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 personalized 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.

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(4-6). 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 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 co-operation 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 is 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 above. 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 Figure 1. Following removal of duplicates, 481 articles were identified via the search strategy of which 464 were excluded using the 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 United States(20-22), two from Sweden(23, 24), and one each from Australia(25), Canada(26), Scotland(27), and the United Kingdom(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 below.

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 months(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 ~1,000(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).

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

#	**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)

The participatory design frameworks reported by six of the nine studies involved a series of step-wise 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≥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).

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

#	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)

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≥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 two 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 seven item checklist for reporting non-pharmacological interventions (Supplementary Material) (18, 19). Scores ranged from two (poorest reporting; n=3 studies) to five (n=1 study; highest quality reporting) of a maximum score of seven. One study(24) scored 5/7 and the remainder scored four 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) 1/3 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, 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 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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Conflict of Interest

All authors declare that they have no conflict of interest.

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This article does not contain any studies with human or animal subjects performed by any of the authors.

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Supplementary material

1. Review search strategy for MEDLINE database

1. co-design$.mp.

2. codesign$.mp.

3. Community-Based Participatory Research/

4. Consumer Participation/

5. action research.mp.

6. participatory design.mp.

7. co-production.mp.

8. experience based design.mp.

9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8

10. Telemedicine/

11. mhealth.mp.

12. m-health.mp.

13. mobile health.mp.

14. Cell Phones/

15. mobile phone$.mp.

16. mobile device$.mp.

17. telehealth.mp.

18. Mobile Applications/

19. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18

20. 9 and 19

21. limit 20 to (english language and humans and yr="2005 -Current")

2. Characteristics of the nine studies included in the review

Disease management studies		
Ben-Zeev (2013) – Chicago, United States(22)		
Aim	To describe the development of a smartphone illness self-management system for people with schizophrenia.	
Study design*	Other design of interest	
Mobile device	Mobile phone / **Smart phone** / Internet / Other mobile device	
Participants – design	All participants from one large psychiatric rehabilitation agency in Chicago. Stage One surveys (n=904 individuals with schizophrenia or schizoaffective disorder + eight practitioners). Mean age individuals = 47yrs; 68% male, 61% Caucasian, 5% Hispanic, 34% less than high school diploma, 74% <$US10,000 annual income. Stage Two design principles (multidisciplinary team of consumers and practitioners with expertise in illness management, behavioural intervention technologies, telemedicine, smartphone software programming, and public health). Stage Three laboratory sessions (n=12 consumers with mean age 45yrs, 75% African American, 75% owned and used mobile device)	
Participants – effectiveness	Effectiveness not evaluated.	
Co-design process		
Theory-based framework**	N	Framework not reported specifically for the co-design component. Intervention developed using the cognitive model of psychosis and the stress-vulnerability model of schizophrenia(41, 42).
Timeframe for design	Not reported.	
Methods for engagement	For stage one service staff surveyed individuals receiving care at the time. Recruitment not reported.	
Co-design process/methods	**Process:** Three stages. Stage 1 needs assessment – survey of people receiving care at the time asking about ownership and use of technology, payment methods and interest in future services. Info combined with electronic health records. Practitioner input collected via survey of potential use of mobile devices for care provision and group discussion facilitated by authors on how mHealth could best be used in this group. Stage 2 design principles – multidisciplinary team worked together to develop (no further detail provided). Stage 3 usability testing – two hour individual lab based testing – participants asked to perform series of tasks on using a smartphone first in presence of facilitators – one to administer and one to scribe. Feedback provided on the interface look and used all modules with comments and observations documented. Finally, brief questionnaire was completed to rank components of the app and give a list of names for the system to rate. Early testing was on web version of app (n=7) with later testing on native app (n=5). **Materials:** Web version of app followed by native version. Other materials not reported. **Number of sessions:** Not reported	

	Frequency of sessions: Not reported **Spacing of sessions:** Not reported **Facilitators:** Authors of paper **Analysis:** Not reported	
Intervention assessed	N	Disease management - process evaluation only
Evaluation results	Y	**Design phase:** Stage one survey: Indicated interest in receiving mHealth services delivered via mobile device (44%) including medication and appointment reminders, check ins with practitioners (38%) and education and information about treatment and services (31%). Practitioners saw value in mHealth platform would be useful for monitoring of symptoms and could be remotely accessed by practitioners, would support and expand services and give individuals tools at any time. Recommended going beyond text messages and emphasized importance of suitability for low literacy. Stage Two not evaluated. Stage Three: First round found app was usable, participants had trouble understanding abbreviations and longer words, text too long, font too small, and buttons too close together. Liked images. Second round positive and all felt could use system. **Usability testing:** Found some design vulnerabilities which resulted in system being adapted to better address consumer needs and preferences. **Effectiveness:** Not assessed.
Berg (2013) – Sweden(23)		
Aim	To describe the process of developing person-centered web support for women with type 1 diabetes during the period of pregnancy through early motherhood.	
Study design*	Other design of interest	
Mobile device	Mobile phone / **Smart phone** / **Internet** / Other mobile device Internet focused. Smart phone component mentioned but not explained.	
Participants – design	Phases One and Two: researchers, mothers with type 1 diabetes, healthcare professional in diabetes and perinatal care, and web designers. Scientific group: Project managers, advisory and scientific reference groups, technical producers, representatives of the target group. Project management group: scientific leader (n=1), project leaders (n=2), and student midwife (n=1). Scientific reference group: Medical experts (n=4), IT expert (n=1) Stakeholder group: Advisory group (doubled as stakeholder consultation group): mothers with type 1 diabetes (n=7), midwives 9n=4) Technical production group: Project leader (n=1), web programmer (n=1), and designer (n=1)	
Participants – effectiveness	Effectiveness not assessed. RCT to be undertaken in the future.	
Co-design process		
Theory-based	Y	Stated used participatory design to capture target groups

framework**		knowledge, experiences and needs (30). Also used a systematic two stage process map for systems development to develop web based support which describes key types of participants who should be part of the development process(34). The two stages include needs assessment, evidence synthesis, and consensus on evidence followed by storyboard, sandpit testing, usability testing, and field testing.
Timeframe for design	15 months from formative phase to final intervention developed.	
Methods for engagement	Not reported.	
Co-design process/methods	**Process:** Mapping exercise of existing similar websites and a needs assessment (previous research by authors and internationally) followed by participatory design process including three main phases: (1) exploration of work, (2) discovery process, and (3) prototyping to capture knowledge, experiences and needs. Scientific reference group continually consulted. Advisory group input on dissemination, content, structure, usability. Technical production group owned IP and gave advice on content, structure, and applicability. Methods for development included a web survey and discussions with professionals and methods of target audience. The design phase included a half day workshop on content using storyboarding resulting in a specification document for website and contractor. Sandpit testing used where a prototype was transformed to a website which was then tested by the Advisory Group (mothers and midwives). Several revisions were undertaken before final website produced. Draft text was also reviewed for format and content. Website developed and amended following feedback from groups above. **Materials:** Storyboard and prototypes. **Number of sessions:** Not reported **Frequency of sessions:** Not reported **Spacing of sessions:** Not reported **Facilitators:** Not reported **Analysis:** Not reported	
Intervention assessed	N	Disease management - process evaluation only
Evaluation results	Y	**Design phase:** <u>Needs assessment</u>: sharing common experiences important (rest not reported). <u>Evidence synthesis</u>: Time of increased risk for mother and baby. Most important to maintain material normoglycaemia, but hypoglycemic episodes are frequent. Women are stressed, worries, pressure and feel insecure and unpredictable. Mothers focus on baby means less focus on own wellbeing. Gap in healthcare for target women makes transition to motherhood challenging. Consensus on evidence: three main components for intervention i.e. information, self-care diary, and forum for peer support. **Effectiveness:** Not assessed.
Dingwall (2015) – Northern Territory, Australia(25)		
Aim	To use a participatory action framework to translate the AIMhi (Australian Integrated mental Health Initiative) MCP (motivational care planning) intervention into electronic format and then conduct an initial	

	exploration of the acceptability, feasibility, and appropriateness of this new resource for service providers working with Aboriginal and Torres Strait Islander people in Northern Territory.	
Study design*	Other design of interest	
Mobile device	Mobile phone / **Smart phone** / Internet / Other mobile device SMS intervention tested on smart phones with additional content provided.	
Participants – design	Expert reference group and service providers involved (n=15) but make up not provided. Service providers (n=15) including health professionals, managers, programme coordinators, and Aboriginal elder involved in delivering mental health, alcohol and other drugs, or chronic disease services to Aboriginal or Torres Strait Islanders. Service providers included Aboriginal and Torres Straight Islanders (n=4) and non-Indigenous (n=11).	
Participants – effectiveness	Disease management – effectiveness not assessed.	
Co-design process		
Theory-based framework**	M	Stated used participatory action framework but not referenced. Original resource based on problem solving therapy and motivational interviewing.
Timeframe for design	Full time frame not reported (initial formative phase 1 month)	
Methods for engagement	Engagement of expert reference group not provided. Recruitment of service providers through purpose sampling using existing professional networks.	
Co-design process/methods	**Process:** Five steps: establish team with Queensland University of Technology, review of EIMhi educational and brief intervention resources with research and development team, establish Expert Reference Group, consult with research team and expert group to revise and review app using story board and screen mock ups, and release first version for further testing and evaluation. 11 semi-structured interviews (individual or small groups; ~40mins duration) with 15 service providers and managers. Service providers in other territories also consulted but not included in current study. **Materials:** Story board and screen mock ups for expert group development. Interview guide for testing of first version. **Number of sessions:** Expert group development sessions not reported, but n=15 interviews for primary testing. **Frequency of sessions:** Not reported **Spacing of sessions:** One per service provider (with one exception) conducted between Oct and Dec 2013. **Facilitators:** Authors facilitated interviews. **Analysis:** Interviews were analysed by all members of the research team using thematic analysis. Consensus reached by team on all points and themes were presented to the expert group for further discussion and cross checking.	
Intervention assessed	Y	15 service providers and managers trialed for one month.
Evaluation results	Y	**Design phase:** support provided for acceptability, feasibility, and

		appropriateness of the app. Key themes: acceptability (visually appealing, easy to use cultural relevance and innovative format), building relationships (breaks down barriers, opens up conversation), broad applicability (to people and settings and ways of using app suggested), constraints to implementation (IT accessibility, time to use longer than paper, resistance by other staff, different Indigenous languages useful), integration with other systems important, and training recommendations (content and process). **Effectiveness:** Not assessed.
Groussard (2015) – Quebec, Canada(26)		
Aim	To design a mobile cognitive assistant to enhance autonomy of people living with acquired traumatic brain injury, based on their expressed needs, and to conduct a proof of concept to show that the assistant meets the needs.	
Study design*	Other design of interest	
Mobile device	Mobile phone / **Smart phone** / Internet / Other mobile device Mobile assistant was a smart phone app.	
Participants – design	Male adults with cognitive brain injuries (n=4) and caregivers (n=3). Adults with head injury were unable to live independently and required help with at least one daily living activity, suffered injury for 5yrs+, able to speak, able to live in a residence where they could go to work or volunteer, and able to use electronic device. Caregivers must have looked after person for six months or more. Age range: 30-70yrs. Other stakeholders: psychoeducators (n=2), and social worker (n=1).	
Participants – effectiveness	Disease management – effectiveness not assessed.	
Co-design process		
Theory-based framework**	Y	Stated participatory (iterative) design methodologies guided the research(32). Followed six stages of participatory design outlined by Dolbec (1) perception of the issue, (2) identification of the issue, (3) exploration and planning of the solutions, (4) implementation of the solution, (5) evaluation of the solution, and (6) dissemination(31).
Timeframe for design	Timeframe for formative phase not reported. Three-weeks to train participants to use the app, and eight-week test/pilot.	
Methods for engagement	Not reported.	
Co-design process/methods	**Process:** Six steps of participatory design. (1) Perception of issue: consulted University laboratory working with people with head injury on who to include in research; (2) Needs identification: semi-structured interviews with participants and caregivers on life satisfaction, social participation, and computer abilities. Given 20 q's about life situations and rated feelings on graduation scale. Also completed standard questionnaire evaluating social participation, and q's about computer use and expectations of the project; (3&4) Exploration, planning, and implementation of solutions: three focus groups to discuss mobile	

	services identified during interviews and determine functionality needed – services presented, discussed, and voted on; (5) Solution evaluation: participants tested the assistive design at home and work, first for six individual meetings of 30 to 60mins. Actions were presented and repeated by participants with time to ask q's. Ability to complete actions rated by interviewer. Next the service was used as intended in scenarios, and finally in real life situations. An 80% success rate needed to move to next stage. The real life phase lasted eight weeks and included fortnightly meetings to collect use and satisfaction information. Appreciation for life questionnaire administered before pilot test, during, and after. **Materials:** Questionnaires, methods for showing participants functions and formats for the app. **Number of sessions:** Interviews (n=4), three focus groups (45mins with 15min break), individual meetings during testing (n=6 per participant 30 to 60mins) **Frequency of sessions:** Not reported **Spacing of sessions:** Not reported **Facilitators:** Not reported **Analysis:** Appreciation for life scores assessed. Interview questions groups according to social participation issues. Focus group votes assessed. Early phase learning data graphed. Usage logs of smartphones assessed.	
Intervention assessed	Y	Tested at home and at work for eight weeks.
Evaluation results	Y	**Design phase:** Three functions proposed for focus groups: time management, money management, and life experience monitoring. During focus groups functions and interfaces for the app were presented, rated, and discussed. Smartphone app then developed. **Pilot test:** Participants used the app more in the first week, then stabilised. Few live events were recorded, and budgeting tool not used as often as anticipated. Use differed significantly between participants. All participants liked the app but only one would have liked to continue using it. Mixed results for life satisfaction scores. **Effectiveness:** Not assessed.
Hanson (2007) – West Sweden(24)		
Aim	For researchers, practitioners and technicians in West Sweden to work together with older people with early stage dementia and their family members to develop a user-friendly technology-based information, education and support service, based on the generic ACTION participatory design model.	
Study design*	Other design of interest	
Mobile device	Mobile phone / Smart phone / **Internet** / Other mobile device Programme included personal computer, videophone, and Internet.	
Participants – design	Phases One and Two: older people with dementia (n=7; 3 women; aged 68-81yrs) and project nurse facilitators (n=2). Inclusion criteria: creative, expressive, willing to contribute and use a computer, 65yrs+,	

	confirmed dementia, Mini-mental state examination (MMSE) score 20+. Phase Three: n= 19 people with dementia and 12 relatives. Inclusion: awareness, family support, 60yrs+, confirmed dementia, MMSE score 25+.	
Participants – effectiveness	Disease management – effectiveness not assessed.	
Co-design process		
Theory-based framework**	Y	Stated used Assisting Carers using Telematics Interventions to meet Older People's Needs (ACTION) participatory design model(33). The process facilitates collaboration between skilled users and designers, is iterative, comprising cycles of development and evaluation until an agreed solution is reached. It comprises three phases: identifying user needs, early programme development, testing and refining.
Timeframe for design	~15 months from formative phase to development of final intervention.	
Methods for engagement	Phase 1 development group recruited from primary healthcare centres.	
Co-design process/methods	**Process:** Three phases. One and Two (identifying needs and development). Development group met weekly for 4 months, then fortnightly for 5 months. Users' needs and preferences explored via discussion groups (tape recorded). Later sessions involved participants photographing and videoing homes to provide useful development material. Changes were made to the programme each session and reviewed at the subsequent session. Tuition on using the computer programme was also provided. The initial programme was quality checked by a geriatrician, modified, and developed into the final 12 week educational support programme. Phase Three (verification) involved programme testing during group sessions (12 weeks) facilitated by two nurses and a multi-media technician. The programme was also installed in participant's homes. Follow up support was available via videophone with nurses and other participants. In-depth interviews with participants and their next of kin were undertaken prior to the star, during the programme and discussion sessions. A focus group and home interviews were held at the end. Lessons learned: prioritise overall wellbeing of participants, allow ample time, provide active and continuous support, select a satisfactory location for meetings ensuring good access, toilets, cafeteria, transport etc. **Materials:** Multimedia screen, videos and photographs from participants. **Number of sessions:** 26 for development phase and 12 for validation phase. **Frequency of sessions:** Phases One and Two: weekly for first 4 months then fortnightly. Phase Three: weekly **Spacing of sessions:** As above **Facilitators:** Nurses and technicians. **Analysis:** Discussion sessions were often recorded and notes were taken to inform further stages. No formal analysis methods reported.	

Intervention assessed	Y	12 week programme tested by people with dementia and 12 relatives.
Evaluation results	Y	**Design phase:** Elders with early stage dementia can be actively involved throughout the entire research and development process. Essential prerequisites are time and ongoing support by skilled practitioners and family members. They can also learn and benefit from user-friendly technology, especially when used together with others in a similar situation. Being involved in the design was enjoyable, improved self-confidence and according to spouses resulted in less irritability and more relaxation. Participants were anxious about using the computer but all except two people enjoyed it and felt it boosted self-esteem (although using mouse could be frustrating). The programme affirmed participant's recent lives, stimulating them to share experiences and maintain a sense of normality. Provided useful information about services people were not previously aware of. Was relaxing, enabled them to bond with younger family members. There was some difficulty logging in. **Effectiveness:** Not assessed.
Hingle (2013) – Airzona, United States(20)		
Aim	To develop and test messages and a mobile phone delivery protocol designed to influence the nutrition and physical activity knowledge, attitudes, and behaviour of adolescents.	
Study design*	Other design of interest	
Mobile device	**Mobile phone** / **Smart phone** / Internet / Other mobile device SMS intervention tested on smart phones with additional content provided.	
Participants – design	One hundred 12 to 18 year olds enrolled in youth programmes between fall 2009 and 2010 (53% female over design and intervention phases). Focus groups (n=59) and class discussions (n=86)	
Participants – effectiveness	12 to 18 year olds enrolled in four youth groups between fall 2009 and 2010 (53% female over design and intervention phases) Pilot study (not true effectiveness; n=32)	
Co-design process		
Theory-based framework**	M	State uses a multistage youth participatory approach (involving youth in intervention, testing, and evaluation) but no reference given.
Timeframe for design	12 months from formative phase to end of pilot study.	
Methods for engagement	Recruitment through youth educators and leaders from 11 youth programmes that did not specifically focus on health. Letters sent home to parents.	
Co-design process/methods	**Process:** Focus groups followed by classroom sessions followed by pilot study. Content for SMS created using literature search, popular consumer resources, and survey of 100 freshman college students. 300 messages developed by research team and tested in focus groups. Messages taken to classroom discussions for refinement. In class students given 25 questions to rate as like, needs adjustment, or don't	

	like based on a class vote. Reasons recorded as to why they weren't liked. Messages categorised as liked or needs adjustment included in pilot study (once amended where necessary). Findings used for SMS intervention. **Materials:** Semi structured script for focus groups. Additional information provided on phone in pilot study e.g. recipes, but no information on how this was developed. **Number of sessions:** Nine focus groups, 4 classroom sessions, 8 week pilot study **Frequency of sessions:** Not reported **Spacing of sessions:** Not reported **Facilitators:** Discussions led by experts in qualitative research with teens. **Analysis:** Written field notes and audio recordings transcribed. Deductive thematic analysis to produce themes from field notes. Two interviewers checked to ensure validity and a summary report was written to inform message delivery protocol.	
Intervention assessed	Y	8 week pilot study. Participants provided with smart phone to ensure all had same technology and messages didn't cost. Two software programmes tested – weeks one to four 'pop up' messages at predetermined times and weeks five to eight one message per day + teaser message once per week to interact with additional content loaded to phone e.g. recipes. Informal small group interviews at end of pilot study to gather feedback.
Evaluation results	Y	**Design phase:** Short messages and quizzes preferred over longer messages (polls, scenarios, and recipes). Messages should be short, direct, and relevant. Voice important i.e. not authoritarian. Additional topic suggestions made and only 2 messages per day maximum from a credible source. **Pilot study:** Participants enjoyed messages but some were better than others. Shared with friends and family. Liked feedback loop on SMS. Preferred two messages per day at predetermined times as these were the ones they could interact with. **Effectiveness:** Not assessed.
Kanis (2009) – Scotland(27)		
Aim	To increase understanding of the design of technologies that support the elicitation and sharing of positive emotions. Further, to develop a tool to encourage social expressiveness that allows investigation and to improve the potential for shared positive communication.	
Study design*	Other design of interest	
Mobile device	Mobile phone / **Smart phone** / Internet / Other mobile device Smart phone app	
Participants – design	Study one: children and young people from local Scottish schools, 6 to 15 yrs, in three classrooms on the Highlands and Islands during an educational event. Approx 50% female. Study two: International (United States, Canada, Romania, Germany, Israel, United Kingdom).	

	Participants on Flckr (photo sharing) and 43 things (where users create goals and desires) social networking sites. ~50 participants over the two studies.	
Participants – effectiveness	Effectiveness not assessed	
Co-design process		
Theory-based framework**	N	Stated as two co-design studies, but no theory mentioned or referenced.
Timeframe for design	Six months for formative phase but timeframe for app development not reported.	
Methods for engagement	Recruitment for studies not reported.	
Co-design process/methods	**Process:** Two studies to inform the design steps and rationale for the app. Study one aimed to test different prefixes for expressing positive effects. Study two aimed to determine how positive expressions can be triggered, shared, and mediated by desktop and internet technology. Studies followed by a review of positive emotions posted on online sites Flickr (photo sharing) and 43things (where users create goals and desires) to gain wider understanding of positive emotions shared on a daily basis. Findings used to develop a smart phone app (PosiPost) which lets users create posts by asking them to finish a sentence starting with a prefix. Users receive one post back for each one they send. A website provides support and displays posts. **Materials:** Study one used a paper slips where participants finished an incomplete sentence with a range of prefixes to capture positive thoughts and posted it in a box. Study two used the same method but rather than paper based did this via online social tools i.e. a blog, emails, and anonymous chat room scenario. **Number of sessions:** Not reported **Frequency of sessions:** Not reported **Spacing of sessions:** Not reported **Facilitators:** Not reported **Analysis:** Postings from both studies were coded into 10 categories by type, by two people to ensure reliability. Postings could have multiple categories.	
Intervention assessed	N	
Evaluation results	Y	**Design phase:** Some prefixes more popular than others e.g. expressing emotions right here right now. Subjective wellbeing includes overcoming negative emotions and experiences, wealth and material possession, flow, progress, and accomplishment, social contact, savouring ordinary activities in daily life. Design consideration results for the app: design for positive reflection, for function, in a positive voice, in an effective format, using a range of prefixes, being cautious not to disclose private information, and to allow people to express emotions immediately. **Pilot study:** No evaluation undertaken. **Effectiveness:** Not assessed.

Lin (2015) – United States(21)		
Aim	To describe the design and development of the intervention tested in the Cell Phone Intervention for You study and to highlight the importance of adaptive intervention design that made it possible.	
Study design*	RCT - 24 month RCT comparing two active interventions to usual care control group. Main outcome: weight change at 24 months. Outcome measurement: Blue tooth body weight scales provided.	
Mobile device	Mobile phone / **Smart phone** / Internet / Other mobile device Smart phone app (10 components that covered personal coaching) vs. personal coaching (six weekly sessions lasting ~2hr each with 5 to 10 per group and monthly coaching phone call + app to monitor weight, diet and physical activity, but no feedback loop). The main feature of the app was prompting behaviour. Iterative/adaptive design where intervention updated throughout the trial.	
Participants – design	Focus groups: n=33 people with same characteristics as target population. First cohort of RCT (n not reported) also provided feedback on app components – incorporated for following cohorts.	
Participants – effectiveness	N=365 overweight or obese (BMI≥25kg/m^2) young adults (18 to 35yrs).	
Co-design process		
Theory-based framework**	Y	Stated used iterative, participatory design where potential users are engaged in the process of design creation(29). Active interventions were based on a behavioural framework including social cognitive theory and techniques from behavioural self-management and motivation enhancement.
Timeframe for design	12 months formative phase (no pilot testing).	
Methods for engagement	Not reported.	
Co-design process/methods	**Process:** Focus groups (n=6) to inform advertising strategies, message framing, preferred format, and intervention content; single-person participatory design sessions for usability evaluation and improvement; technical testing; and phased roll out of the intervention content. A phased roll out was used to deliver app components to ensure they worked and were engaging, with participants giving feedback along the way via reports generated on app use, and calls with participants every 6 months where three q's asked: what do you like/dislike, what changes would you like to help with weight loss, and how is the prompting working or not for you? New components were also designed during first cohort of trial. **Materials:** Paper prototypes of app components were developed, tested, and refined with input before software developed. Testing of prototypes undertaken. **Number of sessions:** Not reported **Frequency of sessions:** Not reported **Spacing of sessions:** Not reported **Facilitators:** Not reported	

	Analysis: Not reported	
Intervention assessed	N	24 month iterative/adaptive RCT comparing two active interventions (cell phone intervention and personal coaching with a mobile app to allow self-monitoring but no feedback) to usual care control group. Results to come in future paper.
Evaluation results	N	**Design phase:** Not reported. **Effectiveness RCT:** Results to come in future paper.
Pulman (2013) – South West United Kingdom(28)		
Aim	To develop an insight into young people's current use of web and mobile technology and its potential impact on HRoL by constructing an in-depth picture of their day-to-day experiences, exploring how they made use of technology in their lives and in relation to their condition and treatment – then building something to help them.	
Study design*	Other design of interest	
Mobile device	Mobile phone / **Smart phone** / Internet / Other mobile device Smartphone app	
Participants – design	Young people (n=9; 7 female; 18 to 21yrs) with type 1 diabetes. Inclusion: type 1 diabetes, six months post diagnosis, within age at date of recruitment, fluent in English. A dietitian reviewed content intended for the app. Clinic staff at Diabetes Centre tested the first prototype. The Patient Advice and Liaison Service reviewed the final versions of the app.	
Participants – effectiveness	Disease management – effectiveness not assessed.	
Co-design process		
Theory-based framework**	Y	Stated uses sociotechnical design principles during the design and build of the app(35). Involves defining human needs using the people associated with, and affected by, the technology. This includes democratic and participative communication and decision making to give people a voice.
Timeframe for design	Not reported	
Methods for engagement	Recruitment of participants from local diabetes centre within a hospital – used a non-random, convenience sample which was purposive.	
Co-design process/methods	**Process:** Semi-structured, in-depth qualitative interviews (1hr duration) covering experiences of mobile and computer technology, diagnosis and how technology used since, aspects of day to day life with diabetes, any technology used related to their condition, and any health related or social apps used. Ideas were explored for how to improve aspects and whether technology would help. Early interviews (n=4) to locate potential ideas for technological development, and latter interviews (n=5) to assist in iterative design process. Ideas from early interviews used to develop three prototypes shown to participants in latter interviews. Participants were observed using the apps to see what needed to be changed re navigation, and what was of interest. They also chose their favourite. The final app on alcohol was developed from course content after	

	examination by a dietitian and was also tested by clinicians (who completed questionnaire). Further feedback sought from Patient Advice and Liaison Service, and following submission to the Apple store. Five iterations of app in total based on all feedback. **Materials:** Prototypes of the apps **Number of sessions:** Nine interviews in total **Frequency of sessions:** Not reported **Spacing of sessions:** Not reported **Facilitators:** Not reported **Analysis:** Interviews were transcribed and loaded onto NVivio for theme identification.	
Intervention assessed	N	Process evaluation only as per above.
Evaluation results	Y	**Design phase:** Three ideas from early interviews taken forward for prototyping (alcohol, illness, and hypoglycaemia) with one (alcohol education guide) taken into final app development. **Effectiveness:** Not assessed.

3. Sufficiency of reporting for the nine studies included in the review*

Author (year)	Setting	Stakeholders	Facilitators	Co-design methods	Materials adequately described	Length of design and sessions clear	Interval and frequency of sessions clear	Score (from previous seven attributes)
Ben-Zeev (2013) – Chicago, United States(22)	Clear	Unclear	Clear	Unclear	Yes	No	No	3
Berg (2013) – Sweden(23)	Clear	Unclear	Unclear	Unclear	No	No	No	1
Dingwall (2015) – Northern Territory, Australia(25)	Clear	Unclear	Clear	Unclear	No	No	No	2
Groussard (2015) – Quebec, Canada(26)	Clear	Unclear	Unclear	Clear	No	Yes	No	3
Hanson (2007) – West Sweden(24)	Clear	Unclear	Clear	Clear	No	Yes	Yes	5
Hingle (2013) – Airzona, United States(20)	Clear	Unclear	Clear	Clear	No	No	No	3
Kanis (2009) – Scotland(27)	Clear	Unclear	Unclear	Unclear	Yes	Yes	No	3
Lin (2015) – United States(21)	Clear	Unclear	Unclear	Clear	No	No	No	2
Pulman (2013) – South West United Kingdom(28)	Clear	Unclear	Unclear	Clear	No	Yes	No	3

*Sufficiency of reporting was undertaken using an amended version of an eight item checklist for reporting non-pharmacological interventions(18, 19)