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OPTIMA-BP: empOwering PaTients in MAnaging Blood Pressure – protocol for a randomised parallel group study comparing use of Kvatchii web-based patient education portal as an addition to home blood pressure monitoring

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ABSTRACT

Introduction Hypertension is the leading modifiable risk factor for cardiovascular disease and is implicated in half of all strokes and myocardial infarctions. One-third of the adults in Scotland have hypertension yet only a quarter of them have their blood pressure (BP) controlled to target (<140/90 mm Hg). Empowering patients to have a better understanding of their condition and becoming actively involved in the monitoring and management of hypertension may lead to improved patient satisfaction, improved BP control and health outcomes and reduction in the use of primary/secondary care hypertension clinics.

Methods and analysis OPTIMA-BP is a randomised parallel group pilot study comparing the use of home BP monitoring accompanied by access to the web-based cardiovascular educational portal (Kvatchii) and home BP monitoring (HBPM) alone in 200 patients with hypertension attending the Glasgow Blood Pressure Clinic, Queen Elizabeth University Hospital, Glasgow. Consented participants will be asked to complete surveys on lifestyle factors, medication adherence, quality of life and hypertension knowledge, understanding and home monitoring. The intervention group will be asked to complete a survey to help evaluate the Kvatchii portal. At 6 and 12 months, the surveys will be repeated via the CASTOR EDC. Both groups will input their HBPM results at 2-month intervals into a CASTOR-EDC survey. OPTIMA-BP will follow-up with participants over 12 months with the study running over 24 months. The primary outcome is HBPM systolic BP area under the curve between baseline and 6 months

Ethics and dissemination OPTIMA-BP was approved by the North of Scotland Research Ethics Committee 2 (22/NS/0095). Current protocol version 1.2 date 6 June 2023. Written informed consent will be provided by all study participants. Study findings will be submitted to international peer-reviewed journals and will be presented at national and international scientific meetings.

Trial registration number ClinicalTrials.gov: NCT05575453. Registered 12 October 2022. https://clinicaltrials.gov/ct2/show/NCT05575453

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Self-monitoring home blood pressure with or without video or application-based interventions can improve health literacy and home blood pressure control in general practice.

WHAT THIS STUDY ADDS

⇒ OPTIMA-BP recruits participants from a secondary care hypertension clinic, randomising participants to home blood pressure monitoring or home blood pressure with access to a web-based educational portal. In addition to home blood pressure, OPTIMA-BP also evaluates the impact on quality of life, blood pressure knowledge and health literacy.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The management of hypertension must switch from the traditional model of office-based management to incorporate new and emerging digital strategies. These digital strategies including the Kvatchii Portal offer the opportunity for more effective monitoring, improvements in treatment adherence but importantly patient empowerment and education.

INTRODUCTION

Hypertension, a leading modifiable risk factor for cardiovascular disease,[1 2] is implicated in half of all strokes and myocardial infarctions. Despite the well-established efficacy of lifestyle modifications and antihypertensive medications in reducing cardiovascular risk, the control of blood pressure (BP) globally remains suboptimal.[3] In Scotland, one-third of the adults have hypertension yet only a quarter of them have their BP controlled to target (<140/90 mm Hg).[4] Several factors contribute to the suboptimal BP control. Individuals may lack

confidence, and their knowledge and understanding of their condition and treatment strategies can be poor which leads to non-adherence to taking prescribed medication and infrequent BP monitoring. Moreover, the importance of effective patient–doctor communication and feedback exchange in optimising hypertension management is underestimated. The challenges in hypertension management have been further exacerbated by the recent COVID-19 pandemic which has led to disruptions of routine BP screenings in primary and secondary care. The limited access to medical care and a shift of focus away from chronic disease management have created additional obstacles. This has created a snowball effect resulting in an increased burden on the National Health Service (NHS) and a backlog of patients awaiting new appointments for their chronic disease.

Currently, there is limited evidence regarding the organisation and delivery of care for patients with hypertension in the community to improve BP control. A Cochrane review conducted in 2010[5] suggested that an organised system involving patient registration, recall and regular reviews, coupled with aggressive antihypertensive drug treatment, proved to be the most effective approach. Interestingly, the review found that self-monitoring of BP was associated with moderate net reductions of −2.5/−1.8 mm Hg. However, the trials investigating educational interventions directed at patients or healthcare professionals displayed heterogeneity.[5 6] The use of home BP monitoring (HBPM) in conjunction with BP education through video-based delivery has been shown to be effective in improving hypertension literacy[7] while, in other studies, application-based interventions have been shown to improve home BP control in general practice populations, over 6–12 months[8 9] compared with usual care.

The utilisation of HBPM, coupled with appropriate education and support, could enable clinicians and patients to share the responsibility of monitoring and decision-making required for effective hypertension management. This approach holds the potential to enhance patient satisfaction, improve BP control and enhance overall health outcomes. Implementing more effective remote consultations and potentially reducing the reliance on primary and secondary care hypertension clinics could also benefit the NHS in managing chronic diseases more efficiently.

In light of these considerations, we aim to investigate whether a web-based BP monitoring and educational portal can enhance BP control in patients with high BP requiring hospital-based hypertension outpatient clinical care. We hypothesise that the web-based platform, coupled with HBPM, will lead to improved BP control among the patients with hypertension, and that the acceptability and engagement with the platform will be sustained over a 1-year follow-up period. Our pilot trial is designed to establish the feasibility of conducting the study using HBPM and a web-based platform, obtain unbiased measures of BP changes in response to the intervention, and gather patient feedback on the usability and acceptability of the platform.

Study objectives

1. Evaluate the knowledge, understanding and attitudes towards hypertension and hypertension management, in a population attending the Glasgow Blood Pressure Clinic (GBPC).
2. Evaluate and establish the use of a web-based educational portal designed to increase knowledge and understanding of hypertension, BP measurement/monitoring and management.
3. Establish the acceptability of HBPM in conjunction with the web-based education and monitoring portal.
4. Establish if using HBPM and the web-based education and monitoring portal improves BP control, lifestyle measures, quality of life and medication adherence.
5. Provide insights and data to support a larger study that can be generalised and applied in other populations.

These findings will inform the design of a larger definitive study, ultimately contributing to the advancement of chronic disease management and remote healthcare consultations.

Methods and analysis

Study setting and participants

The study site is Queen Elizabeth University Hospital in Glasgow which is one of the largest acute hospitals in the UK, serving a population of approximately 560 000 people in the West of Scotland. The GBPC provides a secondary and tertiary level service for patients with hypertension in the West of Scotland. Participants are aged ≥18 years old and attending, have recently attended or have been referred to the GBPC. Inclusion and exclusion criteria are listed in table 1.

STUDY DESIGN

OPTIMA-BP is a randomised parallel group pilot study comparing the use of HBPM accompanied by access to the Kvatchii web-based cardiovascular education portal with HBPM alone.

200 patients with hypertension will be recruited for this pilot study. An invite, participant information sheet and two consent forms will be posted to each potential participant with contact details for the research team. If the potential participant wishes to take part, they can contact the research team by telephone or email. The consent forms are signed at home by the participant and one to the research team by post or email. A second invite may be sent ≥4 weeks after the first to those who have not responded to the initial invite.

Consented participants will perform an eligibility check using a CASTOR EDC (www.castoredc.com) survey. If eligible, they will be asked to enter basic demographic and health information. Participants will be asked to measure their arm circumference to inform BP cuff size. They will then be asked to enter this measurement into the CASTOR EDC survey. After the eligibility check, basic

Table 1 OPTIMA-BP inclusion and exclusion criteria

Inclusion	Exclusion
Aged ≥18 years	Inability to give informed consent
Current attendance at the GBPC or referral to GBPC or discharged from GBPC within 12 months	Non-English speakers
	No internet access
	Clinic or ambulatory BP ≥180/120 mm Hg
	Arm circumference >42 cm
	Inability to perform HBPM
	Inability to use Kvatchii portal
	Pregnancy
	Persistent atrial fibrillation
	An acute cardiovascular event requiring hospitalisation in the previous 3 months
	Chronic kidney disease stage ≥4 or renal dialysis
	Severe or terminal illness limiting study participation

BP, blood pressure; GBPC, Glasgow Blood Pressure Clinic; HBPM, home BP monitoring.

demographic information and arm circumference have been completed, participants will be randomised electronically by CASTOR EDC into two groups (1:1): the intervention group will be given access to the Kvatchii portal and the control group will not have access to the portal.

Participants will be asked to complete surveys on lifestyle factors (diet, exercise, smoking/alcohol status), medication adherence, quality of life and hypertension knowledge, understanding and home monitoring. A HBPM will be sent via post with instructions on use. The intervention group will be asked to complete a survey to aid evaluation of the Kvatchii portal. At 6 and 12 months, the surveys will be repeated via the CASTOR EDC. Both groups will input their HBPM results at 2-month intervals into a CASTOR-EDC survey.

OPTIMA-BP will follow-up with participants over 12 months with the study running over 24 months. At the end of the study period, the study data will be deposited into NHS Greater Glasgow and Clyde (NHSGGC) Safe Haven for linkage to routine care data including laboratory results, inpatient and outpatient attendances and medication prescription information. The data will be returned in an anonymised form for analysis.

A summary of the study design is shown in figure 1 and the detailed participant schedule (Standard Protocol Items: Recommendations for Interventional Trials flowchart) is shown in table 2.

PROCEDURES

Home blood pressure monitoring

HBPM will be performed using an OMRON device following British and Irish Hypertension Society (BIHS) guidelines. We recommend readings be recorded, in triplicate, morning (06:00–12:00) and evening (18:00–00:00) for 4 days within a 7-day period. A minimum of three sets of morning and three sets of evening readings will be required for HBPM to be valid within a 7-day period.

Questionnaires

Each participant will be asked to complete questionnaires in electronic form via CASTOR EDC.

Quality of life: Measured using the Euro-Quality-of-Life-5D (EQ-5D)[10] developed by the EuroQol Group, depression via the Patient Health Questionnaire-9[11] and anxiety via the Generalised Anxiety Disorder 7-item scale.[12]

Health literacy: Assessed at baseline using the BRIEF Health Literacy survey[13] and evaluating health applications survey.

Blood pressure knowledge and lifestyle: Measured using a survey developed to assess BP knowledge and lifestyle.

Medication adherence: Assessed using the Hill-Bone Compliance to High Blood Pressure Therapy Scale.[14]

Kvatchii portal: To examine the acceptability, usability and tolerability of the Kvatchii portal, all participants in the intervention group will also be administered a separate questionnaire of a series of Likert responses about their experiences of using the application, including the System Usability Scale. Questions will address the understanding of the information, asking which the participants liked or disliked, what they did with the information, perceived utility and intrusiveness and timing and content suitability. Engagement with Kvatchii will be assessed by asking participants if they felt the information motivated them to change their lifestyle, helped remind them to take their medications and whether they rated the messages as requested. In addition, we will assess the proportion of messages that were read. Finally, the proportion of patients responding to messages with a rating will be used as a marker of overall engagement. Sample Kvatchii portal content is shown in figure 2.

INTERVENTION

A web-based cardiovascular education and BP monitoring portal has been developed by NHSGGC clinical academics with >20 years of experience in hypertension management and provided through a University of Glasgow spinout company Kvatchii Limited (Kvatchii portal), at no cost. The Kvatchii portal provides information about BP, BP medications and cardiovascular risk reduction including lifestyle changes. The portal provides extensive educational materials on hypertension and cardiovascular conditions, and these are provided in a personalised manner to the user so that they are not

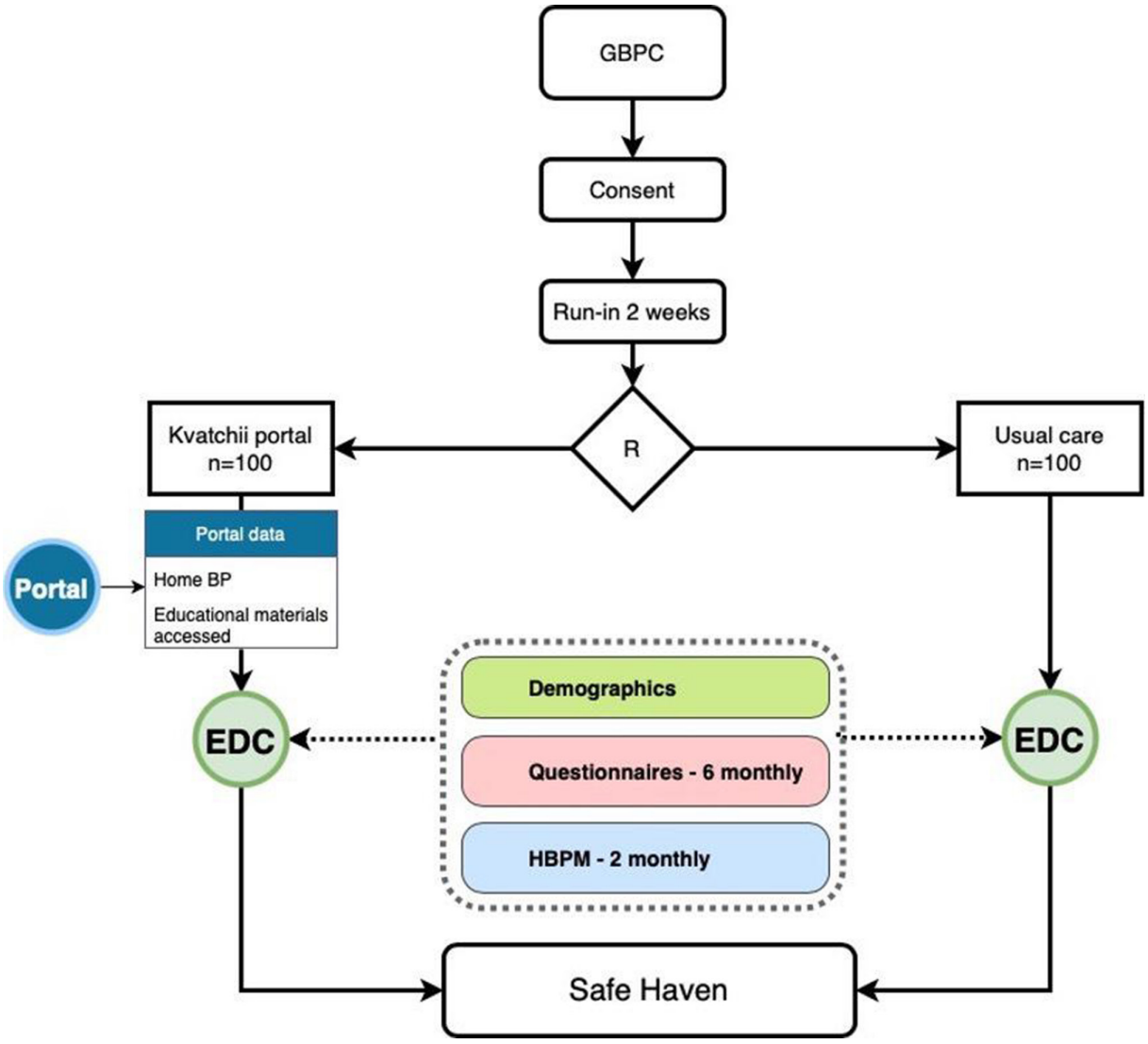

Figure 1 OPTIMA-BP study design. BP, blood pressure; EDC, CASTOR electronic data collection form; GBPC, Glasgow Blood Pressure Clinic; HBPM, home BP monitoring; R, randomise.

inundated with information. No identifiable data will be added or held within the portal and no clinical or treatment advice will be offered by the portal.

OUTCOMES

The primary outcome is the HBPM systolic BP (SBP) area under the curve (AUC) between baseline and 6 months. Secondary outcomes are HBPM diastolic BP (DBP) AUC between baseline and 6 months; HBPM SBP AUC between baseline and 12 months; HBPM DBP AUC between baseline and 12 months; change in lifestyle, quality of life, medication adherence, health literacy and hypertension knowledge and understanding at 6 and 12 months; antihypertensive medication changes at 6 and 12 months; evaluation of the Kvatchii portal.

STATISTICAL ANALYSIS

This is a pilot study and though formal power calculations are not required, OPTIMA-BP is adequately powered for the primary outcome based on experience conducting randomised controlled trials using out-of-office BP measurements in the Glasgow Clinical Research Facility. Assuming HBPM SBP is normally distributed and a SD of 10 in hypertensive subjects, we will need 76 cases and 76 control subjects to reject the null hypothesis with an alpha=0.05 and 80% power. The study requires a total of 200 subjects recruited (152 completed subjects) after accounting for approximately 25% missing data and HBPM errors (typical for HBPM studies).

The baseline characteristics of participants will be summarised overall and by group. Study population characteristics will be reported and compared using one-way analysis of variance for continuous variables and a χ^2 test for categorical variables. Linear regression will be used to compare the HBPM variables between the two groups with adjustment for the baseline HBPM variables. The adjusted mean difference, with a 95% CI and p value will be reported. The primary analysis will be judged at a 5% significance level.

Table 2 Standard Protocol Items: Recommendations for Interventional Trials flowchart - OPTIMA-BP detailed participant schedule

Activity	Run-in −1 month	Baseline 0	Month 2	Month 4	Month 6	Month 8	Month 10	Month 12
Informed consent	X							
Review eligibility	X	X						
Demography	X	X						
Randomisation		X						
Medical and drug history	X	X	X	X	X	X	X	X
Arm circumference	X							
Home blood pressure monitoring		X	X	X	X	X	X	X
Survey - blood pressure		X			X			X
Survey - high blood pressure therapy		X			X			X
Survey - lifestyle		X			X			X
Survey - health literacy		X			X			X
Survey - quality of life, depression and anxiety		X			X			X
Survey - Kvatchii portal		X			X			X

Study management and monitoring

The study is sponsored by NHSGGC (sponsor reference: INGN21CA393). NHSGGC Quality Department is responsible for conducting audits across studies and trials within Research and Innovation as mandated within Good Clinical Practice. NHSGGC Sponsor Audit is a systematic, documented and independent review of any trial, study or process. These audits are intended to ensure compliance with processes and protocols and assist those being audited by identifying and removing issues, not only within the area of focus but with associated processes.

DISCUSSION

Hypertension remains one of the most important and treatable risk factors for cardiovascular disease. The management of hypertension must switch from the traditional model of office-based management to incorporate new and emerging digital strategies. These digital strategies including Kvatchii portal offer the opportunity for more effective monitoring, improvements in treatment adherence and importantly patient empowerment and education.

The results of the OPTIMA-BP study may be generalisable to other similar web-based education portals in particular feedback from the health literacy questionnaire and participant use of the portal may inform further studies and aid other applications. Kvatchii portal could be used in other secondary care BP clinics or scaled up for use in other hypertension populations, for example, primary care. Kvatchii portal could be extended/adapted for use in other therapeutic areas where BP monitoring is

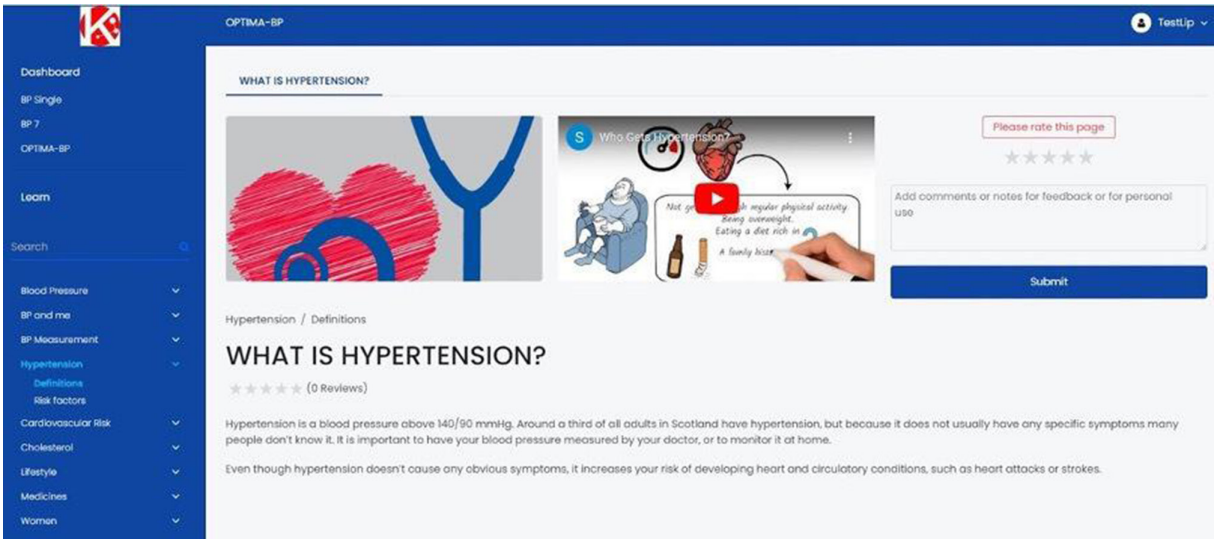

Figure 2 OPTIMA-BP Kvatchii portal screenshot.

important, for example, monitoring of contraceptive pills or use of biological therapies.

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Contributors LM and SP conceived, designed and wrote the protocol for the study. LM and MR obtained ethical approval. LM, SL and SP wrote the paper. All authors reviewed and approved the final manuscript. Those who significantly contribute to the study and results paper will be included as authors in any further manuscripts.

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Competing interests SP is a Professor of Cardiovascular Genomics and Therapeutics at the University of Glasgow and an Honorary NHS Consultant Physician who works in the Glasgow Blood Pressure Clinic. SP is a cofounder and director of Kvatchii Limited and developed the education portal. There are no other competing interests.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by North of Scotland Research Ethics Committee 2 (22/NS/0095). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement No data are available. Manuscript is for study protocol. No data included in protocol.

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