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Co-design of mHealth Delivered Interventions: A Systematic Review to Assess Key Methods and Processes

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Abstract Most mobile health (mHealth) programmes are designed with minimal input from target end users and are not truly personalised or adaptive to their specific and evolving needs. This review describes the methods and processes used in the co-design of mHealth interventions. Nine relevant studies of varying design were identified following searches of six academic databases. All employed co-design or participatory methods for the development of a health intervention delivered via a mobile device, with three focusing on health behaviour change (one on nutrition) and six on management of a health condition. Overall, six key phases of design and 17 different methods were used. Sufficiency of reporting was poor, and no study undertook a robust assessment of efficacy; these factors should be a focus for future studies. An opportunity exists to use co-design methods to develop acceptable and feasible mHealth interventions, especially to support improved nutrition and for minority and indigenous groups.

Keywords Co-design · Community-based participatory research · Participatory action research · mHealth · Telemedicine · Telehealth · Mobile phone · Methods

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Introduction

Poor health resulting from unhealthy diets and physical inactivity is responsible for substantial health loss globally [1]. However, effective face-to-face healthcare delivery, such as individual nutrition consultations, can be difficult to implement on a large scale and have limited reach into some population groups. The broad penetration of mobile and wireless technologies as well as advances in their application offer a potential solution to support individuals in communities to improve their nutrition, lose weight and achieve other health goals. More than half of the world's population now own a mobile phone (38 % own a smartphone), and in most regions, at least 50 % have access to the Internet [2]. However, in emerging and developing nations, younger and more highly educated individuals are more likely to have Internet access and/or use a smartphone [3].

Mobile health (mHealth) programmes have proven efficacy in supporting health behaviour change including for weight loss and disease management [4••, 5••, 6]. However, there is currently a dearth of research focusing on mHealth programmes for minority and indigenous populations [7••, 8]. Such populations often have lower access rates to traditional healthcare [9] and thus mHealth could provide an adjunct solution. Nonetheless, it is important that any intervention is well accepted, used by the target population, and is adaptive to their specific and evolving needs.

Co-design is a process in which targeted end users and other relevant stakeholders form a partnership with researchers and work together on all aspects of intervention development, from needs assessment to content development, pilot testing and dissemination [10]. The iterative nature of co-design fits well when collaborating with minority and indigenous populations because this approach allows for conceptual or tool re-developments and refining based on the social-cultural needs of partnership groups [11, 12•]. As such, co-designed mHealth interventions may be more effective than traditional approaches where interventions are largely designed by researchers and clinicians.

The co-design process is very similar to the more well-known community-based participatory research (CBPR) and is based on the following core principles and values: (1) it is participatory, (2) there is cooperation between partners, (3) there is co-learning with mutual exchange of information between partners, (4) it involves systems development and sustainability and builds on the strengths of the community, (5) it is empowering due to shared decision-making across all aspects, (6) there is implementation of an intervention based on the findings, (7) there is recognition of the community as a social setting not just a physical one and (8) long-term commitment is required by all partners [13]. There are a number of participatory research frameworks in the literature, but in general, they all describe a similar series of sequential phases. For example, Bratteteig [14] describes six phases of the design process: (1) opportunity identification, (2) generation of explicit and implicit knowledge, (3) identification of needs and desires, (4) description of delivery requirements, (5) envisaging the intervention and (6) prototype testing, pilot testing and evaluation.

Co-design is relatively new within healthcare; the concept has typically been used in technical design and to develop service improvements with patients [10]. However, it makes sense to consider this process for the development of all types of healthcare interventions, especially in mHealth research because it is expanding rapidly due to increased connectivity and ownership of devices by all population groups globally [15]. Nonetheless, there is an absence of literature to date summarising the key methods and processes used to co-design mHealth interventions; this is important to provide a guide for future researchers considering using these methods. The aim of this review was to identify and describe the methods and processes used for the co-design of mHealth interventions.

Methods

This review was conducted using methods broadly based on the Cochrane guidelines for systematic reviews of interventions [16]. A protocol for the review was written and agreed upon by all co-authors prior to commencement (available on request from the corresponding author).

Selection Criteria

Types of Studies and Participants

All types of study designs were included and no restrictions were placed on the types of participants.

Interventions and Technology

Interventions were included if they met the following three conditions: (1) described by the authors as co-designed or developed using participatory methods; (2) described the development of an intervention, the aim of which was to support health behaviour change or enable better management of a health condition for healthcare consumers and (3) delivery was via a mobile device. Co-design and participatory methods were as defined by authors, but in general, were intended to include processes where participants and other relevant stakeholders form a partnership and take an active role in intervention development and dissemination [14, 17]. The definition of a mobile device was taken from the Global Observatory for eHealth definition, i.e. mobile phones, patient monitoring devices, personal digital assistants and other wireless devices

[15]; laptops were not considered mobile devices, although Web-based or Internet interventions were included if the authors intended participants to receive the intervention on a mobile device as previously defined.

Outcomes and Duration

The following methods and processes were outcomes of the review:

(1) Theory-based frameworks used for co-design
(2) Timeframe for the co-design process
(3) Number and type of participants/end users and other stakeholders involved
(4) Methods for recruitment or engagement of participants and other stakeholders
(5) Methods and phases of design
(6) Degree of end user input into the final intervention
(7) Tools used during co-design process
(8) Intervention effectiveness

Studies of any duration were included.

Exclusion Criteria

For feasibility purposes and to remain relevant to current mHealth technology, studies published prior to 2005 were excluded. Non-English language publications were also excluded.

Data Sources and Search Strategy

Studies were identified through searches across the following six electronic databases, from January 2005 to January 2016: MEDLINE (biomedical literature); EMBASE (biomedical and pharmaceutical literature); PSYCINFO (psychology and behavioural sciences); Scopus (Sciences, Engineering, Medicine, Social Sciences and some Arts); CINAHL Plus (Cumulative Index to Nursing and Allied Health Literature) and Google Scholar.

The search strategy (Supplementary Material) was first developed for MEDLINE in consultation with a subject librarian, and modified where necessary for other databases.

Data Extraction and Synthesis

Selection of Studies

All references from searches of electronic databases were exported into an Endnote library for review. One of the authors (HE) reviewed the titles and abstracts for congruence with inclusion and exclusion criteria. The full text was obtained for all potentially eligible studies, including those where there was any uncertainty regarding eligibility. HE reviewed the full text of four potentially eligible studies using a short form listing the inclusion and exclusion criteria. This process was repeated by a second author (RD), and a meeting was held to ensure consistency. HE then reviewed all remaining full text studies noting reasons for all exclusions. RD was available to resolve any doubts as to whether specific studies were eligible.

Data Extraction and Management

The following data were extracted into a standardised table (Supplementary Material): Author, year, country, aim, study design, mobile device for delivery and all review outcomes listed earlier. Counting and narrative summary were used to synthesise methods and processes.

Sufficiency of Reporting

This review was likely to include a variety of study designs and therefore assessment of study quality was not appropriate. Furthermore, the review was focused on processes rather than traditional study outcomes. Thus, an assessment of sufficiency of reporting was undertaken using an amended version of an eight-item checklist for reporting non-pharmacological interventions [18, 19].

1. Setting—is it clear where the co-design/development of the intervention took place?
2. Stakeholders—is it clear who was involved in the co-design, and do you know all that you need to about the participants?
3. Facilitators—is it clear who facilitated the co-design process?
4. Procedure—is it clear what co-design methods were used?
5. Materials—are any physical materials used in the co-design process adequately described?
6. Intensity—is the length of the co-design phase and individual sessions clear?
7. Schedule—is the interval and frequency of the co-design sessions clear?
8. Missing—is the description of the overall co-design process complete?

Results

Identification and Selection of Studies

Identification and selection of studies is summarised in Fig. 1. Following removal of duplicates, 481 articles were identified via the search strategy of which 464 were excluded using the

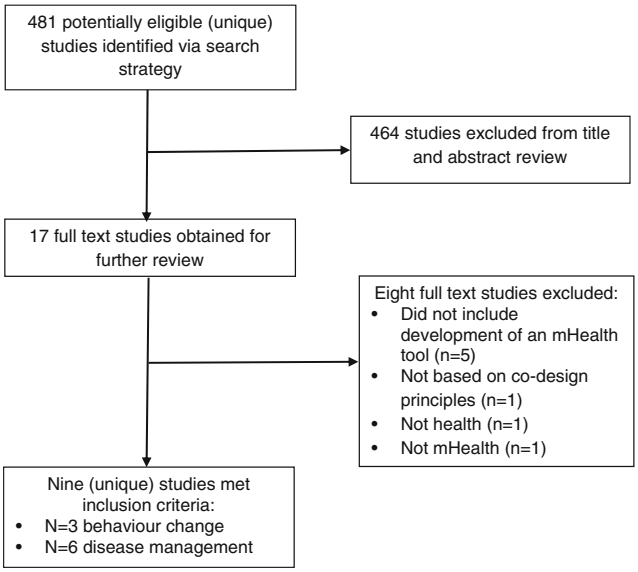

Fig. 1 Identification and selection of studies

title and abstract. Seventeen unique full-text studies were obtained for review, of which nine met inclusion criteria. Included studies were found on Medline ($n = 3$), CINHAL ($n = 3$), EMBASE ($n = 2$) and Scopus ($n = 1$) databases. There were four reasons for exclusion at the full text stage, i.e. (1) did not include development of an intervention (formative research only; $n = 5$), (2) were not based on co-design principles ($n = 1$), (3) were not focused on treatment or management of a health condition ($n = 1$) and (4) the intervention was not delivered by a mobile device ($n = 1$).

Characteristics of Included Studies

The nine included studies were from six countries, with three from the USA [20–22]; two from Sweden [23, 24] and one each from Australia [25], Canada [26], Scotland [27] and the UK [28]. The majority of studies ($n = 6$) developed interventions for delivery on a smart phone. One was text message-based and thus developed for delivery on either a mobile phone or smartphone [20], and two were Internet-based [23, 24]. Most studies ($n = 6$) focused on developing tools for disease management as compared with behaviour change ($n = 3$) [20]. All three behaviour change studies focused on young people, with interventions aimed at improving nutrition and physical activity, positive communication and weight loss (Supplementary Material). With one exception where the focus was management of adolescents with type 1 diabetes [28], all disease management studies focused on adults with a variety of medical conditions, i.e. schizophrenia, type 2 diabetes, mental health and addictions, brain injury and dementia (all $n = 1$). No studies were identified that focused on improving health outcomes for minority and indigenous population groups. Detailed characteristics of included studies are described in the "Review Outcomes" section.

Review Outcomes

Theory-Based Frameworks Used for Co-design

The majority of studies ($n = 6$) reported and referenced using one or more frameworks to inform the co-design or participatory process. One study reported using a framework but did not reference it [20] and two studies [22, 27] did not report using any type of co-design framework. The six referenced frameworks included different versions of participatory design [29–33] ($n = 4$) [21, 23, 24, 26]), process mapping to identify key stakeholders [34] ($n = 1$ [23]), and sociotechnical design principles [35] ($n = 1$ [28]).

Timeframe for the Co-design Process

Five of the nine studies reported information about the timeframe for development of the mHealth intervention. However, not all studies included the same number of phases or cycles of design. The timeframe for the initial formative phase from assessment of knowledge to development of intervention content (prior to pilot testing) was not reported separately. However, the timeframe from the formative phase to the end of the pilot test phase ranged from 12 [20] to 15 months [23, 24] ($n = 3$ studies reporting).

Number and Type of Participants and Other Stakeholders Involved

All nine studies reported on the number and type of people involved in the development of the mHealth interventions. The number of total individual participants involved in formative development ranged from approximately 10 [26, 28] to ~1000 [22]. Type of participants and other stakeholders varied by study, but representatives from the target population or clinical group for which the intervention was intended were always included (at a minimum). Other stakeholders involved in intervention design (across all studies) were carers for those with clinical conditions; relevant clinical and/or public health practitioners; service providers; information technology experts (e.g. software programme developers and Web designers); behavioural experts; students; project managers; elders relevant to the culture of the intended users; relatives of the intended users; education experts and social workers. Two studies specifically mentioned the involvement of an advisory or reference group [23, 25] including scientific, stakeholder and technical members responsible for input and final signoff for all or specific phases of intervention development. Information on age, gender and socioeconomic position of participants and stakeholders was generally poorly reported, with no study displaying a table of participant demographics.

Methods for Recruitment or Engagement of Participants and Other Stakeholders

Five of the nine included studies described recruitment methods, with all using purposive, convenience samples. Specific methods for engagement of individuals were reported by two studies, i.e. letters sent home to parents of children in youth programmes [20] and invitations through existing professional networks [25].

Methods and Phases of Design

The 17 methods used to co-design interventions in the nine studies are summarised in Table 1. The most common methods used were focus groups ($n = 5$) and surveys ($n = 5$), followed by single-person formative interviews ($n = 4$) and single-person design or prototype testing sessions ($n = 4$) and advisory group discussions ($n = 3$) and surveys ($n = 3$).

The participatory design frameworks reported by six of the nine studies involved a series of stepwise phases or cycles, which overall included six key steps: (1) assessment of background knowledge and evidence, (2) assessment of user needs to inform the focus of intervention, (3) assessment of user needs to inform type of technology used, (4) development of the intervention including content and framing, (5) pre-testing of intervention prototypes followed by changes based on feedback, and (6) pilot testing of the intervention the 'real world' providing feedback incorporated into the final version of the intervention. Table 2 summarises the number of phases included by the nine studies. All nine studies reported including an intervention development phase as this was a criterion for inclusion in the review. Most studies ($n \geq 5$) reported assessing user needs to inform the intervention focus, pilot testing, and real-world testing, but only two studies reported assessing the evidence and the background knowledge of participants [20, 23].

Degree of End User Input into the Final Intervention

Table 2 shows the extent to which participants or potential end users had input into each of the identified phases of intervention development. All nine studies reported including end users in the development of intervention content. Most studies ($n \geq 5$) included end users in pilot testing and real-world testing, but only two studies reported including them in assessing the best type of technology for intervention delivery [22, 28], and one included end users in assessing knowledge and background evidence [20].

Intervention Effectiveness

Intervention effectiveness was not assessed by any of the studies in the review. One study reported beginning a randomised controlled trial [21]. One of the authors (HE) searched for the results on appropriate databases and via Google Scholar. She also emailed the corresponding author, but did not get a reply within 2 months. One further study reported planning to undertake an RCT of the effectiveness of the intervention in the future [23].

Sufficiency of Reporting

Studies were scored according to a 7-item checklist for reporting non-pharmacological interventions (Supplementary Material) [18, 19]. Scores ranged from 2 (poorest reporting; $n = 3$ studies) to 5 ($n = 1$ study; highest quality reporting) of a maximum score of 7. One study [24] scored 5/7 and the remainder scored 4 or less. Authors of all studies reported the setting clearly and the majority of studies reported the co-design methods ($n = 5$) clearly. However, few studies adequately described materials used ($n = 2$) or the length and frequency of design sessions ($n = 1$).

Discussion

This review included nine studies which used co-design or participatory-based methods to develop a mobile health intervention to support health behaviour change or disease management. Only one study focused on aspects of nutrition as a main outcome [20]. The main findings from the review are that (1) one third of studies did not use a development framework despite reporting the use of co-design or participatory-based methods, (2) multiple models of co-design were used by studies that did report using a framework, (3) no mHealth study had used co-design to develop an intervention for minority and indigenous groups, and (4) most mHealth studies report insufficient information in their intervention development processes.

The strengths of this review include that it was conducted in a systematic manner across six diverse scientific databases. Further, consistency of included studies was ensured by two co-authors. Nonetheless, it is possible that some relevant studies were missed due to the restricted date range (previous 10 years) and limiting the review to articles published in English. However, a check revealed that the searches did not identify any eligible non-English studies or any eligible studies published prior to 2007. Therefore, it is unlikely that these restrictions resulted in a large number of relevant studies being excluded. Further, although intervention effectiveness was an outcome of this review, publication bias could not be assessed due to lack of a suitable, common quantitative outcome measure.

A strength of the included studies was that the setting and co-design methods were reported sufficiently. However, despite the types of methods used in the co-design phases being named, detail regarding what took place and involving who,

Table 1 Methods used in co-designing interventions in the nine studies of the review

Number	Processes	Number of studies using process (references)
1	Focus groups/ group discussions	5 [20–22, 24, 26]
2	Survey	5 [20–23, 26]
3	Single-person formative interviews	4 [23, 25, 26, 28]
4	Single-person design or prototype testing sessions	4 [21, 26, 28]
5	Advisory team discussions	3 [22, 23, 25]
6	Review of existing resources/technology	2 [23, 25]
7	Pilot study to test user acceptability	2 [20, 26]
8	Storyboarding	2 [23, 25]
9	End users providing photos and video to inform intervention development	1 [24]
10	Asking experts for who should be involved in development	1 [26]
11	Classroom discussions	1 [20]
12	Responding to comments on social media	1 [27]
13	Observation of interaction with intervention	1 [28]
14	Phased roll out of intervention for fine tuning	1 [21]
15	Half-day workshops	1 [23]
16	Expert review of final intervention	1 [24]
17	Sandpit testing of prototype in groups	1 [23]

was insufficient. For example, it was not possible to determine exactly how many co-design sessions were used, who facilitated those sessions, or their length and spacing. This resulted in the findings of the review being limited in terms of their use for future researchers and co-designers. Inadequate reporting of interventions has been explicitly identified as a weakness in much published research on non-pharmacologic interventions [36•, 37•] and mHealth studies [38].

Although CBPR has been used frequently to develop health interventions with minority and indigenous groups, no studies were identified where co-design methods have been used to develop mHealth interventions for these groups. This may be in part due to expectations of lower mobile device ownership and/or connectivity for these groups. However, there are few data available to support or refute this. The World Health Organization states that health research involving indigenous peoples, whether initiated by the community itself or by a research institute, needs to be carried out in a manner that takes cultural differences into account, is based on mutual respect and is beneficial and acceptable to both groups [39]; these priorities align with the core principles and values of co-design and CBPR [13], further signifying its appropriateness for the development of mHealth interventions.

Due to a lack of similar reviews, it was not possible to relate our methods or findings with comparable reviews. However, our review highlights important new areas for future research, i.e. to use co-design methods and processes for the development of mHealth interventions, particularly for supporting

Table 2 Co-design phases and end user input in the nine studies in the review

Number	Phase	Number of studies including phase (references)	Number of studies including end user input into phase (references)
1	Assess background knowledge and evidence	2 [20, 23]	1 [20]
2	Assess user needs to inform intervention focus	5 [21, 22, 24, 26, 28]	3 [24, 26, 28]
3	Assess user needs to inform technology	4 [22, 24, 26, 28]	2 [22, 28]
4	Develop intervention content	9 [20–28]	9 [20–28]
5	Prototype testing	7 [21–26, 28]	7 [21–26, 28]
6	Pilot/real-world testing	6 [20–22, 24, 26, 28]	6 [20–22, 24, 26, 28]

improved nutrition, and for minority and indigenous population groups, and to determine whether co-design is more effective than traditional approaches to intervention development. Co-design and participatory methods have been used successfully to redesign health care services to better fit the needs of consumers [10], thus extending these methods to develop nutrition and health interventions is a logical next step. The fact that co-design principles align with frameworks for indigenous health suggests that co-designed interventions will be better used and accepted, and thus be more likely to reduce inequity. In addition, the broad population penetration of mobile and wireless technologies as well as advancements in their application suggest co-designed mHealth interventions have wide reach and potential acceptability by most populations.

An important implication of this review for researchers and community groups is to ensure sufficiency of reporting using standard checklists for co-design and mHealth interventions. Development of a standard checklist for co-designed studies would also be beneficial, and could be based on a previous example such as that by Hoffman et al. [40]. Adequate reporting enables consistency and repeatability of methods and contribution to systematic review. Further, researchers and communities should consider the time and resources needed when embarking on a full co-design process—our review found a wide range in the level of input into methods and processes, and some studies were limited in this respect. Finally, assessing the effectiveness of co-designed interventions in formal process evaluations and randomised controlled trials is important to determine the efficacy of this method for developing mHealth interventions.

Conclusion

There is limited research to date on the key methods and processes used to co-design mHealth interventions. The nine studies included in this review used a range of co-design models, but few reported use of a development framework and most failed to sufficiently report their intervention development processes. Further, despite the alignment of co-design principles and values with those of minority and indigenous research, no mHealth study had used co-design methods to develop an intervention for these population groups. Future research should consider co-design for the development of mHealth interventions to support better nutrition and for minority and indigenous groups, ensure sufficient reporting and include a robust assessment of efficacy.

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Compliance with Ethical Standards

Conflict of Interest Helen Eyles, Andrew Jull, Rosie Dobson, Ridvan Firestone, Robyn Whittaker, Lisa Te Morenga, Debbie Goodwin and Cliona Ni Mhurchu declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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- •• Of major importance

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