclined to confirm that patients completed iCBT modules either due to financial compensation or regular telephone calls and emails. Our findings underline that neither efficacy nor effectiveness of iCBT has been proven and should not replace face-to-face therapy until evidence for iCBT's benefits is found among service providers and patients. All this means that the European Strategy on enabling transformation of health and care in the digital single market does not meet directly patients' needs but is fostering sharing economic interests.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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Curriculum vitae

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2016–…	Tallinn University of Technology, School of Information Technologies, PhD studies
2013–2015	Tallinn University of Technology, School of Information Technologies, MScEng
2009–2013	Tallinn Health Care College, Bachelor of Health Science (BHS)

4. Language competence

English	Fluent
Estonian	Fluent
Russian	Fluent
Armenian	Fluent

5. Professional employment

2024–…	Health Board, public officer for patient safety and liability insurance issues
2023–…	World Health Organisation, consultant
2023–…	Tallinn University of Technology, lecturer
2024–2024	AS Metrosert, Applied Research Centre, health data ethics and legal counsel
2021–2023	Tallinn University of Technology, early-stage researcher

2021–2021	Asian Development Bank, consultant
2019–2019	(international health information system expert)
2017–2019	Ministry of Social Affairs, project manager
2017–2018	Tallinn University of Technology, curriculum development specialist
2016–2017	Health Board, senior inspector
2014–2017	Tallinn University of Technology, project manager

6. Honours and awards

2023	Vanadzor State University, Armenia
2021	Ministry of Health, Republic of Armenia
2018	Estonian Dental Association, Estonia
2018	Mobility Grant of the French Embassy in Estonia (Ambassade de France, Institute Français d'Estonie)
2015	Fellowship of the British Chamber of Commerce (MTÜ Briti Eesti Kaubanduskoda stipendium)
2013	Tallinn Health Care College, Estonia
2005–2007	Tallinn Tõnismäe Real School

7. Defended thesis

2015, Systematic Review of Digital Online Speech Therapies and Suggestions for Integration with Estonian Health Information System, MScEng, supervisor Prof. Peeter Ross, Tallinn University of Technology, School of Information Technology.

8. Fields of Research

- Digital Health
- Health Law
- Ethics

9. Scientific work

Papers

1. Sogomonjan, M. Challenges and opportunities for e-mental health policy: an Estonian case study. *Contemporary Social Science, 16*(2): 185-198, 2020
2. Sogomonjan, M. and Forcht Dagi, T. Online Sale of Pharmaceuticals: Liberalization of EU Law in the Context of Transnational Criminal Law. In: Digital Development of the European Union, 45−66. Springer, 2023
3. Sogomonjan, M., Kerikmäe, T., Ööpik, P. and Ross, P. A report on the Survey. Attitudes of Estonian Healthcare Professionals to Internet-delivered Cognitive Behavioural Therapy. *Cogent Psychology, 6*(1), 2019

4. Sogomonjan, M. and Perera, K. La télémédecine en Estonie. In: N. De Grove-Valdeyron. Cahiers Jean MONNET Le déploiement de la télémédecine dans les droits nationaux au sein de l'Union européenne, 471−495. Presses de l'Universite de Toulouse 1 Capitole, 2019

5. Sogomonjan, M., Kerikmäe, T. and Ööpik, P. A review Article on Internet-based Psychological Interventions in Primary Care. What is the Global Experience? How Reliable Are Results from RCTs? Lessons Learned from the European, US and Australia Case Studies. *Baltic Journal of European Studies, 8*(2): 146-163, 2018

6. Sogomonjan, M. and Kerikmäe, T. Challenges in the eHealth Regulatory Policy. How Deep is your Law? Brexit, Technologies, Modern Conflicts. Vilnius University Faculty of Law. 27-28.04.2017. Ed. E. Kurelaitytė. Vilnius University Faculty of Law Vilnius, Lithuania: Vilnius University, 367−375. International Network of Doctoral Studies in Law, 2017

7. Kasper, A., Laurits, E. and Sogomonjan, M. Digital Evidence in Estonia. In: V. Franssen and Tosza, S. (Ed.). Cambridge Handbook of Digital Evidence in Criminal Matters. Cambridge: Cambrisge University Press, 2023

8. Zineldin, M., Farhat, A. and Sogomonjan, M. Correlation Between COVID-19 Pandemic, Emotion Intelligence and Depression. *Acta Scientific Neurology, 4*(4), 54-58, 2021

9. Joamets, K. and Sogomonjan, M. Influence of Forced Child Marriage and Domestic Violence on Mental Health and Well-Being. Conflict of Traditions and Rights of Roma Children*. International and Comparative Law Review, 20*(1), 58−76, 2020

10. Hantrais, L., Allin, P., Kritikos, M., Sogomonjan, M., Anand, P., B., Livingstone, S., Williams, M. and Innes, M. Covid-19 and the digital revolution. *Contemporary Social Science, 16*(2): 256-270, 2020

11. Txarramendieta, J., Fullaondo, A., Keenoy, E. M., Vis, C., Etzelmuller, A., Pinto, A. G., Sierra, M., Piera, J., Fernandez, S., Cavallo, M., Carniato, S., Williams, B., Gokay, D., Sogomonjan, M. and Vallejo, L. Final Trial Report 2nd Wave (cCBT). MasterMind project. Final Trial Evaluation, Deliverable 6.5, WP6 - Internet based guided cCBT for treatment of depression, V2.0. EU Commission, 2017

12. Roots, L. and Sogomonjan, M. Kodumaa vahetamise kampaania ei tööta. Äripäev, 2017

Conference presentations

1. Sogomonjan, M. Legal and ethical challenges implementing computerised Cognitive Behavioural Therapy (cCBT) in Estonia, World Conference on Bioethics, Medical Ethics and Health Law: 21st – 22nd December 2024, London

2. Sogomonjan, M. Patient safety in the cross-border healthcare. New Technologies in Health: Medical, Legal and Ethical Issues: 21st – 22nd November 2019, Thessaloniki

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2015	Briti Kaubanduskoja stipendium, Eesti (MTÜ Briti Eesti Kaubanduskoda stipendium)
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