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Medication adherence for patient support

Submission date	Recruitment status	[X] Prospectively registered
07/08/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/08/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2022	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
More than 11 million people in England have type 2 diabetes or hypertension (high blood pressure). Taking medication as prescribed can significantly reduce risks, complications and early deaths associated with these conditions, but many people with these conditions do not take their medication as prescribed. GPs and nurses can support patients in taking their medication but they have limited time. There is therefore a need for low-cost solutions for helping patients to take their medication as prescribed. A promising approach is to use automated telephone interventions. Text and voice messages sent to patients' mobile phones and landlines can deliver personalised and tailored support over a period of time. The aim of this study is to find out whether the use of text and voice messages is feasible and acceptable to patients and whether it helps patients take their medication as prescribed.

Who can participate?
Patients aged 18 or over with type 2 diabetes or high blood pressure from six general practices

What does the study involve?
Participants are randomly allocated to the intervention or control group. The intervention group receive usual care plus interactive text and voice messages to promote medication adherence. The comparator group receive usual care only. The study lasts for 3 months and both groups' medication adherence, blood pressure and blood sugar levels are measured at the end of the study.

What are the possible benefits and risks of participating?
If the results are encouraging, the text and voice messages will be tested in a large study. The study may benefit patients by supporting them to take their medications as prescribed and improving their health. This would also benefit the NHS by reducing hospital admissions, additional consultations, referrals and investigations, and medicine wastage. The risk of side effects is generally very low.

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

When is the study starting and how long is it expected to run for?
December 2014 to December 2018

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

Who is the main contact?
Dr Katerina Kassavou
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Study website
http://www.phpc.cam.ac.uk/pcu/research/research-projects-list/other-projects/maps/

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
34706

Study information

Scientific Title
Feasibility of MAPS (Medication Adherence for Patient Support): a highly tailored text and voice messaging intervention to support medication adherence among patients with type 2 diabetes and/or hypertension in primary care

Acronym
MAPS

Study objectives

This study aims to develop and assess the feasibility of MAPS: a highly tailored interactive text (SMS) and voice (IVR) intervention to promote medication adherence in patients with hypertension and/or type 2 diabetes, in primary care. The objectives are to develop the intervention, finalise the design of the study, and assess the feasibility, acceptability, cost and potential efficacy of the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England Essex Research Ethics Committee, 25/05/2017, ref: 17/EE/0203

Study design
Randomised; Both; Design type: Process of Care, Education or Self-Management, Psychological & Behavioural, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Diabetes; UKCRC code/ Disease: Cardiovascular/ Hypertensive diseases, Metabolic and Endocrine/ Diabetes mellitus

Interventions
Participants will be randomised to the intervention (N=60) or comparator (n=40) group stratified by age, gender, practice and disease condition using a secure, computer random number generator:
1. The intervention group will receive usual care plus interactive text (SMS) and voice (IVR) message intervention aiming to promote medication adherence
2. The comparator group will receive usual care only

Using unequal group sizes will increase the information obtained about participants' use of and response to the intervention. Randomisation will be conducted independently of the study co-ordination and intervention, with blinding of access to further participant information. If more than one member of the same household is included, they will be randomised to the same arm. Contamination between groups will be assessed by asking participants whether they know

anyone else who is participating and which group they are in. Treatment duration will be 3 months for both intervention and comparator group. Follow up data will be collected at the end of the intervention (i.e., 3 months).

Intervention Type
Other

Primary outcome measure
1. Medication adherence:
1.1. Self-reported medication adherence, measured using two items at baseline and 3 months
1.2. Objectively measured medication adherence, collected by electronic monitoring devices (MEMS container caps that record the date and time of each opening) at 3 months
1.3. Objectively measured refill medication data, collected using records from practice or pharmacy dispensary at baseline and 3 months
2. Blood pressure, collected using an electronic sphygmomanometer or other blood pressure monitor devices available in each practice at 3 months
3. Glucose levels (HbA1c), collected using venous blood samples by practice nurse at 3 months

Secondary outcome measures
Quality of life, measured using the self-reported EQ-5D-5L at baseline and 3 months

Overall study start date
31/12/2014

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Patients with primary diagnosis of T2DM and/or hypertension
2. Poorly controlled hypertension and/or T2DM, as indicated by clinical measures or gaps in ordering or filling repeat prescriptions
3. 18 years old and above

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 142; UK Sample Size: 142

Total final enrolment
135

Key exclusion criteria
Patients will be excluded if they:
1. Have a hearing impairment (hearing spectrum lower than 50Hz-20kHz) or a speaking impairment
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 condition (e.g. cancer)
4. Receive kidney dialysis
5. Are participating in another study
6. Plan to move from the area in the next 6 months

Date of first enrolment
01/11/2017

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cambridgeshire and Peterborough CCG
Cambridge
United Kingdom
CB2 8FH

Sponsor information

Organisation
University of Cambridge

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

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/013meh722

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Central Commissioning Facility (CCF); Grant Codes: PB-PG-0215-36032

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
The protocol has been submitted and reviewed by the ethics committee and is available on request to Dr Katerina Kassavou (kk532@medschl.cam.ac.uk). All additional documents (including study protocol, statistical analysis plan, other material) will be included in publications.

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. Participants will be sent a summary of the study findings. Information on the progress of the research and results of this research project will be available on the Behavioural Science Group webpage via the Primary Care Unit website at http://bit.ly /medicaladherence. Professor Stephen Sutton, Dr Katerina Kassavou and Professor Griffin will lead on writing up for publication and dissemination. Estimated date for publication of results is January 2019.

Intention to publish date

01/01/2019

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?
Results article	results	06/01/2019		Yes	No
Results article	results	19/05/2020	26/05/2020	Yes	No
Results article		20/12/2021	14/02/2022	Yes	No
HRA research summary			28/06/2023	No	No