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Inclusive Design Thinking for the Development of Digital Health Applications: A Methodology Review

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Abstract. Inclusive Design Thinking (IDT) is an approach that specifically addresses disadvantaged user groups and involves them in the innovation process. In recent years, IDT has emerged as a particularly promising approach for increasing citizen and patient engagement in the development of digital health applications. Although IDT is based on existing frameworks of design thinking and human-centered design approaches, there is still no overview of its methods for digital health solutions. Our aim was to develop such a systematic overview of the methods used, aligned with the design process, and thereby facilitate the practical application of IDT. 44 IDT methods could have been consolidated and assigned to the phases of the IDT process. This work provides the first systematic overview of IDT methods used for Digital Health (DH). Future work could expand on this and, for example, investigate the effectiveness of the methods in more detail.

Keywords. Inclusive design thinking, digital health, range of methods

1. Introduction

For around a decade, human-centered design (HCD; formerly often referred to as user-centered design, UCD) has played an increasingly important role in the development of healthcare technology: As a result, the needs of patients and healthcare workers could be addressed to a greater extent [1]. HCD not only involves patients and providers in the development of solutions, but also creates the basis for their quality, as required by regulations or the potential criticality of life in the healthcare sector [1, 2, 3]. Thus, HCD takes up the general quality requirements of ISO 9241 for the usability and ergonomics of interactive systems. Poor usability hampers the spread of IT in healthcare [3]. Although the establishment of HCD methods is already increasingly evident, there remains a great need to further reduce the exclusion of specific stakeholder groups in the development of domain-specific solutions [4, 5, 6], particularly for Digital Health (DH) applications [7, 8, 9]. In healthcare, achieving inclusion can be of great importance as either the (co-) users of applications or the direct potential beneficiaries — or at least the owners of the data processed for clinical, reimbursement or research purposes — are

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mostly patients; i.e. groups that are disadvantaged as such, e.g. due to their condition (physical challenges, but also dyslexia, concentration disorders, etc.), or compared to healthcare providers where information asymmetries coin patient-provider relationships. Also, underrepresented groups (such as minorities in general, older people, children or people with disabilities, etc.) often face inequalities and/ or are overrepresented in patient populations [9, 10, 11]. At the same time, we see that current DH applications, despite their potentials, only find slow acceptance in markets, like in Germany [12]. Hence, our contribution also aims at improving the understanding and use of corresponding methods for developing more stakeholder-oriented solutions.

An ongoing and — concerning the aforementioned challenges — promising trend within HCD approaches, not only for software applications, is the use of Design Thinking (DT) [13, 14], also refined as Inclusive Design Thinking (IDT) [15, 16, 17]. IDT in DH, as proposed by [18], involves a shift from a one-size-fits-all approach to a more nuanced understanding of how marginalized communities use DH applications. This approach, as emphasized by [19], considers the social context of use and engages the widest population as actual users. Based on DT, IDT is also a multiphase and iterative approach that can be subdivided into 5 phases [17], each with various potential methods:

- *Empathize*: What are users' needs and what is their reality of life?
- *Define*: Stating users' needs and (compare with) your objectives.
- *Ideate*: "Explore and identify possible solutions, develop outlines, scenarios, and storyboards of learning activities and experiences".
- *Prototype* (Build meaningful and authentic experiences) and
- *Test* (Evaluate your solution and check for opportunities of expression and for means of presentation and engagement. Test accessibility, check your users' understanding, attitudes and motivations).

Despite aforementioned growing recognition that IDT holds potential to realize benefits of DH, we were initially neither able to identify any explicit findings on specific IDT methods tailored for DH development, nor a comprehensive review of methodologies that categorize these methods into the phases of a typical HCD or IDT process. Such a review could significantly advance the rigorous implementation of IDT in DH, thereby ensuring both practical inclusion and the quality of applications. Against this background, the aim of our study is to fill this gap by conducting a comprehensive methodology review. Our research questions are as follows:

1. Which IDT-relevant methods are used with what frequency in the development cycle of DH?
2. In which phase of the IDT process have the methods identified in question 1 been used?

To address these questions, we employed a detailed questionnaire to select and analyze relevant studies, making our selection process and criteria clear.

2. Method

2.1. Search

The review was guided by the PRISMA guidelines [20]. EuropePMC, PubMed and Google Scholar were utilized as complementary resources to conventional literature databases due to the restricted accessibility prevalent in contemporary scientific research. Initially, an exploratory literature search was conducted, followed by a structured search. The search for "inclusive design thinking" AND "digital health" led to the original identification of Sinclair et al. [21] addressing IDT in DH and a corresponding Framework (IDTF). The IDTF does not prescribe a universal methodology, but rather delineates a problem-specific planning process based on DT. Due to the limited available findings, broader search was conducted. "inclusive design thinking" yielded 6 papers but no explicit results for DH. Therefore, the term "inclusion" was removed, and it was queried for "design thinking" AND "digital health", resulting in a more extensive list of results. A systematic analysis of these studies will ensure that the issue of inclusion is considered in the development of solutions. Various alternative terms for DH were gathered and consolidated, while similar approaches such as ID and HDT were also considered. The following three search queries were formulated to cover various aspects of the research domain:

- *"design thinking" AND ("digital therapeutics" OR "(digital|mobile) medicine" OR "medical care" OR ehealth OR health OR healthcare OR healthtech OR mhealth OR telecare OR telehealth OR telemedicine)*
- *"inclusive design" AND ("digital therapeutics" OR "(digital|mobile) medicine" OR "medical care" OR ehealth OR health OR healthcare OR healthtech OR mhealth OR telecare OR telehealth OR telemedicine)*
- *"health design thinking."*

The search was conducted until March 19, 2023. Due to the large number of results with a total of 91,789 articles, only the titles of the articles were searched. The text or abstract were not considered in the search. Thus, an identification of 409 studies could be made. 30 studies were added from eduIDT project (collected there for state-of-the-art analysis by exploratory research within corresponding journal articles and proceedings of conferences or projects; many of them originated from SpringerOpen or oapen.org).

2.2. Preselection

By selectively prioritizing studies with unrestricted access, this approach not only underscores the importance of inclusivity within academic discourse but also ensures the transparency of methodologies used in the identified studies. Consequently, only peer-reviewed full-text articles written in German or English and available as Open Access were included. Of the initial 439 studies, 243 were excluded due to lack of unrestricted access. After removing duplicates (n = 73), articles without peer review (n = 16), articles in languages other than German or English (n = 4), and articles containing only abstracts (n = 9) were excluded. Given the manageable number of 94 relevant studies, no time restrictions were imposed on the search.

2.3. Selection

During the selection process, the remaining 94 studies underwent an eligibility screening using a specially crafted questionnaire to ascertain whether they addressed DH, implemented DT and mentioned utilized methods and tools. In addition, it was checked whether the consideration of the topic of inclusion was mentioned in the identified studies. The determination was made that inclusion encompasses the act of considering specific user groups regardless of their physical or cognitive abilities, gender, age, or other characteristics. As aforementioned, it can be assumed that every patient for whom a solution is developed is permanently or temporarily disadvantaged. Therefore, only studies that developed solutions in DH that were accessible to all patients and not exclusively for healthcare professionals would be considered for further evaluation. The questionnaire of the proficiency test includes the following questions: (1.) Is DT covered in this article (2.) Does this article contain any products, prototypes or solutions for DH? (3.) Does this article mention methods or tools which were used? (4.) Does this article address inclusion? (5.) Is the product, prototype or solution inclusive? (6.) For which people is the product or solution intended? (7.) Was DT used to develop the product? Among the 94 studies, 86 were excluded: 22 did not apply DT, 45 did not address DH solutions, ten studies were excluded because they did not address a tangible or foreseeable real-world solution in the field of DH and their content was limited exclusively to theoretical aspects.

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Consequently, another nine studies were excluded due to their specific focus on healthcare professionals. The remaining eight studies underwent a detailed full-text analysis guided by the following inquiries: (1.) Which methods or tools were used? (2.) Were (I)DT methods applied in distinct phases, or were the researchers' own interpretations used? (3.) Which phase of (I)DT can the methods or tools be assigned to? The review was conducted by a single assessor and subsequently verified by another. The remaining eight studies were of specific relevance to healthcare and inclusivity: Sinclair et al. optimized health messaging in American Sign Language for the deaf community during the COVID-19 pandemic using DT [21]. [22] used DT to design prototypes for young people with cerebral palsy transitioning to adult health services. Hou et al. developed a culturally sensitive app for breast cancer self-management in Taiwan [23]. [24] combined DT with qualitative interviews to optimize app-based interventions for eating disorders. Marti et al. created a solution for pediatric orthodontics, highlighting DT's effectiveness in solving complex healthcare problems [25]. [26] explored the integration of indigenous storytelling with DT for adolescent mental health. Shaveet et al. analyzed a browser extension for reliable health information retrieval among older adults, primarily focusing on the 'Empathize' phase of DT [27]. Eventually, [28] developed a digital solution for heart failure patients, emphasizing patient involvement throughout the DT process.

3. Result

The results of the identification and pre-selection are shown in Figure 1.

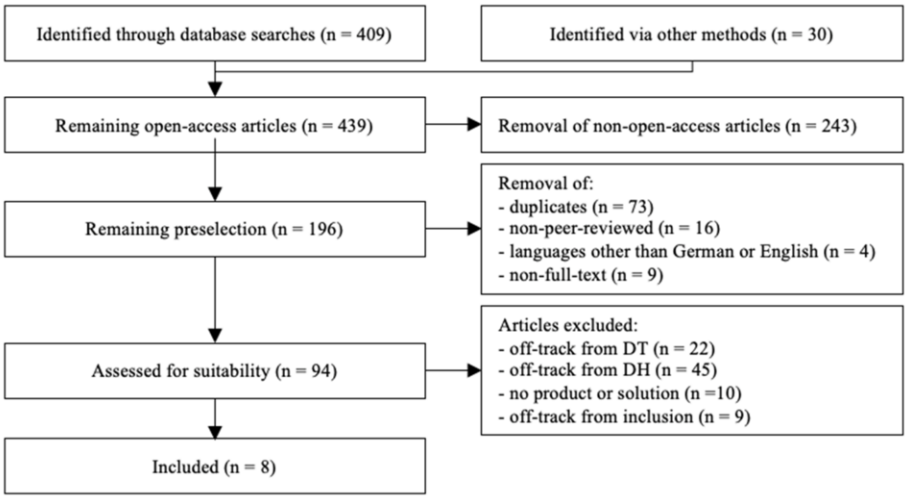

Figure 1. PRISMA flowchart for study identification and inclusion

It was possible to extract 72 methods used as part of DT. Thereof, 69 could be assigned to known approaches, including from the areas of DT or team building if not done already in the original research. After consolidation, a remainder of 44 methods was assigned to respective phases in Table 1 along with identified frequency of use. The sorting was first according to frequency of use, then alphabetically, so that methods are usually more significant when closer to the top of the table.

Table 1. IDT methods, targeted solutions, frequency of use within phases (E=*Empathize*, D=*Define*, I=*Ideate*, P=*Prototype*, T=*Test*)

Method	Targeted Product/ Solution	E	D	I	P	T
Testing With Users [29, p. 55]	App, Digital platform, Videos				2	3
Brainstorming [29, p. 41]	App, Digital platform, Website		2	2		
Interview For Empathy [29, p. 19]	App, Videos	4				
Empathy Probe [29, p. 75]	App, Digital platform, Videos	3				
Literature Review [30]	App, Digital platform	2	1			
Rapid Prototyping [31]	App, Videos				3	
2x2 matrix [29, p. 29]	App, Website			1	1	
Define Insights [32, p. 45]	Digital platform, Videos					
Empathetic Data [29, p. 71]	App	1			1	
Empathy Map [33, p. 20]	App	2				
Find themes [32, p. 43]	App		2			
Personas Creation [33, p. 17]	App	2				

Method	Targeted Product/ Solution	E	D	I	P	T
Questionnaire [34]	App, Digital platform	1				1
Saturate And Group [33, p. 18]	App, Website		1	1		
Select Promising Ideas [32, p. 53]	App, Digital platform			2		
Story Share And Capture [29, p. 23]	App, Digital platform, Website	1	1			
Thematic Analysis [35]	App		1			1
Mock-ups [29, p. 61]	App			1	1	
Affinity Estimation [36]	App		1			
Brainstorm Rules [32, p. 51]	App, Website			1		
Clinical Trial/ Study [37]	Digital system					1
Describe Your Concept [29, p. 77]	App, Website				1	
Describe Your Idea [32, p. 55]	App, Website			1		
Ethnographic Interviews [38]	mHealth app	1				
How Might We...? [29, p. 37]	App, Website		1			
Self-Instruction Cards [23]	App	1				
Icebreaker Questions [39]	App	1				
Idea Matrix [40]	mHealth app			1		
Journey Map [29, p. 25]	mHealth app	1				
Make Prototypes: Present [32, p. 58]	App			1		
Make Sense Of Findings [32, p. 44]	App optimization		1			
Online Survey [41]	Digital system				1	
Persona stories in Game-Storming [42]	App	1				
Platform Research From User's Perspective [27]	Analysis	1				
Point-Of-View Framew. [29, p. 33]	App, Website		1			
Prototype To Decide [29, p. 57]	mHealth app				1	
Prototype To Test [33, p. 37]	Digital system				1	
Qualitative interview [43]	mHealth app					1
Reality Check [32, p. 54]	App, Website			1		
Rose Thorn Bud [44]	mHealth app			1		
Seek To Understand [45]	App	1				
Shooting (video) [29, p. 85]	Digital system	1				
Storyboard [46]	mHealth app				1	
Visual Note [47]	mHealth app			1		

Ten methods were used in several phases, 18 were found in more than one reference. 24 methods were assigned to phase *Empathize* (33.3%), both 14 to *Define* and *Ideate* (each 19.4%), 13 to *Prototype* (18.1%), and seven methods to *Test* (9.7%). References given can be used to find the extended advice we cannot include within this format

(amongst others, Empathy Probe is relatively complicated for a short description; if an overview is sought, [29] provides advice on many methods). As an example, we will briefly introduce Interview for Empathy as probably unfamiliar yet rather initial (and in that sense basic method that we found more frequently). Also, that might help with understanding IDT characteristics:
An Interview for Empathy should be in-person, to learn a person's needs, behaviors and choices. Open question formats with time for reflection are recommended (no question is redundant, but each shall be specific). Ideally, interviewees get to feel encouraged to tell stories. Inconsistencies between actions and interview contents provide useful insights, so does nonverbal communication: hence, two interviewers are suggested for enhanced 'recording' with all their senses available [29, p. 19].

4. Discussion and conclusions

This work provides the first systematic overview of IDT methods used for Digital Health (DH). Concerning the search, the abundance of alternative designations for DH might not have been surveyed completely and only contributions available and without health professionals were studied. Peer-reviewed outlets have been considered, excluding promising theses with relevant content, like [48]. Because of the limited research available, the number of individuals involved was not used as an exclusion criterion. Future research could compensate for that.

For collecting the methods, dedicated applications and tools were extracted during the evaluation, first. Various could be listed, such as digital post-its on a collaborative online whiteboard (Miro), rapid prototyping and "Online Surveys" [41] etc. Those could serve as a basis for creating a toolbox including other useful tools per method, thus facilitating engagement throughout use of the methods. IDEO [32] and d.school-related authors [29, 33] are most frequent original sources. Six out of eight studies were oriented to the five DT phases of d.school. Hence, it might be appropriate for research or practice to be oriented to this model, too. It has been proven that only two methods are currently explicitly known to the process IDT in DH. All other methods compiled come from areas such as DT, research, etc. Consequently, for identifying additional methods it makes sense to focus approaches aimed at the development of people-centric products or services since only the targeted user group of a solution determines whether the topic of inclusion was taken into account respectively and a method is really relevant for IDT.

When comparing the methods identified with corresponding ones from the four HCD phases, we can state some congruence as well as deviations with contemporary scholarly literature for DH [49]. E.g. as following were shared during HCD phase for

1. *context analysis*: questionnaires or focus groups (related to Brainstorming / Idea Matrix / Describe your idea / How Might We Questions), but no observations;
2. *requirements engineering*: use of personas;
3. *design*: mock-ups or prototypes, but no card-sorting;
4. *evaluation*: testing (e.g. with users), but no cognitive walkthroughs.

In a nutshell, the identified IDT methods seem to basically support each phase of HCD without just copying already suggested methods. If we look at the concept of Human Factors & Ergonomics (HF/E), recently also discussed for DH [50], shared design methods are, as per above, focus groups and questionnaires, but also interviews ("for empathy" or of ethnographic or qualitative kind) and surveys (e.g. online). Compared to HF/E, our findings miss e.g. heuristic analyses and, again, observations and cognitive

walkthroughs. Nonetheless, we have some overlap here, too. It could be surveyed in the future to what extent other IDT methods described here could be of complementary use for HCD and HF/E.

Regarding the assignment of methods to DT phases: Documentation of the DT process and its methods is minimalistic or too problem-specific in Sinclair et al. (neither elaborated in [21], nor by other work of these scholars like [17], nor by alternative references [24; 27]), so that few general methods could be identified. Therefore, these studies provided less value to our research questions. Regarding phase assignment in general, fewer methods were identified for *Prototype* and *Test*. This might indicate that these phases may need additional future research. In contrast, the *Empathize*, *Define*, and *Ideate* phases already 'own' numerous methods. Here, the focus should be on evaluating their effectiveness and, where necessary, developing more specific ones. There are methods identified that were applied more frequently, e.g. in different phases. That is why we would propose to focus more on them for teaching and research purposes.

This review did not conduct a comprehensive quality assessment. Consequently, some biases or ambiguities may be present that could affect the interpretation of the results. For improved accuracy and reliability, future work should focus on an assessment of bias risks and the quality of included studies by systematically assessing factors such as frequency of citations and adherence to supporting evidence for citations, illustrations, tables, and other artifacts. Complementing or alternative methods that may yield further outcomes are Pearl-growing or starting with a collection of relevant approaches, with a following search for studies applying the collected methods. In addition to the approaches considered, such as DT and IDT, there are other people-centric approaches, such as HCD, Inclusive HCD, Patient-Centricity, Patient-Centered Design, Participatory Design, or Universal Design. These approaches may provide additional methods that can be applied in IDT and should also be explored. Furthermore, methods from other approaches, such as Agile Software Development, can be applied. This reduces the design phase to a minimum and involves stakeholders in the development process (divided into sub-processes whose content and goals are determined in consultation with the stakeholders during the implementation of the respective project) as early as possible [51]. These agile methodologies could also be useful for IDT to improve user involvement and address their problems, thus increasing the effectiveness and efficiency of development. [52] provide an extensive collection of approaches, theories, methods, frameworks or synonyms for DT as appendices.

A 2018 study had already examined the application of DT in health. The authors determined whether DT had already been successfully applied [53]. However, they did not focus on DH. Therefore, it is useful to evaluate this specific topic to allow for a more accurate assessment of the effectiveness of DT in this domain. Our approach should also analyze whether DT can be used for inclusive design, here. In this light, our methodological approach proved to be appropriate. The results of a preliminary query showed that our search needed to be adapted. Consequently, additional studies could be identified that applied DT in DH (also for development). Those were systematically analyzed to ensure that inclusion was considered. The set of methods and recommendations thus collected was then compiled and evaluated.

To further test the resilience of study's results, follow-up investigations can be carried out that rely on expert interviews, surveys, case studies or on a quantitative study with subsequent statistical evaluation. It should be noted that the recommendations for action derived have not been integrated into practice, but will for facilitated operationalization become part of a teaching initiative on Inclusive Design Thinking in

the Technically-Oriented Subjects at Higher Education Institutions (eduidt.eu). Of course, besides the referenced use or suggestion, the quality of the identified IDT methods has to be checked as well. That should be another topic for future work in this field. With the resulting range of methods, however, guidance has been provided here for applying them to the individual phases of IDT in DH.

Declarations

Conflict of Interest: All authors declare that there are no financial or personal conflicts of interest related to the research, authorship, and/or publication of this article.

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