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A very brief face to face intervention, followed by a text message and/or app intervention to support medication adherence in people prescribed treatment for hypertension in primary care

Submission date
28/01/2019

Recruitment status
No longer recruiting

Registration date
25/02/2019

Overall study status
Completed

Last Edited
07/06/2023

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
This study aims to assess the feasibility of a very brief face to face consultation (VBI) followed by a text message or app intervention aiming to support adherence in patients prescribed antihypertensive medications in primary care. The study aims to generate evidence to decide whether and how to proceed with a full-scale effectiveness and cost effectiveness trial. Thus, the focus of this study is on assessing implementation procedures, including fidelity, and practicalities to deliver the intervention in primary care. This means that the study will estimate recruitment, uptake and retention/attrition rates, as well as different ways to measure medication adherence outcome (self-reported, refill medication, urinalysis for drug concentration, blood pressure) and the cost of a full powered trial. The intervention is based on theory and evidence, including results from a randomised controlled trial (MAPS intervention). The researchers aim to refine parameters of the MAPS intervention and adapt intervention content to a new delivery mode (i.e. app).

Who can participate?
Patients with high blood pressure

What does the study involve?
Participants are randomly allocated to the control or intervention group. The control group receives usual care - the practitioner briefly reviews the patient's medication-taking and blood pressure (and adjusts medication, if necessary). The patient's basic demographics, mobile phone number, self-reported adherence to prescribed medication and recent adherence to antihypertensive medication are all recorded. Blood pressure is recorded, a blood sample is taken and information is provided about urine collection and postage to a central laboratory. In addition to usual care, the intervention group receive a very brief intervention (<5 min) including information about how to register and use the digital intervention (i.e. 3 months text message

and/or app intervention). The intervention includes messages to provide advice and support on a medication taking behaviour. The duration of follow up is about 3 months after the first consultation.

What are the possible benefits and risks of participating?
If successful, this intervention will provide highly tailored support to large numbers of patients who could experience short- and long-term health benefits by taking their medications as prescribed. Given its large reach, the proposed intervention could have a substantial public health impact. The NHS would also benefit from the low cost of implementing the intervention and patients' satisfaction with the health care provided. This study does not involve the test of any medical device/equipment or drugs, so is a low risk study. The main ethical issues concern the process of recruitment, gaining informed consent from participants, the confidentiality of the data provided, the anonymity of the research and the dissemination of the findings. All participants will be informed about the data collected during the course of this study and the confidentiality of data collection process in accordance with the Data Protection Act 2018 and General Data Protection Regulation 2018.

Where is the study run from?
Cambridge University (UK)

When is the study starting and how long is it expected to run for?
September 2018 to May 2020

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

Who is the main contact?
Dr Katerina Kassavou

Contact information

Type(s)
Public

Contact name
Dr Katerina Kassavou

Contact details
Cambridge University
Department of Public Health and Primary Care
Primary Care Unit
Cambridge
United Kingdom
CB2 0SR

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v.03 19/10/18

Study information

Scientific Title
A very brief face to face intervention, followed by a text message and/or app intervention to support medication adherence in people prescribed treatment for hypertension in primary care

Acronym
I Adhere to Medication (iAM)

Study objectives
This study will build upon the positive findings of the literature and the MAPS intervention and assess the feasibility of a VBI followed by text messaging or an app intervention to support adherence to anti-hypertensive medications and improve blood pressure in primary care. The study aims to generate evidence to decide whether and how to proceed with a full-scale effectiveness and cost effectiveness trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East – Tyne & Wear South Research Ethics Committee, NHSBT Newcastle Blood & Transplant Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, Tel: +44 (0)2071048084, Email: nrescommittee.northeast-tyneandwearsouth@nhs.net, 04/01/2019

Study design
interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
High blood pressure

Interventions

Method of randomisation
Randomisation will be stratified by the practitioner conducting the baseline consultation, using the method of random permuted blocks. Patient allocation ratio will be 2:3 (n = 40 usual care : n = 60 intervention). Unequal group sizes has been selected to increase the information obtained about patient's use and evaluation of the intervention. An online randomization tool (www.sealedenvelope.com) will facilitate randomization during baseline consultations. Although the allocation sequence will be concealed, once a participant is allocated, neither the practitioner nor the patient will be blind to allocation.

Control group
The practitioner will briefly review the patient's medication-taking and blood pressure, as per usual care (e.g. and adjust medication, if necessary). If patient's most recent blood pressure exceeds 140/90 mmHg, the practitioner will introduce the study, check eligibility criteria and obtain informed consent. The practitioner will then record to an online CRF patient's basic demographics, mobile phone number, self-reported adherence to prescribed medication and recent adherence to antihypertensive medication. They will then record the BP values, take a blood sample for full lipid profile and glycated haemoglobin (HbA1c) measurement (if patient has comorbidities of type 2 diabetes, cholesterol) and provided information about urine collection and postage to a central laboratory.

Intervention group
In addition to the control group, the intervention group will receive a very brief intervention (<5 min) including information about how to register and use the digital intervention (i.e. 3 months text message and/or app intervention).

The duration of treatment will be 3 months. The duration of follow up will be approximately 3 months after the baseline consultation.

Intervention Type

Behavioural

Primary outcome measure

1. Recruitment rate recorded as the number of eligible participants who consent to participate in the study for 3 months.
2. Attrition rate recorded as the number of participants who consent to participate that remain in the study and complete the follow up measurements at 3 months

Secondary outcome measures

1. Fidelity and engagement with the online CRF measured as the duration and number of activities completed during the baseline consultation
2. Fidelity and engagement with the text message or app measured as the number and consent of text message and app notifications received, interactions, and interaction time intervals during the 3 months intervention
3. Medication adherence measured using the 5-item Medication Adherence Report Scale, two single items, the 8-item Morisky questionnaire, Cumulative Medication Gap and urine analysis at baseline and follow up
4. Systolic blood pressure measured using blood pressure monitors at baseline and follow up
5. Lipoprotein and glycaemic control measured using blood samples at baseline and follow up

Overall study start date

11/09/2018

Completion date
31/05/2020

Eligibility

Key inclusion criteria
Practitioners (practice nurses, health care assistants):
Practitioners will be included if they advise patients with hypertension during annual reviews, medication reviews, blood pressure checks or similar consultations; at least one practitioner will be recruited per practice

Patients (patients with high blood pressure):
Patients will be included if they:
1. Have a diagnosis of HBP, or comorbidities of HBP type 2 diabetes cholesterol
2. Are prescribed at least one antihypertensive medication for at least six months before study recruitment, as confirmed by practice records
3. Have poorly controlled HBP, as indicated by clinical measures
4. Have a good understanding of English
5. Are able to use mobile phones
6. Have the capacity to provide informed consent

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
106 (100 patients and 6 practitioners)

Total final enrolment
101

Key exclusion criteria
Patients will be excluded if they:
1. Have blood pressure > 200/100mm Hg, postural HBP (>20 mmHg systolic drop)
2. Have a diagnosis of dementia, aphasia or other cognitive difficulties that could affect study participation
3. Have had a recent severe life-threatening event or are under treatment for another long-term health condition (e.g. cancer)
4. Receive kidney dialysis
5. Take part in another study
6. Plan to move from the area in the next 6 months
7. BP not managed by their GP practice

Date of first enrolment
01/03/2019

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
United Kingdom

Study participating centre
Not available at time of registration
United Kingdom
-

Sponsor information

Organisation
University of Cambridge

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

Sponsor type
University/education

Website
https://www.research-operations.admin.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

Website
https://www.cambridgeshireandpeterboroughccg.nhs.uk

Funder(s)

Funder type
Government

Funder Name
Programme Grants for Applied Research

Alternative Name(s)
NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Study protocol, statistical analysis plan and a description of the intervention will be available in August 2019, when a peer-revised paper will be submitted for publication.

The results of this research project will be written up for publication in peer-reviewed journals. Findings will also be disseminated through national and international conference presentations and other scientific meetings. If they request, patients will be sent a summary of the study findings. A report with results and recommendations will be sent to all practices taking part in the study. Sutton and Kassavou will lead on writing up for publication and dissemination.

Intention to publish date
28/02/2021

Individual participant data (IPD) sharing plan

The datasets analysed during the current study will be stored in the Cambridge University Repository https://www.repository.cam.ac.uk/. The datasets will include the raw data collected for the primary and secondary outcomes. These will be available after peer-reviewed publications and approval from the authors. The data will be shared for secondary analysis to inform meta-analysis or meta-synthesis of evidence. Participants have consented for their date to be accessed by authorised individuals from regulatory authorities.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/04/2021	28/04/2021	Yes	No