PRACTICE INFORMATION SHEET

The SHIP Study

A service evaluation of the implementation of Hypertension-Plus - implementing a hypertension self-monitoring/management service in primary care

As your practice is currently using or planning to use the Omron Hypertension Plus service, we would like to invite you to take part in a service evaluation of blood pressure management in your practice. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

Hypertension Plus is a telemonitoring and decision support system developed by Omron Healthcare Ltd. building on work undertaken in the TASMINH2, TASMINSR, TASMINH4 and HOMEBP trials (McManus et al Lancet 2101, JAMA 2014, Lancet 2018, BMJ 2021). The system allows GPs and patients to share information about home blood pressure levels and treatment recommendations. It provides reminders for monitoring and alerts for action to both patients and professionals.

The SHIP Study will evaluate the implementation of the Hypertension Plus system in UK primary care with the aim of understanding its impact on take up, blood pressure control and hypertension workload.

This will be done in a service evaluation using anonymised routinely collected data; that is information recorded by practices and patients in their routine care, using the hypertension plus system if they wish. It will compare those using the system with those that do not use the system using both information without the use of hypertension plus with information after implementation (where relevant). This information will be extracted using electronic searches of practice computer systems, secure data transfer and the Omron Hypertension Plus system. Identifiable information will be removed so that there is no way of the research team knowing who the patients are.

Comparing those using and not using the system, we will study: uptake of the system, blood pressure control (using routinely collected blood pressure information), workload (number and length of appointments concerning blood pressure as well as the job roles of those individuals) with simple costing analyses. Further analysis will understand how the system affects related issues such as prescription of medications.

Information collected during the study will be fed back to practices, patients and commissioners of care by means of the summaries of the results. The research team will publish the results in journals and present at conferences. Both traditional and social media will be utilised to support dissemination of findings.

What will happen if we decide to take part?

If you decide to take part, a member of the study team will be in touch to arrange study set up and site initiation. If a practice takes part they will not need to undertake any day to day tasks over and above their usual hypertension management (which may involve using Hypertension Plus). You will be asked to perform a database search at baseline, 6 months later and around 1 year and you will be provided with a downloadable search and simple instructions for this purpose. We anticipate a short set up meeting then three searches taking less than an hour each.

Inclusion criteria – GP Practices:

- Practice is using (or planning to use) the hypertension plus telemonitoring system
- Utilises compatible Electronic Health Record system
- Data available for the previous 2 years from practice recruitment

Exclusion criteria – GP Practices:

- GP Practices that are not able to contribute data

Practice involvement:

- Database search (downloadable search provided)
- Run anonymized report for data extraction at baseline, 6 months and 1 year following practice initiation. Transfer report to evaluation team.

GP involvement:

- Complete study set up and site initiation (approximately 20/30 minutes)

Patient involvement:

We intend to study hypertension management with or without Hypertension Plus. No direct involvement in this evaluation will be needed from consulting patients and we will not be seeking individual patient consent.

- Information regarding hypertension management for adult patients (>18 y) and on the hypertension register will be extracted from the EHR at each participating practice by electronic search and provided in an anonymised form to the analysis team.

- We will compare anonymised data from adults aged 18 years or above with hypertension who have used Hypertension Plus with those that have not

- We will look at data before and after (if relevant) use of Hypertension Plus and for those with blood pressure above and below 140/90mmHg.

Study recruitment period: From February 2022 for around 12 months with follow-up for 12 months following recruitment.

Reimbursement:	**Study Costs** Invoice Study Team
One-off costs to include:	
• Study set up and site initiation	£100
• Database searches data extraction and submission**	
o Baseline search	£ 50
o 6 month search	£ 50
o 12 month search	£ 50
Total one-off costs:	**£250.00**

** if centralised searching or the ORCHID system are used in data extraction then practice costs will be reduced by £50 to allow for consolidated search costs to be paid but retaining the remainder in view of practice work on the project.

Invoicing:	Invoices should be sent to the study team below:
	Anne Smith: anne.smith@phc.ox.ac.uk -
Study Team:	The SHIP Study Primary Care Clinical Trials Unit, Nuffield Department of Primary Care Health Sciences, University of Oxford, Gibson Building, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG.

Will the study data be kept confidential?

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018. We will use anonymised routinely collected data and although multiple items will be extracted from individual clinical records, we do not believe that the data being requested would be sufficient, even in aggregate, to identify an individual.

The participants will be assigned a unique study specific number and/or code in the dataset. The name and any other identifying detail will NOT be included in any study data electronic file which will include clinical codes and values (blood pressure) and consultation information (consulter type, date, timing).

What will happen to the results of this study?

Information collected during the study will be fed back to practices and commissioners of care by means of the summaries of the results. The research team will publish the results in journals and present at conferences. Both traditional and social media will be utilised to support dissemination of findings.

Who is organising and funding the study?

This study is funded by the NIHR via Oxford and Thames Valley Applied Research Collaboration and is being organised by Professor Richard McManus at the University of Oxford, Primary Health Care Clinical Trials Unit in Oxford.

Further information and contact details:

Tel: Anne Smith (The SHIP Study Manager) – 01865 289262

Email: anne.smith@phc.ox.ac.ukThe SHIP Study Primary Care Clinical Trials Unit, Nuffield Department of Primary Care Health Sciences, University of Oxford, Gibson Building, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG.