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REC ref:

**Participant Information Sheet**

**P**rogramme on **A**dherence to **M**edication app.

Testing the acceptability of the PAM smartphone app to support medication adherence, a randomised controlled trial.



**You will need to use an Android smartphone (version 6, 7, 8, or 9) to take part in this study.**

**We would like to invite you to take part in a study to test a new service for people who have high blood pressure.**

Please take time to carefully read this information sheet, and discuss it with others if you wish. Before you decide, 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 research study.

**What is the study about?**

Based on review findings, theory and PPI/E feedback we have developed a smartphone app, which we call PAM app that aims to support medication adherence.

This study aims to evaluate the PAM app and obtain feedback to make changes to the app accordingly and gain a better understanding about whether and how the usage of the app facilitates medication adherence.

The results of this test will help us to develop new ways to support patients to take their prescribed medications and optimise the PAM app.

**Why have I been invited to participate?**

You have been invited to take part because:

* You have a diagnosis of hypertension and/or been prescribed at least one anti-hypertensive.
* Have a basic proficiency in English
* Have and are currently using an Android smartphone

**Do I have to take part?**

It is entirely your decision whether or not you take part. If you decide to be involved, we will ask you to provide a consent form, to say that you understand what the study involves and that you agree to take part. If you take part in this study, you will be free to withdraw at any time, but we will keep anonymised information about you that we already have. However, 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.

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

1. **Baseline meeting**

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| If you have decided to give your consent to take part in this study, you will need to attend a meeting with the researcher. This will be used to introduce you to the app and help you download and set up the app ready for use. It is required that you have your **Android smartphone** when attending the meeting.As part of baseline measures, the researcher will need to measure and obtain a **blood pressure reading** during the meeting. This will be done by the researcher using a portable blood pressure device. If participating remotely, then you will be asked to either do this yourself or provide a most recent reading over the phone.It will last approximately **1 hour,** and it will include procedures 1.1 – 1.2prior to downloading the app and taking a blood pressuring reading.  |

* 1. **Provide consent form**

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| During the meeting, the **researcher** will double **check your eligibility** and respond to any questions you may have about this study, before obtaining your informed consent.  |

* 1. **Questionnaires**

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| The researcher will give you a one-page questionnaire. The questionnaires ask about common difficulties with managing high blood pressure and taking medications It may take approximately **5 minutes** to complete and will be completed before you download and use the app.  |

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**Q. Why will I be allocated to group 1 OR group 2?**

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| The best way of assessing whether this service is practical and effective to patients and if it improves the care they receive, is through a Randomised Controlled Trial (RCT). RCT means that if you take part, you will have equal chance of receiving either of the options being compared:Group 1 (testing this new PAM app) or Group 2 (no use of the app). The decision about which option you will receive is random (i.e. based on chance). Participants will be given a reference number. The reference number will be used to allocate participants at random to Group 1 or Group 2. A computer system will be used for random allocation, which ensures that the groups of patients 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**

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| If you are in group 1, you will be asked to **test the new mobile phone service for one month**. The researcher will provide you with a leaflet with more information about how to use either of these options.The app is free to download and use, however, mobile internet data will be used to install the app.A researcher may contact you via phone during the first 2 weeks of using the app to ensure you are having no issues and respond to any questions you may have. However, no one participant will be contacted more than 2 times within this period. Participants can contact the research team by using the information provided at the end of this information leaflet.  |

**Group 2**

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| If you are in group 2, you will **not** be asked to use the PAM appforthe duration of the study. |

1. **Follow up interview and questionnaire – 1 month**

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| All participants will be invited them to take part in **a face-to-face meeting** to obtain their feedback on the app and their experience using the app. This interview will last around **45 minutes**. All interviews will be **audio recorded** for research purposes.Similarly to baseline, at follow up, the researcher will obtain a **blood pressure reading** during the meeting. This will be done by the researcher using a portable blood pressure device. The research team will give you the follow up questionnaires at the beginning of the follow up interview. It may take **5-10 minutes** to complete and will be completed on a laptop provided by the researcher.  |

**How will we use information about you?**

We will need to use information from you. This information will include your name, contact details, your prescribed medications and information about your health. **People will use this information to do the research** or to check your records to make sure that the research is being done properly.

Personal and identifiable information will be kept **strictly confidential**. The data collected during the research will be used for the purpose of this study.

To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at <https://www.medschl.cam.ac.uk/research/privacy-notice-how-we-use-your-research-data>

For more information about confidentiality please read next pages, otherwise please continue at page 8.

**Will the information I provide be kept confidential?**

Yes. All information collected about you during the course of this study 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, see: <https://www.medschl.cam.ac.uk/research/information-governance/sdhs-security-policy> / and: <https://www.medschl.cam.ac.uk/research/information-governance/frequently-asked-questions> ).

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 University of Cambridge will keep your name, contact details and other information from you and your medical records (e.g. prescribed medications) in order to undertake this study and will act as the data controller for this study. 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 the research study, and make sure that relevant information about the study 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 the research study. 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 study has finished for the purposes of analysis and writing up the results of this study. Anonymised research data will be kept for 10 years after the study has been completed to inform future research. 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.

**What are the possible benefits of taking part?**

We will use the information you give us to assess whether the app effectively supports people with high blood pressure to take their medications as prescribed.

We will also use this information to make recommendations to further improve the app. You may not benefit directly from this, but if successful, this may benefit other people with long-term health conditions.

**What are the possible risks of taking part?**

The study involves little deviation from your usual care. Research risks are no greater than those involved in your usual care. However, you are also advised to contact the research team, if you have any concerns about your participation in this study.

During the interview, 1 month after your consent to take part, we will ask your views about using the app. We will not ask you sensitive or personal questions. Interview will be audio-recorded. Audio-recordings will be transcribed and quotes will be fully anonymised.

**If I am allocated to Group 1, what information will be collected and how this will be kept confidential**?

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| The information you provide during the practice consultation (e.g. your prescribed medications) will be transferred to the app using encrypted internet files. When you install the app, this information will automatically inform the content of your personalised messages (app notifications). The responses you provide to the app notifications will be stored in the app at your mobile device. 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 also collect information about the Wi-Fi you are logging in, and it will also collect accelerometer and location information. This information will be collected to tailor the delivery of the app notifications to your individual routines. All information collected by the app will be stored into the app only. The app will not have functionalities that link your data to any other apps or other social media service (e.g. facebook). All information collected by the app will be sent to Cambridge University using secure communication protocols once per day, and will be deleted from your device after that point. Thus, you should not be concerned about the storage or battery of your device. The app is not power consuming and the data it stores is very little.  |

**Who is organising and funding the research?**

This research is organised by the Department of Public Health and Primary Care, The Primary Care Unit at the University of Cambridge, and is funded by the National Institute for Health Research.

**What will happen to the results of the study?**

We expect that the results of this study will lead to the development of future research to support people to take their prescribed medications as an adjunct to their general practice consultations. Results from this study will also be used to inform the PAM main trial.

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, you should **contact the research team** by email ss2701@medschl.cam.ac.uk or call 01223330355

Alternatively, you may wish to contact the Patient Experience Team, NHS Cambridgeshire and Peterborough CCG via email capccg.pet@nhs.net or telephone 0800 279 2535.

**Who has reviewed the study?**

All research at Cambridge University is looked at by an independent Research Ethics Committee {*include here the ethic committee and the reference number of REC approval*} and have reviewed and approved this research project.

**Research team contact details**

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**Thank you for considering taking part in this study.**