Exploring the factors for the implementation of digital health tools

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
23/03/2021		[X] Protocol		
Registration date 25/03/2021	Overall study status Completed	Statistical analysis plan		
		Results		
Last Edited 06/04/2021	Condition category Other	Individual participant data		
		Record updated in last year		

Plain English summary of protocol

Background and study aims

Digital tools, such as websites, mobile applications, and wearable devices, offer great potential to support people with long-term conditions to be physically active. The Covid-19 pandemic has also increased the awareness and use of these tools. Previous research has demonstrated that digital tools can be effective in supporting people to start being more active. There is also an increasing amount of research looking at the potential of these technologies to help people to stay active in the longer-term. However, the effectiveness and uptake of digital tools relies on more than the technology itself. It is important to consider the needs of those who will use it and understand how digital tools fit into existing healthcare structures and NHS pathways. This project is therefore aiming to understand the factors that influence the successful uptake of digital tools into healthcare practice, at a policy level, for service commissioners and for GPs and specialist clinicians.

The study aims to 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 long-term condition, within current UK NHS care pathways. Additionally, the study will identify how policy and standards for implementation of digital health interventions converge and/or diverge with commissioning and practice-level factors

Who can participate?

Commissioners, GPs, and long-term conditions specialist clinicians in Wessex

What does the study involve?

Each participant will take part one semi-structured interview. The study will also review existing policy documents so that comparisons can be made between different multi-level factors.

What are the possible benefits and risks of participating?

Although there are no specific benefits to taking part, the information captured through the interviews will ultimately help to support the future development of successful digital tools into practice. There are unlikely to be any risks associated with participating in this research.

Where is the study run from? University of Southampton (UK)

When is the study starting and how long do you expect it to run for? From September 2020 to July 2021

Who is funding the study? NIHR ARC Wessex (UK)

Who is the main contact?

Dr Paul Clarkson, P.D.Clarkson@soton.ac.uk

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

288651

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 48004, IRAS 288651

Study information

Scientific 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

Study objectives

- 1. To explore the needs and preferences of GPs, commissioners, and long-term conditions specialist clinicians 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 long-term conditions
- 2. To identify barriers, facilitators and needs of stakeholders to support the development, scaleup and implementation of a digital behaviour change intervention for maintaining physical activity

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 11/12/2020, the University of Southampton Ethics and Research Governance Online (Research Integrity and Governance Team, Building 37, University Road, Southampton, SO17 1BJ; no telephone contact provided; ERGOii@soton.ac.uk), ref: 60495.A1

Study design

Observational interview study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Internet/virtual

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

General practitioners, commissioners, and long-term conditions specialist clinicians

Interventions

The study will involve semi-structured interviews 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. Participants will be recruited via email invitation from the researcher (commissioners) and email invitation from the clinical research network. One interview will be conducted with each participant using video conferencing software or face-to-face interview, if appropriate.

Intervention Type

Other

Primary outcome measure

Needs and preferences of GPs, commissioners, and long-term conditions specialist clinicians 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 long-term condition measured using semi-structured interviews at a single time point

Secondary outcome measures

Barriers, facilitators and needs of stakeholders to support the development, scale-up and implementation of a digital behaviour change intervention for maintaining physical activity measured using semi-structured interviews at a single time point

Overall study start date

01/09/2020

Completion date

31/07/2021

Eligibility

Key inclusion criteria

- 1. General Practitioners, Service commissioners, Long-term condition specialist clinicians in Wessex
- 2. Specialist clinicians supporting people with one or more of the following conditions:
- 2.1. Cardiovascular disease, including Atrial Fibrillation, Hypertension, Heart failure, Peripheral arterial disease, secondary prevention of coronary heart disease
- 2.2. Myocardial infarction: secondary prevention
- 2.3. Stroke/TIA
- 2.4. Asthma
- 2.5. COPD
- 2.6. Chronic kidney disease
- 2.7. Diabetes mellitus
- 2.8. Dementia
- 2.9. Epilepsy
- 2.10. Mental Health
- 2.11. Depression
- 2.12. Osteoporosis
- 2.13. Rheumatoid arthritis
- 2.14. Osteoarthritis
- 2.15. Obesity

Participant type(s)

Health professional

Age group

Adult

Sex

Both

Target number of participants

10

Key exclusion criteria

- 1. Specialist clinicians for conditions other than those listed above
- 2. GPs, Commissioners, Clinicians outside of the Wessex region

Date of first enrolment

12/04/2021

Date of final enrolment

30/06/2021

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Clinical Research Network Wessex

7 Berrywood Business Village Tollbar Way Hedge End Southampton United Kingdom SO30 2UN

Sponsor information

Organisation

University of Southampton

Sponsor details

University Road Southampton England United Kingdom SO17 1BJ +44 (0)23 8059 5058 RGOInfo@soton.ac.uk

Sponsor type

University/education

Website

http://www.southampton.ac.uk/

ROR

https://ror.org/01ryk1543

Funder(s)

Funder type

Research organisation

Funder Name

NIHR ARC Wessex

Results and Publications

Publication and dissemination plan

This study is planned to be published in a high impact journal, such as Implementation Science, BMJ Open, or BMC Health Services Research. The study findings will also support future work on the development and implementation of a digital intervention.

Intention to publish date

30/09/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository (University of Southampton Institutional Research Repository (https://eprints.soton.ac.uk). Consent will be obtained from participants and the data will be available to the research team for analysis using content analysis and synthesis using the Consolidated Framework for Implementation Research, and pseudonymised for publication.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v2.1	14/09/2020	06/04/2021	No	No