Feasibility of a smartphone app for increasing medication adherence

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
23/04/2018		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
15/03/2019	Completed	[X] Results		
Last Edited 03/01/2024	Condition category Circulatory System	[] 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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

2.0; 41380

Study information

Scientific Title

A novel smartphone app for increasing medication adherence in patient's prescribed antihypertensive 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

ΔII

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

ROR

https://ror.org/013meh722

Organisation

Cambridgeshire and Peterborough CCG

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

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