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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

Submission date
20/01/2022

Recruitment status
No longer recruiting

Registration date
13/12/2022

Overall study status
Completed

Last Edited
11/07/2023

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
304500

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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
United Kingdom

England

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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Study participating centre
The Royal Marsden NHS Foundation Trust
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SW3 6JJ

Study participating centre
Nottingham University Hospitals NHS Trust - City Campus
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Study participating centre
The Clatterbridge Cancer Centre NHS Foundation Trust
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Study participating centre
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Heath Road
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IP4 5PD

Study participating centre
Norfolk And Norwich University Hospitals NHS Foundation Trust
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Study participating centre
South Tyneside and Sunderland NHS Foundation Trust
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Study participating centre
Velindre Cancer Centre
Velindre Road
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CF14 2TL

Sponsor information

Organisation
University Hospital Southampton NHS Foundation Trust

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

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?
Protocol article		10/07/2023	11/07/2023	Yes	No
HRA research summary			28/06/2023	No	No