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Optimising patient engagement in digital mental health interventions: Implications and recommendations from a “Best-fit” framework synthesis

Master’s thesis

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Patsientide kaasamise optimeerimine digitaalsetesse vaimse tervise sekkumistesse: Kvalitatiivne kirjanduse ülevaade “parima sobivuse” (best-fit) raamistiku alusel

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Author’s declaration of originality

I hereby certify that I am the sole author of this thesis. All the used materials, references to the literature and the work of others have been referred to. This thesis has not been presented for examination anywhere else.

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Abstract

Background: Digital therapeutics (DTx) provide a promising and readily accessible method to address the increasing global prevalence of mental health disorders, offering the potential to surpass existing barriers in conventional care, and increase access to mental health support. Numerous studies have consistently demonstrated low levels of patient engagement in real-world settings when implementing DTx interventions, and few studies have examined patients' experiences and perceptions to identify possible barriers and facilitators to enhance patient adherence engagement. **The aim of the study:** To synthesise existing evidence on patients' perspectives regarding engagement and adherence with DTx, to provide an improved understanding of how to optimise patient engagement and adherence in the context of DTx. **Methods:** This is a qualitative literature review, employing the "best-fit" framework synthesis methods. The research strategy encompasses a comprehensive review of literature, thematic analysis and synthesis, to construct an evidence-based conceptual model. **Results:** Although DTx offers significant advantages in terms of accessibility, flexibility and adaptability, addressing challenges related to program design, functionality, and the therapeutic alliance is paramount for the efficacy of these interventions. **Conclusions:** This conceptual model could serve as a guide for future development and refinement of DTx interventions, ensuring they are user-centric and tailored to maximise sustained patient engagement and adherence.

This thesis is written in English and is 95 pages long, including seven chapters, 10 figures, and 14 tables.

Annotatsioon

Patsientide kaasamise optimeerimine digitaalsetesse vaimse tervise sekkumistesse: kvalitatiivne kirjanduse ülevaade “parima sobivuse” (best fit) raamistiku alusel

Taust: Digiravimitel (DTx) on suur potentsiaal lahendada üha suurenevat vaimse tervise häirete levimust kogu maailmas, võimaldades patsientidele kiiremat juurdepääsu vaimse tervise abile. Mitmed uuringud on näidanud patsientide madalat kaasatust ning vähest järjepidevust digiravimite kasutamisel. Patsientide kogemusi ning hoiakuid digiravimite kasutamisel ei ole veel palju uuritud, mistõttu ei ole teada, millised on peamised tegurid, mis võimaldaksid patsientide edukamat kaasamist ning eesmärgipärast digiravimite kasutamist. **Eesmärk:** Käesoleva magistritöö eesmärk oli kvalitatiivse kirjanduse ülevaate käigus uurida patsientide kogemusi ning hoiakud seoses digiravimitega, et pakkuda soovitusi patsientide edukamaks kaasamiseks ning suurendada pikaajalist ning eesmärgipärast digiravimite kasutamist. **Metoodika:** Antud magistritöö põhineb kvalitatiivsel kirjanduse ülevaatel “parima sobivuse” (best-fit) raamistiku alusel. Uurimisstrateegia hõlmas süstemaatilist kirjanduse ülevaadet, millele järgnes temaatiline sisuanalüüs. Töö tulemusena valmis tõenduspõhine kontseptsuaalne mudel, mis annab põhjaliku ülevaate patsientide kasutajakogemusest ning seda mõjutavatest faktoritest vaimse tervise digiravimite kasutamisel. **Tulemused:** Digiravimid pakuvad märkimisväärseid eeliseid juurdepääsatavuse, paindlikkuse ning kohaldatavuse tõttu, kuid nende sekkumiste tõhususe tagamiseks on vajalik arvestada ka digiravimite peamiste puudustega. Peamised takistused digiravimite järjepidevaks kasutamiseks patsientide poolt on vähene kasutajasõbralikkus, tehnilised probleemid ning usaldusliku terapeudilise suhte puudumine. **Järeldused:** Kirjanduse ülevaate tulemina valminud kontseptsuaalne mudel võiks pakkuda väärtuslikku sisendit tulevaste digiravimite arendamiseks ja täiustamiseks, tagades nende patsiendikeskse lähenemise, parema kasutajamugavuse ning kohaldatavuse, mis on vajalik patsientide püsiva kaasamise ning digiravimite järjepideva ja eesmärgipärase kasutamise tagamiseks.

Lõputöö on kirjutatud inglise keeles ning sisaldab teksti 95 leheküljel, seitset peatükki, 10 joonist, 14 tabelit.

List of abbreviations and terms

BCT	Behaviour change technique
BeHEMoTh Framework	Behaviour of Interest, Health context, Exclusions and Models or Theories framework
BFFS	"Best-Fit" Framework Synthesis
CASP	Critical Appraisal Skills Programme
CBT	Cognitive-behavioural therapy
CQIMG	Cochrane Qualitative and Implementation Methods Group
CQR	Consensual qualitative research
DALYs	Disability-adjusted life-years
DHI	Digital health intervention
DMHI	Digital mental health intervention
DTA	Digital Therapeutics Alliance
DTx	Digital therapeutics
ENTREQ Statement	Enhancing transparency in reporting the synthesis of qualitative research
HBCI	Health behaviour change intervention
HBM	Health Belief Model
HCI	Human-computer interaction
IBT	Internet-based therapy
iCBT	Internet-based cognitive-behavioural therapy
IPA	Interpretive phenomenological analysis
PHE Model	Patient Health Engagement Model
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomised controlled trial
SaMD	Software as a Medical Device
SCT	Social Cognitive Theory
SPIDER	Sample, Phenomenon of Interest, Design, Evaluation, Research type tool
STC	Systematic text condensatio
TM	Transtheoretical model

TPB	Theory of Planned Behaviour
QES	Qualitative evidence synthesis
WHO	World Health Organization

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1 Introduction

Every year, mental health issues affect more than one billion individuals worldwide [1], and depression stands as the primary contributor to disability on a global scale [2]. The Global Burden of Diseases, Injuries, and Risk Factors Study 2019 [3] highlighted that depressive disorders constitute the most significant portion (37.5%) of disability-adjusted life-years (DALYs) attributed to mental disorders. The significant unmet needs in mental health, compounded by the stress from pandemic-related measures, have fast-tracked the adoption of digital mental health applications and software-based solutions [4].

Digital health is an overarching category that includes various technologies, platforms, and systems designed to engage users in activities related to lifestyle, wellness and health [5]. Examples of systems in digital health encompass health information technologies, telehealth systems, platforms utilising consumer health information, and tools for clinical care administration, among others [5]. “Digital mental health” or “eMental health” is defined as the utilisation of digital health technology for the assessment, aid, prevention, and treatment of mental health conditions [6]. Digital mental health interventions (DMHIs) provide a readily accessible method to address the increasing global prevalence of mental health disorders, offering the potential to surpass existing barriers in conventional care, and increase access to mental health support [7], [8].

Digital medicine is a sub-segment of digital health and is composed of software or hardware products aimed at assessing or intervening in human health [5]. Digital medicine domain encompasses a sub-segment of digital therapeutics (DTx) [5]. The primary distinction between DTx and other digital health technologies lies in their objectives [9]. While general digital health technologies focus on assisting users in lifestyle changes and achieving well-being goals, DTx are specialised technological tools that provide evidence-based interventions for the prevention, management, or treatment of diseases by altering patient behaviour and enabling remote monitoring, leading to improved health outcomes [5], [9]. In contrast to traditional medications, the therapeutic

efficacy of DTx is powered by sophisticated algorithms and high-quality software programs [9].

A focus area for the DTx industry is exploring how these therapeutics can effectively instigate behaviour change on a large scale [5]. There is a growing emergence of DTx applications aimed at treating mental health disorders. A recent study found that the majority of DTx solutions currently available in the market primarily focus on mental health [10]. This rise in mental health focused DTx applications is thought to be significantly driven by the global pandemic, which has highlighted the urgent need for efficient solutions in mental health management [11].

Numerous interventions utilising digital technologies for the treatment of depression have proven to be effective in randomised controlled trials (RCTs), showing the potential to enhance therapy accessibility and contribute to the improvement of overall population mental health [12]. Although DTx presents a promising approach to overcoming obstacles in accessing care, maintaining user engagement within these digital solutions is a challenge confronting the industry [13]. Studies have shown low rates of sustained user engagement when implementing DTx in the real-world settings [14], [15]. Low engagement, defined as insufficient user participation and adherence to an intervention [16], is frequently cited as a primary factor preventing the realisation of the potential benefits of these interventions in real-world scenarios [17], [18], [19], [20], [13].

A limited number of studies have concentrated on exploring the viewpoints of consumers or patients in relation to digital health solutions [21]. A meta-analysis on involvement with digital mental health applications revealed a notably positive correlation between engagement and mental health outcomes [22]. Given that engagement is considered a "precondition" for effectiveness in digital health interventions [18], [23], it has become the central focus of design initiatives [24].

A significant research gap exists in engagement studies concerning the exploration of precise predictors, barriers, and facilitators of engagement [25]. While some earlier studies have examined the factors that can influence engagement within technologies or contexts, there is an absence of a comprehensive review that consolidates these findings [8]. To harness the full potential of DTx in real-world settings, it is imperative to gain a deeper insight into the factors influencing patient engagement [14], [17], and to identify

the specific aspects of these interventions that enhance patient engagement [26]. Importantly, the perspectives and needs of patients themselves are essential to understanding how to optimise delivery of DTx for this population [17]. Subsequently, this knowledge will facilitate the focused development of engagement tactics aimed at encouraging users to interact with interventions in manners that are most likely to yield benefits for them.

The scope of the thesis is confined to the exploration of patient engagement and adherence within the realm of DTx. This targeted approach delves into patient-oriented DTx specifically designed for depression. Focusing solely on DTx allows for a more detailed and concentrated analysis, particularly exploring patients' experiences, barriers, and facilitators of engagement with and adherence to DTx.

The problem statement: Despite the fact that numerous studies have shown low rates of sustained engagement when implementing DTx in the real-world settings [14], [15], a limited number of studies have examined patients' perspectives, and the specific factors affecting engagement with DTx, along with solutions on how to increase engagement with and adherence to DTx [17], [21], [25].

The aim of the thesis is to synthesise existing evidence on patients' perspectives regarding engagement and adherence with DTx, to provide an improved understanding of how to optimise patient engagement and adherence in the context of DTx.

The main research question is: What implications and recommendations can be drawn from the synthesised framework to enhance patient engagement and adherence with DTx?

To answer the main research question, the following three sub-questions need to be answered:

1. What are the common facilitators that influence patient engagement and adherence with DTx?
2. What are the common barriers that influence patient engagement and adherence with DTx?
3. What are the main contributing factors influencing patient engagement and adherence with DTx, and how can they be categorised?

2 Background

Digital mental health is not merely a technological evolution, but signifies a profound paradigm shift in mental healthcare, providing patients with amplified autonomy and the ability to make more informed choices [27]. Mental health interventions are complex in nature, involving various components in their delivery. DTx, specifically, often exhibit higher levels of complexity and heterogeneity in practical application, due to the necessity to consider technical features, the integration of online and offline elements, the balance between human and automated interaction, and varying levels of support provided to users [28], [29].

2.1 Qualitative evidence in health systems decision-making

Although the core concern in health systems decision-making is the effectiveness of interventions, decision-makers are now becoming equally interested in understanding stakeholder perspectives on diverse outcomes, the acceptability and feasibility of interventions [30], and the implications of these interventions for equity and human rights [31]. Qualitative research evidence is instrumental in addressing these multifaceted considerations, because meticulously designed qualitative research enables exploring individuals' experiences and perceptions of the world and can therefore aid in comprehending the factors influencing the success or failure of these systems [32].

The value of qualitative evidence in informing decision-making in healthcare is becoming widely recognized [32], [33], due to significant advancements in the field, such as the establishment of robust methods for conducting qualitative evidence syntheses (QES) [34]. QES is an umbrella term describing a group of review types that analyse and synthesise findings from primary qualitative studies [35]. The use of the term QES is endorsed by the Cochrane Qualitative and Implementation Methods Group (CQIMG), acknowledging that qualitative research requires unique synthesis methods aligned with the qualitative paradigm [36]. QES has evolved at the intersection of traditional systematic review techniques and methodologies used in primary qualitative research

[35], with the objective of consolidating evidence derived from primary qualitative studies to develop new cumulative knowledge [37].

Instead of attempting to present an alternative approach for measuring efficacy and safety, the primary objective of qualitative evidence and its synthesis is to offer insights not frequently provided by quantitative evidence, such as the identification and explanation of patient behaviours [38]. Apart from the World Health Organization (WHO), various other organizations engaged in generating guidance and health technology assessments are progressively incorporating qualitative evidence to address inquiries related to factors such as the acceptability and feasibility of complex interventions [32].

Health behaviour change interventions (HBCIs), used in areas such as health education, health promotion, patient education and psychotherapy, are considered complex interventions [39]. These interventions engage with, and sometimes modify the environment in which they are implemented [40], meaning that produced effects are strongly linked to context [39]. The effectiveness of interventions designed to alter behaviour depends on individuals' thought processes, decision-making, and actions [41]. Acknowledging that complex interventions are contingent on context not only has implications for the impact of the intervention but also for its sustainability, acceptability, and feasibility [42]. Therefore, it is crucial for the success of interventions to be designed based on the real-world patterns of how people think, make decisions and act [43].

In addition to assessing the safety, acceptability, clinical advantages, and feasibility of incorporating DTx into clinical pathways, it is crucial to investigate how and when they work, and for whom [44]. QES is aptly tailored for tackling the complexities in health interventions. It enables the formulation of a theory, explaining the mechanisms and reasons behind an intervention's effectiveness, investigates the perspectives of healthcare recipients or providers, examines the factors influencing implementation, including contextual elements, and assesses how various components of complex interventions interact to yield results [45]. Qualitative evidence derived from patients' experiences cannot establish effectiveness, but it can provide context and contribute to the assessment of the feasibility and acceptability of complex interventions [46].

2.2 Challenges in defining and categorising DTx

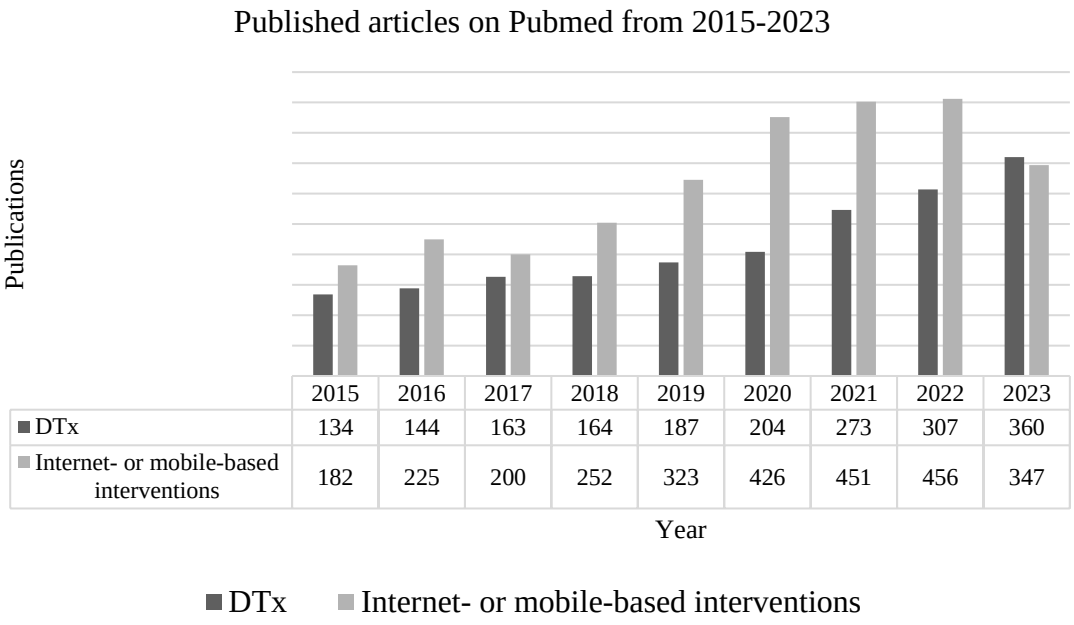
The absence of shared and accepted definitions means that digital psychological interventions span a broad spectrum, ranging from unguided self-help to treatments involving continuous feedback from clinicians. Currently, various terms like *Internet-interventions, e-therapy, online interventions, internet-delivered interventions, and online therapy* are used interchangeably. This inconsistency manifests in two ways: diverse terms are used to describe similar processes, and similar terms are used for different formats [28].

Numerous authors have classified various types of digital psychological interventions based exclusively on their delivery method. For instance, in academic literature, internet- and mobile-based interventions are frequently mentioned. However, this categorisation is problematic as it often encompasses a wide range of applications, such as mobile applications for health behaviour tracking, self-help interventions, or digital elements integrated into conventional face-to-face psychological therapies, commonly referred to as blended care models [47].

Sepah et al. [48] first introduced the term *digital therapeutics* in 2015, defining DTx as "evidence-based behavioural treatments delivered online." DTx fall under the umbrella of digital health, encompassing an array of technologies, products, and services in both healthcare and wellness sectors [5]. Furthermore, since the formation of the Digital Therapeutics Alliance (DTA) in 2017, there has been a dedicated focus on defining and studying DTx – treatment methods reliant on technology. The DTA comprises healthcare companies and stakeholders actively involved in this pursuit [49].

Following a rigorous examination of the existing literature to discern the distinctions between DTx and other internet- and mobile-based interventions, the author has concluded that these terms continue to be utilised interchangeably. To address and illustrate the issue of ambiguous and overlapping use of terminology in current academic literature, the author carried out a targeted investigation on PubMed. This involved two separate search queries. The first search included search terms "digital therapeutics" OR "DTx" and the second search was combined with terms ("internet based" OR "mobile based") AND "interventions". The articles were filtered from 2015-2023. Figure 1. depicts the increasing trajectory of research publications incorporating the term "digital

therapeutics" or "DTx". It also illustrates the prevalent employment of terms such as "internet-based" and "mobile-based" in characterising digital health interventions. Notably, the term DTx started to gain substantial knowledge and usage only in the recent years.



	2015	2016	2017	2018	2019	2020	2021	2022	2023
DTx	134	144	163	164	187	204	273	307	360
Internet- or mobile-based interventions	182	225	200	252	323	426	451	456	347

Figure 1. Published articles on PubMed from 2015-2023 to illustrate the research trends of DTx and internet- and mobile-based interventions. Source: author.

DTx has been recently defined by the DTA as "health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health" [50]. Nevertheless, there is no universally agreed-upon definition, resulting in varied interpretations and applications across different countries and research institutions [51].

DTx are tailored for distinct medical purposes, focusing on diagnosing or addressing specific medical conditions [52]. They are primarily used for behaviour and lifestyle modification [52], and frequently adapt traditional in-person therapy methods, like cognitive behavioural therapy (CBT) for use in mobile applications or online platforms [53]. The concept of DTx is similar to Software as a Medical Device (SaMD) in that they both encompass software utilised for healthcare. SaMD broadly refers to any software designed for various medical uses, whereas DTx is limited to software that actively engages in treatment, managing, or preventing diseases or disorders, backed by clinical

evidence [51]. DTx companies currently concentrate on chronic, behaviour-adjustable conditions and those lacking effective treatment options, addressing significant unmet needs in healthcare [52].

The definition provided by DTA has been adopted for use in the context of this literature review. The DTx described in included studies are categorised based on the level of human assistance – self-guided interventions and supported interventions. Self-guided interventions are designed to be used without any assistance from a trained supporter, whereas supported interventions involve a trained supporter, who may or may not be a trained mental health specialist [29].

2.2.1 DTx for depression treatment

Enhancing the execution of evidence-based practice and public health initiatives relies on the transformation of behaviours. Behaviour change interventions can be described as structured sequences of actions devised to modify specific behavioural patterns [54]. Mental health and behaviour change fields differ in target populations and outcomes but are closely linked. Both involve studying engagement in the context of interventions, and they overlap as behaviour change is essential to mental health recovery, and overcoming mental obstacles is inherent to behaviour change [25].

As DTx is gaining increasing prominence, a noteworthy trend is their substantial influence in the mental healthcare sector [55]. A recent study points out that the majority of DTx solutions currently available in the market primarily focus on mental health [10]. One frequently empolyed example of DTx designed to treat depression is internet-based cognitive-behavioural therapy (iCBT) [56]. CBT is a succesful method for treating depression [57], as it helps patients comprehend their thoughts, emotions and behaviours [58]. Particularly for conditions like depression, where ongoing monitoring and prompt interventions are crucial, DTx offer a significant additional benefit [59].

DTx can offer several advantages over traditional psychotherapy [60]. For example, they are accessible at any time of the day at patient's home, thereby eliminating transportation barriers to treatment and healthcare provider shortages, expecially in rual areas [60]. They are self-guided, enabling patients to complete various modules at their own pace, providing them with autonomy over their therapy [56], and the opportunity for users to maintain their anonymity and privacy in their chosen environment. However, it is

important to acknowledge the possible downsides and possible risks associated with DTx, such as potentially reinforcing the stigma and secrecy around mental illness, and the lack of personal interaction that traditional face-to-face therapy offers [60]. Given that DTx are utilised by individuals with or without the supervision of a healthcare provider or a therapist, maintining high quality in DTx is critical to prevent any harm to patients [61].

Studies indicate that interventions informed and steered by behavioural theories tend to be more effective than those lacking such theoretical underpinnings [62]. Grounding digital interventions in behavioural theories can aid in evaluating and discerning the reasons behind the success or failure of these interventions [63]. Gaining an understanding of the relationships between various behaviour change techniques (BCTs), theoretical aspects of engagement, and metrics of engagement will offer insights into how BCTs can be integrated to enhance and customise the design of DTx, thereby supporting effective engagement [64].

2.3 The complex definitions of patient engagement and adherence

This thesis focuses on the examination of patient engagement and adherence to DTx. One of the challenges of researching this domain lies in establishing a common terminology. Research focusing on the active involvement of patients has frequently employed various terms interchangeably, such as *patient engagement, patient activation, patient involvement, patient participation, patient adherence/compliance, and patient empowerment* [65]. Engagement with digital health interventions (DHIs) is a multidimensional construct and is therefore difficult to measure in both intervention trials and real-world implementation settings [14]. Currently, there is no consensus on how to define what constitutes effective engagement and how to compare engagement across different DHIs [13].

Researchers in the field of human-computer interaction (HCI) define engagement as the act of capturing and sustaining users' attention and interest, as well as their temporal, emotional, and cognitive commitment to an intervention [66]. In accordance with the process-oriented approach to patient engagement outlined in the Patient Health Engagement (PHE) model developed by Graffigna et al. [67], an individual's engagement in care management can vary based on their emotional, cognitive, and behavioural state of mind. The PHE model describes patient engagement as a "process-like and multi-

dimensional experience, resulting from the conjoint cognitive (think), emotional (feel), and conative (act) enactment of individuals toward their health management" [67]. This definition is similar to one provided by Perski et al. [23], who identified three main dimensions of engagement: behavioural, cognitive, and affective. With this comprehensive perspective of patient engagement in mind, the factors influencing this process are diverse and encompass various aspects of the patient's subjective experience. A conceptual model of engagement with digital interventions, developed by Yardley et al. [18], differents engagement between technological and behavioural elements. Engagement with technological aspects, encompassing the user experience of the intervention and its usage, pertains to the manner in which an individual utilises software to facilitate behaviour change. Engagement with behavioural aspects describes how an individual initiates and maintains changes in behaviour, which can potentially lead to positive outcomes [18].

Adherence is sometimes used to describe the use of digital interventions and is often used interchangeably with engagement [68]. Flett et al. [69] chracterise adherence as the extent to which individuals access the content and use it in the manner intended for optimal effectiveness. In this study, "engagement" is defined as the use of DTx software and the associated user experience, while "adherence" relates to the behavioural changes and the way users utilise the software.

3 Methodology and methods

This thesis adopts a research philosophy that predominantly aligns with interpretivism, as delineated by Saunders et al. [70]. However, some elements of pragmatism as well, as it incorporates various methods and theories to understand the phenomenon under study. The research approach is inductive, and the methodological choice is qualitative study [71], as it is based on qualitative literature review, employing "best-fit" framework synthesis [72], methods within an interpretivist framework. The research strategy encompasses a comprehensive review of literature, which forms the foundation for thematic analysis to construct an evidence-based framework as a result of the synthesis. Latter entails combining pertinent evidence from several primary studies with the aim of formulating more robust and generalisable conclusions than can be drawn from the results of a single study [73]. Qualitative evidence syntheses are systematic reviews that synthesise data using qualitative methods. QES are valuable for investigating the impacts of complex interventions and their implementation [42].

When choosing the most appropriate approach for synthesis, interpretive methods, such as meta-ethnography, and predominantly descriptive methods such as thematic synthesis were considered however disregarded because they lack the opportunity to establish integration between the data derived from the incorporated studies and the relevant theory [73], require a rich and thick conceptual and contextual data along with high requirements for expertise and knowledge about the method [74]. The guiding principle for methods selection in qualitative synthesis is to employ a methodology that produces fit for purpose output [75]. According to Booth et al. [76], practice-oriented syntheses with a focus on influencing or altering current practices should provide clear and actionable directives. One approach for gaining such insights is using the "best-fit" framework synthesis (BFFS) [72].

This review is reported according to the Enhancing Transparency in Reporting the Synthesis of Qualitative Research (ENTREQ) statement [77]. The ENTREQ statement consists of 21 items grouped into five domains: introduction, methods and methodology,

literature search and selection, appraisal, and synthesis of findings. For a comprehensive approach, the PRISMA [78] flow diagram was used to report the different phases of searching, screening, and identifying studies for inclusion.

3.1 "Best-fit" framework synthesis (BFFS) methodology and methods

BFFS is an innovative methodology, first described by Booth and Carroll [79] in 2011. The primary principles of framework synthesis are drawn from the framework analysis [80] of primary data. However, this methodology distinguishes itself from other qualitative evidence synthesis approaches primarily by employing a systematic process to identify published frameworks, models, or theories for constructing the synthesis framework, and by blending both framework and thematic analysis methods to accomplish the synthesis [72]. Therefore, BFFS aims to leverage the advantages of both, descriptive and interpretive approaches as it enhances the process of theory construction by involving existing theories, with a particular focus on producing actionable insights [73].

BFFS involves identifying a relevant framework, theory, or conceptual model, aligned with the research question, for specific health behaviours. Subsequently, this chosen framework is then taken apart to its fundamental elements or variables, which constitute the predefined themes of the *a priori* framework, which is the foundation for coding data derived from the included primary research studies [72]. The identification and selection of primary research studies for inclusion in the review follow conventional systematic research process. Compared to more exclusively interpretative methods, this approach offers a swifter, more transparent, and practical process due to pre-coding of a substantial portion of data against the *a priori* framework [81]. Iterative interpretation through inductive, thematic analysis techniques is only necessary for data that falls outside the initial framework's scope [72]. This approach is well-suited for creating conceptual models tailored to specific contexts to describe the decision-making and health behaviours of patients, as it provides a practical way to swiftly conduct qualitative evidence synthesis and develop program theories related to the effectiveness of interventions [72].

The "best-fit" framework synthesis is a seven-step process which is schematically presented on Figure 2.

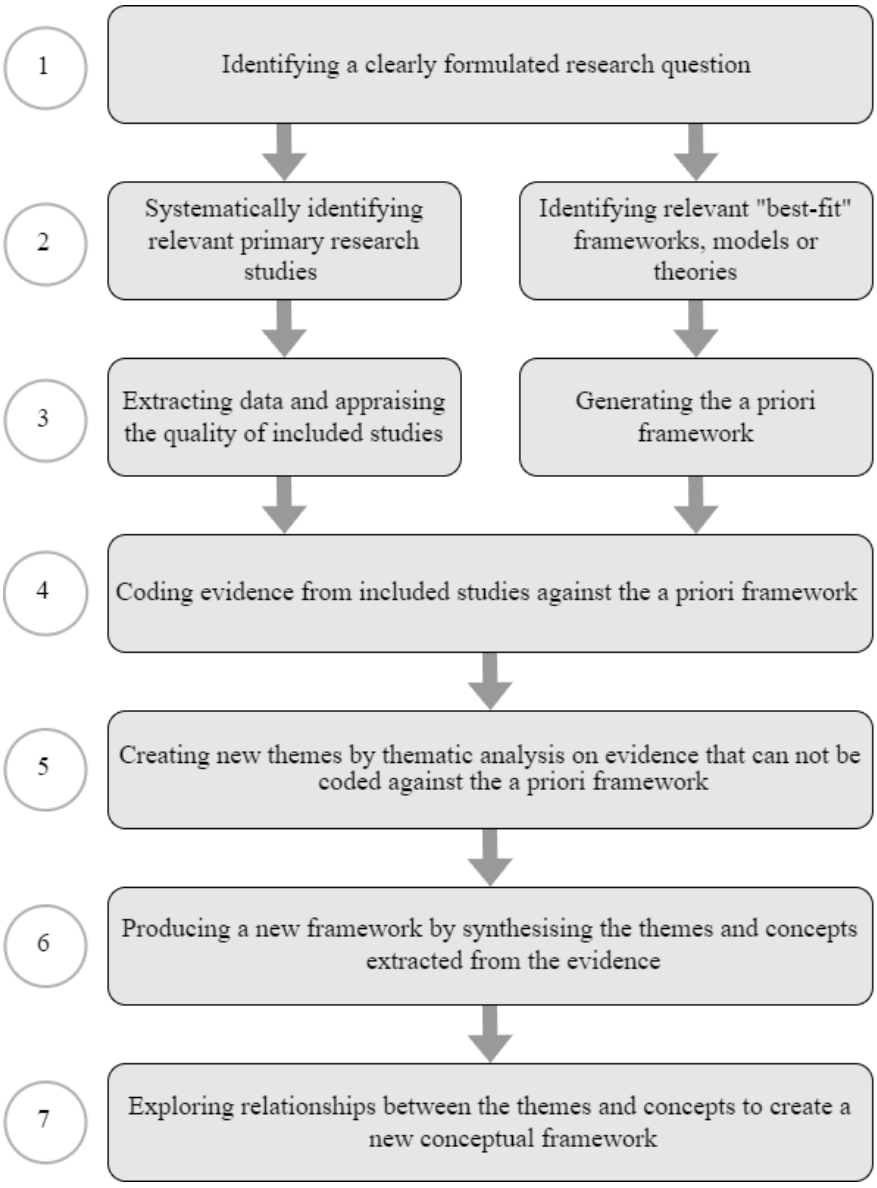


Figure 2. The "best-fit" framework synthesis process. Adapted from [72].

Step 1: Identifying the research question

The development of the research questions was an iterative process that encompassed reviewing relevant articles and experimenting with the essential concepts and keywords in electronic databases. This process helped to identify the existing gap in current evidence and construct an answerable research question. Booth et al. [42] have highlighted the need for focused, relevant questions in qualitative evidence syntheses. Therefore, The SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type) tool [82] was employed to pinpoint the essential components necessary for constructing answerable research questions (see Table 1).

Table 1. Formulation of research questions using the SPIDER tool [82].

SPIDER elements	Keywords
(S) Sample	Adult population with depression
(PI) Phenomenon of interest	A patient-facing digital mental health intervention to treat or manage the symptoms of depression.
(D) Design	QES
(E) Evaluation	Outcomes of interest assessed by qualitative and mixed methods designs, include 1) health outcomes 2) patients' perspectives and experiences with interventions
(R) Research type	Qualitative or mixed methods

The structured framework of the SPIDER tool served as a guide for developing the search strategy for retrieving qualitative and mixed method studies in the following stages of the research.

Step 2a: Identifying relevant primary research studies

When digital health interventions are defined too broadly, summaries of their clinical impacts may fail to draw conclusions due to the heterogeneity of the technologies involved [83].

Identification of relevant primary research studies was systematically conducted in five databases: Medline, APA PsycNET, EBSCO, SCOPUS and Web of Science, which were chosen considering accessibility and relevance (see Appendix 2). Database searches were conducted between October 28th, 2023, and October 30th, 2023. The search strategy was constructed around four key concepts: 1) mental health 2) digital health interventions 3) engagement/adherence, and 4) study type. The process of identifying keywords, facilitated by the structured framework of the SPIDER tool, was subsequently refined, and expanded upon to effectively guide and standardize the search, as recommended by Carroll et al. [72]. The search strategy was first developed in Medline, with inspiration from prior research conducted by Villarreal-Zegarra et al. [84], Borghouts et al. [8] and Akther et al. [85], as they have explored analogous key concepts in their respective research areas. To identify the most relevant research articles, search strings were created using Boolean operators, Medical Subject Headings (MeSH) terms and text words. The detailed procedure of the extensive search conducted in Medline is presented in Appendix

3. The search terms were then adjusted for other databases, necessitating several modifications to accommodate the specific requirements of each database. Search queries for each database are presented in Appendix 3.

The documented complexity of comprehensively searching for qualitative evidence, as noted by numerous authors, may necessitate a more extensive screening of titles, abstracts, and full-text articles to determine their suitability for inclusion [86]. The reference lists of included articles were scanned, and several relevant articles were found through forward and backward citation tracking [87].

The search strategy incorporates formally published, peer-reviewed articles from years 2013 to 2023. To narrow down the search results, limitations were put in place in the process of conducting database searches. The initial searches produced 2709 articles, which were exported to Endnote, a reference management program. After removing duplicates, 2216 articles remained. In the first screening, the author applied the pre-defined inclusion and exclusion criteria (see Appendix 4) to all titles and abstracts. Resulting 24 articles were included for full-text examination. The process of retrieving and screening the articles is presented schematically in Figure 3 and in Appendix 8 as a PRISMA flow diagram.

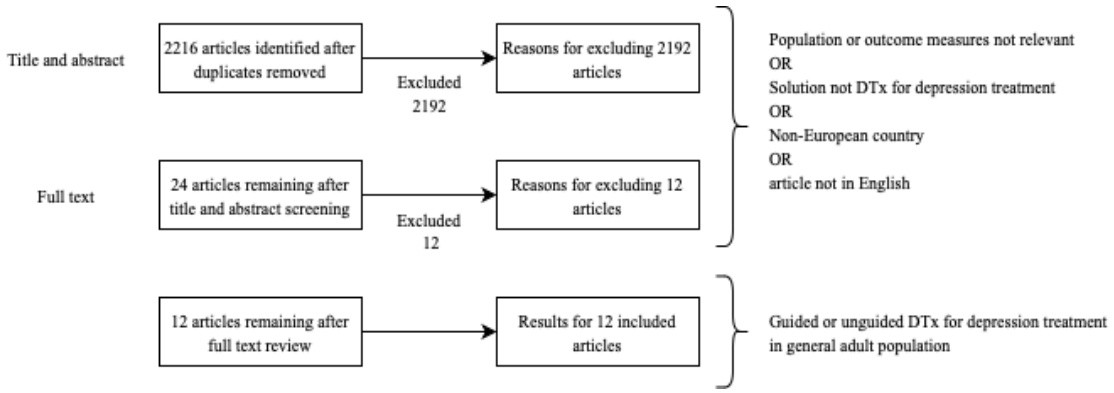


Figure 3. Visual flow of study selection for primary research studies.

Step 2b: Identifying relevant "best-fit" frameworks, models, or theories

In the initial practical application of the "best-fit" method [79], one of the authors determined the foundational theory or model using a grey literature conceptual model, after conducting iterative searches on bibliographic databases and search engines. The authors recognised that this method's shortcoming was its lack of transparency [72]. To

ensure the "best-fit" framework approach can be replicated and effectively utilised by others, it was essential to establish a well-defined, systematic process for identifying relevant models or theories, as the foundation for creating the *a priori* framework for the synthesis [72]. To systematically identify relevant publications, frameworks, conceptual models or theories, the BeHEMoTh strategy [88] was employed. BeHEMoTh (Behaviour, Health condition, Exclusions, Models or Theories) is a systematic question formulation framework, and was most suitable in this context, as it is designed to predefine criteria for retrieving behavioural change models and theories [88]. The application of the BeHEMoTh strategy is presented in Table 2.

Table 2. The BeHEMoTh strategy [88].

Strategy	Terms
Be – behaviour of interest	Behaviour change
H – health context	Digital health
E – exclusions	Regression or integrative model or integrative care model or economic or Markov or animal
MoTh – models or theories	Model or theory or theories or framework or concept or conceptual
Search strategy: (Be AND H AND MoTh) NOT E	

Identification of behaviour change theories, frameworks and models was systematically conducted in Medline database on December 6th, 2023. The search strategy was adapted from Carroll, Booth et al. [74] and was constructed around four key concepts: 1) behaviour change 2) digital health 3) exclusions, and 4) models or theories. The search strategy is presented in Appendix 5, the inclusion and exclusion criteria for screening the titles and abstracts are presented in Appendix 6. The search identified 94 results, which were exported to Endnote reference manager program for screening. The process of identifying and screening the articles is schematically presented in Figure 4 and in Appendix 9 as a PRISMA flow diagram.

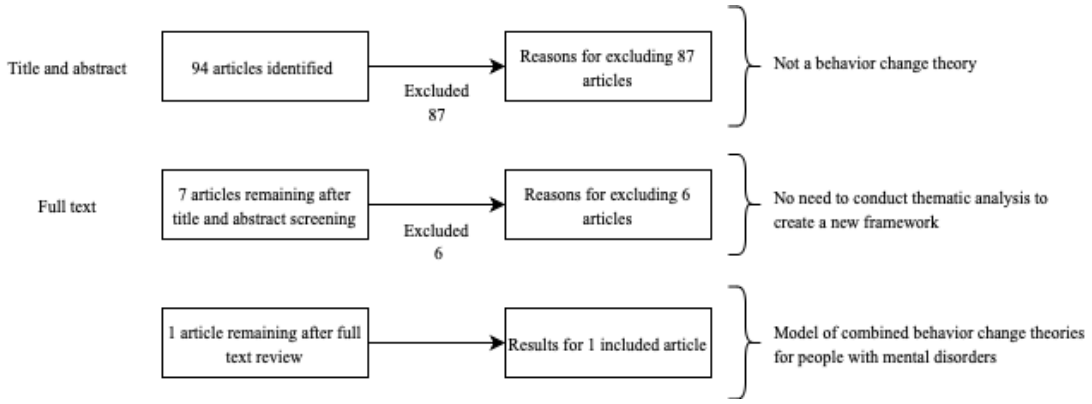


Figure 4. Visual flow of study selection for identifying relevant models, theories or frameworks.

Step 3a: The *a priori* framework

The theoretical framework does not need to perfectly align with the research question or evidence, it simply needs to provide an adequate foundation, as indicated by the term "best-fit" [73]. While conducting a focused exploration aimed at pinpointing relevant theories, models or frameworks pertaining to behaviour modification, the author discovered an existing approach proposed by Naslund et al. [89]. This method integrates four distinct behavioural theories, specifically crafted for the development of digital mental health interventions to individuals suffering from mental illness. Consequently, this finding rendered the synthesis of additional theories or models to formulate a novel *a priori* framework.

Naslund et al. [89] combined the principal components of the following distinguished theories*: 1) Health belief model 2) Theory of planned behaviour 3) Transtheoretical model and 4) Social cognitive theory* (see Table 4). These four theories rank among the most frequently referenced models in health behaviour and have been broadly utilised in steering effective interventions. These interventions address a range of behaviours, encompassing lifestyle choices, management of chronic illnesses, dealing with mental health issues, and the utilisation of health services, as noted by Glanz et al. [90]. Furthermore, these theories have been distinctly applied in designing interventions targeted at individuals with mental health disorders [89]. Each of the mentioned theories are described in Table 3 below.

Table 3. Definitions of the Health Belief Model, Theory of Planned Behaviour, Transtheoretical model and the Social Cognitive theory.

Theoretical model	Definition
Health Belief Model (HBM) [91]	Health behaviours are explained based on perceived susceptibility, perceived severity, perceived benefits of taking action, perceived barriers to taking action, and ability to take action.
Theory of Planned Behaviour (TPB) [92]	Behavioural intention, attitudes toward the behaviour, perceptions of others' views on the behaviour, and perceived control over the behaviour are essential factors in determining the performance of a health behaviour.
Transtheoretical Model (TM)	Behaviour change is conceptualized as progressing through 6 stages: 1) Precontemplation; 2) Contemplation; 3) Preparation; 4) Action; 5) Maintenance; and 6) Termination.
Social Cognitive Theory (SCT) [93]	Behaviour is determined by an individual's social context and is influenced by personal factors, behavioural factors, and environmental factors. Self-efficacy is a key construct.

The Health Belief Model is one of the most extensively used conceptual frameworks for understanding health behaviour, employed by health educators, health professionals and psychologists [91]. The model interprets behaviour by emphasising the beliefs and attitudes of individuals [94]. The theory of planned behaviour highlights behavioural intention as a critical factor influencing the execution of a behaviour [95]. Behavioural health issues in individuals with mental illness frequently present as multifaceted, coexisting and intricately linked, covering both mental and physical health aspects [96]. Therefore, combining elements from various theories could be crucial in creating effective digital health interventions for this vulnerable population [89]. Significant theoretical frameworks for comprehending human behaviour, such as the Health belief model, theory of planned behaviour, the transtheoretical model, and the social cognitive theory offer a valuable foundation for hypothesising what factors or strategies are required to change or modify health behaviours [89].

Table 4. Overlapping constructs across behaviour theories and models. Adapted from [89].

Construct	Construct definition	HBM	TPB	TM	SCT
Attitudes	Emotions associated with performing the behaviour.		X	X	
Awareness	Learning new facts about the behaviour and the possible risks of not performing the behaviour.	X		X	X
Behavioural cues	Use reminders to support healthy behaviours and manage triggers for unhealthy behaviours.	X		X	
Intentions	Personal motivation to perform the behaviour.		X		
Perceived benefits	Perceived benefits of performing the behaviour.	X	X	X	
Perceived barriers	Perceived barriers to performing the behaviour.	X	X	X	
Reinforcement	Rewards for performing the behaviour and for avoiding unhealthy behaviours.			X	
Self-efficacy	Confidence in one's ability to overcome barriers to performing the behaviour.	X	X	X	X
Self-evaluation	Beliefs about how performing the behaviour will make them feel and whether it represents who they want to be.			X	X
Social modeling	Learning by observing others who have successfully performed the behaviour.				X
Social norms	Beliefs about whether other people perform the behaviour or perceive the behaviour as important.		X		X
Social support	Relationships with others that support positive behaviour change			X	X

Note: HBM - Health Belief Model, TPB – Theory of Planned Behaviour, TM – Transtheoretical Model, SCT – Social Cognitive Theory.

Step 3b: Data extraction and quality appraisal

After completing the screening and finalising the number of studies to include, it was necessary to extract data from the included studies. A data extraction form provides a structured approach for examining the articles, considering both their methodology and findings. The data extraction form was developed, which contained all the necessary information for data synthesis, including methodology, sampling, ethics, rigour, data collection and analysis, conclusions, and limitations as well as recommendations. Second, it also included the *a priori* framework concepts that were derived from combining the four behaviour change theories. Extracted data comprised direct quotes from participants, and the authors' summaries of the evidence that were clearly supported by study data.

Evaluating the critical appraisal and quality of primary research is a crucial phase in conducting systematic reviews and synthesising evidence [97], [98]. Quality appraisal was performed simultaneously with data extraction to assess the effects of incorporating studies considered to be of lower quality [99], for which the Critical Appraisal Skills Program (CASP) tool [100] was employed. The CASP tool is the most frequently used criteria-based instrument for assessing quality in qualitative evidence syntheses related to health and social care [101]. The instrument consists of ten questions, with each one targeting a distinct methodological element of a qualitative study. Originally, the CASP tool lacks a specific criterion for evaluating the suitability and clarity of a study's qualitative paradigm [102]. As proposed by Long et al. [102], the CASP tool can be optimised by adding a question regarding the study's theoretical underpinnings. The modified version of the CASP checklist used in this review is presented in Appendix 7. No studies were excluded based on the quality assessment.

Step 4: Coding evidence against the a priori framework

For the framework synthesis, coding of articles was based on the principles outlined by Carroll et al. [72]. The results from the included primary studies were coded against the *a priori* concepts. First, the 12 concepts from the *a priori* framework were used as initial themes for a deductive analysis. Codes were grouped to detect patterns, which lead to identifiying and defining new themes at later stages. The *a priori* concepts and their definitions are presented in Table 5.

Table 5. Concepts from *a priori* theoretical framework for deductive coding.

Concept	Concept definition
Attitudes	Experience positive or negative emotions associated with performing the behaviour.
Awareness	Learning new facts about the behaviour and what the risks of not performing the behaviour might be.
Behavioural cues/triggers	Use reminders to support healthy behaviours and remove or manage triggers for unhealthy behaviours.
Intentions	Personal motivation to perform the behaviour.
Perceived benefits	Perceived benefits or advantages of performing the behaviour.
Perceived barriers	Perceived presence of barriers that makes performing the behaviour difficult.
Reinforcement	Rewards for performing the behaviour and for avoiding unhealthy behaviours.
Self-efficacy	Confidence in one's ability to overcome barriers to performing the behaviour.
Self-evaluation	Individuals' beliefs about how performing the behaviour will make them feel and whether it represents who they want to be.
Social modeling	Learning by observing others who have successfully performed the behaviour.
Social norms	Beliefs about whether other people perform the behaviour or perceive the behaviour as important.
Social support	Helping relationships with others that support positive behaviour change.

Step 5: Creating new themes by performing a secondary thematic analysis

A secondary thematic analysis was performed on data that could not be coded against the framework and new themes were generated. This approach adheres to the principles of conventional thematic analysis in the context of secondary research. It differs from thematic synthesis in that it does not involve explicit line-by-line coding of the data. The process entailed the reduction of data into a small number of relevant concepts that mirrored the data, followed by investigating and delineating these concepts and their interconnections. The author independently analysed the extracted data, attributed potential concepts, and subsequently re-evaluated these concepts after becoming more acquainted with the data. Consequently, the initially identified concepts were altered throughout this process to represent the data and highlight both the commonalities and distinctions within it more accurately. This inductive process is firmly rooted in the data and is interpretative in nature.

Therefore, for data that was considered outside of the *a priori* framework, a list of new themes was produced. This list consolidated these new themes and the data supporting it.

The resulting new themes were related to specific aspects of the interventions which were not represented in-depth in the behavioural theories that formed the *a priori* framework.

Step 6: Developing a new framework by combining a priori and new themes

Initially, a new framework was developed, consisting of a straightforward list of defined concepts and themes. This includes both pre-existing *a priori* concepts supported by evidence from the primary studies and any additional themes that emerged from the thematic analysis. In this initial framework, the connections between the concepts were neither explicit nor detailed, they simply existed as distinct components within it. Subsequently, the evidence supporting the framework was re-examined to identify and depict the relationships among the new framework's concepts.

Step 7: Exploring themes and concepts to create a new conceptual model

Ultimately, a comprehensive conceptual model containing all concepts and themes was synthesised, drawing upon the data extracted from the included studies. The term conceptual model is defined following Imenda [103], who describes conceptual model as a synthesis of various concepts and perspectives drawn from numerous sources, offering a cohesive approach to addressing a problem. The development of a conceptual model resembles an inductive process in which small, discrete objects (concepts) are assembled and incorporated as "internal attributes" under broader, more abstract concepts to form a broader map depicting potential relationships. Meaning that when concepts exhibited common features, the author's interpretation of data reduced these attributes into higher concepts related to the problem under investigation. Accordingly, a conceptual model is constructed from individual concepts, much like a theoretical framework is derived from an overarching theory.

3.2 Ethical considerations and the reliability of the study

In this "best-fit" framework synthesis, transparency was ensured through the meticulous creation and iterative testing of a comprehensive search strategy, which was adapted from reputable authors in respected peer-reviewed journals. Detailed records of the search strategy for primary studies and behaviour change theories can be found in Appendixes 3 and 5, respectively. Additionally, the rationale behind selecting five specific databases is explained in Appendix 2. To enhance transparency further, PRISMA flow diagrams

documenting the database searches, study selection process, screening and inclusion are available in Appendixes 8 and 9. Finally, this literature review is reported according to the ENTREQ statement to provide transparency in reporting. This comprehensive approach not only safeguards the ethical integrity of the study but also reinforces the reliability of the research process.

Respect for cultural sensitivity is a critical aspect of ethical considerations in research, particularly when conducting a literature review on a topic like DTx for depression treatment. In this case, the decision to include only studies conducted in European countries can be attributed to the need for socio-cultural homogeneity. The choice to limit the scope to only European countries is based on the assumption that these nations share certain cultural, social, and healthcare system characteristics that can significantly influence the applicability and effectiveness of DTx. With this limitation, the author aimed to minimise potential cultural variations, such as attitudes towards mental health, healthcare access, and technological acceptance. This enhances the reliability of the study because it allows for more meaningful comparisons and clearer understanding of the specific context in which DTx applications for depression are being implemented, and the importance of cultural sensitivity and the need to avoid making broad generalisations about DTx interventions that might not apply universally in diverse cultural settings.

To guarantee the reliability and transparency of the synthesis findings, sensitivity analysis was performed. Conducting a sensitivity analysis involves assessing how variations in the selection and analysis of included studies might impact the overall synthesis findings. This helps to consider the potential impact of study quality on the synthesis outcomes. Common variables that could influence the synthesis findings include methodological quality, population characteristics, or the type of data collected. Sensitivity analysis entails creating alternative scenarios, such as including only studies of a certain quality level. The data is then reanalysed to see how different selections of primary studies affect the overall synthesis. The findings from different scenarios are then compared with the original synthesis results. This helps to determine, if certain studies had a disproportionate impact on the synthesis outcomes [104]. Conducting a sensitivity analysis provides a comprehensive and transparent understanding of how the selection and characteristics of primary research studies influence the outcomes of the final synthesis [98].

4 Results

4.1 Included studies

From electronic database searches, 2210 potentially relevant records remained after removal of 499 duplicates. These were screened at title and abstract level to leave 18 studies to be assessed for eligibility. After further exclusions against inclusion criteria, 11 studies were excluded, leaving seven included studies. Additionally, reference lists of the included studies were examined, which led to the identification of six more articles previously not discovered in the electronic searches. Out of the six articles, five met the inclusion criteria and were included in the review. Appendix 8 shows the process by which studies were appraised and selected. In total, 12 studies were included in the review. Characteristics of included studies are available in Table 6.

Three studies were conducted in United Kingdom (UK), three were conducted in Ireland, two studies were conducted in Norway, one in Sweden, one in Spain, one in Germany, and one study was conducted internationally, where participants were recruited from five rural areas in the UK, Ireland, Sweden, and Finland. Ten studies described internet-delivered cognitive behavioural therapy (iCBT) programmes, out of which six were guided iCBT programmes with therapist's support, and four were unguided iCBT programmes. One study described guided transdiagnostic internet-based therapy (IBT) and one study unguided chatbot intervention to support mental health and well-being. Descriptions of interventions from included studies are presented in Table 7. Individual interviews were the dominant method of data collection (n = 6), some collected written user feedback through online questionnaires and surveys (n = 5), and one study collected data through individual interviews and focus groups. Analysis methods included thematic analysis (n = 2), grounded theory (n = 1), descriptive-interpretive method (n = 2), structuring content analysis (n = 1), interpretive phenomenological analysis (IPA) (n = 1), constant comparative method (n = 1), phenomenological-hermeneutical approach (n = 1), consensual qualitative research (CQR) (n = 1), systematic text condensation (STC) (n = 1), and conventional content analysis (n = 1).

Table 6. Characteristics of included studies.

	Author, year, country	Research question/aim	Participants (n)	Intervention	Data collection and analysis
P1	Mayer et al. 2022 [105] Germany	To assess the user experience and acceptance of adult patients and healthy adults regarding the self-monitoring app SELFPASS, its self-assessment and its individual interventions.	Total (n = 110) Patients (n = 41) Healthy adults (n = 69)	Unguided iCBT (SELFPASS)	Written user feedback Structuring content analysis
P2	Potts et al. 2023 [106] International	To establish if using a multilingual mental health and well-being chatbot (ChatPal) has an effect on mental well-being.	Total *(n= 87)*	Unguided chatbot intervention (Chatpal)	Written user feedback Thematic analysis
P3	Schneider et al. 2014 [107] United Kingdom	To examine the acceptability of one form of computerised CBT (cCBT)- online self-help for depression- in the context of a workplace trials where the data were largely collected online.	Total ((n = 590)	Unguided iCBT (MoodGYM)	Online questionnaires Grounded theory
P4	Lawler et al. 2021 [108] Ireland	To perform a qualitative analysis of patients' experiences with an iCBT intervention in a routine care setting to achieve a deeper insight into the phenomenon of dropout.	Total (n = 15)	Guided iCBT	Semistructured interviews Descriptive-interpretive method
P5	Knowles et al. 2015 [109] United Kingdom	To explore patient experience of cCBT in a sample of patients with depression treated in primary care, particularly focusing on engagement with the programme and acceptability of therapy delivered by computer without therapist support.	Total (n = 36)	Unguided cCBT (MoodGYM and Beating the Blues)	Semistructured interviews Constant comparative method
P6	Duffy et al. 2023 [110] Ireland	To analyse stakeholders' experience of implementing iCBT in mental healthcare services.	Total (n = 19) Service providers (n = 6)	Guided iCBT	Semistructured interviews

			Commercial representatives (n = 6) Patients (n = 7)		Descriptive-interpretive method
P7	Lillevoll et al. 2013 [111] Norway	To explore patients' experiences of being in iCBT treatment with a focus on the treatment dimensions that they considered helpful.	Patients (*n* = 14)	Guided iCBT (MoodGYM)	Semistructured interviews Phenomenological-hermeneutical approach
P8	Holst et al. 2017 [112] Sweden	To explore primary care patients' experiences of iCBT in depression treatment.	Patients (*n* = 13)	Guided iCBT	Focus groups and interviews Systematic text condensation (STC)
P9	Richards et al. 2016 [113] Ireland	To gain insight into users' experiences of a supported internet-delivered low-intensity treatment 'Space from Depression', for symptoms of depression within an Irish adult community population.	Patients (*n* = 281)	Guided iCBT (Space from depression)	Self-report online questionnaires Thematic analysis
P10	Sayar et al. 2023 [114] Norway	To explore what patients missed in the contact with their therapist in guided iCBT in routine care.	Patients (*n* = 579)	Guided iCBT (eCoping)	Online survey Conventional content analysis
P11	Fernández-Álvarez et al. 2017 [115] Spain	To conduct a qualitative analysis of the subjective experience of a sample of patients who dropped out of a transdiagnostic IBT for emotional disorders.	Patients (*n* = 10)	Guided transdiagnostic intervention (Transversal)	Semistructured interviews Consensual qualitative research (CQR)
P12	Purves and Dutton 2013 [116] United Kingdom	This study used the cCBT package Blues Begone as a means of investigating the process by which a computer-mediated program helped adults with mild depression to help themselves	Patients (*n* = 7)	Unguided iCBT (Blues Begone)	Semistructured interviews Interpretive phenomenological analysis (IPA)

Table 7. Descriptions of applications.

Paper	Application	Description of the application	Therapeutic approach	Therapist support
P1	SELFPASS	SELFPASS is designed to improve the self-management of patients with depression on the basis of an individualised daily mood score. The app does not claim to replace conventional psychotherapy but to support patients during waiting time, in order to bridge the treatment gap. The interventions do not follow a specific order, the app is making individualised propositions based on the daily symptom score.	CBT and digitised elements of other approaches	No
P2	Well-being chatbot ChatPal	ChatPal is a multilingual chatbot, available in English, Scottish Gaelic, Swedish, and Finnish, containing content and exercises such as mindfulness and breathing, mood logging, gratitude, and thought diaries. The chatbot is not designed to diagnose or treat those with severe mental illness.	Psychoeducational content and exercises to promote mental health and well-being	No
P3, P7	MoodGYM	MoodGYM is a free self-help program to teach CBT skills to people with depression and anxiety. The MoodGYM intervention is a modularised course, designed to last five weeks with assessments in the sixth week, although participants proceed at their own pace.	CBT	No
P4, P6, P9	Space from Depression, Space from Anxiety, Space from Depression and Anxiety	Three iCBT interventions for the treatment of depression and anxiety developed by SilverCloud Health. Interventions can be delivered in self-guided or guided formats, with support delivered either synchronously or asynchronously.	CBT	Yes The program uses supporters to monitor patients' progress and provide post-session feedback
P5	MoodGYM and Beating the Blues (BtB)	Both programmes consist of modular sessions lasting approximately 45 minutes, recommended to be completed at a rate of one per week (6 sessions for MG and 8	CBT	No

		for BtB), which guide the user through CBT principles including interactive exercises and weekly homework assignments to be completed between sessions.		
P8	Not described	Not described	CBT	Yes
P10	eCoping clinic programme	The program consists of eight depression or nine anxiety text-based modules provided online. Treatment lasts for 14 weeks, and the patients are expected to spend 7-10 days per module.	CBT	Yes Asynchronous therapist feedback after each completed module
P11	Transversal	Transversal is a transdiagnostic internet-based treatment (IBT). The protocol consists of 12 modules, and participants are encouraged to complete one module per week. Treatment protocols are web-based, self-administered treatments.	Transdiagnostic, including components of positive affectivity	Yes Weekly synchronous therapist support and non-human support through automatically sent reminders.
P12	Blues Begone	Blues Begone was designed to facilitate a virtual therapeutic relationship, it interacts with the user through animated talking heads that are able to give feedback and support. The program is designed to manage the symptoms of depression and anxiety. Contains 30 episodes, providing assessment and an individually tailored program of therapy. The program usually takes eight to 12 weeks to complete.	CBT	No

4.1.1 Quality of included studies

The approach chosen for appraising and reporting the quality of the included studies was to describe what has been observed without excluding any studies. In this case, all potential insights remain included in the synthesis process, because the value of individual studies might only become apparent at the point of synthesis, rather than appraisal. Generally, the quality of the included studies was good, marked by a notable degree of transparency and thorough discussion. Key papers (KP) were identified as those that closely aligned with the research question and fulfilled all the quality criteria. Studies deemed satisfactory (S) corresponded with the review question and satisfied majority of the criteria. Those categorised as unsure (U) failed to meet all quality standards and were approached with caution due to concerns about their reliability. One study [106] was rated poorly (P) due to lack of adequate reporting and transparency regarding data analysis. Ratings for each included study are presented in Table 8.

Table 8. Quality appraisal of included studies using the modified CASP tool [99].

Question	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12
1. Was there a clear statement of the aims of the research?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
2. Is qualitative methodology appropriate?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
3. Was the research design appropriate to address the aims of the research?	Y	-	Y	Y	Y	Y	Y	Y	N	Y	Y	Y
4. Are the study's theoretical underpinnings clear?	-	-	-	-	Y	Y	-	-	-	-	Y	Y
5. Was the recruitment strategy appropriate?	Y	-	Y	Y	Y	Y	Y	Y	Y	N	Y	Y
6. Was the data collected in a way that addressed the research issue?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N
7. Has the relationship between researcher and participants been considered?	N	N	-	Y	N	Y	Y	Y	-	Y	Y	Y
8. Have ethical issues been taken into consideration?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
9. Was the data analysis sufficiently rigorous?	Y	-	Y	Y	Y	Y	Y	N	Y	Y	Y	N
10. Is there a clear statement of findings?	Y	Y	Y	Y	Y	Y	Y	-	Y	Y	Y	-
11. How valuable is the research?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Overall rating	S	P	S	S	S	KP	S	U	U	S	KP	U

Quality rating:
KP: Key paper – Meets all quality criteria and clearly fits with the research question
S: Satisfactory paper – Meets most quality criteria and fits well with the research question
U: Unsure – Lack of clarity regarding criteria and fit with the research question
P: Poor – Does not meet the majority of quality criteria

4.1.2 Sensitivity analysis

The sole paper rated as “poor” in quality appraisal was P2 [106] because it lacked transparency regarding its research design, theoretical foundation, recruitment strategy, and sampling. Additionally, the researcher’s relationship with participants was unclear, and the data analysis description was insufficient. Results of sensitivity analysis are shown in Tables 9 and 10.

The results indicate that P2 contributed to identifying six new themes in thematic analysis, aiding in coding data that did not align with the *a priori* framework. However, P2 did not independently introduce any new themes, so its inclusion did not impact the synthesis findings disproportionately. Excluding this study might have resulted in the loss of valuable data, because the paper supports the results of other studies and does not compromise the reliability of the synthesis findings.

Table 9. Coding of included studies against the a priori framework.

	Concepts	Studies (*k*) coded for concept	Analytic observations
C1	Attitudes	*k* = 6 P4, P6, P7, P8, P9, P11	Depression care pathways should be tailored to be responsive to different patients' experiences to ensure that patients best suited to iCBT are informed of this option. Patient expectations and goals should align with the objectives of the program.
C2	Awareness	*k* = 3 P6, P9, P12	The self-help materials served as a catalyst for new learning experiences. New knowledge enhanced self-esteem and self-awareness. New knowledge fosters personal growth and self-realisation.
C3	Behavioural cues/triggers	*k* = 2 P6, P8	The importance of consistent communication, reminders and professional support in enhancing patient commitment and involvement.
C4	Intentions	*k* = 7 P4, P6, P7, P8, P9, P10, P11	The dynamic interplay between patient engagement and mental health outcomes is evident. Patients who struggled to connect with the intervention program often had differing goals and expectations from the therapy, impacting their commitment. Lack of motivation can influence the psychotherapy outcomes.
C5	Perceived benefits	*k* = 8 P4, P5, P6, P7, P8, P9, P11, P12	Perceived benefits of online treatment, noted for its accessibility and flexibility were highly valued, particularly for offering a sense of anonymity. Concept of having an online supporter was motivating. The content was recognised for stimulating cognitive activity.
C6	Perceived barriers	*k* = 9 P1, P4, P5, P6, P7, P8, P9, P10, P11	The perceived barriers primarily included a lack of individualisation, which might contribute to reduced motivation. The absence of sufficient support and therapeutic alliance were notable concerns. Technical challenges, such as issues with platform functionality and difficulty navigating the program emerged as significant obstacles.
C7	Reinforcement	*k* = 5 P6, P8, P9, P10, P12	Positive reinforcement plays a critical role in therapy, as evidenced by the encouraging effect of positive feedback, and the importance of feeling supported, acknowledged and validated. Motivation

			form the therapist through support, along with recognition of progress and achievements reinforces the therapeutic process.
C8	Self-efficacy	*k* = 6 P4, P7, P8, P9, P10, P12	Notable changes include alterations in thought patterns, and the enhancement of coping strategies, which led to improvements in daily functioning. CBT helped patients recognise their individual ability to effect change, resulting in a sense of relief and feelings of empowerment.
C9	Self-evaluation	*k* = 5 P6, P7, P9, P10, P12	Patients reported changes in their perspectives following the self-help activities, indicating a shift in self-perception and evaluation.
C10	Social modeling	*k* = 0	N/A
C11	Social norms	*k* = 2 P8, P9	The influence of social norms is evident, as patients demonstrated a higher willingness to engage with the program when it was recommended by a trusted source. This highlights the significant role of perceived credibility and trust in healthcare professionals in shaping patient decisions and acceptance of treatment modalities.
C12	Social support	*k* = 7 P4, P5, P6, P8, P9, P10, P12	Social support, particularly from therapist, is crucial in sustaining adherence to online therapy. Many patients expressed a preference for face-to-face interaction with a therapist, especially those undergoing treatment for depression. The absence of a supportive figure significantly reduces the likelihood of patients engaging and completing the program.

Concept 10 was excluded from further analysis, as it was not supported by data. The existing overlaps in the *a priori* framework were beneficial, enabling swift and efficient coding of a substantial amount of data from the included studies. However, the initial framework did not possess adequate depth and complexity to fully account for all the data observed in these studies, and a secondary thematic analysis was undertaken, to create new themes for data, that could not be coded against the *a priori* framework. New themes that emerged from thematic analysis are presented in Table 10.

Table 10. Inductive thematic analysis of included studies: new themes not included in the a priori framework.

	Themes	Studies (*k*) coded for themes	Analytic observations
T1	Therapist's role	*k* = 5 P5, P6, P8, P9, P10	The therapist's role in online therapy is multifaceted, with patients requiring varying levels of support. A critical aspect of the therapist's function may be to accurately identify patients who have difficulties with the format and tasks of online therapy, as opposed to those who do not. This discernment is key to providing appropriate guidance and support tailored to individual needs.
T2	Perceived changes in behaviour	*k* = 3 P6, P9, P12	Patients reported more self-accepting and less self-critical attitudes. Regular logging and monitoring helped to identify key areas of change. Self-help programs can foster healthier behaviour patterns.
T3	Possible risks	*k* = 7 P1, P2, P3, P4, P8, P10, P12	The potential risks of self-help programs include concerns about data security and the confidentiality of personal information. Using the program during severe depression episodes poses an iatrogenic risk of worsening mental health. The absence of immediate assistance in emergency situations is a significant concern. Some patients reported feelings of self-blame and failure when dropping out of therapy, highlighting the importance of addressing safety, security and support mechanisms in such programs to mitigate potential risks and adverse outcomes.
T4	Facilitators of adherence and engagement	*k* = 8 P1, P2, P4, P5, P6, P9, P11, P12	Personalised treatments boost adherence rates. Regular reminders, along with ongoing support and guidance are key in maintaining engagement. Interestingly, technological difficulties or a dislike for computers were not mentioned as barriers, possibly reflecting a growing familiarity with technology among users. The credibility of the program emerged as a vital factor in sustaining engagement. Individually tailored, user-friendly and credible program features enhance patient engagement and adherence.
T4	Barriers to adherence and engagement	*k* = 7 P1, P2, P3, P4, P10, P11, P12	Barriers often stemmed from the severity of depression and the lack of follow-up support. Patients with negative experiences reported deliberate non-adherence due to low satisfaction. Feelings of being inadequately understood, validated, guided or supported negatively affected engagement.
T5	Reasons for dropout	*k* = 6 P2, P3, P4, P7, P9, P11	Participants who drop out can be distinguished in terms of their change in motivation: those who felt ready to leave treatment early and those who had negative reasons for dropping out.
T6	Taking action	*k* = 2 P3, P6	Easy access to the treatment emerged as a significant facilitator for taking action. The act of starting with the program was perceived as an achievement in itself. The intrinsic value perceived by patients gained by simply beginning treatment has positive effect.

T7	Structure and instructions	*k* = 5 P1, P2, P5, P11, P12	Patients expressed a desire for clearer instructions on how to effectively utilise the program. There was confusion about next steps and clearer closure. Programs having a clearly structured format enabled patients to break down their problems into more manageable parts, therefore restoring a sense of order and personal control. A well-defined structure enhances the usability and effectiveness of mental health interventions.
T8	Personalisation	*k* = 7 P1, P3, P4, P5, P6, P7, P12	Patients who found the material irrelevant, often expressed frustration due to lack of personalisation. This frustration was compounded by the absence of adaptive content. Patients expressed a desire for a visual representation of individual results, indicating a preference for more tailored feedback. Where personalisation was evident, it significantly sustained engagement.
T9	Autonomy	*k* = 4 P4, P6, P8, P12	Autonomy stimulated self-responsibility, some reported feeling empowered by the independence. The programs ability to help break down problems, provide structure, and grant personal control over one's situation was highly valued. Autonomy in the therapeutic process enhances patient empowerment, self-efficacy and active engagement in managing one's mental health.
T10	Accessibility and flexibility	*k* = 6 P4, P5, P6, P8, P9, P11	The accessibility of the program at any time, aligning with patient's schedule was seen as advantageous, enhancing privacy, flexibility and autonomy. The flexibility also emerged as a barrier for some, as it was challenging to sustain use and self-discipline. This highlights the complex interplay between the benefits of flexibility and the need for structured support to maximise the effectiveness of digital health interventions.
T11	Enhancing motivation	*k* = 7 P4, P6, P8, P9, P10, P11, P12	The relationship with a therapist was motivating due to presence of human contact, real-time interaction, dialogue and individual guidance. Therapist's role in providing support was seen as key motivator. Supportive therapeutic relationship and positive reinforcement enhances motivation and improves therapy outcomes.
T12	Therapeutic alliance	*k* = 6 P4, P5, P6, P8, P10, P11	Online treatment highlights the interaction between the patient's life, the therapist and the treatment program, suggesting a more complex and interconnected approach to therapy. The concept of therapeutic alliance has therefore evolved into a tripartite model, encompassing the dynamic interplay between the patient, therapist and program dimensions. In unguided interventions, the absence of a therapist was highlighted as a major drawback in establishing a strong therapeutic alliance, highlighting the importance of integrating elements of human provided support into digital therapy programs to enhance therapeutic alliance.
T13	Engaging elements of interventions	*k* = 6 P1, P2, P5, P9, P11, P12	The use of colours, images, humorous content and music was effective in stimulating cognitive activity. Interactive features, graphical elements contributed to maintaining user engagement. Incorporating aesthetically pleasing, interactive, and emotionally resonant elements foster engagement.

5 Framework synthesis

The final conceptual model, representing the results of the framework synthesis, was constructed by meticulously delineating the relationships and reciprocal influences among identified themes and their respective subthemes. The conceptual model (see Figure 5) was composed of seven themes which were further divided into 11 subthemes. The foundational elements on the conceptual model are presented in rounded squares, representing the three overarching domains addressing each research question. These domains are “facilitators of patient adherence and engagement with DTx”, “barriers to patient adherence and engagement with DTx”, and “contributing factors affecting patient adherence and engagement with DTx”. Each domain, the respective themes and subthemes are explained in detail in this chapter.

The purpose of this conceptual model is to support academics, practitioners, and professionals in the development field in comprehending the necessary behaviour changes individuals must adopt over time to consistently embrace new technologies. This conceptual model could serve as a guide for future development and refinement of DTx interventions, ensuring they are user-centric and tailored to maximise sustained patient engagement and adherence.

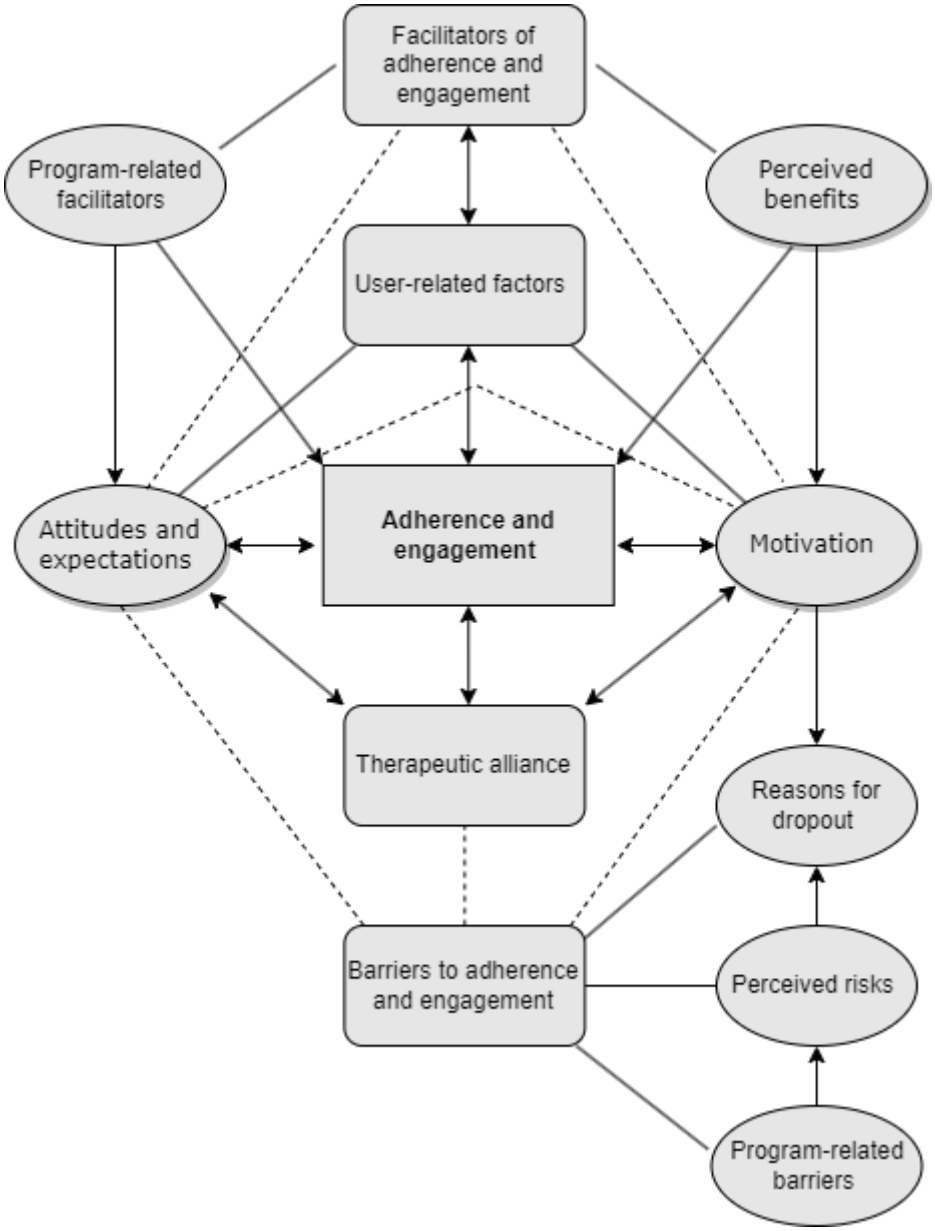


Figure 5. Conceptual model of barriers, facilitators, contributing factors and the relationships between these mediators affecting patient adherence and engagement with DTx. Source: author.

Central to the model is the outcome, which is patient adherence and engagement with DTx for depression treatment. The foundational elements of the model (in rounded squares), their respective subthemes and the relationships between these mediators were mapped, to show direct relationships between these mediators, which are presented as arrows. Causal relationships between the mediators are presented as dashed lines, demonstrating how facilitators may counteract barriers. The user-related factors, such as attitudes and expectations, as well as motivation, serve as intermediary variables that modify the influence of both facilitators and barriers on patient engagement and adherence. The model embraces the dynamic interplay between these elements, proposing

that enhancements in one domain lead to positive changes in others, thereby fostering a more integrated and effective therapeutic experience.

5.1 Facilitators of adherence and engagement

This domain consists of two themes and seven subthemes, which are presented in Figure 6.

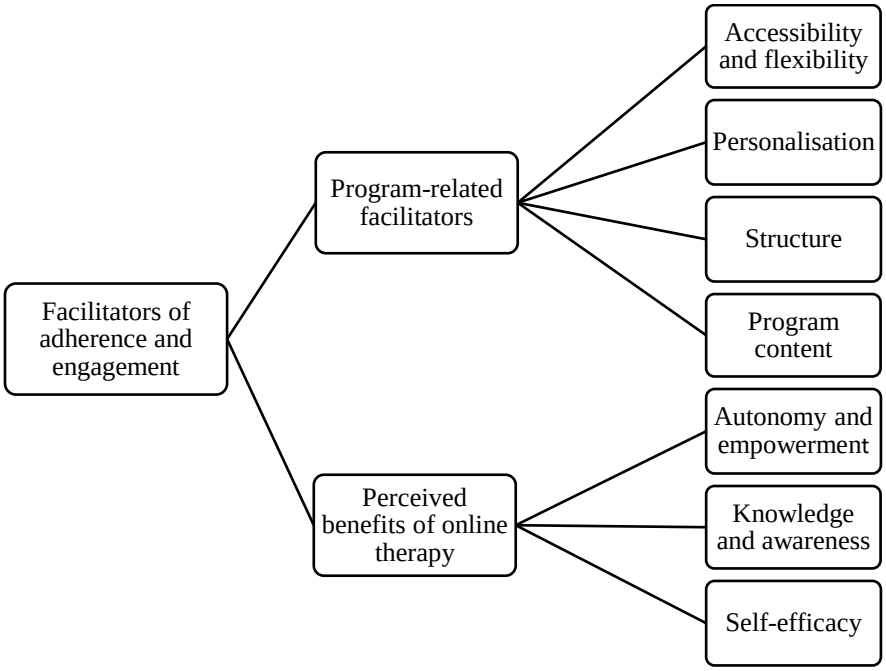


Figure 6. Themes and subthemes under domain "Facilitators of adherence and engagement".

5.1.1 Program related facilitators of adherence and engagement

Accessibility and flexibility. The accessibility of the program at any time, aligning with patient's schedule was highly appreciated [110], [112], [113], [115]. The flexibility of the online interventions also emerged as a barrier for some, as it was challenging to sustain use and self-discipline [109], [112]. However, the ease of access was perceived as an important facilitator for taking action and start therapy [111], [107]. This highlights the complex interplay between the benefits of flexibility and the need for structured support to maximise the effectiveness of digital health interventions.

"I have two small children and it can be incredibly hectic and well—hectic. So, actually, something that I could pick up in the moments where I did have time, was really good

because nobody was checking when I was doing anything, it was just that I could make my way through it at my own pace." [110].

This resultant subtheme from the synthesis regarding accessibility and flexibility of the interventions reveals a nuanced impact on patient adherence and engagement. The ability to access the program at any time, tailored to the patient's schedule, was greatly valued for its convenience and adaptability to individual lifestyles. However, the same flexibility also posed challenges for some patients, as it required a higher degree of self-discipline and made consistent use more difficult. This dichotomy shows the complex relationship between the advantages of flexible digital health interventions and the necessity for structured support to ensure their maximal effectiveness. Therefore, while flexibility and accessibility are key facilitators of engagement and adherence, they also necessitate balanced support structures to cater to varied patient needs and promote sustained treatment adherence.

Personalisation. Patients who found the material irrelevant, often learned a little [111], leading to frustration due to lack of personalisation, which was compounded by the absence of adaptive content [109], [116]. Some patients went to great lengths to filter out irrelevant content, but for some patients it was hard to find and use materials relevant to them, leading to dissatisfaction with the programme [110], [111].

Patients expressed a desire for a visual representation of individual results, indicating a preference for more tailored feedback [105]. Where personalisation and adaptibility was evident, it significantly sustained engagement and enhanced user satisfaction [113], [111]

"There were an awful lot of categories. How could I make it useful? On a daily basis, I had to merge some into larger groups and then work out like, "Alright, now I'm making this type of mistake". It had to be restructured a bit, because I couldn't be bothered to sit and cram all of them. And I didn't need to either." [111].

Interventions, where personalisation and adaptability were effectively implemented, had better outcomes regarding user engagement and adherence. Patients voiced a clear preference for tailored feedback, such as visual representation of individual self-assessment or exercise results. The quote from a patient who had to restructure the program content for it to be more useful and manageable specifically illustrates the

importance of personalisation in enhancing the usefulness and effectiveness of digital health programs.

Structure. Patients expressed a desire for clearer instructions on how to effectively utilise the program [105], [115]. In some cases, there was confusion about next steps and patients lacked clear closure after completing a treatment module [110], [115]. Programs that had a clearly structured format enabled patients to break down their problems into more manageable parts, therefore restoring a sense of order and personal control [109], [110], [116].

"We would finish and then I would get a notification saying I've got a message, and then, yes, it would be a summary, and then next steps - what to do." [110].

The structured approach significantly improves the usability and effectiveness of digital mental health interventions, as patients appreciated receiving structured summaries and guidance on subsequent steps.

Program content. Interactive features, aesthetically pleasing graphical elements, the use of colours, images, humorous content and music was effective in stimulating cognitive activity and enhanced user engagement [105], [106], [116], [110], [113], [115].

"I think graphics is a stimulus. I think the constant ongoing reading of text, especially for those who are not used to it, might result in some people switching off" [106].

Therefore, the incorporation of diverse, interactive, and visually engaging content is crucial in maintaining user engagement and promoting sustained use and adherence to the program.

5.1.2 Perceived benefits of online therapy

Autonomy and empowerment. Autonomy stimulated self-responsibility, and some reported feeling empowered by the independence the online self-help programmes provided [109], [111], [112]. The program's ability to help break down problems, provide structure, and grant personal control over one's situation was highly valued [109], [116]. Autonomy in the therapeutic process enhances patient empowerment, self-efficacy and active engagement in managing one's mental health [109], [111], [112], [116].

"Rather than just saying well here's your pills or sit here and talk to somebody for 35 minutes… Actually felt like I was doing something to help myself." (Female, p. 5) [109].

Knowledge and awareness. The self-help materials served as a catalyst for new learning experiences. Participants reported acquisition of knowledge, new insights or reactivation of once familiar knowledge. Patients learned that their thoughts and ideas about events are not always accurate reflections of reality. This newfound understanding promted them to reflect on past events, feelings and thoughts, indicating a deeper level of self-awareness and cognitive restructuring. New knowledge and enhanced awareness recognised by patients highlights the impact of therapy in altering patients' perceptions, and contribution to improved mental health outcomes through personal growth, self-realisation and recognition of cognitive biases [111], [108], [113], [114], [116].

"There were some astounding facts in there that I didn't know (smiles)… Like you are only as depressed as your last thought. That blew my mind! And yet, it is so, so sensible." (Grace, p. 312) [116].

Self-efficacy. The results clearly indicate a significant increase in self-efficacy among participants, characterised by a shift in thought patterns, and enhanced coping strategies, leading to improved daily functioning [108], [111], [113], [116]. Key developments included breaking the cycle of self-blaming, inactivity, and withdrawal, adopting more self-accepting and less self-critical attitudes. Participants also acquired self-relaxation techniques for stressful situations, and reported improvements in routine activities, diet, and exercise. The majority felt that the programe led to positive changes in various life areas with lasting effects, highlighting the profound impact of self-help interventions on enhancing self-efficacy and overall well-being [108], [109], [111], [112], [113], [114], [115], [116].

"My coping strategies definitely improved. Where previously I might have become panicky or overwhelmed with a stressful situation, I'm getting better at taking a deep breath and reacting more calmly." (p. 16) [113].

5.2 Barriers to adherence and engagement

This domain consists of three themes and two subthemes, which are presented in Figure 7.

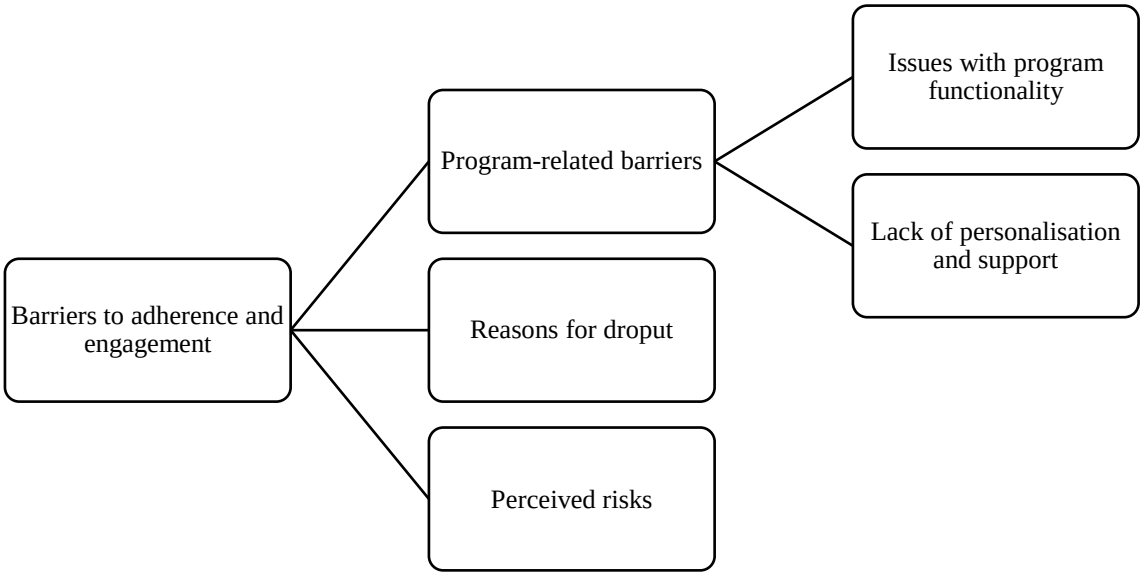


Figure 7. Themes and subthemes under domain “Barriers to adherence and engagement”.

5.2.1 Program-related barriers to adherence and engagement

Issues with program functionality. Technical challenges, such as issues with platform functionality, applications crashing, videos not playing, and difficulty navigating the program emerged as significant obstacles [106], [110], [112], [113], [115].

“I haven't had motivation to use Chatpal lately, even though I understand that the aim of the chatbot is to help me carry on. Technical issues raise the most my threshold to start using it. If it worked smoothly, I probably would have used it more often as a matter of principle.” [106].

Lack of personalisation and support. The findings highlight key barriers to engagement and adherence, centred around lack of personalisation and support [109], [111], [113], [115]. Participants frequently cited the absence of individualisation in the content, which failed to adapt to their specific needs, leading to diminished motivation. The lack of sufficient feedback from the online intervention on progress and exercises further contributed to this issue. This lack of support left patients feeling alone and isolated, emphasising the critical need for more personalised, adaptable content and stronger support systems in such interventions [105], [106], [107], [111] [110], [112], [113], [114], [115].

"With the self-assessment, I might have wished for more tangible results. Where am I now? How strong ise depression in relation to personal events?" (female, patient, p.11) [105].

5.2.2 Reasons for dropout

Reasons for dropout often stemmed from the severity of depression and the lack of follow-up support. Patients with negative experiences reported deliberate non-adherence due to low satisfaction. Feelings of being inadequately understood, validated, guided or supported negatively affected engagement. Responses from the computerised program lacked in depth, which caused frustration [106], [108], [115]. Interestingly, one study conducted by Lawler et al. [108] investigated patients' experiences with an iCBT intervention, and specifically the reasons behind dropping out of iCBT. According to the authors, the patients who dropped out, can be categorised as those, who had negative reasons and those who had positive reasons for discontinuing therapy. Those with negative reasons often dropped out due to low satisfaction, those with positive reasons, felt they got the help they needed and reported positive changes.

"I think it's just that point I sort of felt like I was getting better. I sort of got what I needed out of the program… I was feeling a bit better in my jowls and I didn't think I really needed it too much." (patient, p. 7) [108].

5.2.3 Perceived risks

Self-help programs carry potential risks, including concerns over data security, ambiguity in data storage practises, and maintaining the confidentiality of personal information [106], [116]. There are apprehensions that using the program during severe depression episodes poses an iatrogenic risk of worsening mental health [109], [112]. The lack of immediate assistance in emergencies, with some programs failing to offer aid or referral for worsening conditions, also poses a significant challenge [107].

Additionally, patients have reported feelings of self-blame and failure upon discontinuing therapy or not completing tasks [114]. The use of AI chatbots introduces the risk of generating inappropriate responses, although initiatives like the ChatPal chatbot, which directs users to crisis helplines when the AI fails to comprehend user inputs, attempt to mitigate this [106].

"If you're mildly depressed, or if you've truned the corner, then I think that's when it's appropriate. But I think if you were deeply depressed, and still struggling, then it would be much harder... I think you probably would fail and that would make you feel worse. Because the last thing you need is another failure when you're feeling really down." (Female, p. 6) [109].

These findings reveal critical concerns and challenges associated with self-help programs. Risks such as data security issues, unclear data storage practises, and breaches of confidentiality pose significant threats to user privacy. A notable deficiency in some programs is the lack of immediate support in emergencies, potentially leaving users without necessary aid or guidance during critical times. It is important for these programs to be tailored to the varying degrees of depression severity, as individuals with severe depression might find these programs overwhelming or ineffective, potentially leading to a sense of failure that could aggravate their condition. These findings emphasise the importance of addressing safety, security and support mechanisms in such programs to mitigate the potential risks and adverse outcomes.

5.3 Contributing factors affecting adherence and engagement

This domain consists of two themes and two subthemes, which are presented in Figure 8.

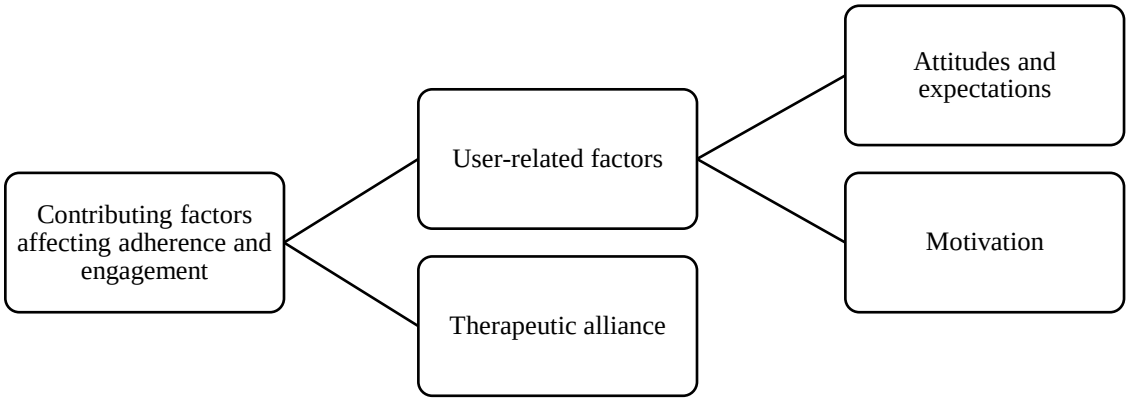


Figure 8. Themes and subthemes under domain "Contributing factors affecting adherence and engagement".

5.3.1 User-related factors affecting adherence and engagement

Attitudes and expectations. Patients' expectations and attitudes towards online therapy may, to some extent, be indicative of their adherence, engagement and eventual outcomes [109], [111], [115]. Patients who were positively attuned to the self-help program, demonstrated a tendency towards greater adherence and frequently reported program completion [109]. Conversely, those who perceived the program content as misaligned with their needs, exhibited poor initial motivation and lower levels of engagement [111]. Interestingly, some patients expressed feeling marginalised and offended when offered the online intervention, perceiving it as lack of prioritisation by healthcare professionals [112]. In contrast, others appreciated the opportunity to access qualified therapy without any financial burden [111].

Another critical factor to consider is the patients' expectations and preferences regarding the amount of support provided in therapy. For some patients, the anonymity and impersonal nature of computerised therapy is beneficial, as they find it challenging to open up to a stranger [107], [112]. In contrast, other patients perceive the lack of interpersonal communication with a therapist as a fundamental problem, believing that therapy without face-to-face contact is ineffective [109], [115].

"From my point of view, the contact with the therapist is an essential aspect of therapy. Therefore I lost all my interest in the therapy and didn't want to continue." (Participant #1, p. 32) [115].

These variations illustrate the complex influence of patients' perceptions and attitudes towards online therapeutic interventions, suggesting that depression care pathways should be tailored to be responsive to different patients' experiences and expectations. This tailoring is crucial to ensure that individuals who are most likely to benefit from online therapy are adequately informed about this treatment option. Additionally, it is imperative that the expectations and goals of patients are congruent with the objectives of the online therapy program. Such alignment is fundamental to enhancing the efficacy and suitability of the therapeutic intervention.

Motivation. Impaired motivation is commonly observed in patients with depression, often manifesting as low self-esteem, apathy, and concentration difficulties [107], [109], [112], [113]. In self-help interventions, patients are expected to actively engage in the

therapeutic process by bringing their own expectations, choosing useful elements from the therapy, independently evaluating outcomes, and incorporating therapeutic practises into daily life [111]. However, many patients reported low engagement and adherence with the interventions, attributing this to the motivational deficits inherent in their depressive states [109], [108], [112], [113], [114].

The results reveal that the role of the therapist in offering support is a key motivating factor for patients [110], [111], [113]. Therapists significantly contribute to patient motivation through providing validation and empathy [114], as well as offering positive reinforcement. This reinforcement can include positive feedback on progress and achievements, which fosters feelings of success and accomplishment in patients [110], [111], [112], [113].

"I had a therapist who called me and checked how I had proceeded and pushed me a bit and said "come on, go through this chapter until tomorrow, I'll call you back then". I needed someone to push me because I had a problem with sitting down and getting things done, to pursue things..." (Patient, p. 49) [112].

The lack of motivation and energy is a critical consideration in designing interventions for people with depression, as it plays a pivotal role in the successful implementation of these interventions for this population. Therapist support can significantly improve patients motivation through support, guidance and feedback. Supportive therapeutic relationship and positive reinforcement can enhance motivation and improve therapy outcomes.

5.3.2 Therapeutic alliance

Participants clearly identified the common feature of the absence of a therapists as a major drawback in building therapeutic alliance [115]. In guided interventions that featured a therapist or a supporter, patients explicitly valued the professional feedback and interpersonal support provided. They described the therapist's role as a key facilitator in translating theoretical understanding into practical application and in enhancing their comprehension of the program's content [111]. Regular e-mails and phone calls from the therapist were perceived positively, especially for patients whose motivation was affected by depression, as they often required external encouragement to persist with the program [110], [112]. Additionally, therapists were able to intervene with personalised advice

when issues arose that were beyond the program's scope [111]. The adaptability and personalisation that human support provides were highly valued, emphasising the profound influence of therapeutic alliance.

"It is as I said before, it is necessary to have a therapist behind to push you a bit, to give support, to encourage you. That's very important, extremely important. Otherwise I don't think I could benefit from a treatment." (Participant #8, p. 34) [115].

In certain instances, patients voiced dissatisfaction with the therapeutic support they received. A lack of clarity regarding the therapist's role in guided iCBT led some users to hesitate in seeking guidance or support [114]. Some patients expressed a desire for their therapist to demonstrate more care, authenticity, and genuine investment in their well-being [113], [114]. A substandard patient-therapist relationship was identified as a factor contributing to patient dropout [108]. Furthermore, there was a notable variaton in patients' expectations regarding the extent of support they anticipated from therapists [112], [114]. These findings highlight the critical importance of clear role definition, empathetic engagement, and consistent quality in the therapist-patient relationship for establishing a strong therapeutic alliance and preventing patient disengagement.

The notion that patients have varying preferences for guidance in online therapy indicates the importance of discerning those who can effectively manage treatment with minimal assistance. This approach could potentially allocate more time and resources to assist patients who require frequent interaction and tailored adjustments to the program's structure. Online treatment highlights the interaction between the patient's life, the therapist and the treatment program, suggesting a more complex and interconnected approach to therapy. The concept of therapeutic alliance has therefore evolved into a tripartite model, encompassing the dynamic interplay between the patient, therapist and program dimensions, as suggested by some of the authors of included studies [110], [111], [114]. In unguided interventions, the absence of a therapist was highlighted as a major drawback in establishing a strong therapeutic alliance, highlighting the importance of integrating elements of human provided support into digital therapy programs to enhance therapeutic alliance.

6 Discussion

This literature review on patient engagement and adherence with DTx has illuminated a complex interplay of facilitators, barriers, and contributing factors, as depicted on the conceptual model derived from the synthesis. This discussion focuses on the dynamics among these elements and their implications for enhancing patient engagement and adherence with DTx.

Facilitators of patient adherence and engagement with DTx

The nature of user-related and program-related factors that contribute to patient engagement and adherence with DTx are complex and multifaceted. Accessibility and flexibility, as well as personalisation and adaptability of these interventions were emphasised as paramount elements increasing the application's usability. Patients valued the ability to engage with interventions at their convenience and align therapy with their schedule. Interventions, where personalisation and adaptability were effectively implemented, had better outcomes regarding user engagement and adherence. Patients voiced a clear preference for tailored feedback, such as visual representation of individual self-assessment or exercise results. The quote from a patient who had to restructure the program content for it to be more useful and manageable specifically illustrates the importance of personalisation in enhancing the usefulness and effectiveness of digital health programs. These findings are in line with the current body of literature emphasising the significance of usability in DTx [5]. A previous study by Jeong et al. [55] pinpointed specific usability aspects that significantly impact therapeutic effectiveness. Their analysis corroborated that perceived usefulness, user attitudes, encompassing both positive and negative views towards the application, and the enjoyment users experience are vital for therapeutic outcomes, and are therefore crucial factors for increasing sustained user engagement, usability and effectiveness within DTx [55].

Programs that offered adaptable content and personalised feedback had higher levels of engagement and satisfaction, suggesting that personalisation is not merely a feature, but a necessity for effective digital interventions. The structure of DTx programs also played

a significant role, with patients favouring clear guidance and sense of progression. Well-defined steps after completing modules imparted a sense of achievement and direction, which is integral for maintaining motivation. ICBT interventions enable patients to complete various modules at their own pace, providing them with autonomy over their therapy [56]. The results from the current synthesis show that autonomy in the therapeutic process enhances patient empowerment, self-efficacy and active engagement in managing their mental health. However, such autonomy might be overwhelming for certain individuals, particularly those with acute episodes of depression, as they might need more guided support. This dichotomy shows the complex relationship between the advantages of flexible self-help digital health interventions and the necessity for structured support to ensure their maximal effectiveness. Therefore, while flexibility, accessibility, and adaptability are key facilitators of engagement and adherence, they also necessitate balanced support structures to cater to varied patient needs and promote sustained treatment adherence.

Furthermore, the applications' interactive nature, including aesthetic elements and multimedia, was found to stimulate cognitive activity, highlighting the importance of diverse and engaging program design. Customising the delivery and content of digital interventions to align with users' needs, motivations and personal traits ensures that users receive guidance that is relevant, appropriate and safe [18]. Therefore, the incorporation of diverse, interactive, and visually engaging content is crucial in maintaining user engagement and promoting sustained use and adherence to the program.

Barriers to patient adherence and engagement with DTx

Technical difficulties and program functionality issues such as malfunctioning platforms, application crashes, non-playing videos, and navigational problems emerged as prominent barriers, often leading to patient frustration and dropout. These technical issues not only disrupt the user experience, but also raise the threshold for initial and continued use of these interventions. Failure to ensure requirements for robust, reliable, and user-friendly technology could significantly undermine the sustained user engagement and adherence with DTx interventions.

The lack of personalised content and sufficient support left patients feeling isolated in their therapeutic journey. The lack of feedback regarding progress, lack of human contact

and lack of clear instructions about the DTx application contributed to disconnection from the therapeutic process. When interventions do not align with the specific needs and contexts of users, it can lead to decreased motivation, which results in decreased adherence and engagement with the intervention. These barriers have also emerged from previous research studies, supporting the statement that usability and functionality problems decrease the likelihood of user engagement because of the mismatch between the program's design and user needs [26]. These barriers suggest that while DTx offers many advantages, it is not without its challenges, and these need to be addressed to ensure the efficacy of these interventions.

Contributing factors affecting patient engagement and adherence with DTx

User-related factors, such as attitudes, expectations, and motivation have a bidirectional relationship with both the facilitators and barriers of patient engagement and adherence with DTx. Positive attitudes and realistic expectations that were aligned with the program's objectives, were associated with higher levels of engagement and treatment adherence, while negative perceptions or misaligned expectations led to disengagement. This finding is supported by previous research, where the authors suggested that users are more likely to engage with a DTx program if there is alignment between their expectations and the program's objectives [23].

Many patients reported having low motivation due to depression, which directly influences both the engagement and adherence with the DTx intervention, and in some cases was reason for dropping out of therapy. The linkage between patient motivation, or the lack thereof, engagement, and the severity of depression finds support in existing literature [14], [23]. However, this relationship is marked by contradictory findings. Certain studies suggest that individuals with more severe depression symptoms exhibit heightened interest in DTx, while other studies indicate an inverse relationship, with more severe symptoms correlating with reduced engagement with DTx programs [14]. The results of the current framework synthesis reveal an important association between diminished motivation as a result of depression, and lower levels of engagement. However, this finding is important as it enables the proposal of customising these interventions to correspond to the severity of depression. Individual adaptation of support levels to meet specific patient needs could potentially reduce the likelihood of patient disengagement and dropout.

Interestingly, one included primary study conducted by Lawler et al. [108] investigated patients' experiences with an iCBT intervention, and specifically the reasons behind dropping out of the program, suggesting that patients who dropped out before completion of the programme can be distinguished in terms of their change in attitudes and motivation - those who felt ready to leave treatment early because of perceived positive changes in behaviour, and those who had negative reasons for dropping out, such as low satisfaction with the programme or finding the treatment ineffective. Other authors have also suggested that the relationship between engagement and motivation could follow an U-shaped pattern, meaning that individuals with the highest and lowest motivation levels may quickly disengage from digital behaviour change interventions, including DTx, due to either successful or unsuccessful behaviour change, respectively [23], [26].

The importance of therapeutic alliance was highlighted as a central mediator, with its absence in unguided interventions marked as a substantial limitation. In guided interventions, the therapist's support was pivotal in navigating the program and bolstering the patients' commitment to the therapeutic process. Other authors have also pointed out that it is necessary to determine when human support adds value, as unguided interventions can be distributed more easily and at lower cost, potentially leading to significant impacts on public health [18]. Human support may be more important, when users seek reassurance, guidance, emotional support, or accountability from an expert. However, as interventions evolve to include features that effectively replicate therapeutic relationship, the necessity for human contact may decrease [18].

6.1 Limitations of the study

In discussing the limitations of generalisability of this study, it is important to acknowledge specific aspects of the study design and the selected population:

Population limitation: This synthesis focused exclusively on studies involving the general adult population with depression diagnosis. As such, the findings may not be fully applicable to specific subgroups, such as adolescents, older adults, or individuals with severe mental illness. The nuances of engagement and adherence to DTx could differ significantly due to varying needs, technology use patterns, and mental health status.

Nature of interventions: The interventions studied were limited to patient-facing, completely self-guided (unsupported), or those with some support. The exclusion of therapist-led interventions and blended care interventions means the findings might not extend to DTx interventions where active and regular professional support is provided, but the dynamics of patient engagement and adherence could vary considerably in more supported settings.

Geographical restrictions: The inclusion of studies conducted only in European countries presents both a limitation and a strength. While this focus allows for a more coherent understanding of DTx in the European context, considering the diverse healthcare systems and policies across several European nations, it limits the generalisability of the findings to other cultural or geographical contexts.

Cultural homogeneity and diversity: The synthesis' restriction to European countries may not fully capture the cultural and socio-economic diversity that exists globally. Cultural factors, including beliefs about mental health and technology can significantly influence the adoption and usage of DTx. However, including several European countries does add a degree of cultural and regional diversity within the European context.

By acknowledging these limitations, the study recognises the constraints under which the findings should be interpreted, especially when considering the applicability of these results to different populations and contexts.

6.2 Implications and recommendations for researchers, designers and developers of DTx interventions

The findings suggest that for DTx to be effective, they must be designed with a deep understanding of the facilitators and barriers to patient engagement and adherence. Personalisation, structured support and engaging content are critical facilitators that should be integrated into DTx designs. Addressing technical barriers and providing clear, empathetic support can mitigate the challenges faced by patients.

This thesis recommends that future DTx should incorporate adaptive content to cater to individual patient needs, utilise engaging and interactive design elements, and ensure robust technical functionality. Furthermore, the incorporation of therapeutic alliance, even in a digital format, could significantly enhance patient engagement and adherence,

suggesting a hybrid model of DTx that combines technology with elements of human support.

In conclusion, this literature review and synthesis provides a nuanced understanding of the factors affecting patient adherence and engagement with DTx, among patients with depression. The implications drawn from this conceptual model highlight the need for personalised, flexible and supportive digital health interventions, that not only resonate with patients' lifestyles, but also provide the necessary structure and support to maintain engagement and encourage adherence.

The author also proposes a need for future research in more diverse populations and intervention types, to build a more comprehensive understanding of patient engagement and adherence with mental health DTx.

7 Summary

The aim of the research was achieved by synthesising existing evidence on patients' perspectives regarding engagement and adherence with DTx, and by providing an improved understanding of how to optimise patient engagement and adherence in the context of DTx. The main research question of this thesis was to provide implications and recommendations from the synthesised findings to enhance patient engagement and adherence with DTx. The implications drawn from the conceptual model highlight the need for personalised, flexible and supportive digital health interventions. This conceptual model can provide guidance for an array of stakeholders, including researchers, policymakers, clinicians, was well as designers and developers of DTx applications. The significance of the conceptual model is in its ability to offer a comprehensive understanding of the intricate factors that influence patient engagement and adherence withing the context of DTx interventions.

The results of synthesis and the conceptual model offer critical insights that have far-reaching implications. Firstly, the model highlights key aspects such as accessibility, flexibility, personalisation, and adaptability as paramount for enhancing the usability of DTx interventions. Secondly, it emphasises the intricate nature of factors influenced both by users and DTx applications, as well as the relationships between the factors and mediators between them.

While DTx offers numerous advantages, it is not without its challenges, including technical and functionality issues that often lead to patient frustration and disengagement. This study also uncovered bidirectional relationships between user-related factors like attitudes, expectations, and motivation. Positive attitudes and aligned expectations were found to correlate with higher levels of engagement and adherence, highlighting the importance of cultivating positive attitudes and aligning patient expectations for higher engagement and adherence. Furthermore, the profound impact of depression on motivation and its subsequent influence on patient engagement highlights the need for tailored approaches in mental health interventions.

Additionally, this thesis uncovered the importance of the therapeutic alliance and highlighted potential risks associated with these interventions. Therapeutic alliance proved to be especially vital in guided interventions, where human support played a pivotal role in fostering patient commitment and guiding them through the program. These findings emphasise that while DTx offers significant advantages in terms of accessibility, addressing challenges related to program design, functionality, and the therapeutic alliance is paramount for the efficacy of these interventions. This thesis provides a valuable foundation upon which to build more effective and patient-centric DTx interventions, ultimately enhancing the landscape of digital mental health.

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Appendix 2 – Searched databases

Full list of searched databases and retrieved search results are presented in Table 11.

Table 11. Searched databases and results.

Database	Reason	Accessed via	Search results
Medline	MEDLINE contains over 30 million references to journal articles in the life sciences, with a primary focus on biomedicine. All research is peer-reviewed. Open access via Pubmed. Allowing focused search using MeSH terms.	Pubmed	507
APA PsycNET	APA PsycNet is the only search platform allowing searching only for American Psychological Association (APA) content. Open access, contains over 5,4 million records. Focused on social and behavioural science content.	PsycNET	89
EBSCO databases	Open access to selected EBSCO provided databases via Tallinn University of Technology Library portal Primo. Peer-reviewed articles.	EBSCOhost Web	150
SCOPUS	Provides peer-reviewed literature covering the fields of science, technology, medicine social sciences and arts, and humanities.	Primo	1274
Web of Science	Web of Science is a platform consisting of several literature search databases. Provides scientific and scholarly research. Open access via Tallinn University of Technology Library portal Primo.	Primo	689

Appendix 3 – Search strategy

Identification of relevant primary research studies was systematically conducted in five databases: Medline, APA PsycNET, EBSCOhost, SCOPUS and Web of Science. Database searches were conducted between October 28th, 2023, and October 30th, 2023. The search strategy was first developed in Medline, with inspiration from prior research conducted by Villarreal-Zegarra et al. [84], Borghouts et al. [8] and Akther et al. [85], as they have explored analogous key concepts in their respective research areas. The detailed procedure of the extensive search conducted in Medline is presented in Table 12. The search terms were then adjusted for other databases, necessitating several modifications to accommodate the specific requirements of each database. The search terms adapted to each database are presented in below.

Table 12. Search concept in Medline (28.10.2023) via Pubmed

Search concept	Search	Results
Search concept 1: Mental health		
Adapted from Adapted from Villarreal-Zegarra D, Alarcon-Ruiz CA, Melendez-Torres G, Torres-Puente R, Navarro-Flores A, Cavero V, Ambrosio-Melgarejo J, Rojas-Vargas J, Almeida G, Albitres-Flores L, Romero-Cabrera AB, Huarcaya-Victoria J. Development of a Framework for the Implementation of Synchronous Digital Mental Health: Realist Synthesis of Systematic Reviews. JMIR Ment Health 2022;9(3):e34760		
MeSH terms and keywords	1."Mental Health"[Mesh] OR "Mental Health Recovery"[Mesh] OR “mental health“[tw] OR "psychological wellbeing"[tw] OR "mental wellbeing"[tw] OR "behavioural health"[tw] Filters: in the last 10 years, English, MEDLINE	123,190
	2. "Depression"[Mesh] OR "Depressive Disorder"[Mesh] OR "Depressive Disorder, Major"[Mesh] OR "Anxiety"[Mesh] OR "Anxiety Disorders"[Mesh] OR "Mood Disorders"[Mesh] OR "Psychological Distress"[Mesh] OR "Mental Disorders"[Mesh:NoExp] OR "Stress, Psychological"[Mesh] OR Depress*[tw] OR “anxiety disorder*”[tw] OR “anxiet*” [tw] OR “Depressive disorder*”[tw] OR “Mood disorder*”[tw] OR “Mental disorder*” [tw] OR “hypervigilance”[tw] OR “mental illness“[tw] OR distress[tw] OR “psychological distress”[tw] OR “Psychologic Stress” [tw] OR “emotional distress”[tw] OR stress[tw] OR “overanxious disorder”[tw] OR “Anxiety Neuros*”[tw] OR neuros*[tw] Filters: in the last 10 years, English, MEDLINE	785,242

	3. 1 OR 2	74,210
	Filters: in the last 10 years, English, MEDLINE	
Search concept 2: Digital health interventions Adapted from Adapted from Villarreal-Zegarra D, Alarcon-Ruiz CA, Melendez-Torres G, Torres-Puente R, Navarro-Flores A, Cavero V, Ambrosio-Melgarejo J, Rojas-Vargas J, Almeida G, Albitres-Flores L, Romero-Cabrera AB, Huarcaya-Victoria J. Development of a Framework for the Implementation of Synchronous Digital Mental Health: Realist Synthesis of Systematic Reviews. JMIR Ment Health 2022;9(3):e34760		
MeSH terms and keywords	4."Telemedicine"[Mesh] OR "Telerehabilitation"[Mesh] OR "Telemetry"[Mesh] OR "Remote Consultation"[Mesh] OR "Technology Assessment, Biomedical"[Mesh] OR "Mobile Applications"[Mesh] OR "Medical Informatics Applications"[Mesh] OR "Therapy, Computer-Assisted"[Mesh] OR "Virtual Reality Exposure Therapy"[Mesh] OR "Videoconferencing"[Mesh] OR Teleconsultation*[tw] OR “digital health”[tw] OR “digital health intervent*”[tw] OR “mobile health”[tw] OR "digital health intervention*"[tw] OR "Mobile application*"[tw] OR "Digital health application*"[tw] OR "Digital mental health"[tw] OR "DMHI*"[tw] OR "Mental health app*"[tw] OR "Mobile app*"[tw] OR "m-health"[tw] OR "e-health"[tw] OR "e-health app*"[tw] OR “e-health”[tw] OR "digital health solution*"[tw] OR "telepsychiatry" [tw] OR "computer-assisted therap*"[tw] OR "online therap*"[tw] OR telepsycholog*[tw] OR "remote consultation*"[tw] OR Telemedicine[tw] OR Telemetry[tw] OR “eTherap*”[tw] OR iCBT[tw] OR teletherap*[tw] Filters: in the last 10 years, English, MEDLINE	258,975
Search concept 3: Engagement/adherence		
MeSH terms and keywords	5. "Patient Participation"[Mesh] OR "Treatment Adherence and Compliance"[Mesh] OR "Patient Compliance"[Mesh] OR "Patient Reported Outcome Measures"[Mesh] OR "Patient Satisfaction"[Mesh] OR "Patient Preference"[Mesh] OR “patient engagement”[tw] OR “user engagement”[tw] OR engagement[tw] OR adhere*[tw] OR engage*[tw] OR usability[tw] OR “user experience*”[tw] OR “user satisfaction”[tw] OR acceptability[tw] OR “user perspective*”[tw] OR “patient perspective*”[tw] OR adoption[tw] OR “effective engagement”[tw] OR “sustained engagement”[tw] OR uptake[tw] OR barrier*[tw] OR facilitate*[tw] OR acceptability[tw] OR „patient Empower*“[tw] OR “patient adhere*”[tw] Filters: in the last 10 years, English, MEDLINE	851,822
Search concept 4: Study type Adapted from Akther, S., Molyneaux, E., Stuart, R., Johnson, S., Simpson, A., & Oram, S. (2019). Patients' experiences of assessment and detention under mental health legislation: Systematic review and qualitative meta-synthesis. *BJPsych Open, 5*(3), E37. doi:10.1192/bjo.2019.19		
MeSH terms and keywords	6. "Qualitative Research"[Mesh] OR "Interviews as Topic"[Mesh] OR "Focus Groups"[Mesh] OR "Nursing Methodology Research"[Mesh] OR "Narration"[Mesh] OR "Video Recording"[Mesh] OR "Personal Narratives as Topic"[Mesh] OR "Tape Recording"[Mesh] OR "Health Knowledge, Attitudes, Practice"[Mesh] OR "Grounded Theory"[Mesh] OR "Document Analysis"[Mesh] OR "Hermeneutics"[Mesh] OR	1,577,129

	"Qualitative research"[tw] OR qualitative[tw] OR "Qualitative analysis"[tw] OR "Focus group*"[tw] OR "Thematic analysis"[tw] OR Interview*[tw] OR thematic[tw] OR theme*[tw] OR survey[tw] OR phenomenograph*[tw] OR “grounded theory”[tw] OR ethnograph*[tw] OR “case stud*”[tw] OR (humanistic OR existential OR experiential OR paradigm*) OR “observational method”[tw] OR “mixed method*”[tw] OR “narrative analysis”[tw] OR “action research"[tw] OR (unstructured OR “open ended” OR “open-ended” OR structured) Filters: in the last 10 years, English, MEDLINE	
Combining search concepts 1 and 2 and 3 and 4		
	7. 3 AND 4 AND 5 AND 6 Filters: in the last 10 years, English, MEDLINE	632
Search concept 5: Limitations Adapted from Adapted from Villarreal-Zegarra D, Alarcon-Ruiz CA, Melendez-Torres G, Torres-Puente R, Navarro-Flores A, Cavero V, Ambrosio-Melgarejo J, Rojas-Vargas J, Almeida G, Albitres-Flores L, Romero-Cabrera AB, Huarcaya-Victoria J. Development of a Framework for the Implementation of Synchronous Digital Mental Health: Realist Synthesis of Systematic Reviews. JMIR Ment Health 2022;9(3):e34760		
MeSH terms and keywords	8. "meta-analysis"[tw] OR "metanalysis"[tw] OR "Systematic review*"[tw] OR "meta-synthesis"[tw] OR "review"[Publication Type] OR "review literature as topic"[MeSH Terms] OR "review"[tw] OR "scoping review" OR synthesis[tw] OR systematic[tw] Filters: in the last 10 years, English, MEDLINE	1,615,653
	9. 7 NOT 8 Filters: in the last 10 years, English, MEDLINE	507

Search concept in SCOPUS database (30.10.2023)

1. TITLE-ABS-KEY ({mental health} OR {mental wellbeing} OR {anxiety disorder} OR depress* OR anxiety* OR {depressive disorder} OR {mood disorder} OR {mental disorder} OR {mental illness} OR stress) AND PUBYEAR > 2012 AND PUBYEAR < 2024 AND (LIMIT-TO (LANGUAGE , "English"))
2. TITLE-ABS-KEY ({teleconsultation} OR {digital health} OR {digital health intervention} OR {mobile application} OR {digital mental health} OR {DMHI} OR {mental health app*} OR {mhealth} OR {e-health} OR {telepsychiatry} OR {computer assisted therap*} OR {online therap*} OR {telepsychology} OR {remote consultation} OR telemedicine OR telemetry OR {etherapy} OR {iCBT} OR teletherap*) AND

PUBYEAR > 2012 AND PUBYEAR < 2024 AND (LIMIT-TO (LANGUAGE , "English"))

3. 1 AND 2

4. TITLE-ABS-KEY ({patient engagement} OR {user engagement} OR adhere* OR engage* OR {user experience} OR {user satisfaction} OR acceptability OR {patient perspective} OR {effective engagement} OR {sustained engagement} OR adoption OR uptake OR barrier* OR facilitat* OR {patient empower*} OR {patient adhere*}) AND PUBYEAR > 2012 AND PUBYEAR < 2024 AND (LIMIT-TO (LANGUAGE , "English"))

5. 3 AND 4

6. TITLE-ABS-KEY ({qualitative research} OR {focus group*} OR {thematic analysis} OR interview* OR {grounded theory} OR {mixed method}) AND PUBYEAR > 2012 AND PUBYEAR < 2024 AND (LIMIT-TO (LANGUAGE , "English"))

7. 5 AND 6

Search concept in EBSCO (30.10.2023)

"mental health" OR "psychological wellbeing" OR "mental wellbeing" OR "behavioural health"

AND Depress* OR "anxiety disorder*" OR anxiet* OR "Depressive disorder*" OR "Mood disorder*" OR "Mental disorder*" OR "hypervigilance" OR "mental illness" OR distress OR "psychological distress" OR "Psychologic Stress" OR "emotional distress" OR stress OR "overanxious disorder" OR "Anxiety Neuros*" OR neuros*

AND Teleconsultation* OR "digital health" OR "digital health intervent*" OR "mobile health" OR "digital health intervention*" OR "Mobile application*" OR "Digital health application*" OR "Digital mental health" OR "DMHI*" OR "Mental health app*" OR "Mobile app*" OR "m-health" OR "e-health" OR "e-health app*" OR "e-health" OR "digital health solution*" OR "telepsychiatry" OR "computer-assisted therap*" OR "online therap*" OR "telepsycholog*" OR "remote consultation*" OR "Telemedicine" OR "Telemetry" OR "eTherap*" OR "iCBT" OR "teletherap*"

AND "patient engagement" OR "user engagement" OR engagement OR adhere* OR engage* OR usability OR "user experience*" OR "user satisfaction" OR acceptability OR "user perspective*" OR "patient perspective*" OR adoption OR "effective engagement" OR "sustained engagement" OR uptake OR barrier* OR facilitate* OR acceptability OR "patient Empower*" OR "patient adhere*"

AND "Qualitative research" OR qualitative OR "Qualitative analysis" OR "Focus group*" OR "Thematic analysis" OR Interview* OR thematic OR theme* OR survey OR phenomenograph* OR "grounded theory" OR ethnograph* OR "case stud*" OR (humanistic OR existential OR experiential OR paradigm*) OR "observational method" OR "mixed method*" OR "narrative analysis" OR "action research" OR (unstructured OR "open ended" OR "open-ended" OR structured)
NOT "meta-analysis" OR "metaanalysis" OR "Systematic review*" OR "meta-synthesis" OR "review" OR "scoping review" OR synthesis OR systematic

Search concept Web of Science database (30.10.2023)

1. TS=("mental health" OR "psychological wellbeing" OR "mental wellbeing" OR "behavioural health")
   Filters: 2013-2023
2. TS=(Depress* OR "anxiety disorder*" OR anxiet* OR "Depressive disorder*" OR "Mood disorder*" OR "Mental disorder*" OR hypervigilance OR "mental illness" OR distress OR "psychological distress" OR "Psychologic Stress" OR "emotional distress" OR stress OR "overanxious disorder" OR "Anxiety Neuros*" OR neuros*)
   Filters: 2013-2023
3. 1 AND 2
   Filters: 2013-2023
4. TS=(Teleconsultation* OR "digital health" OR "digital health intervent*" OR "mobile health" OR "digital health intervention*" OR "Mobile application*" OR "Digital health application*" OR "Digital mental health" OR "DMHI*" OR "Mental health app*" OR "Mobile app*" OR "m-health" OR "e-health" OR "e-health app*" OR "e-health" OR "digital health solution*" OR "telepsychiatry" OR "computer-assisted therap*" OR "online therap*" OR telepsycholog* OR "remote consultation*" OR Telemedicine OR Telemetry OR "eTherap*" OR iCBT OR teletherap*)
   Filters: 2013-2023
5. 3 AND 4
   Filters: 2013-2023
6. TS=("patient engagement" OR "user engagement" OR engagement OR adhere* OR engage* OR usability OR "user experience*" OR "user satisfaction" OR acceptability OR "user perspective*" OR "patient perspective*" OR adoption OR "effective

engagement" OR "sustained engagement" OR uptake OR barrier* OR facilitate* OR acceptability OR "patient Empower*" OR "patient adhere*")
Filters: 2013-2023

7. 5 AND 6
   Filters: 2013-2023

8. TS=("Qualitative research" OR qualitative OR "Qualitative analysis" OR "Focus group*" OR "Thematic analysis" OR Interview* OR thematic OR theme* OR survey OR phenomenograph* OR "grounded theory" OR ethnograph* OR "case stud*" OR (humanistic OR existential OR experiential OR paradigm*) OR "observational method" OR "mixed method*" OR "narrative analysis" OR "action research" OR (unstructured OR "open ended" OR "open-ended" OR structured))
   Filters: 2013-2023
9. 7 AND 8
   Filters: 2013-2023

10. TS=("meta-analysis" OR "metaanalysis" OR "Systematic review*" OR "meta-synthesis" OR "review" OR "scoping review" OR synthesis OR systematic)
    Filters: 2013-2023

11. 9 NOT 10
    Filters: 2013-2023

Search concept PsycNET database (30.10.2023)

"mental health" OR "psychological wellbeing" OR "mental wellbeing" OR "behavioural health" AND Depress* OR "anxiety disorder*" OR anxiet* OR "Depressive disorder*" OR "Mood disorder*" OR "Mental disorder*" OR "hypervigilance" OR "mental illness" OR distress OR "psychological distress" OR "Psychologic Stress" OR "emotional distress" OR stress OR "overanxious disorder" OR "Anxiety Neuros*" OR neuros*

AND Teleconsultation* OR "digital health" OR "digital health intervent*" OR "mobile health" OR "digital health intervention*" OR "Mobile application*" OR "Digital health application*" OR "Digital mental health" OR "DMHI*" OR "Mental health app*" OR "Mobile app*" OR "m-health" OR "e-health" OR "e-health app*" OR "e-health" OR "digital health solution*" OR "telepsychiatry" OR "computer-assisted therap*" OR "online therap*" OR "telepsycholog*" OR "remote consultation*" OR "Telemedicine" OR "Telemetry" OR "eTherap*" OR "iCBT" OR "teletherap*"

AND "patient engagement" OR "user engagement" OR engagement OR adhere* OR engage* OR usability OR "user experience*" OR "user satisfaction" OR acceptability OR "user perspective*" OR "patient perspective*" OR adoption OR "effective engagement" OR "sustained engagement" OR uptake OR barrier* OR facilitate* OR acceptability OR "patient Empower*" OR "patient adhere*"
AND "Qualitative research" OR qualitative OR "Focus group*" OR "Thematic analysis" OR Interview* OR thematic OR theme* OR survey OR "grounded theory" OR "case stud*" OR "observational method" OR "mixed method*" OR "narrative analysis" OR "action research" OR (unstructured OR "open ended" OR "open-ended" OR structured)

Appendix 4 – Inclusion/exclusion criteria for primary research studies

Inclusion criteria

- Primary studies that report qualitative data;
- Studies conducted in European countries;
- Report on an online intervention aimed to treat or manage depression in general adult population;
- Mixed-methods studies with primary qualitative data collection will be included if they meet the criteria of a randomised controlled trial (RCT) and where it is possible to extract the findings derived from the qualitative research;
- Report patients' experience and/or experiences (e.g., user feedback) using a DTx;
- Report on contributing factors that affected patients' experience;
- Include participants aged ≥18 years;
- Be a peer-reviewed article;
- Written in English;
- Not published before 2013.

Exclusion criteria

- Primary studies that report only quantitative data;
- Report on an intervention with a mental health component, but designed for specific patient populations with other medical conditions (e.g. mental health interventions for postpartum depression, patients with diabetes, or other chronic conditions);
- Report on an intervention designed for children and/or adolescents (participants aged less than 18 years);

- Report on interventions with a mental health component, but designed for specific subpopulations (e.g. refugees in a specific setting, or hard to reach populations)
- Report on interventions designed for patients with other mental health conditions or serious mental illness (SMI) (e.g. bipolar disorder, psychosis, or schizophrenia);
- Articles reporting only health care providers' or other stakeholder perspectives, without reporting patients' experiences;
- Articles published before 2013.

Appendix 5 – Search strategy for identifying relevant theories, frameworks or models

Identification of behaviour change theories, frameworks and models was systematically conducted in Medline database on December 6th, 2023. The search strategy was adapted from Carroll, Booth et al. [74]. The search identified 94 results, which were exported to Endnote. Search strategy is presented in Table 13.

Table 13. Search strategy for Medline (6.12.2023).

Search concept	Search
#1 Behaviour change	("behaviour change"[Title/Abstract] OR "behavior change"[Title/Abstract]) AND ((y_10[Filter]) AND (medline[Filter]) AND (english[Filter]))
#2 Digital health	("digital health"[Title/Abstract]) AND ((y_10[Filter]) AND (medline[Filter]) AND (english[Filter]))
#3 Models or theories	("Model"[Title/Abstract] OR "theor*"[Title/Abstract] OR "framework"[Title/Abstract] OR "concept*"[Title/Abstract]) AND ((y_10[Filter]) AND (medline[Filter]) AND (english[Filter]))
#4 Exclusions	("Regression Analysis"[MeSH Terms] OR "regression"[Title/Abstract] OR "integrative model"[Title/Abstract] OR "integrative care model"[Title/Abstract] OR "economic"[Title/Abstract] OR "Markov"[Title/Abstract] OR "animal"[Title/Abstract]) AND ((y_10[Filter]) AND (medline[Filter]) AND (english[Filter]))
(#1 AND #2 AND #3) NOT #4	

Appendix 6 – Inclusion/exclusion criteria for identifying relevant theories, frameworks or models

Inclusion criteria

- Include at least one of the following terms in title/abstract: model, theory, framework;
- An article describing a behaviour change theory, model or framework in the context of digital health;
- Written in English;
- Not published more than 10 years ago.

Exclusion criteria

- Articles not mentioning theories, frameworks or models in title/abstract;
- Articles not written in English;
- Articles published before 2013.

Appendix 7 – The critical appraisal skills programme (CASP) tool for quality appraisal in qualitative evidence synthesis

Quality appraisal was performed simultaneously with data extraction to assess the effects of incorporating studies considered to be of lower quality [99]. A modified version of the CASP tool was used, as proposed by Long et al. [102]. See Table 14.

Table 14. The questions in the modified CASP qualitative checklist tool [102].

1. Was there a clear statement of the aims of the research?
• What was the goal of the research
• Why it was thought important
• Its relevance
2. Is a qualitative methodology appropriate?
• If the research seeks to interpret or illuminate the actions and/or subjective experiences of research participants
• Is qualitative research the right methodology for addressing the research goal
3. Was the research design appropriate to address the aims of the research?
• If the researcher has justified the research design (e.g., have they discussed how they decided which method to use)
4. Are the study's theoretical underpinnings (e.g. ontological and epistemological assumptions; guiding theoretical framework(s)) clear, consistent, and conceptually coherent?
• To what extent is the paradigm that guides the research project congruent with the methods a these have been described?
• To what extent is there evidence of problematic assumptions about the chosen method of data analysis? e.g. assuming techniques or concepts from other method (e.g. use of data saturation, originating in grounded theory) apply to chosen method

(e.g. Braun and Clarke's reflexive thematic analysis) without discussion or justification

• To what extent is there evidence of conceptual clashes or confusion in the paper? e.g. claiming a constructionist approach but then treating participants' accounts as a transparent reporting of their experience and behaviour

5. Was the recruitment strategy appropriate to the aims of the research?

• If the researcher has explained how the participants were selected

• If they explained why the participants they selected were the most appropriate to provide access to the type of knowledge sought by the study

• If there are any discussions around recruitment (e.g. why some people chose not to take part)

6. Was the data collected in a way that addressed the research issue?

• If the setting for the data collection was justified

• If it is clear how data were collected (e.g. focus group, semi-structured interview etc.)

• If the researcher has justified the methods chosen

7. Has the relationship between researcher and participants been adequately considered?

• If the researcher critically examined their own role, potential bias and influence during (a) formulation of the research questions (b) data collection, including sample recruitment and choice of location

• How the researcher responded to events during the study and whether they considered the implications of any changes in the research design

8. Have ethical issues been taken into consideration?

• If there are sufficient details of how the research was explained to participants for the reader to assess whether ethical standards were maintained

• If the researcher has discussed issues raised by the study (e.g. issues around informed consent or confidentiality or how they have handled the effects of the study on the participants during and after the study)

• If approval has been sought from the ethics committee

9. Was the data analysis sufficiently rigorous?

• If there is an in-depth description of the analysis process
• If thematic analysis is used. If so, is it clear how the categories/themes were derived from the data
• Whether the researcher explains how the data presented were selected from the original sample to demonstrate the analysis process
• If sufficient data are presented to support the findings
• To what extent contradictory data are taken into account
• Whether the researcher critically examined their own role, potential bias and influence during data analysis and selection of data for presentation

10. Is there a clear statement of findings?

• If the findings are explicit
• If there is adequate discussion of the evidence both for and against the researcher's arguments
• If the researcher has discussed the credibility of their findings (e.g. triangulation, respondent validation, more than one analyst)
• If the findings are discussed in relation to the original research question

11. How valuable is the research?

• If the researcher discusses the contribution the study makes to existing knowledge or understanding (e.g. do they consider the findings in relation to current practice or policy, or relevant research-based literature)
• If they identify new areas where research is necessary
• If the researchers have discussed whether or how the findings can be transferred to other populations or considered other ways the research may be used

Appendix 8 – PRISMA flow diagram for primary qualitative study selection

The PRISMA [78] flow diagram is adopted to transparently present the study selection phase. See Figure 9.

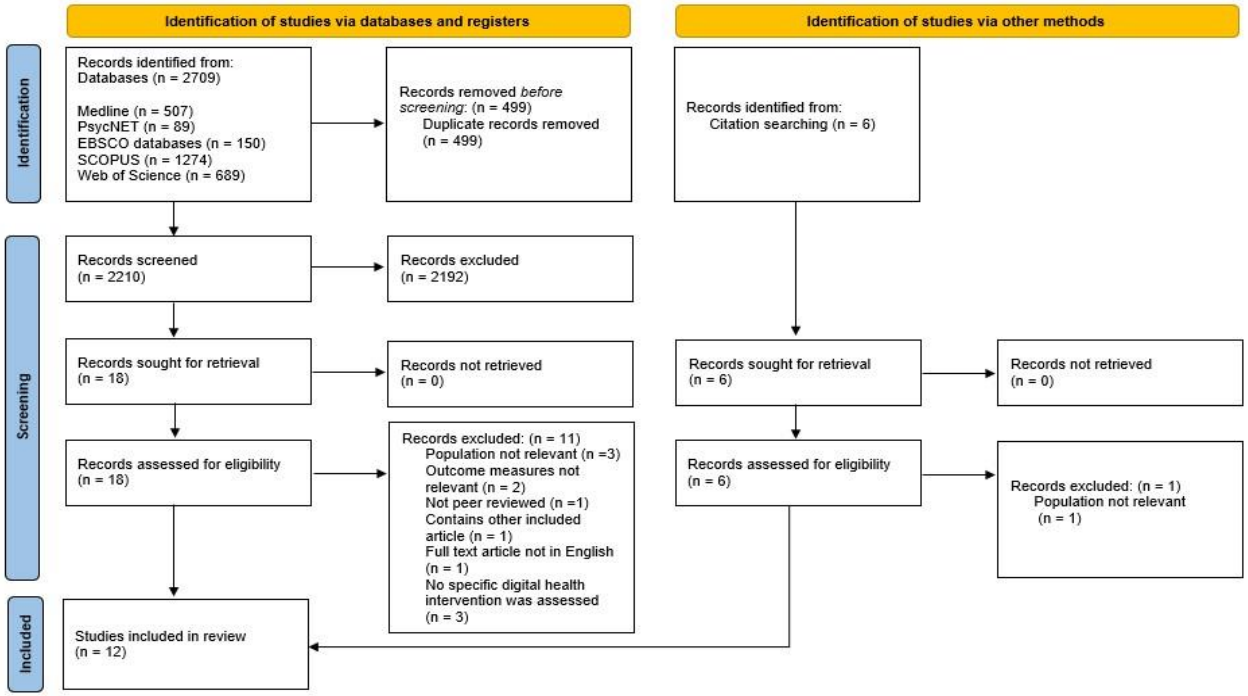

Figure 9. PRISMA flow diagram of the study selection process for identifying primary research articles.

Appendix 9 - PRISMA flow diagram for identifying relevant theories, frameworks or models

The PRISMA [78] flow diagram is adopted to transparently present the study selection phase. See Figure 10.

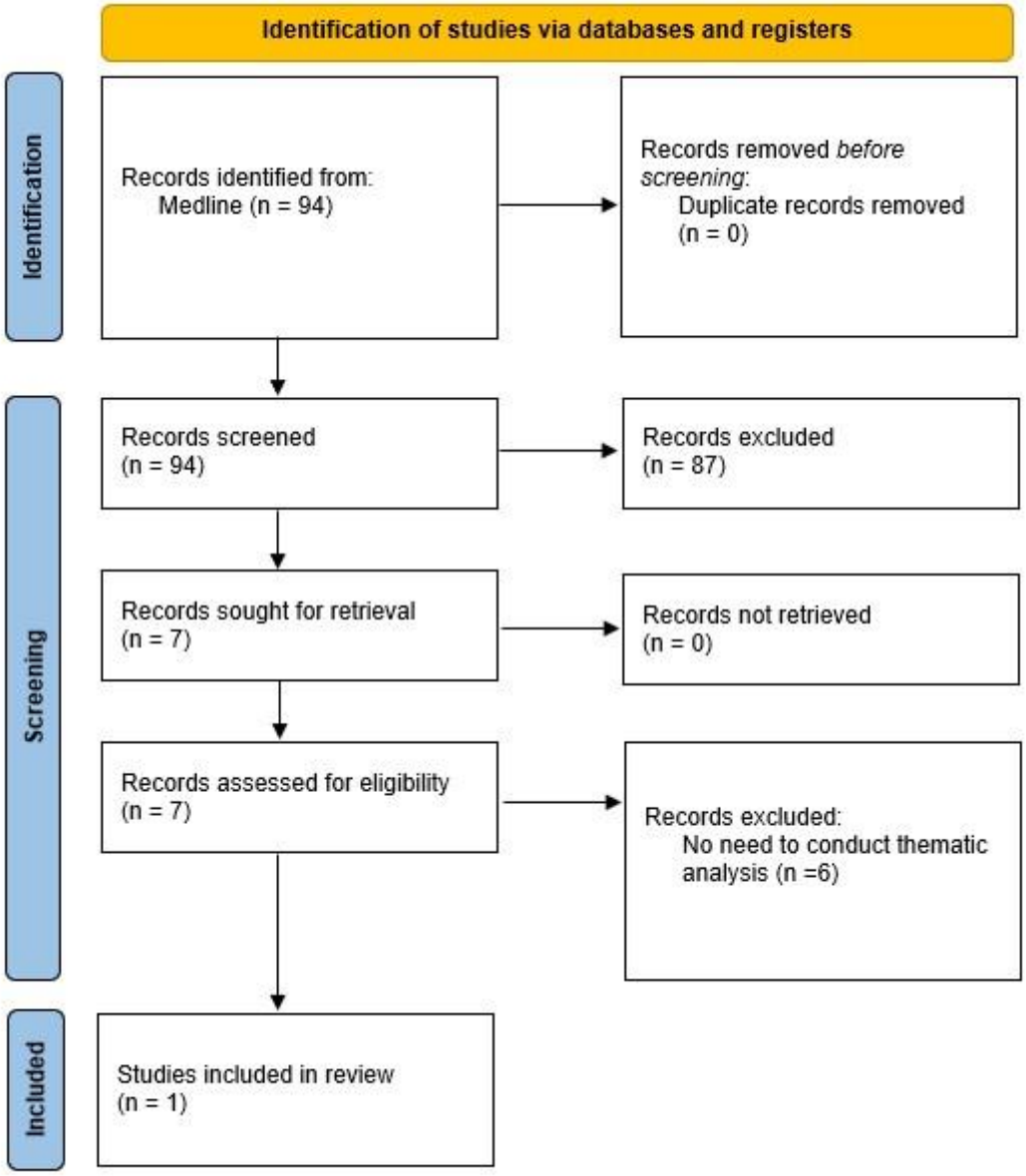

Figure 10. PRISMA flow diagram of the study selection process for identifying theories, models, or frameworks.