

The Mental health Technology Assessment of Quality (MTAQ): Development of a novel quality assurance framework for digital mental health tools

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Abstract

Background: The rapid growth of digital mental health tools offers accessible support for a growing global population with mental health needs. However, concerns exist regarding their safety, efficacy, and overall quality, particularly for tools used outside of healthcare settings. The lack of regulation exacerbates these issues, and existing quality assurance frameworks are limited in scope and not specific to mental health, failing to address crucial aspects such as user experience and evidence-based practices.

Objective: This study aims to develop a novel, comprehensive, and pragmatic quality assurance framework specifically tailored to digital mental health tools – the Mental health Technology Assessment of Quality (MTAQ).

Methods: A convergent mixed-methods design was employed to develop the framework. Participants included mental health service users, academic and health professionals, and digital health provision experts. Quantitative survey data (N=309) were collected and then analysed descriptively to evaluate stakeholder priorities across three domains: user experience, data, and evidence. The survey gathered broad insights into the relative value of various quality factors, supplemented by qualitative data from focus groups and interviews (N=101), which provided richer perspectives in relation to the initial, literature-derived domains. The qualitative data were analysed thematically using a deductive approach.

Results: The study found that intuitive, accessible, user-centred design; robust data privacy and security measures; and rigorous evidence were important to consider when assessing the quality of digital mental health tools. These insights led to the development of MTAQ, covering key quality domains and a structured assessment process.

Conclusions: The MTAQ framework provides the first comprehensive quality assurance framework and criteria specifically for digital mental health tools. By aligning research evidence, stakeholder input, and clinical perspectives, this framework offers a pragmatic, user-informed standard that has broad application to improving the design, assessment, quality, and trustworthiness of tools in this rapidly evolving field.

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Original Manuscript

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Keywords: digital mental health; quality assurance; user experience; data security; evidence

Introduction

With the increasing prevalence of mental health concerns, many consumers are turning to digital mental health tools due to their unique advantages of cost effectiveness and ready availability. However, there is a lack of regulation of those used outside healthcare. Frameworks have been proposed to establish agreed-upon standards, but these overlook key aspects that research and stakeholder perspectives indicate are important to mental health tool quality. This study addressed this issue by consulting mental health service users, academics and health professionals, and digital health provision experts to establish which research-backed aspects of digital mental health tool quality are important across stakeholders and how a quality verification process can best meet their needs.

Background

Improving global mental health has become an urgent priority in recent years. In 2019, an estimated 12.5% of the world's population, nearly one billion people, were living with a mental health condition [1], a figure that surged in the wake of the COVID-19 pandemic [2]. Despite the growing prevalence of mental health issues, access to mental health services is limited, particularly in low- and middle-income countries [3]. Digital mental health products such as smartphone apps, virtual reality, and chatbots offer scalable ways to bridge the gap between demand and capacity. These tools are accessible and affordable and provide additional benefits such as identifying problems in real time, reducing the financial burden of mental healthcare, circumventing stigma against help-seeking, and enhancing therapeutic outcomes [4].

A multitude of digital mental health tools have been developed and launched in response to this potential. By 2021, there were an estimated 20,000 smartphone mental health apps [5], and this sector is projected to show a compound annual growth rate of 15.2% from 2024 to 2030 [6].

Quality concerns

Despite their potential, there are concerns about the safety and efficacy of these digital mental health tools. A systematic review of 293 apps offering treatments for anxiety or depression showed that while 55% mentioned evidence-based frameworks in their app store descriptions, only 10 had published research supporting their effectiveness [7]. Even more concerning, another systematic review [8] found that 6 out of 82 apps for bipolar disorder, a condition with specific and distinct guidelines, contained inaccurate information. For example, one gave potentially dangerous advice to consume alcohol during a manic episode.

Even when validation has been performed, a lack of rigorous scientific evaluation often undermines the reliability of efficacy evidence [9,10]. For instance, a meta-review of studies on mental health smartphone apps [11] found that the few that evaluated effectiveness and efficacy had small sample sizes. Furthermore, where studies have shown digital tools to be effective in treating various mental health difficulties, these benefits commonly occur only compared to inactive controls [12], casting doubt on the importance of the app's mental health content to its effectiveness. Additionally, updates to these tools, which may be continuous if they utilise machine learning, mean that initial evaluations may not reflect the tool's current quality.

Concerns about quality are particularly stark for mental health tools used to support wellbeing outside of healthcare services. Due to long waiting lists for mental healthcare (e.g., reaching 1.2 million people in mid-2022 in the UK [13]), many people access digital mental health tools independently when experiencing mental health symptoms. Moreover, many people without diagnosable mental health conditions access them in pursuit of greater wellbeing. In response to these trends, the most commonly used mental health apps are targeted directly to consumers,

providing self-help tools like mindfulness (e.g. Headspace, <https://www.headspace.com/>) and cognitive-behavioural exercises (e.g. Happify, <https://www.happify.com/>). However, unlike digital mental health tools used within healthcare [14,15], those marketed to consumers are entirely unregulated. This results in consumers not knowing which of the many tools available offers safe, high-quality support and developers lacking metrics against which to check their product's quality.

Means of establishing quality

To address the challenges in evaluating digital mental health tools, one potential solution is for developers to adhere to established international [16] and region-specific standards [17] or frameworks that integrate these guidelines (e.g., ORCHA). These standards are widely recognised, and compliance can facilitate market entry. However, these regulatory frameworks primarily set basic minimum requirements, rather than providing a detailed assessment of the strengths and weaknesses of the tool. As a result, they offer limited utility for developers who are seeking to elevate the quality of their products.

An alternative approach involves developing a more robust framework specifically designed to evaluate the quality of digital mental health tools and provide actionable feedback to both developers and consumers. For example, frameworks such as the Mobile App Rating Scale (MARS) [18,19] or the Enlight Suite [20] offer comprehensive, multidimensional criteria for evaluating digital health apps. However, despite their potential, these frameworks have not gained widespread adoption among either developers or consumers within the mental health tool market. In addition, neither MARS nor Enlight Suite, nor existing industry standards, are specifically tailored to the unique aspects of mental health tools. Therefore, they may fail to account for critical factors that are essential for the nuanced evaluation of digital mental health products, limiting their rigor and overall effectiveness in improving quality.

Research indicates that quality in digital mental health tools encompasses a broad range of factors. For example, *user experience and interface* emerged as key factors in a study analysing reviews of 106 mental health apps, where consumers valued apps with user-friendly interfaces, customisation options, and content variety [21]. Bunyi and colleagues [22] further highlight the importance of prioritising user experience by ensuring accessibility for diverse, underserved, and vulnerable populations, including those with physical, sensory, and cognitive disabilities, to enhance usability and promote equitable access to mental health care. Additionally, providing a good user experience is thought to be crucial for engagement, with intuitive and easily navigable interfaces recommended to improve usability and minimise technical issues [23,24].

A further indicator of quality is a basis in *evidence*. As discussed above, many digital tools and interventions lack fidelity to evidence-based treatments, with rigorous testing often absent. Additionally, essential components such as human support are frequently missing from publicly available versions [25]. This lack of transparency extends to the clinical evidence and technical implementation of apps, with only a small proportion of top-ranked apps providing published trial results, making it challenging for both patients and professionals to assess their credibility [26]. Similarly, Borghouts et al. [24] found that uncertainty about the credibility of the information, particularly regarding the evidence base and the source, may impede user engagement and trust in digital mental health interventions. Furthermore, while approaches such as computerised cognitive-behavioural therapy have shown effectiveness for managing anxiety and depression in adolescents and young people, other digital interventions do not benefit from the same level of consistent evidence [27,28].

Moreover, decision-makers in healthcare settings stress the importance of robust evidence before adopting and scaling digital health tools, with concerns that developers are sometimes unaware of the required levels of evidence needed for approval [29]. However, when it comes to the type of evidence required, an expert workshop with researchers, clinicians, consumers, and policymakers highlighted that while randomised controlled trials are regarded as the “gold standard”

and generally valuable, they may not always be feasible or of the highest quality [30]. Consequently, other forms of evidence, such as adherence data, consumer ratings, safety information, and expert clinical reviews, should also be incorporated to provide a more comprehensive evaluation of digital mental health products. Thus, it becomes clear that the evidence base is a highly complex and multifaceted aspect of digital mental health product quality.

Issues related to *data security and governance* are also highlighted as critical concerns, with both service users and health professionals expressing apprehension about privacy breaches and inadequate protection of sensitive data [31–33]. These concerns often hinder the adoption of digital products, as trust is crucial for their successful implementation. Moreover, professionals value platforms that allow better control over confidentiality, which help mitigate risks and facilitate secure remote assessments [34]. At the same time, as shown by Alhammad and colleagues [35], users demand greater transparency and more robust data protection measures, with privacy features influencing their willingness to engage with such platforms. However, in an analysis of 61 mental health apps in 2017 and 56 apps in 2018, Parker et al. [36] found that many lacked adequate privacy policies, and those that existed often did not meet basic standards for accessibility, readability, and comprehensiveness. Furthermore, these apps frequently sought access to significant amounts of user data without providing clear justification or a comprehensive explanation of how it would be used.

Unfortunately, existing frameworks and guidelines proposed for quality assessment of digital mental health tools fall short of addressing all of these aspects. The Mental Health App Usability Questionnaire (MAUQ) [37], for example, focuses exclusively on usability. Broader frameworks developed by the American Psychological Association [38] and OneMind [39] are primarily designed for consumer use and so are limited in the aspects they can probe. For example, these frameworks do not check for service-user involvement in tool development as they assume consumers do not have access to this information, despite this being a crucial design step that is often overlooked [40,41].

Aim of this study

This study seeks to develop a novel, comprehensive, and pragmatic quality assessment framework aimed specifically at digital mental health products.

This newly developed framework aims to address critical gaps in the quality assurance landscape for digital mental health tools. Firstly, the framework acknowledges that most digital mental health tools operate outside formal healthcare systems and are therefore not subject to established standards or regulations. Secondly, the framework explicitly outlines what constitutes a high-quality tool in a mental health context. Thirdly, while existing frameworks often rely heavily on academic definitions of quality [20], the framework proposed here incorporates user input to ensure it delivers information that is both meaningful and relevant to consumers.

This work followed a thorough, iterative, user-driven, and system-conscious design process, aiming to create a quality assessment tool informed by research and stakeholder contributions, bringing together diverse stakeholders, including partners from the National Health Service (NHS), higher education institutions (HEIs), small and medium-sized enterprises (SMEs), and people with lived experience of mental health difficulties. Specifically, the research questions are:

1. What are the essential quality criteria for digital mental health tools?
2. How can these criteria be organised into a comprehensive quality assurance framework?
3. What are the key steps to effectively apply this framework in practice?

Methods

Design

This study developed a novel quality assurance framework for digital mental health tools using a convergent mixed methods design, where quantitative and qualitative data are collected and analysed in parallel and subsequently merged [42,43]. Quantitative survey data were used to evaluate the

priorities of three stakeholder groups regarding quality in mental health tools and the application of the quality assurance framework. Qualitative data from surveys, interviews, and focus groups provided richer insights into these topics from a smaller sample representing the same three groups. This methodological approach was adopted because the quantitative survey enabled a broad analysis of the relative value of different proposed quality assurance elements, while qualitative data collection facilitated a more in-depth exploration of how well these elements capture stakeholder priorities and what additional factors they consider relevant to quality assurance and its implementation.

Participants

Participants were recruited through voluntary sampling. Advertisements for the online survey were disseminated across social media platforms such as LinkedIn, mailing lists, research opportunity boards, and relevant newsletters, offering a £10 incentive voucher. Participants for the interviews and focus groups were drawn from the survey sample, where they were given the opportunity to opt in for further participation.

The survey collected 309 valid responses, predominantly from female participants aged 21-30, who reported no disabilities and identified as “mental health service user, family member, or member of the public” (see Table 1). Responses were categorised into three professional groups: Mental health service users, Academic/health professionals, and Digital health provision experts. This categorisation ensured that all stakeholders and their differing perspectives were considered during data analysis, thereby enabling a participatory approach to framework development. Mental health service users provided expertise on their experiences using digital mental health tools, academic/health professionals evaluated clinical safety and potential recommendations for users, and digital health provision experts contributed their experiences in developing digital tools.

Table 1. The demographic characteristics of the survey participants (N=309).

Demographic category	Sub-category	n (%)
Gender	Female	201 (65.05)
	Male	90 (29.13)
	Non-binary	14 (4.53)
	Trans-gender	2 (0.65)
	Other	1 (0.32)
	Prefer not to say	1 (0.32)
Age	18-20	45 (14.56)
	21-30	163 (52.75)
	31-40	66 (21.36)
	41-50	24 (7.77)
	51-60	7 (2.27)
	60+	4 (1.29)
Ethnicity	White	141 (45.63)
	Asian/Asian British	75 (24.27)
	Black/African/Caribbean/Black British	55 (17.80)
	Mixed/multiple ethnic groups	19 (6.15)
	Arab	5 (1.62)
	Other ethnic group	9 (2.91)
	Prefer not to say	5 (1.62)

Disability	No	230 (74.43)
	Yes	68 (22.01)
	Prefer not to say	11 (3.56)
Profession	Mental health service user, family member, or member of the public	197 (63.75)
	Health worker or research - clinical, academic, or managerial expert	105 (33.98)
	Technical, product, innovation or commercial discipline - expert in digital health provision	7 (2.27)

Quantitative Data Collection and Analysis

Quantitative data on stakeholder preferences and opinions were gathered through an online survey. As shown in the introduction, an initial review of the existing literature indicated that aspects related to user experience and interface (UX/UI), data, and evidence are essential to the quality of digital mental health tools. The survey questions aimed to refine this initial framework and to determine how it can best be implemented. The survey consisted of three main sections: stakeholders' experiences with mental health digital tools, their priorities and opinions regarding the three identified framework domains, and their views on the feasibility and value of the assessment approach. In addition to multiple-choice questions, the survey included a qualitative component through open-ended questions, allowing for a richer understanding of stakeholder perspectives. The survey was hosted on Qualtrics, using a general anonymised link for completion.

The survey was circulated via organisational newsletters, mailing lists, research opportunity boards, and social media, and it was open from November to December 2023. At the beginning of the survey, participants were provided with information about the study and had the opportunity to contact the researchers for further information before providing informed consent to participate. Following this, participants were asked to provide demographic information that directed them to tailored questions based on their stakeholder group: Mental health service users, Academic/health professionals, and Digital health provision experts. The survey took approximately 15-20 minutes to complete. Responses were manually verified to confirm they were not bot-generated, resulting in 309 usable responses that underwent further analysis. Quantitative data were analysed using Microsoft Excel, with descriptive statistics (e.g., means, standard deviations) computed to summarise the results.

Qualitative Data Collection and Analysis

The qualitative data collection for this study included an online survey, focus groups, and semi-structured interviews, aimed at understanding quality considerations for digital mental health tools. As previously described, the online survey, which collected 309 usable responses, featured open-ended questions allowing participants to elaborate on their experiences and expectations regarding digital mental health tools.

An additional 101 participants took part in focus groups and interviews held between November and December 2023, comprising six online focus groups, one in-person focus group at the Denmark Hill campus of South London and Maudsley NHS Foundation Trust, and one online interview. These were facilitated by experts in digital health, clinical education, and psychology and began with an overview of the project and incorporated open-ended questions to encourage in-depth discussion (e.g., "Can you describe your experience with digital mental health tools?"), supplemented by follow-up prompts to guide conversations towards specific quality markers (e.g., "What are the most important markers or considerations of quality for data management and privacy

in these tools?”). The online focus groups and interviews were conducted via Microsoft Teams and auto-transcribed. Transcripts were reviewed, edited for accuracy, and de-identified. Braun and Clarke’s thematic analysis [44–46] guided the qualitative analysis process. The analysis was conducted in a deductive manner, with the initial domains derived from the literature guiding the thematic mapping of the data.

The researchers started the process by immersing themselves in the data, reading and re-reading survey responses, transcripts, and field notes to gain a deep understanding of the content. Using the predefined domains as a framework, the researchers systematically assigned codes to data segments that were relevant to each domain. For example, segments about ease of use were coded within the UX/UI domain with labels such as “navigation ease”, “functionality”, and “user preferences”. Similarly, data segments concerning privacy and security were coded under the “data” domain, while discussions on scientific validation were coded under the “evidence” domain.

The codes were then examined within each domain to determine how well they supported the predefined themes. This process ensured that the themes were representative of stakeholders’ experiences and perspectives. Any discrepancies or nuances found during analysis were discussed within the research team and used to refine the themes, therefore enhancing their coherence and validity. This deductive approach enabled the systematic validation of the initial domains (themes), confirming they effectively captured the most critical quality considerations for digital mental health tools. The final themes were integrated into the analysis to articulate what each theme represented and how it contributed to the understanding of quality in digital mental health tools, thereby informing the development and refinement of the quality assurance framework and assessment process.

Ethics

Ethical approval was provided by the King’s College London Research Ethics Committee on behalf of the UK Health Research Authority. Informed consent was obtained before participation.

Results

Quantitative Results

As part of the survey, participants were asked to rate the importance of various statements related to the initial domains on a scale from 1 (not important at all) to 5 (highly important). The purpose of this rating was to assess the perceived importance of these principles in establishing the effectiveness and credibility of digital mental health tools.

Effectiveness

Participants’ mean ratings for the effectiveness of digital mental health tools are presented in Table 2. Service users rated “Appropriate and relevant content” as the most important principle for establishing effectiveness, with a mean score of 4.30 (SD = 1.05). Health professionals prioritised “Accessibility and ease of use” at 4.45 (SD = 0.89), while digital health experts rated both “Appropriate and relevant content” and “Continuous evaluation of UX and impact” equally high at 4.50 (SD = 0.55) and 4.50 (SD = 0.84), respectively.

Table 2. Mean ratings for the importance of principles in establishing the effectiveness of digital mental health tools across the initial domains and by stakeholder groups.

Initial domain	Statement theme	Mental health service user		Academic/health professional		Digital health provision expert		Overall	
		M	SD	M	SD	M	SD	M	SD
UX/UI	Lived experience	4.05	1.14	4.24	0.92	4.00	1.55	4.11	1.08
	Accessibility	4.24	1.12	4.45	0.89	4.00	1.26	4.31	1.05

	and ease of use								
	Appropriate and relevant content	4.30	1.05	4.44	0.96	4.50	0.55	4.35	1.01
	Diversity of users considered	4.19	1.05	4.24	1.04	3.67	1.21	4.20	1.05
<i>Data</i>	Data safety governance	3.72	1.22	3.79	1.24	3.67	0.82	3.74	1.22
	Transparency regarding data collection	3.64	1.33	3.68	1.20	4.00	0.89	3.66	1.28
	Risk of harm escalation	4.28	1.00	4.28	1.07	4.00	1.10	4.27	1.03
	Clear protocols for data usage	3.56	1.31	3.53	1.26	3.83	0.98	3.55	1.29
<i>Evidence</i>	Content based on scientific evidence	4.20	1.00	4.37	0.89	3.50	1.05	4.25	0.97
	Clearly defined pathway to change	4.02	1.07	4.23	0.92	3.50	0.84	4.08	1.02
	Continuous review and updating	4.20	1.02	4.29	0.98	3.83	1.17	4.34	1.01
	Continuous evaluation of UX and impact	4.06	1.06	4.18	0.98	4.50	0.84	4.11	1.03
	Research evidence base	3.81	1.17	3.95	1.09	3.67	1.37	3.85	1.15

Credibility

The participants also rated principles related to the credibility of digital mental health tools, as illustrated in Table 3. “Data safety governance” emerged as the most important principle for service users, with a mean rating of 4.41 (SD = 0.90). For health professionals, “Transparency regarding data collection” was rated as the most important principle, with a mean of 4.54 (SD = 0.83). Digital health experts rated “Research Evidence base” the highest, achieving a mean of 4.83 (SD = 0.41).

Table 3. Mean ratings for the importance of principles in establishing the credibility of digital mental health tools across the initial domains and by stakeholder groups.

Initial domain	Statement theme	Mental health service user		Academic/health professional		Digital health provision expert		Overall	
		M	SD	M	SD	M	SD	M	SD
<i>UX/UI</i>	Lived experience	4.09	1.10	4.27	1.04	4.33	0.82	4.16	1.08
	Accessibility	3.62	1.23	3.72	1.18	3.33	1.03	3.65	1.20

	and ease of use								
	Appropriate and relevant content	4.11	1.00	4.19	0.95	4.50	0.84	4.15	0.98
	Diversity of users considered	4.11	1.12	4.12	1.08	4.33	0.82	4.12	1.10
<i>Data</i>	Data safety governance	4.41	0.90	4.48	0.96	4.50	0.84	4.44	0.92
	Transparency regarding data collection	4.34	1.08	4.54	0.83	4.00	1.55	4.40	1.02
	Risk of harm escalation	4.25	1.00	4.40	0.88	4.00	0.89	4.30	0.96
	Clear protocols for data usage	4.26	1.02	4.24	0.90	4.00	1.10	4.25	0.98
<i>Evidence</i>	Content based on scientific evidence	4.39	0.93	4.50	0.91	3.83	1.47	4.42	0.94
	Clearly defined pathway to change	3.91	1.06	4.12	0.90	3.50	1.52	3.97	1.02
	Continuous review and updating	4.11	1.10	4.38	0.92	3.67	1.21	4.20	1.05
	Continuous evaluation of UX and impact	4.10	0.99	4.04	1.11	3.83	0.98	4.07	1.03
	Research evidence base	4.10	1.09	4.36	0.89	4.83	0.41	4.20	1.03

Value of assessment process

Survey participants rated a set of statements tailored to their specific roles regarding the perceived value of a quality assessment process for digital mental health tools. Ratings were provided on a scale from 1 (Completely disagree) to 5 (Completely agree). These results are summarised in Table 4.

Table 4. Mean ratings for the perceived value of the quality assessment process for digital mental health tools by stakeholder groups

Stakeholder group	Statement	M (SD)
<i>Mental health service user</i>	I would be more likely to use a mental health tool that has undergone this NHS-backed quality assurance process over one that has not (1)	4.09 (1.12)
	I would consider tools that have undergone this NHS-backed quality assurance process as more trustworthy (2)	4.13 (1.07)
	This NHS-backed quality assurance process would help users receive better quality support (3)	3.96 (0.97)
	Companies undergoing this quality assurance process for their tools are more appealing to me than those that do not (4)	3.96 (1.06)
	It is important that this quality assurance process is NHS-backed, rather than not (5)	3.97 (1.06)

<i>Academic/health professional</i>	I would feel more confident recommending tools that have undergone this NHS-backed quality assurance process (1)	4.55 (0.72)
	I would consider apps that have undergone this NHS-backed quality assurance process more trustworthy (2)	4.51 (0.79)
	This process will help improve and standardise the quality of digital mental health products (3)	4.35 (0.87)
	I would use tools myself that have undergone this NHS-backed quality assurance process over ones that have not (4)	4.27 (0.86)
<i>Digital health provision expert</i>	This NHS-backed quality assurance process will provide valuable feedback for the development of my tool (1)	4.14 (0.90)
	I would be interested in going through an NHS-backed quality assurance process to obtain expert approval on my tool (2)	4.00 (0.82)
	An NHS-backed quality assurance process would set me apart from my competitors for my end users (3)	3.86 (0.90)
	An NHS-backed quality assurance process would set me apart from my competitors for my clients/customers/payors (if different to end users) (4)	4.14 (1.07)

Time willing to spend on assessing evidence

Participants indicated the amount of time they were willing to spend assessing evidence for a digital mental health tool using a scale ranging from 0 to 100 hours. On average, participants reported a willingness to spend 35.94 hours (SD = 27.12) on this task.

Qualitative Findings

Table 5 summarises the qualitative findings derived from survey responses, focus groups, and interviews. The analysis was guided by three initial domains derived from the literature, namely UX/UI, Data, and Evidence. These domains provided the structure for coding and mapping the qualitative data, which ultimately led to the refinement of the domains that constitute the basis of the MTAQ framework.

Table 5. Themes and sub-themes, illustrative quotes, and the initial and refined domains of the quality assurance framework.

Initial domains	Themes and sub-themes	Illustrative quotes	Refined domains
UX/UI	Tools should be user-friendly, with clear navigation and functionality and easy navigation aligned with user preferences. Transparency with regards to subscriptions and costs. Visual appeal and design crucial for user engagement. Design and usability are crucial for perceived quality and reliability.	• “Simple to navigate, clear instructions, easy to set up.” • “It has to be intuitive and straightforward to navigate regardless of technological fluency.” • “The tool should have a lower barrier to entry, whether that barrier be monetary-wise, user ability-wise or accessibility-wise.” • “If I talk about the surface structure of the tools, the some of the points which will attract me to use the tools [...] will be the visual appearance. How the tools are constructed and easy navigation.” • “Making sure that it’s accessible for people with different needs [...] is the fonts accessible, you’re not using italics, you’re following digital accessibility. [...] looking at the colours, colour of contrast,	UX/UI and Co-design

	Collaboration with academics, clinicians, and lived experience experts in tool development.	differentiations, different things like that, like using a digital accessibility guide when you're building it." • "Many of these apps are not actually free, they're free, maybe for any period of time, but then after that you will still have to pay for them, which can be, you know, an inconvenience for many users." • "What has been really helpful is having service user or people with lived experience involvement in developing it"	
Data	Data privacy policies in mental health apps to protect user privacy. Clear communication about data collection, use, and storage. Transparency about data collection, usage, and privacy. Users should have data control, with options for deletion and clear consent forms.	• "Privacy and safety of data has to be taken care of. I want to understand how my data will be used and what laws protect me." • "Control over personal data and settings, communication is transparent throughout [...]." • "Another most important thing is the privacy. If I can store my information, how will it be stored? Or what about the privacy policy? Will it be disclosed to other people or something like that?" • "If there's somebody externally also monitoring the system, so like if the anonymity was preserved, and I mean just privacy, maybe not anonymity and that that data collection was used in a beneficial way not to sell data to advertisers, it could in the future be beneficial." • "So having a login and a password for your own if it's a more personalised digital mental health tool, you might want to do that so that no one can access if they were just on your phone or on your laptop so that you log in each time." • "I would make sure that it even says that there's a deletion date. [...] But after that deletion date, the data is no longer accessible."	Data Privacy, Security, and Governance
Evidence	Evidence-based content and strategies. Tools backed by research and data-driven insights. Understanding the scientific basis behind the digital mental health tools. Incorporating evidence-based practices.	• "If a tool is developed by academics/clinicians and is evidence based (i.e. there's information of how/why it works) then I would be more likely to trust it." • "Based on evidence, based on the latest scientific understanding, tested and reviewed by a diverse set of people with lived experience." • "Consistently providing accurate information, being transparent about its sources and methods, and maintaining a reputation for reliability." • "There are now a lot of kind of wellbeing apps or apps that have brilliant visuals, but maybe the evidence base is not as strong. And then you've got apps which are a little bit more clinical looking that might be endorsed by a trust like an NHS Trust	Evidence-based Practices and Ongoing Evaluation

		or an endorsed by your clinician.” • “I think when you see that something has got NHS affiliation or I guess you kind of assume one would assume that it’s reached a certain quality standard, you know almost like a kite mark or something like that.” • “I think people like to know the evidence. [...] I think often we forget that service users also know about science. They also know about data, you know, data collection and evidence, and and it’s very important for someone to believe that the whatever what be it [...] that that is going to work and is effective.” • “And I think they work better, if I know, you know, what’s the evidence base behind those of, you know, techniques or activities they are trying to promote. So have having more sort of evidence based or research based perspective and selling it as such.”	
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In addition, participants were asked about their needs, preferences, and expectations in relation to the assessment process, including their expectations for reviewing evidence, collaborating with stakeholders, and engaging in feedback and reporting; the type of evidence they consider essential to demonstrate the quality of mental health tools; and the support needed to conduct assessments. Grouped thematically, and as presented in Table 6, these insights informed the development of an assessment process which could guide the practical implementation of the quality assurance framework.

Table 6. Themes and sub-themes, illustrative quotes, and the preliminary stages of the assessment process

Themes/sub-themes	Illustrative quotes	Preliminary assessment process stages
Clear information on service provision ensuring transparency and understanding between stakeholders Clear privacy policies and transparent data handling practices Clarity of assessment processes Ensuring access to relevant information Upholding professionalism and respect Adaptability to meet client needs Compliance with legal and regulatory considerations	• “I would expect there to be some structure to the feedback and roles/expectations clearly defined.” • “A list of criteria to rank the tool against. Clear understanding of the aims/ goals of the tool.” • “So we try to create apps that will have different options like where you have a voice pad.”	Contracting
Detailed assessment framework conveyed during client	• “Initial training, examples of what would and wouldn’t meet criteria, examples of good	Client onboarding

onboarding including criteria and benchmarks Managing client expectations Presenting a clear timeline Upholding professionalism and respect Accommodating client needs Efficiency in the onboarding process Demonstrating the value and potential impact of the assessment process	practice and ongoing assessor update training” • “Initial meeting with you and client to understand more about the tool and testing requirements; testing the tool first-hand; regular catch-ups to provide feedback and ask for more information if required.” • “Instead of going to the long way of writing, you know, up with, you know, much write ups”	
Reviewing client requirements to tailor accordingly Ensure a comprehensive review of the assessment process to gather relevant client data	• “Initial training to understand exactly what I was supposed to be looking for and then reviews on the evidence gathered to ensure I was collecting the right type of information”	Review of assessment and client requirements
Encourage active participation from clients in providing feedback and collating evidence Offer user-friendly interfaces for clients to provide responses Engage clients in the assessment process by soliciting their input and guiding evidence collation Allowing flexibility and adaptability in the client response process	• “Regular catch-ups to provide feedback and ask for more information if required.” • “I think that in the process of designing the show try the app should kind of be clear”	Client-led response and collation of evidence
A supplier-led review process where clarifications are sought Scoring comprehensively conducted Ensuring quality assurance through a rigorous review and scoring process	• “Clear guidelines of what is needed for the assessment (e.g. use of a rating scale for evaluating the evidence)” • “Relevant statistics about the tool performance (e.g., effectiveness in improving mental health, users’ engagement in the tool in terms of time, frequency etc), reviewing evidence of the content included in the tool and decide if the content are deemed appropriate for inclusion, engage with key stakeholders including clients to review the facilitators and barriers of using the tool, address areas for improvement.” • “That would make something seem kind of trustworthy and reliable. I think yeah. Just having, you know, standards.”	Supplier-led review, clarifications and scoring
Providing details on how well quality criteria is met Provide improvement recommendations	• “Revising, updating and implementing the feedback/insights will be quite iterative and in collaboration with the various people involved.” • “Marking against assessment criteria,	Outcome – provision of scores and feedback

Transparent scoring mechanisms to provide clients with clear outcomes Publish assessment scores on a dedicated certification webpage, showcasing client's achievements Certifying tools that meet quality standards on a dedicated webpage or through a kitemark Maintaining quality assurance in the provision of scores, feedback, and certification	meetings discussing feedback and decisions made in developing the tool and offering ongoing feedback.” • “Also, I would say the ultimately the success of a tool is dictated by the users’ experience rather than specific criteria. So I think you could have criteria in terms of the provision of the service and the actual functioning of the tool. So the more technical parts.” • “I think probably if they know that it’s, you know, in any way linked to some credible organisation or authorities or things like the NHS or [...] the NIHR. So I think having that kind of link and official kind of approval or yeah from a trustworthy organisation that they are aware of.”	
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Mental health Technology Assessment of Quality (MTAQ) Framework

Building on a review of the existing literature in the field of digital mental health, quantitative and qualitative analyses of stakeholder perspectives, and iterative, in-depth discussions within the research team, we now report the MTAQ Framework (see Figure 1). Developed through a rigorous, comprehensive process involving NHS experts, academic institutions, SMEs, and people with lived experience, this framework has been designed to address key gaps in the evaluation of digital mental health tools. The MTAQ framework aims to provide a robust quality assessment, offering a verification mark and assurance of quality for the best digital mental health products. This framework is structured around three core domains, ensuring that digital mental health tools are user-centred, safe, and effective.

[Figure 1 here]

1) UX/UI and Co-design

This domain of the MTAQ framework emphasises the importance of creating user-centred designs that cater to people with mental health difficulties. Digital mental health tools should feature intuitive interfaces, easy navigation, and visual appeal. Developers are encouraged to involve users in the design process through co-design principles, ensuring that tools are not only functional but also culturally sensitive and accessible. Tools should include features such as learning resources, coping strategies, and personalised recommendations to support diverse user needs and preferences.

2) Data Privacy, Security, and Governance

The MTAQ framework accentuates the need for strict data privacy and security measures. Digital mental health tools must provide transparency about how user data is collected, stored, and used. Developers should implement robust privacy policies, secure data management practices, and clear, user-friendly consent forms. The framework also highlights the importance of complying with healthcare standards and data governance practices, including appointing data protection officers to oversee these aspects.

3) Evidence-based Practices and Ongoing Evaluation

The third domain of MTAQ focuses on the necessity of integrating evidence-based practices into digital mental health tools. Tools should be grounded in established research and aligned with relevant medical, psychological, and technological theories. Developers must make sure that their tools are subject to continuous evaluation and improvement based on current research and clinical

feedback. The framework encourages collaboration with clinicians, academics, and people with lived experience to maintain adherence to the latest evidence and guidelines.

The MTAQ framework will be implemented through a structured, rigorous assessment process, which has been refined and crystallised into a sequence of five stages, starting with the setting of a formal agreement and finalising with the expert review, scoring, and certification of the tool or product (see Figure 2). Digital mental health tools assessed against the MTAQ framework will receive a published notification detailing the assessment outcome, completion date, product version, benchmarking (if applicable), and the required date for reaccreditation.

[Figure 2 here]

Discussion

This study presented the development of the Mental health Technology Assessment of Quality (MTAQ) – a novel, comprehensive, and pragmatic framework and process for assessing the quality of digital mental health tools. The quantitative findings showed that different stakeholder groups prioritised various principles when evaluating the effectiveness and credibility of such tools. Service users, for example, focused on the relevance and appropriateness of the content, while health professionals emphasised accessibility and ease of use. Digital health experts placed high value on continuous evaluation of user experience and impact, as well as the evidence base supporting the tools. Furthermore, participants across all groups strongly supported the value of a quality assessment process. The qualitative findings provided key insights in relation to UX/UI, data, and evidence, which guided the refinement of the quality assurance framework. Participants stressed the importance of intuitive and accessible user interface, with specific calls for simpler navigation, lower barriers to access, and the integration of co-design approaches. Participants also advocated for clear communication about data collection, use, and storage, as well as giving users control over their personal data. More than that, there was strong support for tools being evidence-based, with participants preferring solutions backed by research and clear, transparent sources of information.

Links with Existing Literature

The findings of this study align with and expand upon existing literature in the field of digital mental health. The emphasis placed on appropriate and relevant content resonates with previous studies that highlight the importance of tailoring digital interventions to individual needs [24,47–49]. Appropriately tailored content not only facilitates engagement but also increases the perceived value and effectiveness of digital mental health tools [50–52]. Taken together, these findings reinforce the need for participatory approaches in the development of digital mental health tools to better meet the diverse needs of users. The prioritisation of accessibility and ease of use echoes established principles of usability and inclusivity in human-computer interaction research [53,54]. Several studies emphasise that tools designed with user-centred principles are more likely to foster sustained engagement, particularly for populations with varying levels of digital literacy [55–57]. The call for intuitive design and lower barriers to access is further supported by evidence suggesting that complex interfaces and usability challenges act as key deterrents to adoption [24,58].

The prioritisation of continuous evaluation aligns with frameworks advocating iterative and adaptive tool development. The growing literature on agile methodologies and user-centred design [54,59–62] highlights the necessity of ongoing feedback loops to ensure that tools remain relevant, functional, and aligned with emerging user need. This is particularly important in a rapidly changing field, where tools must be adapted to technological advancements, shifting consumer expectations, and the diverse needs of different populations [63]. At the same time, continuous evaluation is necessary to keep up with the evolving standards of evidence in digital mental health, which mirrors the preference for evidence-based tools that participants in this study expressed. Many apps and interventions struggle to meet or demonstrate compliance with these multifaceted standards

[8,25,26,30,64,65], sometimes resulting in paradox where insufficient evidence hinders adoption, which in turn limits the possibility to generate new evidence [65]. Furthermore, clinicians, who are often tasked with prescribing these tools, lack the resources, knowledge or confidence to adequately evaluate them [66–68], a challenge further complicated by the fragmented landscape of quality assurance and regulatory frameworks, as discussed before. Therefore, a more pragmatic, iterative approach to evaluation – one that prioritises adaptability, real-world testing, and ongoing feedback – is increasingly welcomed, with MTAQ being a strong example in this sense.

The findings pertaining to data-related aspects underscore the critical role played by transparency and control over the management of personal information in cultivating user trust, a theme well-established in the literature. For instance, past research has shown that users are more likely to trust and engage with digital health tools when they can exert autonomy over their data, including the ability to manage consent, delete information, and decide how data is shared, but concerns about data being sold to third parties or used beyond their knowledge or expectations might undermine the interaction with such tools [69–72]. Notwithstanding the data privacy concerns, some participants recognised the potential benefits of data sharing, aligning with scholarship that suggests users are generally willing to do so when it enables personalised outcomes or supports the advancement of research [69,70,73]. However, the willingness to share data hinges on clear and transparent communication about how this will be used, a need that may be even more prominent now given the expanding role of artificial intelligence and the ethical implications surrounding its use in digital (mental) health [74–76].

Strengths

This study directly addresses the lack of mental health-specific quality standards in existing digital health frameworks. By adopting a mixed-methods approach, the research incorporates perspectives from a wide range of stakeholders, including service users, healthcare professionals, academic researchers, and technical experts. The involvement of NHS clinical-academic professionals and people with lived experience of mental health difficulties strengthens the findings, confirming they reflect real-world priorities. The framework provides practical recommendations for developers and consumers, enabling safer selection of digital tools while also supporting improvements in mental health outcomes and product quality. The multidisciplinary approach positions the research to bridge gaps between user needs and industry practices.

Limitations

This study has the limitation of lacking a real-world validation phase raises questions about the practical implementation of the proposed framework. The study also has methodological limitations. Stakeholder engagement, while valuable, risks underrepresentation or bias if certain groups are less involved in the process. Additionally, time and resource constraints limited the opportunity for extensive iterative refinement and consultation. Moreover, while the framework was developed with input from multiple stakeholder groups and was developed to accommodate a broad range of digital mental health tools and user demographics, it does not yet address how to integrate with formal healthcare systems or accommodate region-specific regulations and cultural differences, which could restrict its implementation in different settings. Furthermore, the technical focus of the framework may resonate more strongly with developers and researchers, potentially limiting its accessibility for general consumers. Future work should address these contextual differences to improve inclusivity and scalability.

Implications and Recommendations

A number of key implications arise from this study that could inform the development and evaluation of digital mental health tools.

First, integrating co-design principles is essential to ensure that these tools are accessible, intuitive, and reflective of the diverse needs of users. By involving end-users in the design process, developers can create tools that are more responsive to specific user needs, improving both their usability and effectiveness. Second, digital mental health tools must promote transparency in data collection, usage, and storage. Clear communication about data governance policies allows users to retain control over personal information, which is crucial for building trust. Transparent data practices will foster confidence and make users more likely to use and recommend these tools. Third, incorporating mechanisms for regular updates and ongoing evaluation is necessary to make sure that digital tools remain relevant and effective over time. These tools must evolve in response to user feedback and advancements in research to remain useful. Regular evaluation and update allow tools to adapt to changing user needs and the latest evidence, contributing to their continued effectiveness.

Furthermore, the assessment process built around the MTAQ framework delineates a structured, practical approach for ensuring digital mental health tools meet the rigorous quality standards of MTAQ. The process consists of a series of stages, by the end of which compliant products receive the MTAQ verification mark. For users, the certification provides confidence that the tools they use have been thoroughly evaluated and meet established criteria for safety, efficacy, and user experience. For developers, the process offers detailed feedback, highlighting areas for improvement and providing guidance on maintaining and enhancing quality over time. This also includes provisions for reaccreditation, certifying that tools continue to meet high standards and evolve in response to emerging evidence and regulatory changes.

Conclusion

The MTAQ framework proposes a much-needed solution to the challenges surrounding the regulation and quality assurance of digital mental health tools. The growing prevalence of mental health difficulties, coupled with the increasing reliance on digital tools for mental health support, points to the urgent need for clear, robust, and evidence-based frameworks that guarantee the safety and efficacy of these tools. The three core domains of this novel, comprehensive, and pragmatic framework – *UX/UI and Co-Design*, *Data Privacy, Security, and Governance*, and *Evidence-based Practices and Ongoing Evaluation* – are directly aligned with the critical quality concerns identified in the literature and feedback from service users, healthcare professionals, academic researchers, and technical experts. MTAQ has been designed to provide a structured, practice-focused process for evaluating digital mental health tools, supporting developers and consumers in identifying high-quality products. Further real-world validations and adaptation to local contexts are necessary for its broader implementation.

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Conflicts of Interest

The authors confirm that there is no conflict of interest related to the manuscript.

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Supplementary Files