Physical Activity for health in South Asian Men with Prostate Cancer: A feasibility study

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KEY TRIAL CONTACTS

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Committees:	Trial Management Group Trial Steering Committee Patient Advisory Group
Trial Management	Bristol Biomedical Research Centre
Web address	https://www.bristolbrc.nihr.ac.uk/research/research-projects/developing-a-physical-activity-intervention/

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1 FUNDING AND SUPPORT IN KIND

FUNDING AND SUPPORT IN KIND	**Financial and non-financial support given**
NIHR BRISTOL BIOMEDICAL RESEARCH CENTRE Population Health Sciences, Bristol Medical School, University of Bristol Oakfield House Oakfield Grove Bristol BS8 2BN Email: bristolbrc@nihr.ac.uk	Grant funding, methodological expertise and trial management
UNIVERSITY OF BRISTOL Research Governance Team, Division of Research, Enterprise & Innovation University of Bristol, Augustine's Courtyard, Orchard Lane, Bristol BS1 5DD Email: research-governance@bristol.ac.uk Telephone: +44 (0)1173940177	Sponsorship

2 GLOSSARY OF ABBREVIATIONS

AE	Adverse Event
B-IPQ	Brief Illness Perception Questionnaire
BMI	Body Mass Index
BRC	Biomedical Research Centre
CI	Chief Investigator
CRF	Case Report Form
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICH	International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use
ICIQ-MLUTS	Urinary symptoms International Consultation on Incontinence Questionnaire Male Lower Urinary Tract Symptoms Modules
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trials Number
MetS	Metabolic syndrome
NHS R&D	National Health Service Research & Development
PA	Physical Activity
PI	Principal Investigator
PIS	Participant Information Sheet
PSA	Prostate Specific Antigen
QA	Quality Assurance
QC	Quality Control
RCT	Randomised Control Trial
REC	Research Ethics Committee
SA	South Asian
SAE	Serious Adverse Event
SDV	Source Data Verification
SOP	Standard Operating Procedure
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

3 TRIAL SUMMARY

Trial Title	**Physical Activity for health in South Asian Men with Prostate Cancer: A feasibility study**
Short title	**Physical Activity in South Asian men with prostate cancer/ Pro-SAPA**
Chief Investigator	Professor Athene Lane
Trial Design	Multi-centre, single-arm, open-label feasibility trial
Trial Participants	South Asian men with prostate cancer
Sample size	30
Number of study sites	2
Intervention	Physical activity: brisk walking
Treatment duration	3 months
Inclusion criteria	• Adult men (≥18 years) • Previously diagnosed or newly diagnosed with localised or locally advanced prostate cancer • South Asian heritage • Capacity to give informed consent
Exclusion criteria	• Inability to give informed consent • Identified as unsuitable to participate by their clinician, e.g. due to co-morbidities, treatment being received or any other contra-indications to exercise • Use of a mobility aid other than a walking stick, which would prevent the brisk walking intervention
Primary objectives	To assess the feasibility of recruiting men of South Asian heritage with prostate cancer to a physical activity intervention and adherence to the intervention, and to explore the beliefs and experiences of those men regarding the disease, diet and lifestyle interventions to inform prevention, treatment, and future intervention development.
Primary outcomes	• Participant recruitment rate • Adherence to the intervention

Secondary objectives	• To determine how the intervention is implemented by study participants • To assess rates of retention in the study • To assess completeness/feasibility of data collection of physical activity/intensity through pedometer/accelerometers and participant reporting • To assess completeness/feasibility of data collection of participant-reported measures, including symptoms and quality of life, and Prostate Specific Antigen (PSA) • To look at acceptability of diet, lifestyle, and physical acitivity interventions to participants and clinicians • To look at acceptability of the trial procedures including reasons for participants declining the trial • To utilise physical activity data and other measures to inform the design of a larger trial
Internal pilot	N/A
Study duration	Start date: 01/09/2025 Anticipated duration: 16 months Anticipated end date: 31/01/2027

3.1 Plain English Trial summary

Prostate cancer is the commonest male cancer with over 50,000 men diagnosed each year in the UK. Studies have shown that different ethnic groups are more or less likely to develop prostate cancer, with South Asian men less likely to develop prostate cancer than white men. This suggests that being South Asian is a protective factor in whether men develop prostate cancer. However, a higher proportion of South Asian men are diagnosed with advanced prostate cancer and die from prostate cancer than non-South Asian men.

This research aims to investigate a physical activity intervention of brisk walking in men of south Asian heritage who have been diagnosed with prostate cancer. The study will look at the acceptability of the brisk walking intervention (30 minutes a day, on 5 days a week) across two hospitals, and the feasibility of later conducting a larger clinical trial to look at whether the brisk walking intervention improves health. Men will be asked to complete the brisk walking intervention for three months and will receive support to motivate them to do so. They will complete questionnaires and logs to record their step count for 1 week when they join the study, and then at 6 weeks, 3 months and four months after they start the intervention (participants may choose not to start immediately after providing consent. In this case, an alternative start date will be agreed upon if necessary). Information will also be collected from their medical records and through focus groups to find out how they felt about the physical activity. Interviews will also be carried out with some clinicians at the two hospitals to find out how they felt about the physical activity intervention. Additionally, participants will be invited to participate in interviews (or focus groups depending on the participants' preference) to gain insight into their beliefs about and experiences with prostate cancer, and diet and lifestyle interventions that may help with prevention or management of the disease. The main aims of the study are to see whether men

are willing to join the study, and whether they stick to doing the physical activity. Overall, the study will help determine if the intervention shows potential promise and a larger study is worthwhile.

4 BACKGROUND AND RATIONALE

4.1 Evidence explaining why this research is needed now

Prostate cancer is the commonest male cancer with over 50,000 men diagnosed each year in the UK (1). Emergent evidence has shown prostate cancer incidence to differ among ethnic groups. A UK population-based study showed that African-Caribbean men had a three times greater risk of prostate cancer compared to European men, with a much lower incidence rate in South-Asian men (2). Subsequent epidemiological studies have shown the incidence rates of prostate cancer to be significantly lower in South-Asian men compared to white men (3, 4) suggesting being South-Asian is a protective factor to prostate cancer. However, a higher proportion of South-Asian men are diagnosed with advanced prostate cancer (5) and have higher prostate cancer-specific mortality compared to non-South-Asian men (6, 7).

South-Asians are also at higher risk of metabolic syndrome (MetS), a condition characterised by a combination of risk factors that increase the risk of chronic diseases, such as cardiovascular disease and diabetes. A UK population-based study reported the prevalence of MetS to South-Asian men to be higher (46%) compared to African-Caribbean and white European men (27% and 19%, respectively) (8). Risk factors associated with higher prevalence of chronic disease in South Asians compared to other ethnic groups are not well-understood. However, observational studies suggest there to be higher levels of obesity (9), which are likely to contribute to higher levels of MetS. Furthermore, UK South-Asians have been shown to be less physically active than the white British population (10), which is associated with increased risk of diabetes (11), hypertension, and breast cancer in South-Asian populations (12). Observational studies have shown that moderate to vigorous physical activity is associated with a reduced risk of biochemical recurrence and mortality in men with non-metastatic prostate cancer (13, 14). However, these findings are reported from mostly white populations and, therefore, are not representative of the effects of physical activity in South-Asian men with prostate cancer.

Several systematic reviews have been conducted that have assessed home and/or community-based physical activity in South-Asians on a range of different outcomes, including breast cancer (12). The most recent review of randomised controlled trials (RCTs) showed that South-Asian men would benefit from structured, culturally adapted, aerobic physical activity using a behaviour component, such as goal setting, delivered in groups in the community (15). These findings are supported by previous systematic reviews, which recommend using prior qualitative work with South-Asian communities to inform intervention development, including the use of theoretical models and robust study designs (16, 17). At present, no study has been identified that has developed a physical activity intervention in South-Asian men with prostate cancer. Existing evidence cited above recommends studies to co-produce physical activity interventions with South-Asian participants to identify the social and cultural adaptations required to make these interventions feasible and acceptable. Our previous workstream of twenty interviews with South Asian men with/without prostate cancer, and co-production workshop have identified walking as their preferred type of physical activity. It also highlighted the need to embed motivational techniques such as peer and community support to encourage men to adhere to their new regime of physical activity.

5 PLANNED INTERVENTION

5.1 Physical activity intervention

Research nurses at the two sites will be trained to introduce the physical activity intervention to trial participants when they attend the hospital for their baseline visit, or at an agreed alternative start date should the participant choose not to start the intervention immediately after providing consent.

Participants will be instructed to walk at a brisk pace for 30 min (3 miles per hour), on 5 days a week, on top of normal physical activity. They will be provided with an optional wrist/waist worn activity monitor (e.g. pedometer/accelerometer) to monitor number of steps and intensity for three months, the duration of the brisk walk intervention (a document with instructions for use will be provided to participants by the research nurse or research team if needed). Participants will also be asked to record their daily step count and time spent exercising (and to wear their pedometer/accelerometer for at least these periods if using) for a 1 week period at baseline, 6 weeks follow-up, and 3 months follow-up, as well as at one month after the end of the intervention period (4 months follow-up).

Participants will also be offered the option of indoor exercises if they are unable to do brisk walking outside (for example, during winter months). This will include a 10-min step workout to conduct indoors. This exercise routine is designed to be of similar intensity to brisk walking and safe to perform at home. Participants will be advised that these exercises should be repeated three times a day (30 min in total). Additionally, if exercise classes are available that the study can link to and offer to participants, that will be another option. Overall, participants will be instructed to do at least 2.5 hours a week (30 minutes over 5 days) of moderate intensity physical activity.

5.2 Strategies to improve adherence to interventions

Participant-facing documents, including the intervention instructions, have been developed in line with the Behavioural Change Wheel model (BCW), which is a method for characterising and designing behaviour change interventions (18). Findings from our previous workstream to explore barriers and facilitators to physical activity among South-Asian men with prostate cancer or at risk of prostate cancer, have identified Automatic Motivation and Social Opportunity (from the Capability, Opportunity, Motivation to Behaviour model (COM-B) of the BCW, involving six sources of behaviour : physical capability, psychological capability, social opportunity, physical opportunity, reflective motivation and automatic motivation) as two behavioural elements that encourage initiation and adherence to a physical activity in the target group. Subsequent co-production workshops with the study participants have identified Persuasion and Enablement as intervention functions. Intervention functions refer to the function of the intervention that is likely to be effective in changing the target behaviour. Persuasion is defined as “Using communication to induce positive or negative feelings or stimulate action”, and Enablement is defined as “Increasing means/reducing barriers to increase capability or opportunity” (18). These functions can be delivered via different techniques. These are called Behaviour change techniques. Additionally, behavioural change techniques were also explored with the participants. Several techniques for improving intervention adherence (of the BCW) were endorsed including credible source (e.g. Health Care professional delivering the intervention message), information about health consequences (e.g. what the health benefits are for doing an intervention, and what the disadvantages are of not doing more exercise), goal setting (behaviour) (e.g. defining a target of 30 min walking every day), self-monitoring of behaviour (e.g. giving the participant a step count device and a from for recording daily total number of steps), and social support (e.g. friends, relatives, buddies providing encouragement directed at the behaviour).

-Credible source and information about health consequences:

The contact with participants will be initiated by a member of their clinical care team, followed by a conversation with a research nurse. Usual care often encourages patients to increase their level of physical activity and brief on the benefits of physical activities on improving prostate cancer treatment outcomes and survival. Our invitation materials will also provide relevant information on the health consequences of increasing physical activity for prostate cancer patients.

-Goal setting (behaviour) and action planning: participants will be asked to do a 30 min (3 miles per hour), 5 days a week, brisk walking activity (or indoor equivalent). Participants will also be encouraged to plan their walking route and the time at which they will do their exercise. Plans for indoor alternatives when they are unable to do walking outside will also be discussed.

-Self-monitoring of behaviour: participants will be given optional use of an activity monitor (e.g. pedometer/accelerometer) which will link to an app. Another option will be to offer the participants a web or phone application called Steps4Health, https://www.steps4health.org.uk/ developed by University of Leicester, which uses a personalised approach to support people wanting to become more physically active or living with a long-term health condition improve their 24-hour physical behaviours. Participants will be able to choose their preferred method. Additionally, participants will be given a form to record their daily step count and time spent exercising for a 1-week period at baseline, 6 weeks and 3 months follow-up, as well as one month after the end of the intervention period (4 months).

-Social support: participants may wish to find an "exercise buddy". This could be a family member, or a friend . Optional weekly motivational messages will be provided for participants (via text message, WhatsApp message, email or phone call, depending on the participant's preference), which will be available in key languages, to encourage adherence to exercise. Monthly coffee catch-up meetings with other participants and the researcher will be offered during the intervention period. Participants will also be signposted to local community groups that provide health and care services to South Asian men.

6 RESEARCH QUESTIONS, OBJECTIVES AND OUTCOMES

6.1 Research questions

The primary research aim is to establish if a physical activity intervention for men of south Asian heritage with prostate cancer is acceptable and feasible for a larger scale RCT.

6.2 Primary objective

- To assess the feasibility of recruiting men of south Asian heritage with prostate cancer to a physical activity intervention and adherence to the intervention.
- To gain insight into South Asian heritage men's beliefs on and experiences with prostate cancer, and diet and lifestyle interventions for disease prevention and management.

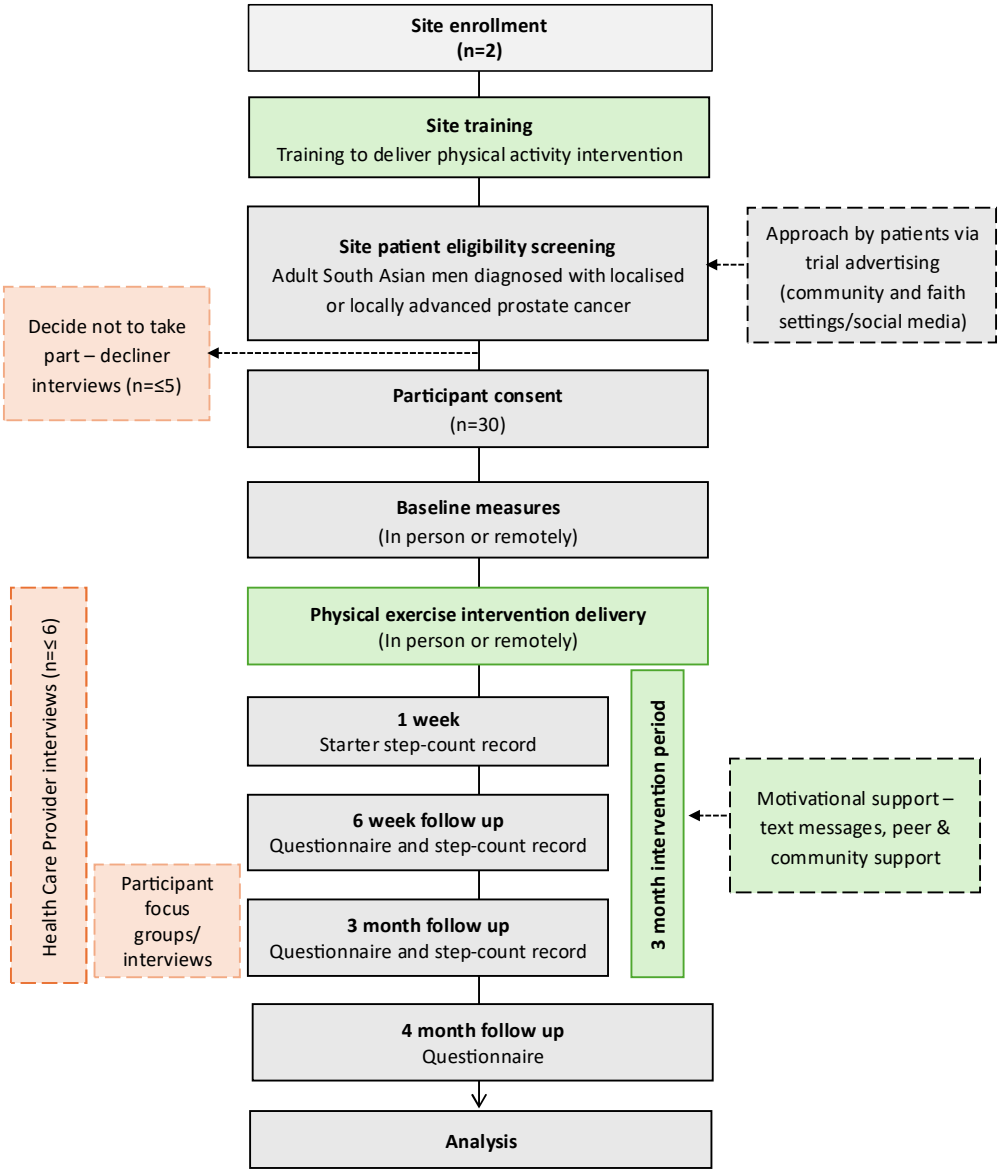
6.3 Secondary objectives

- To determine how the intervention is implemented by study participants
- To assess rates of retention in the study
- To assess completeness/feasibility of data collection of physical activity/intensity through pedometer/accelerometers and participant reporting

- To assess completeness/feasibility of data collection of participant-reported measures, including symptoms and quality of life, and Prostate Specific Antigen (PSA)
- To look at acceptability of diet, lifestyle, and physical activity interventions to participants and clinicians
- To look at acceptability of the trial procedures including reasons for participants declining the trial
- To utilise physical activity data and other measures to inform the design of a larger trial

7 TRIAL DESIGN AND SETTING

7.1 Trial schema


Site enrollment
(n=2)
Site training
Training to deliver physical activity intervention
Site patient eligibility screening
Adult South Asian men diagnosed with localised or locally advanced prostate cancer
Approach by patients via trial advertising (community and faith settings/social media)
Decide not to take part – decliner interviews (n=≤5)
Participant consent
(n=30)
Baseline measures
(In person or remotely)
Physical exercise intervention delivery
(In person or remotely)
Health Care Provider interviews (n=≤ 6)
1 week
Starter step-count record
6 week follow up
Questionnaire and step-count record
3 month intervention period
Motivational support – text messages, peer & community support
Participant focus groups/ interviews
3 month follow up
Questionnaire and step-count record
4 month follow up
Questionnaire
Analysis

7.2 Trial design

Multi-centre, single arm, open-label feasibility trial in patients of south Asian heritage with prostate cancer.

7.3 Setting

Participants will be recruited from two sites:

1. The urology department at the Bradford Royal Infirmary, Bradford Teaching Hospitals NHS Foundation Trust. Bradford has a large South-Asian population with 32.1% identified as Asian or British Asian (2021 census). This study is being conducted in collaboration with Bradford Institute of Health Research who have experience, skills, and methodologies with working with South-Asian communities.
2. The urology department at Southmead hospital, North Bristol NHS Trust. Bristol has a smaller South-Asian community with 6.6% identified as Asian or Asian British (2021 census).

7.4 Trial population

Adult men ≥18 years who have been diagnosed with localised or locally advanced prostate cancer of South Asian heritage residing in the Bradford and Bristol areas.

7.4.1 Eligibility criteria

7.4.1.1 Inclusion criteria

Participants may enter the study if ALL of the following apply:

- Adult men (≥18 years)
- Previously diagnosed or newly diagnosed with localised or locally advanced prostate cancer
- South Asian heritage
- Capacity to give informed consent

7.4.1.2 Exclusion criteria

Participants may not enter the study if ANY of the following apply:

- Inability to give informed consent
- Identified as unsuitable to participate by their clinician, e.g. due to co-morbidities, treatment being received or any other contra-indications to exercise
- Use of a mobility aid other than a walking stick, which would prevent them from carrying out the brisk walking intervention

7.4.2 Co-enrolment in other research studies

Participants may enrol in other studies if they allow the physical activity intervention to be undertaken and if they do not relate to an alternative physical activity intervention.

7.5 Outcomes

7.5.1 Primary outcome

The primary outcomes are:

1. Recruitment rate calculated as the proportion of eligible men who agree to participate in the trial

2. Adherence to the intervention at three months post-intervention start, measured by activity monitor or participant report during the 3-month intervention period

7.5.2 Secondary outcomes

The secondary outcomes are:

1. Level of physical activity during the intervention, measured by Godin Exercise Leisure-time questionnaire, pedometer/accelerometer and participant-reported data.
2. Trial retention measured as the number of participants completing 4 month follow up as a proportion of those consented into the trial
3. Data completeness of physical activity measures over the 4 month follow up through pedometer/accelerometer use and participant reporting
4. Data completeness of participant-reported questionnaire data (measured at baseline, 6 weeks, 3 and 4 months post-intervention start), as listed below:
    i. Godin Exercise Leisure-time questionnaire
    ii. Urinary symptoms International Consultation on Incontinence Questionnaire Male Lower Urinary Tract Symptoms Modules (ICIQ-MLUTS)
    iii. Health-related Quality of life: EQ5D-5L
    iv. Health beliefs: Brief Illness Perception Questionnaire (B-IPQ)
    v. Self-efficacy for exercise
    vi. Participant lifestyle factors e.g. smoking and drinking
    vii. Weight and body mass index
5. Harms of intervention: adverse reactions reported by participants e.g. falls or musculoskeletal problems
6. Availability of PSA levels from routine clinical records (baseline and post intervention at nearest time point of measurement)
7. Attitudes and views of participants about prostate cancer, and diet, lifestyle, and physical activity interventions through interviews/focus groups at some point during the intervention.
8. Attitudes and views of clinicians at the participating sites through qualitative interviews
9. Attitudes and views of participants who declined the trial

7.5.3 Target sample size

The study will aim to recruit 30 participants to the physical activity intervention at two sites. The sample size is based on recommendations for feasibility trials which aim in part to provide a standard deviation estimate for use in a sample size calculation for a larger RCT.(19) We anticipate a recruitment rate of about 25% based on a previous physical activity trial in men with prostate cancer .(26)

7.6 End of trial

Participants end their involvement with the trial when their last planned interaction with the study is complete at the questionnaire completed four months post-intervention start (or efforts to complete this have been unsuccessful), or they have discontinued their participation in the study.

The end of trial will be when the last participant has completed their involvement with the trial, all data collection is complete and any data queries have been resolved, the database has been locked, and subsequent planned data analyses have been completed.

8 TRIAL PROCEDURES

8.1 Trial advertising

Posters/leaflets highlighting the study will be placed in the urology reception areas at the two hospital sites, community and faith settings e.g. mosques, and distributed by social media to south Asian focused organisations, charities and social groups in Bradford and Bristol.

8.2 Screening and identification of participants

Participants will be identified from patient lists and outpatient clinics by their clinical team at the two participating urology departments, and eligibility will be assessed by a delegated member of the clinical team. Men meeting the eligibility criteria who have been diagnosed with localised or locally advanced prostate cancer will be invited to participate in the trial. All screened patients will be documented in a screening log to capture reasons for ineligibility, non-approach and non-consent without identifiable data e.g. name (see section 8.3). Participants will have a range of times from receiving their diagnosis, as there will be some men up to a year post-treatment in follow up clinics and some newly diagnosed. For those newly diagnosed there will be several weeks before they are approached due to clinical investigations for treatment determination. Men will be approached for the study after radical treatments when clinically deemed suitable so likely some months following a diagnosis.

Eligible patients will be provided with an invitation letter and participant information sheet_of the trial ,by the clinical team either by post (followed up with a phone call), or in person in clinic. Patients who express an interest in taking part in the study will then be contacted by a research nurse or other delegated team member with the appropriate training and competency (hereafter referred to as “research nurse” for brevity), or can contact the research nurse or the study team directly through the details provided in the PIS. The research nurse will explain the study, answer any questions the participant may have, and check their eligibility before arranging for informed consent to be received. In addition, patients viewing trial advertising materials at community and faith settings and via local social media groups may contact the research team directly. Eligibility of all potential participants will be assessed by their hospital clinical team before recruitment to the trial.

The trial consent form has an optional clause where participants can consent to being contacted for future research, including interviews/focus group discussions. Consenting participants will be provided with a participant information sheet for the qualitative interviews/focus group discussions and a qualitative consent form (both documents will be available in English as well as Urdu), either by post or in-person at the clinic. Those who consent to the interviews/focus group discussions will be invited by the research team at some point during the intervention period to take part in interviews or focus group discussions, in-person or virtually; the discussions will explore their experiences of the brisk walking intervention, their beliefs and experiences related to prostate cancer, as well as diet and lifestyle interventions that may support prevention or management of the disease.

8.3 Inclusivity

The aims and design of this feasibility study focus on inequalities in prostate cancer outcomes in an ethnic minority group, South Asian men. The study will capture diversity in the men recruited to inform design of the full trial. Translation to key languages will be available as required to aid recruitment of the intended population.

All screened patients will be documented in a screening log which will capture age, ethnicity, a partial postcode to calculate deprivation, and time since diagnosis to monitor the inclusivity of screening and recruitment. Screening data provided to the central trial team will have all patient identifiers removed, with age reported as bands and partial postcodes.

8.4 Consent

The research nurse at the hospital site will receive written informed consent from men wishing to take part in the trial during an in-person visit, once fully informed as to what participation in the study entails. Participants will have previously received a copy of the PIS and had time to consider the information provided. The research nurse will: 1) check that participants have read the Participant Information Sheet, 2) provide them with the opportunity to ask any questions they have about the study, 3) offer to read through the Participant Information Sheet and Consent Form to check their understanding of the study and their participation, and 4) ask participants if they agree to take part. If they agree, participants will be asked to complete and sign the Consent Form before participating. The consent form will include optional clauses for taking part in study focus groups, and for contact at a future date for future research. If participants are unable to attend an in-person meeting, the research nurse will arrange an online meeting or a phone call and follow the same procedure for obtaining consent as described above. The consent form will then be sent by post to the participant to sign and return in a pre-paid envelop.

Participant GPs will be informed subsequently by the central study team by letter about the patient's participation in the trial. All men who enter the study will be logged with the central trial office at the University of Bristol (UoB) and given a unique Study Number.

Patients who decline to participate in the trial will be offered participation in a decliner interview. Interested patients will be provided with a Participant Information Sheet with informed consent received by the research nurse following a procedure similar to the above.

Interview participants who are Health Care Providers will be provided with a Participant Information Sheet with informed consent received by the research team.

8.5 Schedule of assessments and data collection

Baseline data will be collected at an in-person visit with the research nurse following written informed consent (received at the same visit). If participants are unable to attend in person, the baseline questionnaire will be posted or sent electronically for completion. Clinical data will be collected from the participant's medical records by the research nurse or PI e.g. PSA results, and participant-reported data will be collected via questionnaire given to the participant during the visit. Participants will complete follow up questionnaires at 6 weeks, 3 months and 4 months post-intervention start. Participants will also complete 1 week step count logs at these follow up timepoints and at baseline. Questionnaires and logs can be completed by post, online or over the telephone with a researcher. Up to three contact attempts will be made to remind men to complete their step count logs and questionnaires at each time point if not received, via phone/ text/ whatsapp/email/ post.

8.5.1 Trial assessments

	ENROLMENT/ BASELINE	**POST-INTERVENTION START**		
TIMEPOINT	**T0**	**6 weeks**	**3 months**	**4 months**

ENROLMENT:				
Eligibility screen	●			
Informed consent	●			
INTERVENTIONS:				
Pro-SAPA exercise intervention	◄	———	——— ►	
ASSESSMENTS:				
Recruitment rate	●			
Demographics & clinical data*	●			
Physical activity level/intensity	●	●	●	●
Godin Exercise Leisure-time questionnaire [21]	●	●	●	●
EQ5D-5L [22]	●	●	●	●
B-IPQ [23]	●	●	●	●
Change of activity questionnaire	●	●	●	●
Self-efficacy for exercise [24]	●	●	●	●
ICIQ - MLUTS [25]	●	●	●	●
Participant lifestyle factors	●	●	●	●
Weight and body mass index	●	●	●	●
PSA	●			●
Qualitative interviews/focus groups	◄	———	——— ►	

*Age; ethnicity; marital status; employment status (including desk-based/active); co-morbidities; current/pre-cancer exercise levels.

8.6 Qualitative research

A qualitative component will be included within the study to evaluate participants' attitudes to, and experiences of, the intervention.. Up to six participant focus groups (up to three per site) will be held through the intervention period to explore the tolerability of the intervention, experience of the participation, and any other factors that affect adherence.

Qualitative interviews will also be conducted with clinical staff (Health Care Providers interviews) (two consultants and up to four nurses at the two sites) to explore the acceptability and attitudes to the physical activity intervention and how it may be implemented into clinical practice.

Qualitative interviews/focus groups with participants will provide deeper insights into South Asian men's lived experiences of diet and lifestyle in relation to prostate cancer prevention and management. Semi-structured interviews or focus group discussions will be held with up to 30 South Asian men recruited from Bristol and Bradford. Data will be collected through individual, face-to-face semi-structured interviews or small focus group discussions taking place in-person or virtually, depending on participant preference and community context. Interviews will provide depth and confidentiality, while focus groups will enable collective reflection and shared understanding. All sessions will follow a semi-structured topic guide developed from available literature and informed by Patient and Public Involvement and Engagement (PPIE) workshops. These

workshops provided culturally specific insights that shaped the phrasing of questions, the selection of themes, and the emphasis on familiar and trusted community spaces for data collection.

Further, the study will aim to conduct up to five interviews with individuals who declined to participate in the study (decliner interviews). The objective is to explore through interviews with those who declined to participate, reasons for non-participation, reasons specific to PRO-SAPA, other reasons, discussions with others during decision-making, previous experience of research, approach and information received, how they heard about PRO-SAPA, information provided, or understanding of PRO-SAPA aims.

Qualitative data collection and analysis

Interviews and focus groups will be semi-structured and follow a topic guide (informed by literature review, PPIE workshops with South Asian men, and discussion between study researchers) which will encourage participants to discuss their perspectives with regard to the aims above. Interviews and focus groups will be audio-recorded, transcribed verbatim and uploaded into a qualitative software package (NVivo14) to aid data management. Analyses will be conducted by the qualitative researcher on an ongoing basis in an iterative manner, according to principles of thematic analysis by Braun and Clarke (20). The process includes familiarizing with the data, coding, generating and reviewing themes, defining and naming themes, and synthesizing findings.

Sampling and recruitment

Convenient and/or purposive sampling (if possible) will be used to select participants with the aim of including South-Asian men who are diverse in age and treatment type (radical treatment, patients who are under active surveillance, patients who are ongoing or went through androgen deprivation therapy (ADT) and/or surgery), as well as Health care providers (nurses and/or consultants). For the decliner interviews, the nurse conducting initial contact with potential participants will ask those who decline participation in the study if they would be willing to take part in an interview. Those willing to take part in a decliner interview will be provided with a Participant Information sheet specific to these interviews and informed consent will be taken. Members of the clinical teams and the research nurses who supported the study will be invited to participate in the Health Care Providers interviews. They will be provided with a Participant Information Sheet specific to their interviews and informed consent will be taken. All participants who agree to take part in the feasibility trial will be invited to take part in focus group discussions (up to three in each site). Additionally, field notes will be taken during the monthly meet ups with the participants. Information about the focus groups and the field notes will be included in the main Participant Information Sheet and the consent form.

8.7 Change in participation status

Participants can withdraw from (a) any element of the exercise intervention and (b) providing data to the trial, at any time for any reason without affecting their usual care. Changes in participation status will be recorded on the change of participant status form, alongside the reason for withdrawal where possible. Should a participant withdraw from any element of the exercise intervention, efforts will be made to continue to obtain follow-up data on the participant, if they are willing.

8.8 Participant payments

Travel and parking expenses will be offered for any visits incurred as a result of participation. As a thank you for their time and participation, participants will be paid a £20 gift voucher for filling in all the questionnaires and the step count records at the end of the study. Participants in the focus group discussion will also be paid a £25 gift voucher per focus group in accordance with the NIHR guidelines (https://www.nihr.ac.uk/payment-guidance-members-public-considering-involvement-research).

8.9 Communication with participants

Participants will receive questionnaires and step count logs for completion at baseline, then at 6 weeks, 3 months and 4 months post-intervention start.

As part of the intervention, optional weekly motivational messages will be provided for participants, which will be available in key languages, to encourage adherence to exercise. Monthly coffee catch-up meetings with other participants and the researcher will also be offered during the intervention period. Participants will be informed of the study results via a newsletter.

9 SAFETY RECORDING AND REPORTING

The study presents minimal risk to the participants. Participants include men who have received radical treatment or who are living with prostate cancer following other treatments. It is possible that asking men to discuss their experiences of physical activity or exercise in relation to prostate cancer could cause them some distress. The potential risks and burdens will be provided in the Participant Information Sheet to ensure participants are clear about what is involved if they take part in the study. The interview topics, participant's right to decline to answer a question or withdraw from the study without giving a reason will also be emphasised in the Participant Information Sheet as well as prior to the starting of the interview or the workshop. If a participant becomes distressed during the interview, the researcher will ask them if they would like to stop the interview, and if they do not want to stop the interview – the interview will pause until they are ready to re-start it. At the end of the interview, before the participant leaves, they will be de-briefed, and this will include the researcher ensuring that if any difficult topics have been raised that the participant has an appropriate person who they can contact for further support or advice. If they do not have anyone to refer back to, the Debrief Form provides a list of local, free, services for advice and support which the participant can use. If a participant is in distress, the researcher will ensure that the participant has an appropriate person to contact before they leave the interview.

Data confidentiality will be emphasised in the Participant Information Sheet, the Consent Form and before the start of the interviews and workshops. The researcher will explain to the participant before the commencement of their interview that anything they say will be kept confidential but that there are limits to confidentiality, and that this will be broken if someone is believed to be at risk of harm; participants will also be reassured about the focus group/interview being a safe space to share views and experiences. In this case, the researcher would need to inform a relevant person (e.g. a family member, the General Practitioner, or the emergency services). Participation in the focus groups will be known to those who are attending the focus groups.

9.1 Definitions

Adverse Event

An adverse event (AE) is any undesirable event in a subject receiving treatment according to the protocol, including occurrences which are not necessarily caused by or related to administration of the research procedures.

Serious Adverse Event

A serious adverse event (SAE) is any adverse event which:

- results in death,
- is / was life threatening*,
- requires hospitalisation or prolongs an ongoing hospitalisation**,
- results in persistent or significant disability or incapacity,

Other important medical events that may jeopardise the subject and may require medical or surgical intervention to prevent one of the outcomes listed above should also be classed as an SAE.

**"Life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.*

***"Hospitalisation" is defined as an unplanned overnight stay. Note, however, that the patient must be formally admitted – waiting in outpatients or an Emergency Department would not count as hospitalisation (even though this can sometimes be overnight). Planned hospital stays would not be counted as SAEs, nor would time in hospital for "social reasons" (e.g. respite care, the fact that there is no-one at home to care for the patient). Also, if patients had a day-case operation, this would not qualify as hospitalisation. However, if a planned operation was brought forward because of worsening symptoms, this would be considered as an SAE. Hospitalisations for the purpose of the intervention are an exception to SAE reporting unless complications occur.*

9.2 Approach – risk adaptive of following GCP

This study is following a risk-adaptive approach to safety reporting because the intervention is exercise based and low risk.

9.3 Reporting period

The safety reporting period will span from the point of consent until the patient completes follow up at 4 months post-intervention start.

9.4 Reporting overview

Adverse event (AE)	AEs that are unrelated to study procedures will not be recorded
Adverse reaction (AR)	Record in CRF and source data Record assessment of causality, severity and seriousness
Serious adverse event (SAE)	Record in CRF and source data Record assessment of causality, severity and seriousness Report to trial team within 24h of becoming aware (who will report on to Sponsor within 24h)
Suspected serious adverse reaction (SSAR)	Record in CRF and source data Record assessment of causality, severity and seriousness Report to trial team within 24h of becoming aware (who will report on to Sponsor within 24h)

Suspected unexpected serious adverse reaction (SUSAR)	Record in CRF and source data Record assessment of causality, severity and seriousness Report to trial team within 24h of becoming aware (who will report on to Sponsor within 24h) CI will report to REC within 15 days of becoming aware of the event

All safety information, including information relating to safety events that are not subject to expedited reporting but are captured as trial endpoints, will be closely monitored throughout the trial.

Hospital site staff are responsible for reporting SAEs during the study. However, participants are also asked to self-report any inpatient stays in their follow up questionnaires, which will prompt a hospital note review if an unreported SAE is indicated. The SAE information will then be completed and verified by the hospital site. The Principal Investigator at each hospital site is responsible for categorising whether SAEs are serious, and expected/related. Participants will also be asked to report details of any other adverse events that they think might have been related to the intervention in their follow up questionnaires. Such events will then be reviewed by the PI who will assess causality.

9.5 Anticipated events

Anticipated events are defined as safety events that are anticipated for this patient population.

The following events are anticipated in this patient population:

- Hospital admissions – elective and emergency – that can be explained directly or indirectly by their prostate cancer or treatment
- Events relating to sexual, urinary or bowel function as a result of their prostate cancer or treatment

Events of this nature will be recorded in an SAE log but not immediately reported to the Sponsor, unless deemed to be possibly, probably or definitely related to the study.

9.6 Expectedness of events

Expected events are clinical outcomes that routinely occur when delivering the intervention. There are no expected events for the Pro-SAPA exercise intervention.

9.7 Urgent safety measures

The Sponsor and investigator may take appropriate urgent safety measures (USM) to protect a research participant from an immediate hazard to their health and safety. This USM can be taken before seeking approval from the ethics committee.

The main research ethics committee will be notified by email within three days. Information will include that such measures have been taken and the reasons why. Where the USM requires an amendment to study documentation, this will be submitted as a substantial amendment as soon as possible and marked as being in response to USM. A copy of the USM notification will be submitted with the amendment.

If the Principal Investigator (and not the sponsor) has instigated the USM, the sponsor will be notified immediately so that they can assess and report the USM within the timelines required.

NHS R&D offices will require notification in accordance with local policies/procedures. Where applicable, oversight committees will review information relating to USM and report any recommendations to all relevant parties. The funder will be updated on all developments and actions as soon as possible.

10 DATA MANAGEMENT

10.1 Data collection

10.1.1 Data Sources

A full list of source data and location will be maintained in the Data Management Plan (DMP) and a source data log. Hospital records will also form part of the source data for this trial.

Data will be collected using paper case report forms (CRFs) which will be entered into the database as soon as possible.

Participant questionnaires will either be completed on paper (with data entered into the REDCap database by trial staff) or through an email link sent to the participant via REDCap or using the Online surveys platform. Questionnaires can also be completed over the phone with a researcher.

10.1.2 Data System

REDCap will be used to capture and store study data for the trial. REDCap is a web-based electronic central data management system which is built and supplied by Vanderbilt.

Access to the trial REDCap database is managed at an individual level via delegation logs and requires a password that must meet the minimum format requirements.

Participant personal identifiers will be stored securely and separately from clinical data. Only authorised members of the trial team at the University of Bristol or study sites will have access. Participants will be informed of data storage and security processes in the Participant Information Leaflet.

The database contains audit trails to record all changes to the data and who actioned the changes, user permissions and when access was granted and revoked. The database is held on UoB servers that are automatically backed up daily by UoB IT and stored securely.

Online Surveys is a tool designed for academic research and complies with GDPR regulations. It is university approved, and data is encrypted on the server before it is downloaded. Once downloaded, Online Surveys securely destroy their record, and the research team will store the data securely on a University of Bristol secure server in a folder only accessible to the research team.

10.2 Data quality

Throughout the trial, data integrity, accuracy and completeness of data collection will be monitored and reported in compliance with good clinical practice (GCP) guidelines. This may include source data verification, use of automated data validation rules, data cleaning, training and risk-based monitoring (further details of which can be found in sections 11.2-4).

10.3 Essential document storage and security

Essential documentation, as specified by the sponsor, will be stored securely in a paper TMF/ISF at the University of Bristol and study sites, and will only be accessible to authorised staff. All systems where essential documentation is held at the University of Bristol are automatically backed up daily by University IT teams and stored securely. Paper documents will be stored in a secure locked cabinet in a locked room only accessible by authorised study staff.

10.4 Essential document archiving

Essential documentation, as specified by the sponsor, and source data (including REDCap database) will be kept for 5 years after the end of the trial. Documents will be kept at the University of Bristol for this time. At the end of the archiving period, documents will be destroyed by confidential means. All non-essential documentation will be destroyed securely prior to archiving.

Where source data are documented in paper medical records, these records will be identified by a label bearing the name and duration of the trial and clearly stating the 'do not destroy before' date. Where electronic records are in use, local site policy will be followed.

Participant personal identifiers will be archived where they form part of the essential documentation and will be destroyed at the end of the archiving period.

A study archiving plan will be developed, to include the TMF and ISF with sponsor and CI oversight. Sites will retain access to their ISF throughout the archiving period and the trial archive will be available for inspection purposes.

Data held at the University of Bristol will conform to the University of Bristol Data Security Policy and be held in compliance with the UK General Data Protection Regulation (GDPR), tailored by the Data Protection Act 2018.

10.5 Database lock and exports

At the point of data lock all user access to the database will be changed to read-only to prevent any changes to the data. A final data extract will be produced for analysis and a copy archived with restricted access. At the end of the study all sites will be provided with a copy of their site data, or read-only access to their site data, for the archiving period.

10.6 Database archiving

The database export created at the point of database lock will be stored on secure UoB servers for the duration of the archive period. The REDCap database will then be archived following REDCap standard procedures.

10.7 Data sharing

Members of the TMG will develop a data sharing policy consistent with UoB policy. Only anonymised data will be shared. Requests for access to data must be via written confidentiality and data sharing agreements which will be confirmed by the CI (or appointed nominee).

10.8 Qualitative data management

Interviews and focus groups will be audio recorded using University recording equipment. Audio recordings will be uploaded to a University of Bristol secure server in a folder only accessible to the research team. Once uploaded, the audio file will be deleted from the recording devices. Audio recordings will be transcribed and translated using transcription services approved by University of Bristol or by research assistants at the Bradford Institute for Health Research. Transcripts will be

stored securely and will be checked for accuracy against the saved audio-records. Following analysis, all audio recordings will be deleted. Transcripts will be pseudonymised with the study ID and any personal identifiable data will be removed. The transcripts will be retained for 5 years. All published or shared data will be fully anonymised.

11 RISK REVIEW AND MONITORING

The trial will be monitored and audited in accordance with the Sponsor's policy, which is consistent with the UK Policy Framework for Health and Social Care Research. All trial related documents will be made available on request for monitoring and audit by the Sponsor, the relevant REC and for inspection by regulatory authorities.

11.1 Risk Assessment

A risk assessment will be conducted examining what could cause harm, who/what could be harmed and how, and risks to the study integrity. Reasonably foreseeable risks associated with the research study, and actions to control the risks so far as is reasonably practicable, will be identified and documented as soon as possible in a study specific risk assessment. The risk assessment will include any safeguarding risks to participants or others and appropriate mitigations.

The risk assessment documentation and any subsequent revisions will be kept in the TMF. The risk assessment will be an ongoing process. Each time there are changes to the perceived risks and mitigating circumstances these will be agreed by the TMG and CI and documented.

11.2 Monitoring

Monitoring is defined as the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirements.

The purpose of monitoring is to verify that:

- The rights and well-being of the participants are protected;
- The reported study data are accurate, complete and verifiable from source documents;
- The conduct of the study complies with the currently approved protocol, GCP and the applicable regulatory requirements.

Study monitoring activities will be identified based on the study specific risk assessment and will be documented in a Monitoring Plan/Quality management plan. This will be developed by the Sponsor based on the trial risk assessment and according to the relevant SOP (SOP 010 Monitoring & Oversight of research activity)

11.3 Monitoring of study by Sponsor

The trial will be monitored and audited in accordance with the Sponsor's policy, which is consistent with the UK Policy Framework for Health and Social Care Research. All trial related documents will be made available on request for monitoring and audit by the Sponsor and the relevant REC. The University of Bristol has a Service Level Agreement with University Hospitals Bristol and Weston NHS Foundation Trust, whereby the Trust monitors 10% of the University's sponsored studies.

11.4 Monitoring of study by trial team

Monitoring activities to be conducted by the sponsor and trial team will be documented in the Monitoring plan developed by the sponsor as specified in section 11.2. Monitoring activities conducted by the trial team will include:

- Informed Consent process and documentation
- Inclusion and Exclusion criteria verification
- Completed source documents and CRFs, data completeness and other types of data queries
- Study procedures and / or intervention compliance
- Safety documentation and adverse event reporting
- Protocol deviations

The trial team will carry out regular central monitoring and audit of compliance of sites with Good Clinical Practice (GCP) and trial-specific data collection procedures described in the protocol. The trial database will have in-built validation and the TMG will review the completeness of the data throughout the trial. The trial team will not check CRFs or other source data against the data entered to the trial database, unless there are good reasons to visit a site to complete a monitoring visit (e.g. the central monitoring highlights a problem).

The quality of the study data may be monitored through centralised database monitoring. Validation checks are documented in the database specification document. Data completeness and accuracy checks may be run through the study databases. Data queries are usually reported via the study database.

Other study monitoring activities may also be carried out, e.g. remote site monitoring, on site monitoring.

11.5 Training of sites

Initiation training

Before the trial commences at each participating site, training will be organised by the trial team. The provided training will ensure that site research personnel fully understand the protocol, CRFs and the practical procedures for the trial. These sessions may be provided virtually or on-site. They may include training videos and manuals as well as a site initiation meeting. SIV training and ongoing site staff training will be documented in a site training log.

Investigators' responsibilities

Investigators must ensure that local research approvals have been obtained and any required contractual agreements have been signed off by all parties before recruiting any participants. Investigators will be required to ensure compliance to the protocol and completion of the CRFs. Investigators will be required to allow access to trial documentation or source data on request for monitoring visits and audits performed by the Sponsor, trial team or any regulatory authorities.

Investigators will be required to read, acknowledge and inform their team of any amendments to the trial documents approved by the HRA/REC that they receive and ensure that the changes are complied with.

11.6 Protocol compliance

Prospective, planned deviations or waivers to the protocol are not allowed. Accidental protocol deviations will be documented and reported to the CI and Sponsor in line with the Sponsor's reporting requirements (Research Governance Standard Operating Procedure 8 – Quality events). They will also be reported to the TMG. In the event of systematic protocol deviations, investigation and remedial action will be taken in liaison with the CI and the TMG.

Sponsor specific procedures will be followed for the reporting of any breaches.

Sponsor will determine whether it constitutes a serious breach, requiring onward reporting to the REC.

11.7 Serious Breaches to GCP and/or the protocol

A "serious breach" is a breach which is likely to affect to a significant degree:

a. the safety or physical or mental integrity of the subjects of the trial; or

b. the scientific value of the trial.

In the event that a serious breach is suspected, the Sponsor will be notified as soon as possible and within 24 hours of becoming aware of the event. The serious breach will be reviewed by the Sponsor in collaboration with the CI. The Sponsor will determine whether it constitutes a serious breach, requiring onward reporting to the REC. If appropriate, the Sponsor will report it to the REC and the relevant NHS host organisation within seven calendar days of becoming aware of the serious breach.

12 ANALYSES

12.1 Statistical analysis

Analyses will be in line with CONSORT reporting guidelines for clinical trials. All analyses (unless otherwise stated) will be conducted on an intention to treat (ITT) basis. Continuous data will be summarised as mean and SD or median and inter-quartile range (IQR) if distributions are skewed. Categorical data will be summarised as number and percentages.

Randomisation rate and adherence to the intervention will both be reported as a percentage, along with the respective 95% confidence interval.

12.2 Qualitative data analysis:

Audio-recordings, interviews, field notes and focus groups will be transcribed (translated if needed) and anonymised, and then analysed using Nvivo qualitative data software (QSR International, Melbourne, Australia). Using thematic analysis, the transcripts (and the field notes) will be reviewed though stages of familiarisation, developing a codebook, indexing, charting, mapping and interpretation. The process will be iterative and codes/themes will be presented and discussed with the wider research team. Inter-rater reliability (to assess the level of coding consistency between different coders) of the analysis will be assessed using 10% of the transcripts which will be independently coded by another researcher, with discrepancies solved by discussion.

12.3 Frequency of analyses

The primary analysis will take place when follow-up is complete for all recruited participants.

13 TRIAL OVERSIGHT

13.1 Day-to-day management

The trial will be managed by the trial team, through the Bristol BRC. The University of Bristol will act as Sponsor. Day-to-day management of the trial will be overseen by the Chief Investigator (CI) and BRC trial team. The CI and trial team will work with the co-investigators to prepare the final protocol and submissions for regulatory approvals; HRA and REC. The trial team will prepare all trial documentation and data collection forms, and design and implement the data management systems.

The study researchers will be the contact point to provide support and guidance to the participating sites throughout the trial.

13.2 Trial Management Group (TMG)

The trial will be managed by a trial management group (TMG), which will meet approximately 3-6 monthly for the duration of the study. The TMG will comprise all co-investigators, including a PPI representative. Other members of the research team will be invited to attend as required. The TMG will have responsibility for the day-to-day management of the trial and will report to the independent Trial Steering Committee (TSC).

13.3 Trial Steering Committee (TSC)

A TSC will be established to oversee the conduct of the trial. Membership, responsibilities, and reporting mechanisms of the TSC will be formalised in a TSC Terms of Reference. The TSC will make recommendations during the trial to the TMG and will advise on key decisions. It is anticipated that the TSC will comprise of independent members including a Chairperson, relevant experts in the clinical and academic field of this research, and PPI representative(s). The CI, and study researchers will represent the TMG as observers, the attendance of any other TMG members will be agreed by the TSC Chair. Anyone not directly involved in the study team but from the same institution may attend as non-independent members, with the agreement of the TSC Chair. The TSC will meet before recruitment to the trial begins and then approximately every six months or as agreed with the TSC during the trial.

13.4 Trial stopping rules

The trial may be prematurely discontinued by the Sponsor, Chief Investigator (CI), Regulatory Authority, or Funder, based on new safety information or for other reasons provided by the TSC, regulatory authority, or ethics committee.

The trial may also be prematurely discontinued due to lack of recruitment or upon advice from the TSC, who will advise on whether to continue or discontinue the trial. If the trial is prematurely discontinued, no new participants will be recruited and a decision on data collection for active participants will be made in discussion with the Funder, TSC, and Sponsor.

14 PATIENT AND PUBLIC INVOLVEMENT (PPI)

During the intervention development stage and the design stage of this study, a Patient and Public Involvement session has been conducted with 10 South Asian men over the age of 50 with various chronic health conditions and caring needs. The intervention design and participant-facing documents were discussed with the group.

Additionally, The Community Research Advisory Group (CRAG), based at the Bradford Institute for Health Research, will be involved in the delivery of this study. Established in 2016 and hosted by Born

in Bradford, CRAG is an established Patient and Public Involvement (PPI) group, consisting of members of the public who meet on a regular basis to discuss different aspects of the institute's research. CRAG will be consulted during data collection, recruitment and analysis stages on different aspects of the research. A PPI representative will also sit on our study TMG.

15 ETHICAL AND REGULATORY CONSIDERATIONS

15.1 Governance and legislation

This trial will be conducted in accordance with:

- The principles of Good Clinical Practice, as set out in the International Conference for Harmonisation of Good Clinical Practice (ICH GCP) guidelines
- UK Policy Framework for Health and Social Care Research
- Data Protection Act 2018
- UK General Data Protection Regulation

Before any NHS site can enrol participants into the trial, the CI or designee will obtain confirmation of capacity and capability for each site in-line with HRA processes along with other documentation required for the sponsor or designee to grant sites with a full sponsorship letter.

Approved amendments will be submitted to participating NHS Trusts for information or approval, as required.

GCP training and trial specific training for research staff members will be at a level commensurate with their involvement within the trial. Informed consent to participate in the trial will be sought and obtained according to GCP guidelines.

15.2 Research Ethics Committee review and reports

Ethics review of the protocol and other trial related participant facing documents will be carried out by a NHS Research Ethics Committee (REC) and, where applicable, governance checks will be conducted by the Health Research Authority (HRA).

All correspondence with the HRA/REC will be retained in the Trial Master File (TMF). The CI will notify the REC of the end of the trial and if the trial is ended prematurely (including the reasons for the premature termination). Within one year of the end of the trial, the CI will submit a final report with the results to the REC.

15.3 Amendments

All amendments to the trial and its documents will be approved by the Sponsor (and where necessary the funder) before being submitted to the REC/HRA for approval prior to implementation.

It is the Sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC, in accordance with the legislation and HRA processes. All amendments will be documented on the HRA amendment tool regardless of substantiality.

15.4 Financial and other competing interests

The research team must disclose any ownership interests that may be related to products, services, or interventions considered for use in the trial or that may be significantly affected by the trial. Competing interests will be reported in all publications and in the final report.

15.5 Indemnity

The necessary public liability insurance is provided by the Sponsor. The PIS provides a statement regarding indemnity.

16 DISSEMINATION POLICY

A publication policy will be developed, with authorship models agreed in advance with the TMG.

The findings will be disseminated by usual academic channels, i.e. presentation at international meetings, as well as by peer-reviewed publications and through patient organisations and newsletters to patients, where available.

Where possible, information will be disseminated to participating sites and participants in line with timelines for academic audiences (i.e. participant and sites being informed of the study results on or shortly after the date the academic paper is published). Before dissemination materials are drafted, PPI members should be consulted on the proposed methods for dissemination to non-academic audiences.

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18 AMENDMENT HISTORY

Amendment number (i.e. REC amendment number)	Previous version	Previous date	New version	New date	Brief summary of change	Date of ethical approval (or NA if non-substantial)