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Healthier You Hypertension pilot to prevent long-term conditions

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Study Title:	Healthier You Hypertension pilot to prevent long-term conditions
Short Title:	Healthier You-BP
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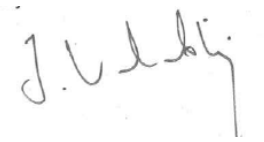
Chief Investigator Signature: 

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Investigator Team, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

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1. SYNOPSIS

Study Title	Healthier You Hypertension Pilot to Prevent Long-Term Conditions	
Short Title/Acronym	Healthier You-BP	
Study Design	A stepped-wedge cluster randomised controlled trial in 210 GP practices within eight Integrated Care Systems (ICSs) (i.e. an average of 26 GP practices within each participating ICS) in England. All eligible individuals within the intervention clusters will be eligible to be referred to the Healthier You Hypertension Pilot to Prevent Long-Term Conditions, a 9-month lifestyle intervention programme, while all individuals within the control clusters will receive usual care.	
Study Participants	Individuals with diagnosed hypertension	
Planned Sample Size	115,500	
Planned Study Period	3 years	
	Objectives	**Endpoints**
Primary	To evaluate the effectiveness of access to the intervention in reducing incidence of long-term conditions when compared to 'usual' care, in individuals with hypertension in any particular GP practice. Of note, the intervention is consistent with current NICE-Guideline recommended care for those with hypertension.	Incidence of long-term conditions at the end of each year in the study period.

2. ABBREVIATIONS

GP	General Practitioner
NHS	National Health Service
MLTC	Multiple long-term conditions
ICS	Integrated Care System
DPP	Diabetes Prevention Programme
NDH	Non-diabetic hyperglycaemia
FPG	Fasting plasma glucose

3. BACKGROUND AND RATIONALE

The prevalence of people with multiple long-term conditions (MLTC, defined as two or more long-term conditions, including physical conditions, mental health conditions, and chronic infections) is increasing (1). MLTCs are associated with poorer health outcomes, higher mortality and greater use of health care services (2-4). While this has led to the development of clinical guidelines for the management of MLTC (5) and of frameworks to support MLTC research (6), prevention of MLTC has received less attention (7,8).

In 2016, the National Health Service (NHS) in England established the Healthier You NHS Diabetes Prevention Programme (DPP), to prevent or delay the onset of type 2 diabetes in adults identified with non-diabetic hyperglycaemia (NDH, (HbA1c 42-47 mmol/mol (6.0-6.4%) or fasting plasma glucose (FPG) 5.5-6.9 mmol/L), also known as pre-diabetes) (9,10). The NHS DPP achieved universal population coverage in England in just over two years and by July 2024, over 1.6 million people with NDH had been referred into the programme and over 700,000 had attended at least one intervention session.

The NHS DPP consists of a 9-month lifestyle intervention supporting weight loss, increased physical activity, and better-quality nutrition (10). It is delivered according to a national service specification by one of four service providers selected through a national competitive process (11): Reed Wellbeing (12), Xyla (13), Thrive Tribe (14) and Living Well Taking Control (15). The national service specification was designed by an Expert Reference Group (16), chaired by the National Clinical Director for Diabetes and Obesity at NHS England (this was the study Chief Investigator, Professor Jonathan Valabhji, up until September 2023). The specification included information provision to raise awareness of the benefits and types of lifestyle changes needed to achieve and maintain a healthy weight, exploration and reinforcement of participants' reasons for wanting to change and their confidence about making changes, goal setting, action planning, coping plans, and relapse prevention.

To date, provision for the NHS DPP has been re-commissioned every few years and is currently on its third framework. In 2021, the NHS England national team ran the latest national competitive process to re-select providers to deliver the NHS DPP. Potential providers were required to bid against criteria set by the national team, and submit their intervention models that were required to be in line with the national service specification. Bids were evaluated by an expert panel including representatives from NHS England and other key stakeholder organisations The five providers appointed to the framework were: Reed Wellbeing, Xyla, Thrive Tribe, Living Well Taking Control and Ingeus (although Ingeus is not currently delivering any contracts).

Local areas (ICBs) select the provider most suitable for their local population needs through a mini-competition process. Framework providers determine whether or not to submit a bid for the local area based on detailed information provided by each local area. NHS England representatives then chair a moderation session for each local area to support the local area members to evaluate the providers' bids against quality criteria submitted by the national team. The provider with the highest score would be awarded the contract for that area.

Each provider follows the same broad structure and following a pilot study performed 2017-2019 involving digital modes of delivery (17), each provider now offers a choice between group-based face-to-face delivery or digital delivery (18). Face-to-face delivery consists of 13 intervention sessions over the 9-month period, while digital delivery consists of 10 engagement periods, each lasting 30 days. Each provider must use a known framework for behaviour change and incorporate specific behaviour change techniques, such as setting goals for intended levels of physical activity.

Each provider will ensure that a multi-disciplinary team of health professionals or specialists relevant to the core components of the Service (i.e. preventing ill health such as cardiovascular disease, behaviour change, weight loss, diet, physical activity and mental wellbeing) is involved in development of the Services and the training of Staff. These must include, for example, a registered dietitian or a registered nutritionist, a registered health psychologist and a qualified physical activity instructor.

An independent evaluation has shown that where the programme was delivered between 2016 and 2018, there was a 7% lower incidence of type 2 diabetes at English population level, that individuals with NDH who were referred to the programme had a 20% reduction in type 2 diabetes incidence compared to those with NDH who were not referred and that individuals who completed the programme (defined as attendance of at least 60% of intervention sessions) had a 31% lower incidence of type 2 diabetes compared to those who did not complete the programme (19-21).

The NHS DPP may have benefits beyond the prevention of type 2 diabetes, given its focus on weight loss, physical activity and better nutrition. A retrospective observational cohort study was undertaken to assess the incidence of long-term conditions, including type 2 diabetes, up to 24 months after each participant's start of the NHS DPP (manuscript currently undergoing peer-review with Nature Medicine). Individuals who had been referred to the NHS DPP and completed the programme were compared to a matched group of individuals who were referred to the NHS DPP but did not attend any programme sessions (the control group). The analysis showed a significant association between completion of the NHS DPP and reduced incidence of some long-term conditions including some cardiovascular conditions. Whilst it was not possible to draw conclusions on the extent to which these were a direct consequence of attendance at the NHS DPP, it highlighted a potential signal around opportunities to prevent or delay

the onset of other long-term conditions by expanding access to a tailored NHS DPP for other cohorts, warranting further testing.

National Clinical Directors and clinical and policy leads across cardiovascular disease and diabetes in NHS England, considered a range of cardiovascular risk factors and conditions which could be piloted through a tailored NHS DPP for other cohorts. The consensus was to expand access to individuals with hypertension. This would require only limited changes to existing NHS DPP interventions. The four providers currently under commission delivering the NHS DPP have agreed to provide the infrastructure and opportunity to rapidly deliver tailored intervention pilots for individuals with hypertension.

There are 9 million people recorded with hypertension in England, 14.8% of the population (22). Individuals with hypertension are at higher risk of cardiovascular disease; approximately half of all strokes and coronary heart diseases are attributable to hypertension worldwide (23). Early diagnosis and effective treatment can prevent progression to cardiovascular disease. The National Institute for Health and Care Excellence recommends GPs to offer lifestyle advice to individuals with suspected or diagnosed hypertension, to help reduce their risk of developing obesity and cardiovascular disease (24).

4. OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

Objectives	**Outcome Measures/Endpoints**
Primary Objective	To evaluate the effectiveness of access to the intervention in reducing incidence of associated long-term conditions when compared to 'usual' care, in individuals with hypertension in any particular GP practice.
Secondary Objectives	To evaluate the effectiveness of access to the intervention in reducing the incidence of associated and not associated long-term conditions, when compared to 'usual' care, in individuals with hypertension in any particular GP practice.

Tertiary Objectives	To determine if, or the extent to which, the intervention supports individuals to achieve or maintain a healthy body weight. To determine if, or the extent to which, the intervention supports individuals to complete the programme, including across groups that share a protected characteristic.

5. STUDY DESIGN

The study will consist of a stepped-wedge cluster randomised controlled trial in 210 GP practices within eight Integrated Care Systems (ICSs) (i.e. an average of 26 GPs within each participating ICS) in England. The pilot will be over three years and additionally include a retrospective review of a 12-month period before initiation of access to the intervention, during which baseline data, including acquisition rates of long-term conditions in people with hypertension, will be assessed:

In the baseline period (12 months prior to study start), all individuals with hypertension from all 210 GP practices within the eight ICSs will receive usual care. Existing retrospectively collected data recorded in the National Bridges to Health Segmentation data will be assessed (for more information see section 9.3).

- In year one (1-12 months after study start), one third of all GP practices within each participating ICS will be randomised to access to the intervention for their patients with hypertension, and the remaining two thirds will be assigned to usual care for their patients with hypertension.
- In year two (13-24 months after study start), a further third of all GP practices within each participating ICS will be randomised to access to the intervention for their patients with hypertension (two thirds in total), and the remaining one third will be assigned to usual care for their patients with hypertension.
- In year three (25-36 months after study start), all participating GP practices within each ICS will be assigned to access to the intervention for their patients with hypertension.

The Healthier You Hypertension Pilot to Prevention Long-Term Conditions is a lifestyle behaviour change programme, over 9 months and 13 intervention sessions. Participants will be supported in setting appropriate goals to help lose weight if overweight or obese, or the maintenance of a healthy weight, as a result of improved diet and increased levels of physical activity. The intervention aims to empower

individuals to take a leading role in establishing and maintaining long-term behaviour changes. The same intervention, delivered by the same providers, has been part of routine clinical care for people with non-diabetic hyperglycaemia (prediabetes) for a number of years now in England, and there should be no additional risks or burdens for participants in the pilot compared to the burdens experienced by participants with prediabetes as part of this routine component of their care.

All eligible individuals with hypertension within GP practices that have been randomised to the intervention arm in year one, two and three, will be offered the opportunity to attend the intervention. Participating GP practices will use bulk mailouts to contact eligible patients in the first 3 months of the year. Individuals who take up this offer will be contacted by the programme provider to arrange an initial assessment, where further details of the programme will be given. They will be given the option to attend face-to-face sessions or digital sessions.

- Face-to-face sessions are 13 intervention sessions, with 16 hours of contact time
- Digital delivery consists of 10 engagement periods, each lasting 30 days.

Completion of the intervention is defined as attendance of at least 60% of intervention sessions (or engagement periods).

The following ICSs have confirmed interest in taking part in the pilot:

1. North West London,
2. Greater Manchester,
3. Herefordshire and Worcestershire,
4. Norfolk and Waveney,
5. Bedfordshire, Luton and Milton Keynes,
6. Leicester, Leicestershire and Rutland,
7. North East and North Cumbria and
8. South East London.

For the purpose of this project these 8 ICSs will be considered the research locations.

Each ICS will gather their own expressions of interest from GPs, ensuring they have the resources and capacity to support the pilot. Using data from the CVDPREVENT national audit (25) (derived from primary care electronic health records) the study team can derive precise estimates of the number of people with a coded diagnosis of hypertension within each potential participating GP practice.

5.1. Randomisation

A random number generator (RANDOM.ORG - True Random Number Service) will be used to create a random number for each GP practice within each ICS. GP practices within each ICS, will be ranked according to this assigned numerical value from highest to lowest and the first third within each ICS will be selected to be in the intervention arm during year one, and the second third within each ICS will be selected to be in the intervention arm during year two. All GP practices will take part in the intervention in year three.

6. PARTICIPANT IDENTIFICATION

6.1. Study Participants

Eligible study participants will be identified by their primary care team.

6.2. Inclusion Criteria

- Diagnosed hypertension
- Individuals aged 18 years or over
- Individuals who are aged 80 years and older are eligible to access the programme if their clinician referrer provides written confirmation to the Provider that the referrer perceives the benefits of the pilot outweigh any potential risks of participating in a weight loss programme for that individual

6.3. Exclusion Criteria

The participant may not enter the study if ANY of the following apply:

- Individuals with an existing or previous diagnosis of non-diabetic hyperglycaemia or type 2 diabetes at any time in the past
- Individuals with an active eating disorder
- Individuals with severe/moderate frailty as recorded on a frailty register
- Individuals who have undergone bariatric surgery in the last two years
- Individuals aged under 18 years
- Pregnant women

If an individual becomes pregnant whilst participating in the Service, the Provider must tailor the Service accordingly, following the specification set out in NICE Guideline PH27, for example adjusting any weight

loss goals. This guidance stipulates recommendations for diet, physical activity and weight management during pregnancy. This criterium has been operationalised since inception of the NHS Diabetes Prevention Programme in 2016.

7. STUDY PROCEDURES

7.1. Recruitment

Eligible participants will be identified in the following ways by a healthcare professional in their primary care team:

1. Opportunistic detection of hypertension
2. An NHS Health Check establishing a new diagnosis of hypertension
3. Identification of existing people with diagnosed hypertension on the GP register (known eligible individuals)

Once eligible individuals have been identified they should be offered a referral into the intervention.

7.2. Informed Consent

NICE Guidelines for the diagnosis and management of hypertension in adults suggest to “offer lifestyle advice to people with suspected or diagnosed hypertension” (24). As the pilot involves routine care following these guidelines, data collection will be undertaken though existing NHSE functions which allow data to be collected and used as required under the statutory duties outlined in the NHS Act 2006 and Health and Social Care Act 2012. Consent will therefore be sought from participating GP practices, rather than individual participants.

Participating GP practices are required by the General Data Protection Regulation (GDPR) to explain to eligible individuals how their data will be used at the point it is collected from them – i.e. before referring them. It is for individual GP practices to determine whether the personal data which needs to be transferred as part of that referral is done based on having obtained specific consent from each individual patient, or whether they are satisfied that the 'public task' and 'healthcare' conditions (Articles 6(e) and 9(h) respectively) for processing under GDPR apply such that consent is not required.

7.3. Potential risks and benefits

Benefits

For those who take part in the intervention, access to a lifestyle behaviour change programme, designed to support weight loss in those who are overweight or obese, to support better quality nutrition and to support increased physical activity.

Risks

Individuals who are aged over 80 years are at increased risk of sarcopenia and are only eligible to access the intervention if their clinician referrer at their GP practice provides written confirmation to the Provider that the referrer perceives the benefits of the intervention outweigh any potential risks of participating in a weight loss programme for that individual. This same process has been operationalised in the NHS Diabetes Prevention Programme and by July 2024, 98K individuals aged over 80 years had been referred to the programme, 5.8% of all referrals.

7.4. Screening and Eligibility Assessment

Eligible study participants will be identified by their primary care team and will be referred to the programme. Participants will then be invited by the provider to attend an Initial Assessment, at which their eligibility will be confirmed and they will be given more information about the programme.

7.5. Baseline Assessments

Participants will be invited to an Initial Assessment at which point their weight and height are measured. Participants will also be asked to complete a Recent Physical Activity Questionnaire (RPAQ) and to record their absolute number of step counts over a period of seven days following provision of the equipment required to measure this.

7.6. Subsequent Assessment

In every subsequent session attended the participant's weight will be measured and at the last intervention, participants will be invited to update the RPAQ questionnaire and number of step counts

7.7. Discontinuation/Withdrawal of Participants from Study

Individuals will be "Discharged" from the intervention in the following circumstances:

- If, after the Provider contacts an individual following referral, the individual does not respond to the Provider after one calendar month from referral provided that the Provider has made a minimum of three attempts to contact the individual and used various different communications channels.
- If an individual misses three consecutive face-to-face sessions for no known reason, and the Provider has offered appropriate remote catch-up sessions, and the Provider has made a minimum of three attempts to contact the individual since the last attended session, using at least two of the following means of communication: letter, phone call, text message or email
- For the Digital Service, where there is no recorded activity for three consecutive calendar months
- When an individual informs the Provider that they no longer wish to participate in the Service; and/or
- On completion of the Final Session (or once the Final Session has been delivered). Once the Final Session is completed then the individual is discharged automatically regardless of the number (or percentage) of sessions attended.

7.8. Definition of End of Study

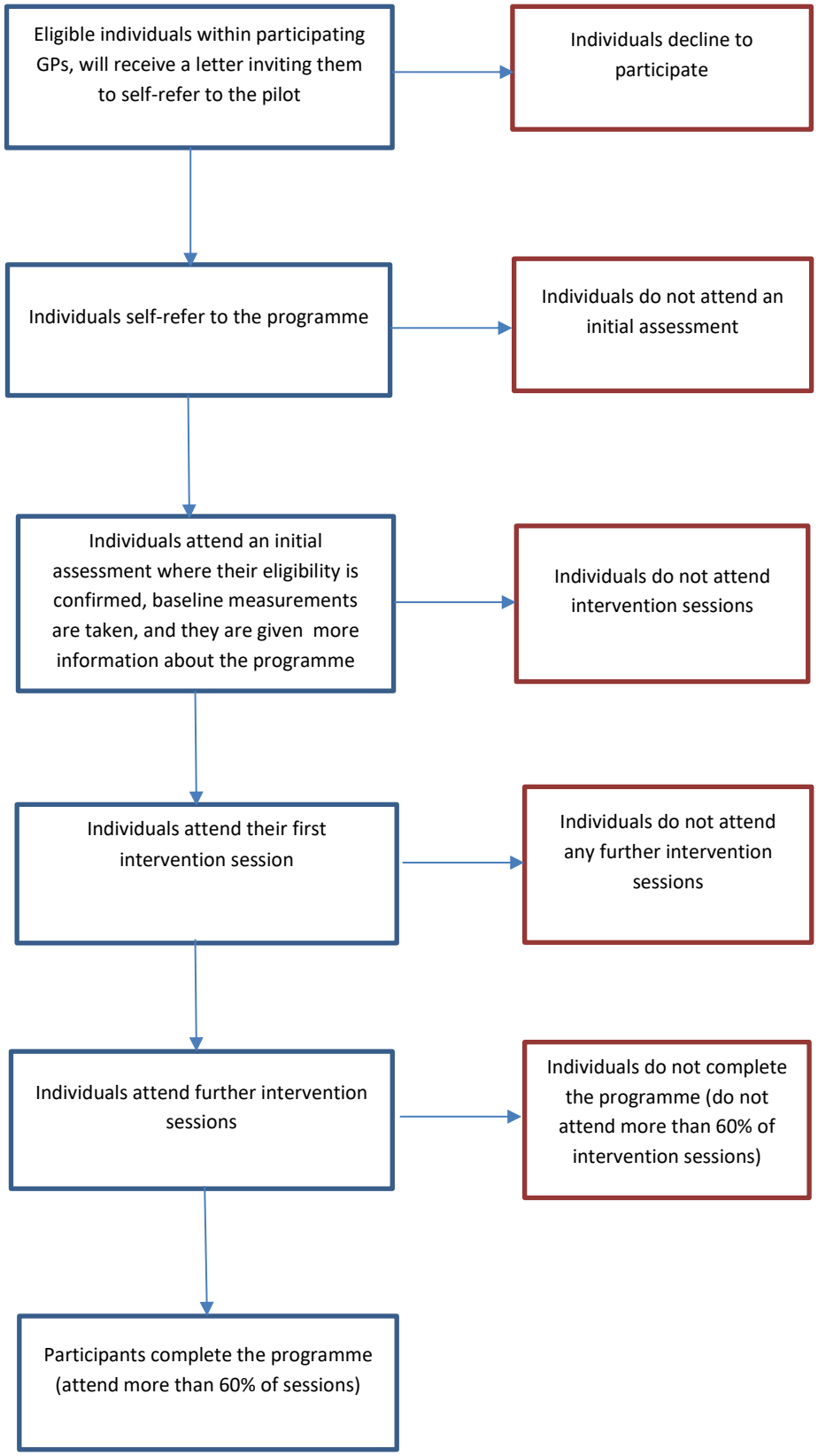
The end of the study will be 12 months after the last person starts the programme during year three.

7.9. Summary

Eligible study participants will be identified by their General Practice and will receive a letter inviting them to refer to the pilot. Depending on local agreements, individuals will refer to the programme, either by contacting the provider directly or by being contacted by the provider. They will then be invited by the provider to attend an Initial Assessment, at which their eligibility will be confirmed and they will be given more information about the programme. Individuals then start the intervention, attending 13 sessions over 9 months.

The flow chart below summarises each step of this process.

Flow chart with in each GP practice



8. INTERVENTIONS

Summary of intervention

The Healthier You-BP is a lifestyle behavioural intervention programme, over a 9-month period and will support and motivate individuals to reduce their risk of developing long-term conditions through weight loss, or maintenance of a healthy weight, through improved diet/nutrition and through increased levels of physical activity.

The Healthier You-BP is a development of the NHS DPP, which has been delivered in England since 2016 and is now part of routine care delivery for people with NDH/prediabetes. A summary of the minor differences in the service specifications between the NHS DPP and the hypertension pilot has been included (appendix 1).

Content of Service

Each Provider has already developed detailed content for the NHS DPP, covering information about the benefits of healthy lifestyles in preventing ill health and aiming to empower individuals to take a leading role in establishing and maintaining long-term behaviour changes. The content provides information and practical tools on nutrition, physical activity and weight management based on national guidance as set out below. The content in the Healthier You-BP will be enhanced to cover further information on the prevention of cardiovascular disease and other long-term conditions.

Dietary Content

As is the case for the NHS DPP, the design and delivery of the syllabus for the Healthier You-BP will be underpinned by the UK Government dietary recommendations as detailed in the Eatwell Guide and support weight loss for individuals who are overweight or obese, or the maintenance of a healthy weight in individuals of healthy weight. The Eatwell Guide shows the proportions on the main food groups that form a healthy balanced diet. This involves increased intake of fibre, fruit and vegetables and oily fish, and decreased intake of saturated fat, sugar, salt and energy:

- Eat at least 5 portions of a variety of fruit and vegetables every day
- Base meals on potatoes, bread, rice, pasta or other starchy carbohydrates; choosing wholegrain versions where possible
- Have some dairy or dairy alternatives (such as soya drinks); choosing lower fat and lower sugar options
- Eat some beans, pulses, fish, eggs, meat and other proteins (including 2 portions of fish every week, one of which should be oily)

- Choose unsaturated oils and spreads and eat in small amounts;
- • Drink 6-8 cups/glasses of fluid a day
- If consuming foods and drinks high in fat, salt or sugar have these less often and in small amounts.

The Provider will support individuals towards achieving the Government's dietary recommendations:

- Use dietary approaches that are evidence based and sustainable in the longer term
- Use motivational interviewing to support individuals in setting appropriate goals
- Individuals will be encouraged to set tailored and achievable short, medium and long term goals which help them to achieve their aims
- The Service must encourage self-monitoring to help individuals review their progress
- For individuals who are overweight or obese and therefore need to lose weight through calorie reduction, the Provider must ensure that this is achieved through the promotion of the balance of food groups as set out in the Eatwell Guide
- Dietary advice must reflect the culinary traditions of the communities in which the Service is being provided, without making assumptions about what individuals eat.

The Provider must also support individuals towards achieving the dietary recommendations in NICE NG136:

- Individuals should be encouraged to avoid excessive consumption of coffee and other caffeine-rich products
- Individuals should be encouraged to keep their dietary sodium intake low

Physical activity

As is the case for the NHS DPP, the Provider will support individuals who are not physically active, to aim to become active daily and minimise time spent being sedentary, with an aim of meeting or exceeding the England CMO recommendations for adults, older adults, disabled adults and pregnant and postpartum women.

For adults (19 to 64 years):

- For good physical and mental health, adults should aim to be physically active every day
- Each week, adults should accumulate at least 150 minutes (2 1/2 hours) of moderate intensity activity (such as brisk walking or cycling); or 75 minutes of vigorous intensity activity (such as running); or even shorter durations of very vigorous intensity activity (such as sprinting or stair climbing); or a combination of moderate, vigorous and very vigorous intensity activity.

- Adults should aim to minimise the amount of time spent being sedentary, and when physically possible should break up long periods of inactivity with at least light physical activity.

For older Adults (65 years and over):

- Older adults should participate in daily physical activity to gain health benefits, including maintenance of good physical and mental health, wellbeing, and social functioning.
- Each week older adults should aim to accumulate 150 minutes (two and a half hours) of moderate intensity aerobic activity, building up gradually from current levels. Those who are already regularly active can achieve these benefits through 75 minutes of vigorous intensity activity, or a combination of moderate and vigorous activity, to achieve greater benefits. Weight-bearing activities which create an impact through the body help to maintain bone health.
- Older adults should break up prolonged periods of being sedentary with light activity when physically possible, or at least with standing, as this has distinct health benefits for older people

Method of delivery

As is the case for the NHS DPP, and in line with NICE guidance (Behaviour change Digital and mobile health interventions, NG183), all individuals will be given a choice between Face-to-Face delivery and Digital delivery. Analyses of individuals who accessed digital interventions found that they were younger and achieved greater weight loss than had been previously achieved through face-to-face interventions, without any evidence of exacerbation of health inequalities (18).

Face-to-Face Service

As is the case for the NHS DPP, the Face-to-Face Service for the Healthier You-BP will be across 9-months and 13 intervention sessions with each session lasting between 1 and 2 hours. The minimum total contact time will be 16 hours.

Additional contact outside of the 13 sessions and minimum of 16 hours, to further engage and to encourage retention will be encouraged. Sessions will be offered in a format and at times that are appropriate to a range of diverse groups in the community and will include evening and weekend sessions to facilitate access for working people. The design of the Service will allow individuals to make behavioural changes gradually and throughout the 9-month duration. The Face-to-Face Service will be delivered using predominantly group sessions designed to be delivered to up to 20 Service Users in each group. Individual contact, in addition to the 13 sessions (either in person or remotely) may also be included to enhance delivery and retention.

Digital service

As is the case for the NHS DPP, digital interventions will consist of nine engagement periods, each lasting 30 days (270 days in total), in addition to digital registration. Engagement will be defined as a minimum of two episodes of active engagement within at least one of six categories of engagement in each 30-day period; communication with a health coach, accessing educational content, logging information against goals, peer support forum, use of interactive tools and time spent in the app.

Weight Loss and Measurement

The providers will collect weight data for all individuals. For the Face-to-Face Service, this must include a weigh-in or recording of a self-reported weight at every session. Data collection of weight measurements for the Face-to-Face Service will be objective and will not be self-reported and taken using appropriately calibrated scales. Scales must meet Class III criteria for levels of accuracy as per UK Weighing Federation guidance (http://www.ukwf.org.uk/res/medicalguidancenotes.pdf) and "Weight Management Interventions: Standard Evaluation Framework" (PHE 2018).

For the Digital Service: the Provider will request that individuals undertake baseline, 3-month, 6-month and 9-month weigh-ins to monitor progress. Where weight is self-reported by individuals as part of the Digital Service, steps to ensure consistency of measurement must be encouraged, for example, using the same scales for each measurement taken.

The Provider must also encourage individuals to use regular weigh-ins as part of self-monitoring. The Provider will ensure that achievable goals for weight loss (for people who are overweight or obese) are agreed and design approaches to support individuals to reduce their calorie intake. A calorie limit of no more than 1,900kcal for men and 1,400kcal for women should support weight loss at a rate of 0.5kg-1kg each week but calorie limits must take into account individual circumstances, such as physical activity level. Weight loss of 5-10% of baseline weight should be used to support individuals who are overweight or obese to understand how much weight loss is required to achieve health benefits and to set achievable targets. Approaches need to support longer term sustainable behaviour change in order to maintain target weight

The Provider will ensure that individuals who are not overweight or obese are not encouraged to lose weight but are supported to maintain a healthy weight in line with NICE Guideline NG7, and that weight loss advice for older individuals manages any risk of Sarcopenia.

The Provider must consider making reasonable adjustments for individuals with a learning disability. Public Health England guidance (Obesity and weight management for people with learning disabilities.

PHE, 2020) states that people with learning disabilities may require alternative methods of weight measurement due to chronic constipation and/or atypical body shape. The Provider must work with the local health system to determine the best process for measuring weight where the mainstream method is not appropriate.

All of these methods of weight recording and of support for weight loss and weight maintenance for both face-to-face and digital modes of delivery, have already been operationalised over a number of years as part of the NHS Diabetes Prevention Programme.

Health inequalities

The Provider most aim to ensure equal access by all individuals, reduce health inequalities and promote inclusion, tailoring the services to support and target those with greatest need through a proportionate universalism approach and equality of access for people with protected characteristics under the Equality Act 2010.

The Provider must be flexible and tailor the service to individual's needs, including, age, physical wellbeing or frailty, weight, personal goals, cultural considerations and culinary traditions. The Provider must also provide culturally sensitive services, ensure access for people who have a physical or mental impairment, have access to appropriate interpreter services and ensure services are accessible to wheelchair users and others with a physical disability. It must also be available for people with low literacy levels, sensory impairment and learning disability and must welcome carers where needed.

9. STATISTICS AND ANALYSIS

9.1. Description of Statistical Methods

All eligible individuals with hypertension from each cluster (GP practice) will be included in the analyses, i.e. an Intention-to-treat based approach. Negative binomial regression models will be used to estimate the association between access to the intervention and the number of new associated conditions at 12-months adjusting for age, sex, ethnicity, deprivation and number of baseline conditions.

Statistical significance will be defined as p-value <0.05.

9.2. The Number of Participants

The sample size required was calculated using the Stepped Wedge Group-Randomised Trials calculator available on the National Institutes of Health website (26). To estimate the parameters required for the

calculator, observational data from the National Bridges for Health Segmentation dataset for individuals with a recorded diagnosis of hypertension within the participating ICSs, was used. For more details on this dataset see section 9.3. Of those with a diagnosis of hypertension recorded in the National Bridges for Health Segmentation dataset in England in 2017/18, 10.80% developed at least one associated condition during the one-year follow up. The intra-correlation coefficient, cluster auto-correlation and within-individual intra correlation were estimated using the methodologies outlined in Ouyang et al (27). Assuming an average of 550 potential participants with hypertension within each GP practice with an incidence rate reducing from 10.80% to 10.26% (which equates to a 5% effect size), an intra correlation coefficient of 0.0012, a cluster auto-correlation of 0.6525 and within-individual intra correlation of 0.0420, would require a minimum of 210 clusters (in total) to achieve 80% power at a 5% significance level.

In a recent post-hoc retrospective study, individuals who completed the DPP were matched to individuals who were referred to the DPP but didn't attend. The study found that the reduced incidence of other associated long-term conditions was around 70% the size of the reduced incidence of type 2 diabetes in those that completed vs those that didn't attend. Given that the NHS DPP was associated with a reduced incidence of type 2 diabetes at population level of around 7% (15), the study has been powered for a 5% reduction (70% of 7%) in other associated long-term conditions at population level.

9.3. Analysis of Outcome Measures/Endpoints

The primary outcome measure will be the incidence of associated long-term conditions in individuals with hypertension receiving care within a participating GP practice at the end of each year in the study period. The secondary outcome measure will be the incidence of long-term conditions (associated and not associated conditions) at the end of each year in the study period. In subgroup analyses of those who are referred to the pilot: weight change, completion and incidence of associated conditions will be measured.

For a full list of associated and not associated conditions, see appendix 2.

Datasets

The outcomes will be measured through the Healthier You Minimum Dataset (MDS) and National Bridges to Health Segmentation Dataset, both to be made available in the Unified Data Access Layer (UDAL) in NHS England.

The Healthier You: Minimum Dataset

The Healthier You MDS is currently collected for all individuals referred to the NHS DPP. NHS DPP providers are contractually required to capture data relating to individuals that are referred to the programme. This includes socio-demographic information, including protected characteristics, as well as records of attendance and outcomes achieved during the intervention. The same data collection will be extended to the Healthier You-BP, with one additional item collected: confirmation of diagnosis of hypertension.

A full list of items collected has been included for information (appendix 3).

The Bridges to Health Segmentation dataset

The Bridges to Health Segmentation dataset is an existing dataset within NHS England that has been produced, maintained and updated regularly since 2019 to support operational functions, care planning and improvement and service evaluation within NHS England (28). The segmentation dataset has been derived from a number of national, predominantly secondary-care, patient-level datasets included in the Unified Data Access Layer (UDAL). The full list of source datasets used to derive the Segmentation dataset, including the time over which data have been longitudinally accrued, have been included for information (appendix 4). The Segmentation dataset includes 35 long-term conditions, the process for selection of which has been outlined previously (29, 30, 31). The Segmentation dataset will be used to assess the number of new associated and not associated long-term conditions that have developed over each year in the study period.

Limitations

Ascertainment of long-term conditions in the Bridges to Health Segmentation dataset is currently derived predominately from hospital and community datasets, rather than general practice: this particularly affects ascertainment of chronic kidney disease, depression and hypertension. However, CVDPrevent (25), a national primary care audit, extracts routinely held GP data on cardiovascular disease, including hypertension and chronic kidney disease and will shortly be added to the Bridges to Health Segmentation dataset (in time for the start of the evaluation).

10. DATA MANAGEMENT

10.1. Access to Data

The Healthier You MDS and the Bridges to Health Segmentation Dataset will be stored in UDAL - a data environment in NHS England which stores data without providing any mechanism for users to relate data records back to known individuals, thus providing an anonymised dataset according to the terminology of the GPDR (" the data is held in a secure de-identified data environment under NHS England's control, which is technically and organisationally segregated from the data environments in which any source identifying data is contained" (32)). Only users that require access to the data, will have access to the data. Creation of UDAL accounts and access to specific datasets within the UDAL environment must be approved by line managers and the data operations team led by the Information Asset Owner and must give justification for access. The UDAL account holder must confirm that mandatory Information Governance training is complete and up to date, and that they will adhere to all relevant IG rules and guidelines, as well as the requirements of the Data Protection Act 1998 and the General Data Protection Regulation (GDPR) and that, in line with acceptable use policy, no record level data will be copied out from the data store. All users must have a contract or honorary contract with NHS England.

11. ETHICAL AND REGULATORY CONSIDERATIONS

11.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

11.2. ICH Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in conformity with relevant regulations and with the principals of ICH Guidelines for Good Clinical Practice.

11.3. Approvals

All relevant documentation will be submitted to the NHS Research Ethics Committee (REC).The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

11.4. Reporting

An End of Study notification and final report will be submitted to the same parties. Findings will be reported in peer-review scientific journals, through conference presentations and through communications to all participating GP practices. The study will be registered to clinicaltrials.gov.

12. FINANCE AND INSURANCE

12.1. Funding

Planned NHS England funding for the proposed Healthier You-BP pilot is around £14M over three years. This requires complementary Applied Research Collaboration funding for support for the trial sponsor, a fulltime quantitative evaluation researcher and a full-time qualitative evaluation researcher also providing project management support.

12.2. Insurance

Chelsea and Westminster Hospital NHS Foundation Trust has appropriate indemnity arrangements in place.

13. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

Any published analyses will supress small numbers (1-4).

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15. AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1	2.1	11/Aug/2025	Emma Barron	Added in details of providers delivering the intervention Change in study title Added in a summary paragraph to section 7 and moved flow chat from section 5 to section 7.