

FLORIDA INTERNATIONAL UNIVERSITY

Miami, Florida

THE BIOPSYCHOSOCIAL RELEVANCE OF DIGITAL HEALTH TECHNOLOGIES
FOR SELF-MANAGEMENT OF CHRONIC CONDITIONS:
INSTRUMENT DEVELOPMENT AND VALIDATION

A dissertation submitted in partial fulfillment of

the requirements for the degree of

DOCTOR OF PHILOSOPHY

in

BUSINESS ADMINISTRATION

by

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2023

To: Dean William Hardin
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This dissertation, written by Polina Durneva, and entitled The Biopsychosocial Relevance of Digital Health Technologies for Self-Management of Chronic Conditions: Instrument Development and Validation, having been approved in respect to style and intellectual content, is referred to you for judgment.

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ACKNOWLEDGMENTS

I am grateful to several individuals who helped me grow throughout graduate school by providing their support, encouragement, and guidance. This dissertation would not have been completed without them.

First, I would like to express my special gratitude to Dr. Cynthia LeRouge whose guidance and support helped me navigate this academic journey and prepare for future academic endeavors. From journal publications to grant and dissertation proposals, Dr. LeRouge's mentorship covered all aspects essential to an academic career. I am sincerely grateful for having had the opportunity and privilege to work and collaborate with Dr. LeRouge and for her incredible patience and kindness as I navigated through graduate school.

Second, I would like to thank my dissertation committee members, Dr. Tala Mirzaei, Dr. Lina Bouayad, Dr. Weirui Wang, and Dr. Weidong Xia, for their valuable input and contributions to my dissertation work. I am particularly thankful to Dr. Weirui Wang for helping me during the qualitative part of my study. In addition, I would like to thank Dr. Julia Bisshops, MD, who generously provided her insights on the health-related aspects of my dissertation and assisted with the participant recruitment activities.

I am also incredibly thankful to faculty members, staff, and students at the Department of Information Systems and Business Analytics. Particularly, I would like to thank Dr. George Marakas for his support during my graduate school journey and his insights and guidance on various aspects of an academic career. Further, I would like to acknowledge Yasemin Shirazi and Janey Sardinas for their help with the administrative aspects of my research. Also, I would like to thank Shangjun Wang and Tian Yu for their help during various stages

of my dissertation study.

I would also like to acknowledge FIU UGS for providing me with Dissertation Evidence Acquisition Fellowship and Dissertation Year Fellowship during my data collection and manuscript writing stages. In addition, I would like to acknowledge Health Informatics Education for funding this study.

Finally, I am grateful to my family and friends whose support kept me going throughout these years despite the difficulties we encountered. And I am grateful to all individuals who participated in various stages of my study, ranging from interviews to surveys, for their valuable time and incredibly useful insights.

ABSTRACT OF THE DISSERTATION

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Positive user experience is crucial for technology end-users and software development companies. Even though a variety of factors can determine user experience, the personal relevance of technology plays one of the most critical roles in defining the nature of user experience with technology. Nevertheless, it is not completely clear what the personal relevance of technology entails or how to measure this construct. Clarifying and operationalizing the construct of personal relevance can benefit a wide range of contexts of technology use. Healthcare and digital health technologies (DHTs) seem to stand out remarkably. DHTs, such as mobile health applications and web-based programs, are gaining increasing attention in chronic disease self-management. User engagement, the major aspect of user experience with DHTs, is critical for driving health behavior changes and improving health outcomes. Yet, user engagement with DHTs remains problematic. The literature recognizes that creating personally relevant DHTs can be a possible solution to low user engagement, but no study conceptualizes and operationalizes this construct. Thus, this study aims to clarify and operationalize digital health relevance. We leverage

the biopsychosocial model of health, which can explicate the healthcare user context in terms of biological, psychological, and social dimensions, to clarify and create a measurement instrument. The study consists of three phases. Phase 1 (construct definition and item generation) used 23 semi-structured interviews to explore the nature of the DHT's relevance and create the item pool. Phase 2 (theoretical analysis) involved an expert panel of 7 individuals to establish the content validity of the item pool created in Phase 1. Finally, Phase 3 (psychometrical analysis) consisted of conducting closed-ended surveys to revise the preliminary version of the measurement instrument developed in Phase 2 and establish the construct validity. During Phase 3, we recruited 225 individuals who completed the survey and conducted PLS-SEM on survey data. Our study contributes to information systems, health informatics, and healthcare. First, our study provides conceptual clarity into the nature of technology relevance and, particularly, digital health relevance. Furthermore, our measurement instrument can be used to guide the design and development of DHTs for chronic conditions. Finally, patients and health providers can use our measurement instrument as a decision aid to select and prescribe DHTs that are most relevant to specific patients.

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CHAPTER 1: INTRODUCTION AND OVERVIEW

Background

Positive user experience is crucial for technology end-users and software development companies. For end-users, positive user experience with technology indicates that technology meets user needs and provides users with meaningful and enjoyable experiences, among others (Ross, 2014). For software development companies, positive user experience with technology is an important product differentiator leading to a company's success and growth (Hogan et al., 2016). Software development companies that invest in user experience tend to see a decrease in customer acquisition costs and an increase in customer retention and market share (Ramli et al. 2022). In addition, every \$1 invested in user experience can bring up to \$100 in return (Hogan et al., 2016; Ross, 2014). Overall, it has become more critical than ever to understand how to create technologies that support positive user experience.

A variety of factors, ranging from user characteristics (e.g., abilities, personalities, needs, and goals, among others) to the context of use (e.g., socio-cultural context, task context, among others), can determine user experience (Allam et al., 2013; Hassenzahl & Tractinsky, 2011; Sulaiman et al., 2015). Even though individual, contextual, and other categories of factors can determine user experience, the personal relevance of technology ultimately plays one of the most critical roles in defining the nature of user experience with technology (Cardoso, 2017; Hassenzahl et al., 2010). Personal relevance, generally defined as a personally meaningful connection to the individual (Priniski et al., 2018), received attention in prior literature on technology use. For example, the information systems (IS) literature recognizes personal relevance as a key facet of user involvement with technology

(by defining user involvement as “a subjective psychological state reflecting the importance and personal relevance of a system to the user” (Barki & Hartwick, 1989)) (Barki & Hartwick, 1989, 1994). As a critical facet of user involvement, personal relevance can improve various aspects of user experience, such as continuance intention, user satisfaction, and computer self-efficacy, among others (Johnson & Yanson, 2018; Santosa et al., 2004; Shiau & Luo, 2013). In addition to these aspects of user experience, personal relevance can be valuable for changes in user behaviors and attitudes following technology use (Dijkstra & Ballast, 2012; Santosa et al., 2004). The Elaboration Likelihood Model, for instance, indicates that relevance is important in motivating individuals to carefully process information, thereby impacting individuals’ attitudes toward something and ultimately changing their behaviors (Petty et al., 2009). For instance, in the context of consumer-facing health technologies, the personal relevance of health messages was shown to enhance the persuasion effect of such messages with respect to health behavior change (Dijkstra & Ballast, 2012).

Although personal relevance is important for user experience (Dijkstra & Ballast, 2012; Santosa et al., 2004), it is unclear what personal relevance of technology entails or how to measure this construct. There are multiple research gaps associated with understanding personal relevance in general and in the context of technology use. First, literature recognizes that personal relevance can be interpreted in multiple ways (Priniski et al., 2018). Some interpretations of personal relevance include personal association, personal usefulness, and identity connection (which are discussed in more detail in the following sections). Second, the personal relevance of technology is not well-defined and is measured too broadly. Personal relevance is generally measured in terms of the extent to which a

technology feels irrelevant or relevant to a user (without any specifications or a point of reference) (e.g., (Barki & Hartwick, 1994; Oyibo & Vassileva, 2019; Petrenko et al., 2020)). Since personal relevance can be interpreted in multiple ways, it is unclear what users mean when they call a technology relevant. Does it mean that they find the technology useful? Does it mean that they find that the technology reflects their self-image? Does it mean something else?

Clarifying and operationalizing the construct of personal relevance can undoubtedly benefit a wide range of contexts of technology use. Nevertheless, chronic care seems to stand out remarkably. Digital health technologies (DHTs), such as mobile health applications and web-based programs, are gaining increasing attention in chronic disease self-management (Alkhaldi et al., 2016; Alkhaldi et al., 2017; Hutton et al., 2011; McClure et al., 2013). Specifically, these technologies can support individuals in making lifestyle changes that could lead to better health (e.g., modifying diet to manage weight) (Taj et al., 2019). User engagement, the major aspect of user experience with DHTs, is critical for driving health behavior changes and improving health outcomes (Alkhaldi et al., 2017; Hutton et al., 2011; McClure et al., 2013). Yet, user engagement with DHTs for self-management of chronic conditions remains problematic (Birnbaum et al., 2015; Lupton, 2013; O'Brien et al., 2018; Perski et al., 2017). A wide variety of studies report low user engagement with DHTs designed for various chronic conditions (Alice et al., 2018; Alkhaldi et al., 2016; Blandford, 2019; Christensen et al., 2009; Cugelman et al., 2011; S. Kelders et al., 2012; Neil et al., 2009).

Problematic user engagement can stem from a lack of understanding of users and their needs (Birnbaum et al., 2015). As personal relevance is concerned with a personally

meaningful connection to the individual (and, in the context of technology use, it would be a personally meaningful connection between the user and technology), clarifying and operationalizing this construct in the context of DHTs for self-management of chronic conditions can shed light on user needs with respect to DHTs and, therefore, address existing issues with user engagement. Indeed, literature recognizes that creating personally relevant DHTs (i.e., DHTs that reflect users and their needs) can be a possible solution to low user engagement (Birnbaum et al., 2015; Yardley et al., 2015). Nevertheless, the literature review does not yield any study that conceptualizes and operationalizes this construct.

Therefore, this study aims to clarify and operationalize the construct of personal relevance in the context of DHTs for self-management of chronic conditions. To inform the construct of interest, we refer to the user context, which is critical for explicating user needs and supporting positive user experience (Birnbaum et al., 2015; Hussain et al., 2018; Yardley et al., 2015). Specifically, the user context can reveal what users are looking for in a specific technology and how technology should be designed to meet user needs.

The user context generally captures user profiles, demographics, cognition, physical abilities, tasks, or other user characteristics pertinent to using a specific technology (Hussain et al., 2018). In healthcare, the user context generally captures the patient's illness experiences (Birnbaum et al., 2015; Hostetter et al., 2014; Marks et al., 2005; Triberti & Barello, 2016). In chronic care, the patient's illness experiences typically go beyond physical sensations and pain (Oris et al., 2018). It is also crucial to consider psychological aspects (e.g., negative emotions, stress, and anxiety) and social aspects (e.g., interference with interpersonal relationships) associated with one's chronic disease. The

biopsychosocial model of health has been previously leveraged to understand the illness experiences of chronically ill patients (Baughman et al., 2003; Gatchel et al., 2007; Kusnanto et al., 2018; Moore, 2018; Vasudevan, 2015). This model is one of the prevailing models in healthcare that can holistically account for the multidimensional experiences of chronically ill patients (Borrell-Carrió et al., 2004). Specifically, this model reveals personally meaningful experiences that shape one's illness with respect to the following dimensions: biological (e.g., functional ability), psychological (e.g., stress and anxiety associated with their health condition), and social (e.g., illness's interference with a social life).

The biopsychosocial model of health can inform patients' illness experiences, and patients' illness experiences can inform the user context for DHTs for self-management of chronic conditions. Thus, this study leverages the biopsychosocial model of health to understand the user context of individuals using DHTs to self-manage their chronic conditions. Understanding the biopsychosocial user context can inform the construct of personal relevance in DHTs for self-management of chronic conditions.

Problem Statement

Personal relevance is important for user experience and engagement with DHTs for self-management of chronic conditions (Birnbaum et al., 2015; Lupton, 2013; Perski et al., 2017). Unfortunately, various interpretations of personal relevance currently exist, and the personal relevance of technology is measured too broadly. Therefore, it is not clear what the personal relevance of DHTs for chronic conditions entails. Furthermore, neither research nor practice currently provides operational insight into measuring this construct. In this research study, we first clarified the meaning of this construct through the lens of

the biopsychosocial model of health, which depicts a holistic user context for the chronically ill. Then, we operationalized this construct by creating a measurement instrument.

To properly recognize the role of the biopsychosocial model in our construct development, we refer to the personal relevance of DHT as the *biopsychosocial relevance of DHT* hereafter.

Purpose and Research Questions

From the end user's perspective (i.e., digital health users), this study aims to:

- a) clarify the construct of the biopsychosocial relevance of DHTs for self-management of chronic conditions;
- b) operationalize the construct of the biopsychosocial relevance of DHTs for self-management of chronic conditions.

As the biopsychosocial model of health, which is used to inform the construct of interest, captures three specific dimensions of health (namely, biological, psychological, and social), the study explores each dimension separately in developing and assessing the construct of the biopsychosocial relevance of DHT. Given these objectives, the study answers the following research questions and sub-questions:

RQ1: What is the nature of the biopsychosocial relevance of DHTs for self-management of chronic conditions from the digital health user's perspective?

RQ1.1.: What is the nature of the biological relevance of DHTs for self-management of chronic conditions from the digital health user's perspective?

RQ1.2.: What is the nature of the psychological relevance of DHTs for self-management of chronic conditions from the digital health user's perspective?

***RQ1.3.:** What is the nature of the social relevance of DHTs for self-management of chronic conditions from the digital health user's perspective?*

***RQ2:** How can one measure the biopsychosocial relevance of DHTs for self-management of chronic conditions from the digital health user's perspective?*

***RQ2.1.:** How can one measure the biological relevance of DHTs for self-management of chronic conditions from the digital health user's perspective?*

***RQ2.2.:** How can one measure the psychological relevance of DHTs for self-management of chronic conditions from the digital health user's perspective?*

***RQ2.3.:** How can one measure the social relevance of DHTs for self-management of chronic conditions from the digital health user's perspective?*

Overview of Methods

To answer these research questions, we leveraged PROM (patient-reported outcome measure) -related research (Porter et al., 2021), which is based on the methodological paradigm of psychometrics (DeVellis, 2016). PROMs are standardized, validated tools that assess patient-reported outcomes (PROs), which are “any report of the status of a patient’s health condition that comes directly from the patient” (FDA, 2009). PROMs can assess a range of individual biopsychosocial outcomes, including health status, well-being and psychological health, symptoms and functioning, health-related quality of life, treatment satisfaction, and others (Philpot et al., 2018). These instruments are commonly used in health research as well as practice to understand patient’s health condition and to prescribe or select treatments that are most relevant to patients based on their perspective on their health. Compared to the instrument development and validation in Information Systems (IS), there exist well-established procedures to develop various PROMs (ranging

from unidimensional to multidimensional, as well as under different measurement models) (McKenna, 2011; Porter et al., 2021). Thus, we leverage the methodological aspects of the PROM development and validation to inform the development and validation of the biopsychosocial relevance of DHT.

We conducted our study in three phases in alignment with the PROM development and validation and the methodological paradigm of psychometrics. Phase 1 (construct definition and item generation) used semi-structured interviews to explore the nature of the biopsychosocial relevance of DHTs for self-management of chronic conditions (RQ1). Through Phase 1, we clarified the concept of the biopsychosocial relevance of DHT and created the item pool for this construct. Phase 2 (theoretical analysis) involved an expert panel establishing the content validity of the item pool created in Phase 1 and creating the preliminary version of the measurement instrument (RQ2). Finally, Phase 3 (psychometrical analysis) consisted of closed-ended surveys to further revise the preliminary version of the measurement instrument developed in Phase 2 and establish the construct validity (RQ2).

Overview of Chapters

This study is organized as follows. Chapter 2 provides an overview of the literature that informed this study. Specifically, prior research on personal relevance and the biopsychosocial model of health is discussed. In addition, Chapter 2 contains a section on the PROM-related research under the psychometric paradigm that informed the methodological aspects of the instrument development and validation. Discussion of the chronic illness instantiation, such as chronic headache pain, concludes Chapter 2. Chapter 3 describes Phase 1 (construct definition and item generation), which leverages semi-

structured interviews. Chapter 4 covers Phase 2 (theoretical analysis), which leverages an expert panel. Chapter 5 is dedicated to Phase 3 (psychometric analysis), which used surveys and PLS-SEM. Chapter 6 concludes this dissertation by describing research conclusions, implications for research, implications for practice, and future work.

CHAPTER 2: BACKGROUND

From Digital Health Relevance to Improved Health Outcomes

Prior studies, both empirical and theoretical, indicate that digital health relevance can lead to user engagement, which can lead to health behavior change and, ultimately, improved health outcomes.

The Behavioral Intervention Technology, Persuasive System Design Framework, as well as the Elaboration Likelihood Model provide insights into how digital health relevance can lead to user engagement, which can lead to health behavior change (Asbjørnsen et al., 2019; Kelders et al., 2012; Oinas-Kukkonen & Harjumaa, 2009; Mohr et al., 2014; Yardley et al., 2016; Petty et al., 2009). For instance, the Behavioral Intervention Technology Model articulates the relationship between DHT aims, elements, characteristics, and workflow (Mohr et al., 2014). DHT aims capture clinical and usage goals. Clinical goals refer to changes in behaviors, cognition, skills, and motivation for specific intervention-related behaviors. Examples of clinical goals include decreasing calorie intake, increasing physical activity, decreasing the amount of depressive thoughts, among others. Further, usage goals capture engagement with DHT and its components. To help users achieve clinical and usage goals, behavioral change techniques (e.g., goal setting, motivation enhancement, among others) should be implemented in the DHT design, specifically in various DHT elements (functional and design features). Characteristics of different DHT elements should reflect user needs and, therefore, be *relevant* to user needs. The interaction with relevant DHT elements can help users actualize various affordances (i.e., “action possibilities” (Gibson, 1979; Volkoff & Strong, 2017) enabled by technology) aligning with behavioral change techniques (Mohr et al., 2014). For instance, a user may interact

with a tracking feature of DHT to monitor their calorie intake. Monitoring calorie intake can enable users to become more aware of their progress, understand certain gaps in their behaviors, and adjust their behaviors, if needed. Overall, as users interact with various DHT elements, they can gradually change their behaviors and, ultimately, achieve specific clinical and usage goals.

Moreover, the Persuasive System Design framework can also be used to capture how individuals engage with DHTs to initiate and adhere to health behavior change (Asbjørnsen et al., 2019; S. M. Kelders et al., 2012; Mohr et al., 2014; Oinas-Kukkonen & Harjumaa, 2009). Particularly, this framework identifies several design features that can facilitate health behavior change: primary task support (e.g., tailoring content), dialogue support (e.g., reminders), credibility (e.g., expertise), and social support (e.g., social networking). Primary task support and, particularly, tailoring content, emphasizes the importance of the relevance of the system content to help users initial and adhere to health behavior change. Furthermore, the elaboration likelihood model (ELM) of persuasion provides insights into how user engagement can lead to health behavior change (Petty et al., 2009). According to the ELM, people use two routes to process information: central and peripheral routes. The central route involves careful and deliberate processing of information. People process information if they are motivated and have capabilities. Further, the peripheral route allows individuals to process information by leveraging cues (e.g., affective states associated with the advocated position) and mental shortcuts (e.g., a message from an expert). The ELM states that both peripheral and central routes can influence individual's attitudes towards something (and associated behavioral changes), yet the central route has a more dominant impact on one's attitudes (and, subsequently, behavioral change). Specifically, individual's

motivation and capabilities, which are part of the central route, play a bigger role in influencing one's processing of information and changes in attitudes (and, subsequently, behaviors) than cues and mental shortcut, which are part of the peripheral route. In healthcare, DHTs that enhance an individual's motivation and capabilities are more likely to result in actual and sustained health behavior change (Short et al., 2015).

The ELM is of particular interest to this study because the model indicates that relevance can determine an individual's motivation to carefully consider and process certain information (Petty et al., 2009; Petty & Cacioppo, 1979). For instance, if a woman has a family history of breast cancer, then she might be motivated to think about a persuasive message about breast self-exams based on perceived self-relevance. Even though the ELM was previously explored in the context of technology use and, specifically, DHTs (e.g., (Song et al., 2021; Xitong et al., 2020)), limited attention was paid to conceptualizing and operationalizing the construct of relevance. At the moment, it is not clear what relevance entails and how to measure this construct because of multiple existing interpretations thereof.

Overall, the above models provide support for digital health relevance leading to user engagement and, ultimately, health behavior change. Finally, the final link of the causal chain from digital health relevance to improvement health outcomes, specifically, the relationship between health behavior change and improved health outcomes was empirically established in several prior studies (e.g., Davidson & Scholz, 2020; Spring et al., 2013; Stenlund et al., 2022). For instance, a positive change in health behaviors pertaining to physical activity, diet, and reduced alcohol and tobacco consumption led to better well-being over the course of 9 years (Stenlund et al., 2022).

Relevance Interpretations

Personal relevance can be interpreted in multiple ways (Priniski et al., 2018). Table 1 summarizes some of the existing interpretations of relevance informed by various theories, such as the four-phase model of interest development (Hidi & Renninger, 2006), expectancy-value theory (Spence, 1983), and self-determination theory (Deci & Ryan, 1990; Priniski et al., 2018).

Table 1: Interpretations of personal relevance (adapted from Priniski et al. 2018)

Theory	Summary	Interpretation of personal relevance
Four-phase model of interest theory (Hidi & Renninger, 2006; Renninger & Hidi, 2016)	The four-phase model of interest theory describes phases in the developing and deepening of an individual's interest in a particular activity. Specifically, it illustrates how an individual can move from situational interest to individual interest. • <i>Situational interest</i> refers to an individual's momentary increase in attention in response to specific activity features. • <i>Individual interest</i> is a tendency to re-engage with a specific activity over time.	Personal relevance can trigger situational interest and maintain individual interest: • Relevance as <i>personal association</i> (i.e., connections to existing interests, prior experiences, and knowledge) may trigger situational interest in the early phases of interest development in a specific activity (Priniski et al., 2018) • Relevance as <i>identity connection</i> (i.e., perceiving an activity as part of one's identity) allows one to develop individual interest and re-engage with a specific activity over time (Priniski et al., 2018; Renninger, 2009).

Theory	Summary	Interpretation of personal relevance
Expectancy-value theory (Spence, 1983)	Expectancy-value theory posits that an individual's expectation for success and subjective task values can affect an individual's goal-related choices (for example, task choice, effort, and persistence). According to this theory, there exist four task values: • <i>Attainment value</i> refers to the importance of the task for an individual's personal and social identities • <i>Utility value</i> refers to the importance of the task for achieving goals • <i>Intrinsic value</i> refers to the enjoyment of the task • <i>Cost value</i> refers to the cost of choosing a specific task over other alternatives	The role of personal relevance lies in two task values, specifically attainment value and utility value, that determine an individual's goal-related choices (Priniski et al., 2018): • Relevance takes the form of attainment value and points to the importance of <i>identity connection</i> between an individual and their task. The association between identity and task can determine goal-related choices. • Relevance also takes the form of utility value and points to the <i>usefulness</i> of a specific task for achieving personal goals. The association between the perceived usefulness of a task and an individual's goals can determine goal-related choices.

Theory	Summary	Interpretation of personal relevance
Self-determination theory (Deci & Ryan, 1990, 2000; Lepper et al., 1973)	Self-determination theory focuses on human motivation and emphasizes the degree to which behaviors are autonomous (i.e., behaviors originate from the self) and relatively controlled (i.e., behaviors are coerced by interpersonal forces). Self-determination theory describes the process of internalization that illustrates how behaviors become more or less autonomously regulated over time. Internalization occurs when an extrinsic motive transforms into a personally endorsed value. Various forms of regulation take place in the process of internalization: • <i>Integrated regulation</i> refers to a behavior that reflects an individual's identity • <i>Introjected regulation</i> refers to a behavior that is performed to avoid self-imposed punishment (e.g., shame) • <i>Identified regulation</i> refers to a behavior that is performed because it enables to achieve a specific goal • <i>External regulation</i> refers to a behavior that is performed to avoid externally imposed punishment	The role of personal relevance lies in the following forms of regulation that take place during the internalization process (Priniski et al., 2018): • Relevance plays a role in integrated regulation. The <i>identity connection</i> between an individual and behavior can support the internalization process. • Relevance also plays a role in the introjected and identified regulations. The <i>usefulness</i> of specific behavior can support the internalization process.

Table 1 illustrates that personal relevance can be interpreted in terms of personal association, personal usefulness, and identity connection. Since there exist multiple interpretations of relevance, the current ways of conceptualizing and assessing this construct in the context of technology use can be problematic. In the context of technology use, users are typically asked whether they view a specific technology as relevant or irrelevant to them (Barki & Hartwick, 1994; Oyibo & Vassileva, 2019; Petrenko et al.,

2020). Since personal relevance can be interpreted in multiple ways, “relevant/irrelevant” assessments can create inconsistency (and, therefore, a threat to reliability) in assessing the same technology with respect to relevance among multiple users.

Some users might perceive technology as relevant if it reminds them of personally meaningful memories or knowledge (relevance as a *personal association*). For example, users who spend a significant amount of time on social media might find a new technology with a social media feature relevant to them. This relevance connection is created through associations (e.g., memories of using and enjoying social media in general). Furthermore, some users might perceive the same technology as relevant if it has a perceived functional value and is useful (relevance as *personal usefulness*) (Priniski et al., 2018). Personal usefulness (or perceived usefulness) is the major construct in studies on technology adoption (Davis, 1989; Venkatesh & Bala, 2008; Venkatesh et al., 2003; Viswanath & Fred, 2000) and refers to the user’s perception of the extent to which a technology can help users achieve their goals. Interpreting personal relevance as usefulness, a user might call a technology relevant if it helps them achieve their goals. Finally, some users might perceive technology as relevant because it aligns with a user’s identity (relevance as *identity connection*). For example, a user who self-identifies as a “gamer” (e.g., someone investing a significant amount of time in playing video games (Shaw, 2011)) might find a new technology with a variety of gaming features personally relevant to them.

Overall, it is critical to clarify the concept of personal relevance of technology as relevance can take different interpretations. To clarify the concept of relevance in DHTs for self-management of chronic conditions (which is the focus of this study), we refer to the user context, which is critical for explicating user needs and supporting positive user experience

(Birnbaum et al., 2015; Hussain et al., 2018; Yardley et al., 2015). In healthcare, the user context generally captures the patient's illness experiences (Birnbaum et al., 2015; Hostetter et al., 2014; Marks et al., 2005; Triberti & Barelo, 2016). In chronic care, the patient's illness experiences typically go beyond physical sensations and pain (Oris et al., 2018). It is also crucial to consider psychological aspects (e.g., negative emotions, stress, and anxiety) and social aspects (e.g., interference with interpersonal relationships) associated with one's chronic disease. The biopsychosocial model of health has been previously leveraged to understand the illness experiences of chronically ill patients (Baughman et al., 2003; Gatchel et al., 2007; Kusnanto et al., 2018; Moore, 2018; Vasudevan, 2015). Specifically, this model reveals personally meaningful experiences that shape one's illness with respect to the following dimensions: biological (e.g., functional ability), psychological (e.g., stress and anxiety associated with their health condition), and social (e.g., illness's interference with a social life). In alignment with this model, we introduce the biopsychosocial relevance of DHT.

Biopsychosocial Model of Health

Overview of the Biopsychosocial Model of Health

George L. Engel introduced the biopsychosocial model of health in 1977 (George, 1977). The biopsychosocial model of health recognizes illness as a subjective and personal experience sculpted by various factors unique to the individual (Fillingim, 2017). Engel believed that clinicians should simultaneously attend to illness's biological, psychological, and social dimensions to understand patients' sufferings (Borrell-Carrió et al., 2004). Studies recognize that the biopsychosocial model of health can be particularly relevant for understanding and managing chronic conditions that require integrated, multidisciplinary

approaches (Kusnanto et al., 2018). Specifically, this model can be used to make a holistic assessment of a patient's health condition (Baughman et al., 2003; Keefe et al., 2002), thereby enhancing the quality of patient care and improving clinical outcomes (Andrasik et al., 2005; Baughman et al., 2003; Gatchel et al., 2007; Kusnanto et al., 2018).

The biopsychosocial model recognizes that biological, psychological, and social dimensions of health are all integral to understanding a patient's health condition (Gatchel et al., 2014; Gatchel et al., 2007). The biological dimension of the biopsychosocial model of health generally refers to physical health, defined as "biological functioning and adaptation" (Manwell et al., 2015). Physical health generally refers to the well-being of the body and the proper functioning of the organism (Nishat, 2021). Various physical pathologies, genetics, comorbidities, lifestyle factors (e.g., diet), and demographics (e.g., age) can determine a patient's physical health.

Furthermore, the psychological dimension of the biopsychosocial model of health generally refers to a patient's psychological health (including mental health and negative emotions associated with one's health condition). Psychological health refers to an individual's "cognitive-emotional functioning and adaptation" (Manwell et al., 2015). In other words, psychological health can generally be defined as the emotional well-being of individuals and the absence of various psychopathologies (e.g., depression, anxiety, stress). Patients with chronic conditions tend to suffer from physical limitations and pain that can lead to emotional distress, thereby worsening patients' psychological health (Turner & Kelly, 2000).

Finally, the social dimension of the biopsychosocial model of health refers to social health, defined as an individual's "interpersonal functioning and adaptation" (Manwell et al.,

2015). Social health involves patients’ engagement with others in their community, the ability to develop and maintain interpersonal relationships, creating boundaries in relationships, and having a supportive network. Patients with chronic conditions tend to restrict their social engagement with others (Meek et al., 2018). Maintaining social health, however, can be critical for the physical and psychological health of a patient with a chronic condition. For example, social support can help patients suffering from chronic pain decrease their pain severity by distracting their attention from their health condition and decreasing pain catastrophizing (Che et al., 2018).

Introducing Dimensions of the Biopsychosocial Relevance of DHT

Overall, physical, psychological, and social health can be essential to understanding users with chronic conditions. To account for these aspects in our contextualization of the biopsychosocial relevance of DHTs for self-management of chronic conditions, we propose the following three dimensions: the biological relevance of DHT, the psychological relevance of DHT, and the social relevance of DHT. We created preliminary definitions for these dimensions by using a general definition of personal relevance (“a personally meaningful connection to the individual” (Priniski et al., 2018)) and core biopsychosocial dimensions of a patient’s health (i.e., physical health, psychological health, and social health). Table 2 summarizes preliminary definitions of the personal relevance dimensions.

Table 2: Dimensions of the biopsychosocial relevance of DHT

Dimension	Definition
The biological relevance of DHT	Perception of a personally meaningful connection between user’s physical health and a DHT for self-management of chronic conditions
The psychological relevance of DHT	Perception of a personally meaningful connection between user’s psychological health and a DHT for self-management of chronic conditions

Dimension	Definition
The social relevance of DHT	Perception of a personally meaningful connection between user's social health and a DHT for self-management of chronic conditions

This study leverages PROM-related research (Porter et al., 2021), which is based on the methodological paradigm of psychometrics (DeVellis, 2016), to clarify and operationalize the construct of the biopsychosocial relevance (and, specifically, the three dimensions introduced above). PROMs are the major psychometrically sound and evidence-based ways of measuring patients' perspectives on their health condition (including biological, psychological, and social dimensions of one's health, as described by the biopsychosocial model of health) (Cohen & Hula, 2020). These measures are widely used in medical research and practice to assess and improve the clinical care of patients (Black & Jenkinson, 2009). For example, PROMs can be used to assess whether the services provided improved a patient's health and well-being.

The study leverages PROM-related research (vs. the IS literature on instrument development) to inform the methodological aspects of our instrument development and validation for the following reasons. Even though the IS literature attempts to provide guidelines on how to develop and operationalize constructs, there have been multiple accounts indicating the lack of rigor in the development of IS instruments. Straub et al. (1989) reported that 62% of the IS studies lacked a single form of instrument validation (Straub, 1989). As a retrospective to Straub's article (eleven years after), Boudreau et al. (2001) found that, even though there was an improvement in the validation of instruments (particularly, concerning reliability assessment), much still needed to be done to achieve rigor in the instrument development and validation (Boudreau et al., 2001). Such a claim was echoed in a later study led by Straub that indicated that there still existed major barriers

to overcome in the instrument, statistical, and other forms of validation (Straub et al., 2004). Content validity assessments were of particular concern to Straub. To address some of the gaps in IS instrument development and validation, Lewis et al. (2005) described a comprehensive methodology for developing sound measures for IS constructs (Lewis et al., 2005). In reviewing IS studies, Lewis et al. (2005) indicated that many studies, addressing a broad range of constructs in IS, used single components of the proposed methodology. Later, additional issues with the IS instrument development and validation were identified. Particularly, MacKenzie et al. (2011) stated that most instrument development procedures assumed that causality flows from the latent variable to the measures thereby implying a reflective measurement model (S. B. MacKenzie et al., 2011). There is a very limited account of studies that provide insights into developing constructs based on a formative measurement model. In addition, there has been little convergence in the IS literature about ways to operationalize multidimensional and higher-order constructs (Wright et al., 2012). Finally, a recent study reviewing IS literature on instrument development pointed out that there still exist various issues associated with IS instrument development and validation (Schmitz et al., 2020). In 2019, only 77% of studies focused on construct development and published in top IS journals reported assessing construct validity (i.e., conducted analytical tests), 33% assessed nomological validity, and 19% assessed content validity.

The methodological aspects of PROM development and validation overcome instrument validation issues discussed in the IS literature. This can be attributed to not only well-established procedures for developing such instruments in healthcare (e.g., the most widely used measures were developed in the 1970s) but also a wide variety of different types of

instruments developed (McKenna, 2011; Porter et al., 2021). In addition, PROMs provide insights into measurement models not commonly leveraged in IS studies (S. B. MacKenzie et al., 2011). Particularly, most PROMs follow formative measurement models, thereby informing how to rigorously develop constructs under such models (Kaltoft et al., 2017). Moreover, there exists a variety of PROMs, ranging from unidimensional to multidimensional (Williams et al., 2016). The methodological aspects of multidimensional PROMs are particularly pertinent to this study as we delineated multiple dimensions of the biopsychosocial relevance of DHT (specifically, the biological relevance of DHT, the psychological relevance of DHT, and the social relevance of DHT).

To further explicate various methodological aspects of how PROMs are developed, we provide a detailed discussion of the PROM development and validation in the following section.

Instrument Development and Validation

Key Considerations for PROMs

PROMs assess patient-reported outcomes (PROs), which are “any report of the status of a patient’s health condition that comes directly from the patient” (FDA, 2009). PROMs can assess a range of individual biopsychosocial outcomes, including health status, well-being and psychological health, symptoms and functioning, health-related quality of life, treatment satisfaction, and others (Philpot et al., 2018). For example, existing PROMs can assess patients’ physical functioning, depression, anxiety, social relationships, and other biopsychosocial aspects of their chronic disease. Individual PROMs can be leveraged to assess a patient’s functioning over time (Williams et al., 2016), the effectiveness of a medical intervention (procedure, treatment, or pharmaceutical intervention) (Weldring &

Smith, 2013; Williams et al., 2016), and any changes in the patient's health condition (Parslow et al., 2019). Moreover, individual PROMs can be aggregated to compare groups of patients and estimate population norms (Cella et al., 2015b; Greenhalgh et al., 2017). For example, aggregated PROMs can be used as an indicator of healthcare quality for some procedures, to inform patients about various treatment options, and to compare risk factors and outcomes of quality monitoring between patient groups.

This study leverages PROM-related research, and, specifically, various methodological aspects of rigorous PROM development and validation, to inform the methodological aspects of our instrument to assess the biopsychosocial relevance of DHTs. Table 3 summarizes key considerations for the PROM development and validation that we attended to in this study.

Table 3: Key considerations for the PROM development and validation

Instrument Attributes	
Category	Generic vs. disease-specific vs. condition-specific
Form	Multi-item vs. single-item
Response scale type	Visual vs. verbal vs. numeric vs. faces vs. Likert-type
Scoring	Sum vs. average; weighted vs. unweighted
Methodological Processes	
Patient involvement	Patients are involved in item generation
Stakeholder input	Various stakeholders are involved in content validity assessments
Psychometric validation	Psychometric techniques are used to validate the instrument
Mode of administration	Electronic vs. paper-and-pencil
Level of application	Individual vs. group vs. population

Instrument Attributes

Various instrument attributes must be considered before the PROM development process: PROM category, form, response scale type, and scoring. PROMs can generally be divided

into three major categories: generic, disease-specific, and condition-specific (Williams et al., 2016). First, generic PROMs cover multiple biopsychosocial dimensions of a patient's health, such as physical functioning, psychological symptoms, role functioning, and others. Widely used generic PROMs include Short-Form-36, Nottingham Health Profile, Sickness Impact Profile, and World Health Organization Quality-of-Life Scale (Bergner et al., 1981; Liliane & Fernando, 2016; Vahedi, 2010; Wiklund, 1990). These PROMs can be used in chronic care to assess patients' perceptions of their overall health condition. Second, disease-specific PROMs focus on the biopsychosocial dimensions pertinent to a specific illness (Williams et al., 2016). Disease-specific PROMs are typically used with other disease-specific indicators, such as clinical and physiological measures (e.g., blood pressure). Examples of disease-specific PROMs include the Patient Perception of Arrhythmia Questionnaire, Cardiac Health Profile of Congestive Heart Failure, Myocardial Infarction Dimensional Assessment Scale, and others (Algurén et al., 2020). Third, condition-specific PROMs focus on specific biopsychosocial dimensions (Williams et al., 2016). Examples of condition-specific PROMs include Kessler Psychological Distress Scale (to assess patient's mental health) and Social Functioning Scale (to assess patient's social health) (Birchwood et al., 1990; Easton et al., 2017).

Furthermore, PROMs can be in the form of single-item and multi-item measures (Williams et al., 2016). Single-item measures are used to measure specific and unidimensional concepts (e.g., the Numeric Pain Rating scale) (Elina et al., 2019). On the other hand, multi-item PROMs are measures formed by more than one item and are used to measure complex concepts with multiple dimensions (Gideon, 2012). For example, health-related quality-of-life measures have multiple dimensions (i.e., physical, psychological, and social) that need

to be considered to understand a patient's quality-of-life status (Cappelleri et al., 2016). Each dimension requires a set of items to ensure that all relevant aspects of a domain are adequately captured. For instance, it is critical to have items covering the patient's sleep, mobility, pain, involvement in daily activities, and other aspects of physical health to understand a patient's physical health holistically.

Various response scale types should also be considered during PROM development. Single-item PROMs commonly use visual analog scales, verbal rating scales, numeric, and face rating scales (Gries et al., 2018). Visual analog scales include horizontal or vertical lines anchored by verbal descriptors at both ends (e.g., from "no pain" to "extreme pain") (Streiner & Norman, 2008). A patient places a line perpendicular to the scale line to indicate the intensity of the effect in question (for example, the intensity of pain). The score is determined by measuring the distance between the lower anchor point and the patient's mark. Furthermore, verbal rating scales are comprised of a list of verbal descriptors describing different levels of the severity of a patient's illness ranging from least to most intense (Gries et al., 2018). Patients read a list of verbal descriptors and indicate the one that best describes their health condition. Moreover, the numeric rating scale represents a continuum that allows patients to rate the effect using integers. The most common numeric rating scale is an 11-point scale ranging from 0 to 10. 0 typically indicates no effect, and 10 indicates the maximum effect (e.g., from no pain to extreme pain). Finally, faces rating scales use a list of pictures to show a continuum of facial expressions indicating how a patient feels (from an unhappy face to a happy face) (Streiner & Norman, 2008). Faces rating scales are commonly used to assess health conditions in the pediatric population as they are fairly simply to use and do not require reading ability.

For multi-item PROMs, multipoint or Likert-type scales are commonly used (Dowling et al., 2016). Likert-type scales represent response levels that are anchored with consecutive integers and verbal labels (Gries et al., 2018). The selection of anchor points for Likert-type scales in PROMs is guided by the nature and purpose of the items in the questionnaire. For example, World Health Organization Quality-of-Life Scale contains 5-point items with various anchor points indicating the level of agreement (ranging from “Not at all” to “Completely”), level of satisfaction (ranging from “Very dissatisfied” to “Very satisfied”), level of quality (ranging from “Very poor” to “Very good”), and others (Vahedi, 2010). Anchor points indicating the level of satisfaction, for instance, are used to understand the extent to which patients are satisfied with various aspects of their life (e.g., physical health, social health, among others). Further, anchor points indicating the level of quality are used to understand the perceived quality of a patient’s life. The selection of appropriate anchor points requires careful consideration of the nature and purpose of individual items.

Furthermore, researchers must consider various aspects of PROM scoring when developing PROMs. First, it is critical to consider the scoring rubric for PROMs. The most commonly used scoring rubrics for PROMs are the scale averages and sum scores (Feißt et al., 2019). The scale average scores can generally be used in multidimensional PROMS to assess the score for each dimension and all dimensions combined. The average scores within dimensions allow researchers and practitioners to assess how a patient scores with respect to a particular dimension of their health (e.g., physical health). The average score of items across multiple dimensions of PROM allows for assessing the overall patient’s health (encompassing the patient’s physical, mental, and social health altogether). For example, World Health Organization Quality-of-Life Scale assesses multiple dimensions

of a patient's health: physical health, psychological health, and social and environmental health (Vahedi, 2010). Each item is assessed on a 5-point Likert scale. The mean score of items within each dimension can be used to assess each dimension of a patient's health. Further, the mean score of items across dimensions can be used to assess the overall patient's health. Mean scores are then normalized in a range from 0 to 100.

Furthermore, the scale sum scores add item responses (Feit et al., 2019). This scoring rubric can be particularly relevant for unidimensional multi-item PROMs focusing on a specific biopsychosocial dimension of a patient's health. For example, Kessler Psychological Distress Scale contains ten 5-point items about a patient's emotional state and measures the overall psychological distress experienced by a patient (Easton et al., 2017). The item responses are added up to calculate the total score. Higher scores indicate a higher level of emotional distress experienced by a patient. Similarly, Social Functioning Scale exemplifies another PROM that leverages the scale sum scores. The scale contains eight 4-point items. Higher scores denote a lower level of the patient's social skills and performance.

Second, factor score computation methods should be considered when researchers develop PROMs (Feit et al., 2019). Most PROMS leverage simple, unweighted summations (or averages) of the item responses. Unweighted summations (or averages) mean that the latent construct influences each item equally. In multidimensional PROMs, it also means that each dimension of health equally contributes to the overall patient's health. For example, the World Health Organization Quality-of-Life Scale equally weights items for each dimension of patient's health (e.g., physical health, mental health, social health).

On the other hand, weighted sum (average) scores imply that weights are assigned to items or dimensions of health (Feißt et al., 2019). The weights are typically determined by experts (e.g., clinicians) and patients. For example, in the SEIQoL-DW measure (which assesses a patient's quality of life), various dimensions of health (e.g., physical function, social function, emotional function, among others) are assigned different weights based on prior explorations of the extent to which each dimension can determine patient's quality of life (Burckhardt et al., 2020).

Methodological Processes

The development of PROMs requires empirical evidence regarding health from the patient's perspective (Revicki et al., 2008). Patient involvement in the PROM development is essential to capturing patients' perspectives on their health conditions and developing a valid patient-centered measure (Wiering et al., 2017). For instance, some previously validated PROMs have emerged from early clinical research involving explorations of the patient's perspective as a healthcare outcome (Weldring & Smith, 2013). Qualitative methods (e.g., interviews and focus groups) are also used to capture and understand patients' perspectives on their health and develop items (Angela et al., 2019).

Furthermore, validating PROMs requires careful consideration of various methodological aspects, including validity, reliability, and generalizability (Weldring & Smith, 2013). Stakeholder input (e.g., clinicians, psychometricians) and psychometric approaches are widely applied to evaluate and validate PROMs (Angela et al., 2019). Stakeholder input is used to assess the content validity of newly developed PROMs, and psychometric techniques (e.g., factor analysis) are used to validate the measures (Cappelleri et al., 2016; Terwee et al., 2018).

Mode of Administration

Paper-and-pencil and electronic modes are the most commonly used modes of administration for PROMs (Cella et al., 2015a). Historically, paper-and-pencil administration was the primary method for collecting PROMs. This mode of administration, however, has some disadvantages. For example, it requires an extra step on the part of staff to complete a manual data entry and scoring. Advances in technology resulted in the availability of electronic resources that can be an alternative to the paper-and-pencil administration of PROMs (Austin et al., 2021). Web-based platforms and touchscreen computers provide a more efficient means of PROM administration.

Level of Application

PROMs can be collected and analyzed at multiple levels: individual, group, and population (Williams et al., 2016). Providers can use individual PROMs to screen and monitor patients' conditions. For example, PROMs can be used to determine the effectiveness of a health intervention (Martin-Delgado et al., 2021). A provider might assess patient's health condition at the beginning and end of a health intervention by using PROMs. Then, pre- and post-intervention scores can be compared to assess whether there exists a change in the patient's health condition.

Moreover, PROMs can be collected and aggregated across groups of patients (Williams et al., 2016). Aggregated PROMs can then be incorporated into decision-making to inform patients about the possible consequences of a specific treatment for their health condition and evaluate the effectiveness of care. For example, PROMs can be collected to compare the effectiveness of a health intervention for patients with a specific health condition (Mills et al., 2016). Patients can be divided into control and treatment groups, and PROMs from

both groups can later be collected and compared to make inferences about the effectiveness of a health intervention.

Furthermore, PROMs can be aggregated at the population level to help decision-makers establish policies to benefit the whole population (Williams et al., 2016). This application of PROMs includes population surveillance of the outcome trends, identification of factors associated with healthcare value to inform payment models, identification of quality improvement activities across healthcare organizations (e.g., standard-setting, adherence to clinical guidelines), and others. For example, PROMs can be used to calculate the Quality Adjusted Life Year, a commonly used metric to determine the cost-effectiveness of specific treatments (Spiegelhalter et al., 1992). The measure can be used to compare the costs and benefits of treatments to inform overall health resource allocation decisions (Williams et al., 2016).

In this study, we leverage the PROM-related research described above to develop a psychometrically sound measure of the biopsychosocial relevance of DHTs for self-management of chronic conditions. Specifically, we address each key consideration associated with PROM development and validation described above to inform various methodological aspects of the biopsychosocial relevance instrument.

Key Considerations for the Biopsychosocial Relevance of DHT

As PROMs require rigorous psychometric development and validation, PROM-related research can inform various methodological aspects of the development and validation of the biopsychosocial relevance of DHT. Thus, we mirror key considerations in the instrument development and validation for PROMs to inform the methodological aspects

of the biopsychosocial relevance instrument. Table 4 summarizes our key considerations in line with PROMs.

Table 4: Key considerations for the biopsychosocial relevance of DHT

Instrument Attributes	
Category	Generic
Form	Informed by generic PROMs but the final decisions are made after the items are developed
Response scale type	
Scoring rubric	
Methodological Processes	
Patient involvement	Users are involved in item generation
Stakeholder input	Various stakeholders are involved in the content validity assessments
Psychometric validation	Psychometric techniques are used to assess and establish validity and reliability
Mode of administration	Electronic
Level of application	Individual and group

Instrument Attributes

This study refers to multidimensional generic PROMs to inform the form, response scaling type, and scoring rubric of the biopsychosocial relevance instrument. As stated previously, generic multidimensional PROMs cover multiple biopsychosocial dimensions of a patient's health and are used in chronic care to assess patients' perceptions of their overall health condition (Williams et al., 2016). Multidimensional PROMs align with this study's focus as the biopsychosocial relevance construct also captures multiple dimensions (such as biological, psychological, and social relevance).

Similar to multidimensional PROMs, we chose to model our biopsychosocial relevance measure as a multi-item measure. Multi-item measures are formed by more than one item and are used to capture complex concepts that have multiple dimensions (Gideon, 2012). For example, health-related quality of life measure has multiple domains (i.e., physical health, psychological health, and social health) that need to be considered to understand a

patient's quality of life status (Cappelleri et al., 2016). Each dimension requires a set of items to ensure that all relevant aspects of a dimension are adequately captured. Given the complexity and multidimensional nature of the biopsychosocial relevance construct, we generated multiple items to adequately assess and capture each dimension of biopsychosocial relevance.

As indicated in the prior section, prior PROMs leveraged a variety of response scale types (ranging from visual analog scales to Likert-type scales) (Gries et al., 2018). Although we considered various response scale types and made the final determination after developing the items, serious consideration was given to Likert-type scales. Likert-type scales are widely used for multi-item PROMs (Dowling et al., 2016), which align with the focus of this study on creating a multi-item measure of the biopsychosocial relevance of DHT. Moreover, Likert-type scales are also commonly used to examine individual perceptions in social sciences (Ho, 2016; Leung, 2011). For example, Likert-type scales were previously used in studies of perceptual measures related to digital health (Chen, 2019; Kelly, 2016).

In addition, we were open to various possibilities for anchor points. As stated previously, PROMs leverage a variety of anchor points (e.g., indicating the level of agreement, frequency of symptoms, and level of satisfaction with health, among others) (Vahedi, 2010). Ultimately, the selection of appropriate anchor points depends on the nature and purpose of the items (Gries et al., 2018). Therefore, in this study, we made final determinations regarding the anchor points after we had generated items for the biopsychosocial relevance measure.

We made final decisions on the scoring algorithm after we developed the items. However, we seriously considered the average scale scores commonly used in multidimensional generic PROMs (Feißt et al., 2019). One of the major advantages of using the average scoring rubric is that it calculates scores with missing items without imputing the missing data. In multidimensional PROMs, dimension scores are calculated using the average item scores within the dimension (Vahedi, 2010). In this study, a higher score would denote a higher level of biopsychosocial relevance. Individual dimension scores can be particularly relevant to users whose illness impacts only one or two aspects of their life. For example, if a user's illness impacts only their physical and psychological health, this user would not need to calculate the social relevance score. However, users whose illness impacts all three dimensions of their health condition (physical, psychological, and social) can calculate the total score of biopsychosocial relevance. The average of all scores across three dimensions can be used to calculate the overall biopsychosocial relevance score.

Regarding the factor score computation methods (i.e., weighted vs. unweighted), we explored various possibilities during our study. Specifically, we leveraged participants' responses to understand whether any particular biopsychosocial dimension had more value to participants than other dimensions.

Methodological Processes

In alignment with research on the PROM development and validation (Wiering et al., 2017), we involved users with chronic conditions in the item generation process. We leveraged qualitative methods (specifically semi-structured interviews) to clarify the user's perspective on the biopsychosocial relevance of DHTs for self-management of chronic conditions. Moreover, our study captured various methodological aspects of the PROM

development and validation (e.g., stakeholder input and psychometric techniques). User involvement and methodological elements of the biopsychosocial relevance measure's development and validation are further discussed in the methods sections in Chapters 3, 4, and 5.

Mode of Administration

Given the focus of this study on DHTs for self-management of chronic conditions, we focused on the electronic mode of administration for the biopsychosocial relevance instrument. The electronic mode of administration is more efficient than paper-and-pencil (Cella et al., 2015a). Moreover, if the biopsychosocial relevance instrument is to be integrated as digital health feedback in the future, the electronic mode of administration will be most convenient for users.

Level of Application

In this study, we developed an instrument to capture individual perceptions of the biopsychosocial relevance of DHTs for self-management of chronic conditions. Users can use individual scores to assess the relevance of specific DHTs for self-management of chronic care. In addition, biopsychosocial relevance responses can also be aggregated (e.g., through digital health feedback) to compare various digital health technologies targeting users with a specific health condition or compare users with various health conditions using specific digital health technology. Overall, we expect our biopsychosocial relevance measure to be leveraged at individual and group levels.

Study Instantiation: Chronic Headache Pain

This study leverages the context of chronic headache pain. Chronic headaches (e.g., chronic migraines, tension-type headaches, new daily persistent headaches, hemicrania

continua) are a major public health issue affecting 10% to 15% of people worldwide (Wang et al., 2016). Chronic headaches are associated with a high economic burden on the healthcare system (Negro et al., 2019). For example, the annual economic burden of migraines in the US is approximately \$78 billion (Gooch et al., 2017). Chronic headaches can also reduce individuals' quality of life as headaches affect various aspects of an individual's well-being (Bakar et al., 2015; Guitera et al., 2002; Pradeep et al., 2020; Terwindt et al., 2003).

Furthermore, chronic headaches are a biopsychosocial phenomenon, which impact an individual's physical, psychological, and social health (Terwindt et al., 2003). First, chronic headaches can affect various aspects of an individual's physical health (specifically pain, physical functioning, physical role limitations, and vitality). Chronic headaches are characterized by throbbing or constant pain in one's head or face (Kernich, 2008). Headache pain can reduce an individual's physical functioning (i.e., capacity to perform a variety of everyday activities (Terwindt et al., 2003)) (List et al., 2012). Disruptions in physical functioning can interfere with an individual's daily activities (i.e., physical role limitations) (List et al., 2012). For example, headaches can affect an individual's ability to perform household chores and reduce productivity at work or school (Holroyd et al., 2007). Moreover, headaches can impact an individual's vitality. For instance, the experience of headaches is associated with an individual's experience of fatigue (Bansevicius et al., 2002). Second, chronic headaches affect an individual's psychological health (Terwindt et al., 2003). Anxiety and depressive symptoms are commonly experienced among individuals with chronic headaches (Buse et al., 2010). Poor mental health can be associated with emotional problems (Garcia-Monco et al., 2007) that can interfere with an

individual's daily activities (i.e., emotional role limitations). For example, headache pain-related anxiety can lead to an enhanced state of alertness during the first indications of pain experiences and avoidance of activities (Nash et al., 2006). Moreover, headaches can impact an individual's social health, especially social functioning (i.e., the extent to which illness interferes with social activities (Terwindt et al., 2003)). Individuals with chronic headaches tend to miss social and leisure activities as well as avoid making plans for the fear of cancellation due to their headache pain (Lipton et al., 2003).

Self-management interventions targeting physical, psychological, and social health can improve headache-related experiences (Mann et al., 2013; Marceglia & Conti, 2017; Probyn et al., 2017). For example, these self-management behaviors can include managing medications to reduce physical pain, dealing with the emotional consequences of pain through meditation, and being a part of social support group, among others (Fillingim, 2017). DHTs have the potential to support self-management interventions for chronic headaches (Mann et al., 2013; Marceglia & Conti, 2017; Peng et al., 2019; Shah & Chiew, 2019). For example, DHTs can track headache episodes and identify triggers, provide users with a guided meditation to reduce headache-related stress, and provide users with emotional support through social networking features.

Even though there exist various DHTs for chronic headaches, literature reports various issues with these technologies (Durneva, 2021; Graaf et al., 2020; Minen et al., 2016). As with other DHTs for chronic pain, there is limited consideration of end-user's needs and preferences in designing and developing these tools (Durneva, 2021). This results in poor adherence to DHT as users stop using technology after a few interactions with it (Minen et al., 2016). Moreover, the existing DHTs for self-management of headaches appear too

narrow in their scope as they focus on specific aspects of headaches while ignoring the other, no less significant, aspects. For example, most DHTs tend to focus only on the physical (e.g., by tracking pain levels) or psychological (e.g., by providing users with Cognitive Behavioral Therapy) aspects (van de Graaf et al., 2020). Overall, there is a need for advancing knowledge of how to holistically design and assess DHTs for self-management of headaches by considering end-user's needs and preferences and accounting for the multidimensional experiences of users with chronic headaches. Thus, by advancing our understanding of relevance in the context of chronic headache pain, this study also contributes to the design of DHT that reflects the needs of the users suffering from chronic headaches.

CHAPTER 3: PHASE 1 - CONSTRUCT DEFINITION AND ITEM GENERATION

Introduction

To clarify the biopsychosocial relevance of DHTs, we used semi-structured interviews (DeVellis, 2016). Semi-structured interviews involve predetermined, open-ended questions with probes and prompts to elicit further information (Ayres, 2008). Semi-structured interviews can reveal the thinking and vocabulary of the target group and discover topics pertinent to understanding the construct of interest (DeWalt et al., 2007). Furthermore, we used the results of our semi-structured interviews to generate a preliminary set of items to measure the biopsychosocial relevance. The items were further assessed and validated in Phase 2 and Phase 3.

Methods

Overview

In instrument development, the first step is to define the construct of interest and generate the initial item pool (Morgado et al., 2017). During this step, one needs to develop a brief definition of the construct of interest, including its scope and dimensions, and generate a pool of items for potential inclusion in the measurement instrument (DeVellis, 2016).

We used semi-structured interviews to update preliminary definitions of the biopsychosocial relevance dimensions (presented in Table 2) and generate an item pool for the measurement instrument. Semi-structured interviews involve predetermined, open-ended questions with probes and prompts to elicit further information (Ayres, 2008). Compared to structured interviews, which contain the same set of questions for all participants, semi-structured interviews allow researchers to adjust the interview protocol

and delve more deeply into certain topics relevant to specific participants (DeJonckheere & Vaughn, 2019). When developing measurement instruments, semi-structured interviews can be used to clarify the construct of interest and help generate an item pool (DeVellis, 2016). Semi-structured interviews can also reveal the thinking and vocabulary of the target group and discover topics pertinent to understanding the construct of interest (DeWalt et al., 2007). For example, in the study developing a scale to measure dyadic efficacy in smoking cessation, researchers used semi-structured interviews to gain information on participants' understanding of dyadic efficacy and the language they used to talk about it (Sterba et al., 2011).

We leveraged a phenomenological approach to semi-structured interviews. Particularly, we referred to hermeneutic phenomenology (Alase, 2017). In hermeneutic phenomenology (as distinguished from transcendental phenomenology), pre-existing knowledge and researchers' understanding of the concepts related to the phenomenon of interest cannot be fully bracketed in interpreting participants' descriptions of the phenomenon (Patton, 2014). On the other hand, transcendental phenomenology focuses on the "lived experiences" of participants and brackets researchers' pre-existing knowledge of the phenomenon of interest. In alignment with hermeneutic phenomenology, we used high-level concepts (biological relevance, psychological relevance, and social relevance) to guide the construction of our interview guide and data analysis.

Furthermore, to ensure the trustworthiness of this study (i.e., internal validity and reliability), we used Lincoln and Guba's strategies and Weber's recommendations for conducting a rigorous qualitative research study (Guba, 1981; Weber, 1990). Specifically, we established validity and reliability through procedures such as member checks, peer

debriefing, code-recode, and researcher triangulation. Member checks involved follow-up surveys to confirm researcher's interpretations of participants responses.

Interview Protocol Development

Our interview protocol aligns with the phenomenological interview method described by Bevan (Bevan, 2014). In the interview protocol, we included a series of broad and open-ended questions that allowed participants to express their opinions extensively and freely. We recognize three aspects in developing a phenomenological interview guide: 1) contextualization (i.e., understanding participants' context in which the experience of the phenomenon of interest is situated) 2) apprehending the phenomenon (i.e., asking questions related to the specific phenomenon of interest), and 3) clarifying the phenomenon (i.e., imaginative variation) (Bevan, 2014). In alignment with the principle of contextualization, our interview protocol started with general questions related to participants' general headache experiences and their experiences with using DHTs for self-management of chronic headaches. Further, after questions about participants' general headache and DHT experiences, the interview protocol transitioned to questions that "apprehend the phenomenon." Particularly, these interview questions focused on participants' experiences with using DHTs to self-manage their physical health (i.e., the biological relevance of DHT), psychological health (i.e., the psychological relevance of DHT), and social health (i.e., the social relevance of DHT). Finally, we added some questions to clarify the biopsychosocial relevance of DHT by using imaginative variation (Bevan, 2014). Imaginative variation is leveraged when the researcher understands a specific element of participants' experience, which is then put through the process of varying its structural

components to uncover invariant parts. We used imaginative variation by exploring areas of improvement in DHTs to self-manage one's physical, psychological, and social health. To inform our interview questions, we used various relevance interpretations (Priniski et al., 2018) and existing PROMs pertinent to understanding individual's headache experiences from the biopsychosocial perspective. Specifically, we used a 36-item Short Form Health Survey (SF-36) that is commonly used to assess and compare the health-related quality of life of individuals suffering from chronic conditions (Arnold et al., 2000; Elliott et al., 2003; Solomon, 1997). The SF-36 covers multiple dimensions of an individual's health: physical functioning, social functioning, physical role limitations, emotional role limitations, mental health, bodily pain, vitality, and general health perceptions. The SF-36 has been the standard measure of health-related quality of life of chronic headache patients as it covers critical dimensions of health that need to be considered for headache assessments (Solomon, 1997). Moreover, the SF-36 is correlated with multidimensional headache-specific PROMs (Fuh & Wang, 2006). The SF-36, however, appears to capture more aspects of chronic headache patients' health conditions than headache-specific PROMs. For example, the Migraine Disability Assessment questionnaire (MIDAS), commonly used to assess outcomes of patients with chronic headaches, correlates with the SF-36. Yet, MIDAS does not cover the psychological dimension of chronic headache patients' health (unlike the SF-36).

Moreover, medical providers, researchers, and patients are typically involved in the development of the PROM questions (Carlton et al., 2020). A researcher with substantial qualitative research methods expertise and familiar with the study constructs reviewed the overall interview protocol. After addressing the feedback provided by this researcher

(particularly, the feedback related to the clarity of the questions, appropriateness of terminology, and the overall organization of the protocol, among others), we invited a medical provider (with experience in treating chronic headache patients) and a researcher (with experience in health communication) to assess the interview questions using the interview protocol refinement framework (Castillo-Montoya & Storrs, 2016). Appendix A contains the checklist for the semi-structured interview protocol that is based on the protocol refinement framework.

In addition, we conducted a pilot study with two users of DHTs for self-management of headaches to ensure that interview questions were clear and easy to understand for participants (Sin, 2010). Specifically, during the pilot study, participants were asked to provide feedback on ambiguous, confusing, or complex questions. Participants' feedback and responses during the pilot study were used to revise the semi-structured interview protocol. Particularly, we revised several questions that contained terms that users might not be familiar with (e.g., social support) by providing verbal definitions of such terms and reorganized the order of several questions (based on the similarity of users' answers to such questions). Appendix B contains our interview protocol.

Recruitment of Participants for Semi-Structured Interviews

Digital health users between 18 and 44 years of age suffering from chronic headaches were recruited for this study. Eligible participants were identified by using the inclusion criteria described in Table 5.

Table 5: Inclusion Criteria

Inclusion Criteria	Explanation
Experience chronic headaches	Chronic headache is one of the most prevalent types of chronic pain, affecting 10% to 15% of people worldwide (Wang et al., 2016). Chronic headaches occur 10-15 times a month for at least three months (Kristoffersen & Lundqvist, 2014; Yancey et al.,

Inclusion Criteria	Explanation
	2014)). Thus, participants who experience chronic headaches were recruited for this study.
Age between 18 and 44 years old	Chronic headaches often occur for the first time in late adolescence and early adulthood (Victor et al., 2010) and tend to disappear with advancing age (Song et al., 2016). According to National Health Interview (2018), the age group of 18-44 has the highest prevalence of headaches (18.7%) (Burch et al., 2021; CDC, 2018). Other age groups have a lower prevalence of headaches: 15.7% for the age group of 45-64, 9.3% for 65 to 74-year old, and 6.1% for 75 years old and older. Thus, participants in the age group with a high prevalence of headaches (18-44 years old) were recruited for the study
Experience with DHTs to self-manage chronic headache	Since the interviews aim to explore participants' perceptions of the biopsychosocial relevance of DHTs for self-management of chronic conditions, we needed to recruit individuals with digital health experience. Given the context of this study (chronic headaches), we recruited individuals who use DHT(s) to self-manage their headaches.

We recruited participants by using a multi-modal recruitment strategy involving traditional (i.e., using hardcopy materials) and online (i.e., using electronic materials) recruitment activities (Close et al., 2013; Gelinas et al., 2017; McRobert et al., 2018; Whitaker et al., 2017). A multi-modal recruitment strategy can minimize the financial and time costs associated with the study recruitment and increase the response rate across various groups of participants (McRobert et al., 2018). We leveraged traditional and online recruitment methods to meet this project's timeline and recruit a diverse group of participants with headaches.

Traditional recruitment activities took place on the FIU campus and at the health centers affiliated with FIU. Flyers about the study were posted at the Health Center, Green Library, Ambulatory Care Center, and mobile health centers at FIU. Moreover, online recruitment took place on social media (Gelinas et al., 2017). Specifically, flyers about the study were posted across various Facebook groups dedicated to chronic pain and headaches. The flyers

were posted after we contacted the group admins and received their permission to advertise the study. In addition to the planned traditional and online recruitment activities, some participants also emailed us indicating that their friends or family members would also be interested in participating in the study and asked for our permission to sign them up.

The flyer for the study contained the QR code that took participants to the Qualtrics sign-up survey. Interested participants provided their names, demographic information (age, gender, ethnicity), headache-related information (duration and type), experience with DHTs for self-management of headaches, and email addresses.

Participants were notified that the study involved two parts: semi-structured interviews and short follow-up surveys to confirm their responses (i.e., member checks). After completing both parts of the study, participants received a \$25 compensation for their time (an average compensation for participation in interviews (Cheff, 2018)).

Data Collection Associated with Semi-Structured Interviews

Sample Size

Twenty-three semi-structured interviews were conducted. Sample size guidelines for qualitative research suggest that having at least 20 participants is sufficient for achieving data saturation, the point at which the incremental learning is minimal (Saunders et al., 2018), (Creswell & Poth, 2017). Conducting at least 20 interviews is also consistent with other comparable qualitative studies that focus on revealing patient's headache experiences (Morgan et al., 2016; Palacios - Ceña et al., 2016; Palacios-Ceña et al., 2017; Seng & Holroyd, 2013; Varkey et al., 2013), exploring digital health perceptions (Anderson et al., 2016; Chang et al., 2013; Simblett et al., 2019; Solem et al., 2019), and scale development studies assessing user experience with digital health (Akter et al., 2013; Chen, 2019).

We achieved complete data saturation at the 23rd interview and stopped our data collection efforts. We calculated a saturation ratio to assess data saturation for each interview and determine when to stop data collection (Guest et al., 2020). The saturation ratio is based on a base size, run length, and new information threshold. The base size refers to the minimum number of data collection events (e.g., interviews) that should be analyzed to calculate the amount of information already gained. Typically, studies employ the base sizes of 4, 5, and 6. Guest et al. (2020), however, found that different base sizes (4 vs. 5 vs. 6) have almost no impact on the outcome. Thus, we choose to use the base size of 4 (the minimum base size). Furthermore, the run length refers to the number of interviews within which we looked for new information. Similar to what is stated by Guest et al. (2020), we used the run length of 2. Finally, the new information threshold refers to the proportion of new information we would accept as evidence that data saturation has been achieved. To ensure that all possible themes and subthemes were discovered, we set the new information threshold as 0% (i.e., complete data saturation).

To calculate the saturation ratio, we first had to sum the number of unique themes (or subcodes) in the first four interviews (given the base size of 4) (Guest et al., 2020). According to Table 6, the total number of unique subcodes in the first four interviews was 69. Then, we needed to find the number of unique subcodes for the first run (interviews 5 and 6): the number of unique subcodes for interviews 5 and 6 was 13. Finally, we had to divide the number of unique subcodes in the first run (i.e., interviews 5 and 6) by the number of unique subcodes in the base interviews (interviews 1-4) to calculate the saturation ratio. As illustrated in Table 6, the saturation ratio for the first run was 18.84%. This number did not match our new information threshold (0%). Thus, we continued our

data collection efforts while updating the saturation ratios. At the 23rd interview, the saturation ratio was 0%, so we stopped collecting data.

Table 6: Data saturation ratios

Interview Number	Number of Unique Subcodes	Saturation Ratio
1	25	Base Interviews contain 69 unique subcodes.
2	19	
3	12	
4	13	
5	10	18.84%
6	3	
7	3	
8	3	
9	5	11.59%
10	4	13.04%
11	5	13.04%
12	5	14.49%
13	2	10.14%
14	2	5.80%
15	0	2.90%
16	2	2.90%
17	1	4.35%
18	1	2.90%
19	0	1.45%
20	1	1.45%
21	1	2.90%
22	0	1.45%
23	0	0.00%

Conducting Interviews

The lead researcher of this study conducted the interviews. Initially, we estimated that the interviews would take between 40 and 60 minutes. Sixty minutes is a reasonable maximum length for semi-structured interviews to minimize researcher and participant fatigue (Adams, 2015). After conducting pilot interviews and revising the interview protocol, we estimated that it would take approximately 40 minutes (on average) to conduct one semi-structured interview.

Zoom®, a collaborative cloud-based conferencing service, was used to conduct semi-structured interviews. Prior research points to the effectiveness and efficiency of collecting qualitative data via Zoom in various health-related studies (Archibald et al., 2019). Zoom permits multi-modal forms of communication: visual and audio. Since increased exposure to screen time can trigger headaches among individuals with chronic headaches (Montagni et al., 2016), participants were invited to join the interviews using the audio modality only. Participants were also informed that if a computer screen did not usually trigger their headaches, they could also use the video option. With the participant's permission, the interviews were recorded.

Participants' consent form was reviewed at the beginning of each interview to ensure that participants understood the study procedures. Participants were informed that there were no right or wrong answers and that they could freely express their opinions. At the end of each interview, participants were reminded of the second part of the study, specifically a follow-up survey to validate participants' responses during the interviews (i.e., member checks) (Guba, 1981). Member checks allowed us to enhance the validity of the interview findings.

Conducting Follow-Up Surveys (Member Checks)

After each transcript was analyzed, we conducted member checks with each participant. A member check refers to a technique to enhance the credibility of results (Guba, 1981). During member checks, the results of our data analysis were returned to participants to check for accuracy and resonance with participants' experiences (Birt et al., 2016). To conduct member checks, we analyzed the interview transcripts, compiled a list of summarized statements that captured participants' perspectives on the relevance of DHTs

they were using, and sent participants follow-up surveys to confirm their statements. Specifically, participants had to indicate whether they agreed or disagreed with a set of statements. Participants had the option to provide comments and corrections for statements they disagreed with. In addition, participants were invited to share any additional information pertinent to their experiences with DHTs that might have been not shared during the interview.

Data Analysis Associated with Semi-Structured Interviews

Interview Transcription

We used otter.ai¹ to transcribe interviews. The audio recordings were destroyed after interviews were transcribed and verified for accuracy (e.g., after typos were corrected). Transcribed interviews were de-identified. De-identified transcripts were uploaded to Dedoose©², a qualitative data analysis software. In Dedoose©, the data are encrypted and securely stored in Microsoft's Azure US server.

Before completing member checks, we associated participants' contact information with their transcripts. Unique IDs to associate transcripts with participants' information were created. Participants' information was stored separately from transcripts in an access-restricted folder on a secure, password-protected, locked machine. We discarded personally identifiable participants' information after we conducted member checks verifying participants' responses following the interviews.

¹ <https://otter.ai/>

² <https://www.dedoose.com/>

Thematic Analysis

We conducted thematic analysis to code the transcripts. Thematic analysis is a method for identifying, analyzing, organizing, describing, and reporting themes within a dataset (Nowell et al., 2017). We took a hybrid approach (both inductive and deductive coding) to thematic analysis (Fereday & Muir-Cochrane, 2006). The lead researcher of this study performed thematic coding activities.

To perform deductive coding, we first developed an a priori coding schema consisting of high-level concepts (i.e., the biological relevance of DHT, the psychological relevance of DHT, and the social relevance of DHT). After we developed an a priori coding schema, we conducted deductive thematic analysis (Fereday & Muir-Cochrane, 2006). We coded interview transcripts using an a priori coding schema during deductive thematic analysis. We were also open to additional major themes to extend our coding schema.

We further analyzed the transcript text using an inductive approach (Fereday & Muir-Cochrane, 2006). We inductively identified specific subcodes within each high-level code. These subcodes (as well as the results of the member checks) were used later to inform items for each relevance dimension.

To ensure the trustworthiness of thematic analysis (i.e., internal validity and reliability), we used Lincoln and Guba's strategies as well as Weber's recommendations for conducting a rigorous qualitative research study (Guba, 1981; Weber, 1990): peer debriefing (i.e., code review), code-recode procedure, and researcher triangulation. Table 7 summarizes our procedures to ensure validity and reliability.

Table 7: Summary of validity and reliability procedures

Trustworthiness criteria	Procedures	Description
Internal validity	Peer debriefing (a code review)	A health communication expert reviewed high-level codes and their contextualized definitions, alignment between high-level codes and sub-codes, conceptual integrity of the entire coding schema, and 20% of data.
Reliability	Stability	15% of data from the first three interviews were re-coded by the lead researcher approximately a month after coding the first three interviews. Cohen's Kappa was 0.85, indicating a high coding stability level.
	Reproducibility	A graduate assistant (not involved in data collection/analysis) coded 15% of the excerpts using high-level coding schema. Cohen's Kappa value was 0.91, indicating a high level of agreement.

The peer debriefing session was conducted to establish internal validity. After coding 12 interview transcripts, the point at which the coding schema stabilized, we invited a health communication expert to conduct a code review (Barber & Walczak, 2009). We trained the invited researcher in the contextual meaning of the constructs for the purposes of this study. The invited researcher then conducted a code review involving the review of high-level codes and their contextualized definitions, alignment between high-level codes and sub-codes codes, conceptual integrity of the entire coding schema, and 20% of data (Barber & Walczak, 2009). We then used the feedback to revise the coding schema. Specifically, the feedback referred to revising the conceptual definitions of high-level codes and the labels of specific subcodes, developing new subcodes to capture specific ideas in some of the quotes, and applying multiple subcodes to specific quotes to capture the multi-dimensionality of participants' experiences.

Moreover, reliability was established concerning stability (i.e., consistency in the private understanding of coding) and reproducibility (i.e., shared understanding of the content being analyzed) (Weber, 1990). To ensure stability, we conducted the code-recode procedure for the first three interviews (Krefting, 1991). Specifically, the lead researcher re-coded 15% of randomly selected data from the first three interviews approximately a month after coding such interviews. The code-recode procedure was specifically applied to high-level codes pertinent to the dimensions of the biopsychosocial relevance of DHT. We chose to establish stability of the coding schema at a high-code level (instead of the subcode level) to develop definitions of the biopsychosocial relevance of DHT (and its dimensions) that could be applicable to not only chronic headaches (which is the context of the study) but also other types of chronic conditions. Subcodes, on the other hand, made specific references to headaches (e.g., triggers of headaches) and, therefore, would not provide us with any room for generalizability. The Cohen Kappa's value was calculated to assess the level of stability. After conducting the procedure, Cohen's Kappa was 0.85, indicating a high coding stability level (McHugh, 2012). In other words, the value of 0.85 indicated that the lead researcher's understanding of high-level codes was consistent over time. The reconciliation activities for 0.15 of quotes were targeted at applying multiple codes to excerpts capturing multiple themes as well as redefining specific codes.

Moreover, a graduate assistant was invited to code 15% of randomly selected excerpts by applying high-level codes related to participants' headache experiences, experiences with using digital health, and the dimensions of the biopsychosocial relevance to ensure reproducibility. First, the graduate student was introduced to the study's purpose, major concepts (i.e., biopsychosocial relevance dimensions), and the coding schema. Second, the

graduate student was asked to code 15% of excerpts as part of their training to enhance their understanding of the major concepts of the study as well as to train them in coding procedures in Dedoose ©. After the first training round of coding, Cohen's Kappa value was 0.54, indicating the graduate assistant's moderate understanding of the major concepts of the study (McHugh, 2012). Conceptual disagreements were taken into consideration to revise the coding schema and the application of codes to specific excerpts. Following the training and revisions to the coding schema, the graduate assistant coded 15% of excerpts (which were not included in the training set) applying high-level codes. We chose to assess reproducibility on a high-level code level for the reasons stated above: particularly, we wanted to ensure that there is some room for generalizability to other conditions in our assessments. Cohen's Kappa value was 0.91, indicating a high level of agreement (McHugh, 2012). The reconciliation meeting was held to discuss 0.09 of the quotes that the graduate assistant and the lead researcher disagreed on. The major reconciliation activities included applying multiple codes to excerpts that capture multiple themes and merging codes whose conceptual meanings overlapped.

Construct Definition and Item Generation

Table 2 contains preliminary definitions of the biopsychosocial relevance dimensions. Through our qualitative analysis, we identified themes most pertinent to participants' understanding of the biopsychosocial relevance of DHTs for self-management of chronic headaches. We reviewed these themes and updated our preliminary definitions of the biopsychosocial relevance of DHTs.

We then created an initial item pool by following the item generation guidelines proposed by DeVellis (2016) (DeVellis, 2016). During this step, it is important to identify a range of

ways in which the central concept of the intended measurement instrument can be stated (DeVellis, 2016). We used subcodes within each biopsychosocial relevance dimension and verified statements from member checks to generate items for the biopsychosocial relevance of DHTs.

The items were phrased in the form of statements about the relevance of DHTs for self-management of chronic headaches and targeted the PROM-type syntax (Patrick et al., 2011). To target the PROM-type syntax, we ensured that items were worded in a manner consistent with the expressions used by participants. We also followed general recommendations for item writing: avoiding lengthy items, aiming for a reading difficulty between 5 and 7th grade, avoiding multiple negatives, avoiding double-barred questions, avoiding ambiguous pronoun references, and avoiding biased and leading questions (DeVellis, 2016). Appendix C contains the item development rubric used to guide the item writing process.

Results of Phase 1

During Phase 1, we collected data from 23 DHT users. The demographic information of our sample generally aligns with the national demographics of headache sufferers. Our participants shared various experiences with DHTs to self-manage their headaches and provided insights into the biological, psychological, and social relevance of DHTs.

Participants' Demographics

The demographic information of our participants is summarized in Table 8.

Table 8: Participants' demographics (Phase 1), N=23

Gender, n (%)	
Female	16 (69.57%)
Male	6 (26.09%)
Non-binary	1 (4.35%)

Ethnicity, n (%)	
White	11 (47.83%)
African American	5 (21.74%)
Asian	4 (17.39%)
Hispanic	2 (8.70%)
Middle Eastern	1 (4.35%)
Age, n (%)	
18-24	4 (17.39%)
25-29	8 (34.78%)
30-34	8 (34.78%)
35-39	1 (4.35%)
40-44	2 (8.70%)

In our sample, 69.57% (n=16) of participants were females, and 26.09% (n=6) were males. This distribution aligns with the national data on the prevalence of chronic headaches among females and males. Specifically, the National Health Interview Survey indicates that females are two to three times more likely to report headaches than males (Eisenstein, 2020). One of our participants, however, identified as non-binary. We could not verify the extent to which our data align with the national demographic information due to the limited reports on the prevalence of headaches among gender minorities (e.g., non-binary, transgender) (Hranilovich et al., 2021).

Furthermore, 47.83% (n=11) of our participants were Whites, 21.74% (n=5) were African Americans, 17.39% (n=4) were Asians, 8.70% (n=2) were Hispanics, and 4.35% (n=1) were Middle Eastern. This distribution partially aligns with the national data on the prevalence of chronic headaches among different ethnicities. Specifically, research indicates that the prevalence of headaches is higher in Whites than in African Americans, Hispanics, and Asians (for both males and females) (Stewart et al., 1996). According to Loder et al. (2015), the average prevalence of headaches (from 2005 to 2012) was 15.5%

for Whites, 14.5% for Hispanics, 14.45% for African Americans, and 9.2% for Asians (Loder et al., 2015).

Finally, the age groups of 25-29 and 30-34 contained the highest number of participants compared to other age groups (n=8 or 34.78%). This age distribution aligns with prior research studies that indicate that the mean age at the onset of chronic headaches is typically between 25 and 30 years old (Kriegler, 2018).

Chronic Headache Experiences

Chronic headaches are a biopsychosocial phenomenon (Terwindt et al., 2003), and our participants generally shared that their headaches affected their physical, psychological, and social health. Participants shared that their headache attacks were usually accompanied by various unpleasant physical sensations, including fatigue, numbness, sensitivity to lights and sounds, and nausea. For instance, one participant said, *“When I have migraines, it is as bad as that I cannot. Yeah, I cannot do anything. I’m just in bed, I feel pain like trying to, to... just wishing it will go away for it to, to end the episode. It is as bad that, when I wake up, and I have a pounding pain in my head. I know. Yeah, I know, I’m going to throw up that day. And it’s going to be a very bad day. So I will throw up maybe 10 minutes after I wake up because pain is so intense. It will cause nausea and vomiting.”*

In addition, participants indicated that their headaches negatively impacted their emotions and mental health. Participants shared a variety of emotions that they experienced when they had headaches: anger, frustration, irritation, and sadness. Some participants also shared that headaches made them feel depressed, stressed, and anxious. For instance, one participant stated, *“It [headache] can make me feel, sometimes it sends me into a depressed*

mood, because I keep wondering, you know, why? Why me? Why do I have to constantly have headaches?”

Moreover, participants shared that their headaches also affected their social interactions and relationships with others. For instance, one participant shared, *“I’ve had to cancel a lot of things last minute, just because I’m in so much pain. I just went out with my brother on Friday. And after two hours, I had to go home because I was in way too much pain to function.”* Most participants also stated that they needed social support to help them deal with their headaches.

General User Experiences with DHTs

Participants used a variety of DHTs to self-manage their chronic headaches: self-tracking apps (e.g., *Migraine Buddy*, *Migraine App*, *Migraine Monitor*, *Migraine Insight*, *Pain Scale*, *Breeze*), meditation apps (e.g., *Calm*, *Headspace*, *Meditation Moments*, *Medito*), and online resources, such as *Healthline* and *WebMD*. Most of the participants (n=17) used *Migraine Buddy*. Some participants used a combination of various DHTs (e.g., a self-tracking app coupled with a meditation app). In our sample, 30.43% (n=7) of participants used more than one DHT to self-manage their headaches and associated symptoms.

Furthermore, participants in our sample engaged with DHTs for self-management of chronic headaches over different periods of time. 39.13% (n=9) of participants stated that they started using DHTs less than 3 months ago. On the other hand, 30.43% (n=7) indicated that they started using DHTs more than 12 months ago. 17.39% (n=4) and 13.04% (n=3) participants reported that they started using DHTs 3-6 months and 6-12 months ago, respectively.

Most participants were generally satisfied with their use of DHTs. Some participants indicated that they found their DHT easy to use. For instance, one participant said, *“Probably, I find it [DHT] easy to use. It's pretty straightforward. And a lot of the kind of triggers, and drugs and all of that a lot of them were pre-populated.”* Moreover, participants discussed a wide range of reasons for choosing a specific DHT to self-manage their headaches: a low price, convenience, doctor’s recommendations, online reviews, credibility, and a limited number of other options available.

Despite generally positive experiences with DHTs, some participants indicated the negative sides of their technology use. Remarkably, some participants described negative connotations associated with their use of DHT. One participant, for instance, stated, *“I think when I did not see any kind of patterns, I got a little bit frustrated. And that's when I kind of stopped using it as frequently. And I think now since I use it [DHT] only to track existing headaches, there is kind of a negative connotation there, right? Because I only use it when I'm already feeling poorly. So I think I was definitely hopeful at first and now it's kind of like more of a negative connotation, because I know I have a headache, if I'm using it, I have a headache.”*

Our interviews also revealed various ways participants perceived a personally meaningful connection between DHTs and their physical, psychological, and social health. The biological, psychological, and social relevance forms of DHTs are discussed in the following sections.

The Biological Relevance of DHT: Overview

Our thematic analysis revealed various aspects of users’ perception of a personally meaningful connection between user’s physical health and DHTs for self-management of

chronic conditions, specifically chronic headaches. Particularly, such a connection (i.e., the biological relevance of DHT) manifested in the following aspects that could be enabled by user interaction with DHT: monitoring one's physical health, building awareness of one's physical health, learning about physical health in general, and managing one's physical health. Figure 1 summarizes the high-level results of our thematic analysis.

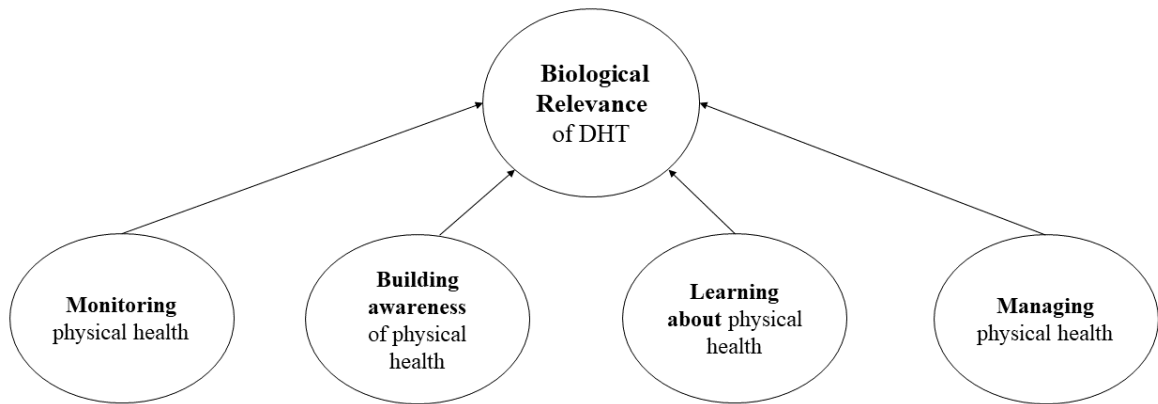


Figure 1: Biological relevance of DHT

We describe each aspect of the biological relevance of DHT in more detail in the following subsections. Appendix D1 contains the evidence-trace table with sample quotes related to each aspect of the biological relevance of DHT.

The Biological Relevance of DHT: Monitoring Physical Health

One aspect in which participants leveraged DHTs to deal with their physical health manifested in user monitoring activities enabled by DHT tracking features. Mainly, participants used tracking features to monitor their physical symptoms, habits (that could affect their physical health), treatments (e.g., medications and pain relief methods), and potential triggers of their headaches (see Figure 2).

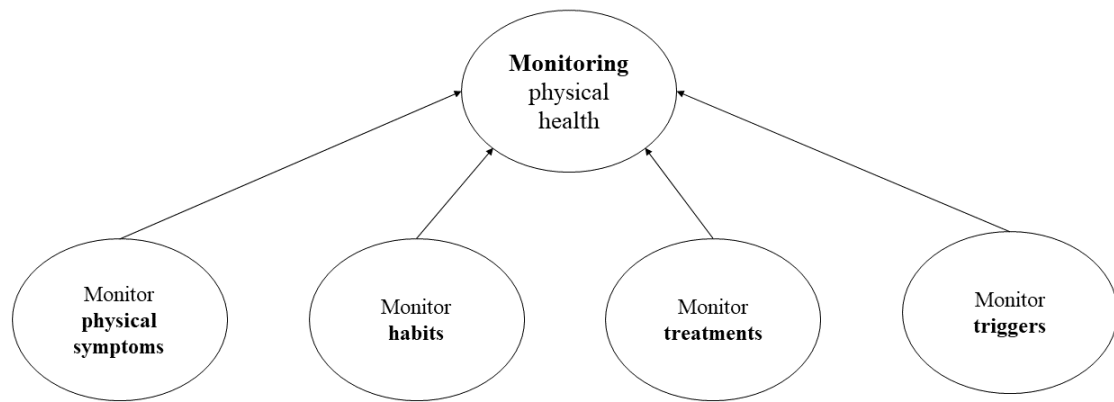


Figure 2: Monitoring physical health

Participants discussed how DHTs enabled them to monitor their physical symptoms, specifically headache episodes and attacks. Particularly, participants used the tracking features of DHTs to monitor their headaches over weeks, months, and even years. Monitoring headaches over a prolonged period generally helped participants become more aware of their headache patterns. For instance, one participant stated: *“I can monitor my headaches from time to time, different times in the day and also it [DHT] has the insight part where I can see like, Okay, what is happening this week, how many days, how much headaches I have been having.”*

In addition to monitoring physical symptoms associated with their headaches, participants also monitored their daily habits that could affect their headaches. For example, participants used the tracking feature to monitor their daily water intake, sleep patterns, eating habits, physical activity levels, and alcohol intake. One participant indicated that tracking her daily habits allowed her to understand some of her headache causes. She said, *“So I think random things like how much water intake you're having, how much you're eating, or whether you're eating good or not, how your sleep patterns happening. And that just give me an insight of like over a month maybe or something that here are the top*

reasons we [DHT] managed to find that here are the top reasons of the headache that you're getting.”

Furthermore, participants shared that monitoring their physical health also involved monitoring their treatments (e.g., medications and pain relief methods) to manage their headaches' physical symptoms (e.g., pain). One participant said, *“I mean, it [DHT] does a really good job of tracking a board of medication. So, I have a migraine, I took my triptan and it, it tracks that.”*

Finally, monitoring potential triggers of one's headaches through the tracking feature of DHT also emerged as another critical aspect of the biological relevance of DHT. One participant shared that an option to add her triggers in DHTs was one of the primary reasons for her use of such a technology: *“I like the fact that when it [DHT] was asking for triggers, it adds for my own personal trigger I can add...Some other apps just, another app, it just gave me a limited trigger, gave me limited information, it didn't give me option, chance to ask me what's my personal trigger. And sometimes it might not even be chocolates or what it's asking, for instance, I feel, I feel headache when this, when I'm really stoved up or I could just take, maybe, pause. I feel a serious headache. But I don't think the part of...people...it is not very popular. So, I could add it to the Migraine Insight. So, I was like, it helps me just keep track, see this is what happened. This is why I'm having this.”*

The Biological Relevance of DHT: Building Awareness of Physical Health

The biological relevance of DHT also manifested in users' increased awareness of their physical health. Mainly, participants shared that their use of digital health enabled them to become more aware of their headache experiences, physical symptoms associated with their headaches, daily habits, treatments, and triggers (see Figure 3).

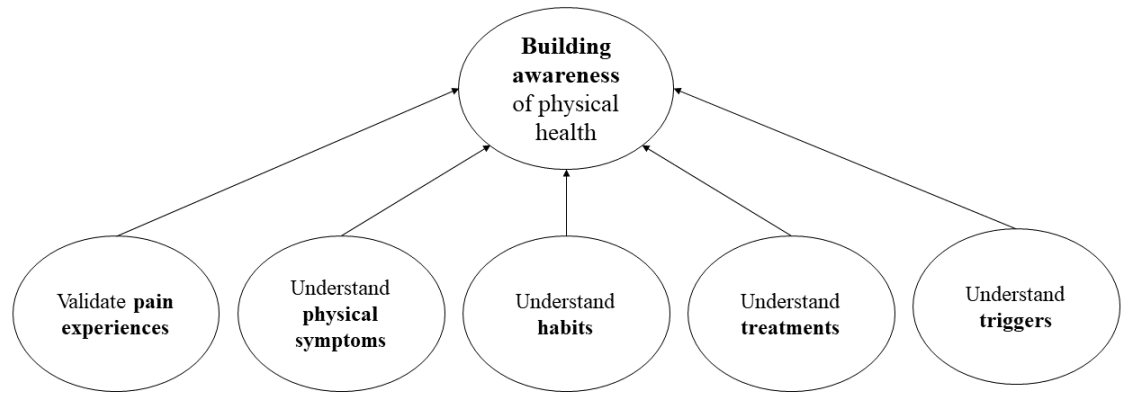


Figure 3: Building awareness of physical health

Some participants indicated that tracking their headaches over time and reviewing their own self-reported records later “validated” their perception of how their headaches have affected their life. For instance, one participant said, *“I guess it [DHT] makes me feel like I mean, on the one hand, like validated that all the headaches are happening. And I’m not like exaggerating in my head.”* Further, another participant stated that their self-reported records of headaches serve as a “proof” of their headaches: *“It’s also some sort of proof that there is pain. Because sometimes people think like you are making it up just to get off things or no, but this way, like you have records, records, and records of our pain. It’s not something you’re making up. Because yeah, I do not choose to one day just be in bed and throw up my, my whole intestines out. It’s, it’s there. It’s something that like happens. And I can see, I can take a hold of my condition by tracking it.”*

Moreover, participants generally indicated that their use of DHTs enabled them to better understand the physical symptoms associated with their headaches. Particularly, some participants said that through their use of DHT, they learned that physical symptoms, such as sneezing or feeling elated, could be linked to an upcoming headache attack. One participant said, *“Um, yeah, it [DHT] actually kind of made me aware that I get really*

happy and really elated, which I didn't realize can be a symptom of a migraine coming on. But that was kind of one of those pre-populated things. I was like, Oh, I feel really good a lot of the time. And bam, it's right there. So it definitely made me aware of at least that physical symptom."

In addition, participants' use of DHTs helped them become more aware of their daily habits (including sleep patterns, physical activity, and water intake, among others) and how their daily habits could affect their headaches. One participant, for instance, indicated that tracking her habits enabled her to get a better understanding of what she should be doing to manage her health: *"I go back and I kind of look into what healthy habits I have been doing at that time and just kind of like gives me a better idea of what things should I continue on doing."*

Building a better understanding of various treatments (including pain relief methods and medications) was also discussed among participants. Participants generally indicated that they could track various treatments that they used to manage their headaches and get a better understanding of what works and what does not work for them. For instance, one participant stated, *"It [DHT] asks what relief methods you have tried. So a lot of them have kind of the ones that have been pre-populated, and kind of take a look at some of them every once in a while and go, Okay, well, I had tried this, maybe it could help."*

The Biological Relevance of DHT: Learning About Physical Health

Learning about physical health, in general, was discussed among participants. Participants indicated their interest in learning about headaches, relief methods, and triggers (see Figure

4).

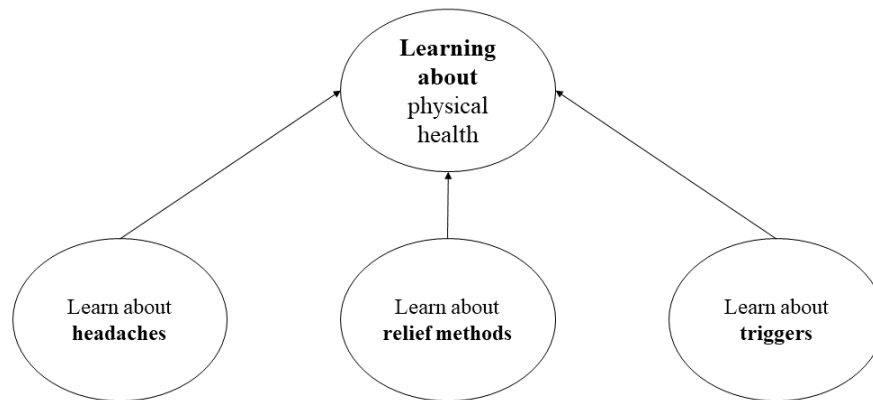


Figure 4: Learning about physical health

Some participants indicated that they were able to learn new information about headaches (and specifically, different types of headaches and associated physical symptoms) through DHTs. Other participants indicated that they did not learn anything new since they had been dealing with headaches for quite some time. However, they would still be interested in some scientifically relevant educational content about headaches. For instance, one participant said, *“Because as I said, I’m dealing with this since many years, and I would consider myself to be relatively, to know relatively much in this field. So yes, if it would be scientifically more relevant, like the information that was delivered to me, then probably yes, then I would probably learn something like how to differentiate if you have a migraine or a cluster headache or something like this.”*

Furthermore, some participants indicated that they were able to learn new information about various triggers of headaches in general. One participant, for instance, stated that she was able to learn about possible triggers of headaches through a DHT. She said, *“I’m looking at the tracker, mainly because when I am good enough about it to, to track it, it’s really helpful, right? It’ll make me think about the triggers outside of what I typically think*

of as triggers, right? Lack of sleep, super stressed, and be like, Oh, I didn't think that this could possibly be a trigger, but something I can examine. So I do mainly utilize that.”

Moreover, participants shared that they would be interested in learning more about various relief methods for their headaches. Some participants indicated that DHTs did not necessarily provide them with new information about the relief methods for their pain. Nevertheless, they would be interested in being exposed to such information through their use of technology. For instance, one participant stated that he would like to see different “strategies” on how he could deal with the onset of his headache by saying, *“Maybe thinking of things like...because a lot of times I can feel a headache coming on, maybe strategies or something you can do to kind of try to make it better or, not as bad. I'm not really sure. A lot of like, hints or strategies, just maybe having something different.”*

The Biological Relevance of DHT: Managing Physical Health

Managing physical health emerged as another critical aspect of the biological relevance of DHT. As summarized in Figure 5, DHT enabled users to manage their physical health (specifically, their headache pain) by supporting them in getting immediate relief from their pain, as well as helping users practice healthy habits, avoid triggers, and predict future headache attacks.

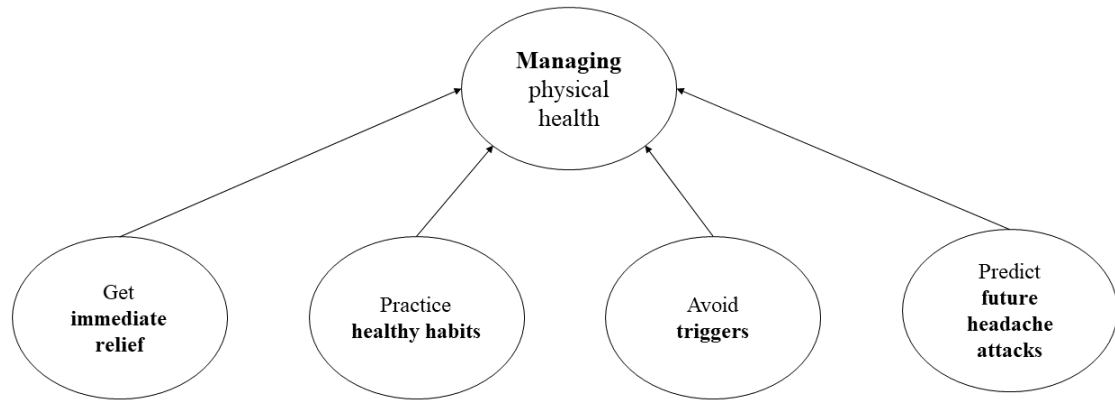


Figure 5: Managing physical health

Participants generally shared that relaxation techniques (e.g., guided meditation) and physical activity recommendations provided by DHT enabled participants to get some relief from their headache symptoms. For instance, one participant shared her experiences with the guided mediation technique in DHT: *“And as I said, the Headspace app, initially, I was offended by how they, settle into the pain. You’ve never felt that kind of pain, if you think you can settle into it in, as a quote and quote, comfy chair. But as soon as I did it, it actually does help to do that. That was a helpful cue.”*

In addition to getting immediate relief from their headache pain, participants also shared that digital health features (e.g., recommendations, notifications, and tracking) enabled them to manage their physical health by motivating them to practice healthy habits. Particularly, participants shared a wide range of healthy habits supported by their interaction with DHTs: for instance, getting a sufficient amount of sleep, practicing healthy eating, being physically active, and avoiding alcohol, among others. Sharing her experiences with DHT, one participant indicated how she improved her sleep patterns through her use of DHT, *“And with this app, It’s teaching me how to get my sleeping pattern on track. Yeah, I might lying in bed, look, I’m not going to sleep, I’m gonna watch my TV show. Oh, and my body telling me otherwise, no, you need to shut it down. So I look*

at that app, and it would let me know, hey, it's time to close your eyes. So it did help me get on the routine pattern for sleeping.” Further, some participants indicated that DHT would provide them with a series of recommendations on what habits they should be practicing and what they should avoid doing. For instance, one participant said, *“...it [DHT] will give some tips and recommendations. Exercise this long. We recommend drink this much amount of water. We recommend not doing this or not spending much because it can, what you choose, Interviewer’s name, what you think are the triggers or whatever. It will also give recommendations on things that you should spend less time doing, like less time in front of a computer screen or the TV and more time outside walking around enjoying nature, having interactions with other people, less consumption of alcohol because it does ask you how much alcohol you drink for that specific day or anything like that.”*

Furthermore, participants stated that the information about possible personal triggers of participants’ headaches provided by DHT enabled them to avoid such triggers in their daily lives. For instance, one participant said, *“So the app, when I check the app, it tells me, tells me these things, I should avoid these things. And I just, when I see it, I see it as a trigger. So I kind of avoid these things. I try to avoid things, I think at least most of it.”*

Another aspect of user interaction with DHT that can enable individuals to self-manage their physical health is using the predictive capabilities of DHTs. Participants sometimes relied on DHTs to predict their next headache attack. One participant, for instance, stated, *“Because when you keep logging it in to the app, the app might tell you the next time you experience a headache or something like that.”*

The Psychological Relevance of DHT: Overview

Our thematic analysis revealed various aspects of users' perception of a personally meaningful connection between users' psychological health and DHTs for self-management of chronic conditions, specifically chronic headaches. Particularly, the psychological relevance of DHT manifested in the following aspects that could be enabled by user interaction with DHT: monitoring one's psychological health, building awareness of one's psychological health, managing one's psychological health, and feeling empowered. Figure 6 summarizes the high-level results of our thematic analysis. In the following sections, we describe each aspect of the psychological relevance of DHT in more detail. Appendix D2 contains the evidence-trace table with sample quotes related to each aspect of the psychological relevance.

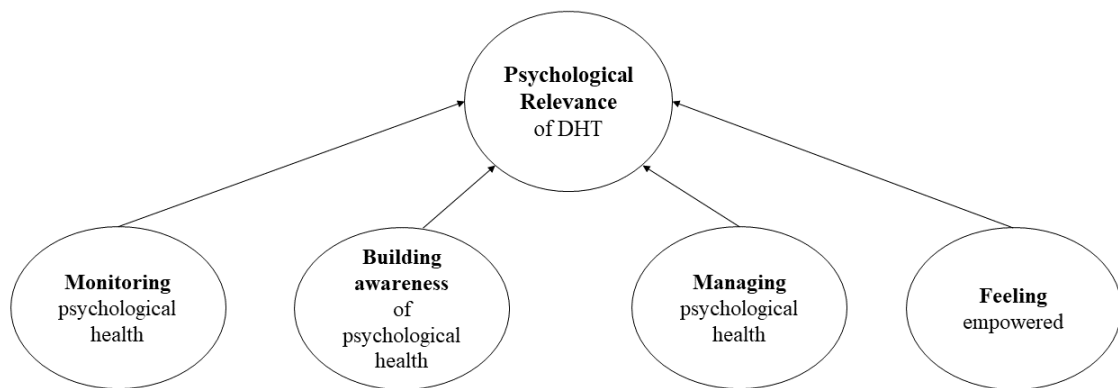


Figure 6: Psychological relevance of DHT

The Psychological Relevance of DHT: Monitoring Psychological Health

Monitoring one's psychological health emerged as one of the aspects of the psychological relevance of DHT. Particularly, participants indicated that their interaction with a DHT enabled them to monitor their emotions and mental health states (Figure 7).

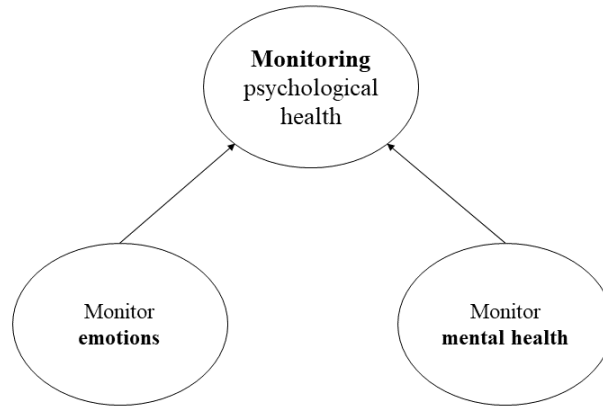


Figure 7: Monitoring psychological health

Some participants shared that when they experienced headaches, they could monitor their momentary emotions (e.g., feeling sad or frustrated) through the tracking feature in a DHT. For instance, one participant stated, *“I would log my symptoms and how I was feeling so then I can get a broader picture of what my overall mood is.”*

Moreover, some participants indicated that they monitored changes in their mental health states (e.g., feeling anxious, depressed, and stressed) in relation to their headache experiences. For instance, one participant shared that she monitored her levels of stress and anxiety along with the physical symptoms of her headaches, *“I can see the Breeze app being useful, because I’ll be able to track when I’m more anxious, when I’m less anxious, because I’m still trying to get to the top of my stress, my anxiety as well.”*

The Psychological Relevance of DHT: Building Awareness of Psychological Health

The psychological relevance of DHT also manifested in users’ increased awareness of their psychological health. Particularly, participants shared that their use of digital health enabled them to become more aware of changes in their emotions and mental health states due to chronic headaches (Figure 8).

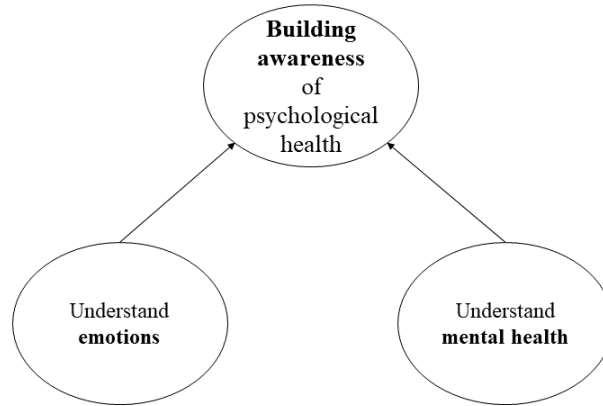


Figure 8: Building awareness of psychological health

Some participants indicated that their interaction with DHTs helped them become more aware of various momentary emotions (e.g., feeling frustrated) they may experience when they get headaches. In some instances, participants shared that they became more accepting of negative emotions as a result of their DHT use. For instance, one participant stated, *“With the Migraine Buddy, it makes me understand that these negative emotions are normal. But yeah, that to stick with it is not a solution. So you have to come out of them and try to do something else.”* In addition, some participants shared that their interaction with DHT helped them realize that they might not know what emotions they would experience during their headache attack, so they would need to prepare for how changes in their emotions could affect their interactions with family and friends.

Furthermore, some participants shared that DHT helped them pay more attention to the mental health changes resulting from their chronic headaches. For example, one participant shared, *“One of the things I learned in the app is my mental health, my mental health. Before, I do hear about mental health, I don't really pay attention about it. All I paid attention to is my digestive system, staying low on body weight. I don't really pay enough attention to mental health. The app really made me to pay more attention on my mental*

health, which why it's very helpful, mental health has to do with the brain or the brain serves as the major organizer and control of your whole body system. So yeah, it's really important.” In addition, some participants indicated that as a result of paying closer attention to their mental health, they started taking specific actions to reduce their stress levels.

The Psychological Relevance of DHT: Managing Psychological Health

Being able to manage one's psychological health as a result of using a DHT was also discussed among some participants. Participants shared that through their use of a DHT they could get immediate relief from negative emotions as well as relieve their mental health issues (including stress and anxiety). Particularly, participants shared that they turned to mindfulness and relaxation techniques enabled by DHT to calm down, reduce anxiety, and fall asleep during headache attacks. For instance, one participant said the following about the relaxation techniques enabled by their DHT, *“I think it's pretty calming. I would think every time I go on, I always have like a pain or like anxiety, or I can't fall asleep. So then that's why I go into that. But then after, wow, I was using the app, the experiences are okay. And then after that I often find relief. So I was like, Yeah, I think it's overall a pretty good experience.”*

The Psychological Relevance of DHT: Feeling Empowered

The feeling of empowerment enabled by user interaction with digital health also emerged across multiple interviews. Users' interactions with a DHT made them feel better about their headache experiences and their ability to manage their chronic headaches. Particularly, participants shared that, as a result of their interactions with a DHT, they

started feeling more positive about their headaches, more in control of their headaches, and more confident and motivated to take action toward managing their headaches (Figure 9).

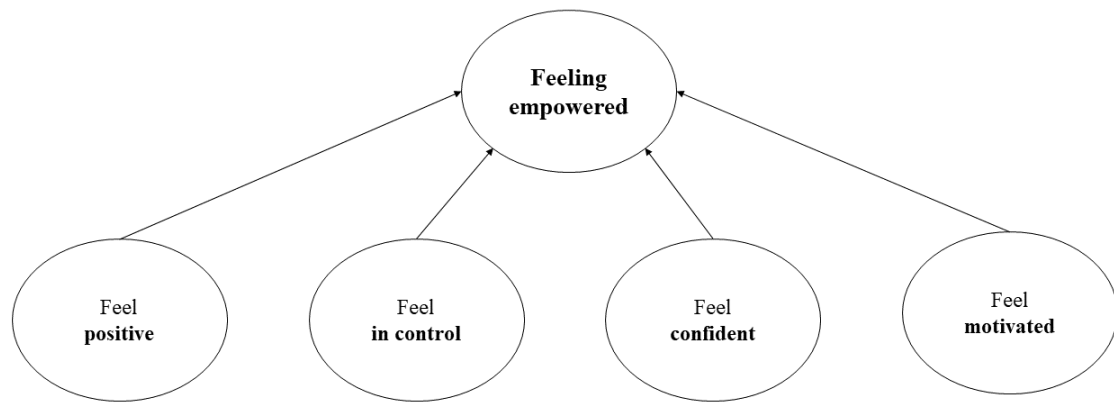


Figure 9: Feeling empowered

Some participants shared that their attitude towards their chronic conditions (specifically, chronic headaches) changed as they kept interacting with DHT. Particularly, some participants indicated that they started thinking more positively about their headaches. For instance, one participant said, *“Yes, I would say it [DHT] reduced them [negative emotions] because I don't get as nervous. When I have headaches I am wondering, Okay, what is really going on? I just don't want to handle random thoughts come in my head, and since I've been on this app, and they helped me manage it a whole lot. Where I'm not thinking negative thoughts. I'm thinking more positive thoughts than anything. And I tell anybody, always do your research. Just don't use app, research and see what it's good for. Maybe that app is not good for you, try another one.”*

Many participants also indicated that using a DHT helped them feel in control of their health and, particularly, their headaches. Some participants specifically attributed this feeling to their self-tracking activities and enhanced awareness of what was happening to their health. For example, one participant said, *“But I noticed that when I do like use it*

[DHT]. And when I actually take it seriously, and put my data and put everything that I'm feeling and, and get back the kind of information, I actually noticed that this kind of makes me feel more in charge of things. So it makes me feel that it's not something, I'm not getting random attacks, I'm doing things that are causing this to happen. And the more I eliminate things I'm doing, the more these things are not going to happen. So yeah, that was really something that I need to remind myself of in order to take care of myself physically and be sure that I'm not just having life go by."

Furthermore, some participants stated that their use of DHT helped them become more confident in their ability to manage and overcome headaches. For example, one participant said, *"I think it [DHT] makes me more self-confident to overcome the headaches, it also makes me not happy but yeah, I have less fear for headaches. So that's something that when I know when I have a headache I have solution for it, and it makes you also feel more connected with others."*

In addition, participants shared that they started feeling more motivated to take action toward managing their health and, particularly, their headaches. For instance, one participant indicated, *"I really think that the app is reflecting on me, because I'm able to see what's going on with my body. But it don't get me down. Because now that I have everything and I am in control, and I can see what I wrote. And it's really helping me out. So it's actually motivating me, it's keeping me motivated. Okay, look, you got this down. You ain't having as many headaches when you started this app. So it's like we go hand in hand. It's like we're joined at the hip, there's a part of me, so as long as I keep this app on my phone. It sent me a message and told me, Hey, we're gonna be down for two hours for maintenance. Okay, I'm glad you're alerting me. That mean get that pen and paper out or*

mark it on my calendar. Hey, okay, this when it happened. So when I do come back, I can notate everything into the app. Okay. Well, while you were down, this is what happened. I really think it's a reflection on me.”

The Social Relevance of DHT: Overview

Our thematic analysis revealed various aspects of users’ perception of a personally meaningful connection between users’ social health and DHTs for self-management of chronic conditions, specifically chronic headaches. Particularly, such connection (i.e., the social relevance of DHT) manifested in the following aspects that could be enabled by user interaction with DHT: feeling supported, learning about communication, and managing social interactions (Figure 10). We describe each aspect of the social relevance of DHT in more detail in the following sections. Appendix D3 contains the evidence-trace table with sample quotes related to each aspect of social relevance.

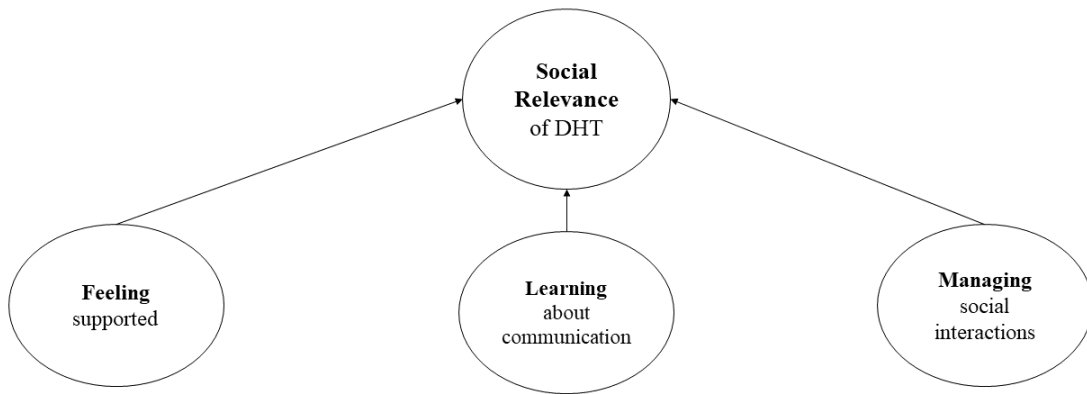


Figure 10: Social relevance of DHT

The Social Relevance of DHT: Feeling Supported

Through their interactions with DHTs, participants received various forms of supports (Figure 11). Our interviews revealed that participants felt supported due to their

interactions with other users and different DHT features. Some participants also viewed a DHT as their friend.

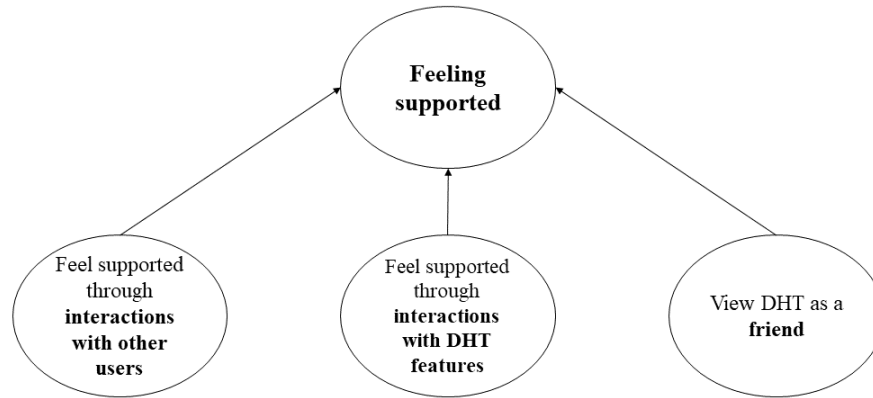


Figure 11: Feeling supported

Some participants used a social networking feature (e.g., a chat) in a DHT. Participants reported that through such a feature, they received both informational (e.g., information about headaches and possible treatments) and emotional supports. These forms of supports helped participants feel like they were part of community, thereby reducing their feelings of isolation and loneliness (commonly experienced among headache sufferers (Andrasik et al., 2005)). For instance, one participant shared the following *“Yes, definitely. I feel supported, it's really good to have community, you know, around you. Making you feel like these are people that are having this same thing.”*

Furthermore, some participants mentioned that their interactions with different DHT features (e.g., notifications, supporting messages, and reminders) helped them further reduce their feelings of isolation and loneliness. For instance, one participant indicated that he found a DHT relevant because it supported him through notifications and opportunities to connect with others, *“There's personal relevance, because it gives me support. So maybe it [DHT] sends a notification with.. saying, Is everything going better? You can also you*

can connect with others. So that's maybe personal relevance, that you're not alone. But you receive notifications with support, or you can connect with others. So I'm not standing alone."

In addition, some participants referred to para-social interactions with DHT by sharing that they viewed a DHT as their friend. Their act of interacting with a DHT and its features helped them feel supported. For example, one participant indicated, *"For the past three months, it'd [DHT] been my, I would say, my close friend, the app was my close friend. I use it all, almost, very regularly. I use it regularly. It has been my close friend. So it's been very helpful manage the migraine and also my activities related to the headache. So I use regularly. I would say, the actual time, I use regularly. The app has been very helpful."*

Social Relevance of DHT: Learning about Communication

Learning how to communicate headache experiences to others emerged as an important aspect of user interactions with a DHT. Some participants indicated that the learning aspect was what they were interested in gaining from their engagement with a DHT. Other participants shared that they learned how to convey their pain to others by learning headache-specific terminology. For instance, one participant shared, *"Before when I first started using the apps, I didn't know how to maintain or how to explain things. Because I didn't know basically. But now that I use the apps, pain management apps, and you see the words when I'm explaining it to someone else that I have, even if it's not a doctor, it's just someone at school, a classmate or, I can explain them with some words. Words that even if I didn't know them before, like type of thing, throbbing. I didn't know that, Oh, what? How was my pain? I don't know, what kind of pain? I don't know, because I didn't know before they were different types of pain. But now I know. So, but it's a word that, Oh, I*

didn't know this word was the word used for this type of thing. But I can tell now people, I learned about it by reading in the apps, basically, the different types of pain, the different types of my triggers and etc. So when I talk to other people, I feel very, because it's not me saying, Oh, I have a headache, migraine and they asked me, oh, what's that? It's a headache. And I will just say, oh, it's a headache but this and that. Now I know what it is. I explain it better.”

The Social Relevance of DHT: Managing Social Interactions

Participants reported DHTs also enabled them to manage their social interactions during their headache attacks (Figure 12).

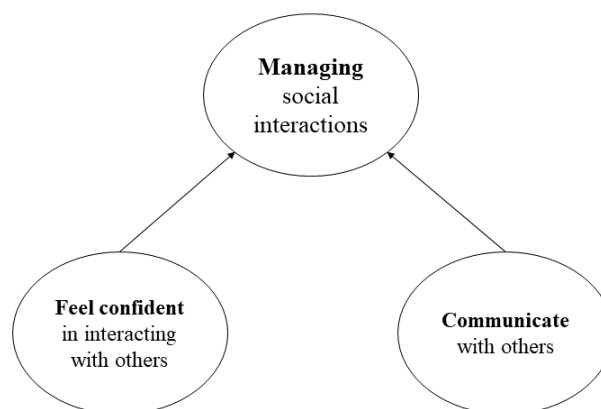


Figure 12: Managing social interactions

Some participants shared that after using DHTs, their social life improved, and they started managing their social interactions better. For instance, one participant said, *“Because maybe I'm having the headache, I could just go and check my phone, and start tracking it. And I know, okay, I'm being tracked, I'm monitoring my health, so I can actually interact with people better, I'm more confident enough to interact with people better. So it does, it did help me like, it has helped with like my social interactions, yes definitely.”*

Participants also shared that their interaction with DHT prepared them for social interactions with others. Notably, some participants shared that DHT enabled them to communicate their headache pain to others and also give a warning to those around them about an upcoming headache attack. For instance, one participant said, *“Because and it [DHT] also helped me give a fair warning to people around me that hey, if I’m snapping, it’s not you. It’s my headache. I am trying to get a hold of it. So yeah, it helps me keep a check on what my mood swings are, or why they are. And if I feel like if I am already irritable, and there’s a slight headache or a slight symptom, which I know will lead to headache. I already keep myself off everybody’s way. And, yeah, I make sure that I feed my dog, exercise as well, so that he doesn’t come and pester me to play with him or he doesn’t get too excited when I’m out of the room or something. I take precautions necessarily to avoid any major blow outs or something.”*

Preliminary Items Measuring the Biopsychosocial Relevance of DHT

As a result of our thematic analysis described above, we developed a preliminary item pool capturing various dimensions of the biopsychosocial relevance of DHT. To measure the biological relevance of DHT, we developed items associated with each aspect of such a dimension (monitoring physical health, building awareness of physical health, learning about physical health in general, and managing physical health). For instance, the following item was developed based on the subcodes associated with the monitoring physical health aspect: “I find this app useful for monitoring my physical symptoms when I experience headaches.”

Furthermore, we developed a set of items associated with psychological relevance of DHT and, specifically, various aspects associated with this form of relevance (monitoring

psychological health, building awareness of psychological health, managing psychological health, and feeling empowered). For example, one item measuring the sense of empowered resulting from user interaction with DHT took the following form: “My use of this app helps me stay positive when I experience headaches.”

Finally, we also created items associated with social relevance of DHT and its associated dimensions (feeling supported, learning about communication, and managing social interactions). For instance, we developed the following item to measure the extent to which DHT enables users to learn about communication: “My use of this app helps me learn how to talk about my headaches with other people.”

Appendices E1, E2, and E3 contain our full set of preliminary items.

Discussion of Phase 1 Results

Even though personal relevance is important for user experience and engagement with DHTs (Birnbaum et al., 2015; Lupton, 2013; Perski et al., 2017), it is not clear what relevance means as multiple interpretations of the construct currently exist (Priniski et al., 2018). We conducted 23 semi-structured interviews with the users of DHTs for self-management of chronic headaches to clarify the nature of the biopsychosocial relevance of DHT (and its corresponding dimensions, such as the biological relevance of DHT, the psychological relevance of DHT, and the social relevance of DHT).

Conceptualizing the Biopsychosocial Relevance of DHT

Phase 1 contributes to IS research by clarifying the nature of the relevance of technology, specifically in the context of healthcare. In our DHT context, we discovered that the biopsychosocial relevance of DHT captures the user’s perception of the degree to which a DHT enables a user to self-manage his or her physical health, psychological health, and

social health. Based on our findings, we updated the definitions provided in Table 2. Table 9 contains our updated definitions of various dimensions of the biopsychosocial relevance of DHT.

Table 9: Updated definitions of the biopsychosocial relevance of DHT

Dimension	Definition
The biological relevance of DHT	Perception of the degree to which a DHT enables a user to monitor their physical health, build awareness of their physical health, learn about physical health in general, and manage their physical health
The psychological relevance of DHT	Perception of the degree to which a DHT enables a user to monitor their psychological health, build awareness of their psychological health, manage their psychological health, and feel empowered
The social relevance of DHT	Perception of the degree to which a DHT enables a user to feel supported, learn about communication, and manage social interactions

As mentioned previously, there currently exist various interpretations of relevance: personal association (i.e., a connection to personally meaningful memories and knowledge), identity connection (i.e., a connection to one's identity), and usefulness (i.e., a perceived functional value of something) (Priniski et al., 2018). Our conceptualization of relevance omits references to personally meaningful memories/knowledge as there were no themes indicating that users find a DHT relevance because it reminds them of something personally meaningful (e.g., personally meaningful memories or knowledge).

Moreover, some of our participants' responses allude to identity connection (e.g., some participants indicated that they view a DHT as a reflection of themselves), but identity connection was not the most prevalent theme discovered in our thematic analysis. Moreover, it is important to note that we used the user context to inform the biopsychosocial relevance of DHT. The user context for this study captures individual's health and illness experiences (with respect to biological, psychological, and social

dimensions in alignment with the biopsychosocial model of health). Some prior studies indicate that illness experiences can lead to an individual's formation of an illness identity (the degree to which an illness becomes integrated into one's sense of self) (Corbin, 2003; Oris et al., 2018). Even though we did not check whether our participants have formed an illness identity, it may be possible that some of them have and that their responses were influenced by their illness identity. In such a case, our conceptualization of the biopsychosocial relevance of DHT would be grounded on individual's illness identity and, therefore, assume identity connection as its integral part. Future studies can explore this assumption in more detail by exploring the extent to which individual's illness identity can impact user interaction with DHTs.

Furthermore, relevance as usefulness seems to align most closely with our conceptualization of the construct. At the same time, the enablement part of our DHT's conceptualization resembles affordances (i.e., "action possibilities") (Gibson, 1979; Volkoff & Strong, 2017), which are determinants of usefulness (Mao & Hovick, 2020). Specifically, Mao & Hovick (2020) conducted a study to explore the use of messaging features in online patient portals. They found that affordances associated with the editability of messages can lead to perceived usefulness of such messages.

Despite conceptual similarity among usefulness, affordances, and relevance, several elements distinguish such concepts. Table 10 provides both general and contextualized definitions of relevance, usefulness, and affordances.

Table 10: Relevance vs. usefulness vs. affordance

	Relevance	Usefulness	Affordance
General definition	Perception of the degree to which technology enables a user to take	The degree to which a person believes that using a particular system	Perception of possibilities for goal-oriented action afforded to

	Relevance	Usefulness	Affordance
	actions towards specific goals in light of his or her user context.	would enhance his or her performance (Davis, 1989)	specified user groups by technical objects (Markus et al., 2008)
Contextualized definition (DHT)	Perception of the degree to which a DHT enables a user to self-manage his or her physical health, psychological health, and social health.	The degree to which a person believes that using a particular DHT would improve his or her health outcomes (Schnall et al., 2015)	Perception of possibilities for supporting certain behaviors, emotions, and cognitions afforded to specified user groups by DHT (Liu et al., 2021)

As stated in the definitions above, technology usefulness captures the user's belief about a specific technology, while relevance and affordances capture the user's perceptions regarding a specific technology. Belief is generally defined as an acceptance of something as true, even without evidence and support (i.e., a state of mind in which trust or confidence is placed in something even without support) (*Definition of belief*, 2022). For instance, a user might get a DHT on their phone. Before they even try different DHT features (i.e., before they collect any evidence for usefulness), they might already form a belief that the DHT will help them manage their health and even improve health outcomes.

On the other hand, relevance and affordances capture users' perceptions, which refer to the use of sensory information to understand or notice something. Affordances refer to users' perceptions of possibility for actions (Markus et al., 2008). A user might get a DHT on the phone and start reviewing different DHT features without trying them. As users perceive such features (e.g., by looking at the interface), they might think that such features would afford them to take specific actions towards their health. For instance, one feature might look like a tracking features, so based on the visual sensory information, a user might perceive this features as the one enabling them to track their health (without even trying

such a feature). In light of that, it is not surprising that affordances can lead to perceived usefulness. A user might form their belief of usefulness of technology as a result of their perception of what different features of such technology could possibly enable them to achieve.

Unlike affordances, relevance does not focus on perception of possibilities. Instead, relevance, with its heavy focus on the enablement part, emphasizes what DHT helps users to actually achieve with respect to managing their health. For instance, a user might get a DHT, screen through different features, and then try different features. The outcome of trying different features results in users' perception of relevance of technology. It may also be possible that in the nomological net, relevance could mediate the relationship between affordances and usefulness. For instance, a user first perceives different features. Then, they try such features and observe what such features actually enable them to achieve. If the outcome is positive (i.e., technology features do enable users to achieve something), users can form a belief of usefulness.

It is important to note that, to some extent, our conceptualization of relevance aligns with the concept of *actualized* affordances, which capture the goal-oriented actions that technical objects have offered to users (Strong et al., 2014). However, the major difference between relevance and actualized affordances lies in the heavy focus on the user context in our conceptualization of relevance. Actualized affordances, however, refer to goal-oriented actions that can be realized regardless of the user context. In cases where the user context is critical (such as healthcare, for instance), it may be possible to leverage our concept of relevance as a proxy for actualized affordances.

The Biopsychosocial Relevance and Health Behavior Change

Furthermore, various aspects of the biopsychosocial relevance of DHT discovered in Phase 1 appear to align with some of the theory-based behavior change techniques (Abraham & Michie, 2008; McKay et al., 2019; Michie et al., 2013) and, therefore, have implications for how relevance can support users' health behavior change processes. Aspects associated with biological relevance (e.g., monitoring physical and building awareness of physical health, among others) are indeed critical for health behavior change, which is essential for improving health outcomes of the critically ill (Araújo-Soares et al., 2018). For instance, monitoring physical health can enable individuals to track their self-management progress and identify areas that might prevent them from achieving their health goals (Burgard & Gallagher, 2006). In addition, building awareness of physical health can enable individuals to understand what is happening to them and seek health solutions when necessary (Gulizar & Duman, 2021). As reported by prior studies, learning about physical health and managing one's physical health are also essential for changing health behavior in self-care interventions (Riegel et al., 2021).

Moreover, psychological health (involving mental health and emotions) is also important in self-care interventions for chronic conditions (Lassi et al., 2014). Monitoring, building awareness of, and managing psychological health can support health behavior change facilitated by self-care interventions for chronic conditions (Riegel et al., 2021). Further, our interviews also revealed that users' feeling of empowerment is part of the psychological relevance of DHT. Indeed, studies indicate that empowerment can improve an individual's confidence and engagement with self-management behaviors for chronic conditions (Wang et al., 2022). Regarding our findings on the social relevance of DHT, Phase 1 indicates that

users can receive social support due to their interactions with other users and specific DHT features. Prior studies report that social support can facilitate health behavior change, leading to improved health outcomes for individuals with chronic conditions (Bardach et al., 2011; Strom & Egede, 2012).

Relevance as a Formative Construct

In Phase 1, we developed a series of conceptual models (Figures 1-12) based on our qualitative findings. The conceptual models provide insight into the measurement model of our construct. Particularly, it appears that the biopsychosocial relevance of DHT and its associated dimensions and subdimensions are formative constructs because our indicators capture different facets of relevance dimensions and subdimension and our indicators can correlate but it is not necessarily expected (Henseler, 2017).

It is also important to note that prior research distinguishes two types of formative constructs: causal-formative and composite (Henseler, 2017). Causal-formative constructs assume that the observed indicators cause the construct (Henseler, 2017; Jarvis et al., 2003). Further, indicators do not need to covary or have the same antecedents or consequences. On the other hand, in the composite constructs, the indicators make up the entire construct; high correlations are common but not required; indicators are required to have the same consequences. Our findings provide support for modeling relevance as a composite formative construct. Table 11 provides a summary of the justification for modeling the biopsychosocial relevance of DHT as a formative (vs. reflective) composite (vs. causal) construct (Henseler, 2017).

Table 11: Justification for modeling relevance as composite formative (from Henseler (2017))

Factor	Reflective	Causal formative	Composite formative	The biopsychosocial relevance of DHT
Relationships between construct and indicators	The construct has an impact on its indicators.	The indicators have an impact on the construct.	The indicators make up the entire construct.	We expect that our indicators make up the entire biopsychosocial relevance of DHT construct as they cover different facets of relevance at all levels of abstraction. For instance, at the lowest level of abstraction, the monitoring physical health sub-dimension is made up of indicators measuring different monitoring activities: monitoring physical symptoms, monitoring habits, monitoring treatments, and monitoring triggers. At the next level of abstraction, associated sub-dimensions make up corresponding dimensions. For instance, monitoring physical health and building awareness of physical health, among others, make up the biological relevance dimension. Finally, at the highest level of abstraction, we have biological, psychological, and social dimensions that make the entire biopsychosocial relevance construct, in accordance with the

Factor	Reflective	Causal formative	Composite formative	The biopsychosocial relevance of DHT
				biopsychosocial model of health.
Expected correlational patterns among indicators	High correlations among indicators are expected.	Indicators can correlate but it is not necessarily expected.		At each level of abstraction, we may expect correlations between dimensions, yet it is not necessarily required. For instance, a DHT could be relevant to a user's psychological health and not necessarily physical health or social health. Similarly, at the lowest level of abstraction, DHT can enable users to monitor their physical symptoms but not treatments, for example.
Validity of scale score	The scale score does not represent the construct.		The scale score represents the construct.	We expect that the score associated with the biopsychosocial relevance of DHT will be used to holistically represent the extent to which DHT is relevant to end-users.
Dropping an indicator	Dropping an indicator does not change the meaning of the construct.	Dropping an indicator increases the measurement error.	Dropping an indicator may change the meaning of the construct.	We expect that dropping an indicator (at the lowest level of abstraction) could affect the holistic nature of our construct. For instance, if we drop an indicator measuring the extent to which DHT enables users to monitor their physical symptoms, the monitoring physical health sub-dimension will become incomplete, as it will miss a critical part of physical health (such as physical

Factor	Reflective	Causal formative	Composite formative	The biopsychosocial relevance of DHT
				symptoms) discovered in our interviews.
Nomological net	Indicators have the same antecedents and consequences.	Indicators are not required to have the same antecedents and consequences.	Indicators have the same consequence.	As digital health relevance is linked to continuous user engagement (Birnbaum et al., 2015), we can expect all three dimensions and their sub-dimensions to have the same consequence (i.e., user engagement). However, we do not necessarily have to expect the same antecedents for our indicators. For example, different technology functions can enable the monitoring aspect (e.g., tracking features), compared to the learning aspect (e.g., content provided to users) of relevance.

Appendices E1, E2, and E3 contain our preliminary set of formative items measuring the biopsychosocial relevance of DHT.

Limitations Associated with Phase 1

We also need to recognize a series of limitations associated with Phase 1. First, our participants have chosen to use DHTs to self-manage their headaches, meaning their motivation and intention might be higher than average. Thus, our results might be skewed toward highly motivated individuals willing to use DHTs. Second, we did not focus on a single instantiation of DHT for self-management of chronic headaches. Instead, Phase 1 involved participants using various DHTs designed for chronic headaches (e.g., *Migraine*

Buddy) and other purposes (e.g., *Calm* for meditation). Third, Phase 1 results might not be necessarily generalizable to DHTs for chronic conditions other than chronic pain. For instance, in the case of DHTs for obesity and overweight, DHTs features related to helping users understand their triggers would not be relevant. Future studies should, however, explore themes identified in our study in relation to other health conditions.

Even though our findings from Phase 1 can be used to guide the design and assessment of DHTs for self-management of chronic conditions, we still need to establish content and construct validities of the biopsychosocial relevance of DHT. Follow-up studies, such as Phase 2 (expert panel) and Phase 3 (surveys), address such objectives and validate our construct.

CHAPTER 4: PHASE 2 - THEORETICAL ANALYSIS

Introduction

Through Phase 1 of this study, we clarified the concept of the personal relevance of DHTs for self-management of chronic conditions through the lens of the biopsychosocial model of health (Ahmadvand et al., 2018). Notably, we conceptualized relevance in terms of biological relevance, psychological relevance, and social relevance in alignment with the biopsychosocial model of health (George, 1977). Our conceptualization of the biological relevance of DHT captures the extent to which DHTs allow users to monitor their physical health, build awareness of their physical health, learn about physical health, and manage their physical health. Furthermore, the psychological relevance of DHTs captures the extent to which DHT helps users monitor their psychological health, build awareness of their psychological health, manage their psychological health, and feel empowered. Finally, the social relevance of DHT refers to the extent to which DHT helps users feel supported, learn about communication, and manage their social interactions.

As a result of Phase 1, we developed a preliminary set of items to measure the biological (see Appendix E1), psychological (see Appendix E2), and social (see Appendix E3) relevance of DHTs. Following the item pool generation, the second step in instrument development is to conduct a theoretical analysis (DeVellis, 2016). The theoretical analysis allows researchers to assess the content validity of the initial pool of items to ensure that a specific set of items aligns the desired construct (Morgado et al., 2017). Establishing content validity is particularly important in validating formative constructs (S. MacKenzie et al., 2011).

During Phase 2 of our study (theoretical analysis), we assessed the content validity of the formative indicators (items) we developed as a result of Phase 1. Based on the content validity assessment, we further revised or deleted items.

Methods

Overview

One of the most common and efficient ways to conduct the theoretical analysis in instrument development is to form an interdisciplinary expert panel consisting of individuals who are knowledgeable about the domain of interest and instrument development (Godfred et al., 2018; Morgado et al., 2017). In alignment with prior digital health studies on instrument development (Akter et al., 2013; Chen, 2019) as well as widely accepted methodological practices in instrument development (Morgado et al., 2017), we conducted a remote interdisciplinary expert panel to assess the content validity of the initial item pool from Phase 1. In the following sections, we describe various activities associated with Phase 2: preliminary item review, development of the content validity protocol, protocol review, data collection, and data analysis.

Preliminary Item Review

Appendices E1, E2, and E3 contain preliminary items developed in Phase 1 (semi-structured interviews). Before conducting the expert panel, a researcher with expertise in health communications was invited to conduct a preliminary review of the items. Particularly, the researcher conducted a brief assessment of the items by reviewing the language and flow of the items. The researcher's feedback was used to make minor revisions to the items. Overall, this step allowed us to establish face validity (i.e., the extent

to which items appear to measure what they intend to measure) of the preliminary pool of items (Nevo, 1985).

Content Validity Protocol

We developed a content validity protocol to ensure that the expert panel members have clear expectations and understanding of the task (Yusoff, 2019). The content validity protocol should contain the study description, construct definitions, the item pool, and the evaluation rubric. We used construct definitions of the biopsychosocial relevance dimensions (see Table 9) and the item pool created in Phase 1 (see Appendix E). To create the evaluation rubric, we used an existing quantitative content validity rubric based on content validity indices (CVIs) (Lynn, 1986). CVIs are the most widely reported and efficient quantitative approach for content validity (Grant & Davis, 1997; Lynn, 1986; Vahid et al., 2015). Prior research used CVIs to assess the content validity of instruments measuring perceptions of technologies (Lam et al., 2021; Sharp, 2010) and PROMs (Miller et al., 2017; Sinclair et al., 2020). We, therefore, used the evaluation rubric based on CVIs to assess the content validity of our item pool.

In alignment with the CVI rubric, each item was assessed with respect to clarity (whether it is clear and concise), importance (whether it is important to measure biological, psychological, or social dimensions of relevance), and representativeness (whether it represents biological, psychological, or social dimensions of relevance) (Grant & Davis, 1997; Lynn, 1986; Vahid et al., 2015). Such assessment criteria allow researchers to assess content validity with respect to congruence (i.e., items represent the intended construct and lack contamination from other constructs), adequacy (i.e., indicator sufficiency and parsimony captured by the importance of a given indicator to the construct of interest), and

clarity (i.e., construct and item clarity), as discussed in a recent IS study on content validity assessments (Schmitz et al., 2020).

For a CVI, a 4-point ordinal scale is used to evaluate the items (e.g., 1- item is not clear, 2 – item needs major revisions to be clear, 3 – item needs minor revisions to be clear, 4 – item is clear) (Lynn, 1986). For items rated 1 to 3 (e.g., from “not clear” to “minor revisions”), panel members were asked to provide qualitative feedback to help us revise/drop such items. In addition, the comment section provided expert panel members with an opportunity to give feedback not only on specific items (i.e., at the lowest level of abstraction) but also on sub-dimensions associated with each dimension of the biopsychosocial relevance of DHT (i.e., at the higher level of abstraction).

Appendix F contains our content validity protocol.

Protocol Review

We conducted a protocol review to ensure the evaluation rubric and instructions were easy to understand. Specifically, we invited a senior doctoral student (ABD) from the Department of Information Systems and Business Analytics at FIU to review the content validity rubric. This student had experiences with developing expert panel protocols. We used the graduate student’s feedback to clarify instructions accompanying the evaluation rubric and revise our study description.

Recruitment of Participants for Expert Panel

Expert panel members should possess expertise relevant to the study (Avella, 2016). For instance, during the PROM development, it is recommended to assemble an expert panel consisting of individuals whose expertise can be relevant to various aspects of PROM

development, including clinicians and psychometricians, among others (Terwee et al., 2018).

We recruited individuals whose expertise is relevant to Phase 2. Table 12 summarizes a list of individuals who participated in the expert panel.

Table 12: Expert panel members' expertise

Domain Expertise	Credentials	Relevance to study
Measurement instrument development in Information Systems	PhD	Our measurement instrument focuses on the use of digital health technologies.
Measurement Instrument development in Human-Computer Interaction	PhD	Our measurement instrument focuses on user interaction with digital health technologies.
Psychometrics	PhD	Our measurement instrument development follows the methodological paradigm of psychometrics.
Health informatics	PhD	Our measurement instrument focuses on the assessment of digital health technologies.
Chronic pain and headache	MD	Our measurement instrument focuses on the context of chronic pain and chronic headaches.
Patient-Reported Outcomes	PhD	Our measurement instrument mirrors existing multidimensional PROMs.
Psychology	PhD	Our measurement instrument contains various items that cover the user's psychosocial illness experiences.

We recruited seven individuals to have sufficient control over the chance agreement (Lynn et al., 1986; Haynes et al., 1995; Vahid et al., 2015). Typically, studies indicate that a minimum of five experts is adequate to provide a sufficient level of control for chance agreement (Lynn et al., 1986). Even though the maximum number of expert panel members has not been established, studies indicate that the number is unlikely to exceed ten. Thus, we chose to recruit seven individuals.

Data Collection Associated with Expert Panel

We emailed potential participants to recruit them. Participants were identified using Google Scholars (e.g., those who have multiple publications on areas relevant to this study: e.g., scale development in IS, Human-Computer Interaction, among others) and a personal network. In total, ten individuals were contacted, and seven agreed to participate. Those who agreed to participate received a Qualtrics survey containing study details, an item pool (in total, we had 38 unique items associated with different relevance dimensions and subdimensions), and an evaluation rubric. Expert panel members were advised that it would take them approximately 30-40 minutes to complete the assessment of the items. The content validity assessments were conducted anonymously, and no personally identifiable information was collected during the assessment of the items. Participants received \$50 Amazon gift cards, as a thank-you for their participation.

Data Analysis Associated with Expert Panel

To analyze the expert panel members' quantitative responses, we calculated (1) S-CVIs (i.e., scale indices) for each dimension and subdimension of the biopsychosocial relevance (as well as all dimensions together, (2) I-CVIs (i.e., item indices) for each item, and (3) probabilities of the chance agreement (P_c) and kappa statistics for each item (Grant & Davis, 1997; Lynn, 1986; Polit et al., 2007; Polit & Beck, 2006; Vahid et al., 2015). All indices and statistics were calculated to assess the entire instrument and individual items with respect to clarity, importance, and representativeness.

The S-CVIs are the scale content validity indices that can be used to assess the overall content validity of the instrument or specific parts thereof. The average of all I-CVIs (i.e., item content validity indices) is used to calculate an S-CVI (Polit et al., 2007). We

calculated S-CVIs for the entire measurement instrument (encompassing three dimensions of the biopsychological relevance), for each dimension (i.e., biological, psychological, and social), and subdimension (i.e., monitoring physical health, learning about physical health, etc.) of the instrument. According to measurement instrument developers, the lowest limit for the acceptability of the S-CVI is 0.8 (Polit et al., 2007). Mainly, measurement instrument developers state that investigators should seek at least 80% of the agreement for new instruments. If the S-CVI is lower than 0.8, researchers should carefully review each item in the measurement instrument (and their associated indices) and make appropriate revisions to them or delete such items.

Furthermore, we calculated I-CVIs (i.e., item content validity indices) for each item. The total number of experts providing a score of 3 or 4 was divided by the total number of experts (Lynn, 1986). The required magnitude of the I-CVI is a function of the number of expert panel members (Polit & Beck, 2006). The I-CVIs should be 1.00 when there are five or fewer panel members (Lynn, 1986; Polit & Beck, 2006). When there are six or more panel members, Lynn (1986) recommends the I-CVIs of no lower than 0.78 to ensure adequate content validity of the items. If the I-CVI is lower than 0.78, the items should undergo major revisions or be deleted entirely.

In addition to I-CVIs, measurement instrument developers recommend calculating the kappa values to adjust for chance agreement among expert panel members (Rodrigues et al., 2017). The chance agreement is an issue of concern in evaluating I-CVIs (Polit et al., 2007). The probability of chance agreement (P_c) should be computed first: $P_c = [N!/A!(N-A)!] * 0.5^N$ to calculate the kappa value. In this formula, N is the total number of experts, and A is the number of experts that provided a score of 3 or 4. Further, the kappa value is

calculated using the following formula: $K = (I-CVI - P_c) / (1 - P_c)$. As the number of expert panel members increases, the I-CVIs and kappa values converge (Polit et al., 2007). The kappa values above 0.74 are considered excellent, between 0.60 to 0.74 good, and 0.40 to 0.59 fair (Rodrigues et al., 2017).

We reviewed items with low scores and qualitative feedback associated with such items. We revised items with low scores based on the feedback provided by our expert panel members (details of feedback are discussed in the next section). If an item received a low score with an indication that it should be dropped, we also reviewed prior literature (both empirical and theoretical studies) to check whether there exists any evidence for retaining such an item (e.g., an item could be measuring an aspect critical to user experience with technology). If there was any prior research support for retaining an item, we would not drop it. In addition, during Phase 3 of the study, we conducted a pretest with 15 participants to ensure clarity of all items (following the revision after Phase 2) and finalize our content validity assessment.

Results of Phase 2

The overall S-CVI (encompassing all biopsychosocial dimensions) was 0.89 for clarity, meaning that 89% of the items were clear on average. Further, the overall S-CVI for importance was 0.94, meaning that 94% of the items were important to measure the biopsychosocial relevance of DHT on average. Finally, the overall S-CVI for representativeness was 0.91, meaning that 91% of the items were representative of the biopsychosocial relevance of DHT on average. Since these S-CVI values were above the minimum threshold of 0.8 (Polit et al., 2007), we can state that our measurement instrument items are generally clear, important, and representative of the biopsychosocial relevance

of DHT. In the following sections, we provide further details about the dimensional S-CVIs, individual I-CVIs, and kappa statistics.

Biological Relevance of DHT

Content validity results illustrate that the biological relevance of DHT items were generally clear, representative, and important to measure the construct. Particularly, the S-CVI was 0.95 for clarity, 0.91 for representativeness, and 0.96 for importance. These S-CVIs exceeded 0.8, the minimum threshold for establishing adequate content validity (Polit et al., 2007). Further, Tables 13, 14, and 15 summarize I-CVIs for each item, the probability of chance agreement (P_c), and kappa statistics with respect to clarity, importance, and representativeness.

Table 13: Clarity of the biological relevance items

Items	I-CVI Clarity	P_c	Kappa statistic
A. Monitoring Physical Health (S-CVI = 0.93)			
A1. I find this app useful for monitoring my physical symptoms when I experience headaches.	1	0.01	1
A2. I find this app useful for monitoring my daily habits that could affect my headaches.	0.86	0.05	0.85
A3. I find this app useful for monitoring my treatments (e.g., medications and relief methods) for my headaches.	1	0.01	1
A4. I find this app useful for monitoring the things that trigger my headaches.	0.86	0.05	0.85
B. Building Awareness of Physical Health (S-CVI = 0.94)			
B1. My use of this app helps me validate my memory of how my headaches have affected my life (for example, by providing a record of my past headache experiences).	0.86	0.05	0.85
B2. My use of this app provides me with a better understanding of physical symptoms associated with my headaches.	1	0.01	1
B3. My use of this app provides me with a better understanding of how my daily habits affect my headaches.	1	0.01	1
B4. My use of this app provides me with a better understanding of various treatments (including	1	0.01	1

Items	I-CVI Clarity	P _c	Kappa statistic
medications and relief methods) that could improve my headaches.			
B5. My use of this app provides me with a better understanding of the things that can trigger my headaches.	0.86	0.05	0.85
C. Learning about Physical Health (S-CVI = 1)			
C1. This app helps me learn new information about different types of headaches and associated physical symptoms.	1	0.01	1
C2. This app helps me learn new information about relief methods for headaches.	1	0.01	1
C3. This app helps me learn new information about the things that can trigger headaches.	1	0.01	1
D. Managing Physical Health (S-CVI = 0.93)			
D1. I find this app useful for providing me with immediate relief from the physical symptoms of my headaches (through relaxation techniques such as guided meditation and stretching recommendations provided by the app, for example).	0.86	0.05	0.85
D2. My use of this app helps me practice healthy habits that can improve my headaches (by providing reminders and recommendations, for example).	1	0.01	1
D3. My use of this app helps me avoid triggers of my headaches.	1	0.01	1
D4. I find this app useful for predicting the next time I will experience the physical symptoms of my headaches.	0.86	0.05	0.85
S-CVI Clarity	0.95		

According to Table 13, S-CVIs associated with specific subdimensions (monitoring physical health, building awareness of physical health, learning about physical health, and managing physical health) ranged from 0.93 to 1, with all S-CVIs exceeding the minimum threshold of 0.8 (Polit et al., 2007). Furthermore, all individual items were generally marked as clear, and the I-CVIs ranged from 0.86 to 1. Ten items (62.5%) had an I-CVI of 1, and the remaining six items (37.5%) had an I-CVI of 0.86. As Lynn (1986) stated, an I-CVI of at least 0.78 indicates a sufficient content validity assessment. Given the I-CVIs in Table 13, all items passed the minimum of 0.78 to be considered clear.

Moreover, we calculated the probability of chance agreement (P_c) and kappa statistic for each item to account for chance agreement. The probability of chance agreement (P_c) ranged from 0.01 to 0.05. It means that the probability that expert panel members would agree on any item by chance alone was between 0.01 and 0.05. For instance, the probability that expert panel members would agree on their score for A1 by chance was 0.01. The probability of chance agreement was used to calculate the kappa values, which adjusted I-CVIs for the chance agreement (Polit et al., 2007). Similar to I-CVIs, the kappa values ranged between 0.85 and 1 (wherein the I-CVIs ranged between 0.86 and 1). All kappa values were above 0.74, indicating excellent content validity (Rodrigues et al., 2017).

Expert panel members provided qualitative feedback to improve several items (particularly those with the I-CVIs of 0.86 or the kappa value of 0.85). For instance, some expert panels suggested we provide consistent examples for several items (e.g., A2, A4), reduce the length of some items (e.g., D1), avoid using passive voice (e.g., one member suggested that we use “this app helps me...” instead of “I find this app useful for...”), and simplify some items (e.g., replacing “validate” with “check” in B1). Furthermore, one expert panel member suggested that we differentiate between “habits” (e.g., items A2 and B3) and “things” (e.g., items A4 and B5) in order to reduce redundancy since “habits” and “things” might be measuring the same aspects.

Table 14: Importance of the biological relevance items

Items	I-CVI Importance	P_c	Kappa statistic
A. Monitoring Physical Health (S-CVI = 1)			
A1. I find this app useful for monitoring my physical symptoms when I experience headaches.	1	0.01	1
A2. I find this app useful for monitoring my daily habits that could affect my headaches.	1	0.01	1

Items	I-CVI Importance	P_c	Kappa statistic
A3. I find this app useful for monitoring my treatments (e.g., medications and relief methods) for my headaches.	1	0.01	1
A4. I find this app useful for monitoring the things that trigger my headaches.	1	0.01	1
B. Building Awareness of Physical Health (S-CVI = 0.92)			
B1. My use of this app helps me validate my memory of how my headaches have affected my life (for example, by providing a record of my past headache experiences).	1	0.01	1
B2. My use of this app provides me with a better understanding of physical symptoms associated with my headaches.	0.86	0.05	0.85
B3. My use of this app provides me with a better understanding of how my daily habits affect my headaches.	1	0.01	1
B4. My use of this app provides me with a better understanding of various treatments (including medications and relief methods) that could improve my headaches.	0.86	0.05	0.85
B5. My use of this app provides me with a better understanding of the things that can trigger my headaches.	0.86	0.05	0.85
C. Learning about Physical Health (S-CVI = 1)			
C1. This app helps me learn new information about different types of headaches and associated physical symptoms.	1	0.01	1
C2. This app helps me learn new information about relief methods for headaches.	1	0.01	1
C3. This app helps me learn new information about the things that can trigger headaches.	1	0.01	1
D. Managing Physical Health (S-CVI = 0.93)			
D1. I find this app useful for providing me with immediate relief from the physical symptoms of my headaches (through relaxation techniques such as guided meditation and stretching recommendations provided by the app, for example).	0.86	0.05	0.85
D2. My use of this app helps me practice healthy habits that can improve my headaches (by providing reminders and recommendations, for example).	1	0.01	1
D3. My use of this app helps me avoid triggers of my headaches.	1	0.01	1

Items	I-CVI Importance	P _c	Kappa statistic
D4. I find this app useful for predicting the next time I will experience the physical symptoms of my headaches.	0.86	0.05	0.85
S-CVI Importance	0.96		

According to Table 14, S-CVIs associated with specific subdimensions of the biological relevance ranged from 0.92 to 1, which exceeded the minimum threshold of 0.8 (Polit et al., 2007). Moreover, all individual items were generally marked as important, and the I-CVIs ranged from 0.86 to 1. Eleven items (68.75%) had an I-CVI of 1, and the remaining five items (31.25%) had an I-CVI of 0.86. Given the I-CVIs in Table 14, all items passed the minimum of 0.78 (Lynn et al., 1986) to be considered important for measuring the biological relevance of DHT. Similar to I-CVIs for clarity (see Table 13), we also calculated the probability of chance agreement (P_c) and kappa statistic for each item. The probability of chance agreement (P_c) ranged from 0.01 to 0.05, and the kappa values ranged between 0.85 and 1 (Rodrigues et al., 2017).

Even though some items were marked as less important than others (e.g., B2, B4, B5), expert panel members provided very limited qualitative feedback on such items. Some expert panels reiterated several clarity issues that, if fixed, could enhance the importance of specific items (e.g., B5, D1, and D4). For instance, expert panel members indicated that “things” in B5 should be clarified using examples.

Table 15: Representativeness of the biological relevance items

Items	I-CVI Representativeness	P _c	Kappa statistic
A. Monitoring Physical Health (S-CVI = 1)			
A1. I find this app useful for monitoring my physical symptoms when I experience headaches.	1	0.01	1

Items	I-CVI Representativeness	P _c	Kappa statistic
A2. I find this app useful for monitoring my daily habits that could affect my headaches.	1	0.01	1
A3. I find this app useful for monitoring my treatments (e.g., medications and relief methods) for my headaches.	1	0.01	1
A4. I find this app useful for monitoring the things that trigger my headaches.	1	0.01	1
B. Building Awareness of Physical Health (S-CVI = 0.89)			
B1. My use of this app helps me validate my memory of how my headaches have affected my life (for example, by providing a record of my past headache experiences).	0.71	0.16	0.66
B2. My use of this app provides me with a better understanding of physical symptoms associated with my headaches.	1	0.01	1
B3. My use of this app provides me with a better understanding of how my daily habits affect my headaches.	1	0.01	1
B4. My use of this app provides me with a better understanding of various treatments (including medications and relief methods) that could improve my headaches.	0.86	0.05	0.85
B5. My use of this app provides me with a better understanding of the things that can trigger my headaches.	0.86	0.05	0.85
C. Learning about Physical Health (S-CVI = 0.95)			
C1. This app helps me learn new information about different types of headaches and associated physical symptoms.	0.86	0.05	0.85
C2. This app helps me learn new information about relief methods for headaches.	1	0.01	1
C3. This app helps me learn new information about the things that can trigger headaches.	1	0.01	1
D. Managing Physical Health (S-CVI = 0.86)			
D1. I find this app useful for providing me with immediate relief from the physical symptoms of my headaches (through relaxation techniques such as guided meditation and stretching recommendations provided by the app, for example).	0.86	0.05	0.85
D2. My use of this app helps me practice healthy habits that can improve my headaches (by providing reminders and recommendations, for example).	0.86	0.05	0.85

Items	I-CVI Representativeness	P _c	Kappa statistic
D3. My use of this app helps me avoid triggers of my headaches.	0.86	0.05	0.85
D4. I find this app useful for predicting the next time I will experience the physical symptoms of my headaches.	0.86	0.05	0.85
S-CVI Representativeness	0.92		

Finally, according to Table 15, S-CVIs associated with specific subdimensions ranged from 0.86 to 1 exceeding the minimum threshold of 0.8 (Polit et al., 2007). As for individual items, fifteen items (93.75%) were marked as representative, with the I-CVIs ranging between 0.86 and 1. Particularly, eight items (50%) received a score of 1, and seven (43.75%) received a score of 0.86. These fifteen items exhibited sufficient content validity since their I-CVIs exceeded the minimum threshold of 0.78 (Lynn, 1986). One item (B1) received the I-CVI of 0.71, below the minimum threshold of 0.78, meaning that the item might not represent the construct of interest. Further, the kappa values indicated that all items exhibited excellent content validity (Rodrigues et al., 2017), except for item B1. B1 received a kappa value of 0.66.

Moreover, several expert panel members provided additional feedback on other items (particularly those with the I-CVIs and kappa's of 0.86 and 0.85, respectively). For instance, some experts indicated that several items (e.g., B5, D3) should contain examples to make them truly representative of the construct of interest. This feedback echoed previously provided expert panel members' feedback on the clarity of such items (e.g., examples should be provided for B5). Further, one expert panel member indicated that C1 was a double-barred question (measuring one's learning about (a) different headaches and (b) physical symptoms associated with different headaches).

Psychological Relevance of DHT

Content validity results for the psychological relevance of DHT indicated that the items are generally clear, representative, and important to measure the construct. Particularly, the S-CVI was 0.97 for clarity, 0.98 for representativeness, and 0.98 for importance. These S-CVIs exceeded 0.8, which is the minimum threshold for establishing adequate content validity (Polit et al., 2007). Further, Tables 16, 17, and 18 summarize I-CVIs, the probability of chance agreement (P_c), and kappa statistics to assess each item's clarity, importance, and representativeness.

Table 16: Clarity of the psychological relevance items

Items	I-CVI Clarity	P_c	Kappa statistic
A. Monitoring Psychological Health (S-CVI = 1)			
A1. I find this app useful for monitoring my momentary emotions (for example, feeling sad, frustrated, surprised) when I experience headaches	1	0.01	1
A2. I find this app useful for monitoring my mental health states (for example, anxiety, depression, stress) when I experience headaches.	1	0.01	1
B. Building Awareness of Psychological Health (S-CVI = 1)			
B1. My use of this app helps me understand my momentary emotions (for example, feeling sad or frustrated) when I experience headaches.	1	0.01	1
B2. My use of this app helps me understand my mental health (for example, feeling stressed or anxious) when I experience headaches.	1	0.01	1
C. Managing Psychological Health (S-CVI = 1)			
C1. I find this app useful for providing me with immediate relief from stress, anxiety, or negative emotions caused by my headaches (through relaxation techniques such as guided meditation and mindfulness, for example).	1	0.01	1
D. Feeling Empowered (S-CVI = 0.93)			
D1. My use of this app helps me stay positive when I experience headaches.	0.86	0.05	0.85
D2. My use of this app helps me feel in control of my headaches.	0.86	0.05	0.85
D3. My use of this app helps me feel confident in my ability to manage my headaches.	1	0.01	1

Items	I-CVI Clarity	P _c	Kappa statistic
D4. My use of this app helps me feel motivated to take action towards managing my headaches.	1	0.01	1
S-CVI Clarity	0.97		

According to Table 16, S-CVIs associated with specific subdimensions of the psychological relevance of DHT were between 0.93 and 1 (above the threshold of 0.8 (Polit et al., 2007)). All individual items were generally marked as clear, and the I-CVIs ranged from 0.86 to 1. Seven items (77.8%) had an I-CVI of 1, and two items (22.2%) had an I-CVI of 0.86.

Moreover, we calculated the probability of chance agreement (P_c) and kappa statistic for each item to account for chance agreement. The probability of chance agreement (P_c) ranged from 0.01 to 0.05. Similar to the I-CVIs, the kappa values ranged between 0.85 and 1 (wherein the I-CVIs ranged between 0.86 and 1). All kappa values were above 0.74.

We leveraged the expert panel members' qualitative feedback to improve several items further. For instance, some expert panel members suggested we use a consistent item structure (starting each item with "this app..."), reduce the length of some items (e.g., C1), remove unnecessary words (e.g., remove "momentary" from B2), and provide consistent examples across similar items (e.g., A1 and B1).

Table 17: Importance of the psychological relevance items

Items	I-CVI Importance	P _c	Kappa statistic
A. Monitoring Psychological Health (S-CVI = 1)			
A1. I find this app useful for monitoring my momentary emotions (for example, feeling sad, frustrated, surprised) when I experience headaches	1	0.01	1
A2. I find this app useful for monitoring my mental health states (for example, anxiety, depression, stress) when I experience headaches.	1	0.01	1
B. Building Awareness of Psychological Health (S-CVI = 0.93)			

Items	I-CVI Importance	P _c	Kappa statistic
B1. My use of this app helps me understand my momentary emotions (for example, feeling sad or frustrated) when I experience headaches.	1	0.01	1
B2. My use of this app helps me understand my mental health (for example, feeling stressed or anxious) when I experience headaches.	0.86	0.05	0.85
C. Managing Psychological Health (S-CVI = 1)			
C1.I find this app useful for providing me with immediate relief from stress, anxiety, or negative emotions caused by my headaches (through relaxation techniques such as guided meditation and mindfulness, for example).	1	0.01	1
D. Feeling Empowered (S-CVI = 1)			
D1. My use of this app helps me stay positive when I experience headaches.	1	0.01	1
D2. My use of this app helps me feel in control of my headaches.	1	0.01	1
D3. My use of this app helps me feel confident in my ability to manage my headaches.	1	0.01	1
D4. My use of this app helps me feel motivated to take action towards managing my headaches.	1	0.01	1
S-CVI Importance	0.98		

Furthermore, according to Table 17, S-CVIs associated with the subdimensions of the psychological relevance of DHT ranged from 0.93 to 1. In addition, all individual items were marked as important to measure the psychological relevance of DHT (i.e., they were above 0.78). Eight items (88.9%) had the I-CVIs of 1, and one item (11.1%) scored 0.86. As we also calculated the kappa values to adjust for chance agreement, Table 17 demonstrates that the kappa values ranged between 0.85 and 1 (where seven items had a kappa value of 1, and one item had a kappa value of 0.85).

There was very limited qualitative feedback on the importance of the items. One expert panel suggested that we review the pairs of items, such as A1 and A2, as well as B1 and B2, as they could be redundant (i.e., emotions can be subsumed under mental health).

Table 18: Representativeness of the psychological relevance items

Items	I-CVI Representativeness	P _c	Kappa statistic
A. Monitoring Psychological Health (S-CVI = 1)			
A1. I find this app useful for monitoring my momentary emotions (for example, feeling sad, frustrated, surprised) when I experience headaches	1	0.01	1
A2. I find this app useful for monitoring my mental health states (for example, anxiety, depression, stress) when I experience headaches.	1	0.01	1
B. Building Awareness of Psychological Health (S-CVI = 1)			
B1. My use of this app helps me understand my momentary emotions (for example, feeling sad or frustrated) when I experience headaches.	1	0.01	1
B2. My use of this app helps me understand my mental health (for example, feeling stressed or anxious) when I experience headaches.	1	0.01	1
C. Managing Psychological Health (S-CVI = 0.86)			
C1. I find this app useful for providing me with immediate relief from stress, anxiety, or negative emotions caused by my headaches (through relaxation techniques such as guided meditation and mindfulness, for example).	0.86	0.05	0.85
D. Feeling Empowered (S-CVI = 1)			
D1. My use of this app helps me stay positive when I experience headaches.	1	0.01	1
D2. My use of this app helps me feel in control of my headaches.	1	0.01	1
D3. My use of this app helps me feel confident in my ability to manage my headaches.	1	0.01	1
D4. My use of this app helps me feel motivated to take action towards managing my headaches.	1	0.01	1
S-CVI Representativeness	0.98		

Finally, according to Table 18, S-CVIs associated with the subdimensions of the psychological relevance of DHT were between 0.86 and 1. In addition, all individual items were marked as representative of the psychological relevance of DHT. Eight items (88.9%)

had the I-CVIs of 1, and one item (11.1%) scored 0.86. As we also calculated the kappa values to adjust for chance agreement, Table 18 demonstrates that the kappa values ranged between 0.85 and 1 (where seven items had a kappa value of 1, and one item had a kappa value of 0.85).

Some expert panel members indicated that C1 (which received the I-CVI and kappa of 0.86 and 0.85, respectively) was hard to follow and should be revised. Further, another expert panel member indicated that “momentary” should be removed from items A1 and B1 as this word might not accurately capture what the items intended to measure (i.e., emotions that occur when individuals experience headaches).

Social Relevance of DHT

Content validity results suggest that the social relevance items were generally representative and important to measure the construct. Particularly, the S-CVI was 0.88 for representativeness and 0.83 for importance. These S-CVIs exceeded 0.8, which is the minimum threshold for establishing adequate content validity (Polit et al., 2007). However, the S-CVI for clarity was 0.76, meaning that some individual items needed to undergo major revisions or be deleted completely. Tables 19, 20, and 21 summarize I-CVIs for each item, the probability of chance agreement (P_c), and kappa statistics assessing items’ clarity, importance, and representativeness.

Table 19: Clarity of the social relevance items

Items	I-CVI Clarity	P_c	Kappa statistic
A. Feeling Supported (S-CVI = 0.67)			
A1. My interactions with other users of the app (for example, through a social chat feature) make me feel supported when I experience headaches.	0.86	0.05	0.85
A2. Different features of the app (for example, notifications and messages) make me feel supported when I experience headaches.	0.57	0.27	0.41

Items	I-CVI Clarity	P _c	Kappa statistic
A3. This app is like a friend to me who supports me when I experience headaches.	0.57	0.27	0.41
B. Learning About Communication (S-CVI = 1)			
B1. My use of this app helps me learn how to talk about my headaches with other people.	1	0.01	1
C. Managing Social Interactions (S-CVI = 0.79)			
C1. My use of this app helps me prepare for social interactions with people in real life (for example, I can give a warning to other people if the app predicts an upcoming headache attack).	0.71	0.16	0.66
C2. My use of this app helps me feel more confident in interacting with people in real life when I experience headaches.	0.86	0.05	0.85
S-CVI Clarity	0.76		

According to Table 19, S-CVIs for subdimensions, such as feeling supported and managing social interactions, did not exceed the minimum threshold of 0.8 (Polit et al., 2007). Particularly, the S-CVIs for such subdimensions were 0.67 and 0.79, respectively, indicating issues with items associated with such subdimensions. All social relevance items had I-CVIs between 0.57 and 1. Particularly, one item (16.7%) had a score of 1, and two items (33.3%) had a score of 0.87. These items exceeded the minimum threshold of 0.78 (Lynn, 1986), indicating sufficient clarity. However, one item (16.7%) had an I-CVI of 0.71, and two items (33.3%) had I-CVIs of 0.57, indicating that these items should undergo extensive revisions to improve their clarity. The probability of chance agreement (P_c) ranged from 0.01 to 0.27, while the kappa values ranged from 0.41 to 1.

The expert panel members indicated that we should remove “different” from A2 and clarify the example (that notifications are app-generated). Furthermore, some expert panel members indicated that C1 sounded too complex and should be simplified and shortened. Regarding A3, several expert panel members indicated that the purpose and the meaning of A3 were unclear (therefore, the item should be considered for removal). Subsequent

assessments of A3 with respect to its importance and representativeness also indicated that A3 might not be appropriate to measure the construct of interest.

Table 20: Importance of the social relevance items

Items	I-CVI Importance	P _c	Kappa statistic
A. Feeling Supported (S-CVI = 0.86)			
A1. My interactions with other users of the app (for example, through a social chat feature) make me feel supported when I experience headaches.	1	0.01	1
A2. Different features of the app (for example, notifications and messages) make me feel supported when I experience headaches.	1	0.01	1
A3. This app is like a friend to me who supports me when I experience headaches.	0.57	0.27	0.41
B. Learning About Communication (S-CVI = 1)			
B1. My use of this app helps me learn how to talk about my headaches with other people.	1	0.01	1
C. Managing Social Interactions (S-CVI = 0.86)			
C1. My use of this app helps me prepare for social interactions with people in real life (for example, I can give a warning to other people if the app predicts an upcoming headache attack).	0.86	0.05	0.85
C2. My use of this app helps me feel more confident in interacting with people in real life when I experience headaches.	0.86	0.05	0.85
S-CVI Importance	0.88		

Furthermore, according to Table 20, all S-CVIs associated with the social relevance subdimensions exceeded the minimum threshold of 0.8 (Polit et al., 2007). Three items (50%) had the I-CVIs of 1. Two items (33.3%) had the I-CVIs of 0.86. These items exceeded the minimum threshold of 0.78 (Lynn, 1986), indicating sufficient importance. Only one item (A3) scored 0.57. The probability of chance agreement (P_c) ranged from 0.01 to 0.27, while the kappa values ranged from 0.41 to 1. A3 had the lowest kappa value of 0.41, which indicated that A3 might not be as important for measuring the social relevance of DHT. Also, some experts noted that C2 was redundant with C1.

Table 21: Representativeness of the social relevance items

Items	I-CVI Representativeness	P _c	Kappa statistic
A. Feeling Supported (S-CVI = 0.81)			
A1. My interactions with other users of the app (for example, through a social chat feature) make me feel supported when I experience headaches.	1	0.01	1
A2. Different features of the app (for example, notifications and messages) make me feel supported when I experience headaches.	0.71	0.16	0.66
A3. This app is like a friend to me who supports me when I experience headaches.	0.71	0.16	0.66
B. Learning About Communication (S-CVI = 1)			
B1. My use of this app helps me learn how to talk about my headaches with other people.	1	0.01	1
C. Managing Social Interactions (S-CVI = 0.79)			
C1. My use of this app helps me prepare for social interactions with people in real life (for example, I can give a warning to other people if the app predicts an upcoming headache attack).	0.71	0.16	0.66
C2. My use of this app helps me feel more confident in interacting with people in real life when I experience headaches.	0.86	0.05	0.85
S-CVI Representativeness	0.83		

Finally, Table 21 illustrates that only one S-CVI associated with the social relevance subdimensions did not exceed 0.8 (Polit et al., 2007). Particularly, managing social interactions had an S-CVI of 0.79. Furthermore, two items (33.3%) had I-CVIs and kappa values of 1. One item (16.7%) received an I-CVI of 0.86 and a kappa of 0.85. Finally, three items (50%) scored 0.71 and 0.66 on the I-CVI and kappa, respectively. In addition to echoing clarity issues associated with such items, the expert panel members indicated that A2 needs to be revised to improve its representativeness.

Discussion of Phase 2 Results

Phase 2 illustrates that our set of items (developed as a result of Phase 1) was generally clear, important, and representative of the biopsychosocial relevance of DHT.

The biological relevance of DHT items (which captures monitoring physical health, building awareness of physical health, learning about physical health, and managing physical health) were generally clear, important, and representative. Only one item related to building awareness of physical health did not score high on the representativeness assessment. Specifically, the I-CVI for B1 (which measures the extent to which DHT enables users to validate their memory of their prior illness experiences) was 0.71, which is below the minimum threshold of 0.78 (Lynn, 1986). Even though the I-CVI for B1 was 0.71, we did not remove this item from the measurement instrument. Our qualitative findings (from Phase 1) suggest that validating memory of one's headache pain can be crucial for building one's awareness of their health condition. In addition, prior research also indicates that reflecting on one's personal health information (which, in our case, refers to the user's headache experiences) can raise one's awareness of their health (Felipe et al., 2015). Overall, the low ratings of the representativeness of B1 can be attributed to clarity issues associated with this item (particularly, some expert panel members indicated that B1 needed to be revised and some words, such as "validated," needed to be replaced to improve clarity). We revised B1 to improve its clarity because the lack thereof, we believe, affected expert panel members' perception of such an item's representativeness of the biological relevance of DHT. Appendix G1 contains the revised items measuring the biological relevance of DHT.

The psychological relevance of DHT captured items related to monitoring psychological health, building awareness of psychological health, managing psychological health, and feeling empowered. Content validity results for the psychological relevance of DHT suggest that the items were generally clear, representative, and important to measure the construct. The feedback provided by the expert panel members was considered to improve the items further. Regarding the importance of the items, one expert panel suggested we review A1 and A2 (which measure the extent to which DHT enables users to monitor their emotions and mental health, respectively) as well as B1 and B2 (which measure the extent to which DHT enables users to understand their emotions and mental health, respectively), as the items within each pair might be redundant (particularly, emotions can be subsumed under mental health). To address this comment, we carefully reviewed the items and existing literature on emotions and mental health. We choose to leave the items separate (i.e., one to measure mental health and the other one to measure emotions) since prior literature distinguishes between mental health and emotions (Gloria & Steinhardt, 2016; Recovery, 2022).

In addition, we added two more items to improve the representativeness of the psychological relevance of DHT further. Particularly, the literature reports that learning about emotions and mental health is critical for chronic pain self-management (Russell & Park, 2018). The learning aspect enabled by DHT also appears in the biological relevance of DHT section. Thus, we added two more items related to learning about one's mental health and emotions. Appendix G2 contains the new and revised items for the psychological relevance of DHT.

The social relevance of DHT captures items measuring the extent to which DHT helps users feel supported, learn about communication, and manage social interactions. Content validity results suggest that the social relevance of DHT items were generally representative and important to measure the construct. However, the representativeness of one specific subdimension associated with the social relevance of DHT did not exceed 0.8. Particularly, managing social interactions had an S-CVI of 0.79. Such a score could result from our limited prior knowledge of how DHTs can be used to help users manage their social interactions with other people in real life, specifically in the context of chronic pain. Self-management of social health was addressed in a limited number of studies on DHTs that pertain to conditions, such as dementia (Brown & O'Connor, 2020).

Furthermore, the overall S-CVI for clarity was 0.76, meaning that some individual items had to undergo major revisions or be deleted completely. Reviewing S-CVIs associated with specific subdimensions of social relevance, one can see that feeling supported (S-CVI = 0.67) and managing social interactions (S-CVI = 0.79) were the dimensions that received the lowest S-CVIs. These subdimensions contained items that required significant revisions/deletions. Along with the individual I-CVIs, we used expert panel members' qualitative feedback to revise and delete items. For instance, A3 (which measures the extent to which users perceive DHT as their friend) was removed from the measurement instrument because several expert panel members indicated that A3 is not appropriate to measure the construct of interest, and the item scored very low. Also, we did not find any empirical support (in the existing literature) to retain such an item (as a critical aspect of user experience with DHTs). In addition, several expert panel members stated that C1 (which measures the extent to which DHT helps users prepare for social interactions) and

C2 (which measures the extent to which DHT helps users feel confident in their social interactions) were redundant (and these items scored low as well). Thus, we removed C2 from the measurement instrument, given that it was more abstract than C1 and, therefore, could be open to multiple interpretations. Appendix G3 contains the revised instrument to measure the social relevance of DHT.

Finally, some limitations of our study should be noted. Particularly, we recognize that expert panel members' feedback is subjective; therefore, our study is subject to biases that might exist among the experts. In addition, the instrument should be further validated with the users of DHT. We addressed this limitation and validated our measurement instrument with the DHT users during Phase 3 of the study.

CHAPTER 5: PHASE 3 – PSYCHOMETRIC ANALYSIS

Introduction

During Phase 1 and Phase 2, we conceptualized the biopsychosocial relevance of DHT, developed associated items, and established the content validity of such items. The final step in the measurement instrument development is to conduct a psychometric analysis to establish the construct validity of the biopsychosocial relevance of DHT (DeVellis, 2016; Morgado et al., 2017).

To conduct psychometric analysis and establish the construct validity, we assessed items from Phase 2 (see Appendices G1, G2, and G3). As described in previous chapters, the biopsychosocial relevance and its dimensions are formative constructs (Jarvis et al., 2003). Thus, we leveraged PLS-SEM to validate our construct of interest (Hair et al., 2011; Hair et al., 2016; Sarstedt et al., 2019). To conduct a proper analysis, we specified a higher-order formative measurement model and developed a structural model relating the biopsychosocial relevance of DHT to continuous usage intention. Finally, we discussed measurement instrument attributes (e.g., scoring).

Measurement Model of the Biopsychosocial Relevance of DHT

To properly validate a construct, one needs to specify its measurement model (Hair et al., 2011; Hair et al., 2016; Sarstedt et al., 2019). The measurement model describes the relationship between the construct and its indicators (or items) (Hair et al., 2016). We specify the biopsychosocial relevance of DHT as a higher-order formative measurement model (Cheah et al., 2018; Hair et al., 2016; Ringle et al., 2012; Sarstedt et al., 2019).

Higher-order constructs refer to constructs that contain multiple dimensions and can, therefore, be extended to any number of layers yielding second-, third-, fourth-, and other-

order constructs (Hair et al., 2016; Sarstedt et al., 2019). For example, satisfaction can be modeled as a second-order construct that captures first-order components, such as satisfaction with price, service quality, and personnel (Hair et al., 2016).

Modeling a construct as a higher-order construct can provide a series of advantages. First, it allows researchers to reduce the number of path relationships and increase model parsimony (Edwards, 2016). Second, higher-order constructs allow researchers to overcome the bandwidth-fidelity dilemma when there is a trade-off between a variety of information and thoroughness of testing to get more certain information (Sarstedt et al., 2019). Finally, it can be particularly useful to model formative constructs as higher-order constructs because it provides means to reduce collinearity among formative indicators (Hair et al., 2016; Sarstedt et al., 2019).

In accordance with the above, we model the biopsychosocial relevance of DHT as a higher-order construct containing three lower-order dimensions: the biological relevance of DHT, the psychological relevance of DHT, and the social relevance of DHT. The biological relevance of DHT and psychological relevance of DHT can be further decomposed into even lower sub-dimensions. As a result of Phase 1 and Phase 2, we established that the biological relevance of DHT comprises monitoring one's physical health, building awareness of one's physical health, learning about physical health in general, and managing one's physical health. Similarly, the psychological relevance of DHT consists of monitoring one's psychological health, building awareness of one's psychological health, learning about psychological health in general, and managing one's psychological health. Even though the social relevance of DHT also contains several sub-dimensions (e.g., feeling supported, learning about communication, and managing social interactions), we

chose not to model the social relevance as a higher-order construct because of a small number of items measuring several social relevance sub-dimensions. Notably, both learning about communication and managing social interactions contain single items (see Appendix G3). According to Hair et al. (2016), single-item measures are not recommended unless specific conditions are met (e.g., a sample size of less than 50, and path coefficients of 0.3 or lower are expected, among others). Since such conditions were not met, we modeled the social relevance of DHT as a lower-level construct with four indicators.

Furthermore, when conceptualizing higher-order constructs, researchers should decide on the measurement model specification of the lower-order constructs and the relationship between the higher-order constructs and their lower-order constructs (Jarvis et al., 2003; Sarstedt et al., 2019). Four types of higher-order constructs account for the measurement model specification and the relationship between higher and lower-order constructs: reflective-reflective, reflective-formative, formative-reflective, and formative-formative (Cheah et al., 2018). Even though these types relate to second-order models only (e.g., a reflective-reflective model contains a higher-order reflective construct comprising several reflective dimensions), they can also be extended to third-, fourth-, and other higher-order constructs (Cheah et al., 2018). For instance, online experiential value in online book and CD retailing can be modeled as a fourth-order reflective construct (Wetzels et al., 2009). The experiential value is a reflective construct consisting of third-order reflective constructs, such as hedonic and utilitarian values. Then, such third-order constructs comprise second-order reflective constructs: customer ROI (under the utilitarian value) and aesthetics and playfulness (comprising the hedonic value). Each of these second-order

constructs also comprises first-order reflective constructs. We model the biopsychosocial relevance of DHT as a composite higher-order formative-formative-formative construct. In addition, prior research distinguishes two types of formative constructs: causal-formative and composite (Henseler, 2017). Causal-formative constructs assume that the observed indicators cause the construct (Henseler, 2017; Jarvis et al., 2003). Further, indicators do not need to covary and have the same antecedents or consequences. On the other hand, in the composite constructs, the indicators make up the entire construct; high correlations are common but not required, and indicators are required to have the same consequences. This study conceptualizes the biopsychosocial relevance construct (and its associated dimensions) as a composite (see Table 11 in Chapter 3 for justification). Overall, Figure 13 summarizes the higher-order formative model of the biopsychosocial relevance of DHT.

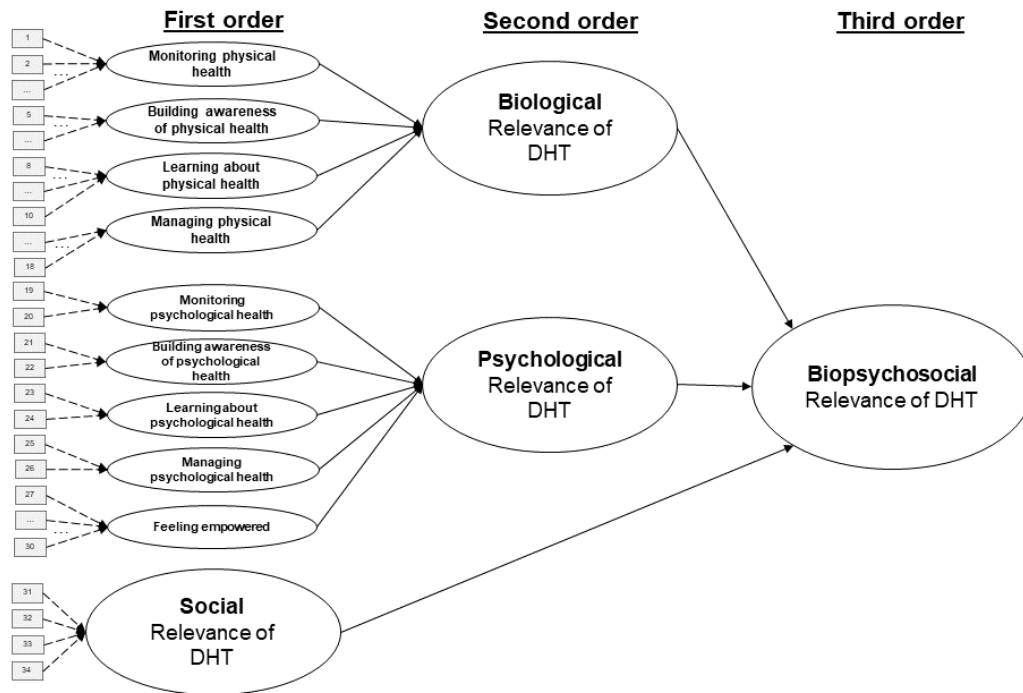


Figure 13: Higher-order formative model

Structural Model of the Biopsychosocial Relevance of DHT

To estimate the biopsychosocial relevance of DHT as a higher-order formative construct, we need to include it in a structural model (Hair et al., 2016; Wetzels et al., 2009). In structural models, higher-order constructs serve as antecedents or consequences embedded in a nomological network (Wetzels et al., 2009). The structural model should include a theoretically related construct (Jarvis et al., 2003). The structural model allows researchers to derive the indirect effects of lower-order constructs as a pairwise product of weights and coefficients of the outcomes (Wetzels et al., 2009).

To embed the biopsychosocial relevance of DHT in a nomological network, we related it to continuous usage intention (see Figure 14).

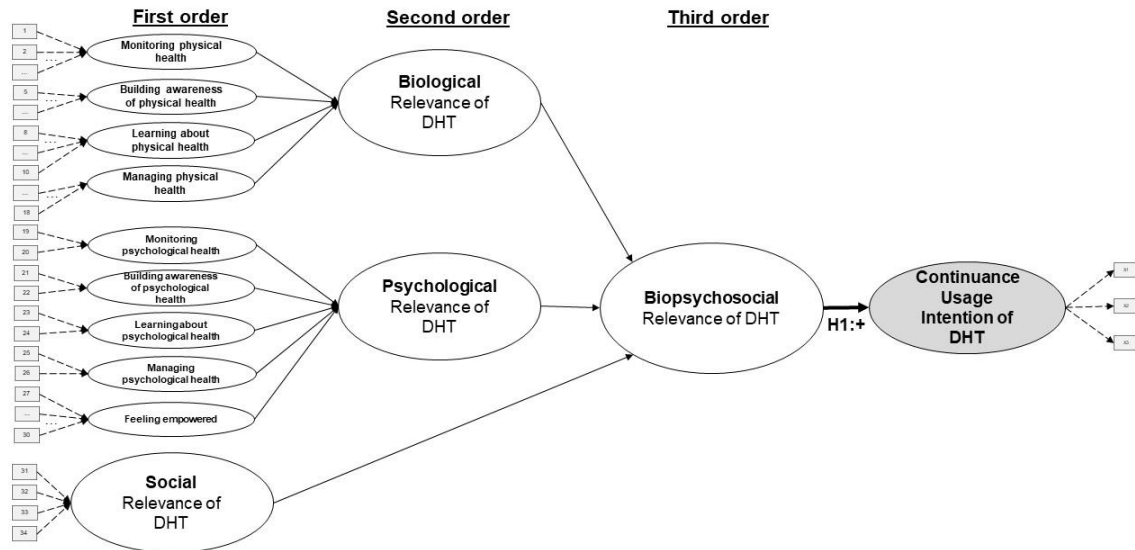


Figure 14: Structural model

Literature reports that the relevance of technology can enhance continuous user engagement (or continuous usage (Perski et al., 2017; Walton et al., 2017)) (Birnbaum et al., 2015; Yardley et al., 2015). Thus, we included the continuous usage intention, which is also a proxy for future usage behaviors (Bhattacharjee, 2001; Liu et al., 2021), in our model. Continuous usage intention is a previously validated reflective, three-item construct (Bhattacharjee, 2001; Kim et al., 2019). In alignment with that, we also tested the following hypothesis:

H1: The biopsychosocial relevance of DHT positively impacts the continuous usage intention of DHT.

We use PLS-SEM to estimate the model and validate the biopsychosocial relevance of DHT.

Methods

Overview

To conduct a psychometric analysis and establish the construct validity of the biopsychosocial relevance of DHT, we collected and analyzed survey data. First, we pretested items developed from Phase 1 and Phase 2 results with 15 DHT users suffering from chronic headaches. Pretesting is a necessary step in measurement instrument development that ensures that potential respondents interpret questions correctly (*Pretesting and Pilot Testing*, 2016). This step was also conducted to ensure the completion of the content validity assessments from Phase 2.

After the pretest, we collected data from DHT users and analyzed it using PLS-SEM, one of the structural equation modeling (SEM) methods (Hair et al., 2011; Hair et al., 2016; Sarstedt et al., 2019). SEM is a multivariate data analysis method that analyzes complex relationships between observable indicators and latent variables (Hair et al., 2011; Hair et al., 2016; Sarstedt et al., 2019). Two types of SEM exist: covariance-based (CB) and partial least squares (PLS). CB-SEM leverages the maximum likelihood estimation procedure, while PLS-SEM uses an ordinary least squares regression-based method. CB-SEM is commonly used to confirm established theories, while PLS-SEM is primarily appropriate for exploratory research (Hair et al., 2017). Furthermore, it is preferred to use PLS-SEM for higher-order formative measurement models. CB-SEM leverages a common factor model approach, which conforms to the measurement philosophy for reflective constructs (Hair et al., 2019). Particularly, correlated indicators are required for the CB-SEM common factor model to generate a valid proxy and represent a construct. On the other hand, PLS-SEM leverages a composite model approach (i.e., indicators can be linearly combined to

form composite variables representing latent variables), thereby conforming to the measurement philosophy of formative constructs.

In addition, compared to CB-SEM, PLS-SEM makes no assumptions about the underlying data and works better with smaller sample sizes (e.g., fewer than 250 participants). PLS-SEM works better with smaller sample sizes and a large number of items because its algorithm computes structural and measurement model relationships separately (instead of simultaneously) using distinct ordinary least squares regressions (Hair et al., 2019).

Since our study aims to explore the biopsychosocial relevance of DHT and model relevance as a higher-order formative construct, we chose to employ PLS-SEM in our analysis.

Measures

To assess the biopsychosocial relevance of DHT, we used items developed from Phase 1 and Phase 2 results (see Appendices G1, G2, and G3). Furthermore, to assess continuous usage intention, we used an existing reflective, three-item measure (based on the measure developed by Bhattacharjee (2000)) that was previously validated in the context of DHT for self-management of chronic conditions (Kim et al., 2019; Liu et al., 2022).

We used a 5-point Likert scale (ranging from “*Strongly Agree*” to “*Strongly Disagree*”) to assess each item. Likert-type scales are commonly used for multi-item measures (Dowling et al., 2016) to explore individual perceptions (Ho, 2016; Leung, 2011). For instance, Likert-type scales were previously used in studies on instrument development of perceptual measures related to digital health (Chen, 2019; Kelly, 2016). In addition, 5-point response scales are less confusing to participants and increase the response rate as compared to 7-, 10-, and other response scales (Bouranta et al., 2009).

In addition to the biopsychosocial relevance of DHT and continuous usage intention, we also collected several variables that could have an impact on user interaction with DHT (to include as potential control variables): gender, the number of months of DHT use, frequency of headaches (expressed in terms of the approximate average number of days per month a user experiences a headache), use of other DHTs (not necessarily for headaches). Some studies indicate that gender plays a significant role in user interactions with technologies (Goswami & Dutta, 2015; van Elburg et al., 2022). For instance, one study showed that males are more likely to use mobile health apps than females (van Elburg et al., 2022). Also, we included the number of months of the DHT use as a control variable because we expect users who have been interacting with a DHT for a long time to have the intention to keep using the DHT in the future because of habit formation (Peng et al., 2021; Wang et al., 2013). In addition, we included the user's frequency of headaches (expressed in terms of the approximate average number of days per month a user experiences headaches). If a user experiences frequent headaches, they may need to use a DHT more often to track their symptoms or seek social support, for example. Finally, we included individual use of other DHTs (not necessarily for headaches). It might be the case that a user has a tendency to engage with DHTs overall, and such a tendency could be captured by a proxy, such as an individual's use of other DHTs.

We also added several attention checks in our survey. Attention checks are items with an obvious correct response (Abbey & Meloy, 2017). Attention checks are used to measure participant survey engagement and prevent careless participants from damaging instrument validity (Kung et al., 2018).

Furthermore, we added reflectively measured items (i.e., global single measures) for each formatively measured construct at all levels of abstraction (Hair et al., 2017; Hair et al., 2011; Hair et al., 2016; Sarstedt et al., 2019). Adding reflective items to assess formatively measured constructs allows researchers to establish convergent validity of the formative constructs by correlating reflective items and latent variable scores associated with formative constructs.

Appendix H contains our measures. When we administered the actual measurement instrument, we fully randomized all items (i.e., presented items to each participant in a completely randomized order). Complete item randomization leads to more accurate measurements and negates the method bias that could affect measures (Loiacono & Wilson, 2020).

Recruitment of Participants for Surveys

We recruited participants by using a multi-modal recruitment strategy involving traditional (i.e., using hardcopy materials) and online (i.e., using electronic materials) recruitment activities (Close et al., 2013; Gelinas et al., 2017; McRobert et al., 2018; Whitaker et al., 2017). A multi-modal recruitment strategy can minimize financial and time costs associated with study recruitment and increase the response rate across various groups of participants (McRobert et al., 2018). We leveraged traditional and online recruitment methods to meet this project's timeline and recruit a diverse group of participants with headaches.

Traditional recruitment activities took place on the FIU campus (e.g., posting flyers on message boards in Green Library). Moreover, online recruitment took place on social media (Gelinas et al., 2017). Specifically, the study was advertised on the online recruiting

platforms, Reddit, and Facebook groups dedicated to chronic pain and chronic headaches. On Reddit and Facebook groups, the online flyers were posted after we contacted the group admins and received their permission to advertise the study. The flyer for the study contained the QR-code that took participants to the Qualtrics sign-up survey. Interested participants provided their name, demographic information (age, gender, ethnicity), headache-related information (duration and type), information about their experience with DHTs for self-management of headaches, and email address in the sign-up survey. Digital health users between 18 and 44 years of age suffering from chronic headaches were recruited for this study. Eligible participants were identified by using the inclusion criteria described in Table 22.

Table 22: Inclusion criteria

Inclusion Criteria	Explanation
Experience chronic headaches	Chronic headache is one of the most prevalent types of chronic pain, affecting 10% to 15% of people worldwide (Wang et al., 2016). Chronic headaches occur 10-15 times a month for at least three months (Kristoffersen & Lundqvist, 2014; Yancey et al., 2014)). Thus, participants who experience chronic headaches were recruited for this study.
Age between 18 and 44 years old	Chronic headaches often occur for the first time in late adolescence and early adulthood (Victor et al., 2010) and tend to disappear with advancing age (Song et al., 2016). According to National Health Interview (2018), the age group of 18-44 has the highest prevalence of headaches (18.7%) (Burch et al., 2021; CDC, 2018). Other age groups have a lower prevalence of headaches: 15.7% for the age group of 45-64, 9.3% for 65- to 74-year-old, and 6.1% for 75 years old and older. Thus, participants in the age group with a high prevalence of headaches (18-44 years old) were recruited for the study
Experience with DHTs to self-manage chronic headache	Since the interviews aim to explore participants' perceptions of the biopsychosocial relevance of DHTs for self-management of chronic conditions, we needed to recruit individuals with digital health experience. Given the context of this study (chronic headaches), we recruited individuals who had experiences with DHTs for chronic headache self-management.

The average compensation for participating in surveys is \$20/hour (Elizabeth et al., 2010). As a result of the pretest (described below), we estimated that the average time to complete the survey was about 20 minutes. We offered \$10 Amazon gift cards as a thank-you for their participation.

Data Collection Associated with Surveys

The survey was administered to participants via Qualtrics. First, we pretested our instrument (see Appendix H) with 15 participants. Pretesting the instrument before the full-scale administration allows researchers to enhance the credibility of their work (*Pretesting and Pilot Testing*, 2016). Pretesting reduces measurement errors, reduces respondent burden, and assesses participants' interpretations of the questions. A minimum of 12 participants is generally recommended for pretesting (*Pretesting and Pilot Testing*, 2016). The inclusion of too many participants is associated with a diminishing return (i.e., the financial and time costs of further pretesting outweigh the benefits of discovering more relatively minor issues and inconsistencies in the survey instrument). During the pretest, we asked participants to answer our measurement instrument items and provide qualitative feedback on items that were not clear. We also used "Pretesting Checklist" (see Appendix I) to assess our instrument (*Pretesting and Pilot Testing*, 2016). This step also ensured that we completed our assessment of the content validity of the items (particularly, that the items, revised as a result of Phase 2, are clear and easy to understand for participants). No issues regarding the clarity of the questions emerged during the pretest.

In total, 225 participants were recruited for the surveys. To determine our sample size, we used a power analysis calculator for structural equation modeling (Cohen, 1992; Hair et al., 2011; Hair et al., 2016; Soper, 2022). In our model (see Figure 15), we have 14 latent

variables (at different levels of abstraction) and 38 observed variables (see Appendix H for the indicators) in total. Thus, for a medium effect size of 0.3, a statistical power of 0.8, and a significance level of 0.05, the minimum sample size to detect effects is 208 participants (Soper, 2022).

The population effect size (i.e., a value measuring the strength of the relationship between variables) is typically unknown, and researchers should make the best guess of the population effect size referring to prior literature (Perugini et al., 2018). We reviewed other comparable studies on user interaction with DHTs and continued usage intention (e.g., (Mao & Hovick, 2020)). In other comparable studies, a small to medium effect size was used to determine the sample size (e.g., (Lazard et al., 2021; Yongmei et al., 2021)). Furthermore, the ideal power of analysis (i.e., the probability of rejecting a false null hypothesis) is 0.8 (or 80%) (Serdar et al., 2021). The alpha level (i.e., a significance level) is traditionally set to at most 0.05 (Perugini et al., 2018).

Data Analysis Associated with Surveys: Overview

We used PLS-SEM to assess our higher-order formative measurement model (Figure 13) and structural model (Figure 14) and validate the biopsychosocial relevance of DHT (Hair et al., 2011; Hair et al., 2016; Sarstedt et al., 2019). Particularly, we estimated our measurement model using a two-step approach (Becker et al., 2012; Ringle et al., 2012), conducted redundancy analysis, and calculated the adequacy coefficient to establish a convergent validity coefficient (Edwards, 2001; S. MacKenzie et al., 2011; Schmiedel et al., 2014), calculated VIFs to assess multicollinearity, assessed outer weights of the indicators and their significance levels for first-, second-, and third-order constructs, and conducted confirmatory composite analysis (Benitez et al., 2020; Henseler, 2017).

Reliability (in other words, internal consistency) is unimportant in assessing formative constructs since formative indicators focus on different aspects of a given construct (Petter et al., 2007). Contrary to reflective indicators, formative indicators should not covary because covariation of formative indicators suggests multicollinearity, which can destabilize a formative construct. Further, assessing discriminant validity is not a standard procedure for formative constructs based on composite indicators, and there currently exist no guidelines on establishing discriminant validity for such constructs.

Furthermore, to assess the biopsychosocial relevance of DHT within the nomological net, we assessed our construct in relation to the continuance usage intention of DHT in the structural model and calculated the coefficient of determination and the effect size of path coefficients. All data analysis activities were conducted in SmartPLS-4©.

Data Analysis Associated with Surveys: Higher-Order Formative Measurement Model

We used a two-step approach to analyze our higher-order formative measurement model (Figure 13) (Becker et al., 2012; Ringle et al., 2012). Compared to other approaches (e.g., a repeated indicator approach), the two-step approach has the advantage of estimating a more parsimonious model on a higher-level analysis. Further, the two-step approach allows researchers to minimize the parameter bias in the structural model.

There exist two types of two-step approaches: the embedded two-step approach and the disjoint two-step approach (Sarstedt et al., 2019). The embedded two-step approach estimates the construct scores of the first-order constructs first. Then, these scores are used as indicators for a higher-order latent variable in a separate analysis. On the other hand, the disjoint two-step approach considers only the lowest-order components of the highest-order construct. The lowest-order components are linked to other theoretically related

constructs in the structural model. In the second stage, the construct scores of the lowest-order components are used to measure a higher-order construct.

The disjoint and embedded approaches produce very similar results (Sarstedt et al., 2019). Thus, we used a two-step embedded approach for our analysis. We first associated indicators with their corresponding first-order constructs to implement the two-step approach in our assessment of the biopsychosocial relevance of DHT. Notably, we modeled dimensions such as monitoring one's physical health, building awareness of one's physical health, learning about physical health, managing physical health, monitoring one's psychological health, building awareness of one's psychological health, learning about psychological health, managing psychological health, feeling empowered, and social relevance of DHT as Mode B formative constructs (Hair et al., 2016). Then, the latent variable scores of the first-order constructs were used to form a corresponding second-order variable (Becker et al., 2012; Ringle et al., 2012). Notably, the latent variable scores of monitoring one's physical health, building awareness of one's physical health, learning about physical health, and managing physical health were used to develop the second-order variable of the biological relevance of DHT using Mode B (Hair et al., 2016). Similarly, the psychological relevance of DHT was formed through the latent variable scores of monitoring one's psychological health, building awareness of one's psychological health, learning about psychological health, managing psychological health, and feeling empowered. Finally, the latent variable scores of the biological relevance of DHT, psychological relevance of DHT, and social relevance of DHT were leveraged to form the formative construct of the biopsychosocial relevance of DHT.

To assess the validity of the biopsychosocial relevance of DHT, we followed the steps described by Hair et al. (2016). We conducted redundancy analysis to assess convergent validity by correlating each formative construct (i.e., the biopsychosocial relevance of DHT and its corresponding dimensions, such as the biological relevance of DHT, the psychological relevance of DHT, and the social relevance of DHT) with reflective measures of such constructs (i.e., global items) (Chin, 1998). The strength of the path coefficient linking a formative construct and a reflective item indicates the validity of the formative indicators (Hair et al., 2016). A magnitude of at least 0.7 (R^2 of at least 0.5) is sufficient to provide support for convergent validity (Hair et al., 2016). We also calculated the adequacy coefficient (R^2_a) to assess the relationship between the biopsychosocial relevance of DHT and its dimensions and sub-dimensions (Edwards, 2001; S. MacKenzie et al., 2011; Schmiedel et al., 2014). R^2_a is calculated by summing the squared correlations between the formative construct and its dimensions (or indicators) and dividing by the number of dimensions (or indicators) (Edwards, 2001). R^2_a exceeding 0.5 indicate that the majority of variance in the items is shared with the formative construct and that the construct is valid. Higher-order constructs and their respective dimensions were assessed in the same way.

Moreover, we assessed multicollinearity (Hair et al., 2016). Compared to reflective items, multicollinearity is not expected among formative items. If multicollinearity is present, researchers should drop redundant items. To examine the presence of the multicollinearity issues, we calculated VIFs for first-, second-, and third-order constructs. VIF values of 5 and higher indicate potential multicollinearity issues (Hair et al., 2011).

In addition to assessing convergent validity and multicollinearity, we assessed the outer weights of the indicators and their significance levels for first-, second-, and third-order constructs. The values of the outer weights can be compared with each other and used to determine each indicator's relative contribution to the construct (Hair et al., 2016). To estimate that, we tested whether the outer weights were significantly different from 0 using the bootstrapping procedure (wherein 5,000 subsamples were randomly drawn from the original dataset). Then, the t-values were calculated to assess the significance of each indicator's weight. It is also important to note that with a large number of indicators, the values of weights decline and become non-significant. Thus, non-significant indicator weights do not necessarily indicate poor measurement model quality. Researchers should also consider the absolute contribution of each indicator (i.e., the information provided by each indicator in isolation from other indicators). Outer loadings (which stem from single regressions of each indicator on its construct) can capture the absolute contribution of an indicator. Thus, when an outer weight is not significant, but an outer loading is significant, such an indicator is absolutely important but not relatively important. For instance, if the outer loadings are high (i.e., above 0.5), the indicators with such loadings should be retained.

Data Analysis Associated with Surveys: Confirmatory Composite Analysis

A confirmatory composite analysis was conducted to examine the overall fit of the model (Benitez et al., 2020; Henseler, 2017). The confirmatory composite analysis determines whether creating a proposed formative construct makes sense and identifies any model misspecifications. This analysis checks the adequacy of the higher-order composite model by comparing its empirical correlation matrix with the model-implied correlation matrix.

The standardized root means square residual (SRMR), unweighted least squares discrepancy (dULS), and geodesic discrepancy (dG) can be calculated to evaluate the goodness of saturated model fit. SRMR should be lower than 0.08, and dULS and dG should be below the 99% percentile of their corresponding reference distribution (Benitez et al., 2020; Benitez-Amado et al., 2017).

Data Analysis Associated with Surveys: Structural Model

Furthermore, we examined the nomological validity of the construct in relation to the continuance usage intention, a previously validated reflective three-item construct (Bhattacharjee, 2001; Kim et al., 2019) (Figure 14). To explore the hypothesized relationship between the biopsychosocial relevance of DHT and the continuance usage intention, we estimated the coefficient of determination (R^2) and the effect size (f^2) of path coefficients (Hair et al., 2016; Ringle et al., 2012; Sarstedt et al., 2019). We performed a bootstrap analysis using 5,000 resamples to obtain the significance of estimates (i.e., t-values).

Results of Phase 3

Participants' Demographics and Health

In our sample, 53.33% (n=120) of participants were females, and 45.33% (n=102) were males. This distribution partially aligns with the national data on the prevalence of chronic headaches among females and males. The National Health Interview Survey indicates that females are more likely to report headaches than males (Eisenstein, 2020). Two of our participants (0.89%) identified as non-binary, and one participant (0.44%) identified as transgender. We could not verify the extent to which our data align with the national

demographic information due to the limited reports on the prevalence of headaches among gender minorities (Hranilovich et al., 2021).

Furthermore, 68.89% (n=155) of our participants were Whites, 19.11% (n=43) were African Americans, 5.33% (n=12) were Hispanics, 4.89% (n=11) were Asians, and 1.78% (n=4) identified as other. This distribution partially aligns with the national data on the prevalence of chronic headaches among different ethnicities. Specifically, research indicates that the prevalence of headaches is higher in Whites than in African Americans, Hispanics, and Asians (for both males and females) (Stewart et al., 1996). According to Loder et al. (2015), the average prevalence of headaches (from 2005 to 2012) was 15.5% for Whites, 14.5% for Hispanics, 14.45% for African Americans, and 9.2% for Asians (Loder et al., 2015).

The age group of 25-29 (32.89% or n=74) contained the highest number of participants compared to other age groups. This age distribution aligns with prior research studies that indicate that the mean age at the onset of chronic headaches is typically between 25 and 30 years old (Kriegler, 2018).

The demographic information of our participants is summarized in Table 23.

Table 23: Participants' demographics (Phase 3), N=225

Gender, n (%)	
Female	120 (53.33%)
Male	102 (45.33%)
Non-binary	2 (0.89%)
Transgender	1 (0.44%)
Ethnicity, n (%)	
White	155 (68.89%)
African American	43 (19.11%)
Hispanic	12 (5.33%)
Asian	11 (4.89%)
Other	4 (1.78%)

Age, n (%)	
18-24	31 (13.78%)
25-29	74 (32.89%)
30-34	65 (28.89%)
35-39	32 (14.22%)
40-44	23 (10.22%)

46.67% (n=105) of participants indicated that they were diagnosed with chronic migraine. 12% (n=27) stated that they were diagnosed with tension headaches, and 8% (n=18) were diagnosed with cluster headaches. 8.89% (n=20) indicated that were diagnosed with other types of chronic headaches, including hemicrania continua, hypnic headache, new daily persistent headache, sinus headache, and TMJ headaches. 24.44% (n=55) stated that they have not been diagnosed with any specific type of chronic headache.

Furthermore, more than half of our participants (57.33% or n=129) indicated that they see a pain specialist to address their headache problem. 32.44% (n=73) reported that they do not see a pain specialist, and 10.22% (n=23) stated that they used to see a pain specialist but not anymore. In addition, 91.56% (n=206) stated that they are using medications to manage their headache pain.

Finally, 16% (n=36) stated that, in addition to chronic headaches, they also suffer from other medical conditions. 79.56% (n=179) indicated that they do not suffer from any other medical condition, and 4.44% (n=10) preferred not to answer.

DHT Usage

Participants used a variety of different DHTs to self-manage their headaches. 70.22% (n=158) of participants used headache-specific DHTs (e.g., *Bezzzy Migraine*, *N-1 Headache*, *Headache Log*, *Migraine Buddy*, among others). *Migraine Buddy* was the most used DHTs, as 44.89% (n=101) of participants indicated using it. Further, 15.11% (n=34) of participants used meditation-related DHTs to self-manage their headaches. Particularly,

participants reported that they used DHTs, such as *Calm*, *Headspace*, *Insight Timer*, among others. 8.44% (n=19) used general wellness DHTs (e.g., Health Log, BetterSleep Relax, among others).

When filling out the survey, 36.44% (n=82) of participants stated that they started using DHTs to self-manage their headaches 3-6 months ago. Further, 25.78% (n=58) indicated that they started using DHTs less than 3 months ago. 21.33% (n=48) started using DHTs between 6 to 12 months ago, and 16.44% (n=37) stated that they started using technology more than 12 months ago. In addition, 27.56% (n=62) participants stated that they used DHTs to self-manage headaches every day; 26.22% (n=59) use DHTs 5-6 times a week; 25.78% (n=58) used the technology 3-4 times a week. Finally, 14.67% (n=33) used the technology 1-2 times a week, and the rest of the participants (5.78% or n=13) used it every other week.

More than half of our participants (51.11% or n=115) reported that they do not use any other DHTs to self-manage their health, except for the ones they use to self-manage their headaches. 36.89% (n=83) indicated that they use other additional DHTs to self-manage their health. 12% (n=27) reported that they used to use other additional DHTs to self-manage their health.

Higher-Order Formative Measurement Model

Tables 24, 25, and 26 summarize the results of a three-step PLS-SEM. Across all three steps, VIFs for individual indicators, subdimensions, and dimensions were below 5, indicating no potential multicollinearity issues (Hair et al., 2011). Some VIFs, however, were close to 5 (e.g., learning about physical health in Table 25), yet did not exceed the value of 5.

Furthermore, the first-order constructs (Table 24) contained several insignificant weights (specifically, BM1, BM3, BA1, BA3, BL4, BMA3, PE2, PE3, and S1). As indicated by Hair et al. (2016), the values of outer weights determine the indicator's relative contribution to the construct. When there is a large number of indicators (as is in our case), the values of weight can decline and, therefore, become insignificant. In such a case, the outer loadings should be examined to ensure the absolute contribution of an indicator to the construct (i.e., the outer loadings reflect single regressions of each indicator on its corresponding construct). As illustrated in Table 24, the outer loadings for indicators with insignificant weights exceeded 0.5 and were statistically significant, illustrating an absolute contribution of an indicator to the corresponding constructs.

*Table 24: Step 1 of PLS-SEM (*p-value < 0.05)*

Construct	Indicators	Outer weights (p-value)	Outer loadings (p-value)	VIFs	R ² _a
Monitoring physical health	BM1	-0.092 (0.528)	0.553 (0.000)*	2.613	0.574
	BM2	0.615 (0.000)*	0.912 (0.000)*	2.172	
	BM3	0.167 (0.201)	0.679 (0.000)*	2.200	
	BM4	0.451 (0.000)*	0.835 (0.000)*	1.979	
Building awareness of physical health	BA1	-0.189 (0.212)	0.409 (0.000)*	1.450	0.532
	BA2	0.250 (0.027)*	0.775 (0.000)*	1.978	
	BA3	0.200 (0.145)	0.775 (0.000)*	2.348	
	BA4	0.408 (0.000)*	0.778 (0.000)*	2.433	
	BA5	0.497 (0.000)*	0.827 (0.000)*	2.910	
Learning about physical health	BL1	0.259 (0.012)*	0.848 (0.000)*	2.361	0.673
	BL2	0.248 (0.005)*	0.801 (0.000)*	2.766	
	BL3	0.216 (0.025)*	0.780 (0.000)*	2.121	
	BL4	0.179 (0.109)	0.821 (0.000)*	3.342	
	BL5	0.314 (0.003)*	0.850 (0.000)*	3.385	
Managing physical health	BMA1	0.468 (0.000)*	0.845 (0.000)*	2.480	0.629
	BMA2	0.397 (0.005)*	0.828 (0.000)*	2.153	
	BMA3	0.080 (0.436)	0.743 (0.000)*	2.019	
	BMA4	0.288 (0.047)*	0.750 (0.000)*	1.654	
Monitoring psychological health	PM1	0.519 (0.000)*	0.883 (0.000)*	1.603	0.806
	PM2	0.594 (0.000)*	0.912 (0.000)*	3.204	

Construct	Indicators	Outer weights (p-value)	Outer loadings (p-value)	VIFs	R ² _a
Building awareness of psychological health	PA1	0.557 (0.000)*	0.925 (0.000)*	2.540	0.848
	PA2	0.529 (0.000)*	0.917 (0.000)*	3.544	
Learning about psychological health	PL1	0.650 (0.000)*	0.929 (0.000)*	3.234	0.790
	PL2	0.458 (0.000)*	0.847 (0.000)*	1.535	
Managing psychological health	PMA1	0.544 (0.000)*	0.895 (0.000)*	2.698	0.809
	PMA2	0.568 (0.000)*	0.904 (0.000)*	1.616	
Feeling empowered	PE1	0.418 (0.009)*	0.877 (0.000)*	3.517	0.697
	PE2	0.137 (0.268)	0.761 (0.000)*	2.132	
	PE3	0.240 (0.081)	0.848 (0.000)*	3.377	
	PE4	0.384 (0.007)*	0.848 (0.000)*	1.869	
Social Relevance of DHT	S1	0.143 (0.193)	0.771 (0.000)*	2.464	0.635
	S2	0.492 (0.000)*	0.869 (0.000)*	2.501	
	S3	0.209 (0.034)*	0.736 (0.000)*	2.155	
	S4	0.383 (0.000)*	0.805 (0.000)*	1.611	

Furthermore, Table 25 provides outer weights and loadings for the second-order constructs. Similar to the indicators in Table 24, several subdimensions forming the relevance dimensions had insignificant outer weights (e.g., monitoring physical health, building awareness of physical health, among others). The outer loadings of such subdimensions were statistically significant, indicating the absolute contributions of such subdimensions to the corresponding dimensions of relevance.

*Table 25: Step 2 of PLS-SEM (*p-value < 0.05)*

Construct	Indicators	Outer weights (p-values)	Outer loadings (p-values)	VIF	R ² _a
Biological Relevance of DHT	Monitoring physical health	0.217 (0.214)	0.805 (0.000)*	2.825	0.752
	Building awareness of physical health	0.233 (0.171)	0.858 (0.000)*	3.901	
	Learning about physical health	-0.046 (0.835)	0.835 (0.000)*	4.712	

Construct	Indicators	Outer weights (p-values)	Outer loadings (p-values)	VIF	R ² _a
	Managing physical health	0.690 (0.000)*	0.962 (0.000)*	4.113	
Psychological Relevance of DHT	Monitoring psychological health	0.149 (0.350)	0.693 (0.000)*	2.797	0.651
	Building awareness of psychological health	0.049 (0.774)	0.732 (0.000)*	3.627	
	Learning about psychological health	-0.023 (0.884)	0.778 (0.000)*	3.821	
	Managing psychological health	0.102 (0.609)	0.819 (0.000)*	3.803	
	Feeling empowered	0.789 (0.000)*	0.980 (0.000)*	2.406	

Table 26 shows outer weights and loadings associated with the biological, psychological, and social dimensions. The biological relevance and psychological relevance have statistically significant outer weights, indicating relative contributions of such forms of relevance to the biopsychosocial relevance. The social relevance does not have a statistically significant outer weight, yet it does have a statistically significant outer loading, meaning that the social dimension has an absolute contribution to the biopsychosocial relevance of DHT.

*Table 26: Step 3 of PLS-SEM (*p-value < 0.05)*

Construct	Indicators	Outer weights (p-values)	Outer loadings (p-values)	VIF	R ² _a
Biopsychosocial Relevance of DHT	Biological Relevance of DHT	0.416 (0.032)*	0.890 (0.000)*	3.330	0.754

Construct	Indicators	Outer weights (p-values)	Outer loadings (p-values)	VIF	R ² _a
	Psychological Relevance of DHT	0.792 (0.000)*	0.974 (0.000)*	3.053	
	Social Relevance of DHT	-0.196 (0.259)	0.721 (0.000)*	2.865	

Tables 24-26 also contain adequacy coefficients (R²_a) to assess convergent validity. The adequacy coefficients exceeded 0.5, meaning that the majority of variance in the indicators at different levels of abstraction is shared with the formative constructs (Edwards, 2001). In addition to adequacy coefficients, we also conducted redundancy analysis to triangulate our convergent validity assessments (Hair et al., 2016). All values in Table 27 exceeded 0.5, providing support for the convergent validity of the formative constructs.

Table 27: Convergent validity

Construct	R ²
Monitoring physical health	0.504
Building awareness of physical health	0.509
Learning about physical health	0.597
Managing physical health	0.536
Monitoring psychological health	0.550
Building awareness of psychological health	0.568
Learning about psychological health	0.605
Managing psychological health	0.645
Feeling empowered	0.598
Biological Relevance of DHT	0.598
Psychological Relevance of DHT	0.735
Social Relevance of DHT	0.715
Biopsychosocial Relevance of DHT	0.629

Confirmatory Composite Analysis

We also conducted a confirmatory composite analysis to examine the overall fit of the model (Benitez et al., 2020; Henseler, 2017). The confirmatory composite analysis checks

the adequacy of the composite model by comparing the empirical correlation matrix with the correlation matrix implied by the model. Table 28 contains the results of the confirmatory composite analysis. The SRMR determines the average magnitude of the discrepancies between expected and observed correlations. Our analysis yielded the SRMR value of 0.042, which is below the threshold of 0.08 (Henseler, 2014). In addition, dULS and dG were below the 99% percentile of their corresponding reference distribution (Benitez et al., 2020; Benitez-Amado et al., 2017). These results confirm the measurement structure of the higher-order composite construct.

Table 28: Confirmatory composite analysis

Discrepancy	Value	HI ₉₉
SRMR	0.042	0.049
dULS	0.095	0.135
dG	0.057	0.740

Structural Model

Figure 15 shows the structural model from the PLS-SEM analysis.

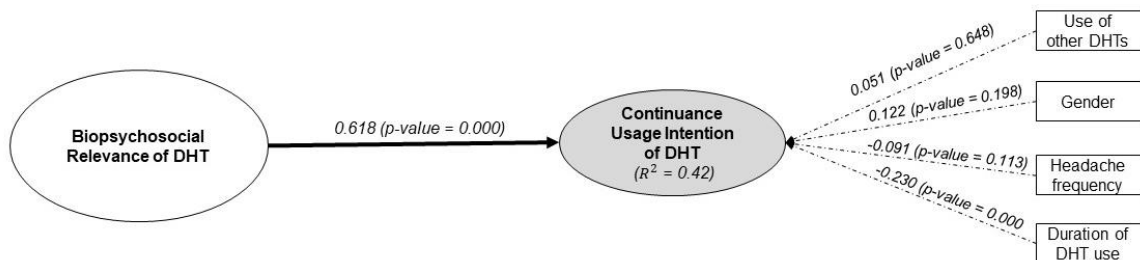


Figure 15: Structural model results

Figure 15 displays the path coefficients and p-values of the structural model. The path coefficient between the biopsychosocial relevance of DHT and continuance usage intention of DHT was 0.618 with a p-value of 0.000. This indicates that we have enough evidence to support H1 and state that the biopsychosocial relevance of DHT positively impacts the

continuous usage intention of DHT. Even though the number of months of DHT use was statistically significant ($p\text{-value} = 0.000$), the path coefficient (-0.230) indicated a negative relationship between the number of months of DHT use and the continuous usage intention of DHT. Other control variables (use of other DHTs, headache frequency, gender) were statistically insignificant.

Furthermore, our model accounted for 42% of the variance with respect to the continuance usage intention of DHT ($R^2 = 0.42$), indicating a moderate explanatory power (Hair et al., 2011). We also estimated the effect size (f^2) to determine the contribution of the biopsychosocial relevance of DHT to the continuous usage intention of DHT. The effect size was 0.581, indicating a medium to high effect size (Perugini et al., 2018).

Measurement Instrument Attributes

Instrument attributes involve a category (generic vs. disease-specific vs. condition-specific), form, response scale type, and scoring (Williams et al., 2016). Our measurement instrument category captures chronic headaches and, therefore, is disease-specific.

As indicated in Chapter 2, PROMs leverage a variety of response scale types (ranging from visual analog scales to Likert-type scales) (Gries et al., 2018). For our measurement instrument, we used a 5-point Likert scale (ranging from “*Strongly Agree*” to “*Strongly Disagree*”) to assess each item. Likert-type scales are commonly used for multi-item measures (Dowling et al., 2016) to explore individual perceptions (Ho, 2016; Leung, 2011). For instance, Likert-type scales were previously used in studies on instrument development of perceptual measures related to digital health (Chen, 2019; Kelly, 2016). In addition, 5-point response scales are less confusing to participants and increase the response rate compared to 7-, 10-, and other response scales (Bouranta et al., 2009).

For the scoring algorithm, the average scale scores can be employed. Average (vs. sum) scale scores are commonly used for multidimensional measures (Vahedi, 2010) and are preferred over sum scale scores because the former can be used to calculate scores with missing items without imputing the missing data (Feißt et al., 2019). A higher score would denote a higher level of biopsychosocial relevance of DHT. Individual dimension scores can be particularly relevant to users whose illness impacts only one or two aspects of their life. For example, if a user's illness impacts only their physical and psychological health, this user would not need to calculate the social relevance score. However, users whose illness impacts all three dimensions of their health condition (physical, psychological, and social) can calculate the total score of biopsychosocial relevance. The average of all scores across three dimensions can be used to calculate the overall biopsychosocial relevance of DHT score.

Regarding the factor score computation methods (i.e., weighted vs. unweighted), we chose not to assign any weights to any particular dimension of the biopsychosocial relevance of DHT because, in the absence of a theory to suggest otherwise, composite dimensions and indicators should have equal weights (Lee & Cadogan, 2013). In our study (and, specifically, Phase 1), participants indicated that all aspects of their health (physical, psychological, and social) were affected by headaches. For instance, headache pain and associated symptoms (e.g., nausea and sensitivity to light) negatively affected participants' physical health. Further, negative emotions and stress associated with headaches impacted participants' psychological health. Finally, headaches also caused disruptions in participants' social health (e.g., participants could not engage in social activities due to their pain). Even though these three areas of health were all affected by headaches,

participants' responses weighted more heavily towards leveraging DHT to self-manage the physical aspect of their health (and this is evident in a comparatively larger number of themes and items describing the biological relevance of DHT). One possible explanation is the limited number of functionalities available in the existing DHTs to self-manage the user's psychological and social health. For instance, some DHTs (e.g., *N1-Headache*) have functionalities primarily targeting the monitoring aspect of users' physical symptoms and a limited number of functionalities to address issues with users' psychological and social health.

Discussion of Phase 3 Results

During Phase 1 and Phase 2, we conceptualized and developed items to measure the biopsychosocial relevance of DHT. This final phase of the study (Phase 3) established the construct validity of the biopsychosocial relevance of DHT items.

We specified the biopsychosocial relevance of DHT as a higher-order formative construct. Through the confirmatory composite analysis, we checked the adequacy of the higher-order composite model by comparing its empirical correlation matrix with the model-implied correlation matrix (Benitez et al., 2020; Henseler, 2017). Our results (particularly, SRMR, dULS, and dG) confirm the measurement structure of the higher-order composite construct. Furthermore, even though some of the outer weights of indicators at different levels of abstraction were insignificant, the outer loadings for all indicators were significant, indicating an absolute contribution of each indicator to our formative constructs (Hair et al., 2016). We also established convergent validity of the biopsychosocial relevance of DHT using two different methods: redundancy analysis (Edwards, 2001) and

adequacy coefficients (Hair et al., 2016). Both methods yielded results that provide support for the convergent validity of our construct.

The structural model provided support for the nomological validity of the biopsychosocial relevance of DHT and demonstrated that the biopsychosocial relevance of DHT positively impacts the continuous usage intention of DHT. These results align with what is stated in the prior literature: the relevance of technology can enhance continuous user engagement (or continuous usage (Perski et al., 2017; Walton et al., 2017)) (Birnbaum et al., 2015; Yardley et al., 2015).

Our control variables, however, did not yield the results we initially expected. Particularly, we expected that gender, the number of months of DHT use, frequency of headaches, and use of other DHTs would have an impact on the continuous usage intention of DHT. Some studies indicate that gender plays a significant role in user interactions with technologies (Goswami & Dutta, 2015; van Elburg et al., 2022). Our results indicated that gender was not significant in the user's intention to continue using a DHT. Furthermore, the user's frequency of headaches was also not important in determining the continuous usage intention of DHT. We initially expected that if a user experiences frequent headaches, they may be more intended to use DHTs in the future. Also, the use of other DHTs had no impact on the continuous usage intention of DHT (contrary to what we expected).

The number of months of DHT use, however, was related to the continuous usage intention of DHT. Yet, our results yielded a negative relationship between the number of DHT use and future intentions to use technology. This finding was surprising because we expected users who have been interacting with a DHT for a long time to have the intention to keep using the DHT in the future as a result of habit formation (Peng et al., 2021; Wang et al.,

2013). Our findings could be attributed to the diminishing marginal utility of DHTs. For instance, a user might learn new information about their headaches using DHTs. Over time, the amount of new information learned from DHTs would decrease, and a user might find little use in their interaction with DHTs. Similarly, a user could become more confident in recognizing their headache triggers as a result of using a DHT over a prolonged period, so their need to interact with a DHT to understand triggers could decrease over time.

We also need to recognize a series of limitations associated with this study. First, our participants have chosen to use DHTs to self-manage their headaches, meaning their motivation and intention might be higher than average. Thus, our results might be skewed toward highly motivated individuals willing to use DHTs. Second, we did not focus on a single instantiation of DHT for self-management of chronic headaches. Instead, our study involved participants using various DHTs designed for chronic headaches and other purposes. Yet, all DHTs were used to manage headaches specifically. Third, the measurement instrument validated during Phase 3 cannot be used to assess DHTs for conditions other than chronic headaches without adaptation. Future research should establish the external validity of our instrument.

CHAPTER 6: DISCUSSION AND CONCLUSION

Overview

Positive user experience is essential for both end-users and software development companies (Hogan et al., 2016; Ross, 2014). Personal relevance of technology is associated with positive user experience and user engagement, which is a critical aspect of user experience, with digital health technologies (DHTs) (Johnson & Yanson, 2018; Santosa et al., 2004; Shiau & Luo, 2013). It is unclear what personal relevance of technology, specifically DHTs, means or how to measure this construct. By leveraging the biopsychosocial model of health, our study fills this gap by clarifying and operationalizing the construct of the biopsychosocial relevance of DHT. This study contributes to information systems, health informatics, and healthcare research and practice.

Implications for Research

Developing Higher-Order Formative Constructs in IS

Prior studies indicate that there exist various issues with the IS instrument development and validation (Boudreau et al., 2001; Schmitz et al., 2020; Straub, 1989). Specifically, MacKenzie et al. (2011) stated that most instrument development procedures are based on the assumption that causality flows from the latent variable to the measures, thereby implying a reflective measurement model (MacKenzie et al., 2011). There is a very limited account of studies that provide insights into developing constructs based on a formative measurement model. In addition, there has been little convergence in the IS literature about ways to operationalize multidimensional and higher-order constructs (Wright et al., 2012). Our study contributes to IS research on instrument development and validation and overcomes the above-mentioned issues by exemplifying how to develop and validate

higher-order formative constructs capturing user interaction with technology. Table 30 summarizes high-level steps used to develop the biopsychosocial relevance of DHT. Future studies can refer to Table 29 during the development and validation of higher order IS instruments following a formative measurement model. It is important to note that Steps 1-3 and 5 can apply to all constructs (not necessarily to higher-order formative constructs) while Step 4 is most pertinent to higher-order formative ones.

Table 29: Steps to develop and validate higher-order formative constructs in IS

Step	Description
1. Conduct a literature review on the construct of interest	Conduct a literature review on the construct of interest and its associated constructs to establish the domain and boundaries of the construct of interest
2. Clarify the construct of interest with individuals representing the target population and develop a preliminary item pool	Leverage qualitative methods, e.g., semi-structured interviews, to clarify the construct of interest: • Develop an interview protocol based on the literature review conducted in Step 1 • Invite several researchers with relevant expertise to review the protocol and provide feedback on the appropriateness and clarity of the questions, as well as the overall flow of the protocol; and revise the protocol, if needed • Conduct a pilot study with at least 2 individuals representing the target population and revise the protocol, if needed • Conduct interviews with individuals representing the target population and calculate saturation ratios to establish saturation ratios and determine the sample size • Analyze qualitative data (e.g., thematic analysis) • Establish reliability (particularly, reproducibility and stability) and validity using various techniques (e.g., member checks, peer debriefing, researcher triangulation) • Develop definitions and a preliminary item pool using sub-codes from data analysis

Step	Description
	• Invite an expert/researcher with relevant expertise to conduct an overall review of the definitions and items
3. Establish content validity	Conduct an expert panel to assess and establish content validity of the items developed as a result of Step 2: • Develop an expert panel protocol • Invite an expert/researcher with relevant expertise to review the protocol and clarity of the instructions accompanying the protocol • Recruit several experts with experiences/backgrounds relevant to the study to complete the assessment • Revise/drop items based on the feedback ◦ If an item scores low and experts indicate that it should be dropped, review the existing literature to determine whether or not to retain it • Validate the revisions by conducting a second round of assessments with experts or individuals representing the target population (i.e., conduct a pretest)
4. Establish construct validity	Conduct surveys to assess and establish construct validity of the items revised as a result of Step 3: • Specify a measurement model (e.g., the order of the construct) • Specify a structural model by including a theoretically related construct • Develop a measurement instrument capturing constructs represented in the structural model as well as global reflective items associated with each formative construct • Use the power analysis to determine the sample size • Recruit individuals representing the target population • Conduct a PLS-SEM to analyze data ◦ Establish convergent validity by conducting redundancy analysis and calculating adequacy coefficients

Step	Description
	○ Establish nomological validity by exploring the relationship between variables in the structural model ○ Assess multicollinearity ○ Assess relative (i.e., outer weights) and, if applicable, absolute (i.e., outer loadings) contributions of each indicator • Revise the measurement instrument, if needed, and conduct additional rounds of surveys, if necessary (if any revisions took place)
5. Describe the measurement instrument	Describe the properties of the developed instrument, particularly: • Instrument attributes (category, form, response scale type, scoring) • Mode of administration • Level of application

Conceptualizing and Operationalizing the Biopsychosocial Relevance of DHT

Our study contributes to IS research by clarifying the nature of the relevance of technology. In our DHT context, we discovered that the biopsychosocial relevance of DHT captures the user's perception of the degree to which a DHT enables a user to self-manage various aspects of his or her physical health, psychological health, and social health. As we discussed in Chapter 3, our conceptualization of relevance is distinct from personal association, identity connection, usefulness, and affordances. Yet, there appear to be a resemblance between *actualized* affordances (Strong et al., 2014) and relevance. In cases where the user context is critical to user interaction with technology (e.g., healthcare), relevance could be used as a proxy for actualized affordances.

In addition to conceptualizing the biopsychosocial relevance of DHT, we also operationalize the construct by mirroring PROM development and validation (Porter et al.,

2021). We discussed various properties (Table 3 and Table 4) to consider during PROM development and validation. Similar to Table 3 and Table 4, we summarize such properties, including instrument attributes, methodological processes, mode of administration, and application level, associated with the biopsychosocial relevance of DHT instrument (see Table 30).

Table 30: Operationalizing the biopsychosocial relevance of DHT

Instrument Attributes	
Category	Disease-specific
Form	Multi-item
Response scale type	5-point Likert type ranging from “ <i>Strongly Agree</i> ” to “ <i>Strongly Disagree</i> ”
Scoring	Average; unweighted
Methodological Processes	
Patient involvement	Users with chronic headaches were involved in item generation and evaluation
Stakeholder input	Individuals with expertise in IS scale development, HCI scale development, PROM development, psychometrics, health informatics, chronic pain and headache, and psychology were involved in content validity assessments
Psychometric validation	Psychometric techniques (PLS-SEM) were used to validate the instrument
Mode of administration	Electronic
Level of application	Individual and group

Instrument Attributes

Instrument attributes involve a category (generic vs. disease-specific vs. condition-specific), form, response scale type, and scoring (Williams et al., 2016). Our measurement instrument category captures chronic headaches and, therefore, is disease-specific. Future studies should, however, establish the external validity of our instrument by validating it in other health contexts. Particularly, future studies could use our high-level frameworks (Figures 1-12) to guide the development of instruments for other types of chronic conditions. These frameworks can be used to construct questions for semi-structured

interviews (e.g., what DHT enables users to monitor with respect to their specific chronic condition) or during literature review to understand specific aspects of DHT enablement with respect to user's self-management efforts. This step would enable researchers to develop items that can later be validated through expert panels and surveys.

As indicated in Chapter 2, PROMs leverage a variety of response scale types (ranging from visual analog scales to Likert-type scales) (Gries et al., 2018). For our measurement instrument, we used a 5-point Likert scale (ranging from “*Strongly Agree*” to “*Strongly Disagree*”) to assess each item. Likert-type scales are commonly used for multi-item measures (Dowling et al., 2016) to explore individual perceptions (Ho, 2016; Leung, 2011). For instance, Likert-type scales were previously used in studies on instrument development of perceptual measures related to digital health (Chen, 2019; Kelly, 2016). In addition, 5-point response scales are less confusing to participants and increase the response rate compared to 7-, 10-, and other response scales (Bouranta et al., 2009).

For the scoring algorithm, the average scale scores can be employed. Average (vs. sum) scale scores are commonly used for multidimensional measures (Vahedi, 2010) and are preferred over sum scale scores because the former can be used to calculate scores with missing items without imputing the missing data (Feißt et al., 2019). A higher score would denote a higher level of biopsychosocial relevance of DHT. Individual dimension scores can be particularly relevant to users whose illness impacts only one or two aspects of their life. For example, if a user's illness impacts only their physical and psychological health, this user would not need to calculate the social relevance score. However, users whose illness impacts all three dimensions of their health condition (physical, psychological, and social) can calculate the total score of biopsychosocial relevance. The average of all scores

across three dimensions can be used to calculate the overall biopsychosocial relevance of DHT score.

Regarding the factor score computation methods (i.e., weighted vs. unweighted), we chose not to assign any weights to any particular dimension of the biopsychosocial relevance of DHT because, in the absence of a theory to suggest otherwise, composite dimensions and indicators should have equal weights (Lee & Cadogan, 2013). In our study (and, specifically, Phase 1), participants indicated that all aspects of their health (physical, psychological, and social) were affected by headaches. For instance, headache pain and associated symptoms (e.g., nausea and sensitivity to light) negatively affected participants' physical health. Further, negative emotions and stress associated with headaches impacted participants' psychological health. Finally, headaches also caused disruptions in participants' social health (e.g., participants could not engage in social activities due to their pain). Even though these three areas of health were all affected by headaches, participants' responses weighted more heavily towards leveraging DHT to self-manage the physical aspect of their health (and this is evident in a comparatively larger number of themes and items describing the biological relevance of DHT). One possible explanation is the limited number of functionalities available in the existing DHTs to self-manage the user's psychological and social health. For instance, some DHTs (e.g., *N1-Headache*) have functionalities primarily targeting the monitoring aspect of users' physical symptoms and a limited number of functionalities to address issues with users' psychological and social health.

Methodological Processes

In alignment with research on PROM development and validation (Wiering et al., 2017), we involved users with chronic headaches in the item generation process. We leveraged qualitative methods (specifically semi-structured interviews) to clarify the user's perspective on the biopsychosocial relevance of DHTs. Furthermore, relevant stakeholders (with expertise in IS scale development, HCI scale development, PROM development, psychometrics, health informatics, chronic pain and headache, and psychology) were involved in content validity assessments. Finally, we used PLS-SEM to establish the construct validity of our instrument.

Mode of Administration

Given the focus of this study on DHTs for self-management of chronic conditions, we focused on the electronic mode of administration for the biopsychosocial relevance instrument. The electronic mode of administration is more efficient than paper-and-pencil (Cella et al., 2015a). Moreover, if the biopsychosocial relevance instrument is to be integrated as digital health feedback in the future, the electronic mode of administration will be most convenient for users.

Level of Application

In this study, we developed the instrument to capture individual perceptions of the biopsychosocial relevance of DHTs for self-management of chronic conditions. Users can use individual scores to assess the relevance of specific DHTs for self-management of chronic care. For instance, if the measurement instrument becomes publicly available (i.e., gets posted online), a user might try out different DHTs and then assess each of them using our relevance instrument. DHTs receiving highest scores can then be considered by users

for the future use. In addition, biopsychosocial relevance responses can also be aggregated (e.g., through digital health feedback) to compare various digital health technologies targeting users with a specific health condition or compare users with various health conditions using a specific digital health technology (discussed in more detail in the following sections).

Measuring Actualized Affordances

Given conceptual similarities between actualized affordances and relevance, our study has implications for the IS stream of work dedicated to affordances.

Particularly, research studies indicate that there is a lack of established and validated measurement instruments of affordances that can be used in quantitative studies (as most studies on affordances are qualitative) (Fromm et al., 2020; Volkoff & Strong, 2017). Furthermore, studies indicate that measuring technology affordances represents a challenge to researchers (Carte et al., 2015). Measuring affordances requires researchers to develop and customize measurement instruments based on a specific context.

Our study overcomes the above-mentioned gaps in quantifying affordances by developing a measurement instrument for the biopsychosocial relevance of DHT. Researchers and practitioners (e.g., IT managers) can use our operationalization of relevance as a proxy to measure different types of affordances that users can actualize through their interaction with technology. Given the context of the study, our current measure captures a specific case of DHTs for chronic headaches. However, we invite researchers to develop similar instruments pertinent to technologies in other contexts.

Measuring Outcomes of DHT Use

PROMs are standardized, validated tools that assess patient-reported outcomes (PROs), which are “any report of the status of a patient’s health condition that comes directly from the patient” (FDA, 2009). PROMs can assess a range of individual biopsychosocial outcomes, including health status, well-being and psychological health, symptoms and functioning, health-related quality of life, treatment satisfaction, and others (Philpot et al., 2018). These instruments are commonly used in health research as well as practice to understand patient’s health condition and to prescribe or select treatments that are most relevant to patients based on their perspective on their health.

The product of our study aligns with PROMs. Particularly, PROMs are used to measure patient’s perception of health outcomes. Our measurement instrument assesses outcomes of technology use, i.e., what technology enables users to achieve after some interaction with it. Thus, our study contributes to health informatics by developing a measurement instrument that can be used to assess the outcomes of user interaction with technology.

Implications for Practice

DHT Design and Assessment

Health technology developers can leverage the construct of the biopsychosocial relevance of DHT to guide the design and evaluation of DHTs for self-management of chronic conditions. For example, during pilot studies, health developers can use the biopsychosocial relevance measure to assess digital health prototypes with end-users who suffer from chronic conditions. Measuring the biopsychosocial relevance during pilot studies can enhance understanding of what drives user engagement with specific DHTs and what might be missing.

Furthermore, given the specificity of the study context (chronic headaches), our study makes particular contributions to the design and assessment of DHTs for chronic headache self-management. Even though there exist various DHTs for chronic headaches, the literature reports various issues with such technologies (Durneva, 2021; Graaf et al., 2020; Minen et al., 2016). For instance, little consideration of end-user needs results in poor engagement with DHTs. Moreover, the existing DHTs for self-management of headaches appear too narrow in their scope as they focus on specific aspects of headaches while ignoring the other, no less significant, aspects. For example, most DHTs tend to focus on the physical aspect of pain (by tracking pain levels only) or on the psychological aspect only (by providing users with Cognitive Behavioral Therapy) (van de Graaf et al., 2020). Thus, there is a need for advancing knowledge of how to holistically design and assess DHTs for self-management of headaches by considering end users' needs and preferences and accounting for the multidimensional experiences of users with chronic headaches. By advancing our understanding of relevance in the context of chronic headache pain, this study contributes to the design of DHT that reflects the needs of users suffering from chronic headaches. Particularly, our measurement instrument can be used to guide the design of DHTs for chronic headaches and address gaps in the existing DHTs.

Decision Aid for Patients and Providers

In addition, our study contributes to healthcare, specifically chronic care, by creating a measurement instrument that can be used to assess DHTs for self-management of chronic conditions. There exist a limited number of instruments to assess DHTs. In addition, the existing tools do not take into account the biopsychosocial context of users, which is critical for users suffering from chronic conditions (e.g., the existing instruments focus on ease of

use, navigation quality, etc.) (DiFilippo et al., 2017; Maheu et al., 2016; Stoyanov et al., 2016; Stoyanov et al., 2015). Our study fills this gap and has implications for patients suffering from chronic conditions (specifically headaches) as well as health providers who treat patients suffering from chronic conditions (specifically headaches).

Chronic care patients who are generally interested in using DHTs to self-manage their chronic conditions can use the biopsychosocial relevance measure to select the most appropriate DHTs among many alternatives. By selecting personally meaningful and relevant DHTs, users can connect with these tools, engage with them, and ultimately derive their value (e.g., health behavior change).

Moreover, the biopsychosocial relevance measure can be integrated into digital health feedback that can later be shared with the providers. Healthcare providers are generally interested in disseminating DHTs into their routine practice (Albrecht et al., 2017; Berkowitz et al., 2017; Kessel et al., 2016). However, providers rarely recommend such technologies to patients in practice (Gordon et al., 2020; Kessel et al., 2016; Leigh & Ashall-Payne, 2019). The biopsychosocial relevance measure can be integrated into various DHTs for self-management of chronic conditions (i.e., through app feedback). The responses can then be collected and compared either across various DHTs or various chronic conditions. For example, users with a specific health condition (e.g., chronic headache) might try various DHTs for pain self-management and assess their relevance. The relevance responses across various DHTs for pain self-management can then be collected and compared. For example, it might be found that a specific DHT for pain self-management is generally perceived as more relevant by headache patients than other technologies. These data can then be shared with health providers and incorporated into

decision aids to inform patients about DHTs for self-management of their chronic conditions.

Future Work

External Validity of the Biopsychosocial Relevance of DHT

Future research work should establish the external validity of our measurement instrument. External validity refers to the generalizability of the study findings (Morgado et al., 2017). Even though high-level dimensions (e.g., monitoring physical health, building awareness of physical health, learning about physical health, and managing physical health) within each form of relevance (i.e., biological, psychological, and social) can be applied to other chronic conditions (e.g., (Araújo-Soares et al., 2018)), the items are not generalizable at the lowest level of abstraction. Particularly, all items make a specific reference to headaches (e.g., *“This app helps me monitor my physical symptoms when I experience headaches”*). Furthermore, some of the items can be pertinent only to chronic pain. For instance, some items reference “triggers” of headaches. Other chronic conditions (e.g., obesity and overweight) might not have any triggers associated with the onset of such a condition.

Future studies should establish external validity in other chronic pain conditions and other chronic conditions. Chronic headache is a type of chronic pain (Benoliel et al., 2019). Given commonalities among chronic pain types (e.g., fatigue and disruptions in psychological health, among others (Sheffer et al., 2007; Simons et al., 2014; Vasudevan, 2015)), items can be revised to capture other chronic pain conditions. Specifically, researchers could use our high-level frameworks (Figures 1-12) and interviews (wherein questions would be reflective of major themes defining relevance dimensions) to develop

items specific to a given chronic pain condition. Content and construct validity assessments can then be carried out in a manner similar to this study. Similar studies can be conducted for other types of chronic conditions.

Minimally Important Difference in the Biopsychosocial Relevance of DHT

During Phase 3 of the study, we established a relationship between the biopsychosocial relevance of DHT and the continuance usage intention of DHT. Particularly, we found that higher levels of relevance can lead to higher usage intention. Future studies should explore a minimally important difference in user perception of the biopsychosocial relevance of DHT (Guyatt et al., 2002; Sedaghat, 2019). Detecting a minimally important difference aligns with the minimal clinically important difference (MCID) of PROMs and is used to determine whether a health intervention makes a difference in patients' health outcomes (Guyatt et al., 2002). Detecting a threshold value of change in user perception of the biopsychosocial relevance of DHT can be particularly useful during the DHT design and development stages. It can indicate whether a change in the DHT design improves user perception of the biopsychosocial relevance of DHT thereby impacting continuous user engagement, health behavior change, and, ultimately, health outcomes (Alkhaldi et al., 2017; Hutton et al., 2011; McClure et al., 2013).

Further, it can allow health technology developers to identify particular features that make technologies relevant in a cost-effective manner. For instance, during pilot studies, health technology developers can conduct controlled experiments to compare various prototypes of DHTs and identify whether there is a minimally important difference in user perception of the biopsychosocial relevance of such DHTs. In addition, detecting a threshold value of

change can be important for continuous usage studies by exploring the relationship between a change in the score and dropped usage.

Antecedents and Consequences of the Biopsychosocial Relevance of DHT

Future studies should also explore the nomological network surrounding the biopsychosocial relevance of DHT and, specifically, various antecedents (e.g., user characteristics) and consequences (e.g., health behavior change) associated with such a construct.

User characteristics can impact user perceptions of technology (e.g., (Hoffmann et al., 2015; Nov & Ye, 2008; Straßmann & Krämer, 2018; Zhou & Lu, 2011)). For instance, personality traits (e.g., extraversion, agreeableness, openness to experience, conscientiousness, and neuroticism) have an impact on technological perceptions (e.g., perceived usefulness, perceived ease of use, and perceived compatibility) of mobile commerce (Zhou & Lu, 2011). Particularly, extraversion has a strong impact on user trust, and neuroticism has a negative effect on trust and the perceived usefulness of mobile commerce.

As the biopsychosocial relevance of DHT is a newly introduced concept, future studies should explore various user characteristics (e.g., personality traits, states, demographics, skills, and abilities) in relation to the biopsychosocial relevance of DHT. For instance, future studies can explore the impact of digital health literacy on user perception of the biopsychosocial relevance of DHT. Digital health literacy captures the degree of skills and abilities necessary to use DHTs (Yoon et al., 2022). Individuals with high levels of digital health literacy can critically analyze the health information from DHTs and leverage such information to make decisions related to their health. We can expect that digital health

literacy will impact the biopsychosocial relevance of DHT. For instance, if a user does not know how to use health information provided by DHTs, it is unlikely that they will be able to build awareness of their health. Similarly, if a user does not understand how to use specific DHT functions (e.g., a self-tracking function), they might not be able to realize the full potential of DHTs (e.g., to help them monitor their health condition over time). It can be of particular interest to also understand how digital health literacy related to various dimensions of the biopsychosocial relevance of DHT. For instance, digital health literacy might have a stronger association with aspects that might require higher levels of user interaction with DHTs (e.g., communicating with DHT other users might require higher levels of involvement with DHTs rather than reading new information about one's health condition). Thus, future research should explore the role of digital health literacy in user perceptions of the biopsychosocial relevance of DHT as well as explore other user characteristics that can be strongly associated with the relevance construct.

In addition to exploring the role of user characteristics in shaping the biopsychosocial relevance of DHT, future studies should also explore the consequences of the biopsychosocial relevance of DHT.

In addition to health behavior change, other consequences associated with the biopsychosocial relevance of DHT should be examined in future studies. For instance, user satisfaction or user enjoyment can be explored. User satisfaction is an important criterion for measuring the success of IT and indicates whether users find a particular technology valuable to them (Zviran et al., 2003). We can expect that users who find DHTs relevant to them will also experience high levels of satisfaction. The strength of the relationship should be explored in future studies.

Conclusion

Personal relevance is an important aspect of user interaction with technology that can lead to positive user experience and, ultimately, intended outcomes of technology use. Understanding personal relevance can be particularly important in the case of DHTs for self-management of chronic condition, as personal relevance can support user engagement, the major aspect of user experience with DHTs that is associated with health behavior change. Given a lack of studies that conceptualize and operationalize digital health relevance, this study addresses this gap and develops a measurement instrument through the lens of the biopsychosocial model of health. Particularly, this study conceptualizes and operationalizes the biopsychosocial relevance of DHT and its associated dimensions (i.e., the biological relevance of DHT, the psychological relevance of DHT, and the social relevance of DHT) using three phases (semi-structured interviews, expert panel, and surveys). The product of this study has implications for both research and practice. First, this study contributes to research by providing guidelines on how to develop higher-order formative constructs in IS, conceptualizing and operationalizing the construct of relevance, providing a proxy for measuring actualized affordances, and providing a way of measuring outcomes of DHT use. Second, this study contributes to practice, specifically, DHT design and assessment and decision aids for patients and providers. Future studies stemming from this work should focus on establishing external validity of the instrument, determining a minimally important difference score of relevance, and exploring different antecedents and consequences of relevance.

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APPENDICES

Appendix A: Interview Protocol Refinement Framework

	Criteria	Feedback for Improvement
Interview Protocol Structure		
☐	Key questions are majority of the questions.	
☐	Questions at the end of the interview are reflective and provide participants an opportunity to share closing comments.	
☐	A brief script throughout the interview protocol provides smooth transitions between topic areas.	
☐	Interviewer closes with expressed gratitude and any intents to stay connected or follow up.	
☐	Interview is organized to promote conversation flow.	
Interview Questions		
☐	The interview questions are relevant to the topic of personal relevance in digital health technologies.	
☐	The interview questions encourage the participants to tell stories about their perception of personal relevance.	
☐	The interview questions are focused but flexible.	
☐	The interview questions are unbiased (e.g., no leading questions).	
☐	The interview questions are free from spelling error(s).	
☐	Only one interview question is asked at a time.	
Length of the Interview Protocol		
☐	All interview questions are needed.	
☐	All interview questions are concise.	
Comprehension		
☐	The interview questions are clear and appropriate for the target audience (chronic headache patients).	
☐	The interview questions are devoid of academic language.	
☐	The interview questions are easy to understand.	

Appendix B: Interview Protocol

Introduction

- Can you hear me ok?
- Thank you for joining today. My name is Polina Durneva. I am a PhD candidate in Information Systems and Business Analytics at Florida International University. I'll be your interviewer today.
- Before we start, I want to check in on a few things with you.
- Are you in a good location for this conversation?
- Is this still a good time for you? The interview will take approximately 40 minutes.
- Great! Your thoughts are very important to advancing health informatics knowledge. I am very thankful for your willingness to share them with me.
- Our discussion will focus on your headaches experiences and your experience with using mobile applications to help you manage headaches.

Verbal Consent

To ensure that you are comfortable with moving forward, I want to first check in on your consent.

- I sent you a consent form yesterday. Did you read this form containing details of this study, risks, benefits, and alternatives?
 - a.<if yes> Do you have any questions about what you read? Do you provide your consent to participate in this research project?
 - b. <if no, PPT to open> Let's go over the information sheet.
- Purpose: The purpose of this study is to explore your experience with digital health technologies for self-management of chronic headaches.
- Number of participants: If you decide to participate in this study, you will be one of 20 people in this research study.
- Duration of the study: Your participation will involve a 60-minute online interview.
- Procedures: if you agree to be in this study, we will ask you the following things:
 - You will participate in a 60-minute online interview.
 - A week after the interview, you will complete a short follow-up survey to confirm your responses.
 - Your answers will be recorded and kept private. Only research team will have access to records.
- Risks: the study has the following possible risks to you. First, there is a moderate risk associated with loss of time. Second, there is a moderate risk of boredom.
- Benefits: There are no direct benefits to you as a participant in this study. However, we will use your input to inform digital health tools providers and software developers about ways to design digital health technologies for headache self-management.
- Alternatives: There are no known alternatives available to you other than not taking part in this study.
- Confidentiality: The records of this study will be kept private and will be protected to the fullest extent provided by law. In any sort of report, we might publish but we will

not include any information that will make it possible to identify you. Research records will be stored securely. Only the researcher team will have access to the records. However, your records may be inspected by authorized University or other agents who will also keep the information confidential.

- Use of your information: We will remove identifiers about you from the identifiable private information. After such removal, the information could be used for future research studies. It can also be distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.
- Compensation and Costs: You will receive a \$25 gift card for your participation. There are no costs to you for participating in this study.
- Right to decline or withdraw: Your participation in this study is voluntary. You are free to participate in the study or withdraw your consent at any time during the study. You will not lose any benefits if you decide not to participate or if you quit the study early. The investigator reserves the right to remove you without your consent at such time that he/she feels it is in the best interest.
- Do you have any questions? Do you provide your consent to participate in this research project?

Ground Rules

Before we start our interview, I would like to go over a few ground rules.

- Your participation is completely voluntary. You can choose to end the call at any time if you decide that you no longer want to participate. There is no effect on your relationship with Florida International University or any organizations (if you mention any) if you stop. Of course, I hope that you will stay with me until the end of the discussion.
- Please feel free to let me know if you need to take a quick break for any reason.
- Everything said here is private, meaning that it will not be shared with anyone. All research transcripts will be de-identified before I code and analyze them. Only summarized statements or de-identified quotes may appear in a research article. No names will be mentioned anywhere.
- There are no right or wrong answers to our questions. I simply want to know your opinion. Please feel free to speak freely.
- You can choose not to answer any questions for any reason.
- I would like to record our audio conversation to accurately capture the information you provide. If you would like to go off recording at any time, just let me know. I can put that question on hold and wait until after the recording is turned off to discuss the question.
- The notes from the recordings will be kept confidential and secure. The audio recordings will be destroyed after the notes are verified.
- This or next week, I will send you a short follow-up survey to confirm your responses. After you confirm your responses, you will receive a \$25 gift card. I will explain more in detail at the end of the interview.

- Do you have any questions about the interview process?
- Do you give me your permission to record our conversation?

<after they say yes>

I am now beginning the recorded interview with your consent and permission to record.

Section 1: Pain Experiences

Let's start this interview by discussing your headache experiences in general.

- Can you please tell me about your headaches? (*physical health*)
 - How much pain do headaches cause you? (*pain*)
- How do you manage this pain?
 - Do you take medications to reduce your headache pain?
 - Do headaches affect your ability to do any daily activities? Can you tell me more about that? (*physical functioning*)

Thank you for sharing this. And let's talk about headaches and your social interactions and relationships.

- Do your headaches affect your social interactions and relationships with others? Can you tell me more about that? (*social health*)
- Do you feel like you need social support when you experience headaches?
 - In other words, do you need other people around you to support you and encourage you when you experience headaches?
- Do you receive enough social support when you have headaches? Can you tell me more about that?

Now, let's talk about the emotional aspect of headaches about the experiences you just described.

- How do your headaches make you feel? (*psychological health*)
 - Do headaches make you feel anxious?
 - Do headaches make you feel sad?
 - <if emotional state is affected by headaches> How do these emotions interfere with your daily activities? Can you please describe it in more detail?
 - How do you manage these emotions?

Section 2: Personal Relevance of Digital Health

Thank you for sharing these experiences. Now, let's transition to talking about mobile applications for self-management of headaches. I want to start with a general question.

- In general, how would you describe an application for self-management of headaches that would be personally relevant to you?

- What comes to your mind when you think about personally relevant mobile applications for self-management of headache? (*Personal relevance*)

Now, let's transition to talking about specific apps you are using to help you deal with your headache. When you signed up for the study, you indicated that you have experience with <Migraine Buddy app>. Let's talk about your use of this app in general.

- How is your experience with this app?
 - What features of the app are you using?
 - Are there any features that you are not using?
 - How often do you use this app?
 - How long have you been using this app?
 - What makes you keep using the app? (*engagement*)
- How does your use of this app make you feel? (*psychological relevance*)
 - Does your use of the app make you feel like you are in control of your health? Can you tell me more about that?
 - Does your use of the app make you feel more confident in your ability to manage your headaches? Can you tell me more about that?
 - Does your use of the app make you feel more motivated to take actions to manage your headaches? Can you tell me more about that?
 - Are there any specific features (or messages) in the app that help to reduce your headache?
 - Any that make you feel better about your headache experience? If yes, can you tell me more about that?
- Do you feel like your use of this app help you feel less isolated? Can you tell me more about that? (*social relevance*)
 - Do you view this app as your friend?
 - <if yes> Can you tell me more about that?
 - Do you feel like your use of the app (or something in the app) provides you with emotional support?
 - Do you feel like your use of the app (or something in the app) provides you with informational support?

Let's talk about the personal connection between you and the <Migraine Buddy> app in detail.

- To what extent do you find this app personally relevant to you? Could you tell me more about that? (*Perceived Personal Relevance*)
 - How useful is this app for managing your headaches? Can you tell me more about that? (*Usefulness*)

- Let's talk about the personalization aspect of the app. To what extent do you feel like this app reflects your personality, preferences, or abilities? Can you tell me more about that? (*Identity Connection*)
- Do you feel like you are learning something new about yourself and your health when you use this app? Can you tell me more about that?
- How did you manage your headaches before you started using the app? (*Personal Association*)
 - Is there anything in the app that reminds you of the ways you managed headaches in the past? What is that? (*Personal association*)
 - To what extent does this app reflect the ways you managed your headaches in the past (before you started using the app) (how you tracked your headaches)? Can you tell me more about that? (*Personal Association*)
- In your opinion, is there anything that this app does not have (but you would like it to have)? If yes, what is it? (*Perceived Personal Relevance*)
 - Would you like this app to be more useful for managing your headaches? Can you tell me more about that? (*Usefulness*)
 - Are there any aspects of your headache experiences (based on what you described at the beginning of the interview) that the app does not really capture?
 - Would you like this app to be more personalized to you? Can you tell me more about that? (*Identity Connection*)
 - Would you like this app to offer features that would allow you to manage your headaches in the same way as you did in the past (before you started using this app)? Can you tell me more about that? (*Personal Association*)
 - Anything else?

Section 3: Biological Relevance

You indicated that headaches affect your physical health in terms of causing you a lot of pain... fatigue... etc... Let's talk about it a bit more.

- Do you find the <Migraine Buddy> app useful for understanding your headache symptoms? (*biological relevance*)
 - What about managing your headache symptoms? (*biological relevance*)
- What about other physical symptoms (e.g., fatigue, tiredness, nausea, etc.)?
- Do you feel like you changed any of your behaviors or daily activities based on the information you get from the app? Can you tell me more about that? (*biological relevance*)
- Have you noticed any change in your physical symptoms after you started using the app? Can you tell me more about that?
- What do you think would you make this app even more relevant for managing your physical symptoms when you have headaches? (*biological relevance*)
 - Any specific features, content, functionalities?

- In your opinion, how important is it that an app for self-management of headaches helps users manage physical symptoms of their headaches?

Section 4: Psychological Relevance

Thank you! Your insights are helpful. Now let's about the emotional aspect of your headaches and the app.

- Have you noticed any changes in your emotions after you started using the app? Can you tell me more about that?
- How useful is the <Migraine Buddy> app for understanding negative or challenging emotions (e.g,...) caused by your headaches? (*Psychological Relevance*)
 - What about managing these emotions?
- <if they experience stress, anxiety, depression> What about understanding stress/anxiety/depression caused by your headaches?
 - What about managing them?
- To what extent does this app help you reduce challenging or negative emotions/negative states when you have headaches? Can you tell me more about that?
 - Does your use of the app help you feel better?
 - Or does the app provide you with resources to alleviate negative emotions?
 - <if it doesn't help with emotions> how do you manage your emotions when you have headaches?
 - Are you using any other apps?
- And what do you think would make this app even more relevant for managing your challenging or negative emotions when you have headaches?
 - Would you add any specific content, design features, functionalities?
- In your opinion, how important is it that an app for self-management of headaches provides users with ways to self-manage their challenging or negative emotions?

Great. I have a few more questions for you. Let's talk about the social aspect of the app.

Section 4: Social Relevance

- <if there is a social networking feature> Do you use the social networking feature (e.g., the chat) in the app?
 - <if yes> Can you tell me more about that (how relevant is this feature in providing you with social support)? (*Social Relevance*)
 - How much emotional support do you get from this feature?
 - How much informational support (information about headaches) do you get from this feature?

- <if no> Can you tell me more about that? Why are you not using this feature?
 - Are you interested in this feature?
- If you were to use it in the future, how would you use it?
 - Emotional support?
 - Informational support?
- Besides some social networking that the app can provide you, does this app help you manage your social relationships and interactions when you have headaches in any way? Can you tell me more about that?
 - <if it doesn't help with social health> how do you manage your social health?
 - Are you using any other apps?
- Have you noticed any changes in your social health after you started using the app? Can you tell me more about that?
- Speaking of the social aspect (social supports and managing your social relationships), what would you change about this app to make it more personally relevant for you?
 - Would you add any specific content, design features, functionalities?
- In your opinion, how important is it that an app for self-management of headaches provides users with social support?
 - What about helping users manage their social life?

Final Catchall

Before we conclude our interview, is there anything else that you would like to share with me?

Closing

Thank you for your participation in the interview. Your insights were great! The interview was very informative and enjoyable.

This or next week you will receive a short follow-up survey to confirm some of your responses. The survey will contain summarized statements based on our discussion today. Once you complete the survey, you will receive your \$25 gift card.

The gift card will be sent to the email address you provided when you signed up for the study, so you will be able to redeem it online. In case you have any issues redeeming it, you can email me at pdurn001@fiu.edu.

Appendix C: Item Writing Rubric

Criteria	The item meets the criterion
The item is not too lengthy.	☐
The item is at the 6 th grade level of the reading difficulty.	☐
The item does not contain double negatives.	☐
The item does not contain double-barreled questions.	☐
The item does not contain ambiguous pronoun references.	☐
The item does not contain misplaced modifiers.	☐
The item uses appropriate grammar.	☐
The item does not contain adjective forms wherein noun forms should be used.	☐
The item does not contain any slang expressions.	☐
The item does not contain any contractions.	☐
The item is not negatively worded.	☐
The item does not contain any leading question.	☐
The item does not contain false premises.	☐
The item is worded consistently with respect to other items.	☐
The item is consistent with the expressions used by participants during interviews.	☐

Appendix D: Evidence-Trace Tables

Table D1: Biological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
<i>Theme</i>	<i>Sub-theme</i>	<i>Sample Quotes</i>
Monitoring physical health	Monitor physical symptoms	<i>“So, you know, it's [DHT] very helpful, it has helped me to monitor my headache and also, the symptom, those that I usually feel before the headache comes in.”</i> <i>“The app so far has been very good. I can monitor my headaches like from time to time, different times in the day and also it has, it has, also has the insight part where I can see like, Okay, what is happening this week, how many days, like, how much headaches I have been having.”</i>
	Monitor habits	<i>“So I think like, like random things like how much water intake you're having, how, how much you're eating, or whether you're eating good or not how your sleep patterns happening. And that just give me an insight of like over a month maybe or something that here are the top reasons we managed to find that here are the top reasons of the headache that you're getting.”</i> <i>“Migraine Buddy is really like getting to the science behind it, tracking your habits, being able to self-diagnose or like, go on this journey from you know, starting with, like an issue and then trying to resolve the issue.”</i>
	Monitor treatments	<i>“I know that you can input your medications that you're using. So some people could use that as well to see to like, overall see how that is kind of affecting them or not.”</i> <i>“I do record what medications that I've taken. And the level of pain that I don't frequently... because you can, of course, go back and see like what helped, you know, did the medication help what other things helped, I don't frequently actually</i>

Table D1: Biological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
<i>Theme</i>	<i>Sub-theme</i>	<i>Sample Quotes</i>
		<i>go back and fill that in after my headache has passed."</i>
	Monitor triggers	<i>"Just it's like I think the app is designed to like, accommodate such things, like I said, it accommodates, I could add my triggers, I could add the drugs I was using or it just suggests, suggests it, it just like updates my information. But this particular app, it's personal. You can add your stuff."</i> <i>"I'm looking at like the tracker, mainly because it's just like, like, when I am good enough about it to to track it. It's really helpful, right? Like, it'll make me think about the triggers outside of like what I typically think of as triggers, right? Lack of sleep, like super stressed, and be like, Oh, I didn't think that this could possibly be a trigger, but something I can examine. So I do mainly utilize that."</i>
Building awareness of physical health	Validate pain experiences	<i>"So yeah, like I, it's also some sort of proof that there is pain. Because sometimes people think like you are making it up just to get off things or no, but this way, like you have records, records and records of, of your pain. It's not something you're making up. Because yeah, I do not choose to one day just be in bed and throw up my, my whole intestines out. It's, it's there. It's something that like happens. And yeah, I can, then I can see, I can take a hold of my condition by tracking it."</i> <i>"Yeah, I would say...Um, I guess it [DHT] makes me feel like I mean, on the one hand, like validated that all the headaches are happening. And I'm not like exaggerating in my head. It can sometimes feel a little, like, upsetting just to go and be like, here are so many headaches with like, so many symptoms to record like, ugh it's happening again, you</i>

Table D1: Biological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
<i>Theme</i>	<i>Sub-theme</i>	<i>Sample Quotes</i>
		<i>know, like frustrated. So I guess, both sides of the coin."</i>
	Understand physical symptoms	<i>"Um, yeah, it actually kind of made me aware that of one of my, I guess, I get really happy and really elated, which I didn't realize can be like a symptom of a migraine coming on. Um, but that was kind of one of those pre-populated things. I was like, Oh, I feel really good a lot of the time. And bam, it's right there. So it [DHT] definitely made me aware of at least that physical symptom."</i> <i>"Yes, I learn something new every time because I used to always wonder when I get a headache, sometimes my ears would start hurting, and I am like, Why are my ears hurting? My head hurts, why is it... But I got, all these things run together. So it's going to trigger something else. If you have one of those intensified migraines, it is going to bother something else with you. It might be your ears, it might be your nose. It might just be in the center of your head, I know if it's in the center of my head, it is dealing with my sinus. So okay, so I know what's wrong on that side and it's triggering the migraines."</i>
	Understand habits	<i>"I go back and I kind of like look into what healthy habits I have been doing at that time and just kind of like gives me a better idea of like what, what things should I continue on doing."</i> <i>"I did find that I was more consistent with my sleep time, because it [DHT] asks me so I wanted to see all maybe that's a key. So yes, I did change my sleep patterns. Like I went to bed a little earlier, and didn't touch the phone until I woke up."</i>
	Understand treatments	<i>"Yes, I think yes because there is a part, I think I'm not sure, it can, maybe I can go check now, that when you are logging in,</i>

Table D1: Biological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
Theme	Sub-theme	Sample Quotes
		<i>it says like, What remedies did you use? So let me go see if I can go get one of the records? Or is it not? Is it another one that I, maybe? I don't know, maybe I can try to make a recording? Oh. I don't know. Maybe I'm just tripping [laughs]. Because I remember that there was an app. Is it Migraine Buddy? That it said, Oh, what kind of remedies did you use that were not medicine? And it could be like the cold pack, the hot pack, [inaudible], aromatherapy, blah, blah, blah, blah. So you go see? And like, maybe next time I can try something that's here."</i> <i>"I think there is. There is ways to add, like what was helpful and what wasn't. So I like that feature. I guess if there was like an easier way to kind of see like a summary of that. That might be helpful. Longer term, but I do think it's nice to be able to go and look back and be like, Okay, I did this for that headache and it helps."</i>
	Understand triggers	<i>Yes, it [DHT] gives me a better understanding about my headaches, and what triggers, which is a good thing, because that's what you want to know, you know, what's triggering a headache. And if an app can tell me this, I say it's a good app. And they need to put more apps out there. Keep them coming. Because if this is gonna help me in the long run, then I'm satisfied and content with it. Like right now. I'm up and about, I woke up with a headache. And it wasn't really intensified. It was one of the short headaches. It was just hurting for a minute.</i> <i>I did find it [DHT] relevant. I think there are things that asks, um, are directly related to symptoms I was feeling, for</i>

Table D1: Biological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
Theme	Sub-theme	Sample Quotes
		<i>example, they asked you know, they asked about the headaches, where did you feel them and they have like a little chart of the head, and I think they they got it like, yes. This is what my mind reveals like, that was relevant. They also I know, they asked about, um, sleep. Like, were you awake from this time to this time? I think that's really important. Because that's a trigger. And they, they do have a list of triggers there. I remember them. And they do. Yes, they were relevant too, almost all of them once they have listed there. I did find them to be my own triggers. I remember they were missing one, which I had to add, which was smell. Because I found out that, like, scented oils and stuff are a trigger of mine. And I didn't know, they didn't have that listed. But I did find it was a trigger for me. That's a small thing. I think the others are, are definitely relevant. Yeah.</i>
Learning about physical health	Learn about headaches	<i>"It's. it like, that's why I like Migraine Buddy. Because it allows you to distinctify very clearly any difference between a headache and a migraine. They are not the same thing. You have too many people who think that, oh my god, my head hurts so horrible. I think I have a migraine, we know a migraine only affects one area of the head. And the symptoms of a migraine are much more severe than a headache."</i> <i>"Um, like I said, maybe adding a bit more the... maybe articles about different types of headaches, like Mayo clinic or something where they describe the headaches, or I don't know, just links to learn more about it."</i>
	Learn about relief methods	<i>"Well, I wish it [DHT] could give me more recommendations on what to do. You know, I said jogs, maybe take a walk or maybe use like ice packs, or maybe</i>

Table D1: Biological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
Theme	Sub-theme	Sample Quotes
		<i>foods that have been used, like I've been having like sweet foods [inaudible] elevates headaches. Yeah. So I wish it could do that, too. That would be really cool."</i> <i>"Just maybe like, thinking of things like, if you like, because a lot of times like I can feel a headache coming on, like maybe like strategies or something you can do to kind of try to make it better or, like not as bad. I'm not really sure. Like, maybe more like.. I don't know, I don't know, like, I mean, I already know, like a lot of like, hints or strategies, just maybe having something different."</i>
	Learn about triggers	<i>"Yeah. I'm looking at like the tracker, mainly because it's just like, like, when I am good enough about it to, to track it. It's really helpful, right? Like, it'll make me think about the triggers outside of like what I typically think of as triggers, right? Lack of sleep, like super stressed, and be like, Oh, I didn't think that this could possibly be a trigger, but something I can examine. So I do mainly utilize that."</i> <i>"Migraine Buddy does a really good job of like, you know, kind of pulling out some really main stream or like more common triggers. And like I mentioned, like, even if sometimes, like, I don't understand why it's happening, like, occasionally I'll have a headache. And I feel like I'm fine. I feel like I'm doing everything right. But maybe something different, like my menstrual cycle, right? It'll remind me like, oh, this could potentially be a trigger. So I think, you know, I think it does a good job doing that."</i>
	Get immediate relief	<i>"I wouldn't say, um, what, like, bring it [headache] from a ten to zero. But it</i>

Table D1: Biological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
<i>Theme</i>	<i>Sub-theme</i>	<i>Sample Quotes</i>
Managing physical health		<i>[DHT] does help to reduce a little bit like momentarily."</i> <i>"And as I said, the the Headspace app, initially, I was offended by how they, you know, Settle into the pain. You've never felt that kind of pain, if you think you can settle into it in a as a quote and quote, comfy chair. But as soon as I did it, it actually does help to do that. That was a helpful cue."</i>
	Practice healthy habits	<i>"And with this app, It's teaching me how to get my sleeping pattern on track. Yeah, I might lying in bed, look, I'm not going to sleep, I'm gonna watch my TV show. Oh, and my body telling me otherwise, no, you need to shut it down. So I look at that app, and it would let me know, hey, it's time to close your eyes. So it did help me get on the routine pattern for sleeping. So now I know hey, go drink some tea, some warm tea to help you sleep better. So I go do that. And I look at my app and I say, Okay, I got an hour left before it asks me to lay down. So it keeps me on track with my sleeping. And I loved it because I'm so used to being up at nighttime because I was a college student. So I'd be up in the day at nighttime and sleep during the daytime. But now that I have this app, it's sending me out with, Okay, look, your body can't keep running like this. It's gonna shut down on you. So it's [DHT] really helping me out a lot."</i> <i>"At the end, if it's over a series of about a month, usually the first two weeks, if we're asked to just simply record after the first week, because they have to collect the data to see what's going on after the first week. They [DHT] can kind of make an initial assumption and say, Well, you might be experiencing this, it encourages</i>

Table D1: Biological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
Theme	Sub-theme	Sample Quotes
		you: (a) to continue recording your symptoms and to stay active, (b) it will give some tips and recommendations. Exercise this long. We recommend drink this much amount of water. We recommend not doing this or not spending much because it can, what you choose, Interviewer, like what you think are the triggers or whatever. It will also give recommendations on things that you should spend less time doing, like less time in front of a computer screen or the TV and more time outside walking around enjoying nature, having interactions with other people, less consumption of alcohol because it does ask you how much alcohol you drink for that specific day or anything like that. Things to cut back on, things to increase in, so it tries to steer you as recommendations for the positives over a longer period of time because I've been using it for three months. After two months if they see consistence, consistent different choices and they see what they think is you know migraine over a longer period of time. Then they give next step recommendations is what I call it. Go see your primary care physician or making a point To see a neurologist, you might have chronic migraine syndrome work, you need to do this or do that. So yeah, I recommend seeing a health care provider later but at the beginning it's self-care and conservative preventative care versus going to see health care provider.”
	Avoid triggers	“So the app, when I check the app, like, it tells me, tells me like, these things, I should avoid these things. And like I just, when I see it, I see it as a trigger. So I kind of avoid these things. I try to avoid things, I think at least most of it.”

Table D1: Biological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
<i>Theme</i>	<i>Sub-theme</i>	<i>Sample Quotes</i>
		<i>“And this tool gave me the information that these are your triggers. And you kind of flared up when that happened, and that happened, and that happened. And it was just like up to me later on to try to alleviate whatever is happening in my daily life to post that. So implementing the information that the app gave me really helped in like, me not having to go everyday to like, track that I have a flare up or track that I have an attack.”</i>
	Predict future headache attacks	<i>“Because when, when, when you keep logging it in to the app, the app might, might tell you the next time you experience a headache or something like that.”</i> <i>“Sometimes it [DHT] is accurate when my headaches are about kicking in. And when it's, when it's about to stop. And sometimes it's not accurate. So I'd say, some apps, they have to be tweaked a little bit. They don't, they're not promised to be right on point.”</i>

Table D2: Psychological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
<i>Theme</i>	<i>Sub-theme</i>	<i>Sample Quotes</i>
Monitoring psychological health	Monitor emotions	<i>“Just mood. You just, there's a few options and you tell it how you, how you feel. And then you do... I'm still getting into it a bit. And then you do lots of mood questionnaires. And then it tells you about yourself. And like extraversion, introversion, mood. And so your level of anxiety on that day. And then obviously, it's like, you track your mood. So you can see what's... Yeah, I don't know. I'm just getting into it.”</i> <i>“I would like, log my symptoms and like how I was feeling so then I can get a</i>

Table D2: Psychological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
Theme	Sub-theme	Sample Quotes
		<i>broader picture of like what my overall mood is."</i>
	Monitor mental health	<i>"Yeah, but with the with the, I can see the Breeze app being useful, because I'll be able to track when I'm more anxious, when I'm less anxious, because I'm still trying to get to the top of my stress, my anxiety as well. Like, it's just, it's, it's ironic. So I studied psychology and stuff, but I'm still you know what I mean, it's, I want to make it...A thought that people that study psychology just know how to hack the life. But they don't [laughs]. Yeah."</i> <i>"Yes, actually, yes, they do have, they do have anxiety and depression in amongst their symptoms and what-not. But it again, it [DHT] doesn't carry it any farther than that."</i>

Table D2: Psychological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
<i>Theme</i>	<i>Sub-theme</i>	<i>Sample Quotes</i>
Building awareness of psychological health	Understand emotions	<i>“Well, yeah. With the Migraine Buddy, it makes me understand that these negative emotions are normal. But yeah, that to stick with it is not a solution. So you have to come out of them and try to do something else. So go try to do an exercise or if it's better go out and just walk and do nothing. And but yeah, it makes me more understand that negative emotions and just taking it is not the solutions for my headaches problems. But I have to do something else, or I have to do exercises to make me feel better.”</i> <i>Yes, it [DHT] helps me to understand that, it's just letting me know, you know, once a headache come on, you don't know what you're gonna be feeling like. You, your kids might run up to you but you might not feel like to be bothered, your spouse would have to come and be like, Hey, come over here. Your mama going through some right now, give her some time to get her herself. And we'll come back later. But yes, it helped me with anxiety, the fatigue. Oh, that's why I'm feeling fatigued because my headache is so extreme. Or that's why I can't go to sleep because of my headaches. It also let me know okay, well, you have mood swings today. So you stay away from people today. Because you just don't want to be mean to nobody for no reason.</i>
	Understand mental health	<i>“Yeah, yeah, I learned some things from the app. You know. For example, one of the things I learned in the app is my mental health, my mental health. Before, I do, I do hear about mental health, I don't really pay attention about it. All I paid attention to is my digestive system, staying low on body weight. I don't really pay enough attention to mental health. The, the app really made me to pay more</i>

Table D2: Psychological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
<i>Theme</i>	<i>Sub-theme</i>	<i>Sample Quotes</i>
		<i>attention on my mental health, which why it's very helpful, you know, mental health has to do with the brain or the brain serves as the major organizer and control of your whole body system. So yeah, it's really important. And also some activities that it could easily affect other body parts. So I'll say that's what else I learned about from the, from the app, very helpful."</i> <i>"I don't think there's anything that really like, to me is like, Oh, this is going to help me reduce my stress more. So seeing these patterns emerge, helped me like then decide what I can do to change these patterns. So I mean, it's not going to take away my stress. But I can look at, you know, like, Okay, I'm getting these, these like headaches in the morning, and I usually wake up and just like pack in stress. And then I don't sleep well, I am like much more susceptible to like, internalizing stress entirely. So, you know, let me go to the gym, let me clear my head, let me go for an outdoor run, or like an outdoor bike ride in the morning. So it's more about like, what practices I can put in place to stop the stress or to I guess, like have a better handle on stress."</i>
Managing psychological health Feeling empowered	Get immediate relief	<i>"I think it's pretty calming. Like, every time, I would think like, every time I go on, I always have like a pain or like anxiety, or I can't fall asleep. So then that's why I go into that. But then after, like, wow, I was using the app, the experiences are okay. And then after that I often find relief. So I was like, Yeah, I think it's overall a pretty good experience."</i>

Table D2: Psychological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
Theme	Sub-theme	Sample Quotes
		<i>"Before, I'd feel quite tense, if I have a headache I would... Mindfulness, I do it when I can't sleep or my head hurts. So now, I've got a mindfulness... That Headspace or I'll go on YouTube, get some mindfulness. After that...And then eventually, I'll feel calm. If there's presently anxiety, it's a little bit more difficult to use mindfulness, because I experienced it from palpitations. And if it's nausea, I can experience nausea with anxiety. So if I ever... when I have panic attacks, I'm sick. And that makes me feel a little bit panicky. So it's establishing the difference between just nausea and an oncoming panic attack for me. So mindfulness has helped me with that."</i>
	Feel positive	<i>"Yes, I would say it [DHT] reduced them [negative emotions] because I don't get as nervous. When I have headaches I am wondering, Okay, what is really going on? I just don't want to handle, you know, random thoughts come in my head, and since I've been on this app, and they helped me manage it a whole lot. Where I'm not thinking negative thoughts. I'm thinking more positive thoughts than anything. And I tell anybody, always do your research, research. Just don't use app, research and see what it's good for. Maybe that app is not good for you, try another one."</i> <i>"Yes, you know, earlier I said, the app has really helped me a lot. So, to know more about my headache, and those things that I've been involved in, you know, outside the app. It has also helped to stabilize my emotional feeling. Before using the app any time I had a headache, I got, I got frustrated. You know. I just I, I find it difficult to, to move to move on with my daily routine, without the app. It</i>

Table D2: Psychological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
Theme	Sub-theme	Sample Quotes
		<i>has really helped me to stabilize my emotional feeling. And also control my anxiety level."</i>
	Feel in control	<i>"I feel very in control. Once I got this app on my phone, I feel total control. Because at first I felt helpless. Like, I didn't know where to turn, and I talked to my doctor and I turned blue in the face. And he was like, well, just take some Tylenol, or just take some ibuprofen, and you'll be fine. They're not trying to send me to no specialist, trying to see why the headache is constantly coming. Because some people look at it like you're exaggerating. But these apps have helped me a lot."</i> <i>"But I noticed that when I do like use it [DHT], and when I actually take the, it seriously, and like, put my data and put everything that I'm feeling and, and get back the kind of information, I actually noticed that this kind of makes me feel more in charge of things. So it makes me feel that it's not something, I'm not getting random attacks, I'm doing things that are causing this to happen. And the more I eliminate things I'm doing, the more these things are not going to happen. So yeah, that was really, that was really something that I need to remind myself of in order to like, take care of, take care of myself physically and be sure that I'm not like, just having life go by."</i>
	Feel confident	<i>"Yes, I feel very confident in managing, managing my headaches. Like right about now looking at my feed on the app, like right about now I shouldn't be having a headache. And I'm not. So I feel very confident with this app."</i>

Table D2: Psychological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
Theme	Sub-theme	Sample Quotes
		<i>"I think it [DHT] makes me more self-confident to overcome the headaches, it also makes me not happy but yeah, I have less fear for headaches. So that's something that when I know when I have a headache I have solution for it, and it makes you also feel more connected with others."</i>
	Feel motivated	<i>"Um, I really think that the app is reflecting on me, because I'm able to see what's going on with my body. But it don't, don't get me down. Because now that I have everything and I am in control, and I can see what I wrote. And it's really helping me out. So it's actually motivating me, it's keeping me motivated. Okay, look, you got this down. You ain't having as many headaches when you started this app. So it's like we go hand in hand. It's like we're joined at the hip, like, okay, there's a part of me, so as long as I keep this app on my phone. Like it sent me a message and told me Hey, we're gonna be down for two hours for maintenance. Okay, I'm glad you're alerting me. That mean get that pen and paper out or mark it on my calendar. Hey, okay, this when it happened. So when I do come back, I can notate everything into the app. Okay. Well, while you were down, this is what happened. So I really think it's a reflection on me."</i> <i>"Um, like, I said, I gave it a seven because every app has their little tweaks in it. And I feel so motivated behind this app that I don't really have to... When I started off, I was popping pills, I was popping Tylenols every two hours just to make my headache go away. But I'm down to not popping them every two hours, I might have to take maybe two</i>

Table D2: Psychological Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
<i>Theme</i>	<i>Sub-theme</i>	<i>Sample Quotes</i>
		<i>pills a day. It didn't brought me a very long way from every two hours taking the Tylenol to make the headache go away. So now all I'm taking is two a day. So I think that's a very good jump for it, with me taking, taking two pills every hour, every two hours, then just take them only two pills a day. So yes, it's very motivating."</i>

Table D3: Social Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
<i>Theme</i>	<i>Sub-theme</i>	<i>Sample Quotes</i>
Feeling supported	Feel supported through interactions with other users	<i>"Yes, definitely. I feel supported, it's like, it's really good to have community, you know, around you. Making you feel like yeah, like, these are people that are having this same thing, you know."</i> <i>"Um, okay, no, from the chat, just trying to, trying to know, trying to learn from one another, you know, the chat has also helped me to, you know, to see people who also suffer from what you, depends on your feeling, you know, then you feel isolated. You feel like it's normal, yeah. Yeah, yeah. So people, people will also feel the pain, so the chat for me, it helps to remove any kind of isolated feeling so you know. And also with chatting, I can learn more about people who also have the kind of pains I'm having and also, you know, when I, when I chat with them I feel my emotions, emotions improve, you know. And also sometimes when people try to talk about the improvement, how they are feeling, you know, the benefits from the app that also helps. Yes. I think all these persons can can enjoy all these things from the app. I think, I will also [inaudible] and I'll be able to manage my headache."</i>

Table D3: Social Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
Theme	Sub-theme	Sample Quotes
	View DHT as a friend	<i>"I was, um, for me, for the past three months, it'd [DHT] been my, I would say, my close friend, the app was my close friend. I use it all, almost, very regularly. I use it regularly. It has been my close friend. So it's been very helpful manage the, the migraine and also my activities related to the headache. So I use regularly. I would say, the actual time, I use regularly. The app has been very helpful."</i> <i>"It's [DHT] just like a friend, you know, even though I know it's not a friend. And it's just an app, this is something I can lean on like a friend, emotional support, even though it's not a human being, and it's just the app on your phone, but this app notifies me when something is about to happen. So this is just like a friend. Hey, some, somebody is about come knock on your door. So yeah, I would say it is my friend."</i>
	Feel support through interactions with DHT features	<i>"I think so. I'm just like, oh, almost like this community feeling right like something that Migraine Buddy does is like they share like stories from other like, people who get migraines. And even though like I don't know the people behind it, you know they won't share any personally identifying information, just like that the insights and like you're discovering new, discovering new information about, you know, migraines that's been curated into like a blog post for you or, you know, interacting with this information does make me feel supported."</i> <i>"There's personal relevance, because it gives me, um, support. So maybe it sends a notification with.. saying, Is everything going better? You can also you can</i>

Table D3: Social Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
<i>Theme</i>	<i>Sub-theme</i>	<i>Sample Quotes</i>
		<i>connect with others. So that's maybe personal relevance, that you're not alone. But you receive notifications with support, or you can connect with others. So I'm not standing alone. That's my personal relevance."</i>
Learning about communication	Learn about communication	<i>"Before when I first started using the apps, I didn't know how to maintain or how to explain things. Because I didn't know basically. But now that I use the apps, like pain management apps, and you see the words they're, when you are, when I'm explaining it to someone else that I have, like even if it's not a doctor, it's just someone at school, a classmate or, I can explain them with some words. Words that even if I didn't know them before, like, type of thing, throbbing. I didn't know that like, Oh, what? How was my pain? I don't know, like, what kind of pain? I don't know, because I didn't know before they were different types of pain. But now I know. So, but it's a word that, Oh, I didn't know this word was the word used for this type of thing. But I can tell now people, like I learned about, about it by reading in the apps, basically, the different types of pain, the different types of my triggers and etc. So when I talk to other people, I feel very, because it's not me saying, Oh, I have a headache, migraine and, and they asked me, oh, what's that? It's like, it's a headache. And I will just say, like, oh, it's a headache but this and that. Now I know what, really what more? What it is. I explain it better."</i> <i>"That is one point that I thought the app was actually going to give to me, because I thought that the... when you sign in, and they tell you that you're going to understand how your migraines work</i>

Table D3: Social Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
<i>Theme</i>	<i>Sub-theme</i>	<i>Sample Quotes</i>
		<i>and stuff like that. You get the feeling that or the tendency to believe that like, I could explain this to people better, because I was really struggling with it. I can explain to people that, Well, I haven't socialized with my family, like I have a headache, but yeah we all get headaches. So having more tools to actually help you communicate with people what you're feeling and how you're feeling it, and just like getting the right terms and using them to communicate what you're feeling, I think having more content, it could be there for people, maybe they can read on, like when they're doing their daily commute. Or maybe they can read a bit before sleep, or it can even have like an audio podcast kind of thing for people. If they're not willing to do the reading, they could just like listen to it, that could really help."</i>
Managing social interactions	Feel confident in interacting with others	<i>"Yeah, it does. Because like, maybe I'm having the headache, I could just like, go and check my phone, and like start tracking it. And I know, okay, I'm being tracked, like, I'm monitoring my health, so I can actually interact with people better, like I'm more confident enough to, like, interact with people better. So it does, it did help me like, it has helped with like my social interactions, yes definitely."</i> <i>"Like I said, as long as I have this app, yep. Before this app, I would cut myself off from the world and just bury myself in the house. I didn't want nobody to bother me. I unplugged house phones, anything that made noises, I unplugged it, and I put a big sign on my door, Please don't ring my bell. But with this app, it is bringing me back into my social life, it's bringing me back where I could go</i>

Table D3: Social Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
Theme	Sub-theme	Sample Quotes
		<i>grocery shopping, or I could go to a friend's engagement party, or I could conduct a meeting without these headaches being triggered. So I think it is good to have these apps out there that you can lean on for emotional support. And I'm really motivated by having this app."</i>
	Communicate with others	<i>"Yes, definitely. Because and it [DHT] also helped me, you know, give a fair warning to people around me that hey, if I'm snapping, it's not you. It's my headache. I am trying to get a hold of it. So yeah, it helps me keep a check on how my what my mood swings are, or why they are. And if I feel like an if I am already irritate you know, irritable, and there's a slight headache or like a slight symptom, which I know will lead to headache. I already keep myself off everybody's everybody's way. And, yeah, I make sure that I feed my dog, exercise as well so that he doesn't, you know, he doesn't come and pester me to play with him or he doesn't get too excited when I'm out of the room or something. So yeah, I take precautions necessarily to avoid any major blow outs or something."</i> <i>"Yes, it does. Because it [DHT] alerts me like it might come in, and a symptom checker might pop in and say, Hey, are you feeling any fatigue today? Are you nauseated with this headache. And I might click off, No, I'm not nauseated. No, I'm not having anxiety. It kind of mellowed me out where now that I, if I can see it, it won't bother me. Because it's managing my pain. So I'm like, Okay, it's only gonna last, it might say, Hey, it's gonna last seven minutes. So I just sit there and I ride these seven minutes out,</i>

Table D3: Social Relevance of Digital Health Technology for Self-Management of Chronic Conditions		
<i>Theme</i>	<i>Sub-theme</i>	<i>Sample Quotes</i>
		<i>and I just be quiet. When somebody come up to me. I might just show them one finger and just say, give me a minute. And when it died down, and I'm like, yes, what was your question?"</i>

Appendix E: Preliminary Version of the Measurement Instrument Items

Table E1: Items for Biological Relevance of Digital Health Technology for Self-Management of Chronic Conditions	
<i>Dimension</i>	<i>Items</i>
A. Monitor Physical Health	A1. I find this app useful for monitoring my physical symptoms when I experience headaches. A2. I find this app useful for monitoring my daily habits that could affect my headaches. A3. I find this app useful for monitoring my treatments (e.g., medications and relief methods) for my headaches. A4. I find this app useful for monitoring the things that trigger my headaches.
B. Build Awareness of Physical Health	B1. My use of this app helps me validate my memory of how my headaches have affected my life (for example, by providing a record of my past headache experiences). B2. My use of this app provides me with a better understanding of physical symptoms associated with my headaches. B3. My use of this app provides me with a better understanding of how my daily habits affect my headaches. B4. My use of this app provides me with a better understanding of various treatments (including medications and relief methods) that could improve my headaches. B5. My use of this app provides me with a better understanding of the things that can trigger my headaches.
C. Learn About Physical Health	C1. This app helps me learn new information about different types of headaches and associated physical symptoms. C2. This app helps me learn new information about relief methods for headaches. C3. This app helps me learn new information about the things that can trigger headaches.
D. Manage Physical Health	D1. I find this app useful for providing me with immediate relief from the physical symptoms of my headaches (through relaxation techniques such as guided meditation and stretching recommendations provided by the app, for example). D2. My use of this app helps me practice healthy habits that can improve my headaches (by providing reminders and recommendations, for example). D3. My use of this app helps me avoid triggers of my headaches.

	D4. I find this app useful for predicting the next time I will experience the physical symptoms of my headaches.
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Table E2: Items for Psychological Relevance of Digital Health Technology for Self-Management of Chronic Conditions	
<i>Dimension</i>	<i>Items</i>
A. Monitor Psychological Health	A1. I find this app useful for monitoring my momentary emotions (for example, feeling sad, frustrated, surprised) when I experience headaches. A2. I find this app useful for monitoring my mental health states (for example, anxiety, depression, stress) when I experience headaches.
B. Build Awareness of Psychological Health	B1. My use of this app helps me understand my momentary emotions (for example, feeling sad or frustrated) when I experience headaches. B2. My use of this app helps me understand my mental health (for example, feeling stressed or anxious) when I experience headaches.
C. Manage Psychological Health	C1. I find this app useful for providing me with immediate relief from stress, anxiety, or negative emotions caused by my headaches (through relaxation techniques such as guided meditation and mindfulness, for example).
D. Feel Empowered	D1. My use of this app helps me stay positive when I experience headaches. D2. My use of this app helps me feel in control of my headaches. D3. My use of this app helps me feel confident in my ability to manage my headaches. D4. My use of this app helps me feel motivated to take action towards managing my headaches.

Table E3: Items for Social Relevance of Digital Health Technology for Self-Management of Chronic Conditions	
<i>Dimension</i>	<i>Items</i>
A. Feel Supported	A1. My interactions with other users of the app (for example, through a social chat feature) make me feel supported when I experience headaches. A2. Different features of the app (for example, notifications and messages) make me feel supported when I experience headaches. A3. This app is like a friend to me who supports me when I experience headaches.

B. Learn About Communication	B1. My use of this app helps me learn how to talk about my headaches with other people.
C. Manage Social Interactions	C1. My use of this app helps me prepare for social interactions with people in real life (for example, I can give a warning to other people if the app predicts an upcoming headache attack). C2. My use of this app helps me feel more confident in interacting with people in real life when I experience headaches.

Appendix F: Content Validity Protocol

Dear Participant,

Thank you for taking the time to participate in the expert panel! Your expertise and judgment can greatly contribute to this study.

Please, read the following information about the study to confirm your participation. In case you have any questions, feel free to email Polina Durneva at pdurneva@fiu.edu

Purpose Of the Entire Study:

The goal of the entire study is to develop a measurement instrument to assess user's perspective on consumer-facing digital health technologies (e.g., mobile apps and online programs) for self-management of chronic conditions and, specifically, chronic headaches. The study leverages the biopsychosocial model of health (which considers individual's physical health, psychological health, and social health) (Engel, 1977).

Particularly, the instrument aims to assess user's perspective on consumer-facing digital health technology in terms of digital health's relevance to user's physical health (e.g., physical symptoms, lifestyle, habits, treatments), psychological health (e.g., negative emotions and mental health problems), and social health (e.g., having a supportive network, being able to build and maintain relationships).

In alignment with the biopsychosocial model of health, the study develops and validates an instrument to assess user's perspective on the following dimensions of digital health's relevance:

- (1) Biological Relevance of Consumer-Facing Digital Health: digital health's relevance to user's physical health
- (2) Psychological Relevance of Consumer-Facing Digital Health: digital health's relevance to user's psychological health
- (3) Social Relevance of Consumer-Facing Digital Health: digital health's relevance to user's social health

The study is being conducted in three phases:

- Phase 1 (23 semi-structured interviews with individuals suffering from chronic headaches and using digital health technologies to self-manage their headaches) explored user interaction with digital health technologies, how users perceive digital health's relevance to different dimensions of their health, and what users gain from their interactions with digital health technologies. A set of items

to assess biological, psychological, and social dimensions of relevance were constructed based on the semi-structured interviews.

- Phase 2 (expert panel) aims to assess the content validity of the items developed in Phase 1.
- Phase 3 (surveys) aims to validate the items from Phase 2.

As an expert, you are participating in Phase 2 of the study.

Purpose Of This Expert Panel:

The goal of this expert panel is to assess the content validity of the items measuring biological relevance, psychological relevance, and social relevance of consumer-facing digital health technologies. Specifically, the expert panel members should assess each items with respect to:

- (1) Clarity (i.e., whether the items are clear and concise)
- (2) Representativeness (i.e., the extent to which items represent biological, psychological, and social relevance dimensions)
- (3) Importance (i.e., the extent to which items are important to measure biological, psychological, and social relevance dimensions)

Number Of the Expert Panel Participants:

If you choose to participate in the expert panel, you will be one of 7 expert panel members in this study.

Duration Of the Expert Panel:

Your participation will take ~40-50 minutes.

Procedures:

If you agree to participate, you will have to assess each item with respect to clarity, representativeness, and importance on a 4-point scale. You will also have an option to provide qualitative feedback. Your answers will be kept private. Only research team will have access to the records.

Risks and Discomforts:

First, there is a moderate risk associated with loss of time. Second, there is a moderate risk of boredom.

Benefits:

There may be no direct benefits to you as a participant in this study. However, your input will be used to revise the measurement instrument to assess consumer-facing digital health technologies for self-management of chronic conditions and, specifically, chronic headaches.

Alternatives:

There are no known alternatives available to you other than not taking part in this study.

Confidentiality:

The records of this study will be kept private and will be protected to the fullest extent provided by law. In any sort of report, we might publish but we will not include any information that will make it possible to identify you. Research records will be stored securely, and only the researcher team will have access to the records. However, your records may be inspected by authorized University or other agents who will also keep the information confidential.

Use of Your Information:

Identifiers about you might be removed from the identifiable private information that, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Compensation and Costs:

As a thank-you for your participation, you will receive a \$50 Amazon e-gift card.

Right to Decline or Withdraw:

Your participation in this study is voluntary. You are free to participate in the study or withdraw your consent at any time during the study. You will not lose any benefits if you decide not to participate or if you quit the study early. The investigator reserves the right to remove you without your consent at such time that he/she feels it is in the best interest.

Researcher and IRB Contact Information:

If you have any questions about the purpose, procedures, or any other issues relating to this research study you may contact Polina Durneva at FIU Department of Information System and Business Analytics, pdurneva@fiu.edu.

If you would like to talk with someone about your rights of being a subject in this research study or about ethical issues with this research study, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

Participant Agreement:

If you have read the information in this form and agree to participate in this expert panel, please put your initials below:

Initials:

Biological Relevance of Consumer-Facing Digital Health Technology

Biological relevance of digital health technology refers to digital health's relevance to user's physical health (e.g., physical symptoms, lifestyle, habits, treatments). By conducting semi-structured interviews with digital health users, the lead researcher of this study identified that the biological relevance of digital health technology captures the extent to which digital health technologies help users:

- (1) monitor their physical health,
- (2) build awareness of their physical health,
- (3) manage their physical health,
- (4) learn about physical health in general.

Please assess the following items with respect to clarity, representativeness, and importance.

Note: this study focuses on the context of chronic headaches. Thus, the items refer to user's self-management of chronic headaches by means of using digital health technology. The items are worded from the first person's perspective since the goal is to develop a measurement instrument to be used by users. In addition, "app" refers to digital health technology.

Clarity of items (whether the wordings and phases of the items are clear and concise)

-----Items to Assess Provided Here-----

If you rated any of the items above as 1 (item is not clear), or 2 (item needs major revisions to be clear), or 3 (item needs minor revisions to be clear), please provide some comments on your assessment:

Representativeness of items (the extent to which items represent the biological relevance dimensions such as (A) monitoring physical health, (B) building self-awareness of physical health, (C) learning about physical health, and (D) managing physical health)

-----Items to Assess Provided Here-----

If you rated any of the items above as 1 (item is not representative), or 2 (item needs major revisions to be representative), or 3 (item needs minor revisions to be representative), please provide some comments on your assessment:

Importance of items (the extent to which items are important to measure the biological relevance dimensions such as (A) monitoring physical health, (B) building self-awareness of physical health, (C) learning about physical health, and (D) managing physical health)

Note: "construct" refers to a specific dimension of the biological relevance (e.g., monitoring physical health, etc.)

-----Items to Assess Provided Here-----

If you rated any of the items above as 1 (item is not necessary to measure the construct), or 2 (item is providing some information but is not essential to measure the construct), or 3 (item is useful but not essential to measure the construct), please provide some comments on your assessment:

Psychological Relevance of Digital Health Technology

Psychological relevance of digital health technology refers to digital health's relevance to user's psychological health (e.g., negative emotions and mental health problems). By conducting semi-structured interviews with digital health users, the lead researcher of this study identified that the psychological relevance of digital health technology captures the extent to which digital health technologies help users:

- (1) monitor their psychological health,
- (2) build awareness of their psychological health,
- (3) manage their psychological health,
- (4) feel empowered.

Please assess the following items with respect to clarity, representativeness, and importance.

Note: this study focuses on the context of chronic headaches. Thus, the items refer to user's self-management of chronic headaches by means of using digital health technology. The items are worded from the first person's perspective since the goal is to develop a measurement instrument to be used by users. In addition, "app" refers to digital health technology.

Clarity of items (whether the items are clear and concise)

-----Items to Assess Provided Here-----

If you rated any of the items above as 1 (item is not clear), or 2 (item needs major revisions to be clear), or 3 (item needs minor revisions to be clear), please provide some comments on your assessment:

Representativeness of items (the extent to which items represent the psychological relevance dimensions such as (A) monitoring psychological health, (B) building self-awareness of psychological health, (C) managing psychological health, and (D) feeling empowered)

-----Items to Assess Provided Here-----

If you rated any of the items above as 1 (item is not representative), or 2 (item needs major revisions to be representative), or 3 (item needs minor revisions to be representative), please provide some comments on your assessment:

Importance of items (the extent to which items are important to measure the psychological relevance dimensions such as (A) monitoring psychological health, (B) building self-awareness of psychological health, (C) managing psychological health, and (D) feeling empowered)

Note: "construct" refers to a specific dimension of the psychological relevance (e.g., monitoring psychological health, etc.)

-----Items to Assess Provided Here-----

If you rated any of the items above as 1 (item is not necessary to measure the construct), or 2 (item is providing some information but is not essential to measure the construct), or 3 (item is useful but not essential to measure the construct), please provide some comments on your assessment:

Social Relevance of Digital Health Technology

Social relevance of digital health technology refers to digital health's relevance to user's social health (e.g., having a supportive network, being able to build and maintain relationships). By conducting semi-structured interviews with digital health users, the lead researcher of this study identified that the social relevance of digital health technology captures the extent to which digital health technologies help users:

- (1) receive social support,
- (2) learn about social interactions in general,
- (3) manage their social interactions.

Please assess the following items with respect to clarity, representativeness, and

importance.

Note: this study focuses on the context of chronic headaches. Thus, the items refer to user's self-management of chronic headaches by means of using digital health technology. The items are worded from the first person's perspective since the goal is to develop a measurement instrument to be used by users. In addition, "app" refers to digital health technology.

Clarity of items (whether the items are clear and concise)

-----Items to Assess Provided Here-----

If you rated any of the items above as 1 (item is not clear), or 2 (item needs major revisions to be clear), or 3 (item needs minor revisions to be clear), please provide some comments on your assessment:

Representativeness of items (the extent to which items represent the social relevance dimensions such as (A) receiving social support, (B) learning about social interactions, and (C) managing social interactions)

-----Items to Assess Provided Here-----

If you rated any of the items above as 1 (item is not representative), or 2 (item needs major revisions to be representative), or 3 (item needs minor revisions to be representative), please provide some comments on your assessment:

Importance of items (the extent to which items are important to measure the social relevance dimensions such as (A) receiving social support, (B) learning about social interactions, and (C) managing social interactions))

Note: "construct" refers to a specific dimension of the social relevance (e.g., receiving social support, etc.)

-----Items to Assess Provided Here-----

If you rated any of the items above as 1 (item is not necessary to measure the construct), or 2 (item is providing some information but is not essential to measure the construct), or 3 (item is useful but not essential to measure the construct), please provide some comments on your assessment:

If you have any additional feedback, please provide your feedback below:

Appendix G: Revised Measurement Instrument Items

Table G1: Revised Items for Biological Relevance of Digital Health Technology for Self-Management of Chronic Conditions	
<i>Dimension</i>	<i>Items</i>
A. Monitor Physical Health	A1. This app helps me monitor my physical symptoms when I experience headaches. A2. This app helps me monitor my daily habits (for example, my diet or physical activity) that could affect my headaches. A3. This app helps me monitor my headache remedies. A4. This app helps me monitor my headache triggers (for example, stress, weather events, etc.).
B. Build Awareness of Physical Health	B1. This app helps me check my memory of my previous headache experiences (for example, it provides a record of my past self-recorded headache experiences). B2. This app helps me better understand my physical symptoms associated with my headaches. B3. This app helps me better understand how my daily habits (for example, my diet or physical activity) affect my headaches. B4. This app helps me better understand what headache remedies can improve my headaches. B5. This app helps me better understand my headache triggers (for example, stress, weather events, etc.).
C. Learn About Physical Health	C1. This app helps me learn new information about different headaches in general. C2. This app helps me learn new information about physical symptoms associated with different headaches in general. C3. This app helps me learn new information about daily habits (for example, diet or physical activity) that can affect headaches in general. C4. This app helps me learn new information about headache remedies in general. C5. This app helps me learn new information about headache triggers (for example, stress, weather events, etc.) in general.
D. Manage Physical Health	D1. This app is useful for providing me with ways to relieve my headaches (for example, it provides recommendations or techniques to reduce pain). D2. This app helps me practice healthy habits that could improve my headaches (for example, it provides reminders to practice healthy habits).

	D3. This app helps me avoid my headache triggers (for example, it sends alerts about possible triggers) D4. This app helps me predict the next time I will experience a headache.
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Table G2: Revised Items for Psychological Relevance of Digital Health Technology for Self-Management of Chronic Conditions	
<i>Dimension</i>	<i>Items</i>
A. Monitor Psychological Health	A1. This app helps me monitor my emotions (for example, feeling sad, angry, or frustrated) when I experience headaches. A2. This app helps me monitor my mental health (for example, my levels of anxiety, depression, or stress) when I experience headaches.
B. Build Awareness of Psychological Health	B1. This app helps me better understand my emotions (for example, feeling sad, angry, or frustrated) when I experience headaches. B2. This app helps me better understand my mental health (for example, my levels of anxiety, depression, or stress) when I experience headaches.
C. Learn About Psychological Health	C1. This app helps me learn how headaches can affect emotions (for example, feeling sad, angry, or frustrated) in general. C2. This app helps me learn how headaches can affect mental health (e.g., levels of anxiety, depression, or stress) in general.
D. Manage Psychological Health	D1. This app is useful for providing me with ways to improve my emotions when I experience headaches (for example, it provides positive messages that make me feel better). D2. This app is useful for providing me with ways to improve my mental health when I experience headaches (for example, it provides relaxation techniques that make me feel better).
E. Feel Empowered	E1. This app helps me stay positive when I experience headaches. E2. This app helps me feel like I am in control of my headaches. E3. This app helps me feel confident in my ability to manage my headaches. E4. This app helps me feel motivated to take action towards managing my headaches.

Table G3: Revised Items for Social Relevance of Digital Health Technology for Self-Management of Chronic Conditions	
<i>Dimension</i>	<i>Items</i>
A. Feel Supported	A1. My interactions with other app users (for example, through a chat feature) make me feel supported when I experience headaches. A2. The app features (for example, app messages or notifications) make me feel supported when I experience headaches.
B. Learn About Communication	B1. This app helps me learn how to talk about my headaches with other people.
C. Manage Social Interactions	C1. This app helps me be prepared for social interactions in real life (for example, I can warn other people about an upcoming headache).

Appendix H: Measurement Instrument Items

Note: All items leveraged a 5-point Likert scale ranging from 1=Strongly Disagree to 5=Strongly Agree

Abbreviation	Item
Continuance Usage Intention of DHT	
CU1	I intend to continue using this app rather than discontinue its use.
CU2	My intentions are to continue using this app rather than any alternative means.
CU3	I will continue to use this app in the future.
Global Items for Convergent Validity – Third Order	
GL1	Overall, this app helps me manage my headaches.
GL2	Overall, this app is relevant to my headaches.
Global Items for Convergent Validity – Second Order	
BGL1 (biological)	Overall, this app is relevant to my physical health when I experience headaches.
PGL1 (psychological)	Overall, this app is relevant to my psychological health when I experience headaches.
Global Items for Convergent Validity – First Order	
BGL2 (biological)	Overall, this app helps me manage my physical health when I experience headaches.
BGL3 (biological)	Overall, this app helps me monitor my physical health when I experience headaches.
BGL4 (biological)	Overall, this app helps me better understand my physical health when I experience headaches.
BGL5 (biological)	Overall, this app helps me learn new information about my physical health when I experience headaches.
PGL2 (psychological)	Overall, this app helps me manage my psychological health when I experience headaches.
PGL3 (psychological)	Overall, this app helps me monitor my psychological health when I experience headaches.
PGL4 (psychological)	Overall, this app helps me better understand my psychological health when I experience headaches.
PGL5 (psychological)	Overall, this app helps me learn new information about my psychological health when I experience headaches.
PGL6 (psychological)	Overall, this app helps me feel empowered when I experience headaches.
SGL1 (social)	Overall, this app is relevant to my social health when I experience headaches.
Biological Relevance of DHT Items	
BM1 (monitoring)	This app helps me monitor my physical symptoms when I experience headaches.
BM2 (monitoring)	This app helps me monitor my daily habits (for example, my diet or physical activity) that could affect my headaches.

Abbreviation	Item
BM3 (monitoring)	This app helps me monitor my headache remedies.
BM4 (monitoring)	This app helps me monitor my headache triggers (for example, stress, weather events, etc.).
BA1 (building awareness)	This app helps me check my memory of my previous headache experiences (for example, it provides a record of my past self-recorded headache experiences).
BA2 (building awareness)	This app helps me better understand the physical symptoms associated with my headaches.
BA3 (building awareness)	This app helps me better understand how my daily habits (for example, my diet or physical activity) affect my headaches.
BA4 (building awareness)	This app helps me better understand what headache remedies can improve my headaches.
BA5 (building awareness)	This app helps me better understand my headache triggers (for example, stress, weather events, etc.).
BL1 (learning)	This app helps me learn new information about different headaches in general.
BL2 (learning)	This app helps me learn new information about physical symptoms associated with different headaches in general.
BL3 (learning)	This app helps me learn new information about daily habits (for example, diet or physical activity) that can affect headaches in general.
BL4 (learning)	This app helps me learn new information about headache remedies in general.
BL5 (learning)	This app helps me learn new information about headache triggers (for example, stress, weather events, etc.) in general.
BMA1 (managing)	This app is useful for providing me with ways to relieve my headaches (for example, it gives recommendations or techniques to reduce pain).
BMA2 (managing)	This app helps me practice healthy habits that could improve my headaches (for example, it provides reminders to practice healthy habits).
BMA3 (managing)	This app helps me avoid my headache triggers (for example, it sends alerts about possible triggers).
BMA4 (managing)	This app helps me predict the next time I will experience a headache.
Psychological Relevance of DHT	
PM1 (monitoring)	This app helps me monitor my emotions (for example, feeling sad, angry, or frustrated) when I experience headaches.
PM2 (monitoring)	This app helps me monitor my mental health (for example, my levels of anxiety, depression, or stress) when I experience headaches.

Abbreviation	Item
PA1 (building awareness)	This app helps me better understand my emotions (for example, feeling sad, angry, or frustrated) when I experience headaches.
PA2 (building awareness)	This app helps me better understand my mental health (for example, my levels of anxiety, depression, or stress) when I experience headaches.
PL1 (learning)	This app helps me learn how headaches can affect emotions (for example, feeling sad, angry, or frustrated) in general.
PL2 (learning)	This app helps me learn how headaches can affect mental health (e.g., levels of anxiety, depression, or stress) in general.
PMA1 (managing)	This app is useful for providing me with ways to improve my emotions when I experience headaches (for example, it provides positive messages that make me feel better).
PMA2 (managing)	This app is useful for providing me with ways to improve my mental health when I experience headaches (for example, it provides relaxation techniques that make me feel better).
PE1 (empowered)	This app helps me stay positive when I experience headaches.
PE2 (empowered)	This app helps me feel like I am in control of my headaches.
PE3 (empowered)	This app helps me feel confident in my ability to manage my headaches.
PE4 (empowered)	This app helps me feel motivated to take action towards managing my headaches.
Social Relevance of DHT	
S1	My interactions with other app users (for example, through a chat feature) make me feel supported when I experience headaches.
S2	The app features (for example, app messages or notifications) make me feel supported when I experience headaches.
S3	This app helps me learn how to talk about my headaches with other people.
S4	This app helps me be prepared for social interactions in real life (for example, I can warn other people about an upcoming headache).

Appendix I: Pretest Checklist

Administration

- How long does the survey take to complete?
- Did the time to complete the survey vary widely among the test participants?
- Are the instructions for each section clear?

Organization

- Do the different sections flow reasonably from one to the next?
- Are all questions necessary in order to collection information on your topic?
- Are the questions within each section logically ordered?

Content

- Are the questions direct and concise?
- Are the questions free of necessary technical language and jargon?
- Are there questions that make responded feel uncomfortable, embarrassed, annoyed, or confused?

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PUBLICATIONS

LeRouge, C., Durneva, P., Lyon, V., & Thompson, M. (2022). Health Consumer Engagement, Enablement, and Empowerment in Smartphone-Enabled Home-Based Diagnostic Testing for Viral Infections: Mixed Methods Study, *JMIR mHealth and uHealth*, 10(6), e34685. <https://doi.org/10.2196/34685>

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Hertelendy, A., McNulty, E., Mitchell, C., Gutberg, J., Lassar, W., Durneva, P., & Rapp, D. (2021). Crisis leadership: The new imperative for MBA curricula. *The International Journal of Management Education*, 19(3). <https://doi.org/10.1016/j.ijme.2021.100534>

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LeRouge, C., Durneva, P., Sangameswaran, S., & Gloster, A-M. (2019). Design Guidelines for a Technology-Enabled Nutrition Education Program to Support Overweight and Obese Adolescents: Qualitative User-Centered Design Study. *Journal of Medical Internet Research*, 21(7), e14430. <https://doi.org/10.2196/14430>