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Feasibility of a smartphone app for increasing medication adherence

Submission date
23/04/2018

Recruitment status
No longer recruiting

Registration date
15/03/2019

Overall study status
Completed

Last Edited
03/01/2024

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
About eight million people in England receive treatment for high blood pressure. Treatment for high blood pressure usually consists of one or more blood pressure lowering medicines. Taking medication as prescribed can significantly reduce risks, complications and early deaths associated with these conditions. However, many people with these conditions do not take their medication as prescribed. Community pharmacists can support patients in taking their medication, but they have limited time. A promising approach to help patients take their medication is to use low-cost digital solutions such as smartphone apps. This study is designed to test a new smartphone app (Healthera) that has been developed to help patients to take their medication, to find out whether the app might work to help patients take their medication as prescribed and whether patients like using it.

Who can participate?
Patients aged 18 and over who have been prescribed any type of blood pressure lowering medication and attend a participating community pharmacy in the East of England or London during the recruitment period

What does the study involve?
The pharmacist (or another member of the pharmacy team) tells the patient about the app when the patient collects their blood pressure medication at the pharmacy counter. The pharmacist then prints a label containing a QR code and attaches it to the box of medication. The patient downloads the app to their smartphone and scans the label containing the QR code. This automatically sends information about the medication to the patient's phone and sets up a schedule of reminders. The patient can also use the app to send messages to the pharmacist and to receive replies from the pharmacist. Patients are randomly allocated to use one of two versions of the app (a basic version without two-way communication and a standard version permitting two-way communication with the pharmacist) or a control app (Medisafe). Interviews are also conducted with patients as well as pharmacy staff to try to understand their experiences around using the app and of participating in the study.

What are the possible benefits and risks of participating?
If the results of this study are encouraging, the effectiveness of the app will be tested in a larger

trial. Participants may find using the app and receiving reminders to take their medication helpful. Participants will contributing to the development and evaluation of an intervention that has the potential to reach a large number of people and provide them with tailored, low-cost support to take their medication. Interviewed participants will have the opportunity to talk openly about their experiences of using the app, how it assists with medication taking and of participating in the study. Participants may benefit from knowing that data from this study could inform future research on improving adherence to blood pressure lowering medication. Risks are minimal although there is the possibility of inconvenience, discomfort or intrusion. The researchers have tried to minimise the time involved, while still allowing sufficient time for the procedures to be completed. Participants may find that the app irritating. However, the researchers need to assess the acceptability of the app and the extent to which users engage with it and find it helpful. Participants may withdraw from the study at any time. Some participants may experience discomfort with the blood pressure measurement, and others may prefer not to have their blood pressure measured. Again, this is a feasibility study, and the researchers need to assess the feasibility of the measurement procedures. The main burden with the interviews will be the time spent by participants but it will be made clear how long the interview with the patient and with the pharmacist will last. Interviewees will not be asked questions of a personal or sensitive nature. Participants will be able to stop the interview at any time if they wish.

Where is the study run from?
Community Pharmacies in East of England and London (not yet identified) (UK)

When is the study starting and how long is it expected to run for?
October 2017 to August 2021 (updated 08/06/2021, previously: July 2021 (updated 09/03/2021, previously: June 2021 (updated 04/09/2020, previously: December 2020)))

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Stephen Sutton

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2.0; 41380

Study information

Scientific Title
A novel smartphone app for increasing medication adherence in patient's prescribed anti-hypertensive medication in a community pharmacy setting: a randomised feasibility trial

Study objectives
To test the feasibility and acceptability of a smartphone app to improve medication-taking behaviour in patients prescribed anti-hypertensive medications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/04/2019, North West – Liverpool East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull St., Manchester, M1 3DZ, +44 (0)207 104 8235, nrescommittee.northwest-liverpooleast@nhs.net), ref: 19/NW/0120

Study design
Parallel-group randomized feasibility trial with individual allocation to three arms

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Adherence to anti-hypertensive medication

Interventions
Randomisation will be stratified by pharmacy using the method of random permuted blocks:

Control arm: Medisafe app
Intervention arm 1: Healthera medication reminder app with pharmacist communication function
Intervention arm 2: Healthera basic medication reminder app without pharmacist communication function

Duration of interventions will be 3 months. Follow-up will be at the end of the 3-month testing period and will consist of a 45-minute pharmacy visit.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Medisafe app

Primary outcome measure
Measured at baseline and follow-up meeting (3 months):
1. The proportion of potential participants who cannot participate because of technology issues but who are otherwise eligible
2. Participation rate (the proportion of eligible patients who agree to take part)
3. The number of participants randomised (in total; per pharmacy; and per month)
4. The proportion of participants in each trial arm who download and install the App (uptake rate)
5. The proportion of participants in each trial arm who use the App for 1 week, 1 month and 3 months
6. The proportion of participants who attend the pharmacy for follow-up and provide complete

outcome measures
7. The proportion who drop out, reasons for loss to follow-up

Secondary outcome measures
Measured at baseline and follow-up meeting (3 months):
1. Medication adherence measured using Medication Adherence Report Scale (MARS)
2. Systolic blood pressure
3. Health status measured using the EQ5D-5L
4. Resource use (additional visits to the pharmacist as a result of using the App) and health service costs (time taken by pharmacist to explain intervention) measured to inform the economic evaluation in the main trial
5. Use of the study interventions and potential mediators of their effects on medication adherence and systolic blood pressure
6. Feasibility/acceptability of the interventions and of conducting a cost-effectiveness trial using qualitative interviews post-trial

Overall study start date
01/10/2017

Completion date
14/08/2021

Eligibility

Key inclusion criteria
1. Aged 18 years of age and over
2. Prescribed any type of blood pressure lowering medication and attending a participating community pharmacy in the East of England or London during the recruitment period
3. Owns a smartphone (Android or iPhone)
4. Has a valid email address
5. Has an adequate understanding of verbal and written English
6. Is able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 102; UK Sample Size: 102

Total final enrolment
106

Key exclusion criteria
1. Is using a pill organiser or similar medication reminder system
2. Is taking part in another research project on medication adherence

Date of first enrolment
01/07/2019

Date of final enrolment
14/05/2021

Locations

Countries of recruitment
United Kingdom

Study participating centre
Community Pharmacies in East of England and London (not yet identified)
United Kingdom
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Sponsor information

Organisation
University of Cambridge

Sponsor details
School of Clinical Medicine
Cambridge
England
United Kingdom
CB2 0SZ

Sponsor type
University/education

Website
http://www.cam.ac.uk/

ROR
https://ror.org/013meh722

Organisation
Cambridgeshire and Peterborough CCG

Sponsor details
Lockton House, Clarendon Road
Cambridge
England
United Kingdom
CB2 8FH

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Two papers from this investigation will be prepared for publication in peer-reviewed journals, reporting findings from the feasibility trial and interviews with trial participants and pharmacists. Findings will also be disseminated through national and international conference presentations and other scientific meetings.

Intention to publish date
30/06/2023

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		03/01/2024	03/01/2024	No	No