UNIVERSITY OF CAMBRIDGE

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PARTICIPANT INFORMATION SHEET

Programme on **A**dherence to **M**edication (PAM): A very brief nurse-led intervention, followed by a text message or a smartphone app to support medication adherence in people prescribed treatment for hypertension in primary care. A randomised controlled trial.

We would like to invite you to take part in a trial to test a new service developed for people who receive treatment for hypertension (high blood pressure) in primary care.

Please take the time to carefully read this information sheet and discuss it with others if you wish. Before you decide whether or not to take part, it is important that you understand why this study is being conducted, what it will involve and how your information will be collected, used, and stored for the purposes of this trial.

You need to use any mobile phone OR an Android smartphone version 6, 7, 8, or 9 to take part in this trial.

What is the study about?

People with hypertension (high blood pressure) have been prescribed medication to help control their blood pressure. We are interested to find out how GP Surgeries could support people to take their prescribed medications in a way that improves their health.

We have developed a new General Practice service to support medication adherence; which we call Programme on Adherence to Medication (or PAM). PAM involves a very brief consultation with your practice nurse, followed by a text messaging programme or a smartphone app.

To develop this new service, we have talked to experts, patients with high blood pressure, the public, and health care providers in GP practices, and we have pre-tested it over a period of 3 months with more than 300 patients at 25 GP practices across the East of England and London. Based on feedback, we have optimised this service and we are now launching it at 50 GP practices across the East of England and London.

We would like you to take part in this trial and help us evaluate how well this service performs compared to the usual care, and whether it is a cost-effective solution for the NHS. The results of this trial will help us to develop new and widely available methods to support patients who receive treatment for hypertension in primary care.

Why have I been invited to participate?

You have been invited to take part because:

- Your GP surgery is taking part in this trial
- You are registered with the GP surgery
- Your records indicate that you are currently prescribed medications to manage hypertension; or hypertension and type 2 diabetes or high cholesterol
- Your participation will help us to evaluate and improve this new service

Do I have to take part?

It is entirely your decision whether or not to take part. If you decide to be involved, we will ask you to provide your consent, to say that you understand what the study involves and that you agree to take part.

If you take part in this trial, you will be free to withdraw at any time, but we will keep anonymised information about you that you have already provided. A member of the research team might contact you to ask the reason for your decision, if you are happy to report it, because this will help us evaluate the practicalities of conducting this research. If you wish to withdraw, this will not affect the care you receive from your GP practice.

What will happen if I decide to take part in this study?

If you decide to take part, you will be asked to complete the activities reported below.

1. Attend a remote consultation (using telephone or video) with your practice nurse or health care assistant

If you have decided to take part in this study, you will need to attend a consultation with your practice nurse.
It will last approximately 20-30 minutes, and it will involve the activities 2-4 described below.
The consultation will be conducted remotely i.e. by phone or video call with your practice nurse, as part of your usual health check. Your practice nurse will liaise with you to ask you whether you prefer a phone or video consultation.

2. Provide verbal informed consent

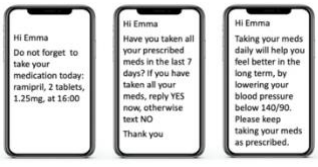
During the remote consultation, the practice nurse will provide you with a brief overview of the trial procedures and will double check your eligibility to participate in this trial. You can ask any questions you may have about your participation in this trial.
If you are happy with the responses given and you would like to proceed, your nurse will ask and confirm your verbal consent to participate (you can find a copy of your Consent Form enclosed at the end of this information sheet).
With your consent the researchers will access and collect information from your practice records. The collected information will be about the medications you've been prescribed for blood pressure and your blood pressure readings during the past year. If you have also been diagnosed with Type 2 Diabetes or High Cholesterol, the medications you've been prescribed for either or both of these health conditions, as well as your glucose or cholesterol tests results will be collected from your practice records.
For training and monitoring purposes, your practice nurse might ask your verbal consent to audio-record the consultation. Audio-recording your consultation is optional. However, we would like to encourage you to agree to audio-recording your consultation because this information will help us form recommendation about how to improve the consultations provided to patients. You can indicate during the consent process if you agree to it. You can take part in the study and not agree for your consultation being audio-recorded.

3. Review your prescribed medications

Your practice nurse will ask you about the medications you've been prescribed for high blood pressure and some questions to understand the way you've been taking your prescribed medications to treat hypertension.

4. Being randomly allocated to Group 1 or Group 2

You will then be randomly allocated to group 1 OR group 2 and your practice nurse will inform you about which group you have been allocated into during the consultation.
Why will you be allocated to group 1 OR group 2?
The best way to assess if this service is practical, and effective and if it improves the care patients receive, is through a Randomised Controlled Trial (RCT). RCT means that if you take part, you will have equal chance to receive either of the options provided: Group 1 (test this new PAM service) or Group 2 (continue with usual care).
The decision about which option you will receive is random (i.e. it is based on chance). Participants will be given a reference number. The reference number will be used to allocate participants randomly into Group 1 or Group 2. A computer system will be used for random allocation, which ensures that the groups of participants receiving the two options are similar. In this way, a fair comparison can be made between groups at the end of this trial. This process is called 'randomisation'. Your GP will not have access to this process.
Group 1, the PAM service. If you are in group 1, your practice nurse will ask you a few more questions and will provide you with the option to receive free advice and support using either the text messaging service or the smartphone app for the following 12 months. Your practice nurse will then provide you with more information about the PAM messages and how to use either or both these options; for example, if you select the text messaging, you will have the opportunity to switch to the smartphone app.



Example of PAM messages

The messages will aim to provide personalised advice for medication taking, following your practice consultation. During the 12 months, you will also have the option to change the duration, frequency, and times of the intervention messages, or stop receiving the messages at any time.
This mobile service is free. However, standard charges apply for responding to text messages. Mobile internet data will be used to install or update data from the app.
Group 2, usual care. If you are in group 2, you will be asked to continue receiving the usual care provided by your GP practice, with no access to the PAM service.

5. Monitor your health at home after your remote consultation

After your remote consultation, you will be asked to monitor your health at home and provide clinical outcomes, as per procedures 6-8 described below, as well as complete a questionnaire.
All participants, **both group 1 and group 2**, will be required to complete these procedures.

6. Measure and report your blood pressure

Your practice nurse will ask you to measure and record your blood pressure for two days, and to report the blood pressure readings to the PAM trial. You will be asked to report your blood pressure readings by post or at an online webpage.
A blood pressure monitor will be posted to you at home, with instructions on how to measure and report your blood pressure readings. The blood pressure monitors and all the material you will receive will be fully sanitised.
Monitoring and reporting your blood pressure is an essential requirement for your participation in this trial.

7. Provide a pee (urine) samples

Your practice nurse will ask you to provide a small urine sample (10mL) at a completely clean (sterile) container and post the sample to the laboratory for analysis.
You will be posted the urine sample container with instructions on how to collect and store the sample. This material will be fully disinfected. You will be asked to post the sample to the laboratory using a FREEPOST sealed plastic bag.
Providing a urine sample is an essential requirement for your participation in this trial.

8. Provide a finger prick blood sample (subsample of patients)

If you have been diagnosed with Type 2 Diabetes or High Cholesterol, in addition to high blood pressure, your practice nurse will ask you to provide a finger prick blood sample (i.e. few drops of blood) and post the sample to the laboratory for analysis. If you have Type 2 Diabetes you will be asked to provide few drops of blood for analysis of HbA1c; if you have High Cholesterol you will be asked to provide few more drops of blood for analysis of lipid profile.
The blood sample collection tube and all the material you need to collect the finger prick blood sample will be posted to you, and it will be fully disinfected. The blood sample collection material has been designed to be easy to use, and full instructions will be provided.
You will be asked to post the sample to the laboratory using a FREEPOST sealed plastic bag.

9. Complete Questionnaires

Your practice nurse will ask you to complete a pack of three questionnaires. The questionnaire will ask you to respond to questions about your health and wellbeing and your health-related behaviours. It also includes questions about the use of health care resources, for example the number of visits to your GP practice or to hospital, as well as some additional information to help us estimate the cost (for both patient and the NHS) to treat hypertension. You can complete a hard copy of the questionnaire and post it back to the research team using a FREEPOST envelope or you can provide your answers online at a webpage.
It may take 15-20 minutes to complete the three questionnaires.

At 6 months from baseline you will be asked to complete two of these questionnaires.

10. Monitor your health at home, at 12 months follow up
Twelve months after your remote consultation

Twelve months after the remote consultation with your practice nurse, the research team will contact you and ask you to complete your annual up health check. That is:

- Measure and report your blood pressure
- Provide a urine sample
- Provide a finger prick blood sample (if applicable)
- Complete questionnaires

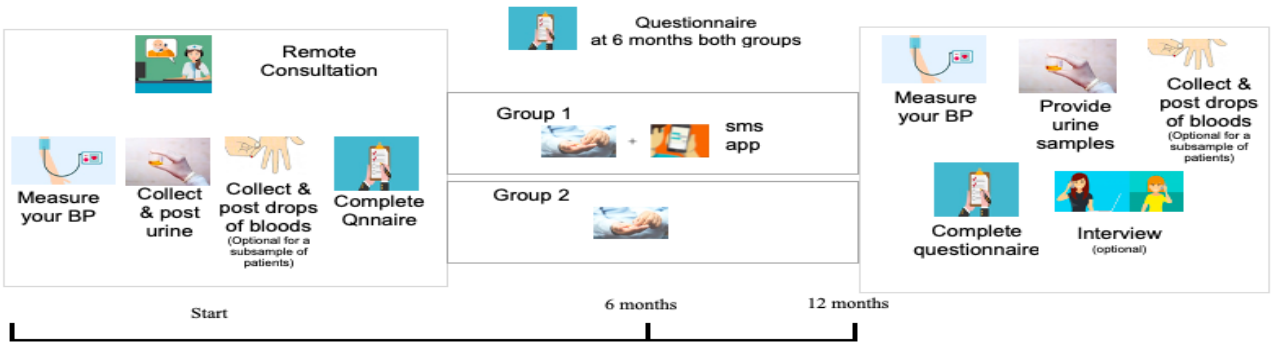
All participants; **both group 1 and group 2** will be asked to complete these procedures remotely 1 year after their baseline health check.

Completing your 1-year health check is an **essential requirement** for your participation in this trial.

11. Follow up interview at 12 months follow up (optional)

We will randomly select some participants from Group 1 and Group 2 and invite them to take part in a telephone interview. The interview will aim to obtain participants' views about taking part in this trial and it will last 45 minutes. Taking part in the interview is optional, and you can take part in this trial even if you do not agree to be contacted for an interview at 12 months. You can indicate during the consent process if you agree to it. You can take part in the study and not agree to participate at the interview.

PAM trial overview



What are the possible risks of taking part?

Taking part in the PAM trial involves little deviation from your usual care. Consultations and diagnostic/ clinical tests (i.e. blood pressure, blood samples, urine samples) in routine use within the NHS will be undertaken remotely and with the guidance of your practice nurse.

The blood pressure monitors are widely used and recommended by the British Heart Foundation and the British and Irish Hypertension Society. The urine sample collection tubes and the blood samples collection material are UKAS accredited material.

The instruction about how to complete the clinical tests remotely will be guided by your practice nurse and overseen by our clinical collaborators (Professor Jonathan Mant and Professor Simon Griffin at the University of Cambridge and Professor Richard McManus at Oxford University) who have expertise in developing and monitoring the procedures for remote clinical tests during research trials and in practice.

Analysis of the clinical outcomes will be performed by accredited laboratories (i.e. NHS Trust University Hospitals of Leicester and Doctors Laboratory). Although research risks are no greater than those involved in your usual care, and all procedures have been tested and approved by other patients and health care providers, it is possible that some participants may find these procedures distressing, in which case they will exempted from these tests. You are free to withdraw from this trial at any time.

If you are allocated to Group 1 (the PAM service), you will be provided with advice about your prescribed medications for 12 months. However, some people may not like being reminded about taking medications for a health condition, such as hypertension. The PAM service will provide you with options to reduce the frequency of the messages or stop receiving the messages at any time. Please contact the research team pam@medschl.cam.ac.uk if you have any concerns about your participation in this trial.

If you are selected and attend the follow up interview, 12 months after your consent to take part, we will ask your experiences with and recommendations about your taking part in this trial. We will not ask you sensitive or personal questions. Interviews will be audio-recorded. Audio-recordings will be transcribed by a third party, the direct quotes maybe published, but they will be **fully anonymised**. The procedure of data confidentiality will be followed for the audio-recordings of your remote consultation.

If during this trial, you became upset or report a potentially serious health concern or problem to the research team, we will ask you to contact your GP practice. Alternatively, with your permission, we will contact your GP on your behalf.

What are the possible benefits of taking part?

We will use the information you give us to assess whether the PAM service is a cost-effective solution to support the treatment of people with high blood pressure in comparison to the current usual care. Whichever group you are in, we will also use the information you provide to make recommendations to healthcare providers in general practices about how best to support patients to manage their high blood pressure during usual care consultations.

You may not benefit directly by taking part in this trial, but if successful, your participation will provide evidence to improve the advice and support we offer to people with long-term health conditions.

How will we use information about you?

We will need to use information provided by yourself and from your medical records to conduct this trial. This will include your name, contact details, your prescribed medications and information about your health (e.g. your blood pressure reading during the past year). People will use this information to do the research or to check your records to make sure that the research is being done properly. All the data you provide will be anonymised. Personal and identifiable **information will be kept strictly confidential**. The data collected during the research will be used only for the purpose of this trial. To help us with this, please make sure that your mobile phone is used by the owner only (i.e. yourself), and it is not shared with others. Lost or stolen mobile phones should be reported immediately to the study team so data can be deleted by the study team. To safeguard your rights, we will use the minimum personal identifiable information possible. You can find out more about how we use your information at this website https://www.information-compliance.admin.cam.ac.uk/data-protection/research-participant-data

How will we keep your information strictly confidential?

All information collected about you during the course of this trial will be kept in accordance with the Data Protection Act 2018 and General Data Protection Regulation (GDPR, 2018). The University of Cambridge is compliant with the information governance policy to store sensitive personal information (for more information about the confidentiality policy, please see https://www.medschl.cam.ac.uk/research/information-governance/sdhs-security-policy/)

The blood samples will be sent to the Doctors Laboratory in London. The urine samples will be sent to the laboratory at Leicester Hospital NHS Trust. The laboratory staff will assess urine sample for concentration of anti-hypertensive and the blood samples for HbA1c and/or lipid profile levels. Blood and urine samples will not be retained after analysis. Only members of the research team will have access to the analysed data. All procedures involved in the blood sample analysis will comply with the Human Tissue Act 2004.

The University of Cambridge and the NHS Cambridgeshire and Peterborough Clinical Commissioning Group (CCG) are the co-sponsors for this study based in the United Kingdom. The Cambridge University will keep your name, contact details and other information provided by you and your medical records (e.g. prescribed medications) in order to undertake this study and will act as the data controller for the trial. This means that we are responsible for looking after your information and using it properly. The research team at the University of Cambridge will use this information as needed, to contact you about this trial, and make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the study. Certain individuals from the co-sponsor and regulatory organisations may look at your medical and research records to check the accuracy of this research. Co-sponsors and regulatory organisations will receive reports

from this research without any identifying personal information. The University of Cambridge will keep identifiable information about you for 1 year after the trial has finished for the purposes of analysis and writing up the results of this study. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained.

If I am allocated to Group 1 and I select to use the app, what information will be collected and how this will be kept confidential?

The information you provide during the consultation (e.g. your prescribed medications) will be transferred from your GP practice to the PAM app using encrypted internet files. When you install the PAM app, this information will automatically inform the content of your personalised messages (i.e. app notifications).

When installing the app, you will be asked to confirm that you allow the app to access your device location and to access photos, media and files on your device. Do not be confused! The app will not have access to your photos, media or files stored in your mobile phone, but it will create and upload files using the specific permission.

The app will collect information about the Wi-Fi you are logging in, the GPS data of your phone, and the accelerometer information of your phone. This information will be collected to inform knowledge about how to tailor the delivery of the app notifications to each participant individual routines. For example, participants will not be sent notifications if the app detects, by the accelerometer of your smartphone, that you are exercising.

During the course of the trial, all information you provide will be stored in the app at your mobile device only. The app will not have functionalities that link your data to any other apps or other social media service (e.g. Facebook). The information collected by the app will be sent to the University of Cambridge using secure communication protocols once per day and it will be deleted from your device after that point.

Thus, you should not be concerned about the storage or the battery life of your device. The app is not power consuming and the data it stores is very little (e.g. size of a picture at your phone).

Who is organising and funding the research?

This research is organised and led by the Department of Public Health and Primary Care, The Primary Care Unit at the University of Cambridge. The trial is funded by the National Institute for Health Research and the Chief Investigator is Professor Stephen Sutton.

What will happen to the results of the study?

We expect that the results of this study will lead to the development of a new service to support people to take their prescribed medications in a way that improves their health. We will also use the data from this study to write publications in peer-reviewed academic journals and conduct presentations at conferences. If you wish, a summary of the results will be sent to you after the end of the study. Please contact the research team to arrange that for you.

What if something goes wrong?

Should you wish to make a complaint or raise a concern about this trial, you should **contact the research team in the first instance**. If your complaint relates to the NHS treatment and the care you receive from your practice, please contact the Patient Experience Team, NHS Cambridgeshire and Peterborough CCG via email capccg.pet@nhs.net or telephone 0800 279 2535. In the event that something does go wrong and you are harmed during this research then you may have grounds for a legal action for compensation against the University of Cambridge. You do not need to prove that you were harmed due to someone's negligence (please quote sponsor insurance reference HVS/2019/2718).

Who has reviewed the study?

The Cambridge East independent Research Ethics Committee (REC reference: 19/EE/0354) and the Health Research Authority have reviewed and approved this research project.

Research team contact details

If you have any questions or require more information about this trial, please contact Dr. Katerina Kassavou.

E-mail: pam@medschl.cam.ac.uk| Telephone: 01223330456 | Address: University of Cambridge Department of Public Health and Primary Care, The Primary Care Unit, East Forvie Site, Cambridge CB2 0SR

To indicate your decision about taking part in this trial and book your consultation with your practice nurse, please complete the enclosed reply slip and send it back in the FREEPOST envelope

OR complete it online at this website http://bit.ly/pamtrial