A study protocol: co-designing a mobile application to enhance communication, safety and wellbeing for people living at home with early stage dementia

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Abstract

Background: There is a growing interest in using mobile applications in supporting health and wellbeing. Evidence directly from people with dementia regarding the acceptability, usability and usefulness of mobile apps is limited.
It builds on 'My Health Guide' which was co-designed with people with cognitive disabilities.
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Objective This paper describes the protocol of a study evaluating an app designed for supporting wellbeing with people living with dementia, specifically focusing on enhanced safety through improved communication between users. It builds on 'My Health Guide' which was co-designed with people with cognitive disabilities.

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Key words: co-design, dementia, mobile application, communication, safety

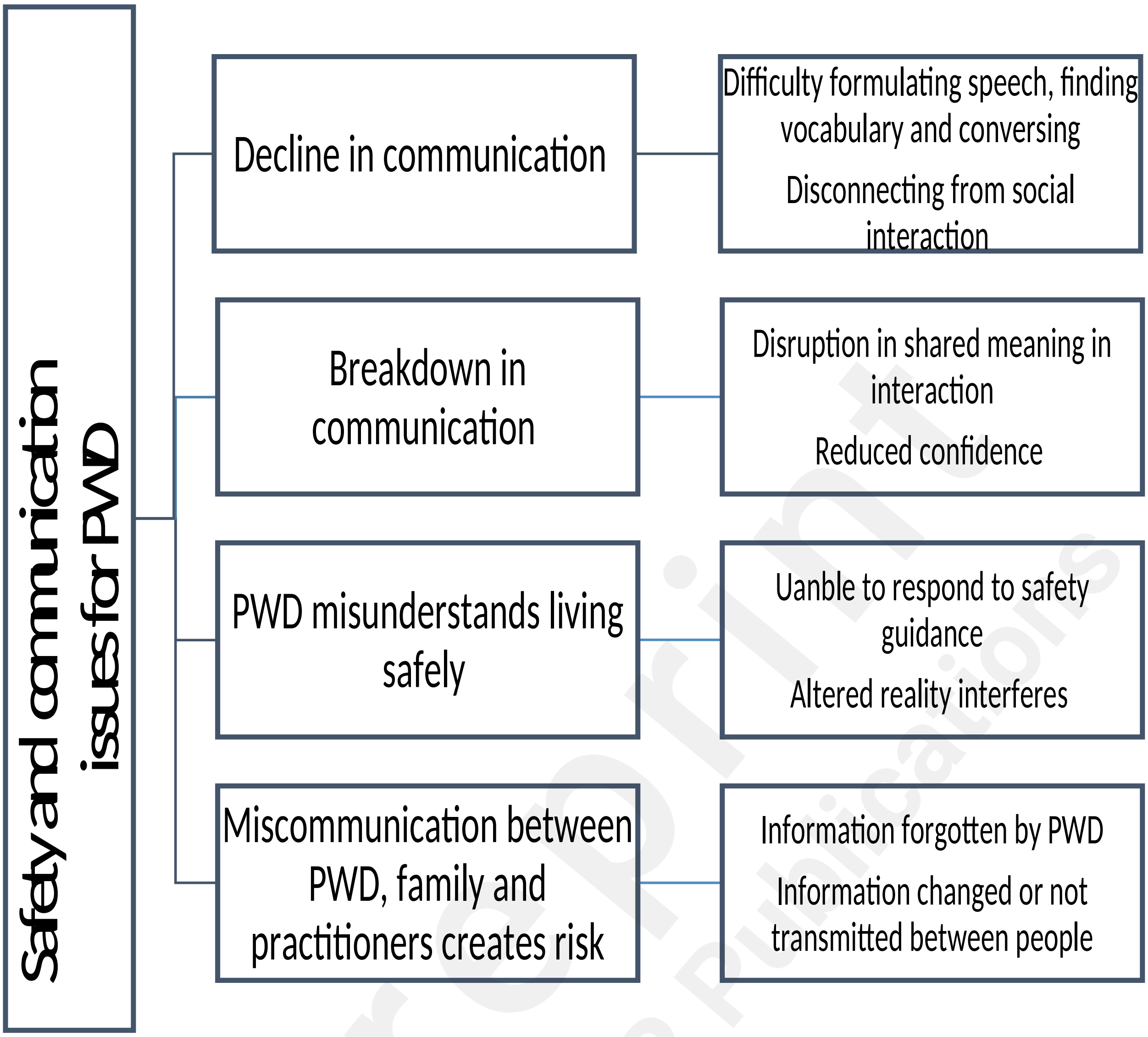
Background

This paper presents a protocol of a study examining an app used and managed by people living with dementia (PWD) and their families to improve communication and so reduce risks and enhance safety. Many PWD have complex health and wellbeing needs, requiring carefully balanced care plans that need to be implemented across multiple settings where health related activity and care takes place [1]. These can be difficult to manage for people with a complicated care regime, who may depend on a range of people for support, and also may have variable or deteriorating cognitive abilities affecting how they communicate with their family and practitioners. Confusion can be compounded by complex health and social care systems that are difficult to navigate [2, 3], adding to potential risks to safety. Minimising risks associated with poor management of health in PWD is a priority for governments [4] and for family carers [5]. The rapid development of digital technology has enhanced timely communication in society and offers innovative ways to support health and wellbeing for older people [6, 7]. Previous studies investigating the role of digital technology in supporting safety for PWD, have focused mainly on passive monitoring for people at late stage dementia [8]. There are fewer examples of the evaluation of interventions with PWD that take account of the outcomes that they and their families identify as priorities, throughout the course of dementia [5]. Where research has gathered user views of safety in primary care, people have identified the importance of basic physical needs such as being clean, comfortable, safe and secure at home, but also emphasised social and emotional concerns, for example, feeling respected and being able to see, hear and understand in order to communicate with others [9]. The background to the paper considers the issues of safety for people living with dementia and the implications for safety of communication difficulties specific to PWD, the role of assistive technology and potential of the My Health Guide app for enhancing safety, and Normalisation Process Theory as an explanatory model for the app intervention.

Safety for people living with dementia

Dementia is a neurological condition typified by a decline in brain function and structure affecting cognitive processing, such as memory, communication and control of physical movement [10]. There are different forms of dementia, characterised by specific symptoms and progression of the disease. However, the characteristics of progressive confusion, difficulty managing routine activities and limited communication are always evident, often associated with reduced awareness of risk and increased tendency to have accidents. For example, 18% of short stay emergency admissions to hospital of PWD in England in 2012/13 were related to injuries [11]. A number of safety issues have been reported in the literature [12], including injuries (eg. falls, ingesting dangerous substances, sharp objects, fires/burns), behaviour (eg. wandering and getting lost, inability to respond rapidly to a crisis, aggressive behaviour) and misuse of medication [13]. The progressive nature of dementia, together with a process of distancing from social interaction due to limited cognition and communication, may deepen an individual's vulnerability and susceptibility to compromised safety (Figure 1).

Figure 1: The relationship between communication issues for PWD and safety



The principal management of the condition involves alleviating the symptoms in order to maintain an active life, such that PWD frequently continue to live independently and safely with support from family and friends in their own homes [14]. Thus, there has been a shift from finding a cure for dementia to seeking life-enhancing and supportive strategies for the person within their social context. Such an approach emphasises relationships and interactions with the family and wider community, as embodied in the concept of personhood [15, 16] and relationship centred care [17]. Service users prioritise positive relationships, trust with care professionals and effective communication, when they consider patient safety in primary care [18], endorsing the importance of enhancing these for people living with dementia.

Safety implications of communication difficulties in dementia

Relationship centred care depends on effective interaction and communication between PWD and those in their social network, whether this is between professionals, formal carers or family and friends [19]. The cognitive deficits present in PWD will always be associated with declining language and communication skills with distinctive difficulties and strengths evident in early, middle and late stages of dementia (Table 1). Specific patterns of communication difficulties linked to types of dementia have been identified [20, 21], but three general features need to be considered in developing an intervention to improve communication. First, communication is a social act, depending on interaction and conversation, rather than a simple transaction of information from or to PWD [22]. Thus, communication difficulties and breakdown result from the interplay between two individuals, one with declining language skills and their conversation partner, suggesting that an intervention must enhance the interaction *between* PWD and others in their social world. This applies to both verbal and written communication. Second, changes occur in sensory skills, such as visual and auditory acuity, affecting the way communication is scaffolded [22]; it would be a mistake to assume that audio and written word, for example, automatically augments communication. Third, PWD undergo changes in how they experience reality, with increasing confusion and disorientation as the condition progresses, affecting how they interpret the world. This reduces the opportunity for reliable shared meaning during any communication interchange. Enhancing communication to support patient safety has been identified as one of the top ten priorities by practitioners and service users [23]. However, currently, there is little empirical or theoretically backed evidence underpinning the best approaches to intervention that support communication with PWD [22, 24] and enhance safety [25].

Table 1: Characteristics of communication difficulties in dementia (22)

Communication and cognitive difficulties	**Communication and cognitive strengths**
Early stage dementia	
Mild difficulty with remembering names and places	Talks in full sentences and maintains conversation appropriately
Difficulty with abstract language and conversation	Maintains understanding of concrete language
Mild difficulty with memory and visuospatial activities	
Lapses in attention occasionally	Aware of difficulties
Middle stage	
Increasing difficulty with word finding and reduced use of 'content' words	Conversational turn taking maintained
Difficulty understanding complex instructions	Able to read aloud and understands familiar written phrases
Increasing difficulty with memory, attention and maintaining topic of conversation	Maintains familiar, over learnt skills such as hair brushing, drinking from a cup
Difficulty organising and planning	
Late stage	
Significant difficulty expressing needs	Appropriate affective responses to sensory stimuli and music
Inappropriate verbal/vocal productions	Able to cooperate with appropriate cues (touch, vision and emotion)
Lack of any speech in some cases	
Severe difficulty understanding spoken language	
Severe memory difficulties	
Difficulty maintaining attention	

Dementia and assistive technology

Assistive technology and telecare have become a central element of policy and guidance for improving care for PWD [4, 26, 27], although issues of adoption by PWD remain challenging [28]. The largest growth in the use of technology with older people, has focused on safety and security in the community [27], but often as 'passive' devices, such as smoke detectors, that involve no participation by PWD. Studies investigating technology that requires active involvement and engagement with devices indicate that PWD did not use features on technology devices related to safety. Even when a digital assistive devise has been co-developed with PWD, there appears to be a disparity between acceptance and use [29, 30]. Using devices may be perceived by some people as reinforcing negative identities and ageist stereotypes [31]. A recent scoping review demonstrated the importance that older adults placed on expressing their identity as one of independence, self-reliance and competence, thus influencing their decisions about adopting technological solutions [32]. The cultural meaning attached to digital devices is evident in society, such that one item (eg. a smartphone) can symbolise independence and modernity, whilst another (eg. alarms) may symbolise stigma and dependence [33].

Smart mobile and wearable technology, as seen in smart phone apps, can overcome issues of acceptability and self-image. Assisting with real time monitoring of health and social aspects of an older person's life [33], together with the ease of use, offers promising outcomes. However, the proliferation of apps for health care has not been matched by robust research, with a major criticism levelled at the limited evaluation of clinical outcomes [34, 35]. Principles for developing and applying app technology are emerging [36], with personalisation expressed as a priority [35, 37]. Other essential considerations include quality of the content, usability, matching app to users' health literacy levels and security/privacy issues [38].

My Health Guide

In England, the NHS has created a library of apps and online tools that aim to help people manage their health and well-being [39]. They have been approved in terms of clinical safety, data protection, security and usability. However, there are only two apps in this library specific to dementia. Whilst a general web search indicates a proliferation of apps, few have been evaluated [40]. The My Health Guide (MHG) app [41] was developed to help people with learning disabilities and those who support them to be in control of their health and well-being (Table 2). People can use the app to explain their needs and concerns, to help them understand how to act on advice given by health and social care professionals, to keep and share information about themselves and their needs, to record consultations to listen again at a later date. It can be used by health and social care practitioners to understand someone's needs better; providing quick access to key information that facilitates communication and interaction with the person. It is user-led and therefore embodies user preferences and potentially captures the lived experience, thus ensuring a person-centred approach is integrated into care. App users (and their families) are able to build a customised personal profile containing relevant information that the user controls, such as *how* best to communicate with others, such as format (e.g. pictures, text, audio, video) and in turn, how best others can communicate with them. All written content can be spoken to the user by the app, simply by clicking the Text-To-Speech icon.

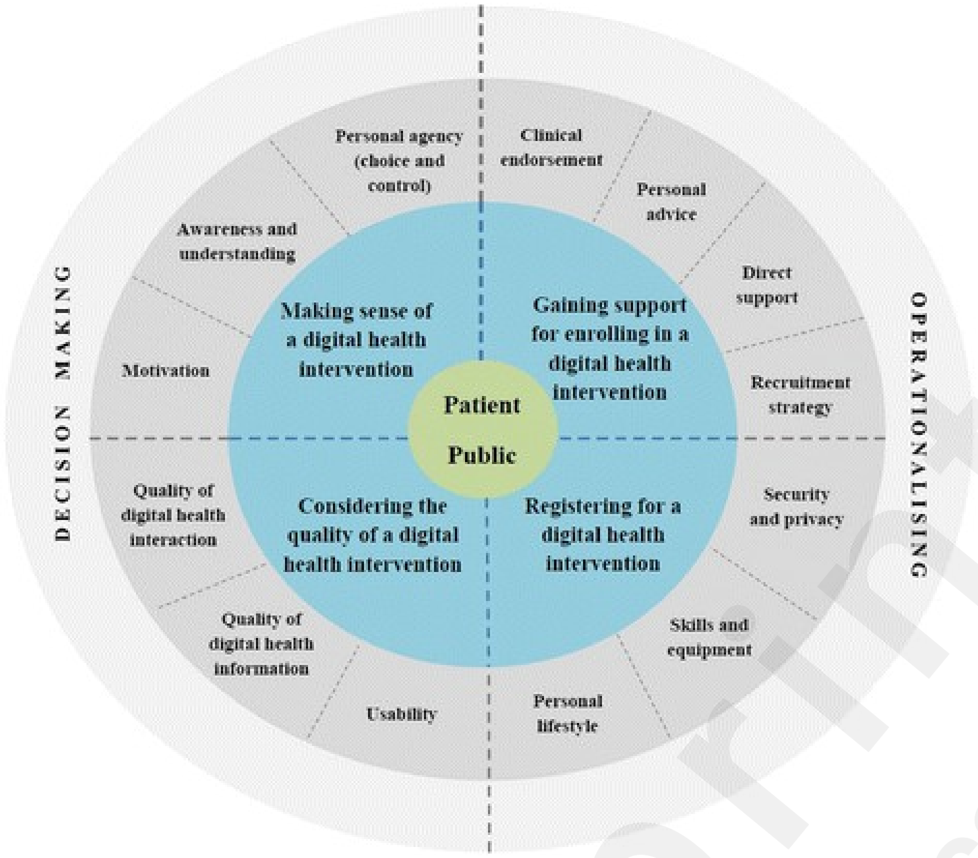
Table 2: Key features of My Health Guide [41]

Key features of My Health Guide
App users control the content Users have control over how it is used by creating boxes to store things that are important to them. Boxes can be labelled using photos or text
Enables flexible use Each box can store content captured as text, picture, video or audio Content can be created using the app or users can add content already stored on their device. Written content can be spoken to the users by clicking on a text to speech icon
Enables personalisation Prioritises 'important things about me' enabling users to build a life story that can be shared with other people when they visit for appointments or social events App users can personalise their app, including adding profile photo, colour, font size, reminders and in-app PIN for security
Contains an appointment facility Includes an appointment facility to create appointment
Contains contacts and sharing facility Users can record the details of friends, family and carers and can share their boxes with anyone in their contacts list. Contacts will be notified by e-mail and can log-in to My Health Guide's web interface on their browser. The web interface lets contacts: • Stay in touch with the app user's latest activities. • Suggest content additions to the boxes they can see (app users will be able to accept or decline additions). • Send app users alerts. The app user will see the alert next time their app synchronises with the server.
Able to store documents Documents can be uploaded into the app to store them in one place

Normalisation Process Theory

Interventions involving digital apps are complex interventions, depending on interacting components such as users' understanding, usability of the app and adoption, contingent on individual, group and organisational behaviour [42]. Normalisation Process Theory (NPT) has been developed to improve understanding of how complex interventions work looking beyond the workability of systems [43] to issues such as the effects of e-health interventions on roles and responsibilities of all those involved, how interventions affect interaction between service users and practitioners and outcomes for service user, and implications for practitioners. NPT is a middle range theory that explores issues of how interventions work in practice in more depth. It provides a framework for multi-faceted analysis to understand the actions and interactions influencing implementation and how new interventions and practices come to be normalised in health and social care contexts. Conversely, it can aid explanation as to why technologies fail to be routinely adopted when implemented in organisational contexts [44]. There are four key constructs that can be applied to service users and practitioners using the digital app. First, the construct of *coherence* is used to describe the way individuals understand the meaning of a new technology and its associated practices; second, the construct of *cognitive participation* explains the relational work needed to sustain a 'community of practice' for a new intervention; third, *collective action* signifies the operational work required to enact new practices and fourth, *reflexive monitoring* applies to the appraisal of new practices. The theory examines the process of changes that occur in individual and collective behaviour and allows the dynamics of human agency to be connected to context. It has explanatory power, opening up the process of 'work' that is required for adoption and integration of new interventions. The current study will use NPT alongside the Digital Health Engagement Model (figure 2) [45] to provide a clear guide for designing and evaluating the digital intervention of MHG.

Figure 2: Digital health engagement model [45]



Methods

The study will build understanding of the suitability of MHG for people living with early stage dementia, considering the impact of dementia on using a mobile app and adaptions required to support communication and safety for PWD. The research design prioritises co-designing adaptations for MHG [46], together with a scoping review of the factors that influence adoption of new technology drawn from previous research. The study includes co-designing with the digital design company, Maldaba, experienced and approved in creating MHG for people with learning disabilities and co-designing with service users [41]. The previous evaluation showed that MHG was used for appointment reminders, documenting information about an individual, recording medical information, and noting people’s feelings. Results suggested the app was easy to operate, but availability of support was an important factor in the adoption and use of the app. Furthermore, users demonstrated a preference for using the app for interaction and conversation with individuals in their informal support networks. The study will employ a design research method [47], to conduct an iterative process of reviewing and redesigning the MHG app with PWD over three cycles (figure 3). In order to investigate if the design features are beneficial for PWD, this study will examine the applicability of MHG for PWD (initially with early stage dementia), identify specific changes to improve the app for future service users and develop successive iterations together with service users, their families and practitioners in the field. Design research aims to develop and improve interventions in a continuous cycle of refinement with service users.

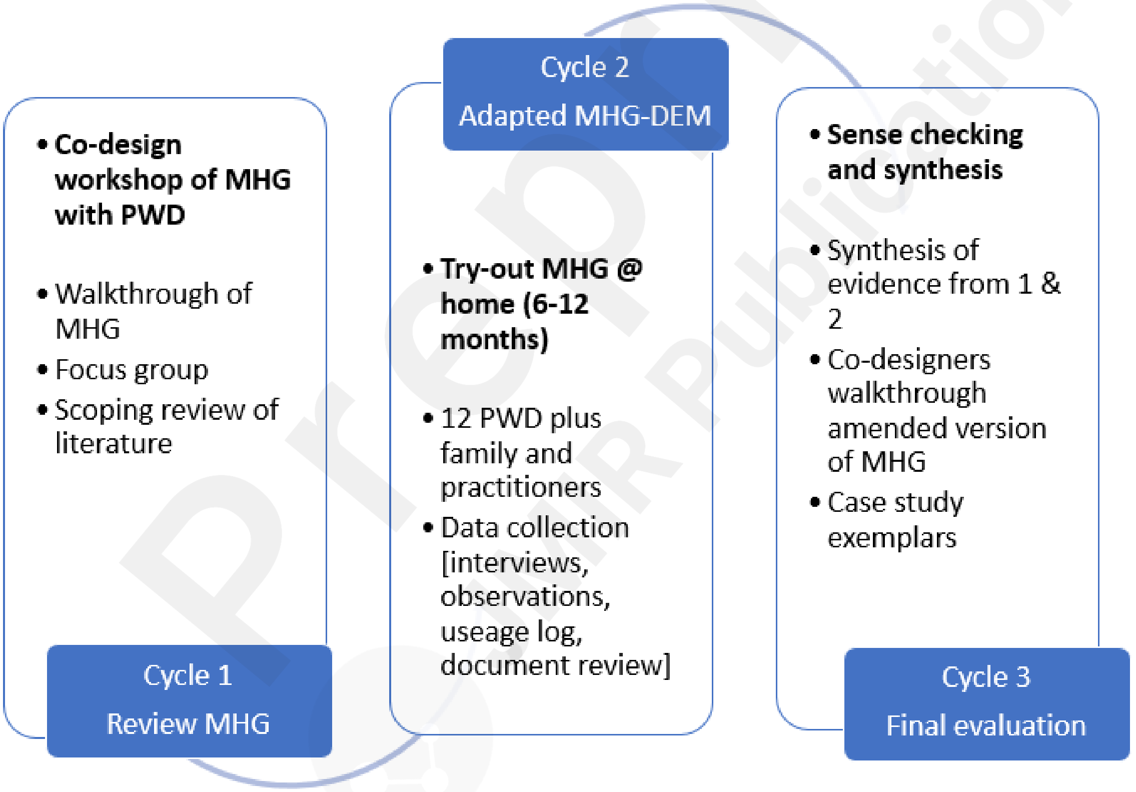
The main aims of the study are:

1. To evaluate the
    a. Usability of the current MHG design for people living with early stage dementia
    b. Meaningfulness of MHG for people with early stage dementia in a community context living independently
    c. How the functions of the app can be personalised (occupation, safety, social interaction and memory)
2. To extend understanding of the benefits and challenges of using MHG app for people with early stage dementia and their support network
    a. To explore the experiences of people living with dementia using MHG to identify the barriers and facilitators of adoption of the app.
    b. To explore whether and how the app contributes to improved communication between service users, their social networks and formal carers/professionals involved in regular and occasional support.
    c. To explore the role of MHG for supporting patient safety and develop an

explanatory model of potential contribution of MHG app to patient safety for people living with dementia, their social networks and professionals.

3. To investigate adaptations to the My Health Guide app with service users with early stage dementia

Figure 3: Cycles of design research for My Health Guide



Multiple case studies will be used to record and report in-depth evidence of the app's usefulness and usability for PWD, using a number of sources of data. Yin's [48] six stage case study process will be used, together with other guidance [49], to support the rigour of the design. Case studies are valuable for exploratory and explanatory purposes and suited to contemporary phenomena where ‘how’ and ‘why’ questions are posed. They are particularly appropriate for research questions aiming to understand and evaluate the complexities of implementing and adapting an existing intervention with a new group of service users. Purposive case selection will be adopted to ensure that the cases illustrate a variety of contexts. Data will be analysed using deductive and inductive approaches.

The research will take place over 24 months employing the following steps:

- Preparation, months 1-6: negotiate arrangements with partners, obtain ethical approval, set up advisory group, prepare walkthrough workshop;
- Cycle 1, months 6: collection of data for review and remodelling of MHG in walkthrough workshop with up to 24 co-designers (PWD, carers and practitioners)
- Cycle 2, months 7-18: recruiting and working with up to 12 co-designers with dementia and up to 12 people from their health and social network;
- Cycle 3, months 18-24: final walkthrough workshop and sense checking event with co-designers, reporting (end of project workshop and written report), dissemination with co-designers, impact activities

Participants

Participants will be recruited with partners delivering home care in the North West of England over 12 months using the inclusion/exclusion criteria outlined in Table 3. Participants with early stage dementia, living at home, will be identified and introduced to the study by home care practitioners, who routinely visit PWD living at home. They will provide study information leaflets and introduce the researchers to the family, where PWD have expressed an interest. The sampling will be purposive in order to have participants with varied experience of dementia, background and living arrangements. As the data collection for each participant will be predominantly qualitative, drawing on data from a number sources for detailed case studies, a total of twelve participants with dementia will be recruited, together with family members who offer support (spouses/partners and children), formal carers and regular practitioners (up to 24 in total). Formal carers and practitioners will be those who have routine involvement with the person with dementia (at least one contact per week).

Table 3: Inclusion and exclusion criteria

Inclusion criteria	**Exclusion criteria**
Medical diagnosis of dementia	No diagnosis of dementia
PWD at early stage, according to WHO factsheet (https://www.who.int/news-room/fact-sheets/detail/dementia)	PWD at late stage
Living in own home or extra care housing	Living in care home
Symptoms of memory loss and cognitive changes, but living independently	Extensive cognitive confusion
Adequate vision and motor skills to manage tablet computer	Unable to handle tablet computer
Supported by family carer and/or formal carers	Receiving no support from carers
General health is stable and well managed	Experiencing regular bouts of acute illness
Able to converse in English	Limited spoken English

Patient and Public Involvement and Engagement (PPIE)

The study will use participatory methods with patient and public involvement integrated in the study as part of the design process. For the purposes of governance, and ensuring involvement of professionals in the co-design (in keeping with guidance from NICE 2018[36]), we will establish a ‘critical friends’ group for guidance in designing the study. This will consist of a person living with dementia, a practitioner and an academic experienced in dementia research. Trustworthiness and credibility of the findings will be enhanced through involvement of external partners in peer reviewing and sense checking research plans, findings and interpretation. Specific tasks will include commenting on the study design and study documents, developing and conducting data collection and analysis and dissemination of the findings.

Data sources and collection for case-based evidence

Design research is conducted iteratively in collaboration with stakeholders. Formative evaluation provides the opportunity to improve the design of the intervention and is integral to the process. Three iterative cycles of review, formative evaluation and redesign will be conducted (figure 2) using a range of data sources that will provide triangulation of the evidence. In the first cycle, a workshop for a walkthrough of the current app will be delivered, in the community with people with early stage dementia, their carers, and practitioners, to review the current version of MHG, investigating the usefulness and usability of the app. The walkthrough will involve observations, interviews and focus group activities. Responses will be recorded and analysed using thematic analysis. Potential changes and recommendations for the redesign will be discussed and enacted by the app developers [41].

The second cycle will involve 12 PWD, living independently, and associated family/practitioners using the app in everyday life. Each case will be visited in their home context (2 visits over 3-6 months) to collect a range of data (Table 4). The third cycle will involve analysis of the data from Cycle 2, together with data generated at final walkthrough/ sense checking workshop with PWD, family and practitioners.

Table 4: Summary of data collection

Data source	Detail of data collection
Usage logs	Usage data (frequency of use, length of time using the app) will be collected from all participants in the data collection period (in collaboration with the developers).
Semi structured interviews	Face to face, semi-structured interviews with PWD, those in social networks and professionals will be conducted at two time points to assess initial and ongoing use and experience of the app over a time frame of up to 12 months. These interviews will be adapted appropriately to the cognitive status of individuals with dementia. Researchers will undertake appropriate training to conduct interviews with people living with dementia. Interviews will be recorded and uploaded to NVIVO for automated transcription.

	The interviews will be conducted using a topic guide, which will be based on the objectives of the MHG app along with questions exploring the potential of the app to facilitate communication with health and social care professionals. They will be structured to reflect NPT. The topic guide will be used flexibly in interviews and emerging themes will be explored in subsequent interviews in line with conventions of qualitative data collection.
Observation of app use	In order to obtain contextual data of people using the app in different contexts we aim to observe up to 12 PWD (with or without key people in their social network) in each setting (home, extra care housing). We will observe participants using the app either on a pre-arranged visit when PWD receives an episode of care or on the same day as the interviews are conducted. Observations will focus on the interaction between PWD and a regular formal carer/professional, such as the Admiral Nurse. These will be carried out using a structured form augmented by field notes.
Review of document uploaded to app	Documentary data will be collected in the form of photographs, drawings and other visual data. Participants will decide whether they want to produce this material for research purposes, and if so, will chose the formats that are most relevant to them. More formal documents such as relevant notes of meetings (case conferences) or action plans will be collected. Documentary data will be summarised using structured forms based on the key features of MHG.

Data analysis

The qualitative data analysis will employ an abductive approach [50], enabling a continuous dialogue between theory, data from user experience and existing models of engagement. Such an approach gains from both inductive and deductive analysis, ensuring the findings combine both new empirical evidence with previous evidence. This will align well with the iterative design process and cycles of evidence collection and redesign of the MHG. The analysis will be conducted by two researchers trained and experienced in qualitative research. NVIVO software will be used to support data management and analysis. In keeping with qualitative research, involvement of the user participants will provide opportunity for sense making exercises to provide assurance regarding trustworthiness and credibility of the analysis and interpretation. The app developers will form part of the research team, bringing their expertise to support the interpretation of findings, identifying areas for redesign and preparing amended prototypes for evaluating during the cycles of the design research process. Framework analysis will be used to collate and analyse the data for the case studies, in order to describe, explain and compare the similarities and differences between cases. This will contribute to the final evaluation of the application of MHG to people living with dementia.

Ethics and governance

We are following ethical guidance from the University of Manchester ethics committee and have approval according to their standardised system. Recruitment, data transfer and data storage are in accordance with legislation and guidance from the research institute. Written informed consent will be obtained from all participants and arrangements are in place for data obtained to be anonymised and stored securely. The study participants will be at early stage dementia and will have capacity to consent. If the participant's capacity to consent changes during the research cycles, researchers will adopt the Mental Capacity Act Code of Practice and work alongside experienced practitioners to ensure appropriate checks are in place. The study will be managed on a day-to-day basis by a Project Management Group consisting of experienced researchers that will meet monthly to plan and monitor progress. A critical friends group will be established to provide guidance for the development of study material, analysis and interpretation of findings and dissemination.

Results

Digital technology is developing rapidly and using apps to manage many elements of daily life are becoming routine. Given the context of social distancing introduced to combat coronavirus in 2020, it is particularly urgent to understand the views of people living with dementia, and those in their social and care network, of using an app focused on supporting communication and wellbeing. The study will enable us to evaluate MHG's usability and value for PWD and identify adaptions to improve implementation. It will consider how using the app might contribute to improved communication and potentially to improved safety through a personalised approach to recording health and wellbeing issues important to people living with dementia in the community. The study will also provide a methodological contribution through illustrative case studies of the way an app is employed in people's home context, drawing on normalisation process theory. This will provide the basis of an explanatory model of the relationship between factors such as communication, social and healthcare networks, cognitive strengths and weaknesses and enhancing safety in the community.

Discussion

Evaluating a mobile application for enhancing communication, safety and wellbeing for people living with dementia contributes to key ambitions enshrined in policy and practice, championing the use of digital technology and supporting people with dementia to live safely in their own homes. The study uses a co-design method to enable the voice of users with dementia to highlight the benefits and challenges of technology and shape future development of apps that potentially enhances safety through improved communication.

Ethics approval: obtained from the University of Manchester Ethics Committee Ref 2020-8665-13751

Consent for publication: Participants will give written consent to participate in the study including the publication of anonymised data.

Availability of data and material: Supporting data will be available on request from the corresponding author.

Competing interests

No potential conflict of interests.

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Authors' contributions

The design of the study was developed by all the authors. KD and BNO jointly led the manuscript drafting. All the authors critically reviewed drafts of the paper and agreed final version.

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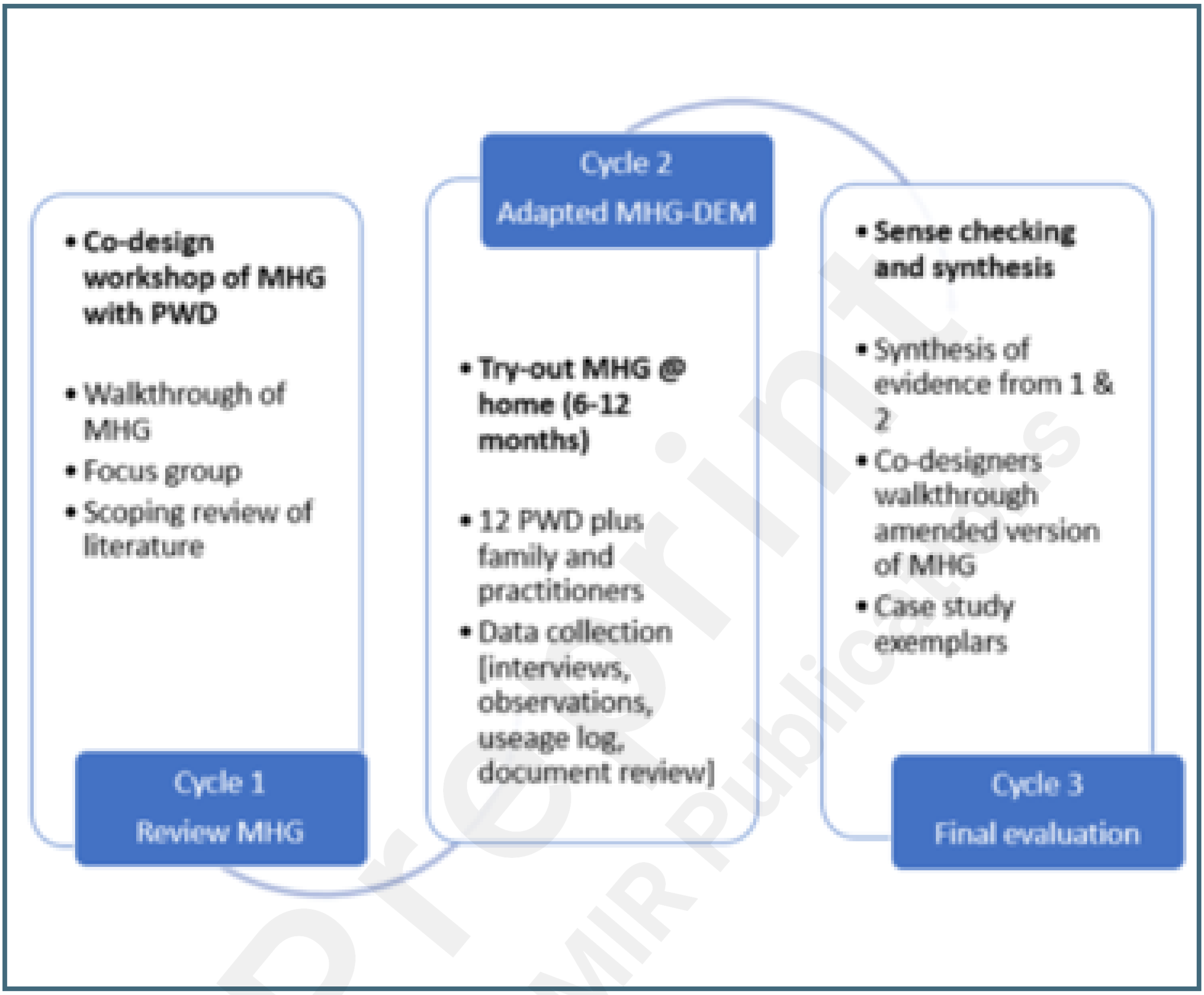
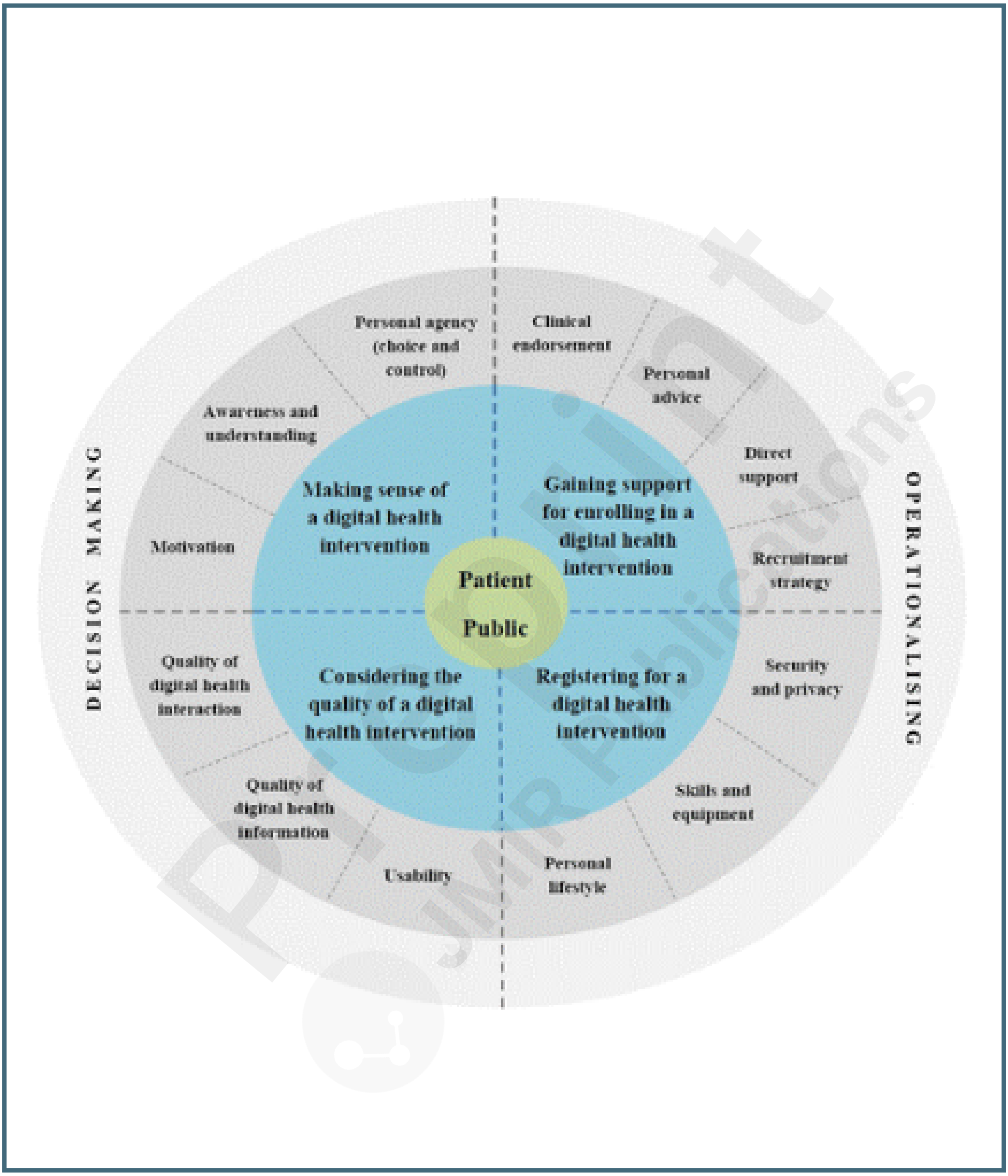
Supplementary Files

Figures

Cycles of design research for My Health Guide.



Digital health engagement model [45].



The relationship between communication issues for PWD and safety.