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Assessing acceptability of a brief face-to-face intervention, and app or text message prompts to take medication in people with high blood pressure

Submission date
20/11/2018

Recruitment status
No longer recruiting

Registration date
01/02/2019

Overall study status
Completed

Last Edited
28/09/2020

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Currently in England, 12 million people are diagnosed with high blood pressure (hypertension). Taking medication as prescribed can significantly reduce illness and early deaths associated with high blood pressure, however many people do not take their medication as prescribed. Not taking medication as prescribed (non-adherence) reduces the effectiveness of treatment, and means that medicines are wasted, costing the NHS several hundred million pounds a year. Nurses in primary care can support patients to take their medication as prescribed but have limited time. Low-cost interventions that advise and support patients to take their tablets as prescribed are needed. One promising approach is to use very brief advice, delivered by practitioners and digital interventions such as text messaging services or smartphone apps. Very brief advice could signpost patients to ongoing support provided by a digital intervention. Digital interventions could be used to support patients between their GP visits, and as reminders for patients to take their medication when prescribed.
This study will test whether people find a text messaging service and app which provides individualised support for medication adherence acceptable. The results will help to improve the reminders before further trials to assess their effect on adherence.

Who can participate?
Adults with high blood pressure and health care practitioners

What does the study involve?
All participants will receive the reminders for 30 days, and can choose whether they would like it to be delivered via text messages or app notifications while they continue to take their prescribed medication. The researchers will also interview patients about their experiences using the reminders. Additionally, the text messages or app will ask questions requiring participant answers. Healthcare practitioners' experiences of using a brief face-to-face intervention will also be explored during the 90-minute think-aloud interviews.

What are the possible benefits and risks of participating?
This is a behavioural intervention, which does not involve changing the care practitioners provide to patients or the care patients receive by their health care practitioners. Thus, we consider that this study is low-risk.
The VBI has been designed to facilitate patients' reasons of medication non-adherence and to enroll them into the text messaging or app intervention.
The results of this pre-testing study will form recommendations about how best to support people take their prescribed medications by delivering a very brief advice.
The text messaging service and app intervention has been designed to reflect research which suggest digital interventions may enhance medication adherence, by providing ongoing support following practitioners' consultations. It is anticipated that this element of the digital intervention will increase patients' feelings of satisfaction with the continuous care they receive from the practice. If feasible, this low-cost intervention could reach people even in the most deprived areas.
All participants in this study will contribute to the design of a low cost and scalable intervention. This might not directly benefit them, but if acceptable, this intervention will have the potential to reach large number of people and provide them with highly tailored support.

Where is the study run from?
Department of Public Health and Primary Care, University of Cambridge School of Clinical Medicine (UK)

When is the study starting and how long is it expected to run for?
November 2018 to April 2019

Who is funding the study?
NIHR (UK)

Who is the main contact?
Katerina Kassavou, kk532@medschl.cam.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
40382

Study information

Scientific Title
Economical Service for Medication Adherence (ESMA): Pre-testing a brief face-to-face intervention, followed by a text messaging service or smart phone app to support adherence to medications prescribed for high blood pressure

Acronym
ESMA

Study objectives
Currently in England, 12 million people are diagnosed with high blood pressure. Taking medication as prescribed can significantly reduce risks, complications and early deaths associated with these conditions, however many people do not take their medication as prescribed. Non-adherence to medication reduces the effectiveness of patient treatment, and means that a substantial amount of medicines are wasted, costing the NHS several hundred million pounds a year.

Nurses in primary care can support patients to take their medication as prescribed but have limited time. Therefore, low-cost interventions that advise and support patients to take their tablets as prescribed are needed. One promising approach is to use very brief interventions (VBI), delivered by health care providers, and digital interventions such as text messaging services or smartphone apps. Digital interventions could be used to support patients between their GP visits, and as reminders for patients to take their medication when prescribed.

Thus, this study will pre-test the acceptability of a VBI and a text messaging service and app which provides individualised support for medication adherence using patient participants aged 18 or above diagnosed with hypertension. All patients in this study will receive the intervention for 30 days, and are able to choose whether they would like it to be delivered via text messages or app notifications whilst continuing to take their prescribed medication. The researchers will also interview patients about their experiences using the intervention. Additionally, the intervention will ask questions requiring participant answers, which will be statistically analysed. All practitioners in this study (i.e. practice nurses) will pre-test the VBI using think-aloud protocols.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/11/2018, London - West London & GTAC Research Ethics Committee (+44 (0)207 104 8098, NRESCommittee.London-WestLondon@nhs.net), ref: 18/LO/1959

Study design
Non-randomised; Both; Design type: Process of Care, Psychological & Behavioural, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hypertension

Interventions
Practitioners will pre-test the brief face-to-face intervention. They will attend a 90 minute meeting with a member of the research team. At the beginning of this meeting, the researcher will explain the nature and aims of this pre-test study, detail the participant's right to withdraw at any time, and obtain informed consent from the practitioner to participate in the study, if appropriate. It will be explained that in the full study, practitioners will be responsible for recruiting and enrolling participants face-to-face. Therefore, in this pre-test trial, practitioners will be testing the brief face-to-face intervention, made up of a web-based recruitment system and brief face-to-face consultation script. The brief face-to-face consultation script will be used by practitioners to accurately explain the study to potential participants in the following feasibility trial. Practitioners will also practice using the web-based recruitment system will include inputting patient's personal information (e.g. name and contact details), their prescriptions, and tick boxes to ensure eligibility in accordance with the inclusion/exclusion criteria. Both these materials will be practiced with a dummy patient (the researcher) through the use of role play. After the role play, the researcher will ask the practitioner about their opinions on the training and their experiences when using the brief face-to-face consultation script and web recruitment system, as well as their opinions on the practicality/usefulness of the intervention in regards to medication adherence in real-world care. Recommendations for improvement will also be explored.

As a pre-test of the tailored text message and app intervention (digital intervention), participants will receive either text messages or app notifications for a period of 4-weeks (30 days). The researcher will ask each participant which delivery mode they would prefer and the participant will receive their preferred choice. Before receiving the intervention, the researcher will provide more information on how to receive the text messages or how to download the app. If a participant would prefer to use the app, they will need to have a smart phone. The intervention aims to advise and support participants to take their medications as prescribed through the use of personalised reminders. The intervention will also send occasional messages /notifications for participants to respond to.

After the end of the 30 days pre-testing the digital intervention, patient participants will be asked to engage in an interview. The research team will approach all participants to arrange the meeting, based on their time and location preferences. Participants will be also offered the option for the interview to be conducted using the telephone. During the follow up interview, a member of the research team will ask questions regarding whether the interventions aided the participants' medication adherence, their opinions on the content of the messages and notifications, how they found the structure of the app (was it easy to navigate?) and their recommendations for improvement of any part of the study.

The stakeholders' consultations will be conducted through the online questionnaire platform Qualtrics, and are expected to take up to one hour of the participant's time. Qualtrics will first present participants with a description of the proposed intervention, which will then be followed by a small number of open-ended questions for each participant to complete. Practitioners will be asked about their views on the intervention content and delivery mode and the proposed strategies to recruiting patients. Patients will be asked their views and recommendations about the intervention content and delivery mode. Commissioners will be asked about the intervention content and delivery mode and the evidence needed to inform a decision whether to commission the intervention. Academics will be consulted about the intervention content and the design of the trial.

Intervention Type
Other

Primary outcome(s)
1. Acceptability of the VBI delivered by practitioners assessed using think-aloud protocols during the 90-minute interview between practitioners and researchers
2. Acceptability of the text or app prompts assessed using a 60-minute interview of patient participants, arranged for after the 28-day intervention

Key secondary outcome(s))
1. Barriers to the VBI delivered by practitioners assessed using think-aloud protocols during the 90-minute interview between practitioners and researchers
2. Facilitators of the VBI delivered by practitioners assessed using think-aloud protocols during the 90-minute interview between practitioners and researchers
3. Barriers to the text or app prompts assessed using a 60-minute interview of patient participants, arranged for after the 28-day intervention
4. Facilitators of text or app prompts assessed using a 60-minute interview of patient participants, arranged for after the 28-day intervention

Completion date
30/04/2019

Eligibility

Key inclusion criteria
Practices:
1. At least 400 registered patients
2. At least two eligible practitioners (those who conduct medication adherence reviews, annual reviews or those collecting clinical outcomes by the targeted population as part of usual care)

Patients:
1. Aged 18 years or older
2. Diagnosis of high blood pressure
3. Prescribed at least one antihypertensive medication for at least 3 months (as confirmed by practice records)
4. Poorly controlled hypertension, as indicated by clinical measures (i.e. blood pressure >140/90 mmHg for a period of 3 months before recruitment)
5. Have a good understanding of English
6. Have and are able to use a mobile phase
7. Capacity to provide informed consent

Stakeholders:
1. For patient consultations, the same criteria as above are applied
2. For practitioner consultations, the same criteria as above are applied
3. Academics and healthcare commissioners are eligible if they have relevant experience and expertise (i.e. behaviour change interventions, commissioning of primary care services)

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
23

Key exclusion criteria
Patients:
1. Hearing impairment (hearing spectrum lower than 50Hz-20 kHz)
2. Speaking impairment
3. Diagnosis of dementia, aphasia or other cognitive difficulties which could affect study participation
4. Recent severe life-threatening event or are under treatment for another long-term condition (e.g. cancer)
5. In receipt of kidney dialysis
6. Participating in another study
7. Plan to move from the area during the next 4 months

Stakeholders:
1. Difficulty reading or understanding English
2. Unable to provide informed consent
3. For patient consultations, the same criteria as above will be applied

Date of first enrolment
09/01/2019

Date of final enrolment
31/03/2019

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Cambridge Institute of Public Health
Forvie Site
Cambridge Biomedical Campus
Robinson Way
Cambridge
United Kingdom
CB2 0SR

Sponsor information

Organisation
University of Cambridge

ROR
https://ror.org/013meh722

Organisation
Cambridgeshire and Peterborough CCG

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0615-20013

Results and Publications

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/. Participants have consents for their date to be accessed by authorised individuals from regulatory authorities. Raw data will become available

after peer-reviewed publication, and will be available upon request to Katerina Kassavou kk532@medschl.cam.ac.uk. Raw data refer to self-reported measures of adherence. Data will be available for meta-analysis studies, testing the mechanism by which interventions might bring about changes in medication adherence outcome.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/09/2020	28/09/2020	Yes	No
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes