Research Participants’ Engagement and Retention in Digital Health Interventions Research: Protocol for a mixed-methods systematic review

Luciana Terceiro, Mudassir Inram Mustafa, Maria Hägglund, Anna Kharko

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Abstract

Background: Digital health interventions have become increasingly popular in recent years, expanding the possibilities for treatment for various patient groups. In clinical research, the development of the intervention continues, but there are still obstacles to overcome regarding participant engagement and retention. This may be partially due to the digital health platforms used, which may lack adequacy for participants.

Objective: This systematic literature review aims to investigate the relationship between digital health platforms and participant engagement and retention in clinical research. It aims to map and analyse key concepts and definitions of engagement and retention, as well as identify design characteristics that influence them.

Methods: The proposed review will be a mixed-method systematic literature review, analysing qualitative and quantitative studies. The search strategy includes the electronic databases PubMed, IEEE Xplore, CINAHL, Scopus, Web of Science, APA PsycINFO, and the ACM Digital Library. The review will encompass studies published between January 2018 and June 2024. Criteria for inclusion will be digital healthcare interventions conducted via digital health platforms like websites and web and mobile applications utilised by patients and informal caregivers as research participants. The main outcome will be a narrative analysis with key findings regarding terminologies and descriptions, and critical factors, concepts and definitions concerning research participants’ engagement and retention. Quality assessment and appraisal will be done via the mixed-methods assessment tool. Data analysis and synthesis will follow the PRISMA 2020 flow diagram. Quantitative data will be qualitized and integrated into qualitative data, which will be analysed using thematic analyses and syntheses.

Results: The study expects to map and summarise critical concepts, definitions of participant engagement and retention, and the characteristics of digital health platforms that influence them. The systematic review is expected to be completed in June 2025.

Conclusions: This systematic review aims to contribute to the growing digital clinical research and patient-centred design fields, providing a comprehensive reference for developing more engaging and effective digital platforms and software for clinical research. Clinical Trial: CRD42024561650; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=561650

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Research Participants’ Engagement and Retention in Digital Health Interventions Research: Protocol for a Mixed-methods Systematic Review

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Abstract

Background:
Digital health interventions have become increasingly popular in recent years, expanding the possibilities for treatment for various patient groups. In clinical research, the development of the intervention continues, but there are still obstacles to overcome regarding participant engagement and retention. This may be partially due to the digital health platforms used, which may lack adequacy for participants.

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Systematic review registration (PROSPERO): CRD42024561650; https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=561650

Keywords:
eHealth; mHealth; medical informatics; digital healthcare; clinical research informatics; digital health intervention; digital health platform; participant engagement; participant retention; design guidelines.

1. Introduction

In 2022, over 100,000 healthcare mobile applications were available in Apple and Google app stores combined [1]. Digital healthcare has transformed care delivery through a diverse fleet of technologies, from mobile applications and wearable devices to biosensors and the Internet of Things [2]. It offers a myriad of innovative ways to provide treatments, monitor health conditions, assist and empower patients with diverse needs to be more in charge of their health, and enable healthcare professionals to deliver better service [3]. Following the expansion of the digital healthcare range, digital health (DH) interventions have also increased exponentially (see Textbox 1).

Through online treatments, DH interventions promise to improve healthcare, enhancing accessibility, effectiveness, and personalisation [2,4]. DH interventions are available in commercial applications, as easily accessible healthcare, and as part of clinical research (see Figure 1). When conducted as part of clinical research, they share the same benefits as general digital healthcare. DH interventions also allow for the development of effective treatments for more patients [4], are more community-inclusive [5], decrease health disparities [6], and improve study generalizability and validity [7,8]. Successful clinical research generates evidence that, in turn, promotes healthcare improvements [9].

In clinical research, DH interventions are designed following the principles of clinical research informatics (CRI) [10]. DH interventions delivered via CRI can potentially accelerate the process, from initial research to "real world" outcomes, contributing to increasing scale and distribution, cost and resource optimisation, and facilitating financial auditing processes [5,9,11,12]. CRI principles can be particularly useful for the design and research of DH interventions, where engagement and retention are challenging.

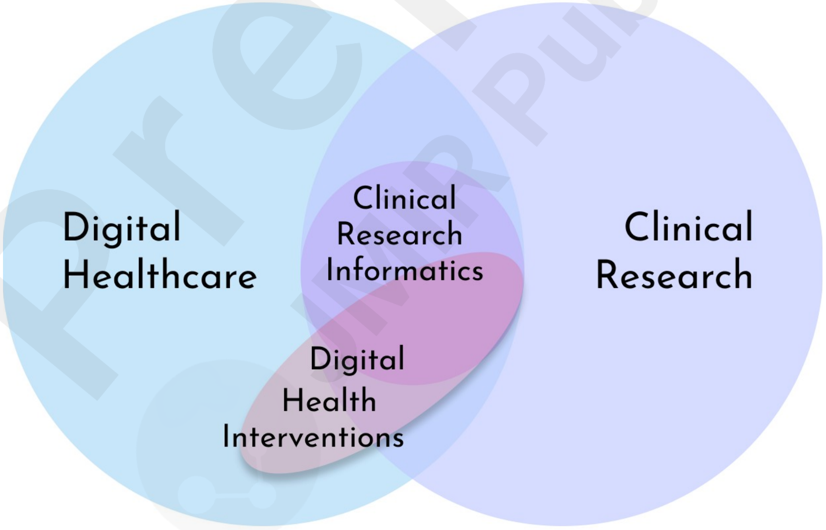

Figure 1. Digital health interventions are part of general digital healthcare and clinical research. The latter can be delivered via clinical research informatics or commercial health platforms and software.

Both engagement and retention of clinical research participants are crucial in the study of DH interventions, but the concepts have varying definitions. Frequently, different terminologies are used interchangeably, like involvement, participation, acceptability, and completion rates, among others. Engagement can be described as the extent and manner in which people actively use a resource [13]. Perski et al. define engagement as two main concepts: a subjective experience, meaning a state of focus and interest with a temporal dissociation, and behaviour, described as usage over time [14]. It is often connected to concepts like adherence, duration, and frequency that can be quantified through concrete measurements like opening or using a mobile application, frequency of times, or the duration of the use [15]. Participant retention, in turn, refers to the proportion of recruited participants who remained in the study until its end and in an optimal number in order to not compromise the study's validity [16,17]. Retention encompasses activities and tactics “to keep patients enrolled and from withdrawing or dropping out” [18].

Engagement and retention numbers vary considerably. Intervention dropout from Internet-based treatment for psychological disorders, for example, may vary between 30% and 50% [19]. While the lack of engagement or retention may be due to the intervention quality or outside factors, an often overlooked component is the design of DH platforms. Considering the DH platforms' design choices and how they impact participant engagement and retention could help make DH interventions better. Comprehending that there is still an opportunity to explore the concepts and practical factors related to engagement and retention, this systematic literature review will focus on DH platforms’ design choices concerning engagement and retention and their relationship with research participants' behaviour.

1.1. Objectives

The relationship between DH platforms and research participants is receiving growing interest, as evidenced by the increase in research. Studies examine participant engagement and retention in various settings, e.g., mHealth or web-based platforms [15,20], or focusing on particular patient groups, e.g., older adults with dementia or digital mental health interventions [21–24].

However, a comprehensive literature review on the relationship between DH interventions and participant engagement and retention in digital clinical research has yet to be conducted. This review aims to fill this gap by examining DH platforms used in this context, mapping the various concepts and definitions that capture the engagement and retention of research participants in DH interventions conducted for clinical research, and identifying aspects and characteristics that hinder or promote participants' engagement and retention in this context, exploring the DH platforms design factors and features that affect them. The key concepts relevant to the review are defined in the Textbox 1.

Textbox 1. Key concepts.

Digital health (DH) intervention — Interventions delivered via digital technologies such as smartphones, websites, wearables, video games, or text messaging [2,25,26]. A DH intervention offers guidance, information, and support for a diversity of physical or mental health conditions via a digital platform [27]. Also known as health informatics interventions: interventions designed to help people avoid, recover from, or cope with disease and disability or to improve the quality and safety of healthcare [28]; digital self-help interventions [29]; self-guided eHealth interventions [30]; eHealth interventions [31].

Digital health (DH) platforms — Websites, web-based or mobile applications used to access DH interventions.

Digital clinical research — Clinical research that is conducted via DH platforms. It may include DH interventions, digital data collection, and electronic Case Report Forms, among other resources. Only digital clinical research encompassing DH interventions will be considered for this study.

Research participant —Recipients of intervention, e.g., patients or informal caregivers.

Participant engagement — Length and depth of participant's involvement with the DH intervention.

Participant retention — Duration and continuity of the participant's involvement with the DH intervention.

2. Methods

This systematic review was submitted for registration with the International Prospective Register of Systematic Reviews (PROSPERO) on June 8, 2024 (CRD42024561650) to avoid bias in conducting and reporting findings. According to the study's progress, amendments will be made if necessary [32].

2.1. Review question

The review question was elaborated using the Population-Exposure-Outcome (PEO) statement, as outlined in Table 1. As pointed out by Bettany-Saltikov and McSherry, the choice of PEO is due to the be more appropriate for qualitative questions, which is the main objective of this literature review, and more adequate to define associations between particular exposures and factors and related outcomes [33,34]. The overall review question is: What factors and aspects promote research participants' engagement with and retention in DH interventions in digital clinical research? This was further broken down into two specific research questions:

Research Question 1: How are engagement and retention of research participants defined in DH interventions conducted for clinical research?

Research Question 2: What user interface elements, interaction design and platform resources influence research participants' engagement and retention in DH interventions?

Table 1. PEO structure.

Population	Research participants - patients, informal or family caregivers
Exposure	User interface, interaction elements and platform resources of digital health interventions conducted in clinical research
Outcomes	Engagement and retention

2.2. Methodology choice rationale

The choice to perform a mixed-method systematic literature review is due to the number of individual studies that have already been conducted in digital healthcare and DH interventions, providing substantial evidence for the review.

The methodology selected for this systematic literature review is the mixed-methods systematic review (MMSR) [35]. It is a valuable approach that formally combines qualitative and quantitative data to synthesise evidence when addressing complex questions that require a comprehensive understanding of a subject [36]. By integrating the findings of effectiveness (quantitative evidence) and participant’s experiences (qualitative evidence), an MMSR can offer a comprehensive and nuanced perspective, enabling one to make well-informed and balanced choices considering the quantitative data and the qualitative insights [37].

One key justification for utilising an MMSR is the recognition of the diverse types of information, which is likely the case in this study. These multifaceted considerations necessitate a more holistic approach. The two perspectives—qualitative and quantitative—are often interdependent and complementary. Qualitative data can shed light on the context, patient and informal caregivers' experiences, and barriers to engagement and retention, which quantitative data alone may not fully capture. Hence, both perspectives are essential to presenting a comprehensive and nuanced synthesis in a systematic review.

2.3. Search strategy

In the scope of this investigation, we will analyse studies that (1) offered a DH intervention; (2) employed a DH platform component, such as a mobile app, website, or text-messaging process; (3) collected engagement and retention-related measurements and data - qualitative, quantitative, or both; and (4) had a digital interface with research participants - patients and informal caregivers - to interact with the DH intervention. The DH platforms can be designed specifically for clinical research or not. Commercial health applications will be considered if they are used for clinical research purposes.

The search strategy for this systematic literature review was developed in collaboration with Görel Sundström, a librarian from Uppsala University, and the researchers involved in this study: Luciana Terceiro, MSc, Anna Kharko, PhD, Mudassir Mustafa, PhD, and Maria Hägglund, the study's principal supervisor.

The research team utilised the keywords specified in the PEO (Population, Exposure, Outcomes) statement to construct the search strategy and incorporate synonyms for these keywords, as exemplified in Table 2. The keywords refinement process involved different approaches: tests conducted by the librarian, consultation of referenced articles to analyse the keywords they employed, and expert reviews conducted by our research team. The keywords selection process was performed to ensure the search would capture studies using various terminologies to address the same research questions.

Table 2. Preliminary Web of Science search strategy (to be adapted for the other databases)

Main topic	Search number	Database search algorithm

User Engagement, User Retention, Metrics	1	("active user*" OR Attrition OR "Click rate" OR "Completion rate*" OR "Frequency of use" OR "Follow up" OR Login OR "log in" OR "Returning user*" OR "Session duration" OR "Sign in" OR "Study complet*" OR "Time spent" OR usage OR "User actions" OR "Use Rate*" OR "User metric*" OR "user session*")
	2	((Caregiver* OR "Healthy Volunteer*" OR "Research Subject*" OR participant* OR patient* OR subject* OR user*) **NEAR/3** (accept* OR activit* OR adher* OR attitude* OR barrier* OR challeng* OR complian* OR discontinu* OR Disengagement* OR Dropout* OR Efficien* OR Effectiveness OR engag* OR evalutation* OR experience* OR Finish* OR involvement* OR interaction* OR obstacle* OR participation* OR perception* OR perspective* OR retention* OR satisf* OR visit* OR view*))
	3	1 OR 2
Clinical Research Informatics / Digital care	4	("Clinical informat*" OR "Clinical research informat*" OR "Clinical trials informatic*" OR CRI OR "digital care" OR eHealth OR e-health OR etherap* OR "e-Mental health" OR "Health informati*" OR iCBT OR "Internet Cognitive Behavioral Treatment*" OR "medical informatic*" OR mHealth OR m-health OR mtherap* OR m-therap* OR "Online Clinical Trial*" OR telerehabilitation)
	5	(("clinical research" OR "clinical trial*" OR "medical research" OR health OR intervention* OR psychotherap* OR therap* OR "self-help program*" OR treatment*) **NEAR/3** (Computer* OR cyber OR Digital OR electronic OR informatics OR Internet OR Mobile OR Online OR Smartphone OR "Technology Based" OR "Web based"))
	6	4 OR 5
Design and aspects of software or digital platform	7	("Interaction design*" OR Interface OR Usability OR "User centered design*" OR "Visual design*")
Combining all topics	8	3 AND 6 AND 7

The search will be conducted across a range of electronic databases: PubMed, IEEE Xplore, CINAHL, Scopus, Web of Science, APA PsycINFO, and the ACM Digital Library. These databases are chosen based on their relevance to the research topic and their widespread use in academic and research communities.

In addition to the electronic database searches, the research team will employ additional search methods to identify potential studies that may not be captured through the database searches. It includes hand search, which involves manually scanning relevant journals; back-forward citation tracking, where we examine the references of identified articles; and reference checking to ensure no valuable sources are overlooked during the review process.

This systematic literature review does not involve collecting primary data; therefore, ethical approval is not required for this research.

2.4. Study selection criteria

The PEO statement outlines the eligibility criteria for study inclusion and exclusion, delineating them by population, exposure, and outcomes (see Table 3).

Table 3. PEO inclusion and exclusion criteria.

PEO	Inclusion criteria	Exclusion criteria
Population	Research participants, study participants, patients, informal caregivers, carers, caregivers, and users. No exclusion based on age or gender.	Researchers, physicians, doctors, nurses, social care workers, social workers, dentists, and healthcare professionals.
Exposure / Environment	User interface and interaction design of digital health interventions	Engagement and experience related to the intervention and/or treatment itself. Experience with content quality (text and multimedia content).
Outcomes	Engagement and retention to the study	Efficacy of the treatment, efficacy related to the intervention/treatment itself.
Study methods	Qualitative methods, Quantitative methods, mixed methods	Reviews (systematic, scoping, meta-analysis, etc.).
Publication types	Formally published peer-reviewed journal articles, conference papers	Grey literature, opinion pieces, protocols, reviews
Geographical considerations	Initially not limited to any geographical area	

2.4.1. Types of studies

Qualitative Studies: Qualitative interviews, focus group discussions, usability studies, participatory research, participatory design, case studies, grounded theory research, thematic and content analysis of textual data, phenomenological studies, narrative research, and ethnographic observations.

Quantitative Studies: Randomized controlled trials (RCTs), cohort studies, longitudinal studies, experimental studies, case-control studies, cross-sectional studies, and observational studies.

Mixed-methods studies: Studies integrating qualitative and quantitative data collection and analysis methods within a single research design, encompassing but not restricted to convergent design, sequential explanatory design, and sequential exploratory design.

In the case of studies addressing the same DH intervention and cohort of individuals, only the study with broader and more detailed data regarding engagement and retention-based measurements will be considered, unless the studies present different aspects of the two mentioned subjects.

Studies such as grey literature, editorials, letters, opinion papers, and theses and dissertations will be excluded.

2.4.2. Time period

The study will consider articles published from January 2018 to June 2024. This seven-year publication window was chosen because the research team recognises the rapid evolution in the Technology and Informatics domain. Consequently, studies conducted before 2018 may contain outdated information and were excluded from consideration.

2.4.3. Language

Due to resource constraints, the study will exclusively include articles published in English. The research team acknowledges that this approach limits the inclusion of studies performed in different parts of the world and published in other languages.

2.5. Study screening

Initially, a search conducted by an independent librarian will identify potentially eligible studies based on predefined keywords that consider the inclusion and exclusion criteria. The results from this initial search will undergo deduplication: Duplicates will be identified and removed using EndNote 21, employing the Bramer et al. guidelines [38]. The remaining studies will be imported into Rayyan [39]. There, data will be screened in two steps: (1) title and abstract screening, and (2) full-text screening., During the first step, at least two reviewers will independently review the titles and abstracts, blinded to the authors' names and to each other's review decisions (i.e., double-blinded) [39]. After, the potential articles will have their full text screened, filtered, and categorised according to the predefined inclusion and exclusion criteria. In the event of disagreements between the two reviewers, at either stage of the review process, a third reviewer will be consulted to reach a consensus.

2.6. Data extraction

The data extraction will use a standardised data extraction form elaborated by the research team. The form is designed to capture study information such as:

1. Identification: study ID, authors, year, country, publication type and analysis type (qualitative, quantitative, mixed-methods).
2. Characteristics: research participants' characteristics, age, sample size, intervention description, digital platform or software and the medium used,
3. Results: engagement and completion measurements, results and findings presented in qualitative and quantitative data, and measurement tools.

Other information may be added as the research team considers it relevant to the analysis. One reviewer will independently extract the data, and a second reviewer will check it for accuracy and completion. The extracted information will be organized in a previously formatted table in Microsoft Excel software. Qualitative data regarding results and findings will also be collected. The qualitative data will be analysed using NVivo 14 software afterwards.

2.7. Quality assessment and appraisal

The study plans to employ the mixed-methods assessment tool (MMAT) for quality assessment and critical appraisal [40]. The choice was based on the fact that MMAT provides, in a single tool, a methodological approach to assess quality criteria on a diversity of study designs, such as qualitative studies, quantitative randomised controlled trials, quantitative non-randomised, quantitative descriptive and mixed-methods studies [41]. The evaluation aims to assess aspects such as the clarity of the research question, appropriateness of the study design, data collection methods, data analysis, findings and interpretation of results and outcomes.

2.8. Data analysis & synthesis

The selection procedure will be presented following the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols) 2020 flow diagram to facilitate visualising the identification, screening, and number of included article steps, as seen in Figure 2 [42].

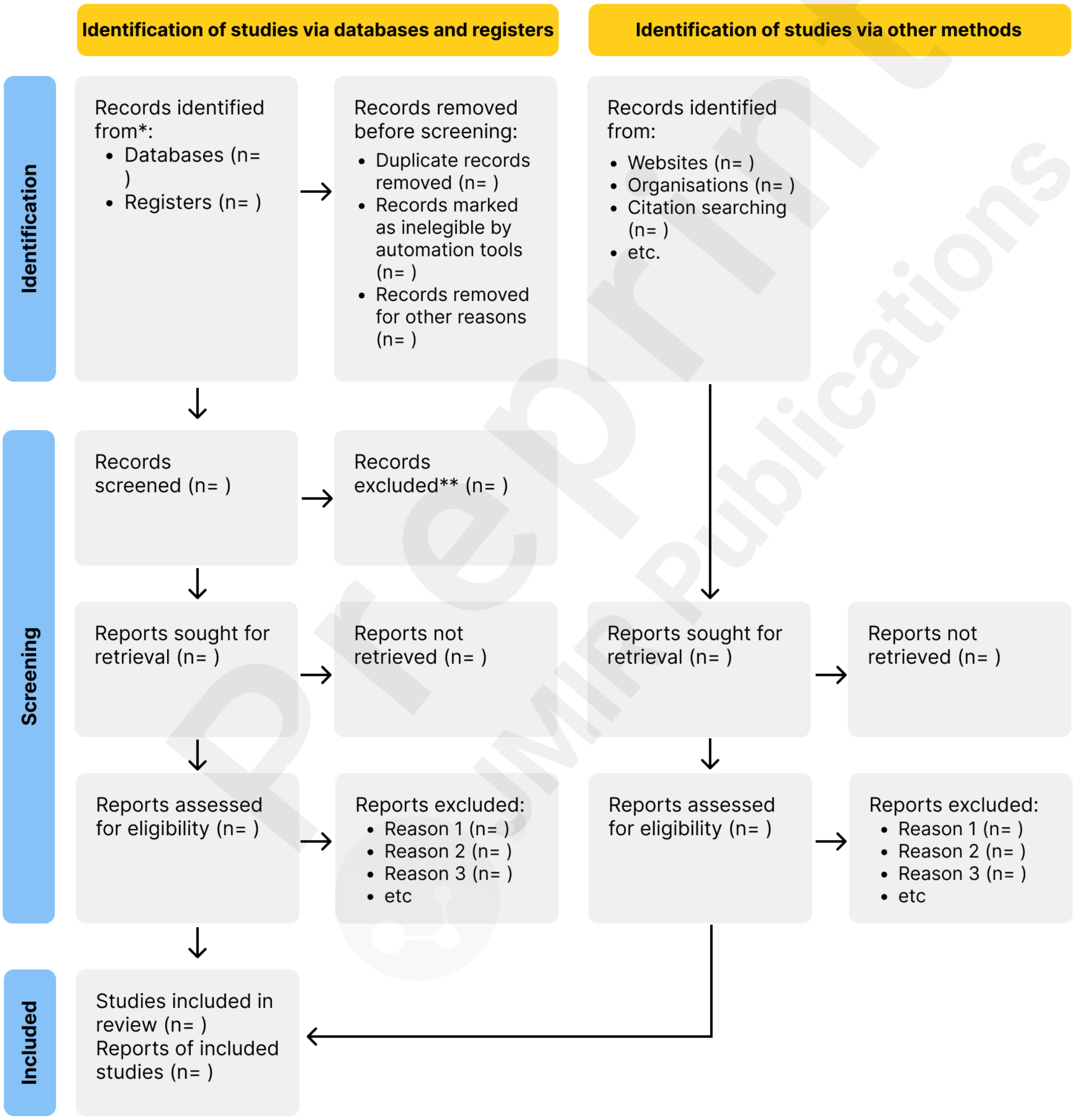

Figure 2 - Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols.

Data related to the identification of the study and its characteristics will be organised in summary tables. Since the data will potentially arise from diverse study designs, quantitative data will be submitted to a data transformation process to be qualitized to be converted into qualitative data in the form of themes and categories and afterwards summarised in a narrative synthesis to allow further integration with qualitative data [37,43,44]. Once qualitative and quantitative data are integrated, they will be compiled through a thematic analysis in order to identify the main concepts regarding engagement and retention. The codes for this investigation will be developed by one of the reviewers and checked by at least one member of the research team. The codes will be built using the Persuasive System Design framework developed by Oinas-Kukkonen and Harjumaa as a basis [45]. Kelders et al. have already applied this framework in the digital health area [20]. Two independent reviewers will conduct the coding, and discrepancies and new codes will be discussed between the two reviewers. If no agreement is reached, a third reviewer will be consulted to reach a consensus. Afterwards, the major themes and subthemes will be summarised in a narrative synthesis. One of the authors will compose the narrative synthesis, and a second author will assess and provide appraisal.

2.9. Dissemination strategy

The dissemination plan encompasses a series of steps in order to promote transparency regarding the process. The results of this study will be disseminated as a scientific publication in a peer-reviewed journal and presented at conferences. Plain-language summaries will also be produced to share in various channels, such as social media, ResearchGate, and technology and healthcare websites.

3. Results

As of June 2024, the literature review has conducted two pilot searches to test and refine keywords and verify the initial quality of results. As the review question stipulates the inclusion of a wide range of research designs, including qualitative and quantitative designs, the main results from our investigation will be organised into major themes and subthemes, and key findings regarding terminologies and descriptions will also be present. The review aims to establish the critical factors, concepts and definitions regarding research participants' engagement and retention in DH interventions and present them in a narrative synthesis. The study is undertaken without external funding. The results are expected to be published as a systematic literature review and submitted for publication in June 2025.

4. Discussion

Despite the undeniable benefits of technology in clinical research, various aspects still demand further investigation and development, such as the relationships between research participants and the technology that mediates it. As highlighted by Johnson, connected technologies have provided many new opportunities in clinical research in recent years, such as increasing research awareness, recruitment options, and delivering interventions and treatments [46]. However, achieving a high rate of participation required to ensure the quality of the investigation's results is still a challenge. To fulfil these new opportunities, researchers and developers within clinical research informatics are becoming more aware that developing satisfactory software for research participants to expand intervention reach is essential. Although a "user-centric" approach has increased through participant-centred initiatives, according to Kaye et al., digital clinical research is still on the journey to find ways to reduce the time and labour requirements that hinder participant involvement [7,47]. Offering a proper setting to a plurality of participants is fundamental to guaranteeing clinical research quality; otherwise, CRI risks increasing healthcare inequalities and disparities. The computerisation of society, including digital healthcare, may cause unintended and negative consequences [48]. Technological interventions that do not consider socioeconomic factors such as financial situation, race, ethnicity, age, education, and digital literacy present higher chances of producing intervention-generated inequalities, increasing the digital divide, and may only benefit the already more advantaged populations [26,28,49].

Researchers have long experimented with strategies for engagement and retention. Attributes like suitability to devices and technology, system usability, visual design, content, and adaption to literacy levels should be carefully observed to promote higher accessibility. These factors influence access conditions by minimising attrition but do not necessarily guarantee engagement, retention, and adherence. Another raised aspect is that engagement and retention may be promoted by factors that pertain to the particular characteristics of the digital platforms and software, like usability and system features, and others are research strategies, such as compensation, as pointed out by Amagai et al. [15]. On the other hand, aspects like gamification, reminders and notifications, social support provided within the DH intervention, personalisation and tailored content and features, incentives and rewards, lower levels of technical difficulties and system errors, adequacy to participant's physical and cognitive conditions, adequacy to technology literacy levels, are pointed out as incentives to maintain participant’s engagement and retention [15,20,21].

Establishing factors that can be applied to various scenarios is challenging since there is an extensive range of health applications for conducting healthcare interventions and diverse studies utilising different measures of their usefulness and effectiveness. Indeed, further limitations that may constitute challenges for this investigation include the potential heterogeneity of studies, methods, sample populations, and terminologies. However, preliminary findings show that concepts like personalisation and fit to participants' conditions and needs, as mentioned previously, are helpful no matter the intervention. This literature review strives to collect these concepts and determine how studies could comply with them.

Systematic reviews are considered one of the best sources of research evidence and have supported decision-making in healthcare in recent decades [41,50]. Acknowledging the relevance of this resource, this review aims to contribute to the growing field of digital clinical research and patient-centred design, providing a comprehensive reference for developing more engaging and effective digital platforms and software for clinical research.

Acknowledgements

The authors would like to thank Görel Sundström for assisting with the search strategy.

Data Availability

The data used for the review are openly available and can be retrieved from the following databases: APA PsycInfo, PubMed, and Web of Science Core Collection.

Authors Contributions

Idea conception: LHT, AK, MH; initial manuscript draft: - LHT; manuscript revision - LHT, AK, MH, MIM; visualisation - LHT. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

Conflicts of Interest

None declared.

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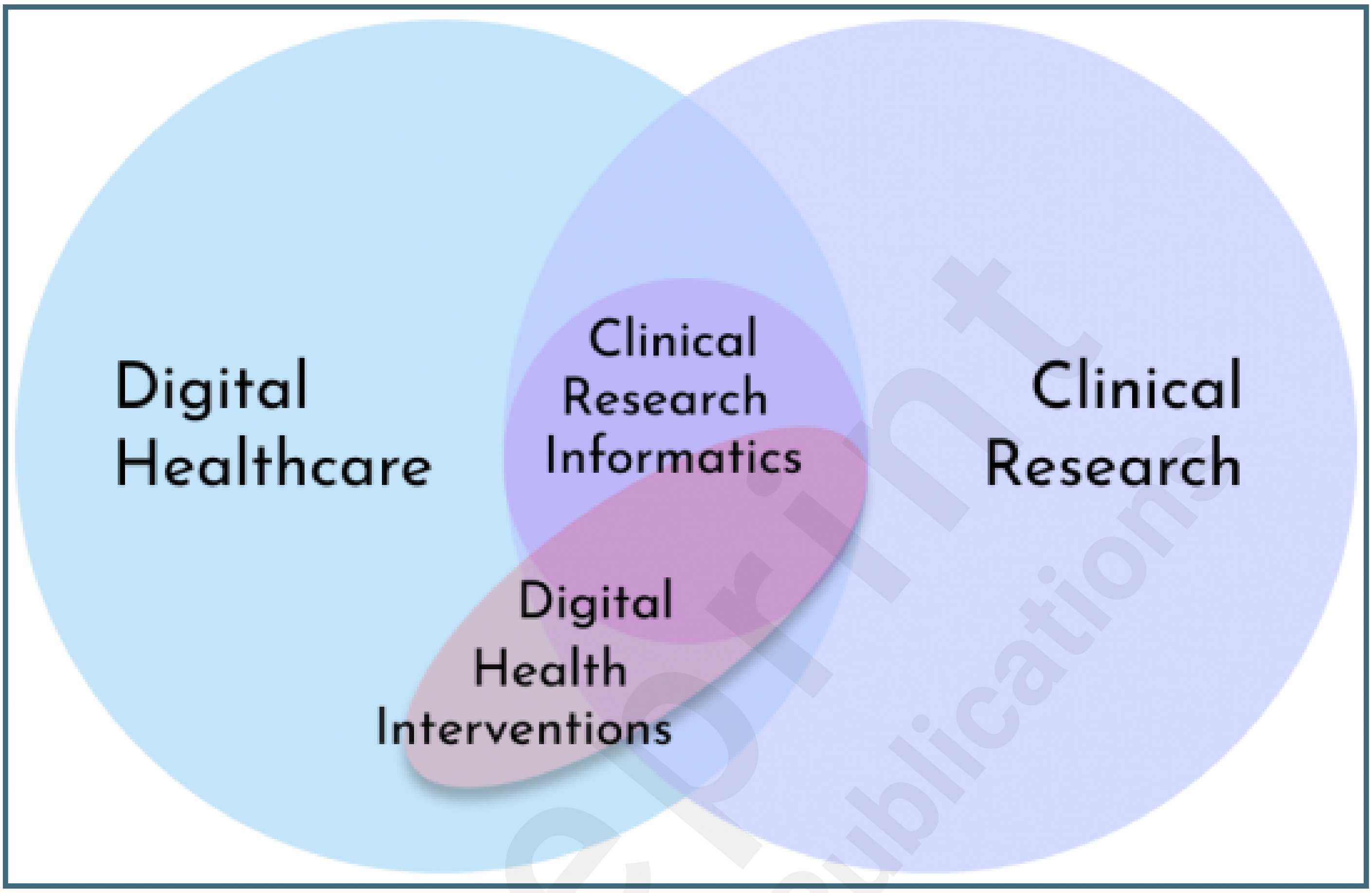
Supplementary Files

Figures

Digital health interventions are part of general digital healthcare and clinical research. The latter can be delivered via clinical research informatics or commercial health platforms and software.



Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols.