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</table>
| Complete List of Authors: | O'Connor, Siobhan; University of Manchester, School of Nursing, Midwifery and Social Work; University of Glasgow, General Practice and Primary Care  
Hanlon, Peter; University of Glasgow, General Practice and Primary Care  
Garcia, Sonia; York Health Economics Consortium  
Glanville, Julie; University of York, York Health Economics Consortium  
O'Donnell, Catherine; University of Glasgow, General Practice and Primary Care  
Mair, Frances; University of Glasgow, General Practice and Primary Care |
| Primary Subject Heading: | Health informatics |
| Secondary Subject Heading: | Qualitative research, Patient-centred medicine |
| Keywords: | digital health, eHealth, recruitment, engagement, systematic review, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS |
Title

Barriers and facilitators to engagement and recruitment to person-centred digital health interventions: protocol of a qualitative systematic review

Authors

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Abstract

Introduction: Patients, carers and the general public are beginning to use digital health tools to assist in managing chronic illness, to support independent living and self-care, and remain connected to healthcare providers. However, engaging with and registering to use person-centred digital health interventions, such as telehealth or telecare systems, mobile health applications, patient portals and personal health records varies considerably. Many factors affect patients, carers and the general public’s decision to engage with and sign up to consumer digital health platforms.

Objectives: The primary aim is to identify the barriers and facilitators these stakeholders experience to engagement and recruitment to person-centred digital health interventions, and if possible, to develop a taxonomy of digital health enrolment strategies and a new conceptual model of digital health engagement and recruitment processes.

Methods: A qualitative systematic review will be conducted by searching six electronic databases; MEDLINE, CINAHL, PubMed, EMBASE, Scopus and the ACM Digital Library between 2000-2015. Titles and abstracts of studies along with full text papers will be screened by two independent reviewers against pre-determined inclusion and exclusion criteria. A data extraction form will be used to provide detail of the included studies. Quality assessment will be conducted using the Consolidated Criteria for Reporting Qualitative Research checklist. All disagreements will be resolved through discussion with an independent third reviewer. Analysis will be guided by framework synthesis and informed by
Normalization Process Theory and Burden of Treatment Theory, to aid conceptualisation of
digital health engagement and recruitment processes.

Discussion: This qualitative systematic review will explore the factors that affect
engagement and enrolment in person-centred digital health technologies. It will advance our
understanding of consumer readiness for digital health by examining the complex factors that
affect patients, carers and the general public’s decision to take part.

Systematic review registration: PROSPERO 2015: CRD42015029846. Available from:
http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42015029846

Keywords: eHealth, digital health, telemedicine, recruitment, engagement, systematic review

Word Count: 3,194
Strengths and limitations of this study

• This will be the first synthesis of qualitative studies to explore patients, carers and the general public’s experiences of engagement and recruitment to person-centred digital health technologies.

• We will systematically identify and critically appraise the available evidence on this important topic, identify research findings and highlight any knowledge gaps.

• It is envisaged that the results of this review will contribute to a framework that describes the barriers and facilitators that affect patients, carers and the general public’s decision to participate in digital health interventions, to the development of a preliminary conceptual model of the digital health engagement and recruitment process; and, if possible, the creation of a taxonomy of digital health enrolment strategies.

• This work will advance our understanding of the readiness of patients, carers and the general public towards digital health.

• Findings may be limited by; 1) the inclusion of English language publications as this could exclude potentially useful studies which may result in cultural and publication bias, 2) the synthesis of qualitative studies which may result in the loss of some explanatory context that could limit the generalisability of findings, or 3) the data analysis and synthesis which will be based on a sample of data extracted by the review team and not the original data.
INTRODUCTION

Changing lifestyle patterns over the last century have seen growing numbers of people with one or more chronic illnesses, including heart disease, diabetes and cancer. Such conditions are the leading cause of death, disease and disability worldwide,[1-3]. This combined with ageing populations, who have complex health and social care needs, is creating a huge resource burden on health systems,[3,4] with increases in healthcare utilisation and unplanned admissions.[5]. To become more sustainable, health services are beginning to move from treating illness in acute hospital settings to promoting more preventative care and the self-management of long-term conditions in the community where possible,[6,7].

Person-centred digital health technologies are being developed and trialed to further this agenda, by promoting active and healthy ageing, supporting individuals to manage long-term conditions at home and assisting them to remain connected with health and social care providers. Examples include telehealth and telecare systems,[8], electronic personal health records (PHRs),[9], mobile health applications or ‘apps’,[10] and assisted living devices and sensors,[11]. It is hoped that these types of consumer focused digital products and services could lead not only to better health outcomes but also a reduction in the utilisation and cost of primary, secondary and tertiary health services,[12].

Many person-centred technologies have only been evaluated in small pilot studies or Randomised Controlled Trials (RCTs). While the results of these can sometimes demonstrate positive outcomes,[13], many people choose not to participate as they can experience numerous barriers to the use of such technologies that affect their decision to take part,[14-16]. Carers, who can play a vital role in assisting a person to engage with and use digital health technologies in everyday life, are also often overlooked when evaluating such
interventions,[17-20] and can encounter challenges when supporting a person to sign up and use a digital health product or service.[14]. However, while non-participation is a significant issue,[21,22], there are also many factors that can facilitate the engagement and recruitment of patients, carers and the general public to the use of person-centred health interventions.[23,24]. While over the last decade or so an increasing number of primary studies have examined these complex issues, there has as yet, been no attempt to synthesise what this literature tells us about the key challenges or the outstanding research gaps surrounding patient, carer and public engagement with digital health.

In addition, many of types of person-centred digital health platforms often fail to be rolled out or integrated as part of routine health service delivery or personal use.[25]. Although there is a large literature on difficulties recruiting to clinical trials,[26] many challenges only emerge when health technologies are scaled up and implemented in “real-world” complex health systems,[27]. Some of these problems stem from the initial phases of implementation when engaging with different stakeholders, and also in reaching and enrolling patients and others into using the digital health technology.[24,28]. Arguably, a better understanding and detailing of these problems, especially in relation to engaging and recruiting at scale and in real-life settings, will help researchers and implementers design better systems and enrolment strategies and will inform health services managers and policy makers of changes that need to be made to overcome and mitigate such barriers. The existing literature at present is fragmented and does not yet provide a coherent picture of barriers and facilitators to engagement and recruitment of patients, carers and the general public to person-centred digital health interventions.
There have been repeated calls for more research that synthesises the findings from qualitative evidence to support both policy and the implementation of research, [29]. For example, a synthesis of qualitative research can help to better inform the design of RCTs to test the effectiveness of new technologies, aid in the understanding of complex interventions as well as human experiences and behaviour, all of which can be used to inform health policy and practice, [30,31]. The volume of qualitative systematic reviews has been growing slowly over the last number of years, [32] due in part to the work of the Cochrane Qualitative and Implementation Methods Groups (CQIMG) and others who are championing the role qualitative synthesis can play in building the base for effective evidence that can be adopted and implemented in practice, [33,34].

At present, there is little if any published qualitative systematic reviews looking at different aspects of person-centred digital health interventions. In particular, there is no qualitative systematic review on the topic of consumer digital health engagement or recruitment although it has been highlighted as a research gap that needs attention, [14,35]. An understanding of the barriers patients, carers and the general public experience when trying to engage and enrol in person-centred digital health products and services would help ensure the full value of these interventions can be realised, [36]. Similarly, robust evidence on the factors that facilitate participation could improve recruitment to future digital health initiatives. Theoretical frameworks have been used previously to aid many types of qualitative synthesis, [25,37,38] as established models can help to explain the phenomenon under consideration and make the findings of the synthesis more accessible to application in practice, [39]. This review will therefore incorporate two empirically grounded sociological theories, Normalization Process Theory (NPT) and Burden of Treatment Theory (BOT), as they are relevant to understanding how individuals embed new interventions in everyday
routine and the burden that this process entails,[40,41]. NPT in particular has been widely
used in eHealth implementation research,[42,43] and BOT was built on the conceptual
foundations of NPT to expand our knowledge of the difficulties patients experience when
coping with new treatment modalities and enacting self-care strategies,[44] so they are both
directly applicable to this qualitative synthesis. This qualitative systematic review aims to
synthesize currently available knowledge about barriers and facilitators to engagement and
recruitment across a range of consumer oriented digital health technologies and highlight
knowledge gaps and areas for further research. If possible, we will also aim to develop a
taxonomy of digital health recruitment strategies and a preliminary conceptual model of the
digital health engagement process.

Objectives

Primary

To examine the factors (barriers and facilitators) that affect patients, carers and the general
public’s decision to engage with and enrol in person-centred digital health interventions.

Secondary

To determine what engagement and recruitment strategies have been utilised to sign patients,
carers and the general public up to digital health products and services.

METHODS

This protocol was written in accordance with the Preferred Items for Reporting Systematic
Reviews and Meta-analysis Protocols (PRISMA-P) checklist.[45]. Reporting of the full
systematic review will follow the Enhancing Transparency in Reporting the Synthesis of Qualitative Research (ENTREQ) statement.[46]. An interdisciplinary team of researchers will be involved in the qualitative systematic review with expertise ranging from general practice and primary care, to nursing, health informatics and information science. An initial ‘scoping search’ will be carried out to help identify key papers and search terms that are relevant to the research topic. This process will be carried out by conducting a preliminary search of online bibliographical databases via Ovid; the use of the ‘related articles’ function in PubMed, reference and footnote tracking of relevant papers found, citation tracking of relevant papers found, the use of personal knowledge, and consultation with experts in the field. The results will help to inform the initial design of the search strategy for the review which will be piloted and refined as appropriate. Figure 1 outlines the detailed workflow of the proposed review.

Search Strategy

A team of information specialists at the York Health Economics Consortium (YHEC), who specialise in conducting systematic reviews, will be consulted to assist with the design of the search strategy. There is likely to be three groups of search terms referring to; person-centred digital health technologies, engagement and recruitment, and factors that affect participation i.e. barriers and facilitators (Table 1). Guidance will be sought from the Cochrane Handbook for Reviews of Interventions on the most robust way to systematically search the literature,[47] and other novel strategies such as text mining,[48,49] will be explored and applied where appropriate. The following six databases; CINAHL, (EBSCHOHost), PubMed, Medline, Embase, Scopus and the ACM Digital Library, will be systematically searched to identify published peer-reviewed scientific literature that are relevant to the research
objectives. YHEC will run searches, remove duplicate citations and provide an Endnote database file of citations for screening.

Table 1 Search strategy

<table>
<thead>
<tr>
<th>Search</th>
<th>Search terms that will be modified for use across multiple databases</th>
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</thead>
<tbody>
<tr>
<td>#1</td>
<td>Search Electronic Health Records [MeSH Terms]</td>
</tr>
<tr>
<td>#2</td>
<td>Search Cellular Phone [MeSH Terms]</td>
</tr>
<tr>
<td>#3</td>
<td>Search Social Networking [MeSH Terms]</td>
</tr>
<tr>
<td>#4</td>
<td>Search Telemedicine [MeSH Terms]</td>
</tr>
<tr>
<td>#5</td>
<td>#1 OR #2 OR #3 OR #4</td>
</tr>
<tr>
<td>#6</td>
<td>Search recruit*</td>
</tr>
<tr>
<td>#7</td>
<td>Search enrol*</td>
</tr>
<tr>
<td>#8</td>
<td>Search participat*</td>
</tr>
<tr>
<td>#9</td>
<td>Search engage*</td>
</tr>
<tr>
<td>#10</td>
<td>#6 OR #7 OR #8 OR #9</td>
</tr>
<tr>
<td>#11</td>
<td>Search barrier*</td>
</tr>
<tr>
<td>#12</td>
<td>Search challenge*</td>
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<tr>
<td>#13</td>
<td>Search impediment*</td>
</tr>
<tr>
<td>#14</td>
<td>Search facilit*</td>
</tr>
<tr>
<td>#15</td>
<td>#11 OR #12 OR #13 OR #14</td>
</tr>
<tr>
<td>#16</td>
<td>#5 AND #10 AND #15</td>
</tr>
</tbody>
</table>

The challenges of searching the qualitative literature have been well documented,[50-52] and studies have shown that traditional database searching can reveal as little as 30% of research
papers that are relevant to the topic under review.[53]. Therefore, other search methods will be used to supplement the results of the systematic review and identify relevant studies. These will include reference or footnote tracking; using the ‘related articles’ function in PubMed; citation tracking; personal knowledge and personal contacts and contacting experts in the field.

Eligibility Criteria

The review will adhere to the following criteria. These were developed using a modified PICO framework, which stands for population, intervention, control and outcome.[54] (Table 2).

Table 2 PICO criteria for including studies

<table>
<thead>
<tr>
<th>Population</th>
<th>Any individual (adult or child). This includes patients, carers, the general public and professionals who would be aware of the experiences of these stakeholder groups.</th>
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<tbody>
<tr>
<td>Intervention</td>
<td>Any health intervention delivered by a digital technology (hypothetical or in development, simulated or real-world) which takes information from patients, carers or the general public or provides some form of advice or feedback about their health. This includes, but is not limited to:</td>
</tr>
<tr>
<td></td>
<td>• Web-based interventions on PCs or mobile platforms,</td>
</tr>
<tr>
<td></td>
<td>• Mobile health applications or apps,</td>
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<tr>
<td></td>
<td>• Patient portals or personal health records</td>
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<tr>
<td></td>
<td>• Interventions delivered by SMS or IVR (interactive voice</td>
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</table>

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml
<table>
<thead>
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<th>Control</th>
<th>None</th>
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<tbody>
<tr>
<td>Outcome</td>
<td>Qualitative data on the factors (barriers and facilitators) to engagement and recruitment. Qualitative data on enrolment strategies.</td>
</tr>
<tr>
<td>Study type</td>
<td>Original qualitative studies, studies involving secondary analysis of qualitative data or qualitative studies that are part of a mixed methods study. The study must have direct contact with individuals or direct observation using any form of qualitative method.</td>
</tr>
<tr>
<td>Setting</td>
<td>Any ‘usual’ setting (hypothetical or in development, simulated or real-world) such as primary, secondary or tertiary care, the home or workplace.</td>
</tr>
<tr>
<td>Timing or Phase of Implementation</td>
<td>Engagement or recruitment phase only.</td>
</tr>
</tbody>
</table>

Papers will be included if they meet the PICO criteria. Below is a detailed description of the inclusion and exclusion criteria.

1) **Types of studies:** Original qualitative studies, studies involving secondary analysis of qualitative data or qualitative studies as part of a mixed methods study (e.g. a major component must be qualitative and describe a qualitative methodology). Certain types of studies will be excluded from the review including those using the following methodologies:

   a. literature or systematic reviews and meta-analyses;

   b. descriptive case studies; lexical studies that analyse natural language data presented as qualitative results;
c. qualitative studies using questionnaires or other methods that do not involve direct contact or observation of participants;

d. commentary articles written to convey opinion or stimulate research/discussion with no research component;

e. studies describing an individuals’ experience in a Randomised Controlled Trial (RCT). This review is focusing on barriers and facilitators to engagement and enrolment to person-centred digital health interventions rather than the wider literature on recruitment to clinical trials that has already been addressed in previous reviews,[26].

2) **Types of eHealth interventions:** Any health intervention delivered by a digital technology (hypothetical or in development, simulated or real-world), which takes information from patients, carers or the general public or provides some form of advice or feedback about their health. This includes, but is not limited to, web-based interventions on Personal Computers (PCs) or mobile platforms, mobile health applications or apps, patient portals, personal health records and interventions delivered by SMS or IVR (interactive voice recognition). Certain technologies will be excluded from the review including those whose primary intervention is; telephone based with no additional technological function (e.g. telephone counselling or triaging service); Internet based with no additional interactive function (e.g. searching for health information online); or an implantable device that is remotely monitored.

3) **Types of participant:** Any individual (adult or child). This includes patients, carers, the general public and professionals who would be aware of the experiences of these stakeholder groups.

4) **Types of settings:** Any ‘usual’ setting (hypothetical or in development, simulated or real-world) such as primary, secondary or tertiary care, home or workplace.
5) **Phase of implementation**: Qualitative research which explores the engagement or recruitment phase of a person-centred digital health intervention. This can span from gauging an individual’s readiness for a digital health intervention, to the initial marketing or reach of the initiative, to actively signing people up to use the technology so they are registered on the digital application or system. Therefore we will not explore: pre-engagement work based solely around designing the interface and functionality of a digital health intervention; patients, carers or the general public’s use of these types of technologies; why they drop out or fail to continue using them; their attitudes or beliefs towards the digital health intervention or their satisfaction with it, except as pertaining directly to engagement or recruitment.

6) **Date of publication**: between 1 January 2000 and 19 August 2015

7) **Language**: English

**Screening**

Each title and abstract will be screened by two independent reviewers using DistillerSR software. All journal articles that meet the inclusion criteria set out above will be obtained in full text format for further screening and assessment. Two independent reviewers will conduct the second level full paper screening by applying the inclusion and exclusion criteria. A third party will be involved to resolve any conflicts that occur in determining the relevance of the titles, abstracts and full text papers so that a consensus over inclusion and exclusion of each article can be reached. A flow diagram will be used to report the selection process and reasons for exclusion as suggested by the PRISMA guidelines,[55].
Data extraction

Data extraction will be carried out using a comprehensive, standardised extraction template that will be designed based on the specific characteristics of this review, including aims of the study, design and methodological approach taken, and key findings such as barriers and facilitators and a description of recruitment strategies. It will be piloted on a subset of relevant papers and refined where appropriate. The extraction process will be conducted by two individual reviewers based on the relevant articles previously identified through the screening process. A third party will be involved where disagreements arise over the relevancy of the data to the review topic which will assist in reaching consensus and creating a robust dataset. This will result in a table that provides the following details:

- Bibliographic information such as the journal name, year, volume and page numbers;
- Study characteristics such as the type of technology, recruitment strategy used and qualitative approach taken;
- Participant characteristics (sociodemographics) and information about the number and type of individuals who participated or declined to participate;
- Main findings such as the barriers and facilitators to engagement or recruitment.
- Details of engagement or enrolment strategies used.

Quality assessment of included studies

The Cochrane Qualitative and Implementation Methods Groups and others recommend critically appraising qualitative research as it helps assess whether the study adequately addresses the different dimensions of research quality such as credibility, transferability, dependability, and confirmability,[56,57]. Although some are sceptical of this approach,[58], a range of tools and checklists have been devised for this purpose. One such checklist is the
Consolidated Criteria for Reporting Qualitative Research (COREQ), which offers a list of questions for assessing qualitative studies.[59,60]. While, the review team acknowledge that the assessment of qualitative research involves well-honed interpretative skills rather than relying solely on simplistic scoring criteria,[61], the COREQ checklist will be applied to this review as it can enable a rapid evaluation of different types of qualitative studies and their major strengths or weaknesses. Two reviewers will independently assess the quality of the relevant studies and discussion will be used to resolve any conflicts. An independent third reviewer will be contacted if necessary to settle unresolved disagreements. No study will be excluded based on quality assessment as methodologically weak studies may still offer valuable insights.[57].

**Data analysis/synthesis**

This review will synthesise qualitative literature on patients, carers or the general public’s experiences of digital health engagement and recruitment. Our analyses will be informed by framework synthesis as it allows a priori model to be used to facilitate analysis,[62,63]. As outlined, Normalization Process Theory and Burden of Treatment Theory will be used during coding and synthesis, due to their highly conceptual relevance to the review topic. This process will be guided by the framework approach, which follows a five stage process: (1) familiarisation, (2) identifying a thematic framework, (3) indexing, (4) charting, (5) mapping and interpretation,[64]. This series of analytical steps will facilitate in-depth interpretation of data until a rich and coherent understanding emerges. Overarching concepts will be mapped onto constructs from NPT and BOT, although we will be open to the identification and coding of emergent themes that sit outside these theoretical frameworks, in order to inform development of a preliminary model of digital health engagement and recruitment,[65]. The enrolment strategies identified during the analyses will also be classified, if possible, to create
a taxonomy of digital health recruitment approaches. NVivo software will be used to aid analysis.

DISCUSSION

Engaging and recruiting patients, carers and the general public to person-centred digital health technologies is a complex process that needs to be fully explored if we are to capitalise on the value these interventions can offer. To date, existing research on this topic has not been synthesised. The qualitative systematic review aims to address this gap in the scientific literature by providing insights into what helps and hinders patients, carers and the general public to participate in digital health products and services. This will inform our understanding of the readiness of these three important stakeholder groups towards digital health. We will use the findings of our analysis and synthesis work to create a framework that describes the barriers and facilitators that affect patients, carers and the general public’s decision to participate in digital health interventions, to produce a preliminary conceptual model of the digital health engagement and recruitment process, and, if possible, to devise a taxonomy of digital health enrolment strategies. We anticipate that this work will be relevant to a wide range of stakeholders including: researchers responsible for developing and evaluating person-centred digital health interventions; health professionals who may want to recommend new electronic systems and applications to patients and carers; the general public who want to engage with and sign up to use novel health technologies; local and national health services who wish to implement new digital services and enrol a variety of users on them; and policy makers who wish to address barriers to digital health engagement and recruitment. The results of this qualitative systematic review will be widely disseminated through publication in peer reviewed open-access academic journals, research meetings, conference presentations and social media. Public engagement is also important and will be
achieved through knowledge translation events and activities such as seminars, workshops and the use of social media.

**Competing interests** The authors declare that they have no competing interests.

**Contributors** SOC, FM and COD conceptualised the study and designed the review. JG and SG designed the search strategy with input from SOC and FM. SOC wrote the first draft of the protocol with input from FM and COD. SOC, FM, COD, PH, JG and SG contributed to the writing of the final manuscript. All authors read and approved the final version of the manuscript. FM is the guarantor of this research.

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**References**


   http://ewic.bcs.org/content/ConWebDoc/54716


Figure 1 Proposed workflow of the qualitative systematic review

419x523mm (300 x 300 DPI)
### PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist

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<td>Yes</td>
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<td></td>
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<tr>
<td>Contact 3a</td>
<td></td>
<td>Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author</td>
<td>Yes</td>
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<tr>
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<td>Describe contributions of protocol authors and identify the guarantor of the review</td>
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<tr>
<td>Objectives 7</td>
<td></td>
<td>Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>METHODS</strong></td>
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<tr>
<td>Eligibility criteria 8</td>
<td></td>
<td>Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review</td>
<td>Yes</td>
</tr>
<tr>
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<td>Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage</td>
<td>Yes</td>
</tr>
<tr>
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<td></td>
<td>Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated</td>
<td>Yes</td>
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</tr>
<tr>
<td>Selection process</td>
<td>11b</td>
<td>State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)</td>
<td>Yes</td>
</tr>
<tr>
<td>Data collection process</td>
<td>11c</td>
<td>Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators</td>
<td>Yes</td>
</tr>
<tr>
<td>Data items</td>
<td>12</td>
<td>List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications</td>
<td>Yes</td>
</tr>
<tr>
<td>Outcomes and prioritization</td>
<td>13</td>
<td>List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale</td>
<td>Yes</td>
</tr>
<tr>
<td>Risk of bias in individual studies</td>
<td>14</td>
<td>Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis</td>
<td>Yes</td>
</tr>
<tr>
<td>Data synthesis</td>
<td>15a</td>
<td>Describe criteria under which study data will be quantitatively synthesised</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td>15b</td>
<td>If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as $I^2$, Kendall’s $\tau$)</td>
<td>Not applicable</td>
</tr>
<tr>
<td></td>
<td>15c</td>
<td>Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)</td>
<td>Not applicable</td>
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<tr>
<td></td>
<td>15d</td>
<td>If quantitative synthesis is not appropriate, describe the type of summary planned</td>
<td>Yes</td>
</tr>
<tr>
<td>Meta-bias(es)</td>
<td>16</td>
<td>Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Confidence in cumulative evidence</td>
<td>17</td>
<td>Describe how the strength of the body of evidence will be assessed (such as GRADE)</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.*

**Barriers and facilitators to engagement and recruitment to digital health interventions: protocol of a systematic review of qualitative studies**

<table>
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</tr>
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<tr>
<td>Article Type: Protocol</td>
</tr>
<tr>
<td>Date Submitted by the Author: 02-Jun-2016</td>
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</tbody>
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| Complete List of Authors: O'Connor, Siobhan; University of Manchester, School of Nursing, Midwifery and Social Work; University of Glasgow, General Practice and Primary Care
Hanlon, Peter; University of Glasgow, General Practice and Primary Care
Garcia, Sonia; York Health Economics Consortium
Glanville, Julie; University of York, York Health Economics Consortium
O'Donnell, Catherine; University of Glasgow, General Practice and Primary Care
Mair, Frances; University of Glasgow, General Practice and Primary Care |
| Primary Subject Heading: Health informatics |
| Secondary Subject Heading: Qualitative research, Patient-centred medicine, Health informatics, General practice / Family practice |
| Keywords: digital health, eHealth, recruitment, engagement, systematic review, Telemedicine < BIOTECHNOLOGY & BIOINFORMATICS |
Title

Barriers and facilitators to engagement and recruitment to digital health interventions: protocol of a systematic review of qualitative studies

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Abstract

Introduction: Patients and the public are beginning to use digital health tools to assist in managing chronic illness, support independent living and self-care, and remain connected to health and care providers. However, engaging with and enrolling in digital health interventions, such as telehealth systems, mobile health applications, patient portals and personal health records, in order to use them varies considerably. Many factors affect people’s ability to engage with and sign up to consumer digital health platforms.

Objectives: The primary aim is to identify the barriers and facilitators patients and the public experience to engagement and recruitment to digital health interventions. The secondary aim is to identify engagement and enrolment strategies, leading if possible to a taxonomy of such approaches, and a conceptual framework of digital health engagement and recruitment processes.

Methods: A systematic review of qualitative studies will be conducted by searching six databases; MEDLINE, CINAHL, PubMed, EMBASE, Scopus and the ACM Digital Library for papers published between 2000-2015. Titles and abstracts along with full text papers will be screened by two independent reviewers against pre-determined inclusion and exclusion criteria. A data extraction form will be used to provide details of the included studies. Quality assessment will be conducted using the Consolidated Criteria for Reporting Qualitative Research checklist. Any disagreements will be resolved through discussion with an
independent third reviewer. Analysis will be guided by framework synthesis and informed by Normalization Process Theory and Burden of Treatment Theory, to aid conceptualisation of digital health engagement and recruitment processes.

Discussion: This systematic review of qualitative studies will explore factors affecting engagement and enrolment in digital health interventions. It will advance our understanding of readiness for digital health by examining the complex factors that affect patients' and the public’s ability to take part.


Keywords: eHealth, digital health, telemedicine, recruitment, engagement, systematic review

Word Count: 3,081
Strengths and limitations of this study

• This will be the first synthesis of qualitative studies to explore patients’ and the public’s experiences of engagement and recruitment to digital health interventions.

• We will systematically identify and critically appraise the available evidence on this important topic, identify research findings and highlight any knowledge gaps.

• It is envisaged that the results of this review will contribute to: a catalogue of barriers and facilitators that affect people’s ability to engage with and sign up to digital health interventions; a taxonomy of engagement and enrolment strategies used if possible; and a preliminary conceptual framework of digital health engagement and recruitment processes.

• This work will advance our understanding of the readiness of patients’ and the public for digital health.

• Findings may be limited by; 1) the inclusion of English language publications as this could exclude potentially useful studies which may result in cultural and publication bias, 2) the synthesis of qualitative studies which may result in the loss of some explanatory context that could limit the generalisability of findings, or 3) the data analysis and synthesis which will be based on a sample of data extracted by the review team and not the original data.
INTRODUCTION

Changing lifestyle patterns over the last century have seen growing numbers of people with one or more chronic illnesses, including heart disease, diabetes and cancer. Such conditions are the leading cause of death, disease and disability worldwide [1-3]. This combined with ageing populations, who have complex health and social care needs, is creating a huge resource burden on health systems [4,5] with increases in healthcare utilisation and unplanned admissions [6]. To become more sustainable, health services are beginning to move from treating illness in acute hospital settings to promoting more preventative care and the self-management of long-term conditions in the community where possible [7,8].

Person-centred digital health interventions are being developed and trialled to further this agenda, by promoting active and healthy ageing, supporting individuals to manage long-term conditions at home and assisting them to remain connected with health and care providers. Examples include telehealth and telecare systems [9], electronic personal health records (PHRs) [10] and mobile health applications or ‘apps’ [11] among others. It is hoped that these types of digital products and services could lead not only to better health outcomes but also a reduction in the utilisation and cost of primary, secondary and tertiary health services [12].

Many of these digital health interventions have only been evaluated in small pilot studies or Randomised Controlled Trials (RCTs). While the results of these can sometimes demonstrate positive outcomes [13], many people choose not to enroll as they can experience numerous barriers, some of which relate to the complex recruitment procedures in trials [14-16]. While non-participation is a significant issue [17,18], there are also many factors that can facilitate patients’ and the public to engage with and sign up to digital health platforms [19,20]. Although there is a large literature on difficulties recruiting to trials [21], many challenges
only emerge when technologies are scaled up and implemented in “real-world” complex health systems [22,23]. This is an important distinction, as RCTs have pre-defined protocols and strict inclusion criteria that can often mask wider implementation issues [24,25]. Problems that can arise when technologies are scaled up begin in the initial phases of implementing a digital health intervention in practice, when engaging with different stakeholders, when encouraging people to register for digital products and services on offer (or which might be offered in the future) and then facilitating them to sign up for it. The journey by which such technologies are implemented can span a long timeline of individual and organisational change processes, not all of which occur sequentially [26]. As a result, this review is focusing on the initial phases of rolling out digital health products and services, in particular the engagement and recruitment of users. By engagement, we mean the processes by which patients’ and the public become aware of and understand digital health technologies for example through promotional efforts and marketing campaigns. Recruitment on the other hand encompasses the processes that people are involved in when enrolling or signing up to digital health products or services, such as actively filling out paper based registration forms or creating online profiles or accounts. There has as yet, been no attempt to synthesise what this literature tells us about the key challenges or the outstanding research gaps surrounding engagement and recruitment to digital health.

There have been repeated calls for more research that synthesises the findings from qualitative evidence to support both policy and the translation of research into clinical practice [27]. For example, a synthesis of qualitative research can aid in the understanding of complex interventions as well as human experiences and behaviour, all of which can be used to inform health policy and practice [28,29]. The volume of qualitative systematic reviews has been growing slowly over the last number of years [30] due in part to the work of the
Cochrane Qualitative and Implementation Methods Groups (CQIMG) and others who are championing the role qualitative synthesis can play in building the base for effective evidence that can be adopted and implemented in everyday practice [31,32]. At present, there is little if any published systematic reviews of qualitative studies looking at different aspects of person-centred digital health interventions. In particular, there is no systematic review on the topic of digital health engagement and recruitment, although it has been highlighted as a research gap that needs attention [14,25]. An understanding of the barriers patients’ and the public experience when trying to engage and enrol in digital health products and services would help ensure the full value of these interventions can be realised. Similarly, robust evidence on the factors that facilitate this process could improve recruitment to future digital health initiatives.

In addition, theoretical frameworks have been used previously to aid many types of qualitative synthesis [24,33,34] as established models can help to explain the phenomenon under consideration and make the findings of the synthesis more accessible to application in practice [35,36]. Therefore, this review will incorporate two empirically grounded sociological theories, Normalization Process Theory (NPT) and Burden of Treatment Theory (BOTT), as they are relevant to understanding how individuals embed new interventions in everyday routine and the burden that this process entails [37,38]. NPT in particular has been widely used in eHealth implementation research to examine different stages of the process through its four main constructs; ‘Coherence’, ‘Cognitive Participation’, ‘Collective Action’ and ‘Reflexive Monitoring’ (see Figure 1) [39,40]. BOTT was built on the conceptual foundations of NPT to expand our knowledge of the difficulties patients experience when coping with new treatment modalities and enacting self-care strategies [41] so they are both directly applicable to this qualitative synthesis. This systematic review of qualitative studies
aims to identify and synthesise currently available knowledge about barriers and facilitators to engagement and recruitment across a range of digital health interventions and highlight knowledge gaps and areas for further research. If possible, we will also aim to develop a taxonomy of digital health engagement and recruitment strategies used and a preliminary conceptual framework of digital health engagement processes. Arguably, a better understanding and detailing of these difficulties and the processes involved will help researchers and those in industry design better systems and enrolment strategies and inform health service managers and policy makers of changes that need to be made to improve digital health engagement and recruitment.

Objectives

Primary

To examine the factors (barriers and facilitators) that affect patients’ and the public’s ability to engage with and enrol in digital health interventions.

Secondary

To determine what engagement and recruitment strategies have been utilised to sign people up to digital health products and services.

METHODS

This protocol was written in accordance with the Preferred Items for Reporting Systematic Reviews and Meta-analysis Protocols (PRISMA-P) checklist [42]. Reporting of the full systematic review will follow the Enhancing Transparency in Reporting the Synthesis of Qualitative Research (ENTREQ) statement [43]. An interdisciplinary team of researchers will be involved in the systematic review with expertise ranging from general practice and primary care, to nursing, health informatics and information science. Members of this team
have conducted and published numerous high quality systematic reviews and the collective skillset will enable a robust review to be carried out [33,34]. An initial ‘scoping search’ will be carried out to help identify key papers and search terms that are relevant to the research topic. This process will be carried out by conducting a preliminary search of online bibliographical databases via Ovid; the use of the ‘related articles’ function in PubMed, reference and footnote tracking of relevant papers found, citation tracking of relevant papers found, the use of personal knowledge, and consultation with experts in the field. The results will help to inform the initial design of the search strategy for the review which will be piloted and refined as appropriate. Figure 2 outlines the detailed workflow of the proposed review.

Search Strategy

A team of information specialists at the York Health Economics Consortium (YHEC), who specialise in conducting systematic reviews, will be consulted to assist with the design of the search strategy. There is likely to be three groups of search terms referring to; person-centred digital health interventions, engagement and recruitment, and factors that affect these processes i.e. barriers and facilitators (see Table 1). Guidance will be sought from the Cochrane Handbook for Reviews of Interventions on the most robust way to systematically search the literature [44] and other novel strategies such as text mining [45,46] will be explored and applied where appropriate. The following six electronic databases; CINAHL, (EBSCHOHost), PubMed, Medline, Embase, Scopus and the ACM Digital Library, will be systematically searched to identify published peer-reviewed scientific literature that are relevant to the research objectives. YHEC will run searches, remove duplicate citations and provide an Endnote database file of citations for screening.
Table 1 Search strategy

<table>
<thead>
<tr>
<th>Search</th>
<th>Search terms that will be modified for use across multiple databases</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1</td>
<td>Search Electronic Health Records [MeSH Terms]</td>
</tr>
<tr>
<td>#2</td>
<td>Search Cellular Phone [MeSH Terms]</td>
</tr>
<tr>
<td>#3</td>
<td>Search Social Networking [MeSH Terms]</td>
</tr>
<tr>
<td>#4</td>
<td>Search Telemedicine [MeSH Terms]</td>
</tr>
<tr>
<td>#5</td>
<td>#1 OR #2 OR #3 OR #4</td>
</tr>
<tr>
<td>#6</td>
<td>Search recruit*</td>
</tr>
<tr>
<td>#7</td>
<td>Search enrol*</td>
</tr>
<tr>
<td>#8</td>
<td>Search participat*</td>
</tr>
<tr>
<td>#9</td>
<td>Search engage*</td>
</tr>
<tr>
<td>#10</td>
<td>#6 OR #7 OR #8 OR #9</td>
</tr>
<tr>
<td>#11</td>
<td>Search barrier*</td>
</tr>
<tr>
<td>#12</td>
<td>Search challenge*</td>
</tr>
<tr>
<td>#13</td>
<td>Search impediment*</td>
</tr>
<tr>
<td>#14</td>
<td>Search facilit*</td>
</tr>
<tr>
<td>#15</td>
<td>#11 OR #12 OR #13 OR #14</td>
</tr>
<tr>
<td>#16</td>
<td>#5 AND #10 AND #15</td>
</tr>
</tbody>
</table>

The challenges of searching the qualitative literature have been well documented [47-49] and studies have shown that traditional database searching can reveal as little as 30% of research papers that are relevant to the topic under review [50]. Therefore, other search methods will be used to supplement the results of the systematic review and identify relevant studies. These will include reference or footnote tracking; using the ‘related articles’ function in
PubMed; citation tracking; personal knowledge and personal contacts and contacting experts in the field.

Eligibility Criteria

The review will adhere to the following criteria. These were developed using a modified PICO framework, which stands for population, intervention, control and outcome [51] (see Table 2).

Table 2 PICO criteria for including studies.

<table>
<thead>
<tr>
<th>Population</th>
<th>Any individual (adult or child). This includes patients’, the public and health professionals who would be aware of the experiences of these stakeholder groups.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>Any health intervention delivered by a digital technology (hypothetical or in development, simulated or real-world) which takes information from people or provides some form of advice or feedback about their health. This includes, but is not limited to:</td>
</tr>
<tr>
<td></td>
<td>• Web-based interventions on PCs or mobile platforms,</td>
</tr>
<tr>
<td></td>
<td>• Mobile health applications or apps,</td>
</tr>
<tr>
<td></td>
<td>• Patient portals or personal health records</td>
</tr>
<tr>
<td></td>
<td>• Interventions delivered by SMS or IVR (interactive voice recognition).</td>
</tr>
<tr>
<td>Control</td>
<td>None</td>
</tr>
<tr>
<td>Outcome</td>
<td>Qualitative data on the factors (barriers and facilitators) to engagement and recruitment. Qualitative data on engagement and enrolment strategies.</td>
</tr>
<tr>
<td>Study type</td>
<td>Original qualitative studies, studies involving secondary analysis of qualitative data or qualitative studies that are part of a mixed methods study. The study must have direct contact with individuals or direct observation using any form of qualitative method.</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Setting</td>
<td>Any ‘usual’ setting (hypothetical or in development, simulated or real-world) such as primary, secondary or tertiary care, the home or workplace.</td>
</tr>
<tr>
<td>Timing or Phase of Implementation</td>
<td>Engagement or recruitment phase only.</td>
</tr>
</tbody>
</table>

Papers will be included if they meet the PICO criteria. Below is a detailed description of the inclusion and exclusion criteria.

1) **Types of studies**: Original qualitative studies, studies involving secondary analysis of qualitative data or qualitative studies as part of a mixed methods study (e.g. a major component must be qualitative and describe a qualitative methodology). Certain types of studies will be excluded from the review including those using the following methodologies:

   a. literature or systematic reviews and meta-analyses;
   
   b. descriptive case studies; lexical studies that analyse natural language data presented as qualitative results;
   
   c. qualitative studies using questionnaires or other methods that do not involve direct contact or observation of participants;
   
   d. commentary articles written to convey opinion or stimulate research/discussion with no research component;
e. studies describing an individual’s experience(s) in a Randomised Controlled
Trial (RCT). This review is focusing on barriers and facilitators to engagement
and enrolment to person-centred digital health interventions rather than the
wider literature on recruitment to clinical trials that has been addressed in
previous reviews [21].

2) Types of eHealth interventions: Any health intervention delivered by a digital
technology (hypothetical or in development, simulated or real-world), which takes
information from patients’ or the public or provides some form of advice or feedback
about their health. This includes, but is not limited to, web-based interventions on
Personal Computers (PCs) or mobile platforms, mobile health applications or apps,
patient portals, personal health records and interventions delivered by SMS or IVR
(interactive voice recognition). Certain technologies will be excluded from the review
including those whose primary intervention is; telephone based with no additional
 technological function (e.g. telephone counselling or triaging service); Internet based
with no additional interactive function (e.g. searching for health information online);
or an implantable device that is remotely monitored.

3) Types of participant: Any individual (adult or child). This includes patients’, the
public and health professionals who would be aware of the experiences of these
stakeholder groups.

4) Types of settings: Any ‘usual’ setting (hypothetical or in development, simulated or
real-world) such as primary, secondary or tertiary care, home or workplace.

5) Phase of implementation: Qualitative research which explores the initial phases of
implementation i.e. engagement and recruitment phase, before individuals start using
a digital health intervention. This can span from gauging an individual’s readiness for
a digital health intervention, to the initial marketing or reach of the initiative, to
actively signing people up to use the technology so they are registered on the digital application or system. Therefore we will not explore: pre-engagement work based solely around designing the interface and functionality of a digital health intervention; patients’ or the public’s use of these types of technologies; why they drop out or fail to continue using them (non-usage or attrition) [52] or sustain their use of them (retention) [53]; their attitudes or beliefs towards a digital health intervention or their satisfaction with it, except as pertaining directly to engagement or recruitment.

6) Date of publication: between 1 January 2000 and 19 August 2015

7) Language: English

Screening

Each title and abstract will be screened by two independent reviewers using DistillerSR software [54]. All journal articles that meet the inclusion criteria set out above will be obtained in full text format for further screening and assessment. Two independent reviewers will conduct the second level full paper screening by applying the inclusion and exclusion criteria. A third party will be involved to resolve any conflicts that occur in determining the relevance of the titles, abstracts and full text papers so that a consensus over inclusion and exclusion of each article can be reached. A flow diagram will be used to report the selection process and reasons for exclusion as suggested by the PRISMA guidelines [55].

Data extraction

Data extraction will be carried out using a comprehensive, standardised extraction template that will be designed based on the specific characteristics of this review, including aims of the study, design and methodological approach taken, and key findings such as barriers and facilitators and a description of engagement and recruitment strategies. It will be piloted on a
subset of relevant papers and refined where appropriate. The extraction process will be conducted by two individual reviewers based on the relevant articles previously identified through the screening process. A third party will be involved where disagreements arise over the relevancy of the data to the review topic which will assist in reaching consensus and creating a robust dataset. This will result in a table that provides the following details:

- Bibliographic information such as the journal name, year, volume and page numbers;
- Study characteristics such as the type of technology and qualitative approach taken;
- Participant characteristics (sociodemographic) and information about the number and type of individuals who signed up or declined to take part;
- Main findings such as the barriers and facilitators to engagement or recruitment;
- Details of engagement or enrolment strategies used.

**Quality assessment of included studies**

The Cochrane Qualitative and Implementation Methods Groups and others recommend critically appraising qualitative research as it helps assess whether the study adequately addresses the different dimensions of research quality such as credibility, transferability, dependability, and confirmability [56,57]. Although some are sceptical of this approach [58], a range of tools and checklists have been devised for this purpose. One such checklist is the Consolidated Criteria for Reporting Qualitative Research (COREQ), which offers a list of questions for assessing qualitative studies [59,60]. While, the review team acknowledges that the assessment of qualitative research involves well-honed interpretative skills rather than relying solely on simplistic scoring criteria [61], the COREQ checklist will be applied to this review as it can enable a rapid evaluation of different types of qualitative studies and their major strengths or weaknesses. Two reviewers will independently assess the quality of the relevant studies and discussion will be used to resolve any conflicts. An independent third
reviewer will be contacted if necessary to settle unresolved disagreements. No study will be excluded based on quality assessment as methodologically weak studies may still offer valuable insights [62].

Data analysis/synthesis

This review will synthesise qualitative literature on patients’ or the public’s experiences of digital health engagement and recruitment. Our analyses will be informed by framework synthesis as it allows a priori model to be used to facilitate analysis [63]. As outlined, Normalization Process Theory [37,39,40] and Burden of Treatment Theory [38,41] will be used during coding and synthesis, due to their highly conceptual relevance to the review topic. This process will be guided by the framework approach, which follows a five stage process: (1) familiarisation, (2) identifying a thematic framework, (3) indexing, (4) charting, (5) mapping and interpretation [64]. This series of analytical steps will facilitate in-depth interpretation of data until a rich and coherent understanding emerges. Overarching concepts will be mapped onto constructs from NPT and BOTT, although we will be open to the identification and coding of emergent themes that sit outside these theoretical frameworks, in order to inform development of a preliminary model of digital health engagement and recruitment [65]. The engagement and enrolment strategies identified during the analyses will also be classified, if possible, to create a taxonomy of approaches. These might include traditional forms of mass media and recruitment via health professionals, to more contemporary methods utilising social media and online advertising to reach and enrol large numbers of people. NVivo software will be used to aid analysis [66].
DISCUSSION

Engaging and recruiting patients’ and the public to digital health interventions is a complex process that needs to be fully explored if we are to capitalise on the value these technologies can offer. To date, existing research on this topic has not been synthesised. The systematic review of qualitative studies aims to address this gap in the scientific literature by providing insights into what helps and hinders patients’ and the public to engage and enrol in digital health products and services. This will inform our understanding of the readiness of these important stakeholder groups for digital health. We will use the findings of our analysis and synthesis work to create a catalogue that describes the barriers and facilitators that affect people’s ability to sign up to digital health interventions, and if possible, devise a taxonomy of digital health engagement and enrolment strategies. From this, we will produce a preliminary conceptual framework of digital health engagement and recruitment processes. We anticipate that this work will be highly relevant to a wide range of stakeholders including: researchers and industry who are developing and evaluating person-centred digital health interventions; health professionals who may want to recommend new electronic systems and applications to patients and the public who want to engage with and sign up to use novel technologies; local and national health services who wish to implement new digital services and enrol a variety of users on them; and policy makers who wish to address barriers to digital health engagement and recruitment. The results of this systematic review will be widely disseminated through publication in peer reviewed open-access academic journals, research meetings, conference presentations and social media. Public engagement is also important and will be achieved through knowledge translation events and activities such as seminars, workshops and the use of social media.

**Competing interests** The authors declare that they have no competing interests.
**Contributors** SOC, FM and COD conceptualised the study and designed the review. JG and SG designed the search strategy with input from SOC and FM. SOC wrote the first draft of the protocol with input from FM and COD. SOC, FM, COD, PH, JG and SG contributed to the writing of the final manuscript. All authors read and approved the final version of the manuscript. FM is the guarantor of this research.

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**References**


Figure 1 Four constructs of Normalization Process Theory (NPT)

Coherence
How individuals make sense of a new intervention

Cognitive Participation
How individuals engage with a new intervention to ensure 'buy in' and sustained use

Reflexive Monitoring
How individuals appraise and evaluate a new intervention

Collective Action
How individuals operationalise a new intervention in practice by investing effort and resources
Figure 2 Proposed workflow of the qualitative systematic review
419x523mm (300 x 300 DPI)
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<th>Section and topic</th>
<th>Item No</th>
<th>Checklist item</th>
<th>Checklist item complete</th>
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<td></td>
<td></td>
</tr>
<tr>
<td>Title:</td>
<td></td>
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</tr>
<tr>
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<td>Identify the report as a protocol of a systematic review</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Update 1b</td>
<td>If the protocol is for an update of a previous systematic review, identify as such</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Registration 2</td>
<td>If registered, provide the name of the registry (such as PROSPERO) and registration number</td>
<td>Yes</td>
<td></td>
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<tr>
<td>Authors:</td>
<td></td>
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<tr>
<td>Contact 3a</td>
<td>Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Contributions 3b</td>
<td>Describe contributions of protocol authors and identify the guarantor of the review</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Amendments 4</td>
<td>If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Support:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sources 5a</td>
<td>Indicate sources of financial or other support for the review</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Sponsor 5b</td>
<td>Provide name for the review funder and/or sponsor</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Role of sponsor or funder 5c</td>
<td>Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>INTRODUCTION</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rationale 6</td>
<td>Describe the rationale for the review in the context of what is already known</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Objectives 7</td>
<td>Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>METHODS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eligibility criteria 8</td>
<td>Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Information sources 9</td>
<td>Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Search strategy 10</td>
<td>Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Data management</th>
<th>11a</th>
<th>Describe the mechanism(s) that will be used to manage records and data throughout the review</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection process</td>
<td>11b</td>
<td>State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)</td>
<td>Yes</td>
</tr>
<tr>
<td>Data collection process</td>
<td>11c</td>
<td>Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators</td>
<td>Yes</td>
</tr>
<tr>
<td>Data items</td>
<td>12</td>
<td>List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications</td>
<td>Yes</td>
</tr>
<tr>
<td>Outcomes and prioritization</td>
<td>13</td>
<td>List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale</td>
<td>Yes</td>
</tr>
<tr>
<td>Risk of bias in individual studies</td>
<td>14</td>
<td>Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis</td>
<td>Yes</td>
</tr>
<tr>
<td>Data synthesis</td>
<td>15a</td>
<td>Describe criteria under which study data will be quantitatively synthesised</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Data synthesis</td>
<td>15b</td>
<td>If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall’s τ)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Data synthesis</td>
<td>15c</td>
<td>Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Data synthesis</td>
<td>15d</td>
<td>If quantitative synthesis is not appropriate, describe the type of summary planned</td>
<td>Yes</td>
</tr>
<tr>
<td>Meta-bias(es)</td>
<td>16</td>
<td>Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Confidence in cumulative evidence</td>
<td>17</td>
<td>Describe how the strength of the body of evidence will be assessed (such as GRADE)</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.