The Application of Human-Centered Design Approaches in Health Research and Innovation: A Narrative Review of Current Practices

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Abstract

Background: Human-centered design (HCD) approaches to health care strive to support the development of innovative, effective, and person-centered solutions for health care. Although their use is increasing, there is no integral overview describing the details of HCD methods in health innovations.

Objective: This review aims to explore the current practices of HCD approaches for the development of health innovations, with the aim of providing an overview of the applied methods for participatory and HCD processes and highlighting their shortcomings for further research.

Methods: A narrative review of health research was conducted based on systematic electronic searches in the PubMed, CINAHL, Embase, Cochrane Library, Web of Science, PsycINFO, and Sociological Abstracts (2000-2020) databases using keywords related to human-centered design, design thinking (DT), and user-centered design (UCD). Abstracts and full-text articles were screened by 2 reviewers independently based on predefined inclusion criteria. Data extraction focused on the methodology used throughout the research process, the choice of methods in different phases of the innovation cycle, and the level of engagement of end users.

Results: This review summarizes the application of HCD practices across various areas of health innovation. All approaches prioritized the user’s needs and the participatory and iterative nature of the design process. The design processes comprised several design cycles during which multiple qualitative and quantitative methods were used in combination with specific design methods. HCD- and DT-based research primarily targeted understanding the research context and defining the problem, whereas UCD-based work focused mainly on the direct generation of solutions. Although UCD approaches involved end users primarily as testers and informants, HCD and DT approaches involved end users most often as design partners.

Conclusions: We have provided an overview of the currently applied methodologies and HCD guidelines to assist health care professionals and design researchers in their methodological choices. HCD-based techniques are challenging to evaluate using traditional biomedical research methods. Previously proposed reporting guidelines are a step forward but would require a level of detail that is incompatible with the current publishing landscape. Hence, further development is needed in this area. Special focus should be placed on the congruence between the chosen methods, design strategy, and achievable outcomes. Furthermore, power dimensions, agency, and intersectionality need to be considered in co-design sessions with multiple stakeholders, especially when including vulnerable groups.

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KEYWORDS
human-centered design; design thinking; user-centered design; design-based research; methodology; review; mobile phone
Introduction

Background

Health systems are experiencing a progressive imbalance between available resources and increasing needs. The world population is growing, and the incidence of chronic diseases is rising; however, the funds allocated to health care are limited [1,2]. The need to provide optimized, individualized, and person-centered care is growing. Addressing these competing needs and complex problems requires novel and creative approaches for the development of health care solutions. Design approaches to health care promise to aid the development of innovative, effective, and person-centered solutions to health challenges, supporting the realization of a future for health care that is preventative, personalized, and participatory in nature [3,4]. Different medical disciplines are increasingly applying human-centered design (HCD) to a range of complex questions, from process optimization to product design and social innovation [5-7]. HCD is often described as an iterative, collaborative, and people-centered approach for designing products, services, and systems and is argued to be particularly well-suited for solving complex challenges [8]. In recent years, a growing number of health care professionals have applied HCD to develop person-centered health care solutions in collaboration with patients [9]. For example, the Department of Obstetrics and Gynecology at Mayo Clinic used HCD to develop a new prenatal care model designed to demedicalize a healthy pregnancy experience [10]. By enabling women to meaningfully participate in the process through the use of self-measurement tools, their levels of engagement, sense of control, confidence, and reassurance significantly increased. Another example is the nurse-led quality improvement project at Kaiser Permanente Northern California. HCD principles were used for a patient-centered approach to improve inpatient pain management. The experiences of frontline nurses, patients, and managers were collected, evaluated, and applied to improve the care experience of patients and the work experience of care providers [11].

However, the application of HCD beyond the design sector and its adoption in health research is still in its infancy [4,12]. The number of HCD studies that describe a full project cycle is limited, and even fewer publications focus on the evaluation of research projects that use HCD [13]. A recent scoping review on the application of HCD in global health provided a first overview of its application and health outcomes in public health. The review concluded that increased methodological rigor in the application and reporting of HCD is needed to allow for more acceptance and integration of design practices into research and development [13,14]. However, currently, there is no integral collection of HCD approaches and methods used in the development of health innovations. We performed this review to fill this gap.

HCD evolved from the collaborative design movement and covers a range of overlapping collaborative processes and techniques such as, and not limited to, participatory design, ethnography, cocreation, contextual design, co-design, and empathic design. These processes share several principles: the active involvement of users, an iterative design process, and the organization of multidisciplinary teamwork [15-17]. The term HCD, as a collaborative multimethod approach, is often used interchangeably with terms such as design thinking (DT) or user-centered design (UCD) because of their similar design philosophies. DT is an approach that prioritizes developing empathy for users, working in collaborative multidisciplinary teams, and using an iterative process with rapid prototyping techniques for potential solutions [18]. Similarly, UCD, although deeply rooted in human-computer interactions, is described as both a philosophy and a set of methods in which end users actively influence and are involved in the design process [13]. As these principles are akin to those of HCD, this review includes both DT and UCD as variations that apply HCD principles to further explore their similarities and differences.

Objective

In this review, we systematically explore the following question: how is HCD, and the closely related approaches of DT and UCD, applied in the development of innovations for health research? We specifically focus on the applied research methodologies and design methods used throughout the study. We investigate the level of engagement of end users during the HCD design processes. As a result, we provide an overview of the current application practices of HCD in health research and a practice-oriented collection of the used design methods to aid future researchers in their choice of methodology.

Methods

Overview

A total of 2 librarians, 1 from medical sciences and 1 from social sciences, assisted with the development of a search strategy and the selection of the appropriate databases. Our research included health research related to biomedical, nursing, and allied health and public health sciences. We performed multiple test runs to optimize the search strategy before the first search in July 2019. A final search was performed in August 2020 to update the included publications. The protocol for this review can be found in Multimedia Appendix 1.

Search Strategy

We performed electronic searches in the following databases: PubMed, CINAHL, Embase, Cochrane Library, Web of Science, PsycINFO, and Sociological Abstracts. Gray literature searches were not included. We searched for studies in the English language that were published between 2000 and 2020. For medical databases, the following terms were used: Human-centered OR Human-centred OR User-centered OR User-centred AND Design OR approach OR Design thinking. For nonmedical databases, the following search terms were added: Health OR Medic OR Clinic. The exact search algorithms per database can be found in Multimedia Appendix 2.

Eligibility Criteria

We included health research studies that applied HCD, UCD, or DT; focused on the development process of a health innovation; and provided a detailed description of the design process, which included the applied process steps or phases,
the applied design methods per process step or phase, and a
description of the involved design team and end users. We
excluded studies if they did not focus on the design process and
did not provide a detailed description of the design processes
and the HCD, DT, or UCD methods used in the study. No
specific criteria were formulated related to the end user
population.

We conceptualized a health innovation as it is applied within
the context of health research according to the World Health
Organization concept of “Health innovation identifies new or
improved health policies, systems, products and technologies,
and services and delivery methods that improve people’s health
and wellbeing.”

Screening and Data Extraction
We downloaded relevant papers on the Endnote bibliographic
software (Clarivate Analytics) and removed duplicates. We then
uploaded the Endnote database with the remaining papers on
Rayyan, a web application that supports the initial screening of
publication titles and abstracts [19]. A total of 2 reviewers
independently screened the titles and abstracts for inclusion
eligibility and subsequently screened the full-text articles
independently for inclusion. We resolved disagreements through
discussions. To determine the level of agreement, both Cohen
κ value and the percentage of agreement were calculated.

Data Retrieval and Analysis
We conducted a stepwise analysis of the included publications,
 focusing on (1) study characteristics, including design phases
 and methods, (2) level of end user involvement, and (3) quality
 assessment.

Study Characteristics
We extracted the following data from each article: year of
publication, first author, title of the study, aim of the study, end
user of the innovation, type of innovation, study design, design
approach, design approach reference, design process phases,
applied research and design methods, and the design-based
problem-solving strategy.

For the classification of the applied qualitative and quantitative
research and design methods, research methods were defined
as “methods traditionally used within scientific research,
oriented towards understanding” and design methods were
defined as “methods not traditionally used with scientific
research, oriented towards action or solution creation for defined
problems” [20,21]. These distinctions were made based on the
discussions between the authors. To define the design-based
problem-solving strategy, we used the categories of
problem-focused strategy (PFS) versus solution-focused strategy
(SFS). Studies that use a PFS aim to define or reframe the
problem before formulating possible solutions. Studies that use
an SFS approach focus on the development of a predefined
solution, investing little time in defining or reframing the
problem [22].

Level of Involvement of the End User
To define the level of engagement of the end user, we adopted
a modified framework proposed by Druin [23], which was
originally used to categorize the participating role of children
in a design process. The participating roles were users, testers,
informants, or design partners, with increased levels of
involvement for each role. Users help researchers and designers
understand the problem context and user needs. The role of
testers builds upon this role by including end users as part of
the initial or functional prototype testing. In the role of
informants, end users are involved during various stages of the
design process, and they contribute to idea generation and
provide feedback on the initial and functional prototypes. In the
role of design partners, end users are considered equal partners
of the design team and are involved at all stages of the design
process and fully included during the decision-making processes.

Quality Assessment
We assessed the quality of reporting and analysis of the study
designs using the Mixed Methods Appraisal Tool (MMAT),
which allows for the appraisal of studies for literature reviews
that include qualitative, quantitative, and mixed methods studies
[24]. As most HCD studies apply a multimethod approach, we
considered this tool fit for purpose. The MMAT contains 2
general screening questions and 5 study design–specific criteria
for assessing quantitative and qualitative studies. For mixed
methods studies, we applied both sets of criteria, in addition to
5 specific mixed methods criteria. The scores per item could
vary between yes (criterion is met), no (criterion is not met),
and can’t tell (paper did not report appropriate information to
rate this criterion).

One of the authors first performed the data retrieval and
conducted the stepwise analysis described above. Subsequently,
both authors reviewed and discussed the results.

Results
Overview
In the following sections, we have provided an overview of the
literature search results and the study characteristics of the
included studies. Subsequently, several aspects of the studies
have been highlighted, including the applied design theories,
guidelines, strategies, and design process steps. Furthermore,
we evaluated the applied research and design methods and the
role in which end users were involved throughout the studies.

Our literature search identified 7560 records. Of the 7560 papers,
after the removal of 4072 (53.86%) duplicates and exclusions
on the basis of abstract for 3097 (40.97%) papers and full text
for 309 (4.09%) papers, 82 (1.08%) articles were included in
the final analysis (Figure 1). Interrater agreement on the
inclusion and exclusion of the studies was 96%, with Cohen
κ=0.81.
Study Characteristics

Of the 82 included papers, 68 (83%) were published between 2015 and 2020. Most studies originated from the United States (34/82, 41%), the Netherlands (7/82, 9%), the United Kingdom (6/82, 7%), and Canada (6/82, 7%). Most studies focused on patients as the end users and developed health innovations with a focus on improving patient care. The most common type of study design was a mixed methods strategy (47/82, 57%), that is, a combination of qualitative, quantitative, and design methods. Of the 82 studies, 33 (40%) combined only qualitative methods with design methods. A detailed overview of the study characteristics is presented in Table 1.
### Table 1. Characteristics of the included studies.

| Author                  | Country       | Title                                                                 | End user population                          | Innovation type                  | Design approach                  | Study design   |
|-------------------------|---------------|-----------------------------------------------------------------------|----------------------------------------------|----------------------------------|----------------------------------|----------------|
| Bae et al [25]          | Korea         | Development of a user-centered health information service system for depressive symptom management | Patients who experience depression          | Web-based system                | User-centered system development | Mixed methods |
| Birnie et al [26]       | Canada        | ICanCope PostOp: user-centered design of a smartphone-based app for self-management of postoperative pain in children and adolescents | Children and adolescents who have recently undergone any type of day surgery | Pain self-management app         | UCD^a               | Mixed methods |
| Brox et al [27]         | Norway        | User-centered design of serious games for older adults following 3 years of experience with exergames for seniors: a study design | Seniors                                     | Serious game                     | UCD                | Mixed methods |
| Cairns et al [28]       | United Kingdom| Rethinking the foam cosmesis for people with lower limb absence       | People with lower limb absence               | Foam cosmesis for prosthetic limbs | User-centered product design     | Mixed methods |
| Carey-Smith et al [29]  | United Kingdom| A user-centered design process to develop technology to improve sleep quality in residential care homes | Older people with sleep or wake pattern disturbance | Sleep improvement technology     | UCD                | Qualitative |
| Caro et al [30]         | Mexico        | FroggyBobby: an exergame to support children with motor problems practicing motor coordination exercises during therapeutic interventions | Children with motor coordination problems   | Exergames for children with motor problems | UCD                | Qualitative |
| Catalani et al [31]     | Kenya         | A clinical decision support system for integrating tuberculosis and HIV care in Kenya: a human-centered design approach | HIV clinical care providers                 | Clinical shared decision support system | HCD                     | Mixed methods |
| Cawood et al [32]       | New Zealand   | Creating the optimal workspace for hospital staff using human centered design | Hospital staff                               | Nonclinical workspaces           | HCD                | Qualitative |
| Civan-Hartzler et al [33]| United States   | Bringing the field into focus: user-centered design of a patient expertise locator | Survivors of breast cancer                  | Patient expertise locator for web-based health communities | UCD                | Qualitative |
| Connelly et al [34]     | United States | Development of an ecological momentary assessment mobile app for a low-literacy, Mexican American population to collect disordered eating behaviors | Mexican-American women                      | Patient experiences assessment app | User-centered, iterative design | Mixed methods |
| Crespin et al [35]      | Canada        | Feasibility of adapting the fundamentals of laparoscopic surgery trainer box to endoscopic skills training tool | Surgeons and gastroenterologists            | Laparoscopic surgery training box | UCD                | Mixed methods |
| Curtis et al [36]       | United Kingdom| Targeting parents for childhood weight management: development of a theory-driven and user-centered healthy eating app | Parents of children with weight management problems | Healthy eating app               | UCD                | Mixed methods |
| Dabbs de Vito et al [37]| United States | User-centered design and interactive health technologies for patients | Patients with a lung transplant             | Personal health tracking app      | UCD                | Mixed methods |
| Author                          | Country     | Title                                                                 | End user population                                                                                                                                  | Innovation type                  | Design approach | Study design |
|--------------------------------|-------------|----------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-----------------|--------------|
| Das and Svanaes [38]           | Norway      | Human-centered methods in the design of an eHealth solution for patients undergoing weight loss treatment | Patients undergoing weight loss treatment                                                                                                         | eHealth solution for weight loss treatment | HCD             | Mixed methods |
| Davies et al [39]              | United Kingdom | Recommendations for developing support tools with people suffering from chronic obstructive pulmonary disease: co-design and pilot testing of a mobile health prototype | People with COPD²                                                                   | Mobile app for COPD self-management | User-centered, iterative design | Mixed methods |
| Dijkstra et al [40]            | The Netherlands | Development of ehome, a mobile instrument for reporting, monitoring, and consulting drug-related problems in home care: human-centered design study | Home care nurses, general practitioners, and pharmacists                                                                   | e-home solution for monitoring and consulting | HCD             | Mixed methods |
| Eberhart et al [41]            | United States | Using a human-centered design approach for collaborative decision-making in pediatric asthma care | Parents and children who are dealing with asthma management in a lower income environment                                                                 | Physical decision-making aids    | HCD             | Qualitative   |
| Erol Barkana and Açik [42]     | Turkey      | Improvement of design of a surgical interface using an eye tracking device | Surgeons who perform kidney tumor cryoablations                                                                 | Eye-tracking device               | UCD             | Qualitative   |
| Erwin et al [43]               | United States | Development of a framework and tool to facilitate cost-of-care conversations with patients during prenatal care | Patients receiving prenatal care                                                                                                                  | Conversation framework          | HCD             | Qualitative   |
| Ettinger et al [44]            | South Africa | Building quality mHealth for low resource settings                    | Community health care workers                                                                                                                    | mHealth app to inform clinical decision-making | HCD             | Mixed methods |
| Fabri et al [45]               | United Kingdom | Using design thinking to engage autistic students in participatory design of an online toolkit to help with transition into higher education | Students with autism                                                                   | Web-based toolkit               | DT²             | Mixed methods |
| Farinango et al [46]           | Colombia     | Human-centered design of a personal health record system for metabolic syndrome management based on the ISO 9241-210:2010 standard | Individuals at risk for metabolic syndrome                                                                                           | Personal health record system | HCD             | Mixed methods |
| Ferris and Shepley [47]        | United States | The design of neonatal incubators: a systems-oriented, human-centered approach | Infants, medical practitioners, and family members                                                                                       | Neonatal incubators             | HCD             | Qualitative   |
| Foley et al [48]               | United States | Primary care women’s health screening: a case study of a community engaged human centered design approach to enhancing the screening process | Women receiving health screening in primary care                                                                                      | Health screening tool            | HCD             | Qualitative   |
| Fortuna et al [49]             | United States | Adapting a psychosocial intervention for smartphone delivery to middle-aged and older adults with serious mental illness | Middle-aged and older adults with serious mental illness                                                                                   | Mobile app for medical and psychiatric self-management | UCD             | Qualitative   |
| Author             | Country         | Title                                                                 | End user population                                      | Innovation type                                      | Design approach | Study design |
|--------------------|-----------------|------------------------------------------------------------------------|----------------------------------------------------------|------------------------------------------------------|-----------------|--------------|
| Furberg et al      | United States   | A digital decision support tool to enhance decisional capacity for clinical trial consent: design and development | People diagnosed with fragile X syndrome and clinicians  | Tablet-based decision support tool                   | UCD             | Qualitative  |
| Gačnik et al       | Slovenia        | User-centered app design for speech sound disorders interventions with tablet computers | Children with speech-language pathology                  | App for speech sound disorder therapy                | UCD             | Mixed methods|
| Garvelink et al    | Canada          | Development of a decision guide to support the elderly in decision making about location of care: an iterative, user-centered design | Older adults and their informal caregivers              | Decision guide (physical)                            | UCD             | Mixed methods|
| Garvelink et al    | Canada          | Deciding how to stay independent at home in later years: development and acceptability testing of an informative web-based module | Seniors with loss of autonomy                           | Interactive website                                 | UCD             | Qualitative  |
| Garvin et al       | United States   | Descriptive usability study of CirrODS: clinical decision and workflow support tool for management of patients with cirrhosis | Clinicians caring for patients with cirrhosis           | Clinical decision and workflow support tool (digital) | UCD             | Mixed methods|
| Garzo et al        | France          | Design and development of a gait training system for Parkinson’s disease | People with Parkinson disease                           | Gait training app                                    | UCD             | Mixed methods|
| Gaynor et al       | United States   | A user-centered, learning asthma smartphone application for patients and providers | People with asthma                                      | Mobile app for asthma self-management                | UCD             | Qualitative  |
| Gill et al         | Canada          | Feasibility and acceptability of a mobile technology intervention to support post abortion care (The FACTS study phase II) after surgical abortion: user-centered design | Women who underwent an abortion                         | Web-based intervention for postabortion care support | UCD             | Mixed methods|
| Giunti et al       | Spain           | More stamina, a gamified mHealth solution for persons with multiple sclerosis: research through design | Young adults who have been diagnosed with multiple sclerosis | mHealth solution                                     | UCD             | Qualitative  |
| Godinho et al      | Portugal        | Improving accessibility of mobile devices with EasyWrite               | Motor-disabled persons who experience text-entry difficulties when using mobile devices | Text-entry method for mobile devices                 | User-centered approach | Mixed methods|
| Gould et al        | United States   | Development and refinement of educational materials to help older veterans use VA mental health mobile apps | Older veterans                                           | Educational material for mobile mental health apps    | UCD             | Mixed methods|
| Green et al        | United States   | Tracking care in the emergency department                              | Emergency department physicians                         | Emergency department tracking board                  | UCD             | Qualitative  |
| Griffin et al      | United States   | Creating an mHealth app for colorectal cancer screening: user-centered design approach | People at risk for colorectal cancer aged ≥50 years      | mHealth screening solution                           | UCD             | Mixed methods|
| Author                  | Country     | Title                                                                 | End user population                                      | Innovation type                      | Design approach | Study design |
|------------------------|-------------|----------------------------------------------------------------------|----------------------------------------------------------|---------------------------------------|----------------|--------------|
| Grossman et al [63]    | United States | Leveraging patient-reported outcomes using data visualization       | Patients with heart failure and health care providers for patients with heart failure | Data visualization                  | UCD            | Mixed methods |
| Hafiz et al [64]       | Denmark     | The internet-based cognitive assessment tool: system design and feasibility study | Patients with unipolar and bipolar disorder              | Web-based cognitive assessment tool   | UCD            | Mixed methods |
| Hardy et al [65]       | United Kingdom | How inclusive, user-centered design research can improve psychological therapies for psychosis: development of SlowMo | People who fear harm from others                        | Digital solution for psychological therapy | UCD            | Qualitative   |
| Harte, R. [66]         | Ireland     | Human-centered design study: enhancing the usability of a mobile phone app in an integrated falls risk detection system for use by older adults | Older adults with fall risk                             | Mobile app for fall risk detection    | HCD            | Mixed methods |
| Hartzler et al [67]    | United States | Design and feasibility of integrating personalized PRO\textsuperscript{b} dashboards into prostate cancer care | Patients receiving prostate cancer treatment          | Patient dashboard                     | HCD            | Mixed methods |
| Herschman et al [68]   | Canada      | Development of a smartphone app for adolescents with lupus: a collaborative meeting-based methodology inclusive of a wide range of stakeholders | Adolescents with lupus                                   | Mobile app for adolescents            | UCD            | N/A\textsuperscript{A} |
| Horsky and Ramelson [69]| United States | Development of a cognitive framework of patient record summary review in the formative phase of user-centered design | Clinicians                                               | Patient record summary review         | UCD            | Qualitative   |
| Huberty et al [70]     | United States | Development and design of an intervention to improve physical activity in pregnant women using Text4baby | Pregnant women                                           | SMS text messaging                    | UCD            | Mixed methods |
| Isenberg et al [71]    | United States | An advance care plan decision support video before major surgery: a patient- and family-centered approach | Patients who are preparing for major surgery             | Advance care planning decision support video | HCD            | Mixed methods |
| Johnston et al [72]    | United States | Designing and testing a web-based interface for self-monitoring of exercise and symptoms for older adults with COPD | Older adults with COPD                                    | Web-based interface for self-monitoring of exercise | UCD            | Mixed methods |
| Lan Hing Ting et al [73]| France      | Examining usage to ensure utility: co-design of a tool for fall prevention | Older adults with fall risk                             | Balance assessment tool               | HCD            | Mixed methods |
| Luna et al [74]        | Argentina   | User-centered design improves the usability of drug-drug interaction alerts: experimental comparison of interfaces | Physicians                                               | Drug–drug interaction alert system    | UCD            | Mixed methods |
| Ma, Wu and Chang [75]  | Taiwan      | A new design approach of user-centered design on a personal assistive bathing device for hemiplegia | Patients with stroke and hemiplegia                       | Personal assistive bathing device     | UCD            | Qualitative   |
| Author                      | Country       | Title                                                                 | End user population                           | Innovation type                  | Design approach | Study design |
|-----------------------------|---------------|----------------------------------------------------------------------|-----------------------------------------------|----------------------------------|----------------|-------------|
| Madrigal-Cadavid et al [76] | Colombia      | Design and development of a mobile app of drug information for people with visual impairment | People with visual impairment                  | Mobile app for drug information  | UCD            | Qualitative |
| Marker and Monzon [77]      | United States | Iterative development of a web-based intervention for families of young children with type 1 diabetes: DIPPer academy | Parents of children with type 1 diabetes       | Web-based intervention           | UCD            | Mixed methods |
| Marko-Holguin et al [78]    | United States | A two-way interactive text messaging application for low-income patients with chronic medical conditions: design-thinking development approach | Patients with low income and chronic medical conditions | Interactive SMS text messaging app | DT             | Mixed methods |
| Martin et al [79]           | Ireland       | A qualitative study adopting a user-centered approach to design and validate a brain computer interface for cognitive rehabilitation for people with brain injury | People with brain injury                       | Brain-computer interface         | UCD            | Qualitative |
| McGinn et al [80]           | Ireland       | A human-oriented framework for developing assistive service robots   | People with disabilities                       | Assistive service robot          | HCD            | Qualitative |
| McMullen et al [81]         | United States | Designing for impact: identifying stakeholder-driven interventions to support recovery after major cancer surgery | Patients who recover from major cancer surgery | Web-based educational platform for patients | UCD            | Qualitative |
| Melnick et al [82]          | United States | Patient-centered decision support: formative usability evaluation of integrated clinical decision support with a patient decision aid for minor head injury in the emergency department | Emergency department physicians                | Electronic clinical decision support | UCD            | Mixed methods |
| Nunez-Nava et al [83]       | Colombia      | Human-centered development of an online social network for metabolic syndrome management | People with metabolic syndrome                 | Web-based social network         | HCD            | Mixed methods |
| Person et al [84]           | Tanzania      | Community co-designed schistosomiasis control interventions for school-aged children in Zanzibar | School-aged children                           | Intervention to reduce schistosomiasis transmission | HCD            | Qualitative |
| Petersen, and Hempler [85]  | Denmark       | Development and testing of a mobile application to support diabetes self-management for people with newly diagnosed type 2 diabetes: a design thinking case study | People with newly diagnosed type 2 diabetes    | Mobile app for newly diagnosed patients with type 2 diabetes | DT             | Qualitative |
| Raguzeos et al [86]         | United States | Am I OK? using human centered design to empower rheumatoid arthritis patients through patient reported outcomes | Patient with rheumatoid arthritis              | Dashboard to display PROs        | HCD            | Qualitative |
| Author                  | Country         | Title                                                                 | End user population                                           | Innovation type                      | Design approach | Study design  |
|------------------------|-----------------|----------------------------------------------------------------------|---------------------------------------------------------------|--------------------------------------|-----------------|---------------|
| Ray et al [87]         | United States   | Computerized clinical decision support system for emergency department-initiated buprenorphine for opioid use disorder: user-centered design | Emergency department physicians                               | Computerized clinical decision support system | UCD             | Qualitative   |
| Rothgangel et al [88]  | The Netherlands | Design and development of a telerehabilitation platform for patients with phantom limb pain: a user-centered approach | Patients with phantom limb pain                               | Tele-rehabilitation platform          | UCD             | Mixed methods |
| Salmon et al [89]      | Congo           | Alternative ultrasound gel for a sustainable ultrasound program: application of human centered design | Local clinicians who use point of care ultrasound              | Alternative ultrasound gel            | HCD             | Mixed methods |
| Schild et al [90]      | Germany         | A digital cognitive aid for anesthesia to support intraoperative crisis management: results of the user-centered design process | Anesthesiologists                                              | Digital cognitive aid for intraoperative crisis management | UCD             | Mixed methods |
| Sedlmayr et al [91]    | Germany         | User-centered design of a mobile medication management                | People who use medication                                     | Mobile interface for medication manage-ment | UCD             | Mixed methods |
| Seeber et al [92]      | Germany         | A design thinking approach to effective vaccine safety communication | Parents and babies                                             | Effective vaccine safety communication | DT              | Qualitative   |
| Sonney et al [93]      | United States   | Applying human-centered design to the development of an asthma essentials kit for school aged children and their parents | School-aged children and their parents who deal with asthma management | Asthma essential kit                  | HCD             | Qualitative   |
| Srinivas et al [94]    | United States   | Context-sensitive ecologic momentary assessment: application of user-centered design for improving user satisfaction and engagement during self-report | Middle-aged women with obesity                                 | Patients’ experiences assessment app | UCD             | Mixed methods |
| Stevens et al [95]     | The Netherlands | The development of a patient-specific method for physiotherapy goal setting: a user-centered design | Physiotherapists and patients                                  | A new method for goal setting          | UCD             | Qualitative   |
| Taylor et al [96]      | United States   | User-centered development of a web-based preschool vision screening tool | Parents of preschool-aged children with amblyopia              | Web-based vision screening tool       | UCD             | Mixed methods |
| Timmerman et al [97]   | The Netherlands | Co-creation of an ICT-supported cancer rehabilitation application for resected lung cancer survivors: design and evaluation | Health care professionals and survivors of lung cancer          | ICT-supported cancer rehabilitation program | UCD             | Mixed methods |
| Tucker Edmonds et al [98]| United States   | Creation of a decision support tool for expectant parents facing threatened perinatal delivery: application of a user-centered design approach | Prospective parents                                            | Decision support tool                 | UCD             | N/A           |
### Study design

#### Design approach
- **Qualitative**: user-centered design (UCD)
- **HCD**: human-centered design
- **Mixed methods**: a combination of qualitative and quantitative approaches

| Author                     | Country       | Title                                                                 | End user population                                                                 | Innovation type                                      | Design approach       | Study design |
|----------------------------|---------------|----------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------|-----------------------|--------------|
| van der Weegen et al [99]  | The Netherlands | The development of a mobile monitoring and feedback tool to stimulate physical activity of people with a chronic disease in primary care: a user-centered design | People with chronic disease                                                         | Mobile monitoring and feedback tool                  | UCD                   | Qualitative  |
| Vechakul et al [100]       | United States  | Human-centered design as an approach for place-based innovation in public health: a case study from Oakland, California | Citizens of Castlemont neighborhood                                                  | Novel programs to reduce inequities in infant mortality rates | HCD                   | Qualitative  |
| Vermeulen et al [101]      | The Netherlands | User-centered development and testing of a monitoring system that provides feedback regarding physical functioning to elderly people | Older adults                                                                       | Mobile interface for a monitoring system             | User-centered development process | Mixed methods |
| Vilardaga et al [102]      | United States  | User-centered design of learn to quit, a smoking cessation smartphone app for people with serious mental illness | People with serious mental illnesses who smoke                                       | Smoking cessation app                                 | UCD                   | Mixed methods |
| Wachtler et al [103]       | Australia      | Development of a mobile clinical prediction tool to estimate future depression severity and guide treatment in primary care: user-centered design | People with depressive symptoms                                                      | App for improvement of treatment allocation for depression | UCD                   | Qualitative  |
| Willard et al [104]        | The Netherlands | Development and testing of an online community care platform for frail older adults in The Netherlands: a user-centered design | Frail older adults                                                                | Web-based community platform                         | UCD                   | Mixed methods |
| Woodard et al [105]        | United States  | The Pathways fertility preservation decision aid website for women with cancer: development and field testing | Women survivors of cancer                                                            | Decision aid website for young women with cancer    | UCD                   | Mixed methods |
| Wysocki et al [106]        | United States  | A web-based coping intervention by and for parents of very young children with type 1 diabetes: user-centered design | Parents of young children with type 1 diabetes                                       | Web-based coping resource                            | UCD                   | Qualitative  |

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**a** UCD: user-centered design.  
**b** HCD: human-centered design.  
**c** COPD: chronic obstructive pulmonary disease.  
**d** mHealth: mobile health.  
**e** DT: design thinking.  
**f** FACTS: factors affecting combination trial success.  
**g** VA: veterans affairs.  
**h** PRO: patient-reported outcome.  
**i** N/A: not applicable.  
**j** ICT: information and communication technology.

### Design Theories and Methodologies

This review explores the various applications of HCD approaches, including HCD, UCD, and DT. Of the 82 studies, HCD was used in 21 (26%) studies, whereas 4 (4%) studies applied a DT approach. Most (57/82, 70%) used a UCD approach. All approaches prioritized the users’ needs and the participatory and iterative nature of the design process. Some HCD definitions included a focus on a multiple stakeholder or system perspective, whereas some UCD definitions aimed at...
increasing usability or user friendliness of the solution. These design approaches are generally characterized by the use of different standards or models.

A total of 3 standards or models were frequently mentioned in the studies and used as references. These models overlap in their attempt to classify the distinct phases of the design process but operationalize the steps differently. The UCD ISO Standard 9241-210 for HCD of interactive systems encompasses a 5-phase design process including (1) understanding and specifying the context of use, (2) specifying user requirements, (3) producing design solutions, (4) evaluating design against requirements, and (5) delivering design solutions that meet user requirements. The HCD IDEO Field Guide to Human-Centered Design and the Hasso Plattner Institute (HPI) School of Design Thinking models are characterized by different versions of a similar 3-phase design process: (1) inspiration, (2) ideation, and (3) implementation. Studies that applied DT worked with a multiphase approach that included versions of the following phases: (1) empathizing with stakeholders, (2) defining the problem, (3) generating ideas for solutions, (4) prototyping the solutions, and (5) testing the solutions. In Figure 2, we have illustrated how the different approaches to the HCD process align.

Of the 82 articles identified, 57 (70%) applied a UCD approach, 21 (26%) used HCD, and 4 (5%) used DT. In 17% (14/82) of the studies, the concepts of HCD and UCD were referred to interchangeably; of these 14 studies, 9 (64%) studies referred to the use of the ISO 9241-210 standard. In the 5% (4/82) of studies that applied DT, the concept was used interchangeably with HCD in all cases. These studies referred to the IDEO Field Guide to Human-Centered Design or the HPI School of Design Thinking Guide as standards. For clarity, we have continued to report the results of the HCD and DT studies and UCD studies separately in this review.

**Design Strategies and Methods**

Of the 82 studies, 74 (90%) applied an SFS versus 8 (10%) applied a PFS to drive the design process. Thus, most design studies focused on directly generating solutions or developing a specific predefined solution. Only a minority used design-based methods to define the problem and selectively gather information before proceeding to solution development. Of the 74 studies that applied an SFS, 55 (74%) applied the UCD approach. Of the 8 studies that applied a PFS, 6 (75%) applied an HCD and DT approach. Overall, HCD and DT appears to be the preferred approach for problem-driven strategies, whereas UCD is generally applied for solution-driven strategies.

The design processes comprised several design cycles during which multiple qualitative and quantitative methods were used in combination with specific design methods. Of the 82 studies, 47 (57%) applied a mixed methods approach, and 33 (40%) applied qualitative methodology. A synthesis of the methods used in the different phases of the included studies is presented in Table 2 (details about the described design methods can be found in Multimedia Appendix 3). The first design phase—understanding the context—was often characterized by the use of a limited range of design-based methods. During the second and third phases—problem specification and idea
generation—a broader range of design methods was used in different studies. In the fourth phase—testing of solutions—the range of design methods was reduced again. Some design-based methods were applied in multiple phases of the process, for example, personas, intervention mapping, or the Wizard of Oz technique; however, most were uniquely used in a single phase. Overall, qualitative methods or mixed methods were mostly used in the first and last phases of the design process to understand user needs or to evaluate user experiences. In the first phase of the process, qualitative methods such as interviews and observations as well as literature reviews were commonly used to understand the problem context. In later stages, the use of methods diverges based on the type of foreseen solution, for example, digital or nondigital solutions. Quantitative methods were used to either support qualitative findings during the first phase of the process or as an evaluation instrument in the later design phases.
Table 2. Meta-analysis of applied research and design methods.

| Design phase                        | Qualitative methods                                      | Quantitative methods              | Design methods                          |
|-------------------------------------|----------------------------------------------------------|-----------------------------------|-----------------------------------------|
| Understanding the context           | Literatures review, Observations, Expert meetings, Delphi technique, Diary studies | Surveys (not specified)           | Storytelling, Metaphors, Personas, Experience mapping |
| Specify the problem or user need    | Focus groups, Interviews, Delphi technique, Contextual inquiry, Observations, Critical incident technique | Context assessments, Needs assessments, Surveys (not specified) | Participatory workshop, Personas, Use case scenarios, Decision matrix, MoSCoW, House of quality analysis, Goal, question, metric approach, Roleplay, User journey mapping, Intervention mapping, System mapping, Low functional prototype, Use case diagram |
| Generate ideas and design solutions | Observations, Interviews, Focus groups, Literature review | Usability surveys, Feasibility surveys, Surveys (not specified) | Brainstorm, Round Robin Concept Ideation, Voting, Round table discussions, Sketching, Visual mind maps, Idea or concept voting, Storyboarding, User narratives, Use case scenarios, Low functional prototyping, High functional prototyping, Intervention mapping, Heuristic evaluation, Task analysis, SWOT or competitor analysis, User journey map, Wizard of Oz method, Card sorting, Weekly sprints, Think-aloud techniques |
| Test solutions                      | Interviews, Observations, Focus groups, EMA            | Usability surveys, Feasibility surveys, Viability assessments, EMA, Surveys (not specified) | Low functional prototyping, High functional prototyping, Roleplay, Story boarding, Card sorting, Simulations, Intervention mapping, Cognitive walkthrough, Brainstorm (general), Heuristic evaluation, Workflow evaluation, Participatory workshop, Wizard of Oz method, Value versus effort matrix, Think-aloud techniques |

aMoSCoW: must have, should have, could have, won’t have.
bSWOT: strengths, weaknesses, opportunities, and threats.
cEMA: ecological momentary assessment.
End User Involvement

In 6 studies (UCD 5/6, 83%; HCD and DT 1/6, 17%), the end users were actively involved as users, that is, as information sources but not as active participants in the design process. In 27 (UCD 21/27, 78%; HCD and DT 6/27, 22%) studies, the end users participated as testers; that is, they were involved in the first and last phases of the design process as testers of the developed solutions. In 28 (UCD 22/28, 79%; HCT and DT 6/28, 21%) studies, the end users were involved as informants.

Figure 3. Levels of end user involvement during human-centered design processes.

Quality Assessment of the Studies

Using the MMAT, 16% (13/82) of the included studies met ≥1 MMAT reporting criteria, based on the study type. The remaining studies had to be rated as unclear on all MMAT reporting criteria. An overview of the quality assessment results can be found in Multimedia Appendix 4 [25-106]. The biggest limitation to the quality assessment was the lack of uniformity in reporting and the broad extent of the design studies that needed to be captured in limited words for publication. In fact, most studies used multiple research and design cycles and generally offered limited details about the applied methodology.

Discussion

Principal Findings

In this review, we explored how different HCD approaches, including DT and UCD, were applied for the development of innovations in health research. Overall, the concepts of HCD and DT, and HCD and UCD, were used interchangeably in 22% (18/82) of the included studies. This applied to all studies that referred to HCD and DT; however, UCD was defined as a standalone entity in 84% (48/57) of the papers that used this approach. Most of the studies using HCD and UCD interchangeably referred to the ISO 9241-210 standard. This aligns with the theoretical framework pursued by the studies, that is, a problem-driven versus a solution-driven strategy. DT- and HCD-based studies commonly engaged in understanding the underlying problem and focused on a broad range of health, social, or medical topics. They often included a focus on human values and a multistakeholder or systems perspective. Instead, UCD-based approaches focused primarily on the direct identification of a solution and were mostly used in health technology innovation. They often focused on human factors to increase the usability or user friendliness of the solution. The limitations of this functional approach in promoting human interests have been previously described as a potential shortcoming of UCD [107].

It has been reported that designers who use a problem-driven design strategy produce solutions with the best balance between quality and creativity [22]. However, in this review, 90% (74/82) of the included studies used a solution-driven strategy. Although the evaluation of solutions can be used to further define the design problem, this was not an objective of the included studies. Their solution-driven approach generally focused on generating a large number of ideas and solutions, potentially leaving the initial design problem ill-defined and ignoring the relationships between various stakeholders. However, health care innovation
could significantly benefit from problem-driven design processes, especially from the perspective of resource efficiency. Innovation in health care is characterized by a development or implementation cost trade-off. Therefore, it is critical that the most impactful innovations be prioritized based on a critical understanding of the underlying problem [108].

HCD in health research is often perceived as a single unitary method, as emphasized by the reference to a single practitioner guideline in the included studies. However, in this review, we found that the application of HCD entails a wide array of design methods and techniques that can be used selectively and that are dependent on the specific design case. Design methods diverge from the traditional methods of academic research as they are primarily oriented toward action or solution of defined problems rather than toward theory and hypotheses building. To date, little is known about their effectiveness according to evidence-based medical standards. The creation of a new product, system, or service to improve health might be considered an outcome from a design perspective but would not be considered a health outcome from a scientific perspective [13,14]. In the literature, a scientific method is described as a strategy to understand the nature of a phenomenon, whereas a design method is a strategy to invent things of value. According to this distinction, science is analytical and design is constructive and it is therefore difficult to assess both methods according to the same standard [20]. However, according to Frey and Dym [109], many of the validation techniques found in medicine can be used for the validation of design methods. For example, where medicine uses animal models and clinical trials to test medical treatments, detailed simulations and controlled field experiments of design methods could be developed for the explicit purpose of evaluating design methodologies [109].

This logical, empirical approach toward the evaluation of design methods fits well with, for example, the field of engineering design, which is based on mathematical modeling, as it is most appropriate for closed, objective problems that can lead to binary (yes or no) answers. However, HCD approaches often address open, complex problems that involve both objective and subjective elements without a single correct answer. For design methods addressing open, complex problems, a relativist validation approach that gradually builds confidence in the usefulness of the methods can be considered a more appropriate paradigm [110]. A relativist approach to design claims no absolute objectivity for methods or models; however, it assumes that a valid method or model is only one of the many possible ways of measuring or describing a real situation. In a relativist approach to design methods, validity becomes a matter of practical use and contextual functionality rather than formal and universal accuracy. The validity of design methods becomes a contextual, semiformal, and conversational process, because establishing models of usefulness is a conversational matter [111]. It is important to note that a relativist approach toward the evaluation of design methods does not antagonize the logical, empirical approach toward the evaluation of scientific research methods used in HCD processes.

There is an ongoing demand for the development of a design science with systematic and formalized design methods that adhere to the values of the empirical scientific method: objectivity, rationality, and universalism [112,113]. Scientific design methods have been developed in engineering and computer science; however, there is limited evidence that the systematic use of design practices leads to measurable and reproducible results in health research [112]. Design researchers themselves still debate whether design conforms to a scientific activity or represents an academic discipline with a rigorous culture of its own [20,113]. As a result, critical appraisal and best practice selections of design methods in health research remain challenging.

In this review, the diverse reporting formats challenged our ability to assess the quality of the studies from an evidence-based perspective. Although initial guidelines have been proposed to improve the reporting of design studies in health research, this is still an area that is in development [14]. The guidelines by Bazzano et al [14] represent the first detailed overview of reporting items for health research that includes design approaches. Although we acknowledge that this reporting guideline is an important first step toward improving transparency, evaluability, and wider dissemination of design approaches in health research, it is, however, debatable whether the application of these guidelines is feasible in the context of health research manuscripts. The level of detail that the Bazzano [14] guidelines propose implies that the design research component should be reported as a standalone article, separate from the connected empirical studies. Most of the design studies included in this review offered limited details about their multimethod design cycles, possibly because of the word count limits that most scientific journals apply. It would be almost impossible to describe a multimethod design process in adequate detail and also effectively report on the research and design outcomes in a single manuscript. Applying the Bazzano [14] guidelines with rigor is likely to result in the reporting of separate design cycles across multiple manuscripts, and essential findings for the design process might appear fragmented or be lost among reports that are published separately.

However, it could be argued that the separate publication of multiple waves of data collection in design research is preferable for both researchers and reviewers to support the validity, reliability, and reproducibility of design-based health research. Rather than aiming for complex integrated manuscripts, multiple publications would allow researchers to report in more detail on both their methods and findings and also allow for easier critical appraisal and quality assessment by reviewers. In addition to traditional research articles, innovative publication formats such as registered reports could be used to submit design research protocols and results that are judged on their methodological robustness rather than the potential novelty of the findings [114]. We recommend registering the design research protocols in a research registry to address the issue of potential fragmented data publication. This would allow for systematic referencing to previous design activities, even when their results have not been published.

The active engagement of stakeholders is one of the key principles of the HCD approach. Stakeholders can be defined as “individuals, organizations or communities that have a direct interest in the process and outcomes of a project, research or policy endeavor” [115]. In health care innovation, the
engagement of diverse stakeholders is essential to the development of a shared agenda for responsible innovation and for the co-creation of social value [116]. However, a multistakeholder innovation process brings about several challenges. HCD practitioners acknowledge the challenge of equitably including the experience and expertise of all participants in the design process. Although the importance of creative interdisciplinary collaborations between various disciplines in health care is increasing, it is still a relatively new and complex phenomenon [117]. Each stakeholder brings their own motivations, attitudes, priorities, and incentives to the process, and such differences will influence the cocreative space and interpersonal interactions. HCD practitioners should critically reflect on the participatory methods that they intend to apply, considering the possible contribution of each participant in the design process to facilitate the effective use of their expertise and experiences [16]. This is particularly important when working with vulnerable patient groups or health care professionals with limited time to participate in co-design sessions [118].

An earlier study suggested that HCD processes can rely too much on anecdotal evidence of key stakeholders who might not fully understand what they want and need [31]. However, a more strategic application of HCD aims to identify themes that describe people’s deeper needs and values rather than their wishes and desires and uses those themes to inform the creation of innovative strategies and solutions [119]. Field studies with the use of qualitative methods, such as observations, to study key stakeholders and their activities in their own environments could offer a valid alternative [120].

In addition, it is essential for HCD practitioners to take power dimensions and the agency of different stakeholders into account, especially during co-design sessions. To achieve inclusive design processes, intersectonal aspects should be considered for stakeholder engagement and methodological choices, such as gender identity, class, sexuality, geography, age, and disability and ability [121,122]. Reflective project planning aids and frameworks for involving patients and the public in research and design projects should be used to guarantee meaningful engagement of stakeholders and facilitate democratic design processes [123,124].

Study Limitations
At present, MMAT is the most comprehensive tool available for appraising multimethod studies [125]. Although the MMAT is a tool that allows for the critical appraisal of most common types of study designs, the tool seems less appropriate for HCD, DT, and UCD because of the inclusion of multiple research and design cycles and the often-limited word space to describe the applied methodologies and methodological choices in detail. To our knowledge, there is no appropriate tool available for the critical appraisal of design studies in health research.

In this review, we have only reviewed articles that described the complete development processes of a health innovation. This criterion might have limited the inclusion of studies that describe the complete process through multiple publications. For example, in a few studies, the authors referred to future studies in which they expressed the intention to test a designed solution in a randomized controlled trial. Those studies were not included in this review. Furthermore, no selection criteria for the end user populations were applied. This might have influenced the choice for the use of particular design methods, as design researchers need to take intersectional aspects into account, as mentioned in the Discussion. Although this was not the main objective of this review, future research could focus on the application of design methods and their suitability for specific stakeholder populations in health care.

In addition, our search strategy was limited to scientific databases related to biomedical, nursing, and allied health and public health sciences, and gray literature was not included. Disciplines that publish design research related to health systems outside this scope were not considered in our searches. Finally, the existence of different design methods and models with principles related to HCD and the interchangeable use of these terms in the literature made it challenging to scope and perform a fully systematic search.

Conclusions
A wide variety of design practices and methods such as HCD, DT, and UCD are increasingly being applied in health research. In our analysis, HCD- and DT-based projects tended to primarily follow integrated and problem-driven approaches, whereas UCD-based projects engaged in more functional and solution-driven approaches. Most of these design studies used mixed methods approaches, combined qualitative and quantitative research with design methods, and frequently referred to the following 3 design guides: the IDEO Field Guide to Human-Centered Design, the HPI School of Design Thinking Guide, and the ISO Standard 9241-210.

The increasing use of design-based approaches such as HCD and DT and UCD in health research subjects them to evaluation according to traditional biomedical standards. However, the analytic approach of the scientific method versus the constructive approach of the design method impedes the assessment of both methods according to the same standard. To address the validation of design methods, a relativist validation approach that gradually builds confidence in the usefulness of methods could be considered a more appropriate paradigm for design methods, particularly those that are concerned with subjective elements of the design process.

Specific standards for reporting HCD practices in health and biomedical research have been developed in recent years. However, these reporting standards remain challenging to apply for single design research papers because of the extensiveness of multimethod design processes in combination with customary word limits in biomedical publications. Separate publications detailing the multiple waves of data collection in design research might be preferable for both researchers and reviewers to support the validity, reliability, and reproducibility of design-based health research. In addition, innovative publication formats such as registered reports could be used to submit design research protocols and results that are judged on their methodological robustness rather than the potential novelty of the findings. Furthermore, future research on HCD approaches in health should focus on the development of an HCD practitioner guideline for stakeholder engagement that takes stakeholder
roles, experiences, expertise, agency, and power dimensions into account.

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Conflicts of Interest
None declared.

Multimedia Appendix 1
Review protocol.
[DOC File, 52 KB - Multimedia Appendix 1]

Multimedia Appendix 2
Search strategy.
[DOC File, 31 KB - Multimedia Appendix 2]

Multimedia Appendix 3
Descriptions of the design method included in the review.
[DOC File, 53 KB - Multimedia Appendix 3]

Multimedia Appendix 4
Mixed Methods Appraisal Tool checklist.
[DOC File, 274 KB - Multimedia Appendix 4]

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Abbreviations

DT: design thinking
HCD: human-centered design
HPI: Hasso Plattner Institute
MMAT: Mixed Methods Appraisal Tool
PFS: problem-focused strategy
SFS: solution-focused strategy
UCD: user-centered design

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