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Decoding Digital Therapeutics: A Qualitative Analysis of Software Features in German Digital Health Applications

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Abstract. Digital therapeutics (DTx) offer significant potential for enhancing patient care, but their functional elements remain underexplored. This study systematically analyzes and clusters 197 distinct features across 35 DTx, organizing them into 19 themes and six overarching dimensions. It distinguishes between features considered digital active ingredients and excipients of DTx, providing a comprehensive framework of their interactions. These findings offer valuable insights for stakeholders in the field, advancing the understanding of DTx building blocks.

Keywords. digital health, mobile health, software as a medical device, DiGA, features, functionality

1. Introduction

The rapid growth of digital health technologies has introduced a new era of healthcare interventions, with digital therapeutics (DTx) emerging as a promising approach to improve patient care and health outcomes. DTx represent digital health solutions with a demonstrable positive therapeutic impact, intended to treat or alleviate a disease, disorder, condition, or injury [1]. These tools are expected to have a significant impact on healthcare delivery and consumption globally, with the potential to address chronic conditions and other challenging-to-treat illnesses [2]. The growing market for DTx is projected to reach $8.9 billion by 2027 [3].

Despite the promise of DTx in addressing chronic and other challenging conditions, there is still limited understanding of the specific functions and features that make these applications effective [4]. To bridge this gap, this study aims to systematically analyze the user-centered features of a representative sample of DTx regulated as medical devices in the European Union that have demonstrated their effectiveness. This goal leads to the following research question (RQ):

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- RQ: What are the key features and characteristics of DTx that have demonstrated their effectiveness, and how can these features be systematically categorized?

2. Methods

We used a qualitative research approach to analyze and categorize DTx features systematically. Publicly available information from 35 permanently listed DTx in the DiGA directory maintained by the German Federal Institute for Drugs and Medical Devices (BfArM) was collected. This source ensured the inclusion of applications that meet high regulatory requirements, such as those for medical devices and high-quality clinical evidence. The DiGA directory provides a structured data pool with documents such as the instructions for use. To enhance the comprehensiveness of our analysis, we supplemented the data from the DiGA directory with additional information gathered from the Google Play Store and official application manufacturer websites. This supplementary data provided details not explicitly covered in the DiGA directory. The data was analyzed in three phases using the Gioa methodology [5], an inductive approach ideal for qualitative data. In the first phase, we developed 1st-order concepts by identifying technical feature categories aligning closely with the original wording. Afterward, these categories were abstracted into broader themes and aggregated into dimensions. A second researcher independently reviewed the coding to enhance reliability and reduce researcher bias. Any discrepancies were resolved through discussion, and expert consensus was achieved to ensure the robustness and credibility of the findings. To report our research, we adhere to the Standards for Reporting Qualitative Research (SRQR) [6].

3. Results

The 35 DTx approved for permanent use in the German healthcare system target various health conditions. 17 focus on mental health, while others focus on various conditions, such as chronic pain (3), sleep disorders (1), and obesity (2). Technologically, the dataset includes 13 web-only applications, seven web and mobile applications, and 15 mobile only applications. To gain visual insights, over 200 screenshots, along with instructions for use and manufacturer websites, were analyzed. Each application showcased, on average, five to ten distinct features, resulting in 197 unique 1st-order concepts. These were grouped into 19 2nd-order themes and further consolidated into six aggregate dimensions, as shown in Figure 1. The six aggregate dimensions that were formed are: *User Engagement and Incentives*, *User Preferences and Data Security*, *Data Collection and Monitoring*, *Health Interventions*, *Content Libraries and Resource Management*, and *Communication and Information Exchange*. Table 1 provides an overview of these dimensions and corresponding 2nd-order themes.

User Engagement and Incentives features focus on adherence through visualization and gamification elements, including *Progress Overviews and Data Visualizations* (e.g., progress bars, graphs, and statistical overviews), *Goal Management and Rewards* such as personal or pre-set goals, and related rewards like medals, and less commonly, *Reminders and Notifications* for appointments or exercises. *Activity Feeds and Exercise*

Overviews display overviews of recommended exercises, supported by *Usage Instructions and Tips*, which give guidance for specific functions.

User Preferences and Data Security contains *Data Security Measures* (e.g., password protection, two-factor authentication, biometric login or data protection rights management), and *Settings and Customatization* features which allow users to personalize their profiles and other app data.

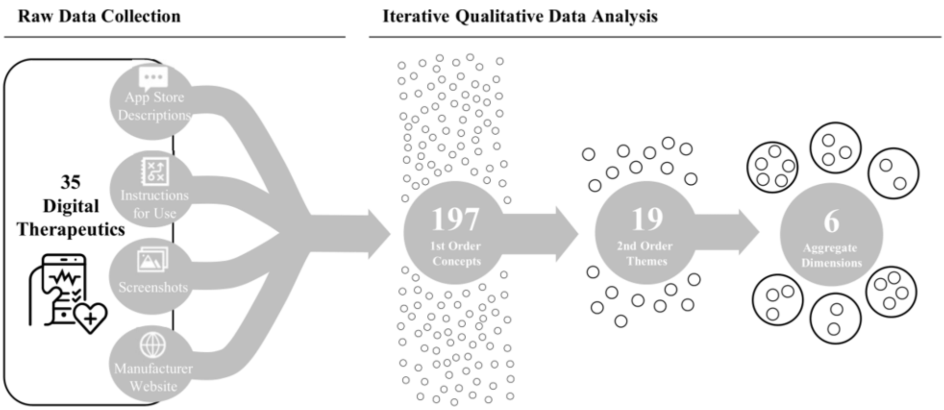

Figure 1. Research process from raw data collection to iterative qualitative data analysis.

Table 1. Overview of the aggregate dimensions and 2nd-order themes with the number of unique features.

Aggregate Dimension	2nd Order Themes	Quantity
User Engagement and Incentives	Activity Feed and Exercise Overview	8
	Reminders and Notifications	8
	Goal Management and Rewards	14
	Usage Instructions and Tips	4
	Progress Overview and Data Visualization	17
User Preferences and Data Security	Settings and Profile	3
	Data Security Measures	6
Data Collection and Monitoring	User-reported Structured Data Tracking	30
	User-reported Unstructured Data Tracking	8
	Sensor-driven Structured Data Tracking	9
Health Interventions	Structured Exercise Programs	31
	Interactive Health Interventions	11
	Health Education Elements	19
Resource Management and Data Security	Non-customizable Content Libraries	4
	Filterable Content Libraries	4
Communication and Information Exchange	Communication with Healthcare Providers	8
	Communication with Customer Support	4
	Community Building and Social Engagement	2
	Reports and User Data Export	7

Data Collection and Monitoring involves *User-reported Structured Data Tracking* possibly in the form of questionnaires for pain or general health status, among others, and *User-reported Unstructured Data Tracking* (e.g., diary functions without specific input formats). Finally, *Sensor-driven Data Tracking* leverages sensors or wearables to collect data related to steps, blood pressure, or even automated meal recognition through pictures.

Health Interventions is the most feature-rich dimension, including *Structured Exercise Progams* that are personalized and scientifically proven, such as physical, hypnosis, breathing, or cognitive exercises. *Health Education Elements* provide articles and quizzes on specific medical conditions, while *Interactive Health Interventions* include chatbots with multiple choice answers or free text input, virtual reality applications, or live exercise feedback through camera-based pose tracking that require additional user interaction.

Content Libraries and Resource Management are less prevalent and include *Non-customizable Content Libraries* and *Filterable Content Libraries* with resource collections like recipes or health tips.

Finally, *Communication and Information Exchange* features in-app chats and calls with customer support and digital interfaces for healthcare providers to view and manage patient app content through separate web applications. Some applications also support *Community Building and Social Engagement* among users through forums, and a few enable *Reports and User Data Export* for personal use or sharing with healthcare providers.

4. Discussion

The systematic analysis of 35 DTx revealed that *Health Interventions* are the most dominant and diverse features, followed by *User Engagement and Incentives* and *Data Collection and Monitoring*. Other features, such as *Communication and Information Exchange* and *User Preferences and Data Security*, were less prelevant.

Analogous to medications, DTx are composed of digital active ingredients, digital excipients, and specific modes of action [7]. In our study, *Health Interventions* represents the core digital active ingredient, encompassing modes of action such as Cognitive Behavioural Therapy, exercise therapy, or other disease-specific mechanisms. Supporting dimensions like *User Engagement and Incentives* and *Content Libraries and Resource Management* function as digital excipients, enhancing the effectiveness of the primary intervention. Personalization is achieved through *Data Collection and Tracking*, providing insights for healthcare professionals via *Communication and Information Exchange*. Together, these elements form the therapeutic framework of DTx, shown in Figure 2.

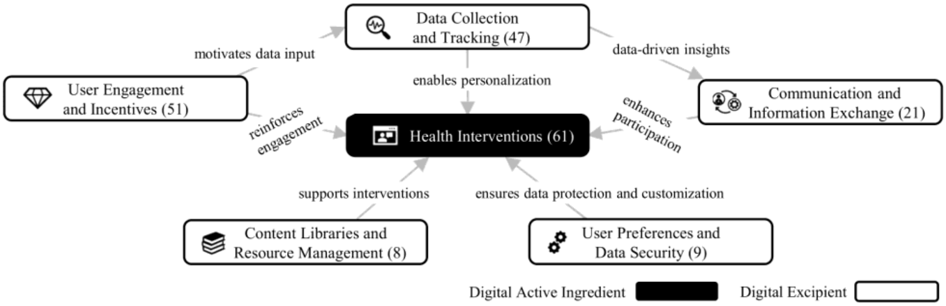

Figure 2. Feature framework of digital therapeutics with the number of 1st-order concepts in brackets.

A notable finding is the limited use of advanced technologies like artificial intelligence or serious gaming in current DTx, likely due to the need for solid clinical evidence and adherence to regulatory requirements, which can hinder rapid adoption [8]. Unlike previous studies focused on Cognitive Behavioral Therapy apps for depression [4], our research offers a comprehensive view of DTx as regulated applications for various health conditions. It introduces a systematic classification framework for DTx features and highlights key design and implementation trends. Using the Gioia methodology, we developed a multi-layered framework, which is the first of its kind for DTx, enhances academic understanding, and has practical implications for their development and implementation.

One limitation of our study is the variation in the amount of data available for each application. To address this, data from multiple sources was cross-referenced whenever possible to ensure accuracy and completeness. Additionally, the dataset is limited to DTx found in Germany's DiGA directory, which currently focuses on low-risk devices. With DTx constantly evolving, our work is a snapshot of features in time.

5. Conclusions

The potential of DTx to improve health outcomes depends on creating engaging solutions rooted in solid clinical evidence. Incorporating advanced digital technologies has the potential to enhance effectiveness, but it presents a significant challenge due to the need to gather new evidence. Additionally, DTx can potentially enhance patient-provider interactions and data-driven insights through connected wearables, which is still limited for current solutions. The systematic framework developed in this study provides valuable guidance for designing future solutions that address challenges like adherence, ultimately contributing to treatment success. With new reimbursement pathways for DTx emerging worldwide, this work can be a crucial resource for developers, researchers, and entrepreneurs in developing new DTx.

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