A Transdisciplinary Framework for Ethical Mobile Mental Health

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Abstract

Mobile mental health has been touted as a means of increasing access to mental health care. But there are significant challenges to the implementation of mobile mental health, such as limited evidence of effects and concerns with privacy and security. These challenges pose notable ethical concerns that must be addressed in order to ensure good and fair delivery of mental health care. Adding to this complexity is the multidisciplinary nature of the field and the need to involve all stakeholders to ensure ethical development and use of these technologies. In this thesis, I explore multidisciplinary perspectives and ethical experiences in mobile mental health with the aim of developing a transdisciplinary framework. This thesis makes five original contributions. First, it presents a comprehensive cross-disciplinary review of the ethics of mobile mental health (Chapter 3) including an in-depth evaluation of ethical issues in the wild (Chapter 4). These studies found ethical issues and considerations not conveyed in the literature and proposed elements of ethically designed apps for depression. Second, I present similarities and differences in the discussion and prioritisation of ethics across disciplines (Chapters 3) which supported the thesis aims and the importance of multidisciplinarity. Third, I used these findings to develop ethical design cards for digital mental health and show support for their use as a toolkit to help multidisciplinary teams to consider ethical issues when designing and developing digital mental health interventions (Chapter 5). Fourth, I present original research exploring how multidisciplinary stakeholders conceptualise ethical digital mental health (Chapter 5). I found that this was largely grounded in the adage of doing no harm, which was impacted by the values underlying the design and use of the technologies. Finally, I conclude the thesis by amalgamating these findings into a transdisciplinary framework that advances understanding and provides practical guidance on developing and using ethical mobile mental health (Chapter 6).

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Statement of Authorship

Here is a breakdown of the contribution made by Dionne Bowie-DaBreo (the student), Sandra Sünram-Lea and Corina Sas (PhD supervisors), and Heather Iles-Smith (NHS placement supervisor) to each chapter. Names are ordered based on the approximate amount of contribution in decreasing order.

Chapters 1-2: Introduction and background

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- The contribution of all co-authors outlined above is correct, and
- The student can incorporate these papers within the thesis.

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1 Introduction

1.1 Overview

Mental health is a global health concern, with around one in six people experiencing a common mental health problem in any given week (Mental Health Foundation, 2016). Common mental health disorders like anxiety disorders and depression are particularly disabling because of their wide prevalence and significant impact on functioning and daily living (GDB 2019 Disease and Injuries Collaborators, 2020). Despite this, it is estimated that less than 40% of adults with common mental health disorders in England were accessing treatment (McManus et al., 2016). This highlights a significant unmet need for more treatment options and mental health resources (NICE, 2023a, 2023b, 2023c).

Digital mental health has the potential to increase access to treatment by using digital technologies for mental assessment, prevention, treatment, and support (Bond et al., 2023; Price et al., 2013; Ralston et al., 2019, Torous et al. 2020; WHO, 2011). Evidence suggests that mobile mental health interventions, such as internet-delivered interventions and mental health apps, may be effective in treating depression (Ben-Zeev et al., 2019; Firth et al., 2017; Lecomte et al., 2020; Ma et al, 2021; Păsărelu et al., 2017; Seegan et al., 2023) and anxiety disorders (Akin-Sari et al., 2022; Carl et al., 2020; Clark et al., 2022; Lecomte et al., 2020; Linardon et al., 2019; Richards et al., 2020). But there are notable uncertainties. Only a minority of apps that are available to the public have any evidence (Torous et al.,2017), highlighting significant ethical concerns about their use in people with mental health problems. Other potential risks and challenges around the use of mobile mental health technologies included concerns with privacy and data security, lack of transparency, and limited guidance and regulation. This makes it increasingly difficult for healthcare professionals and people with mental health problems to know which mobile mental health interventions are safe, effective, and useful. For mental health professionals, these uncertainties impair their ability to practice ethically and in line with professional codes of conduct (American Psychological Association, 2017; British Psychological Society, 2021). There is therefore great need for clarity and guidance around the ethics of mobile mental health.

There is a vast literature base discussing potential ethical issues and considerations in mobile mental health. This largely comprises of expert commentaries and reviews of potential ethical issues, often including hypothetical examples of potential risks such as data misuse and exploitation (Bauer et al., 2017; O’Doherty et al., 2016). But there are notable limitations in the existing literature and its approach to ethics. Firstly, there is limited empirical evidence on the ethics of mobile mental health showing how often these concerns occur, in what context, and why. It is therefore unclear how much of the concerns are anticipatory versus actual risks. Secondly, the scope of these discussions varies widely across papers, with some focusing on specific areas like privacy while others provide overarching review of many considerations. This inconsistency in approach means that one would have to be widely read to get the full picture of ethics in mobile mental health. This becomes even more of a challenge given the different disciplinary perspectives in discussing ethics in mobile mental health. Papers may be written for a clinical audience, with a focus on the ethical implications of using mobile mental health in clinical practice (Karcher & Pressure, 2016; Lustgarten & Elhai, 2018; Palmer & Burrows, 2021; Torous & Roberts, 2017). Conversely, some papers target developers and focus on privacy and confidentiality in the context of data handling and security (Jones & Moffitt, 2016; Parker et al., 2017). I argue that given the multidisciplinary nature of mobile mental health, there is need for all stakeholders to be aware of all ethical issues. It is not possible to ethically deliver mobile mental health interventions without knowledge of potential ethical issues around the technological development and context of these devices. Similarly, developers cannot design ethical mobile mental health interventions if they are unaware of the broader ethical implications around use in treatment and impact on healthcare services. Finally, while the literature includes many frameworks to evaluate mobile mental health interventions, there are fewer frameworks seeking to increase the development of ethical mobile mental health. I consider that while evaluation frameworks play an important role in helping people to choose and assess mobile mental health technologies, they are not focused on the design of more ethical technologies (Agarwal et al., 2022; American Psychiatric Association, 2023; Lagan et al., 2021; Nurgalieva et al., 2020). There is therefore need for more practical guidance to assist in increasing ethical practices and responsible design and innovation in mobile mental health.

This thesis seeks to address these challenges through a series of studies exploring the ethics of mobile mental health, stakeholder values and conceptualisations of ethical digital mental health, and how these can be applied to produce ethical mobile mental health technologies. It investigates ethical issues across the lifespan of mobile mental health to address 5 main aims:

1. To provide a comprehensive review of ethical issues in mobile mental health, including ethical issues arising from real-world use
2. To investigate stakeholder values in digital mental health and how these align with their conceptualisations of ethical digital mental health
3. To study if and how ethical issues and values in mobile mental health differ across the disciplines involved

4. To investigate the acceptability and feasibility of a practical design tool to help multidisciplinary development teams to develop ethical digital mental health technologies
5. To develop a transdisciplinary ethical framework to guide the design and evaluation of mobile mental health technologies.

1.2 Thesis Construction

1.2.1 Thesis Structure

This thesis uses a three-pronged approach to address the research aims. This includes: (1) literature review in areas of ethics, digital and mobile mental health, and regulatory frameworks; (2) studies on stakeholder perspectives and experiences of mobile mental health and ethical issues in the wild; and (3) practical application of findings to improve ethical design and innovation in mobile mental health.

The thesis comprises of a background chapter on the clinical context and relevant ethical approaches (Chapter 2), a chapter of reviews on the ethics of mobile mental health (Chapter 3), two empirical chapters containing four studies (Chapters 4 and 5), and a general discussion of the overall thesis (Chapter 6).

1.2.2 Rationale for Alternative Format

This thesis is the result of a PhD studentship under the AffecTech ITN, which was funded by the Horizon 2020 Innovative Training Network of the European Union under the Marie Skłodowska-Curie grant agreement no. 722022. Throughout this studentship, I was required to submit several papers for publication and presentation at conferences. As a result, the studies in this thesis (Chapters 2-5) are written in publishable manuscript format, with four papers having already been published or presented at conferences. I therefore consider it appropriate to submit this thesis by alternative format. The papers have been written to address the thesis aims and present one coherent story leading to the development of a transdisciplinary framework for ethical mobile mental health.

1.2.3 My Contributions

I was responsible for research conceptualisation, study design, data collection, data analysis, and manuscript development for all studies in this thesis. This was done under guidance and consultation with my supervisors, Professor Sandra Sünram-Lee, Professor Corina Sas, and Professor Heather Iles-Smith.

2 Background

2.1 Common Mental Health Disorders

Mental health is a global health concern, with the Mental Health Foundation (2016) estimating that one in six people will experience a common mental health problem in any given week. The National Institute for Health and Care Excellence (NICE) describes common mental health problems as those that affect more people combined than other mental health disorders (NICE, 2011a). This includes depression and anxiety disorders such as generalised anxiety disorder (GAD), panic disorder, phobias, and obsessive-compulsive disorder (OCD) (McManus et al., 2016; NICE, 2011a). About 6.2 million people in England (12.7%) have depression (Office for Health Improvement and Disparities, 2023) and it is estimated that more than eight million people in the UK (18%) have some form of anxiety disorder (Fineberg et al., 2013). Prevalence rates of anxiety disorders in England range from 5.9% for GAD, 2.4% phobias, 1.3% OCD, and 0.6% panic disorder (McManus et al., 2016). The most recent Adult Psychiatry Morbidity Survey (McManus et al., 2016) also found that almost 8% of people in England have a common mental health disorder not otherwise specified (previously referred to as mixed anxiety and depression). Common mental health disorders cause marked emotional distress and can significantly impair functioning and daily living. The Global Burden of Disease Study 2019 (GDB 2019 Disease and Injuries Collaborators, 2020) found depression and anxiety disorders to have higher disability adjusted life years (DALYs) than other mental health disorders including schizophrenia and bipolar disorder. Depression has been shown to be particularly disabling, ranking fourth and sixth in the leading causes of burden in people aged 10 to 24 years and adults 25 years and over, respectively. Anxiety disorders were also relatively high in the list of causes of burden, ranking sixth in people aged 10 to 24 years and 15th in adults 25 years and over.

The International Classification of Diseases 11th Revision (ICD-11) classified these common mental health disorders under mood disorders, anxiety or fear-related disorders, obsessive-compulsive or related disorders, and disorders specifically associated with stress (World Health Organisation (WHO), 2023). Depressive disorders are characterised by “depressive mood (e.g., sad, irritable, empty) or loss of pleasures accompanied by other cognitive, behavioural, or neurovegetative symptoms that significantly affect the individual’s ability to function” (WHO, 2023). This lasts for at least two weeks and is accompanied by physiological changes, feelings of worthlessness or guilt, and/or cognitive changes such as reduced concentration, indecisiveness, recurrent thoughts of death, or suicidal ideation. Depression is widely considered to be related to disordered affect regulation, an all-encompassing term for efforts to change or influence valenced responses (Gross, 1998; 2015). Affect regulation includes efforts to regulate stress responses (coping), moods (mood regulation), and emotions (emotion regulation). Individuals with depression are considered to have difficulty with the management of their affective states, rather than difficulty with the generation of affect (Brockmeyer et al., 2012; Joormann et al., 2012; Joormann & Quinn, 2014). That is, people with depression experience affect – most often depressed mood, sadness, and guilt – but have profound difficulty regulating these affective states. As such, their affective states are no longer functional and reflect disordered responses to their internal and external environments. Cognitive and biological responses to stressful life events are thus central to the development of depression and its prevention and treatment (LeMoult, 2020).

Maladaptive cognitions and behavioural responses are also central to the development and maintenance of anxiety disorders. ICD-11 (WHO, 2023) states that anxiety or fear-related disorders are "characterised by excessive fear and anxiety and related behavioural disturbance". Symptoms are severe enough to cause significant distress or functional impairment including impaired social, educational, or occupational functioning. These include difficulty concentrating, irritability, poor sleep, and physiological symptoms such as heart palpitations, sweating, or gastrointestinal symptoms. People may also actively avoid situations or events that they perceive as threatening or anxiety-provoking, which can reinforce these perceptions and the associated anxiety response (Beck & Clark, 1997; Wells, 1999). Anxiety disorders can affect mood and may co-occur with mood disorders such as depression. Like mood disorders, anxiety disorders reflect difficulties with emotional self-regulation. Anxiety and worry are normal emotions that everyone feels throughout life towards situations that they perceive as threatening or stressful. For some people, feelings of anxiety and worry persist or are excessive for the situation and level of threat. Abnormal anxiety responses are thought to arise from maladaptive cognitive processes, such as automatic emotional-processing bias for negative information and defective attentional control (Hirsch et al., 2019). Cognitive models of disorders such as GAD and social anxiety disorder have also considered the role of metacognitions in the development and maintenance of these conditions. Wells and Carter (2001) described two types of worry in their metacognitive model of GAD: (1) worry around external and noncognitive internal events, and (2) worry around these thoughts themselves, that is, worry about worry. Meta-mood (Salguero et al., 2013) and fear of emotions (Williams et al., 1997) have been shown to increase symptoms of common mental health disorders and the likelihood of adopting avoidance behaviours to minimise distress (Yoon et al., 2018).

Understanding the mechanisms underlying these disorders has led to the development of clinically effective treatments for common mental health disorders. Treatments typically fall within the domains of pharmacological, psychological, physical, and psychosocial or complementary treatments (e.g., Kamenov et al., 2015). Some interventions seek to target a specific area of impairment – affect, cognition, physiology, or behaviour – while others may be more holistic in their approach. Psychological interventions for common mental health disorders may be aimed at prevention, early intervention, treatment, or relapse prevention, a distinction that may in turn impact the components of the intervention such as the therapeutic techniques, strategies, and processes (Petrik & Cronin, 2014). This will also impact the intended user, specifically whether the intervention is suitable for clinically diagnosed disorders, at-risk populations or people with subthreshold symptoms, or nonclinical populations. It would be remiss to assume that all interventions are effective for everyone. It is therefore important that interventions are appropriately matched to suit a person's needs and mental health problems (National Collaborating Centre for Mental Health, 2023; NICE, 2011a, 2022a). Research has shown some psychotherapeutic interventions to be more effective for treating common mental health disorders than others (e.g., Butler et al., 2006; National Collaborating Centre for Mental Health, 2011; NICE, 2022b; Parikh et al., 2016; Tolin, 2010; Zhang et al. 2022). Predominating this research has been cognitive behavioural therapy (CBT), with other common psychological interventions including interpersonal therapy (IPT), problem-solving therapy, behavioural activation, and psychoeducation. Clinical guidelines on depression have recommended CBT, IPT, and behavioural activation as effective first line treatments (NICE, 2022a; Parikh et al. 2016). More specifically, NICE (2022a) recommended a matched care approach for new episodes of less severe depression, with treatment options (in order of clinical plus cost effectiveness) including guided self-help, CBT, behavioural activation, group exercise, group mindfulness and meditation, IPT, selective serotonin reuptake inhibitors (SSRIs), counselling, and short-term psychodynamic psychotherapy (STPP). For new episodes of more severe depression, a matched care approach was also recommended, with treatment options (in order of clinical plus cost effectiveness) including CBT plus an antidepressant, CBT, behavioural activation, an antidepressant, individual problem-solving, counselling, STPP, IPT, guided self-help, and group exercise. CBT and mindfulness-based cognitive therapy (MBCT) have been recommended as the most appropriate first line relapse prevention interventions for depression (NICE, 2022a; Parikh et al., 2016). NICE's guidelines for anxiety disorders (NICE, 2005, 2011a, 2013a, 2018a, 2020) recommended a stepped care approach, which means offering the most effective, least intrusive intervention first in line with patient needs and preferences. Recommended treatments for anxiety disorders vary by condition but typically include individual or group CBT. For some disorders, like GAD and panic disorder with or without agoraphobia, clinical guidelines recommended self-help based on CBT as a first line low intensity intervention (NICE, 2011a, 2020). This can be delivered by a range of mediums including written materials and digital interventions.

2.2 Digital Mental Health

The Adult Psychiatry Morbidity Survey (McManus et al., 2016) estimated that less than 40% of adults with common mental health disorders in England were accessing mental health treatment. Digital mental health technologies have been touted as a means of increasing access to mental health care and support (Bond et al., 2023; Price et al., 2013; Ralston et al., 2019, Torous et al. 2020; WHO, 2011). Digital mental health is the use of digital technologies for mental health assessment, prevention, treatment, and support (Wies et al., 2021). The NHS Long Term Plan (NHS, 2019) outlined plans to offer a ‘digital first’ option for most within a “model of tiered escalation depending on need” (p. 92). Within this model of care, people will have more treatment at home with the option for monitoring using wearable devices. The plan envisions that “people will be helped to stay well, to recognise important symptoms early, and to manage their own health, guided by digital tools” (p.92).

The offerings for digital mental health vary by technology, intervention, and intended use (Torous et al., 2021). There is a range of digital mental health technologies, with mobile mental health interventions like internet-delivered interventions and mental health apps being the most widely used (Bond et al. 2023). Bond et al. (2023) outlined a suite of digital mental health technologies which ranged from digital interventions to artificial intelligence (AI) and included:

- Digital health apps: apps for delivering healthcare or supporting wellbeing. Examples of uses in digital mental health include psychoeducation, mood tracking, diaries, peer support or social networking, and patient management (e.g., Goldberg et al., 2022; Larsen et al. 2019; Lecomte et al., 2020)
- Virtual reality (VR): a simulated environment with scenes that can be explored using a VR headset or interactive studio. Examples of uses in digital mental health include exposure therapy, simulation-based training, and empathy machines (e.g., Dellazizzo et al., 2020; Park et al. 2019; Wiebe et al., 2022).
- Natural language processing: a branch of AI that uses machine learning to understand written and spoken words. Examples of uses in digital mental health

include chatbots, speech analysis, and semi-automated digital therapy (e.g., Funk et al., 2020; Harvey et al., 2022; Zhang et al., 2022).
- Data science: examining large amounts of data to find patterns and extract meaning. Examples of uses in digital mental health include process mining, digital phenotyping, association analytics, and time series analytics (e.g., Ahmed et al., 2022; Marsch, 2020).
- Supervised machine learning: a subcategory of AI that uses labelled data to train a computer algorithm to classify and predict outputs. Examples of uses in digital mental health include predicting outcomes and triaging (e.g., Abd-alrazaq et al., 2022; Garriga et al. 2022; Triantafyllidis & Tsanas, 2019).
- Robotics and sensing: use of robots and sensors in mental health care and support. Examples of uses in digital mental health include facial expression analysis, affective computing, and socially assistive robots (e.g., Abbasi et al., 2022; Mohr et al., 2017; Rasouli et al., 2022).

These technologies may be combined and integrated in digital mental health interventions, for example a mental health app with an AI-driven conversational agent (chatbot) that uses natural language processing to guide users through the intervention and to provide support (Malik et al., (2022).

Digital mental health interventions also vary widely in how and by whom they are intended to be used. Roland et al. (2020) described digital tools in mental health as either mediated by consumers and communities or by the health system. In the former group were technologies such as social networking sites, personal health trackers, meditation and mental wellness apps, mental health apps and games, and online peer support forums. In the latter group were online information and education; digital assessment; human, computer, and self-guided therapies; and digital tools for managing clinical services, training, and clinical decision supports. These technologies spanned four broad uses – promotion and prevention, prediction and assessment, interventions, and monitoring and management. Digital tools for promotion/prevention were said to target the wider population while prediction/assessment focuses on subclinical problems, and interventions and monitoring/management tools are intended for people with moderate to severe disorders. Generally, digital tools mediated by consumers and communities fell more in the categories of promotion and prevention than those mediated by the health system.

Similarly, Pineda et al. (2023) – in an update of the taxonomy of in-person and digital interventions in Muñoz et al. (2018) – presented four types of digital mental health interventions categorised by: (1) if the intervention is delivered by a healthcare professional and (2) the level of healthcare professional support provided. Type 1 digital mental health interventions were described as those delivered synchronously or asynchronously by healthcare professionals using telehealth such as telephone calls or video conferencing. Type 2 interventions are also delivered synchronously or asynchronously by healthcare professionals but utilise digital tools such as email, apps, or virtual reality as adjuncts to treatment. Comparatively, Type 3 and Type 4 interventions are self-help interventions that differ in the level of human support provided. Type 3 digital mental health interventions were described as guided self-help, that is, digital self-help interventions with human support to provide guidance and to encourage adherence. Type 4 interventions are the most user-led and unsupported intervention, described by Pineda et al. (2023) as fully automated self-help without the need for human support.

The level of healthcare professional input and support is a key factor in how digital mental health interventions are used and their place in the standard care pathway. NICE guidelines (NICE, 2011, 2013, 2020, 2022a) recommended unguided and/or guided self-help, including digital self-help interventions, for treating and managing depression, GAD, panic disorder, and social anxiety disorder. In the NHS, unguided self-help (self-help with little to no contact with a healthcare professional) may be offered by primary care services such as GP practices as a low intensity intervention without referral to more in-demand mental health services. Psychological interventions for common mental health disorders are most commonly delivered in NHS Talking Therapies for anxiety and depression services, previously named Improving Access to Psychological Therapies (IAPT) (National Collaborating Centre for Mental Health, 2023). Within these services, self-help interventions are offered as guided self-help delivered with the support of a psychological wellbeing practitioner. This is reflected in NICE’s early value assessment guidance on digitally enabled therapies for anxiety disorders (NICE, 2023a) and depression in adults (NICE, 2023b), which recommended several digitally enabled therapies to be used with appropriate healthcare professional support, while further evidence is generated. The increased use and acceptance of guided digital self-help in mental health services is also reflected in NICE’s early value assessment guidance on guided self-help digital CBT for children and young people with mild to moderate symptoms of anxiety or low mood (NICE, 2023c). This reflects some key challenges in digital mental health. Firstly, there is evidence suggesting that human-supported digital mental health interventions may be more effective than unsupported digital mental health interventions for more severe mental health problems (Werntz et al., 2023) and concomitant mental health and chronic disease conditions in adults (Sasseville et al., 2023). But there was some variation in findings that makes it difficult to draw firm conclusions on the level and type of support needed for best outcomes (Bennett et al., 2019; Bernstein et al., 2022; Werntz et al., 2023). The delivery of digital mental health interventions with support is also intended to help manage the risk of self-help interventions by providing some degree of monitoring and guidance from a healthcare professional (NICE, 2023a, 2023b). This balancing of benefits and risks reflects several considerations around the use of digital mental health interventions that will be introduced in section 2.3, with a focus on mobile mental health. This is further discussed in more detail in Chapter 3, where I present a scoping review on the ethics of mobile mental health for common mental health disorders.

2.3 Benefits and Risks of Mobile Mental Health

Research into the effectiveness of mobile mental health has generally shown positive results and potential benefits in treating common mental health disorders. Clinical trials and reviews of apps for depression have reported significant reductions in depressive symptoms (Ben-Zeev et al., 2019; Firth et al., 2017; Lecomte et al., 2020; Ma et al, 2021; Păsărelu et al., 2017; Seegan et al., 2023) and improvements in well-being (Bakker et al., 2018). Similar findings have been reported for anxiety disorders, with mobile mental health interventions found to be more effective than waitlist controls (Akin-Sari et al., 2022; Carl et al., 2020; Lecomte et al., 2020; Richards et al., 2020) and at times as effective as face-to-face treatment (Clark et al., 2022; Linardon et al., 2019). There was evidence supporting the use of apps for assessment and psychoeducation (Magee et al., 2018), symptom tracking or mood monitoring (Firth et al., 2017; Magee et al., 2018), cognitive training and problem solving (Akin-Sari et al., 2022; Arean et al., 2016), and treatment approaches such as CBT (Carl et al., 2020; Firth et al., 2017; Torous et al., 2017), behavioural therapy and dialectical behaviour therapy (Torous et al., 2017), mindfulness (Firth et al., 2017; Huberty et al., 2021), and transdiagnostic approaches (Ben-Zeev et al., 2019). Evidence suggested that treatment effects may be related to the severity of mental health problems, with some studies showing larger effect sizes in people with higher levels of symptomatology at baseline (Kim et al., 2023; Mureşan et al., 2012; Venkatesan et al., 2022). As with traditional interventions, such results may be related to the greater room for improvement in people with greater initial impairment. However, it is also possible that the interventions most benefited those with more severe symptoms, which is of note considering that many digital mental health interventions target subthreshold and nonclinical populations. It is therefore key that technological interventions are developed with specific patient needs, diagnosis, and severity in mind to ensure that they can be matched with appropriate users for the best outcomes.

The literature on mobile mental health also suggested wider potential benefits of these interventions, including providing timely support, reducing costs of mental healthcare, overcoming stigma in seeking help for mental health problems, and improving clinical outcomes (Koh et al., 2022). One of the most widely expected benefits of digital mental health is the potential to increase access to care because of lower costs compared to standard care psychological treatment (Wies et al., 2021). Digital mental health is often touted as a means to receive care and support whenever, wherever which could potentially improve the detection, prediction, and prevention of mental health problems. Yet, evidence suggested that these benefits were not being fully captured or realised in clinical practice. While there were many studies supporting the effectiveness of mobile mental health technologies, these findings often reflect technologies developed and assessed in academia rather than those available to the public. Torous et al. (2017) reported that only one-third of apps for depression reviewed in the literature were available for download in app stores, with research reviews of the app marketplace uncovering a worrying lack of evidence for most apps (Huguet et al., 2016; Larsen et al., 2016, 2019; Qu et al., 2020). Moreover, even when evidence was available, this was at times of poor quality which impacted the strength and certainty of findings (Goldberg et al., 2022; Lecomte et al., 2020). A recent systematic meta-review of meta-analyses of randomised controlled trials of mobile phone-based interventions for mental health found that as comparators in studies became more rigorous, the magnitude of effects and the strength of the evidence diminished (Goldberg et al., 2022). This was also evident in NICE’s early value assessments on digitally enabled therapies for anxiety disorders and depression in adults, with several of the assessed technologies not recommended for use in the NHS with further evidence generation because of a lack of any relevant clinical effectiveness evidence (Barnish et al., 2023; Chong et al., 2023; NICE, 2023a, 2023b). There were also concerns with the evidence-base underlying the design of these technological interventions. For example, while CBT apps for depression were found to incorporate several treatment strategies, many omitted key treatment processes such as challenging core beliefs and conceptualisation in favour of psychoeducation, monitoring and tracking, and thought records (Magee et al., 2018; Radovic et al., 2016). Because of this, some apps were described as evidence informed such that they incorporated some theoretical principles and strategies but did not show high fidelity to evidence-based treatments such as CBT or behavioural therapy (Huguet et al., 2016; Stawarz et al., 2018).

These uncertainties pose notable challenges to the implementation and routine adoption of mobile mental health interventions in healthcare. The 2020/21 IAPT dataset (NHS Digital, 2021) recorded 657,322 therapy appointments at the start of treatment, of which only 2.7% were ‘guided self-help computer’ and 0.45% ‘nonguided self-help computer’. Comparatively, 23% of appointments at the start of treatment were ‘guided self-help book’ and 8% were ‘nonguided self-help book’ suggesting that bibliotherapy may be favoured over digital mental health interventions perhaps because of their lower costs or lower perceived risks. The limited evidence and unclear evidence-base of most mobile mental health interventions raises uncertainties and ethical concerns not just with the effectiveness of these technologies, but potential adverse effects and risks (Karcher & Presser, 2018; Lustgarten & Elhai, 2018; Marshall et al., 2020; Martinengo et al., 2019; Palmer & Burrows, 2021; Sanches et al., 2019; Schueller & Torous, 2020; Stawarz et al., 2018; Torous & Roberts, 2017a; Wisniewski et al., 2019; Wykes et al., 2019). These concerns are especially relevant to direct-to-consumer mobile mental health interventions which are marketed to the public through app stores such as the Google Play store or Apple App Store (Huguet et al., 2016; Larsen et al., 2016, 2019). A systematic assessment of depression and suicide prevention apps found that only 5 of the 69 (7%) apps reviewed incorporated all suicide prevention strategies outlined in clinical guidelines (Martinengo et al., 2019). The most commonly included suicide prevention strategies were information and education – including emergency contact information (65/69, 94%) and suicide-related education (35/69, 51%) – and direct access to a crisis helpline (46/69, 67%). Fewer apps provided activities to deter suicidal thoughts (33/69, 48%), tracking of mood and suicidal thoughts (28/69, 41%), access to support networks (28/69, 41%), and safety plan development (26/69, 38%). Moreover, six apps provided an incorrect crisis helpline number, including two widely downloaded apps. Similarly, reviews of publicly available apps for depression have highlighted insufficiencies in the treatment and safety information provided, including limited disclaimers and integration in real-world care (Kumar & Mehrotra, 2017; Larsen et al., 2019; Qu et al., 2020; Shen et al., 2015) and inadequate reporting of expert involvement (Shen et al., 2015; Stawarz et al., 2018).

Another widely discussed risk related to privacy and data security of mobile mental health technologies (e.g., Huckvale et al., 2019; Koh et al., 2022; Kretzschmar et al., 2019; Lustgarten & Elhai, 2018; Sanches et al., 2019), particularly how users’ data is protected, how matters related to privacy and data security are communicated to users, and the use and sharing of users’ data without their informed consent. An assessment of 36 top-ranked apps for depression and smoking cessation in the commercial app marketplace found that only 69% of apps incorporated or linked to a privacy policy (Huckvale et al., 2019). Of those, 72% provided descriptions of technical security measures and 65% outlined the use of cookies. But only 52% described how to delete or opt out of sharing data, and only 32% gave information on data retention.

In total, 23 apps informed users that their data would be shared with third parties, with only 6 of these apps stating that personal data would not be shared. Despite this, Huckvale et al. (2019) found that 33 of the 36 apps transmitted data to one or more third party, with 29 sending data to analytics and advertising services provided by Facebook or Google despite only 17 of these outlining this in their privacy policy. As a result, authors cautioned that healthcare professionals should not rely on privacy policies given the inadequacy of information provided but should instead assume that data may be shared with commercial entities. They concluded that there was a need for regular privacy reviews considering both privacy policies and technical security reviews. These concerns are reflected in several papers outlining privacy and security risks in digital mental health, including risks to confidentiality and compliance with ethical codes of practice, use of data for unauthorised or unintended purposes, and interception of data by unauthorised parties and cybercriminals (Jones & Moffitt, 2016; Karcher & Presser, 2018; Lustgarten & Elhai, 2018; Martinez-Martin et al., 2020). To better protect users' privacy and confidentiality, Kretzschmar et al. (2019) advised that personal information should be confidential, shared information should be deidentified, privacy practices and limitations should be transparent, and users should be reminded of these practices when asked.

These challenges are closely connected to concerns with transparency in digital mental health, seen in the overall poverty of information on the evidence-base, privacy, and effects of these technologies (Kretzschmar et al., 2019; Wykes et al., 2019; Wykes & Schueller, 2019; Zelmer et al. 2018). This could negatively impact users' trust and their ability to give truly informed consent (Jones & Moffitt, 2016; Lustgarten & Elhai, 2018; Nurgalieva et al., 2020; Sanches et al., 2019; Schueller & Torous, 2020; Torous & Roberts, 2017a, 2017b; Wykes et al., 2019; Wykes & Schueller, 2019). Wykes and Schueller (2019) proposed the Transparency for Trust (T4T) principles which outlined the information that should be given to potential users to help them decide if to download and use a health app. The four principles were privacy and data security, development practices, feasibility, and health benefits, with several questions presented for each principle such as 'Who will have access to the data?' (privacy and security) and 'What was the impact on clinical outcomes?' (health benefits). The authors proposed that this information would be provided by developers, stating "Our view is that formal regulation is not needed. We just need the information to allow patients (and patient groups) to make informed choices" (p. 6). But it is unclear how this would be monitored or enforced in practice given the pervasive concerns with the accuracy and completeness of information on digital mental health.

2.4 Regulation and Evaluation of Digital Mental Health

Many of the challenges of digital mental health interventions, including the potential for unmitigated risks and misuse, largely related to a lack of adequate guidelines, regulations, and evaluations (Karcher & Presser, 2018; Larsen et al., 2019; Wies et al., 2021). A scoping review of digital mental health for young people reported that a lack of technical and medical standards of these technologies may impact their adoption and implementation in clinical settings (Wies et al., 2021). The limited ethical and regulatory guidance for digital mental health increased the uncertainty of benefits and risks, particularly in the absence of adequate assessment and clinical validation. While there are several applicable standards (NHS Digital, 2023a, 2023b, NHS England, n.d.) and medical device regulations (Medicines and Healthcare products Regulatory Agency (MHRA), 2020, 2023), these are not specific to digital mental health. As outlined in this chapter, digital mental health technologies have unique challenges that require specific consideration outside of regular medical device regulation and policy (Carl et al., 2022; Singh & Sagar, 2022). Adding to the complexity are ongoing debates as to which digital mental health technologies should be classed as medical devices and how (and if) to regulate the commercial marketplace of wellbeing technologies (NHS Confederation Mental Health Network, 2023; Singh & Sagar, 2022). Carl et al. (2022) also highlighted the importance of including psychologists in multidisciplinary teams that make regulatory decisions on digital therapeutics for mental health because of their understanding and experience of using digital mental health interventions in practice. The authors concluded with a call for relevant regulatory agencies, professional organisations in psychology, and community mental health providers to “cooperate in cross-disciplinary efforts to develop a clinically and scientifically appropriate model for the regulation of mental and behavioural health care in the ‘digital age’” (p. 133). Seeking to address these shortcomings and concerns, the MHRA is exploring and producing guidance on regulating digital mental health technologies (MHRA, 2022), but it is unclear when this guidance will be published.

In the absence of clearer regulation, there has been a greater focus on evaluation. In 2017, Public Health England provided guidance on criteria for health app assessment which outlined the need for evidence of effectiveness, regulatory approval including regulation as a medical device, clinical safety, privacy and confidentiality, security, usability and accessibility, interoperability, and technical stability (Public Health England, 2017). Also in 2017, the NHS launched the NHS Apps Library (https://digital.nhs.uk/services/nhs-apps-library) – a database of health (including mental health) apps which aimed to provide people with access to apps they could trust

(Bauer & Murphy, 2017). Apps were included in the database after being evaluated using the service's Digital Assessment Questions, which have now evolved into the Digital Technologies Assessment Criteria for health and social care (DTAC). DTAC (NHS England Transformation Directorate, n.d.) outlines the national baseline criteria for digital health technologies for use in the NHS and social care and includes clinical safety, data protection, technical security, interoperability and usability, and accessibility standards. The NHS Apps Library was decommissioned in 2021. It was previously closed in 2015 after an assessment found notable privacy and data protection issues in most of the apps (Huckvale et al., 2015).

Outside the NHS, several evaluation frameworks have been developed to help people – largely healthcare professionals – to decide if digital (mental) health technologies are suitable for use (Agarwal et al., 2022; American Psychiatric Association, 2023; Lagan et al., 2021; Nurgalieva et al., 2020). Lagan et al. (2021) identified a total of 70 different frameworks for assessing health apps, with 39 (56%) assessing mobile health apps broadly and seven (10%) focused on mental health apps. The most common evaluation areas were privacy and security, and evidence-base or clinical foundation. The authors concluded that while there were differences across the frameworks, there seemed to be common questions. They considered that their Mhealth Index and Navigation Database (MIND) framework (https://mindapps.org/) encompassed objective questions from the majority of frameworks. MIND is an online evaluation tool to help potential users to decide if an app may be suitable for them based on a number of characteristics. It is based on the American Psychiatric Association's App Evaluation Model (American Psychiatric Association, 2023) which outlined five levels for evaluation: access and background, privacy and security, clinical foundation, usability, and data integration towards the therapeutic goal. The American Psychiatric Association (2023) stated that there is no minimum or maximum number of levels in the model that an app should meet in order to be considered good to use. Rather, the model aims "to give the psychiatrist and the patient sufficient information from which to make an informed decision that they deem correct for their situation".

Similarly, Torous and Roberts (2017a) proposed an ethical framework using a decision-tree model to help clinicians to implement mobile health technologies in psychiatric practice. This framework proposed several steps, starting with assessing potential benefits of the technologies before assessing potential risks to the psychiatrist-patient relationship. If the benefits were clear and the risks manageable, the clinician would then get informed consent from the patient for use of the technology. Clinicians should also discuss any confidentiality concerns, and finally they should ensure the mobile mental health intervention aligns with treatment goals and expectations. While Torous and Roberts (2017a) advised that patients should be involved in these discussions, they placed the onus on the healthcare professional to assess and manage the aforementioned risks. The structure of these models therefore leaves the evaluation of the app and decision for use up to the clinician and patients, a decision which raises ethical questions regarding liability, competence, and due care. These frameworks also did not consider the role of developers in designing more ethical technologies and providing robust evidence of any claimed benefits. They are therefore limited in their perspective and offer a reactive, rather than proactive solution. It is therefore not surprising that some clinicians may opt not to adopt new technologies given the singular responsibility for managing risks and potential professional and legal consequences (Lustgarten & Elhai, 2017; Martinez-Martin et al., 2020). Relatedly, there have been calls for greater multidisciplinary considerations and involvement in digital mental health (Carl et al., 2022; Martinez-Martin et al., 2020). This is explored further in Chapter 3 of this thesis, with cross-disciplinary reviews of the ethics of mobile mental health and relevant professional codes of conduct.

2.5 The Role of Ethics in Mental Health Care

In Sections 2.3 and 2.4, I summarised key benefits and risks in mobile mental health. Some authors framed these as potential ethical concerns or challenges, yet many of these discussions failed to provide context around what is meant by ethics and why it matters. Mental health professionals have long been guided in their work by ethical principles and codes of conduct aimed at ensuring good and fair delivery of care in the best interests of the client, the profession, and wider society (American Psychological Association, 2017; British Psychological Society, 2021). In the broadest sense, ethics is concerned with individual and social good, and universal standards of right and wrong (Tännsjö, 2013). This often relates to but is not limited to issues of harm, fairness, and rights. There are three broad categories of ethical theories: metaethics, normative ethics, and practical ethics (LaFollette & Persson, 2013). Metaethics is the study of moral language and the status of moral judgements. More relevant to this thesis are normative ethics and practical (or applied) ethics. Normative ethics is concerned with general principles or theories around how we should live that are aimed at helping us to differentiate right from wrong and good from bad. These principles form the basis of practical ethics which focuses on how we should behave in specific situations.

While there are many normative theories, two main perspectives are consequentialism and deontological ethics (Beauchamp & Childress, 2019; LaFollette

& Persson, 2013; Tännsjö, 2013). Consequentialism is grounded in the idea that we should act to produce the greatest good for the greater number of people. It is therefore focused on outcomes rather than if the act in and of itself was good. Within consequentialism is the theory of utilitarianism, which considers that "an action is right if and only if in the situation there was no alternative to it which would have resulted in a greater sum total of welfare in the world" (Tännsjö, 2013, p.18). This means that the right action is that which maximises happiness, wellbeing, or desires above all other actions. Conversely, deontological ethics focuses on a person's duties and actions, rather than the consequences of these (Beauchamp & Childress, 2019; LaFollette & Persson, 2013; Tännsjö, 2013). The most prominent of deontological theories is Kantianism, which espouses that moral duty is the categorical imperative, that is, something that we ought to do regardless of our personal desires. This is based on universal rules that govern action and the idea that we should not treat ourselves or others as a means, even if it achieves a favourable end. As such, consequences are not considered to affect whether an action is right or wrong because consequences are unpredictable. Instead, we should follow prohibitions and obligations such as to not kill or to not lie. These theories are useful to consider in evaluating how mobile mental health ought to be. For example, should mobile mental health technologies strive to produce the best outcomes regardless of the methods? Should technologies give users honest but negative feedback on their mental health status even if this affects their wellbeing? But as they examples show, they give little practical guidance to help decide right from wrong.

Bridging the gap between these normative theories and applied ethics is principlism or principle-based ethics, best known by the principles of biomedical ethics (Beauchamp & Childress, 2019). Beauchamp and Childress (2019) noted that each of these normative moral theories are instructive and contribute to the understanding of moral life and the development of biomedical ethics. They outlined a framework of moral principles based on moral norms arising from the common morality, where common morality was described as the set of universal norms shared by everyone committed to morality regardless of cultures, groups, or locations. Beauchamp and Childress (2019) described these principles as general guidelines that can be used to develop specific rules. They therefore serve as a starting point to reflect and consider moral problems in biomedical ethics. The four principles are: (1) respect for autonomy, a norm of respecting the decision-making capacity of autonomous people, (2) nonmaleficence, a norm of avoiding causing harm, (3) beneficence, norms of providing benefits and balancing risks, and (4) justice, norms of fairness in distribution of benefits and risks for all people. Related to these principles are rules, rights, and virtues that guide ethical decision-making and resolving ethical conflicts. Beauchamp and Childress (2019) advised that the four principles provide a framework of norms that must be specified to achieve more concrete guidance. This involves narrowing the scope of the norms and outlining rules to guide action. In the event of moral conflicts, the process of weighing and balancing should be used to decide which moral norms should be prioritised to reach judgements in specific cases. Finally, the framework outlined important virtues for healthcare professionals, where a virtue is a dispositional character trait that is socially valuable and reliably present. These were care, compassion, discernment, trustworthiness, integrity, and conscientiousness. Virtues are described as providing a moral compass for healthcare professionals and are no less important than principles. Explaining the relationship between the principles and virtues, Beauchamp and Childress (2019) stated “We need not reject principles of obligation in favour of virtues of caring, but moral judgement involves moral skills beyond those of specifying and balancing general principles” (p.75).

The principles of biomedical ethics has had significant influence on healthcare ethics. They are reflected in the American Psychological Association’s ethics code (2017) which outlined five ethical principles described as “aspirational goals to guide psychologists toward the highest ideals of psychology” (p. 2). These were:

A. Beneficence and nonmaleficence: striving to benefit others in their work and taking care to do no harm. Includes safeguarding, resolving conflicts of interest, guarding against misuse of influence, and capacity to practice.
B. Fidelity and responsibility: establishing relationships of trust and awareness of professional responsibilities to society and communities in which they work. Includes upholding professional standards, ethical compliance of self and others, and pro bono work.
C. Integrity: promoting accuracy, honest, and truthfulness in all professional activities. Includes no fraud or theft, and transparency.
D. Justice: recognising fairness and justice for all in access to and benefits of psychology. Includes awareness of and managing potential biases and limits to competence or expertise.
E. Respect for people’s rights and dignity: respecting the dignity and rights of everyone. Includes autonomous decision-making, inclusion and diversity, and removing biases and prejudice from professional activities.

These principles are reflected in the association’s ethical standards which are enforceable rules for conduct as psychologists. Similarly, the British Psychological Society’s code of ethics and conduct (2021) outlined principles and applied codes that serve as guidelines for decisions making. The code is based on four ethical principles with each having a statement of values, namely:

- Respect: respect for the dignity of people, recognising the worth of all human beings. Consideration of authority or influence over others and people's rights.
- Competence: ability to provide services to established standards. Consideration of continuing development and recognition of limits of knowledge or expertise.
- Responsibility: appropriate responsibility, autonomy, and influence. Consideration of avoiding harm and misuse or abuse of duties.
- Integrity: being honest, truthful, and consistent. Consideration of fairness in actions and being objective and unbiased in judgements and actions.

While these ethical theories and professional codes of conduct provide a foundation for ethical practices in digital mental health, there is also a need to consider ethics and values in the space of technology design. Value sensitive design is a useful framework for exploring the role and impact of values on technology design. It stems from the recognition that technology arises from human thoughts and ideas, and is influenced by the designer, including their experiences, values, and beliefs (Friedman & Hendry, 2019). Value sensitive design considers that technology is not only influenced by values, but it can also influence individual and societal values through its impact on human behaviour and practices (van de Kaa et al., 2019). This interactional relationship considers the influence of a technology's design, the context for its use, and the people who use it (Davis & Nathan, 2015). Value sensitive design defines values as "what a person or group of people consider important in life" (van de Kaa et al., 2019). It emphasises moral and ethical values, that is, those related to human welfare and justice. But it also considers "personal and conventional values [that] can become morally implicated" within the complexity of social life (Friedman & Hendry, 2019, p. 23). Values portray what ought to be, not what is. They embody social and ethical issues that are then reflected in a technology's design (van de Kaa et al., 2019). As such, value sensitive design provides a means to advance the design of moral and ethical technology. Value sensitive design was intended to be generalisable across technologies, populations, values, and contexts. It does not focus on a specific value but instead considers a broad set of values and how to engage with these in the design process. There are a number of commitments in value sensitive design that shape the design process. These include an interactional relationship between technology and human values; analyses of direct and indirect stakeholders; and consideration of the differing values of designers, the project, and stakeholders. It is an iterative design process integrating conceptual, empirical, and technical investigations. Conceptual investigations seek to identify and understand the different stakeholders, their values and potential value conflicts that may arise from using the technology. Empirical investigations are design research studies which help designers to better understand the users' values, needs, and practices. Lastly, technical investigations aim to explore how people use technologies to support the values identified in the conceptual and empirical investigations. Friedman and Hendry (2019) outlined several methods of value sensitive design, including stakeholder analysis, value source analysis, value scenario, value sensitive action-reflection model, and envisioning cards. The methods of value sensitive design aim to help with stakeholder identification and interaction, eliciting and identifying values, values analysis, design principles and longer-term design thinking, and facilitating ethical design. Understanding how values may impact technology design is particularly important for technologies with multiple stakeholders who will each have their own views and values. This may result in differing opinions and priorities which may lead to ethical and design conflicts (van de Kaa et al., 2019). Friedman and Hendry (2019) noted that values are interconnected and in balance such that a shift in prioritising one value will affect others. These conflicts can be navigated by comparing and ranking values "especially when non-compatible values point in different directions for the development of new technologies" (van de Kaa et al. 2019, p. 3). In these situations, designers may change the design of the technology to overcome the conflict or may instead prioritise some values over others. Value sensitive design provides methods to navigate these challenges in order to facilitate the design of responsible and ethical technologies.

2.6 The Present Thesis

In this chapter, I have provided an overview of mental health care for common mental health disorders and the potential of digital mental health to increase access to much needed treatment and support. Widespread implementation of these technologies has been hindered by notable challenges, which pose potential risks and ethical concerns. While there have been many suggested frameworks for evaluating these technologies, these are often reactive and place the responsibility on healthcare professionals. This does not align with several calls for more multidisciplinary consideration and involvement in the evaluation and regulation of digital mental health technologies. Digital mental health is by its nature a multidisciplinary field integrating computer science, bioengineering, human computer interaction (HCI), and mental healthcare. But this is not widely reflected in the literature, with limited consideration of how multidisciplinarity can produce both challenges and solutions for digital mental health. This thesis seeks to address these gaps by exploring multidisciplinary perspectives and ethical experiences in mobile mental health with the aim of developing a transdisciplinary framework. In Chapter 3, I present two cross-disciplinary reviews on the ethics of digital mental health. The first of these reviews explores differences and similarities in ethical codes and principles for professional disciplines involved in digital mental health with the aim of understanding priorities and practices that may affect the design, development, and delivery of these technologies (Chapter 3.1). Following on from this is a scoping review of ethical issues in mobile mental health for common mental health disorders, including exploration of how ethical concepts and issues may differ across disciplines (Chapter 3.2).

Chapter 4 builds on these reviews to explore ethical issues and experiences in the wild, using the example of publicly available apps for depression. This chapter includes three papers on two studies. The first study presents a content analysis and ethical review of apps for depression in the commercial app marketplace, with a focus on evaluating treatment fidelity and alignment with clinical guidelines (Chapter 4.1) and potential ethical issues (Chapter 4.2). Next, I present a qualitative study analysing user reviews of apps for depression with the aim of capturing user perspectives and ethical experiences of using the apps in real-world contexts (Chapter 4.3).

Chapter 5 presents the final study, which is a multidisciplinary stakeholder workshop exploring values in digital mental health and conceptualisations of ethical digital mental health. This study also presents a set of ethical design cards which I designed based on the findings of the studies in Chapter 4. In this study, I explore with professional stakeholders the acceptability and feasibility of using the cards as a toolkit to help multidisciplinary development teams to design ethical digital mental health technologies. The thesis concludes with Chapter 6 which provides a general discussion of the overall thesis and an amalgamation of the findings into a coherent framework.

3 The Ethics of Mobile Mental Health: Cross-Disciplinary Reviews

This chapter includes two papers that explore the ethics of mobile mental health and how concepts and discussion in this area may be vary across different disciplines and perspectives.

The first paper titled ‘Transdisciplinary ethical principles and standards for mobile mental health’ presents a preliminary exploration into the ethical codes and principles across professional disciplines involved in mobile mental health. It sought to understand how different disciplines viewed ethical conduct and standards and the key principles outlined. Moreover, it aimed to synthesise these ethical ideas and principles across disciplines as an early step in conceptualising a transdisciplinary framework. This paper was presented at ACM DIS 2020 Workshop: Mental wellbeing: future agenda drawing from design, HCI and big data.

Building on this, the second paper titled ‘The ethics of mobile mental health for common mental health disorders: A cross disciplinary scoping review’ explored ethical ideas and issues in mobile mental health in the literature. It not only sought to understand the scope of these issues, but how they were discussed and prioritised across disciplines and audiences. This paper has been prepared for publication.

3.1 Transdisciplinary Ethical Principles and Standards for Mobile Mental Health

Bowie-DaBreo, D., Iles-Smith, H., Sünram-Lea, S. I., & Sas, C. (2020, July 6-7). *Transdisciplinary ethical principles and standards for mobile mental health* [Conference presentation]. ACM DIS 2020 Workshop: Mental wellbeing: future agenda drawing from design, HCI, and big data, online conference.

Transdisciplinary ethical principles and standards for mobile mental health

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Abstract

This position paper addresses the continued ethical challenges in mobile mental health and the need for transdisciplinary ethical principles and standards to facilitate the development of ethically designed mental health technologies. By comparing and synthesising ethical codes of conduct across disciplines in digital mental health – namely psychology, healthcare, human computer interaction, computer science, and engineering – we suggest transdisciplinary ethical principles and standards to facilitate the development of ethically designed mental health technologies. These preliminary findings form part of a larger research project which seeks to develop a transdisciplinary approach to the ethical design, marketing, and implementation of mental health technologies.

Author Keywords

mobile mental health; digital mental health; codes of conduct; ethics; principles; standards; transdisciplinary

CSS Concepts

• **Social and professional topics~Computing / technology policy** • Applied computing~Law, social and behavioral sciences~Psychology

Psychology
- American Psychological Association [2]
- The British Psychological Society [8]
- European Federation of Psychologists' Associations [10]

Healthcare
- Health and Care Professions Council [11]
- American Medical Association [1]

Computer science/HCI
- Association for Computer Machinery [3]
- The British Computer Society [7]
- Department of Health and Social Care [9]

Engineering
- National Society of Professional Engineers [14]
- Institute of Electrical and Electronics Engineers [12]
- The Royal Academy of Engineering [18]

Box 1. Professional codes of ethics sampled in the study

Introduction

There has been much discussion of the ethics of mobile mental health [4-6,13,15-17]. Issues include privacy and data security; risks and safety concerns; benefits and evidence; and related issues of transparency, trust, and informed consent. While there has been greater awareness of the ethics of mobile mental health, there are limited transdisciplinary frameworks to effectively guide and improve ethical practice. Mobile mental health is a multisector industry, requiring collaboration of many disciplines including psychology, healthcare, computer science, human computer interaction (HCI), and engineering. Research has shown the importance of multisector involvement in the design of mobile mental health, yet there is a lack of shared language and standards bridging the unique demands of each discipline. To address this, we reviewed ethical codes across disciplines in digital mental health to compare principles and standards with a view of promoting transdisciplinary guidance and best practices. Data collection and preliminary insights are described.

Search and review of ethical codes

Search for ethical codes of conduct was performed in Google search using the terms 'psychology codes of ethics', 'computer science codes of ethics', 'HCI codes of ethics', 'engineering codes of ethics', 'healthcare codes of ethics', and 'codes of ethics for mental health'. We were interested in reviewing professional codes of ethics and excluded other discussion on ethics (including academic research) from review. A sample of 11 professional codes were selected across disciplines (Box 1). Codes were reviewed and data extracted pertaining to ethical principles and standards. Findings were synthesised into transdisciplinary ethical principles and standards for digital mental health.

Ethical principles and standards

Most codes described ethical principles as guidelines and best practices to be aspired to, with accompanying standards governed by the professional bodies. While thematically similar, there were differing ethical principles and focus across the codes reviewed. For example, psychology codes of ethics prioritised client care and welfare, and standards related to duty of care and competence. Comparatively, engineering codes, while also prioritising benefits and avoidance of harm, emphasised standards related to professional reputability and responsibility. Findings were synthesised into eight ethical principles: beneficence, nonmaleficence, competence, integrity, justice, fidelity, responsibility, and respect for rights and dignity of all people (Box 2). These transdisciplinary ethical principles and standards are presented in Figure 1.

Discussion

This position paper proposes preliminary transdisciplinary ethical principles for digital mental health. While our review found some principles and standards were more prevalent than others (eg, avoidance of harm), we consider all transdisciplinary principles to be equally relevant and important for ethical practice. We encourage multidisciplinary teams to reflect on these principles in the development of digital mental health and to consider how innovative design can be used to overcome potential ethical conflicts. In their ethical reflections and deliberations, it is also important for development teams to consider not only their own ethical practices, but the principles and values embedded in the technologies they design and develop. Digital mental health should reflect these key principles and standards to ensure safe, accurate, and effective delivery of care for all.

Ethical principles

Beneficence
Doing good or benefiting others, directly or indirectly

Nonmaleficence
Doing no harm or managing harms to gain benefits

Integrity
Being honest, moral, and accountable for one’s actions

Fidelity
Being faithful and consistent in promises and deeds

Justice
Being fair and reasonable in action and interactions

Competence
Being appropriately skilled and knowledgeable

Responsibility
Having a duty or obligation to perform in a certain manner

Respect for the rights and dignity of all people
Respecting human rights, differences, and freedoms

Box 2. Descriptions of transdisciplinary ethical principles

Nonmaleficence
Avoidance of harm
Safety
Safeguarding
Security

Respect for rights and dignity of all people
Confidentiality
Non-discrimination
Privacy
Autonomy
User centred/User needs
Informed consent
Diversity
Managing power imbalances
Non-harassment

Competence
Knowledge and skillset
Acknowledging limitations of self, team, and products
Evidence-base/Scientific rigour
Continuing development of self, team, and products
Quality
Reflection on motives, actions, and outcomes
Reliability of methods, products, and interventions
Validity of methods, products, and interventions

Justice
Fairness in actions, interactions, and design
Fair trade
Accessibility of resources and services for all
Inclusiveness
Conservation of resources

Beneficence
Ensuring benefits for others/Human welfare
Effectiveness

Responsibility
Legal compliance
Professional standards
Ethical compliance
Communication/Public outreach
Collaboration/Cooperation for transdisciplinary design
Evaluation of methods, actions, products, outcomes
Documentation of methods, actions, and outcomes
Peer review
Reporting of ethical concerns and breaches
Social responsibility
Duty of care
Environmental impact/sustainability
Interoperability of systems

Integrity
Accountability
Honesty
Managing conflicts of interest
Transparency of motives, actions, communications
Accuracy
Authorship/Intellectual property rights
Objectivity
Reputability
Appropriate data use

Fidelity
Trustworthiness
Continuity/Consistency of actions, outcomes, products
Faithfulness

Figure 1. Transdisciplinary ethical principles and abridged standards

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3.2 The Ethics of Mobile Mental Health for Common Mental Health Disorders: A Cross Disciplinary Scoping Review

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Review

The ethics of mobile mental health for common mental health disorders: a cross disciplinary scoping review

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Abstract

Background: The field of mobile mental health has developed rapidly in the past decade. Yet, discussion and understanding of related ethical issues continues to trail behind. Preliminary review of the literature showed discussion of ethical concepts of mobile mental health varied across disciplines and sectors such as computer science, mental health, and human computer interaction. There is need for greater integration of these perspectives to create a shared understanding of these concepts and to generate relevant frameworks to guide the design, use, and adoption of mobile mental health.

Objectives: This scoping review explored the ethics of mobile mental health across the main disciplines involved. In doing so, it aimed to generate deeper understanding of the current state of ethical issues of mobile mental health technologies and how these concepts vary across sectors and stakeholders. This was used to generate recommendations for advancement of the field.

Methods: We searched cross disciplinary databases (PubMed, PsycInfo, Embase, ACM Digital Library, Academic Search Ultimate, and Scopus) for relevant publications using MeSH (Medical Subject Headings) and search terms related to ethics and mobile mental health. Papers were included in the review if they directly discussed (1) common mental health disorder(s), (2) mobile mental health, and (3) the ethics of mobile mental health. In total, 21 relevant papers were included in the review.

Results: The most common author discipline in the included papers was mental health, with only 38% of papers including authors from two or more disciplines. We found 12 overarching themes capturing ethical issues and considerations in mobile mental health: harms, privacy, duty, inequalities, benefits, autonomy, standards, validity, conflicts of interest, clinical practice, intentions and values, and acceptability. Ethical themes related to four main components, which we conceptualise as systems in mobile mental health, specifically the individual, the treatment, the industry, and governance. Author discipline and ethical framework used impacted the evaluation of ethical themes and issues, with multidisciplinary papers discussing more ethical themes than papers with single discipline authorship.

Conclusions: There continues to be significant ethical issues and considerations in mobile mental health for common mental health disorders. Our findings showed benefit of multidisciplinary discussions in providing more comprehensive ethical reviews and evaluations than papers with authors from a single discipline. We therefore encourage more multidisciplinary involvement and empirical research on the ethics of mobile mental health beyond commentaries and reviews.

Keywords. mobile mental health, digital mental health, depression, anxiety, ethics, scoping review

Introduction

Ethics in mobile mental health

Ethics relates to what is good or moral for individuals and society [1]. Ethical practice in mental health encompasses actions that are "good" and in the best interest of the client, the profession, and society. This includes acting in the best interest of others and doing no harm; being trustworthy and responsible for one's actions and decisions; ensuring competence in skills and practice; being honest and transparent in one's actions; being fair; and respecting individual freedoms, rights, and equality [2,3].

Under these broad ethical principles lie more specific standards that guide mental health professionals in areas such as privacy and confidentiality; record keeping; competency and training; conflicts of interest; advertising and self-promotion; assessment, therapy, and research; and human relations [2]. The purpose of these comprehensive ethical standards is to protect individuals who may often be vulnerable and at-risk of harm. Ethical frameworks are therefore important to ensure best practices, non-abuses of power, and public assurance and confidence in the quality of mental health care available.

With the emergence of new mental health technologies comes the need to consider the ethical implications of their use and to develop relevant ethical frameworks and standards. In the past decade, there has been great investment in the potential of mobile devices to assist in the management of mental health. Mobile applications and digital interventions have been highlighted for their potential to reduce barriers to treatment and to increase access to care [4–8]. Yet, more research is still needed to demonstrate that these mental health technologies are effective, safe, and in line with client needs [9–11]. There has been criticism of mobile mental health due to the proliferation of mobile applications for mental health and wellbeing lacking empirical evidence to support their claims and use [11,12]. Concerns therefore arise regarding the ethical implications of developing such apps and devices without sound theoretical and empirical basis, and in the use of apps by clinical populations with little evidence of their safety and effectiveness.

Concerningly, the discussion of ethical and social implications of new mental health technologies has been trailing the development and advancement of these technologies. This has led to calls for greater controls and regulations for existing and future digital interventions [13,14]. The Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health and Care Excellence (NICE) in the UK are currently exploring and producing guidance on regulating digital mental health technologies [15]. Yet, the commercial app marketplace already lists hundreds of mental health apps, most of which are not regulated [16–19]. Other organisations such as the American Psychiatric Association [20] have attempted to provide guidance and standards on the use and integration of mobile mental health within existing healthcare systems. However, the specific roles and responsibilities of these agencies vary from providing guidance to developers [21] to assisting practitioners in deciding if a mobile mental health technology is suitable for use [20]. These varied approaches reflect the rapidly evolving nature of mobile mental health and questions concerning who is responsible for ensuring ethical practice and safety, and how to ensure compliance with regulations and standards. Moreover, these attempts are not always successful, as seen with the previous NHS app library which was decommissioned after two failed attempts to assess (mental) health apps [22]. Even less is known about the guidance and regulations of more advanced digital mental health technologies such as affective wearables, and whether these should be classed as medical devices, mobile applications, or self-regulation technologies. The classification of these devices will have a significant role in determining the level of scrutiny, guidance, and regulation faced, and hence in the confidence of agencies to recommend and to integrate such technologies into ethical healthcare practices.

With healthcare agencies differing in their approaches to addressing the evaluation and regulation of mobile mental health interventions, the responsibility for the use of existing and rapidly evolving technology often falls on the individual practitioner [20,23–25]. This results in new ethical and social challenges and added burden of care placed on the individual clinician through the recommendation and use of mobile mental health. Such increased (and uncharted) ethical implications can have far-reaching professional and legal consequences for practitioners who may opt not to adopt new technologies given the risk and singular responsibility for use. There is therefore need for the ethics of mobile mental health to be considered more broadly across all the systems and sectors involved in order to develop comprehensive frameworks to guide the design, development, and use of these new treatment modalities [17,26].

A multisector problem

Mobile mental health is a wonderfully multidisciplinary field uniting mental health, computing, bioengineering, and human computer interaction (HCI). Each field brings with it its own ethical considerations and standards. In their review and synthesis of professional codes of ethics across disciplines in mobile mental health, Bowie-DaBreo et al. [27] found differences in ethical principles and focus across the codes reviewed. For example, psychology codes of ethics tended to prioritise client care and welfare, duty of care, and competence. Comparatively, engineering codes, while also prioritising benefits and avoidance of harms, emphasised professional reputability and responsibility.

A preliminary review of the literature on the ethics of mobile mental health showed that while many of the same considerations for traditional mental healthcare apply, discussions sometimes diverged along the varying industries and sectors [28]. Broadly speaking, discussions on the ethical and social implications of digital technologies for health and mental health generally centre on ideas of privacy, data security, safety, informed consent, evidence and effectiveness, evaluation, and regulation [25,29,30]. For computing and app developers, much of the ethical debate centres on privacy and confidentiality in the realm of data security and protection [29,31]. This includes issues such as the need for clear privacy policies, transparent informed consent practices, and regulations protecting against the unauthorized sharing of information with third parties. Conversely, papers targeted to mental health professionals also focus on ethical issues related to clinical use of mobile mental health and client care and safety [17,25,30,32], including risk assessment, safeguarding during out-of-office hours, and impact on the therapeutic relationship and clinical effectiveness.

Another important but less discussed sector is the individual user who may seek to use mobile mental health as a form of unguided self-help. While some users may benefit from autonomous management of mental health concerns, the lack of practitioner input places treatment decisions and evaluation solely on the user. Potential users may consult online app databases and evaluative platforms such as PsyberGuide [11,33] to assist in judging an app's quality, security, and evidence. However, these platforms do not evaluate apps' adherence to theoretical or treatment guidelines, fit with individual user needs, or broader ethical considerations. These gaps in evaluation are important considering that only a minority of mental health apps seem to align with clinical guidelines [34]. Bowie-DaBreo et al. [35] also found several ethical issues conveyed in user reviews of apps for depression ranging from reports of adverse events from using the apps, to issues with access, support, autonomy, privacy, and transparency. Some users reported feeling worse after using some apps, with reports of inappropriate treatment content and bullying and harassment, particularly in peer support communities. The review also highlighted potential facilitators of benefits and harms, that is, factors which may not be conventional ethical concepts but had indirect ethical implications. These included issues with apps' usability, design, and support which had the potential to impact the consistent and accurate delivery of mental health treatment.

The level of risk to the individual practitioner and user becomes even greater when considering the depth of knowledge required to make a true assessment of risk and competence. The above frameworks have focused on assessing individual technological interventions. However, they fail to adequately address the ethical implications related to the vulnerability of user data and the potential for use and misuse within the larger perspective of big data, the digital economy, commercial gain, and surveillance [36–38]. One must therefore consider the true ability of a clinician or individual user to assess the safety, security, and risk of such digital technologies, and thus of the ethical implications in placing the responsibility for this decision at the microlevel without the necessary societal regulations and policies. With the increased awareness of the use, misuse, and potential manipulation of individual data, valid concerns are raised regarding how to protect vulnerable populations. Furthermore, questions arise as to the impact such practices and ethical concerns may have on the use, uptake, and effectiveness of these technologies, with users potentially limiting or manipulating their use of technology to protect their identity, data, and image [36]. This raises further questions regarding how mobile mental health may be safely and effectively used, and thus the ethical and social implications of this new era.

The ethics of mobile mental health is therefore complex, with the greater impact on society still unknown. The introduction of personal technology to mental health care creates debate such as the commercialisation of health, the pathologisation of typical mental health processes, and the motives underlying the development of new technological treatments. Beyond safety, one must also consider issues of liability, responsibility, and fairness in determining how to protect individuals from possible harm from the use of such devices, and who is truly responsible for protecting and managing the risk of vulnerable populations. It is therefore apparent that whilst the ethical themes remain much the same, the specific ethical and social issues of mobile mental health go beyond those of traditional mental healthcare.

Objective

Current ethical standards do not adequately address the complexity of mobile mental health. Preliminary review of the literature of ethical issues of mobile mental health found that while there is an awareness of the great importance of these concepts, there remains a fragmented and delayed response to addressing these challenges. It is apparent that a major challenge to the understanding and development of ethical frameworks is the multidisciplinary nature of the field of mobile mental health. The melding of the fields of computer science, bioengineering, HCI, and mental healthcare produces greater challenges than merely that of the coordination and communication of multidisciplinary teams. One must also consider the amalgamation of ethical knowledge, codes, and practices resulting from such combined efforts.

Current discussion of the ethical and evaluative challenges of new technologies for health and mental health often reflect these individual fields, with perspectives for technicians and developers, health agencies and services, psychologists and practitioners, commercial entities, and societies. However, it is apparent that ethical and social frameworks must be better integrated to include all these perspectives and to incorporate ethical concepts related to technical design and development, healthcare policies and guidance, clinical practice, research, commercial regulations, legal implications, governance, and greater implications for the individual user and society.

There is therefore a need to comprehensively review the ethical discourse in the field of mobile mental health to understand the pertinent ethical and social issues, and their presentation across various sectors and stakeholders. This paper presents results of a scoping review of the literature on mobile mental health addressing the following questions:

> (1) What are the ethical issues in mobile mental health?
> (2) Which sectors, disciplines or stakeholder perspectives are represented in the discussion and research on the ethics of mobile mental health?
> (3) How does the discussion on the ethics of mobile mental health vary across sectors and disciplines?

This is an initial step towards creating a shared understanding and language of the ethics of mobile mental health, and thus developing transdisciplinary principles, standards, and recommendations to guide the design, use, and adoption of mental health technologies.

Methods

We performed a scoping review to map relevant literature on the ethics of mobile mental health across the main sectors in the field. The review focused on technologies for common mental health problems, such as depression and anxiety because of the high prevalence of these conditions and their significant impact on the global burden of disease [39]. We followed the Arksey and O'Malley framework [40] as outlined in the following stages:

Identifying the research question

This review sought to understand potential ethical issues in mobile mental health and how these are framed and discussed across various disciplines in the field.

Identifying the relevant studies

We sought to map and synthesise the literature on the ethics of mobile mental health across sectors and disciplines. To achieve this, we searched a breadth of literature sources to gain a comprehensive view of the ethical concepts and themes. Search was done in April 2022 using a three-step strategy:

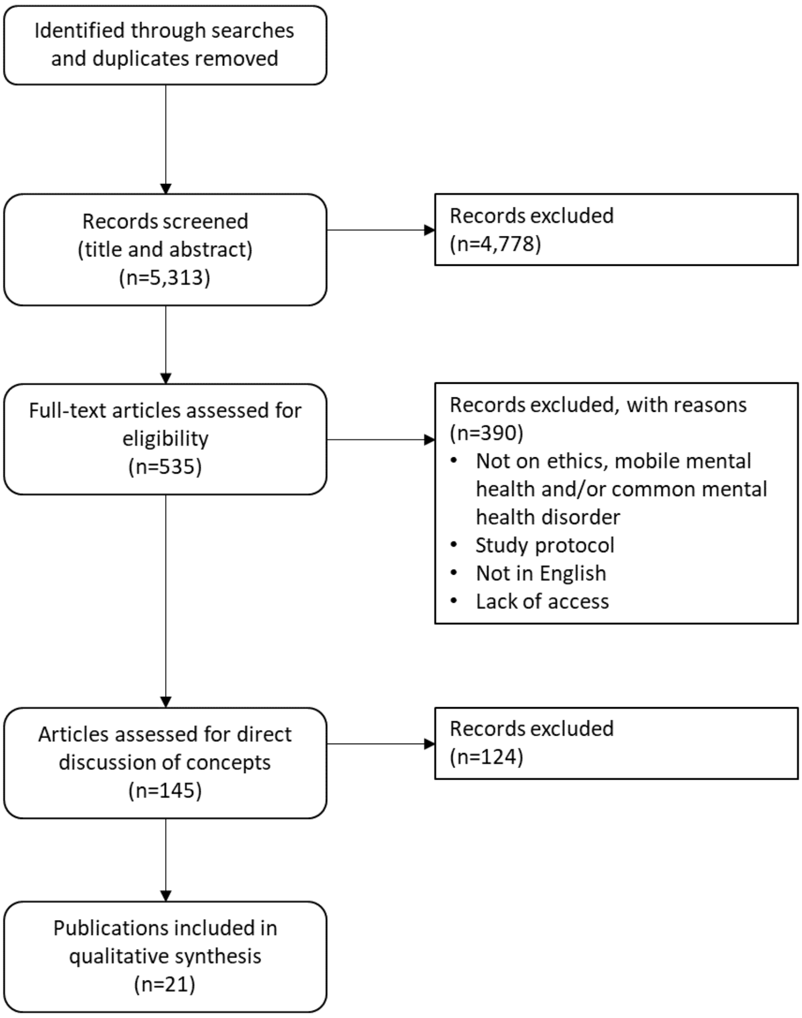
(1) An initial limited search of PubMed and PsycInfo using search term 'ethics' AND 'mobile mental health' to identify important key words to be included in the full search.
(2) A search of the following electronic databases using refined search terms: PubMed, PsycInfo, Embase, ACM Digital Library, Academic Search Ultimate, and Scopus. A sample search strategy can be found in Appendix 1.
(3) Additional sources were identified from grey literature in (OpenGrey, HMIC), reference lists of relevant literature, and Google search.

Search returned 5,313 results after duplicates were removed (see Figure 1).

Selecting studies to include

Inclusion criteria aimed to select the most relevant studies on the ethics of mobile mental health. Studies were included in the review if they explicitly (1) focused on common mental health disorder(s), (2) focused on mobile mental health, defined as the use of mobile technology for the delivery of mental healthcare, and (3) discussed the ethics of mobile mental health. Studies were also limited to those in English and accessible online. We chose to limit the review to papers discussing common mental health disorders like depression and anxiety disorders because these are the most prevalent mental health disorders with the highest burden of disease [39]. Because of this, they are often the target disorder for mobile mental health interventions and would provide a useful foundation to understand ethical issues of mobile mental health. After initial screening of titles and abstracts, we sifted full-text articles to identify eligible studies. A large number of papers briefly referenced ethics or common mental health disorders such as depression without directly discussing these concepts. To ensure we captured the most relevant studies, we decided to further limit inclusion criteria (2) and (3) to explicit discussion of ethics and a common mental health disorder in the title, abstract, or keywords. Based on this, articles were excluded if they did not explicitly discuss mobile mental health, ethics (title, abstract, or keywords), and common mental health disorders (title, abstract, or keywords), or if their online version was not accessible (Figure 1). In total, 21 relevant publications were included in the review (Appendix B).

Figure 1. Flow diagram



Charting the data

Data was extracted in line with the research questions and objectives. A data charting form was developed a priori to capture key variables. Additional changes were made iteratively throughout coding to capture relevant information not initially included in the form (Table 1).

This included identification of ethical issues and recommendations. Data extraction and coding was done by the first author in consultation with all authors.

Collating, summarising and reporting results

Descriptive numerical analysis was done on the extracted data in line with the research questions and objectives. Thematic analysis was used to explore ethical issues and concepts, with themes used to integrate, interpret and report the data across disciplines.

Results

Description of publications

A total of 21 full-text publications were included in the review and thematic analysis. All papers were published between 2017 to 2022, with the most papers published in 2020 (n=7) followed by 2019 (n=5). More than half of the papers (13/21, 62%) included authors from a mental health discipline with HCI (6/21, 25%) and ethics (5/21, 24%) being the next most common disciplines. Eight of the 21 (38%) papers had authors from two to three different disciplines most commonly mental health, health, and a technological discipline such as HCI or engineering. Almost 50% (10/21) of studies included authors from the US, followed by the UK (6/21, 29%). This should be considered when contextualising discussions on the use and potential ethical issues of mobile mental health, and the applicability of these ideas to different cultural or economic contexts.

Most papers were reviews or commentaries. There were two qualitative studies – one on prototype design [41] and the second on views and experiences of digital phenotyping [42]. Papers focused on a range of mobile mental health technologies, most commonly apps (9/21, 43%) followed by artificial intelligence (AI) (6/21, 29%), digital phenotyping (5/21, 24%), and digital health more broadly (5/21, 24%). Less commonly discussed technologies were chatbots (2/21, 1%) and virtual reality (VR) (1/21, 1%).

Table 1. Distribution of codes

Codes	Papers, n (%)
Author discipline	
Mental health	13 (62)
Human computer interaction (HCI)	6 (25)
Ethics	5 (24)
Health	4 (19)
Computer science	1 (5)
Engineering	1 (5)
Library and information science	1 (5)
Social politics	1 (5)
Multidisciplinary	
Yes	8 (38)
No	13 (62)
Author location	
United States	10 (48)
United Kingdom	6 (29)
Germany	3 (14)
Denmark	3 (14)
Ireland	2 (10)
Norway	2 (10)

Australia	1 (5)
Belgium	1 (5)
China	1 (5)
Cyprus	1 (5)
Indonesia	1 (5)
Italy	1 (5)
Luxembourg	1 (5)
Article type	
Commentary	5 (24)
Review	5 (24)
Qualitative study	2 (10)
Scoping review	2 (10)
Systematic review	2 (10)
Content analysis	1 (5)
Ethical analysis	1 (5)
Evaluation	1 (5)
Narrative review	1 (5)
Rapid review	1 (5)
Audience	
General or unclear	10 (48)
Designers or developers	4 (19)
Multidisciplinary	4 (19)
Clinicians	2 (10)
Researchers	1 (5)
Target disorder[a]	
Mental health	10 (48)
Depression	7 (33)
Anxiety disorders	1 (5)
Depression and anxiety	1 (5)
Anxiety and mood disorders	1 (5)
Stress	1 (5)
Technology[ab]	
Apps	9 (43)
Artificial intelligence	6 (29)
Digital phenotyping	5 (24)
Digital health	5 (24)
Chatbots	2 (10)
Virtual reality	1 (5)
Definition of ethics	
Yes	0
No	21 (100)
Ethical framework	
Yes	13 (62)
No	8 (38)
Publication year	
2017	1 (5)
2018	3 (14)
2019	5 (24)
2020	7 (33)
2021	3 (14)

2022	2 (10)

[a] Added after initial data charting form

[b]Some studies included more than one type of technology

Ethical frameworks

None of the studies included a definition or broad description of ethics. More than half of the publications (13/21, 62%) used a named framework to present and discuss ethical issues in mobile mental health, with six papers using two different frameworks (Table 2). The most commonly used framework was biomedical ethics [43] which was referenced in 5 of the 21 papers. Other frameworks were specific to professional codes of ethics, (digital) health interventions (e.g., evaluation of digital health application and health related digital autonomy) or the interrelations between humans, society, and technology (e.g., critical ecological framework and social informatics). Several frameworks included principles or domains which are outlined in Table 2. These most often included concepts around autonomy, benefits, and harms. Some of the more theoretical ethical frameworks focused on values, with papers applying these to the design, development, acceptability, and use of mobile mental health technologies [41,44]. Papers that used ethical frameworks tended to discuss more ethical themes (mean 6.5, range 2 to 11) than those that did not (mean 5.4, range 2 to 7), but the significance of this difference is not known.

Table 2. Descriptions of frameworks

Framework	Description
3-ACEs [45]	Developed by Thornicroft & Tansella [46] for the ethical analysis of mental healthcare services. It has nine principles: (1) autonomy, (2) continuity, (3) effectiveness, (4) accessibility, (5) comprehensiveness, (6) equity, (7) accountability, (8) coordination, (9) efficiency.
American Academy of Child and Adolescent Psychiatry (AACAP) code of ethics [47]	The AACAP code of ethics [48] includes 10 principles for mental health professionals working with children and young people: (1) developmental perspective, (2) beneficence, (3) nonmaleficence, (4) autonomy, (5) confidentiality, (6) fidelity, (7) scholarly and research activities, (8) justice, (9) professional rewards, (10) legal considerations.
APA ethics code [16,49]	The APA ethical principles of psychologists and code of conduct [2] provides guidance for psychologists and professional standards. It outlines five aspirational general principles: (1) beneficence and nonmaleficence, (2) fidelity and responsibility, (3) integrity, (4) justice, (5) respect for people's rights and dignity.
Biomedical ethics [16,50–53]	Beauchamp and Childress's [43] principles of biomedical ethics is widely used to discuss ethical issues in clinical medicine. There are four principles to assist ethical decision-making and resolve ethical conflicts: (1) respect for autonomy, (2) beneficence, (3) nonmaleficence, (4) justice.
Critical ecological framework [44]	Extension of Fullagar et al. [54] notion of mental health apps as part of digital ecologies of youth mental health. It questions the separation of the individual (the user) and the technology (the apps) and analyses mental health apps as digital cultural texts and material objects.
Ecosophy [44]	Guattari's [55] theory of ecosophy as an ethical and political concept. There are three interrelated domains that cannot be

	separated: (1) the environment, (2) social relations, (3) human subjectivity.
Ethical pluralism [41]	Ethical pluralism recognises shared universal values and cultural differences whereby everyone has their own value system and value hierarchy.
Evaluation of Digital Health Application [56]	It includes 3 domains (formulation, innovation and ethics) with 13 assessment criteria: (1) purpose, (2) study design, (3) theoretical frameworks, (4) methodology, (5) users, (6) development process, (7) accessibility, (8) features, (9) results, (10) confidentiality, (11) competency, (12) consent, (13) contingency.
Health Related Digital Autonomy framework [50,52,53]	Builds on the concept of autonomy as presented in biomedical ethics to consider specific challenges of digital health such as artificial intelligence and social media. It consists of five criteria: (1) availability of alternatives, (2) intentionality, (3) understanding, (4) independence, (5) empowerment.
Social informatics [57]	An examination of the social aspects of technology whereby mobile mental health is part of a broader sociotechnical system in which society and technology influence each other.
Theoretical framework of acceptability [42]	Developed by Sekhon et al. [58] for health interventions, it is focused on the user's point of view throughout the intervention development lifecycle. It has seven components: (1) affective attitude, (2) burden, (3) ethicality, (4) coherence, (5) opportunity costs, (6) perceived effectiveness, (7) self-efficacy.
Virtue ethics [41]	Aristotelian virtual ethics is concerned with the values that achieve human flourishing and 'the good life'. It involves the combination of phronesis (knowledge acquired through experience), episteme (scientific knowledge) and techne (technical knowledge) to promote the values that lead to human flourishing.

Ethical issues and considerations in mobile mental health

We found 12 overarching themes that captured ethical issues and considerations for mobile mental health for depression and anxiety (Table 3). Papers discussed between two to 14 ethical themes (mean 6.1 themes). Most of the publications (15/21, 71%) discussed issues related to possible harms or safety [16,41,44,49–53,56,57,59–63]. Other commonly discussed concepts were privacy (14/21, 67%) [16,49,52,53,56,57,59–66], duty (13/21, 62%) [16,41,44,45,50–53,56,57,61,64,66], inequalities (13/21, 62%) [16,41,44,45,50–53,57,59,60,62,65], benefits (12/21, 57%) [16,44,45,47,52,57,59,61–63,65,66], autonomy (12/21, 57%) [16,41,42,45,49,50,52,53,56,60,63,66], and standards (12/21, 57%) [16,44,51–53,56,57,59,60,62,63,65].

Ethical themes and issues were found to relate to 4 main components of mobile mental health:

(1) the individual: the person with depression and/or anxiety
(2) the treatment: the clinical content, context, and effects
(3) the industry: the development and commercialisation of mobile mental health technologies
(4) governance: overarching standards and regulation for all aspects of mobile mental health.

These issues and considerations are described below within each component followed by recommendations outlined in the papers to address some of the issues.

The individual

Autonomy

A key ethical theme for people using or considering using mobile mental health was autonomy (12/21), including issues with informed consent and disempowerment [16,41,42,45,49,50,52,53,56,60,63,66]. Rooksby et al. [42] reported that participants' key concerns with digital phenotyping were loss of autonomy, control, and dignity. Rubeis [45] considered that "a service should preserve and promote patients' independence and the reinforcement of their strengths" (p. 550), including being able to engage with treatment at their own speed and when needed. Factors impacting autonomy included insufficient information for people to make decisions about their care including which app to select [16,45], automated profiling without informed consent [52,53], and privacy concerns and control over the use and sharing of personal and sensitive data [42,49,50,66].

Table 3. Ethical themes across 4 main components of mobile mental health

Component and themes	Papers, n	References
The individual		
Autonomy	12	16,41,42,45,49,50,52,53,56,60,63,66
Acceptability	2	42,44
The treatment		
Harms	15	16,41,44,49–53,56,57,59–63
Inequalities	13	16,41,44,45,50–53,57,59,60,62,65
Benefits	12	16,44,45,47,52,57,59,61,62,63,65,66
Validity	11	16,41,49–53,60,61,65,66
Clinical practice	7	44,45,51,52,57,62,65
The industry		
Duty	13	16,41,44,45,50–53,56,57,61,64,66
Conflicts of interest	9	16,44,47,49,52,53,57,59,66
Intentions and values	7	16,41,42,44,52,53,62
Governance		
Privacy	14	16,49,52,53,56,57,59–66
Standards	12	16,44,51,52,53,56,57,59,60,62,63,65

Gillett and Saunders [60] noted that may be difficult to protect autonomy when using machine learning techniques because the use of data may not be known at the time of collection. Alvarado and Morar [50] also raised concerns with AI technologies in mental health, particularly AI depression detectors in social media. They noted that these technologies were often a black box with no understanding or scrutiny of their inner functioning. This lack of transparency therefore makes it difficult for people to make truly informed choices in whether or not to use these technologies.

Moreover, by not knowing how technologies (like emotion recognition technologies) function, people are limited in understanding "their own surroundings and experiences, which includes what is being done, why it is being done and how it is being done to them" [50, p. 27]. This is said to undermine the person's ability to know and competently relay their own experiences. Barry et al. [41] also reported that some people found the language used in some mental health apps to be "patronising" and undermining a person's self-assessment of their mental health problems. This could be disempowering by suggesting that people are not able to assess their own wellbeing. This autonomy may be further diminished by emotion recognition technologies in social media which seek to extract and use information that a person may not have chosen to share for that purpose [50,52,53]. This raises concerns with technological paternalism [52,63]. As Laacke et al. [52] stated, “detecting signs of depression does not by itself justify the assumption that there is a desire for treatment. It does not per se justify a medical intervention into users’ personal lives” (p. 10).

Acceptability

Two papers discussed ethical issues related to acceptability [42,44], with Rooksby et al. [42] considering it an important aspect of effectiveness that is interrelated with ethics, particularly autonomy and informed consent. They defined acceptability as “what the user or beneficiary of the technology thinks and feels” [42, p. 3] and discussed several aspects of the acceptability of digital phenotyping that were shared by participants in interviews and focus groups. Participants considered that digital phenotyping could have potential benefits in addressing a notable unmet need for mental healthcare, but there were concerns that it would not mean better support if there was not a mental health service behind the digital phenotyping app. Other potential harms included the use of digital phenotyping by universities and the impact this could have on self-determination and possible discrimination based on labels generated by the app. These concerns were connected to additional issues with privacy and the handling of invasive or very sensitive data collection, and particularly the desire for people to have control over how their data was collected and shared. Acceptability of digital phenotyping was affected by the perceived relevance of the data being collected, with participants questioning “why a mental health app would need to collect information that is not ‘logically’ related to mental health” [42, p. 8]. This included automatic collection of photos, recording keys clicked, tracking other apps on a device specifically dating and LGBTQ+ apps, and recording content such as messages or from the microphone. These were all considered unacceptable largely because of concerns with privacy and potential for misuse.

There were also concerns that self-report measures for anxiety, depression, and wellbeing may trigger negative thoughts and feelings and were perhaps better administered by a healthcare professional. Similarly, Williams and Pykett [44] noted that while mental health monitoring apps may ease the burden on mental health services and improve access to treatment, they will not be accepted without the involvement of human support. They highlighted tensions between the ethics and politics of designing mental health technologies and trade-offs between user needs, mental health services capacities, and ideas of “what and who should be responsible for mental distress” [44, p. 12].

Recommendations in the literature

Suggestions to address ethical issues related to autonomy and acceptability in the papers included:

- explicit consent from users before any data is collected or used in mobile mental health technologies including automatic profiling such as in AI depression detectors [52,53,56]
- clear and detailed information about all aspects of the technological intervention – including purposes, functionality, risks, benefits, costs, and privacy policies – so people can give true informed consent before use [42,49,52,53,65]
- case-based examples to help people understand how technology works, how data is handled, and potential risks before giving consent [42]
- information on alternative treatment options and how to access them so people can make a truly informed choice on which treatment may suit them best [52]

- information on mental health particularly for digital phenotyping technologies to support users' psychoeducation, self-reflection, and insight into their mental health [42]
- user control over what information is collected, for example being able to disable the listening function of the device or have a noise jamming tool to prevent recording of audio, having clear opt in before such information is recorded and opt out later if wished [66]
- designing technologies to empower users in their mental health care by actively involving them in all treatment decisions and actions, especially for digital phenotyping or automatic profiling technologies [52].

The treatment

Validity

Over half of the papers (11/21, 52%) discussed issues related to the validity of the mobile mental health intervention, with a focus on accuracy and fidelity [16,41,49–53,60,61,65,66]. Issues around the validity of technologies were raised for AI [50–53], remote monitoring [60], voice-based approaches for assessing stress [66], and mental health apps [16,41,49,61,66]. Most broadly were concerns that mental health technologies did not do what they claimed, with examples of false advertising and unverified benefits [49,66]. There were also questions around the treatment fidelity of mobile mental health technologies, such as their compliance with clinical guidelines [16] and evidence-based approaches [16,65].

More specifically, studies discussed concerns of risk if algorithms used to predict or diagnose disorders were not accurate, perhaps because of insufficient data in training datasets [51], undetectable errors AI systems [50], or inaccurate and biased AI decision-making [52,53]. Alvarado and Morar [50] noted that AI technologies often use "non-medically relevant proxies derived from statistical correlations in elements of datasets that are not recognisable to medical professionals as medical phenomena" (p 26). They cautioned that this could lead to measurement bias whereby technologies "may not be capturing 'depression per se but rather other medically irrelevant phenomenon such as syntactic distance between words, time of posting or search terms related to famous sad songs." (p. 26). There were also concerns with the quality of data recorded in remote monitoring apps, with Gillett and Saunders [60] stating "although remote monitoring offers a wealth of data to be collected, it is imperative that such data is validated and shown to be clinically significant before broader conclusions are drawn from it" (p. 54).

Barry et al. [41] raised further concerns that mobile health apps "are a poor replacement for the multisensory signals picked up in an interview about emotional wellbeing" (p. 2712), particularly questioning whether technologies can be designed to "be used to consider more deeply the kind of deliberate withholding of communication, often subconsciously or unconsciously done, especially but not only in mental health consultations" (p. 2712). Some authors raised concerns with the quality of information presented to users [16,60] and the push towards self-diagnosis and self-treatment [60]. Self-assessment was seen as carrying the risk of people falsifying their responses to potentially over- or underreport their mental health concerns [41]. There was also the risk that apps may use unvalidated assessment tools instead of the standardised measures used in clinical practice [61].

Clinical practice

Seven papers (33%) also described ethical issues related to the use or impact of mobile mental health on clinical practice [44,45,51,52,57,62,65]. Gamble [57] considered that mobile mental health technologies should be used as a tool rather than a replacement for mental health professionals with Tekin [62] believing important humanistic elements of treatment would be missing from some mobile mental health technologies such as psychotherapy chatbot interventions, stating “the methods of [other medical] intervention are arguably more moral because they are humanistic in nature: doctors, nurses, therapists, and other medical professionals – all actual humans – are physically there to bear witness to individuals’ suffering, listen to their stories, and offer help” (p. 12). Other papers questioned the capacity and ability of healthcare professionals to use and respond to the level of patient data generated by these technologies [44,57]. Khanna and Carper [65] reported that “there remains a marked research-to-practice gap between efficacy trials and understanding of how to promote treatments acceptance and implementation in the community” (p. 64). Mobile mental health technologies were said to offer opportunities for greater coordination and continuity of care across services and over a longer period of treatment [45], but services needed to ensure adequate management of threats to patient confidentiality and privacy [65].

Benefits

Mobile mental health has many potential benefits as discussed in over half of the papers (12/21, 57%) [16,44,45,47,52,57,59,61–63,65,66]. Mental health apps were suggested to potentially benefit the efficiency of services, which Rubeis [45] defined as having comparable or better cost-effectiveness compared with face-to-face therapy. They noted that there was evidence that guidance – that is, support from a mental health practitioner or coach – can mediate cost-effectiveness, such that guided interventions were found to be cost-effective but unguided interventions were not or were uncertain. Similarly, Williams and Pykett [44] cited evidence that mental health apps had positive mental health outcomes when used with humans and healthcare organisations.

But many papers questioned the clinical benefits of mobile mental health technologies, particularly criticising the lack of evidence on efficacy and clinical outcomes [16,47,57,61–63]. Some papers further noted that when there were studies, many had limitations related to their sample size and comparators including the use of waitlist controls instead of an active treatment group [45,57,59,62]. There was also evidence that some apps had only small to medium effects or no benefit at all [45], with few reporting benefits beyond three months [62].

Harms

Most publications (15/21, 71%) discussed potential harms of mobile mental health, with issues related to safety, pathologisation, and overreliance on the technologies [16,41,44,49–53,56,57,59–63]. There were risk concerns over the inaccurate prediction or diagnosis of mental health problems [50,51,59–61], an issue closely related to the ethical themes of validity. Tekin[62] connected this risk to potential issues with data privacy and security which could result in people’s personal health information being used fraudulently. They noted this could result in inaccurate data in medical records which could affect future healthcare provision and possibly have wider impact on a person’s social or work life.

Safety concerns also included potential worsening of mental health problems because of unsuitability of mobile mental health interventions for some people, for example people with addictive behaviours to mobile technologies [57]. Mobile mental health technologies may also be misaligned to a person’s individual needs [57] or may include content that could be triggering for some people [61]. Papers also discussed potential risks over information overload from frequent notifications or check ins [57] and misuse of these interventions [60], including overreliance on self-help without healthcare professional support [52,57,60].

There were also concerns about how safety and safeguarding was considered for vulnerable groups such as children and young people or people with more severe mental health problems [16,41,61]. Qu et al. [61] found that most apps for depression do not provide any information on handling or preventing risk of suicide. Barry et al. [41] raised concerns about how emergency responses may be provided if needed and the ethical responsibilities this placed on healthcare professionals and services. This extended to research on digital mental health, with many studies failing to include contingency planning [56].

There were additional ethical concerns specific to research on mobile mental health technologies. Graham et al. [51] considered that Institutional Review Boards may have limited knowledge of new and innovative technologies which would make it difficult to accurately assess risk. There were also some concerns that it could be unethical to include people who were currently experiencing significant mental health problems in co-design or research [41].

Fundamental to these concerns is the ongoing lack of evidence and understanding of the risks and safety concerns of these technologies [16,49,63] with more research still needed.

Other harms of mobile mental health included the potential medicalisation of everyday experiences [44,52,53,60] or broader social and political problems such as those faced by refugee populations [62]. William and Pykett [44] questioned who decides what is typical or atypical when using passive data collection to predict mental health problems. This was thought to be especially problematic because it involved the use of technology to predict and/or treat perceived problems, with Ploug and Holm [53] noting that “some of the information only becomes ‘sensitive’ or ‘medical’ because it is used by the AI for mental health screening” (p. 22).

Inequalities

In addition to ethical issues around harms and safety, many papers (13/21, 62%) discussed equality considerations, with issues related to access and accessibility, potential biases, inclusion and diversity, or discrimination or stigma [16,41,44,45,50–53,57,59,60,62,65]. AI algorithmic bias was a key equality issue with papers discussing the potential for this to replicate existing stigma and discrimination [53,57,60]. Gamble [57] considered that “to be effectively and ethically implemented in [mobile health] apps, AI must be examined through a socially conscious lens in each state of its development, from conception and design to deployment and regulation” (p. 509-510). More specifically, Graham et al. [51] advised that “those involved in making decisions about the selection, testing, implementation, and evaluation of AI technologies must be aware of ethical challenges, including biased data (e.g., subjective and expressive nature of clinical text data; link of mental illnesses to certain ethnicities)” (p. 115). Alvarado and Morar [50] also cautioned that “multiple protected features – such as socio-cultural traits of language use, socio-economic backgrounds, race, gender, etc. – could be used by [machine learning] to label someone as ‘depressed’. This could lead to the normalisation of emotive expression considering that data is more immediately available and more often analysed for majority groups” (p. 26). Similarly, Tekin [62] questioned the application of westernised conceptualisations of mental health problems to other cultures, such as Middle Eastern communities. They noted that there are many cultural differences in how mental health difficulties may be expressed which may impact the relevance and benefits of these technologies.

There was concern that ‘labelling’ of mental health problems may also perpetuate stigma and discrimination, particularly through “unintended labelling in the context of social media” [52, p. 11]. Remote monitoring using wearable devices or other visible technologies may also increase stigma and discrimination against people with mental health problems [60], but Rubeis [45] noted that the anonymity of some mobile mental health interventions may actually help people to bypass social stigma and access treatment. Mobile mental health technologies are typically touted for their potential to improve access to care [41,45,59], with Ebert et al. [59] questioning the ethical implications of withholding or not facilitating access to these technologies as complementary treatment options. They noted that mobile mental health technologies may especially benefit people who cannot or may not want to access traditional face-to-face treatments, with Rubeis [45] outlining that possibility of apps to overcome barrier to mental health treatment such as costs, stigma, time and travel, and self-disclosure. While mobile mental health may increase access to care for some, papers noted that this would not benefit everyone and may instead increase health inequalities for people who have limited access to technology [52,60].

Recommendations in the literature

Suggestions in the papers to address ethical issues related to the intervention and its use in clinical practice included:

- There should be human oversight of mobile mental health technologies, including AI tools in mental health care [57]
- Developers and healthcare services should provide clear positioning of where mobile mental health fits into the care pathway [51] including mobile mental health as a treatment option rather than a replacement for traditional face-to-face treatment [52]
- Developers and healthcare services should provide guidance on the level of healthcare professional support needed and how to access support [45,51,62], with support including clinical guidance, reminders, and monitoring treatment adherence [49]
- Healthcare professionals should include people in discussions and decisions around their treatment, and ensure mobile mental health technologies align with patients' needs and preferences [47]
- Developers and healthcare services should provide clear information on all aspects of the treatment, including AI algorithms and training datasets [51], potential risks and benefits, and safeguarding [57,61,65]
- Mobile mental health interventions should be validated and evaluated through well-designed trials to show potential benefits and clinical utility before use [63,65,66]
- The effectiveness of mobile mental health technologies should be based on research of the entire app and not just its use of evidence-informed elements, with links to studies provided in technologies descriptions [57]
- Healthcare professionals should provide patients with information on the effectiveness of the intervention, including evidence-base or lack thereof, and potential risks and benefits [49]
- Healthcare professionals should review and try mobile mental health technologies before use in clinical practice, including review of evidence and intervention content [49]
- Healthcare professionals should be aware of potential ethical issues in mobile mental health and apply existing standards and guidelines to mitigate these risks [47,56]
- Mobile mental health technologies should provide safety resources and safeguarding for vulnerable people such as those at risk of suicide [57,61,65], for example, providing contacts for local emergency services and call centres, and connecting directly with carers when needed [57]

The MedTech industry

Intentions and values

In framing their discussions of ethical issues of mobile mental health, some papers (7/21) considered the intent behind the development of mobile mental health or the values underlying technologies [16,41,42,44,52,53,62] (Table 4). Tekin [62] questioned the motivation behind the development of chatbot psychotherapy technologies, suggesting that replacing human healthcare professionals with chatbots does not reflect genuine concern for the mental health of refugees. Ploug and Holm [53] also noted concerns with the purported "medical purpose" of AI depression detectors, outlining potential uses that would fall outside this intention. These scepticisms are captured in Williams and Pykett's [44] statement that we "need to question what is 'intended' to be produced through interactions with apps: where attention is designed to be oriented, and to query the set of knowledges, technical mechanism, affects, and affordances that are drawn upon in clinical research and commercial development of monitoring mental health apps" (p. 12). They noted the wider "political and economic rationales" behind the development of mobile mental health technologies.

Values in mobile mental health were discussed from the perspective of developers and users [16,41,42,52]. Barry et al. [41] considered that "disciplinary differences – HCI, computer science, medical practice and research, psychology and communications studies – each contributes different interests, foci, methodologies and theoretical frameworks and differing approaches to ethical considerations. This has implications for whose values become embedded in design earliest and how" (p. 2716). Rooksby et al. [42] defined the "ethicality" of digital phenotyping as "the extent to which [it] fits with individuals' value systems" (p.10), with key values for users being autonomy, control and dignity. Values were described as intrinsic or extrinsic, where intrinsic values were seen as valuable in their own right (such as health or happiness) while extrinsic values supported these [41]. Examples of extrinsic values were privacy, security and trust. Barry et al. [41] considered that computing ethics tended to focus on extrinsic values but there has been a push towards focusing on more human values. A review of the depression app marketplace suggested that developers prioritised evidence-informed design and privacy over evidence generation, safety and safeguarding, duty of care, transparency, credibility and informed consent [16].

Duty

More than half of the papers (13/21) highlighted ethical issues related to the duty of mobile mental health, with focus on developers, users and the technologies themselves [16,41,44,45,50–53,56,57,61,64,66] (Table 4). A notable concern across papers was duty to protect users, including how technologies would safeguard against potential harms and who was legally and ethically responsible for users' safety and treatment decisions [16,52,53,66]. While some questioned whether this fell to the companies behind the technologies [66], Williams and Pykett [44] suggested mental health monitoring apps "are part of a wider rationality of the redistribution of responsibility for health and ill-health" (p. 12) with the belief that more responsibility was being placed on the individual user for managing their own mental health. But Gamble [57] considered that technologies like chatbots were only a tool to address mental health problems but could not replace mental health professionals.

Bowie-DaBreo et al. [16] highlighted the responsibilities of developers of mobile mental health technologies, including "ensuring the competence of the development team, providing evidence of intervention validity and safety, safeguarding and duty of care, and compliance with regulations" (p. 12). They highlighted issues with accountability related the transparency and accuracy of information provided. Rubeis [45] defined accountability as "legitimate expectation of patients, families, and the wider public regarding the responsible acting of services" (p. 551) and outlined similar concerns with accountability for the quality of apps and transparency of data and privacy policies. Transparency was widely discussed and encouraged for all aspects of mobile mental health, from the underlying functionalities and accuracy of technologies [50,52] to evidence on efficacy [16,61], data collection and sharing [16,52,56,64], risks and safety [16,52], and costs and sources of funding [16].

Conflicts of interest

Issues with transparency were closely tied to conflicts of interest in mobile mental health. Conflicts of interest were discussed in nine papers [16,44,47,49,52,53,57,59,66], with issues specific to commercialisation and the involvement of third parties (Table 4). There were concerns that business and pricing models of mobile mental health technologies, and particularly apps, were not clearly outlined [16]. The commercialisation of mobile mental health could also spur on the development of low quality, nonevidence-based technologies

[59]. These may be difficult to distinguish from scientifically evaluated programmes because of limited transparency in the app marketplace and technology descriptions [16,59]. This may limit people's ability to make informed decisions about whether to use specific apps and the associated costs.

Slavich et al. [66] also questioned when it is appropriate to use information from digital health technologies for commercial purposes, such as suggesting (and advertising) paid mental health services or medication when a voice-based stress assessment technology detected elevated levels of stress. Added to this were concerns over how such technologies, including AI systems, were trained and developed with questions over potential conflicts of interest and bias that could have financial benefits to developers [53].

A key concern with the commercialisation of mobile mental health was the selling of user data and the implications of this on privacy and confidentiality [47]. Many papers flagged ethical issues around third-party involvement in mobile mental health, including the connection to social media sites [57] and the selling of user data to inform consumer habits [52], credit assessment and penal purposes [53]. There were also concerns that insufficient data security and governance could result in the misuse of users' personal information by third parties [49].

Recommendations in the literature

Suggestions to address ethical issues related to industry and commercialisation of care included:

- Developers should consider ethics, risks, and safety in the design of mobile mental health technologies [51,57,63], including the use of ethical approaches to design such as responsible innovation, value sensitive design [16], reflective design, participatory design, and building phronesis into the HCI design process [41]
- Developers should consider the value systems and needs of patients, healthcare professionals, and the healthcare system when designing mobile mental health interventions [41]

Developers should acknowledge and reflect on their own subjective value systems and those of multidisciplinary collaborators and the impact this may have on the design and use of mobile mental health intervention [15,41]

- Developers should consider service design and not just technology design of mobile mental health technologies, including how the technology fits into or disrupts existing systems [42]
- Design and development of mobile mental health technologies should include input and feedback from people with lived experience or those working closely with the target population [16,41]
- Developers and researchers should acknowledge any conflicts of interest and mitigate this risk through independent data collection, evidence generation and transparent policies [65]
- Developers and companies of mobile mental health technologies should have clear policies on how to handle technological malfunctions and data breaches, including immediately notifying users of such incidents and providing identity protection services and compensation as needed [66]
- Developers should ensure responsible advertising and descriptions of mobile mental health technologies, including appropriate age restrictions in app stores and app descriptions [61] and clear information on how technologies should be used within the context of the broader healthcare system [57]

- Developers should have ongoing risk assessment and mitigation, including continuous reflection and stakeholder engagement on the long-term impact of the technology [16]

Governance

Privacy

Ethical considerations around privacy, confidentiality, and data security were discussed in 14 papers (67%) [16,49,52,53,56,57,59–66]. Most broadly were ethical issues around respect for people's privacy and data minimisation, that is, only collecting personal information if and when needed. Insel [64] questioned if it was too intrusive to collect some types of data, such as geolocation or speech, and whether this risked becoming surveillance rather than just measurement. They considered that "for psychiatry, one of the most informative phone signals might reside in the 'digital exhaust', such as search history or social media posts. Those signals might confess suicidal intent or early signs of psychosis. Does the value of this information outweigh the intrusion of privacy required to obtain it?" (p. 276).

Privacy considerations included not just what information should be collected, but who owned that information once it was collected and use by mobile mental health technologies [49,64]. Wang et al. [49] noted that personal information was held by the mental health technology rather than a healthcare professional, which added complexity to determining necessary precautions. Many papers highlighted ethical issues related to unclear information on the privacy and security of users' personal information including how this may be stored, used, and shared [16,49,57,60,61,62,65]. Mobile mental health technologies may collect a large volume of personal and sensitive information regarding people's mental health, location, behaviours, and contacts. But this may not always be considered medical in nature and may therefore not be covered by regulations to protect privacy and security of personal health information [57,60,62]. Moreover, mental health technologies may link to or operate through another tool such as social media sites that will have their own privacy policies and third-party arrangements [52,57]. There were risks that third parties could use personal and sensitive information in ways the user did not intend, such as commercial purposes or credit assessment [47,52,53,61]. There were also concerns that some mobile mental health apps may not have reliable security, for example "they might transmit unencrypted personal data over insecure network connections or allow ad networks to track users, raising serious concerns about their ability to protect the confidentiality of user information" [62, p. 7]. This carried risks of data being intercepted and used fraudulently by cybercriminals, which could have implications on a person's credit rating, finances, and even the accuracy of medical records.

Authors noted that concerns with privacy had the potential to impact other ethical issues such as autonomy and access [57]. People may have less control over their personal data in the absence of clear and transparent privacy policies and information, which may in turn impact their willingness to use mobile mental health interventions.

Standards

Ethical issues around standards, regulations, and guidelines – or rather the lack thereof – were discussed in 12 (57%) papers [16,44,51,52,53,56,57,59,60,62,63,65]. This is closely related to other ethical themes on privacy, validity, and harms. Gamble [57] considered that clinical standards on safety, efficacy, and privacy were lacking for mental health apps, with Graham et al. [51] highlighting the lack of established standards on the use of AI and other innovative technologies in healthcare settings. Some papers noted that many commercially available mental health technologies appeared to lack regulatory approval [16,60] with others highlighting the lack of regulations to protect the privacy and security of personal information [57,60,62]. Williams and Pykett [44] stated "given the current lack of a clear overarching regulatory framework for mental health apps, an important future research task will be to identify and shape the governance issues surrounding the use of predictive mental health vulnerabilities and risks, and biases in computational algorithms unpinning forthcoming apps" (p. 12).

Recommendations in the literature

Suggestions to address ethical issues related to governance included:

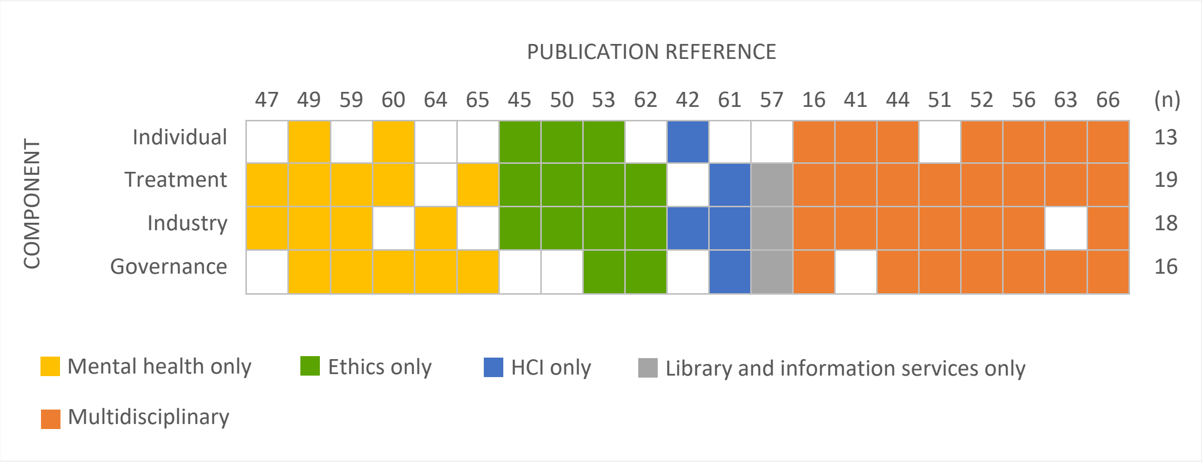
- Technologies should have easily accessible and understandable privacy policies [57,61] and information on privacy and data security presented within the technology itself [57]
- There should be clear and transparent information on what information is collected by mobile mental health technologies and how this is used, stored, shared, and protected [42,57,61,66]
- Healthcare professionals should ensure technologies have appropriate privacy and data security before use to protect patients' confidentiality [49,56,57] and should help patients to understand any risk to their privacy and personal health information from using mobile mental health technologies [49]
- Technologies should comply with regulatory approvals for the local jurisdiction where it is intended to be used [57,64] and appropriate standards where available [57]
- Developers should consider the benefits of anonymised mobile interfaces to protect users' privacy and confidentiality, along with any potential risks [57]
- Technologies should collect only what data is needed for intervention to be effective [64]
- Technologies should include controls on how and when information is collected and shared [42,59,66]
- Developers should consider where data should be stored (e.g., on the person's phone or in the cloud) and how to mitigate potential risks with these systems [64]
- There should be multidisciplinary involvement on the privacy and data security of mobile mental health technologies [66]
- Examples of measures to protect privacy and data security include firewalls for professional protection, encrypted transmission of data and communications, and use of secure channels of communication only [59]
- Continued development and oversight of ethical guidelines and an overarching regulatory framework for mobile mental health technologies [44,57,59,65], including how to select reputable and effective technologies [59] and guidelines on clinical practice and risk mitigation [65]

Multidisciplinary perspectives

The use of ethical frameworks varied across disciplines. Biomedical ethics was used by ethicists [50,53] and multidisciplinary authorships [16,51,52], while other single discipline papers applied more specialised frameworks. Where a framework was used, authors from mental health only disciplines applied professional codes of ethics [47,49], with these papers seemingly targeted to clinicians. Comparatively, HCI only [42] and library and information services only [57] papers used frameworks related to intervention acceptability and social informatics respectively (see Table 2 and Appendix B).

The most commonly discussed ethical issues across disciplines were related to the treatment (19/21, 91%) and the industry (18/21, 86%) (Figure 2). Papers from mental health only authors most often discussed ethical issues related to the treatment (5/6, 83%) and governance (5/6, 83%) while papers from ethics only authors most often discussed the treatment (4/4, 100%) and the industry (4/4, 100%). Five out of eight (63%) papers with multidisciplinary authors discussed all four components of mobile mental health compared with only one paper from mental health only (1/6, 17%) and ethics only authors (1/4, 25%), and no papers from HCI only or library and information services only.

Figure 2. Frequency of the 4 main components across papers with authors from a single discipline or multiple disciplines



PUBLICATION REFERENCE

COMPONENT	47	49	59	60	64	65	45	50	53	62	42	61	57	16	41	44	51	52	56	63	66	(n)
Individual		🟨		🟨			🟩	🟩	🟩		🟦			🟧	🟧	🟧		🟧	🟧	🟧	🟧	13
Treatment	🟨	🟨	🟨	🟨		🟨	🟩	🟩	🟩	🟩		🟦	▨	🟧	🟧	🟧	🟧	🟧	🟧	🟧	🟧	19
Industry	🟨	🟨	🟨		🟨		🟩	🟩	🟩	🟩	🟦	🟦	▨	🟧	🟧	🟧	🟧	🟧	🟧		🟧	18
Governance		🟨	🟨	🟨	🟨	🟨			🟩	🟩		🟦	▨	🟧		🟧	🟧	🟧	🟧	🟧	🟧	16

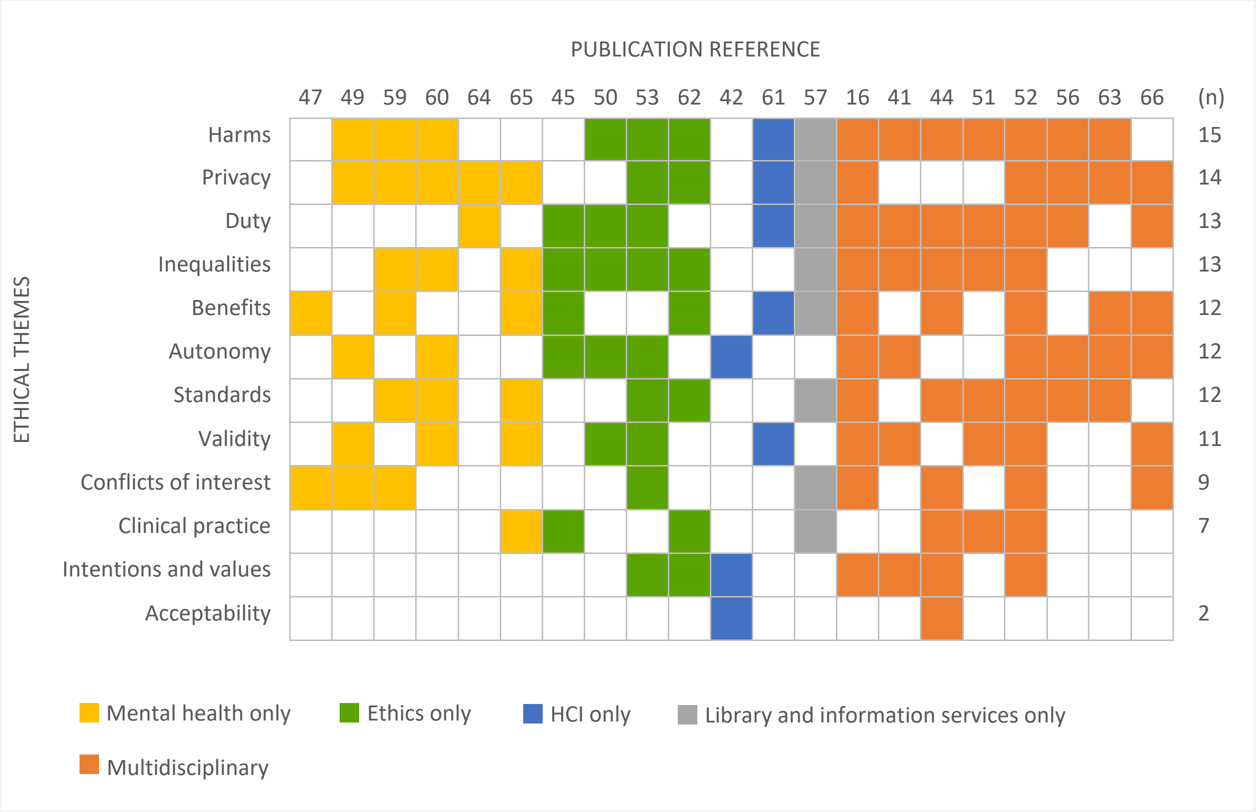
🟨 Mental health only 🟩 Ethics only 🟦 HCI only ▨ Library and information services only

🟧 Multidisciplinary

Issues related to harms, privacy, duty, and benefits were discussed across all disciplines (Figure 3). More ethical themes were discussed in multidisciplinary papers (mean 7.25, range 5 to 11) compared with papers written by authors of a single discipline, except for library and information services [57]. Papers with authors from an ethics only background discussed mean 6.5 themes (range 5 to 9), while mental health only authored papers discussed mean 4.5 themes (range 2 to 6) and HCI only papers discussed mean 4 themes (range 3 to 5).

None of the papers with only HCI authorship discussed inequalities, standards, conflicts of interest, or clinical practice. Conversely, none of the papers with only authors from mental health disciplines discussed intentions and values, or acceptability. The most commonly discussed ethical themes also varied by discipline (Figure 4). Multidisciplinary papers most often discussed ethical issues related to duty and harms, while mental health only and ethics only authored papers most often discussed issues around privacy and inequalities, respectively. This suggests that the ethical issues and perspectives presented differ depending on authors' backgrounds and areas of expertise and gives support for multidisciplinary teams and collaborations. However, these findings summarise a relatively small number of publications and should therefore be interpreted with this in mind.

Figure 3. Frequency of ethical themes across papers with authors from a single discipline or multiple disciplines



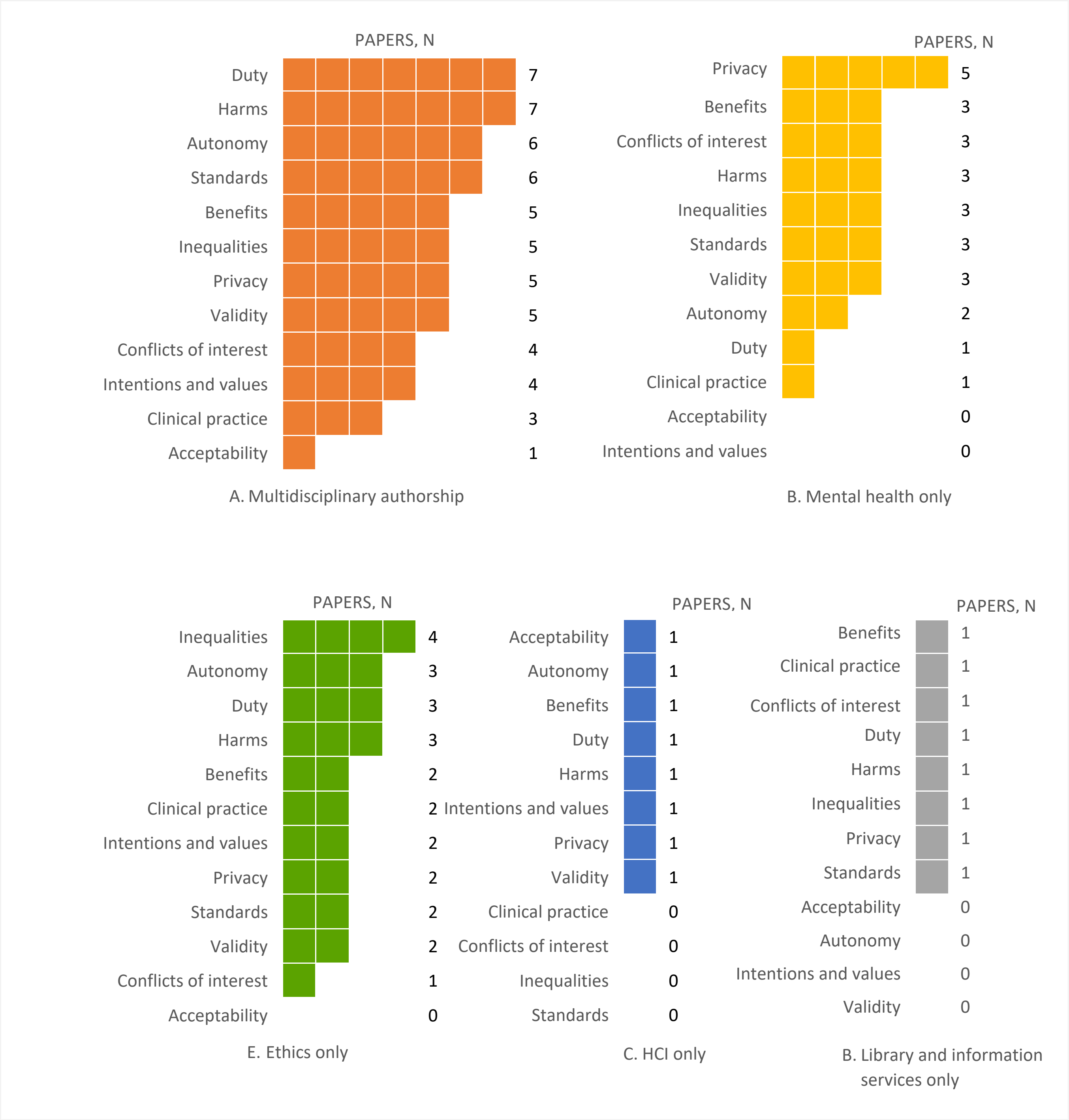
	47	49	59	60	64	65	45	50	53	62	42	61	57	16	41	44	51	52	56	63	66	(n)
Harms		🟨	🟨	🟨				🟩	🟩	🟩		🟦	⬛	🟧	🟧	🟧	🟧	🟧	🟧	🟧		15
Privacy		🟨	🟨	🟨	🟨	🟨			🟩	🟩		🟦	⬛	🟧				🟧	🟧	🟧	🟧	14
Duty					🟨		🟩	🟩	🟩			🟦	⬛	🟧	🟧	🟧	🟧	🟧	🟧		🟧	13
Inequalities			🟨	🟨		🟨	🟩	🟩	🟩	🟩			⬛	🟧	🟧	🟧	🟧	🟧				13
Benefits	🟨		🟨			🟨	🟩			🟩		🟦	⬛	🟧		🟧		🟧		🟧	🟧	12
Autonomy		🟨		🟨			🟩	🟩	🟩		🟦			🟧	🟧			🟧	🟧	🟧	🟧	12
Standards			🟨	🟨		🟨			🟩	🟩			⬛	🟧		🟧	🟧	🟧	🟧	🟧		12
Validity		🟨		🟨		🟨		🟩	🟩			🟦		🟧	🟧		🟧	🟧			🟧	11
Conflicts of interest	🟨	🟨	🟨						🟩				⬛	🟧		🟧		🟧			🟧	9
Clinical practice						🟨	🟩			🟩			⬛			🟧	🟧	🟧				7
Intentions and values									🟩	🟩	🟦			🟧	🟧	🟧		🟧				
Acceptability											🟦					🟧						2

🟨 Mental health only 🟩 Ethics only 🟦 HCI only ⬛ Library and information services only

🟧 Multidisciplinary

Differences in the discussion of ethical issues were seen not only in the ethical themes discussed but also the ethical issues considered within some themes. For example, 14 of the 21 papers discussed privacy but the ethical issues considered varied. All disciplines discussed potential ethical concerns with the sale or use of user data by third parties [47,49,52,57,61,62,66]. Most disciplines also discussed issues with data security [49,57,60,62,64,65,66] and confidentiality [16,47,56,57,60,62,65], with the exception of HCI only papers. Issues around privacy of personal information more broadly were discussed in papers by library and information services only [57], mental health only [49,64], and ethics only authors [53], with few mental health only [64] and multidisciplinary [66] papers also discussing issues with intrusion. More specific ethical issues around privacy policies were discussed in papers by mental health only [49], HCI only [61], and multidisciplinary [16] authors, but only mental health only [64,65] and multidisciplinary [16] papers considered how these issues may impact users' informed consent. Overall, privacy issues were most comprehensively discussed in papers from authors from mental health only backgrounds and more narrowly explored in the small sample of HCI only papers included in the review.

Figure 4. Frequency of ethical themes across papers with authors from a single discipline or multiple disciplines



Discussion

We conducted a scoping review of the literature on the ethics of mobile mental health with the aim of mapping these concepts across the different disciplines and sectors involved. To the best of our knowledge, this paper is the first to review the ethics of mobile mental health from a disciplinary perspective. We found 12 overarching themes that captured ethical issues and considerations for mobile mental health for depression and anxiety, namely: harms, privacy, duty, inequalities, autonomy, benefits, standards, validity, conflicts of interest, clinical practice, intentions and values, and acceptability. Overall, 71% of the publications discussed issues related to possible harms or safety [16,41,44,49–53,56,57,59–63]. Other commonly discussed concepts were privacy (67%) [16,49,52,53,56,57,59–66], duty (62%) [16,41,44,45,50–53,56,57,61,64,66], inequalities (62%) [16,41,44,45,50–53,57,59,60,62,65], benefits (57%) [16,44,45,47,52,57,59,61–63,65,66], autonomy (57%) [16,41,42,45,49,50,52,53,56,60,63,66], and standards (57%) [16,44,51–53,56,57,59,60,62,63,65]. Specific ethical considerations under each theme are presented in the results, with findings showing nuanced considerations based on the type of technology. For example, there were notable concerns with the impact of AI technologies in mental health on autonomy because of the automated nature of these technologies that could inhibit users' decision making and self-insight [41,50,60]. We discuss our findings below, starting with the overall evidence landscape followed by the disciplinary perspective of ethics and a systems approach to the ethics of mobile mental health.

The evidence landscape

Our search of the literature returned over 5,000 unique results, of which only 145 papers met the criteria for full-text screening. Moreover, only 21 of these full-text papers directly discussed the ethics of mobile mental health for common mental health disorders. Several excluded papers included only brief mention of ethical issues such as privacy or data security or discussed these issues without explicitly focussing on ethics [e.g., 67–69]. Some excluded papers also discussed digital mental health more broadly, at times in the context of digital health [e.g., 70,71]. These findings suggest that ethics continues to be underdiscussed within the vast literature of digital mental health, more often being a passing consideration than the primary focus of research. This presents a challenge for people seeking information on ethical issues and design, as these concepts may not be discussed holistically or explicitly. Readers may therefore need to infer ethical considerations implicitly mentioned in the literature, with authors sometimes presenting these as evaluation frameworks [72,73] rather than ethical frameworks.

Adding to this challenge is the poverty of empirical research on the ethics of mobile mental health, with most of the papers reviewed being commentaries or reviews. This likely reflects the challenge of conducting research into ethical issues, specifically how to ethically research ethics in mobile mental health. Our review included two qualitative studies [41,42]. Neither study specifically recruited people with common mental health disorders, instead including a general student population [42] and clinical staff [41]. Both studies sought to evaluate mobile mental health technology prototypes, with findings reporting participants' views of the technologies including potential ethical issues and considerations. Explorations of the ethics of mobile mental health in the wild were less direct, instead adopting content [61] or ethical [16] analyses of the commercial app marketplace. In doing so, these studies assessed the technology descriptions and features of mobile mental health technologies with note of potential ethical concerns but without user involvement. Such approaches mitigate the risks of exposing people with mental health disorders to potentially triggering or harmful situations but are limited by their need to infer how these findings may apply to the indication for use. In an attempt to better overcome these shortcomings, a more recent study by Bowie-DaBreo [35] explored ethical issues of direct-to-consumer apps for depression using qualitative analysis of user reviews. A strength of this study was capturing users' voice in the thematic analysis of ethical issues, but this approach was limited by its use of secondary data. The evidence landscape is therefore limited by the preponderance of indirect methods to investigate the ethics of mobile mental health and the predominance of expert opinion without empirical investigation. This highlights a pressing need in the field of mobile mental health to consider how best to empirically and ethically research and evaluate the ethics of mobile mental health technologies in the wild.

Findings from this scoping review also demonstrated the need for more research into the ethical issues and considerations for specific mental health conditions. Mental health technologies will likely share many of the same ethical considerations regardless of the specific type of technology or target condition. Most papers included in the review discussed issues related to harms [16,41,44,49–53,56,57,59–63], privacy [16,49,52,53,56,57,59–66], duty [16,41,44,45,50–53,56,57,61,64,66], and inequalities [16,41,44,45,50–53,57,59,60,62,65]. Yet, as our review shows, there is likely to be additional ethical considerations related to the target condition or technology type. For example, papers discussing digital phenotyping [42] and AI depression detectors [50,52,53] raise notable concerns with the unconsented tracking and labelling of mental health problems. This is unlikely to be an issue for technologies that track patient reported outcomes. Similarly, we expect some ethical considerations for technologies for common mental health disorders to differ from those for severe mental illness or wellbeing [35]. It is therefore important for authors to clearly report the population or disorder of interest when discussing the ethics of mobile mental health, with consideration of how this may differ from other mental health disorders. Designers and users of mobile mental health technologies should also consider ethics in the broader class of technologies as well as the specific technology and condition of interest.

Disciplinary perspectives

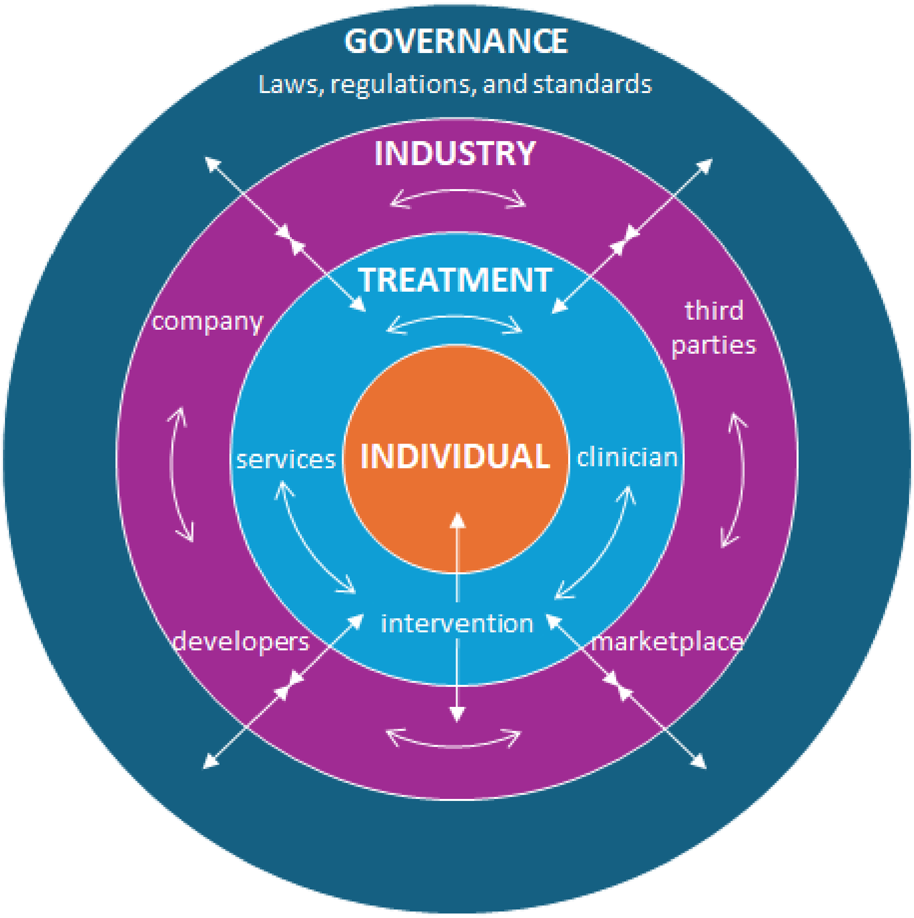
A key objective of this review was to understand how the pertinent ethical issues and concepts in mobile mental health varied across disciplines and sectors. The perspective of authors when evaluating or exploring ethical concepts is notable because this may impact the ethical themes and issues considered and prioritised. This in turn may influence the recommendations and guidance for the design and implementation of digital mental health. Of the papers reviewed, 61% had at least one author from a mental health background [16,44,47,49,51,52,56,59,60,63–66], while 25% had at least one HCI author [16,41,42,61,63,66] and 24% had at least one author with a background in ethics [45,50,52,53,62]. Authors from other disciplines were largely underrepresented in the literature. This is notable considering the variations in ethical codes and standards across disciplines. For example, Bowie-DaBreo et al. [27] found that engineering professional codes of ethics prioritised benefit and avoidance of harm and emphasised professional reputability and responsibility. While our review included only one paper with an author from an engineering background [51], its discussion of ethical issues relating to clinical practice, duty, harms, inequalities, standards, and validity seem to align with these ethical codes. Similarly, mental health professional codes of ethics were shown to focus on client care and welfare, duty of care, and competence [27], as reflected in papers from mental health only authorship which focused on issues related to privacy and confidentiality, benefits, conflicts of interest, harms, inequalities, standards, and validity. The literature on the ethics of mobile mental health would therefore benefit from the involvement of authors from disciplines across the field in order to capture ethical perspectives that may not be considered by some disciplines. Moreover, our findings show benefit of multidisciplinary authorship for more comprehensive ethical evaluations and considerations. Yet, only eight of the 21 papers reviewed included authors from more than one discipline [16,41,44,51,52,56,63,66] highlighting the continued need greater multidisciplinary collaboration in mobile mental health [34].

This is supported by our finding that papers from some disciplines did not consider specific ethical themes or issues. For example, papers from only authors with a mental health background did not discuss ethical issues related to intentions and values or acceptability while HCI only authored papers did not discuss clinical practice, conflicts of interest, inequalities, or standards. Differences in perceptions and prioritisation of ethical concepts or values is likely to be reflected in the design, use, and evaluation of mobile mental health technologies. Moreover, how well a technology aligns with these ethical values and norms may also impact its acceptability and adoption [74]. Our findings show that author discipline influenced their choice of ethical framework to evaluate mobile mental health, with ethicists and multidisciplinary author teams tending to use the principles of biomedical ethics [16,50–53], while mental health only disciplines applied professional codes of ethics [47,49] and HCI only [42] and library and information services only [57] papers used frameworks related to intervention acceptability and social informatics respectively. These differences in the ethical framework applied are likely to have affected the ethical lens used in the respective papers and the ethical themes discussed. But while the frameworks may have differed in their ethical focus and approach, it is notable that many of the frameworks captured in this review included similar principles, specifically benefits, harms, and autonomy. This is not surprising considering that many professional codes of ethics [e.g., 2,3,27] and discussion of medical ethics are grounded in principlism, specifically Beauchamp and Childress's principles of biomedical ethics [43]. The ethical principles of beneficence, nonmaleficence, respect for autonomy, and justice are pervasive throughout discussions and evaluations of the ethics of mobile mental, as reflected in our finding that more than half of the papers reviewed discussed at least one ethical theme related to these principles. The most common ethical theme across all papers was harms followed by privacy, duty, inequalities, benefits, autonomy, and standards. The principle of biomedical ethics and related frameworks provide applied ethical theories to discuss ethical issues and conflicts in mobile mental health in a way that is easy to understand and contextualise. But as our findings show, it may fail to capture more abstract ethical ideas such as social and political concepts presented in social informatics [57] or ecosophy [44,55] or the broader explorations of ethical experiences and human flourishing in virtue ethics [41]. There is a risk that failure to consider ethics outside the most commonly applied frameworks may confine the discussion and consideration of the ethics of mobile mental health to preexisting ideas in this area. We therefore encourage authors to not limit their approach and conceptualisation of ethics but rather to be expansive in their ideas, discussions and the frameworks used.

A systems approach to the ethics of mobile mental health

Regardless of the disciplinary perspective or ethical framework used, our findings suggest that ethical themes and issues centred around four main components of mobile mental health: the individual, the treatment, the industry, and governance. These components and their related ethical themes are interrelated, akin to systems in systems theories such as socio-ecological models [75]. These perspectives emphasise the interrelations and connections between different systems. This is seen in ecological models that present the interplay between the individual, directly impactful institutions, interconnections between these institutions, and broader social and cultural factors. At the centre of these models is the individual, with theories seeking to explore the direct and indirect impact of these systems. Systems thinking is also reflected in HCI, with a system defined as a set of interacting units and the relationship between these units [76]. We draw similarities from these models and the discussion on the ethics of mobile mental health to propose a system approach to considering the ethics of mobile mental health (Figure 5). At the centre of these ethical conceptualisations or evaluations lies the individual, that is the person with lived experience of common mental health disorders. They are the primary consideration for avoiding harm, producing benefits, and respecting autonomy. Yet they are less directly involved in the discussion on the ethics of the technologies designed for their use. While almost half of the papers reviewed had no clearly intended audience, the remaining were seemingly targeted towards clinicians, developers, or multidisciplinary professionals. None of the papers appeared to target people with lived experience of mental health problems – 'the individual' – as the reader. In the reviewed papers, the individual was presented as being directly involved in ethical themes of acceptability and autonomy, that is, their attitudes and acceptance of mobile mental health and their free choice to use or not use these technologies. The ethical issues in the individual system are interrelated to the treatment, which includes components such as clinicians, healthcare services, and the intervention itself. The components themselves are interrelated but also have relationships with the individual as seen in the ethical issues discussed, namely related to harms, benefits, clinical practice, validity, and inequalities. Unlike the issues in the individual system, these themes discuss issues that happen to the individual, whereby they are acted upon rather than being the actor. In this sense, the individual is conceived as a passive actor in these considerations. This mirrors ethical issues of paternalism flagged by Laacke et al. [52] and Tonning et al. [63] and shows a need for more research and discourse including the voices and experiences of people with lived experience. Without this, there is a risk that ethical ideas and theories do not adequately capture real-world experiences of people most affected by the use of these technologies.

Figure 5. Systems in ethical mobile mental health



This is even more apparent when considering ethical issues related to the industry and governance. Our findings show that ethical themes seemingly related to the industry tended to focus on intentions and values, duty, and conflicts of interest. As with the treatment system, the industry system is proposed to include many interconnected components such as developers, third parties, and the wider technology marketplace. The ethical issues within this system are interrelated with issues in the treatment system and the individual system. For example, companies or technology developers have a duty to provide transparent and accurate information on their technologies [16,45,50,52,56,64], which in turn can impact the perceived validity of the treatment and their use in clinical practice, and the individual's ability for truly informed consent before use. Overarching these systems is the broadest level of governance, that is the standards and regulations in the field. Ethical issues in this system impact all aspects of mobile mental health. This is clearly seen with issues related to privacy, which have clear implications and interrelations with the commercialisation of mobile mental health technologies (the industry), the confidentiality of patient information in clinical practice (the treatment), and the individual's right to privacy and freedom to choose how their personal information is used and stored.

We consider there to be several benefits to adopting a systems approach to the ethics of mobile mental health. Firstly, it clearly captures the key systems in ethical mobile mental health, their interconnected components, and the potential ethical issues in each system. By doing so, it encourages further thought and research into other ethical issues in these systems and the interrelations between these themes and issues. Moreover, it highlights the key actors that should be included in further research, discussions, and development of ethical frameworks and ethical design. We therefore encourage additional research to explore the validity of this approach for conceptualising and discussing the ethics of mobile mental health, including any additional systems and the utility of this approach in fostering further understanding and application of ethics in field. We also encourage multidisciplinary partnerships and collaborations in not only evaluations of the ethics of mobile mental health but the design, evaluation, and implementation of these technologies more broadly. Our findings suggest that multidisciplinary perspectives are more likely to consider the range of ethical issues across the lifespan of mobile mental health – from acceptability, technology and intervention design, regulation, informed choice, and clinical use and outcomes. It is therefore important for more transdisciplinary discussions and frameworks to comprehensively evaluate and guide ethical mobile mental health.

Limitations

This review provided a multidisciplinary perspective of the ethics of mobile mental health and a systems approach for conceptualising ethical themes and issues. We conducted a broad search of the literature but were limited by the relatively small number of papers that directly discussed the ethics of mobile mental health for common mental health disorders. This may have limited the findings and discussion and it is possible that other important ethical issues were presented in the excluded papers. Despite this, the reviewed papers presented detailed discussion of the ethical themes and issues in the field, allowing for the mapping and synthesising the literature on the ethics of mobile mental health across sectors and disciplines. Further research may benefit from expanding the scope to explore these concepts in mobile mental health for complex or severe mental health conditions or digital mental health interventions more broadly.

Another limitation of this review, and the literature on the ethics of mobile mental health more broadly, is the high proportion of commentary papers and general reviews. This may affect the quality of the evidence base, with increased risk of bias in the ethical issues selected and how these are reported. Commentary papers can also be limited by their consideration of hypothetical ethical issues, which may or may not manifest in real-world use of mobile mental health technologies. While it is important for the literature to explore the potential risks and ethical conflicts in the field, there is also a need for more research showing the frequency and real-world presentation of these issues in order to ensure the validity and applicability of these frameworks in real-world settings.

Conclusions

This study advanced the literature on the ethics of mobile mental health by providing a detailed review of how these concepts are discussed across the different disciplines in the field. It provided a comprehensive overview of the evidence landscape and the ethical issues in mobile mental health for common mental health disorders. Our findings showed that multidisciplinary papers provided more comprehensive ethical reviews and evaluations than papers with all authors from a single discipline. Discussions on the ethics of mobile mental health centred on four main components: the individual, the treatment, the industry, and governance. We propose a systems approach that can be used to better consider the key systems involved, their interconnections, and implications. Our findings also showed a need for more empirical research on the ethics of mobile mental health beyond commentaries and reviews, including greater involvement of potential users and people with lived experience. We conclude by encouraging more multidisciplinary involvement in the design and research of mobile mental health in order to increase ethical understanding and practices.

Acknowledgements

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Conflicts of interest

None declared.

Abbreviations

AI: artificial intelligence
HCI: human computer interaction
MHRA: Medicines and Healthcare products Regulatory Agency
NHS: National Health Service
NICE: National Institute for Health and Care Excellence

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Appendix A. PubMed search strategy which was adapted for other databases

Search	Search String
S1	mental health[MeSH] OR mental health[tiab]
S2	mental disorders[MeSH] OR mental disorder*[tiab]
S3	emotion* disorder*[tiab]
S4	mood disorder*[tiab]
S5	affective disorder*[tiab]
S6	S1 OR S2 OR S3 OR S4 OR S5
S7	ethics[MeSH] OR ethic*[tiab] OR bioethics[tiab]
S8	morals[MeSH] OR moral*[tiab]
S9	policy[MeSH] OR policy[tiab] OR regulation*[tiab] OR guideline*[tiab] OR framework*[tiab]
S10	nonmaleficence[tiab] OR non-maleficence[tiab]
S11	beneficence[tiab]
S12	justice[tiab]
S13	autonomy[tiab]
S14	best practice*[tiab]
S15	S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14
S16	mobile mental health[tiab] OR mobile-based intervention[tiab]
S17	mobile health[tiab] OR mHealth[tiab] OR m-Health[tiab]
S18	digital mental health[tiab]
S19	digital health[tiab] OR digital medicine[tiab] OR digital psychiatry[tiab]
S20	telemedicine[MeSH] OR telemedicine[tiab] OR telepsychiatry[tiab] OR telehealth[tiab] OR telepsychotherapy[tiab]
S21	mobile applications[MeSH] OR mobile application*[tiab] OR app[tiab] OR apps[tiab]
S22	computers, handheld[MeSH] OR smartphone[tiab] OR cell phone[MeSH] OR cell phone[tiab] OR mobile phone[tiab]
S23	wearable electronic devices[MeSH] OR wearable*[tiab]
S24	monitoring, ambulatory[MeSH] OR ambulatory monitoring[tiab] OR passive sensing[tiab]
S25	digital phenotyping[tiab]
S26	ecological momentary assessment[MeSH] OR ecological momentary assessment[tiab]
S27	biosensing techniques[MeSH] OR sensors[tiab] OR biosensors[tiab]
S28	S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27
S29	S6 AND S15 AND S28

Appendix B. Details of papers included in the review

Publication [reference]	Disciplines	Location	Target audience	Framework	Ethical themes, n
Alvarado & Morar (2021) [50]	Ethics	US	General/unclear	• Biomedical ethics • Health Related Digital Autonomy Framework	n=5 out of 12 themes The individual (1/2) • Autonomy The treatment (3/5) • Harms • Inequalities • Validity The industry (1/3) • Duty Governance (0/2)
Barry et al. (2017) [41]	HCI Health	Ireland UK	Developers	• Ethical pluralism • Virtue ethics	n=6 out of 12 themes The individual (1/2) • Autonomy The treatment (3/5) • Harms • Inequalities • Validity The industry (2/3) • Duty • Intentions and values Governance (0/2)
Bowie-DaBreo et al. (2020) [16]	HCI Health Mental health	UK	Developers	• APA ethics code • Biomedical ethics	n=10 out of 12 themes The individual (1/2) • Autonomy The treatment (4/5) • Benefits • Harms • Inequalities • Validity The industry (3/3) • Conflicts of interest • Duty • Intentions and values Governance (2/2) • Privacy • Standards
Ebert et al. (2018) [59]	Mental health	Belgium Cyprus Denmark Germany Italy Luxembourg Norway	General/unclear	None	n=6 out of 12 themes The individual (0/2) The treatment (3/5) • Benefits • Harms • Inequalities The industry (1/3) • Conflicts of interest Governance (2/2) • Privacy • Standards

Gamble (2020) [57]	Library and information science	US	General/unclear	• Social informatics	n=8 out of 12 themes The individual (0/2) The treatment (4/5) • Benefits • Clinical practice • Harms • Inequalities The industry (2/3) • Conflicts of interest • Duty Governance (2/2) • Privacy • Standards
Gillett & Saunders (2019) [60]	Mental health	UK	General/unclear	None	n=6 out of 12 themes The individual (1/2) • Autonomy The treatment (3/5) • Harms • Inequalities • Validity The industry (0/3) Governance (2/2) • Privacy • Standards
Graham et al. (2019) [51]	Engineering Health Mental health	US	Multidisciplinary	• Biomedical ethics	n=6 out of 12 themes The individual (0/2) The treatment (4/5) • Clinical practice • Harms • Inequalities • Validity The industry (1/3) • Duty Governance (1/2) • Standards
Insel (2018) [64]	Mental health	US	Multidisciplinary	None	n=2 out of 12 themes The individual (0/2) The treatment (0/5) The industry (1/3) • Duty Governance (1/2) • Privacy
Khanna & Carper (2022) [65]	Mental health	US	General/unclear	None	n=6 out of 12 themes The individual (0/2) The treatment (4/5) • Benefits • Clinical practice • Inequalities • Validity The industry (0/3) Governance (2/2) • Privacy • Standards

Laacke et al. (2021) [52]	Ethics Mental health	Germany	General/unclear	• Biomedical ethics • Health Related Digital Autonomy Framework	n=11 out of 12 themes The individual (1/2) • Autonomy The treatment (5/5) • Benefits • Clinical practice • Harms • Inequalities • Validity The industry (3/3) • Conflicts of interest • Duty • Intentions and values Governance (2/2) • Privacy • Standards
Liem (2020) [56]	Computer science Health Mental health	Australia China Indonesia US	General/unclear	• Evaluation of Digital Health Application	n=5 out of 12 themes The individual (1/2) • Autonomy The treatment (1/5) • Harms The industry (1/3) • Duty Governance (2/2) • Privacy • Standards
Ploug & Holm (2021) [53]	Ethics	Denmark Norway	General/unclear	• Biomedical ethics • Health Related Digital Autonomy Framework	n=9 out of 12 themes The individual (1/2) • Autonomy The treatment (3/5) • Harms • Inequalities • Validity The industry (3/3) • Conflicts of interest • Duty • Intentions and values Governance (2/2) • Privacy • Standards
Qu et al. (2020) [61]	HCI	Ireland UK		None	n=5 out of 12 themes The individual (0/2) The treatment (3/5) • Benefits • Harms • Validity The industry (1/3) • Duty Governance (1/2) • Privacy
Rooksby et al. (2019) [42]	HCI	UK	Developers	• Theoretical framework of acceptability	n=3 out of 12 themes The individual (2/2) • Autonomy • Acceptability The treatment (0/5)

					The industry (1/3) • Intentions and values Governance (0/2)
Rubeis (2020) [45]	Ethics	Germany	Multidisciplinary	• 3-ACEs	n=5 out of 12 themes The individual (1/2) • Autonomy The treatment (3/5) • Benefits • Clinical practice • Inequalities The industry (1/3) • Duty Governance (0/2)
Slavich et al. (2019) [66]	HCI Mental health	US	General/unclear	None	n=6 out of 12 themes The individual (1/2) • Autonomy The treatment (2/5) • Benefits • Validity The industry (2/3) • Conflicts of interest • Duty Governance (1/2) • Privacy
Sussman et al. (2018) [47]	Mental health	US	Clinicians	• American Academy of Child and Adolescent Psychiatry (AACAP) code of ethics	n=2 out of 12 themes The individual (0/2) The treatment (1/5) • Benefits The industry (1/3) • Conflicts of interest Governance (0/2)
Tekin (2020) [62]	Ethics	US	Multidisciplinary	None	n=7 out of 12 themes The individual (0/2) The treatment (4/5) • Benefits • Clinical practice • Harms • Inequalities The industry (1/3) • Intentions and values Governance (2/2) • Privacy • Standards
Tonning et al. (2019) [63]	HCI Mental health	Denmark	Researchers	None	n=5 out of 12 themes The individual (1/2) • Autonomy The treatment (2/5) • Benefits • Harms The industry (0/3) Governance (2/2) • Privacy • Standards

Wang et al. (2020) [49]	Mental health	US	Clinicians	• APA ethics code	n=5 out of 12 themes The individual (1/2) • Autonomy The treatment (2/5) • Harms • Validity The industry (1/3) • Conflicts of interest Governance (1/2) • Privacy
Williams & Pykett (2022) [44]	Mental health Social politics	UK	General/unclear	• Critical ecological framework • Ecosophy	n=9 out of 12 themes The individual (1/2) • Acceptability The treatment (4/5) • Benefits • Clinical practice • Harms • Inequalities The industry (3/3) • Conflicts of interest • Duty • Intentions and values Governance (1/2) • Standards

4 Ethical Issues in Mobile Mental Health Apps for Depression

Chapter 3 presented an overview of the ethics of mobile mental health based on existing literature and frameworks. As demonstrated in the scoping review, much of the literature in this area consists of expert commentaries and conjectures of potential ethical issues and ideas, with limited empirical evidence. It was therefore important to better understand how these concepts presented in the real-world and the ethical experiences of people who used mobile mental health. This chapter presents three papers exploring ethical issues and experiences of commercial apps for depression sampled from the main app marketplaces. I chose apps for depression for these reviews given the high prevalence and impact of this disorder. Apps for depression have also been recommended as a treatment option for people with depression, making a review of the offering in this space especially relevant.

The first paper in this chapter is titled ‘Evaluation of treatment descriptions and alignment with clinical guidance of apps for depression on app stores: systematic search and content analysis’. This study explored concerns with the evidence-base and effectiveness of mobile mental health apps by evaluating how well commercial apps for depression aligned with NICE recommended guidelines and evidence-based approaches. The second paper titled ‘A call for responsible innovation in mobile mental health: content analysis of the depression app marketplace’ built on this by utilising principlism and professional ethics codes to evaluate ethical issues in the depression app marketplace. The final paper titled ‘User perspectives and ethical experiences of apps for depression: a qualitative analysis of user reviews’ advanced these findings further by evaluating user views and ethical experiences of apps for depression based on their user reviews. This paper aimed to not only investigate the presentation of ethical issues in the wild, but to also capture the user voice in the discussion on ethics. All papers in this chapter have been published in peer-reviewed journals.

4.1 Evaluation of Treatment Descriptions and Alignment with Clinical Guidance of Apps for Depression on App Stores: Systematic Search and Content Analysis

Bowie-DaBreo, D., Sünram-Lea, S., Sas, C., & Iles-Smith, H. (2020). Evaluation of treatment descriptions and alignment with clinical guidance of apps for depression on app stores: systematic search and content analysis. *JMIR Formative Research, 4*(11): e14988. https://doi.org/10.2196/14988

Original Paper

Evaluation of Treatment Descriptions and Alignment With Clinical Guidance of Apps for Depression on App Stores: Systematic Search and Content Analysis

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Abstract

Background: The use of apps for the treatment of depression shows great promise. However, there is uncertainty regarding the alignment of publicly available apps for depression with clinical guidance, their treatment fidelity and evidence base, and their overall safety.

Objective: Built on previous analyses and reviews, this study aims to explore the treatment and safety issues of publicly available apps for depression.

Methods: We conducted a content analysis of apps for depression in the 2 main UK app stores (Google Play and Apple App Store). App store listings were analyzed for intervention content, treatment fidelity, and fit with the National Institute for Health and Care Excellence (NICE) guidelines for the treatment of depression in adults.

Results: A total of 353 apps for depression were included in the review. App descriptions reported the use of 20 treatment approaches and 37 treatment strategies. Many apps used transdiagnostic (155/353, 43.9%) and multitheoretical interventions to treat multiple disorders including depression. Although many interventions appeared to be evidence-informed, there were issues with treatment fidelity, research evidence, and fit with clinical guidelines. None of the apps fully aligned with the NICE guidelines for depression.

Conclusions: App developers have adopted many evidence-informed treatments in their interventions; however, more work is needed to improve clinical validity, treatment fidelity, and the safety of apps. We urge developers to consult relevant guidelines and standards, and to engage in reflective questioning on treatment and safety to address these issues and to improve treatment content and intervention design.

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KEYWORDS

mobile mental health; mHealth; mobile apps; depression; clinical guidance; NICE guidelines; NHS; safety; ethics; content analysis

Introduction

Management and Treatment of Depression

Depression is an affective disorder characterized by persistent low mood; loss of interest or pleasure; increased negative thoughts and feelings; and associated emotional, cognitive, physical, and behavioral difficulties [1-3]. Within the United Kingdom, the National Institute for Health and Care Excellence (NICE) seeks to improve outcomes for people using the National Health Service (NHS) and other public health services through the provision of evidence-based guidance, quality standards, and performance metrics. NICE guidelines for the treatment and management of depression in adults [4,5] recommend a stepped care approach of clinical and cost-effective interventions. Following early intervention through screening, assessment, and psychoeducation, first-line treatments for subthreshold or mild to moderate depression include low-intensity psychosocial interventions, specifically guided self-help based on cognitive behavioral therapy (CBT) or group physical activity programs. Persons with less severe depression who decline or do not respond well to these interventions should be offered high-intensity psychological interventions—specifically CBT, interpersonal therapy (IPT), behavioral activation, or behavioral couples therapy—or antidepressants. If declined, individuals may be offered counseling or short-term psychodynamic psychotherapy.

For moderate to severe depression, NICE advises a combination of antidepressants and high-intensity interventions (CBT or IPT), with relapse prevention consisting of antidepressants and CBT or mindfulness-based cognitive therapy (MBCT). Complex and severe cases of depression receive the highest level of care, which may include multidisciplinary care, specialist mental health services, and crisis resolution.

Network meta-analysis of clinical evidence for the treatment of depression in adults found self-help with support to be more effective than psychoeducation and self-help without support [4]. These self-help interventions included (from better to worse outcomes): computerized psychodynamic therapy with support, computerized CBT with support, computerized behavioral activation with support, computerized CBT without support, psychoeducational website, and computerized mindfulness intervention. Although the 2018 NICE draft guidelines did not specifically recommend mobile apps, their 2019 guidelines for depression in children and young people [6] advised the use of digital CBT in cases of mild depression. This included CBT delivered via a computer, tablet, or phone.

Building on this guidance, NHS England and NICE developed a digitally enabled therapy assessment program aimed at evaluating the use of digital therapy products in the NHS Improving Access to Psychological Therapies (IAPT) services [7,8]. The program assessed 14 digitally enabled therapies (ie, psychological interventions delivered on the web or through apps with the support of a therapist). Of these, 6 targeted depression in adults [9-15]. Digital therapies were assessed based on 4 criteria: content, technical standards, clinical effectiveness, and cost impact. In line with NICE guidance, content assessment of digital therapies for depression evaluated adherence to CBT and fit within a blended care model. Following expert evaluations, only 3 digital therapies were recommended for trialed use within IAPT services [11,12,14]. For those not recommended, treatment issues included misalignment with the therapist-guided model of care [10], poor user and treatment experiences [13], and incomplete treatment content for depression because of the use of a transdiagnostic approach [15]. Only one of the therapies offered a web- and app-based program [12], with others being solely web-based.

Mobile Apps for Depression

The use of apps for the management of depression has shown promise in providing accessible and low-cost mental health interventions. Randomized controlled trials and reviews of apps for depression have reported significant reductions in depressive symptoms [16-22] and improvements in well-being [23]. There is evidence of the use of apps for assessment and psychoeducation [24], symptom tracking or mood monitoring [19,24], cognitive training and problem solving [16], and a range of treatment approaches, including CBT [19,22], behavioral therapy (BT) and dialectical behavior therapy (DBT) [22], mindfulness [19], and transdiagnostic approaches [17].

Although highlighting the potential of mobile mental health, research cautioned that findings did not reflect apps available to the public through the app marketplace. Torous et al [22] showed that only one-third of apps for depression reviewed in the literature were available for download in app stores, with research reviews of the app marketplace uncovering a worrying lack of evidence for most apps [25-27].

Content analyses and marketplace reviews of publicly available apps found hundreds of apps marketed for depression. Given the overwhelming number of apps, reviewers often limited analyses to a subset [27-30] such as apps using specific approaches [25,31,32]. The most common functionalities of apps for depression included psychoeducation [25,27,29-31], assessment [25,28,29,31], and symptom management [25,30,31]. Approximately one-third of apps for depression provided therapeutic treatment [31] or interactive interventions [29]. CBT apps for depression incorporated several strategies but were criticized for overlooking treatment processes such as challenging core beliefs and conceptualization in favor of education, monitoring and tracking, and thought records [24,30]. Overall, the authors commented that although some apps seemed to be evidence informed, reflecting some theoretical principles and strategies, the apps did not demonstrate high fidelity to evidence-based treatments such as CBT or BT [25,32] and generally lacked evidence supporting use and efficacy [21,23,25,27].

Reviews of publicly available apps for depression also highlighted insufficiencies in the treatment and safety information provided, including limited disclaimers [27], limited encouragement for users to seek in-person care [29], and inadequate reporting of affiliations or expert involvement [31,32]. Reviews of the ethics of mobile mental health [33,34] have also raised concerns with acceptance [35], risks and safety of apps [36-47], and the poverty of evidence regarding benefits and outcomes [36-40,42-46,48,49]. Therefore, there is uncertainty as to how well apps for depression match existing clinical guidelines and recommendations, their treatment fidelity (ie, adherence to components of a treatment orientation) and evidence base, and their safety for use with or without support.

Overview of Study

This study builds on previous analyses and reviews to explore treatment descriptions of publicly available apps for depression and their alignment with clinical guidance as conveyed in app store listings. The decision to review app listings rather than downloaded apps reflects the lack of a comprehensive overview of all treatment options marketed to the public through the marketplace for apps for depression. Guided by NICE guidelines and literature on the ethics and safety of mobile mental health, we conducted content analysis of apps for depression listings in the UK app marketplace. This study aims to answer the following questions: (1) What treatment approaches and strategies are named or described in app listings of apps for depression? (2) Are treatment fidelity and evidence-informed development evident in descriptions of apps for depression? (3) Do descriptions of apps for depression reflect NICE guidelines for the treatment and management of depression? We hope that this study will advance research and discussion on the treatment content and safety of publicly available apps for depression, in particular their marketing to the public, fit with clinical guidance, and discrepancies between public health digital therapies and direct-to-consumer products. In doing so, we seek to promote improved standards and best practices in the design and marketing of mental health apps.

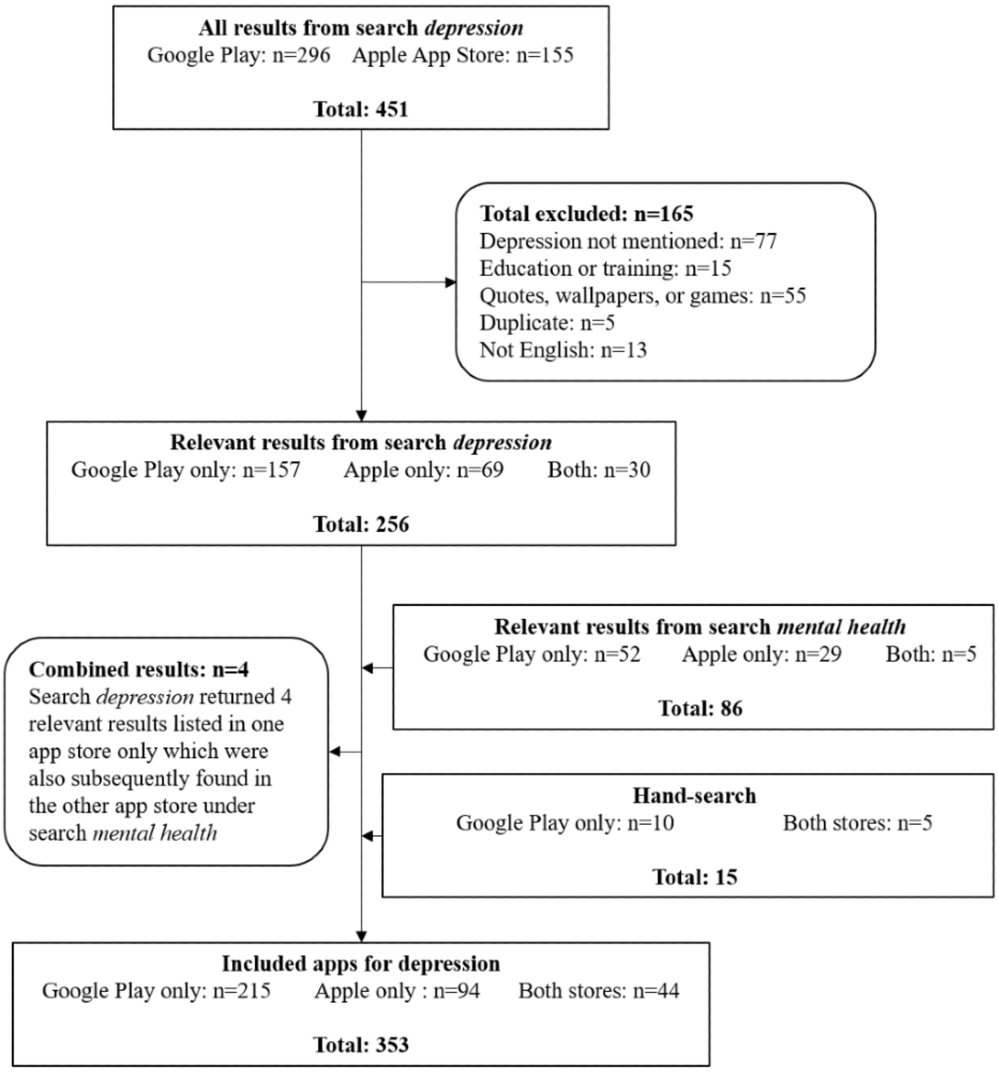
Methods

Sampling Methods

App search and data collection was conducted between October and November 2018, guided by methods used by Shen et al [31] and Stawarz et al [32]. The first step involved search of apps in the 2 main UK app stores: Google Play and Apple App Store. The initial search was performed using the search term *depression*. For the review, apps for depression were defined as apps with app store listings mentioning depression or depressive symptoms. Apps were included in the review if they met the following criteria: (1) app description included terms *depression*, *low mood* or *mood disorder*, *mood management*, *negative thoughts*, or *distress* and (2) app listing was in English. Apps were excluded if they (1) did not mention depression or depressive symptoms, (2) were for professional training, (3) only provided quotes or wallpapers, or (4) were duplicates, that is, copies of an app listed within the same app store. Duplicates did not include free and paid versions of apps or apps listed in both stores; in these cases, all relevant apps were included in the review. Apps were also not excluded if they targeted another mental health problem (eg, anxiety) once they mentioned depression or depressive symptoms. This initial search returned 451 apps (296 in Google Play and 155 in Apple App Store). Of these, 256 unique apps met the inclusion criteria (Figure 1).

A second search of the same app stores was performed using the term *mental health* aimed at detecting apps for depression that were not returned in the primary search. Finally, a hand search of the same app stores for apps for depression that were reported in previous research but not returned in the searches was performed. These searches yielded an additional 97 eligible apps. This resulted in a total of 353 unique apps for depression being included in the analysis (Multimedia Appendix 1).

Figure 1. Sampling flowchart.



Content Analysis

This study aims to explore treatment descriptions and fit with clinical guidance of apps for depression, as evident in app store listings and websites. Before the review, a list of variables was compiled to extract data on app information, developer information, treatment information, and usage. Data were initially extracted from app listings and websites verbatim or using yes or no coding to indicate the presence or absence of variables. Throughout this process, coding was developed iteratively as treatment information emerged. Treatment codes were informed by NICE guidelines [4-6], literature on the treatment of depression [50,51], and app reviews [25,29]. Final coding is presented in Multimedia Appendix 2. Data extraction and coding were led by the first author and revised through group discussion until consensus was reached among all authors.

Descriptive statistics of the app data were computed using SPSS version 25. Categorical variables were recoded numerically before analysis. Spearman rank correlation coefficient was used to explore associations within- and between-treatment approaches and treatment strategies as part of the analysis of treatment fidelity and evidence-informed interventions. Chi-square tests were also performed to determine associations between developer type and treatment variables.

Results

Treatment Descriptions of Apps for Depression

App store descriptions typically touted the suitability and benefits of apps for depression or related difficulties. The findings indicate that 28.3% (100/353) of apps targeted solely depression, with most apps targeting depression alongside other difficulties, notably anxiety and stress (Table 1). Just under one-half (174/353, 49.3%) of all apps targeted multiple (4 or more) disorders.

Less than one-third of apps (108/353, 30.6%) offered a disorder-specific intervention, that is, an intervention designed to treat a single mental health problem (eg, depression), whereas 43.9% (155/353) of apps described transdiagnostic interventions treating multiple disorders using the same treatment content. A further 25.5% (90/353) of apps reported treatment of multiple disorders with varied content for each.

In this analysis, the treatment approach was defined as theoretical or treatment orientation such as CBT, whereas treatment strategies were the techniques employed in the delivery of the intervention, such as cognitive reappraisal. Our review identified 20 treatment approaches and 37 treatment strategies. For some apps, approaches (36/353, 10.2%) and strategies (115/353, 32.6%) were not clearly presented. As per previous research, the most common approach was psychoeducation, with assessment and CBT frequently used (Table 2). There was also a high use of complementary and alternative therapies.

Table 1. Frequency of target disorders in apps for depression (N=353).

Target disorders	Apps, n (%)
Multiple	174 (49.3)
Depression	100 (28.3)
Depression and anxiety	34 (9.6)
Depression, anxiety, and stress	27 (7.7)
Suicide or self-injury	4 (1.1)
Anxiety and stress	3 (0.8)
Stress	3 (0.8)
Depression, anxiety, and bipolar disorder	2 (0.6)
Anxiety	1 (0.3)
Sleep	1 (0.3)
Depression and stress	1 (0.3)
Depression and bipolar disorder	1 (0.3)
Depression, bipolar disorder, and schizophrenia	1 (0.3)
Depression, anxiety, and trauma	1 (0.3)

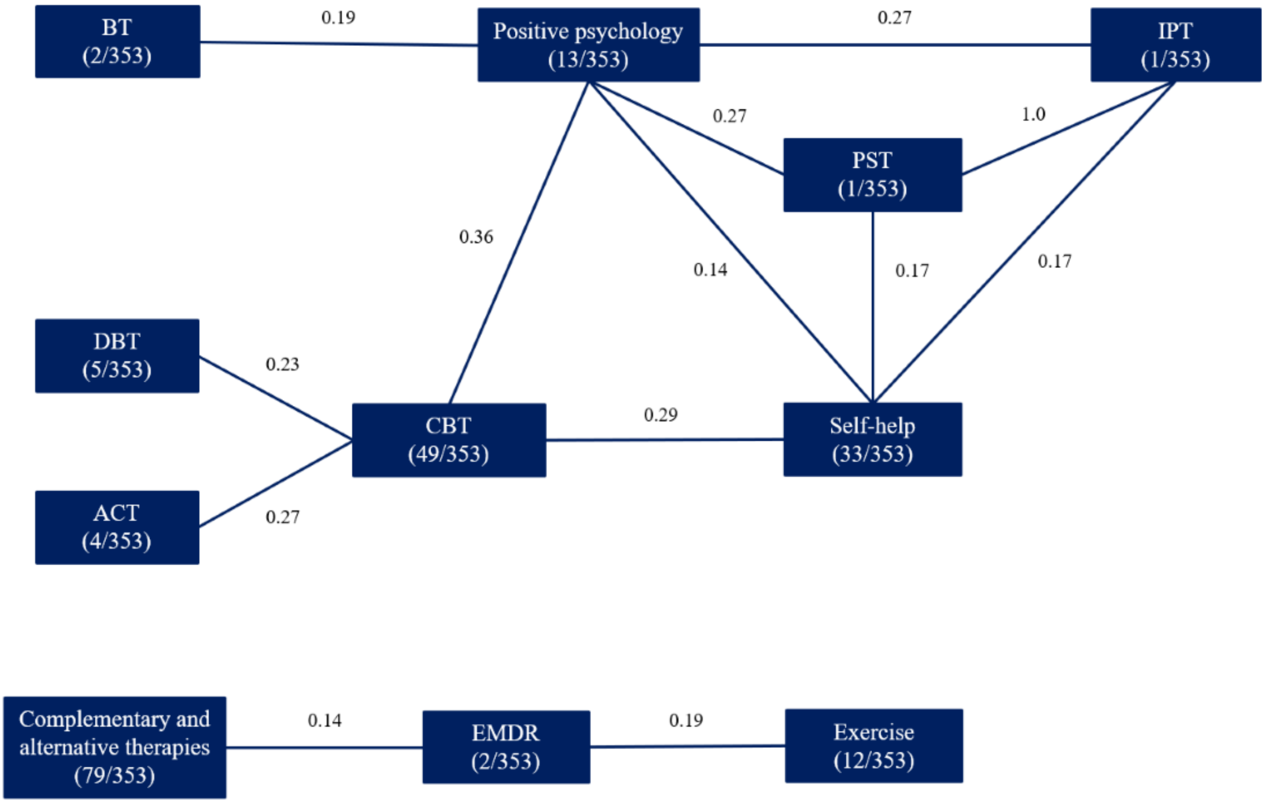
Table 2. Treatment approaches of apps for depression (N=353).

Treatment approach	Apps, n (%)[a]
Psychoeducation	141 (39.9)
Complementary and alternative therapies	79 (22.4)
Screening or assessment	66 (18.7)
Cognitive behavioral therapy	49 (13.9)
Psychosocial	46 (13.0)
Self-help	33 (9.4)
Online therapy	19 (5.4)
Positive psychology	13 (3.7)
Exercise	12 (3.4)
Dialectical behavior therapy	5 (1.4)
Acceptance and commitment therapy	4 (1.1)
Cognitive training	4 (1.1)
Spiritual or faith based	3 (0.9)
Behavioral therapy	2 (0.6)
Eye movement desensitization and reprocessing	2 (0.6)
Interpersonal therapy	1 (0.3)
Mindfulness-based cognitive therapy	1 (0.3)
Motivational interviewing	1 (0.3)
Neurostimulation	1 (0.3)
Problem-solving therapy	1 (0.3)

[a] Percentages do not add up to 100% because some apps use multiple approaches.

Our review found that 59.2% (209/353) of app listings reported only 1 identifiable treatment approach, with others describing combinations of 2 to 6 approaches (n=317 [missing cases excluded]; mean 1.53, SD 0.92; mode 1). There were 59 unique combinations of approaches. This is captured in Figure 2, which maps significant positive associations between treatment approaches, providing insight into the most commonly used treatment combinations (the correlation table is given in Multimedia Appendix 3). Despite the low frequency of some approaches, these results illustrate patterns in the treatments used, such as combinations of different cognitive approaches (acceptance and commitment therapy, CBT, and DBT).

Figure 2. Significant associations between treatment approaches in apps for depression (Spearman rank correlation coefficients, *P*<.01). ACT: acceptance and commitment therapy; BT: behavioral therapy; CBT: cognitive behavioral therapy; DBT: dialectical behavioral therapy; EMDR: eye movement desensitization and reprocessing; IPT: interpersonal therapy; PST: problem-solving therapy.



Eclecticism in treatment was also evident in the variety of treatment strategies (Table 3). Overall, 22.9% (81/353) of apps described only 1 identifiable treatment strategy, with the remaining naming between 2 and 16 strategies (n=238 [missing cases excluded]; mean 2.53, SD 1.82; mode 1). There were 112 unique combinations of strategies (Multimedia Appendix 1).

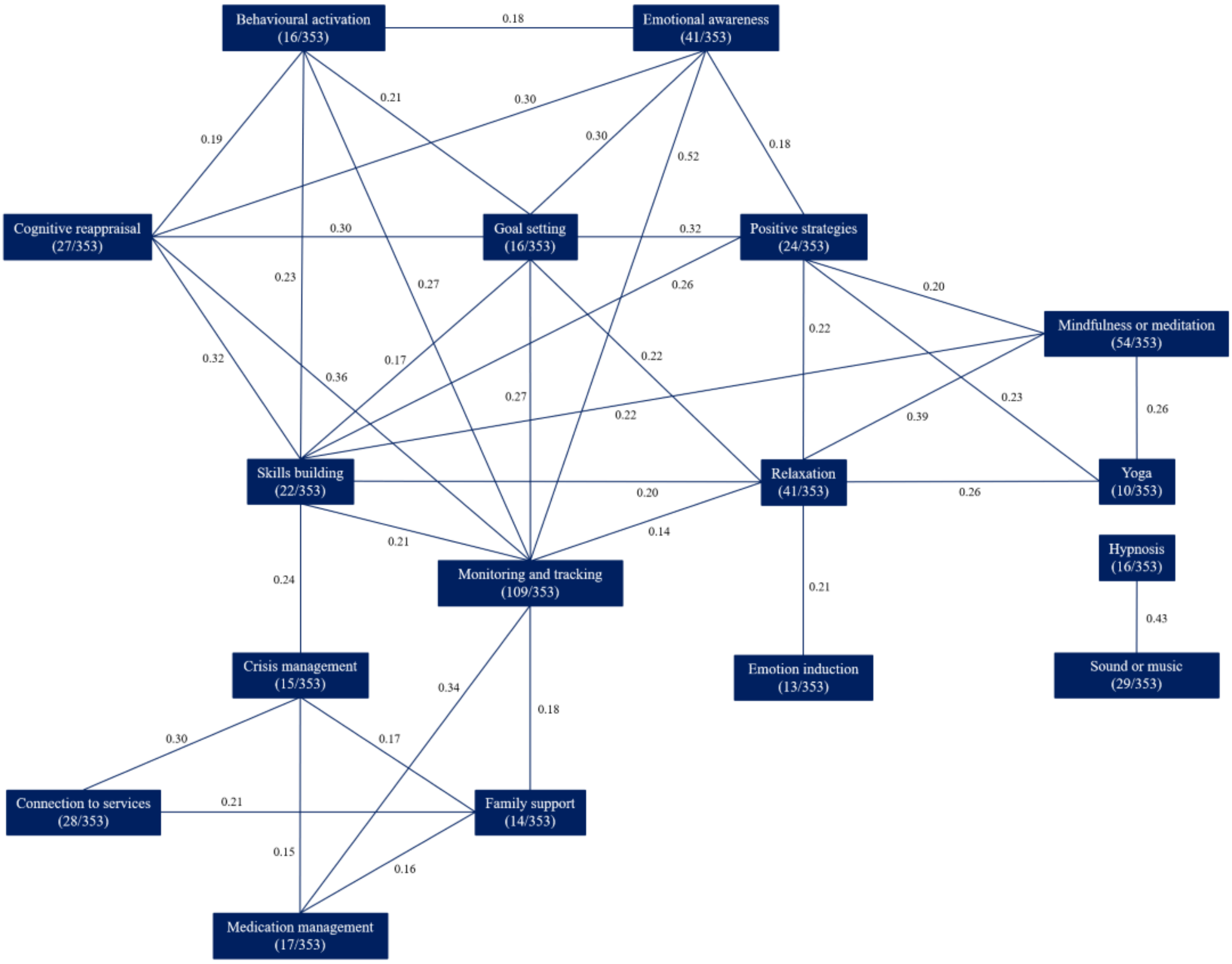
These strategy combinations are illustrated in Figure 3, which captures the significant positive associations between the most commonly identified strategies (n>9; the correlation table is given in Multimedia Appendix 4). As with the treatment approaches, patterns emerged in the reported use of treatment strategies. Such patterns suggest evidence-informed development, as seen with the associations between the use of emotional awareness, cognitive reappraisal, behavioral activation, and monitoring and tracking, which are all emotion regulation techniques typically employed in treatments for depression, such as CBT and evidence-based multitheoretical [50] and transdiagnostic [51] approaches.

Table 3. Treatment strategies of apps for depression (N=353).

Treatment strategies	Apps, n (%)[a]
Monitoring and tracking (including diaries)	109 (30.9)
Mindfulness or meditation	54 (15.3)
Emotional awareness	41 (11.6)
Relaxation	41 (11.6)
Peer support	34 (9.6)
Sound or music	29 (8.2)
Connection to services	28 (7.9)
Cognitive reappraisal	27 (7.7)
Positive strategies	24 (6.8)
Lifestyle or nutrition	22 (6.2)
Skills building	22 (6.2)
Medication management	17 (4.8)
Behavioral activation	16 (4.5)
Goal setting	16 (4.5)
Hypnosis	16 (4.5)
Crisis management	15 (4.2)
Family support	14 (4.0)
Emotion induction	13 (3.7)
Yoga	10 (2.8)
Distraction or grounding	5 (1.4)
Acupressure	4 (1.1)
Chatbot	4 (1.1)
Self-compassion	4 (1.1)
Bodily awareness	3 (0.9)
Coaching	3 (0.9)
Gamification	3 (0.9)
Motivation enhancement	3 (0.9)
Problem solving	3 (0.9)
Cognitive bias modification	2 (0.6)
Exposure	2 (0.6)
Neuro-linguistic programming	2 (0.6)
Acceptance	1 (0.3)
Art therapy	1 (0.3)
Chromotherapy	1 (0.3)
Emotional freedom techniques	1 (0.3)
Havening	1 (0.3)
Transcranial direct current stimulation	1 (0.3)

[a] Percentages do not add up to 100% as some apps use multiple strategies.

Figure 3. Significant associations between most common treatment strategies in apps for depression (Spearman rank correlation coefficients, *P*<.01).



CBT was associated with 13 of the 37 strategies (where significant associations are *P*<.01), including cognitive reappraisal, monitoring and tracking, and emotional awareness (Table 4).

Mindfulness meditation was also often used in CBT apps; however, only one app was identified as having a mindfulness-based cognitive approach. Although these associations suggested some evidence-informed development, there were shortcomings in the reported use of these strategies across CBT app listings. Specifically, except for monitoring and tracking (41/49, 84%), less than half of all CBT app store descriptions mentioned the use of these strategies (Multimedia Appendix 5). Only 49% (24/49) CBT app listings described the use of cognitive reappraisal, whereas 45% (22/49) mentioned emotional awareness, 16% (8/49) used goal setting, and 14% (7/49) reported the use of behavioral activation. In addition, although a high number of CBT apps employed the use of monitoring and tracking of mood, thoughts, and behaviors, fewer reported the use of screening or assessment (8/49, 16%), with only half of these app listings naming the measure used. More often, CBT apps described the use of psychoeducation (15/49, 31%), although this too was underutilized or underreported.

Table 4. Spearman rank correlation coefficients for cognitive behavioral therapy and all strategies (N=353).

Treatment strategies	Spearman correlation coefficient, ρ	*P* value
Cognitive reappraisal	0.62	<.001
Monitoring and tracking (including diaries)	0.44	<.001
Emotional awareness	0.42	<.001
Skills building	0.30	<.001
Relaxation	0.29	<.001
Goal setting	0.23	<.001
Mindfulness or meditation	0.22	<.001
Behavioral activation	0.19	<.001
Chatbot	0.19	<.001
Exposure	0.19	<.001
Self-compassion	0.19	<.001
Positive strategies	0.15	.004
Coaching	0.14	.008
Emotional freedom techniques	0.13	.01
Havening	0.13	.01
Connection to services	–0.12	.03
Crisis management	0.12	.03
Sound or music	–0.09	.09
Cognitive bias modification	0.08	.14
Neuro-linguistic programming	0.08	.14
Yoga	0.08	.14
Bodily awareness	0.05	.33
Motivation enhancement	0.05	.33
Problem solving	0.05	.33
Hypnosis	–0.05	.37
Family support	0.04	.41
Acupressure	–0.04	.42
Gamification	–0.04	.49
Distraction or grounding	0.02	.69
Acceptance	–0.02	.70
Art therapy	–0.02	.70
Chromotherapy	–0.02	.70
Transcranial direct current stimulation	–0.02	.70
Medication management	–0.01	.80
Emotion induction	0.01	.87
Peer support	0.008	.88
Lifestyle or nutrition	–0.002	.97

Alignment With Clinical Guidelines on the Treatment of Depression

In terms of adherence to clinical guidance, 67.1% (237/353) of apps reported the use of at least one treatment approach recommended in NICE guidelines for the treatment of depression. Over half of all apps (181/353, 51.3%) described an early intervention, namely, assessment or psychoeducation, whereas 19.8% (70/353) of apps described the use of a NICE-recommended psychological approach (ie, CBT, BT, IPT, or web-based therapy).

Although 13.9% (49/353) of apps adhered, to some extent, to NICE’s recommendation for digital CBT, only 3.7% (13/353) of CBT apps suggested use with in-person support (Multimedia Appendix 5). Most CBT apps (37/49, 76%) appeared to use a transdiagnostic approach to treat multiple disorders, including depression. However, app descriptions did not specifically address the treatment of comorbidities or the suitability for use in complex cases. Moreover, only 18% (9/49) of CBT apps appeared to have published research on use or outcomes. In total, only 1 CBT app (MoodKit-Mood Improvement Tools) was found to have both published research and advice to use on its own or to enhance professional treatment. However, this app was not marketed as a comprehensive CBT program but rather as a mood improvement toolbox incorporating principles and techniques of CBT. Overall, none of the app store descriptions aligned with clinical guidance when assessed for evidence of NICE-recommended evidence-based interventions, therapist-guided models of care, and clinical effectiveness.

Further Treatment and Safety Issues

Overall, evidence of app use, safety, and outcomes was not available for most apps (314/353, 89.0%). Despite this, most app store descriptions (285/353, 80.7%) did not provide a disclaimer regarding treatment, appropriate use, or limitations. When provided, disclaimers ranged from caution that the app does not replace traditional care, guidance to contact a health care provider in cases of emergency, explicit statements of when the app should not be used, or nonliability claims. Less common but concerning were instances where app descriptions included inaccurate information (15/352, 4.3%)—such as unsupported claims that specific techniques (eg, daily journaling) were the most effective in treating depression—or unsafe claims (8/352, 2.3%), for instance, unsupported statements that users would not need to see a health care professional, would not experience any risks or harms, or would experience immediate benefits.

Our review of the identified skills and expertise of developers found that about one-third (117/353, 33.1%) of apps for depression explicitly mentioned the involvement of health care professionals, either in consultation or as a part of the development team. As many as 57.8% (204/353) of apps appeared to be developed by private entities without explicit mention of the involvement of health care or other multisector stakeholders. The importance of multidisciplinary development teams was reflected in the absence of research conducted by private entities without mention of stakeholder involvement—specifically, all but one app, which reported published (29/353, 8.2%) or unpublished (10/353, 2.8%) research involved health care (22/39, 56%) or academia (17/39, 44%). Differences in developer type and treatment approach were also noted. The reported use of psychoeducation was associated with development by private entities without stakeholders (χ^2_1=5.4; P=.02) but was less associated with academia (χ^2_1=4.5; P=.04). Private entities (without stakeholders) were also associated with the use of complementary and alternative therapies (χ^2_1=4.7; P=.03) but less associated with the use of CBT (χ^2_1=14.7; P<.001). Comparatively, development teams with health care were associated with the use of CBT (χ^2_1=20.3; P<.001), with 61% (30/49) of CBT apps explicitly mentioning the involvement of health care in app design or development.

Discussion

Principal Findings

The app marketplace offers potential users a range of apps marketed for the treatment and management of depression. To the best of our knowledge, this study is the first to provide a comprehensive review of treatment descriptions of publicly available apps for depression, exploring all reported treatment approaches and strategies and the interrelations between them. In doing so, we considered issues of treatment fidelity and the quality of information presented to potential users to allow them to make informed treatment decisions. This research is particularly novel in its consideration of the alignment of publicly available apps for depression with clinical guidelines [4,5]. Our findings highlighted notable shortcomings in treatment descriptions and clinical relevance, demonstrating the need for improved regulation and evaluation of direct-to-consumer mental health technologies.

Treatment Descriptions of Apps for Depression

The Popularity of Transdiagnostic Approaches

App store descriptions provided a range of treatment information, with no standardized reporting of intervention details, such as target disorder, intervention type, and treatment approaches and strategies. As such, there was wide variation in the amount and quality of treatment information provided by different apps.

With regard to target disorder, less than one-third of apps targeted solely depression, with the majority marketed for multiple disorders. To cater to this multiplicity of mental health problems, over 40% (155/353, 43.9%) of apps adopted transdiagnostic approaches. Proponents of transdiagnostic approaches [51-54] highlight the shared constructs and mechanisms underlying many disorders, suggesting benefits in the development and use of treatments across multiple mental health problems. Sauer-Zavala et al [54] presented 3 categories of transdiagnostic approaches, namely, universally applied therapeutic principles, as seen in the application of CBT to treat multiple disorders; modular treatments, whereby evidence-based strategies are selected based on a client’s individual needs rather than diagnosis; and shared mechanism treatment that targets the underlying mechanisms in a class of disorders. There is potential value in the development of transdiagnostic apps for the treatment of depression [17]. However, as seen in the categorizations of transdiagnostic approaches, such treatments require a strong evidence base and rationale underlying development and use. Developers seeking to design transdiagnostic interventions should therefore consider the type of transdiagnostic approach to be employed, the evidence base underlying their intervention, and the evidence needed to justify use and effectiveness with the target populations. Although many apps appeared to adopt transdiagnostic approaches, this was not explicitly stated in app listings, with none reporting use of existing transdiagnostic treatment models [51,53].

Treatment Approach and Evidence-Informed Development

Developers typically described at least one treatment approach, with several app descriptions reporting the use of 2 or more approaches. Psychoeducation was the most popular approach, as per previous reviews [25,27,29-31]. This is not surprising given the relative ease of creating informational apps rather than interactive interventions. More surprising was the frequency of complementary and alternative approaches, which were more common than assessment and CBT. This may also reflect the ease in developing complementary and alternative app therapies, which typically provided content such as sound, music, or hypnosis or mindfulness meditation recordings. This was supported by our findings that private entities without stakeholder input were more likely to develop psychoeducation and complementary and alternative app therapies rather than interactive evidence-based interventions. Although complementary and alternative therapies may offer supplementary management of mental health difficulties, research is needed to demarcate how and by whom such apps should be used, the effectiveness and outcomes of their use for depression, and fit within existing evidence-based treatment models.

Our analysis also identified 37 unique treatment strategies, with just under half of all apps describing the use of 2 or more strategies. The plethora of strategy combinations suggested idiosyncrasies in depression treatments or their marketing within app stores. Without standardized reporting of treatment approaches and strategies in app stores, potential users are left to decipher app store descriptions for clues of the intervention before download. Further research is therefore needed to determine how accurately app interventions reflect their app store descriptions and the range of unique combinations of approaches and strategies in depression treatments as determined by use of the apps.

This study provides novel insights into patterns of approaches and strategies across all apps for depression, with significant associations found between theoretically similar orientations and methods. CBT apps for depression demonstrated significant associations with several elements of CBT, including cognitive reappraisal, monitoring and tracking, goal setting, behavioral activation, emotional awareness, and skills building [25,55-57]. However, except for monitoring and tracking, less than half of all CBT apps for depression reported use of these strategies. Moreover, as noted by Huguet et al [25], other core elements were either underreported or absent. Therefore, apps demonstrated some treatment fidelity in their described interventions; however, there remained significant gaps in descriptions of theoretical principles and methods.

Eclecticism in Apps for Depression

Although many apps appeared to lack the core elements of specific approaches, several apps reported the use of multiple approaches and unique combinations of strategies. These seemingly multitheoretical interventions are reflective of the eclecticism in treatment seen in traditional mental health care [58-61]. In real-world settings, decisions to offer eclectic or integrative treatments require clinician judgment, knowledge, and expertise to adapt established interventions to meet the needs of individual cases. In this sense, integrative care may be more complex than manualized treatments; therefore, they may be more difficult to deliver effectively outside of in-person care. Most mental health apps do not benefit from flexible clinical decision making and in-the-moment expertise and thus require clear information and evidence supporting their methods, use, and outcomes. Therefore, the lack of research for most apps is concerning and questions the validity of apps to deliver the promised effects. Apps did not report use of multitheoretical treatment models [50,58] but rather tended to cite benefits of individual treatment approaches that were then combined in their intervention. This design approach further supported the suggestion that apps were evidence informed rather than evidence based [25,27,32].

Alignment With Clinical Guidelines on the Treatment of Depression

Another important consideration in assessing app validity and suitability is their alignment with clinical guidance. For our study, we focused on fit with NICE guidelines for the treatment and management of depression in adults [4,5,7]. First, we considered the reported use of NICE-recommended treatment approaches that are not specific to mobile mental health. We then considered alignment with NICE recommendations on digital therapies for depression, specifically the use of CBT, provisions for in-person support, and evidence of clinical effectiveness. Superficially, approximately two-thirds of app descriptions mentioned the use of treatment approaches outlined in NICE guidelines, that is, at face value, most apps appeared to incorporate aspects of clinically recommended treatments, including psychoeducation, CBT, IPT, and BT [4,5,50,62,63]. A more detailed review of these apps is warranted to determine fidelity to these approaches.

Specific reference to the use of mobile mental health within NICE guidelines was reflected in recommendations for guided self-help [4] and digital CBT [6,7]. Few apps fit this framework, with only 13 apps offering CBT with suggested use with practitioner support. Given the lack of evidence of clinical effectiveness of these apps and pervasive shortcomings in descriptions of core components of CBT, we did not find any of the 353 app listings reviewed to fully align with treatment criteria in NICE guidelines. In their present state, apps may be more suited to provide supplement treatment for depression through their focus on specific aspects of care, such as mood tracking or goal setting. There were several strategies in apps for depression that aligned with aspects of treatment in the NICE framework, namely, apps offering monitoring and tracking, mindfulness, peer support, crisis management, and medication management. These strategies could act as tools to support treatment within the stepped care model utilized by the NHS. For example, monitoring and tracking apps could be utilized in active monitoring, whereas medication management apps could play an important role in increasing patient adherence to pharmacological treatments [64,65]. NICE analysis of the clinical effectiveness of mindfulness and peer support found both offered potential benefits in treating and managing depression but lacked enough evidence to support recommended use [4]. Therefore, there is some justification in the use of these techniques to complement clinically effective treatments, as determined by individual needs and preferences of users.

Implications for App Design, Development, and Marketing

This study highlights notable shortcomings in the treatment design and marketing of direct-to-consumer apps for depression. There are persisting uncertainties regarding the treatment fidelity and validity of these apps, with more research needed to support the prevalent use of transdiagnostic and multitheoretical approaches and complementary and alternative app therapies. Our review shows a marked discrepancy between the digital interventions recommended for use within the UK public health system and apps for depression available to the public via the app marketplace. Developers hoping to create digital therapy products for use within the NHS should consult relevant guidance [4-7,63,66], standards [67-70], and technical specifications [71,72] to ensure that their app aligns with key criteria, including the use of evidence-based treatments, provisions for blended care, and evidence of clinical effectiveness. Although developers not targeting the public health system are not bound by these guidelines, we urge all developers of apps for depression to be au fait with best practices and to use these as a foundation in developing their digital interventions and innovations. New treatment approaches and methods are encouraged but must emerge from existing knowledge, evidence, and best practices.

In creating and distributing mental health interventions, app developers have a duty of care and responsibility for the content they design and develop and how it is marketed to the public. Regardless of the choice of treatment, developers and app stores have an obligation to provide potential users with enough information to help them make informed decisions regarding an app’s suitability for their needs. Insufficient treatment information and lack of research evidence impair the abilities of potential users to make safe and informed choices and to adequately prepare for risks and outcomes [44,73]. The lack of evidence-based apps and the eclectic nature of some interventions warrant greater safety considerations given the use by potentially vulnerable persons. Efforts should be made to assess and mitigate potential risks and harms, to protect vulnerable groups, and to provide potential users with accurate and transparent information regarding treatment, safety, and outcomes. App stores should facilitate standardized reporting of information about target users, target disorders, intervention type, treatment approach, clinical evidence, compliance with guidelines and standards, expected benefits and outcomes, potential risks, safety and safeguarding, and general guidance on use and stage in treatment. App listings should also clearly outline the level of support provided and guidance on additional support for optimal use and outcomes.

Developers are encouraged to embrace the complexities of mobile mental health and to be innovative in their intervention design and development through multidisciplinary collaboration to produce clinically valid, effective, and safe treatments. To facilitate this process, we present several reflective questions for developers to engage with at the outset and throughout the design and development of mental health technologies. These questions aim to help developers to frame the rationale for their intervention, to assess their strengths and limitations in the design and development process, and to consider the treatment and safety needs involved.

Reflective Questioning for the Design and Development of Mobile Mental Health

Skills and Expertise

The following questions encourage reflection on the skills and expertise of the development team, specifically their competencies, multidisciplinary expertise, and user involvement:

- What knowledge and skills do you require for your project to be a success?
- Are you part of a multidisciplinary team? Do you need expert involvement?
- Is the development team sufficiently knowledgeable and skilled in clinical care, psychological interventions, theoretical principles, evidence-based practices, safety and safeguarding, clinical guidelines and standards, ethics, and codes of conduct?
- How will you involve user groups in planning, design, development, and research?

Treatment Design

Questions on treatment design aim to assist developers in considering the rationale for their app interventions, the intended target disorders and users, and the appropriate treatment orientation and strategies required to produce a quality app:

- Who are you developing the app for (consider demographics, target disorder, mental health difficulties and needs of users, and treatment histories and needs of users)?
- Why have you selected that group of target users?
- What stage of treatment will your app address (consider early intervention, first-line intervention, relapse prevention, crisis management, etc)?
- Will your app span more than one treatment stage? How will this be achieved through your intervention and app design?
- Do you intend your app to be used as a standalone intervention or supplementary to traditional care? How will this be reflected in your intervention and app design?
- What level of support will you provide users (consider connection to in-person services, crisis management, blended care, etc)?
- Do you wish to develop a disorder-specific intervention, or will you target multiple disorders using a transdiagnostic approach?
- What type of transdiagnostic approach will you employ (consider the 3 categories of transdiagnostic approaches discussed by Sauer-Zavala et al [54])?
- Will your app intervention target the disorder (eg, depression) or specific symptoms (eg, poor sleep)? How will this be reflected in your intervention and app design?
- What is your treatment approach?
- Why have you chosen this treatment approach? How does it align with your rationale, skills and expertise, and intervention design?

- How does your app intervention reflect evidence-based treatments and clinical guidelines?
- For app interventions adapted from evidence-based treatments (eg, CBT), will your app include all core treatment elements? How will this be achieved through your intervention and app design?
- What innovations will your app offer? Will these fit the existing models of care?
- What would make this project a success for you?

Safety and Duty of Care

Developers should also reflect on the safety of mental health apps and their role in designing, developing, and maintaining safe mobile mental health:

- What do you consider to be your roles, responsibilities, and duty of care as the developer of a mental health app? How is this reflected in your app design, development, and marketing?
- What values are important to you in the design, development, and deployment of this technology?
- Has your app been designed, developed, and marketed with safety in mind?

We encourage developers to use these reflections not only throughout design and development but also in the deployment, maintenance, and marketing of their apps.

Limitations

This study explores treatment descriptions and alignment with the clinical guidance of apps in the UK app marketplace for depression. It builds on previous content analyses to provide a comprehensive overview of treatment content and clinical validity as evident in app store descriptions; however, it is not without limitations. First, we chose to conduct manual search and data extraction of app listings rather than to use a script to pull data from the app stores. Both methods have been used in previous marketplace reviews and offer their own benefits and limitations. Our decision to perform manual search reflects our focus on the marketing of apps to the public, with this method allowing for a first-person experience of searching, identifying, and evaluating all returned apps. This meant that search results—and therefore the final list of apps reviewed—may differ slightly from those returned through a script. However, we believe our findings benefited from the firsthand navigation of the app marketplace and the challenges potential users may encounter in their search for suitable apps. Similarly, although a strength of the review was the inclusion of all apps for depression, this limited our focus on app store descriptions rather than downloaded apps. Our review captured issues in the marketing and treatment descriptions of apps but acknowledges that there may be discrepancies between app store listings and in-app content. Therefore, there is scope for further research to explore these issues through the use and in-depth evaluation of apps. The iterative nature of the review also allowed for rich data collection but limited rigorous research methods such as blinded coding and interrater reliability. Therefore, future reviews would benefit from the use of these methods to strengthen the current findings.

Although the analysis was largely descriptive, correlation calculations were performed to explore relationships within- and between treatment approaches and strategies. The large number of calculations may have resulted in increased type II errors. To mitigate this, findings are reported as significant at $P<.01$. We opted to not perform a correction calculation (eg, the Bonferroni correction or false discovery rate), as we believe it more beneficial for the development of future research to limit the risk of type I errors, which would exclude potentially interesting findings from the discussion. Results should be interpreted with this in mind. Finally, this study was framed and conducted within the United Kingdom. It is expected that findings will be relevant to other health care markets; however, country-specific practices may exist. The application of findings should be done with this in mind.

Conclusions

This study advanced previous content analyses by providing a comprehensive overview of treatment descriptions of publicly available apps for depression. This is the first content analysis of apps for depression to explore the full range of reported treatment approaches and strategies and their fit with clinical guidelines. App developers have adopted many evidence-based treatments in their interventions; however, much work remains in improving the validity, fidelity, clinical relevance, and safety of apps offered directly to consumers. We encourage developers to consult guidelines and standards and engage in reflective questioning regarding treatment and safety. Developers are urged to transfer this information to potential users through transparent and sufficiently detailed app listings to allow users to make informed decisions before app download and use.

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Authors' Contributions

DB is the guarantor of this study. This study forms part of DB’s PhD research. DB was responsible for the study design, data extraction, coding and analysis, and drafting of the manuscript. SS, CS, and HI provided ongoing consultation and supervision. All authors have reviewed and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

List of all 353 apps for depression included in the review.
[XLSX File (Microsoft Excel File), 53 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Full code list used in content analysis of apps for depression.
[DOCX File , 20 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Spearman rank correlation coefficients for treatment approaches.
[DOCX File , 51 KB-Multimedia Appendix 3]

Multimedia Appendix 4

Spearman rank correlation coefficients for treatment strategies.
[DOCX File , 131 KB-Multimedia Appendix 4]

Multimedia Appendix 5

Treatment content of cognitive behavioral therapy apps for depression.
[XLSX File (Microsoft Excel File), 23 KB-Multimedia Appendix 5]

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Abbreviations

BT: behavioral therapy
CBT: cognitive behavioral therapy
DBT: dialectical behavioral therapy
IAPT: Improving Access to Psychological Therapies
IPT: interpersonal therapy
MBCT: mindfulness-based cognitive therapy
NHS: National Health Service
NICE: National Institute for Health and Care Excellence

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4.2 A Call for Responsible Innovation in Mobile Mental Health: Content Analysis of the Depression App Marketplace

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A Call for Responsible Innovation in Mobile Mental Health: Content Analysis of the Depression App Marketplace

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Abstract. Mobile mental health presents many ethical challenges in the wild. These ethical issues were explored through a content analysis of the depression app marketplace. App search in Google Play Store (UK) and Apple App Store (UK) found 353 unique apps for depression. Analysis uncovered a range of ethical issues and highlighted the limited presence of ethical values. Our findings suggest a need for designers to adopt a responsible innovation approach to creating mental health technologies that meet these ethical demands.

Keywords. mobile mental health, ethics, responsible innovation, content analysis

1. Introduction

There has been increased discussion of the ethics of mobile mental health [1-5] with authors highlighting issues in areas of privacy and data security; risks and safety; benefits and evidence; and transparency and trust. Content analyses of apps for depression report insufficient evidence of app use and outcomes [1,2,6,7], poor fidelity to evidence-based interventions [1,8], limited disclaimers and integration of real-world care [2,7,9,10], inadequate reporting of expert involvement [8], and insufficient privacy policies [9]. Few authors have framed these discussions within existing ethical frameworks, such as biomedical ethics [5] and the principles of the American Psychological Association [3,4].

Principlism [11] and professional ethical codes [12-14] provide structure for reflection on ethical practice and issues which are highly relevant to mobile mental health. Our research builds on previous content analyses to explore the ethics of mobile mental health, with a focus on apps for depression. Guided by principlism, professional ethics, and the literature on the ethics of mobile mental health, we conducted a content analysis of app store listings of apps for depression to determine: (1) *What ethical issues are evident in the depression app marketplace*? and (2) *How do these issues reflect ethical values in app design, development, and marketing*? This study extends our previous evaluation of depression app store treatment descriptions [1] by providing an ethical review of depression app store listings with the aim of framing findings within existing ethical frameworks and developing guidance for increased ethical practice

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2. Methods

App search and data collection was conducted between October to November 2018. Detailed methods were outlined in our companion paper [1] and will not be repeated in full. Search was performed in the two main UK app stores—Google Play and Apple App Store—using the terms “depression” and “mental health”. Apps for depression were defined as those with app store listings mentioning depression or depressive symptoms. Search returned 353 unique apps for depression (see [1] for sampling flowchart).

Data extraction and coding were done iteratively within the research team using a list of variables compiled prior to review and developed throughout as ethical issues emerged (see [1] for coding and list of eligible apps). This was guided by established ethical principles [11] and professional codes of conduct in disciplines relevant to mobile mental health [12-14]. Descriptive statistics were computed using SPSS version 25.

3. Results

Analysis found several ethical issues summarised herein under related ethical principles.

3.1 Beneficence

Beneficence relates to doing good or benefiting others. App store descriptions widely touted the suitability and benefits of apps for depression. Yet, there was a notable lack of evidence to support these claims, with most apps (89.0%, 314/353) lacking research evidence of app use, efficacy, risks, or outcomes. This is an especial concern given our previous findings questioning the treatment validity and fidelity of many apps. As reported in [1], none of the apps reviewed fully aligned with clinical guidelines, with app descriptions conveying limited use of evidence-based approaches.

3.2 Nonmaleficence

Nonmaleficence relates to doing no harm. In addition to limited evidence of outcomes and potential adverse effects, there were noted issues in areas of safety. Most app descriptions (80.7%, 285/353) did not provide disclaimers of use or limitations, with some even stating inaccurate information (4.3%, 15/352) or unsafe claims (2.3%, 8/352). Moreover, app listings offered limited provisions for vulnerable groups such as children and young people. Most app store age ratings of apps for depression were rated as appropriate for children and young people; 92.8% (233/251) of apps in Google Play were assigned an age rating of PEGI3 (suitable for all ages) while the most assigned age rating in Apple App Store was 4+ (43.5%, 60/138) followed by 12+ (37.0%, 51/138).

3.3 Responsibility

Responsibility refers to one’s duty or obligation to perform in a certain manner. For our review, it included ensuring the competence of the development team; providing evidence of intervention validity and safety; safeguarding and duty of care; and compliance with regulations. Overall, there was inadequate reporting of the involvement of multisector stakeholders and experts in app design and development. As many as 57.8% (204/353) of apps appeared to be developed by private entities without mention of the involvement of healthcare or other stakeholders. There was also a poverty of apps reporting certification by regulatory bodies, with only five (1.4%) stating some form of certification such as a CE mark for a medical device. There was no standardised reporting of certification in app stores, adding to the difficulty in locating this information.

3.4 Integrity

Integrity describes being honest, moral, and accountable. It includes transparency and accuracy of information communicated to the public. A pervasive finding was the lack of thorough and accurate information provided in app listings regarding fundamental aspects of apps, such as treatment information, evidence, risks and safety, developer information, and app costs and sources of funding. While developer contact information was provided for 91.2% (322/353) of apps, a third (31/94) of apps in Apple App Store failed to provide any contact information. Information on sources of funding was also not found for 84.4% (298/353) of apps, with only four apps declaring that they had received no external funding. This not only highlights issues with transparency with respect to app business models, but also raises questions of possible conflicts of interest that can pose potential risks to user rights.

3.5 Autonomy

Autonomy relates to self-determination and the right to make informed decisions without deception. Without accurate and transparent information, potential users are unable to make informed choices regarding the selection and use of apps. This applies to all aspects of apps, with the poverty of information in areas of treatment, evidence, developer information, and business models all negatively impacting users' informed consent. This was further seen with issues of privacy and confidentiality. In total, 74.2% (262/353) of app listings provided a privacy policy, yet only 41 (11.6%) apps made explicit mention of privacy policies in app store descriptions. Google Play listed information on app permissions for all apps (n=259), but this was not provided in Apple App Store. Overall, only three (0.9%) apps explained the reason for permissions in their app store description, allowing users to make informed considerations about permissions prior to download.

3.6 Justice

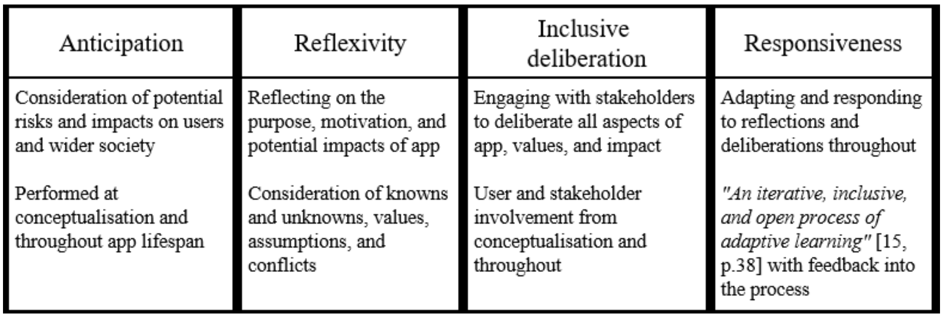
Justice describes being fair and reasonable. It includes issues related to equality and access to care, which in the case of mobile mental health may be impacted by initial and future costs. Although most apps were advertised as free to download (94.3%, 333/353), 60.3% (213/353) were free with in-app advertising, purchases, or subscriptions. Yet, these costs were often not outlined in app descriptions, limiting users' capacity to make informed decisions about treatment costs and their ability to access continuous care.

4. Discussion

This study demonstrates several ethical issues in app stores and listings of apps for depression. These issues have been presented under the ethical principles of beneficence, nonmaleficence, responsibility, integrity, autonomy, and justice. By using principlism as a guide [11], our review captures not only the ethical shortcomings of depression apps, but their interrelations and complexities. Singular examples of ethical issues, such as a lack of evidence, often reflect multiple ethical concerns, in this case related to questions of benefits and harms, lack of transparency of treatment information, and insufficient information for users to make informed choices. There is therefore value in the application of principlism in helping to frame these ethical issues and their wider impact.

While our review highlighted a range of issues, we can infer ethical priorities in the design of apps for depression based on the reduced incidences of some issues as well as progress made since previously reported findings. This is most apparent in the case of privacy practices, with our study finding a higher frequency of the provision of privacy policies than previously reported [9]. Similarly, while apps continue to fall short in their use of evidence-based interventions, our findings demonstrate an attempt by many to develop evidence-informed apps [1]. App developers appear to prioritise these areas and the associated values of privacy and validity relative to other aspects of app design and development. Despite calls for increased evidence [3,4], apps for depression continue to be significantly under researched. Additional safety concerns persist with the continued underuse of disclaimers [7] and inadequate guidance and provisions for use by vulnerable populations [2]. This raises concerns of the undervaluing of safety and welfare, risk minimisation, and duty of care. The insufficiency of information throughout also highlights undervaluing of transparency, credibility, and informed consent.

Our review demonstrates the complexity of mobile mental health and the difficulty developers may have in navigating ethical issues and value conflicts. Developers may feel the need to prioritise some values over others, e.g., by prioritising app production over evidence-based development or prioritising universal access over safeguarding. To assist in navigating these ethical complexities, we encourage responsible innovation [15] and value sensitive design [16] in mobile mental health. Responsible innovation is *"a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability, and social desirability of the innovation process and its marketable products"* [15 p.39]. We believe by applying the four dimensions of responsible innovation—anticipation, reflexivity, inclusive deliberation, and responsiveness—developers would better anticipate and respond to ethical issues and conflicts (Figure 1).



Anticipation	Reflexivity	Inclusive deliberation	Responsiveness
Consideration of potential risks and impacts on users and wider society Performed at conceptualisation and throughout app lifespan	Reflecting on the purpose, motivation, and potential impacts of app Consideration of knowns and unknowns, values, assumptions, and conflicts	Engaging with stakeholders to deliberate all aspects of app, values, and impact User and stakeholder involvement from conceptualisation and throughout	Adapting and responding to reflections and deliberations throughout *"An iterative, inclusive, and open process of adaptive learning"* [15, p.38] with feedback into the process

Figure 1. Four dimensions of responsible innovation applied to mobile mental health

A strength of this approach is the emphasis on responsiveness which encourages iterative reflection, inclusion, and adaptation throughout the design and innovation process for the app lifespan. As developers will not be able to fully anticipate all outcomes or risks of apps at design stage, it is crucial through continuous reflection and stakeholder engagement to envisage and amend the long-term impact of apps.

Responsible innovation also encourages developers to use ethical or moral conflicts (e.g., access vs safeguarding) to propel innovation to meet both moral obligations [17]. In such a manner, developers may consider how to design and develop apps that assess users' capacity to make informed choices regarding their treatment, rather than limiting access to all potentially vulnerable groups or providing open access without safeguarding measures. We encourage developers to reflect on value conflicts and ethical issues and to work with stakeholders to utilise technology to design new ways of overcoming ethical challenges and improving ethical practice.

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4.3 User Perspectives and Ethical Experiences of Apps for Depression: A Qualitative Analysis of User Reviews

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User Perspectives and Ethical Experiences of Apps for Depression: A Qualitative Analysis of User Reviews

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Apps for depression can increase access to mental health care but concerns abound with disparities between academic development of apps and those available through app stores. Reviews highlighted ethical shortcomings of these self-management tools, with a need for greater insight into how ethical issues are experienced by users. We addressed these gaps by exploring user reviews of such apps to better understand user experiences and ethical issues. We conducted a thematic analysis of 2,217 user reviews sampled from 40 depression apps in Google Play and Apple App Store, totaling over 77,500 words. Users reported positive and negative experiences, with ethical implications evident in areas of benefits, adverse effects, access, usability and design, support, commercial models, autonomy, privacy, and transparency. We integrated our elements of ethically designed apps for depression and principles of nonmaleficence, beneficence, justice, autonomy, and virtue, and we conclude with implications for ethical design of apps for depression.

CCS CONCEPTS •Social and professional topics~Professional topics~Computing profession~Codes of ethics•Human-centered computing~Human computer interaction (HCI)~HCI design and evaluation methods•Applied computing~Law, social and behavioral sciences~Psychology

Additional Keywords and Phrases: Mobile mental health, Depression, User experiences, Ethics, User reviews

1 Introduction

Mental health is a global health concern, with one in six people estimated to experience a common mental health problem in any given week [77]. Among these common mental health problems, depression, defined by persistent negative mood and diminished positive affect [100], has been shown to be particularly disabling, standing as the second leading cause of disability worldwide and a significant contributor to the global burden of disease. More specifically, people experiencing depression may present decline in functioning associated with the presence of depressed mood or the loss of interest or pleasure, accompanied by physiological changes (weight loss or gain, fatigue), insomnia or hypersomnia, psychomotor agitation or retardation, feelings of worthlessness or guilt, or cognitive changes (reduced concentration, indecisiveness, recurrent thoughts of death, or suicide ideation) [5]. Given the level of impairment and high prevalence, it is not surprising that an increasing body of work both in academia and in commercial settings has focused on the design and development of more accessible, cost-effective digital interventions for depression, with potential to remove situational and attitudinal barriers which often accompany traditional interventions.

Digital mental health is the use of technology for mental health care, support, and resources [132]. This commonly includes online resources for mental health information and psychoeducation; online therapy; blended care integrating technology-based self-care with in-person support; smartphone applications; and biosensors and wearables for detecting, monitoring, and tracking mental health symptoms [13, 54, 124].

While such technological approaches to the treatment of depression have the potential to revolutionize care, much remains unknown about their long-term effectiveness, risks and implications, and broader impact on individuals, health care systems, and society [94, 131]. Notable concerns have been raised surrounding the ethical implications of digital mental health and the potential for unmitigated risks or misuse, often due to a lack of adequate ethical guidelines, regulations, and evaluations [55, 61, 70, 102]. These concerns are particularly relevant for the subfield of mobile mental health, specifically publicly available mental health apps accessed through app stores such as the Google Play store or Apple App Store. So far, these major app marketplaces remain largely ungoverned, offering direct-to-users, as consumers, mental health products for unsupported self-care [48, 61, 62].

Work in this space has focused on evaluating the content [19, 20, 48, 71, 93], functions [60, 91, 111], and quality [61, 117, 131, 133] of apps for depression. There is also a sizable body of work discussing ethical issues in mobile mental health, including apps for depression [52, 55, 59, 70, 72, 73, 75, 90, 102, 107, 117, 119, 121, 133, 134]. Yet, there is still a need to position these discussions within ethical theories and frameworks, and in doing so, to provide clear ethically informed design, development, and deployment guidelines for such apps. Moreover, there is a poverty of research exploring user experiences of publicly available apps for depression and the potential impact of ethical issues on their use and adoption.

To address these gaps in ethical understanding and user experiences we report a study of 2,217 user reviews sampled from 40 apps for depression listed in Google Play and Apple App Store (UK) to understand how apps for depression can be better designed to account for users' feedback in their reviews. We sought to answer the following research questions:

- What are users' perceptions and experiences of publicly available apps for depression?
- What ethical issues are evident in app store user reviews of apps for depression?
- Based on user experiences, what are the key elements of ethically designed apps for depression?

The contribution of our work is three-fold. First, we provide diverse user perspectives of apps for depression and how aspects of their design and development impact not only users' experiences of the apps, but their mental health and wellbeing. Second, our analysis and discussion of ethical issues of apps for depression is framed within user reviews, resulting in concrete examples of ethical concepts rather than abstract and often ambiguous concepts from ethics theory that may be difficult to apply in design. Third, we generated several implications for designing better ethics-informed apps for depression. We integrate our elements and these implications within a framework for the design of ethical apps for depression that can leverage ethical dimensions from biomedical ethics [95] and virtue ethics [114], together with suggestions for navigating the tensions among key ethical areas.

2 RELATED WORK

There has been an expanse of innovation and research on digital health technologies for depression, with apps being one of the most widely developed and used. Research has shown the potential benefits of mobile mental health, but there are ethical concerns of how these impact users in the wild. Here, we outline the literature on mobile mental health for depression and the ethical challenges in this field.

2.1 HCI research on depression

HCI work on depression has grown significantly in the past decade, ranging from exploring the impact of depression on one's use of technology [24, 46] and social media behaviors [7, 38] to detecting or predicting depression symptomatology from social media data [66, 101, 126].

Efforts to develop more objective methods of detecting depression include multimodal systems [17, 39] integrating for instance audio with facial or body data [130]. HCI work on the detection of depression also includes the use of commonly available technologies such as smartphone sensors [10, 78, 128] for passive or active data collections. Beyond prediction and detection, a growing body of HCI work centers on the design of technology for the treatment or management of depression symptoms [58], leveraging memory technologies [92], game interventions [35], virtual reality [12], social robots [97], or chatbots [45]. Most commonly, technological interventions for depression are delivered online or via apps [99, 129, 136]. While much of the HCI work in this area has focused on technologies for the self-management of depression, others have sought to enhance face-to-face treatments by using technology in existing health care systems [16] or in blended care [110].

The design and development of technologies for depression can be a difficult space to navigate in HCI, with challenges ranging from access to and co-design with vulnerable user groups, to the potential impact of sensitive content on the wellbeing of designers and researchers [102]. To address such challenges, researchers have explored novel design methods to increase understanding of users' lived experiences of depression, real-world contexts for use and adoption, and the potential impact of proposed technologies [53, 85, 105].

HCI work in depression has also sought to improve digital intervention by exploring factors impacting engagement and adoption [36, 68] and improved clinical outcomes [28]. Factors impacting use and effectiveness of mental health technologies and self-management include (but are not limited to) appropriate client support [28, 96], managing expectations [51], provision of social support [63], and designing for flexibility in use [36] and fluctuations in symptoms [36].

2.2 Mobile mental health for depression

With the advent of smartphones and commercial apps, mobile apps are among the most used technologies for depression, often throughout the entire lifespan of depression, from screening and detection to treatment and relapse prevention. This is supported by the extensive body of research in mobile mental health, where clinical trials [9, 40] and systematic reviews [94, 118] have highlighted the efficacy of app interventions for depression. Apps for depression have been reported to significantly reduce depression symptoms and improve overall wellbeing, with common depression app functionalities including psychoeducation [48, 60, 61, 71], screening and assessment [48, 60, 91, 108], symptom management [48, 93, 108], interactive interventions [60], and tracking of moods, thoughts, or behaviors [40, 71, 93]. Publicly available app interventions for depression may be based on existing evidence-based treatments such as cognitive behavioral therapy (CBT) [40, 118], and behavioral activation and dialectical behavior therapy [118]. However, few of these apps demonstrated high fidelity to the adopted treatment approach [20, 72, 107, 111], causing them to be more aptly described as evidence-informed, rather than truly evidence-based. There is also high prevalence of complementary and alternative treatments for depression, including mindfulness meditation [30-32], hypnosis, and sound or music therapy [20].

Publicly available app interventions for depression also appear to adopt innovative uses of traditional treatment approaches and strategies, with frequent use of integrative, multi-theoretical, or transdiagnostic approaches [20]. These innovations reflect the eclectic delivery of clinical interventions in the wild [65] but unfortunately often lack research evidence supporting apps' specific design and use in treating depression [20]. The poverty of research on apps for depression in the wild also limits knowledge of use and adoption beyond academic research. There are also concerns with high rates of attrition and issues with treatment adherence of apps for depression [14, 98]. Studies have suggested users may engage with such apps for short-term symptom management but discontinue their use once the symptoms are no longer an immediate concern, with some users describing apps as a 'crutch' to help them cope until they find a more sustained means of managing their difficulties [29]. There is therefore need for more evidence on the use of apps for depression in the wild to better understand user experiences and implications for design to improve the quality and acceptance of these apps.

2.3 Perspectives in user reviews of mental health apps

App store user reviews provide concise expressions of users' perspectives and experiences of the app reviewed. In the case of apps for depression, user reviews can provide unique insights into app use, benefits, and challenges. Previous studies on user reviews in mobile mental health have analyzed reviews of general mental health apps [2, 3, 89], mood tracking apps [26], chatbot app for social support [112], CBT apps [115, 116], apps for bipolar disorder [81], and CBT apps for depression [111]. To the best of our knowledge, only one study has focused specifically on apps for depression [111]. These studies mainly aimed to explore user expectations [2, 81, 89, 111], needs [2, 81, 89], and experiences [2, 26, 81, 89, 111]. User review studies also explored specific app features such as social support [112], persuasive design elements [116], or usability [3]. A few of these studies analyzed how apps are used [81] and their main features related to adoption [115]. User review studies varied in the number of apps included (ranging from one [112] to 106 [2, 3]) and the number of reviews analyzed (ranging from 1,000 [26] to 88,125 [89], with a median of 1,287 [111]).

Users' reasons for using apps varied across the range of app types reviewed and included use for tracking mood and monitoring symptoms [26, 81], self-reflection and insight [26, 81], managing mental health conditions [26], supporting in-person treatment [26, 81, 111], and as a replacement to real-world care or support [111]. User reviews described both positive and negative user experiences, but were predominantly positive [2, 89, 111, 115]. Previous findings indicated that the most significant facilitator of positive user experiences was usability [2, 3, 81, 89, 115, 116], particularly app stability and ease of use. Other features associated with positive user experiences included monitoring and tracking [81, 89, 111, 115, 116], meditation and relaxation [111, 115], in-app communities [2, 81, 115, 116] or support [89, 112], goal setting [115], reminders or notifications [89, 115, 116], information resources [2, 115], personalization and customization [2, 111], and persuasive design features [116].

For CBT apps for depression, users appreciated both CBT and non-CBT features, such as tracking and meditation, but some users voiced the importance of evidence-based content [111]. Across all apps, the scientific or evidence-base was infrequently discussed in user reviews [2, 81, 89, 111, 116]. Discussion of specific features of intervention design was most detailed in studies that focused on a specific type of app [26, 81, 111]. For example, Nicholas et al. [81] highlighted specific intervention needs of people with bipolar disorder, such as the need for additional moods or symptoms to be tracked in the app. Similarly, Stawarz et al. [111] captured several aspects of CBT apps for depression that were important to users, including the ability to share data with their therapist and the importance of apps to focus also on positive aspects instead of merely on negative thoughts or feelings (i.e., lack of positivity).

The main negative user experiences of mental health apps were often related to poor usability [2, 3, 81, 89, 115], with users reporting technical issues and bugs [2, 3, 89, 115, 116]; interface design issues such as poor layout, readability, or navigation [3, 89, 115]; limited guidance on use [2, 3, 81]; data loss [2]; and negative effects on device battery or memory usage [2, 3, 81, 89]. Other factors which negatively impacted user experience included concerns with app content, such as poor quality or missing content [2, 81, 89], issues with privacy and security [2, 81, 89, 111, 115], poor customer service [2, 89, 115, 116], and issues with costs or billing [2, 81, 89]. Concerns with app privacy and security focused on issues with data storage and security [81, 89, 111], app permissions [2, 81], passwords [81, 111], privacy policies [2, 89], and data sharing with third parties [81, 89]. Some apps offered better privacy in paid compared to free versions [81], which many users believed to be unethical as they considered privacy to be a right that should not have to be bought.

Only two user review studies of mental health apps explicitly mentioned ethics [81, 89]. Discussion of ethics was limited and focused mostly on privacy [81, 89], and excessive in-app advertisements [89]. This is surprising considering the importance of ethics in mental health care to ensure the safe and effective delivery of interventions. Moreover, it is surprising that much of the findings from user review studies of mental health apps focused on the usability and functioning of apps, with less discussion of elements of mental health care such as intervention design, clinical benefits, and adverse effects. Although there has been greater discussion of the ethics of mobile mental health in the literature, to the best of our knowledge, there are no studies that have used user reviews to discuss how these ethical issues may be experienced by users of publicly available mental health apps in the wild. More specifically, there is a gap in user review studies of apps for depression outside of CBT, and the ethical experiences that may be unique to users of these apps. Given the high prevalence and burden of disease associated with depression [77], we believe there is a need for more studies to inform the ethical design of apps for depression in order to increase people's access to safe and effective app interventions.

2.4 The ethics of mobile mental health

Mental health professionals have long been guided in their work by ethical principles and codes of conduct aimed at ensuring good and fair delivery of care in the best interests of the client, the profession, and wider society [6, 22].

Related to this, a rather distinct body of work has focused on extensive discussion of the ethics and evaluation of mobile mental health including apps for depression. Ethical issues commonly discussed include concerns regarding privacy and data security [37, 41, 47, 52, 55, 59, 70, 73, 83, 102, 107, 117, 120, 121, 133-135], particularly related to how users' data is protected, how matters related to privacy and data security are communicated to users, and the use of users' data without their informed consent. This is related to ethical issues in areas of risks and safety [52, 55, 59, 70, 72, 73, 75, 90, 102, 107, 117, 119, 121, 133, 134], and benefits and evidence [47, 52, 55, 59, 70, 72, 74, 75, 90, 102, 107, 117, 119, 121, 133-135], with especial concerns for apps targeting suicide risk assessment and prevention [72]. The lack of evidence on the use, effectiveness, and adverse effects of most publicly available apps for depression [19, 20, 107, 111] increases the risks to users of these technologies. Moreover, it demonstrates a lack of transparency in the intervention being delivered and its effects [19, 20, 59, 133-135], which may negatively impact users' trust [19, 20, 59, 120, 133, 134] and their ability to give truly informed consent [19, 52, 70, 83, 102, 107, 120, 121, 133, 134]. Yet, these issues were largely absent in studies of user reviews of apps for depression or more general mental health apps. Other ethical issues emerging from the literature but not evident in user review studies included the importance of user involvement in the ethical development of mental health technologies [23, 117, 133-135], respect for human rights and diversity [37, 102, 135], and challenges with standards and regulation [23, 55, 70, 72, 107, 120, 133].

Few researchers have framed their discussions of mobile mental health within existing ethical frameworks. Jones and Moffitt [52] and Karcher and Presser [55] referenced the professional ethical principles of the American Psychological Association [6] to provide guidance for app development and the use of mobile health in clinical practice, respectively, while Schueller and Torous [107] framed their discussion of the ethics of digital mental health interventions using the principles of the Belmont Report. These frameworks reflect principlism or principle-based ethics [95], which is an approach to applied ethics involving the use of moral principles to analyze concrete cases and issues. Although evident in professional ethical codes [6, 22], this approach is perhaps best known by the principles of biomedical ethics [15], which are widely used to discuss ethical issues in clinical medicine. There are four principles of biomedical ethics: (1) respect for autonomy, i.e., respect for the decision-making capacity of autonomous people, (2) beneficence, i.e., providing benefits and balancing risks, (3) nonmaleficence, i.e., avoiding harm, and (4) justice, i.e., fairness in distribution of benefits and risks for all people. These principles are used to assist with ethical decision-making and to resolve ethical conflicts.

Sanches et al. [102] used bioethics [15] as a lens to present their review of the ethics of HCI research on affective health, with a focus on how the principles were reflected in HCI research and the design of affective health technologies. Their findings showed that most papers on affective health in HCI research did not discuss any ethical concerns. Of those that did, most discussed matters related to autonomy, specifically respect for the self-determination of people with affective disorders, and their data privacy. Nonmaleficence was also evident and related to the involvement of people with affective disorders in research, diagnostic claim, and providing feedback on negative affective states. With respect to the latter, the authors found possible risks associated with monitoring negative experiences as is done in some apps for mood tracking. Fewer papers reviewed discussed benefits or justice. Bowie-DaBreo et al. [19, 20] also adapted ethical frameworks in their review of ethical issues within app store descriptions of apps for depression. Their findings highlighted the relevance of principles of beneficence, nonmaleficence, responsibility, integrity, autonomy, and justice [19]. In addition to previously discussed findings related to the lack of evidence of claimed benefits, apps for depression were also found to be poorly aligned with existing clinical guidelines [20]. This was associated with nonmaleficence, with concerns related to the limited guidance and disclaimers in app store descriptions to guide safe and effective selection and use of apps for depression [19]. Issues of responsibility and integrity included inadequate involvement of multisector expertise in app development, and limited reporting of apps' regulatory status, sources of funding, and business models. These challenges had potential impact on users' autonomy in making treatment decisions and fair access to care. Based on these findings, Bowie-DaBreo et al. [19] advocated for the application of these ideals using a responsible innovation approach [88], which encourages a process of anticipation, reflection, inclusive deliberation, and responsiveness in the design and development of new technologies [125].

These reviews show the utility of principlism in framing ethical evaluations of apps for depression. The theory provides a structured approach for ethical guidance and practice, particularly when compared to more abstract theories such as consequentialism (the greatest good (outcomes) for the greater number), deontology (focus on actions, duty, and responsibility, not outcomes), and virtue ethics (how one's character or values should be) [114]. Yet, although principlism is widely used in the practical application of ethics, some consider it to be too prescriptive and encourage integration with other ethical theories and ideals [49]. This is relevant for HCI work in depression, as researchers and designers can often feel limited when discussions of ethics and associated guidelines arise. The present study therefore aims to shed light on the users' voice and experiences of ethical issues pertaining to apps for depression, and to use this perspective to shape actionable guidance for the design and development of ethical apps for depression. We approached ethics in the broadest sense, as relating to individual and social good and universal standards of right and wrong [114]. This often relates to, but is not limited to issues of harm, fairness, and rights.

3 App Review Study

3.1 Sampling method

We now describe the method for sampling the apps and for sampling the user reviews. The search for apps for depression was conducted on the two main app stores (UK version): Google Play Store and Apple App Store, during October-November 2018, guided by methods used by Shen et al. [108] and Stawarz et al. [111]. Separate searches were performed using the terms "depression" and "mental health", as well as a hand-search for apps for depression which were reported in previous research but not returned in the searches. For this research, apps for depression were defined as apps with app store listings mentioning depression or depression symptoms. Apps were included in the review if they met the following criteria: (1) app description included terms "depression", "low mood/mood disorder", "mood management", "negative thoughts", or "distress"; and (2) app store listing was in English. Apps were excluded from review if they: (1) did not mention depression or depression symptoms, (2) were for professional training, (3) only provided depression quotes or wallpapers, or (4) were duplicates, i.e., copies of an app listed within the same app store. Apps were not excluded from review if they targeted another mental health problem (e.g., anxiety) once they mentioned depression or depression symptoms, as outlined in inclusion criteria (1). This returned a total of 353 unique apps for depression for which we captured the number of users rating them, number of downloads, and users' ratings (from 1 to 5). Of these apps, 89% (316/353) explicitly mentioned use for depression in their app store descriptions. The remaining were marketed for mood management (4.8%, 17/353), mental health problems implicitly including depression (2.5%, 9/353), low mood/mood disorder (2.0%, 7/353), distress (0.8%, 3/353), and negative thoughts (0.3%, 1/353).

From this large set of apps, we decided to focus on a subset of them, to allow for the in-depth analysis of a rather large user reviews data. To include a wide breadth of user reviews and ethical experiences, we sampled 40 apps for depression that were rated by many users but varied in their users' ratings. Users' ratings are scores (1 to 5) given to an app by users in the app stores, with 1 being the lowest rating. We chose not to sample apps based on high user ratings as positive user ratings may not accurately reflect user experiences [119]. We ranked all 353 apps according first to the numbers of users rating them, and second to users' ratings. Firstly, we identified the 20 most rated apps for depression, or those with the highest number of user ratings across the app stores. We considered that apps with the most user ratings would likely also have high users' ratings, and thus may not fully reflect the range of ethical issues. To address this, we also identified the 20 lowest rated apps for depression which were downloaded by at least 1,000 users. Apps were not sampled based on treatment approach as we wished to capture ethical experiences across the range of interventions marketed for depression. By sampling 40 apps, we hoped to capture different user perspectives and ethical experiences across the many apps for depression in the app marketplaces. We felt a smaller sample of apps limited by treatment approach (e.g., CBT) would not truly reflect the ethical issues in this direct-to-consumer space. Apps were removed from selection and replaced by the next app in the category if they were no longer listed in the app stores or if the app had no user reviews. This resulted in six apps being removed from the lowest rated apps. The final 40 sampled apps are listed in Appendix A.1 Table 2 and Table 3.

Then, user reviews were purposively sampled in December 2018. For each app the 50 '*most helpful reviews'* (determined by the app store filter for sorting reviews) were extracted from each platform, with a total of 100 reviews being sampled for apps listed in both stores. Additionally, the 50 '*most critical reviews'* (also an app store filter) were extracted from apps listed in Apple App Store; this categorization was not available in Google Play. For apps with fewer reviews, all reviews were sampled. User reviews were excluded from selection if they lacked content, for example consisted of only 'emoji' symbols, or did not discuss user experiences, for example stated only what the app did ("This is a diary"). We did not specifically search for ethics-related posts because we consider ethics to be intrinsic in mental health care. Therefore, we expected users' reviews of their experiences of using apps for depression to include some discussion of individual or social good, harms, or other ethical issues. This led to a final set of 2,217 valid user reviews with an average of 35 words per review, totaling over 77,500 words. These reviews were extracted verbatim and exported to ATLAS.ti for analysis (see Figure 1 for sampling flowchart).

3.2 Thematic analysis

Thematic analysis was used to explore user experiences and ethical issues of apps for depression, using the methods and guidelines for thematic analysis outlined in Braun and Clarke [21]. After sampling, the user reviews were first coded as 'positive', 'negative', and 'ambivalent'. 'Positive' and 'negative' were defined as reviews which only discussed the positive or negative parts of the app. Reviews were coded as 'ambivalent' when users discussed both positive and negative aspects of the app. The user's numerical rating of the app was also recorded. Inductive codes were generated from the user reviews to capture the content, context, and ideas expressed. This included the use of in vivo codes to reflect important concepts and the user's voice. This iterative process involved ongoing review of quotes and consolidation of codes. The final code list was then categorized into themes guided by the inductive codes and the idea of ethics as standards of right and wrong that apps for depression should encompass. Coding, thematic development, and mapping were done by the first author with ongoing discussion with all authors over six months, until consensus was reached. Our findings present the main ethical themes that were evident in our sample of user reviews. We do not include quotes from the user reviews to ensure that we protect users' identities and comply with best ethical practices in research. This research received institutional ethics approval.

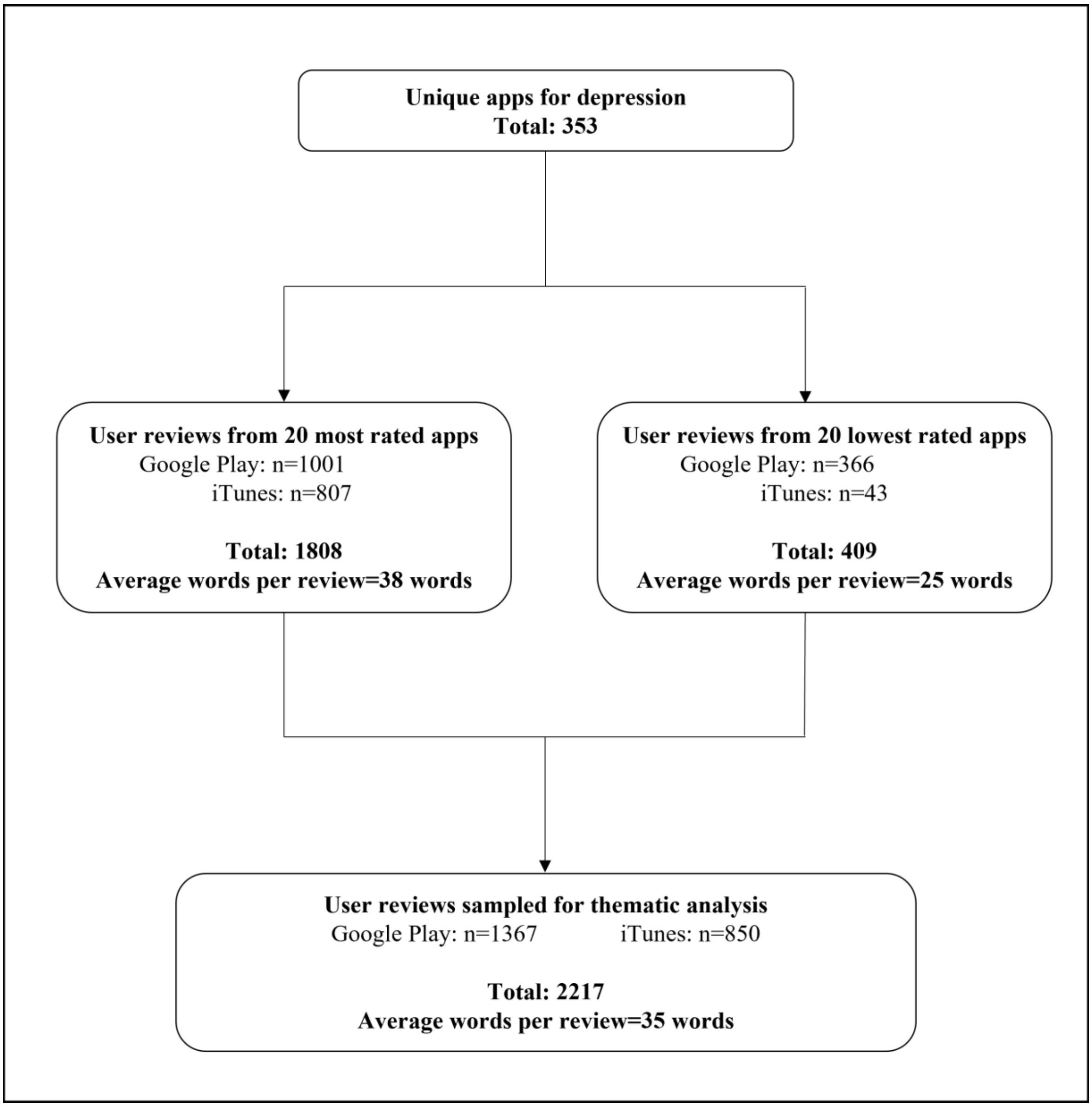

Figure 1: Sampling flowchart for user reviews

4 FINDINGS

4.1 Summary of sample of apps for depression

The sampled apps included a range of interventions representative of the different types of apps for depression available in the app marketplace. Based on their app store descriptions, approximately a third of the apps (35%, 14/40) provided a multi-theoretical intervention incorporating more than one treatment approach. The most common interventions were assessment (25%, 10/40), CBT (20%, 8/40), mindfulness or meditation (20%, 8/40), psychosocial interventions (20%, 8/40), and psychoeducation (18%, 7/40) (Appendix A.1 Table 4).

The 20 most rated apps for depression ranged in number of ratings from 4,082 to 85,394 (n=20; median 10,043) in Google Play and 13 to 160,019 (n=12; median 465.5) in Apple App Store. The mean users' rating for these apps in Google Play was 4.4 (n=20; SD 0.3; range 3.8-4.8), with apps rated similarly in Apple App Store (n=12; mean 4.4, SD 0.4; range 3.5-4.9). The most common intervention in this group of apps was mindfulness or meditation (40%, 8/20), followed by CBT (20%, 4/20) and psychosocial approaches (20%, 4/20) (Appendix A.1 Table 4).

For the lowest rated apps, the number of ratings ranged from 8 to 1,639 (n=20; median 27) in Google Play and 1 to 71 (n=4; median 19.5) in Apple App Store. The mean users' rating was 3.3 (n=20; SD 0.4; range 2.5-3.7) in Google Play and 3.1 (n=4; SD 1.5; range 1.0-3.8) in Apple App Store. The most common interventions in the lowest rated apps were assessment (40%, 8/20), followed by psychoeducation (25%, 5/20), and CBT (20%, 4/20) and psychosocial approaches (20%, 4/20) (Appendix A.1 Table 4).

4.2 Summary of user reviews

Over half of all user reviews (53%, 1178/2217) were positive, with 27% (592/2217) classed as negative, and 20% (447/2217) as ambivalent. This is not surprising given that there were more user reviews written for the most rated apps compared with the lowest rated apps, with the former also having higher users' ratings. In our sample, the apps with higher users' ratings also tended to have more positive reviews (Appendix A.1 Table 4). Interestingly however, all apps bar one had negative reviews with 85% of apps (34/40) having a range of positive, negative, and ambivalent reviews. Just over half of all reviews had a user rating of 5 (51%, 1129/2217). The next most common rating was 1 (22%, 482/2217), then 4 (14%, 312/2217), 3 (7%, 164/2217), and 2 (6%, 130/2217).

4.3 Benefits and harms of apps for depression

4.3.1 Benefits of apps for depression.

Benefits of apps for depression describe the positive effects of apps on users' mental health, wellbeing, and development. Almost half of all reviews (42%, 921/2217) across 36 of the 40 sampled apps described at least one benefit of apps for depression. In particular, apps helped users to manage their mental health problems (including depression, anxiety, stress, and bipolar disorder) at different stages of their disorders, from prevention through to treatment, recovery, and relapse prevention. Apps also helped with managing difficult situations, providing support or connections to services during low moments. Users often expressed feeling that they had no one else to turn to and sought comfort in the app to help them cope with challenges or moments of distress.

Many users described how using apps for depression helped them identify and understand their patterns of thinking, leading to better management of thoughts, more positivity, and change in perspective. Users reported improvements in emotion regulation, from greater emotional awareness to better management of affect. Emotional and bodily awareness was achieved through diverse methods including actively tracking thoughts and moods in order to increase insight, or mindfulness approaches. Emotion regulation was also supported through encouragement of simple activities and small steps to feeling better, i.e., behavioral activation. This included goal setting and the creation of new habits and routines, such as daily walks, meditation, or better sleep hygiene.

More generally, apps helped users with their overall wellbeing, including personal development. Users described apps as having a positive impact on their balance and focus, gratitude, motivation, engagement, and openness. For some, this led to increased confidence, self-efficacy, and insight into their mental health and wellbeing.

4.3.2 Risks, adverse effects, and safety.

An important finding is the reporting of risks, adverse effects, and safety concerns of apps for depression (10%, 220/2217). We define risks as anything which could potentially harm users, while adverse effects are negative outcomes experienced by users from using the app. Risks associated with apps for depression included the provision of harmful advice and the potential for misdiagnosis, failure or errors in delivering important information, or the risk of users' overreliance on the app. With respect to misdiagnosis, reviews pointed out the mismatch between the tracked data or app's prediction of their experience and their actual experience. For example, some users complained that apps described them as feeling well when they had reported continued symptoms of depression.

App errors posed additional risks in terms of not delivering essential elements of interventions, such as prompts to take medication or to complete tasks. Some users expressed concerns that apps had failed to remind them to take their medication until several hours later, making them question the benefit of the app.

A lesser reported risk was the potential for apps to lead users to become over reliant on them. A few users felt apps had the potential to be addictive, especially apps with peer support communities. There were also concerns that apps may foster dependence on in-app support because of the increased frequency of contact and perceived access to support whenever needed. Dependency on apps for depression has the potential to negatively impact intervention effectiveness, mental health outcomes, and user autonomy that is crucial in self-care.

For some, using apps led to adverse effects such as feeling worse after use, harassment, or mistreatment. Some users reported discomfort with completing aspects of the intervention, stress because of difficulties accessing the intervention or poor app or intervention design, and poor quality of support. For example, negative mood tracking can become problematic as it can increase users' awareness of it and feelings of self-deprecation. Other negative outcomes of using apps for depression were experiences of bullying, harassment, or mistreatment by in-app or peer support. Alleged harassment or mistreatment of users included unwanted sexual advances, rude or judgemental comments, and trolling behaviour from in-app or peer support.

These types of negative experiences were especially evident in apps with peer support. While some users used peer support communities to offload their emotional burdens by venting, others expressed wanting more support and responsiveness, leading to feelings of rejection when not received. Feelings of rejection were also voiced when users were declined treatment or when in-app support was delayed.

Risks and adverse effects highlight the great importance of safety and safeguarding in apps for depression. In this context, safety is ensuring apps are safe and free from known risks and harms, while safeguarding refers to specific measures to protect vulnerable people from harm or abuse. A key finding is the limited number of reviews that described apps for depression as providing a safe space or being designed with safety in mind. These concerns relate mostly to proper monitoring and moderation of peer support to prevent misuse by users, insufficient communication of apps' limitations, and insufficient support for safety and safeguarding. Regarding misuse, several reviews expressed concerns that apps for depression may fail to provide a safe place for all their users. Misuse can be arguably linked to users' limited psychoeducation, and more importantly to apps' limited moderation and regulation.

Reviewers also highlighted the importance of being aware of app limitations in providing adequate support or access to therapists whenever needed. This was demonstrated in user reviews where reviewers advised others to seek in-person care or to contact emergency services when in crisis. In one instance, this was reiterated in a developer's reply to a review in which they advised the user that the app was not a replacement for a real therapist or a crisis tool. The user was advised to seek professional help and to create an emergency plan outside of the app. This example demonstrates some attempt by developers to safeguard users, though more direct referral to appropriate mental health or crisis services is warranted for better and more responsible safeguarding. It also highlights the need for monitoring and safeguarding of app store user reviews, with safety extending beyond apps and their content. From our sample of user reviews, it is clear that some users post very personal and at times sensitive and triggering content in app store reviews. Yet only 63% (25/40) of the sampled apps had at least one developer reply to user reviews in the app stores. It is unclear whether users who posted reviews containing safety concerns were contacted privately by developers or app stores. There was also a call from a small number of users for app stores to take more responsibility to regulate or ban apps that were deemed to be exploitative or unsafe.

Users also demanded greater support for safety and safeguarding, in particular protection within apps given their use by vulnerable people. This was not limited to instances of bullying and abuse, but also included a need for appropriate referrals to real-world treatment when needed and explanations for why some users were refused care. The latter may reflect in-app attempts to safeguard users who were not suited for an app intervention, but typically left them feeling rejected and helpless.

4.4 Facilitators of benefits and harms

4.4.1 Usability.

Benefits, avoidance of harms and risks, and safety are the foundation of ethical apps for depression. These areas are also indirectly affected by apps' usability, design, and support. Usability was the most common theme emerging from user reviews (43%, 940/2217), with users reporting both positive and negative experiences. We consider usability to be how well an app provided its intervention to ensure users were able to use it effectively and safely. In this context, poor usability which affected access to support or accurate data collection and reporting has potential risks and harms to users. Thus, while usability is not a conventional ethical concept, it can be considered a structural factor with ethical implications. Usability concerns include those of app stability, ease of use, device functionality, and app customization.

Most reviews on app stability highlighted issues with technical difficulties, app failures, and poor responsiveness affecting the use of the app. Issues with app stability occurred at early stages of signing up, logging in, as well as crashing throughout use. For some apps, multiple user reviews reported the same technical difficulties without reply from the developer. Other issues included lag in the running of the app, frequent crashing or freezing, or challenges with specific elements of apps not functioning as expected, such as sounds not working in meditation recordings, notifications not appearing, and in-app communications failing to be sent or received.

User experiences were also impacted by app updates or lack thereof. A small number of user reviews expressed appreciation for updates which fixed technical issues, improved app content and design, and enhanced app functioning. For some apps, lack of updates negatively affected performance. For others, updates brought changes that negatively impacted the app or intervention such as inaccurate reporting of user-generated data. When apps worked as intended, many users found them to be simple and easy to use. This was not the experience for all users with some apps described as too complex and hence less easy to use and with limited user support to navigate such complexity.

Discussions on usability also pertained to device functionality. This includes how the app functioned on specific mobile devices, such as smartphones versus tablets, as well as how apps affected a device's functioning, with some apps interrupting phone calls, sounds and volume settings, or battery life and memory. Few reviews described issues with devices or other apps affecting app functionality, such as losing progress in the app intervention because of a phone call. Loss of tracked data or in-app data was also related to poor error recovery. Some users voiced frustration at being unable to edit user data such as messages, diary entries, and logs. This was especially frustrating when keeping track of important data such as medication or self-assessment of symptoms.

Other difficulties in this area included being unable to restart tasks, with some users feeling restricted by app inflexibility, for example being unable to change previously selected intervention goals. Some users appreciated the range and flexibility of in-app customizations, but a minority thought apps had too many options leading to unnecessary complexity and negative user experience.

4.4.2 Design of intervention and design of app interface.

Like usability, design (30%, 657/2217) had indirect ethical implications related to how the design of the therapeutic intervention delivered through the app and the design of the app interface affected intervention validity, app safety, or accuracy of data.

Positive reviews on intervention design related to the intervention approach and the content provided. But negative experiences stemmed from users' disagreement with the intervention content, including beliefs that the intervention was too generic, lacked depth, or was created by people without experience of mental health difficulties. Some users believed in the validity of the apps, but others expressed concerns with the theoretical orientation or evidence base. Other reviews reflected users' critique of the assessment tools aimed to predict their level of depression. This included concerns that assessments were not valid and may generate false results, for example because they did not allow users to answer 'non-applicable' to questions that did not apply to them. Related to this, there were also concerns with using apps for self-diagnosis, with a few users highlighting the potential for invalid results due to false reporting by users.

Some user reviews highlighted areas of app design and particularly its interface. These were mostly positive, reflecting enhanced user experiences and treatment delivery. These consist of several persuasive design features [84], such as notifications and reminders, tailored interventions, tunnelling using stepped tasks, rewards and gamification, or self-monitoring. Some users also expressed a desire for more persuasive design features. Others wished for more meaningful data, ranging from data on app usage, before-after data to monitor the effects of intervention activities on their emotional states, more open-ended data entry for better self-expression and accuracy, and improved data storage and long-term data collection.

4.4.3 Support.

Another factor which greatly impacted benefits and harms of apps for depression was the provision of support (38%, 838/2217). Support for users fell within four broad categories: developer support, therapeutic support, social support, and support for real-world care.

User reviews provided users with a platform to not only voice their experiences and concerns with apps, but also to reach out to developers in the hope that they may address these difficulties. Some users reported positive experiences of developer support, via response to their app store reviews or other in-app methods of reporting issues. Developer support was typically needed to address issues with usability but also extended to help resolving errors with payment. Several users reported difficulty in accessing developer assistance, with some expressing frustration with the lack of responses to queries. This, along with app instability and lack of updates, led users to believe some developers had abandoned the apps and their user base.

Users also equally discussed the importance of therapeutic support. Therapeutic support in apps for depression consisted of three types: (1) online therapy with qualified counsellors, (2) peer support, and (3) in-app support provided by chatbots. Several users were satisfied with the therapeutic support received but others noted shortcomings and additional support needs, including the need for human support, more frequent and consistent delivery of support, and provision of support at specific points in the intervention such as after self-assessment or when dealing with adversity. As a result, some users emphasized that in-app support was not equivalent to in-person care. Concerns about the competence of in-app support were not limited to therapists, with a small number of reviews outlining concerns with chatbot communications. The most notable issue was the inappropriateness of chatbot responses which users thought showed a lack of understanding and insufficient technological capacity to provide adequate support. In these cases, users felt the chatbot did not appropriately interpret and reply to their communications, but rather provided responses based on what it thought the user would say. This led some to describe interactions with chatbots as scripted or robotic.

More generally, some users expressed dislike of therapeutic support which they found to be patronizing, impersonal, or inauthentic. However, more users described having a positive therapeutic alliance which was genuine and made them feel heard and understood. This helped some users through difficult times in their depression, with some feeling they were able to contact their therapist when needed.

While social support could be also problematic, as discussed in 4.3.2, for some users, apps helped to increase their social support and connections with others. Feelings of increased understanding from others, social connections, and community were common benefits of apps with peer support. Users described receiving help from 'like-minded' persons and how this helped them to feel less alone. Users also benefitted from providing support to their peers, describing feelings of empowerment, empathy, and improved social relations.

These benefits extended beyond the app to impact some users' real-world connections. For a subset of reviewers, using apps for depression made it easier to talk about their mental health difficulties with loved ones. Apps also helped some users to feel more comfortable sharing information about their mental health with their real-world health care provider. Users described previously having difficulty getting their primary care provider to understand their challenges and felt that the app made this easier by legitimizing their mental health concerns or providing a summary report of their data which they could share with their doctor.

4.5 Justice and rights

4.5.1 Autonomy.

Autonomy (the capacity to make informed decisions free from coercion or deception) is an important concept in self-care and mobile mental health, as reflected in its presence as a major theme in user reviews (33%, 734/2217). In this context, the concept of autonomy centered on four main areas: app choice, treatment options, in-app options and customization, and user's voice.

With respect to app choice, the depression app marketplace allows potential users to take an active role in researching and selecting apps and their interventions. Some users embraced this freedom of choice and wished to shop around for the best app to meet their needs. Several users reported having tried similar apps before finding the one that they preferred, with some users expressing a desire to try apps before buying. But less transparent costing affects this as users often encountered paywalls after choosing to trial an app that they believed was free.

Apps also provide users with greater choice regarding the type of interventions available and facilitate their engagement in treatment planning and decisions, with options to select treatment paths, goals, in-app support, or frequency and duration of use. This placed some responsibility on users to take an active role in treatment decisions and fit of care, with one review even guiding others on how to select a therapist that fits based on the therapist's biography. Apps viewed as lacking in treatment options or flexibility resulted in some users feeling forced to complete aspects of the intervention against their will, such as having to complete tasks at set timings rather than being able to customize the intervention based on their individual needs.

In addition to treatment choices, apps also offered users in-app options for customization (discussed in 4.4.1) which let users make apps better fit their needs and individual preferences. Again, a lack of options in this area led some to voice frustration and feelings of apps being limited in choice.

A unique aspect of publicly available mental health apps is the opportunity for users to express themselves in app store user reviews. This gives users a voice to share their treatment experiences and needs, to report grievances, to help others in selecting treatment options, and to potentially influence future app design and development. User reviews helped potential users to select app interventions, often by providing explicit recommendations for use, or recommendations for alternative treatments. In this manner, user reviews functioned as a community of peer referrals and support.

4.5.2 Access.

Apps for depression provided many users with increased access to care with almost 30% of reviews (645/2217) discussing some aspect of this theme in their review. Three main concepts were discussed, namely the barriers to real-world care, preference of apps over real-world care, and barriers to apps for depression.

User reviews showed that apps for depression have the potential to reduce barriers to care that may affect the more vulnerable groups. Many users sought help for their mental health difficulties via apps due to the difficulties of physically accessing in–person care, often due to work or childcare demands, or treatment costs. Apps were also a preferred alternative to in-person care, for people who wished to avoid treatment as usual or human support. App interventions were said to be accessible whenever and wherever needed, with many describing them as a therapist in their pocket. Users appreciated the expediency of apps compared to standard care and the frequency of contact from in-app support. However, some users expressed disappointment when they did not receive support as promptly as expected.

Access to care was also negatively impacted by disruptions to the continuity of care. Some users reported unexpected disruptions to app interventions due to technical difficulties, app updates, unnotified termination of in–app support, and increased app costs. For some, this led to increased feelings of frustration or anxiety.

While some users found apps to be more affordable than other treatment options, many reviews highlighted app costs or paywalls as barriers to care. In some instances, users voiced frustration at being told to pay for an app that claimed to have a free trial. Some users also expressed disappointment at the costs of apps for depression, which they believed should be cheaper than face-to-face treatment. Other barriers included age restrictions and refusal of care by apps, presumably due to concerns with safety or suitability of care.

4.5.3 Commerce.

Over 20% (21%, 463/2217) of user reviews commented on matters related to apps' costs, business models, and consumer rights. This was one of the most passionately discussed themes with users expressing strong opinions over the pricing and billing practices of apps. Some users believed apps for depression were more affordable than standard care, but others thought apps were too costly. This was associated with an unwillingness or an inability to pay for treatment, with many believing that mental health care should be free.

Some users compared app pricing with other apps or online interventions, expressing an unwillingness to pay more when they believed they could access similar content for free elsewhere. Users expressed a desire for more free content in apps, longer trial periods, and greater flexibility in payments.

Apps' costs and billing practices form part of their business models, with some developers disclosing that users' financial support (via payment) was needed to maintain app operations. Other apps included ads to partially fund costs. The adoption of a commercial business model to health care was not always well received by users, with some describing developers as "money-grabbing" and not focused on helping people.

Apps business models and their transparent practices greatly influenced how users perceived the app, its developers, and their intentions. This was not always negative, with users expressing appreciation for apps with financial aid or flexible pricing options. However, a small number of users called on the app stores to take more responsibility to regulate or ban apps that are perceived as exploitative and deceitful.

4.5.4 Privacy.

A significant finding is that less than 5% of user reviews (4.8%, 107/2217) mentioned privacy. In the context of apps for depression, privacy pertains to respect and protection of users' information, including personal details, identifiable user data, intervention data (whether collected actively through user entry or passively via apps), and usage data.

A minority of users praised apps for keeping their details private and considered apps and their data to be secure. Users also appreciated anonymity which they believed helped them be more open in expressing themselves and seeking help, while also making them feel safe.

However, almost 80% of user reviews discussing privacy highlighted concerns ranging from a need for greater secrecy or anonymity, concerns with the collection of sensitive user data before confirming access to the intervention, and concerns with data security and the sharing of user data with third parties. While some users found app privacy policies to be accessible and easy to understand, they did not always agree with the practices outlined in relation to their use of personal data. This was especially a concern for data sharing with third parties such as social media sites.

A key aspect of privacy was users' desire to be in control of their data, from what is collected, to how it is stored and shared. Some users needed increased data protection, while others overlooked potential privacy issues with requests for cloud storage to protect the loss of data.

4.5.5 Respect.

Although respect was a minor theme in user reviews (1%, 31/2217), it is an important element of ethical apps for depression relating to inclusiveness, accessibility, and respect for the rights and dignity of all people. Few apps were praised for their inclusiveness and efforts to improve accessibility, such as having communities for LGBTQ+ and teenagers. More often, reviews highlighted issues in these areas, with users expressing need for apps' greater cultural awareness and suitability of support, increased language options, and accessibility for users with impairments. This included calls for apps to have captions for audio content that made using the app difficult for people who are deaf or hard of hearing.

4.6 Virtue of apps for depression

4.6.1 Transparency and Trust.

The themes of transparency and trust emerged in almost a quarter of our user reviews (23%, 509/2217), with largely negative experiences being reported under insufficient key information and reduced trust in apps or developers.

Several users outlined an insufficiency of information regarding app costs and billing practices, treatment processes and access to care, or elements of support. With respect to costs, users' main concerns surrounded hidden costs, paywalls, and unexpected charges. This had implications on access to care, with some users expressing frustrations with apps that asked them to provide personal information and to complete questionnaires before informing them that they had to pay to access the intervention.

Few reviews highlighted the importance of information, and awareness of the limitations of apps for depression to manage expectations and experiences. While user reviews helped potential users gain knowledge and perspective about apps for depression, transparent information on app costs, treatment details, expected outcomes, and limitations should be readily available from the app developers and the app itself.

Issues with transparency affected some users' trust in apps and developers. Several reviews showed users' trust to be impacted by fidelity, perceived intentions, and ethical and legal compliance. Fidelity is related to truthfulness, i.e., the app does as it says it would. This involved providing the support promised and achieving the expected results. In cases where the app was not as promised, some users questioned app or developers' motives. Negative views of developers' motives were most often related to beliefs that the app was created to exploit vulnerable people for financial gain. As a result, some users described apps as scams seeking to profit off people with mental health difficulties.

Less surprising, users were more likely to express trust in the app and positive perceptions of motives when they had positive experiences or outcomes from using the app. In these cases, users described developers as humanitarians working for the greater good. This is accompanied by expressions of gratitude and praise for caring about others.

4.6.2 Social impact.

A minor theme in user reviews was the wider social impact or social good of apps for depression beyond the individual user (0.8%, 18/2217). These users believed apps for depression had the potential to positively impact attitudes towards mental health difficulties, reducing stigma and normalizing mental health care.

There was also belief that apps had the potential to positively impact communities and wider society by changing mental health care and providing support to more people. As such, developers were urged to consider their civic duty and the social impact of apps they develop.

5 DISCUSSION

We reviewed and analyzed user reviews of publicly available apps for depression to capture user perspectives and ethical experiences, and key elements of ethically designed apps for depression. This study provides a novel contribution to the literature on the ethics of apps for depression in particular, and mobile mental health more broadly. To the best of our knowledge, our study is the first to analyze user reviews of apps for depression for themes related to user experiences of ethical issues. Findings captured diverse user perspectives of apps for depression and how their design, development, and delivery impacted user experiences and wellbeing. The framing of ethical issues within user reviews provided concrete examples of ethical concepts which can sometimes be too abstract and ambiguous for everyday application. These findings and their design implications are explored in greater detail in the following section.

The sample of user reviews of apps for depression was largely positive, with less than half of all reviews categorized as negative or ambivalent. This may reflect our sampling method of selecting reviews from the most rated apps, followed by the lowest rated apps. Despite this, even highly rated apps had some negative reviews and discussion of ethical issues. We were therefore successful in sampling a diverse range of user reviews to convey the breadth of experiences and potential ethical issues. Findings showed several factors that impacted user experiences and provided insight into what users considered to be elements of 'good' apps for depression. Some of these elements reflected common themes in user reviews of mental health apps, notably mention of app usability, design, costs, developer support, and privacy echoing some of previous findings [2, 89]. Ease of use and good product usability were key to positive user experiences, with apps for depression being well received when they were thought to be interactive, enjoyable, and easy to use. This was an important aspect of apps for depression, with user reviews prioritizing both usability and design, an outcome also confirming previous ones [89].

Despite the prominence of these themes in reviews, users were found to be forgiving of errors and app instability when they had an overall positive experience of using the app, at times due to a positive alliance with in–app support or to positive outcomes. Not surprisingly, the effects of using apps for depression had a prominent impact on whether apps were perceived favorably, with users who benefited from use describing positive user experiences, while the inverse was true for risks and adverse effects. User perspectives and ethical experiences are therefore complex and influenced by the interplay of several factors. Findings suggest a possible hierarchy of how these elements are valued by users relative to their individual needs and preferences, with support and benefits seemingly the most important factors for positive experiences of apps for depression. This is not surprising when we consider the unique challenges of depression, particularly the persistence of negative thoughts and affect which can disable functioning and activities of daily living. This makes support for users' engagement, adherence, and benefits, especially important in apps for depression. More research is needed on user values in apps for depression and broader mobile mental health, and how these impact user expectations, use, and adoption.

Our study extended the findings of the one previous user review study on apps for depression [111]. Stawarz et al. [111] however, limited their review to user experiences of CBT apps for depression. But by sampling from all apps for depression regardless of treatment approach, our study provides insight into user experiences across the spectrum of treatment options in the depression app marketplace. This is important as although CBT is considered the gold-standard in psychotherapy for depression, it is not the only digital intervention accessed and used by people with depression [20]. Moreover, although Stawarz et al. [111] mention some ethical concepts, such as privacy and trust, they do not discuss their ethical implications. Our study not only explicitly focuses on the ethical experiences and issues of apps for depression, but shows how traditionally non-ethical concepts, such as usability and design, also have great impact on benefits, harms, and safety. Apps for depression are by nature apps designed and developed to be used by people with mental health difficulties who may be more vulnerable and have greater needs for guidance and support. We therefore consider our study's focus on the ethics of these apps to be of great importance and to fill a glaring gap in the existing evidence.

5.1 Implications for the design of ethical apps for depression

In this section, we reflect on our key findings and how they can inform the design of apps for depression. We contrast our implications for design of such apps with design recommendations or guidelines previously suggested and articulate how ours extend those in new ways. As our findings indicate, it is not enough to solely focus on the app itself, but rather developers must consider the interrelated elements around apps for depression that contribute to user experiences and ethical implications. Ethics can be a daunting topic, at times presented too abstractly for practical application and other times too rigidly [49]. Our work provides a fresh approach to better understand key ethical challenges as reflected in user reviews of apps for depression written by end users, most of them with lived experience of mental health difficulties. Our findings captured key elements that should be considered for the ethical design of apps for depression. These were: benefits, anticipation of risks, safety and safeguarding, usability, design, support, autonomy, access, fair commerce, privacy, respect, transparency and trust, and social impact (Table 1).

Table 1: Elements of ethically designed apps for depression

Element	Description
Benefits	Apps for depression should provide direct benefits to individual users, such as a reduction in symptoms, better affect regulation, and greater insight into their mental health difficulties, and indirect benefits to communities and wider society
Anticipation of risks	Designers should anticipate and avoid foreseeable risks and harms, such as worsening symptoms and adverse effects from use, negative experiences of support, and trolling or abuse in peer support communities. Risk anticipation and management should be an iterative and responsive process occurring throughout the app lifespan
Safety and safeguarding	Apps for depression should be designed with safety in mind, with clear measures such as continuous risk assessment and monitoring, links to crisis support, and connection to real-world services, in place to protect vulnerable people from harm
Usability	Apps for depression should be technological stable, easy to use and amend, and should not interfere with a device's normal functioning especially delivery of digital interventions
Design	App interventions for depression should be valid, reliable, and evidence based. Apps should utilize appropriate persuasive design features such as tailoring of interventions to users' needs and stage of treatment, to increase adherence and adoption
Support	Apps for depression should provide users with adequate developer and therapeutic support and should facilitate improved social support either in-app or in users' daily lives. Apps should support connections to real-world care and services should it be appropriate or needed for the individual user
Autonomy	Apps for depression should enable and respect user autonomy by involving users in treatment planning and decisions and app customization and controls. Apps should also help users in developing autonomy and should not create overreliance on the app itself
Access	Apps for depression should increase access to care through the removal of situational and attitudinal barriers, such as financial barriers, waitlists for face-to-face therapy, and negative perceptions or stigma associated with having depression or seeking care.
Fair commerce	Apps for depression should employ fair and ethical business models which avoid conflicts of interest between commercial practices and duty of care, and respect users' commercial and human rights.

Element	Description
Privacy	Apps for depression should respect and protect users' privacy with clear privacy policies, requests for user data proportionate to need, and robust data security
Respect	Apps for depression should demonstrate respect for all people, including respect for human rights, diversity, cultural differences, and disabilities
Transparency	All information and processes should be transparent and easy to understand, including costs, billing, risks, privacy policies, etc.
Trust	Apps and developers should be truthful and trustworthy. Developers should avoid any intentions or actions which may be fraudulent, deceptive, or exploitative
Social impact	Designers and developers of apps for depression should consider their broader social impact and civic duty in the design and marketing of apps

These elements can be used as heuristics to sensitize and reflect on ethics throughout the entire process of designing apps for depression. We argue that these elements could lay the foundation and contribute towards an ethical framework for the design of apps for depression. To organize these elements for easier use and ethical understanding, we structure them within broader dimensions from existing ethical frameworks [15, 95, 114] and conclude with implications for ethical design of apps for depression.

We integrated our elements of ethically designing apps for depression within the frameworks of principlism [15, 95] and virtue ethics [114], specifically principles of nonmaleficence, beneficence, justice, respect for autonomy [15, 95], and virtue [114]. We have chosen to use the framework of principlism [95], and specifically biomedical ethics [15], given its relevance to, and previous use for mental health care [6, 22] and mobile mental health [19, 52, 55, 102]. While useful, the principles of biomedical ethics are yet insufficient, as they do not support organizing all our ethical elements. To address this limitation, we extended the leverage of this framework with virtue ethics [114] which resonated in user reviews but is not strongly highlighted in traditional discussions on biomedical ethics [15]. In doing so, our discussion advances a framework for the ethical design of apps for depression, which is richer, more nuanced and builds on the existing frameworks. We now describe each of these elements organized under the principles of nonmaleficence, beneficence, justice, respect for autonomy, and virtue, with the most novel findings and their implications being unpacked first.

5.1.1 Nonmaleficence: problematic peer support, in-app diagnosis, tracking negative moods, and problematic usability.

Nonmaleficence is the ethical concept of avoiding harm [15]. A key outcome concerning this principle is that our findings provide a more cautious view on the benefit of social support compared to previous studies on users reviews of mental health apps in general [115, 116], and bipolar disorder apps [81] or chatbots [112], particularly with regard to peer support in users' online communities [81]. While some apps for depression leveraging such communities were perceived as beneficial for strengthening users' social connections and sense of community, for other apps, the peer support was perceived as not only limited but particularly harmful leading to users feeling ignored when not supported promptly, feeling worse when listening to other's mental health challenges, feeling judged when sharing their own experiences, or even bullied or targeted through inappropriate sexual comments. These are particularly important findings, especially since previous research has provided limited evidence of the harm done by mental health apps [75].

Previous work has shown that the support needs of people living with depression varied based on the stage of their depression [109]. People who were unwell, or in an early stage of getting better, needed tangible support for daily living, such as the support with detecting early warning signs of depression, and support for attending treatment. Support needs differed for people who were getting better and remain well, and included support for attending treatment, the continued presence of supporting people, and emotional support in "striving for normality" in life [109]. Our findings confirm support but also further extend these previous ones, by showing that people may have different support needs when using apps for depression depending on their stage of depression or in the intervention. For some users, apps for depression were not able to meet all their support needs, with some users needing human support or more continuous presence of supportive figures. Regardless of the stage in depression, everyone valued support that showed positive regard, empathy, understanding, acceptance, and non-judgement [109] Our findings showed that peer support in apps for depression may fail to adequately provide the needed support, particularly if peer support communities are insufficiently moderated or lack training. The focus on depression and the negative experiences of others may also be detrimental for some users who may be striving for normality by seeking supportive interactions focused on "normal everyday things" and not solely on their depression [109]. Peer support in apps for depression therefore needs to be carefully considered and designed to, in order to specifically provide users with much needed sources of support.

For this, we suggest that support in apps for depression should be tailored to the stage of depression and the associated support needs. As indicated by our findings, common support needs of people using apps for depression included continued support through ongoing connections with therapists and peer communities and human support providing unconditional positive regard and acceptance. We also suggest that apps for depression which involve peer support should provide ground rules for sharing experiences, and psychoeducation on how to adequately respond to other users' negative shared experiences, together with the option of training users to facilitate emotional co-regulation among peers. We extend previous suggestions for trained moderators to ensure confidentiality of online mental health interventions [64], with design implications for depression apps to moderate peer support through both trained (or training) facilitators, and machine learning and natural language processing algorithms which have been already explored for the detection of online antisocial behavior [18, 82].

Also related to adverse effects is our finding that some apps for depression led to automatic misdiagnosis based on user generated data. This is a novel outcome for apps for depression, although previous findings have highlighted the ethical concerns of how, and to whom diagnostic claims are communicated more broadly through affective technologies [102], as they can perpetuate stigma, discrimination, and worsening of mental health difficulties. Hence design suggestions to address these concerns could include those previously suggested ones for affective health technologies such avoidance of diagnostic labels, or explicit advice within the app for users to seek support and interpretation of the tracked data with a mental health professional [33, 34, 110]. But this is not sufficient, as seen in our finding that app generated reports intended to be shared with a health care professional contained errors in the data recorded and the summary provided. Apps with user generated data should be designed with multiple opportunities for data entry as well as the checking and correcting of errors in data. In-app error reporting should be clearly visible to allow users to easily flag errors in their data to developers who should provide a quick response to address these concerns. Our findings also indicate additional users' concerns regarding the validity of the diagnosis tools, or the data used to inform such diagnoses. This indicates the value of psychoeducation with respect to the validity of any such tools, their scientific underpinning, and the population for use. Any outcomes need to be sensitively communicated as highlighted above.

Another important outcome related to the principle of nonmaleficence concerns the tracking of negative emotional content. Previous user reviews studies suggested tracking moods and thoughts, and activities for mood regulation as key features for mental health apps [115, 116], which our findings extend to user reviews of apps for depression. One distinction in our findings is the challenge experienced by some users with tracking and visualization of negative feelings and thoughts which could negatively impact or worsen users' experience, and ultimately depression symptoms. While monitoring moods or symptoms, and recording thoughts are often part of interventions for depression [48], this is typically done in the context of positive therapeutic alliance or support. Without this support, there is a risk that negative thoughts and affect persist and worsen as users focus on the ills in their life. These outcomes extend to commercial apps for depression the previous findings from academic research on affective health technologies [102] and the suggestion for sensitive design of such feedback to support reflection or users' actionability [106] and agency through DIY approaches for better understanding of their data [122]. To address this concern, another design implication for apps for depression could be to provide the option of more ambiguous visualization [103] of the moods and thoughts being tracked, with emphasis on supporting self-compassion, mindfulness, and acceptance rather than the precise and detailed capture of negative patterns. This design implication also leverages findings on the value of compassion theory for depression [57] allowing users to benefit from self-compassion while engaging in a softer form of monitoring which we call *compassionate self-monitoring*. Moreover, the design of interventions for apps for depression should consider the aim of the intervention (e.g., the purpose of the user tracking their moods), the design needed to facilitate this, and the evidence-base behind this design. Further to this, apps should be researched to see if they work as intended, how they compare to standard care, and if there are any risks or adverse effects associated with their use.

We also support previous suggestions regarding the application of ethics models, frameworks for mental health apps, or reputable websites [27, 75, 83, 90] such as American Psychiatric Association (APA) App Evaluation Model [4], One Mind PsyberGuide [86] or ORCHA [87]. These can be followed not only by therapists recommending apps to their patients or users to inform their apps' selection, but more importantly we suggest that they should be also followed by developers to inform their design of apps for depression and by app stores to check apps' suitability before being uploaded. With respect to the latter, in the light of our findings on some of the apps' harmful impacts, it is paramount to ensuring that only apps which are safe to be used by people with depression or other mental health conditions should be uploaded to app stores, as safety is arguably even more important that apps' effectiveness [4, 75].

5.1.2 Beneficence: users' limited awareness of app business models and science- and evidence-basis, and problematic usability.

Beneficence relates to both benefits and minimization of risk [15]. It is therefore closely linked to nonmaleficence. Our findings showed that beneficence is challenged by four key issues, which prevent users from reaping the full benefits of apps for depression. There is also the risk that if not addressed, the most serious of these issues can become harmful.

The first issue is users' limited awareness of the business models underpinning apps for depression and how, as they stand, these models require the monetization of users' mental health-related data. Given the prevalence of user reviews demanding free apps and their limited privacy literacy [43, 76, 83], it is likely that users of apps for depression operate under two distinct yet conflicting mental models. On the one hand, they hold the assumption that apps for depression, like many mobile apps, are affordable tools with valuable functionalities. On the other hand, they hold the assumption that apps for depression should not share their sensitive data with third parties and thus monetize it. This is akin to the traditional health care context, regulated by strong professional standards, legal and fiduciary protection of patients' best interest and therefore their private data [43].

Our findings support the idea of users having confounding mental models, with them expecting for instance respect of their private and sensitive data on apps for depression, despite these apps operating outside the traditional health care context [43]. In fact, commercial apps for depression are geared towards revenue and are largely unregulated. Thus, they are not obliged to follow the fiduciary protection of users' best interest [90] but rather maximize their own revenue. Therefore, the trade-off that some users make, often with limited awareness, is that the cost of free apps is their private data [27, 43, 90]. For context, in 2021 the mental health apps market reached between USD500 million [11] and USD1 billion, experiencing a massive growth at an annual rate of over 20%. It is estimated to reach over USD3 billion by 2027 [123]. This is impressive, given that most of these apps are currently free or low cost, relying on in-app purchasing of extra features (which our user reviews show dislike for) and tailored advertisements leveraging user data [44, 113] with new forms of monetizing such data through personalized and customized features also being explored [11]. This is a notable ethical issue due to the potential exploitation of people with depression who may be vulnerable and seeking care [8].

To address this challenge, we encourage supporting users' understanding of apps' business models and potential trade-off of apps' cost and their monetization of user data. For this, we can think of novel designs for materializing apps' business models, to ensure transparency of what data is being collected and for what purposes. One can also think of providing in-app support for educational content on business models, or generic training provided in app stores. In addition, we also suggest that apps for depression are provided not only as "free" albeit in exchange for users' data, but also in paid versions to ensure users' choice over the ownership, security, and privacy of their data. Indeed, our findings and user reviews of apps for bipolar disorder show that users are willing to pay for good apps [81]. With better understanding of the commercial side of apps for depression, users would be better equipped to benefit from their use.

We also suggest the value of better managing users' expectations with upfront and complete information on app costs. Related to this is the two main sources of app costs: the cost of the app itself and the cost of therapists' support, which appear entangled, shaping users' expectations of the apps. Our findings indicate that users' mental modes of free app use appear to extend towards also accessing free therapeutic support. Users' interest in circumventing the cost of such support is reflected in their wishes for free access to apps for depression and the therapeutic support provided. This leads to an interesting tension between developers' commodification of commercial mental health apps and users' expectation of their right to free mental health care [1, 50]. This perceived right to care is probably greater in countries with national health care systems, such as the NHS in the UK, which does not charge patients for mental health treatment. However, the growing demand for professional therapeutic support is met with a significant shortage of mental health practitioners worldwide [25]. In this context, mental health apps in general, and those for depression in particular, appear to offer their users the opportunity to fill this gap by allowing access to therapists' support. It is a model more in line with private mental health care. Professional therapists' support is a costly resource, irrespectively of being delivered face to face or through mental health apps. The challenge of apps for depression is managing users' expectations of these products and their place in the health care system, as well as the cost of the app and the cost of therapeutic support provided in-app. One way to address this challenge is the clear decoupling of these costs by providing transparent information and user education to help them more realistically manage expectations that quality private therapeutic support is not a free, although the use of the app may be.

In relation to beneficence principle, our findings also confirm previous ones on the limited scientific underpinning and evidence-based effectiveness of mental health apps [20, 72, 81, 115, 116] showing also that only a few users of apps for depression share such concerns. While many user reviews relayed experiencing benefits of apps for depression, the lack of evidence into these benefits makes it difficult for users to easily find the most suitable and effective apps to meet their needs. This was seen in our finding that many users shopped around to find the best apps for depression. This is concerning when considering that some users seek out apps for depression when distressed or in moments of crisis. There is therefore risk that potential users may not be able to find suitable evidence-based apps during these vulnerable moments, which could cause further distress and worsened mental health. As previous research shows, most depression management and suicide prevention apps do not fully adhere to clinical guidelines, with errors found in the crisis contact information provided in 6 of the 69 apps reviewed [72]. To address this, we argue that more work is needed from developers to address the continued shortfall in evidence-based apps for depression [111]. This is essential to ensure apps are safe and effective, which in turn can increase users' perception of apps' credibility and trustworthiness [111, 116]. We also suggest the value of educating users about the importance of apps' scientific underpinning and evidence-based effectiveness, by designing new tools which apply existing ethical models and frameworks to empower users make more informed choices of their apps for depression.

While previous findings also indicated usability concerns of mental health apps such as bugs [3] or technical issues [81, 115, 116], our outcomes show how these issues negatively impact benefits of apps for depression and risk potential harm. Poor usability can hinder user engagement and long-term adoption of mental health apps in general [79, 80] and those for depression in particular, and thus limit apps' potential benefits. This outcome is surprising given the ubiquity of mobile technologies and the focus on user experience in both industry and academia which assumes that usability issues have been adequately ironed out. Given however the massive growth of mental health apps including those for depression, one possible explanation is that developers may prematurely upload or update their apps on the marketplace without being fully tested and stable. To address this issue, both app developers and app stores should be responsible to ensure that apps are stable and updated regularly with stable new versions. Moreover, Torous and colleagues [119] pointed out that apps should "stand the test of time" providing continuing support. Based on our findings, we add to this the need for developers to be responsible for providing exit strategy for discontinuing apps which people with mental health conditions have used, as this may lead to loss of data and harmful consequences due to feelings of abandonment. Apps for depression not only deliver interventions, but also provide a continuous and reliable presence in users' lives. Our findings showed how unnotified discontinuation of interventions or support could trigger negative thoughts or feelings for some people with depression and potentially lead to adverse effects. We therefore build on the previous suggested option of extending use of research prototypes deployed in the wild [104] until alternative solutions are provided, for instance of easy transfer to another available app with similar functionalities. We also advise developers to think of apps as therapeutic supports, and in doing so, to consider the support users need to adjust to changes in app content and delivery. With this in mind, we encourage designers and developers to engage in responsible innovation [88, 125] to anticipate potential usability and design risks throughout the app's lifecycle and to engage in participatory design to better understand how usability and design can negatively impact users with depression. Developers should also iteratively assess risks and safety of their app and promptly correct errors and user reported concerns.

5.1.3 Justice: refusal of care due to screening and affordable apps for depression.

Justice concerns fairness in how benefits and risks are distributed for all people [15]. Under this principle are ethical issues related to access, equality, and rights. An important outcome is that while most reviews appreciated therapeutic support, others expressed concerns regarding refusal of care. Refusal of care is a problematic barrier to access even if it is being informed by the need to safeguard users. This outcome extends previous ones on affective health technologies where researchers employed screening to exclude people whose mental health may be negatively impacted by taking part in research [102]. In the context of apps for depression, it would be useful that not only the apps' functionalities are described in app store listings, but also their limitations and inappropriateness for people with severe mental health conditions who should be directed towards real-world mental health services. We argue for the importance of transparent information for setting right expectations of what apps for depression do, and more importantly what they cannot do in terms of treatment details, expected outcomes, and support. User reviews suggested that users were more understanding of limits to care when clearly explained, but they expressed strong disapproval and feelings of rejection when this was unclear. This uncertainty may trigger negative thoughts and core beliefs about self and others, as the person tries to understand why they have been denied care when others have not. By clearly outlining contraindications and limitations of apps for depression both within the apps and their app store descriptions, this can be minimized or avoided. This is also in line with traditional mental health care standards [6, 22], which outline the need to actively involve users in safeguarding decisions and practices. This is key for supporting prospective users to make more informed choices [51] and to easily access the right level and type of intervention for depression to meet their individual needs.

The issue of accessing professional therapists' support through apps for depression and the cost of such support raises interesting ethical challenges under the principle of justice. Sadly, covering the cost to access such therapeutic support may be particularly problematic for economically disadvantaged users, who arguably are at higher risk of mental health conditions such as depression. Addressing this issue may require policy makers' efforts towards covering the cost of mental health apps by health insurance providers, or collaborations with health care providers towards supporting subsidized subscriptions and affordable payment plans for recommended apps for depression. In the UK, apps for depression will need robust evidence of clinical and cost effectiveness compared with standard care to be considered and recommended for use in the NHS [20]. This raises an ethical conundrum as developers may not invest in evidence-based design and research of apps for depression, resulting in few apps being available through the NHS. This further proliferates the unregulated direct-to-consumer marketplace, where some users may struggle with selecting and paying for quality apps for depression. We therefore encourage developers of apps for depression to explore how they can make their apps more accessible to users in their respective health care systems, and to invest in evidence-based design and research to gain entry to these markets.

Another avenue to address this tension is exploring new ways in which users' data can provide revenue to the users themselves, which can then be used to purchase therapeutic support. This is grounded in work of sociology of health scholars [69] who have highlighted the unethical monetization of data of users' experience of illness whose gathering is not always automatic but requires users' labor. As prosumers (users of apps and creators of data), users contribute significantly to growing the new data economy of digital patient experience with only the indirect benefit of their apps being improved. Users receive no financial compensation for their crucial contribution which is commodified by the app developers. This opens up an interesting design space where HCI researchers can work closely with developers, users, and business studies researchers to co-design new and fairer business models towards more ethical distribution of profit generated from user data.

Our findings show that users of apps for depression largely discussed access in terms of app costs and their ability to use apps wherever and whenever needed. Few user reviews discussed issues related to accessibility for people with other disabilities, despite evidence of poor accessibility in digital health [23]. It is possible that people with additional disabilities, such as hearing or visual impairments or cognitive disabilities, are not readily using apps for depression or sharing their experiences in user reviews. This is therefore a limitation of our research and user review studies, which may fail to capture the full breadth of users and non-users [73]. Though limited, there was some evidence of accessibility issues in our findings, with developers urged to consider the additional needs of users with other disabilities. We therefore echo existing advice on accessibility in digital health [23] and encourage developers to utilize guidelines such as Web Accessibility Initiative's (WAI) POUR guideline [127] when designing apps for depression. The design and development of apps for depression should also be involve people with lived experience of depression to understand and design for specific accessibility needs related to their mental health difficulties [23, 107]. We also encourage more research to further explore accessibility needs and issues in mobile mental health for depression.

5.1.4 Respect for autonomy: supporting users' privacy literacy, choices, and flexible use of apps for depression.

The principle of respect for autonomy acknowledges people's right to make their own decisions or to act on their own freewill without pressure or coercion [15]. Our findings confirm previous ones from user reviews of mental health apps [64, 81, 111, 116] on the value of supporting various user choices, including that of specific treatment options or customization of apps' features. Our findings indicate that balance is needed to provide sufficient options: not too few which users may feel lack flexibility, and not too many which may lead to users feeling overwhelmed. This echoes findings of a systematic review on computerized CBT indicating that high level of autonomy can be both empowering and demanding [56].

Our findings showed that increased user choice and autonomy also meant increased user responsibility. Users' responsibilities included choosing app interventions from the app marketplace, selecting treatment options and in-app support, providing support to others in peer support apps, ensuring appropriate use of the app and correct data entry, and reporting errors to developers. Some user reviews even suggested users were responsible for safeguarding oneself by understanding the limitations of apps before use. While some research has discussed user responsibility as a benefit of mental health apps [29], little is known of the potential impact of this responsibility on treatment outcomes, potential risks and harms, and the type of support needed to ensure safe and effective autonomous use of apps for depression. More evidence is also needed on how much user responsibility is appropriate in apps for depression, and where in the intervention this may be best applied. People with depression may need more support at the start of the intervention when motivation, moods, and behavioral activation may be lowest [109]. Too much user responsibility at this stage of treatment may therefore become a barrier to care but could be used to propel treatment goals and progress if increased appropriately as the intervention progresses. Through participatory design with people with lived experience of depression, apps for depression can be created to balance self-determination with support.

This is closely related to issues of users' privacy and informed decisions around sharing their personal health data. Although the literature tells of well acknowledged privacy violations of mental health apps [83], our findings surprisingly indicate that less than 5% of reviews mentioned privacy concerns. This contrasts with previous outcomes from a smaller study of user reviews of CBT apps for depression [111], indicating a concerning lack of awareness of users of apps for depression regarding privacy implication. Besides previously suggested recommendations for clear and transparent communication of privacy policies [26, 27, 75, 83, 116], in the light of our findings, we also suggest supporting users' privacy literacy through, for instance in-app training or app store descriptions. Following previous recommendations that mental health apps should implement security and privacy mechanisms [83], we also encourage app stores to request that developers explicitly state in their app store descriptions if and what security extensions [67] are in place. We also encourage explicit informed consent practices for apps for depression as has been previously suggested for online mental health interventions [64]. Inspired from security research [67] and ethical practices in traditional mental health care [6], apps for depression should present users with a brief comprehensible privacy summary and terms of use to be reviewed and agreed upon before the app's first use. Only then can a user be said to be truly informed and autonomous in their decision-making.

5.1.5 Virtue: foundations of transparency for trust, and wider social good.

Our findings showed how user experiences were impacted by more than just the app itself, with users also commenting on apps' purpose or developers' intentions. Users believed apps should have a clear purpose centered on helping those in need, with positive experiences, gratitude, and support voiced for apps which were thought to be designed from a place of care and good intentions. This is akin to the ethical concepts of virtue, which considers how a person's character or values ought to be [114].

Within this theme, we found issues related to transparency and trust. The concepts of transparency and trust were more nuanced in the user reviews than in the literature, which is focused largely on issues of privacy, security, benefits, and safety [120, 134]. While these elements also emerged in our thematic analysis, users' trust in apps and developers were often tied to users' perceptions of developers' motives, commonly influenced by their views of app costs, business models, and developer support. Some users alleged apps were scams based on their negative experiences of payments and subscriptions, while others made this accusation for apps with paywalls, limited trials, and misleading offers of free content. For some, paid apps reflected developer greed, with more trust in free apps which were thought to arise from developers' good will. When compared to the lower prevalence of discussions on privacy and security, our findings show a disparity between users' concerns in this area and the focus on privacy in the literature [47, 70]. This highlights a need for further research into the concept of trust in mobile mental health in the wild, to explore the many factors impacting user trust and their interrelations, as well as their impact on the use and adoption of apps for depression. Research is also needed to explore if negative perceptions of paid apps and developers are unique to users of apps for depression, or if they can be generalized to other mental health apps.

When designing apps for depression, developers must consider their target audience and the importance of truthfulness, fidelity, and trust. It is important that apps for depression do as they promise, and that all elements of apps are clearly and openly communicated to users. Transparent app design and honest communication of apps' offerings and limitations is key to fostering positive perceptions and interactions with the app and in-app support. This is akin to therapeutic alliance which is the bedrock of effective interventions for depression. All aspects of apps for depression should be freely communicated to users, from costs, billing practices, treatment approach, risks, privacy, or evidence. Apps for depression should also be designed so that not only is the app easy to use, but information about the app is easy to access and to query.

5.2 Ethical tensions in the design of apps for depression

A key finding from our analysis of user reviews was the interrelations between ethical themes, such that a shortcoming in one area often negatively impacted others. For example, a lack of app updates affected app functioning pertained to poor usability but also demonstrated inadequate developer support. Similarly, high app costs not only affected users' abilities to access care but also impacted their perceptions of developers' intentions and motives, leading to diminished trust in the app. This has the potential to create both situational and attitudinal barriers to care and thus impact users' help–seeking behaviors and mental wellbeing. As the user quotes showed, these scenarios are not hypotheticals but reflect challenges faced by real people seeking help for real concerns.

These interrelations are further complicated by potential mediating factors. Using the previous example of poor usability, our findings showed that issues in this element impacted user safety and wellbeing if technical difficulties limited access to care or accuracy of user data. Likewise, app costs were more likely to reduce user trust when impacted by limited transparency and inadequate notification of payment processes and business models. In seeking to design ethical apps for depression, there must be greater reflection on, and understanding of how all elements of apps affect user experiences and outcomes. The interrelation of ethical themes in mobile mental health is an under researched area warranting greater attention and guidance in navigating ethical design and tensions. This opens up an interesting HCI research space for novel design methods grounded in ethics models that can better support designers and developers to create more ethical apps for depression. The interrelations between elements of ethically designed apps for depression convey both positive and negative associations. In the case of positive associations, successful implementation of one element (e.g., developer support) would be expected to enhance related elements (e.g., usability). Designers should therefore consider how elements are positively related and use this to strengthen the ethical design of apps.

However, cases of negative associations may prove more difficult to navigate and overcome as designers are faced with conflicting elements, both of which represent an important aspect of 'good' apps for depression. This may result in ethical tensions akin to moral conflicts or dilemmas [15, 125]. An example of this can be seen in the tensions between access to care and safety and safeguarding. Developers may prioritize access to care by allowing all age groups to use the app without restriction. This may have potential risks and safety concerns if vulnerable groups (such as children and young people) use the app without appropriate guidance or protections [20, 91]. Risks may also increase if app content or interventions are not specifically designed for these groups, e.g., adult–standardized assessment measures. In this scenario, increased access may reduce safety and benefits. Similarly, developers may prioritize safety and safeguarding by implementing strict criteria for access, with users not meeting these criteria not being granted access to the intervention. In this case, an increase in safety potentially reduces access to care, as was the case with apps whose screening intake resulted in many users being refused treatment. Designers and developers may seek to resolve ethical tensions by prioritizing one element over the other (e.g., access vs. safety). This approach, however, may result in ethical shortcomings which may potentially impact other ethical elements. This is an even greater risk given the poverty of research into the interrelations and mediations of ethical elements to guide which factors may more greatly impact outcomes.

Alternatively, we favor the responsible innovation approach [88] which encourages designers to use moral conflicts to inspire, rather than hinder innovation [125]. Ethical tensions present important design opportunities for development teams to resolve through innovative technological design. For example, designers wishing to increase access to care for young people while ensuring safety may incorporate a way to assess a young person's understanding and competence in making decisions regarding their care. This capacity assessment could then be used to determine whether the young person can make an informed choice for care, as per Gillick competence [42], and be granted access accordingly. Although this competence assessment would likely still restrict access for some users (perhaps with parental consent required in those cases), it would increase both access and safety (and likely autonomy), resulting in a more ethically designed app.

5.3 Limitations

App store user reviews provided a valuable dataset for the exploration of user experiences of publicly available apps for depression. However, this was not without limitations. Firstly, by sampling pre-existing data this thematic analysis was confined to the content and context of the user reviews. Unlike traditional qualitative methods such as interviews or focus groups, we were unable to probe user statements, confirm interpretations of user statements, or further explore specific themes. As such, this study provides a good start for future studies exploring these findings and the interrelations of ethical elements in greater detail.

Moreover, the sampling of pre-existing data prevented the consistent collection of information from all users. User reviews therefore reflect content about apps for depression that users deemed to be important. This varied across users, limiting the ability to make conclusions for the entire sample of reviews. While we used frequencies to determine major and minor themes in user reviews, it is important to note that these figures do not necessarily represent all user experiences as some users may not have commented on all elements experienced. It is therefore important to interpret frequencies as the number of users who discussed specific elements in their reviews, rather than the number of users experienced these elements. Our analysis included 2,217 user reviews of apps for depression. While a few user review studies have included larger samples [2, 89], our sample of user reviews was more than most studies in this area [3, 26, 81, 111, 112, 115]. As with these studies, our findings contained rich user data and a wealth of information on user perspectives and ethical experiences. We suggest additional qualitative research using focus groups or interviews to further explore ethical experiences of apps for depression and to advance our preliminary findings in this area.

This research aimed to sample a cross-section of reviews from apps for depression to capture the range and complexity of user experiences. As such, the sample included both the most rated and the lowest rated apps for depression, and from these samples of the most helpful and most critical reviews as determined by app stores. Due to the nature of app usage and user behaviors, there were a greater number of app store reviews for the most rated apps, with the lowest rated apps being less reviewed and having shorter user reviews. It is possible that this impacted the proportion of positive, negative, and ambivalent reviews in the sample. However, we consider this to reflect the reality of app stores, with an imbalance in how apps are rated, downloaded, and reviewed. Our sampling methods captured a wider range of negative and ambivalent reviews than reported in previous studies [111] and was successful in exploring a wide range of user perspectives and ethical experiences. However, the disparity should still be kept in mind when interpreting the valence in user reviews.

Lastly, our sample of apps for depression included apps targeting depression or depression symptoms. We chose a broader definition of 'apps for depression' as we considered that people with depression, particularly those without a formal diagnosis, may not always search for apps using the term 'depression' but rather may seek apps to help with low mood or feelings of distress. We acknowledge that this may have resulted in apps targeting more general mental health difficulties being included. In our sample of 40 apps for depression, 38 apps explicitly mentioned use for depression. Of the remaining two apps, one targeted low mood while the other was a professional diagnostic tool for all mental health conditions including depression. We therefore believe the apps included in our analysis to reflect apps marketed for depression in app stores. Apps for depression are often transdiagnostic and may target multiple mental health conditions along with depression [14]. It is therefore possible that some user reviews for these apps may be from users who have other mental health difficulties. We consider these perspectives to be valuable in reflecting the range of experiences of people who use apps for depression, particularly considering the notable mental health comorbidities associated with depression [77]. This increases the generalizability of our findings and design recommendations to other mental health apps which may also have some of the same ethical issues. Further research is recommended to explore ethical issues specific to apps for depression and the unique experiences of users with depression.

6 Conclusion

Mental health apps have potential benefits in the treatment of depression and the increased access to care. This was reflected in our study, with many reviews expressing positive views of apps and a range of benefits to mental health and wellbeing. User reviews also provided invaluable insight into the challenges users experience when using apps for depression, and the ethical issues encountered. Our study demonstrated the complex interrelations between ethical elements of apps for depression, and the need for designers and developers to consider the entirety of apps and the role they play in users' lives. We presented key elements to be considered in the design of ethical apps for depression and advanced implications for design organized under the principles of biomedical ethics. In doing so, we encourage a responsible innovation approach to overcome ethical tensions through thoughtful design and user involvement. This study is novel in its capturing of user voices and experiences of ethical issues in apps for depression in the wild. It provides developers with an applied framework and context to guide their design and conceptualization of new ethical mental health technologies.

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APPENDICES

A.1 Supplementary tables

Table 2: 20 most rated apps for depression included in our analysis of user reviews

App name	Developer	Users' rating (/5)		No. of user ratings	
		Google Play	Apple App Store	Google Play	Apple App Store
Headspace	Headspace, Inc.	4.6	4.8	85394	160019
Doctor on Demand	Doctor on Demand, Inc.	4.7	4.1	20593	13
Simple Habit Meditation	Simple Habit, Inc.	4.7	-	15601	-
TalkLife	TalkLife	4.5	4.5	15498	625
Medication Reminder & Pill Tracker	MyTherapy	4.6	-	14701	-
7 Cups	7 Cups of Tea	4.2	4.4	14431	666
Abide: Christian Meditation & Prayers	Carpenter Code Inc.	4.7	-	13971	-
Your.MD: Symptom Checker	Your: MD	4.3	4.7	12711	195
Pacifica: Stress & Anxiety	Pacifica Labs Inc.	4.4	4.7	10778	486
Youper	Youper, Inc.	4.8	4.9	10151	517
Relaxing Anti-Stress Sounds	Dandelion Soft	4.0	-	9935	-
Wysa	Touchkin	4.5	3.6	9620	28
Stop, Breathe & Think	Stop, Breathe, Think	4.3	-	8889	-
Gentle Wakeup: Sleep & Alarm Clock	Dr Alexander Rieger	4.4	-	6705	-
Moodpath: Depression & Anxiety Test	Moodpath	4.6	4.6	6680	2019
Secret Diary	Zheko	3.8	-	6601	-
Aware: Meditation & Mindfulness	zoojoo.be	4.7	-	5157	-
SuperBetter	SuperBetter, LLC	4.3	4.4	5036	431
Remente: Self Improvement	Remente	4.4	4.6	4280	445
BetterHelp: Online Counselling	BetterHelp	3.9	3.5	4082	244

Table 3: 20 lowest rated apps for depression included in our analysis of user reviews

App name	Developer	Users' rating (/5)		No. of user ratings	
		Google Play	Apple App Store	Google Play	Apple App Store
Depression Test	FXT Tech	2.5	-	8	-
DSM-5 Differential Diagnosis	Unbound Medicine, Inc.	2.7	-	122	-
Depression Support	MyHealth Teams	2.9	-	23	-
MoodHacker	ORCAS	2.9	1.0	16	1
My Possible Self	My Possible Self Ltd	3.0	4.4	23	15
Social Force (IntelliCare)	CBITs	3.0	-	14	-
Anxiety & Depression Symptoms	Twayesh Projects	3.1	-	307	-
Talkspace Counselling & Therapy	Talkspace	3.4	3.8	1639	71
WellMind	Blue Step Solutions	3.4	3.3	82	24
IntelliCare Hub	CBITs	3.4	Not listed	28	Not listed
Worry Knot (Intellicare)	CBITs	3.4	Not listed	26	Not listed
UpLift for Depression	UpLift	3.4	-	9	-
MHF	Together for Change	3.5	-	40	-
WellTrack: Interactive Self-Help Therapy	CyberPsyc	3.5	-	31	-
Depression Test	Japps Medical	3.5	-	1385	-
CogniFit Brain Fitness	CogniFit Inc	3.6	-	593	-

App name	Developer	Users' rating (/5)		No. of user ratings	
		Google Play	Apple App Store	Google Play	Apple App Store
Depression Self-Help Guide:CBT	Xandy App Ideas	3.6	-	8	-
Depression Test	MoodTools	3.7	Not listed	199	Not listed
Aware (diagnose yourself)	Heretic Hammer	3.7	-	23	-
Slumber Time (Intellicare)	CBITs	3.7	-	14	-

Table 4: Summary of app interventions and valence of reviews included in our analysis (sorted from high to low ratings)

App name	Intervention (from app store description)	Type of review [n (%)]		
		+ve	Ambivalent	-ve
Youper	ACT | CBT	112 (79)	22 (15)	7 (5)
Abide: Christian Meditation & Prayers	Mindfulness or meditation	30 (61)	15 (31)	4 (8)
Aware: Meditation & Mindfulness	Mindfulness or meditation	36 (72)	12 (24)	2 (4)
Simple Habit Meditation	Mindfulness or meditation	40 (80)	8 (16)	2 (4)
Headspace	Mindfulness or meditation	62 (38)	39 (24)	62 (38)
Medication Reminder & Pill Tracker	Medication management	30 (60)	10 (20)	10 (20)
Moodpath: Depression & Anxiety Test	Assessment | CBT | Mindfulness or meditation | Psychoeducation	63 (56)	37 (33)	13 (11)
Pacifica: Stress & Anxiety	CBT | Mindfulness or meditation | Psychosocial | Self-help	96 (69)	27 (19)	16 (12)
TalkLife	Psychosocial	76 (47)	36 (22)	49 (31)
Remente: Self Improvement	Psychoeducation | Self-help	60 (71)	17 (20)	8 (9)
Your.MD: Symptom Checker	Assessment | Psychoeducation	79 (75)	5 (5)	21 (20)
Doctor on Demand	Online therapy	46 (84)	4 (7)	5 (9)
Gentle Wakeup: Sleep & Alarm Clock	Mindfulness or meditation	38 (76)	7 (14)	5 (10)
SuperBetter	BT | Positive psychology | Psychosocial	46 (39)	30 (25)	43 (36)
Stop, Breathe & Think	Mindfulness or meditation	36 (74)	5 (10)	8 (16)
7 Cups	Online therapy | Psychosocial	42 (29)	46 (32)	56 (39)
Wysa	CBT | DBT | Exercise	36 (60)	16 (27)	8 (13)
Relaxing Anti-Stress Sounds	Sound therapy	29 (58)	12 (24)	9 (18)
Secret Diary	Emotional awareness | Monitoring and tracking	32 (65)	16 (33)	1 (2)
BetterHelp: Online Counselling	Online therapy	57 (43)	14 (10)	63 (47)
Aware (diagnose yourself)	Assessment	2 (25)	0	6 (75)
Depression Test (MoodTools)	Assessment	14 (70)	3 (15)	3 (15)
Slumber Time (IntelliCare)	Sound therapy	1 (20)	2 (40)	2 (40)
My Possible Self	CBT | IPT | Positive psychology | PST | Self-help	3 (17)	3 (17)	12 (66)
CogniFit Brain Fitness	Assessment | Cognitive training	7 (19)	6 (16)	24 (65)
Depression Self-Help Guide:CBT	Psychoeducation | Self-help	1 (33)	0	2 (67)
Talkspace Counselling & Therapy	Online therapy	23 (31)	10 (14)	41 (55)
Depression Test (Japps Medical)	Assessment	27 (54)	19 (38)	4 (8)
MHF	Psychoeducation | Psychosocial	5 (25)	4 (20)	11 (55)
WellTrack: Interactive Self-Help Therapy	ACT | Assessment | CBT | Self-help	12 (52)	3 (13)	8 (35)
IntelliCare Hub	Assessment | Psychoeducation	1 (8)	2 (15)	10 (77)
UpLift for Depression	CBT	2 (11)	4 (22)	12 (67)
Worry Knot (Intellicare)	Cognitive reappraisal | Distraction or grounding | Monitoring and tracking | Problem solving | Skills building	3 (50)	0	3 (50)
WellMind	Psychoeducation | Self-help	13 (35)	7 (19)	17 (46)
Anxiety & Depression Symptoms	Psychoeducation	9 (56)	1 (6)	6 (38)
Social Force (IntelliCare)	Psychosocial	0	0	2 (100)
Depression Support	Psychosocial	2 (12)	2 (12)	13 (76)
DSM-5 Differential Diagnosis	Assessment	6 (20)	1 (3)	23 (77)
Depression Test (FXT Tech)	Assessment	1 (100)	0	0
MoodHacker	CBT | Positive psychology | Psychosocial | Self-help	0	2 (67)	1 (33)

5 Conceptualising Ethical Digital Mental Health and the Applicability of Ethical Design Cards: A Multidisciplinary Workshop

Chapter 5 brings together several findings and developments from the previous chapters in the final paper titled ‘Conceptualising ethical digital mental health and the applicability of ethical design cards: a multidisciplinary workshop’. In this paper, I sought to capture the views and experiences of professionals who had either designed or delivered mobile mental health interventions. This paper comprises two studies. The first study explored participants’ key values in digital mental health and their conceptualisation of ethical digital mental health. I was interested in seeing how these values aligned with the literature on values and the findings from Chapter 4.3 which outlined user perspectives. I was also interested in seeing if and how participants conceptualised values within the concept of ethical digital mental health. The second study in this paper explored the practical application of ethics in the design of digital mental health technologies. In Chapter 3.2 and 4, I outlined notable concerns in mobile mental health, which were presented as ethical elements, themes, and systems. I amalgamated the findings in the studies presented in Chapter 4 to develop a prototype set of ethical design cards aimed at facilitating multidisciplinary discussion and design of ethical mobile mental health technologies. Chapter 5 presents these ethical design cards and reports findings on their acceptability and feasibility as a toolkit to promote more ethical technologies. This paper has been prepared for publication.

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Original paper

Conceptualising ethical digital mental health and the applicability of ethical design cards: a multidisciplinary workshop

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Abstract

Background: There has been increased interest in the use of digital mental health interventions as a treatment option to increase access to care and support. Yet, there continues to be notable challenges with the implementation of these technologies, with ongoing ethical concerns. This has resulted in calls for greater multidisciplinary involvement to better understand the range of ethical issues and to create practical tools to increase the design and development of ethical digital mental health interventions.

Objectives: This research had two objectives. Firstly, it aimed to explore perspectives on ethical digital mental health via multidisciplinary workshops with people experienced in delivering mental health care or developing mobile mental health technologies. Secondly, we introduced a prototype set of ethical design cards with the aim of exploring their acceptability and feasibility as a method to improve ethical practices and design in digital mental health.

Methods: We conducted three online workshops with 10 people who had past or present experience of delivering mental health care or designing or developing mobile mental health. Each workshop was divided into two parts. The first half of the workshop explored values in digital mental health and definitions of ethical digital mental health through individual recording and ranking of values, followed by group discussion. In the second half of the workshop participants were introduced to a prototype set of ethical design cards followed by group discussion on their feasibility, applicability, and content. Data was analysed thematically.

Results: Participants listed 60 key values in digital mental health which were themed into 15 core values: privacy, effectiveness, usefulness, accessibility and inclusivity, autonomy, transparency, ease of use, accuracy and reliability, trust, personalisation, support, acceptability, person-centred design, connectivity, and enjoyment. Individually, participants considered privacy and effectiveness to be the most important values. But group discussion proposed the concept of a values matrix, where all values were considered important in the design process. Participants used these values as the basis of their conceptualisations of ethical digital mental health. There was good acceptability of using the ethical design cards in the design of digital mental health technologies, with suggestions for improvements.

Conclusions: This research made two key contributions. Firstly, our findings showed several core values in digital mental health, which we have suggested can be used in a values matrix. This is proposed as a practical tool to make ethics less abstract. Secondly, we presented a set of ethical design cards for digital mental health, with findings showing good acceptability and applicability of the cards throughout the design process particularly within multidisciplinary teams. We encourage further research on these concepts and the use of the cards in practice.

Keywords. mobile mental health, digital mental health, ethics, values, value sensitive design

Introduction

Background

The ethics of digital mental health

There has been great interest in the potential of digital mental health to increase access to evidence-based mental health care and support. The UK's National Institute for Health and Care Excellence (NICE) recently recommended several mobile mental health interventions for use in the NHS with healthcare professional support, while further evidence is generated [1–3]. These NICE early value assessments highlight the potential of digital mental health to increase access to mental health interventions that may improve symptoms and overall functioning, especially in the absence of alternative treatments in standard care. But they also acknowledge the limited evidence on these technologies and the need for continued research and evidence generation [4,5]. This sums up an ongoing challenge in the field of digital mental health and a fundamental ethical concern. While there is a growing body of literature on digital mental health, research shows that there continues to be limited evidence on publicly available mental health technologies, particularly those listed in the commercial app stores [6–12]. This means that the effectiveness and outcomes from using these technologies are largely unknown, posing potential risks to users and the broader healthcare system [13–20].

A scoping review of the literature on the ethics of mobile mental health for common mental health disorders (D Bowie-DaBreo, in preparation) found that potential harms and privacy concerns were the most commonly discussed ethical issues, followed by duty, inequalities, autonomy, benefits, and standards. Ethical issues and the frameworks underlying these discussions were found to vary by author discipline, with papers with multidisciplinary authorship providing more comprehensive ethical evaluations and considerations than papers by authors of the same discipline [6,21,22]. Some ethical issues were not discussed by some disciplines, for example none of the papers from only human computer interaction (HCI) authors discussed inequalities, standards, conflicts of interest, or clinical practice [11,23], while none of the papers with only mental health authorship [23–29] discussed intentions and values, or acceptability (D Bowie-DaBreo, in preparation).

This supports previous calls for greater multidisciplinary collaboration in mobile mental health in order to fully capture the range of ethical considerations and issues in the field [7]. This is especially notable when considering the potential impact of values on the development, use, and research of digital mental health technologies [6,21,23,30]. Values may be intrinsic (valuable in their own right) or extrinsic, that is, supporting intrinsic values [30]. Examples of intrinsic values are health and happiness, while extrinsic values may include privacy, security, and trust. Research suggests that developers and users of digital mental health technologies may have differing values which could impact the development and acceptance of these technologies, respectively. A review of the depression app marketplace suggested that developers prioritised evidence-informed design and privacy, with less focus on research, safety, duty of care, transparency, credibility, and informed consent [6]. Comparatively, key values for users included autonomy, control, and dignity [23]. It is therefore important to better understand the values of developers of digital mental health technologies in order to explore how these may affect the design of digital mental health interventions, and also how this may differ or conflict with the values and needs of potential users.

Value sensitive design

Value sensitive design is a useful framework for exploring the role and impact of values on technology design. At its core is the premise that technology is influenced by human values and in turn influences values through its impact on human behaviours and practices [31,32]. Value sensitive design considers the impact of values held by individuals involved in the design and development of technology, but also wider societal values. Here, values are defined as “what a person or group of people consider important in life” [32]. Value sensitive design emphasises moral and ethical values – that is, those related to human welfare, dignity, justice, and human rights [33] – but also considers “personal and conventional values [that] can become morally implicated” within the complexity of social life [31, p. 23]. van de Kaa et al. [32] considered that values capture social and ethical issues which are then reflected in a technology’s design. Values discuss what ought to be, not what is. In doing so, value sensitive design provides a means to advance the design of moral and ethical technology without being overwhelmed by abstract ethical theories and philosophies.

Value sensitive design can be applied across technologies, populations, values, and contexts. It considers how to engage with a wide range of values using an iterative design process that integrates conceptual, empirical, and technical investigations [31,33,34]. This includes: (1) identifying and understanding different stakeholders, their values, and potential value conflicts; (2) researching users’ values, needs, and practices; and (3) exploring how people use technologies or the systems designed to support the identified values. Friedman and Hendry [31] outlined several methods of value sensitive design, including stakeholder analysis, value source analysis, value scenario, value-oriented semi-structured interview, value sensitive action-reflection model, and envisioning cards. The methods of value sensitive design aim to help with stakeholder identification and interaction, eliciting and identifying values, values analysis, design principles, and facilitating ethical design.

Understanding how values may impact technology design is particularly important for technologies with multiple stakeholders who will each have their own views and values. This may result in differing opinions and priorities which may lead to ethical and design conflicts [32]. Friedman and Hendry [31] described values as interconnected and in balance such that a shift in prioritising one value will affect others. How well a technology aligns with societal values and norms may also impact its acceptability and adoption [23]. van de Kaa et al. [32] posited that these conflicts can be navigated by comparing and ranking values “especially when non-compatible values point in different directions for the development of new technologies” (p. 3). In these situations, designers may change the design of the technology to overcome the conflict or may instead prioritise some values over others. Value sensitive design methods such as value dams and flows can be used to help resolve ethical tensions in design choices. In the value dams and flows method, any objectionable design options are removed (value dams) before prioritising the most favoured of the remaining options (value flows) [31].

To assist with this, some have suggested benefit in having heuristics of values that could be used as a starting point when considering the values of specific technologies [31, 33]. Friedman and Kahn [33] developed a list of specific values with ethical importance, grounded in deontological and consequentialist theories, which were further revised by Friedman et al. [34]. These 13 human values with ethical import were human welfare, ownership and property, privacy, freedom from bias, universal usability, trust, autonomy, informed consent, accountability, courtesy, identity, calmness, and environmental sustainability. The authors [31,33,34] noted that the heuristic of values was not intended to be a complete list of human values, but rather offered a starting point for consideration and discussion. They further acknowledged criticism of this approach, including the potential of prioritising some values over others and excluding some altogether. Friedman and Hendry [31] highlighted the challenge of avoiding “reification of a certain set of values or world views, while at the same time positioning those bringing value sensitive design into their research and design process to build upon each other’s prior work” (p.27). They concluded that exploration of these issues and tensions may be best done in practice.

Ethical design cards for digital mental health

Design tools, such as cards, scenarios, and toolkits, have been used in HCI to make theoretical concepts more practical. They have been applied to facilitate consideration and discussion of concepts ranging from value sensitive design [31,36,37] to technology acceptance [35]. Design cards allow for simplified presentation of oft complex concepts using different mediums such as written descriptions, visuals, and reflective questions. In doing so, they provide a toolkit "for ideation, co-design, heuristic critique, evaluation, and other purposes" [31, p. 64].

With this in mind, we designed a prototype set of ethical design cards for digital mental health (Figure 1). The full set of cards can be found in Appendix A. The cards aim to assist developers in designing ethical and responsible digital mental health technologies. They are intended to be used as a toolkit to help multidisciplinary development teams to reflect, discuss, and anticipate ethical issues throughout the technology design process. The cards were designed by the first author (DB) in consultation with all authors and incorporate findings from our previous studies on the ethics of mobile mental health [6,7,38,39]. The card set includes:

(1) Instruction card: this provides a brief outline of the toolkit including aims and use.
(2) Six ethical categories: these are the overarching ethical themes that were identified in our previous studies [6,7,38,39] as being especially relevant to digital mental health technologies, namely outcomes and effects, integrity, reliability and validity, human rights, duty of care, and justice.
(3) 15 ethical elements cards: within each ethical category are related ethical elements cards, with each card pertaining to one element (see Table 1 for description of categories and elements). The front of the ethical elements cards provide written and visual descriptions of the concept, while the back of the card present several questions (*Reflections*) to help developers to explore these concepts more deeply.
(4) Six *What users say* cards: each ethical category also has a separate card with a sample of user quotes generated from previous research [39] which seeks to illustrate how the ethical issues may present in real-world use of digital mental health.
(5) *Ethical tensions* card: This card provides a concise overview of ethical tensions with the aim of helping developers to consider ethical conflicts and how to innovate to overcome these tensions in the design of their digital mental health technology.

The ethical design cards were designed to be used flexibly and iteratively throughout the design and development process. The instruction card outlines the following suggested guidance for use, but this is by no means prescriptive and there is no right or wrong way to use the cards:

- Step 1: At the beginning of the conceptualisation of the specific digital mental health technology, review the ethical categories and elements and consider how these concepts will be reflected and addressed in the design process and the digital mental health product.
- Step 2: Use the reflections provided with each ethical element to further explore these ethical concepts and to take practical steps to overcoming ethical challenges.
- Step 3: Read the *What users say* card provided in each ethical category for clarification and real-world examples of the ethical concepts and issues as experienced by real users of digital mental health.
- Step 4: Utilise the *Ethical tensions* card to explore potential ethical conflicts in the design of digital mental health technologies, and to consider innovative ways to overcome these conflicts.
- Step 5: Continue to use the ethical design cards throughout the design, development, and deployment of the digital mental health technology to identify and overcome ethical challenges as these arise.

Figure 1. Ethical design cards for digital mental health

These cards focus on concepts of equal access, just treatment, and fairness for all persons

ELEMENTS TO CONSIDER:
- Access
- Fair commerce

ETHICAL TENSIONS

Ethical design in digital mental health is not always an easy and straightforward process. Ethical concepts are not always black and white, and ethical decisions often lack one clear answer or resolution. Moreover, ethical concepts such as those presented on these cards are often interrelated, such that issues with one ethical element (such as privacy) may impact others (autonomy, risks, integrity etc.).

Similarly, designers and developers may find they are faced with conflicting ethical elements, such that the prioritisation of one element (such as access to care) may negatively impact another element (safety and safeguarding).

It is therefore important for designers and developers of digital mental health technologies to be aware of potential ethical tensions, and to use these conflicts to inspire innovative design of ethical and responsible mental health technologies.

Table 1. Ethical categories and elements in the ethical design cards for digital mental health

Categories and elements	Description
Outcomes and effects	**Direct and indirect impacts of the technology on users and wider society**
Anticipation of risks	Consideration and management of potential risks and harms
Benefits	Direct benefits to users’ mental health and wellbeing
Social impact	Broader social impact and civic duty in design and marketing of technology
Integrity	**Issues related to honesty, accountability, and morality**
Transparency	Transparency and ease of understanding information and processes
Trust	Fostered by truth and trustworthiness of developers and the technology
Reliability and validity	**Issues related to ethical impact of consistency, functionality, and fidelity**
Design	Impact of the design of the user interface and intervention itself
Usability	Functions as it should for reliable delivery of digital intervention
Human rights	**Respect for individual freedoms, choices, differences, and rights**
Autonomy	Promotes and facilitates users’ autonomy and informed choice
Privacy	Respect and protection of users’ privacy and confidentiality
Respect for all	Respect for all people, including accessibility and diversity
Duty of care	**Responsibility for safe and supportive mental health technologies**
Competence	Developed and delivered with appropriate technological and clinical skills
Safety and safeguarding	Developed with safety in mind and protections for most vulnerable users
Support	Developer and therapeutic support, and fostering social support
Justice	**Issues related to equal access, just treatment, and fairness**
Access	Ability to increase access to treatment by removing barriers
Fair commerce	Fair and ethical business models avoiding conflicts of interest

Objectives

This research had two objectives. Firstly, it aimed to explore perspectives on ethical digital mental health via multidisciplinary workshops with people experienced in delivering mental health care or developing mobile mental health technologies. Specifically, it sought to understand participants' values around digital mental health and how they defined ethical digital mental health. Secondly, this study introduced participants to a prototype set of ethical design cards with the aim of exploring their acceptability and feasibility as a method to improve ethical practices and design in digital mental health. In doing so, we sought to answer the following questions:

(1) What are the key values in digital mental health?
(2) How do participants describe ethical digital mental health?
(3) What is the acceptability, feasibility, and barriers to using the proposed ethical design cards?

The findings of this research will inform the development of a framework for ethical mobile mental health and the applicability of using ethical design cards to guide the design of mental health technologies.

Research methods

Participants

We conducted three online workshops between March to May 2021 with people who had past or present experience of delivering mental health care or designing or developing mobile mental health. Ethical approval for this research was granted by Lancaster University's Faculty of Science and Technology Research Ethics Committee. Participants were recruited via emails distributed through our professional and research networks, including universities and research centres. Participants were not required to have experience or knowledge of ethics or ethical design. In total, 10 participants (four men, six women; mean age 33.6 years, range 25 to 47) took part in the workshops with backgrounds in psychology (n=3), computer science (n=3), HCI (n=2), biomedical engineering (n=1), and computer science and psychology (n=1). Three participants were PhD students; four were researchers with roles including postdoctoral researcher, research associate, and research fellow; two were psychologists; and one was a lecturer in mental health. All participants had past or present experience in the design or development of mental health technologies. Participants were allocated to groups sequentially based their disciplinary background in order to encourage multidisciplinary discussions. The groups were:

- Group 1 (n=2): computer science (n=1), psychology (n=1)
- Group 2 (n=4): HCI (n=2), computer science (n=1), psychology (n=1)
- Group 3 (n=4): computer science (n=1), computer science and psychology (n=1), biomedical engineering (n=1), psychology (n=1).

Group 1 was a pilot group to test the running of the workshop and therefore included fewer participants. No changes were made to the workshop structure, procedures, or materials after this pilot, so group 1 was included in the research participants and findings.

Procedure

All workshops were conducted remotely using Microsoft Teams. Throughout the workshop, participants were asked to write their responses in Miro (https://miro.com), an online whiteboard that can be used to visualise ideas and facilitate group discussion and collaboration. Before agreeing to take part, all participants were provided with information on the research and the online workshop. Participants provided informed consent and completed a short questionnaire on their demographics, discipline, and professional experience in mobile mental health. Participants received an electronic version of the relevant ethical design cards two days before the workshop. They were instructed that they could look over the cards and print them before the workshop, but this was not required. Each workshop was approximately two hours and was divided into two parts.

Study 1: Values and ethical digital mental health

The first half of the workshop explored values in digital mental health and definitions of ethical digital mental health. Participants were given a definition of values as "what a person or group of people consider important in life" [33]. They were firstly asked to work individually to list up 10 key values in digital mental health and to rank these in order of importance. Participants wrote their chosen values in their individually allocated space on the Miro whiteboard before coming together as a group to discuss. As a group, participants were then asked to discuss and decide the key values and to rank these in a values hierarchy. Next, participants were asked to define or describe ethical digital mental health before sharing their professional experiences of ethical issues or challenges in the field.

Study 2: Ethical design cards

The second half of the workshop focused on the ethical design cards (Appendix 1). Each workshop group was given two different ethical categories: (Group 1) *Outcomes and effects* and *Integrity*, (Group 2) *Reliability and validity* and *Human rights*, and (Group 3) *Duty of care* and *Justice*. During the workshop, participants were given a brief overview of the ethical design cards and their proposed use. Participants were then given time to review the cards by themselves with the option of using the Miro whiteboard to record any comments, feedback, and suggestions. To aid this review, participants were asked to think of a past or current digital mental health project that they were involved in and to consider how the cards could be applied to this project. Participants then regrouped to share and discuss their perspectives of the cards and the application to their chosen scenarios. This discussion included suggestions of how the cards could be used in the design process, ideas around the content and design of the cards, and consideration of potential barriers and facilitators to use.

Data analysis

All workshops were audio recorded, and the recordings were anonymised and transcribed. DB conducted thematic analysis of the workshops and interview transcripts using the methods and guidelines for thematic analysis outlined in Braun and Clarke [40]. Thematic analysis is "a method for identifying, analysing, and reporting patterns (themes) within data. It minimally organizes and describes your data set in (rich) detail…and interprets various aspects of the research topic" [40, p. 79]. We chose thematic analysis as the data analysis method because this approach is not theoretically bounded and our research did not aim to develop new theories, for example as is done in grounded theory [41], but rather to explore participant perspectives and differences in themes across disciplines. We used an inductive realist approach to thematic analysis, such that coding was data driven and reported the experiences and the reality of participants. We did not deductively code the data using existing theories, such as value sensitive design, because we wished to start from the bottom up in exploring participants' discussions of the concepts. We also did not attempt to infer the impact of wider sociocultural contexts or structures on participants' accounts. While we explored how these accounts may differ based on a participant's disciplinary background, the analysis did not seek to understand or theorise the social influences underlying these views.

We used the following steps to analyse our data as outlined in Braun and Clarke [40]:

1. Familiarising yourself with the data: DB transcribed the workshops, then read and re-read the transcripts to become familiar with the content and to note initial ideas.

2. Generating initial codes: coding was done systematically across all workshop transcripts using ATLAS.ti (version 9). This involved organising the transcript data into more meaningful groups for further analysis.
3. Searching for themes: codes were then reviewed and grouped into potential themes.
4. Reviewing themes: themes were reviewed to check how well they fit the data extracts and the codes. This led to some themes being reworked or merged into more distinct groups.
5. Defining and naming themes: we continued to refine the themes, including defining and labelling themes and identifying any subthemes.
6. Producing the report: finally, we drafted the research manuscript including selecting participant quotes to illustrate the findings and conducting final analysis of the data.

In Study 1, participants listed 60 key values in digital mental health that were then themed into core values using the methods outlined above. Core values were then cumulatively scored based on rankings of importance, with higher ranked values having higher scores. For example, if a participant listed and ranked three values, then the most important value would be scored *3*, the second scored *2*, and the last *1*. These cumulative scores were analysed alongside the thematic analysis.

Results

Study 1: Values and ethical digital mental health

Core values in digital mental health

Participants listed a mean average of seven (range four to nine) key values in digital mental health, which we themed into 15 core values (Table 2). Two values were overwhelming listed as important in digital mental health: privacy and effectiveness (Figure 2). Other highly ranked values included usefulness, accessibility and inclusivity, and autonomy.

Table 2. Descriptions of core values in digital mental health (listed alphabetically)

Core values	Description
Acceptability	Acceptance of the technology by users or potential users
Accessibility and inclusivity	Interrelated concepts related to designing and deploying digital mental health so it can be used by as many people as possible
Accuracy and reliability	Correct and consistent delivery of digital mental health, including dependability, technical stability, and accurate information and outputs
Autonomy	Self-determination and agency over one's experience including interactions and data sharing. Also related to user motivation
Connectivity	Integration with existing systems, including interoperability
Ease of use	Usability and simplicity of digital mental health technologies to make them easy to access and use
Effectiveness	Grounded in evidence-based approaches and evidence that the technology works, as reported in clinical and real-world benefits
Enjoyment	Appeal of technological intervention, including fun and motivation to use
Person-centred design	Person-based approach to design of digital mental health that is led by people with lived experience of the target condition
Personalisation	Customisation and tailoring of a technology or intervention in line with a person's individual needs and preferences
Privacy	Privacy and confidentiality of a person's data, including security, compliance with GDPR[a] and allowing for discrete use. Also includes ease of understanding privacy-related information, including terms and conditions of use
Support	Assistance using the app or completing the intervention, including human support and technological support
Transparency	Clear information about the technology and intervention, including its purpose, approach, evidence, and expected outcomes

Trust	Understanding of and belief in the technology, intervention, and developers, with connections to integrity and compassion
Usefulness	Meeting people’s needs in a way that is relevant and meaningful for their lives and their mental health problems.

[a] GDPR: General data protection regulation

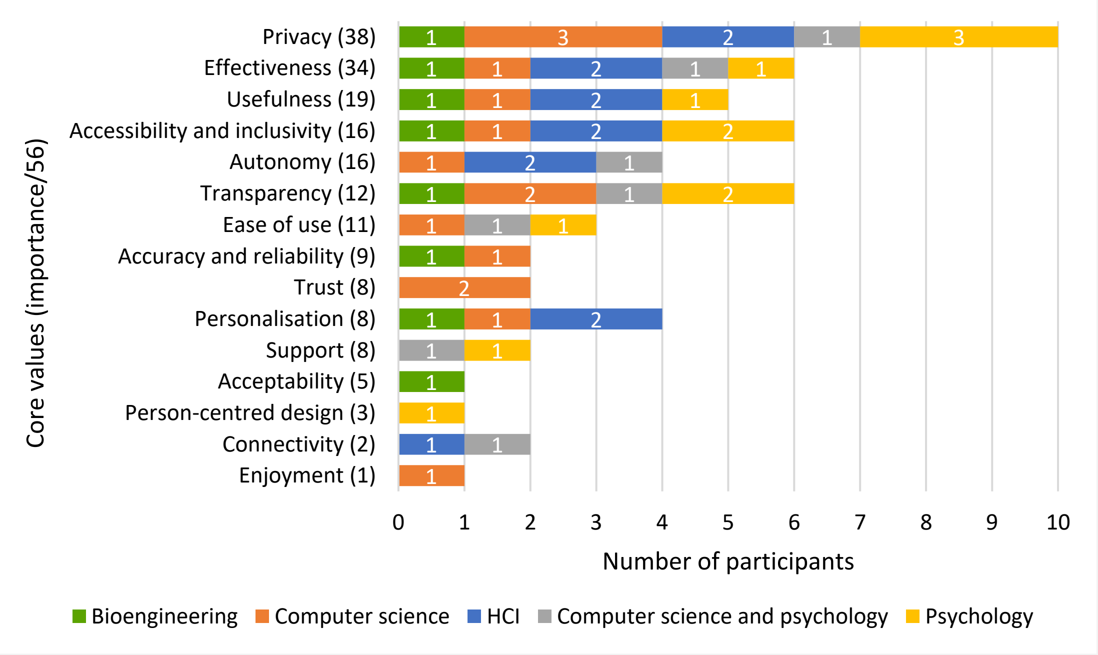
Privacy

Privacy was the most commonly listed value and ranked the most important with a cumulative score of 38 out of 55, where 55 is the highest possible score if all participants ranked it as the most important value (Figure 2). All participants listed key values related to privacy, with eight of the 10 participants ranking privacy in their top three most important values (see Appendix B for each participant’s ranking of key values). Most participants linked privacy with data security and considered this to be a top priority for digital mental health. Participants also spoke of the importance of keeping users’ personal information private particularly for vulnerable people with mental health conditions because “if their data or information about their condition is publicly accessible then that puts them in an even more vulnerable position” [P2, computer science].

Few participants spoke about privacy more broadly in the context of people being able to use digital mental health discretely, with one participant connecting privacy with preventing stigma:

> Privacy as in privacy of the data, but also privacy for the person, that the technology doesn’t add a stigma. Because mental health conditions already are very stigmatising for the person, so it’s important that the technology doesn’t add an additional stigma. And it’s also if there is a stigma then they won’t be using the technology. [P6, HCI]

Figure 2. Frequency and importance of core values in digital mental health



Participants tended to describe privacy differently depending on their discipline. Participants from computer science backgrounds generally focused on privacy in relation to the technology or data security while psychologists mentioned confidentiality, with one connecting this to the creation of a safe place “where you can be sure that your confidentiality is kept” [P7, psychology].

Effectiveness

Effectiveness was also highly ranked in importance (34/55) and listed as a key value by six participants. Participants discussed effectiveness in terms of evidence-base and proven outcomes:

> I think it’s important that if we are developing for mental health that [there] is something that it is grounded on, like interventions that we know that work and that are translated in a meaningful way. [P5, HCI]
>
> Obviously in psychology, you are going to be evidence-based. And I mean this both within the app in terms of making sure that the concepts and methods and theories within the app are based in proven methodologies. But also that those methodologies are tested within the app as well. Because it is a novel approach to using that technique probably with a new audience, as well as making sure that it has got the theory in it but that it is being researched in itself. [P8, psychologist]

Few participants also described effectiveness as important to ensure that people did not experience worse mental health from use, but safety was not listed by any participant as a key value:

> I put first effectiveness because I think the main thing is really we don’t want to have an intervention or technology that makes people’s condition worse. We want something that works for them clinically. And so as [P5] said, I think it is important that it is evidence-based and probably developed together with clinical psychologists. So designed for effectiveness and to not create any more harm to the user. [P6, HCI]

Usefulness, personalisation, and person-centred design

Participants also highly ranked values around the usefulness of digital mental health (19/55). This related to how well digital mental health aligned with and met users’ needs, with discussions showing interrelations between this concept, personalisation, and person-centred design. Five participants listed key values associated with usefulness, with four ranking it in their top three values (Appendix B). Usefulness was described in terms of how well a digital intervention met a user’s needs in terms of compatibility, meaningfulness, and appropriateness. It was associated with adding value to a person’s life rather than an additional burden and was strengthened by involving people with lived experience to ensure relevance of content and delivery. Related to this were key values around personalisation. Personalisation and tailoring were listed as key values by four participants but were ranked lower in importance (8/55). Participants described personalisation as a means to achieve usefulness and alignment with users’ needs. This was especially related to the differing mental health needs across people with the same disorder:

> Tailoring and personalisation, that is very important I think because it is like everybody is different. And even if you take people living with depression, like everyone has very different experience, different symptoms, and a different way to cope with it. And we have the means with technology to do this with tailoring. So, it is important to consider that and [to] propose an appropriate solution for the

> person as opposed to a solution that would try to fit everyone’s needs and, in the end, would not meet any need. [P6, HCI]

One participant described this as user centric stating “Whatever technology it is, it needs to be adaptable to the user, so it needs to be able to accommodate to a certain extent to what the user needs” [P2, computer science]. Yet, only one participant listed person-centred design as a key value (3/55), which they thought was important to differentiate from personalisation:

> I did not specifically put personalisation because I think sometimes you can have a very niche technology that can be designed for a very small subgroup. I work with a very large population so that has few personalisation within the technology. But I think just the idea of it being individually focused or individually led and designed by individuals. I am using a lot of the person-based approach. [P8, psychology]

They considered that person-centred design could increase the compassion and empathy of digital mental health interventions by “really thinking about the emotional side of some of these feelings and the situations that people be going through using the app [which] can sometime be lost.”

Accessibility and inclusivity, ease of use, and acceptability

Accessibility and inclusivity was a relatively highly ranked value (16/55) that also considered how to include people with lived experience in the co-design of digital mental health to make sure “you are not leaving a group of people behind, people that may be in the digital divide for example” [P3, computer science]. Participants described interrelated values of ease of access, accessibility, inclusion, and inclusivity. They considered that digital mental health should be designed to be used by as many people as possible, which required design for accessibility and inclusivity:

> There are a few things that come up here in terms of usability, user centric, acceptability of the user, and accessibility. I think that they all broadly fall into a category of accessibility, that is how well people can actually access and use the technology. I mean, there are slight differences between technological access and technological literacy, but I think those things are part of the same consideration of accessibility. Can people get hold of it? Can people actually use and access it? [P10, computer science and psychology]

> Accessible in terms of costs, in terms of taking into account the special needs of the users in terms of like age, demographics, [disabilities], but also if you consider populations with mental health conditions, they might have special needs...it might not be like physical special needs, but it might be more cognitive like memory impairments. I put it last, but in the end, if the app is too expensive the user will not use it at all. [P6, HCI]

Factors to consider when designing accessible and inclusive technologies included languages, disabilities, additional needs of people with mental health problems, age, ethnicity, costs, digital inequalities, digital literacy, and ease of use.

Like accessibility, ease of use was seen as interrelated with access. Several participants mentioned ease of use or usability when discussing values, but only three participants listed it as a key value (11/55). One participant noted that the traditional conceptualisation of usability did not sufficiently capture this value in digital mental health:

> In terms of usability, I suppose that the word usability is a little bit narrow and thinking about it a little bit more, that does not just include the usability issues of a specific app, but possibly includes the whole range of usability from accessibility,

> assess. And I am looking at things like barriers and facilitators of technology adoption in general. [P10, computer science and psychology]

Factors related to ease of use included how much time was needed to do the intervention, simplicity, and demands on the user. Two participants discussed how ease of use and accessibility may impact acceptability of digital mental health, but only one participant listed this as a key value (5/55).

Autonomy

Four participants listed key values related to autonomy (16/55), which included having agency over one's experience and a "sense of control over the data you share, who you share your data with and also in terms of the intervention" [P6, HCI]. This was largely related to privacy, but one participant considered this too limited in focus:

> Privacy I think is important. I am not sure it is one of the most important things from some of the work that I have done. It seems to be a factor, but certainly not the main one in terms of autonomy. I felt like mental health applications should seek to facilitate the autonomy of the users and put them in charge of their data so that they can make informed decisions. [P10, computer science and psychology]

In this sense, issues with privacy were framed around informed consent, individual decision-making, and control, rather than data security or protections.

Transparency, trust and accuracy and reliability

Transparency was a commonly listed value named by six of the 10 participants, but it was not highly ranked in importance (12/55). Participants discussed the importance of users having information and understanding about all aspects of a digital mental health technology: "It is just being really, really clear – Why is this being used? Who developed it? Who should be using it, etc. And what research was behind it and what that showed" [P8, psychology]. This applied to all digital mental health technologies, including those using artificial intelligence (AI):

> Explainability of the algorithms behind the technology, which means that if you are using some kind of sophisticated complicated algorithm that is giving some predictions for the mental status of the user, it should be sort of explainable that they can trust the technology and they can understand why they are receiving these outputs. [P1, biomedical engineering]

Participants closely linked transparency to trustworthiness, but only two participants listed trust as a key value (8/55):

> It is really good to have transparency behind some of the algorithms that are making decisions about things and how things work, but I think really the only reason that we are concerned about transparency is, or one of the main reasons is trust in technology and a lack of transparency is an obvious barrier to trust. I guess transparency feeds into two things: it feeds into trust, and it feeds into autonomy and the idea that people should be in charge of or at least aware of the decisions that are made about their mental health. [P10, computer science and psychology]

Trust in digital mental health was thought to be related to how much a person understood the technology, its rationale, and how it worked:

> I do a lot of work in cognitive assessments for various things and in a few of those, people do not know or people are concerned that they are not sure why they were assigned a certain rank, or what aspect of cognition that the application is testing. And when they do not know that, they have less trust in the algorithm. There are

> also various apps that do things like, they sample your voice to determine whether you are about to have an episode of bipolar disorder. And when people do not know what the fundamental logic is behind something, I think they are much less likely to trust it. [P10, computer science and psychology]

Participants considered that trust could be built through co-design with people with lived experience, privacy and data security, and the validity of the intervention. Two participants also highly valued the accuracy and reliability of digital mental health (9/55), that is, that technologies work as they should and provided accurate information or outputs:

> The technology should work, and it is important that it is actually informative and it is actually considering the actual outputs. That the actual output should make sense, and it should be accurate. We do not want to give inaccurate predictions to users that are not correct. [P1, biomedical engineering]

But one participant noted that all technologies will have technical difficulties at some time, and therefore questioned the importance of reliability as a key value.

Support

Two participants listed key values around support, with both ranking this in their top three most important values (8/55). Support included human support and technological support:

> For the application itself to offer some support in terms of if there are any problems using the app. If people have any concerns about how the app works and so on, or what the implications of their results might be, if it is monitoring or measuring. [P10, computer science and psychology]

One participant considered that “the main goal of digital mental health is to support patients in any way” [P7, psychology]. They discussed the importance of peer support from people with lived experience to ensure the usefulness of the intervention content and delivery. They also described the importance of support to provide a safe and non-judgemental space:

> From experience, I find that digital mental health that does not come from people with lived experienced – that does not include a peer support or lived experience element – can often be off. It is just not targeting, not answering the right questions or not giving the best information. I think that is quite an important point. And as a service user that I think about making a connection and having a safe place to talk or seek support, or to gain resources in a non-judgemental way. [P7, psychology]

Connectivity

Connectivity was a lesser discussed value (2/55) that related to how digital mental health technologies fit into existing technical and ecological systems:

> Interoperability with existing systems. It does not necessarily apply to all mental health technologies, but I think it is becoming increasingly important to consider things like how a particular application will tie in with clinical pathways and so on. [P10, computer science and psychology]

> I think something that would be fantastic when designing would be to build bridges too. So not having a standalone thing but that, for instance, what you are having on your phone is also linked to what you work on in therapy or other aspects of your environment that build like a bigger picture for your mental health. [P5, HCI]

The idea of digital mental health as a way to build bridges and links to existing treatments and systems was thought to potentially increase evidence-based design and participatory approaches to produce useful and effective technologies.

Enjoyment

The final value of enjoyment was little discussed in the workshop, with mention by one participant who ranked it lowest in importance (1/55). This value related to having digital mental health that is fun and attractive to users with the participant asking, “Is it something I feel like using on a daily basis, maybe once a week, once a month?” [P4, computer science]. Ideas to improve enjoyment and motivation included gamification, with another participant noting that although they had not listed fun as a key value, they drew parallels from the fun and motivation of video games as a way to engage users in digital mental health interventions.

Multidisciplinary perspectives of values

All disciplines listed key values in privacy, effectiveness, usefulness, and accessibility and inclusivity. When amalgamated across participants, participants from computer science listed the most core values (11/15) with other disciplines listing seven (HCI, computer science and psychology) or eight (biomedical engineering, psychology). There was much similarity in the values chosen across disciplines, with a few notable differences. Only participants from psychology (including computer science and psychology) listed values around support, with one participant [P7, psychology] listing and describing several key values that fell within the broader core value of support. These included: connection, safe place, support, peer support, lived experience, and non-judgemental. Comparatively, only participants from computer science explicitly listed values around trust but group discussions showed that this value was reflected in other related values such as transparency.

Group discussion of participants’ individually listed values allowed participants to elaborate on their chosen values, with much overlap in what participants considered to be important in digital mental health. It also highlighted some differences in descriptions and conceptualisation of values between participants and across disciplines. One participant [P9, psychology] conceptualised the values as ethical values and did not include other values in their list. They stated, “When I talk about the ethical values, I did not consider autonomy…my value vocabulary is being restricted because it is ethical values, not other values that are important for me in the development of software.” The idea of a value vocabulary was seen throughout the discussions, with participants often using differing terminology to describe similar concepts, for examples, *access* and *accessibility* were often used interchangeably, as were *efficiency* and *effectiveness*, and *personalised* and *user centric*. Participants observed that the language used to describe values sometimes differed across disciplines:

> One thought now has to do with how we defined concepts in different disciplines. As a computer engineer, when I think of privacy, I am often thinking of how to store the data in a way that is encrypted and how to make sure that only the people that are talking should see this information…to me now, it is more clear that [P9] was talking about interpersonal privacy which is a different set of concerns, right? But this is often what happens when we put different disciplines together, you spend a few times making sure that everyone is talking about the same thing. [P3, computer science]

This was particularly seen in discussions on privacy, accessibility, and fairness:

> I feel like fairness, when we are talking about fairness in AI and fairness in society, which is often talking about different things. Like fairness in data and how data is able to represent different user groups…fairness in AI often tends to be in terms of…so basically you have a system and the system does some sort of classification and you want to make sure that the classification, may it be some diagnosis or some other, is sort of representing everyone sort of equally. Whereas fairness in design often tends to be more at the level of which problems do you choose to focus on. So, it is before a level before the system is made. [P3, computer science]

One participant considered that there was a need to be careful of the language used particularly in multidisciplinary disciplinary teams:

> Even saying something like ‘user’ or ‘significant’ is very different to different people and I think that the translation of those concepts are ethical issues. If you have got a sales team going out there and saying ‘We are having a significant impact’ and they are speaking at a research event…then you are kind of giving off false information. [P8, psychology]

But generally, there was an acknowledgement that the group discussion of values allowed participants to consider values they had overlooked and to consider other perspectives. One participant noted that a person’s list of key values would reflect their own personal values and experiences, which meant that they may not know what they do not know:

> I had not thought about accessibility…I think that is quite important so I think I would copy, paste it, and put it high somewhere. And in fact, accessibility is…actually quite important for mental health, but it is not something that figures very high when we are designing…I think it is interesting and potentially problematic that when you are designing that the things that are important for the design also tend to be things that the designers are experiencing themselves…It is how to expand the list of concerns that we have in the design process outside of, even of the participants that we engage with. There is always going to be blind spots, obviously. But for me it was very clear that accessibility is super important. It is a complete blind spot for us currently. [P3, computer science]

Participants agreed that selection and prioritisation of values would differ depending on the perspective used, for example “From the developer perspective, maybe privacy and confidentiality might be a priority…from the user experience side of this, it would probably be a bit reversed” [P4, computer science]. One participant noted that even the definition of digital mental health may differ across disciplines which may affect the values identified and prioritised:

> I think we see digital mental health completely differently…I think of digital mental health as support groups, apps that give you strategies for parents and my experience in digital enterprises is working with parents where we give them resources…There’s no assessment. It’s a help-seeking process...I am thinking of patients who need some kind of support and help and might look into this app or might look at strategies for that. I am not looking at it from the assessment point of view or research point of view because that is not what first comes to mind. I think if I look at it from a researcher’s point of view, then I agree more with a lot of things that are being said…I think it shifts considerably depending on how you look at it and what you think of. [P7, psychology]

Outside of multidisciplinary differences, there was also discussion of how values may differ throughout the lifespan of digital mental health technologies. One participant [P3, computer science] thought that values may change from the initial conceptualisation and early design of a technology to later in the design process and testing. They considered that values around trust, transparency and inclusion were particularly important in the early design process and co-design with people with lived experience, but this may shift to a prioritisation on reliability during testing.

Values matrix: interrelations and tensions

A key finding from the group discussions on values was the change in participants’ willingness to rank values based on importance. When working by themselves, all participants provided some hierarchical ordering of which values they thought were most important in digital mental health (Appendix B). But participants found this more difficult when asked to work together to agree on the most important values. One participant considered that “there is a logical sequence of priorities” and some values were needed “to have this foundation of a technology that is tested. You know that it works and you build up, build up and up and up” [P2, computer science]. They noted that “if the technology does not work, then whatever else you do, it just simply does not matter”. But many participants thought that all values were important:

> I think it is difficult because everything is important…we are trying to build a puzzle and there are different pieces and they need to match together and maybe within each of these pieces there will be a hierarchy in terms of like, if we are looking for a good user experience and we are looking at the interface design, there may be a hierarchy there. But that is not more or less important than having a good method that, as some others are saying, that it is evidence-based not only as a traditional intervention maybe, but also how that intervention is mediated by what we have designed. [P5, HCI]

One participant was concerned that a values hierarchy would be too static to adapt to the different phases in the design and development of digital mental health technologies and suggested “some kind of toolbox or a tool that would help me reflect on what’s important for me or to collectively come to terms, for example in co-design workshops” [P3, computer science]. Another participant thought a hierarchy would result in some values being overlooked:

> I think it might be a bit dangerous to have a hierarchy because that means like, ‘OK, I am going to address number 1, 2, 3 first and then if I have some time I look at number 4 and 5…even if it forces the key values, if they are ranked last we are less likely to address them in the end as opposed to if we have them on the same level to start with. [P6, HCI]

Participants proposed that a values matrix would be more appropriate for structuring values in digital mental health, especially considering differences in conceptualisation across disciplines:

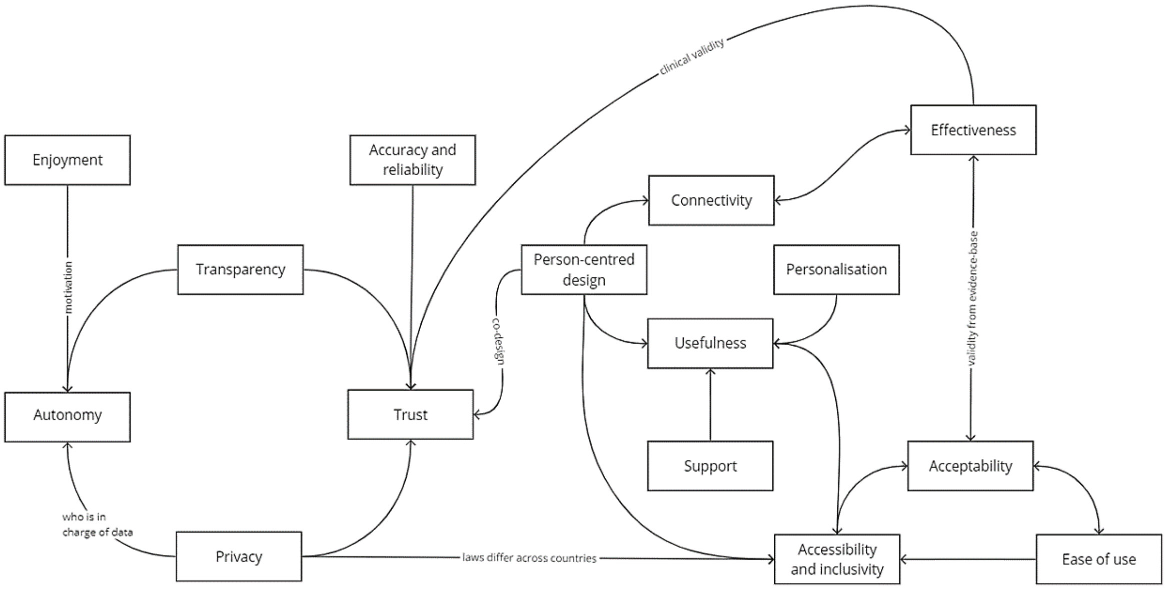
> I said more of a values matrix than hierarchy because they are also interconnected and you cannot really have trust without having data security or compassion without the usefulness, they are also interconnected. [P8, psychology]

They considered that a values matrix would portray the interrelations between values which would better capture the importance of these values in digital mental health:

> I quite like this concept of the matrix because there are many things that may be seen individually within their own cluster, but at the same time they would not be valuable if they were not linked to other clusters within the matrix. [P5. HCI]

These interrelations between values were evident in participants’ descriptions of key values (as discussed previously) and their visual representations of these in Miro (Appendix C). These have been integrated and presented in Figure 3.

Figure 3. Interconnections between core values



Some participants recognised tensions in trying to design or deliver ethical digital mental health. P4 [computer science] suggested such decisions could involve a “benefit to risk ratio” but there were uncertainties around who would define the benefits and who it may benefit. These tensions and their implications in designing and delivering digital mental health are shown in Figure 4. Participants agreed that digital mental health could increase access to care for people who may be unable to attend face-to-face treatment, but some questioned whether a prioritisation of lower cost treatments could affect quality of care and outcomes:

> One of the concerns that I have with digital health in general is the motivation for it comes from costs increasing and so therefore becomes as a way of making health care more affordable. And often ends up being developed with efficiency in mind and with sort of like providing, you know, more efficient health care. And often I just think that it might end up sometimes rushing things or just not caring so much about what are the long-term consequences of making people…I guess the ethics could be out to slow it down a bit in a way to become more attentive to the long-term consequences of changing how we care for each other in our society…digitally, of course we can reach people that may be far away. It does not have to be done in hospitals or you can reach people in their homes and you can provide more contextualised care and so on. But when it comes at the same time, when the implementation comes with a cost reduction attached to it, then I am also thinking whether the quality of care increases or not. [P3, computer science]

Participants noted that while digital mental health could increase access to care, it could result in lower levels of support and changes to the patient-therapist relationship. P7 [psychology] relayed that people using digital mental health tended to be looking for quick solutions rather than the therapeutic relationship that underlies traditional evidence-based interventions. Another participant discussed how to deliver responsible and reliable interventions while respecting a person’s autonomy and relayed concerns about how this could impact safety:

> I guess from my research…my PhD was really looking at missing incidents for people living with dementia. One of the themes in the PhD was the trade-off often between the respect for autonomy and the need for safety, and that was something that

> came up quite a lot. So, monitoring in some ways poses a bit of a threat. Intrusive digital monitoring could impact falls and deprivation of liberties, safeguarding issue, and that is kind of an ethical conflict that comes up quite a lot. [P10, computer science and psychology]

Connected to this were concerns on how to ensure patient safety while offering anonymous interventions, with one participant acknowledging the benefits and risks of anonymity:

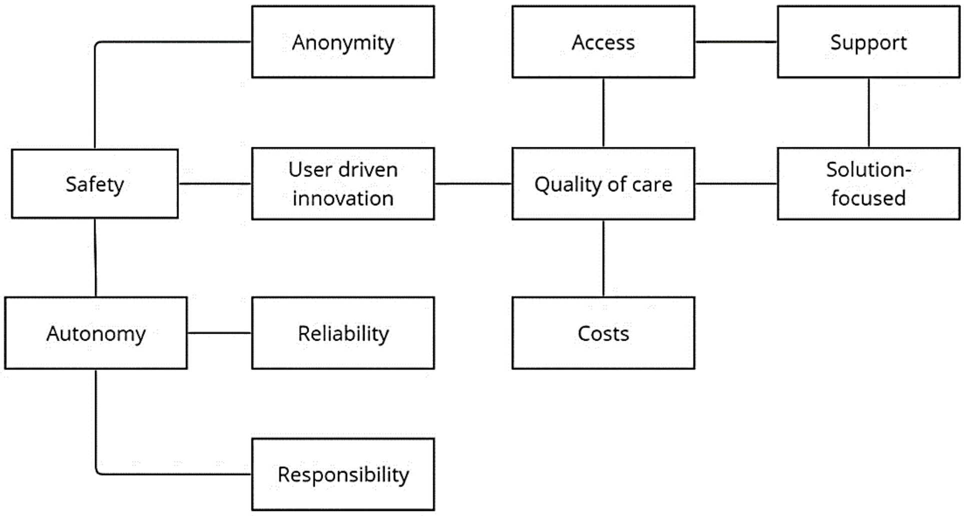
> I was thinking that anonymity is another kind of distance as well. It has got again pros and cons because if I can deny who I am, I can feel more comfortable to open up. It is the two sides of the online disinhibition effect by John Suler. He said we could feel that disinhibited in a malingering way, so harming people on the Internet or feeling, for instance, more generous because of the anonymity. Both of them, distance and anonymity, are good and bad and it makes things more difficult. [P9, psychology]

These challenges showed the importance of including people with lived experience in the design of digital mental health. But one participant relayed the difficulty of person-centred design or user driven innovation because of safety concerns of conducting research or early-stage design with people with lived experience who may be vulnerable because of their mental health problems:

> If you are not working with clinical groups, the Ethical Board is more lenient… so we use always healthy subjects basically. But then we are also missing out on particular problems that people who may have a diagnosis could highlight. It lowers the risk, but it also lowers the type of things that we can do or ignores the quality perhaps. User driven innovation is particularly difficult, particularly as inter-design practice we are more moving from designing and implementing but more like codesigning and designing in everyday life practices makes it very, very difficult to do. And so what we are doing, we are using proxies for example. [P3, computer science]

This was another tension that needed to be navigated when designing quality digital mental health interventions.

Figure 4. Tensions in ethical digital mental health



Defining ethical digital mental health

While participants easily listed several values in digital mental health, they appeared to have more difficulty defining ‘ethical digital mental health’. They considered that ethical digital mental health was “very linked to these values that we were talking about” [P5, HCI] and used this as the basis of their discussions. From this, participants defined ethical digital mental health as: (1) doing no harm, (2) responsible, (3) beneficial, (4) person-centred, (5) honest and transparent, and (6) private (see Table 3 for descriptions of these qualities and quotes).

Table 3. Qualities of ethical digital mental health

Qualities	**Description and sample of quotes**
Do no harm	Ensures patient safety, but also considers the possibility of harm as a result of failings in other areas of the technology or intervention, such as data security: *Safety, with respect to the technology but also the risk when you have an emergency with the patient. Maybe he has got suicide ideation and it is difficult to assess him or her if he is in another country.* [P9, psychology] *We talked mainly I feel about ‘do no harm’ in terms of the condition and the health status of the person, but I think it is also a matter of thinking about the data that you share and who you share it with. Because say if you share data with like insurance companies then it is going to do harm in terms of the person's life in a broader sense, as in getting a mortgage, getting finding a job. This kind of things. Or the stigmatising aspect of the technology can do harm in terms of socializing. So I think it is broader than just doing harm in a medical sense.* [P6, HCI]
Responsible	Responsibility for designing and delivering ethical digital mental health, including ethical design, duty of care, and safeguarding: *So I guess the ethics could be to slow [design] down a bit in a way to become more attentive to the long-term consequences of changing how we care for each other in our society…whether the quality of care increases or not.* [P3, computer science] *The way I see the whole ethical framework around digital mental health is more of an issue of responsibility. For example, when you would propose some solution to a problem? It is about responsibility. Do you take the responsibility as the maker of this thing, to make the best decisions for a user? Or do you then, like how do you leverage that with the autonomy of the user? I mean, if you conduct an experiment with vulnerable population, you go through all of this process of going through study, going through an ethics committee. And this is basically to sort of delineate where responsibility lies. I know from experience that if you want to conduct the study in Germany and you ask people if they have suicidal thoughts, then by law you are obliged to intervene or to react. So simply receiving this information already by law forces you to have an intervention in mind as well. This is the way that I see it a little bit, as a responsibility issue. Where does it lie after you leave it up to the user? Or do you overtake some of that as the maker of the technology?* [P2, computer science]
Beneficial	Provides help and benefits to users, including being accessible to all users and evidence-based: *I think for me, digital mental health has to be helpful. The whole point of digital mental health is to help patients. I think putting the importance of evidence-based, yes it is important, but I also think of a few instances where the evidence shows that you have tested it, however, the end users have not benefited from it too much. It does not do any harm, but it does not do much good either. So what is the point of developing something that doesn't help?* [P7, psychology] *I have worked on a few applications designed for lower income households and they have just not been designed in the right way that would allow those people to use them, i.e. required constant access to Wi-Fi. And this was five or six years ago where that was not a given, so I definitely take your point on the accessibility issues.* [P10, computer science and psychology]

Person-centred	Focuses on the needs, autonomy, and preferences of the individual and actively involving them in their care, including co-design of digital mental health interventions: *Every individual may have their own definition of what mental health is for them here and so I guess…if you are designing with a particular, you know, focusing and directing people towards a particular solution, you are not listening to how the individual has defined what is important for them in their lives and what health is for them basically*. [P3, computer science] *Maybe one an important aspect would be linked to the value of personalisation or tailoring to user needs. You cannot develop a digital mental health app…that is too broad. Being specific on who your target group is and designing for that specific group could be also doing no harm or like reducing the risk of being useless for a specific population.* [P5, HCI]
Honest and transparent	Clearly and readily presents accurate information about all aspect of the technology and intervention: *I am thinking of some of the quite popular apps that have a low evidence base, but the app curators quite often overstate what the evidence is and that does tend to recur quite a lot, so transparency is one aspect of that. Transparency and honesty…I think there need to be, from the part of the developers, a clearly stated evidence base and the limits of that evidence base, and I think that is really important.* [P10, computer science and psychology] *I do not think there is a right answer to the responsibility, where does it lie? I think it is really complex. I think as long as you are transparent on where the responsibility lies. I mean, for me, those two are linked because obviously if you say by interacting with this platform we cannot provide resources or further help because this is just limited to a platform, but I think you need just to be clear about it and state it really obviously at the beginning about who has responsibility for what. And maybe some platform and some apps can offer services, can offer further help, but I think it needs to be clear and for me that links back to transparency.* [P7, psychology]
Private	Respects a person's privacy and data, including data minimisation, data security and appropriate data sharing: *I would also add privacy as one of the top qualities in ethical digital mental health. Because I think at the end, we are collecting data from the users and they need to know, we need to know if they agree to share their data and that their privacy needs to be respected. Maybe they do not want their social people to know about health status or they do not want their data to be shared. So we should consider the privacy of the users as well.* [P1, biomedical engineering] *I think when we talk about privacy, we often mean quite a lot of different things, including who the data is shared with, whether that is appropriate data sharing. But one kind of imperative that I keep seeing in studies that I am interested in and bids and things like that, there is a lot of technology developers who seek lots and lots of data in order that they might spot patterns later on. And I think that often itself becomes an imperative. That is not necessarily in the best interests of the person, so it is a privacy issue. But I think it is about being sensible about what data is collected, not just who that data is being shared with.* [P10, computer science and psychology]

Participants considered that the principle of 'do no harm' was fundamental to ethical digital mental health and a central point connecting all other ethical considerations. One participant noted that "All of those values that we talk about, if not done well could do harm. For example, just being anxious about 'Is my data being kept confidential?' The fact that someone has to be anxious over that could do harm." [P1, biomedical engineering]. Another emphasised that the design of the technology and the intervention were linked to 'do no harm':

> I think that would be also very linked to the user experience design from the specific digital thing that we are designing or building, and that also linked to the

> psychological underpinnings, like the sort of intervention or method that you are trying to deliver. And both would be linked to 'do no harm', because if you do a very bad user interface, for example, even if the psychological underpinnings are really good, the person will get really frustrated and really anxious, and that could be doing harm. It is almost like, as we were saying, everything is connected. [P5, HCI]

But some participants noted that ethics was not as easily defined as 'do no harm' or as black and white:

> I think 'do no harm' is an easy out as well because it is so easy in medical care to say, 'Oh, you know, do no harm' but there's so much about…well, what about euthanasia? You are technically killing someone but helping them to deal with the pain. It is very hard to have right or wrong clear boundaries between that. So, I think that although [do no harm] is the standard go to for all ethics, as soon as you start trickling down into things like the values, that is when it gets trickier. [P8, psychology]

Study 2: Prototype ethical design cards for digital mental health

Acceptability and potential impact of using the cards

The prototype ethical design cards generally had high acceptability amongst participants, with all describing potential benefits and impact that could arise from using the cards. Potential impact from the use of the ethical design cards fell into four main areas: knowledge and skills building, making ethics actionable, facilitating discussion, and monitoring and evaluation.

Knowledge and skills building, particularly for less experienced developers

Some participants thought that using the ethical design cards would help them to feel more confident considering and defending ethics in their projects. The cards were thought to be useful as a teaching aid, for example to "help also in a classroom setting and it will help to bring this reflective aspect to the research in a very helpful way as well" [P3, computer science]. More broadly, the cards were thought to be helpful in facilitating general training in teams. Some participants thought that while the cards did not necessarily introduce them to ethics, they "added to probably the knowledge base" [P4, computer science]. One participant stated that he initially struggled to understand the utility of the cards because his previous experience working for a large technology company included extensive consideration of adverse events and mitigation. But he added:

> I do see the utility of those cards because they really put in a very simple and very direct way to the unenlightened…I mean, OK maybe it is not the best this word, but to a person that does not have this broad perspective...It just really puts things into context and can really get them up to speed very quickly with all of the things that they need to consider. [P2, computer science]

Making ethics more actionable

Related to this was the potential of the cards to "legitimise the concern with ethics and make it actionable" [P3, computer science]. Participants discussed how the toolkit would have helped them to better anticipate ethical issues in their previous projects rather than addressing these after they already arose:

> Not sure if my outcome would have been different, but the design process would have been smoother and I would have had a clear purpose from the beginning as opposed to almost like, going with the flow and wait until an issue arose, then to discuss it after. At least I think it would have been considered simultaneously to the development or even before. [P4, computer science]

> It is very important for designing a technology. But also if you do research and there are different issues that we had to consider because they happened. We did not anticipate them and then we had to apply for ethics one month and it took, you know, one, two, three weeks. And so it delays a lot of the process as opposed to if you have already thought and discussed and agreed on what you are going to do and how you are going to address these points before hand, it makes it much, much easier. [P6, HCI]

In addition to helping developers to better anticipate ethical issues, the cards also made ethical concepts more tangible and allowed developers “to see these concepts individually and how they can fit together in different ways” [P5, HCI]. The idea of making ethics actionable was further expanded by one participant who suggested that by just using the cards, one could already engage in more ethical design.:

> How much of the intervention you can make it be meta?... so by doing the cards you are showing human rights. You are showing autonomy because then they are practicing it as they go through as well [P8, psychology]

Facilitating discussion in multidisciplinary teams

Participants considered that a key benefit of the ethical design cards was the potential for them to stimulate discussion around ethics in design teams. The cards were thought to “be very helpful in structuring discussions and highlighting certain issues around digital mental health” [P10, computer science and psychology] and also “provide a language for everyone to talk about the same thing and understand each other, so it is a great basis” [P6, HCI]. In doing so, they could help improve multidisciplinary teamwork and the involvement of people with lived experience:

> I think what would be the most useful is that it provides a kind of structure and guidelines and would have brought the team together as a whole. We work very well and I know there can be huge divides in teams and even you know having all development outsourced as well. So that's really really tough how you navigate that. But I think it would have made the concept that we are all in it together in terms of thinking about all of these things and provide direction of what we needed to focus on. We're in totally new territory trying to work things out, and this is a really nice way of thinking about the right things at the right time – the team rather than you know, as a psychologist, I need to do this study as a developer, I need to build this page. I think that would have really helped. [P8, psychology]

> I think an interesting use case that I have not seen done would be to have patients and the public involved with designers and developers at the early stage of conception. A designer and developer will probably have quite a functional approach to understanding these sorts of issues, and I think somebody with lived experience or somebody who cares for somebody with lived experience might prioritize these things in a different way. So I do think that the earlier on that this can be done for any project that better. And I also think it is something that could, it levels the playing field between some of the people with lived experience and some of the developers and it creates a kind of a neutral platform for people to have a discussion. [P10, computer science and psychology]

Monitoring and evaluation

Lastly, participants saw some value in the use of the ethical design cards to monitor and track a team’s ethical considerations, actions, and progress throughout the design process:

> I think if I was to use this with like the steering committee or the PPI group that is guiding the development of the app, it would work perfect. It is set, so whether it is a week-by-week workshop we are having and discussions, I think that would work really nice because it gets us to think about the development process from different angles each week. And that outcome could be written up nicely and kind of held as a tick box exercise. We can go back to see this kind of trace. The decisions we make along the way, which I think is usually helpful. [P4, computer science]

Practical application and use of the cards

Participants discussed several considerations around the application and use of the ethical design cards. These related to the intended users and applicability to different interventions. P3 [computer science] considered that the cards seemed to focus on technologies for mental health conditions, rather than wellbeing:

> One of the things that made me think that this is very focused on the stages of treatment, and we might be designing for outside of a treatment setting – I think the question of the disorder or specific symptoms, I think we are mostly focused on symptoms, at least in my line of research. We are focused on specific, you know, somatic practices, not so much on any disorder. Which is why we are not focusing on a specific user group. So, the benefit was a bit difficult is what I am trying to say. But that's because my project is a bit fuzzy. When it comes to anticipation of risks, I thought the harmful guidance was particularly important. I was a bit thinking, like 'What is wrong diagnosis?' I was assuming that I suppose some systems will be focused on diagnosing, right? So, I do not think it would apply. [P3, computer science]

They added that the cards could be difficult to use if a developer had not yet decided on a particular user group because it would be "very difficult to think of particular benefits" [P3, computer science]. However, they considered that the cards could actually be useful in helping to articulate this better. The cards could also help explore ethical issues across different user groups:

> To just reflect on this concept, and what these concepts mean for adolescents instead of children. For example, what vocabulary we could be using and how it will be different from the one that we were using for the children. So just to have these reflections that will frame the whole design. And then also I find these cards to be a good tool, for example, to envision different user journeys and how the ethical tensions could be different for different personas, so again trying to frame it for a specific target group and trying to find this benefits and risks of using different sort of designs to support autonomy, privacy, respect for all. [P5, HCI]

Participants thought the cards were applicable across different disciplines but noted that their use could differ depending on a person's background or the stage in the design process:

> I could see a very good place for these cards in terms of app development, so that is a positive. How it is being used across the different disciplines, I think it might vary a bit or it might need to vary. So for example, in my Department, and I think that kind of brought about the question, would reliability and validity, does it apply similar for research? Because I feel like the first starting once I use those words, we jump to thinking about the research when we are going to actually test the app as opposed to the actual development phase. However, I think if I was to use this with like the steering committee or the [patient and public involvement] group that is guiding the development of the app, it would work perfect…If we were to split it, for example in the reliability and validity, it might be conversations with more researchers on the

> app, developers or designers, for example. But when we come to human rights, I would probably want to have those conversations with end users, or maybe a combination or subset of different groups so I could see the cards being used in different ways. [P4, computer science]

Participants considered how the cards could be used throughout the design process, with most seeing benefits in using the cards at the early stage of design:

> So absolutely at the beginning and throughout the life cycle of the project...I think some of those issues could have been addressed earlier, especially so I am thinking of a very specific project where we, the research involved going into schools. But the app was already fully fledged and developed and it just that there were certain issues that just have not been thought about very much. As I say, it requires constant access to the Internet and if you were using a mobile data plan, it would almost certainly have eaten up quite a lot of people's credit. So I think that that could have been done at the very early stage of the design process and throughout. And not just the design of the app, but also later on when we were thinking about conducting research, because I think it is important now...that when we are designing things we do not just think about what is required for the application itself, but what is in addition required to conduct the research to show that the application is valid and that also needs to be built in an early stage. [P10, computer science and psychology]

P3 [computer science] suggested that some cards would be helpful early in the design process, while others would be easier to consider later on when the technology was more concrete and developed:

> The social impact [card] would be very useful already, since before even start ideating in terms of like, how are we changing the world by putting these ideas out there. Versus things like transparency that I would say it would be easier to think more in terms of maintenance…after being deployed and as the system is being incremented on later…And especially also yeah, the anticipation of risks can also be, it is also very useful to have as early as possible, because the benefit is still that is part of the design process I would say. [P3, computer science]

P6 [HCI] reflected that using the cards later on in the design process could help identify potential ethical issues that were not considered, but this may be difficult to do or address:

> If you have a current project it might be easy to just – and if you are in the early design stage – to use the card straight into the process. But for me it is harder maybe to reflect on what I did and especially because it means that I have done something wrong potentially…Maybe if you are later on in the process, reflecting back maybe might be a bit more difficult, and also because there you have less margin in what you can change at that stage. Like I cannot change anything at that stage, so you know it is done so I might not want to reflect as much on it as well. So yeah, definitely to use them early design stage. [P6, HCI]

To help with this, it was suggested that the cards could be used iteratively throughout the technology lifecycle in order to manage expectations that all ethical issues should be considered at the start.

Potential barriers to use

Participants discussed several potential barriers to using the ethical design cards. Some were practical barriers such as time, costs, and applicability to the project. Time was said to be a potential constraint to the use of the cards, especially for smaller development teams:

> Sometimes the teams are really small, so if they have to cope with different tasks, I mean the same person doing different tasks, they could struggle with time to invest with a device like this. But they could be interested as well. [P9, psychology]

This could be further confounded by challenges of working in multidisciplinary teams:

> One thing that comes with working in interdisciplinary team is the challenges, especially regarding communication. And so in this particular project we have like loads of issues with communicating with developers. As in, it is a difficult time for them. They are overwhelmed and it is really hard to even start a conversation with them. So that would be, I think, the main challenge for me, like how to use the cards. As in how to get everyone to have the time to sit around and discuss these issues together. And I think it might be the same, you know with clinical psychologists, as in it is a difficult time for them as well. They are overwhelmed. So how can we get, you know, everybody together. [P6, HCI]

In addition to time, one participant also noted that there could be concerns about “the cost of the changes” to address any ethical issues identified from using the ethical design cards:

> I think one of the reasons for the difficulty of the benefits from the cards could be the cost of the changes. You can understand what are the good changes you can achieve with the cards, but when you incorporate reality – what are the costs of the changes in the industry? [P9, psychology]

Another participant also opined that the cards may not be applicable to all digital mental health projects, with particular consideration of the relevance of using with public services rather than direct to consumer digital mental health interventions and current versus future models of care:

> There was a big focus on current models of care…it is not a barrier, it is more that it is not directly, obviously was not actually applicable immediately. So I had to think a bit on how this could work. It is always the same question for me. It is like the early technology versus late technology. [P3, computer science]

In addition to these practical barriers were personal and attitudinal barriers around people’s buy-in and willingness to use the ethical design cards:

> I think that if you have some sort of experience working with this concept, this is really useful because it can, it is almost like a checklist that allows you to make sure that you have considered all of these things. But if you do not have the experience, I think it may feel a bit like difficult to grasp, even if you understand the concept you may not be sure how to do it in a practical way. [P5, HCI]

> If you do not have the experience with this type of issues, you may feel a bit lost in terms of how to address them. [P6, HCI]

It was suggested that buy-in could be increased by linking the use of the cards to compliance with external standards such as the Organisation for the Review of Care and Health Apps (ORCHA) or NICE guidelines. P8 [psychology] further commented that use of the cards could falter with changing priorities:

> This is very good for planning and for getting down information to help the team understand what they need to do…I think a team could do this with really, really good intentions and mean everything, but then it gets dropped really, really quickly. Just be busy or business decisions change…how as an organization to create an ethical culture? But it is kind of like as things come up, how do you call it out? That it is ethical so that you can then manage it rather than it being like, oh, this is just a design thing we need to fix and then accidentally doing something that is not accessible or reduces autonomy. [P8, psychology]

It was also thought to be important to get buy-in from all members of multidisciplinary teams and providing support to help this:

> There is a lot of mixed teams from different areas, and they might not feel comfortable answering some of these. They might think, well, that is not my job, but it is really important. So this is everyone's job. So being very compassionate about them and helping support them through it...Being really, really sort of thoughtful in terms of describing exactly what is needed for each question. And then yeah, but around sort of telling the story why this matters. [P8, psychology]

Views and critique of the content of the prototype ethical design cards

Participants provided feedback on the ethical design cards, ranging from the specific ethical categories reviewed and aspects of the cards such as the *Reflections*, *Ethical tensions*, and *What users say* cards.

Ethical categories and elements

Participants provided mixed feedback around the ethical category of reliability and validity, particularly the *Design* and *Usability* cards. One participant noted that these were “very concrete and I felt like it could be used as a checklist, I mean the questions at the back. So, to me it felt more applicable than the other [cards]” [P6, HCI]. However, another noted that “design and usability are very broad terms that could be broken down to like smaller pieces that are easier” [P5, HCI]. They suggested that usability heuristics could be used to make this information more understandable to people from a nontechnical background.

They were more positive about the human rights cards, with these thought to especially highlight the importance of these ethical issues:

> The concept of the human rights part of the cards, I think for me really stood out because I think the word or the words human rights came across stronger, whereas my team would have probably downplayed it a bit in terms of autonomy and these things previously. [P4, computer science]

> I think the choice of words is really good: human rights. You may think, ‘OK, autonomy, privacy. Alright, I have addressed that’. But when you see human rights, it makes you feel like ‘OK, this is basics’. This is what I need to address, you need to guarantee that these are respected. And it may help to share your points, you know, within an interdisciplinary team. With developers, it is hard to communicate and it is hard to start discussion. And if you say ‘OK, we need to consider this in order that you know human rights are respected within our technology’, I think it helps a lot as opposed to say, ‘OK we need to consider the user autonomy’. It is a stronger point in my opinion. [P6, HCI]

Similarly, the *Social impact* card in the outcomes and effects category was particularly influential in facilitating consideration and reflection on these issues:

> When it comes to the [social impact] card, I thought these questions are absolutely amazing and I think we should have them yesterday already like in our design process. In terms of like it is particularly relevant, and I think all design should start with these questions. What are we doing because we are throwing things into the ponds, and we are changing things. [P3, computer science]

But as mentioned previously, some participants found some of the other potential risks and benefits too clinically focused for their work in wellbeing and prevention. Participants had slightly more difficulty with concepts under justice, in particular fair commerce, with some admitting that they were unsure what the term meant or why technologies would not be designed with this in mind. One participant admitted that they could not understand why such issues would occur unless developers had “already dishonest intentions” [P2, computer science]. Despite the initial confusion around these concepts, the workshop enabled participants to discuss the challenges in commercial apps and the potential trade-offs that may be made to access digital mental health technologies:

> If you like the product and you want to help develop a product and then you probably want to pay because you are paying either way. If it is free, probably you are the product, and we have seen that not in the scope of mental health applications, maybe, but with other free platforms that we use. And it is quite frightening how you were followed around the Internet and in places. You know, you buy in the store something and then you see on YouTube advertisement for the same thing. So of course it is not ‘everything needs to be free or accessible’, and there is always a price. And then it is I guess figuring out where you can have the most access to people and where it is still a functioning thing that can be developed and it continues being useful. [P2, computer science]

An additional challenge to this was the increased risks to the brand of larger companies in developing novel and potentially uncertain technologies. This made the market more accessible to smaller companies who may not have the resources to ensure adequate data collection, fairer business models, or adequate competence in the design process. One participant further considered that this could lead some smaller companies to oversell their benefits “because if a smaller company’s app is not showing to be successful, then it will just go out of business” [P10, computer science and psychology]. This was thought to have implications on fair commerce that could be considered in the cards.

Issues with business models and fair commerce were also discussed for cards related to integrity, and in particular trust, with participants discussing examples of unauthorised use of users’ data that would undermine trust in not just that specific product, but digital mental health more broadly. In this context, it was suggested that issues with trust and transparency stemmed from issues with the implementation of technologies, rather than the technology itself:

> The technology cannot be separated from how it is implemented. And so here I do not know if, how would the current technology be transparent. I would say more like it's not so much how might the smart garments will be transparent, but how it then is implemented, how it is used and by whom are the stakeholders, if there is a doctor or a patient. So how transparent is this communication about what you can or cannot do? And so when we develop technology we are not just developing the artifact, we are developing the whole thing that goes around with it, we are developing the whole system as well as the technical system. And this can also take many forms. [P3, computer science]

Participants therefore considered the category of integrity and the content within to be valid and important to discuss given the numerous examples of breaches in the real-world, but there were suggestions to refine how this was presented to consider the concepts in the social technical system.

Relatedly, participants saw value in the cards related to duty of care but noted that this was not always black and white. There was acknowledgement that while developers may try to protect user data from third parties, they were legally required to share some information with some governmental bodies. One participant considered that there was a need for realistic expectations in the amount of risks developers can or should anticipate:

> You know that you can really set yourself back quite a lot by having to consider absolutely everything and it sometimes, it even comes to very banal cases of, well, what if they lose consciousness while looking at their phone? You know it's another risk, but it's ridiculous. I mean that there is just absolutely no way for anyone to consider anything that is just beyond the application that they are making, you know. So, I think there needs to be some sort of a middle line somewhere that leverages how much would you want to emphasize on all of those things. And whether in that particular use case there are actually really that important. [P2, computer science]

They further considered that anticipation of risks and the level of competence or support needed would vary case by case, depending on a user’s individual needs, presenting problem, and complexities. Moreover, there should be acknowledgement of the limits of the technology or developer to adequately manage some risks that may be outside the intended use case or context:

> It is quite a big thing reporting adverse events. You know if some children have started being violent or families, what do you do? I do not feel like I have the responsibility to handle this kind of, you know, as a researcher, it is quite a big thing to handle and this links back to responsibility. I think you need to make it very clear that this is either a research project or this is an app to support to a certain degree, but we cannot support throughout the whole thing you know. If something really bad happens, you need to go to your GP or you need to go to social services. You know, it's a limitation to what modern technology and digital technology or apps or website can do. [P7, psychology]

P1 [biomedical engineering] noted that competence should be considered not just of the development team or healthcare professionals delivering treatment, but also the technology itself. This was particularly relevant for technologies using biosensors and algorithms:

> The more data we can collect from the body, the more multiorgan data we have, the more multimodal data that we have, the more accurate we can have. We can develop the algorithms based on that, of course are complicated and complex factors behind it, but a technology that captures your brain activity and your heart rate at the same time maybe if they can manage it, maybe it's more trustable than a technology that only is based on a single organ…and I think that should be considered, like it's true that the more you add, the more you get. But you should also know how to develop the algorithms based on that. So, it's not that is always that the more complex are better. I don't think it is a great mentality. You should

> know to go on with the simplest and non-trivial algorithm and technology. [P1, biomedical engineering]

Regardless of the specific challenges impacting duty of care and responsibilities, it was noted that "we are not developing computer games and we are not developing, you know, Candy Crush apps. Essentially whoever is going to be using this app has got mental issues. They are always related to someone with mental health issues too, so is already in a very vulnerable place" [P8, psychology]. It was suggested that this should be stated repeatedly in the cards:

> Remember that you are talking to vulnerable people. Remember that the end users are vulnerable and are, you know, in a difficult situation for whatever issue, whether it is dementia or depression or whatever it is. And therefore, keeping that in mind throughout every single step, whether you're a developer or whoever you are when you're using those cards is very important because you are not talking to your typical Joe, you are talking to a vulnerable population. And it is important to keep that in mind all the time and maybe it is just a matter of saying 'This is about mental health ethics', you know, just stating it over and over again and reminding people that this is what we are working towards. Helping people with mental health that are vulnerable essentially. [P8, psychology]

Other aspects of the ethical design cards

Some participants saw especial value in the *Reflections* provided for each ethical element. They were described as applicable and concrete, such that they could be used as a checklist:

> I tend to go directly to the reflection side because the questions are more concrete in like it helps me understand what it means really as opposed to the theory. Even if there is this very nice diagram, I am more attracted to the reflection side and I think the questions from you make it more clear what it means as opposed to having the definitions. [P6. HCI]

> We are dealing with vulnerable people, so it is important to look at the ethical consideration of what that means and having specific forms like these cards. And like I especially like the reflection bit, when it says you know – Have you thought of that? What does this mean? What do we mean by this? And I think that is just at least at the minimum, it would make people think about what is involved in what they are doing and that is a good start anyways. [P7, psychology]

P8 [psychology] thought that the questions could be difficult to answer, particularly for developers who were less clear on aspects of their technology such as their intended user. They suggested that the cards could be customised so that users could consider and record only the information needed at that point in their design process. They further suggested that more blank space and less questions could be on the cards "because this is an amazing place to store this information and to have it as a repository of this information over time".

Participants also saw the value in the concept of the *What users say* cards, with one participant stating "I really love the user stories. I think that for me was one of the most important elements, is having a quote with a reminder of why these things are important because it really brings it to life" [P8, psychology]. There were suggestions to include both negative and positive user experiences, to show "what happens if this goes wrong" [P8, psychology] as well as "positive quotes, as in why it would be worth addressing this so that it would make a better user experience" [P6, HCI]. P5 [HCI] suggested that the user quotes could benefit from a little more context to "help envision different user journeys". But some admitted that they used the *What users say* cards less and felt they were "a bit disconnected" perhaps “because it is the way it is presented digitally because it is not printed” [P3, computer science].

One participant considered the *Ethical tensions* card to be the most helpful “because they encompass everything in a very simple way, but like useful. And then if you want to get more then you go to the individual cards, but I think it wrapped it up very nicely” [P5, HCI]. P8 [psychology] also thought that “the ethical tensions is actually a bit that you might get the most interest in where people realise actually, it is really tough and it is sort of building up that getting thoughts from people. I believe this oh, but I believe this and then OK, how do you navigate in between?” Some participants were unsure how to use the ethical tensions card, though they considered this to be an important inclusion in the card set. P3 [computer science] noted that they would probably not use the card to solve ethical tensions but rather to further explore tensions through design and research. It was suggested that examples or a more concrete description of the idea behind the tensions card could help users better understand and use them in their design process.

Discussion

To the best of our knowledge, this research is the first to explore multidisciplinary values in digital mental health and definitions of ethical digital mental health. Participants identified numerous key values which we grouped into 15 core values. Individually, they resoundingly considered the most important values to be those related to privacy and effectiveness. This reflects the literature on digital mental health and the overwhelming emphasis on these concepts [6–12,21,25,43–45]. Comparatively, in group discussions, there was consensus that all values were important with concerns that a hierarchy could result in some values being overlooked. A novel finding of this research is the suggestion to consider these within a values matrix in digital mental health, which would allow exploration of interconnection, tensions, and importance. Participants described these values as the basis of ethical digital mental health and particularly the idea of doing no harm. Another original contribution is the introduction of the ethical design cards for digital mental health. Our findings showed good acceptability and feasibility of using the toolkit to facilitate the design of ethical digital mental health technologies, with particular value of using the cards in multidisciplinary design teams. These findings and their potential impact are explored in more detail in the following sections.

Conceptualising ethical digital mental health

When asked to list key values in digital mental health, participants collectively listed over 60 values, with an average of seven values each. We grouped these into 15 core values (listed here in participants’ individual ranking of importance): privacy, effectiveness, usefulness, accessibility and inclusivity, autonomy, transparency, ease of use, accuracy and reliability, trust, personalisation, support, acceptability, person-centred design, connectivity, and enjoyment. The core values were each distinct yet interrelated, reflecting the interconnectedness and balance of values as described in value sensitive design [31]. There is currently very limited evidence exploring values in digital mental health. Burr and Powell [42] conducted a preliminary exploration of ethical values and principles in digital mental health interventions. Their findings suggested that the most significant values were transparency, privacy, evidence-based, accountability, explainability, and clarity. These align with several of our core values in digital mental health and provide support for the validity of our findings. There were also notable similarities between our core values in digital mental health and the value sensitive design heuristic of human values with ethical import often implicated in system design [33,34]. In particular, seven of the 15 core values fully or partially aligned with eight human values in the heuristic, specifically: privacy–privacy, effectiveness–human welfare, usefulness–human welfare, accessibility and inclusivity–ownership and property, accessibility and inclusivity–freedom from bias, autonomy–autonomy, autonomy–informed consent, ease of use–universal usability, and trust–trust. There was less obvious alignment of the other values, with heuristic values of courtesy, identity, and environmental sustainability not reflected in participants' values in digital mental health. Conversely, our study found eight core values in digital mental health not adequately captured in the heuristic, specifically: transparency, accuracy and reliability, personalisation, support, acceptability, person-centred design, connectivity, and enjoyment. This suggests that while the value sensitive design heuristic of human values with ethical import may provide a starting point to explore values in digital mental health, it omits several important values. We therefore propose that it would be more useful for developers to consider the core values in digital mental health reported in this research when designing digital mental health technologies. It is also important to note that, like the heuristic of human values with ethical import often implicated in system design, the core values are not an exhaustive list of values in digital mental health but should be used as a springboard to further explore these concepts [31,33,34]. There was some evidence suggesting that users or people with lived experience may have differing values to developers [6,23,]. Rooksby et al. [23] found that key values for users included autonomy, control, and dignity. Comparatively, participants in this research – collectively grouped as developers, psychologists, or academics – overwhelming prioritised privacy and effectiveness. More research is therefore needed exploring values in digital mental health across stakeholder groups.

This study contributed not only to the understanding of values in digital mental health, but importantly to the interplay between these values. Participants considered that a hierarchical list of values would be too static to adapt to the differing design processes and considerations for different digital mental health technologies. Moreover, it would fail to capture the potential interrelations between values and their full importance in digital mental health. Instead, we proposed a values matrix which outlined the core values in digital mental health and provides a space to explore interconnections, tensions, and priorities. Matrices have been used in healthcare to help assess patient care by exploring aims for improvement against core competencies [46]. Bingham et al. [46] described this as a conceptual framework that allows for the tabular presentation of quality outcomes against the knowledge and skills needed to affect those outcomes. Based on our findings, we consider this a useful approach that can be applied to digital mental health. We present an example with five of the core value to demonstrate how this may look in practice (Figure 5), but more research is needed to determine the key areas for assessment. The workshop discussions also identified several important aspects to the values that should be considered when using the matrix:

(1) **All core values in digital mental health are important.** There may be situations where one value may be more relevant than others, for example if a technology does not work then other values may not matter. This idea is reflected in some evaluation frameworks such as the American Psychiatric Association's app evaluation model [47]. But overall, it was agreed that all core values were important and should be considered at some stage in the design process.

(2) **Core values are interconnected but distinct.** The group discussions showed notable interrelations in how participants conceptualised and discussed the values. Core values were considered to be distinct from each other, but issues with one value would likely impact others. This strengthened the view that all core values are important.

Figure 5. Example of a values matrix using a sample of the core values

	Core values in digital mental health				
	Privacy	Effectiveness	Usefulness	Accessibility and inclusivity	Autonomy
Has this value been considered in the design process?					
Stage of design					
Key considerations					
Anticipated risks					
Interconnection with other values					
Tensions in values					
Design solution					

(3) **There will be tensions between some core values.** Just as some values are interconnected, some values were found to conflict with each other [31,32,48]. Value tensions should be considered when designing digital mental health interventions, with the values matrix serving as a potential tool to aid these discussions.

(4) **Stakeholders may differ in how they view values.** Different disciplines or stakeholder groups may differ in how they conceptualise and describe values. There may be differences in the language used or terminology may carry different meanings in different contexts. For example, the terms *significant* and *reliable* have very specific meanings in research settings that may differ from everyday usage. It is therefore important for multidisciplinary teams to discuss values to ensure a shared vocabulary throughout the design process. Stakeholders may also differ in their prioritisation of values, with a values matrix providing a resource to consider values that may have otherwise been overlooked.

(5) **Core values should be considered throughout the technology lifespan.** Different values may have different weights depending on the stage in the design process or technology lifespan. For example, technological reliability and stability may be considered more relevant later in the design process than in early design. A values matrix can be used throughout to explore any changing priorities and to ensure that all relevant values have been considered.

(6) **Core values form the basis of ethical digital mental health.** Participants considered that ethical digital mental health was very much linked to the core values which, if not sufficiently considered, had the potential to do harm. This aligns with value sensitive design and supports the suggestion that values capture social and ethical issues that are then reflected in a technology's design [32].

We observed that participants had more difficulty defining ethical digital mental health than listing values. The latter may have been made easier because they were prompted with a simple definition of values to start – "what a person or group of people consider important in life" [33]. It is also possible that participants found it more difficult moving from practical concepts to more abstract ideas. Indeed, without cues or context, how many of us can freely define and discuss ethics? A values matrix may therefore offer a practical tool to introduce the discussion of ethics into the design and development of digital mental health technologies.

Ethical digital mental health was described as digital mental health technologies that do no harm, and are responsible, beneficial, person-centred, honest and transparent, and private. These proposed qualities showed good alignment with our previous research which proposed 14 elements of ethically designed apps for depression based on the analysis of user reviews [39] (see Figure 6 mapping of alignment between studies).

Figure 6. Mapping alignment between the qualities of ethical digital mental health and the elements of ethical apps for depression [39]

More research is needed to further refine these concepts and to explore how a values matrix and qualities of ethical digital mental health may be applied in practice to increase the ethical design and use of these technologies. In the next section, we explore one such example of the practical application of ethics with discussion on the findings around our ethical design cards.

Ethical design cards for digital mental health

There was generally high acceptability and interest in the proposed ethical design cards for digital mental health. Participants considered that the cards could be used throughout the design and research of these technologies to help development teams to better consider and discuss ethical issues and considerations. Participants found some of the cards more useful than others, particularly those around human rights and social impact. But generally, there was positive feedback on the content of all ethical categories and elements.

Key benefits to using the cards included building knowledge and skills, making ethics actionable, fostering multidisciplinary discussions, and monitoring and evaluation. Participants generally thought that the cards did not introduce them to new ethical ideas but rather strengthened their existing ethical knowledge and understanding. There was suggestion that the cards may be especially suited to developers with less experience, but there was also caution that people with less experience may be less willing to engage with the cards. There were a number of potential barriers to using the cards that are important to consider for further development. Firstly, it was apparent that developer buy-in would be needed, with potential resistance because of time, costs, and conflicting priorities. Developers in this research were largely from academia, with the one participant with an industry background showing the most uncertainty towards the cards. The challenges of introducing ethical processes in industry is reported elsewhere, with Burr and Powell [42] noting that some developers felt unable to complete their ethical assurance case because of a lack of time driven by business needs and drivers. One developer was quoted as saying that the process would have to be usable in an agile product development context and would ideally be integrated into the early design process. This reflects the proposed use of the ethical design cards, which seek to proactively address ethical issues before they occur, rather than relying on the evaluation of technologies after they have been developed [47,49]. But more research is needed involving stakeholders in industry in order to explore their values in digital mental health and attitudes towards ethical tools and approaches such as the ethical design cards. The literature base shows a poverty of evidence capturing industry perspective on ethics in digital mental health (D Bowie-DaBreo, in preparation). We therefore propose that next steps in the development of the ethical design cards and the wider ethical framework include engagement with commercial developers to capture their voice in the refinement of the toolkit.

Another notable barrier to the use of the cards was the possibility that some people may feel uncomfortable engaging with the cards throughout the design process. The group discussion suggested that some people may feel judged when engaging with ethics, such as feeling criticised (at times by themselves) for previous oversights or mistakes. Responsible design and innovation involves an openness to inclusive deliberation involving open discussions, debate, and engagement on the potential impact of the technology [50]. Moreover, there should be responsiveness in adapting and responding to these reflections and deliberations throughout. The next iteration of the ethical design cards should therefore consider how to design the cards to stimulate ethical discussion rather than judgment. Findings from this research also highlighted other areas for improvement in the toolkit:

- Flexibility: While the instructions outlined that the cards could be used flexibly, there was suggestion that this could be emphasised so that development teams would not feel pressured to have to go through all of the cards. This can also be highlighted during any training on how to use the cards.
- Format: Several participants felt that the cards could be improved by being presented both physically and digitally. Online use of the cards was tied to the potential to use the cards more iteratively and to create a database of designing for these abstract concepts. Other suggestions to make the cards and the concepts more accessible included having more visualisations such as posters, spreadsheets, or follow-up emails to remind development teams of the concepts discussed and potential actions.
- Concepts: There was suggestion that concepts like design and usability were quite broad and could be broken down to make them easier to understand. There was also question around how clinically focused to present the ethical concepts, for example concepts around models of care versus more general wellbeing.
- Scenarios and examples: participants saw value in the multidisciplinary workshop as a method of exploring the ethical concepts and the ethical design cards. They thought it

would be helpful to present a hypothetical technology or scenario rather than using the cards to reflect on a past technology, as the latter could provoke feelings of judgment over ethical issue not previously considered.

- Customisation: participants suggested that the card set should include blank cards so that people could add their own questions, responses, user feedback, and ethical tensions as they worked through the card set in their design process.
- Ethical tensions: participants suggested this should be presented with the introduction card and at the forefront of the process. There was also suggestion of alternative formats for exploring ethical tensions, such as using a board with different columns.

Overall, the findings from these studies provide a foundation to understanding how professional stakeholders conceptualise ethical digital mental health and their acceptance and willingness to employ a design card toolkit to increase ethical design. More research is needed investigating the use of the cards in practice and their impact on design process and outcomes.

Limitations

This study has many strengths and notable limitations. To the best of our knowledge, it is the first study to explore multidisciplinary views of values in digital mental health and conceptualisations of ethical digital mental health. Participants came from a range of relevant disciplines in the field, and all had experience of developing or delivering digital mental health interventions. The study was limited by its small sample size which meant that there were limited numbers of participants from each discipline. This is perhaps related to workshops being held during the COVID-19 pandemic, which may have impacted participant recruitment and availability. As a result, while the findings provided valuable insight into disciplinary perspectives and differences, these should be considered as a starting point for further research with larger and more diverse stakeholder groups. The small sample size further meant that each ethical category of the proposed design cards was discussed by only one workshop group, again limiting the generalisability of findings. Despite this, this study shows great potential for the use of ethical design cards as a means of facilitating discussion and ethical consideration in multidisciplinary teams.

This study was exploratory and encouraged participants to engage in open group discussions to reach consensus on values and definitions of ethical digital mental health. Participants considered that the workshops were a great method of facilitating ethical understanding and multidisciplinary discussions that could be used in practice with the ethical design cards. While all workshop groups actively engaged in the group discussions and the respectful sharing of ideas, it is possible that this approach may have encouraged groupthink and low opposition. This could partially explain participants difficulty in prioritising values in the group discussions despite previously ranking values individually. This could be addressed with more structured research methods for group decision-making, such as the Delphi method. This approach was not used because of the small sample size and the challenges of conducting online research during the pandemic. Future research into values and qualities of digital mental health may wish to consider adopting this process to further explore core values in digital mental health.

Conclusions

This research made two key contributions to the evidence on the ethics of digital mental health. Firstly, our findings showed several core values in digital mental health, which we have suggested may be considered using as a values matrix. This study outlined important aspects of a values matrix and suggested use in exploring ethics. This was strengthened by the finding that participants used these values as the basis for their conceptualisation of ethical digital mental health. This supported the relevance of value sensitive design in digital mental health and provided a practical approach to start discussions on ethics in this area. Secondly, this research presented a prototype set of ethical design cards for digital mental health, with findings showing good acceptability and applicability of the cards throughout the design process particularly within multidisciplinary teams. We encourage further research on these concepts and the use of the cards in practice.

Acknowledgements

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Conflicts of interest

None declared.

Abbreviations

AI: artificial intelligence
GDPR: general data protection regulation
HCI: human computer interaction
NICE: National Institute for Health and Care Excellence
NHS: National Health Service

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Appendix A. Prototype ethical design cards

FRONT

INSTRUCTIONS

This set of ethical design cards has been designed to assist designers and development teams in the design and development of ethical and responsible digital mental heath technologies.

The cards are grouped in 6 ethical categories, each containing individual elements that are important in ethical digital mental health. These categories are:

- Outcomes and effects
- Reliability and validity
- Human rights
- Duty of care
- Justice
- Integrity

The cards can be used flexibly and iteratively throughout the design and development process. The broader ethical categories may be used as a checklist of ethical concepts to consider in the design and development of digital mental health technologies. Moreover, the individual ethical elements can help designers and developers better understand, anticipate, and design for ethical considerations and issues.

BACK

Suggested guidance for use:

Step 1: At the beginning of the conceptualisation of the specific digital mental health technology, review the ethical categories and elements and consider how these concepts will be reflected and addressed in the design process and the digital mental health product

Step 2: Use the reflections provided with each ethical element to further explore these ethical concepts and to take practical steps to overcoming ethical challenges

Step 3: Read the ‘What Users Say’ cards provided in each ethical category for clarification and real-world examples of the ethical concepts and issues as experienced by real users of digital mental health

Step 4: Utilise the ‘Ethical Tensions’ card to explore potential ethical conflicts in the design and development of digital mental health technologies, and to consider innovative ways to overcome these conflicts

Step 5: Continue to use the ethical design cards throughout the design, development, and deployment of the digital mental health technology to identify and overcome ethical challenges as these arise

FRONT

ETHICAL TENSIONS

Ethical design in digital mental health is not always an easy and straightforward process. Ethical concepts are not always black and white, and ethical decisions often lack one clear answer or resolution. Moreover, ethical concepts such as those presented on these cards are often interrelated, such that issues with one ethical element (such as privacy) may impact others (autonomy, risks, integrity etc.).

Similarly, designers and developers may find they are faced with conflicting ethical elements, such that the prioritisation of one element (such as access to care) may negatively impact another element (safety and safeguarding).

It is therefore important for designers and developers of digital mental health technologies to be aware of potential ethical tensions, and to use these conflicts to inspire innovative design of ethical and responsible mental health technologies.

BACK

Consider the following examples of ethical tensions in digital mental health and make note other tensions that arise in the design and development of the current digital mental health technology.

Support v. Autonomy

The provision of various types of support may negatively impact aspects of users’ autonomy, particularly if support overrides users’ involvement in their treatment decisions and planning. Consider how both of these elements may be incorporated and respected in the design of the current technology.

Autonomy v. Benefits

There may be a need to balance users’ autonomy with the delivery of mental health interventions to ensure expected benefits and to minimise risks. Consider how to allow freedom of choice and flexibility of use while still producing benefits and evidence-based treatments.

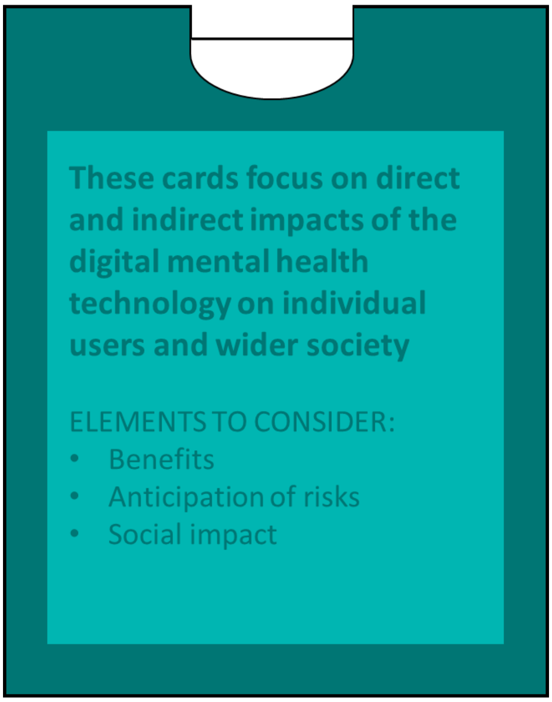
Access v. Safety and safeguarding

Technologies may seek to protect vulnerable users by limiting access to care (e.g. to minors). Consider how responsible innovation may be used to design safe and accessible technologies that reduce barriers to care.

FRONT

OUTCOMES AND EFFECTS

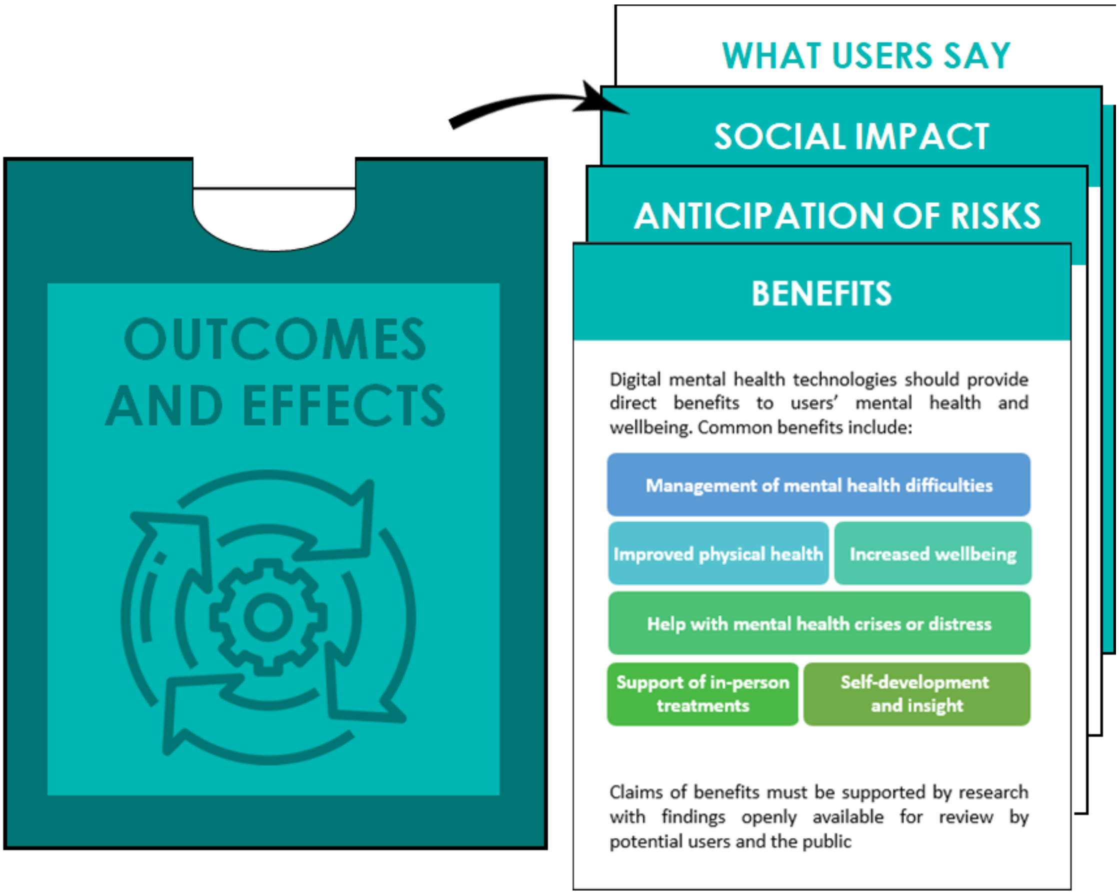
BACK



These cards focus on direct and indirect impacts of the digital mental health technology on individual users and wider society

ELEMENTS TO CONSIDER:

- Benefits
- Anticipation of risks
- Social impact



OUTCOMES AND EFFECTS

WHAT USERS SAY

SOCIAL IMPACT

ANTICIPATION OF RISKS

BENEFITS

Digital mental health technologies should provide direct benefits to users' mental health and wellbeing. Common benefits include:

- Management of mental health difficulties
- Improved physical health
- Increased wellbeing
- Help with mental health crises or distress
- Support of in-person treatments
- Self-development and insight

Claims of benefits must be supported by research with findings openly available for review by potential users and the public

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BACK

REFLECTIONS

What are the anticipated benefits and outcomes of the current digital mental health technology?

Who is the current digital mental health technology being developed for?

What stage of treatment will the current technology address? Consider early intervention, first-line intervention, relapse prevention, mental health crisis

Will this technology target the disorder (eg, depression) or specific symptoms (eg, poor sleep)?

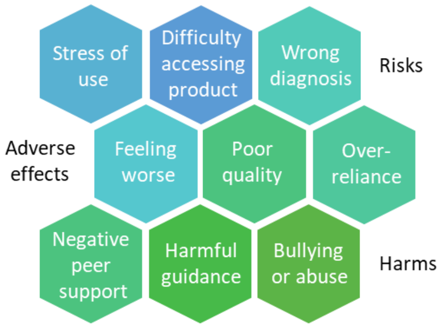
How will the benefits and outcomes of the current digital mental health technology be measured and evaluated?

How will evidence of its benefits be disseminated to potential users and the wider public?

FRONT

ANTICIPATION OF RISKS

Designers and developers should anticipate and avoid foreseeable risks and harms of digital mental health technologies.



Risk anticipation and management should be an iterative and responsive process occurring throughout the technology's lifespan

BACK

REFLECTIONS

What potential risks or harms may arise from the use and adoption of the current technology?

Who will be most impacted by this technology? Consider individuals and groups

Have relevant stakeholders been included in the deliberation of these risks and harms?

Do the anticipated benefits justify and outweigh any potential risks and harms?

How will potential risks and harms be mitigated in the design, marketing, and deployment of the current digital mental health technology?

What is the plan to evaluate and address future risks and harms of the current technology?

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FRONT

SOCIAL IMPACT

Designers and developers of digital mental health technologies should consider their broader social impact and civic duty in the design and marketing of these products.

Potential areas of impact include:

- **Attitudes towards mental health difficulties**
- **Reduction of stigma**
- **Normalisation of receiving mental health care**
- **Wider benefits to communities and society**

BACK

REFLECTIONS

What are the civic duties of designers or developers of digital mental health?

How will the current digital mental health technology impact communities and wider society?

What impact will this technology have on mental health care and healthcare systems?

What innovations will this technology offer? Will these fit the existing models of care?

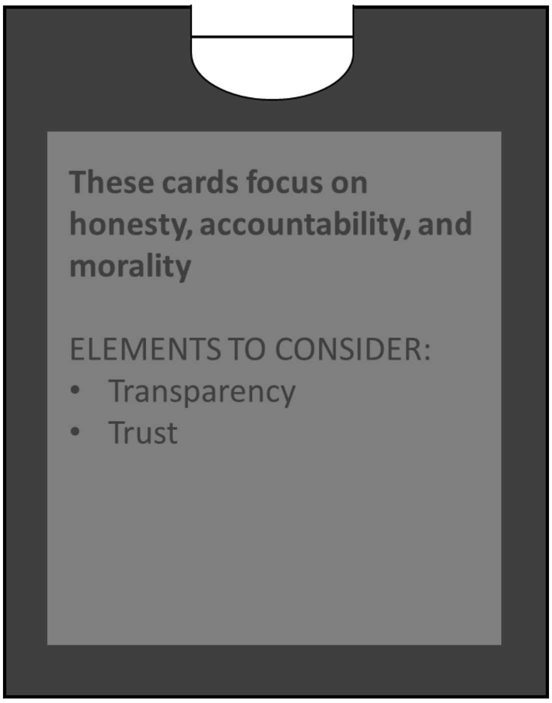
How will the design and messaging of the current technology promote positive attitudes and representation of mental health difficulties?

How can designers and developers advocate for mental health and wellness?

How will the immediate and long-term social impact of the current technology be assessed?

FRONT

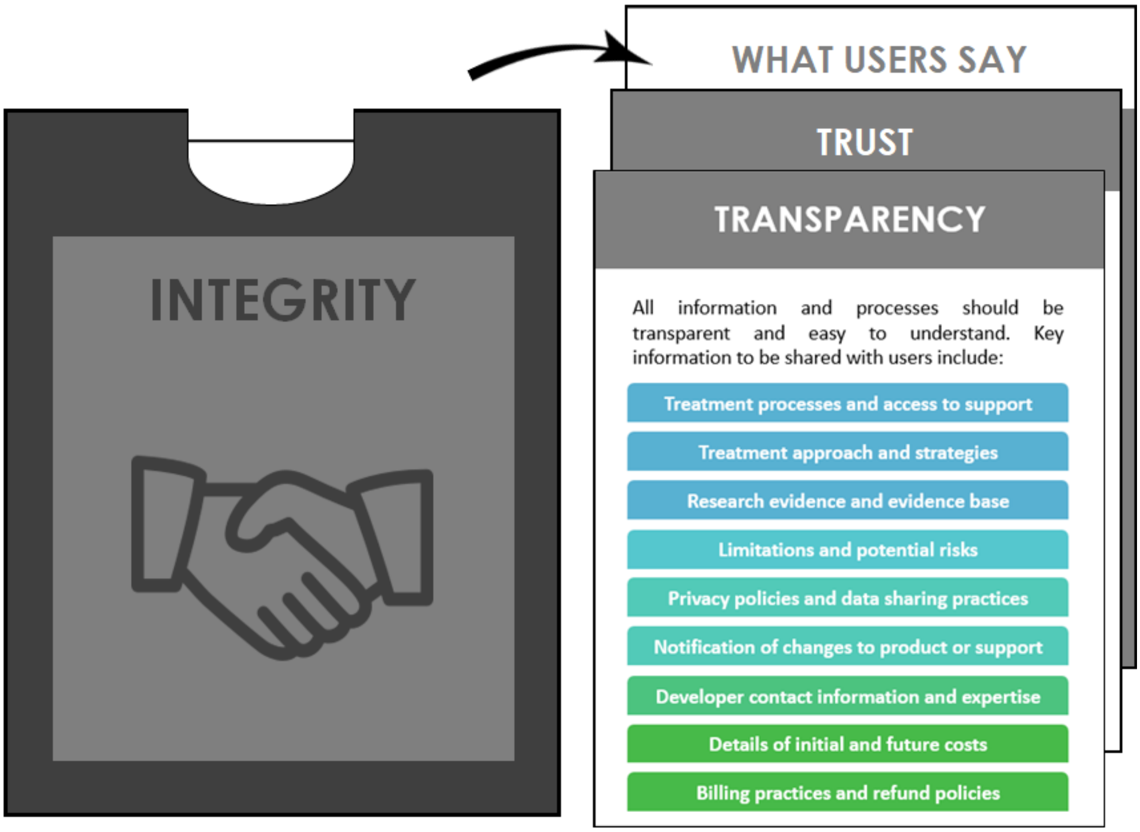
BACK



These cards focus on honesty, accountability, and morality

ELEMENTS TO CONSIDER:

- Transparency
- Trust



TRANSPARENCY

All information and processes should be transparent and easy to understand. Key information to be shared with users include:

- Treatment processes and access to support
- Treatment approach and strategies
- Research evidence and evidence base
- Limitations and potential risks
- Privacy policies and data sharing practices
- Notification of changes to product or support
- Developer contact information and expertise
- Details of initial and future costs
- Billing practices and refund policies

FRONT

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BACK

REFLECTIONS

What information do users' need about the current digital mental health technology?

What information do *potential users* of this digital mental health technology need to help them to make informed decisions regarding suitability of treatment, potential benefits, and limitations and potential risks?

What information do *current users* of this want and need to support their continued use?

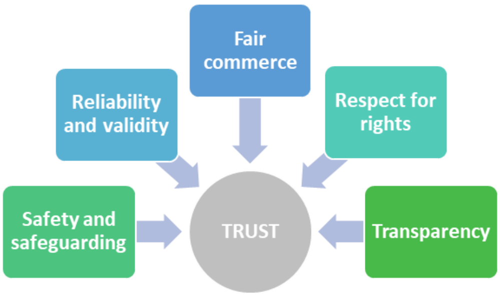
How would the current technology be transparent about existing or future machine learning algorithms used to infer a personalised intervention?

FRONT

TRUST

Digital mental health technologies and developers should be truthful and trustworthy. Designers and developers should avoid any intentions or actions which may be fraudulent, deceptive or exploitative.

Some factors impacting users' trust:


Fair commerce
Reliability and validity
Respect for rights
Safety and safeguarding
TRUST
Transparency

BACK

REFLECTIONS

What are users' most important needs for trust in digital mental health? Consider the relative importance of factors such as safety, validity, commercial practices, respect, and transparency

How may these factors impact users adoption and adherence of the current technology?

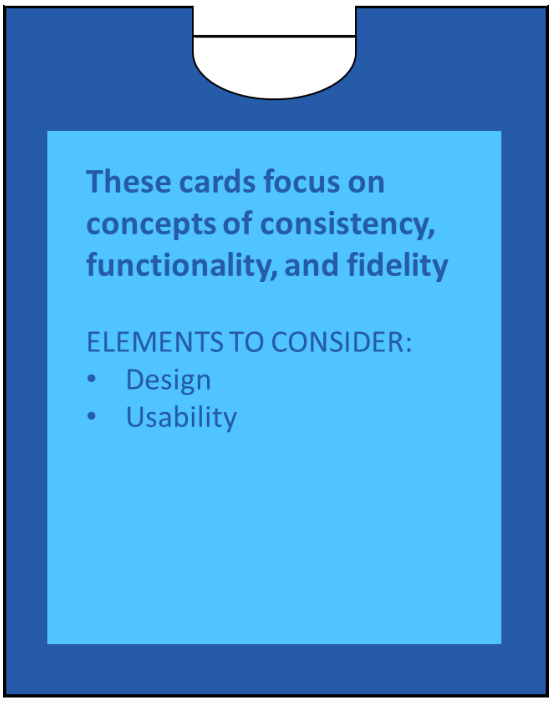
How can users' trust in the current digital mental health technology be fostered?

What are the plans to repair user trust should concerns and challenges arise?

FRONT

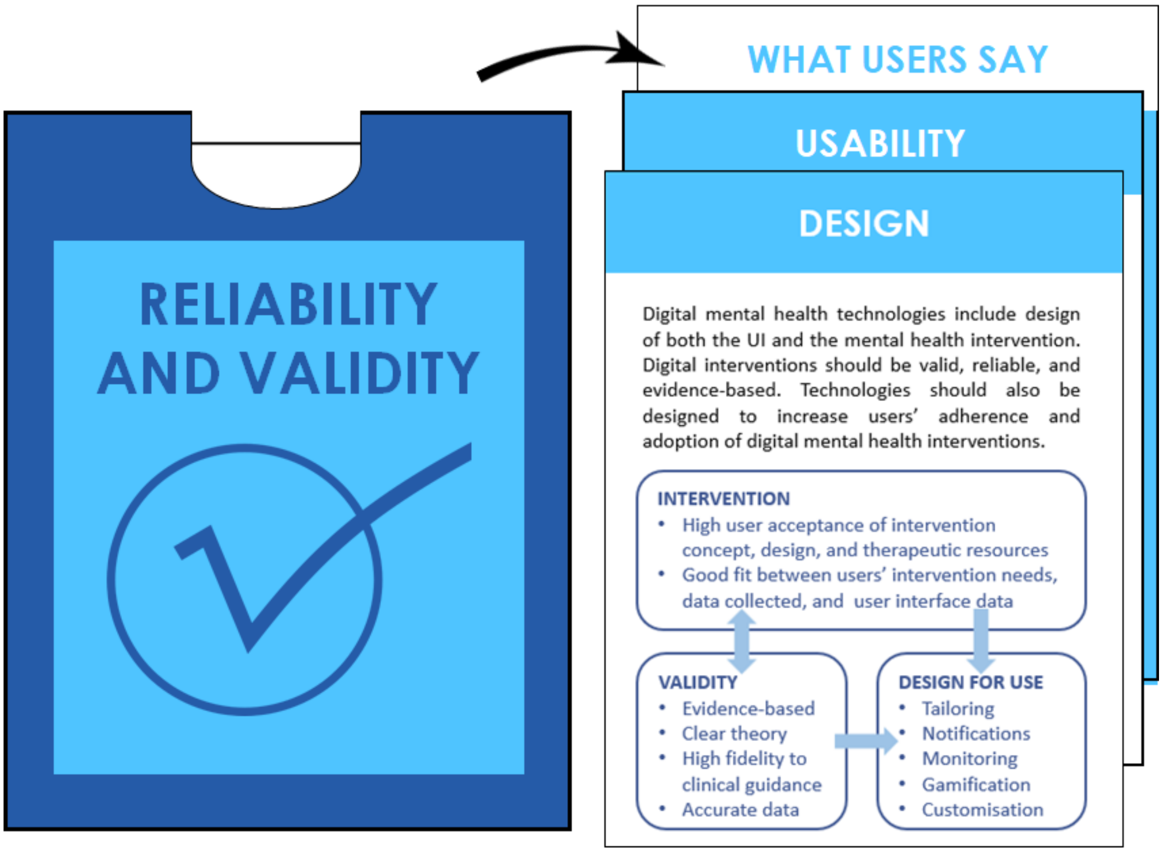
RELIABILITY AND VALIDITY

BACK



These cards focus on concepts of consistency, functionality, and fidelity

ELEMENTS TO CONSIDER:
- Design
- Usability



RELIABILITY AND VALIDITY

WHAT USERS SAY

USABILITY

DESIGN

Digital mental health technologies include design of both the UI and the mental health intervention. Digital interventions should be valid, reliable, and evidence-based. Technologies should also be designed to increase users' adherence and adoption of digital mental health interventions.

INTERVENTION
- High user acceptance of intervention concept, design, and therapeutic resources
- Good fit between users' intervention needs, data collected, and user interface data

VALIDITY
- Evidence-based
- Clear theory
- High fidelity to clinical guidance
- Accurate data

DESIGN FOR USE
- Tailoring
- Notifications
- Monitoring
- Gamification
- Customisation

FRONT

USABILITY

Digital mental health technologies should function as intended and advertised, with consistent updates and repairs to fix issues as they occur. Examples of issues to consider include:

- **Bugs and glitches**
- **Lags and delays**
- **Sign up or login errors**
- **Start-up errors**
- **Poor ease of use**
- **Unstable updates**
- **Data errors or loss of progress**
- **Disruption to device (in cases of apps)**
- **Poor error recovery**
- **Poor responsiveness**

Poor usability can impact access to support, reliable delivery of interventions, and accurate data collection and reporting, all of which pose potential risks and harms to users.

BACK

REFLECTIONS

What standards and heuristics can be consulted and adopted to ensure good usability of the current digital mental health technology?

How will the development team ensure this digital mental health technology functions as it should?

How will bugs and glitches be promptly addressed throughout the technology's lifespan? How will users report errors and issues?

How often will updates be performed to ensure reliable treatment delivery and access to care?

How will possible disruptions to the technology's functioning be addressed to avoid interruption or discontinuation of treatment and support to users?

FRONT

DESIGN

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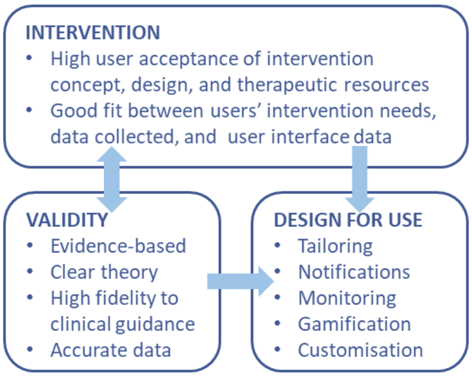

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- Evidence-based
- Clear theory
- High fidelity to clinical guidance
- Accurate data

DESIGN FOR USE
- Tailoring
- Notifications
- Monitoring
- Gamification
- Customisation

BACK

REFLECTIONS

What are users' UI and intervention needs?

What is the treatment approach of the current digital mental health technology? Why was this approach chosen?

How does this digital mental health intervention reflect evidence-based treatments and clinical guidelines?

For digital interventions adapted from evidence-based treatments (e.g. CBT), will all core treatment elements be included? How will this be achieved through the intervention and technological design?

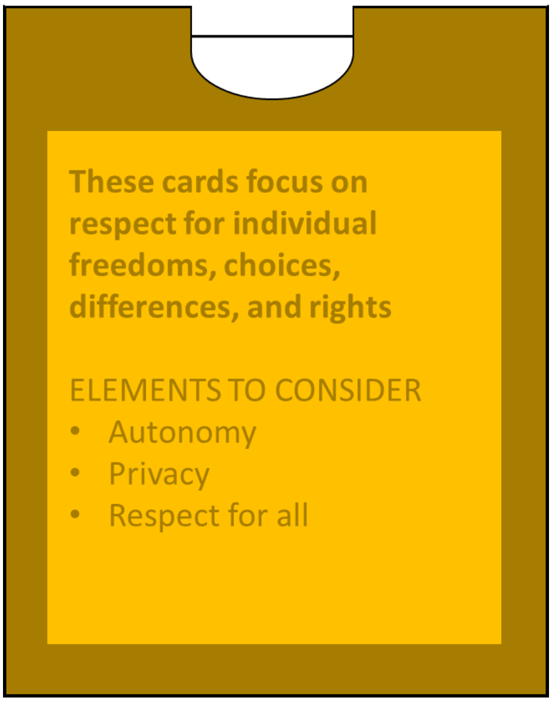
What innovations will the current technology offer? Will these fit the existing models of care?

How will this technology facilitate high user acceptance, adherence, and adoption?

FRONT

HUMAN RIGHTS

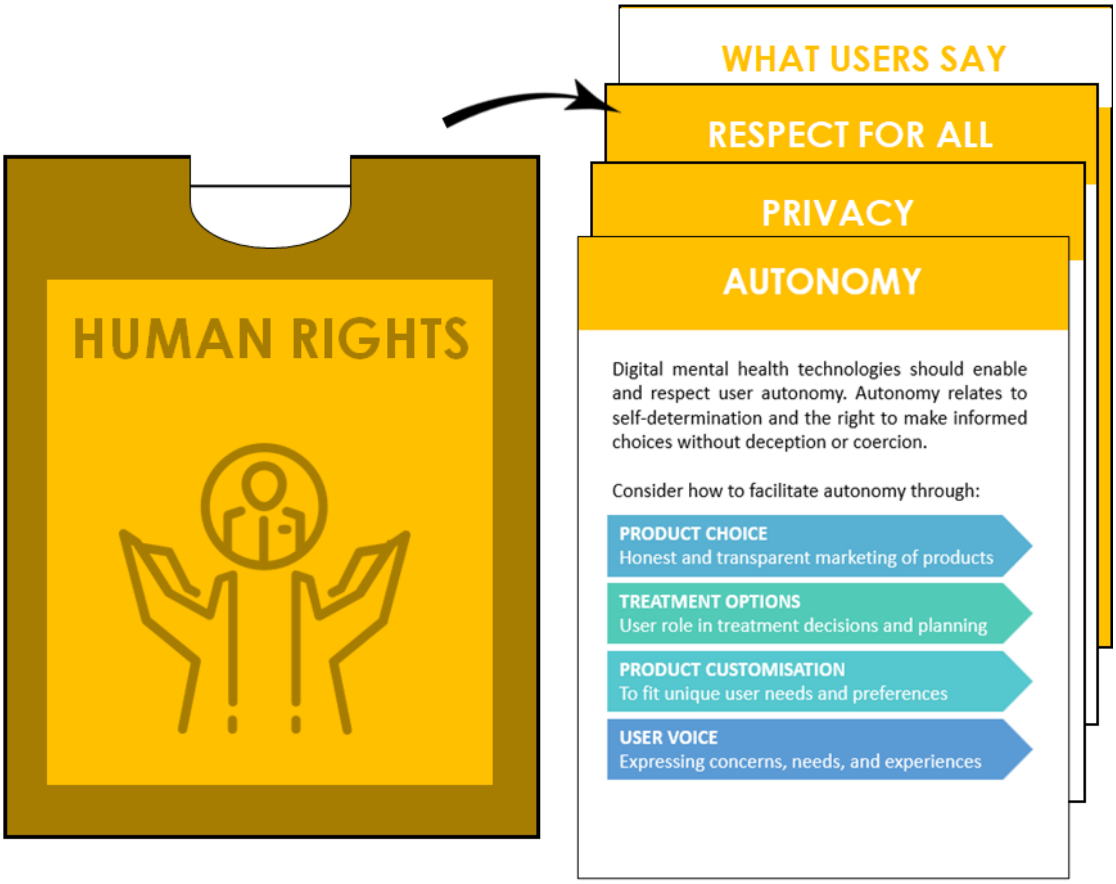
BACK



These cards focus on respect for individual freedoms, choices, differences, and rights

ELEMENTS TO CONSIDER

- Autonomy
- Privacy
- Respect for all



HUMAN RIGHTS

WHAT USERS SAY

RESPECT FOR ALL

PRIVACY

AUTONOMY

Digital mental health technologies should enable and respect user autonomy. Autonomy relates to self-determination and the right to make informed choices without deception or coercion.

Consider how to facilitate autonomy through:

PRODUCT CHOICE
Honest and transparent marketing of products

TREATMENT OPTIONS
User role in treatment decisions and planning

PRODUCT CUSTOMISATION
To fit unique user needs and preferences

USER VOICE
Expressing concerns, needs, and experiences

FRONT

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TREATMENT OPTIONS
User role in treatment decisions and planning

PRODUCT CUSTOMISATION
To fit unique user needs and preferences

USER VOICE
Expressing concerns, needs, and experiences

BACK

REFLECTIONS

How is the value of autonomy reflected and respected in the design of the current technology?

How will the current digital mental health technology help users to develop increased autonomy and self-efficacy?

Will the current digital mental health technology require explicit informed consent prior to use?

What role will users play in treatment decisions and planning? What choices will users be offered?

What influence will users have on product design or customisation? What choices will be offered?

How will user voice by facilitated and encouraged in the design and development of this technology?

FRONT

PRIVACY

Digital mental health technologies should respect and protect users' privacy and confidentiality.

PRIVACY	**CONFIDENTIALITY**
An individual's right to control how their personal information is collected, used, or shared with others	A duty of those entrusted with (mental) health information to keep that information private bar specific limits

This involves:
- clear and accessible privacy policies
- informed consent with limits to confidentiality
- requests for user data proportionate to need
- robust data security
- deidentified or anonymous data collection
- user choice and control of data

BACK

REFLECTIONS

What are users' needs for privacy?

How will the privacy and confidentiality of users' data be protected? Have major risks to privacy and data security been anticipated?

What standards and guidelines can be consulted and adopted to ensure good data security and privacy in this digital mental health technology?

Is the development team knowledgeable of the legal and professional responsibilities regarding privacy and confidentiality? Consider national or state laws and regulations

Is there a clear and accessible privacy policy? Is this written so lay persons can easily understand how their data will be collected, used, and shared?

FRONT

RESPECT FOR ALL

Digital mental health products should demonstrate respect for all persons.

Important areas to consider include:

Human rights

Diversity

Inclusiveness

Accessibility

Cultural differences

RESPECT

BACK

REFLECTIONS

What are users' needs for respect?

Are all members of the development team aware of universal human rights and consumer rights?

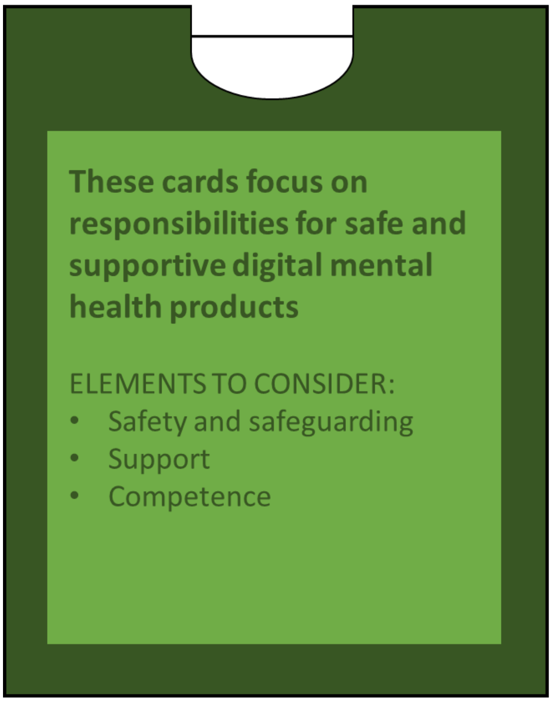
What values do you consider to be important in the design of ethical digital mental health. How are these reflected in the design and development of the current digital mental health technology?

How may these values differ from users'? How will potential biases in the design of the current technology be managed and removed? Consider how the role of language, representation, content, graphics, illustrations, etc.

How will the development team ensure the current technology is inclusive and accessible to all users?

FRONT

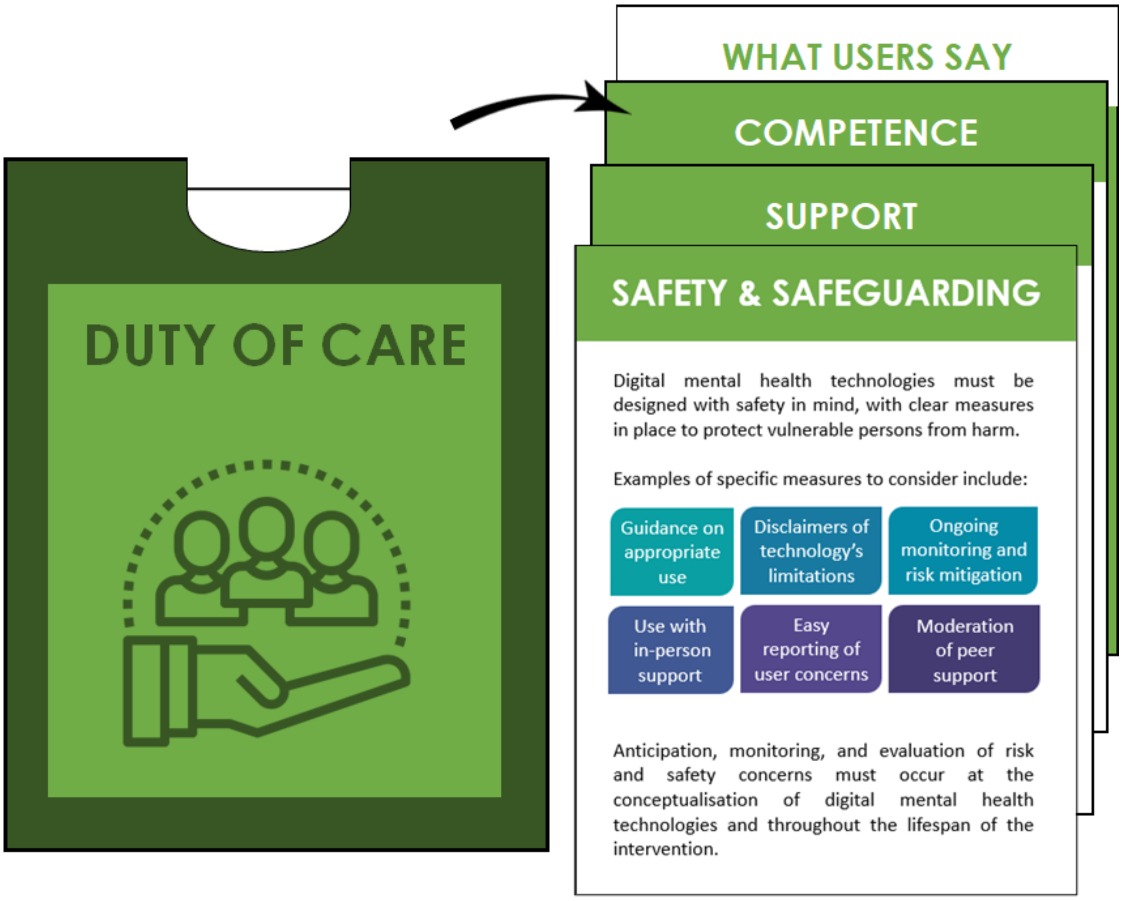
BACK



These cards focus on responsibilities for safe and supportive digital mental health products

ELEMENTS TO CONSIDER:

- Safety and safeguarding
- Support
- Competence



SAFETY & SAFEGUARDING

Digital mental health technologies must be designed with safety in mind, with clear measures in place to protect vulnerable persons from harm.

Examples of specific measures to consider include:

- Guidance on appropriate use
- Disclaimers of technology's limitations
- Ongoing monitoring and risk mitigation
- Use with in-person support
- Easy reporting of user concerns
- Moderation of peer support

Anticipation, monitoring, and evaluation of risk and safety concerns must occur at the conceptualisation of digital mental health technologies and throughout the lifespan of the intervention.

FRONT

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BACK

REFLECTIONS

What are users' needs for safety and safeguarding in the current digital mental health technology?

Who is responsible for the safety of users? How will this be communicated to potential users?

What are the roles, responsibilities, and duty of care of designers and developers of digital mental health technologies?

Has the current technology been designed, developed, and marketed with safety in mind?

What are the potential limitations of this digital mental health technology? How will these be communicated to potential users?

How will the development team monitor and protect vulnerable users? What specific measures and processes are needed?

FRONT

SUPPORT

Digital mental health should provide users with adequate developer and therapeutic support. It should facilitate improved social support either in the technology or in users' daily lives.

DEVELOPER SUPPORT
- Accessible reporting and resolution of issues
- Quick response to queries and concerns
- Ongoing updates and development

THERAPEUTIC SUPPORT
- Examples: therapists, coaches, or chatbots
- Value of authentic human support and contact
- Importance of frequency, quality, competence

SOCIAL SUPPORT
- Promoting understanding, social connections, and community

Technologies should also support connections to in-person care where appropriate or needed.

BACK

REFLECTIONS

What are users' needs for support? How will this be reflected in the design, development, marketing, and maintenance of the current digital mental health technology?

What level of therapeutic support will users receive? Consider connection to in-person services, crisis interventions, blended care, etc

Will the current technology be used for self-help or supplementary to in-person mental health care? How will this be reflected in the intervention and technology design?

How will the current technology facilitate positive supportive experiences and therapeutic alliance?

What level of developer support will be provided to users throughout the technology lifespan?

FRONT

COMPETENCE

Digital mental health technologies must be developed with appropriate technological and clinical expertise and skills.

Competence in digital mental health extends to:

BACK

REFLECTIONS

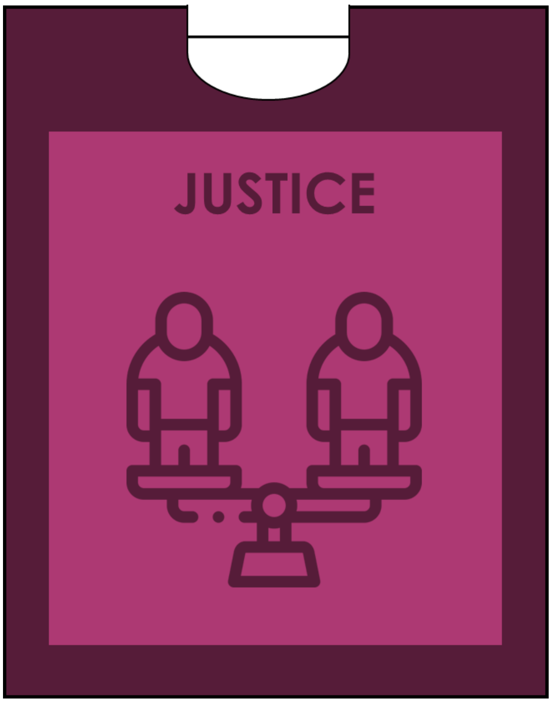
What knowledge and skills are needed for the current digital mental health technology to be a success? Consider competency in the areas of designer/developer expertise, therapeutic support, non-practitioner support, intervention content, lived experience with mental health problems

Is the development team knowledgeable and skilled in technological and clinical areas pertinent to digital mental health?

Is the current technology being designed and developed with multidisciplinary stakeholders? Is there a need for additional expert involvement?

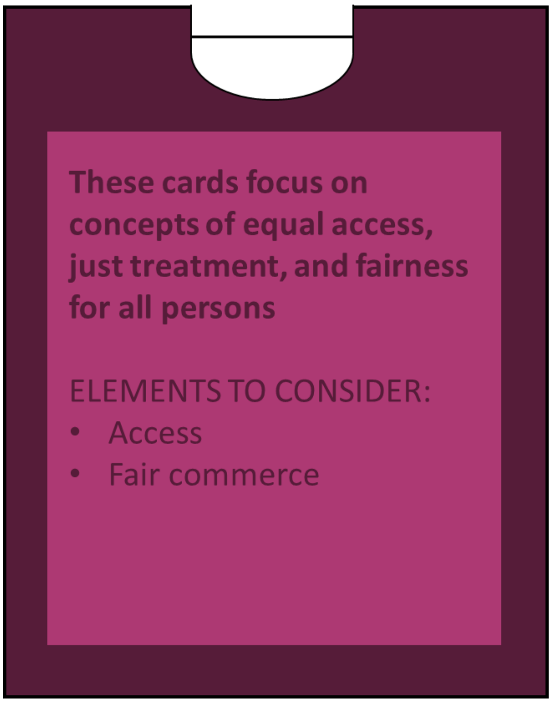
How will user groups and persons with lived experiences of mental health difficulties be involved in the planning, design, development, and research of the current technology?

FRONT



JUSTICE

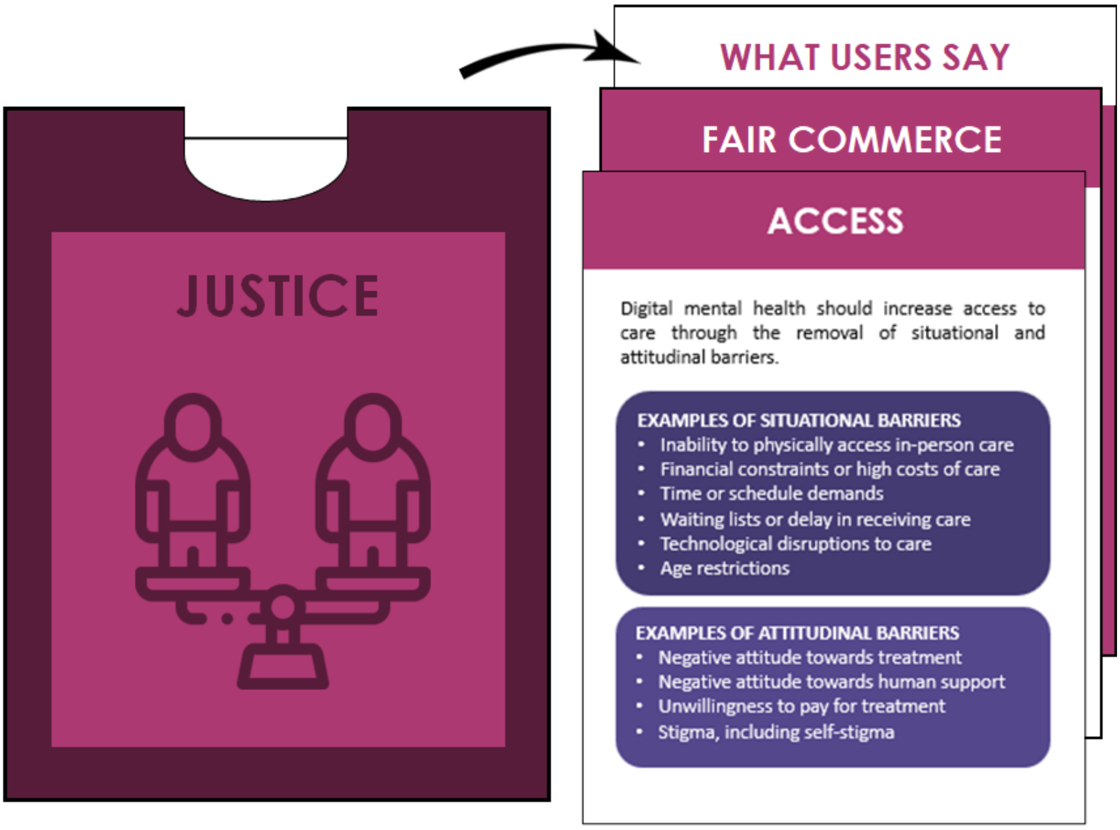
BACK



These cards focus on concepts of equal access, just treatment, and fairness for all persons

ELEMENTS TO CONSIDER:

- Access
- Fair commerce



JUSTICE

WHAT USERS SAY

FAIR COMMERCE

ACCESS

Digital mental health should increase access to care through the removal of situational and attitudinal barriers.

EXAMPLES OF SITUATIONAL BARRIERS

- Inability to physically access in-person care
- Financial constraints or high costs of care
- Time or schedule demands
- Waiting lists or delay in receiving care
- Technological disruptions to care
- Age restrictions

EXAMPLES OF ATTITUDINAL BARRIERS

- Negative attitude towards treatment
- Negative attitude towards human support
- Unwillingness to pay for treatment
- Stigma, including self-stigma

FRONT

ACCESS

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- Age restrictions

EXAMPLES OF ATTITUDINAL BARRIERS
- Negative attitude towards treatment
- Negative attitude towards human support
- Unwillingness to pay for treatment
- Stigma, including self-stigma

BACK

REFLECTIONS

What situational and attitudinal barriers to care may users of the current technology face?

How will this digital mental health technology reduce treatment barriers and increase access to care? Consider existing situational and attitudinal barriers to care and how these may be addressed in the technology's design, marketing and deployment

What potential barriers may the current digital mental health intervention introduce? What user groups may be particularly vulnerable to new barriers created by digital mental health technologies?

How will the current technology avoid the digital divide and strive to provide equal access to care?

FRONT

FAIR COMMERCE

Digital mental health products should employ fair and ethical business models which avoid conflicts of interest and respect users' commercial and human rights

Matters to consider include:

Fair costs
Transparent pricing
Flexible pricing options
Transparent business models
Appropriateness of commercial business practices within healthcare
Declared sources of funding
Declared conflicts of interest
Risks of third party involvement
Respect for consumer rights

BACK

REFLECTIONS

What business model would the current digital mental health technology be based on? What are the possible ethical implications of this model?

What are the primary motives behind the design and development of the current product? How is this reflected in the business model and practices?

How can transparency in sources of funding, business model, and practices be ensured?

What potential conflicts of interest may arise? Consider possible conflicts with the commercialisation of healthcare, compromise of care for profits, use of paywalls to access care, etc.

How can these potential conflicts of interest be safeguarded against?

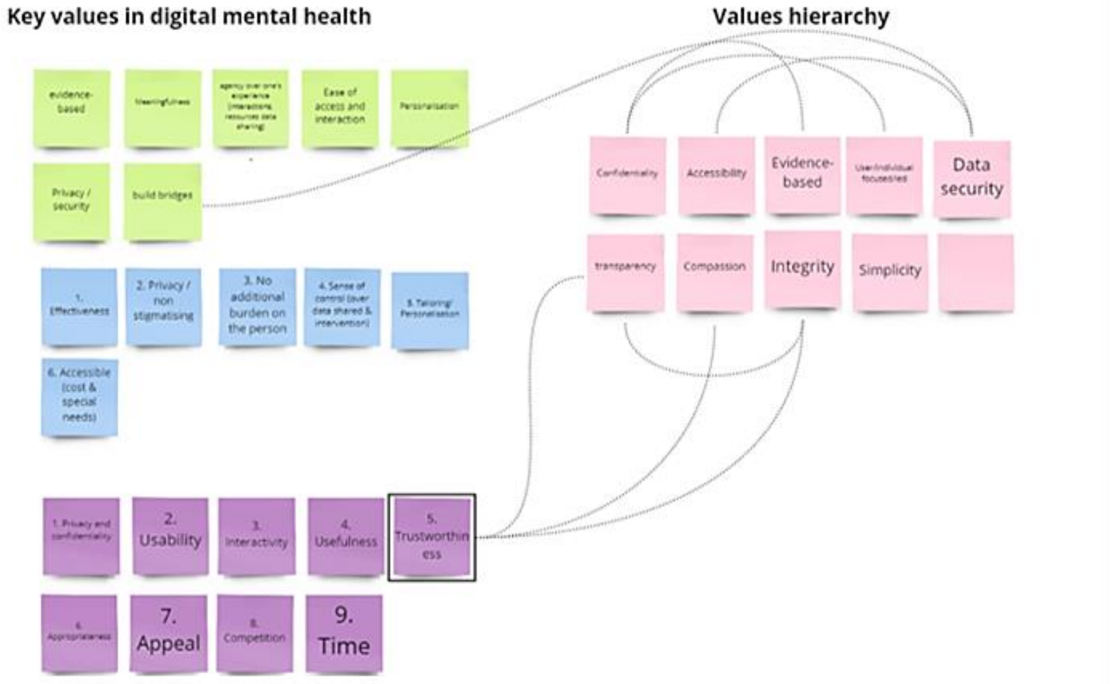
Appendix B. Most important core values synthesised from participants' ranking of key values, where 1 is ranked as most important

Core values	**P1**	**P2**	**P3**	**P4**	**P5**	**P6**	**P7**	**P8**	**P9**	**P10**
Privacy	1	2	3[a]	1	6	2	3	1	3	4
Effectiveness	2[a]	1			1	1		3		1
Usefulness	5			3	2	3	2			
Accessibility and inclusivity	6		6		4	6		2	2	
Autonomy			2		3	4				5
Transparency	7	4	5					5	1	6
Accuracy and reliability	2[a]		3[a]							
Ease of use				2				6		2
Trust			1	4						
Personalisation	8	3			5	5				
Support							1			3
Acceptability	4									
Person-centred design								4		
Connectivity					7					7
Enjoyment				5						

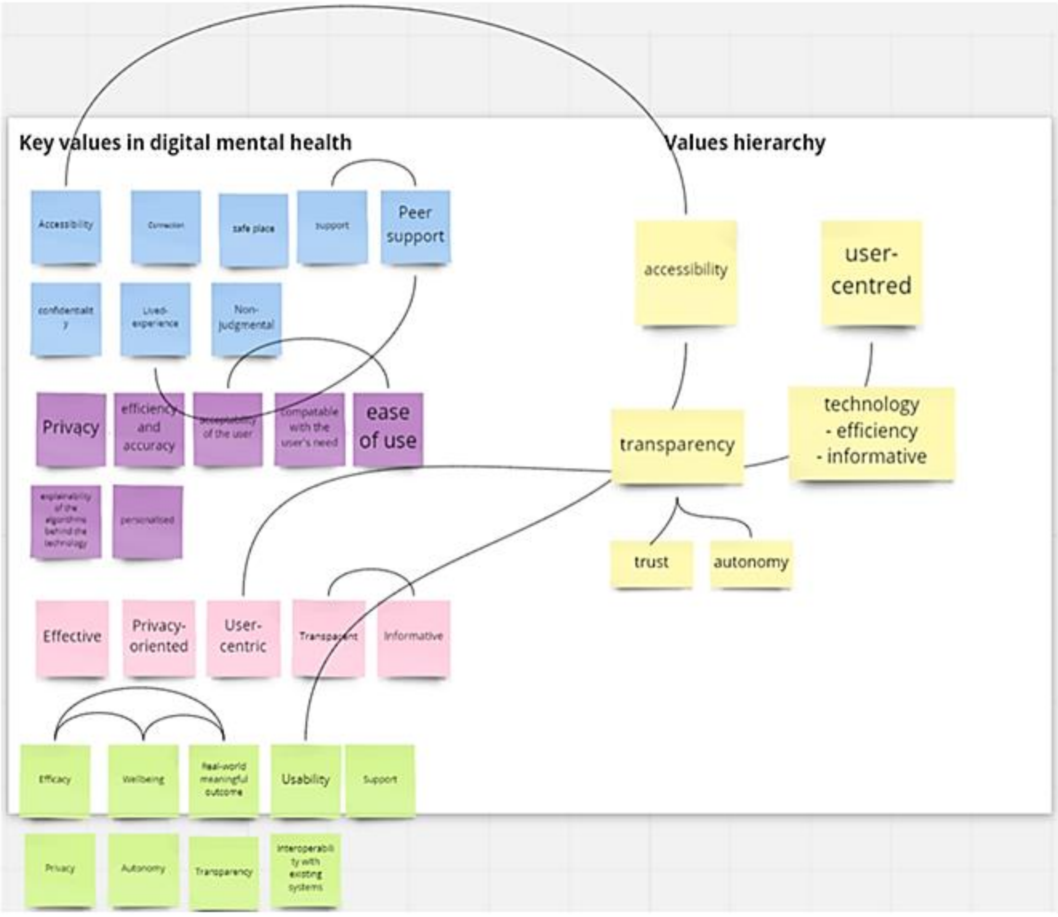
[a] values with same ranking of importance

Blank cells show that the participant did not list the value

Appendix C. Participants' visualisations of the interrelations between key values



a. Workshop 2



b. Workshop 3

6 Thesis Discussion

6.1 Thesis Aims and Summary of Findings

This thesis explored ethical issues and considerations in mobile mental health with the overarching aim of developing a transdisciplinary framework for ethical mobile mental health. Mobile mental health is the most common application of digital mental health. It involves the use of mobile technologies such as internet-delivered interventions and mental health apps for mental health assessment, prevention, treatment, and support (Bond et al. 2023; Wies et al., 2021). Mobile mental health (and digital mental health more broadly) has been touted for its potential to increase much needed access to mental health treatment and support (Bond et al., 2023; Price et al., 2013; Ralston et al., 2019, Torous et al. 2020; WHO, 2011). But there are notable challenges and concerns that may impact the good and fair delivery of mental health care, leading many to frame these as ethical issues or considerations (Kretzschmar et al., 2019; Torous & Roberts, 2017a; Wykes et al., 2019). There is much literature discussing ethics in mobile mental health, yet there are substantial gaps in the evidence base. Firstly, there is a poverty of empirical evidence and an overabundance of commentaries and literature reviews. There is also a need for multidisciplinary perspectives to inform practical guidance and tools for ethical practices and responsible design. In this thesis, I sought to address these challenges through a series of studies exploring the ethics of mobile mental health, stakeholder values and conceptualisations of ethical digital mental health, and how these can be applied to produce ethical mobile mental health technologies. Table 1 outlines the main aims of the thesis and how these aligned with the research questions in the studies presented in Chapters 3 to 5.

Table 1. Thesis aims mapped to study research questions

Thesis aim	Relevant research questions
1. To provide a comprehensive review of ethical issues in mobile mental health, including ethical issues arising from real-world use	**Chapter 3.2: a cross disciplinary scoping review** • What are the ethical issues in mobile mental health? **Chapter 4.1: content analysis of treatment descriptions** • What treatment approaches and strategies are named or described in app listings of apps for depression? • Are treatment fidelity and evidence-informed development evident in descriptions of apps for depression? • Do descriptions of apps for depression reflect NICE guidelines for the treatment and management of depression?

Thesis aim	Relevant research questions
	Chapter 4.2: content analysis of depression app marketplace • What ethical issues are evident in the depression app marketplace? **Chapter 4.3: qualitative analysis of user reviews** • What ethical issues are evident in app store user reviews of apps for depression? • Based on user experiences, what are the key elements of ethically designed apps for depression?
2. To investigate stakeholder values in digital mental health and how these align with their conceptualisations of ethical digital mental health	**Chapter 4.2: content analysis of depression app marketplace** • How do these issues reflect ethical values in app design, development, and marketing? **Chapter 4.3: qualitative analysis of user reviews** • What are users' perceptions and experiences of publicly available apps for depression? **Chapter 5: a multidisciplinary workshop** • What are the key values in digital mental health? • How do participants describe ethical digital mental health?
3. To study if and how ethical issues and values in mobile mental health differ across the disciplines involved	**Chapter 3.1: transdisciplinary ethical principles and standards** • To compare principles and standards across disciplines in digital mental health **Chapter 3.2: a cross disciplinary scoping review** • Which sectors, disciplines or stakeholder perspectives are represented in the discussion and research on the ethics of mobile mental health? • How does the discussion on the ethics of mobile mental health vary across sectors and disciplines?
4. To investigate the acceptability and feasibility of a practical design tool to help multidisciplinary development teams to develop ethical digital mental health technologies	**Chapter 5: a multidisciplinary workshop** • What is the acceptability, feasibility, and barriers to using the proposed ethical design cards?
5. To develop a transdisciplinary ethical framework to guide the design and evaluation of mobile mental health technologies	All of the above, with framework presented in Chapter 6

The first aim was addressed in Chapters 3.2 and 4, with all studies providing rich descriptions and examples of the ethical issues and considerations in mobile mental health. These findings provide two levels of insight. Firstly, the studies each presented detailed reviews of ethical issues, with specific examples (Chapters 3.2 and 4.2) and real-world user experiences (Chapter 4.3). This level of detail is useful in showing the breadth of ethical concerns and can help developers, healthcare professionals, and potential users to be aware of specific challenges that have been noted and experienced. However, this level of detail is less helpful for broader discussions on the ethics of mobile mental health and guidance on how to design more ethical and responsible technologies. The studies therefore also provide a second level of insight through the overarching ethical themes capturing these more detailed examples. The scoping review of the ethics of mobile mental health (Chapter 3.2) grouped ethical issues under the following themes: harms, privacy, duty, inequalities, autonomy, benefits, standards, validity, conflicts of interest, clinical practice, intentions and values, and acceptability. Chapter 4.1 adds to this level of understanding by providing a focused review of issues related to effectiveness and evidence-base which were flagged as key concerns in the literature (Huguet et al., 2016; Stawarz et al., 2018; Torous, 2017). This study mirrored these concerns with none of the apps for depression reviewed appearing to align with clinical guidelines in terms of their treatment approach, provision of human support, and evidence of effectiveness. Over 40% of the apps reviewed adopted a transdiagnostic approach, but there was no information on the specific evidence-base underlying these interventions or the effectiveness of this approach.

The second aim was assessed in Chapters 4.2, 4.3, and 5. I explicitly explored values in digital mental health with participants who had experience designing or delivering mobile mental health interventions (Chapter 5). Participants identified 60 key values in digital mental health which were then themed into 15 core values. I also inferred values in mobile mental health based on the findings of studies on the app marketplace. This is based on the premise that values reflect what people consider to be important (van de Kaa et al., 2019) and the assumption that these would be prioritised and reflected in user reviews and app descriptions. Based on these findings and the existing literature (Rooksby et al., 2019), values were found to differ across stakeholders, with users seeming to value autonomy, benefits, usability, and support, while developers prioritised privacy, effectiveness, and evidence-informed design.

The third aim was explored in Chapter 3 through two cross disciplinary reviews. A transdisciplinary review of professional codes of ethics showed similar principles and standards across disciplines relevant to mobile mental health. But there were some differences that could impact values and priorities when designing or implementing mobile mental health technologies. Psychology ethics codes (American Psychological Association, 2017; British Psychological Society, 2018; European Federation of Psychologists' Associations, 2005) prioritised care and welfare, and standards related to duty of care and competence. Comparatively, engineering codes (National Society of Professional Engineers, 2019; Institute of Electrical and Electronics Engineers, 2014; Royal Academy of Engineering, 2011), while also prioritising benefits and avoidance of harm, emphasised standards related to professional reputability and responsibility. Findings were synthesised into eight ethical principles: beneficence, nonmaleficence, competence, integrity, justice, fidelity, responsibility, and respect for rights and dignity of all. In the scoping review, disciplinary differences were also evident in how authors discussed ethics in mobile mental health. Author discipline appeared to influence the choice of ethical framework used and also the ethical issues discussed. Of note, papers written by multiple authors from different disciplines discussed more ethical themes than papers by authors of the same discipline. Furthermore, some disciplines did not discuss some ethical issues, suggesting need for multidisciplinary working to ensure adequate consideration of the key issues in ethical mobile mental health. This supports the aims of this thesis and the proposed framework outlined in Section 6.2.

The fourth aim was addressed in Chapter 5 through multidisciplinary workshops exploring the acceptability and applicability of a prototype set of ethical design cards for digital mental health. There was generally high acceptability and interest in the ethical design cards. Participants considered that the cards could be used throughout the design and research of digital mental health technologies to help development teams to better consider and discuss ethical issues. The cards were thought to be especially beneficial for facilitating multidisciplinary discussions and creating a shared vocabulary.

The fifth and final aim of the thesis involved the development of a transdisciplinary framework based on the aforementioned findings. This framework is made up of three components: (1) multidisciplinary involvement, (2) values and principles of ethical digital mental health, and (3) a toolkit for designing ethical digital mental health. It is grounded in the importance of multidisciplinarity and stakeholder involvement, from which core values and principles emerge and are utilised to propose specific tools for the design and implementation of ethical mobile mental health. This framework is presented in Figure 1 and described in Section 6.2.

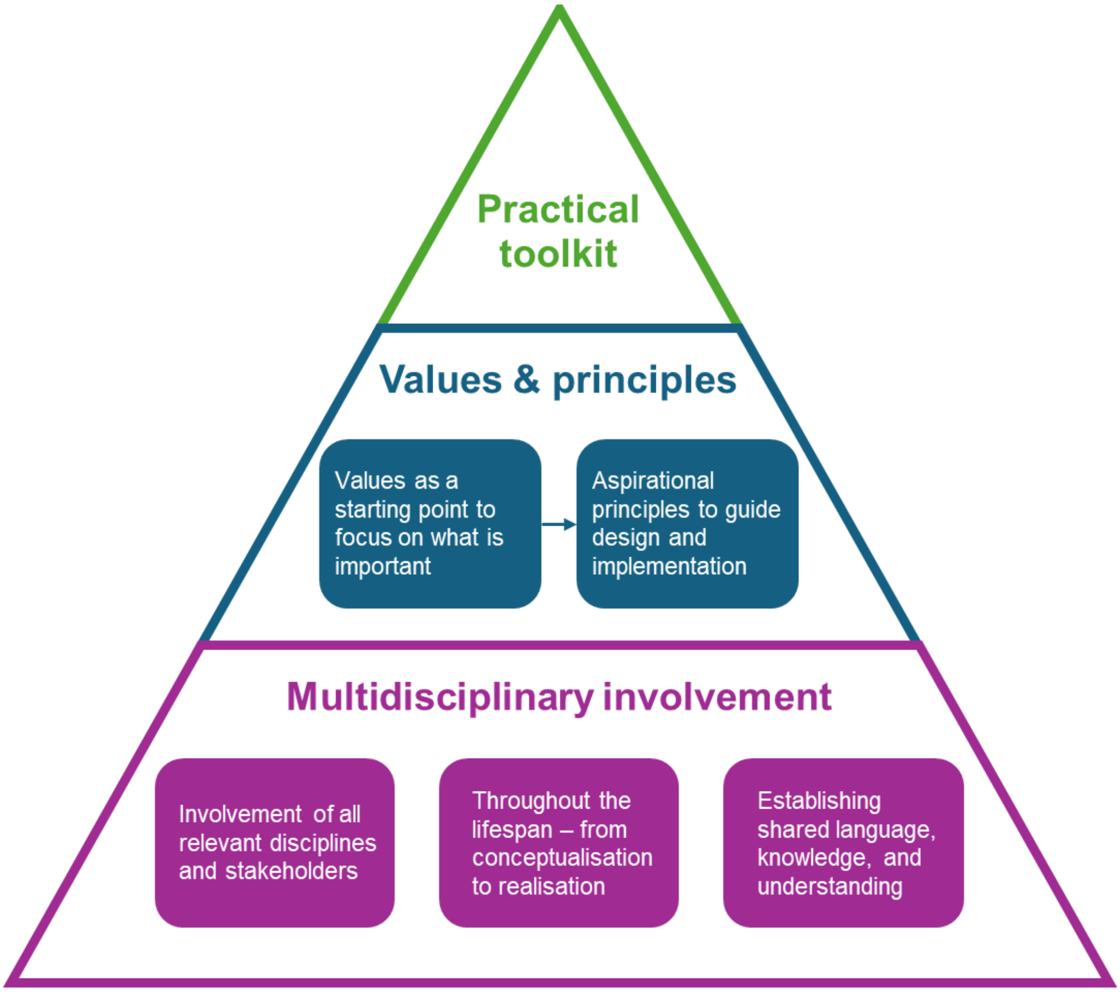


Figure 1. Transdisciplinary framework for ethical mobile mental health

6.2 Transdisciplinary Framework for Ethical Mobile Mental Health

A. Multidisciplinary Involvement

At the core of this framework is the importance of multidisciplinary involvement in not just the development and implementation of digital mental health interventions, but also the development of theories, frameworks, and guidance that are used to inform this space. This is supported by the studies in this thesis showing both similarities and differences across the relevant disciplines in mobile mental health. In Chapter 3.2, I found that there were significant similarities in the ethical issues discussed across disciplines, with commonly discussed issues including harms, privacy, inequalities, duty, autonomy, benefits, and standards. This may reflect the saturation of these issues in the literature leading to widespread knowledge and agreement (Jones & Moffitt, 2016; Karcher & Pressure, 2016; Lustgarten & Elhai, 2018; Palmer & Burrows, 2021; Parker et al., 2017; Torous & Roberts, 2017). But there were notable areas of divergence that highlight the need for involvement from all disciplines and stakeholders. Chapter 3.2 identified gaps in the discussion of ethical themes and considerations in papers written by authors from a single background. For example, none of the papers with only HCI authorship discussed inequalities, standards, conflicts of interest, or clinical practice. Conversely, none of the papers with only authors from mental health disciplines discussed intentions and values, or acceptability. On the other hand, papers written by multiple authors from different backgrounds included the most ethical themes and the fewest gaps. This is important not only in ensuring the most important ethical issues are considered, but also because different disciplines may view and approach these issues differently. In Chapter 5, group discussion amongst professionals from different disciplines – developers, psychologists, and academics – highlighted some differences in descriptions and conceptualisation of values between participants and across disciplines. Participants often used differing terminology to describe similar concepts, for example, access and accessibility were often used interchangeably, as were efficiency and effectiveness, and personalised and user centric. This led to participants suggesting the need for a shared vocabulary to facilitate multidisciplinary discussions and understanding. Even more so, participants acknowledged that the multidisciplinary workshop acted as a tool in and of itself that could be used in training to increase ethical understanding in digital mental health. As a result, multidisciplinarity is the pillar of ethical digital mental health and the foundation of the proposed framework.

The findings of this thesis suggest that multidisciplinary involvement should include three components. Firstly, it should involve multidisciplinary teams and stakeholders in the design, use, adoption, and evaluation of mobile mental health technologies. Multidisciplinary teams designing and developing mobile mental health should include people from all disciplines and backgrounds relevant to the specific technology. This may include but is not limited to mental health professionals, computer scientists, engineers, ethicists, and people with lived experience. Additional stakeholders outside of the development team should also be consulted to ensure adequate consideration of the breadth of ethical issues around the design and use of the specific technology. Secondly, this involvement should span the technology lifespan, with multidisciplinary and stakeholder input from early conceptualisation throughout late-stage design, evaluation, use and adoption. This is especially important considering the findings in this thesis that multidisciplinary perspectives are more likely to consider the range of ethical issues across the lifespan of mobile mental health – from acceptability, technology and intervention design, regulation, informed choice, and clinical use and outcomes. Lastly, multidisciplinary involvement should facilitate the development of a shared language and understanding of the ethics of mobile mental health. Multidisciplinary teams should initially explore potential differences in team members' conceptualisations and experiences of ethics in digital mental health in order to establish a common starting point to build mutual understanding and development. Areas of discussion to consider include exploring the idea of ethics and ethical digital mental health, priorities for designing ethical technologies, and intentions for how the technology should be used. In doing so, multidisciplinary teams are more likely to explore ethics beyond the most commonly applied frameworks and to be expansive in their consideration and management of ethical issues.

B. Values and Principles of Ethical Digital Mental Health

The findings of this research suggest that values form the basis of how people conceptualise ethical digital mental health. For some, normative ethical theories (Beauchamp & Childress, 2019; LaFollette & Persson, 2013; Tännsjö, 2013) can be too abstract and difficult to apply in practice. This was observed in the multidisciplinary workshops (Chapter 5), with participants seemingly having initial difficulty defining ethical digital mental health, despite demonstrating good understanding of issues in the area. There also seemed to be some hesitancy towards ethical deliberations, with few participants suggesting some people may feel judged when reflecting on previous work or mistakes. These findings suggest that there is a need to make ethics more approachable and to shift perceptions of ethics from one of judgement and beleaguered obligation (Tännsjö, 2013) to a positive approach towards creating and implementing good and fair technologies. I propose that this could be achieved by using values as a starting point. Participants readily engaged with the tasks and discussions on values and appeared to find this easier to reflect on and to share with others. This may reflect the shift in language and the framing of discussions around what they considered to be important. This framing firstly focuses on something positive – What is important? – rather than a judgement on what should be avoided. Secondly, it shifts the discussion to what they themselves consider important rather than focusing on prescriptive obligations (Beauchamp & Childress, 2019; LaFollette & Persson, 2013; Tännsjö, 2013). Yet, it is still aspirational and focusing on what ought to be (van de Kaa et al., 2019), and in doing so embodying social and ethical issues.

In Chapter 5, I outlined core values of digital mental health stemming from participants' individual reflections and group discussions. These were: privacy, effectiveness, usefulness, accessibility and inclusivity, autonomy, transparency, ease of use, accuracy and reliability, trust, personalisation, support, acceptability, person-centred design, connectivity, and enjoyment. There are several important aspects to the values that should be considered:

1. **All core values in digital mental health are important.** There may be situations where one value may be more relevant than others. But all core values are important and should be considered at some stage.
2. **Core values are interconnected but distinct.** Core values are considered distinct from each other, but issues with one value would likely impact others.
3. **There will be tensions between some core values.** Value tensions should be considered when designing digital mental health interventions.
4. **Stakeholders may differ in how they view values.** Multidisciplinary teams should discuss values to ensure a shared vocabulary. Stakeholders may also differ in their prioritisation of values.
5. **Core values should be considered throughout the technology lifespan.** Values may have different weights depending on the stage in the technology lifespan.
6. **Core values form the basis of ethical digital mental health.** Ethical digital mental health is linked to the core values which, if not sufficiently considered, have the potential to do harm.

More research is needed to further explore the values in digital mental health and the key considerations for applying these values in practice.

Building on these core values are the principles of ethical mobile mental health that represent ideals for good and fair mobile mental health interventions. The American Psychological Association (2017) described their principles as “aspirational goals to guide psychologists toward the highest ideals of psychology”. In a similar manner, I consider the principles of ethical mobile mental health to be aspirational goals to guide the design and implementation of these technologies. These principles are derived from the qualities of ethical digital mental health presented in Chapter 5. Ethical digital mental health was described as digital mental health technologies that do no harm, and are responsible, beneficial, person-centred, honest and transparent, and private. In Chapter 5, I showed how these qualities mapped well onto the elements of ethical apps for depression. As shown in Figure 2, these qualities also show good alignment with the principles of biomedical ethics (Beauchamp & Childress, 2019), professional ethics codes (American Psychological Association, 2017; British psychological Society, 2021), and the transdisciplinary ethical principles and standards presented in Chapter 3.1. But the proposed principles of ethical mobile mental health are enhanced by the simplified language used to convey these principles across audiences and the inclusion of specific ethical elements in mobile mental health that are not explicitly presented in the other frameworks, specifically person-centred and private.

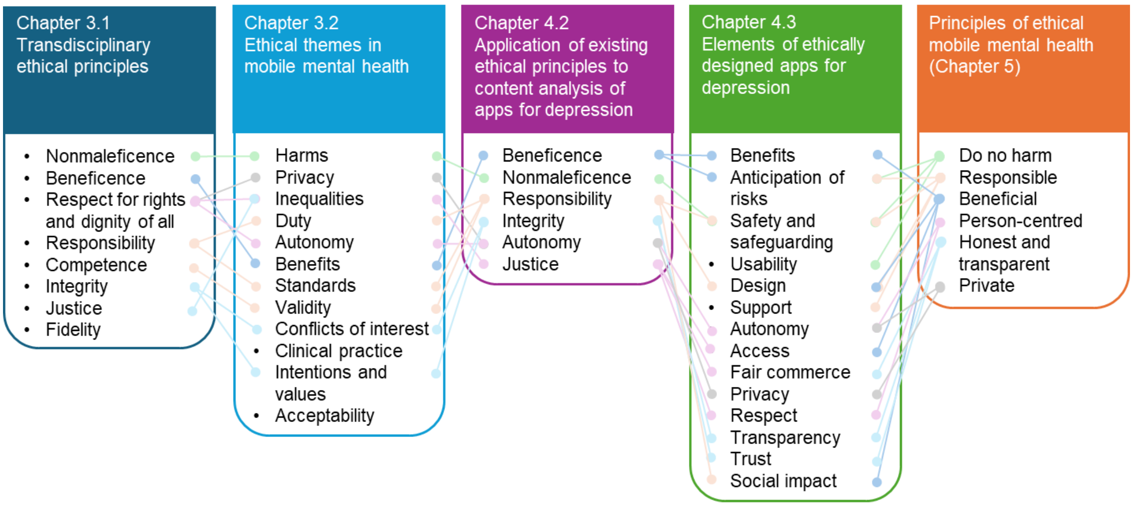


Figure 2. Development of principles of ethical mobile mental health

The principles of ethical mobile mental health therefore sit it in the framework as the overarching standard of mobile mental health, which can be achieved through multidisciplinary involvement and value driven approaches (Figure 3). Multidisciplinary teams are encouraged to reflect on these principles in the development of mobile mental health interventions and to consider not only their own ethical practices, but the principles and values embedded in the technologies they design and develop (Davis & Nathan, 2015; Friedman & Hendry, 2019; van de Kaa et al., 2019). Mobile mental health should reflect these key principles to ensure safe, accurate, and effective delivery of care for all.

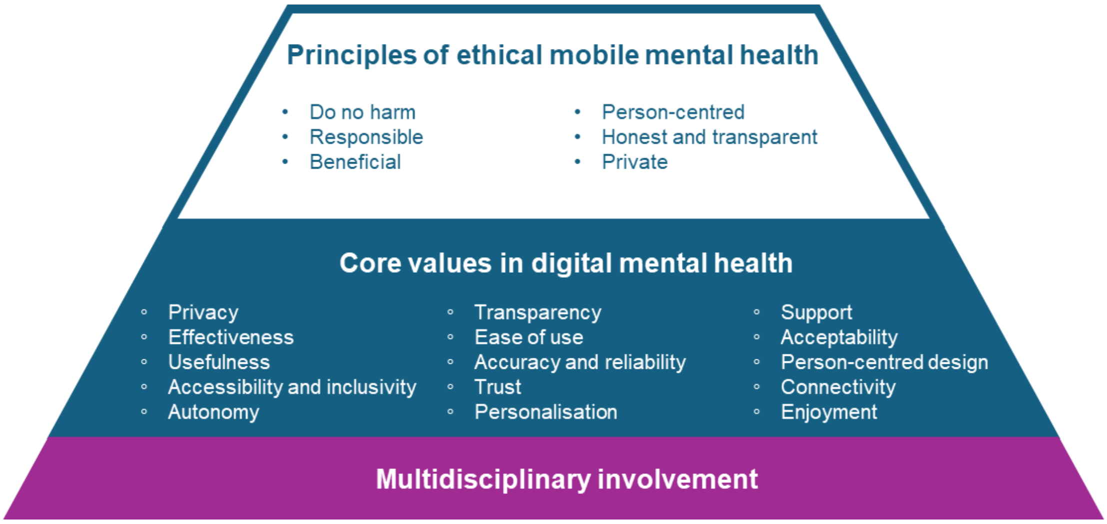
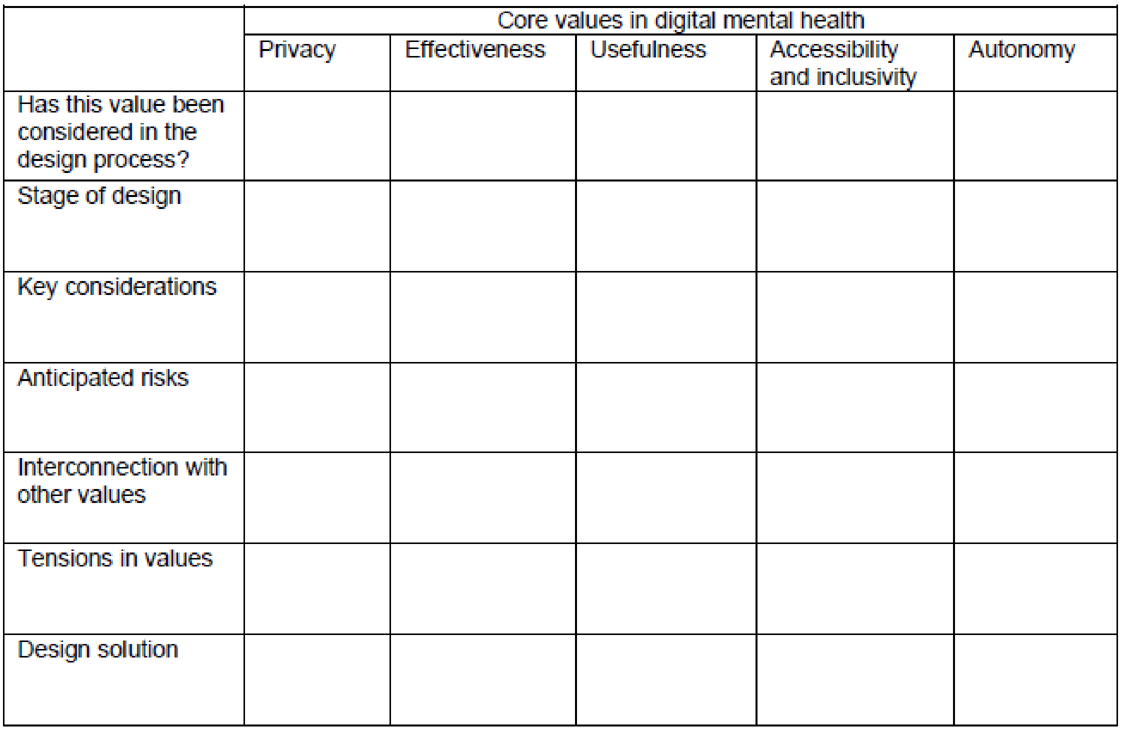


Figure 3. Relationship between values and principles in the framework

C. A Toolkit for Designing Ethical Digital Mental Health

The third and final component of the framework presents evidence-based tools to practically apply these concepts to the design and implementation of mobile mental health. These include (1) a values matrix and (2) ethical design cards.

A key contribution of this thesis is the idea that values may be best considered and assessed in a values matrix which would outline the core values in digital mental health and provide a space to explore interconnections, tensions, and priorities. Matrices have been used in healthcare to help assess patient care by exploring aims for improvement against core competencies. Bingham et al. (2005) described this as a conceptual framework that allows for the tabular presentation of quality outcomes against the knowledge and skills needed to affect those outcomes. A matrix would be a useful approach for assessing values and, in turn, beginning the discussion of potential ethical issues and considerations in digital mental health. In Chapter 5, I presented an example of how a values matrix may be applied to the design process to assess how different considerations may impact or be impacted by the specific values. This example – shown again here in Figure 4 – considered the stage in the design process, anticipated risks, and possible tensions. A values matrix could help multidisciplinary teams to consider values that may have otherwise been overlooked, explore value tensions and how these may be addressed, and explore any changing priorities through the lifespan to ensure that all relevant values have been considered.

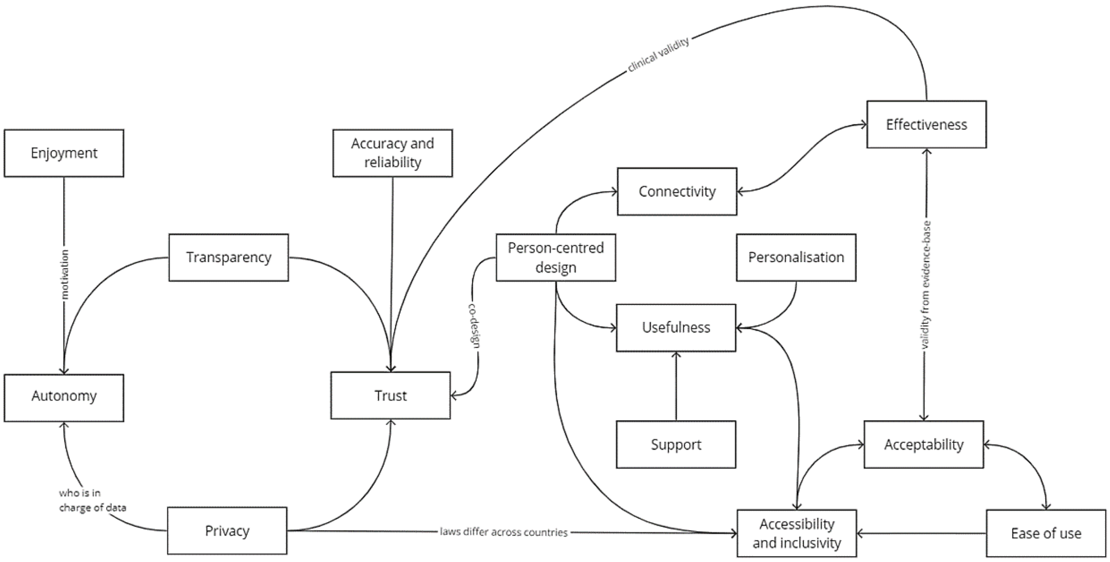


	Core values in digital mental health				
	Privacy	Effectiveness	Usefulness	Accessibility and inclusivity	Autonomy
Has this value been considered in the design process?					
Stage of design					
Key considerations					
Anticipated risks					
Interconnection with other values					
Tensions in values					
Design solution					

Figure 4. Example of a values matrix using a sample of the core values

This exercise would be further enhanced by utilising the visualisations of interconnections and tensions described in Chapter 5 and again here in Figure 5.

A. Interconnections between core values



B. Tensions in ethical digital mental health

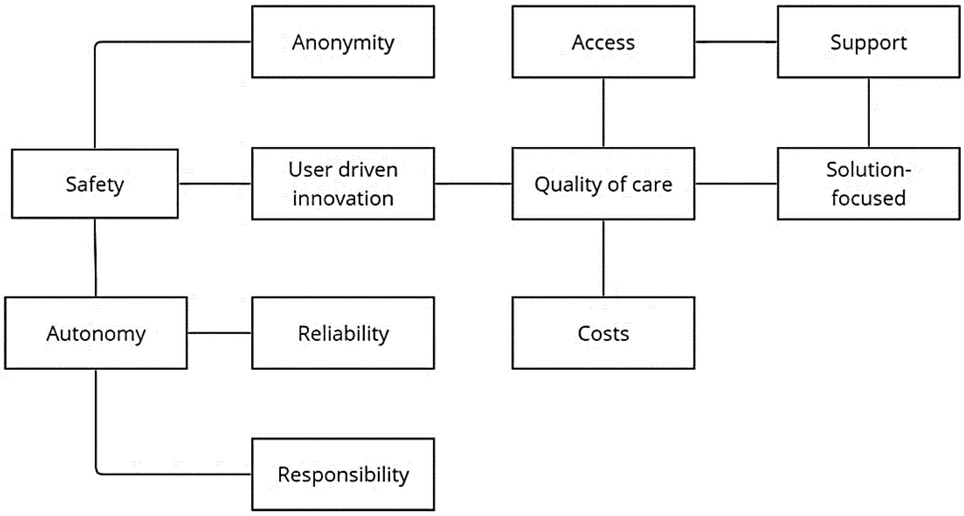


Figure 5. Visualisations of interconnections and tensions in ethical digital mental health

Participants in the multidisciplinary workshops expressed wanting more tangible and visual media to explore these concepts. They were highly interested in the idea of exploring ethical tensions but were unsure how these would be considered and navigated in the design process. Responsible innovation (Owen et al., 2013; van den Hoven, 2013) encourages developers to use ethical or moral conflicts (e.g., autonomy versus safety) to propel innovation to meet both moral obligations. Developers are therefore encouraged to reflect on value conflicts and ethical issues and to work with stakeholders to design new ways of overcoming ethical challenges and improving ethical practice. I propose that these visualisations and the values matrix can serve as tools to facilitate these reflections and design decisions. Multidisciplinary teams can also use the visual tools to anticipate potential risks and impacts of technologies, and to ultimately monitor and balance these throughout the technology lifespan.

The design of ethical mobile mental health technologies can be further encouraged and supported through the use of ethical design cards. Chapter 5 of this thesis presented a prototype set of ethical design cards aimed at facilitating multidisciplinary discussions and ethical design. These cards had high acceptability and applicability, with all participants considering them a useful toolkit for building knowledge and skills, making ethics more actionable, facilitating multidisciplinary discussions, and monitoring and evaluation of ethical considerations and solutions. The proposed steps to using the cards included reviewing the ethical categories and elements, using reflections and real-world examples to explore these concepts, and utilising the ethical tensions card to resolve conflict through design. Participants considered that the cards could be used throughout the design process, but most saw benefits particularly in the early stage of design. This aligned with Burr and Powell (2022) which reported industry preferences for using such tools in an agile development context and integrated into the early design process. There were a number of potential barriers around the use of the cards, with a need to consider the potential demands on costs, business models and pressures, and time. The ethical design cards are not proposed to be an additional burden in the design process, but as a flexible tool that can be used from conceptualisation and throughout. Addressing ethical design right at the start would likely result in time and cost saving later on because of the reduced need for addressing ethical issues and corrections. This is reflected in participants' experiences of having to rectify unanticipated ethical issues, resulting in time delays and increased frictions in design teams. Ethical design is therefore an investment in quality digital mental health interventions that is likely to see returns in increased implementation and positive outcomes.

Participants also provided helpful feedback for the next iteration of the cards, including suggestions for scenarios to work through when using the cards, having a board to visually explore ethical tensions in design, and having an online database with design examples of both ethical issues and designs that overcome ethical issues.. This database could include the recommendations to address ethical issues detailed in Chapter 3.2, which would provide practical evidence-based tips for a range of ethical challenges. Additionally, the prototype set of cards would benefit from amendments to the ethical categories and content to reflect the findings of this thesis and the proposed framework. It is therefore a work in progress, but one nonetheless that can be used by multidisciplinary development teams to get conversations going, to build skills, and to make ethics actionable. Further research should continue to evaluate the use of the cards and steps to overcome the noted barriers. Research is also needed on the attitudes of industry stakeholders towards ethical frameworks and facilitators of ethical design and implementation of these technologies.

7 Conclusion

This thesis aimed to comprehensively explore the ethics of mobile mental health to evaluate the breadth of ethical issues and considerations, stakeholder values and conceptualisations of ethical digital mental health, and how these can be applied to produce ethical mobile mental health technologies. I used a three-pronged approach to address the research aims, reflected in the thesis structure and the progression of studies. First, I conducted literature review in areas of ethics, digital and mobile mental health, and regulatory frameworks. This resulted in the development of preliminary transdisciplinary principles and ethical themes. Next, I conducted an in-depth review of ethical issues in the wild, including analysis of user perspectives and ethical experiences in mobile mental health. This study was unique in capturing the users' voice in discussions of ethical experiences and is a notable strength of this thesis. Finally, I looked at the practical application of these findings to improve ethical design and innovation in mobile mental.

This thesis makes a number of original contributions to the field which have the potential to positively impact the ethical design and implementation of mobile mental health technologies. First, it presented a comprehensive cross-disciplinary review of the ethics of mobile mental health and outlined several ethical issues and considerations not conveyed in the literature. Second, I presented similarities and differences in the discussion and prioritisation of ethics across disciplines which highlighted the importance of multidisciplinarity and supported the aim of developing a transdisciplinary framework. Third, I used these findings to develop ethical design cards for digital mental health and showed support for their use as a toolkit to help multidisciplinary teams to consider ethical issues when designing and developing digital mental health interventions. Fourth, I presented original research exploring how multidisciplinary stakeholders conceptualise ethical digital mental health and the values underlying the design and use of these technologies. Finally, I concluded the thesis by integrating these findings and tools into a transdisciplinary framework for the design and implementation of ethical digital mental health with suggestions for further research and development. It is hoped that this research and the proposed framework will advance understanding and provide practical guidance on developing and using ethical mobile mental health.

Abbreviations

Abbreviation	Meaning
APA	American Psychological Association
CBT	cognitive behavioural therapy
GAD	generalised anxiety disorder
GDPR	General data protection regulation
HCI	Human computer interaction
ICD	International Classification of Diseases
IPT	interpersonal therapy
MBCT	mindfulness-based cognitive therapy
MHRA	Medicines and Healthcare products Regulatory Agency
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
OCD	obsessive compulsive disorder
SSRI	selective serotonin reuptake inhibitors
STPP	short-term psychodynamic
WHO	World Health Organisation

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