

# To evaluate how effective a guided self- help cognitive behavioural therapy (CBT) intervention is in reducing the impact of hot flushes and night sweats (compared to treatment as usual) at 6 months post randomisation in men taking hormone therapy for prostate cancer

<b>Submission date</b> 20/01/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 13/12/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/07/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Hormone therapy medication is widely used to treat prostate cancer. It works by blocking or reducing the amount of testosterone in the body. This stops or slows down the cancer's spread. While effective as a medication, 80% of men suffer from Hot Flushes and Night Sweats as a result of taking it. These side effects can occasionally be so troublesome that some men decide to stop taking the medication allowing the cancer to grow.

Unfortunately, there are few established effective treatments for men with Hot Flushes and Night Sweats. Our previous research has shown that cognitive behavioural therapy (CBT), a type of talking therapy, can help both men and women manage hot flush and night sweats in a positive way by changing how they think and behave.

This study will evaluate how effective a self-help CBT programme is in reducing the impact of hot flushes and night sweats in men taking hormone therapy for prostate cancer. This will be delivered by a trained member of the existing prostate cancer nursing team.

### Who can participate?

Men with a diagnosis of prostate cancer currently receiving hormone therapy and experiencing problematic hot flushes and night sweats from seven hospitals around the UK.

### What does the study involve?

Half of the participants will be randomly assigned to a 4-week self-help CBT programme and the

others will receive treatment as usual.

Participants randomised to the self-help programme will be given a cognitive behavioural therapy booklet to work through consisting of information and exercises to help manage symptoms and improve wellbeing. There will also be two virtual group workshops delivered by the cancer nurse specialist team. Men in this arm will also receive a CD/ audio file demonstrating breathing and relaxation exercises.

All participants will complete study questionnaires at baseline, 6 weeks and 6 months.

What are the possible benefits and risks of participating?

Previous research has shown that guided self-help CBT (delivered by a clinical psychologist) to men undergoing prostate cancer treatments, is an effective way of reducing HFNS symptoms. If you are randomised to the group that receives the guided self-help CBT (delivered by your cancer nurse specialist team), it is possible that you will experience a similar benefit. If you are in the treatment at usual group, you may not benefit during the trial, but we hope that you will find it a positive experience. You may also benefit from the self-help CBT booklet and CD that will be offered to you at the end of the trial.

Whichever group you are randomised into, you will be helping to contribute to our understanding of how best to help men, with a diagnosis of prostate cancer undergoing ADT, who suffer with problematic HFNS.

There are no known risks of participating in this trial. You are free to withdraw from the study (including the optional interview) at any time. We will ask you why you have changed your mind in case there is anything we could do differently, but you do not have to tell us if you prefer not to. You will then receive usual NHS care. Your decision will not affect future treatment or prevent you from taking part in future research studies.

If you decide to withdraw from the trial, we will keep and use any data we have collected from you up to that point, but you will not be asked to complete any more assessments.

If you decide to withdraw from the optional interview, you can request for any data collected to be deleted. However, it may not be possible for you to withdraw your data once the analysis has started because the data collected will already be pseudonymised and have been used but you can inform the research team if you do not want your anonymised interview content to be used in publications.

Where is the study run from?

University Hospital Southampton NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?

May 2021 to October 2023

Who is funding the study?

The National Institute for Health Research (NIHR) (UK).

Who is the main contact?

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## Contact information

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Scientific

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**Additional identifiers****EudraCT/CTIS number**

Nil known

**IRAS number**

304500

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

CPMS 51149, NIHR201542, IRAS 304500

**Study information**

Scientific Title

A multicentre randomised controlled trial of virtual self-help cognitive behavioural therapy to MANage the impact of hot flush and night sweat (HFNS) symptoms in patients with prostate CANcer undergoing androgen deprivation therapy (MANCAN2)

## **Acronym**

MANCAN2

## **Study objectives**

### **Primary Objectives:**

To determine whether the addition (to Treatment as Usual (TAU) of virtual self-help Cognitive Behavioural Therapy (CBT), delivered by a patient's existing prostate cancer Clinical Nurse Specialist (CNS) team, reduces the impact of HFNS at 6 months post randomisation in men with prostate cancer undergoing ADT.

### **Secondary Objectives:**

#### **To determine:**

1. The effect of the intervention on the impact of HFNS at 6 weeks post randomisation
2. The effect of the intervention on HFNS frequency
3. The effect of the intervention on men's HFNS beliefs and behaviours
4. The effect of the intervention on quality of life (QoL)
5. The effect of the intervention on other symptoms including anxiety, depression, mood, and sleep
6. The effect of the intervention on men's compliance with ADT
7. The level of fidelity of the CBT when delivered by a patient's existing prostate cancer clinical nurse specialist (CNS) team
8. Resource use analyses
9. Prostate cancer CNS team experiences of introducing this new intervention
10. Participant acceptability of the intervention
11. Explore barriers and facilitators to implementing the intervention into routine practice
12. Health economics of the intervention

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 16/12/2021, West Midlands - South Birmingham Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 207 104 8143; southbirmingham.rec@hra.nhs.uk), ref: 21/WM/0259

## **Study design**

Interventional randomized controlled trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Home

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Sweating caused by prostate cancer androgen deprivation therapy

## Interventions

Mancan2 is a mixed method study:

1. A Randomised Controlled Trial (RCT)
2. A Process Evaluation

### 1. Randomised Controlled Trial:

This study is a phase 3, multi-centre, individually randomised controlled trial of virtual or face-to-face self-help CBT intervention (plus treatment as usual (TAU)) delivered by cancer nurse specialist team, versus TAU alone.

Approximately 150 men with a diagnosis of prostate cancer currently receiving hormone therapy and experiencing problematic HFNS symptoms will be randomised to one of the two randomisation arms.

A minimum of 7 NHS sites which host a prostate cancer Multi Disciplinary Team will be selected with considerations given to ensure ethnic, geographic and NHS setting diversity to optimise generalisability of results. Each site will aim to run two sequential groups of the intervention of 6-8 men per group (total of 24-32 men, per NHS site).

Potentially eligible participants will be approached by members of the site research team. There will be two channels of recruitment - recruitment during normal clinic visits (face to face or electronically if the clinical appointment is delivered via video conference or telephone) or the research team at site will screen potentially eligible patients by reviewing lists of patients that could be eligible (for example patients in remote follow up as part of their routine care).

The site research team will give each potentially eligible patient an invite pack which includes a Participant Information Sheet, Informed Consent Form, Screening Questions, Contacts Form and a Study Decline Form.

Participants who consent to participate will be randomised to the CBT+TAU arm (intervention) or the TAU arm (control). Participants in both arms will be asked to complete study questionnaires at three time points: Baseline; 6 weeks and 6 months. At the end of the study, participants randomised to the control arm will receive a copy of the CBT booklet and the CD/ audio file.

Participants randomised to the intervention arm will receive a 4-week guided self-help Cognitive Behavioural Therapy (CBT) programme. The programme comprises of a CBT Booklet, an audio file/ CD demonstrating breathing and relaxation exercises and two virtual or face-to-face group workshops (pre and post intervention) delivered by members of the cancer nurse specialist team. The 4-week guided self-help CBT in this study will aim to improve patients understanding of Hot Flushes and Night Sweats (HFNS). Participants will have access to helpful information, tips, skills and strategies to help them to manage their HFNS symptoms more effectively.

The CBT booklet has a total of four sections for the participants to work through over the 4-week intervention period. Participants will be advised to work through one section each week. They will be advised to set aside 30 minutes each day plus an additional 2 hours each week so

that they can practice the new skills. The pre and post intervention virtual or face-to-face group workshops will run for 1 hour 50 minutes each. At the end of their post intervention workshop, participants will complete a patient evaluation questionnaire.

## **2. Process Evaluation**

The purpose of the process evaluation is to:

1. Understand CNS team the experiences of introducing and running the intervention.
2. Explore participant acceptability and satisfaction.
3. Establish whether the intervention has potential to become a routine practice service.

To achieve this semi-structured interviews and questionnaires will be conducted with patients, key stakeholders and the team delivering the intervention. The interviews will consider four areas identified by the Normalisation Process Theory.

Specifically, staff interviews will help us understand site team attitudes, dynamics, perception of the intervention and ability to integrate it into current work.

Patient interviews will help us understand the impact, barriers and facilitators to taking part in this trial and provide insight of self-help CBT as a sustainable treatment option.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Hot flush and night sweat symptoms measured using the HFNS Rating Scale at baseline and 6 months

## **Secondary outcome measures**

1. Hot flush and night sweat symptoms measured using the HFNS Rating Scale at baseline and 6 weeks
2. HFNS frequency measured using a subscale of the HFNS Rating Scale, at 6 weeks and 6 months, compared to baseline
3. HFNS beliefs and behaviours measured using the HFNS Beliefs and Behaviour Scale, at 6 weeks and 6 months, compared to baseline
4. Quality of life measured using the EORTC QLQ-C30 and EORTC QLQ-PR-25, at 6 weeks and 6 months, compared to baseline
5. Anxiety, depression, mood and sleep measured using:
  - 5.1. Generalised Anxiety Disorder Questionnaire (GAD7), at 6 weeks and 6 months, compared to baseline
  - 5.2. Patient Health Questionnaire-9 (PHQ9), at 6 weeks and 6 months, compared to baseline
  - 5.3. Work and Social Adjustment Scale (WSAS), at 6 weeks and 6 months, compared to baseline
  - 5.4. Pittsburgh Sleep Quality Index (PSQI, item 6), at 6 weeks and 6 months, compared to baseline
6. Compliance to ADT measured by percentage of men compliant with the planned duration of ADT at 6 weeks and 6 months
7. Fidelity of CBT measured using:
  - 7.1. Audio recordings of the virtual (pre- and post) intervention group workshops. An independent person will rate a random selection of these for adherence to the treatment manual
  - 7.2. Workshop Attendance logs (completed by CNS) will measure patient compliance to the virtual pre and post group intervention workshops
  - 7.3. Post-intervention questionnaire completed by patients will measure how much of the booklet/CD patients engaged with and what lifestyle changes they have made
8. Resource usage analyses measured using:

- 8.1. CNS team logs to record staff training cost, time to deliver intervention in a virtual capacity.
- 8.2. Participant resource use questionnaire
- 9. Prostate cancer CNS team experiences of delivering this new service measured using interviews with prostate cancer CNS team members
- 10. Participants' acceptability of the intervention measured using interviews with participants
- 11. Barriers and facilitators to implementing the intervention into routine practice measured using interviews with CNS team, medic and manager
- 12. Health Economics of the intervention measured using:
  - 12.1. Measurement of quality-adjusted life years (QALY)
  - 12.2. Collection of data on expected service use
  - 12.3. Collection of data pertaining to the cost of the intervention

**Overall study start date**

01/05/2021

**Completion date**

31/10/2023

## Eligibility

**Key inclusion criteria**

- 1. A diagnosis of prostate cancer
- 2. Localised or advanced disease stage. Patients may have had potentially curative treatments including, but not limited to, radiotherapy, brachytherapy or surgery.
- 3. Currently receiving ADT, and anticipated to require a minimum of 6 months further continuous treatment at the point of registration into the trial. Treatment may have been planned for either a fixed duration (for example, but not limited to, 2 years after radiotherapy) or permanent. Treatment may be with either adjuvant (following potentially curative treatment) or palliative intent. LHRH analogues, LHRH antagonists and surgical castration are all acceptable forms of androgen deprivation. Androgen receptor antagonists, including but not limited to, bicalutamide, enzalutamide, apalutamide or darolutamide, or abiraterone, may be given in combination with androgen deprivation according to local practice.
- 4. Presence of problematic HFNS symptoms defined as a HFNS Rating Scale score of two or more.
- 5. Ability to read and understand English without assistance
- 6. 16 years or older
- 7. Ability to attend virtual (or face-to-face) group workshops through video conferencing software. If this is not feasible, participants must be able to participate in one-to-one workshops by telephone

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Male

**Target number of participants**

Planned Sample Size: 150; UK Sample Size: 150

### **Key exclusion criteria**

1. Currently with uncontrolled biochemical, radiological or clinical disease progression or relapse if this would be anticipated to interfere with trial participation as determined by the local principal investigator or co-investigator
2. Currently receiving chemotherapy. Prior chemotherapy must have been completed with a minimum of 4 weeks elapsed between the date of the final dose and confirmation of eligibility. Concomitant use of bone health agents, including zoledronate and denosumab is allowed
3. Currently receiving radical multi-fraction external beam radiotherapy or brachytherapy These must have been completed with a minimum of 4 weeks elapsed between the date of the final fraction/treatment and confirmation of eligibility. Single fraction radiotherapy to sites of painful bony metastatic disease or 'STAMPEDE style' palliative prostate radiotherapy is allowed
4. Intention to receive ADT on an intermittent schedule
5. Use of experimental drugs within other interventional clinical trials. Co-recruitment to observational studies, or studies of surgery or focal ablation techniques where the interventional component is complete, is acceptable
6. Currently receiving androgen deprivation as a neoadjuvant treatment
7. Medical or psychiatric conditions or other factors that, in the view of the local PI, are likely to impact on the ability of the patient to participate in the trial procedures and interventions

### **Date of first enrolment**

04/03/2022

### **Date of final enrolment**

31/03/2023

## **Locations**

### **Countries of recruitment**

England

United Kingdom

Wales

### **Study participating centre**

**University Hospital Southampton NHS Foundation Trust**

Southampton General Hospital

Tremona Road

Southampton

United Kingdom

SO16 6YD

### **Study participating centre**

**Guy's and St Thomas' NHS Foundation Trust**

St Thomas' Hospital



Westminster Bridge Road  
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SE1 7EH

**Study participating centre**  
**The Royal Marsden NHS Foundation Trust**  
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**Study participating centre**  
**Nottingham University Hospitals NHS Trust - City Campus**  
Nottingham City Hospital  
Hucknall Road  
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United Kingdom  
NG5 1PB

**Study participating centre**  
**The Clatterbridge Cancer Centre NHS Foundation Trust**  
Clatterbridge Hospital  
Clatterbridge Road  
Bebington  
Wirral  
United Kingdom  
CH63 4JY

**Study participating centre**  
**East Suffolk and North Essex NHS Foundation Trust**  
Heath Road  
Ipswich  
United Kingdom  
IP4 5PD

**Study participating centre**  
**Norfolk And Norwich University Hospitals NHS Foundation Trust**  
Norfolk & Norwich University Hospital  
Colney Lane  
Norwich

United Kingdom  
NR4 7UY

**Study participating centre**

**South Tyneside and Sunderland NHS Foundation Trust**  
Sunderland Royal Hospital  
Kayll Road  
Sunderland  
United Kingdom  
SR4 7TP

**Study participating centre**

**Velindre Cancer Centre**  
Velindre Road  
Cardiff  
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## **Sponsor information**

**Organisation**

University Hospital Southampton NHS Foundation Trust

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.uhs.nhs.uk/home.aspx>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

NIHR Central Commissioning Facility (CCF)

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

30/04/2024

**Individual participant data (IPD) sharing plan**

All data generated or analysed during this study will be included in the subsequent results publication

**IPD sharing plan summary**

Published as a supplement to the results publication

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol article</a>		10/07/2023	11/07/2023	Yes	No