Protocol 14th Sept 2020, v2.1

NIHR Applied Research Collaboration (ARC) Wessex
Theme: Long-Term Conditions: Integrating person-centred care approaches to optimise healthy living. **Work Stream 2**: Innovation and technology for healthy living

Programme: "Digital and non-digital behaviour change interventions to support the maintenance of physical activity for adults with long-term conditions: mixed methods studies"
Short title of programme: **M**aintenance **O**f Physical Ac**T**ivity Be**H**aviour (**MOTH**)

Project title: Exploring the factors that facilitate and hinder the implementation of digital tools for self-management of long-term conditions within existing healthcare structures and pathways

IRAS short title: Exploring the factors for implementation of digital health tools (Ref. 288651)

Researchers

Dr Paul Clarkson (PC)

Prof Suzanne McDonough (SM)

Dr Euan Sadler (ES)

Prof Maria Stokes (MS)

Dr Aoife Stephenson (AS)

Dr Philip O'Gorman

Background

A long-term or chronic condition (LTCs) has been defined as "a condition that cannot, at present, be cured but is controlled by medication and/or other treatment/therapies" (DH 2012). Self-management has been defined as "the tasks that individuals must undertake to live with one or more chronic conditions" and includes having the confidence to manage medical, role and emotional needs (US Institute of Medicine 2004). While it is not always possible, or indeed necessary, to involve a healthcare professional in day-to-day management, having a resource that is able to provide support and advice when needed can be beneficial (Schaffler et al 2018). Improving and maintaining physical activity is key to supporting health, wellbeing and functional daily activities (Public Health England 2016) and is often recommended as part of interventions to support LTCs (Rausch Osthoff et al 2018, WHO 2019, NICE 2018, DH 2012). Such self-management interventions have been reported to help improve levels of physical activity in the short-term for people with a LTC (Alothman et al 2017, Williamson et al 2015). However, barriers exist to taking part in face-to-face self-management interventions to support physical activity behaviour change, including family commitments, transport issues, cost and personal disabilities (Peyrot et al 2009, Sprague et al 1999). Additionally, many self-management interventions have not traditionally acknowledged the complexities associated with the individual and contextual factors in their environment (Mills et al 2014; Glazier et al 2006; Kennedy et al 2005). This is particularly pertinent, given the increased prevalence of LTCs amongst lower socio-economic groups and the associated poor outcomes of current self-management interventions for these populations, suggesting that they are not appropriately designed for those requiring support (Conn et al 2013, Nolte and McKee 2008).

Self-management interventions that are delivered digitally, often via the internet, offer some potential to address some of the barriers to access, implementation and to achieve sustainable outcomes. A narrative review of mobile apps for supporting self-management of certain long-term conditions reported consistent benefit for people with diabetes, some benefit for other conditions such as heart failure and asthma, but no benefit for people with chronic obstructive pulmonary disease or chronic kidney disease (Scott et al 2020). Another recent systematic review included a wider range of technological interventions for LTCs, reported improvements in self-management support and quality of life (Irani et al 2020). Digital interventions are also considered to be acceptable by people with a LTC (Woods et al 2019, Castle-Clarke 2018, Algeo et al 2017).

Improvements in clinical outcomes and health behaviours have been reported, such as a reduction in systolic blood pressure for people with hypertension (McLean et al 2016) and uptake of physical activity across a variety of long-term conditions (Berry et al 2018, Roberts et al 2017, Connelly et al 2013). However, many existing studies only focus on the initiation of such behaviours, rather than the potential for a digital tool to support the maintenance of self-management behaviours such as physical activity. Studies that have reported on the maintenance of physical activity beyond 3 months have typically used non-digital interventions or have not included LTC populations. As an example of this, Grimmett et al (2019) identified only two studies that used digital interventions to support the maintenance of PA for cancer survivors. However, only one was included in the meta-analysis and reported effectiveness. Samdal et al (2017) identified four studies which used digital interventions to support >3-month maintenance of physical activity for people who were obese or overweight. These studies reported modest effect sizes, while only one included people with a LTC outside of obesity (diabetes) and reported only a lower level of deterioration in PA. Stellefson et al (2013) included 15 studies using digital interventions for people with a variety of LTCs in their review, however, only four included a maintenance period and three of these included PA as an outcome. All three studies did not report maintenance of PA behaviour.

The use of digital interventions to support the maintenance of health behaviours is intrinsically linked with the concept of engagement (McClure et al., 2013, Donkin et al., 2011, Danaher et al., 2006). Engagement with digital behaviour change interventions has been linked with the digital technology itself, the setting and the individual (Perski et al 2017). Understanding the contextual environment associated with their implementation is therefore important for sustained effectiveness. Correspondingly, concerns have been raised about the inclusivity of digital interventions, particularly amongst older age groups. However, internet usage is growing, with 91% of UK adults reported to be recent internet users in 2019 and age group differences narrowing in recent years (ONS 2019). There is also increasing recognition of the need to develop digital resources that are accessible for people with lower levels of health literacy and that incorporate the views and needs of users (Department of Health and Social Care 2019; Rowlands et al 2015).

Nevertheless, the widespread implementation and adoption of digital health interventions into healthcare has been sporadic at best (Ross et al 2016; Wachter 2016; Murray et al 2011). A recent systematic review by Ross and colleagues (2016) explored factors of importance influencing the implementation of e-health interventions drawing on the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al 2009). Results corresponded with the constructs of the CFIR, which included the importance of micro-level factors relating to the user and technology, the relevance of setting (both internal and external) and the processes used for implementation. The relationship between the internal organisational setting (meso-level) and the external policy environment (macro-level) was considered to influence implementation, in terms of limited policy or standards to drive the successful introduction of digital health interventions. These macro factors were reported to have a knock-on effect for individual uptake (Ross et al 2016). Furthermore, it is suggested that the complexities between the dynamic interaction of these multi-level factors lead to the lack of sustained adoption of e-health interventions (Greenhalgh et al 2004, 2017).

For individuals who live with a LTC, management of their health on a daily basis requires effective navigation of complex personal and system level interactions. Lorig and Holman (2003) identified six skills relevant to effective personal self-management, including identification and utilisation of resources, such as the internet; developing a partnership with healthcare providers, and decision making, action planning, problem solving and self-tailoring. A recent study exploring the development and feasibility of a new digital intervention for managing joint pain reported the importance of understanding the context of implementing such a resource within existing healthcare structures (Clarkson et al 2020). The World Health Organization (WHO) also recommend exploring the wider ecosystem associated with the implementation of digital resources, suggesting that a failure to do so could impact both the effectiveness and sustainability of such interventions (WHO 2019).

Since Ross and colleagues (2016) highlighted the lack of policy and healthcare standards in this area, there has been a greater emphasis on establishing recommendations and guidelines to support both infrastructure and resource development for digital health interventions to support self-management of LTCs. At a macro level, the WHO recently launched a draft global strategy to support the advancement of digital health for supporting widespread health coverage (WHO 2020). In the UK, the National Institute for Health and Care Excellence (NICE) introduced standards for digital health technologies (2019), whilst NHSX (National Health Service user eXperience) was established in 2019 to "lead policy, implementation and change" for digital transformation (NHSX 2020). Other professional associations and organisations aligned with the UK's National Health Service (NHS) have also developed policy documents and strategic plans in this area, including the Royal College of General Practitioners (2019) and The Health Foundation (2019). Recommendations for effective implementation include; the need for appropriate infrastructure and governance, standards for ensuring that digital interventions are safe and engaging, and that technologies are relevant within the wider social and organisational context, to reduce inequalities.

While the framework from NICE (2019) provides a guideline for commissioning digital health resources, implementation locally at a meso level can be complex. Maniatopoulos et al (2019) explored commissioning pathways associated with the implementation of a digital diagnostic tool for people with peripheral arterial disease. The factors identified as hindering implementation included competing priorities, lack of collaboration between care settings and commissioners, high costs and limited relevant evidence. In a similar study looking at commissioning self-management support for people with LTCs more generally, Reidy et al (2016) reported that commissioning decisions were often driven by national policy directives which were difficult to achieve, rather than localised need. On a practice level, numerous studies have described the general challenges associated with implementing digital health innovations, including issues related to staff capacity and the means to adopt a new intervention within existing complex health and social care pathways (Maniatopoulos et al 2019, Jefferies et al 2017, Ross et al 2016). A number of facilitators to implementation have also been described; often reflecting the need to plan and manage the identified challenges as part of intervention development and testing. For example, Ross et al (2016) report that issues related to adaptability can be overcome through ensuring that the intervention's target audience are involved in the development process. Furthermore, concerns about cost and efficiency can be managed through demonstrating cost-effectiveness and fit to existing structures and pathways. Consequently, it is important to understand the different multi-level contextual factors associated with implementing a new digital health intervention to support self-management of LTCs and the potential interactions and conflicts between policy, commissioning and practice. We, therefore, aim to:

Aims

- Explore the barriers, facilitators, needs and preferences that influence the implementation of a digital health intervention for self-management to maintain physical activity in people with a LTC, within current UK NHS care pathways
- Identify how policy and standards for implementation of digital health interventions converge and/or diverge with commissioning and practice-level factors

Objectives

- To conduct interviews with service commissioners, General Practitioners and LTC Specialist healthcare professionals to explore their needs and preferences in relation to using and recommending digital health interventions and the perceived contextual factors facilitating and hindering the implementation of a digital self-management tool to support self-management to maintain for people with a LTC.
- To identify barriers, facilitators and needs of stakeholders to support the development, scale up and implementation of a digital behaviour change intervention for maintaining physical activity.
- To conduct a review of policy related to digital health, specifically focused on general recommendations for implementation into existing NHS healthcare structures and pathways which can be analysed alongside interview data to determine potential conflicts at different structural levels.

Methodology

This study follows on from the platform provided by a previous NIHR-CLAHRC funded project to develop and test the feasibility of digital tools for the self-management of joint pain (Clarkson et al 2020). The present study is also part of a wider programme of research to explore the maintenance of physical activity in people with a LTC. This programme aims to develop a new digital health intervention to support people to stay active, which will be rigorously developed and tested alongside users for planned implementation into practice. The present study is, therefore, integral to understanding the wider contextual environment of implementing such a digital health resource. The study aims to gain an early understanding of the perspectives, needs and perceived challenges among our stakeholders, which is considered to be an essential stage to the development of an effective plan for implementation of healthcare interventions into health and social care (Ross et al 2018; May 2006).

Developing research that considers the interaction between technology and its wider context is beneficial for ensuring that digital interventions effectively meet the needs of stakeholders in context, are cost-effective and improve efficiencies in practice (Ross et al 2016; May 2013; Maniatopoulos et al 2009; McLoughlin et al 2009, 2012).

<u>Policy review</u>

Policy is defined by the Cambridge Dictionary to be: “a set of ideas or a plan of what to do in particular situations that has been agreed to officially by a group of people, a business organization, a government, or a political party” (Cambridge University Press 2020). The scope of this review will relate to recommendations for implementation and adoption of digital resources, included in UK policy documents, guidelines and reports. Reports from the WHO and subsidiary organisations, which have implications for the NHS, will also be included within the scope of this review.

Search strategy

A search strategy will be developed using terms adapted from a scoping review on the use of digital health interventions to support the maintenance of physical activity in people with LTCs and preliminary searches of the literature (Appendix A). An academic librarian will also advise on appropriate terms and strategy related to the aims of the review. Given that the aim of this review is to identify the general recommendations associated with the implementation of digital interventions to support self-management at an organisational level, it may also be important to include terms related to ‘self-management’.

We will search for policy documents using the NICE Evidence Search tool (https://www.evidence.nhs.uk/) and in Scopus, due to its large database which includes policy resources (Elsevier 2020), PubMed and key journals. These journals will include ‘Implementation Science’, ‘BMC Health Services Research’, ‘British Medical Journal Open’ and the ‘Journal of Medical Internet Research’, based on existing work published in this area by Ross et al 2016, Maniatopoulos et al (2019), Jefferies et al 2017 and Reidy et al 2016. The reference lists of the identified results will also be searched to identify further relevant policy documents that may have been missed in the initial searches. Additionally, we will search for policy documents from the World Health Organization (European Region) website and from subsidiary organisations, such as non-governmental organisations working in the area of digital health implementation that have an impact on the UK, using the same terms. We will also search The King’s Fund Library Database (https://koha.kingsfund.org.uk/) and The Public Health England Grey Literature Index (https://phelibrary.koha-ptfs.co.uk/greylit/) Finally, we will consult with experts in the field of digital health to identify further sources of evidence that may have been missed. Documents will be read to determine relevance to the UK health system.

Policy selection

Initial searches will be conducted by one researcher (PC). Results will be assessed for relevance to the UK NHS independently by two further researchers (SM/TBC) by reading through the documents in relation to the eligibility criteria for the review (see below). Any discrepancies will be verified through discussion. Relevant data will be extracted from the documents using a data extraction table, based on the scope of the review.

Eligibility criteria

As the digital health field is rapidly changing, to ensure relevance to current practice, we will limit policy, and associated documents (see below) to a five-year period, from 2015 – 2020. While unlikely to be condition specific, policy documents will not be excluded if related to the implementation and/or adoption of digital health interventions for a specific condition. Given that comparison will be made to qualitative interview results with UK commissioners, GPs and specialists, policy will be excluded if not applicable to the UK NHS (see below).

The following criteria will also be used to determine eligibility for inclusion in the review:

- White papers on digital health, encompassing eHealth (information/communication) and mHealth (mobile) technologies will be included. Green papers will be excluded due to being formative in nature (House of Commons 2010)

- Documents for inclusion: Policy documents, Reports, Guidelines, Policy reviews, Standards on digital health

- For European-wide documents on digital health implementation, relevance to the NHS will be based on applicability to a publicly funded healthcare system such as the NHS services and infrastructure.

- English language only.

Data extraction and Analysis

Relevant text relating to determinants (barriers and facilitators) and strategies related to the implementation of digital health interventions, both generally and if applicable, to self-management or maintenance of physical activity for LTCs from the documents will be extracted verbatim. These data will be coded using a content analysis approach to categorise, develop and refine emerging themes. Content analysis has been used in previous reviews of policy and organisational reports (e.g. Macuácua et al 2019; Reidy et al 2016) and is therefore considered a valid and replicable approach to identifying contextually relevant information (Krippendorff 2004). The extracted data will be read repeatedly, with meaning units created in relation to the research aim and objectives before being coded independently by two researchers (PC, SM). Categories will be established based on the codes and discussed between the researchers to reach a consensus on the final themes (Erlingsson and Brysiewicz 2017).

The results of the review will inform the interviews, which are planned as part of the second phase of this project. Specifically, this is likely to inform questions about how recommendations for digital health implementation are operationalised at commissioning, organisational and practice levels. In doing so, it may be possible to understand the conflicting and facilitating factors that exist between recommendations and practical implementation.

Interviews

We will conduct up to 10 interviews each with service commissioners at Clinical Commissioning Groups (CCG) in the Wessex region, General Practitioners (GPs) and LTC specialist healthcare professionals. In these interviews, we aim to understand the barriers and facilitators to implementing digital tools to support self-management and more specifically the activation and maintenance of physical activity for people with LTCs, in an NHS healthcare context. We also aim to understand the needs and preferences of GPs and LTC specialists in relation to using and recommending such interventions to support self-management for maintaining physical activity. This number of interviews was found to be appropriate to ensure data saturation in a study about digital health services with GPs (Fagerlund et al 2018) and in a study with UK commissioners (Reidy et al 2016). Although these interviews will only be conducted in one UK region, Wessex represents a mix of both rural and urban areas. Hampshire makes up the largest proportion of Wessex, with an estimated population of over 1.8 million (including Southampton and Portsmouth) (ONS 2018). Hampshire also has an ageing population, which is representative of the wider UK population and of those with long-term conditions (Hampshire County Council 2019, DH 2012). We will aim to include GPs and LTC specialists from both settings and with different LTC populations, based on The Quality and Outcomes Framework (QOF) from 2017/18 (NHS Digital 2018) to ensure that the results are as generalisable as possible to other geographical regions. The list of LTCs includes:

- Cardiovascular disease, including AF, HTN, Heart failure, Peripheral arterial disease, secondary prevention of coronary heart disease
- Myocardial infarction: secondary prevention
- Stroke/TIA
- Asthma
- COPD
- Chronic kidney disease
- Diabetes mellitus
- Dementia
- Epilepsy
- Mental Health
- Depression
- Osteoporosis
- Rheumatoid arthritis
- Osteoarthritis
- Obesity

Recruitment

Service commissioners for primary care and community services (many of whom will also be GPs) will be identified from publicly held information available on CCG websites, with contact initially made by email to all commissioning groups in Wessex. Specific commissioners may also be identified through existing clinical academic contacts at the University of Southampton and will also be contacted by email with details of the study. A convenience sample of commissioners will be chosen based on the response to the email invitation. This approach has been chosen due to previously cited difficulties in recruiting commissioners to take part in research interviews (Reidy et al 2016).

Practice GPs and LTC specialists will be recruited through local Clinical Research Network (CRN) groups or through existing clinical-academic contacts at the University of Southampton. Both GPs and LTC specialists will be contacted by email or letter in the first instance to provide information about the study. We will aim to recruit LTC specialist healthcare staff who provide support for one or more of the conditions shown above. A further email may be used to follow up with potential participants if no reply has been received after 10 days. We will undertake a further follow-up telephone call (if appropriate) or email 10 days later.

We will purposively sample both GPs and LTC specialists who indicate an interest in taking part to ensure a mix of gender, age, location and LTC management experience within the sample. This approach is based on a similar approach used in recent interview studies with GPs, conducted in the south of England, and which demonstrated to be an effective strategy (Geraghty et al 2019, McKelvie et al 2019). It is anticipated that it will be necessary to approach approximately 20 GPs and LTC specialists to achieve the necessary recruitment numbers based on existing qualitative studies with these professional groups in a UK setting (McKelvie et al 2019, Miller and Holman 2014).

All potential participants will be provided with an information sheet (Appendix B) and given sufficient time to consider their involvement and ask questions about the study. Each participant will be asked to sign a consent form (Appendix C) before taking part. If the interview is to be conducted in-person, the consent form will be provided by a researcher before the interview takes place. If the interview is to be undertaken virtually (using Microsoft Teams), the consent form will be sent to the participant via the SafeSend encrypted service (SafeSend.soton.ac.uk). We will ask the participant to sign (or digitally print) and return the form using the SafeSend service. Each participant will be provided with a signed copy of the consent form.

Data collection

Interviews will be conducted at a date and time that is suitable for participants. Each interview will be conducted either virtually or in-person on NHS premises or at the university. Participants will be asked whether they require any support to attend the interview and if so, we will ensure that these needs are met. Interviews will last no longer than one hour, take place in a private room and will be digitally recorded. Participants will be asked to record on a demographics sheet (if the interview is conducted in-person) or share verbally (if virtual) their gender, age, location of practice/commissioning area. This information will allow us to determine the personal and geographical spread of our recruited group.

An indicative topic guide based on the constructs of the CFIR (Damschroder et al 2009) will be made available to participants before the interview takes place (Appendix D). This topic guide has been developed using the guidance from McCracken (1988) and Prescott (2011). This has included review of the literature related to CFIR, self-reflection, discussion and feedback from our research team who are from different professional backgrounds, to develop the indicative topic guide. We will continue testing of this topic guide with GP and LTC specialist colleagues at the university of Southampton to ensure content and face validity.

Each interview will be downloaded onto the University of Southampton server after the interview has taken place, with access restricted to the researchers working on the project and a nominated transcriber that has a confidentiality agreement with the University of Southampton. Once the digital recording has been downloaded onto the server, the device used for recording will be erased.

Data analysis

After transcription, a similar content analysis approach (as outlined above in the policy review data analysis section) will be used to analyse themes and related subthemes related to stakeholder perceptions of the barriers and facilitators to implementation of digital health interventions. These data, alongside the findings of the policy review, will be analysed using the five domains of the CFIR (see below).

Data synthesis using the CFIR

We will explore the synergies and differences between policy, commissioning and practice in relation to the implementation and adoption of digital health interventions to support the self-management of LTC. To do so we will use the CFIR (Damschroder et al 2009) constructs to synthesise the results of the policy review and qualitative interviews. The CFIR is made up of five interrelated domains (Damschroder et al 2009):

1. Intervention characteristics
2. Outer setting
3. Inner setting
4. Characteristics of individuals
5. Process of implementation

The “intervention characteristics” domain will focus on the factors related to components of the digital health intervention, their acceptability and the strength of evidence for such interventions. The outer setting domain will reflect the barriers and facilitators to implementation of digital health interventions in relation to the “economic, political and social context” (Damschroder et al 2009, p5). The inner setting domain will reflect the organisational context in relation to the “structural, political and cultural context” of implementing a digital resource (Damschroder et al 2009, p5). The “Characteristics of individuals” domain will mainly describe the findings from GPs and LTC specialists in relation to their needs and preferences associated with using and/or recommending a digital health intervention to support self-management and maintenance of physical activity in people with LTCs, and how these factors shape implementation. Domain five will be used to describe the factors that facilitate or hinder implementation in relation to the “process of implementation”. This domain relates to the active processes that may be necessary to facilitate implementation, such as the need for facilitators to manage change in the organisation or the need to consider multi-level sub-processes (Damschroder et al 2009, Pettigrew et al 2001).

Damschroder et al (2009) provides a more detailed description of each domain, which will be used as a taxonomy to support our analysis.

Expected outcome and impact of the research

This project is part of a larger programme of research entitled Maintenance Of physical acTivity beHaviour (MOTH), which aims to develop, test and implement a new digital intervention to support the maintenance of physical activity for people with LTCs. Consequently, this project will be integral to identifying important contextual factors for implementing such an intervention. In doing so, these factors can be applied to our future intervention to ensure that it can be effectively embedded within current healthcare practice.

Dissemination strategy

We will aim to publish the findings from this project with linked anonymity through the use of codes linked to participants quotes, to support the wider implementation of digital health interventions into practice. Future planned stakeholder events will also provide an opportunity to share the findings from this work with commissioning and clinical partners in Wessex. In doing so, the results may support more effective and efficient implementation of digital interventions locally.

Ethical considerations

All potential participants will be provided with a participant information sheet (Appendix B), which will provide information on the aim and nature of the research, the data being collected and stored. All data collected and analysed will be anonymised with a participant ID number and linked only to the role of the participant e.g. commissioner, LTC specialist, GP. All electronic data will be stored in a secure location on the University of Southampton server, whilst any printed materials, including written consent forms which will be stored in a locked cabinet in the School of Health Sciences at the university.

Audio files from the interviews will be made available to a professional transcriber, who has a service agreement with the University of Southampton, using a secure transfer site (safesend.soton.ac.uk). The transcripts will also be transferred back to the research team using this secure method and imported into the NVivo software for analysis. The professional transcriber will delete the data file once the transcription has been received back by the research team. The NVivo file will be stored securely on the University of Southampton server. Data will be stored for ten years in accordance with the University of Southampton Research Guidelines.

Ethical approval will be sought from the School of Health Sciences Ethics Committee through ERGO for the stakeholder interviews in this project. We will also seek approval from the Health Research Authority through the Integrated Research Application System before data collection.

Timescale (provisional)

Sept 2020 – Completion and agreement of protocol, ethics application submitted to ERGO and approved / IRAS application / Policy review searches, policy selection and verification

Sept 2020 – Oct 2020 – IRAS application to HRA for approval / Policy review data extraction / Policy review content analysis

Nov 2020 – Jan 2021 – Recruitment of interview participants / Conduct interviews / Policy review content analysis

Jan 2021 – July 2021 – Conduct interviews / Transcription / Content analysis of interview data / Synthesis using CFIR

July 2021 + - Draft publication

Appendix A: Search terms

Appendix B: Participant Information Sheet

Appendix C: Consent form

Appendix D: Indicative topic guide

Appendix A: Search Strategy

Digital terms (from scoping review – Clarkson et al 2020) (OR)

1. (wireless OR wearable* OR wristband* OR "wrist band*" OR wristworn OR "wrist worn" OR watch* OR smartwatch* OR "smart watch*")
2. ("text messag*" OR sms OR "short message service*" OR email* OR “electronic mail*" OR mms OR "multimedia messag* service")
3. ("Digital health" OR "digital health intervention" OR (e W/1 health) OR (m-health) OR (n-screen) OR (n-device*)) OR (digital W/1 therap*))
4. (Intranet OR internet OR "internet delivered" OR website* OR "computer based" OR software OR online OR "on-line" OR net OR web)
5. (“e media" OR emedia OR etrain* OR "e train") OR (“e media" OR emedia OR etrain* OR "e train")
6. (Telehealth OR telerehabilitation OR "pervasive technolog*" OR “pervasive comput*" OR "ubiquitous technolog*" OR "ubiquitous comput*")
7. (mobile* OR smart* OR phone OR smartphone OR "cell phone" OR cellphone OR tablet) W/1 (app*)
8. (fitness OR activity OR movement) W/1 (track OR monitor OR sensor OR "just-in-time adaptive-intervention*" OR lifelog* OR "life log*" OR "quantified self" OR "self-monitoring device*" OR accelero* OR pedometer OR automated OR activit*)
9. (Actigraph*)
10. (“Wireless technology")
11. (Gamification)
12. (Exergaming OR "exer-gaming" OR virtual OR gamercis* OR "active video game*")
13. (Non-face-to-face)
14. (Video*)
15. (Software)
16. ("User computer interface")
17. ("Health technolog*")
18. 1-17 with OR

Implementation terms (from Ross et al 2016) (OR)

19. Adopt*
20. Implement*
21. Facilitate*
22. Normali?
23. Routin*
24. Fulfil*
25. “Carry out”
26. Use
27. Appl*
28. “Take up”
29. 19 – 28 with OR

Self-management terms (based on Morton et al 2017) (OR)

30. Self-manage*
31. Self-monit$r
32. Self-care
33. Self-help
34. “Chronic disease management”
35. 30 – 34 with OR
36. 18 AND 29 AND 35
37. Limit to years 2015 – 2020

Appendix B: Participant Information Sheet

Participant Information Sheet (v1.1, 14/09/20)

Study Title: Exploring the factors that facilitate and hinder the implementation of digital tools for self-management of long-term conditions within existing healthcare structures and pathways

Researcher: Dr Paul Clarkson, Dr Aoife Stephenson*, Prof Maria Stokes, Prof Suzanne McDonough*, Dr Euan Sadler

*Royal College of Surgeons in Ireland

ERGO number:

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others, but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

Digital technologies are considered to offer much potential in healthcare, to assist with diagnostics, improve efficiencies in practice and support self-management efforts (WHO 2020). For people with a long-term condition (LTC), such tools have been found to be effective at promoting physical activity (Berry et al 2018, Connelly et al 2013), a key recommendation for maintaining and improving health and wellbeing (Public Health England 2016). However, the implementation and adoption of digital tools into practice is complex, requiring consideration of macro, micro and meso level factors, and particularly how such factors interact with each other. Existing research suggests that digital tools to support self-management must be established within existing healthcare structures to be fully adopted (Clarkson et al 2020). It is, therefore, important to understand the different contextual factors associated with implementation of digital tools. This research project is part of a larger programme of work within the NIHR Applied Research Collaboration (ARC) Wessex, which ultimately aims to develop a digital tool to support people with a LTC to maintain physical activity in the long term. In this project, we aim to undertake interviews with NHS service commissioners, General Practitioners (GP) and LTC specialists to explore the facilitators and barriers to implementation of such a digital tool within current NHS pathways. We will also undertake a review of policy recommendations in this area and identify areas of agreement and conflict with the interview findings. This research project is sponsored by the University of Southampton.

Why have I been asked to participate?

We are approaching you to take part in this research as you are either an NHS commissioner, GP or a healthcare professional working alongside people with a LTC. We are interested in finding out your unique perspective on the challenges and potential facilitators for implementing digital tools within the NHS and the factors associated with adoption for people with a LTC.

What will happen to me if I take part?

If you decide to take part after reading this information sheet, please contact the researcher using the contact details below. Please be aware that as we are aiming to recruit a geographically diverse range of participants, you may not be selected to take part if there is increased interest from one area. If you are selected to take part, we will ask you to sign a consent form. This will be sent to you via an encrypted digital service called SafeSend (SafeSend.soton.ac.uk). We will ask you to complete this form and return it via the SafeSend service. A researcher will then sign the form and return you a copy. We will arrange a convenient time with you to undertake the interview, either virtually (using Microsoft Teams) or in-person at your location or at the University of Southampton, if appropriate. If the interview is to be undertaken virtually, the researcher will send you a digital invite to take part. There will be no need to download any software as most internet browsers will support the use of Microsoft Teams online. It will be up to you to decide whether you turn on the camera function in Teams. The interview will take no longer than one hour and will be audio/video-recorded to ensure that we do not miss any content and for transcription purposes. The overall project is being undertaken throughout 2020 and we anticipate writing up the findings in early 2021.

Are there any benefits in my taking part?

There are no direct benefits to taking part in this research. However, your input is likely to improve the development of future digital support for people with LTCs and ensure relevance to current healthcare structures and pathways.

Are there any risks involved?

There are unlikely to be any risks associated with taking part in this research. We will ensure that the time burden of taking part is minimised as much as possible.

What data will be collected?

We will ask you to record or share verbally your gender, age, location of practice/commissioning area. This information will allow us to determine the personal and geographical spread of our recruited group. The interview will be audio/video-recorded digitally using Teams (if virtual) or up to two digital devices (if in-person). These data will be collected by one researcher on the project and will be stored in a digitally secure location on the University of Southampton server.

Will my participation be confidential?

Your participation and the information we collect about you during the course of the research will be kept strictly confidential. We will ensure that age and location information are reported in non-specific terms to maintain confidentiality. If the demographic information is initially collected on paper, the researcher will ensure that it is safely transferred to the university site where it will be transcribed and then stored in a password protected secure server location. Paper copies will be safely destroyed at this time.

Interview recordings will be safely stored in a secure server location. If interviews are conducted off-site, the researcher will ensure the safe transfer of these devices to the university. Once the audio-video recordings have been uploaded to the server and checked for quality, the versions on the digital devices will be permanently deleted. Signed consent forms will be kept in a separate physical location to the collected data. Audio/video files will be transferred securely using an encrypted service called SafeSend (Safesend.soton.ac.uk) to a transcriber who has a confidentiality agreement in place with the university. Once the transcript has been completed, it will be transferred back to the researcher using the same facility. The audio/video file will then be deleted by the transcriber. Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will be asked to sign a consent form to show you have agreed to take part. If you agree to take part, please contact the researcher directly using the details at the end of this document.

What happens if I change my mind?

You have the right to change your mind and withdraw without giving a reason and without your participant rights being affected. To withdraw, please contact the researcher using the details at the end of this document. If you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only.

What will happen to the results of the research?

The collected interviews will be analysed and written up for publication alongside the results of a policy review. Your personal details will remain strictly confidential. Research findings made available in any reports or publications will be pseudonymised through key-coding and will not include information that can directly identify you without your specific consent. Access to the codes will be restricted to the research team and password protected.

Where can I get more information?

Further information can be obtained from: Dr Paul Clarkson – P.D.Clarkson@soton.ac.uk

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

Thank you for taking the time to read this information sheet and considering taking part in the research.

Appendix C: Consent form (v1, 14/09/20)

UNIVERSITY OF Southampton

CONSENT FORM

Study title: Exploring the implementation of digital tools for self-management within existing healthcare structures and pathways

Researcher name: Dr Paul Clarkson, Dr Aoife Stephenson*, Prof Maria Stokes, Prof Suzanne McDonough*, Dr Euan Sadler

**Royal College of Surgeons in Ireland*

ERGO number:

Participant Identification Number (if applicable):

Please initial the box(es) if you agree with the statement(s):

I have read and understood the information sheet (14th September 2020/*version no.1.1 of participant information sheet*) and have had the opportunity to ask questions about the study.	
I agree to take part in this research project and agree for my data to be used for the purpose of this study.	
I understand my participation is voluntary and I may withdraw for any reason without my participation rights being affected.	
I understand that should I withdraw from the study then the information collected about me up to this point may still be used for the purposes of achieving the objectives of the study only.	
I understand that I may be quoted directly in reports of the research but that I will not be directly identified (e.g. that my name will not be used).	
I understand that special category information (gender) will be collected about me to achieve the objectives of the study	
I understand that taking part in the study involves audio/video recording which will be transcribed and then destroyed for the purposes set out in the participation information sheet.	
I understand that my personal information collected about me such as my name will not be shared beyond the study team.	

Name of participant (print name)..

Signature of participant..

Date..

Name of researcher (print name)..

Signature of researcher ....

Date..

[14th Sept 2020] [V1] [Ethics/IRAS reference (*if applicable*)]

Appendix D: Indicative Topic Guide for interviews with NHS Commissioners, GPs and LTC Specialists

Project title: Exploring the factors that facilitate and hinder the implementation of digital tools for self-management of long-term conditions within existing healthcare structures and pathways

Introductions

[Time duration of interview – Up to 1 hour]

Thank you for attending this interview.

This research is about exploring the factors that facilitate and hinder the implementation of digital interventions for self-management of long-term conditions into existing NHS structures and pathways. We know that many existing digital interventions are not well implemented in practice and that part of the reason for this is that they do not always take into account the complexities of existing practice.

We are conducting interviews to gain a better understanding of the needs and preferences of NHS commissioners, GPs and LTC specialists and to determine the factors that influence successful implementation at different levels of the healthcare system. We are also undertaking a review of policy and guidance in this area and will utilise all of these findings to provide recommendations for the implementation of digital health interventions.

We are interested to explore the specific barriers and facilitators in relation to the implementation of an app to support the activation and maintenance of physical activity for people with long-term conditions. We are particularly interested in cardiovascular disease, MI, stroke, COPD, depression and obesity.

This interview will be recorded to ensure that nothing is missed. Once complete, this recording will be transcribed.

Do you have any questions before we start?

Definitions:

When I refer to ‘digital health intervention’, I am referring broadly to a variety of technological interventions that may be used to support self-management of a LTC. These may include apps on a mobile device, smart systems, web-based interventions, gaming-based platforms, and more broadly telemedicine that provides feedback to the user.

Self-management – “the tasks that individuals must undertake to live with one or more chronic conditions”, which includes having the confidence to manage medical, role and emotional needs (US Institute of Medicine 2004)

1. Have you used or recommended a digital health intervention or supported the implementation of a digital intervention into practice?

Prompts:

- How did this work?
- Was the intervention considered acceptable by you and the person with a LTC?

- Was it adapted to your setting?
- Was the intervention considered feasible and sustainable?

2. In your view, what makes a successful digital health intervention to support self-management for people with a LTC (or specific, if interviewing LTC specialist in particular area)

Prompts:

- Core components of the intervention (intervention source = developed internally/externally), Quality of evidence, perceived advantage of using intervention, trialability, design quality, cost
- Adaptable periphery (adaptable elements, structures and systems related to the intervention and organisation), complexity, processes, adaptability to local context
- Consideration of patient needs

3. Thinking specifically about an app for supporting people with a LTC to initiate physical activity and then to maintain physical activity in the longer-term. What are the barriers to implementation in your setting? What would enable such an app to be used in your setting?

Prompts:

- Complexity (organisational/technological)
- Understanding context
- Mechanisms for introduction/referral to the app – involvement of healthcare professional / app store download
- Tailoring
- Digital literacy

4. What influence does policy or guidelines have on your use, recommendation or decision to implement a digital health intervention in your service/s?

Prompts:

- From government or professional body
- From CCG to primary/secondary care
- Social influence (GP practice network, Peer group, other CCGs)
- Outer setting ("economic, political and social context") interrelationship with inner setting ("structural characteristics, networks and communications, culture, climate, and readiness") (Damschroder et al 2009)
- Tariffs/Performance related funding

5. What is needed practically to implement a digital health intervention into practice and ensure that it is sustainable?

Prompts:

- Training and education
- Facilitation
- Incentivisation
- Monitoring

6. Other comments/thoughts?

Prompts:

- Other contextual factors that should be considered
- Processes of implementation

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