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REC ref: 19/NE/0018

**Participant Information Sheet**

**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.**

You are being invited to take part in a research study conducted by the University of Cambridge. 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 purpose of this research?**

We are developing a new service involving very brief face-to-face consultation with a health care practitioner, followed by a text messaging or an app service, to support people about the way in which they take their prescribed medications. We would like you to help us evaluate whether this new service is practical and acceptable. This service is designed to provide support for medication adherence to people with hypertension (high blood pressure) only, or high blood pressure and other health conditions, e.g. type 2 diabetes or raised cholesterol. The information gained will help us to develop new ways to support patients to take their prescribed medications. This will also help us to make recommendations to health care providers within primary care about how best to help patients to take their medications regularly and achieve the relevant long-term health benefits.

**Why have I been approached?**

You have been approached because your GP practice records indicate that you are currently prescribed medications to manage high blood pressure, or high blood pressure and type 2 diabetes or cholesterol. Your experience will help us evaluate and improve this new service. Your participation in this study will help us to design the next stage of this research.

**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 sign 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 without giving a reason. If you wish to withdraw, this will not affect the care you receive from your GP practice. Your personal data will continue to be retained by the University of Cambridge on a secure password-protected server for purposes of analysis and writing up the results of this study. If you decide to withdraw from the study, a member of the research team might contact you to ask the reasons for your decision. This will help us evaluate the practicality of conducting this research.

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

The best way of assessing whether this service is practical and acceptable 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 an approximately equal chance of receiving either of the options being compared: Group 1 (testing this new service) or Group 2 (continuing with your usual care). 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.

You will need to use a mobile phone or an Android smart phone (version 6, 7, 8, or 9) in order to take part in this study. The service is free, however broadband data charges may apply to viewing of the videos or using the app.

If you decide to take part, you will need to attend an appointment with your health care practitioner at your practice. During the practice visit, the practitioner will double check your eligibility and respond to any questions you may have about this study, before obtaining your informed consent. You will be asked to provide a written informed consent for the research team to access and collect information from your practice records. This information will be about your prescribed medications. You will also be asked to respond to very brief questionnaires and provide clinical measures, i.e. blood pressure (if you have high blood pressure) and blood samples (if you also have type 2 diabetes or cholesterol). You will also be asked to provide urine samples. These measures will be taken to estimate different ways to obtain accurate measures and to identify the procedures in doing so within primary care. For patients with high blood pressure, the practitioner will measure blood pressure using blood monitoring devices. Three records of sequential blood pressure readings at 1-minute intervals will be collected. The blood pressure readings will be sent to the research team. For patients who also have type 2 diabetes and/or cholesterol, the practitioner will take blood samples (one sample for HbA1c and one sample for cholesterol).

You will be allocated to Group 1 or Group 2 and your practitioner will inform you about your group allocation. Below there is a description of what the allocation in each group involves.

***Group 1****.* Participants in this group will:

* Be asked some questions about their medication taking behaviour by the health care practitioner
* Receive information about the text messaging/app service
* Be asked about whether they prefer to test the intervention by using the text messaging service or the app (information on how to use this service will be provided in a leaflet with a link to a video)

During the three months of this study, you will be able to request to switch from the text message to the app, if you prefer so. The frequency and times of the messages will be decided during the appointment with the health care practitioner, and you will have the option to change these during the three month service by contacting the research team. The messages will aim to provide advice and support for medication taking following your practice consultations (please see examples of text messages/app notifications at the end of this information sheet).

***Group 2*.** Participants in this group will:

* Continue receiving the usual care provided by their general practice, with no access to the text or an app service.

Three months after allocation to groups, participants in both groups will be sent follow-up questionnaires and asked to attend the practice. During the practice meeting, the healthcare practitioner will take clinical measures (mentioned at third paragraph, page 2 of this document).

Clinical measures collected at the beginning and at the end of the study will be sent to laboratories for analysis. The blood samples will be sent to the Addenbrooke’s Hospital laboratory for measurement of HbA1c and cholesterol (lipoprotein: hdl, ldl). One urine sample will be taken and sent to the Leicester Hospital laboratory to measure concentration of anti-hypertensive medication in the urine. All the results will be sent to the research team directly.

At 3 months follow up only, we will select some patients from Group 1 and Group 2 and invite them to take part in a face-to-face or telephone interview to obtain their views about their experiences of taking part in this study. This interview will last around 45 minutes.

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

We will use the information you give us to further develop this service to support people with high blood pressure or associated conditions (e.g. type 2 diabetes and cholesterol) to take their necessary medications as prescribed. We will also use this information to make recommendations to healthcare providers in general practices about how best to help people take their prescribed medications and achieve the relevant long-term health benefits. You may not benefit directly from this, but if successful, this may benefit other people with similar conditions, who do not take their medications as prescribed.

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

If you are allocated in Group 1, you will be provided with advice and reminders about your medications for 3 months. However, some people may not like being reminded about taking medications for a health condition, such as high blood pressure. The service will provide you with options to select less or stop receiving advice and reminders at any time. You are also advised to contact the research team, if you have any concerns about your participation in this study. If you are allocated in Group 2, there are no risks associated with taking part in this study.

During the interview at the end of the study, we will ask your views about taking part in this study. We will not ask you sensitive or personal questions. You can withdraw from this study at any time.

If during the study, 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 practice on your behalf.

**Will my taking part in this study be kept confidential?**

**Yes**. Personal and identifiable information will be kept strictly confidential and will not be retained after the end of this study. The data collected during the research will be used for the purpose of this study. However, anonymous data from this study will be placed in the University of Cambridge repository (i.e. anonymised database).

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

**Yes.** All information that is collected about you during the course of this study will be kept strictly confidential and proceed in accordance with the Data Protection Act 2018 and General Data Protection Regulation (GDPR, 2018). All information will be anonymised and stored securely on a password protected database hosted at the University of Cambridge and separately from individual responses. 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).

It will not be possible for anyone to identify our particular responses. Access to the information will be restricted to the research team for the purposes of this research project.

Urine samples and blood samples will be fully anonymised before being sent to laboratories for analyses, so that it will not be possible for the laboratory staff to identify participants. The laboratory staff will assess urine sample for concentration of anti-hypertensive and the blood samples for HbA1c and/or cholesterol levels. After analysis, the laboratory staff will send the anonymised results directly to the research team. 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.

Your general practice will be informed about your participation in this study but won’t have access to the individual data you provide*.* All information provided via text message or mobile phone app will be kept on a secure University of Cambridge data server hosted in the Clinical School Computing Service.

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 only receive information without any identifying information. The people who receive the information will not be able to identify you and will not be able to find out your name, contact details or other personal and identifiable information. Cambridge University will keep identifiable information about you after the study has finished for the purposes of analysis.

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. 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 /. If you require more information about the practice of confidentiality, please contact the research team by email at iam@medschl.cam.ac.uk.

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

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 download the app, this information will automatically inform the content of your personalised reminders. For example, if you are prescribed amlodipine 5mg and you agree with your health care providers to be reminded about this medication, the app will send you notifications like ‘have you taken your amlodipine yet? Please reply with ‘yes’ or ‘no’. This message will be sent at the time that you will select during the consultation with your health care provider (please see some example screenshots of the app notifications at the end of this information sheet). The responses you provide to the app notifications will be stored in the app at your mobile device. The app will also collect information about the Wi-Fi you are logging in, it will also collect accelerometer and location information. This information will be collected to test the practicality to tailor the SMS/app messages to peoples’ 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 the Cambridge University servers using encrypted internet files, for the purposes of analysis, and will be deleted from your device after that point.

**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. We will also use the data from this study to write publications in peer-reviewed academic journals and 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?**

We do not anticipate any major risks or problems associated with participating in this study. However, the University of Cambridge has public liability and professional indemnity insurance to cover any negligent harm caused. Should you wish to make a complaint or raise a concern, you can contact the research via an email: iam@medschl.cam.ac.uk or telephone 01223330456. 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 in the NHS is looked at by an independent Research Ethics Committee. The North East – Tyne & Wear South Research Ethics Committee (REC Reference number 19/NE/0018) and the Health Research Authority have reviewed and approved this research project.

**Research team contact details**

E-mail: iam@medschl.cam.ac.uk

Address: The Primary Care Unit, Department of Public Health and Primary Care
 University of Cambridge, Institute of Public Health, Forvie Site
 Cambridge, CB2 0SR

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

**Example of the text messages or app notifications**

