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Advancing the use of sensor-based digital health technologies (sDHTs) for mental health research and clinical practice

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In collaboration with

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Final report

Authors: Lucia Cesnakova; Benjamin Vandendriessche; Jennifer Goldsack

With contributions from: Nelson Freimer, Helen Fisher, Simona Carini

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1. Executive summary

The Digital Health Measurement Collaborative Community (DATAcc) by the Digital Medicine Society (DiMe), in collaboration with the UCLA Depression Grand Challenge, and supported by an Academic Advisory Committee and Wellcome (see Acknowledgements), present here recommendations for advancing the use of sensor-based digital health technologies (sDHTs) for mental health research and clinical practice.

This work builds on the results of the Digital Sensing Workshop held from February 28 through March 2, 2023, at UCLA. More than 50 leading mental health and computer science researchers, industry experts, advocates, and funders from six countries came together across five working groups to discuss a shared vision and common goals for incorporating sDHTs in mental health research and care. Additionally, we share insights from two **expert workshops run by Wellcome** in July 2024 on the ethical and social considerations of using sDHTs and sensor data in mental health research. Contributors came from Colombia, India, Kenya, South Africa, Uganda, the UK, and the US and brought clinical, commercial, community, lived experience, research, and technical perspectives.

To delve deeper into the topics identified in these workshops, we applied a mixed-methods approach to:

1 **Identify** the most promising behavioral and physiological aspects of health relevant to anxiety, depression, and psychosis that can be effectively and acceptably measured using sDHTs and outline the current state of sDHTs to capture these aspects of health;

2 **Explore** the characteristics of fit-for-purpose sDHTs, along with potential development, usage, and implementation barriers;

3 **Develop** concrete and actionable recommendations on how to advance the use of sDHTs for mental health.

We conducted research in two phases. The first phase **included qualitative in-depth interviews** with clinicians, researchers, individuals with lived experience, and care partners across low, middle, and high-income countries (LMIC and HIC, respectively). A **narrative literature review** established a comprehensive summary of the evidence available about relevant aspects of depression, anxiety, and psychosis and the use of sDHTs to capture them.

The second phase took learnings from the workshops, interviews, and literature review to conduct a **modified Delphi process** with a panel of experts. The panel included clinicians, researchers, care partners, and individuals with lived experience across LMIC and HIC countries and identified high-priority aspects of mental health, sDHT characteristics, barriers to adoption, and consideration to drive adoption of sDHTs in mental health research and clinical practice. Figure 1 showcases the diversity in the participants' demographics, expertise, and background in all research phases.

Candidate aspects of mental health for digital measurement

We identified the following behavioral and physiological aspects of health that are impacted by mental health and can be captured with sDHTs:

- **Aspects of sleep** and **social behavior** have the strongest scientific evidence and validation in mental health. Measures of sleep are commonly captured using sensors embedded in wristband wearables or via smartphone sensors. More advanced sDHTs include sleep pads, radar-based contactless sensors, and home-use electroencephalography or even polysomnography solutions. Social behaviors can be inferred from common smartphone features, including GPS, Bluetooth, WiFi, and microphones, as well as app usage patterns (e.g., texts, calls, social media).

- **Physical activity** and **stress responses**, such as those indicated by an increase in heart rate, are also well-supported by research. Heart rate can be measured via photoplethysmography (PPG) and electrocardiography (ECG) sensors embedded, often embedded in wrist or chest patch form factors. Additionally, physical activity can be quantified from GPS, actigraphy, and indoor positioning systems.
- **Speech and language-**derived measures are promising emerging indicators of mental health conditions but require substantial research to validate and generalize findings and algorithms. Microphones are the primary sensor used to capture speech and language.
- Stress-related **breathing changes** can be captured with chest impedance measurements or wearable stethoscopes, and **gastrointestinal symptoms** such as gastric motility can be captured with electrogastrography, while weight changes and body composition can be captured with weight scales with whole body impedance sensors. The application of these technologies in mental health is still in its early stages.

Technology characteristics of fit-for-purpose sDHTs

We identified technology characteristics that are important when considering an sDHT for mental health. Some apply across therapeutic areas, some are more specific to mental health conditions. This is by design, as most sDHTs that are available today were not specifically developed for mental health.

- The most important general technology characteristics for sDHTs are **ease of use**, **reliable performance**, strong **data privacy and security**, and **long battery life**. **Interoperability** is considered very important in both clinical practice and research.
- **Condition-specific** technology characteristics include: in depression, offline functionality allows sDHT usage without an active internet connection and minimal user interaction requirements address low motivation during episodes; in psychosis, discreet, non-obtrusive designs help prevent paranoia; and in anxiety, well-chosen alerts to avoid worsening symptoms or exacerbating clinical anxiety.
- General considerations and research questions guiding research and development of sDHTs for mental health conditions include ensuring their effectiveness, safety, validating their use in diverse populations, and focusing on scalability, sustainability, and ethical practices with clear descriptions of risks, benefits, and data policies.

Considerations for implementation in clinical research and practice

We asked the panel of experts to think about what is needed to successfully implement sDHTs for mental health application from the lens of their personal experience.

- Key considerations for sDHT implementation in clinical research include balancing user **engagement** with technology **utility**, offering participation **incentives**, managing the burden of **active assessments versus passive data collection**, and ensuring **training** for participants and research staff. Trust-building through **clear communication** of study goals, risks and benefits, data use, and feedback is crucial.

- For clinical practice, implementation priorities include **long-term usability**, clinician-oriented **feedback**, an **unobtrusive device design** to reduce stigma, and **improved access and affordability** through introduction of subsidies, lowering production and usage costs, or extending insurance coverage.

- Sensor, hardware, and algorithm components of sDHTs are currently not likely to have been developed for a specific mental health condition. It is critical that **clinical validation** is conducted in the appropriate population(s) to ensure that behavioral and physiological traits specific to mental health conditions are reliably captured. The development of sensors and algorithms that generate a measure that is specific to a mental health condition (e.g., an anxiety level score) will generate **actionable insights** that are more specific to that condition and will require less interpretation by and training of clinicians.

- Capturing **contextual information** is essential across many therapeutic areas, such as accounting for environmental changes, emotional stress, comorbidities, or medications that may impact the measures. Given the significant influence of surroundings on mental health, this becomes especially critical for products designed to address mental health conditions.

Barriers to adoption and use, and mitigation strategies

We found that several barriers impede the widespread adoption of sDHTs in the mental health field. Understanding these challenges and implementing targeted solutions will be important to support broad adoption and use.

- The largest barriers to adopting sDHTs in mental health research and care include **high costs** and **limited access**, **data privacy concerns**, **poor technological literacy**, and a lack of adaptation to the specific needs of clinical populations. Additional barriers include **signal misattribution** and insufficient **user-centered design** for the intended population.

- Mitigating **cost and access** challenges requires financial subsidies, insurance coverage, infrastructure development, and device donations.

- **Building trust** involves demonstrating trustworthy practices, such as **transparent communication** about data use and scientific evidence, **compliance** with privacy regulations, and **co-designing** solutions with end-users and lived experience experts.

- To ensure high **usability**, user **engagement**, and sDHT **effectiveness**, training for users and clinicians, culturally tailored implementations, and thorough testing with diverse populations are essential.

Actionable recommendations to improve adoption of sDHTs for mental health

Our report identifies the following recommendations to guide future innovation and development, funding decisions, and research focus areas:

- ✔ **Advance clinical research and practical applications for validated sensor-based measures:** Measures of sleep, physical activity, stress, and social behaviors have the strongest evidence for research and clinical utility in mental health, with broad expert and patient support, and should be prime targets for **clinical research and practice**. Emerging measures derived from speech and language require further validation, while research into the relationship between mental health conditions and gastrointestinal symptoms, breathing rate, and body temperature is in its infancy.

- ✔ **Integrate and innovate sensors, validate and refine algorithms:** Today, non-mental health specific sDHTs with well-tested sensors are readily available in a variety of form factors and can be implemented into clinical research and practice for mental health conditions. Researchers, developers and funders should assess the available **validation evidence** carefully in the intended population, factoring in the maturity of the sDHT and all relevant available evidence. **Algorithms** should be validated and refined for mental health indications, ensuring they reliably generate insights into aspects of health in the intended populations. Beyond well established sensors, research and development should focus on **novel sensor modalities**, e.g., those that capture subtle behavioral cues, or non-invasively measure biochemical components in sweat or other bodily fluids.

- ✔ **Incorporate qualitative data into AI models alongside sensor data:** Building sDHT datasets in populations of high interest will be important to develop more effective and specific AI-based research, diagnostic and prognostic tools for mental health. **AI models** must address typical considerations such as biases in the data and model interpretability. More specifically for mental health, AI models may also encode culturally relevant practices, such as storytelling and meditation techniques that could be leveraged to develop more personalized therapies. AI agent therapists could provide on-demand empathic support, including in low resource settings, and in closed-loop sDHT feedback systems.

- ✔ **Develop infrastructure, standards and norms for measuring mental health:** **Standardization** and **interoperability** of sDHT data and systems will be critical to integrating these technologies into clinical practice. Efforts should focus on establishing **core data elements**, creating interoperable **platforms**, and fostering **collaboration** through public-private partnerships and centralized hubs for research and innovation. **Ontologies** for specific mental health conditions should be developed, which will be an important enabler to harmonize research data collection efforts and ensure compatibility with major health information exchange formats. We discuss core data elements for sDHTs in this report.

- ✔ **Improve access, equity, and inclusion:** Overcoming barriers like the **cost of products** and **inequitable access** requires financial support mechanisms, inclusive design, and communication campaigns. Providing **accessibility features** and **multilingual interfaces**, and conducting **community engagement** should build trust and encourage widespread adoption of sDHTs in mental health, among clinicians and people with mental health conditions alike.

Figure 1: Diversity of expert participants who contributed to the report

The figure shows participants' self-reported data for country of residence, age, gender, healthcare access, income level, and experience with sDHTs. Expert categories included lived experience (n=31), researchers (n=27), clinicians (n=20), care partners (n=19), and others (n=9). The latter includes public health professionals, administrators, policymakers, and physicians. Since participants could select multiple categories (e.g., clinician and lived experience expert), the total exceeds the number of participants.

66 Research participants:

31 Lived experience experts *(56.4%)*

27 Researchers *(40.9%)*

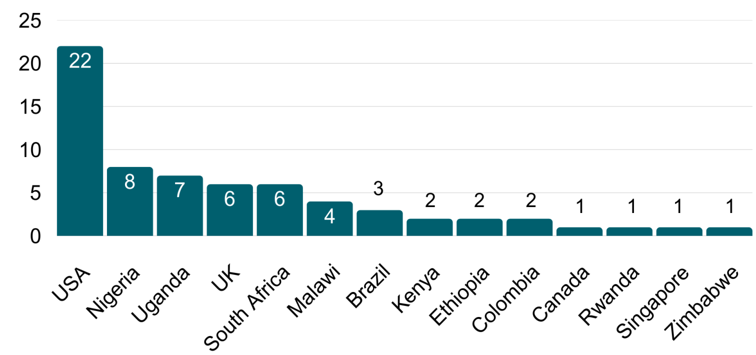
20 Clinicians *(30.3%)*

19 Care partners *(28.8%)*

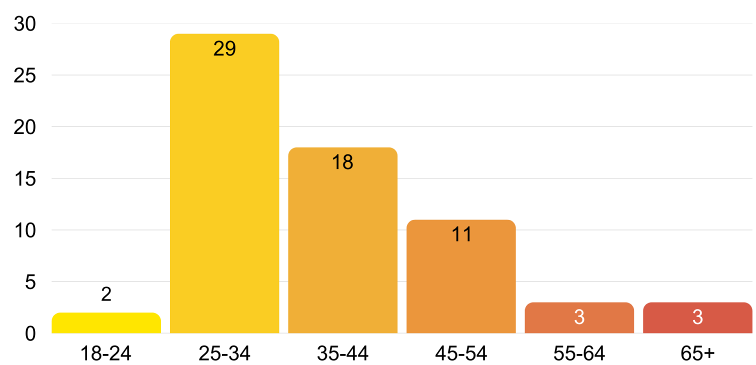
9 Other *(13.6%)*

Out of 66, 38 are in a single expert category, and 28 are in mixed/multiple categories.

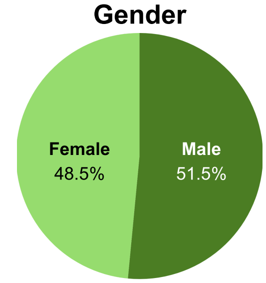
Country



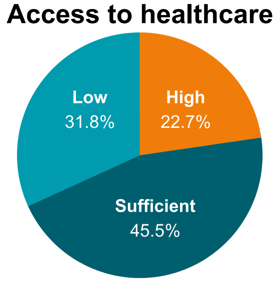
Ages of participants (Years)



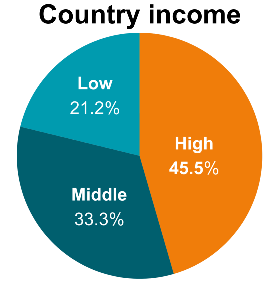
Gender



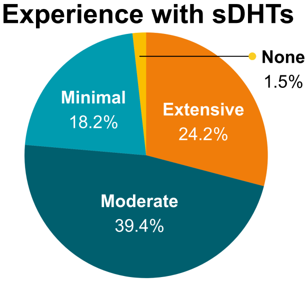
Access to healthcare



Country income



Experience with sDHTs



Organizations who helped us reach the participants:

Global Mental Health Action Network

GLOBAL MENTAL HEALTH PEER NETWORK

Healthy Brains Global Initiative

MQ Mental health research

2. Introduction

Mental health conditions affect an estimated 970 million people globally, making them one of the leading causes of disability worldwide [1], and their prevalence and impact is increasing [2]. This rising trend highlights the urgent need to improve health outcomes for affected individuals and their families and communities worldwide. Left undetected or untreated, mental health conditions worsen physical health outcomes, productivity, and quality of life, as well as increase healthcare costs. Anxiety and depression are among the most prevalent mental health conditions [4] and schizophrenia's prevalence, incidence, and burden has increased more than twofold since 1990 [5]. Early treatment is known to significantly improve long-term outcomes in all these conditions [5, 6]. Addressing these challenges requires innovative solutions to enhance prevention, diagnosis, and treatment by offering new ways to understand and manage mental health conditions.

Sensor-based digital health technologies (sDHTs) offer a promising path forward, enabling the continuous monitoring of behaviors and physiological signals that can reveal changes in mental health status. These technologies have the potential to transform not only clinical care, but also research for conditions like anxiety, depression, and psychosis. In clinical practice, sDHTs can deliver personalized, actionable insights that guide earlier and more effective interventions, potentially preventing conditions from worsening, reducing stigma, and empowering individuals to manage their well-being. In research, these tools provide an objective means to assess behaviors and physiological indicators in natural environments, enhancing our understanding of disease mechanisms, identifying biomarkers, and refining diagnostic criteria. The dual application of sDHTs in both research and clinical settings creates opportunities to bridge gaps between the two, fostering innovations in mental health care and advancing evidence-based practices.

For example, wrist-worn actigraphy demonstrates the ability to monitor sleep patterns, which are often disrupted in anxiety and depression. This can aid understanding of the impacts of mental health conditions on sleep, and potentially enable timely interventions [7,8,9,10,11,12,13]. Another example is GPS to study mobility and infer social behavior, which brings the potential for identifying patterns of isolation in conditions like psychosis [14,15,16]. More novel speech and language-derived measures are in earlier stages of validation and could become predictors of mood swing episodes or social withdrawal [15,16,17,18,19,20,21,22,23].

The efficacy demonstrated in a research setting now needs to be translated to larger-scale studies and real-world clinical utility, which is determined by the maturity level and complexity of an sDHT, how specific its claims are to mental health conditions (e.g., a specific measure of sleep that is known to correlate with depression that requires interpretation by a clinician versus an autonomous assessment of a psychotic episode), and their intended user (e.g., a clinician versus a person living with a mental health condition). Continued research and refinement are needed to improve accuracy, reliability, and clinical utility, ensuring that these tools meet the specific needs of diverse populations.

In this report, we identify behavioral and physiological aspects of health that are relevant to anxiety, depression, and psychosis, and that can be effectively and acceptably measured using sDHTs. By incorporating insights from literature, workshops, worldwide clinical experts and individuals with lived experience, we identify barriers, propose evidence-based solutions, and provide actionable recommendations to ensure the successful, equitable, and inclusive implementation of fit-for-purpose sDHTs in mental health clinical research and clinical practice to improve patient outcomes globally.

Importantly, the report does not intend to identify or recommend specific products as the speed of development for sDHTs is high, and small feature changes may have an outsized impact on its fit for purposes. We focus on higher-level technology characteristics and selection and implementation recommendations that are important to evaluate when selecting a fit-for-purpose sDHT to capture your measure(s) of interest. These technology characteristics and other recommendations are not necessarily mental health specific. Still, they were captured as part of a research protocol that asked participants to specifically consider their own experiences with mental health, be they personal and/or professional. Mental health-specific considerations are discussed throughout the report.

3. Opportunities for sDHTs to add value in mental health research and clinical practice

sDHTs present transformative opportunities to improve mental health research and clinical practice.

Key opportunities include:

- The ability to capture behavioral and physiological aspects of health, such as sleep patterns, physical activity, and stress indicators, can provide valuable insights into the progression, management, and prognosis of conditions like depression, anxiety, and psychosis. They can also help stratify clinical or at-risk populations to identify individuals who may benefit most from specific treatments and support early detection and prevention strategies.

- In clinical research, enabling the collection of rich, real-world data to inform the development and assessment of evidence-based interventions.

- In clinical practice, providing tools for continuous monitoring and personalized patient care. sDHTs can also be deployed as intervention companions, offering real-time feedback from sensor data analysis, personalized user guidance, and data insights for carers and clinicians.

Research into and development of sDHTs should address challenges such as lack of clinical validation and progress beyond pilot studies to fully realize their benefits in diverse settings. Additionally, a concerted effort towards the standardization of core data elements – the technical specification of a dataset, including a description of the data properties and relevant metadata, i.e., an ontology – is essential to ensure the scalability and interoperability of sDHTs. This could be achieved by conforming to research and clinical data exchange standards like Clinical Data Interchange Standards Consortium (CDISC) and Health Level Seven International (HL7 International). The findings in this section are synthesized from all research activities and complemented by the authors' subject matter expertise. Each of the following sections provides more details on how we collected data, and the methodology used to interpret it.

3.1 Candidate aspects of mental health for digital measurement

An **aspect of health** is a behavioral construct or physiological process that is known to correlate with the health condition of interest. A **meaningful aspect of health** is something a patient does not want to become worse, wants to improve, or prevent [24]. To assess an aspect of health digitally, one or more associated digital measures that are meaningful to a patient and clinician need to be identified. Next, we can select one or more sDHTs to capture those measures. For instance, the number of sleep interruptions in a particular sleep window is an aspect of sleep that can be measured with a wrist-worn actigraphy sDHT.

Table 1 reports **clinical utility** of the identified aspects of mental health and **sensors** (sDHTs) that can measure them. We synthesized these aspects of mental health and associated digital measures from all research activities (qualitative interviews, Delphi panel, and literature review), and those with the most mentions (interviews, Delphi) or available evidence (literature) are presented in Table 1. The last column outlines **considerations for their deployment and implementation**.

Table 2 defines **meaningful aspects of health** and other measurable concepts for the higher-level categories used in Table 1 (e.g., sleep, social activities, physical activity). It summarizes **condition-specific considerations** for depression, anxiety, and psychosis as synthesized for all research activities. In some cases, the findings from the literature review and participants (qualitative interviews and Delphi panel) overlap; in other cases, the participants value different aspects of their condition than those usually targeted by sensor research. We further discuss this important insight into sensor capabilities versus preference and meaningfulness to the individuals, clinicians, and researchers in Section 5.

We assessed the **importance and relevance** of the identified aspects of health and digital measures as follows: the aspects of health and measures presented to the Delphi participants were based on a prior literature review and interviews. Participants were asked to identify measures they considered important for mental health and specific conditions (depression, anxiety, psychosis; see Section 6.5.2.1.4). In this case, the participants were asked if they recommended each aspect of health from the list of the aspects of health with answers on a 5-point Likert scale: *Definitely no, Probably no, I'm not sure, Probably yes, Definitely yes.* To further evaluate the responses, we calculated a weighted average to interpret the results. Each rating on the Likert scale (1-5) was multiplied by the total count of the responses (how many people chose that rating). Then, we divided the results into Low, Medium, and High categories based on the range of scores. The cutoff points for Low, Medium, and High categories were determined by analyzing the distribution of the weighted averages and dividing them into three distinct ranges.

The most frequently recommended targets were sleep, physical activity, social behaviors, and heart rate-related stress measurements. Speech and language, breathing-related symptoms, gastrointestinal symptoms, and body temperature were also recommended but less frequently. This feedback aligns with findings from the literature review: sleep, physical activity, and social behavior have the strongest evidence supporting their use in measuring aspects of mental health. Speech, language, and heart rate measurements show medium evidence, suggesting feasibility but requiring further research to validate their clinical utility. Breathing-related symptoms, gastrointestinal measures, and body temperature have the least evidence, with limited sources addressing their relevance in mental health (see Section 6.4.2.1 for literature findings).

Research participants also proposed several candidate digital clinical measures that are not included in Tables 1 and 2, as they cannot yet be effectively and/or directly captured by sDHTs. Typically, these are signs and symptoms of a subjective nature that are currently better captured by patient self-report (e.g., subjective feelings such as mood, cognitive abilities, changes in habits and behaviors) or symptoms that require more cutting-edge sDHTs that have not yet reached the necessary level of maturity in terms of technology readiness or validation in mental health populations (e.g., complex behaviors such as disorientation, brain activity, continuous non-invasive blood pressure, and continuous or frequent sampling of biochemical markers through non-invasive or minimally invasive wearable sensors, such as measuring cortisol levels in sweat).

Table 1: We discuss the clinical utility for categories of behavioral and physiological aspects of health as defined by the narrative literature review, qualitative interviews, and Delphi panel. We describe relevant sensors for each category, summary information on the identified evidence, and implementation considerations. Each column header specifies the sources of the presented information (literature review, qualitative interviews or Delphi panel).

Behavioral or physiological aspects of health	**Clinical utility** *(Source: literature)*	**Sensors used to measure signals relevant to assessing the aspect of health** *(Source: literature)*	**Evidence level and implementation considerations** *(Source: literature, interviews, Delphi)*
Sleep	**Identifying sleep disturbances** that are frequent clinical markers of mental health conditions [7,19]. **Monitoring treatment effectiveness** by tracking changes in sleep patterns in response to treatment interventions [12,19]. **Understanding the relationship** between sleep and mental health [7,8,23,25]. **Personalizing treatment** plans such as cognitive behavioral therapy for insomnia [13,23].	**Accelerometers** are widely used in actigraphy and polysomnography to measure body movement and can be used to quantify certain aspects of sleep. They are often embedded in smartphones and wearable sDHTs. Whether or not actigraphy is sufficiently accurate to quantify a relevant measure of sleep, against the reference standard polysomnography (PSG), will depend on your intended use case [18]. **Electroencephalography** (EEG) used to be restricted to specialized monitoring clinics but are becoming more widely available in form factors compatible with home use [26]. **Electrocardiography** (ECG) and **photoplethysmography** (PPG) sensors can capture heart and respiratory rate, which can be used to infer sleep stage information (e.g., REM sleep), typically in combination with other sensors such as accelerometers and/or EEG. PPG can also be used to derive oxygen saturation which is affected by sleep, and certain conditions such as sleep apnea which may be comorbid with mental health conditions [27]. **Light sensors** measure light exposure, which can be used to infer sleep-wake patterns [7].	Despite ample data and high levels of evidence in sleep measurement, more research with larger sample sizes is needed to establish the clinical utility of these sensor technologies in mental health populations. The sDHT should be able to distinguish between lying in bed and being asleep. Accurate detection of falling asleep and waking up are important for measurement accuracy. Current data suggests that actigraphy-based algorithms can estimate sleep and awake times with a reasonable degree of accuracy, though not perfectly aligning with PSG measurements [28]. Changes in sleep measures and behaviors can be predictive of clinical symptoms associated with mental health conditions as captured through standardized scales [17,29] (e.g., GAD-7 or PHQ-9). Changes in sleep quality due to other factors, such as comorbidities, medications, or sleep disturbances directly caused by a measurement technology (e.g., it has a light on during the night) should be captured. Some of the sensors are under-explored in the literature, for example sleeping pads and contactless sensors [30,31].

Behavioral or physiological aspects of health	Clinical utility *(Source: literature)*	Sensors used to measure signals relevant to assessing the aspect of health *(Source: literature)*	Evidence level and implementation considerations *(Source: literature, interviews, Delphi)*
		Microphones can be used to detect sounds associated with sleep, such as snoring, which may impact sleep quality [7]. **Smartphone usage** based on screen on/off events, touch screen events [7], battery usage patterns [15] or stationary mode of the phone [7]. Studies found that these methods could reliably identify sleep duration, bedtime, and wake time over extended periods, however these studies have small sample sizes and validity of these measurements needs to be further researched. **Sleep tracking pads** are sDHTs that are typically placed under the mattress and capture motion, sound, and heart rate to analyze sleep patterns [32]. Contactless **radar-based** sDHTs are also being investigated to track motion, heart rate, and respiratory rate during sleep [33].	See Core Measures of Sleep as defined by the Digital Health Measurement Collaborative Community (DATAcc) by the Digital Medicine Society (DiMe) for more information on how to capture meaningful aspects of sleep.
Social behavior	**Objective assessment** of social interaction frequency, mobility patterns, and communication [7,15,16,34]. Changes in sensor-derived social measures could serve as **early warning signs** of mental health deterioration or relapse, enabling timely intervention [19,35,36,37]. Tracking social behavior with sensors can help **monitor treatment**	**GPS sensors** track location data, offering insights into mobility patterns and social engagement. Studies often use GPS data to infer aspects of social behavior, such as time spent at home, in social settings, and the number of locations visited [16,23]. These studies rely heavily on correlations and comparisons between clinical and non-clinical groups, providing useful context information but inconclusive evidence. Validation against reference measures of social behavior remains limited.	Although social isolation, withdrawal, and communication difficulties are recognized as significant contributors to and consequences of various mental health conditions, the use of these sensors for measuring social aspects in general and in mental health is less prevalent. Using passive sensors to detect social avoidance behaviors is an emergent focus in mental health research because interpreting these behaviors involves many complex factors such as time spent at home or in social settings, other location data, communication patterns from call and text logs, and

Behavioral or physiological aspects of health	Clinical utility *(Source: literature)*	Sensors used to measure signals relevant to assessing the aspect of health *(Source: literature)*	Evidence level and implementation considerations *(Source: literature, interviews, Delphi)*
	progress and evaluate the effectiveness of interventions targeting social skills or reducing social isolation [19,37,38]. Sensor data can inform the development of **personalized interventions** tailored to individual social needs and preferences [34,38,39].	**Call and text message logs** and other app usage patterns can provide insights into communication patterns and social interaction frequency. Several sources reference call and SMS data as indicators of social connectedness [34,40]. While these logs objectively measure communication frequency, their link to the quality and nature of interactions needs further study [7,10,14,41]. **Bluetooth** and WiFi signals can be used to detect nearby devices, enabling the mapping of social networks through proximity. As noted in one study, Bluetooth protocols are often disabled in research studies, making this a more emergent tool in need for further refinement [15]. **Social media activity** analysis offers insights into online behavior, language, and emotion expression. While this data provides a valuable perspective on online social dynamics, its connection to real-world social behavior and mental health needs careful interpretation and further validation [40,41].	activity levels from motion sensors. These data points must be contextualized with individual baselines and habits. Social behavior measurements often rely on positioning [18,39,44] data, which is highly privacy-sensitive. sDHTs targeting measures of social behavior should thus focus on building trust and implementing good privacy and security controls. Social behavior measurements are reliant on establishing behavioral baselines and incorporating self-reported assessments to provide critical context, such as via questionnaires, ecological momentary assessments (EMAs), or merging of sensor and non-sensor data.
Physical activity	Sensor-based measures offer **objective assessments** of physical activity levels, addressing limitations of self-report methods in groups who may experience cognitive or motivational challenges [9,18]. Low levels of physical activity is a risk factor for several mental and physical health conditions [45].	**Accelerometers** measure acceleration, capturing movement and activity levels. Accelerometers are widely used in physical activity research, have been extensively validated against reference measures and are integrated into smartphones, wearable fitness trackers, and other form factors [9,15,18]. For very precise measurement of movement, accelerometer data can be augmented with **gyroscope** and	The level of evidence for measuring physical activity with sensors is promising but still evolving. While the evidence suggests that measuring physical activity with sensors holds promise for enhancing mental health assessment and care, further research is needed to establish their clinical utility in rigorous validation studies, improved data quality control measures, and larger-scale clinical trials. Physical activity is a form of therapy; i.e., engaging

Behavioral or physiological aspects of health	**Clinical utility** *(Source: literature)*	**Sensors used to measure signals relevant to assessing the aspect of health** *(Source: literature)*	**Evidence level and implementation considerations** *(Source: literature, interviews, Delphi)*
	Monitoring activity levels during treatment helps track progress, assess how **effective interventions** are, and adjust treatment plans as needed [9,18,41]. Research suggests that shifts in physical activity patterns may be linked to changes in mental health symptoms, which could provide an **early warning** of worsening symptoms, allowing for **timely intervention** [12,22].	**magnetometer** sensors. **GPS sensors** track location and movement, providing insights into distance traveled and location-based activity patterns. GPS can estimate overall activity levels based on movement patterns, but it is less precise than accelerometers for capturing detailed activity intensity and duration. Validation against reference standards is limited [16,29]. Sensors embedded in **smartwatches** or **fitness bands** can provide comprehensive activity tracking. The accuracy and reliability of these wellness products varies and typically require dedicated validation studies to demonstrate agreement with more rigorously validated tools and/or in the intended context of use (patient population and environment) [15,21].	in exercise can affect mental health symptoms as measured by self-report measures. For physical activity, it is important to capture baselines and individual habits to prevent misinterpretation of the collected data. Although individuals with mental health conditions may have statistically significantly lower levels of physical activity compared with healthy controls overall [46], more research is needed to understand how the levels of activity change across stages and severities of mental health conditions as measured by standardized scales (e.g. PHQ-9). See Core Measures of Physical Activity as defined by DATAcc by DiMe for more information on how to capture meaningful aspects of physical activity.
Stress and autonomic response	Numerous studies have consistently demonstrated that alterations in heart rate variability (HRV), reflecting autonomic nervous system modulation, are associated with various neuropsychiatric illnesses [9,11,18]. HRV can serve as an **objective marker** of clinical status and potentially aid in diagnosis, treatment monitoring, and risk stratification. HRV can be also used to **monitor and predict stress response** in mental health conditions [45].	**ECG** is considered the reference standard for measuring heart rate and HRV. Studies use traditional Holter ECG monitors or adhesive cardiac patches to measure HR(V). HRV has long been known as a proxy for autonomic nervous system activity, which is often dysregulated in mental health conditions [9]. **PPG** is a non-invasive optical technique that measures changes in blood volume in the microvasculature. This technology is commonly used in wrist-worn wearables like fitness trackers and smartwatches. While not as precise as ECG, PPG-based heart rate measurements have been validated against ECG in several studies and can estimate	Despite high levels of evidence on clinical meaningfulness, and how easy it is to capture heart rate data, the clinical utility of heart rate and HRV in mental health are still under investigation. Quantifying stress is complex and likely requires additional context data, such as physical activity, to assess the potential origin. Heart rate-derived measures are known to be affected by both mental and physical stress. More research is needed to establish the sensitivity and specificity of microphone-assessed breathing rate. The evidence for using wearable sensors to directly assess breathing-related symptoms in mental health is limited.

Behavioral or physiological aspects of health	Clinical utility *(Source: literature)*	Sensors used to measure signals relevant to assessing the aspect of health *(Source: literature)*	Evidence level and implementation considerations *(Source: literature, interviews, Delphi)*
	HRV biofeedback (HRVB), a technique that trains individuals to regulate their HRV through breathing exercises and real-time feedback, has shown promise as an **intervention** to reduce anxiety [47]. HRV can assess **emotional responses in real-world settings** during periods of stress, anxiety, or heightened emotional arousal [13,16,48]. Rapid and shallow breathing is a hallmark symptom of anxiety and panic attacks. Real-time monitoring of breathing patterns using sensors could help identify these episodes and provide feedback for interventions aimed at regulating breathing and reducing anxiety [49]. Some psychiatric medications can have respiratory **side effects**, such as shortness of breath or difficulty breathing. Respiratory monitoring could be used to monitor these potential side effects and inform treatment decisions [50].	heart rate with reasonable accuracy [9,36,45,48]. It is possible to derive respiratory rate from ECG and PPG sensor measurements, or more specialized **bioimpedance** measurements on the chest [51]. Changes in heart rate patterns can sometimes be associated with respiratory distress or irregular breathing [19,36]. **Chest impedance** measurements [51] and **wearable stethoscopes** are emerging technologies that can also measure skin temperature. Some studies employ cardio-fitness **chest straps equipped with ECG sensors** to capture heart rate data. These straps provide a more secure and stable attachment compared to **wrist-worn devices**, potentially reducing motion artifacts [48]. **Electrodermal activity (EDA)**, also known as galvanic skin response (GSR), measures changes in the electrical conductance of the skin, which are correlated with stress and arousal levels [52]. Contrary to measuring heart rate and HRV, application of EDA is underexplored in the literature. A smartphone's built-in **microphone** can be used to detect breathing sounds [7]. Similarly, wearable stethoscopes are an emerging technology that can measure heart and respiratory rate through auscultation [53].	The correlation of breathing patterns with physical activity is important to understand as physical activity and other unrelated causes affect breathing rate. EDA sensor calibration and placement to assess electrodermal responses and sweating requires careful management of environmental factors to obtain a reliable measurement. For example, calibration must distinguish between stress-induced sweating and the influence of environmental temperature.

Behavioral or physiological aspects of health	**Clinical utility** *(Source: literature)*	**Sensors used to measure signals relevant to assessing the aspect of health** *(Source: literature)*	**Evidence level and implementation considerations** *(Source: literature, interviews, Delphi)*
Speech measures	Speech analysis can provide objective measures of thought disorder, a hallmark symptom of schizophrenia. Metrics such as incoherence, derailment, and illogical thinking can be automatically extracted from speech samples, offering a quantifiable assessment of this challenging clinical feature [54]. Changes in speech patterns, such as increased disorganization or negative emotional content, may **predict relapses** [54]. Analyzing speech characteristics over time can help **track the effectiveness of interventions** [54]. Passive sensing of speech and language can provide continuous and ecologically valid data that **complements** traditional clinical assessments and interviews [55,56].	**Microphones** are the primary sensors used to capture speech data. This data can be analyzed using various techniques, including acoustic analysis and natural language processing (NLP), to extract meaningful features related to speech and language [7,10,56].	Though the evidence for clinical utility of measuring language and speech is growing, there is a need for more validation studies comparing speech analysis to reference standard clinical assessments of language and communication. Evaluating speech is an emerging concept due to its specificity to the condition and low awareness with mental health experts on the possibilities of NLP. Speech is also very heterogeneous, with a high need for setting an individual baseline and calibration to establish within-subject changes of variables. Specific considerations for artificial intelligence (AI) methods include the need for balanced datasets. For example, men tend to be over-represented in psychosis clinics, and thus the gender imbalance in the training sample may bias the final prediction model to perform better in men [54].
Gastrointestinal health	Evaluation of food intake patterns and related gastrointestinal issues, such as gastric and intestinal motility, could offer valuable insights into the **relationship between gastrointestinal health** (microbial balance, inflammation, and nutrient absorption) **and mental health conditions** that links (mood and cognitive function) via the gut-brain axis.	**Electrogastrography** (EGG) is a non-invasive method to measure gastric motility but this method is mostly confined to clinical labs [57]. Connected **weight scales** nowadays often incorporate whole body impedance sensors which can provide a measurement of body composition [58].	The evidence for sDHT-based monitoring of gastrointestinal symptoms is limited in literature. Researchers also need to carefully consider comorbidities and other factors that may affect appetite, food intake, or digestion. For example, psychiatric medication that can cause weight gain.

Behavioral or physiological aspects of health	**Clinical utility** *(Source: literature)*	**Sensors used to measure signals relevant to assessing the aspect of health** *(Source: literature)*	**Evidence level and implementation considerations** *(Source: literature, interviews, Delphi)*
Body temperature and temperature perception	Disruptions in circadian rhythm are common in mental health conditions like depression and bipolar disorder. Monitoring body temperature patterns could help identify these disruptions of circadian rhythm and potentially inform treatment strategies [11,12]. Changes in body temperature can reflect alterations in autonomic activity, which are often observed in conditions like anxiety and stress [9]. Some psychiatric medications can affect body temperature regulation. Monitoring temperature could help detect potential side effects and guide medication adjustments [9].	**Temperature sensors** embedded in wearables such as rings, smartwatches and fitness trackers can measure skin temperature [11,18].	The evidence for using skin temperature measured by wearable sensors as a reliable indicator of mental health status is still limited. While some studies have found associations between skin temperature and conditions like depression, more research is needed to establish the clinical significance of these findings.

> "I would definitely say it [the issue] was the falling asleep. I would not be able to get to sleep, and if I did, I'd wake up early in the morning, especially if I was anxious about something."
>
> - *Individual with lived experience*

Table 2: We define meaningful aspects of health and other measurable concepts of interest, including condition-specific considerations. Each column header specifies the sources of the presented information (literature review, qualitative interviews or Delphi panel).

Behavioral or physiological aspects of health	**Meaningful aspects of health and other measurable concepts of interest** *(Source: interviews, Delphi, literature)*	**Condition-specific considerations** *(Source: interviews, Delphi)*	**Condition-specific considerations** *(Source: literature)*
Sleep	Changes in **sleep duration** (time spent sleeping), **sleep quality**, and **sleep behaviors** (e.g., insomnia, hypersomnia, difficulty falling asleep) are key aspects of health across mental health conditions. The individual's perception of changes in sleep quality or **difficulties falling and staying asleep** are also important.	Depression: **Time spent sleeping** and **fatigue**. Anxiety: **Initial sleep onset latency** (difficulty falling and staying asleep). Psychosis: **Changes in usual sleep and awake times** and **sleep window issues** (not being able to fall or stay asleep).	Depression**:** Studies have linked depression to **reduced sleep efficiency**, increased **sleep fragmentation**, **shortened REM latency**, **insomnia**, and **hypersomnia** [7,8,18,25]. Anxiety: Research indicates that **insomnia** and **sleep disturbances** are prevalent in anxiety disorders [7,29]. Psychosis: **Sleep abnormalities** are widely observed in schizophrenia, including **disrupted sleep-wake cycles** and **altered sleep architecture** [8].
Social behavior	**Socializing less/social isolation** and **avoiding social locations** overall were identified as key aspects of health across mental health conditions. Individual preferences and "baseline" habits need to be captured for accurate analysis.	Depression and psychosis: **Loss of interest in usual activities**. Anxiety: **Changes in social media/internet interactions** (for example, less time in social interactions and more time spent on phone). Psychosis: **Disorientation** is a potential measurement target, based on associated behaviors. Events like **outgoing text messages and calls** are often highlighted in the literature [9], although they were not considered very important by our respondents, or were noted as requiring further investigation.	Depression: **Social isolation and withdrawal** such as more time spent at home, **decrease in the frequency and duration of social interactions** via phone or text messages, **shrinking social network** [9,15,29]; **changes in typing speed and frequency** on a phone [39]. Anxiety: **Reduced time spent in social locations** (e.g., restaurants, bars), less likely to **initiate** calls, text messages, or social media interactions [29,34]. Location-derived features tended to be among the most important factors in predicting moment-to-moment symptom changes [59]. Psychosis: **Social withdrawal and isolation** [10,14,60,61], **disruption of social routines**, such as less outgoing text messages or calls

Behavioral or physiological aspects of health	Meaningful aspects of health and other measurable concepts of interest *(Source: interviews, Delphi, literature)*	Condition-specific considerations *(Source: interviews, Delphi)*	Condition-specific considerations *(Source: literature)*
			[35]. Higher social communication together with lower physical activity predicted manic symptoms in bipolar affective disorder [9,62]. In one case, the **number and duration of phone calls** was influenced by the occurrence of auditory verbal hallucinations [23].
Physical activity	**Time spent in physical activity** is meaningful, with reduced engagement in physical activities often indicating a worsening of mental health states across various conditions [9,18,46,63].	Depression: **Walking volume** in the context of daily activity. Depression and psychosis: Evaluating the **physical locations where physical activity is performed** is important for evaluation of its context (e.g., at home, outside, in the gym, or unusual places). Anxiety and psychosis: **Restlessness** and **repetitive movements** are often present in anxiety and psychosis and are an interesting target to evaluate when the condition deteriorates. Measurements of restlessness and repetitive movements are underexplored in literature, even though they can be feasibly captured by sDHTs, via accelerometers and gyroscopes.	Depression: Depression is often associated with **reduced overall physical activity levels**, including **decreased step counts** and less time spent engaging in moderate-to-vigorous physical activity [9,15,18,19,64]. For example, an increase in **daily step count** by 300 steps indicated a meaningful reduction in depression scores (e.g., BDI-II) [46]. Measuring a core symptom of depression, **psychomotor retardation**, as the changes in movement speed and variability using accelerometers can provide objective evidence [18,19]. Anxiety: Changes in **physical activity levels** [47]. Psychosis: **excessive and purposeless movements**, **agitation** [9,19].
Stress and autonomic response	**Tachycardia** and **heart rate variability (HRV)** are frequently used as proxy measures for stress. Resting heart rate is also valuable according to both evidence from literature and the participants in our research. Similarly, **electrodermal activity (EDA)** can be used as a proxy measure to	Depression: Elevated **resting heart rate**. Anxiety and psychosis: Instances of **elevated/rapid heart rate**. Psychosis and anxiety: Instances of **increased respiratory rate** (fast or rapid breathing).	Depression: Studies have linked **lower HRV** to depression and research indicates that individuals with depression may have a **higher resting heart rate** compared to healthy controls [9]. Can be associated with **irregular breathing patterns during sleep**, including sleep apnea [19]. Anxiety: **Increased and rapid heart rate** and

Behavioral or physiological aspects of health	Meaningful aspects of health and other measurable concepts of interest *(Source: interviews, Delphi, literature)*	Condition-specific considerations *(Source: interviews, Delphi)*	Condition-specific considerations *(Source: literature)*
	quantify stress, even though the evidence in the literature is scarce. **Respiratory pattern changes** are underexplored in literature, and potentially applicable to only some specific mental health conditions, for example anxiety. **Increased respiratory rate** [9] is considered a potentially valuable indicator of a stress response.		**rapid and shallow breathing** as a physiological response to perceived threats or stressor [9,19,47]. Psychosis: Research consistently points to significant autonomic nervous system dysregulation in schizophrenia which can manifest as **altered heart rate and HRV patterns. Lower HRV** has been linked to more severe negative symptoms, such as apathy and social withdrawal [9].
Speech measures	**Sentiment of speech** (negative/positive), **speaking rate,** and **prosody** (rhythm, intonation, emphasis) are the most important concepts. Speech measures are extremely variable, both inter- and intra-individual, and condition-dependent. For example, one person with anxiety may have rapid speech with a high pitch due to nervousness, whereas another may pause frequently, struggling to articulate thoughts.	Depression: **Sentiment of speech** ("depressive language" [60]), **"I" sentences**, and **speaking rate** Anxiety: **Speaking rate, prosody (rhythm, intonation, emphasis),** and **sentiment of speech** Psychosis: **Disorganized speech** or **impoverished content** [54], **reduced fluency**, **speaking rate,** and **content of speech**	Depression: **Reduced speech output**, **longer pauses**, **slower speech rate** [18,44], **depressive language** [65] Anxiety: **Increased speaking rate**, **repetitions**, **interruptions**, speech **content** reflecting worry and fear, changes in **pitch** and **tone** [34,48,55] Anxiety: **Incoherence**, **derailment**, **illogicality**, **poverty of content**, **reduced volume**, **longer pause** [54]
Gastrointestinal health	**Changes in dietary behaviors** and resulting **weight gain or weight loss** are important across explored conditions.	Anxiety: **Changes in gastric and bowel motility** (e.g., increased urgency, diarrhea, or constipation) unrelated to dietary behaviors is a potential target. Depression: **Appetite** changes.	Anxiety: **Abdominal pain** and **abnormal bowel habits** during periods of anxiety [66].

Behavioral or physiological aspects of health	Meaningful aspects of health and other measurable concepts of interest *(Source: interviews, Delphi, literature)*	Condition-specific considerations *(Source: interviews, Delphi)*	Condition-specific considerations *(Source: literature)*
Body temperature and temperature perception	These measures were least valued and least explored by the panel of experts and literature review. **Changes in body temperature** or **instances of hot or cold flashes** were reported several times by the participants in qualitative interviews. **Self-reports of hot or cold flashes** could offer insights into symptom exacerbation in mental health conditions.	Depression: **Instances of chills** or feeling cold was reported by one individual with lived experience during the interview. Anxiety: **Sweating**. Psychosis: Instances of **hot flashes**.	Depression: Changes in **body temperature** according to **circadian rhythms** [12]. Anxiety: **Elevated skin temperatur**e due to heightened sympathetic nervous system activity [9]. Psychosis: **Temperature dysregulation** [9].

Insights from participants

“ ”

"I remember feeling severe fatigue. It didn’t matter how much sleep I got.”
- *Individual with lived experience*

“...[people] with anxiety are usually restless. They do things repetitively.”
- *Clinician*

“...my weight tends to go up when I’m depressed because I’m not into exercising like I would say I normally do.”
- *Individual with lived experience*

“The greatest value I could see would be within the areas of total movement, intensity of movement, location of movement, and how repetitive the [non-walking/running] movement is.” - *Individual with lived experience*

“Self-closure, away from relatives. The loss of appetite for general activities…”
- *Clinician*

“I think rapid heartbeat is a kind of alarming, panic-inducing thing for people who have anxiety. They’ll notice they have difficulty getting a breath in.” - *Clinician*

3.1.1. Integrating sDHTs into interventions for mental health and wellbeing

In addition to passive data collection and monitoring, sDHTs can also be integrated into **mental health interventions**, shifting to actively improving mental health and well-being.

For example, **heart rate variability** (HRV) measured by sDHTs has been used to assess stress levels [45], and has shown potential in assisting biofeedback therapeutic interventions. Indeed, HRV biofeedback (HRVB) is an intervention that entrains respiration rate to modulate HRV, which may result in reduced anxiety. Further work could establish HRVB as a remote intervention to reduce anxiety, also potentially useful for low-resource settings [46].

The NightWare system is an interesting example of an intervention that uses heart rate and motion data from a commercially available smart watch to detect **physiological signs of distress caused by nightmares**. The smart watch generates haptic feedback to arouse the user enough to end the nightmare, usually without fully awakening the patient [67]. This method is beneficial for a variety of patients, including, as an example, veterans with post-traumatic stress disorder (PTSD). In low-resource settings, this system could potentially be utilized by leveraging its use of commercially available hardware, which is increasingly affordable and accessible. Additionally, its standalone functionality eliminates the need for continuous connectivity or advanced infrastructure, making it adaptable for areas with limited healthcare resources.

Solutions that utilize sDHTs can also be incorporated into **cognitive behavioral therapy** (CBT), a structured, evidence-based form of psychotherapy that focuses on identifying and modifying negative thought patterns and behaviors to improve emotional regulation and mental well-being. CBT, augmented with sDHTs, can be used in collaboration with clinicians or provider networks, or as health benefits offered by employers. In low-resource settings, sDHT-enabled CBT can provide scalable, cost-effective options by leveraging remote access and offline capabilities, reducing the reliance on in-person therapy. These assisted interventions can be coupled with insights from sDHTs, such as commercial wearables, for more actionable insights.

Currently, some **therapy programs** rely primarily on actively **collecting user self-reports** that are shared with healthcare providers. Examples include SilverCloud, which delivers structured CBT modules for managing depression that are accessible 24/7 from any device; Wysa, which uses an AI-powered platform to offer users immediate evidence-based support for managing anxiety; and PTSD Coach, a mobile app designed for veterans that offers coping tools and strategies for individuals managing PTSD symptoms. In the future, these solutions could implement sDHTs to collect data passively and more continuously, also paving the way towards closed-loop feedback systems. The inclusion of sDHTs would reduce the burden on users to regularly input data, thereby increasing adherence and accuracy, and could address the limitations of sporadic self-reporting, such as recall bias and incomplete data.

Finally, **health and wellness apps** provide yet another way to manage long-term care for individuals with mental health conditions. While these apps do not intend to treat, diagnose, or medically manage a condition, they often include fitness trackers that can offer instructions, tips, gamification, and motivation for mindfulness, meditation, exercise, mood management, and sleep. These types of apps can provide personalized insights and recommendations, helping users identify patterns and make informed decisions about their health. Many apps integrate real-time feedback and progress tracking, empowering individuals to take proactive steps toward improving their mental and physical wellbeing, for example by gamification features or reaching set goals (e.g., step count goal in FitBit, or activity rings in Apple Watch). Whether or not a health app is fit-for-purpose for specific mental health conditions and makes appropriate claims requires careful evaluation. Commercial wearable devices with health and fitness tracking, such as Oura rings, Apple Watches, or Google Fitbits, are examples of technologies that translate users' data and lifestyle habits into personalized insights.

3.2 Technology characteristics of fit-for-purpose sDHTs

To be effective and widely accepted, sDHTs must meet specific **hardware and software characteristics** to ensure they are functional, user-friendly, and capable of delivering reliable, high-quality data over time while being fit-for-purpose for the unique needs of individuals with mental health conditions. Table 3 reports these characteristics and features. Rather than focusing on specific products, which evolve rapidly, we highlight technical characteristics important for selecting fit-for-purpose sDHTs. While not all are specific to mental health, we address several mental health-specific ones.

For each characteristic, we provide a short description and the level of evidence found during the literature review, key considerations to assess with sDHTs, and routes to action to successfully develop or implement sDHTs in mental health. All recommended actions were born out of research activities that queried participants about their experience and recommendations in the context of their experiences with mental health. Logically, many apply to other therapeutic areas as well. We include recommendations for specific mental health conditions where available or applicable.

We compiled a list of specific features and characteristics of sDHTs, based on the Wellcome workshops, qualitative interviews, and literature review. These results were presented to the Delphi panelists, who were asked to recommend the features they considered most important specifically for sDHT application in mental health. Characteristics were ranked by the number of endorsements in the same way as for the aspects of health (see description in Section 3.1), with frequently recommended ones listed as high importance and others as lower importance.

> “ I think usability has to be number one, because a lot of people who have mental health issues are going to be completely discouraged right away if it's not easy to use. ”
>
> - *Individual with lived experience*

Table 3: Technology characteristics and considerations for fit-for-purpose sDHTs. Each column header specifies the sources of the presented information (literature review, qualitative interviews or Delphi panel).

Technology characteristic	**Short description and state of the evidence** *(Source: literature)*	**Key considerations to assess in sDHTs** *(Source: interviews, Delphi, literature)*	**Routes to action** *(Source: interviews, Delphi, literature)*
1. Characteristics of high importance			
Usability	Good usability of sDHTs ensures that they are **intuitive**, **accessible**, and **user-friendly**, **seamlessly integrating** into users' daily lives while **providing actionable feedback** and fostering sustained **engagement**. While feasibility and acceptability are frequently reported, several challenges remain, particularly concerning working with individuals with lived experience to co-design important user interface elements and design aspects.	Individuals with lived experience and clinicians have to be involved in design phases and iterative testing. Ideally, lived experience plays a large role in technology development. In some cases, for example psychosis, the individuals may rely on their caregivers, so development should also take their needs into account. Products and their user interfaces should be designed with simplicity and ease of use in mind, minimizing the need for technical expertise. Development of sDHTs should incorporate human-centered design.	Prior to development, conduct thorough assessments to understand the specific needs, preferences, and challenges of individuals with mental health conditions and/or clinicians via surveys, focus groups, or interviews. Employ an iterative design process that involves creating prototypes and testing them with target users to incorporate their feedback early and often.
Sensor performance	Reliable sensor performance of sDHTs means **accurate**, **consistent**, and **uninterrupted data collection**, enabling **trustworthy insights** generated from the data. Our research identified very limited examples of sensor performance assessments directly related to a mental health condition. Instead, the focus is on identifying meaningful measures of mental health conditions, regardless of the specific sensor(s) needed to capture it.	Verification of the sensor(s) demonstrates that the required performance was met against a pre-specified set of criteria. This stage occurs computationally *in silico* or at the bench *in vitro*. In a verification process, sensors are benchmarked against a performance standard, and they need to achieve this performance consistently over time (intra-sensor comparison) and uniformly across multiple sensors (inter-sensor comparison). The choice of performance standard depends on the physical construct captured (acceleration, light, etc.). Hardware sensor components should maintain accuracy without frequent manual calibration or provide a user-friendly method to do so if it is unavoidable.	New sensor modalities and updates of existing ones are constantly in development. When developing an sDHT for a mental health application, or for any other therapeutic area, it is important to identify a sensor (modality) with a thorough verification record, and preferably one that is commercially sold, as opposed to only available for research applications. Development of open access data sharing platforms to accelerate the availability of sensor benchmarking data should be encouraged.

Technology characteristic	Short description and state of the evidence *(Source: literature)*	Key considerations to assess in sDHTs *(Source: interviews, Delphi, literature)*	Routes to action *(Source: interviews, Delphi, literature)*
Algorithm performance	Algorithm reliability for sDHTs is defined as the ability of the algorithm to **process the sensor data consistently and correctly**, **without errors**, **failures**, **or unexpected behaviors.** Analytical validation relies on reference measures which are not always available, in which case they may need to be developed from scratch which is a time-consuming process. Additionally, existing analytical validation evidence may not be sufficient if your intended context of use cannot be easily replicated under lab conditions, which may require real-world analytical validation studies.	Analytical validation demonstrates that algorithms processing the sensor data achieve a level of performance that meets or exceeds that of a well established reference standard. Examples of analytical validation: • A simple algorithm for sleep-wake classification performs slightly better compared to more complex machine learning and deep learning models, suggesting that the simpler approach can be an effective tool when appropriately designed and validated [28]. • A neural network model was used to predict daily social anxiety scores from GPS data, achieving moderate accuracy compared to a self report [16].	Invest in collecting larger and more diverse datasets that capture a wider range of individuals, mental health conditions, and real-world contexts. This will enable the training and validation of more generalizable and robust algorithms. Encourage open access sharing of datasets and foundational models, enabling researchers and developers to design upon and improve existing algorithms. sDHT developers should be incentivized to share their analytical validation data to allow others to evaluate if that evidence is sufficient to cover their intended context of use.
Performance in specific clinical population	A fit-for-purpose sDHT must **reliably and accurately measure, predict, or identify** a clinically meaningful outcome or state in the specific population it is intended for. The current body of evidence contains many examples of research feasibility and pilot studies. A large gap exists between that state and demonstrating clinical utility for mental health conditions, which requires larger scale studies.	Clinical validation demonstrates that the sDHT acceptably identifies, measures, or predicts the clinical, physical, functional state, or experience, in the appropriate context of use. sDHTs should be validated under real-world conditions to ensure they perform as expected, are sensitive to meaningful clinical changes, and provide results that are consistent and actionable within the intended population. An example of clinical validation is comparing an sDHT to measure specific aspects of motion to detect mood episodes, earlier than possible with the current standard of care, to facilitate timely interventions and improve patient outcomes [19].	Appropriately designed large-scale clinical trials should be sponsored to conduct rigorous clinical validation of promising technologies and digital clinical measures of interest, in appropriately diverse mental health populations. Lived experience experts should participate in clinical validation.

Technology characteristic	**Short description and state of the evidence** *(Source: literature)*	**Key considerations to assess in sDHTs** *(Source: interviews, Delphi, literature)*	**Routes to action** *(Source: interviews, Delphi, literature)*
General quality and performance factors	**Seamless operation** and **resilience** to technical failures or environmental disruptions are also important to ensure an sDHT is adapted to its intended context of use. The most frequently reported operational interruptions relate to software (e.g., during software updates, rebooting, and network problems).	Hardware components should withstand long-term use, including physical wear. Software components should identify and address malfunctions promptly. The software should operate without frequent crashes, glitches, or performance issues, and operating system updates should not disrupt functionality. Delphi participants emphasized the importance of the sDHT to keep functioning without user interaction (to counteract low motivation) or when offline (to counteract a deliberate choice to not be connected) for people with depression. In addition to passive sDHTs, ambient sensors and smart home technologies can also provide passive sensing capabilities.	Design robust and user-friendly hardware that is tested extensively with people with lived experiences to ensure it meets their needs. Develop robust software and hardware that was tested to withstand the intended use environment (e.g., poor internet connectivity in a low resource setting).
Data privacy and security measures	Good data privacy and security measures in sDHTs ensure the protection of user data through **robust encryption**, **secure storage**, and **transparent consent** and **communication processes**, **safeguarding confidentiality** and **compliance with regulations**. While the importance of data privacy is acknowledged in the literature, the actual implementation of privacy and security controls varies considerably across studies. While some studies detail data protection strategies, others only briefly mention them, and some completely omit discussions of privacy considerations [10]. Some sources reveal that participants often feel uncomfortable with certain types of data collection, especially audio	Privacy: The sDHT should transparently explain what data is collected, how it is used, and who has access to it; patients need to be given the option to provide explicit consent to provide their data to others; data should be de-identified (cannot be traced back to individuals unless explicitly required and consented to do so); users should be clearly informed about and offered transparent and accessible options to govern their data (e.g., withdrawing consent, data export, or deletion requests); technologies should comply with local regulations that govern personally identifiable information (PII) and health data (e.g., HIPAA, GDPR). Cybersecurity: Patient data should be de-identified and encrypted in transit, at rest (storage), and during analysis; technologies should require strong user authentication methods (e.g., multi-factor authentication, biometrics) to prevent unauthorized access; software and hardware vulnerabilities should be identified, disclosed, and addressed; standard monitoring for security threats should be part of the technology design; protocols should be established for responding to data breaches or cyberattacks.	The key considerations (left column) are not specific to sDHTs specifically designed for mental health applications, nevertheless they are critical to ensure: Due to the stigma associated with certain mental health conditions, information on people's diagnosis should never be inadvertently disclosed or made available to unauthorized personnel, not involved in the research or delivery of care. People with mental health conditions often come from vulnerable populations, and information about their condition may be used against them if an unauthorized disclosure happens.

Technology characteristic	Short description and state of the evidence *(Source: literature)*	Key considerations to assess in sDHTs *(Source: interviews, Delphi, literature)*	Routes to action *(Source: interviews, Delphi, literature)*
	recording [21,68].		Certain symptoms of mental health conditions (e.g., anxiety, paranoia) could be amplified by badly executed privacy and security controls.
Long battery life	Battery life that **lasts for a required period of time** and is fit-for-purpose is important for uninterrupted monitoring and user convenience, **supporting reliable data collection** over extended periods and **reducing the need for frequent charging**. The literature review highlights that battery life is a critical factor influencing the feasibility and acceptability of sDHTs for mental health. Low-power sensors and optimization techniques are an active field of development.	The sDHTs should undergo rigorous real-world usability testing to validate the battery life under typical usage conditions; battery-saving and efficient data transmission methods should be employed where possible; for extended use or in areas with limited access to charging, alternative charging solutions should be provided (e.g., external batteries, power banks, charging cases, solar panels). One of the most direct ways to conserve battery is to be judicious about how often sensor data is collected. Instead of constant or high-frequency sampling, event-triggered (e.g., change in motion) or dynamic sampling (e.g., if measures are stable, decrease sampling frequency and vice versa) can be used.	Support development of low-power energy efficient sensors (such as application-specific integrated circuits (ASICs) with ultra-low power consumption). Support and clinically validate optimization strategies such as adaptive data sampling methods or optimized data uploads.
Verification and validation factor: Resistance to environmental factors	This is a component of verification and analytical validation. We call it out separately as it is considered important to allow broad adoption of sDHTs for mental health conditions in underserved settings. An sDHT's sensor has to be **reliable** and algorithms have to continue to operate at the same performance **under varying environmental conditions,** such as temperature, humidity, motion, or exposure to water and dust.	The sDHT should be tested for durability in various environmental settings (simulated or real-world) before implementation. These factors include temperature tolerance, humidity and moisture resistance, durability under motion (e.g., during travel, exercise), dust resistance, and impact resistance.	Clear user guidance on sDHT limitations and proper care as a function of environmental conditions should be provided.

Technology characteristic	**Short description and state of the evidence** *(Source: literature)*	**Key considerations to assess in sDHTs** *(Source: interviews, Delphi, literature)*	**Routes to action** *(Source: interviews, Delphi, literature)*
Accessibility features	Accessibility features require **inclusive design**, to encourage high usability for individuals with **diverse abilities**, **language skills**, and **technological literacy**, while accommodating their physical, sensory, and cognitive needs. The literature offers limited direct evidence or commentary on the accessibility and inclusive design of sDHTs used in populations with mental health conditions.	Accessibility features should be included where appropriate for target populations, including elderly, adolescent, pediatric, visual impaired, mobility impaired, low literacy, and low cognitive ability populations.	Conduct studies specifically focused on the needs and experiences of diverse mental health lived experience groups, which may present a unique combination of accessibility features. Involve intended users early and often in the design and development process to ensure that their needs and perspectives are considered.
Interoperability	**Interoperability** is the ability of products and systems to seamlessly connect, share, and integrate data across platforms for efficient care coordination. While some studies highlight specific instances of data exchange [9], a comprehensive and standardized approach to data exchange for mental health conditions is lacking, and considered needed by experts.	Key factors to assess include compliance with data standards, electronic health record (EHR) compatibility, scalability, and data regulations. Research examples of data exchange and integration platforms include REDCap and Purple Robot [15,36].	Experts in data exchange formats, mental health researchers and clinicians, and people with lived experience should collaborate to identify the key data elements, file formats, and protocols to build a comprehensive data ontology for mental health conditions. That ontology should be compatible with research standards (e.g., CDISC) and clinical standards (e.g., FHIR).
2. Characteristics of lower importance			
Customization and personalization	**Customization and personalization** of sDHTs involves: 1) the ability to tailor features and interfaces to specific users needs and desires, and 2) the ability to receive personalized recommendations based on individualized symptoms and treatment plans.	If possible, end users should be involved in the development and testing phases to identify opportunities for meaningful customization. Where applicable and reasonable, product features (e.g., notification frequency, goal setting, or symptom tracking options, sampling frequency) should be customizable.	Support research focused on developing and validating personalized algorithms and models [59]. Encourage data sharing to build diverse datasets for training and validating personalized models.

Technology characteristic	Short description and state of the evidence *(Source: literature)*	Key considerations to assess in sDHTs *(Source: interviews, Delphi, literature)*	Routes to action *(Source: interviews, Delphi, literature)*
	Literature sources emphasize the limitations of applying population-based models to individual sensor data, highlighting the importance of considering individual variability in behavior and symptom manifestations.	Features such as progress tracking, rewards, gamification, or reminders, can improve engagement and motivation to use the sDHT. For example, in anxiety, Delphi participants highlighted the need for carefully selecting alerts, notifications, and feedback to the user to prevent the notifications themselves impacting their anxiety. Additionally, we found that individuals with anxiety are most interested in co-creation efforts.	Develop user-friendly tools enabling clinicians and individuals to customize interfaces, data collection, feedback, and interventions to suit their needs, and as reasonable.
Availability of multiple device form factors	Availability of multiple product form factors can provide **alternative options** that are considered non-obtrusive, discreet, familiar to a user's preferences, and able to seamlessly integrate into daily life without drawing attention to the user's mental health condition. For instance, the same sensor(s) could be provided as a watch, bracelet, tag, or pendant. Currently, smartphones and consumer wearables are the dominant form factors used in the research of mental health conditions.	Products should be unobtrusive and avoid signaling mental health conditions to others, be comfortable for extended wear or use, leverage form factors users are already accustomed to, and be adaptable to different lifestyles, work environments, and cultural norms. Delphi participants indicated that this technology characteristic is particularly important for individuals with depression, to avoid needing to learn something new during periods of low motivation. For individuals with psychosis, they indicated the importance of sDHTs that do not look or feel overly obtrusive or surveillance-like to avoid exacerbating paranoia. In addition to common smartphone and wellness applications, ambient sensors integrated into smart home environments are emerging in mental health research. These can detect changes in activity levels and room occupancy, potentially revealing indicators of social withdrawal or changes in routine [44].	Ongoing technological improvements can yield smaller, more powerful, and less obtrusive sDHT form factors. This opens possibilities for integrating sensors into everyday objects, such as clothing, eyeglasses, and even implanted devices, potentially enabling more seamless and continuous data collection.

Insights from participants	
Insights from participants “ ”	**“The power supply in our country is not that stable… it’s better if you have a long battery life.”** - *Researcher (from LMIC)* **“It can’t be complicated… if people have to go through all of these extra steps, they’re not going to use it, so it has to be simple.”** - *Clinician* **“I think that if it was something discreet and maybe not obvious as a medical device… that would be good versus something that’s noticeable for a specific disorder or disease.”** - *Individual with lived experience* **“There should be instructions on how to use it and it should be as simple as possible… because these are people who already have issues with remembering things.”** - *Clinician*

3.2.1 Considerations for implementation in clinical research and practice

Table 4 showcases the main considerations for implementing sDHTs in clinical research and practice. We captured several subtle differences between research and clinical practice that are explained in more detail in the sections below the table. We highlight the most important considerations for sDHTs and separate them into pre-implementation considerations (relevant while designing a study or implementing a new sDHT in clinical practice), engagement considerations (relevant during the study or care delivery) and post-engagement considerations (relevant when concluding a study or the delivery of care).

Delphi panel participants were provided with a list of activities and considerations for applying sDHTs in research studies and clinical practice (for more detail see Sections 6.5.2.2.1 and 6.5.2.2.2). They rated the importance of each item on a scale, which allowed us to uncover the most important considerations for implementing sDHTs in both research and clinical settings.

Table 4: Main considerations for implementing sDHTs in clinical research and practice. "R" marks a research consideration; "P" marks a clinical practice consideration; "( )" indicates the research findings did not directly include this consideration but it is considered best practice.

Pre-implementation considerations	R	P	Engagement considerations	R	P	Post-engagement considerations	R	P
Cost burden	✓	✓	Frequency of active interactions	✓	(✓)	Study result sharing	✓	
sDHT impact on symptoms	✓	(✓)	Sharing of actionable insights	✓	✓	User feedback on sDHT	✓	(✓)
Training & onboarding needs	✓	✓	Offline and charging capabilities	✓	✓			
Usability, including UX	✓	✓	Support infrastructure	✓	✓			
Data privacy and security controls	✓	✓	Building and maintaining relationships	✓	✓			
Scalability needs		✓						
Cost effectiveness		✓						
Low stigmatization		✓						

3.2.1.1 Clinical research

Engagements in research studies are typically relatively short and reimbursed, resulting in research participants often being willing to tolerate somewhat higher discomfort and engagement requirements for the duration of the study. A delicate balance between the number of ecological assessments and the perceived obtrusiveness of the sDHT data collection instruments is critical, despite the acknowledgement that frequent data collection is important to derive actionable insights from clinical research studies.

Several **general considerations** emerged for implementation of fit-for-purpose sDHTs in research studies in mental health:

- Fair compensation is critical, particularly in mental health studies where vulnerable populations may face additional barriers to participation, such as financial constraints or stigmatization.
- Participants prefer longer intervals between self-reports or questionnaires to reduce perceived obtrusiveness, despite the utility of frequent assessments.
- Participants valued receiving study results after study completion, while real-time result sharing should prioritize acute, actionable changes over ongoing data collection updates. An example could be a notification alerting a participant to elevated stress levels based on heart rate variability, accompanied by a suggestion to take a break, engage in a relaxation exercise, or seek support if the stress persists.

Several **specific considerations** for mental health conditions emerged:

- For **anxiety**, personalization and customization of sDHTs were considered low priority since custom alerts could exacerbate symptoms. People with anxiety also communicated a desire to be treated as an equal contributor to the research team in order to remain engaged and have a better sense of control and engagement.
- For individuals with **psychosis**, it is important to report sudden changes in symptoms to the investigators and the care team to ensure adequate action can be taken if necessary.

Before initiating a study (pre-implementation), steps must be taken to ensure participant engagement and the integrity of the collected data. Key pre-study activities included assessing participants' prior experiences with sDHTs, establishing symptom baselines, and offering training and support, preferably via phone or contact person. Co-creating research, testing technologies before participation, and clearly communicating the scientific rationale for the study were all of lower importance compared to the key actions, though still relevant. The main recommendations in this phase include activities to:

- Establish familiarity with the sDHTs and provide tailored training materials (e.g., demonstrate how to wear and maintain the sDHTs, explain how to use apps to log symptoms, offer offline training materials such as leaflets or visual aids).
- Conduct pre-study check-ins to address concerns and reinforce understanding of study procedures.
- Clearly communicate the study's objectives, benefits, and data use policies.
- Ensure accessibility, such as offline solutions in low-resource settings.

> "Fostering participant engagement and motivation prior to the study start could be enhanced by building a sense of community and maintaining regular pre-study check-ins. Such check-ins can help address concerns, reinforce understanding of the study procedures, and keep participants engaged and ready to contribute meaningfully."
>
> - *Individual with lived experience*

While selecting technology and assessing data collection considerations, ease of use, reliability, comfort, discreet design, high support availability, and strong data privacy and security (e.g., encryption, user authentication) should be kept in mind. The sDHTs used in clinical research should:

- Have intuitive, user-friendly interfaces.
- Implement robust encryption, de-identification, and user authentication protocols.

- Establish support infrastructure that is responsive to the immediate needs of the participants and investigators, such as dedicated personnel, dedicated AI agents, or direct routes to contact the research team.
- Create alert systems for participants and the study team about changes in their data that may indicate changes in a participant's clinical state.

> "Regarding the support, it is important to clarify to the patients what to expect, the answer time, the time availability, and reinforce alarm signs of their condition. It is important that the participant can act if they have an emergency, rather than wait for a support answer."
>
> - *Physician using digital health technologies*

The following **accessibility and inclusion features** were regarded as of high importance: dynamic font size, text-to-speech functionality, and offering translations. Providing connectivity or offline options where applicable, and providing readily accessible information about support options, opt-out processes, and data privacy and security (e.g., via app, leaflet, a contact person, etc.) were also considered important.

The successful implementation of an sDHT in clinical research requires addressing access, equity, and participant inclusion with the following activities:

- Offering fair compensation based on industry guidelines (e.g., National Institutes of Health (NIH), Clinical Trials Transformation Initiative (CTTI), local ethical committees, fair market value calculations).
- Clearly outlining the benefits of participation, including post-study technology access.
- Maintaining non-judgmental, empathetic relationships with participants to build trust.
- Ensuring connectivity and charging solutions in resource-limited settings.
- Collecting participants' feedback on the study, including sDHT user feedback.

> "One of the ways to ensure that participants are comfortable and engaged is to establish a supportive relationship with them and acknowledge their emotions, and also foster a non-judgmental and empathetic connection."
>
> - *Individual with lived experience and clinician*

3.2.1.2 Clinical practice

Clinical practice and care is a long-term engagement and use of technology, which impacts the recommendations around fit-for-purpose sDHTs.

Implementation of fit-for-purpose sDHTs in clinical practice and care comes with several **specific considerations**:

- Comfort and usability should be prioritized. sDHTs must be intuitive, unobtrusive, and comfortable to reduce anxiety or stigma often associated with mental health conditions. For example, discreet designs can help mitigate paranoia in psychosis or minimize sensory overload in anxiety disorders.
- While scalability is often essential for maximizing impact (i.e., enabling implementation of solutions across diverse healthcare settings and populations), it is not the sole indicator of success. In some contexts, smaller-scale, tailored implementations may be more effective in delivering meaningful outcomes for patients, such as those in underserved areas or individuals with severe conditions requiring personalized approaches. For example, localized programs for individuals with PTSD may provide more targeted support.
- sDHTs must be compatible with the long-term nature of mental health care, maintaining reliability and affordability. They should integrate seamlessly into clinical workflows without exacerbating the strain on providers or systems, especially in resource-constrained settings.
- Providing ongoing training for clinicians, based on the complexity of the sDHT, is critical. Additionally, involving family members and care partners is particularly important for mental health patients who may struggle with independent use of the sDHT, such as those experiencing severe depression or cognitive impairment due to psychosis.
- Dashboards designed for the acuity of the specific mental health condition that is being managed are essential for clinicians to monitor progress. These tools should be intuitive enough not to introduce additional burden on care providers. If a dashboard has a patient facing component, the ability to toggle or customize notifications should be considered to encourage participation in the care pathway without providing overwhelming information, which is of particular importance for individuals with anxiety. An approach where data is made available to both clinician and the patient fosters autonomy, collaboration, and engagement.

> “The technology should be comfortable to wear and not so glaring, as patients might be stigmatized for using this technology. Oftentimes, patients don't want others to find out about their mental condition, especially if they are receiving therapy or mental health care. They wouldn't want to be labeled as someone with mental health issues due to the device they are using.”
>
> - *Individual with lived experience and clinician*

Before implementation of sDHTs in clinical practice, it is essential to prepare patients, clinicians, and support systems for effective and sustainable adoption. Here, "sustainable" refers to solutions that are practical, reliable, and seamlessly integrated into daily workflows over time, without creating unnecessary burdens for users. The most important activities for this phase include efforts to:

- Train both patients and clinicians in the use of the technology, with additional training for caregivers when needed. Adapt training materials and communication to the cultural and technological literacy of the user base.
- When providing training to caregivers or family members, consider the potential impact on the patient's sense of autonomy. For example, training should only involve caregivers if the patient is incapacitated or otherwise unable to manage the sDHT independently, to avoid creating a feeling of disempowerment.
- Provide scientific rationale and practical guidance tailored to each condition.
- Offer connectivity or offline options where necessary.

> "Training to families and caregivers should be considered only when the patient is incapacitated in some way."
>
> \- *Individual with lived experience*

Technology and data collection considerations for the duration of the selected intervention or period of time should be focused on features that will allow long-term use and engagement, particularly ease of use, reliability and comfort. The technologies used in clinical research should:

- Ensure intuitive interfaces, ease of use, and comfort for long-term wear.
- Focus on unobtrusive designs that reduce stigma.
- Implement robust data privacy measures.
- Ensure both clinicians and patients receive appropriate levels of feedback.

Accessibility and inclusion features that provide equitable access and content tailored to diverse user needs are essential for the success of sDHTs. Ongoing support is also important, whether through dedicated resources or the availability of wider support networks and peer connections. Successful implementation should aim to:

- Reduce cost barriers through lowering technology production and usage costs, introducing subsidies or insurance coverage or enabling the use of existing devices (including older models) where possible.
- Provide accessible technical and clinical support, preferably through assigned contact persons or readily available resources.
- Create or support peer support networks to enhance motivation and engagement.

> “ The cost of the innovation should be correlated with the financial statuses of the targeted individuals. Additionally, benefits to the patient and provider need to be clearly spelled out in an easy-to-access format (webpage, leaflet, etc.). ”
>
> - *Clinician*

3.2.2 Core data elements and requirements for fit-for-purpose sDHTs

Core data elements for fit-for-purpose sensor-based digital health technologies (sDHTs) are the essential information necessary to effectively monitor and address mental health conditions, including metadata - the data that describe and give information about other data (e.g., the timezone data is collected in, file format information, the sampling frequency of a sensor, the units after conversion). Defining core data elements is essential to ensuring data interoperability.

Table 5 summarizes core data element categories essential for the development and standardization of sDHTs tailored to mental health. Identifying specific data elements for sensor signals and measures is out of scope for this report. The table includes examples and covers aspects of sample-level (“raw”) data, through algorithmically processed outputs, to actionable insights for the users.

This summary of core data elements aims to lay the basis for future research and development and highlights the urgent need for the development of widely accepted data standards and practices tailored to specific mental health conditions. Such standardization will be essential to enable the field to build upon and effectively evaluate each other's work, fostering collaboration and advancing the utility of sDHTs in mental health care.

Table 5: Categories of core data elements and reference materials to advance the development and standardization of digital measures in mental health.

Data element	Short description	Examples
Sample-level data, i.e., direct sensor output(s)	Direct measurements captured by the sDHT sensor(s) without significant processing, interpretation, or modeling. Capturing this data is important for developing new algorithms, assessing that current algorithms are still working as expected when expanding the context of use, and monitoring for degradation of signal quality due to changes in use environment or other factors.	• Photoplethysmography (PPG; light absorption changes due to blood flow). • Acceleration in X, Y, Z axes (movement or orientation changes in three-dimensional space captured by an accelerometer). • Angular velocity in X, Y, Z axes (rotational motion or orientation changes captured by a gyroscope). • Sound (raw audio or decibel levels in the surrounding environment captured by a microphone). • Skin conductance (changes in electrical conductance of the skin captured by a galvanic skin response sensor, also known as electrodermal activity, or EDA).
Processed sensor outputs	Derived measures obtained by interpreting sample-level or other “raw” sensor outputs through algorithms or models. Meaningful insights can be generated from these derived measures directly or by combining them into higher level multimodal and/or contextualized insights. Capturing as many intermediate “outputs” as possible is important for the same reasons as indicated in the row above.	• Heart rate (HR; number of heartbeats per minute derived from a cardiac signal, such as PPG). • Step count (derived by detecting repetitive motion patterns from accelerometer and gyroscope data). • Energy expenditure (estimated calories burned, inferred from activity intensity and duration inferred from accelerometer, gyroscope, and/or heart rate data). • Environmental noise levels (strength and categorization of surrounding sounds to assess context or noise exposure). • Sympathetic response (indirect measurements of a stress response because of a change in EDA and/or HR and/or respiratory rate (RR)). • Stress state derived from HR, EDA, and physical activity data. • Sleep quality assessment from accelerometry, HR data, and self-report. • Emotional state from interacting patterns with a personal device, and a video analysis.
Actionable insights	This stage translates processed outputs into specific, clear guidance or actions tailored to the end user’s needs. It enables informed decision-making or behavior change by providing targeted recommendations or alerts.	• Sending a notification to take a mindfulness break when stress levels exceed a threshold. • Sending a prompt to consult a healthcare professional if activity levels and mood ratings show a steady decline over the past week, suggesting potential clinical state worsening.
Demographics data and medical history data	User demographics that are not dynamically measured by the sDHT but are critical for personalizing insights, interpreting clinical insights, and tailoring interventions. Medical history should be taken or be on file to	• Demographic information (e.g., age, gender, ethnicity, occupation). • Medical history (e.g., chronic conditions, medications, allergies). • Lifestyle details (e.g., daily routines, exercise habits, sleep preferences). • Environmental context (e.g., location, location type (urban/rural), climate, time zone).

	inform the clinical decision-making process and assess the impact of comorbidities on the measured data.	
Environmental data	Contextual information about a user's surroundings derived from the direct sensor output.	• Light exposure (e.g., natural and artificial light levels). • Ambient noise levels (sound intensity (e.g., decibels) or specific patterns (e.g., loud, sudden noises)). • Geolocation (e.g., GPS data to assess movement, travel routines, or social interaction patterns). • Air quality (e.g., temperature, humidity, and pollutant levels).
sDHT metadata	Data captured about how a user interacts with the product and how it operates.	• Time stamps of events in universal standard time (UST). • Battery levels and charging patterns. • Connectivity status (e.g., assessing Wi-Fi, Bluetooth, or mobile network connectivity). • Product usage patterns (e.g., frequency and duration of app or product usage). • System performance (e.g., sensor accuracy, app crashes, and data transmission reliability, data transmission logs, data integrity metrics (such as missing data), access and authentication logs).
sDHT technical specifications	Information about the product or system being used, including its hardware, software, and operational configurations.	• Product specifications (e.g., information about sensors, processor, memory, storage). • Software versioning (e.g., details of firmware, app versions, and operating systems). • Operational status (e.g., product uptime, error logs, and diagnostic reports). • Sensor type and calibration information (if applicable).

3.3 Considerations for research and development of sDHTs targeting mental health conditions

3.3.1 Key considerations for research and development

The development and implementation of sDHTs to improve our understanding of, and the standard of care for, mental health conditions must address the critical gaps and challenges that this report identified. Funding strategies should align with the considerations outlined and the research questions in section 3.3.2 and prioritize areas that address the critical gaps we outline in this section.

Clinical validation across diverse populations and contexts is a key missing factor consistently reported in our research. This lack hampers the generalizability and applicability of research findings across diverse groups and settings. Future funding decisions should prioritize:

- Clinical trials that represent diverse demographic, cultural, and clinical settings to ensure broad applicability and effectiveness of fit-for-purpose sDHTs.
- Targeted clinical validation of fit-for-purpose sDHTs in appropriately defined populations based on a clear understanding of the intended measurement, assessment, or outcome claims to a specific mental health problem. For example if the technology claims utility as an early intervention, it needs to prove that it shortens the time from symptom emergence to appropriate intervention.
- Identification of trans-diagnostic measures on top of condition-specific measures.
- Projects that design and test sDHTs in diverse populations and low-resource settings.

Limited **progress beyond pilot studies** is an issue not specific to the mental health field, although our mental health specific literature review did also identify this concern. Advances in other therapeutic areas can be potentially transferable into the mental health field. The best example is stride velocity 95th centile (SV95C), which became the first wearable-derived digital clinical outcome assessment qualified by the European Medicines Agency (EMA) for use as a secondary endpoint in trials for Duchenne muscular dystrophy in 2019 [69]. Despite promising developments, many initiatives remain at the pilot or feasibility stage and have not progressed to being employed in clinical trials or integrated into routine care. Research efforts and funding should support:

- Transitioning from feasibility studies to large-scale trials by prioritizing research that moves beyond proof-of-concept in multi-site trials with larger, more representative sample sizes.
- Emphasizing practical implementation and real-world usability by encouraging research that integrates sDHTs into existing clinical workflows and patient care pathways.

Research studies that evaluate sDHTs often have small **sample sizes**, which reduce the statistical power and reliability of the findings, making it difficult to draw conclusions. Future studies must involve larger sample sizes or apply more appropriate statistical methods and trial designs for smaller sample sizes to produce scientifically robust findings. This shift will improve confidence in the reliability and validity of the results. In line with improvements in sample sizes and progress beyond pilots outlined in the previous paragraph, priority funding should be provided to projects that:

- Demonstrate readiness to scale from feasibility studies to large-scale clinical trials and integration into routine care by reviewing plans for scaling, including well-defined trial protocols, recruitment strategies for diverse and representative populations, and collaborations with healthcare providers to test real-world implementation.

Funding efforts should also support **standardization of digital clinical measures** for mental health as this step is critical to allow efficient data exchange and collaboration. Some general standards already exist for sDHTs that provide a starting point. Future research should 1) adopt existing standards, and 2) develop and implement additional standards for specific mental health conditions, such as uniform measure definitions and data ontologies grounded in meaningful aspects of mental health, patient needs, and clinical priorities. Standardized data structures can also enhance meaningful adoption in marginalized communities by highlighting disparities and addressing gaps relevant to their specific contexts.

As a part of standardization efforts, accurately **capturing comorbidities and other medical factors**, such as chronic or acute physical illnesses, medication use, and treatment history, is critical for the effective development and deployment of sDHTs targeting mental health conditions. These factors can influence mental health and can affect the interpretation of sensor data. For example, certain medications may alter physiological signals like heart rate or sleep patterns, while chronic illnesses such as diabetes or cardiovascular conditions can introduce confounding variables. Research and support strategies should prioritize:

- Development of standardized protocols for recording comorbid conditions and medication use.
- Integration of variables into data collection and analysis pipelines to enhance the accuracy of insights and outcomes.

Developing **novel digital measures** for symptoms and behaviors important to mental health conditions can address gaps identified by patients, researchers, and clinicians. Examples include appetite changes, repetitive movements, and cognitive impairments. Although these advancements will require substantial research, development, and validation, incorporating them into sDHT development pipelines will improve our understanding of mental health conditions and add great value to research and care. Novel tools bring the opportunity to improve understanding of underlying mechanisms of the mental health conditions, treatment effects, long-term prognosis and other important factors shaping an individual's experience on their care journey. Therefore, from a long-term perspective, the funding should support research and development targeting unaddressed symptoms and behaviors.

3.3.2 Research questions for research and development

To guide the development and implementation of sDHTs, research should be guided by the following key questions (Table 5). For each question, we provide examples of how it could be addressed and evaluated. These questions were developed based on the Delphi process results and complemented with subject matter expertise of the authors and collaborators.

Table 6: Questions to guide research and development of sDHTs for mental health.

Area of focus	Questions to guide research	Example approaches
Effectiveness	How will the technologies prioritize clinical benefits and reduce risks associated with using sDHTs for mental health monitoring and/or intervention?	Prioritizing patient-centric outcomes, co-designing technologies with lived experience experts (e.g., FDA Patient-Focused Drug Development Guidance), implementing real-time monitoring systems that alert clinicians in cases of acute episodes or deterioration, and designing sDHTs to balance “chatiness” and clinical utility, and non-obtrusiveness.
Safety	How will these technologies ensure patient safety across diverse contexts of use?	Testing technologies in as many relevant real-world settings as possible, from at-home assessments to high-risk inpatient environments to identify potential safety issues (e.g., the approach followed by PfireLab); developing robust clinical protocols for emergency escalation.
Validation and evaluation	How will the technology be verified and analytically and clinically validated for accuracy, usability, and effectiveness?	Demonstrating the required performance of the sensor and the sample-level data it generates, demonstrating comparative results to the established reference standard measurement in analytical validation (e.g., this paper), conducting clinical validation studies involving diverse demographic and clinical populations, performing usability studies or testing usability as a part of validation studies, and collecting and publishing evidence from verification and validation studies.
	What methodologies will ensure thorough testing across diverse populations?	Incorporating stratified sampling techniques to reflect diverse geographic, socioeconomic, and clinical characteristics (e.g. the FDA draft guidance on Diversity Action Plans); partnering with community organizations to reach underrepresented groups and ensure cultural sensitivity in study design.
Scalability and sustainability	What strategies will support the scalability and sustainability of sDHTs from pilot studies to widespread implementation?	Developing modular designs for sDHTs that allow for easy adaptation to different healthcare settings without compromising core functionality, partnerships with public health systems to support scalable infrastructure, and training programs for healthcare providers to introduce the most recent findings and evidence (such as the CancerX Digitally Enabled Patient Navigation Blueprint).
	How will sDHTs align with existing healthcare infrastructure to enhance efficiency and effectiveness?	Ability to integrate with electronic health records (EHRs), designing solutions that complement existing clinical workflows (similar examples are addressed in DiMe’s V1C Care Transition Toolkit), and supporting ongoing clinician training.
Bias and limitations	What potential biases exist in the data collection and analysis processes of sDHTs?	Evaluating demographic representation in training datasets or differences in sDHT performance across populations (e.g., skin tones (example), activity levels, or cultural contexts); allowing researchers, clinicians, and patients to understand how data is processed and analyzed; helping identify and address inherent biases.
	How are researchers and developers mitigating these biases to ensure equitable outcomes?	Community-led approaches to co-design and testing; establishing independent advisory and review panels to identify biases; training clinicians and researchers on interpreting outputs from sDHTs with an awareness of potential biases; emphasizing caution when using outputs to make critical

Area of focus	Questions to guide research	Example approaches
		decisions.
Maintenance and upgrades	How will the technology be updated to address emerging needs and technological advancements?	Inclination towards modular and adaptable technologies that can integrate new features or improvements without requiring full replacement; establishing a feedback loop with end-users; regular assessment of advancements in sensor precision, software analytics, and clinical knowledge and integrating them into upgrades (e.g., FDA's total product lifecycle management program); implementing update mechanisms that ensure minimal user disruption.
Accessibility, equity, and diversity	What steps will ensure that sDHTs are designed and tested with diverse populations, including underrepresented groups and those in low-resource settings?	Mandating inclusion of diverse populations in research trials (e.g., FDA's Diversity Action Plan and the DATAcc Toolkit for Inclusive Product Development).
	How will the technology address barriers to accessibility for individuals with physical or cognitive disabilities, limited technological resources, or varying levels of digital literacy?	Developing culturally sensitive, multilingual interfaces; designing intuitive interfaces, accessible visuals, and audio prompts and ensuring accessibility for individuals with disabilities; providing training programs for patients, clinicians, and caregivers to improve digital literacy and adoption.
	How can these technologies be made affordable in resource-limited settings?	Improved affordability through cost-sharing models, open-source software, and partnerships with device manufacturers; providing low-bandwidth and offline-capabilities; introducing ability to use older hardware and software models with the technology.
Ethical approaches and consent	How will the technologies mitigate ethical risks arising from implementation and use of sDHTs?	Co-designing with individuals with lived experience; tailoring solutions for specific mental health conditions (e.g., depression, anxiety, psychosis); including features like customizable settings (e.g., frequency of alerts) to give users greater control and reduce feelings of over-surveillance or helplessness; allowing patients to view their own data in a user-friendly format.
	How will the technologies ensure transparency in data collection and processing?	Creating patient-friendly documentation explaining what data is collected, how it is processed, and who has access; implementing robust encryption, de-identification, and secure storage measures to prevent misuse of data by unauthorized parties; establishing clear policies prohibiting secondary use of collected data (e.g., for marketing or surveillance) without explicit consent.
	Does the consent to use the sDHTs in clinical research or care include key elements explaining risks, benefits, access, and use of the technology and collected data?	Risks, benefits, limitations, and intended uses of the technology; information about all stages of data handling from collection to analysis and storage; information about which parties and individuals have access to data and (if applicable) for what purpose, and whether any third parties have access to data; implement clear and actionable mechanisms that allow participants to revisit, modify, or withdraw their consent at any time.

4. Barriers to impact of sDHTs on clinical research and practice

Adoption of sDHTs in mental health research and clinical practice faces barriers and challenges. High costs and limited access remain pervasive challenges, particularly in low-resource settings around the world, alongside concerns about data privacy and security, which in turn impact trust and engagement. Additionally, poor technological literacy, lack of training, and the absence of user-centered design can hinder effective use. Context-specific factors, such as cultural sensitivity and diverse user needs, further hinder implementation. Addressing these barriers requires a concerted effort toward equitable access, tailored education, robust privacy measures, and inclusive, co-designed solutions to ensure that sDHTs achieve their full potential in improving mental health outcomes.

4.1 Barriers and challenges impacting adoption of sDHTs in mental health research and practice

More **scientific evidence on the effectiveness of sDHTs** in mental health is needed, primarily in clinical practice but also in clinical research, especially due to a lack of large impactful clinical trials, which poses a challenge to sDHT adoption and integration. For example, for conditions such as depression and anxiety, evidence is somewhat more established [7,9,10,21,38], with validated sDHTs like activity trackers and sleep monitors demonstrating feasibility and early signs of efficacy [19,23,39]. However, for conditions like psychosis or bipolar disorder, evidence is more emergent [7,15,23,68], and studies are in pilot or feasibility stages [14,21].

It is imperative that the "early majority", i.e., stakeholders who are not early adopters or innovators, know which sDHTs to trust and how and when to use them. Increasing awareness and knowledge about existing research and ongoing studies emerged as an important mitigation strategy from the Delphi panel, which will require a continued effort to collect efficacy data in real-world settings. While the literature review spanned multiple mental health conditions, the majority of identified studies were in pilot or feasibility phases, often using already validated sDHTs in a new specific clinical population and context. There were also methodological concerns, e.g., the methods used for determining condition severity were not consistent from one study to another [7,14,15,16,18,20,21,38,44,47,48,59,64,70,71,72].

Insights from participants

"Individuals are prone to be interested in devices that are backed with evidence, so efforts should be made to improve mental health outcomes with relevant evidence behind it." - *Individual with lived experience and clinician*

"I would like to see more progress beyond proof of concept and feasibility studies in academic settings. It feels like that's most of what exists today." - *Individual with lived experience and care partner*

Cost and limited access to technologies is a critical factor inhibiting the adoption of sDHTs, emerging as one of the most significant barriers across all explored conditions - depression, anxiety, and psychosis. While several studies provided sensors and smartphones to participants, financial accessibility was not widely addressed in the literature, underscoring the need for greater focus on this issue in future research and development of fit-for-purpose sDHTs. This challenge is particularly pronounced in low- and middle-income countries (LMICs), as well as low-resource settings in any geography. Ultimately, affordability will determine whether these technologies achieve widespread adoption, irrespective of other factors.

Insights from participants	
“ ”	**“There are so many people who would not be able to afford these devices regardless of [their] cost, so it'd be good to fund organizations to locate these people and make the devices available to them for free.”** - *Individual with lived experience* **“The major thing is about cost, accessibility. Chronic mental illness is tied to poverty.”** - *Clinician* **“I’d probably say 90% of it is the cost. I just haven’t had the spare cash to kind of fund one because they are a luxury item.”** - *Individual with lived experience*

The literature describes measures taken to ensure **data privacy and security**, indicating that this aspect is generally well-managed in clinical research, at least in the referenced publications. The measures include:

- Implementing encryption protocols to protect data during storage and transit [22,37,56].
- De-identification or pseudonymization of participant data [22,37,73].
- Multi-factor authentication or role-based access controls [68].
- Obtaining informed consent with clear explanations of how data will be used, stored and accessed [15,22,34].
- Controls to ensure patient control over their data, including deletion requests [22].
- Compliance with established global or local regulations [9,15,73].

Despite these efforts, perceptions of potential risks can still impact willingness to engage in research, highlighting the strong imperative for clear communication about these protections. We noted uncertainty related to data privacy and control of data in several interviews. Interestingly, some of the interviewees, especially the lived experience experts, had fewer concerns about these aspects as long as the goal of the technology use was met (e.g., they would not have any concerns transmitting their data to their clinician for review as a part of remote care).

Insights from participants	
“ ”	**“People understand that there’s a duty of confidentiality when they go to a doctor, for example. But people worry when it comes to private companies that their data is going to move and you lose control of where it goes, who has it.”** - *Researcher* **“Data privacy and security are a high priority and the patient should be assured that their data is not going to be misused by anyone.”** - *Researcher* **“Most patients with anxiety are often worried about their data, data privacy, and security.”** - *Care partner* **“Most people find it difficult to share their information even when it is for research purposes.”** - *Individual with lived experience and clinician* **“I don’t have an issue in divulging such information to a medical healthcare professional at all.”** - *Individual with lived experience*

Sensor-based technologies in mental health raise important **ethical issues**, particularly around privacy, consent, and data ownership. Additionally, there is a risk of exacerbating inequities if these technologies are inaccessible to marginalized groups. Mental health populations may be vulnerable and face heightened risks of coercion or exploitation in certain contexts, making it essential to implement safeguards that prioritize autonomy and prevent harm when introducing innovative solutions.

Ethical barriers identified in this report include perceived invasiveness of passive and continuous data collection in private settings; data protection and security challenges; and ethical issues related to individuals limited versus hyper awareness of passive and continuous data collection and monitoring [60]. An inadequate informed consent process can be a barrier that intensifies ethical concerns, making it essential to tailor consent procedures specifically to the use of sDHT-based solutions in populations with mental health conditions.

Insights from participants

“ ”

“It's essential to make sure the commercial off-the-shelf device manufacturers are not using the data from these studies without consent.” - *Researcher*

“The ethics of partnering with the device company would need to be closely examined. [Data can offer] valuable insight for them to better tailor their product(s).” - *Individual with lived experience*

“Informed consent only gets you so far when many participants are not fluent in legal language and don’t understand their rights. The responsibility is on the people collecting and managing the data to safeguard it.” - *Individual with lived experience*

“I would ask populations experiencing psychosis specific questions to ensure they understand what the study is about/involves.” - *Clinician and researcher*

Participants highlighted **accurate analysis of data within individuals’ contexts**, particularly in distinguishing mental health symptoms from measures related to other activities. If data analysis cannot reliably distinguish changes in mental health symptoms from unrelated data and account for individual differences, insights risk being inaccurate or irrelevant, potentially harming users or lowering engagement [9,10,16,23,35,48]. The participants raised concerns about this potential for misattribution (see the quote below). Additional challenges included background noise during collection of audio signals, lack of sensor accuracy (especially for GPS), biases in training data, low model sensitivity and specificity, and missing data due to sensor, charging, or connectivity problems.

Insights from participants

“ ”

“...the fact that I’m sitting around at home for 10 hours might signal something to whoever is using the data, but to me, it doesn’t mean anything. That’s my normal routine.” - *Clinician*

“Qualitative data from participants will be key.” - *Individual with lived experience*

“Subjective assessment is always essential to support any data-driven solutions.” - *Researcher*

> **“When it comes to mental health conditions, it is important to note that there are individual differences. The way people react to the same events or issues differs.”** - *Individual with lived experience and clinician*

The interview participants noted that they welcome **data and insight sharing from the product to the user** tailored to their needs and preferences, whenever feasible within the context of a research study. For people with **anxiety**, too many notifications and information sharing might trigger additional anxiety. Balancing access to actionable insights while avoiding overburdening the user is crucial. Clinicians and researchers benefit from detailed dashboards with granular data for diagnosis and intervention, while patients may prefer simplified feedback or more detailed insights based on individual preferences.

Insights from participants

“ ”

> **”I'd want to get as much feedback as possible, and I think that's an important element to explore as part of the study or intervention.”** - *Individual with lived experience*
>
> **“Feedback is critical for participant motivation.”** - *Individual with lived experience*
>
> **“Be transparent, simplified data reporting goes a long way with also helping them (the patients) get treatment in the long run so make it clear.”** - *Individual with lived experience*
>
> **“It is essential to provide feedback to the participants of the study and share the findings with relevant stakeholders.”** - *Clinician and researcher*

Sensor-based **technologies not adapted to the needs of individuals with mental health conditions** create a risk of being ineffective or even counterproductive. These technologies may overlook the cognitive, emotional, and sensory challenges that many users face, such as difficulty managing complex interfaces, heightened sensitivity to obtrusive features, or the stigma associated with visible products. This barrier was uniformly considered highly significant for depression, anxiety, and psychosis. Delphi participants highlighted establishing baseline measurements, particularly for depression and anxiety (“good” vs. “bad” days).

> “ I would like to know my baselines of a 'good' vs 'bad' day. ”
>
> - *Individual with lived experience and researcher*

Poor technological literacy, education, and training for individuals with mental health conditions are substantial barriers to the adoption and effective use of sDHTs. In low-resource settings, where cost and limited digital exposure already constrain access, the lack of adequate training and support exacerbates these challenges. Without targeted education and skill-building, even the most advanced technologies will fail to reach their potential impact or achieve widespread adoption. For psychosis, providing support was the most frequently mentioned need, while for anxiety, remote training and education options were viewed as particularly favorable.

Insights from participants

“While solutions are positive, I think asking people to dedicate themselves to learn something can be frustrating for people with mental health concerns [depression], given the amount of fatigue, apathy, and avolition they may experience plus general responsibilities they have. Individuals with psychosis may present with poor mental status from time to time in periods of acute psychosis.” - *Researcher and clinician*

“The new devices sometimes make things easier, but sometimes I have some hard time doing it by myself. I always have to ask someone to help me with the devices. I have limited skills to use technology.” - *Individual with lived experience*

Poor technology literacy, education, and training for providers can severely limit the effective integration of sDHTs, especially in mental health care. Without adequate knowledge of how these tools function or how to interpret the data they generate, providers may struggle to incorporate them into clinical workflows or make informed decisions. This gap can lead to underutilization, reduced trust in the technology, and missed opportunities for personalized care.

“ ...the majority [of clinicians] have no idea about telepsychiatry or tele-mental health services or any other digital health technology that supports mental health. ”

- *Clinician*

The need for **involvement of end users in the creation and development** of an sDHT solution was noted frequently, mostly in the expert workshop held by Wellcome in the summer of 2024 and by the Delphi panel. Active engagement of end users in the development process is critical and can substantially enhance the adoption and effectiveness of sDHTs by ensuring they are practical, relevant, and tailored to the users’ needs.

Insights from participants

“Studies, apps, and technology are made for people so it is vital that these people have to be involved.” - *Care partner*

“Lived experience expertise goes a long way because it offers insights from people who have gone through a similar experience rather than the professionals. Look deeper into this option when looking for those to partner with.” - *Individual with lived experience*

“This is the most critical factor in usability.” - *Individual with lived experience*

Language barriers, lack of specific cultural sensitivity in design and content that fails to align with cultural norms or values can create distrust and disengagement. Without cultural sensitivity, these tools may overlook critical factors that shape mental health experiences, resulting in reduced adoption and impact.

Insights from participants	
“ ”	**“Understanding the population you are working with or recruiting from is integral to make sure the study minimizes many challenges that could have been prevented.”** - *Clinician and researcher* **“Individuals with diverse cultural backgrounds should be considered and engaged with first to learn about different cultures as this will foster understanding.”** - *Individual with lived experience and clinician*

General distrust in technology in health and medical settings was noted in the interviews and expert workshops, as well as by the participants in the Delphi panel. They identified this distrust as the most context-sensitive challenge, dependent on the access, resources, and cultural background of the individuals in the presented use-cases (e.g., whether they were from high access or low access settings, or have used smart technologies before or not).

Insights from participants	
“ ”	**“I don’t want to enter a black box, like being a blind person doing stuff that I don’t know exactly what’s happening.”** - *Individual with lived experience* **“Anxiety will work to erode trust, so efforts to convince may backfire. Just providing hard solid tangible facts may be the best case scenario.”** - *Individual with lived experience* **“If people are aware of the impact of technology, I think they will be able to trust this technology in mental health.”** - *Care partner*

Limited access to connectivity and charging capabilities goes hand in hand with the issues related to cost challenges. This lack of access can also be a challenge in hard-to-reach or rural regions of high-income countries, so mitigations should be designed to ensure reliable collection of sensor data for further analysis. Our results also identify that these challenges may result not only from a lack of technical infrastructure and access, but also considerations specific to mental health conditions, such as a lack of motivation in depression. Inconsistent data collection from connectivity or charging issues undermines insight generation, making the technology less effective for patients and clinicians.

Insights from participants	
“ ”	**“There is always going to be a risk of the participant not re-charging the device due to a lack of motivation. So having someone do the task for them would be good.”** - *Individual with lived experience* **“Consistency of power is a problem, the option to have an alternative source is good, however, if I can't even move out of my bed, how shall I get to the charging stations?”** - *Individual with lived experience and care partner* **“In developing countries these options will be critical.”** - *Individual with lived experience* **“In Africa the use of Wi-Fi is sometimes expensive, not everyone has access to Wi-Fi.”** - *Care partner*

4.2 Proposed mitigation strategies to address identified barriers

During the expert workshops in the Summer of 2024 and the Delphi panel, participants discussed mitigation strategies for the identified barriers and challenges. Rather than linking these strategies to specific challenges or categorizing them by priority level, we present them in Table 7 as key strategies and considerations for the entire lifecycle of sDHT development, research, deployment, and evaluation.

Table 7: Strategies and approaches for mitigating barriers to research into and adoption of sDHTs in mental health research and clinical practice.

sDHT lifecycle phase	Core strategies	Additional actions	Insights from research participants
Development and testing of sDHT solutions	Design for simplicity. Co-create with users. Conduct pilot tests. Offer 24/7 technical support.	Capture relevant medical history and strike a balance between needs for **data collection** and **practical use**. Incorporate **lived experience expertise**. Collect **multiple data streams** for contextual insights. **Test battery** draining before deployment. Recognize **immediate risk** (e.g., suicidal ideation) and be able to act upon it.	Design simple, calming interfaces, offer customization options, or connect users to support or peer groups. Ensure sDHTs clearly report to the user that hardware and software are operating as they should.
Data privacy and security	Comply with regional data privacy and security regulation. Include standard monitoring practices for security threats.	**De-identify**, **minimize** and **encrypt** patient data in transit and storage and during analysis. Transparently **explain data flows**, and who has **access** to what data and for what purpose (e.g., in informed consent). **Minimize collection of PII** (personally identifiable information, such as name, phone number, address, email, etc.). Strictly **prohibit re-identification** of individuals from de-identified study data.	Provide reassurance and transparency about data privacy and security in the user's local language and tailored appropriately to the user's level of understanding.
Ethics and informed consent	In the informed consent document, transparently explain what is being measured, what data is collected, where it is stored, who has access, and for	Transparently and clearly **explain the risks and benefits** Transparently communicate and provide a straightforward **method to opt out** from research any time (e.g., button in app, email or phone contact, leaflet).	Add accessibility options, translations, a glossary for technical terms, simplified language, or video or visual aids to informed consent documents.

sDHT lifecycle phase	Core strategies	Additional actions	Insights from research participants
	what purpose the data will be used.	Evaluate **changes in an individual's risk** over time. Ask patients about their **understanding** during informed consent. Seek **renewed consent** if data is used beyond the original scope.	
Implementation in clinical research	Provide clear rationale for the use of these technologies for research purposes. Include small but frequent assessments. Report results of the study after it concludes. Include lived experience insights in research study design.	Collect **personalized context information** about the participants. Establish a **baseline** of behaviors prior to the study Offer 24/7 technical **support** Inform participants about any mid-study changes and reobtain consent. Investigate **if the sDHT impacts symptoms** and behaviors.	Collect additional data on biochemical markers (e.g., vitamin deficiencies, hormonal profiles). Consider development of person-specific models and subgroup algorithms,real-time prompts for unusual signals , and algorithms to detect untruthful data. Support use of older technology and let the participants or patients keep the products post-study for added value.
Implementation in clinical practice	Provide clear rationale for the use of these technologies for clinical care purposes (for example, in informed consent). Provide ongoing training and engagement.	**Build capacity** in provider and patient settings to enable them to become more involved, interested, and engaged. **Collect baseline** or usual data/behaviors from the participant prior to any intervention that may impact such data/behaviors.	For psychosis and anxiety, sudden changes in or exacerbation of symptoms should trigger an alert or notification system for the clinician. Include self-reports and diaries to gain better insights into patients' subjective experiences and reports.
Access, equity, and inclusion	Provide financial subsidies, insurance coverage, or grants to organizations to cover the cost of products for patients who cannot afford them. Provide products for the duration	Form **partnerships** with sDHT manufacturers to offer devices at free or discounted rates. Provide **data plans, SIM cards,** or **pre-loaded plans** alongside study sDHTs. Support offline data processing - analyze data directly on the	Offer insurance coverage and integration with healthcare systems. Leveraging existing products the individual already owns. For regions with limited connectivity,

sDHT lifecycle phase	Core strategies	Additional actions	Insights from research participants
	of the research study or care intervention. Develop low-bandwidth versions of the used sDHTs Provide power banks or other alternative charging methods where necessary. Aim for inclusive enrollment in research	sDHT without the need to upload. Offer **paper-based options** for education and training. Offer **translations**, **disability access**, and materials appropriate for specific **sociodemographic populations**. Learn about **cultural sensitivities** before the study or intervention begins. Low-resource settings: Set up **charging stations** in local community centers, clinics, or other public spaces. For **psychosis**, providing support systems (community, connection to care partners or clinicians) may be useful, while for anxiety, remote training and education options can be favorable.	create communal spaces offering both support for the condition and reliable connectivity or charging of devices. For **psychosis** and **anxiety**, when motivation is low and individuals may be more forgetful, design devices that account for these behavioral changes.
Knowledge, education, and awareness	Provide ongoing training to providers and clinicians within specific clinical/care contexts.	**Educate** researchers and technology developers on best practices for data privacy and security. **Provide training** within specific clinical care contexts. **Collaborate** with trusted community leaders, religious figures, and cultural organizations to improve awareness. **Partner** with patient advocacy groups and trusted community organizations to improve trust. Encourage the creation and publication of **shared datasets**. **Share** real-world case studies, research results, and testimonials. **Publish** results of research studies.	When patients with severe mental health conditions are incapacitated, offer engagement opportunities and training about digital technologies for their families and/or care partners. Organize workshops and seminars for care providers and communities. Share feedback, success stories, or publications with stakeholders and communities.

5. Recommendations to improve adoption of sensor-based technologies for mental health

5.1 Aspects of mental health for digital measurement

Sleep, **physical activity**, **stress**, and **social behavior** demonstrate the strongest evidence of utility in mental health research and are supported by expert and patient preference. Larger-scale studies are required to support evidence of clinical utility. These aspects of health are most primed for clinical implementation. **Speech** and **language**-derived measures show promise but require further research to validate their utility in mental health conditions, which may include initial clinical pilot studies. Finally, **breathing-related** symptoms, **gastrointestinal** symptoms, and **body temperature** lack substantial evidence of utility in mental health research, and still require basic research to determine their relevance to mental health. Table 8 outlines a proposed roadmap to guide investments, based on these findings.

> "It is important to research sleep patterns and how you can reduce the need to use medications for sleep and anxiety, by monitoring what situations are more prone to affect our sleep."
>
> - *Individual with lived experience*

Table 8: Proposed roadmap and investment recommendations as a function of relevant aspects of health, with the expected realized value.

Report findings	Roadmap and investment recommendations	Realized value
Sleep, **physical activity**, **stress**, and **social behavior** have the strongest evidence and expert (lived experience, clinical, research) preference, positioning them as important aspects of mental health to measure.	Support larger-scale studies that will provide efficacy evidence beyond proof of concept and feasibility studies. These studies should have larger sample sizes, and include diverse demographic, cultural, and clinical settings to yield conclusive and generalizable evidence. Support integration in clinical practice, as well as engagement of clinicians and patients about the benefits of integrating novel insights into their lives and practice.	Evidence of sDHT efficacy Stakeholder engagement Uptake in clinical practice
Speech and **language** derived measures show intermediate evidence, suggesting feasibility but requiring further research to validate their clinical utility.	Support research generating evidence to mature the technology and establish its value for mental health conditions. Explore their implementation in clinical practice via pilot and feasibility studies.	Evidence of sDHT efficacy Faster go/no-go decisions for continued research support and funding Evaluation of feasibility in clinical practice

Report findings	Roadmap and investment recommendations	Realized value
Breathing-related symptoms, **gastrointestinal symptoms**, and **body temperature** have the least evidence, with only limited sources addressing their relevance in mental health.	Support fundamental research to find out if these symptoms play an important role in mental health.	New scientific evidence

> "I think measurement and understanding about psychosis and the most severe conditions is currently the least developed and highest priority for improvement."
>
> - *Researcher*

5.2 Development of technologies and sensors

Accelerometers, **GPS** and **photoplethysmography** (PPG) are well established for measuring aspects of sleep, physical activity and stress. **Localization** via GPS, Bluetooth and WiFi, **microphone** recordings, and **phone and app usage** as well as **light sensors** are promising emerging technologies for measuring **social behaviors**, as well as important context information to inform data from other sensor modalities. Other sensor modalities with robust evidence of function and utility, although not necessarily in mental health populations include **electroencephalography** (EEG) and **electrocardiography** (ECG). **Electrodermal activity** (EDA), under mattress **sleep pads**, **radar**-based technologies, skin **temperature sensors**, **electrogastrography** (EGG), and **impedance** sensors have the least efficacy evidence for mental health applications and require more research.

Due to their ubiquity, **smartphones** and wrist-band **wearables**, which often incorporate multiple sensor modalities, provide a fast adoption pathway in mental health populations, provided these sDHTs are appropriately analytically and clinically validated. New form factors, such as **chest patches** and **contactless sensors** are in development and are likely to open new applications in mental health.

Sensor development should focus on three priorities:

1. Integration of well-established sensors in unobtrusive form factors (such as wrist bands and rings that are generally well accepted by users) for multimodal data collection.
2. Establishing that existing algorithms generating insights into sleep, physical activity, and other relevant aspects of mental health, are performing as expected in these populations and can be further refined.

3. Development of more advanced sensors, including entirely new sensor modalities that capture subtle behavioral cues or measure biochemical components in bodily fluids in a patch form factor.

When developing new sDHTs or updating existing ones, passive data collection to keep user burden low (especially during times of low motivation), unobtrusive designs, and low power consumption should be prioritized. Additionally, improving algorithms to increase their clinical utility for mental health applications should be top of mind.

Table 9 lists the sensors discussed in this report, and recommendations for short-term improvement roadmaps, as well as longer-term development opportunities. These are areas that would benefit the most from support and funding and are most likely to give a return on investment. Because most sensors are technically mature, most of the recommendations focus on algorithmic improvements. The table does not distinguish between research or clinical practice applications as one should always start by identifying a meaningful aspect of health, before considering how to measure it, including which sDHT may be able to accomplish that in the intended context of use.

> “Speed of innovation, strategies to have an MVP [minimal viable product] and move to more mature technologies are important. It is possible to target patients with less severe disorders and then move to more severe and more impactful. This will allow [the researchers] to iterate the technologies with less risk and later move to more complex cases.”
>
> - *Researcher and care partner*

Table 9: Proposed roadmap and investment recommendations for sensors used in mental health research.

Sensor	Roadmap and investment recommendations
Accelerometers	Expand use in measuring sleep and physical activity across diverse mental health populations. Develop algorithms to differentiate between activities relevant to mental health exacerbations more accurately.
Photoplethysmography (PPG) and electrocardiography (ECG)	Clinically validate HRV-based stress quantification algorithms in mental health conditions and assess what level of detection threshold is clinically meaningful.
GPS sensors	Clinically validate social mobility patterns for mental health conditions like depression and anxiety. Develop multimodal algorithms to contextualize location data with emotional or behavioral states.
Wireless protocols (Bluetooth and WiFi)	Address privacy concerns related to proximity-based social interactions. Analytically validate the approach against self-reported social engagement.
Microphones	The performance of natural language processing (NLP) models should be assessed in specific mental health conditions and geographic regions to determine their potential clinical utility to detect exacerbations or other clinically meaningful changes that inform treatment.
Phone and app usage, calls and text message logs	Analytically validate this approach against self-reported phone and app usage. Clinically validate as indicators of social connectedness and early signs of withdrawal in an appropriate population.
Electrodermal activity (EDA)	Define an appropriate level of EDA sensitivity that is clinically meaningful. Analytically validate EDA as a signal to derive stress responses, most likely in a multimodal set up that includes a heart rate measurement as well, against self-reported stress scores.
Sensors embedded in contactless technologies (e.g., radio-wave-based sensors)	Investigate through usability and analytical validation studies that contactless sensors for sleep assessment are fit-for-purpose for measuring relevant aspects of sleep in mental health conditions.

> “ As a patient, I would like to understand better when I might be approaching a low or high. There are often key indicators, such as the sensations that come with a drop in blood sugar or feelings of fatigue. ”
>
> - *Individual with lived experience*

5.3 Advances in AI

Advances in the field of machine learning and artificial intelligence (AI) are setting the stage for rapid development of algorithms (models) that can process large datasets and have higher detection sensitivities than the current standard of care. When foundational models become available that infer information about relevant aspects of mental health, that development speed will increase further.

Building sDHT datasets in populations of high interest is important to develop more performant and specific AI-based diagnostic and prognostic tools for managing mental health. AI models must address typical considerations such as biases in the data and model interpretability. AI models that encode culturally relevant practices could be leveraged to develop more personalized therapies. AI agent therapists could provide always available empathic support, including in low-resource settings, and in closed-loop sDHT feedback systems. Table 10 outlines recommendations for advancing the use of AI for developing more performant sDHTs for mental health applications.

> "Wearable sensors and brain-computer interfaces could monitor neural and emotional states in real time, helping communities manage stress and trauma. AI-driven personalized therapies could integrate culturally relevant practices, such as storytelling or meditation techniques. Early detection tools and AI-powered virtual therapists could provide accessible, empathetic support in underserved regions."
>
> - *Individual with lived experience, clinician, and researcher*

Table 10: Short and long-term recommendations for leveraging AI in mental health sDHTs.

Application category	Short-term improvement roadmap	Longer-term development opportunities
Monitoring	Design studies to capture a very large dataset to train AI models for symptom monitoring in a particular mental health condition. Fine-tune existing foundational models for mental health monitoring, incorporating sensor data alongside other datasets.	Develop context-aware AI models that integrate environmental, lifestyle, and sensor data for more granular monitoring. Develop models that are small enough to run on a low-powered sDHT to reduce reliance on connectivity and optimize battery life.
Prediction	Develop predictive models to identify risk of exacerbations for individuals with a specific mental health condition.	Invest in advanced predictive analytics that leverage longitudinal and multimodal datasets to understand early warning signs and long-term patterns in mental health.
Treatment optimization	Develop algorithms that tailor interventions to an individual's needs, such as adjusting therapy intensity based on real-time feedback from sDHTs.	Create agentic AI systems that evolve treatment plans based on individual response data, enhancing precision in both medication and therapy adjustments.
Natural language processing (NLP)	Implement NLP for sentiment and tone analysis in speech to assess emotional well-being. Address challenges in linguistic variability and cultural differences affecting NLP models.	Develop NLP models capable of understanding and predicting mental health symptoms in underrepresented languages and dialects.
Clinical decision support	Focus on developing foundational explainable AI tools tailored to mental health clinical practice. These tools should provide interpretable insights into patient data, reducing clinician cognitive load while ensuring accuracy.	Improve and build on explainable AI tools that simplify clinical data interpretation while maintaining accuracy and reducing the cognitive load on clinicians, with a particular focus on low resource settings that may not have access to sufficient clinicians.
Digital therapeutics	Design a study to develop an AI-driven therapeutic intervention, such as a real-time biofeedback system, and run a pilot study.	Deploy that system in a larger study to clinically validate that it improves mental health outcomes.

5.4 Development of infrastructure

Standardization and interoperability of sDHT data and systems are critical to integrating these technologies into clinical practice.

Throughout this report we outline the need to champion **standardization** efforts to facilitate data harmonization (through ontologies across research and clinical care) and data exchange (via standard organizations such as CDISC and HL7) to facilitate collaboration on dataset generation and the development of clinical workflows.

Funding and resources should be directed towards:

- Developing and supporting the adoption of **core data elements** for sDHTs (see Section 3.2.4) specific to mental health.
- Supporting the creation of comprehensive digital clinical measure **ontologies** for mental health conditions. This would create a universal language for interpreting sensor outputs and linking them to clinical outcomes.
- Establish minimum interoperability requirements for sDHT developers, ensuring data compatibility and reducing silos.
- Supporting the development of interoperable platforms compatible with existing electronic health records (EHRs) and application programming interfaces (APIs) that facilitate easy and secure data exchange between different sDHT platforms and healthcare systems.
- In the long term, creating centralized repositories for mental health sensor data, enabling secure data sharing for research and clinical purposes.
- Supporting the development of long-lasting partnerships with healthcare providers and insurers.

It is important to support the creation of **infrastructure that supports learning**, knowledge sharing and public-private cross-pollination between researchers, clinicians, technology developers, policymakers, and patient advocates. To achieve this goal, funding should:

- Support the development of open access solutions, open datasets and longitudinal observation studies that will grow public databases of information about relevant mental health conditions.
- Create centralized hubs to facilitate collaborative exploration of new targets, sensors and unmet needs in mental health. These hubs can provide platforms for multidisciplinary teams, including clinicians, engineers, and data scientists.
- Support cross-pollination through public-private partnerships. Partnerships between academic institutions, healthcare providers, technology developers, policymakers, and patient advocates can accelerate innovation and adoption of sDHTs in mental health.

> “ If open-source research can contribute to the development using the provided data, I fully support it. For me, the most important thing is ensuring the data remains accurate and isn’t manipulated. ”
>
> - *Individual with lived experience*

5.5 Improving access, equity, and inclusion

Overcoming barriers like the cost of products and inequitable access requires financial support mechanisms, inclusive design, and communication campaigns. Providing accessibility features and multilingual interfaces, and conducting community engagement will enhance trust and encourage widespread adoption of sDHTs by people with mental health conditions and clinicians alike.

Section 4 describes barriers to adoption of sDHTs stemming from lack of trust, inequity and poor access . Here, we summarize the most valuable recommendations to advance the aspects of innovation and adoption that lie beyond the technological capabilities of sensors and technologies:

Address **cost and affordability issues** to improve access to digital technologies.	• Provide financial subsidies, insurance coverage, or grants to reduce costs of the technologies and support technological infrastructure (such as charging capabilities) for patients, caregivers, and providers. • Support the development of low-cost, affordable and energy-efficient sensors and technologies. • Partner with technology developers to provide access to technologies in exchange for data insights, ensuring compliance with data privacy and security measures that protect individuals with mental health conditions.
Support culturally and demographically **inclusive design**	• Involve diverse end-users in the co-design process to ensure that technologies are tailored to the needs of specific populations. • Require implementation of accessibility features during development and testing of sDHTs, such as multilingual interfaces, content supporting varied literacy levels, simple and intuitive user interfaces, offline functionality, text-to-speech and voice command features and others.
Build **awareness and understanding**	• Provide opportunities for both healthcare providers and the general public to engage with the rationale behind the use of sDHT to build understanding and confidence. • Provide ongoing training for clinicians, caregivers, and patients to ensure intended use of the technologies and interpret their outputs. • Partner with community leaders and advocacy organizations to disseminate information, reduce stigma, and build trust in mental health sDHTs.

Addressing challenges such as the cost of products and inequitable access will require targeted financial support mechanisms, inclusive design approaches, and well-crafted awareness building. Researchers and developers should incorporate accessibility features and meaningfully engage communities to build trust and encourage widespread adoption of sDHTs among individuals with mental health conditions and clinicians.

These efforts align with the broader recommendations outlined in this report, emphasizing the need for equitable, patient-centered technologies that empower users and facilitate more effective mental health research and care. By addressing these barriers, sDHTs can fulfill their potential to transform mental health outcomes, advance research, and build trust in innovative digital health solutions.

> I definitely think there needs to be a universal baseline and ongoing monitoring of mental health across the lifespan, given the onset of mental health conditions in youth. Just like we provide free vision and hearing screens to children, the same needs to be done for mental health. That would likely require the use of technology to reach more people.
>
> - *Clinician and researcher*

6. Appendices

6.1 Glossary

Accessibility: The extent to which a technology or intervention is available and usable by diverse populations, including those with disabilities or limited resources.

Analytical validation: Evaluates the performance of an algorithm to convert sensor outputs into physiological metrics using a defined data capture protocol in a specific subject population.

Care partner: Carer, caregiver; a person who provides support - physically, emotionally, or practically - to an individual with a specific health condition, helping them manage daily life and medical needs. This role includes helping with daily needs, managing the household, and supervising health care.

Clinical validation: Evaluates whether the physiological metric acceptably identifies, measures, or predicts a meaningful clinical, biological, physical, and/or functional state or experience, in the stated context of use and specified population.

Concept of interest (COI): In a regulatory context, a COI is the measurable aspect of an individual's clinical, biological, physical, and/or functional state or experience that the assessment is intended to capture (or reflect).

Data privacy: The set of rules, regulations, practices, and/or processes that ensure only authorized individuals and organizations see patient data and medical information.

Data security: The practice of protecting digital health data from unauthorized access, corruption, or theft throughout its entire lifecycle.

Digital health literacy: Ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem.

Ecological momentary assessments (EMA): Real-time, self-reported measures of an individual's behaviors or symptoms captured through digital tools to reduce recall bias.

Effectiveness: The extent to which a technology or intervention achieves its intended outcomes.

Fit-for-purpose: In the context of use of a Digital Health Technology (DHT) in a clinical investigation, a conclusion that the level of validation associated with a DHT is sufficient to support its context of use.

High-income countries (HICs): Economies classified by their high gross national income per capita, often having advanced healthcare infrastructure.

Human-centered design: An approach to interactive systems that aims to make systems usable and useful by focusing on the users and their needs and requirements, and by applying human factors and usability knowledge and techniques.

Informed consent: Process that requires a potential trial participant (or patient receiving intervention during their health care journey) be given all of the information needed to make a sound decision about whether to volunteer to willingly participate. For informed consent to be meaningful, participants need to be "tech-literate" enough to understand the specifics of how their data will be obtained and used, or they need to be appropriately supported to understand these specifics.

Individual with lived experience: Person with lived mental health experience; someone who has personally experienced a mental health condition.

Interoperability: The ability of different information systems, devices, and applications to access, exchange, integrate, and use data in a coordinated manner, within and across organizational, regional, and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally.

Low- and middle-income countries (LMICs): Economies with lower gross national income per capita, often facing healthcare access and infrastructure challenges.

Passive sensing: The use of digital tools to collect behavioral and physiological data without requiring active input from the user, such as activity tracking via wearables.

Researcher: Person conducting research with human subjects, in a clinical, academic, or other context.

Sensor-based digital health technology (sDHT): Technology that uses sensors to collect and analyze physiological and behavioral data for health monitoring and intervention.

Sensor: A transducer that converts a physical, biological, or chemical parameter (for example, temperature, pressure, flow, or vibration) into an electrical signal. A sensor is typically hardware.

Standardization: Developing consistent protocols, metrics, and data definitions to ensure compatibility and comparability across technologies and studies.

Usability: The ease with which users, including patients and clinicians, can interact with a technology effectively and comfortably.

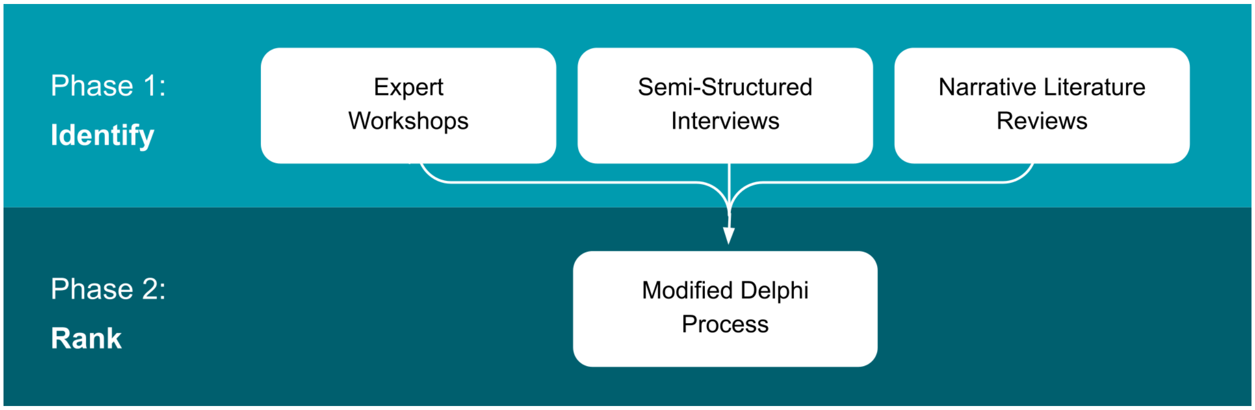
Verification: The evaluation of sensor accuracy, precision, consistency, and uniformity.

6.2 Mixed methods approach and report creation

The research was conducted in two phases (Figure 2):

- Phase 1 leveraged expert workshops, a narrative literature review and semi-structured qualitative interviews with subject matter experts to identify relevant information.
- Phase 2 used two rounds of a modified Delphi process to examine the results identified in Phase 1 and rank them according to their importance, as viewed by the Delphi panelists.

Figure 2: Schematic overview of the research methodology.



The mixed-methods approach informed the sections of the report in the following ways:

Section 3.1: Targets for digital measurement in mental health

- Phase 1 identified high-value meaningful aspects of health and concepts of interest [6].
- Phase 2 ranked the identified aspects of health into high, medium, and low importance categories, both for mental health overall, as well as for depression, anxiety, and psychosis separately.

Section 3.2: Characteristics of fit-for-purpose sDHTs for mental health conditions

- Phase 1 identified characteristics of fit-for-purpose sDHTs for mental health conditions. Additionally, insights from the mental health workshop held by Wellcome in the summer of 2024 were included. The literature review results were complemented by DiMe's subject matter expertise to inform the technology implementation and core data elements sections.
- Phase 2 ranked the identified technology characteristics using a Likert scale into "high," "medium," and "low" importance, which were subsequently categorized as characteristics of "higher" and "lower" importance.

Section 3.3: Considerations for research and development of sDHTs targeting mental health conditions

- Findings from the Wellcome mental health workshop in July 2024 were used as input for the Delphi panel, and, combined with DiMe subject matter expertise, to distill findings that inform future funding decisions for future research.

Section 4.2: Proposed mitigation strategies to address identified barriers

- Phase 1 identified mitigation strategies, complemented by insights from the Wellcome mental health workshop held in the summer of 2024, and DiMe subject matter expertise.
- For each challenge identified in Section 4.1 marked as high importance, phase 2 presented three potential mitigation strategies. The interquartile ranges were used to identify the most important

mitigation strategies - the most important were the strategies with median distribution and those that were the closest to the median by 25%.

Section 5: Recommendations for roadmaps and investments in early detection and monitoring of mental health symptoms

- The results from Sections 3-4 informed this section. The Delphi panel in phase 2 described recommendations for advancement of established and emerging technologies.
- Short-, medium-, and long-term recommendations for funding roadmaps were derived from these results.

6.3 Discussion workshops on digital sensors in mental health research: social and ethical considerations

6.3.1 Methods

The small group workshops held by Wellcome on the 9th and 16th July 2024 brought together people from different countries and with a range of experiences and perspectives to discuss the risks, trade-offs, mitigations and benefits for individuals and society from the use of digital sensors in mental health research.

Nine experts attended the workshop on 9th of July, and eight experts attended the workshop on 16th of July. Each session was held online and lasted two hours. The experts originated from Colombia, India, Kenya, South Africa, Uganda, the UK and USA. They included lived experience experts, campaigners, mental health researchers and digital technology experts, clinicians, mental health service providers and Wellcome staff.

6.3.2 Synthesis of findings

6.3.2.1 The privacy implications of digital sensors

Many attendees raised concerns about data privacy, particularly the risk of "**inverse privacy**," where researchers or developers know more about participants than participants know themselves. Examples included search histories indicating specific diseases or sensor data revealing pregnancy. One attendee noted the higher risk of identifiability when multiple data points are combined.

Attendees also discussed the **responsibility** of researchers in cases of immediate threats to life, balancing anonymised data use with the need to act quickly, and highlighted the lack of clear legal guidelines in such scenarios. **Collective privacy** was another key topic, with concerns about sensors capturing information about others, such as conversations recorded by microphones or GPS tracking revealing group habits. One researcher noted they "obfuscate coordinates" to minimize data collection and retrieve only distance travelled.

Cybersecurity concerns were a key focus, covering data collection and transfer methods, data storage risks over time, and privacy in data flows and analysis platforms. Attendees highlighted vulnerabilities like insecure Bluetooth connections and the need for clear access controls within research teams.

Discussions emphasized the role of **regulations** (such as General Data Protection Regulation and the Health Insurance and Portability Accountability Act) in improving digital technology protections, but gaps remain, particularly for sensor data not classified as personal information. Attendees stressed the importance of privacy and security by design, standard checks for bias in AI models, and addressing commercial concerns around sharing code for testing.

Funders were seen as crucial in setting **high standards for data protectio**n, with a focus on co-developing these standards with representatives from low- and middle-income countries to ensure inclusivity. Data ownership and benefit distribution were raised as critical mitigations, advocating for transparent communication about data use and participant consent, with options for renewed or staged consent.

The principle of **data minimisation** was highlighted as essential, though some attendees noted challenges in balancing this with the need for comprehensive data to support meaningful research. There was general scepticism about data maximalist approaches, with a preference for participatory risk modelling to address complex risks and harms. Attendees called for cautious evaluation of data collection practices to ensure ethical and effective research outcomes.

6.3.2.2 Rationale for digital sensor use

Some attendees raised concerns that digital sensors in mental health research **could worsen symptoms**. For example, constant monitoring might aggravate paranoia in patients with psychosis, while replacing human contact with remote monitoring for depression or anxiety could intensify feelings of loneliness. There could also be a contradiction in the use of “a potential source of anxiety as part of the solution to manage that anxiety”.

While combining human connection with digital therapies was seen as potentially positive, attendees emphasized the importance of **training** clinicians and healthcare professionals to interpret sensor data effectively, noting that devices are useless without proper understanding.

There was agreement on the need for **robust evidence to justify the use of digital sensors**. Some participants noted patient concerns about wearables being viewed as a cheaper, rather than more effective, treatment option. Attendees also discussed **research practices**, noting that excluding high-risk participants from trials limits real-world applicability. They stressed the need for mental health research to openly address unique challenges, involve patients iteratively in research design, and use multi-layered communication strategies to maximize benefits and mitigate risks.

6.3.2.3 Equity of access

Attendees discussed **equity of access** to digital therapies, highlighting challenges in low-resource settings. For example, sensors reliant on constant internet access often fail in remote areas without connectivity, while natural disasters and limited device storage further complicate usage. **Environmental factors**, such as humidity or climate, can impact sensor accuracy, and gendered differences in device placement, such as pedometers working best in pockets, affect usability.

Social factors, including device sharing in communities, or factoring in gender differences, can compromise data reliability and privacy. Researchers suggested providing dedicated devices to participants to build trust, reduce sharing, and ensure tangible benefits. Challenges were also noted in working with young people, particularly in schools where smartphones are prohibited.

6.3.2.4 Upskilling and best practice standards across industry and academia

Security and privacy concerns were highlighted, with an emphasis on implementing "**privacy by design**". Many academic researchers lack the expertise to ensure compliance and often depend on private companies for data storage, increasing potential risks. Although commercial organizations may exhibit greater accountability, the high cost of privacy measures and fast-paced development timelines often hinder meaningful community engagement. Attendees recommended standardized guidelines to promote user involvement and safeguard data security in research and development projects.

User involvement in research and development varies significantly between academia and industry. Academic researchers often aim for a slower, more thoughtful approach to community engagement, while tight timelines in tech companies often limit such efforts. There is also a lack of clear guidelines for both academia and industry that hinders consistent and meaningful user participation. Attendees suggested that regulated frameworks or mandatory rules are needed to ensure user input is integrated into product development effectively across sectors.

6.3.2.5 Working ethically with patient populations

Engaging patient populations in research requires careful consideration of the risks and **ethical complexities** involved. Participants often express concerns about the balance between their contributions and how their data is used, emphasizing that they do not want to feel exploited for the benefit of others. Vulnerable groups, such as individuals affected by poverty, are more likely to feel coerced into participation, raising ethical questions about how to ensure voluntary and informed consent in such settings.

Maintaining ethical standards also involves **understanding accessibility** and continuously **evaluating risks**. While the initial intent of research may be positive, unforeseen political or social changes could impact participants over time. Researchers must consider ways to minimize burdens, such as offering participants the ability to opt out at different stages and providing clear communication about how data will be used. Transparency and adaptability are key to fostering trust and ensuring that participants feel respected and protected throughout the research process.

6.3.2.6 Participant involvement and co-production

Researchers should avoid assuming complete knowledge of a topic or adopting an "i-methodology" that prioritizes their own perspectives over those of participants. **Engaging individuals with lived experience** as co-producers, particularly those with technical expertise in digital and data systems, is crucial for creating meaningful and inclusive research. This approach can help address the high failure rates of many apps by ensuring that solutions are designed with end-user needs in mind. **Reciprocity** is also essential, requiring researchers to equitably share the benefits of their work with participants, particularly in the settings where solutions are intended to be deployed.

Meaningful co-production involves engaging participants from the very beginning of the research process, moving beyond simple consultation to active collaboration. In this "**ladder of involvement**", techniques like iterative testing and A/B testing can refine consent processes and study designs, fostering trust and ensuring the acceptability of research methods and outcomes. Co-production benefits extend to improved recruitment, adherence, and retention, as demonstrated in examples where community preferences were incorporated, such as altering study materials to match cultural preferences. Transparent communication and layered information delivery further enhance participant engagement and ensure that research aligns with the needs of diverse communities.

While co-production is highly valued, it is inherently challenging and **lacks standard guidelines or metrics** to evaluate its effectiveness. Attendees stressed that co-production methods should be defined collaboratively by those involved in the process rather than imposed externally. Current gaps in standard practices and education limit researchers' ability to implement co-production effectively. Funders and institutions can play a pivotal role in addressing these gaps by supporting the development of guidelines, training, and resources to facilitate high-quality co-production, ultimately leading to more equitable and impactful research.

6.3.2.7 Acknowledgements

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6.4 Semi-structured interviews

6.4.1 Methods

Participants for the interviews were recruited through word of mouth, researcher networks, and social media/website posts. The study was IRB exempted under 45 CFR 46.104(d)(2) Tests, Surveys, Interviews (Exempt Research Determination from 05/03/2024 by Pearl IRB, ID: 2024-0175). After providing informed consent, participants were interviewed via Google Meet and transcripts were automatically generated. The transcripts were de-identified, reviewed for accuracy against the audio recordings, and corrected for discrepancies. The de-identified, edited transcripts were used for coding and analysis.

Data coding and organization were conducted using ATLAS.ti, a qualitative analysis software. Relevant text segments were coded, grouped into categories, and refined into broader themes to identify data patterns.

Nineteen stakeholders (11 clinicians/researchers, 7 individuals with lived experience, and 1 care partner) were interviewed between May 30th and June 20th, 2024. The clinician/researcher group (6 women, 5 men, average age 43.4 ± 10.9 years) included 6 clinicians (therapist, counselor, or physician), 3 researchers (focused on mobile health, patient data, and mental health in Africa), and 2 with combined clinical and research roles (public health and AI/machine learning). They represented high-income high-resource (n = 2), high-income low-resource (n = 3), middle-income (n = 4), and low-income (n = 2) countries, with home countries including the USA, England, Ethiopia, Zimbabwe, Nigeria, South Africa, Uganda, and Brazil.

The group with lived experience (4 women, 3 men, average age 43.9 ± 9.6 years) had diagnoses of depression, anxiety, bipolar disorder, schizoaffective disorder, or schizophrenia. They resided in high-income high-resource (n = 3), high-income low-resource (n = 1), and middle-income (n = 3) countries, including the USA, South Africa, Northern Ireland, and Brazil. One care partner from a low-income country in East Africa also participated.

6.4.2 Synthesis and analysis of findings

The interviews focused on three main areas of interest: 1) core behavioral and physiological aspects of mental health detected by sDHTs, 2) technology/device characteristics and preferences, and 3) gaps or challenges for broader adoption.

6.4.2.1 Core behavioral and physiological aspects of mental health detected by sDHTs

Sleep disruptions, including changes in duration, quality, and difficulty falling or staying asleep, were linked to anxiety and depression. Participants reported fatigue, waking frequently, or complete inability to sleep during periods of high anxiety.

Changes in physical activity levels were tied to mental health as well. Reduced activity often signaled depression, while restlessness and repetitive movements were linked to anxiety or psychosis. Participants described increased lethargy during depressive episodes and noted exercise as an important factor in maintaining wellness. This quality was also the case for an individual with schizoaffective disorder. Weight gain due to lack of physical activity was also noted across the mental health conditions.

Social behaviors such as withdrawal or, conversely, increased socializing were linked to exacerbations in mental health symptoms. Isolation was a common behavior during depressive episodes, while some participants reported using socializing and alcohol as coping mechanisms for anxiety. Monitoring social patterns may help detect underlying issues; however, establishing a baseline of one’s social behavior preferences was noted as crucial.

Elevated **heart rate**, chest tightness, and difficulty breathing were common indicators of anxiety. Clinicians noted these physiological changes, often tied to panic attacks, as key markers that sDHTs could monitor to better understand and manage anxiety symptoms. **Sweating and temperature changes**, linked to anxiety or stress, were highlighted as physical symptoms of mental health conditions.

6.4.2.2 Technology/device characteristics and preferences

Long battery life was emphasized, particularly in low-resource settings where electricity access is limited. Solar-powered or alternative charging options were suggested to enhance usability in these contexts.

Participants valued **simplicity in device design**, noting that complex interfaces could deter usage, especially for individuals with mental health challenges. Clear data presentation through dashboards that are easy to interpret for both patients and clinicians was seen as crucial.

Participants preferred technologies that allow **control over features** like alerts, feedback, and target goals. Transparency about data usage and user involvement in development were identified as key to fostering trust and adoption.

Discreet, versatile designs were preferred, with options beyond traditional wrist-worn devices, such as pendants or other accessories. Cultural and religious considerations, such as avoiding specific materials or designs, were also highlighted as critical for global adoption.

6.4.2.3 Gaps or challenges for broader adoption

Cost was identified as a major barrier, especially in low-resource settings. Clinicians emphasized the link between chronic mental illness and poverty, noting that affordability is critical for adoption. Individuals with lived experience also highlighted cost as a limiting factor, with one describing sDHTs as a luxury item beyond their financial reach. Participants suggested that high-quality features often come with prohibitive costs, making affordability a priority for wider accessibility.

Concerns about **data privacy and control** were common. Participants expressed interest in selectively sharing data with providers, such as a psychiatrist, while limiting access for others, like a midwife. Concerns were higher regarding private companies managing health data, with fears about losing control over how it is used or shared. However, some participants were comfortable sharing data with medical professionals, suggesting that trust and transparency are key factors in addressing privacy concerns.

Signal misattribution was noted as a challenge in distinguishing mental health symptoms from other activities. Clinicians highlighted the need for sDHTs to differentiate between anxiety-related signals and those caused by exercise or normal routines. For example, participants questioned whether physiological markers like sweating or heart rate spikes could reliably indicate stress versus physical activity.

Technological literacy was identified as a significant gap among both end users and clinical teams. Participants noted that users, particularly those with limited access to resources, may need additional training to effectively use sDHTs. Clinicians also emphasized the need for simple, user-friendly instructions, especially for individuals with memory issues or limited digital competence. One participant expressed frustration with adapting to modern technology, while others noted that clinicians themselves often lack familiarity with telehealth tools, further complicating adoption.

6.5 Narrative literature review

6.5.1 Methods

The primary search focused on studies using sDHTs to assess behavioral and physiological markers of depression, anxiety, and psychosis. Two databases, PubMed and EMBASE, were chosen for their comprehensive coverage. Databases like AJOL and LILACS were considered for their language diversity but excluded due to navigation difficulties, a large volume of non-English texts, and poor auto-translation quality.

Search terms (Table 11) were structured in nine layers, with layers 1-5 used as search terms and layers 6-9 as database filters. A supplemental search was added to capture studies on passive sensor technologies for depression, anxiety, and psychosis that were initially overlooked. Inclusion/exclusion criteria (Table 12) defined the scope for eligible studies.

Three reviewers conducted a rigorous multi-round review process to ensure adherence to inclusion/exclusion criteria and consensus on selected articles. In the first round, primary and secondary reviewers jointly reviewed 20% of titles/abstracts to achieve >90% agreement. If this threshold was not met, additional 20% batches were reviewed until consensus was reached. They then independently reviewed 40% of remaining publications, meeting to confirm selections and align with the third reviewer for conceptual verification. In the second round, reviewers followed a similar process with full-text articles, extracting texts for review and achieving >90% agreement through iterative collaboration. After clarifying criteria for therapeutic areas, virtual reality, artificial intelligence, and smartphones, a third round of review evaluated 143 papers, narrowing them to 58 eligible for data extraction and thematic analysis.

Data extraction and quality assessment preceded thematic analysis, using a modified CASP checklist aligned with Wellcome guidelines. Key areas assessed included: 1) mental health conditions (depression, anxiety, psychosis), 2) sDHTs, 3) efficacy, validation, adherence, usability, or feasibility, 4) detectable mental health signs/symptoms via sDHTs, and 5) gaps or limitations in technology.

Thematic analysis grouped and synthesized key findings to describe the current state of research, methods, and technologies. It also identified strengths, limitations, and research gaps, providing direction for future studies.

Table 11: Search terms

#	Theme/COIs	Terms
1	Mental Health Conditions	(“Mental Disorders”[Mesh] OR “mental health condition”[tiab] OR “mental illness*”[tiab] OR “serious mental illness”[tiab] OR “major depressive disorder”[tiab] OR “bipolar disorder”[tiab] OR “schizophrenia spectrum disorders”[tiab] OR “anxiety disorder*”[tiab] OR “post-traumatic stress disorder”[tiab] OR “psychosis” [tiab] OR “obsessive-compulsive disorder”[tiab])
2	sDHTs	(“Wearable electronic devices”[Mesh] OR “Monitoring, physiologic”[Mesh] OR "Digital Technology"[Mesh] OR "Biomedical Technology"[Mesh] OR "digital health*"[tiab] OR “digital medicine”[tiab] OR “sensor*”[tiab] OR “sensor-based”[tiab] OR "remote"[tiab] OR “connect*”[tiab] OR "electronic health"[tiab] OR "eHealth"[tiab] OR "mobile health"[tiab] OR "mHealth"[tiab] OR "health technolog*"[tiab] OR "artificial intelligence"[tiab] OR “wearable”[tiab] OR “smartphone”[tiab] OR “phone”[tiab] OR “mobile”[tiab])
3	Traits and symptoms	(“Behavior”[Mesh] OR “Signs and Symptoms”[Mesh] OR “Risk Factors”[Mesh] OR “behavior*”[tiab] OR “behaviour*”[tiab] OR “characteristic*”[tiab] OR “physiolog*”[tiab] OR “exacerbat*”[tiab] OR “relaps*”[tiab] OR “wors*”[tiab] OR “sign*”[tiab] OR “early” [tiab] “symptom*”[tiab] OR “trait*”[tiab] OR “phenotype*” [tiab] OR “biomarker*” [tiab])
4	Outcomes research	(“Patient Outcome Assessment”[Mesh] OR “Treatment Outcome”[Mesh] OR “Evidence Gaps”[Mesh] OR “outcome assessment”[tiab] OR “intervention outcomes”[tiab] “early intervention outcomes” [tiab] OR “research gaps”[tiab] OR “unmet needs”[tiab] OR “traject*” [tiab])
5	Combination of concepts	#1 AND #2 AND #3 AND #4
6	Publication date	#5 AND (2014/01/01:2024/04/05[dp])
7	English only	#6 AND (english[Filter])
8	Human adults	#7 AND “Humans”[Mesh] AND “Adult”[Mesh]
9	Publication type	#8 NOT (“comment”[pt] OR “editorial”[pt] OR “letter”[pt])
10	Separate search of the following phrases also used in PubMed:	1. “Passive sensor technology for depression” 2. “Passive sensor technology for anxiety” 3. “Passive sensor technology for psychosis”

Table 12: Inclusion/Exclusion Criteria

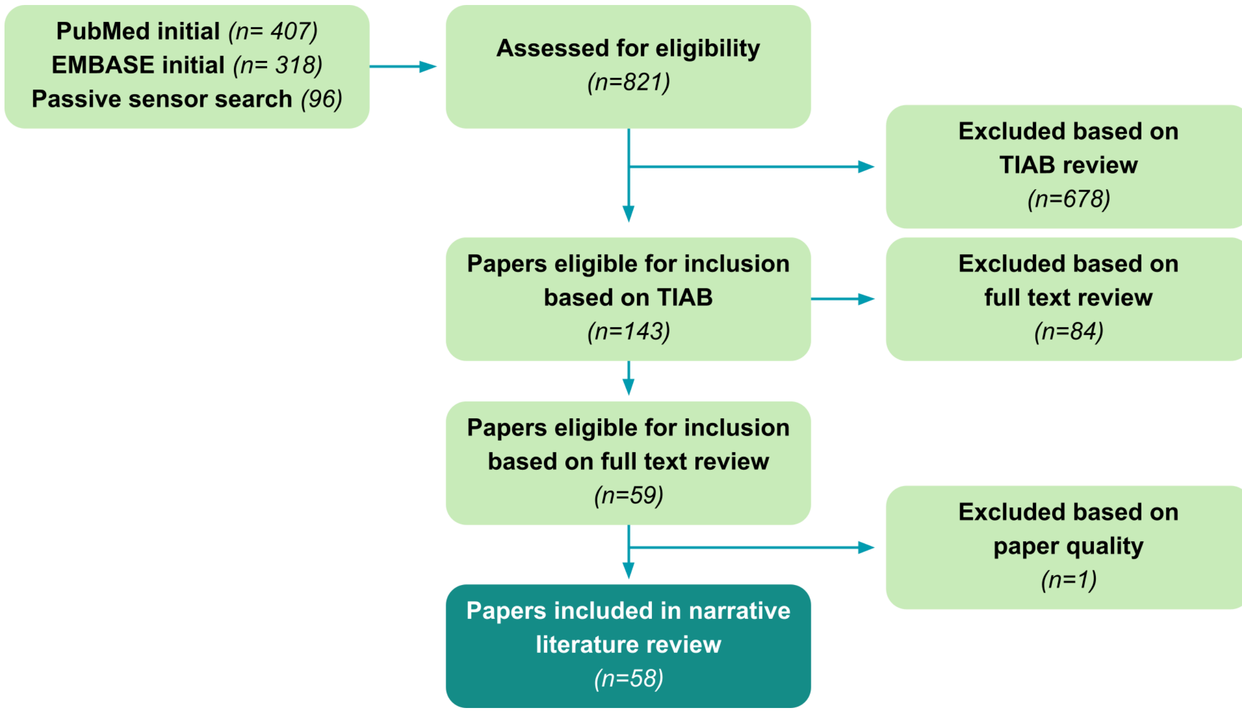
Inclusion criteria	Exclusion criteria
• Research focused on individuals with depression, anxiety, or psychosis. • Studies describing behavioral and/or physiological aspects of early symptoms and exacerbations. • Studies discussing the use of sDHTs in monitoring, predicting, or managing these mental health conditions. • Qualitative, quantitative, or mixed-methods studies including case studies, cohort studies, clinical trials, observational studies, and reviews. • Research published in the last 10 years to ensure relevance to current technology and clinical practices. • Articles written in or translated to English.	• Studies that do not focus on depression, anxiety, or psychosis, or that do not involve the use of sDHTs in these contexts. • Technologies that are not sensor-based. • Studies for which full texts are not available for in-depth analysis. • Non-peer-reviewed sources.
Foundational Determinants for Inclusion/Exclusion Criteria	
• Publications that primarily reviewed machinery or non-invasive clinical imaging technology (like CT, MRI, or X-ray) were not included. • To mitigate the inclusion of varied technology types, studies investigating mental health through non-sensor-based technologies including virtual reality, telehealth (remote assessments involving a clinician), or eHealth were not included, unless such a service or tool was combined with a sensor-based technology. • Natural language modeling (NLM) and text-to-speech or speech analysis software were included in the study.	

6.5.2 Synthesis and analysis of findings

The PubMed and EMBASE searches yielded 821 publications, of which 58 (7.1%) were included in the narrative literature review. The search adhered to the CONSORT guidelines for reviews. Figure 3 details the search eligibility process and results.

Thematic analysis resulted in 3 core themes emerging from the literature: 1) behavioral and physiological aspects of mental health captured by sDHTs, 2) characteristics of effective or acceptable sDHTs, and 3) gaps or challenges in the literature, including barriers to more widespread adoption.

Figure 3: CONSORT Diagram Search Inclusion Results



6.5.2.1 Core behavioral and physiological measures of mental health detected by sDHTs

Several studies investigated **sleep** in individuals with mental health symptoms including depression [17,18,20], schizophrenia [8,36], and anxiety [7,17]. Across studies of depression, changes in sleep measures were associated with higher depression scores. For example, longer duration in bed was associated with higher depression scores, but total sleep time can either increase or decrease due to depression on an individual basis due to the heterogeneous nature of the condition [18]. Compared to polysomnography, the sensor-based technologies often offer lower sensitivity and specificity when distinguishing between sleep and wake states [28]. Along with the studies focusing on depression, in studies of anxiety and schizophrenia, some evidence suggested sensor-based sleep measures were predictive of clinical symptoms as captured through standardized scales [17,29].

Outcomes measures for sleep found in our study were mostly focusing on sleep duration [8,36,37,68,74,75], one of the Core Measures of Sleep as defined by DiMe previous work. Other measures used included sleep architecture, sleep stability, sleep quality, insomnia, or hypersomnia [25]. Another important measure identified in the literature were changes to circadian rhythms [11,12,76], which also consist of changes to individual sleep patterns.

Measures of **physical activity** were also commonly assessed across mental health conditions, including depression [18,19,21,22,46,70], bipolar affective disorder [77], and schizophrenia [9]. In general, depression was negatively associated with physical activity, such that less physical activity, potentially compounded with other negative health and environmental factors, was related to higher depression symptoms [18]. In one study [46], physical activity as measured by step count was related to depression improvement in the context of cognitive behavioral treatment. This study also refers to a minimal daily threshold of 100 steps per day to consider potential vegetative symptoms commonly associated with major depression, yielding less than 100 steps per day; and calculates clinically meaningful reduction in BDI-II of 5 points if a patient's weekly step average increased by 300 steps each week. Though the literature often does not specify the nature of observed mobility, it would be favorable to include the context of physical activity and step count (e.g., walks in nature, walking to social engagements, etc.). Notably, lowered engagement in physical activities is found across mental health conditions including depression, depressive episodes in bipolar disorder, and schizophrenia [9]. Although patients with severe mental illness may have statistically significant lower levels of physical activity compared with healthy controls overall [63], more research is needed to understand how the levels of physical activity change across stages and severities of mental health conditions.

Though step count has been the predominant outcome measure [22,35,36,46,64,71,78], other employed outcome measures of physical activity were walking time [64], resting vs. active time, activity intensity [36,] or caloric expenditure [79]. Locations and distance traveled were also monitored to observe mobility of the individuals and thus infer their movement [14,22,23,37,71,76,78].

The detection of **social behaviors** through passive sensors is an emerging area of interest in mental health research. Various sensors can infer social behavior, including smartphone GPS to track regularly visited locations and visit duration, Bluetooth as a proximity sensor to detect closeness to others with Bluetooth-enabled devices, and microphone data to identify noisy environments [18,39,44]. Though these findings can offer useful data to form assumptions about one's social behaviors, collecting additional contextual data (for example, through ecological momentary assessment [14] or self-reported questionnaires [71]) should be advised to understand particular details of individual behaviors. Other indicators of social engagement included phone activity metrics such as outgoing SMS text message and call logs, as well as specific app usage like social media [9]. In one study, changes in depression were associated with alterations in GPS features like "location" and "transitions" in individuals with depression and anxiety - indicating both exercise and social interactions [39]. In another study with individuals with generalized and social anxiety disorders, location-derived features tended to be among the most important factors in predicting moment-to-moment symptom changes, but there were large individual differences suggesting potential for heterogeneity in the observed symptom changes between individuals [59]. In individuals with bipolar affective disorder, a decline in social communication (measured via initiated calls and SMS) and physical activity predicted increased depressive symptoms, but higher social communication and lower physical activity predicted manic symptoms [9,62]. In another study evaluating the relationship between auditory verbal hallucinations (AVH, a symptom present in a number of psychiatric disorders) and social functioning among participants equipped with a smartphone, the number and duration of phone calls was influenced by the occurrence of auditory verbal hallucinations [23].

Outcome measures for social engagement and avoidance can be inferred from either location and mobility sensing (GPS, Bluetooth, passive microphone recording), or from device or application use (calls, SMS, engagement with specific apps). Often, these measures were coupled with questionnaires and ecological momentary assessments to assess self-reported specifics about individuals' conditions (e.g., how much control schizophrenia patients feel they had over their AVH). Alternatively, coupling datasets (e.g., phone usage with battery level to exclude times when devices were powered off) could be advised to ensure correct interpretation of collected data.

Heart-related measurements, such as resting heart rate [59,68] and heart rate variability (HRV) [45,59,80,81], are important for understanding physiological stress and can indicate autonomic nervous system dysfunction. Some studies even included symptoms related to temperature, blood pressure, and respiration [9]. Heart rate is frequently measured in the context of stress, a common symptom across many mental health conditions. Psychological stress increases heart rate and decreases the standard deviation of interbeat intervals.

Several studies showed elevated baseline heart rates in individuals with bipolar disorder, PTSD, and panic disorder. However, these studies did not collect contextual data on physical activity of the participants to elaborate on the potential cumulative causes of the elevated baseline heart rate levels. In these studies, measured heart rate was either collected together with sleep data [76] or together with self-reported mood tracking [79]. Heart rate variability - variation in time between each heartbeat - is a better established outcome measure connected to stress and anxiety. Low HRV has been associated with anxiety disorders and stress [82], whereas high HRV is thought to indicate good emotion regulation abilities [83]. Measurement of HRV captured by sDHTs has been used to develop algorithms assessing various levels of stress [45] and has shown potential in assisting therapeutic interventions as a measure of biofeedback during HRV biofeedback training [47,81].

Speech and language are promising measures for detecting and monitoring mental health symptoms including symptoms of PTSD [65], schizophrenia/psychosis [54], depression, bipolar disorder, and mania [9]. Some of the conditions even have a set of linguistic markers; for example, "depressive language," which includes specific phrases, text sentiment, more first-person pronouns, and negative emotion words than healthy controls, etc. [60] Indeed, greater depressive language and first-person singular use was associated with increased PTSD symptom severity [65]. Several linguistic features, as assessed with natural language processing (NLP) approaches, have been mapped to both increased speech phenomena available for analysis (during disorganized, disconnected speech) and decreased speech phenomena (such as impoverished content, reduced fluency) in individuals with psychosis [54].

Outcome measures of speech are often presented as speech-NLP markers, an innovative genre of biobehavioral or biosocial markers [54]. Though NLP-derived markers show great promise, they rely on good representation of the population in the training samples. For example, men tend to be overrepresented in psychosis clinics, and thus the gender imbalance in the training sample may bias the final relapse prediction model to perform better in men. Some language models currently in use are known to replicate societal bias against women and LGBTQ2+ communities [54]. Other than NLP-derived outcome measures, it is possible to measure speaking rate, number of pauses, pitch (loudness), and speaking duration [14,23,55]. Many of these factors have been shown to be predictive of depression severity [29,65].

6.5.2.2 Technology/device characteristics and preferences

A caveat of sDHT use has been a **reduction in battery life**, a hardware characteristic. An integrated analysis on mobile phone sensors highlighted that participants noticed as much as a 3-hour decrease in battery life per one charging from a fully charged device when using an application that scanned Bluetooth and GPS every 5 minutes in the background for the following assessment of localization and proximity measures [15]. In this study, the majority of participants reported that battery life was affected by the study app.

A different study on depression and anxiety reported **technical issues** due to lack of internet connection or wrong phone settings, resulting in lost data [76]. Hardware challenges may also vary by geographic location. A study in rural Nepal noted main feasibility challenges included phone battery charging, data usage exceeding prepaid limits, and the burden of carrying a mobile phone [21].

Many studies focused on **wearable watches** (like FitBit, AppleWatch, Vivofit, Actiwatch) or smartphone app interventions leveraging GPS, microphones, and light sensors [17,18,37,46,71]. Many **smartphone apps** were Android-only or limited to older iOS versions, potentially due to changes in newer iOS versions that often amend or hinder some of the app functionalities accessing data from hardware sensors [10,21,29]. Several of the apps were developed to be compatible with both Android and iOS operating systems [8,76].

Compatibility of software for integration with electronic medical records (EMRs) was also discussed in the literature as not yet a ubiquitous capability [9]. When integrated and interpreted within EMRs, providers could make use of passively collected data in everyday care. However, this interoperability between software platforms is not yet in place and would require implementing best practices and measures of data security and patient privacy per specific regional regulations and requirements.

Apart from sensing technologies that incorporate **ease of use** in their original design (such as watches, patches, mobile phones, etc.), the literature also included other sDHTs like electroencephalograms (EEGs) and electrocardiograms (ECGs) that have high functionality but typically require some level of clinical monitoring or involvement. Coupling such more complicated sensor technologies (such as finger EEGs) with apps or software solutions (for example, the immersive 3D video game Dojo for adolescents experiencing anxiety) appears promising to deliver enhanced engagement and ease of use for their target users [80].

Lastly, device or software functionality may be adapted based on the **study population context.** Much can be learned from other applications of DHT-based interventions in low-income areas, such as reducing the app file size, supporting a wider range of smartphones, cultural adaptation of content, incorporating considerations around connectivity and data transmissions, the impact of battery charging availability, etc. [84]

6.5.2.3 Gaps or challenges for broader adoption

While the literature spanned multiple mental health conditions within the categories of interest, including depression, anxiety, schizophrenia, PTSD, psychosis, and bipolar disorder, most of the studies were in the **pilot or feasibility testing phase** [18,47,85], often using already-validated sensors in a new specific clinical population and context. Certain devices were primarily researched in the context of interventions but have not been integrated into practical use following the pilot study [8,14,23,35,54,56].

There were also **methodological concerns** and lack of consistency across studies. For example, in the depression literature, the methods used for determining depression severity were not consistent from one study to another. Sample sizes were often small, resulting in limited generalizability or sampling bias (e.g., college students).

Though useful and promising, sensor technologies have their limitations when it comes to processing data, and particularly **disambiguating signals from noise**. In the literature, we indeed saw such difficulties with signal detection systems, particularly for mobility monitoring for depressive social isolation [44,70]. Additionally, for studies detecting ambient audio or speech, background noise or muffled sound often limited sound and speech analysis [12,54,86].

Some papers noted that **lack of standardization** and calibration of sensors limits comparisons across studies, as smartphone and wearable devices contain different combinations of central processing units (CPUs), graphics processing units (GPUs), and operating systems, or measure the same concepts in different ways (e.g., different sampling rates in accelerometry) [9]. Though few hardware changes can be expected between different device makers, better standardization of specific outcome measures (e.g., setting minimal requirements on sensor performance and output) is the key to unified and standardized digital technology-derived outcome measures for specific clinical populations and contexts.

Lack of sensor precision was also noted in one study, which led to participant frustration due to inaccurate GPS location data [10]. In another study, GPS or activity data were not collected in some instances due to participants spending time indoors, issues with connectivity, or issues with phone charging [21]. Where machine learning models are used to evaluate data, issues may arise from low sensitivity or specificity, or biases based on the used training data [11].

Other studies outside of mental health have demonstrated that the **desire to seek novel measures or interventions and adhere to them** is higher among participants with a higher illness burden or condition severity [86]. In the literature, we saw that participants with a higher illness burden (e.g., history of admission to hospital, history of suicide attempts) due to bipolar disorder were more likely to have perfect or high adherence [74].

Several studies depended on self-reported ecological momentary assessments (EMAs) from patients and a combination of ecological momentary interventions (EMIs), but it is unclear how this process would **translate to real-world experience** [38,59,72,87]. Though possibly providing a powerful tool to collect real-time self-reports without recall bias or loss of context, EMAs and EMIs also have limitations in potential minimization of symptoms, or may be perceived as disruptive, creating a burden to complete frequent assessments during the day. Adherence was also variable depending on the duration of follow-up, decreasing with longer follow-up duration. Across the literature, studies followed individuals using sDHTs from 2 weeks up to 7 months. The source of recruitment also impacted adherence and drop-out rates, with an open-enrollment study noting high drop-out as compared to targeted participant recruitment [10]. Patient, user, and clinician education around sDHTs may help on this front as only one study mentioned user education in the context of schizophrenia [73].

Therefore, developers of solutions employing sDHTs should strive to produce user-friendly and engaging training materials and offer additional resources or contact information to support continued use of these technologies. Improved user experience may also result from **engaging users/patients in designing tools and research studies**. sDHT-based solutions often involve debates over privacy issues, and study participants frequently cite privacy as an area of concern, especially in remote monitoring studies [68]; in contrast, most papers merely described their methods for **protecting data privacy**, which included secure communication with external servers, anonymization of data, scrambling audio (rendering speech incomprehensible), or processing data locally as opposed to sending them to an external server [10].

6.6 Modified Delphi process

6.6.1 Methods

Our Modified Delphi process consisted of remotely completing online surveys designed to gather expert opinions and develop recommendations for the use of digital technologies in mental health. The study was IRB-exempted under 45 CFR 46.104(d)(2) Tests, Surveys, Interviews (Exempt Research Determination from 10/24/2024 by Pearl IRB, ID: 2024-0448). We administered two rounds of surveys to gather insights on the identified topics. After each survey round, the results were analyzed and shared back with the participants. After the surveys were completed, we offered three timeslots for voluntary debriefing calls, where the results were further presented and discussed with the participants.

After the completion of the literature review and the semi-structured interviews with stakeholders, a list of themes was drafted to incorporate the findings from both approaches. The themes were checked for redundancy and to ensure that they were relevant to the objectives of this project. Themes were reviewed by the team and the final list was converted into questions for the Modified Delphi Questionnaire. In the first survey, the four major themes that emerged were: 1) end-user requirements and preferences for technology characteristics, 2) barriers to adoption, 3) addressing gaps and areas for future research and development, and 4) core measures of mental health detected using sDHTs.

As context may play a role in the importance of the themes, the first round of Delphi survey was drafted to elicit recommendations based on 3 cases: 1) an individual with lived depression experience in the USA, 2) an individual with lived anxiety experience in Argentina, and 3) an individual with lived psychosis experience in Nigeria (Table 13). The questions were the same for each case in the first round of the survey. The response options provided to the participants for evaluation were developed from the results of the previous project research, including the literature review, patient interviews, and expert workshops. Before the scenarios were provided, demographics and socioeconomic information were collected about the participants. Feedback from the Wellcome team and academic advisory committee was utilized to finalize this survey before sharing it with the Delphi panel.

Table 13: Modified Delphi survey scenarios, first round.

Case 1: Beth is a 35-year-old woman who has been managing symptoms of major depression for the past decade. She currently takes antidepressant medication, which has helped, but she still experiences periods of extremely low mood that interfere with her ability to work and participate in activities she enjoys. She tends to feel her mood "“slipping” before these periods of extreme lows. She sees a therapist 1-2 times/month. Despite having access to advanced healthcare in the USA, there is limited availability of local mental health services where she lives. She meets with her therapist remotely via Telehealth. Beth’s therapist noted that Beth sometimes misses sessions due to her depressive episodes, making it difficult to monitor her mental health consistently. Beth owns a smartwatch, which she mostly uses to track physical activity and sleep patterns. Sometimes she experiences challenges - for example, difficulty navigating complex interfaces when she is feeling depressed or anxious, and also unreliable data tracking on the smartwatch, such as pinpointing the precise time when she falls asleep. Her therapist asked if she’d be willing to participate in a research study, where she would be asked to share information from her smartwatch to better understand if there may be relationships between Beth’s activity levels/sleep and her mood. This data will be available to her therapist and two more people in the study team. Beth has concerns about privacy, as the therapist did not have a way to directly integrate Beth’s information into her electronic health record. She is worried that someone other than her therapist and study team may access her data without her knowing.
Case 2: Chioma is a 23-year old woman living in Nigeria who has been experiencing symptoms of psychosis. She faces significant challenges in accessing care. The nearest hospital is located in the city, which is costly and difficult to travel to. Chioma owns an old mobile phone which she uses to call and text her parents. However, her phone calls are now scarce and her family became concerned when she stopped calling and visiting. She would spend most of her time isolated in her room, speaking to herself. Chioma's symptoms include hearing voices of people that are not there and believing that she is being watched or followed. Her condition has made it hard for her to maintain daily activities, and she often forgets to eat. Chioma’s parents are worried about the stigma associated with mental illness in their community and are unsure how best to help her. A group of volunteer researchers offer to drive Chioma to the nearest hospital once per month to meet with a mental health team. They also offer her participation in a research study, where she would receive a better phone and use it to monitor her sleep and speech with its microphone. They say regardless of her decision to participate in the study, they would still make the trip to the hospital every month.
Case 3: Mateo is a 40-year-old man who has been managing anxiety symptoms for the past twenty years. He is not currently taking medication or receiving consistent medical treatment due to the high costs. Mateo feels a sense of worry and tension about work and family pressures. He occasionally experiences panic attacks where his heart races and he feels sweaty, which he most commonly attributes to stress. Despite his openness to technology, Mateo has limited access to digital health tools where he lives in rural Argentina. He once purchased an inexpensive wearable device to monitor his heart rate, but it broke, and he has not been able to replace it. Mateo faces significant barriers in managing his anxiety disorder. The lack of affordable medications and specialized care means he has to rely on his own strategies to cope. The stigma around mental health in his community further complicates his situation, making it difficult for him to seek support openly. Mateo understands the potential of digital health technologies to monitor his symptoms, even if he has not been a frequent user. He has been offered participation in a research study, where he can sign up for receiving a high-end smartwatch from the researchers for the duration of the study. He would be asked to answer questions on the smartwatch and share his health data. He is considering whether to enroll in this study.

In the second round of the survey, the scenarios from the first round set the specific contexts of use for the sDHTs (Table 14): 1) clinical research vs. clinical care, 2) high vs. low income and healthcare access region, 3) established vs. emerging technology, and 4) value proposition and future outlooks for sDHTs. Feedback from the Wellcome team and academic advisory committee was utilized to finalize this survey before it was shared with Delphi panelists from high-, middle-, and low-income countries.

Table 14: Modified Delphi survey scenarios, second round.

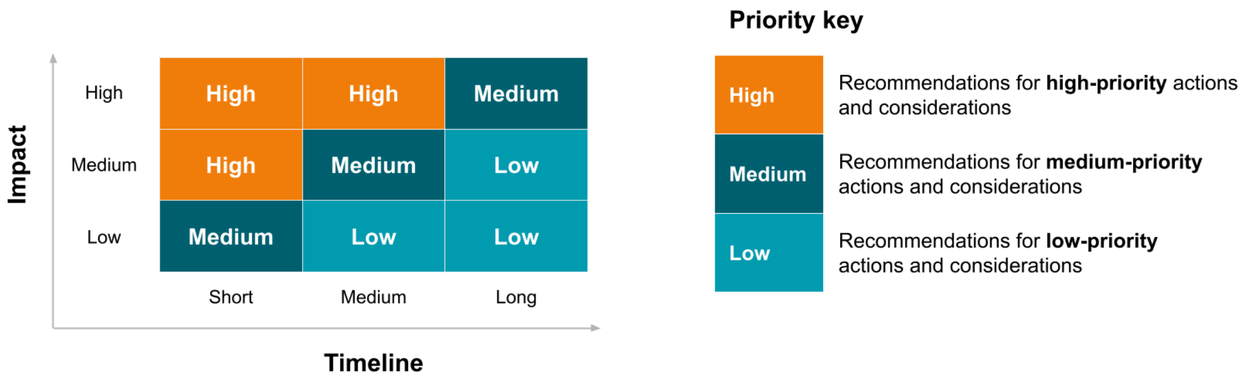
Case 1: Digital Technologies in Clinical Research of Mental Health Let's revisit the three individuals from our previous discussion: Beth, living in the USA, with depression, she relies on telehealth for therapy due to limited access to in-person care. Chioma, in Nigeria, facing worsening psychosis with little to no access to effective treatment. Matteo, in rural Argentina, enthusiastic about digital health technologies but limited by both access to technology and therapy options. Imagine Beth, Chioma and Matteo were all invited to participate in a clinical research study testing a new therapy for their respective conditions. This engagement is short-term, lasting two months, during which they will be provided with the necessary digital health devices for the research. These devices, equipped with advanced sensors, will be used to continuously measure changes in their symptoms. By capturing this data points, the sensors help assess the effectiveness of the therapy on their conditions. Their involvement includes consenting to the study, following study procedures, using the devices provided, and collaborating with the research team to ensure accurate data collection.
Case 2: Digital Technologies in Long-Term Mental Health Care and Monitoring Well done! Our three participants - Beth, Chioma, and Matteo - have successfully completed a clinical research study testing a novel therapy for their mental health conditions. Years later, these therapies have been approved and are now available globally. Thanks to advancements in digital health, these therapies are designed to be used alongside digital tools. These include connected devices for collecting data, algorithms that evaluate specific aspects of the mental health condition, and feedback loops that provide insights to the clinicians, enabling them to monitor progress and adjust treatment plans for their patients as needed. The patients are asked to use these devices together with therapy to better assess its effects in real time and communicate data to their clinical care team. The devices can be also used to communicate with their clinicians, therapists, and other professionals involved in their clinical care journey. Beth, Chioma, and Matteo now have the chance to receive this innovative therapy. However, it requires long-term engagement involving commitment to long term device use, data sharing, and evaluation of insights with their clinician. This will be useful for ongoing monitoring and evaluation of individual response to treatment and trajectories of their condition. For this scenario, let's assume that all three participants own a suitable device and have access to the necessary technological infrastructure (such as connectivity or charging) for this therapy.
Case 3: Regional, Cultural, and Accessibility Considerations Until now, we have focused on general scenarios, setting aside the specifics of regions, cultures, and access to healthcare and technology. Let's now dive deeper into these critical aspects by considering the unique circumstances of each individual. Though Beth lives in a rural area in the United States with limited access to specialized healthcare, she has resources that make navigating these challenges easier. She owns a car and can drive to the nearest city for therapy, prescriptions, or medical procedures. Her health insurance covers most of her medical expenses. She has a well-paying job, enabling her to purchase technology like a smartwatch online and get it delivered to her home without significant financial strain. Chioma lives in rural Nigeria, where access to specialized healthcare is much more limited. She does not have access to personal transportation, making it difficult to reach distant clinics or hospitals. There is little to no health insurance coverage available, leaving her to bear the full cost of the specialized healthcare services. Limited internet access and outdated infrastructure mean she cannot easily access the latest technologies, such as a

smartwatch.
Case 4: Advancing Established Technology for Mental Health Populations Imagine a well-established technology; for example, validated sensors and algorithms to measure sleep in mental health conditions. These technologies are accurate, reliable, and supported by extensive research. Imagine the measurement of sleep is increasingly being integrated into mental health care and research with the goal of enhancing outcomes and advancing understanding the relationship of sleep to mental health in various conditions. The developers of these technologies want to ensure effective, long-term use in mental health conditions supported by scientific evidence. This involves addressing potential gaps in its adoption and deployment; and exploring how it can excel in quality compared to other available solutions.
Case 5: Advancing Emerging Technologies for Mental Health Populations Emerging digital sensor technologies are being actively researched to enhance mental health assessment and intervention. An example of such new sensing technology could be a wearable patch sensor or smartwatch algorithm that analyzes restlessness and repetitive movements associated with stress and anxiety. The researchers and developers of these technologies want to ensure that their products are functional, robust, scientifically valid, and effective. While still in the research and development phase, the creators have the unique opportunity to set up systems, infrastructure, and commercial and non-commercial initiatives to position the technology for successful implementation and adoption.
Case 6: Future Outlooks for Digital Health Technologies in Mental Health In this survey, we've explored the current state of digital health technologies and their implementation in mental health care, various conditions, geographical and access considerations. Now, let's imagine the possibilities a hundred years into the future. Based on your expertise and experience, imagine you could design any kind of future technology for mental health conditions. What would you want to measure or understand about mental health conditions (such as depression, anxiety and psychosis) that is currently lacking effective or accessible technology? Where do you see the greatest opportunities for digital sensing technologies to deliver the most significant value in improving mental health care and outcomes? For example, as an early indicator, faster diagnosis, therapy effectiveness, continuous monitoring, uncovering underlying condition mechanisms, enabling more precise stratification of patient populations, etc.

The collected qualitative data with response options were analyzed using descriptive statistics. The qualitative data collected from the open text fields were thematically analyzed and coded according to the presented themes. Where a scoring or rating of the presented concepts was a part of the question, a 5-point Likert scale was used. To further evaluate the responses, we calculated a weighted average to interpret the results. Each rating on the Likert scale (1-5) was multiplied by the total count of the responses (how many people chose that rating). Then, we divided the results into *Low*, *Medium*, and *High* categories based on the range of scores. The cutoff points for Low, Medium, and High categories were determined by analyzing the distribution of the weighted averages and dividing them into three distinct ranges

In the two cases of considerations to advance adoption of established and emerging technologies, the participants were asked to rate the timeline and impact of the provided actions and activities. The results were then placed in a prioritization matrix that positions the timeline on the horizontal axis and impact on the vertical axis (Figure 4). Verbatim quotes from the participants were also noted and we present them throughout this report.

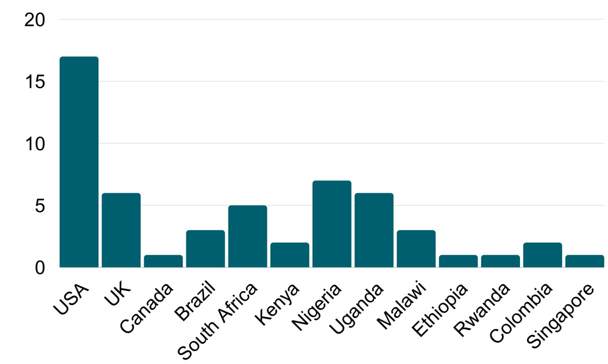
Figure 4: Prioritization matrix for evaluation of the questions that assess timeline and impact of the proposed strategies and actions.



The participants for both rounds of the survey originated from high-, middle-, and low-income countries and covered a wide spectrum of expert categories (lived experience, clinicians, researchers, care partners, and others), as well as ages, care access levels, and experience with the use of sDHTs (Figure 5). The participants were allowed to select multiple category designations, explaining the variety in responses. The first survey was conducted with 52 participants and the second survey was conducted with 49 participants. Two more participants joined after the first survey was concluded, and 6 participants provided their insights only in the first survey, but not the second one.

Figure 5: Participant overview for modified Delphi process.

Country



Expert category

56.4% Lived experience *(n=31)*

32.7% Care partner *(n=18)*

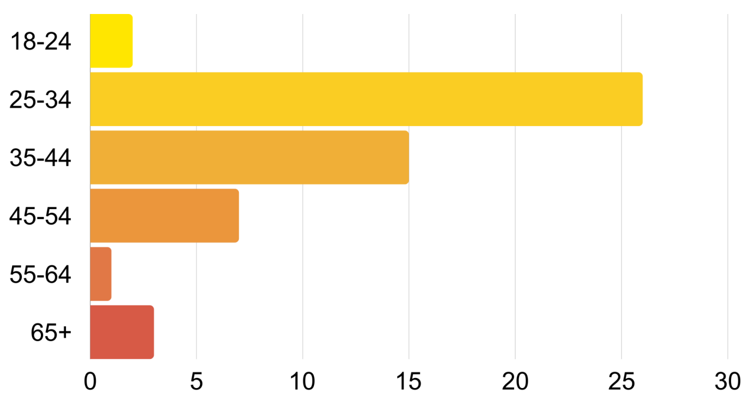
25.5% Clinician *(n=14)*

43.6% Researcher *(n=24)*

12.7% Other *(n=7, e.g., public health professionals, administrators, policy-makers, physicians)*

*(*Experts could indicate their alignment with more than one category of specialization)*

Ages of participants (Years)



Participant categories overview

12 Lived Experience (LE)
2 Care partners (CP)
3 Clinicians
10 Researchers
1 Other
5 LE + CP
4 LE + Researcher
1 LE + Other
1 LE + Clinician
2 CP + Researcher
1 CP + Clinician
3 Clinician + Researcher
1 Clinician + Researcher + Other
1 LE + CP + Other
2 LE + CP + Researcher
1 LE + CP + Clinician
1 LE + Clinician + Researcher
1 CP + Clinician + Researcher
1 CP + Researcher + Other
1 LE + CP + Clinician + Other
1 LE + CP + Clinician + Researcher + Other

55 Total

6.6.2 Synthesis and analysis of findings

6.6.2.1 Modified Delphi survey round one

6.6.2.1.1 End-user requirements and preferences for technology characteristics

In this section, we asked participants the following question:

"*Please consider the presented use-cases and your knowledge of signs and symptoms of depression. Please read the list of the technology/device characteristics below, and indicate those you would recommend as the most important factors for technologies used as interventions and in research in depression.*"

The same question was presented for cases of depression, psychosis, and anxiety, and response options were rated with a Likert scale: *Definitely not, Probably not, I'm not sure, Probably yes, Definitely yes*. Figure 6, Figure 7, and Figure 8 show the rating of response options for each of the three presented cases. Table 15 lists the technology/device characteristics for use of digital health technologies as interventions and in research in the presented cases of depression (high-income country, limited access), psychosis (lower middle-income country, low access), and anxiety (upper middle-income country, low access).

The qualitative data provided additional insights into desirable technology characteristics. Ability to maintain function without user interaction or when offline, ability to provide feedback or insights from data, availability of tech support, and non-obtrusiveness and trustworthiness of technologies were the most frequent desired technology characteristics. Other suggestions included affordability, style of the product (i.e., blending with other accessories and not visually indicative of a mental health condition), GPS, gamification and usable interface, features for improved access (multiple languages, text-to-speech, etc). We feature the verbatim responses in section 3.2.

Figure 6: Recommended technology characteristics for the presented case of depression, as rated by participants. Please use Table 15 as the legend for this figure.

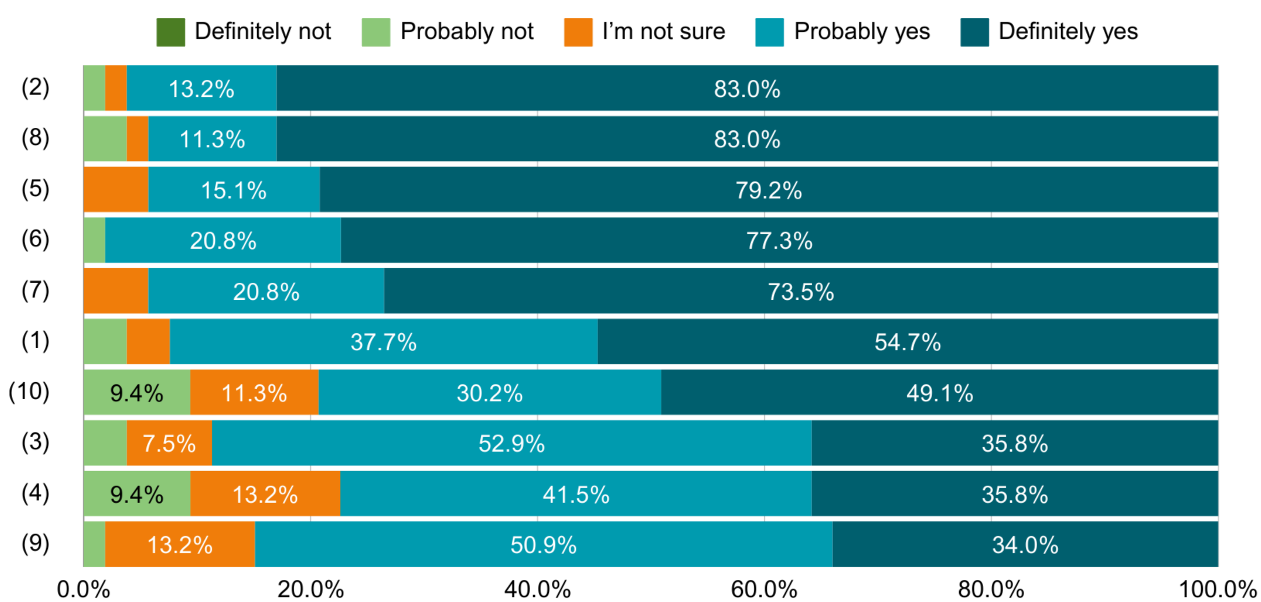


Figure 7: Recommended technology characteristics for the presented case of psychosis, as rated by participants. Please use Table 15 as the legend for this figure.

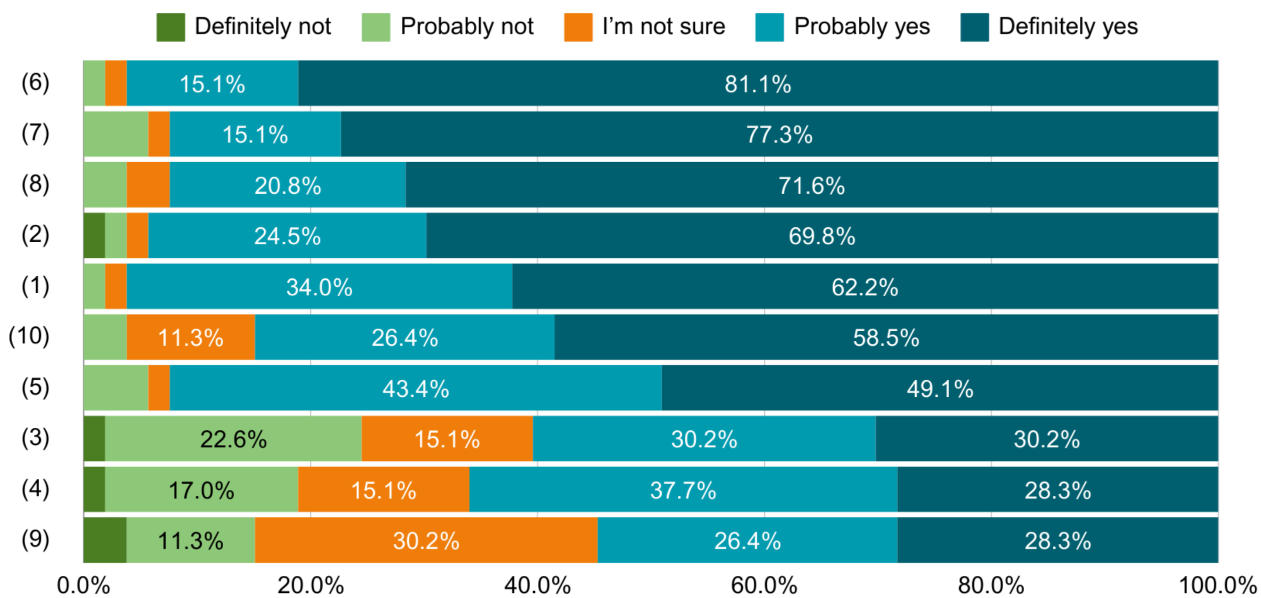


Figure 8: Recommended technology characteristics for the presented case of anxiety, as rated by participants. Please use Table 15 as the legend for this figure.

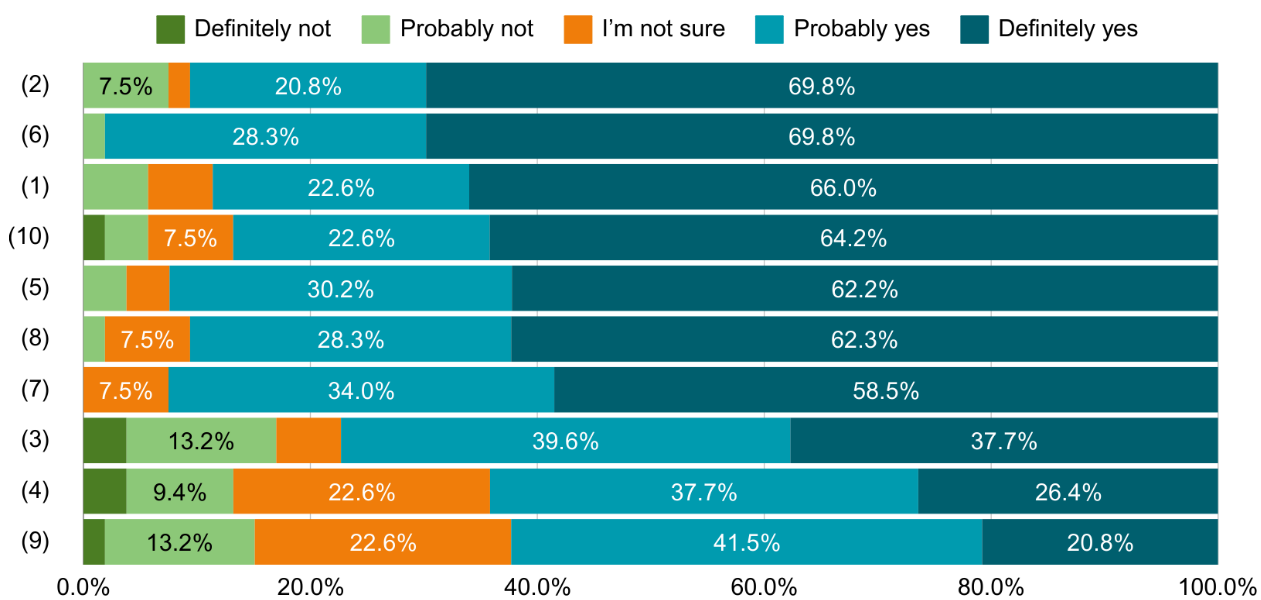


Table 15: Technology characteristics for use of digital health technologies.

(1) Long battery life
(2) Good usability
(3) Customization and personalization
(4) Availability of multiple device forms/types
(5) Reliable sensor performance
(6) Reliable hardware and software performance
(7) Good data security measures
(8) Good data privacy measures
(9) Device interoperability
(10) Resistance to environmental factors

6.6.2.1.2 Barriers to adoption

In this section, we asked our participants:

"Please continue to consider an example case and your knowledge of depression/psychosis/anxiety. For each of the items below, indicate whether you think it may be a significant challenge or barrier to using a sensor-based device for healthcare and research purposes in people who struggle with depression."

The same question was presented for cases of depression, psychosis, and anxiety, and a Likert scale was provided to rate the response options: *Never a challenge, Usually not a challenge, I'm not sure, Usually a challenge, Always a challenge*.

When assessing barriers to adoption, the respondents differentiated between the diagnoses and contexts (such as access to care or environmental factors) of the presented case studies - mostly viewing the challenges as more pressing in the low access and low resource settings. Figure 9, Figure 10, and Figure 11 show the rating of response options for each of the three presented cases according to the presented Likert scale. Table 15 then lists the barriers to using sensor-based technologies.

From qualitative data, the most predominant challenge not mentioned in the options was interpretation of other medical factors that can confound the findings about one's mental health state Other identified challenges were lack of education about sDHTs, lack of support from providers' and individuals' networks, technology interference with habits or therapy (needing to charge the device or interact with it at certain times or for a certain duration of time), or the technology design not being appropriate to population characteristics (e.g., sociodemographics). From the responses, we can assume that trust in technology used in health or medical settings is more subjective and context-dependent. We feature the verbatim responses in section 4.1.

Figure 9: Challenges or barriers to using a sensor-based device for healthcare and research purposes in the presented case of depression, as rated by participants. Please use Table 16 as the legend for this figure.

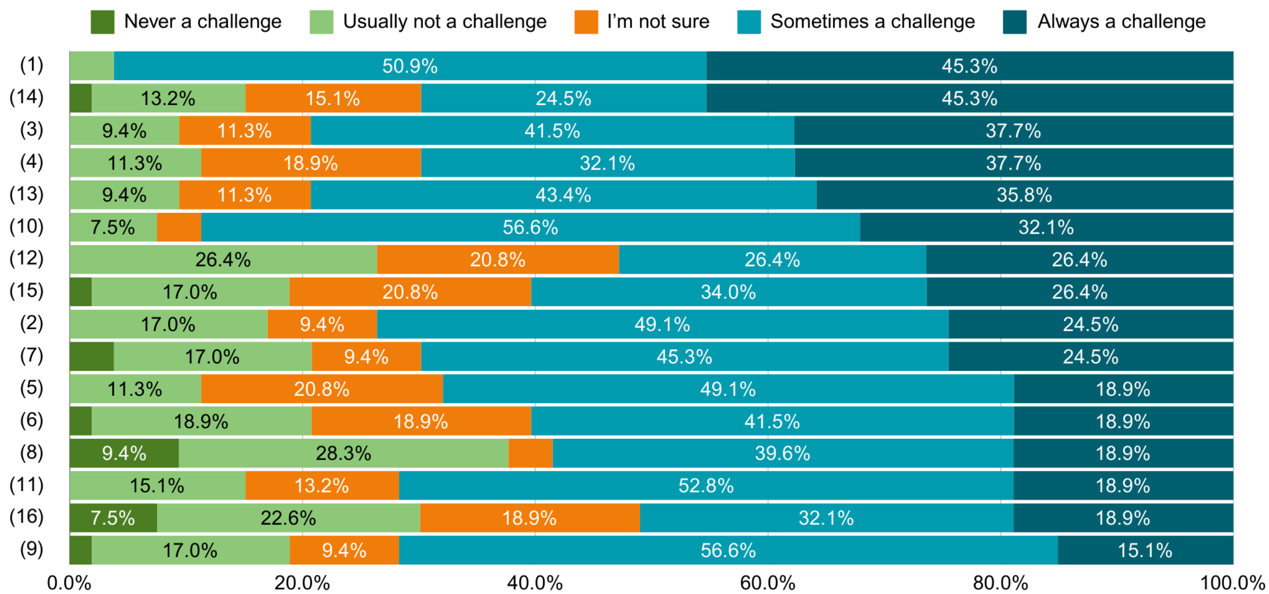


Figure 10: Challenges or barriers to using a sensor-based device for healthcare and research purposes in the presented case of psychosis, as rated by participants. Please use Table 16 as the legend for this figure.

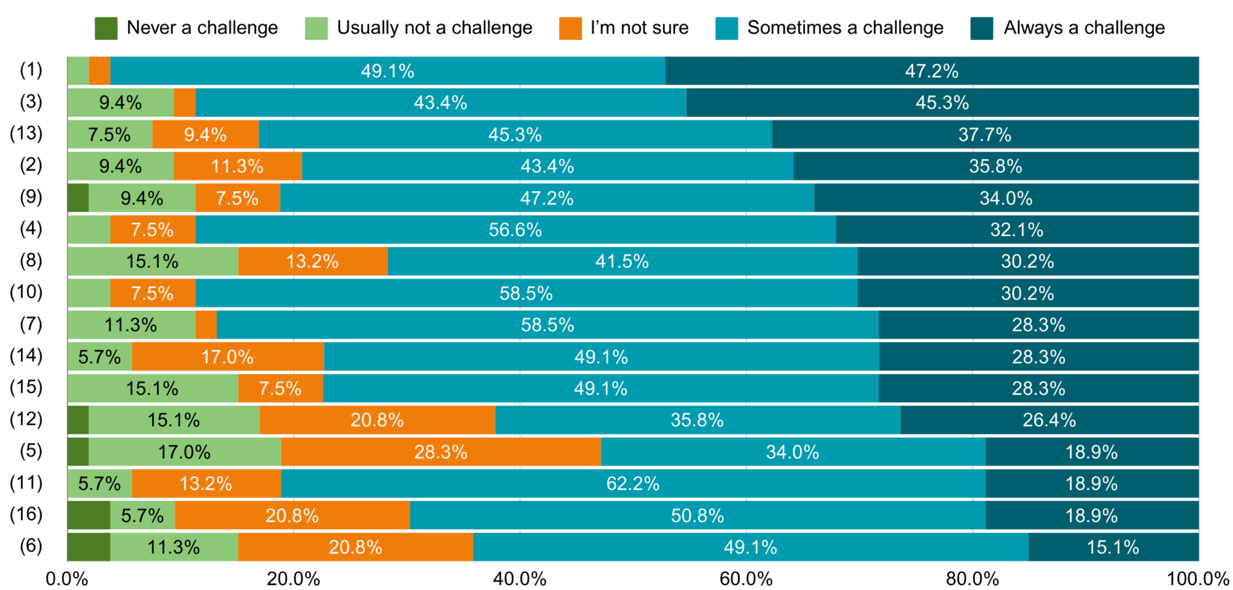


Figure 11: Challenges or barriers to using a sensor-based device for healthcare and research purposes in the presented case of anxiety, as rated by participants. Please use Table 16 as the legend for this figure.

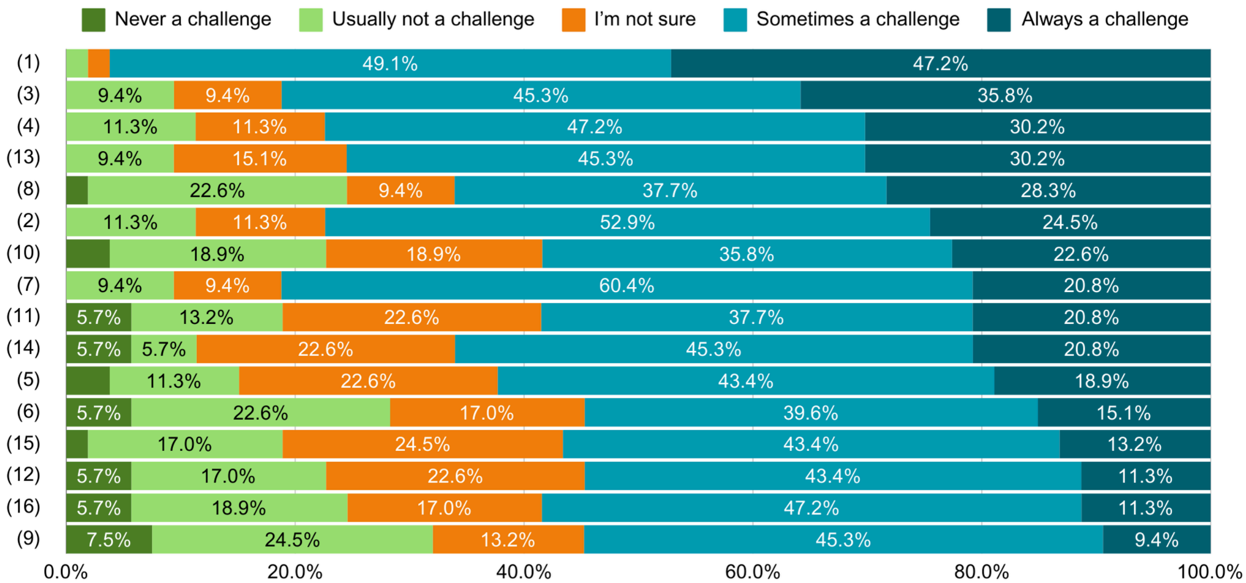


Table 16: Challenges or barriers to using sensor-based technologies

(1) Cost and limited access to devices
(2) Truthful analysis of data within individual contexts
(3) Data privacy concerns
(4) Cybersecurity concerns
(5) Not being able to see results on an individual level
(6) Not enough evidence on the use of sDHTs in mental health
(7) Limited access to connectivity
(8) Limited access to charging/electricity
(9) General distrust in technology in health/medical setting
(10) Poor technological literacy, education, and training - patients
(11) Poor technological literacy, education, and training - providers
(12) Devices and apps not culturally appropriate
(13) Tech not adapted to needs of population with mental health issues
(14) Lack of involvement in development of study, technology, or apps
(15) Ethical issues in development and implementation
(16) Inadequate informed consent process

6.6.2.1.3 Addressing challenges and mitigation strategies

When a participant identified a specific barrier or challenge as important, they were presented with several mitigation strategies and asked to select the most suitable ones for the issue. From these options, the participants selected up to three most important mitigation strategies. Based on these answers, we were able to identify the most appropriate mitigation strategies, captured in Table 6 in this report.

6.5.2.1.4 Core measures of mental health detected using sDHTs

The respondents were initially invited to rate the core aspects of health uniformly for all the explored mental health conditions (Figure 12):

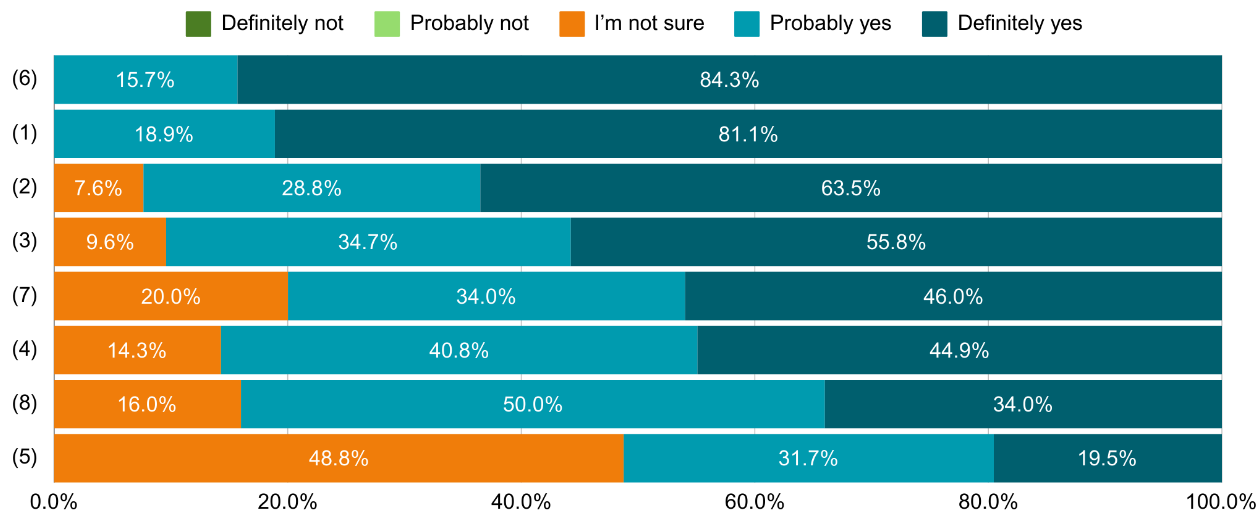
"Please consider the presented use-cases and your knowledge of signs and symptoms of mental health conditions (such as depression, anxiety, or psychosis). For each of the behavioral or physiological measures listed below, indicate whether you would recommend it as an area/measure of interest for signs and symptoms of said mental health conditions."

The participants then evaluated the measures with a Likert scale: *Definitely no, Probably no, I'm not sure, Probably yes, Definitely yes*. If participants marked a specific core aspect of health as an important target to measure, they were invited to evaluate the specifics of this measurement target for each of the three conditions (depression, anxiety, psychosis) in additional question that followed:

"*For each of the items that you selected, please prioritize the top three specific signs and symptoms you believe are most important for detecting and monitoring for each of the three areas (depression, anxiety, or psychosis).*"

An example would be selecting "sleep" as the main concept, and then options such as "sleep duration" or "sleep quality" for each of the conditions. The participants were able to select up to three of the options that they considered the most important. Based on the answers to both the initial selection and the expanded selection, we were able to identify the most appropriate measurement targets for mental health, captured in Table 2 in this report. We feature the verbatim responses in section 3.1.

Figure 12: Recommendations of the Delphi participants for behavioral or physiological measures of mental health (all three conditions combined): (1) Sleep (changes in how much and how well a person sleeps), (2) Physical activity (change in how much or how well a person moves or exercises), (3) Heart rate-related symptoms, (4) Breathing-related symptoms, (5) Body temperature and subjective temperature perception, (6) Social behavior (spending time with family, friends, or associates; visiting social places; interacting with online social networks; etc.), (7) Speech and language, (8) Gastrointestinal symptoms (eating, digestion, etc.).



6.6.2.2 Modified Delphi survey round two

6.6.2.2.1 Digital technologies in clinical research of mental health

In this section we asked our participants:

"Think about your knowledge and experience in mental health and research setting (if applicable). Also, consider the results from the first round of our survey. For the purposes of this question, please assume all have access to the intervention. To make sure that individuals are safe, comfortable, supported, and engaged in this research study, which aspects would you recommend the research teams prioritize?"

The participants then evaluated the aspects with a Likert scale: *Crucial, Important, I'm not sure, Nice to have, Not important at all.* Figure 13, Figure 14, and Figure 15 show the rating of response options by the participants. Table 17 then shows the response options arranged by importance of considerations for the use of sDHTs in clinical research according to the rating, based on weighted averages of the response data.

In addition to the response options, qualitative feedback was collected via open text fields. We feature the verbatim responses in section 3.2.2.1.

Other topics considered interesting to explore included:

- Creating a **motivating interface** - i.e., one with prompts that encourage healthy habits ("Move alert cleared!" "Well done!" etc.).

- Building a sense of **community** via a platform-type experience, such as anonymized online chats or forums, if the nature of the study allows it and it would not create additional biases for the research.
- **Offline solutions**, which are particularly important in poor and hard-to-reach areas without power or internet access.
- **Instant messaging,** such as WhatsApp, as a more successful channel of communication than emails or phone calls in some parts of the world.

Figure 13: Rating key recommendations and considerations to ensure individuals feel safe, comfortable, supported, and engaged while participating in clinical research on people with mental health conditions who utilize sDHTs: Before the study. Please use Table 17 as the legend for this figure.

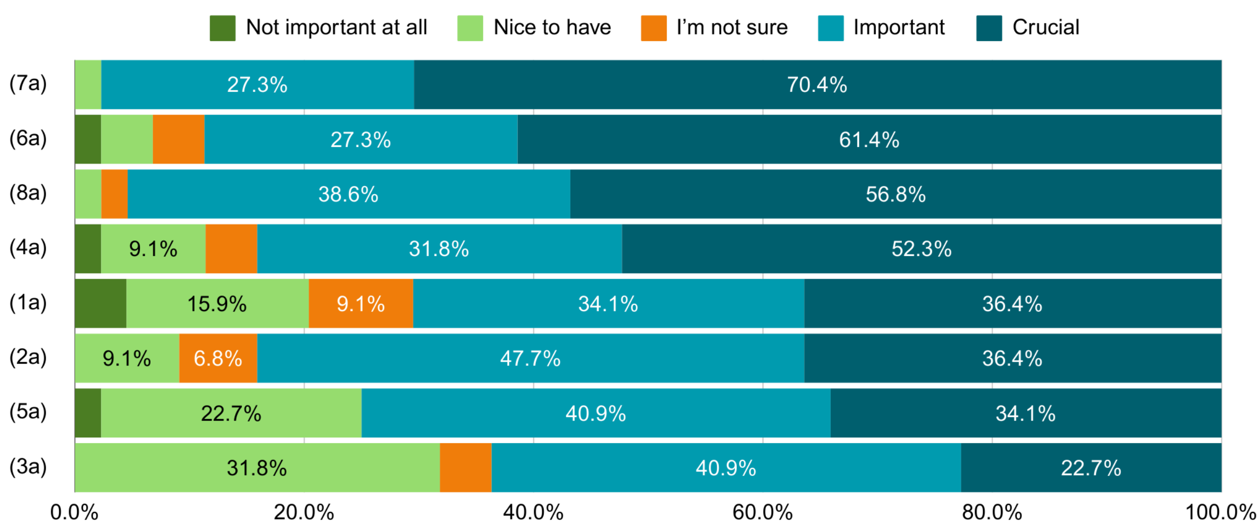


Figure 14: Rating key recommendations and considerations to ensure individuals feel safe, comfortable, supported, and engaged while participating in clinical research on people with mental health conditions who utilize sDHTs: Technology considerations and data collection. Please use Table 17 as the legend for this figure.

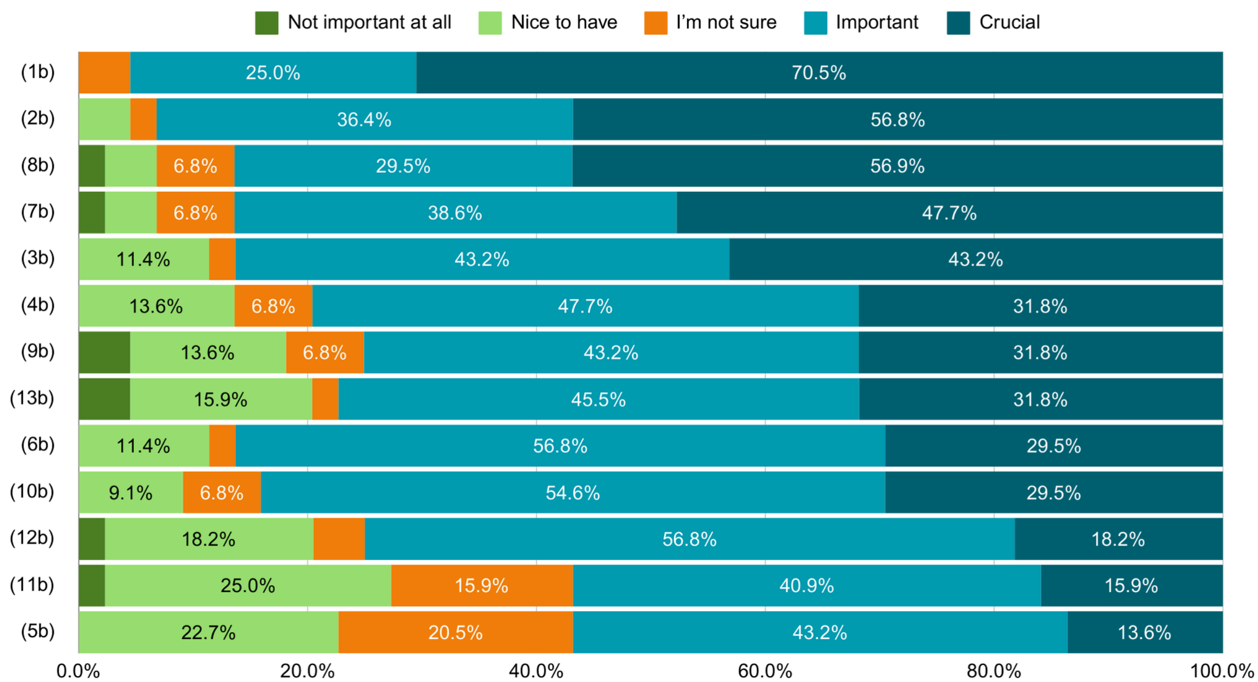


Figure 15: Rating key recommendations and considerations to ensure individuals feel safe, comfortable, supported, and engaged while participating in clinical research on people with mental health conditions who utilize sDHTs: Accessibility, inclusion, education, and support. Please use Table 17 as the legend for this figure.

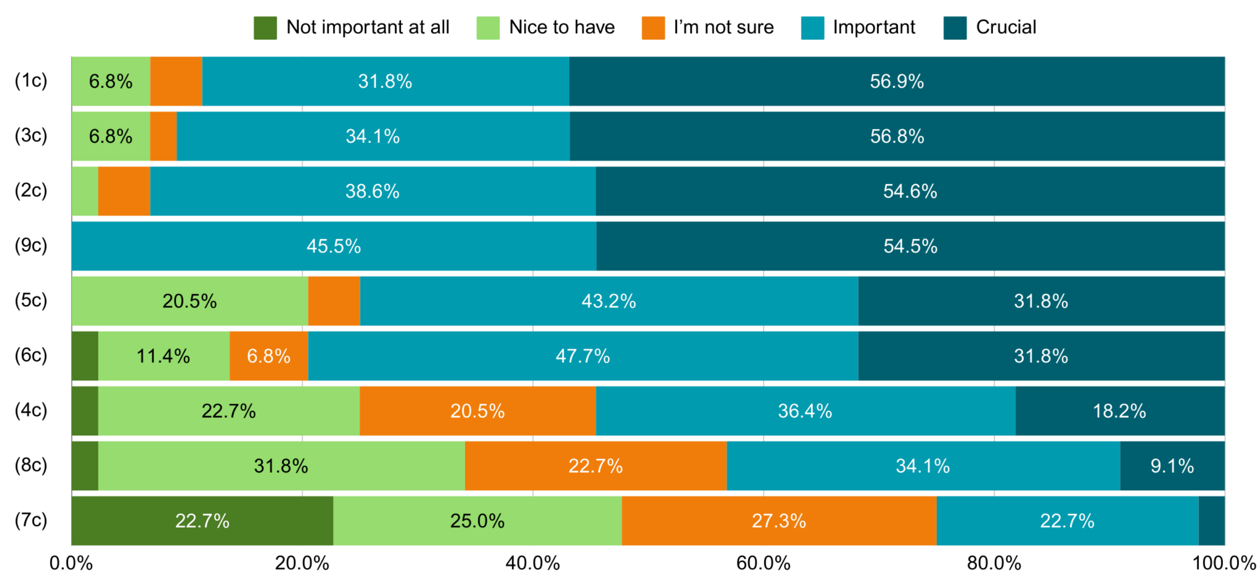


Table 17: Rated importance of considerations that will ensure individuals feel safe, comfortable, supported, and engaged while participating in clinical research on people with mental health conditions who utilize sDHTs, according to the calculated weighted average from the survey responses.

<table>
<tr><td>Considerations of high importance for clinical research</td><td>
Before the study

(2a) Establish participants’ level of experience with sDHTs
(4a) Train participants to use the technology before the study
(8a) Collect baseline data about participants
(6a) If applicable, provide connectivity or offline options
(7a) Implement good data privacy and security measures

Technology considerations and data collection

Technology needs to be

(1b) Easy to understand, operate, and use
(2b) Reliable, in both hardware performance and sensor readings
(3b) Discreet, unobtrusive, and comfortable
(4b) Password-protected, with password shared only with the participants

(6b) Information about data privacy and security need to be readily accessible to the participants during the study
(7b) Participants and (8b) investigators and study team need to be alerted about sudden changes in their readings that may indicate changes in their clinical state, and be able to act upon these alerts
(10b) Standardized questionnaires and surveys should be collected during specific time points in the study (e.g., every 2 weeks)

Accessibility, inclusion, education and support

(1c) Accessibility features should be part of the technology design (translations, larger fonts, text to speech, etc.)
(2c) Participants need to be fairly compensated for their participation in the study
(3c) Participants need to have the option to opt out of the study at any time in a way that is transparently communicated and actionable
Support should be provided to participants via (5c) phone and/or (6c) assigned contact person
(9c) After the end of the study, participants should be informed about the study results

</td></tr>
<tr><td>Considerations of medium importance for clinical research</td><td>
Before the study

(1a) Active involvement in co-creation of the research and influencing decisions about the technologies used
(3a) Allowing participants to test the technology before committing to participating in the study
(5a) Additional information provided about the rationale for the research, scientific context, or real-world use of similar approaches

Technology considerations and data collection

(9b) Input of additional signs and symptoms in the technology interface at any time (e.g., in the form of a diary or responses to questions)
(12b) Ability for participants to see tailored feedback from their data readings in real time throughout the study
(13b) Ability for investigators and study team to see feedback from the collected data of participants’ data readings in real time or near real time throughout the study

</td></tr>
</table>

Considerations of **low importance** for clinical research	**Technology considerations and data collection** • (5b) Ability to customize or personalize the technology or its alerts, notifications, or outputs to participants' specific needs • (11b) Smaller and shorter assessments of participants' condition and wellbeing collected throughout the day (for example, "What is your mood right now?") **Accessibility, inclusion, education and support** • (4c) Support should be provided to participants via email • (7c) After the end of the study, participants should return the technologies/devices to the study team • (8c) After the end of the study, participants should keep the provided technologies/devices for personal use

6.6.2.2.2 Digital technologies in long-term clinical care for mental health

In this section we asked our participants:

"*Think about your knowledge and experience in mental health care. Also take into consideration the results from the first round of our survey. For the purposes of this question, please assume all have access to the intervention. To make sure that individuals are safe, comfortable, supported, and engaged in this health care setting while receiving the intervention for their condition, which aspects would you recommend the healthcare teams most focus on?*"

The participants then evaluated the aspects with a Likert scale: *Crucial, Important, I'm not sure, Nice to have, Not important at all.* Figure 16, Figure 17 and Figure 18 show the rating of response options by the participants. Table 18 then shows the response options arranged by importance of considerations for the use of sDHTs in clinical practice and care according to the rating, based on weighted averages of the response data.

In addition to the response options, qualitative feedback was collected via open text fields. We feature the verbatim responses in section 3.2.2.2.

Other topics considered interesting to explore included:

- The technology should be **comfortable** to wear and not glaring or obvious, to **prevent further stigmatizing** the individuals.
- **Refresher trainings** and routine checks by the technology manufacturers might be considered.
- All communication should be provided in the patients' and clinicians' preferred language.
- Providing additional **incentives** for clinicians.

Figure 16: Participants' evaluation of key recommendations and considerations for the use of sDHTs in clinical care: Before implementation. Please use Table 18 as the legend for this figure.

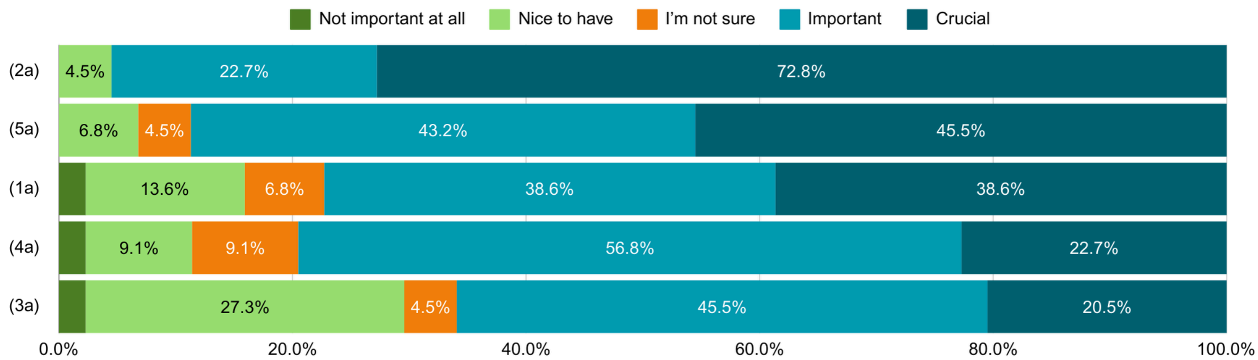


Figure 17: Participants' evaluation of key recommendations and considerations for the use of sDHTs in clinical care: Technology considerations and data collection. Please use Table 18 as the legend for this figure.

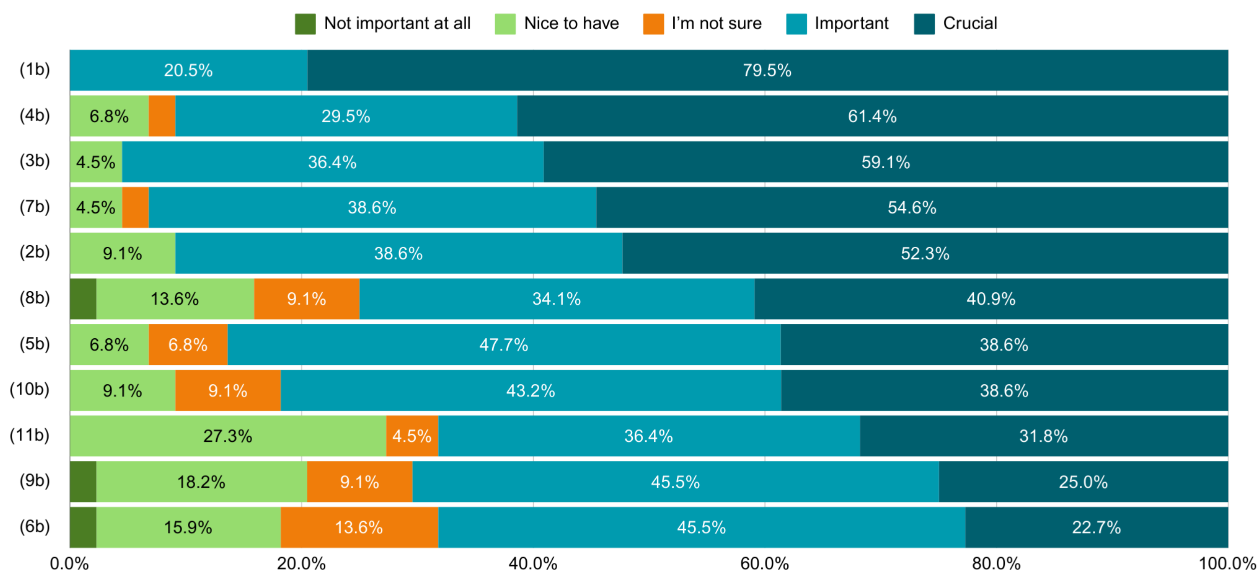


Figure 18: Participants' evaluation of key recommendations and considerations for the use of sDHTs in clinical care: Accessibility, inclusion, education, and support. Please use Table 18 as the legend for this figure.

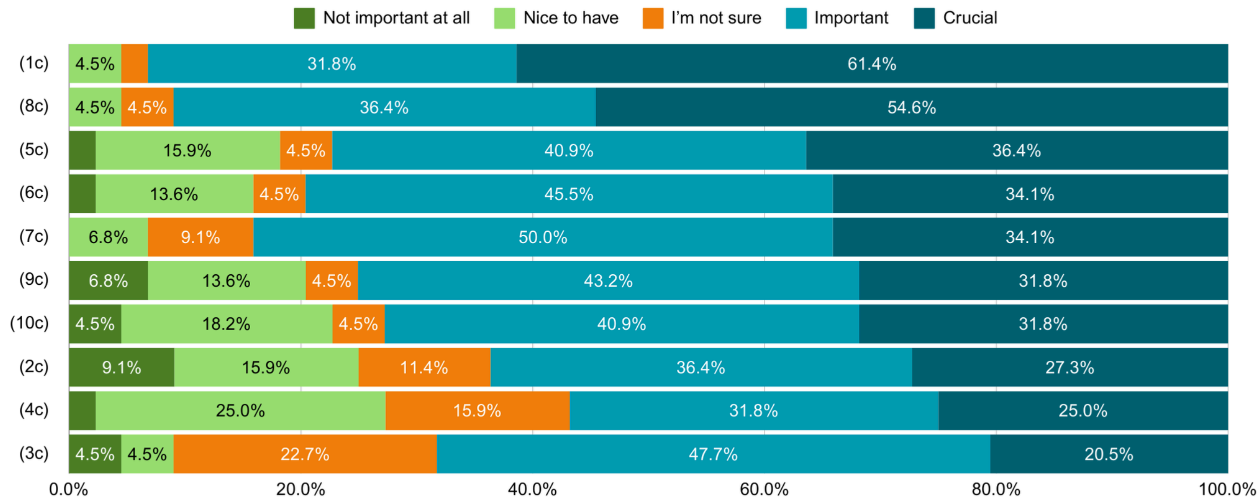


Table 18: Rated significance of considerations that will ensure individuals feel safe, comfortable, supported, and engaged during the continued use of sDHTs in clinical care for mental health conditions, according to the calculated weighted average from the survey responses.

Considerations of **high importance** for clinical care	**Before implementation**
	• (2a) Both patients and clinicians should be trained on how to use the technology prior to its use in their mental health care
	• (5a) If required in a specific location, connectivity options need to be provided to the patients and providers
	Technology considerations and data collection
	• Technology needs to be
	  ○ (1b) Easy to understand, operate, and use
	  ○ (2b) Discreet, unobtrusive, and comfortable
	  ○ (3b) Reliable, in both hardware performance and sensor readings for long periods of time
	  ○ (5b) Password-protected, with password shared only with the patients
	• (4b) Good data privacy and security measures need to be in place and transparently communicated to the patients and clinicians (where their data go, how the data are protected, who has access to the data, how the data will be analyzed, etc.)
	• (7b) Clinicians need to be alerted about sudden changes in their patients' readings
	• (10b) Clinicians should be able to see feedback from the collected patient data in real-time or near real-time (e.g., via dashboard)
	Accessibility, inclusion, education and support
	• (1c) Accessibility features should be part of the technology design (translations, larger fonts, text to speech, etc.)
	• Patients and clinicians need to be alerted about sudden changes in their readings that may indicate changes in their clinical state, and be able to act upon these alerts

	○ (7c) Patient alert actions: confirm, add more information, reach out to the clinician, request support, etc. ○ (8c) Clinician alert actions: reach out to the patient, share with the care team, etc.
Considerations of **medium importance** for clinical care	**Before the implementation** ● (1a) Both patients and clinicians need to be invited into the implementation, planning, and testing of the technologies used during the intervention ● (4a) Patients and clinicians should be provided additional information and scientific rationale about the use of the technology for their specific condition **Technology considerations and data collection** ● (8b) Patients need to be able to input signs and symptoms that may indicate changes in their clinical state into the technology interface at any time and be able to act upon such changes (confirm, add more information, reach out to study team, request support, etc.) **Accessibility, inclusion, education and support** ● Support should be available to patients and providers via (5c) phone and (6c) assigned contact person at any time ● (3c) Patients should have the option to use the therapy independently, without relying on the accompanying technology ● (9c) Continuous education (in the form of remote learning, seminars, newsletters, etc.) on the science, advancement, and use of the technology in mental health settings should be available to the patients, clinicians, and communities ● (10c) The patients need to have options for connecting with peers or support groups virtually or locally
Considerations of **low importance** for clinical care	**Before the implementation** ● (3a) Training should be available for the patients' families or care partners **Technology considerations and data collection** ● (6b) The patients need to be able to customize or personalize the technology or its alerts, notifications, or outputs to their specific needs ● (9b) Patients should be able to see tailored feedback from their data readings in real time or near real time ● (11b) Feedback from collected data should be available to other people on the patient's' care team if necessary (for example, other specialists) **Accessibility, inclusion, education and support** ● (2c) Patients should be able to use technologies/devices they already own ● (4c) Support should be provided to patients and providers via email

6.6.2.2.3 Regional, cultural, and accessibility considerations

In this section we asked our participants:

"*What technological and non-technological solutions would you recommend to best address the unique challenges and needs in each of these two scenarios?*" (scenarios in section 6.4)

"*Think about your knowledge and experience in mental health care. Also take into consideration the results from the first round of our survey. For the purposes of this question, please assume all have access to the intervention. To make sure that individuals are safe, comfortable, supported, and engaged* *in this health care setting while receiving the intervention for their condition, which aspects would you recommend the healthcare teams most focus on?*"

The participants then evaluated the aspects with a Likert scale: *Only for low access/resource, More for low than high access/resource, Equally important for both, More for high than low access/resource, Only for high access/resource.* Figure 19 and Figure 20 show participants' rating of response options. Table 19 then shows the response options arranged by recommendation importance and considerations for the use of sDHTs in high- and low- resource and access to care settings. The findings from this section were incorporated into the recommendations (section 5) in this report.

The participants were also able to provide qualitative feedback:

- *"For Chioma [low resource setting], focus on community-driven initiatives, such as training local mental health advocates and improving access to affordable medications," - Individual with lived experience and care partner*
- *"In the case of Chioma's circumstances [low resource setting], it is quite obvious that she needs more financial support for technology costs or access. Financial support should be more for patients with low access and resources," - Individual with lived experience and clinician*
- *"Both all need to be treated equally without any discrimination," - Individual with lived experience, clinician, and researcher*
- *"I feel setting shouldn't determine these factors. Best practice should apply in both contexts. HC and LMIC are misnomers; there are people in LMIC with high income country opportunities and the same in reverse. The population/individual is more important," - Researcher*
- *"Overall, having no insurance or being underinsured is a barrier, makes seeking help harder, and can be discouraging. I've found this to contribute to decreased mental well-being - [it is] a point of consideration," - Individual with lived experience*
- *"Consider using mobile health units who can reach people in rural areas," - Care partner*

Figure 19: Participants' evaluation of recommendations and considerations for the use of sDHTs in high- and low- resource and access to care settings: Technology considerations and data collection. Please use Table 19 as the legend for this figure.

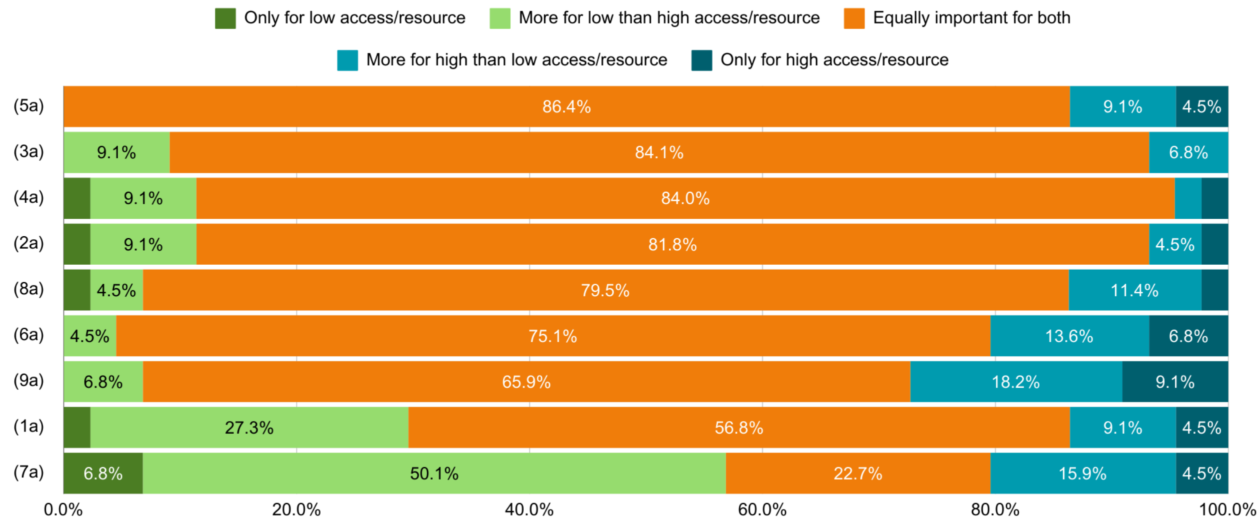


Figure 20: Participants' evaluation of recommendations and considerations for the use of sDHTs in high- and low- resource and access to care settings: accessibility, inclusion, education, and support. Please use Table 19 as the legend for this figure.

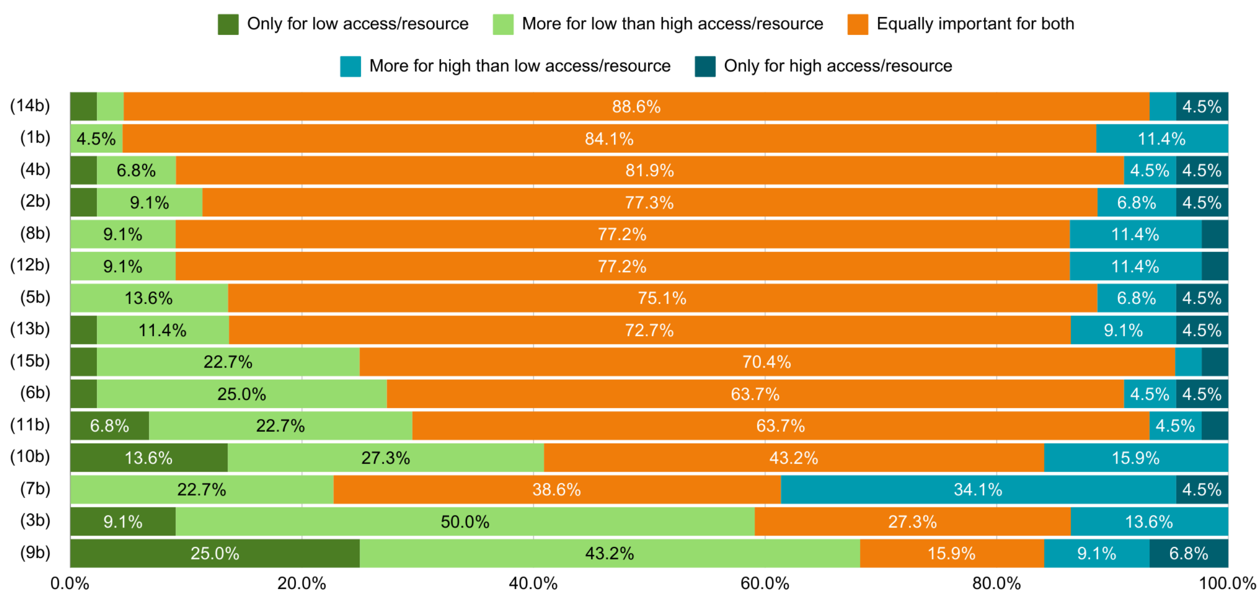


Table 19: Rated importance of considerations and recommendations for the use of sDHTs in high- and low- resource and access to care settings, according to the calculated weighted average from the survey responses.

Considerations found as equally important for both high- and low-resource and access to care settings	**Technology considerations and data collection** • (2a) Designing technology as user-friendly and easy to operate • (3a) Sustainable and environmentally friendly solutions • (4a) Reliable performance and accurate sensor readings over time • (5a) Strong data security and privacy safeguards • (8a) Providing feedback to technology users in a suitable format (physical or electronic), tailored to their resource settings, accessibility needs, and preferences for clarity and relevance **Accessibility, inclusion, education, and support** • (1b) Co-designing the solutions and technologies with patients and clinicians • (2b) Collaborating with local researchers or clinicians • (4b) Accounting for individual differences (symptoms, comorbidities, lifestyle) in technology design • (5b) Providing accessibility features (translations, larger fonts, text-to-speech, etc.) • (8b) Combining digital tools with in-person care for comprehensive support • (12b) Offering 24/7 support for patients and/or clinicians (via phone, email, or contact person) • (14b) Including options for connecting with peers or support groups virtually or locally
Considerations slightly more important in low-resource and access to care settings	• (6b) Offering training and materials based on literacy levels and tech experience • (13b) Educating families, local organizations, and communities • (15b) Providing volunteering programs to enhance access and support
Considerations slightly more important in high-resource and access to care settings	• (6a) Providing customizable and personalized features • (9a) Ensuring data can seamlessly integrate with healthcare providers or provider networks • (7b) The ability to use technologies/devices the user already owns
Considerations substantially more important in low-resource and access to care settings	• (7a) Offering offline functionality • (1a) Producing durable, long-lasting technology with extended battery life • (3b) Providing support for data access, connectivity, and charging infrastructure (data plans, communal spaces with Wi-Fi, etc.) • (9b) Financial support for technology costs or access • (10b) Expanding insurance to cover technology solutions • (11b) Technology literacy education for users

6.6.2.2.4 Advancing established technology for mental health populations

In this section we asked our participants:

"*Below is a list of actions designed to address gaps in the implementation and adoption of well-established sensor-based technologies, such as sleep monitoring tools, for sustainable use in mental health care and research. Based on your experience, how would you categorize each action in terms of: timeline - how quickly it can be implemented and deliver results, and impact - how big the effect of the action would be once implemented?*"

The provided response options were evaluated by the participants with the presented likert scale (*Timeline: Short-term win (Quick to implement with immediate benefits), Medium-term gains (Requires moderate effort and shows results over time), Long-term results (Requires significant effort or long-term changes to achieve results); Impact: High impact (Creates significant and lasting benefits), Moderate impact (Provides meaningful but limited benefits), Low impact (Contributes minimally to patient benefit).* Figure 21 shows the placement of the response options on the prioritization matrix (Figure 4). Table 20 then shows the response options arranged by recommendation priority and considerations for the advancement of established digital health technologies.

Figure 21: Participants' evaluation of recommendations and considerations for the advancement of established digital health technologies. For the response options legend, please see Table 20.

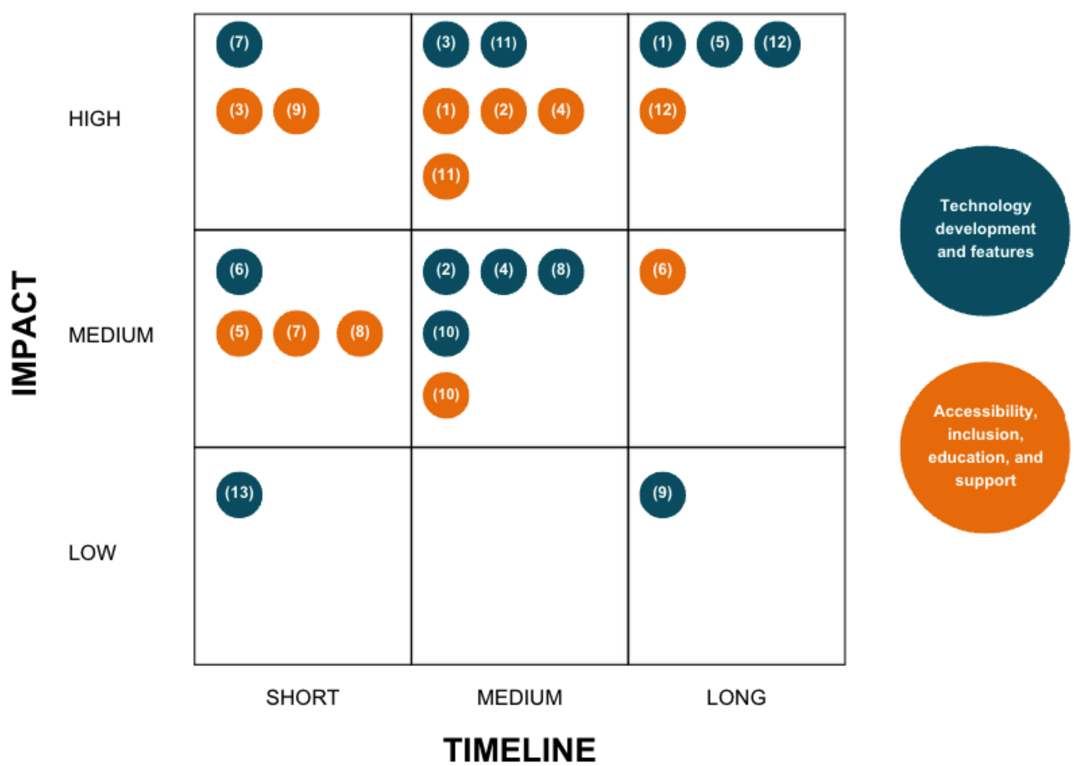


Table 20: Rated priority of considerations and recommendations for the advancement of established digital health technologies.

High-priority considerations and actions	
Short-term win, high impacts	**Accessibility, inclusion, education, and support** ● (3) Incorporate accessibility features (e.g., large fonts, text-to-speech, translations) ● (9) Offer dedicated technical support for patients and healthcare providers
Medium-term effort, high impact	**Technology development and features** ● (3) Develop portable and low-maintenance technology solutions ● (11) Engage in ongoing validation of technologies in specific patient populations and subpopulations **Accessibility, inclusion, education, and support** ● (1) Make technologies more affordable through subsidies or grants ● (2) Offer low-cost or community-shared versions of the technology ● (4) Tailor solutions to the unique needs of underserved populations and low-resource settings, such as ensuring affordability, cultural relevance, language accessibility, and compatibility with limited technological infrastructure
Short-term win, medium impact	**Technology development and features** ● (6) Enhance user experience through simplified interfaces ● (7) Add sensing modalities to measure additional metrics (e.g., GPS, stress, etc.) **Accessibility, inclusion, education, and support** ● (5) Leverage existing technologies/devices owned by participants ● (7) Provide training programs, workshops, and seminars for patients and clinicians ● (8) Launch awareness campaigns about the benefits of technology use in mental health
Medium-priority considerations and actions	
Long-term effort, high impact	**Technology development and features** ● (1) Improve device accuracy and reliability for long-term use ● (5) Ensure data interoperability with existing healthcare systems ● (12) Conduct longitudinal studies to evaluate long-term impact **Accessibility, inclusion, education, and support** ● (11) Establish partnerships with healthcare services or insurance providers for coverage or providing free healthcare at the point of access ● (12) Integrate the metrics into broader mental health management systems
Medium-term effort, medium impact	**Technology development and features** ● (2) Ensure compatibility with various hardware forms and operating systems ● (4) Incorporate AI for personalized insights, predictions, and early intervention ● (8) Improve energy efficiency and extended battery life ● (10) Gather continuous user feedback for product improvements **Accessibility, inclusion, education, and support** ● (10) Develop peer support networks and communities for users

Short-term win, low impact	**Technology development and features** • (13) Incorporate gamification features to boost engagement
Low-priority considerations and actions	
Long-term effort, medium impact	**Accessibility, inclusion, education, and support** • (6) Share data to contribute to broader mental health research
Long-term effort, low impact	**Technology development and features** • (9) Design environmentally sustainable and recyclable hardware

6.6.2.2.5 Advancing emerging technology for mental health populations

In this section, we asked our participants:

"*Below is a list of actions designed to help sensor-based technologies in their early phases of research and development to establish themselves as safe, efficient, and effective tools for evaluating mental health states and symptoms, whether in research or healthcare. Based on your experience, how would you categorize each action in terms of: Timeline - how quickly it can be implemented and deliver results, and impact - how big the effect of the action would be once implemented?*"

The provided response options were evaluated by the participants with the presented Likert scale (*Timeline: Short-term win (Quick to implement with immediate benefits), Medium-term gains (Requires moderate effort and shows results over time), Long-term results (Requires significant effort or long-term changes to achieve results); Impact: High impact (Creates significant and lasting benefits), Moderate impact (Provides meaningful but limited benefits), Low impact (Contributes minimally to patient benefit).* Figure 22 shows the placement of the response options on the prioritization matrix (Figure 4). Table 21 then shows the response options arranged by recommendation priority and considerations for the advancement of emerging digital health technologies.

Figure 22: Participants' evaluation of recommendations and considerations for the advancement of emerging digital health technologies. They were asked to rate the impact and timeline of presented response options. For the response options legend, please see Table 21.

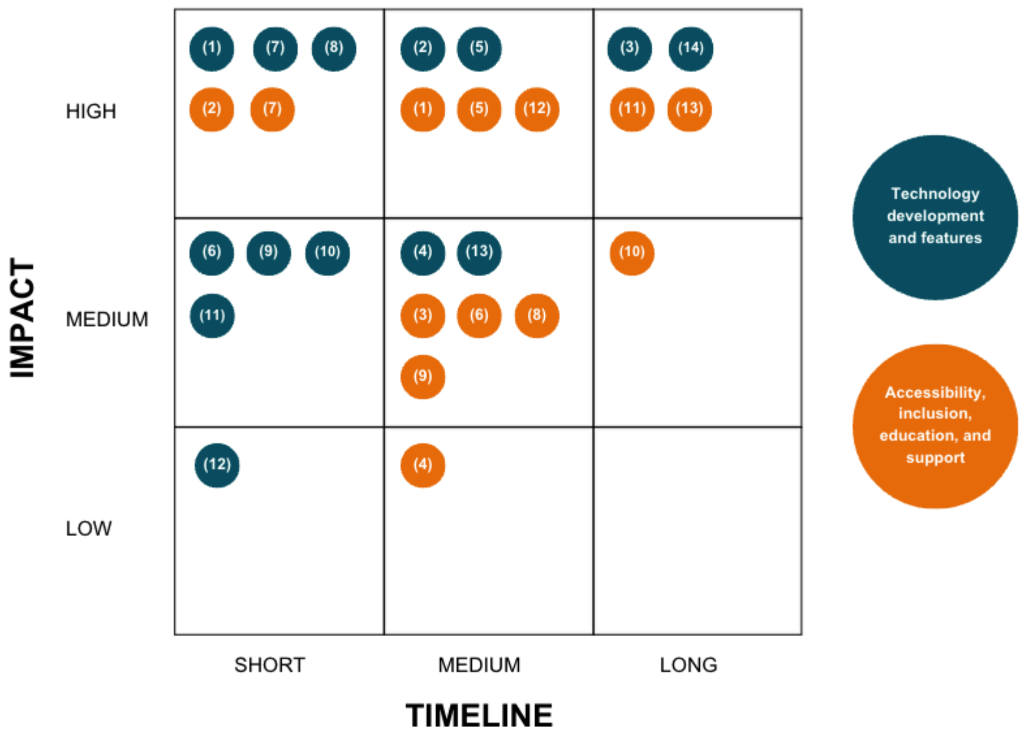


Table 21: Rated priority of considerations and recommendations for the advancement of emerging digital health technologies.

High-priority considerations and actions	
Short-term win, high impacts	**Technology development and features** • (1) Ensure sensor-level outputs are analytically validated and meet pre-specified requirements (e.g., the minimum sampling rate for heart rate monitors) • (7) Ensure robust data security, deidentification, and encryption protocols from the outset **Accessibility, inclusion, education, and support** • (2) Integrate accessibility features (e.g., large fonts, text-to-speech, translations) • (7) Provide open channels for feedback and troubleshooting during early deployments
Medium-term effort, high impact	**Technology development and features** • (2) Test against clinical gold standards of measurement and therapy to establish scientific validity • (5) Combine multi-modal sensing capabilities (e.g., combining movement, heart rate, and sleep data) **Accessibility, inclusion, education, and support** • (1) Design user-friendly interfaces suitable for individuals with varying levels of tech literacy

	• (5) Engage patients, care partners, and clinicians in co-design processes • (12) Build partnerships with advocacy groups and communities to promote awareness and establish trust
Short-term win, medium impact	**Technology development and features** • (6) Test for power efficiency and battery draining of the solutions • (8) Develop clear user consent processes for data collection and sharing • (9) Pilot technologies with small, diverse user groups to refine usability and functionality • (10) Develop practices and prototypes which allow for incremental improvements during R&D • (11) Include features for user control over data to enhance trust and adoption
Medium-priority considerations and actions	
Long-term effort, high impact	**Technology development and features** • (3) Conduct rigorous validation studies to ensure efficacy, accuracy, and reliability in specific patient populations • (14) Plan for scalability in future deployments to transition from prototypes to mass production **Accessibility, inclusion, education, and support** • (11) Build partnerships with healthcare providers to integrate technology into existing care pathways • (13) Plan for scalability in future deployments to in both research and care settings
Medium-term effort, medium impact	**Technology development and features** • (4) Adapt algorithms and systems to individual user variability • (13) Plan for continuous updates to keep the technology aligned with new research findings **Accessibility, inclusion, education, and support** • (3) Test for comfort and wearability in various physical and environmental conditions • (6) Develop educational resources for users to understand the technology's purpose and function • (8) Establish support ecosystems (e.g., help desks, online resources) for patients and clinicians • (9) Include ongoing ethical review processes as technology evolves
Short-term win, low impact	**Technology development and features** • (12) Incorporate transparency in data processing to explain how algorithms work to users and clinicians
Low-priority considerations and actions	
Long-term effort, medium impact	**Accessibility, inclusion, education, and support** • (10) Explore funding opportunities for non-commercial applications, such as grants or partnerships
Medium-term effort, low impact	**Accessibility, inclusion, education, and support** • (4) Allow customization of alerts and feedback to suit user preferences

6.6.2.2.6 Future outlooks for digital health technologies in mental health

In this section we asked the participants to provide answers to two questions:

Based on your expertise and experience, imagine you could design any kind of future technology for mental health conditions. You can think generally, or within our case examples of depression, anxiety, and psychosis.

Question 1: What would you want to measure or understand about mental health conditions (such as depression, anxiety, and psychosis) that is currently lacking effective or accessible technology?

Question 2: Where do you see the greatest opportunities for digital sensing technologies to deliver the most significant value in improving mental health care and outcomes? For example, as an early indicator, faster diagnosis, therapy effectiveness, continuous monitoring, uncovering underlying condition mechanisms, enabling more precise stratification of patient populations, etc.

This first question explored the nature of the potential needs for innovation in future digital mental health solutions. The qualitative responses were coded and the following concepts emerged from the data (ordered by descending frequency of mention):

- Personalized understanding of signs and symptoms
- Early detection (including improving access in underserved areas or populations, e.g., youth, LIC)
- Better understanding of underlying mechanisms
- Passive measurement of non-physical aspects, without need of input (e.g., mood, perception, attitude)
- Physiological metrics and their relation to mental health (e.g., hormones, blood sugar, ketones)
- Understanding triggers for exacerbations
- Predictive models, AI
- Improving quality of life
- Measuring therapy effectiveness
- Early detection and measurements of psychosis (least developed from mental health conditions)
- Suicide prevention
- Analysis of relation to genetic data
- Analysis of external influences
- AI-enhanced therapies (e.g., CBT)
- Systemic support in therapy

The second question explored where our respondents see the most value that sDHTs can offer for mental health. The qualitative responses were coded and the following concepts emerged from the data (ordered by descending frequency of mention):

- Understanding underlying disease mechanisms
- Continuous monitoring of signs and symptoms
- Early detection
- Faster diagnosis
- Timely intervention
- Therapy effectiveness measurement
- Understanding subgroups and better stratification of patients
- Improved access to treatments and care

- Prevention (both overall and relapse prevention)
- Community/peer networks and support systems
- Personalized treatment
- Reducing stigma
- Suicide prevention
- Better development of new therapies
- Objective measurements and data

6.7 External resources

Table 21: additional external resources that can be used to assess and improve specific technology characteristics described in Section 3.2.

Technology characteristic	Short description and state of the evidence *(Source: literature)*	Valuable evaluation resources
Usability	Good usability of sDHTs ensures that they are **intuitive**, **accessible**, and **user-friendly**, **seamlessly integrating** into users' daily lives while **providing actionable feedback** and fostering sustained **engagement**.	V3+ framework: This framework provides resources to evaluate usability of sDHTs to incorporate human-centered design into sDHT development, risk analysis, and more. The DiMe Seal is a symbol of quality and trust, awarded to digital health software products that demonstrate performance against a comprehensive framework of standards and best practices in evidence, usability, privacy, and security with equity woven throughout.
Sensor performance	Reliable sensor performance of sDHTs means **accurate**, **consistent**, and **uninterrupted data collection**, enabling **trustworthy insights** generated from the data.	V3+ framework: This framework provides resources to conduct verification as a critical component to establish that an sDHT is fit-for-purpose. If the sDHT meets the definition of a medical device, also refer to the appropriate local regulations on conducting verification.
Algorithm performance	Algorithm reliability for sDHTs is defined as the ability of the algorithm that incorporates the sensor-generated data to **interpret this data consistently and correctly**, **without errors**, **failures**, **or unexpected behaviors.**	V3+ framework: This framework provides resources to conduct analytical validation as a critical component to establish that an sDHT is fit-for-purpose. In addition, the Validating Novel Digital Clinical Measures resource developed by Digital Health Measurement Collaborative Community (DATAcc) by the Digital Medicine Society (DiMe) provides a decision-making process for selecting appropriate reference measures when conducting analytical validation.
Accurate performance in specific clinical population	The sDHT **reliably and accurately measures, predicts, or identifies** a clinically meaningful outcome or state in the specific population it is intended for.	V3+ framework: This framework provides resources to conduct clinical validation as a critical component to establish that an sDHT is fit-for-purpose in a specific clinical population.
General quality and performance factors	In addition to requirements related to the performance of a sensor and processing sensor output into actionable insights, **seamless operation** and **resilience** to technical failures or environmental disruptions are also important to ensure an sDHT is adapted to its intended context of use.	If the sDHT meets the definition of a medical device, refer to the appropriate local regulations (e.g. MDR or MHRA regulation). Best practices for quality control in technology development should be adopted, i.e., Quality Management Systems (QMS, ISO 13485 and FDA CFR 21 part 820) and software lifecycle processes (IEC 62304 and IEC 82304-2).
Data privacy and security measures	Good data privacy and security measures in sDHTs ensure the protection of user data through **robust encryption**, **secure storage**, and	GDPR (EU), HIPAA (USA), NIS Regulations 2018 (UK), PIPEDA (Canada), ICH E6 (R2) (international), WHO Digital Health Guidelines (international).

Technology characteristic	Short description and state of the evidence *(Source: literature)*	Valuable evaluation resources
	transparent consent and **communication processes**, **safeguarding confidentiality** and **compliance with regulations**.	Applicable standards: SOC 2, ISO/IEC 27001, ISO/IEC 27701, ISO 27799.
Long battery life	Battery life that **lasts for a required period of time** and is fit-for-purpose is important for uninterrupted monitoring and user convenience, **supporting reliable data collection** over extended periods and **reducing the need for frequent charging**.	V3+ framework: This framework provides resources to evaluate usability of sDHTs.
Verification and validation factor: Resistance to environmental factors	Where applicable, the sDHT ensures **reliable performance and data accuracy under varying conditions** such as temperature, humidity, motion, or exposure to water and dust. We specifically addressed this characteristic as it was noted as important for broad adoption in underserved areas.	V3+ framework: V3+ is an instructional framework widely adopted by developers and users of sDHT tools.
Accessibility features	Accessibility features require **inclusive design**, enabling ease of use for individuals with **diverse abilities, languages,** and **technological literacy**, while accommodating their physical, sensory, and cognitive needs.	Company-wide accessibility guidelines should be present, and adherence regularly evaluated. V3+ framework: This framework provides resources to evaluate usability of sDHTs.
Interoperability	The ability of products and systems to seamlessly connect, share, and integrate data across platforms for efficient care coordination.	HL7 FHIR IEEE 11073 IEEE 1752.1-2021 Standard for Open Mobile Health Data—Representation of Metadata, Sleep, and Physical Activity Measures FAIR principles

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