



# BMJ Open Telehealth versus self-directed lifestyle intervention to promote healthy blood pressure: a protocol for a randomised controlled trial

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## ABSTRACT

**Introduction** Weight loss, consumption of a Dietary Approaches to Stop Hypertension dietary pattern, reduced sodium intake and increased physical activity have been shown to lower blood pressure (BP). Use of web-based tools and telehealth to deliver lifestyle counselling could be potentially scalable solutions to improve BP through behavioural modification though limited data exists to support these approaches in clinical practice.

**Methods and analysis** This randomised controlled trial will compare the efficacy of a telehealth versus self-directed lifestyle intervention in lowering 24-hour SBP in patients with overweight/obesity (body mass index  $\geq 25$  kg/m<sup>2</sup>) and 24-hour SBP 120–160 mm Hg. All participants receive personalised recommendations to improve dietary quality based on a web-based Food Frequency Questionnaire, access to an online comprehensive weight management programme and a smartphone dietary app. The telehealth arm additionally includes weekly calls with registered dietitian nutritionists who use motivational interviewing. The primary outcome is change from baseline to 12 weeks in 24-hour SBP. Secondary outcomes include changes from baseline in 24-hour diastolic BP, daytime SBP, nighttime SP, daytime diastolic BP, nighttime diastolic BP, total Healthy Eating Index-2015 score, weight, waist circumference and physical activity. Other prespecified outcomes will include change in individual components of the Healthy Eating Index-2015 score, and satisfaction with the Healthy BP research study measured on a 5-point Likert scale.

**Ethics and dissemination** The study has been approved by the Geisinger Institutional Review Board. Results will be disseminated through peer-reviewed publications and conference presentations.

**Trial registration number** NCT03700710.

## INTRODUCTION

The American College of Cardiology/American Heart Association (ACC/AHA) 2017 Hypertension Guidelines redefined hypertension as having two blood pressure (BP) readings measured on at least two separate occasions  $\geq 130/80$  mm Hg.<sup>1</sup> With this updated

## Strengths and limitations of this study

- This randomised controlled trial will compare the efficacy of a telehealth versus self-directed lifestyle intervention in lowering blood pressure through lifestyle modification in patients with elevated blood pressure and overweight/obesity.
- The proposed interventions under investigation are low-cost and potentially scalable.
- Primary endpoint data will be collected using 24-hour ambulatory blood pressure monitoring at baseline and at 12 weeks, and additional secondary endpoint data will be collected including Healthy Eating Index-2015 score assessed by Food Frequency Questionnaire, weight, waist circumference and physical activity, assessed by questionnaire.
- While participants and some of the study staff are unable to be blinded, researchers assessing study outcomes and conducting analyses will be blinded to the arms.
- A limitation is that there is no control arm receiving no intervention at all.

definition, nearly half of the US adult population has hypertension.<sup>2</sup> Obesity, Western-style dietary patterns rich in sodium and processed foods, and low physical activity have been implicated in the pathogenesis of hypertension and cardiovascular diseases.<sup>1–3</sup> The ACC/<sup>1</sup>AHA Hypertension guidelines recommend lifestyle modification as class I recommendations for all patients with hypertension as well as those with elevated systolic BP (SBP) (120–129 mm Hg) since weight reduction, consumption of a low-sodium Dietary Approaches to Stop Hypertension (DASH)-type diet, and increased physical activity can lower BP substantially.<sup>4–6</sup>

Despite recognition that addressing lifestyle behaviours is of high importance to address cardiometabolic risk, delivery of lifestyle modification in clinical care remains

challenging due to time constraints, lack of referral resources and other competing priorities.<sup>7,8</sup> Some possibilities to address this gap include the use of app-based interventions and the use of telehealth to deliver lifestyle counselling remotely. A recent systematic review and meta-analysis found that app-based interventions have the potential for aiding patients make healthy nutrition behaviour changes and improving nutrition-related health outcomes.<sup>9</sup> Prior studies have found that telehealth lifestyle coaching interventions are similarly effective as traditional, in-person delivered interventions for helping patients achieve weight loss.<sup>10,11</sup> However, limited data exist on the efficacy of telehealth-delivered strategies in lowering BP through lifestyle modification. Most BP telehealth studies typically include remote monitoring of BP and antihypertensive medication, making it difficult to assess the impact of lifestyle modification.<sup>12,13</sup>

It remains unclear whether telehealth lifestyle counselling further lowers BP through healthy behaviour modification on top of app-based interventions. To help inform health systems and payers in devising scalable, low-cost strategies to improve hypertension control through lifestyle modification, we aim to compare the efficacy of a self-guided versus a telehealth dietitian-led approach using web-based tools in reducing 24-hour SBP from baseline to 12 weeks.

## METHODS AND ANALYSIS

### Study design/setting

The Healthy BP study is a randomised controlled trial (RCT) comparing a self-guided versus a dietitian-led telehealth approach using web-based tools to help patients lower BP from baseline to 12 weeks through lifestyle modification. The study intervention period of 12 weeks was chosen as prior studies suggest this time frame is adequate to observe an improvement in BP with lifestyle modification<sup>3,14,15</sup> and to minimise the chance that a patient in either arm would undergo a change in antihypertensive medication. The RCT is being conducted at two sites (Danville, Pennsylvania, USA Wilkes-Barre, Pennsylvania, USA) within the Geisinger Health System. Recruitment began 16 January 2019.

### Study population

A total of 200 participants will be included. Eligibility criteria include  $\geq 18$  years of age, body mass index (BMI)  $> 25$  kg/m<sup>2</sup>, access to a telephone and either a computer or smartphone with internet access, 24-hour ambulatory SBP between 120–160 mm Hg, and successful completion of the run-in period (enter dietary data entry into LoseIt app ([www.loseit.com](http://www.loseit.com)) for at least 5 out of 7 days; enter weight into a comprehensive weight management website ([www.bmiq.com](http://www.bmiq.com))). Exclusion criteria include: inability to understand English, myocardial infarction, stroke or atherosclerotic cardiovascular disease within prior 6 months, planned or previous bariatric surgery, pregnancy, breast feeding or planned pregnancy prior to the end of

participation, self-reported average consumption of  $> 21$  alcoholic beverages per week or binge drinking, psychiatric hospitalisation in past year, current angina or plans to leave the area prior to the end of the study, current participation in another clinical trial, and principal investigator discretion (ie, concerns about safety, compliance). The broad 24-hour SBP inclusion range was chosen to allow participation among patients recommended to make lifestyle modifications per the ACC/<sup>1</sup>AHA Hypertension Guidelines.<sup>1</sup> For patients with 24-hour or daytime SBP  $\geq 145$  mm Hg, the principal investigator discussed the results with patients and their providers on whether they wished to start or escalate antihypertensive medication therapy, or commit to making lifestyle modifications through the research trial. Patients who had antihypertensive medication started or escalated could be re-evaluated for eligibility with 24-hour ambulatory BP monitoring (ABPM) at least 2 weeks after the medication change.

### Interventions

All participants in both arms will receive instructions to access the BMIQ website and set up an account on LoseIt, a meal-logging app that integrates with the BMIQ website. BMIQ is an evidence based, Health Insurance Portability and Accountability Act (HIPAA)-compliant programme developed by Louis Aronne.<sup>16</sup> Educational materials on the BMIQ website include materials to promote weight loss, eating a DASH-type diet (increasing intake of fruits/vegetables, whole grains, protein sources from plants, lean meats, and seafood, and decrease sodium, sugar intake and saturated fat), reducing sodium intake, increasing physical activity, setting goals, overcoming barriers and relapse prevention. A list of the session topics, with a few customisations by the study team, are shown in [table 1](#). Participants also will receive a personalised nutrition report based on the Viocare Food Frequency Questionnaire (FFQ) that suggest ways to improve their dietary habits to best align with national dietary guidelines.<sup>17</sup> If participants encounter problems with using LoseIt or BMIQ, research staff will provide assistance. If no data are logged for more than a week, research staff will reach out to patients via text messages or phone calls to help troubleshoot any problems. To encourage adherence with dietary data entry, participants will receive virtual lottery tickets (lottery drawings for 10 US\$300 gift certificates) each week in which they enter at least 5 days/week of dietary data and 2 days/week of weights. All participants will be offered the opportunity to participate in grocery store tours at a local grocery store (Weis Markets).

Overarching participant goals include: (1) weight loss of 3% at 12 weeks; (2) consume a healthier dietary pattern (high in fruits, vegetables, whole grains, low-fat dairy, vegetable/fish/poultry sources of protein, healthier sources of fat and avoid sugar and salt); (3) reduce sodium intake to  $< 2300$  mg/day and (4) at least 180 min/week of moderate/vigorous intensity physical activity.

The self-guided intervention group will receive access to web materials but no additional support from dietitians.

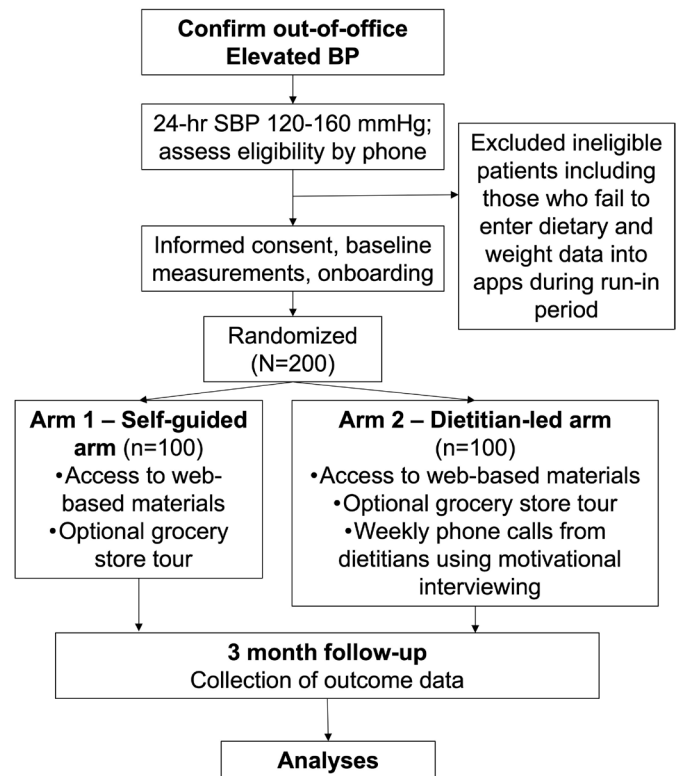
**Table 1** BMIQ session topics

| Week       | Topic   |
|------------|---|
| Week 1     | Welcome! getting started, self-monitoring diet and sodium |
| Week 2     | Healthy eating for weight loss                            |
| Week 3     | Walk off the weight                                       |
| Week 4     | Setting SMART goals for weight control                    |
| Week 5     | Gaining control of your food environment                  |
| Week 6     | Take the bite out of stress eating                        |
| Week 7     | Social cues & you   |
| Week 8     | Pump up my activity plan                                  |
| Week 9     | Navigating restaurants & grocery stores                   |
| Week 10    | Don't let slips trip you up!                              |
| Week 11    | Feeding your mind   |
| Week 12    | Sharpening my problem-solving skills                      |
| Week 13    | Don't let success slip away                               |
| Week 14    | Graduation!   |
| (Optional) | Do it yourself meals                                      |
| (Optional) | Food cravings   |
| (Optional) | Getting a hold over hunger                                |
| (Optional) | How successful weight losers do it                        |
| (Optional) | Incorporating highly desired foods                        |
| (Optional) | Navigating the food label                                 |
| (Optional) | Triple trouble: sugar, fat and salt                       |

The telehealth dietitian-led intervention group additionally will receive weekly telephone calls (initial call 30–60 min, follow-up calls 15–20 min) from a study dietitian. This approach is informed by Carver and Scheier's control systems theory<sup>18</sup> and the situated learning theoretical framework.<sup>19</sup> Control systems theory describes human behaviour as a 'continual process of moving toward, and away from, various kinds of mental goal representations, and this movement occurs by a process of feedback control.' By using the app and website and conversing with dietitians remotely, situated learning will occur through activities and experiences in the context of participants' own environments. Dietitians in this study explore participants' goals and values and help patients set an attainable goal around a health behaviour for the week and assess their progress towards those goals using motivational interviewing techniques and principles from. Motivational interviewing skills will be continually developed through biannual training sessions by a motivational interviewing expert. Dietary data entered in the LoseIt app is used to estimate average daily intake of sodium, fruits and non-starchy vegetables, which can be used for guidance for goal-setting around sodium intake and fruit and vegetable intake.

### Recruitment and baseline 24-hour ABPM

Participants will be recruited using multiple methods from 16 January 2019 to approximately 28 February 2021 (7–8 per month). The primary source of recruitment will



**Figure 1** Study flow. BP, blood pressure; SBP, systolic blood pressure.

be done by identifying patients with elevated outpatient BP using Geisinger electronic health record data. Additional sources of recruitment will include patients with Geisinger Health Plan insurance who have elevated BP during health screenings and referrals from Geisinger providers and self-referrals. Potential participants will then be invited to complete a baseline 24-hour ABPM to confirm their elevated BP outside the office as recommended by guidelines.<sup>20</sup> The 24 hours ABPM will be provided to participants free of charge, using SpaceLabs Ontrak devices. Participants will be asked to retake the 24-hour ABPM if fewer than 14 daytime measurements or 7 night-time measurements are obtained. Awake and sleep times will be self-reported; if participants fail to report their awake and sleep times on the activity diary, the SpaceLabs Ontrak activity monitor will be examined visually to determine awake and sleep times.<sup>21</sup> The study flow is shown in figure 1.

### Baseline study visit, Run-in period, randomisation and blinding

Participants who meet inclusion criteria are then invited to an initial study visit where informed consent will be obtained, along with weight, waist circumference and completion of Viocare FFQ,<sup>17</sup> the International Physical Activity Questionnaire (IPAQ) Short Form<sup>22</sup> and other study questionnaires.

Participants will register for a BMIQ web account, download the LoseIt app, and shown how to sync LoseIt to BMIQ, and access various features of LoseIt and BMIQ.

Participants will then be instructed to enter dietary data daily and weight data during the run-in period and throughout the trial. If participants enter complete dietary data (three eating occasions per day) for 5/7 days and enter their weight into the BMIQ website, they will be eligible to continue to randomisation.

Participants who are struggling with completing dietary data entry during the run-in period will be contacted by telephone to inquire about any issues, and the run-in period will be extended until at least 5 out of 7 consecutive days of dietary data entry is complete. Participants who complete the run-in period will then be contacted by telephone for randomisation assignment. Randomisation assignments will be generated by a computer program, and an unblinded staff member will open a sealed opaque envelope with the randomised intervention sequence, and notify participants of their intervention group assignment.

Participants, dietitians and the member of the study team assigning randomisation cannot be blinded. All other members of the study team are blinded, including study team members assessing outcomes and conducting statistical analyses.

### Outcome assessment

Outcomes will be assessed as the mean (continuous) change from baseline to the 12-week follow-up visit. The primary outcome is change in 24-hour SBP, assessed using ABPM with SpaceLabs Ontrak ABPM devices.<sup>21</sup> Secondary outcomes include changes in 24-hour diastolic BP (DBP), daytime SBP, night-time SBP, daytime DBP, night-time DBP, total Healthy Eating Index (HEI)-2015 score, weight, waist circumference, 24-hour DBP, clinic SBP, clinic DBP and physical activity (total metabolic equivalent of task (MET)-min per week). The HEI-2015 score will be assessed using the Viocare FFQ,<sup>23</sup> and total MET-min per week assessed using the IPAQ-short form. Weight will be measured without shoes or outerwear using a calibrated scale in clinic or by home scales—in the case of remote research visits necessitated by the Novel COVID-19 pandemic (table 2). Other outcomes include change in individual components of the HEI-2015 score and patient satisfaction (5-point Likert score).

### Adaptations to trial during COVID-19 pandemic

In late March 2020 and onwards, adaptations were made due to the COVID-19 pandemic, which necessitated minimising in-person contacts to preserve clinic space to allow for social distancing and conserving personal protective equipment (table 2). While we were able to continue primary outcome data collection with 24-hour ABPM, the requisite shift to primarily remote study visits required us to instruct patients to self-measure weight and waist circumference, which could potentially result in some underestimation.<sup>24 25</sup> As we are unable to perform automated office BP in most participants during the pandemic, change in automated office BP measures were removed as a secondary outcome. Fortunately, we were

**Table 2** Adaptations to trial during COVID-19

| <b>Research personnel unable to conduct in-person visits from 16 March 2020-current. Recruitment reliant on referrals.</b> |  |
|--|--|
| <b>Recruitment</b>   |  |
| Baseline 24 hours ABPM   | Increased collaboration with clinical staff to perform 24 hours ABPM testing for patients with elevated outpatient blood pressure readings   |
| Baseline study visit   | Study visits planned for late March 2020 were postponed until remote adaptations were made and approved by the IRB. Remote baseline study visits began in May 2020 using telephone calls and study materials mailed or dropped off at participants' houses. Weight and waist circumference measured using home scales and tape measures (rather than in clinic); automated office blood pressure unable to be performed.                                       |
| Grocery store tour   | Weis Markets introduced a virtual grocery store tour option for participants.  |
| Follow-up visit and 24 hours ABPM  | Follow-up study visits and 24 hours ABPMs in late March 2020 were postponed until remote adaptations were made and approved by the IRB. Remote follow-up visits and 24 hours ABPMs were conducted using telephone calls and study materials mailed or dropped off at participants' houses. Weight and waist circumference measured using home scales and tape measures (rather than in clinic); clinic automated office blood pressure unable to be performed. |

ABPM, ambulatory blood pressure monitoring; IRB, institutional review board.

able to continue the trial with adaptations although time windows were necessarily extended by approximately 1 month during March and April 2020 as there was a large degree of uncertainty on how to proceed and stay-at-home orders in Pennsylvania were in effect.

### Sample size calculation

In a meta-analysis of six trials comparing the effect of dietitian medical nutrition therapy to usual care, medical nutrition therapy reduced SBP by 4.7 mm Hg.<sup>26</sup> In the Atherosclerosis in Communities Study, every 1 mm Hg population-wide decrease in SBP was associated with a reduction of 20.3 heart failure events, 12.1 stroke events and 13.5 coronary heart disease events in African-Americans, and 13.3 heart failure events, 4.8 stroke events and 9.0 coronary heart disease events in whites.<sup>27</sup> Initially, the original sample size plan was for 160 patients, based on a conservative estimated drop-out rate of 25% and an SD of 8.8 mm Hg change in 24-hour SBP to detect a difference of 4.6 mm Hg between study arms. In order to determine whether there was a need to request additional funding from the funder (Geisinger Health Plan), a preplanned interim analysis was performed on 9/13/19, showing that the SD for change in 24-hour SBP was larger

than expected (SD 9.9) in the first 28 participants. Thus, a revised power calculation was performed. With an anticipated drop-out rate of 25%, the updated sample size of 200 patients (150 completers) we expect to have >80% power to detect a difference of 4.6 mm Hg between study arms in change of 24-hour SBP. For other outcomes, we expect to have >80% power to detect a difference of 6.9 in total HEI-2015 score with a SD of 15 units for change in total HEI-2015 score, and >80% power to detect a difference of 2.1 kg between groups, assuming an SD of 4.5 kg for change in weight.

### Statistical analysis

The primary contrast will be the between-group difference in 24-hour SBP from baseline to 12 weeks. The primary analyses will be intention to treat including all randomised participants who complete the trial with outcomes data, using unpaired t-tests. We will conduct complete case analyses; participants with missing data will be excluded from analyses. We will also examine whether 24-hour SBP improves at 12 weeks compared with baseline for each arm. A two-sided alpha of 0.05 will be used for analyses. Sensitivity analyses excluding non-adherent patients (<25% days with complete dietary data) will also be conducted. In sensitivity analyses, we will compare the end of period values (not baseline change) with and without adjustment for baseline. We will test for an interaction between treatment assignment and baseline 24-hour SBP ( $\geq$  or  $<$  130 mmHg) as an analysis of the DASH-Sodium trial found that low-sodium intake and the DASH diet had greater BP-lowering effects in those with higher baseline SBP.<sup>28</sup> Since it is possible that the effects of the interventions could be different during the COVID-19 pandemic, we will also conduct exploratory analyses testing whether change from baseline to 12 weeks in 24 hours SBP and other study outcomes differ in participants who completed the intervention prior to 3/1/2020 versus participants who completed the intervention after 3/1/2020. All outcome measures will be assessed for a normal distribution, and non-normally distributed outcomes will be log-transformed. Likert scales will be assessed on a continuous scale or dichotomised. Continuous outcomes will be compared via linear regression, while dichotomised outcomes will be compared via logistic regression. Since the primary and secondary outcomes will be collected during study visits, no interim data on the outcomes will be available for patients who discontinue the study.

### Ethics and dissemination

Initial ethical review and approval for this study was obtained from the Geisinger Institutional Review Board (IRB) on 10 January 2018 (current protocol version 1.22; approved 8/6/2020). Protocol amendments will be communicated to members of the study team and updated on the ClinicalTrials.gov website. Data will be collected using Research Electronic Data Capture (REDCap) software on a secure, password-protected server. Study

investigators are responsible for ensuring adherence to the protocol and guidelines for Good Clinical Practice. Symptomatic hypotension is possible in patients using BP-lowering medications and hypoglycaemic is possible for patients on diabetes medications undergoing dietary changes. Participants will be educated about the symptoms of hypotension and hypoglycaemic. Study staff will inform investigators of all patient adverse events occurring throughout the trial.

Dissemination of research will occur through several pathways. Research results will be submitted for publication to peer-reviewed journals and presented at national conferences. Summaries of Healthy BP findings will be provided locally to Geisinger leadership and health-care providers and nationally to other stakeholders and through press releases. After completing the study, participants and their primary care providers receive a summary of study results.

### Patient and public involvement

There was no specific patient or public involvement in the planning of this study. We will disseminate summary findings from this trial to study participants and to Geisinger's patient population.

### WHO TRIAL REGISTRATION DATA SET

1. Primary registry and trial identifying number: ClinicalTrials.gov Identifier NCT03700710.
2. Date of registration in primary registry: 10/9/ 2018.
3. Secondary identifying numbers: N/A.
4. Source of monetary or material support: Geisinger health plan (grant number N/A).
5. Primary sponsor: Geisinger clinic.
6. Secondary sponsors: None.
7. Contact for public queries: Christina Yule; 570-214-5233; cmyule@geisinger.edu.
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9. Public title: Remote dietary counselling to promote healthy diet and BP.
10. Scientific title: Remote dietary counselling to promote healthy diet and BP.
11. Countries of recruitment: USA.
12. Health conditions studied: high BP.
13. Interventions:

Active Comparator: self-guided approach.

In the self-guided arm, participants will receive access to web-based tools to help achieve healthy lifestyle changes to lower their BP. The web-based tools include: (1) a web-based FFQ (Viocare FFQ), which will provide a snapshot of participants' dietary habits in the past 6 months as well as personalised recommendations for areas to improve; (2) access to BMIQ (www.bmiq.com), an evidence-based programme developed by Louis Aronne at Columbia University, which

includes programme materials for weight loss and leading a healthy lifestyle; (3) LoseIt ([www.loseit.com](http://www.loseit.com)), a meal-logging app that integrates seamlessly with the BMIQ website.

Experimental: dietitian-led approach

In the dietitian-led arm, dietitian will use motivational interviewing in 15–30 min telephone calls with participants. The BMIQ website will be used to share participant dietary data (LoseIt) and weight data with dietitians. Participants will receive access to web-based tools to help achieve healthy lifestyle changes to lower their BP. The web-based tools include: (1) a web-based FFQ (Viocare FFQ), which will provide a snapshot of participants' dietary habits in the past 6 months as well as personalised recommendations for areas to improve; (2) access to BMIQ; (3) LoseIt ([www.loseit.com](http://www.loseit.com)), a meal-logging app that integrates seamlessly with the BMIQ website.

#### 14. Key inclusion and exclusion criteria

**Inclusion Criteria:** 24-hour ambulatory SBP 120–160 mm Hg, BMI  $\geq 25$  kg/m<sup>2</sup>, access to a telephone, access to a computer or smartphone with internet access, complete dietary data entry using LoseIt for at least 5 out of 7 days during run-in period, enter weight into the BMIQ portal during run-in period.

**Exclusion Criteria:** inability to understand English, myocardial infarction, stroke or atherosclerotic cardiovascular disease procedure within last 6 months, current treatment for malignancy, planned or previous bariatric surgery, pregnant, breast feeding or planned pregnancy prior to the end of participation, self-reported average consumption of >21 alcoholic beverages per week or binge drinking, psychiatric hospitalisation in past year, current symptoms of angina, planning to leave the area prior to end of the study, current participation in another clinical trial, principal investigator discretion (ie, concerns about safety, compliance).

15. Study type: randomised, parallel-arm, interventional study; study staff assessing outcomes and statistical analysis are masked. Purpose is to compare the efficacy of a self-guided versus a telehealth dietitian-led approach to lower BP through lifestyle modification.

16. Date of first enrolment—16 January 2019.

17. Sample size—200.

18. Recruitment status—recruiting.

19. Primary outcome—change in 24-hour systolic SBP (Time Frame: Baseline to 12-week follow-up) Measured by 24-hour ambulatory ABPM (SpaceLabs Ontrak).

#### 20. Key secondary outcomes

Change in 24-hour diastolic DBP (Time Frame: Baseline to 12 weeks follow-up) Measured by 24-hour ambulatory ABPM (SpaceLabs Ontrak).

Change in Daytime Systolic SBP (Time Frame: Baseline to 12 week follow-up) Measured by 24-hour ambulatory ABPM (SpaceLabs Ontrak).

Change in Night-time Systolic SBP [ Time Frame: Baseline to 12 week follow-up ] Measured by 24-hour ambulatory ABPM (SpaceLabs Ontrak).

Change in Daytime DBP (Time Frame: Baseline to 12 week follow-up) Measured by 24-hour ambulatory MBPM (SpaceLabs Ontrak).

Change in Night-time Diastolic DBP (Time Frame: Baseline to 12 weeks follow-up) Measured by 24-hour ambulatory ABPM (SpaceLabs Ontrak).

Change in Total HEI - 2015 score (Time Frame: Baseline to 12 week follow-up) Assessed by Viocare FFQ (score 0–100, 100=best possible score).

Change in Weight (Time Frame: Baseline to 12 week follow-up) Weight measured at baseline and 12 week visits using a calibrated scale without shoes.

Change in Waist Circumference (Time Frame: Baseline to 12 weeks follow-up) Measured using Gulick II tape measure.

Change in Physical Activity (MET-minute per week [ Time Frame: Baseline to 12 weeks follow-up]). Measured by IPAQ Short Form.

Change in Clinic SBP [ Time Frame: Baseline to 12 weeks follow-up ] Measured by average of 3 readings using Omron HEM 907XL.

Change in Clinic DBP [ Time Frame: Baseline to 12 weeks follow-up ] Measured by average of 3 readings using Omron HEM 907XL.

21. Ethics review—status approved, date of approval 2 October 2018.

22. Completion date—ongoing.

23. Summary results—N/A.

24. IPD sharing statement—Individual participant data collected for this trial will be made available to others; all available data will be deidentified. The protocol, statistical analysis plan, informed consent form and ethics committee approval will be made available.

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**Contributors** MT: writing original draft, review and editing; CY: project administration, investigation, review and editing; HB: project administration, investigation; SK: investigation, data curation, review and editing; CC: methodology, review and editing; AN: methodology, review and editing; SPJ: methodology, review and editing; LB-D: conceptualisation, funding acquisition, investigation, methodology, review and editing; ARC: conceptualisation, data curation, formal analysis, funding acquisition, investigation, methodology, supervision, review and editing. All authors have approved the final version.

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**Disclaimer** Funders had no role in the study design, collection, management, analysis, interpretation of data, or the decision to submit the report to publication.

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not required.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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