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Complementary therapy for the management of 'white coat hypertension syndrome' (a condition where a patient's blood pressure is higher when measured at a doctor's office than in other settings)

Submission date
21/08/2024

Recruitment status
Recruiting

Registration date
26/11/2024

Overall study status
Ongoing

Last Edited
25/11/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This research will examine the impact of personalised complementary therapy for the management of generalised anxiety disorder (GAD) and white coat hypertension syndrome (WCHS) within early-phase oncology clinical trial patients and patients with advanced cancer.

Who can participate?
Adult patients with cancer referred for early-phase clinical trials. Cancer patients attending secondary care appointments, including secondary breast cancer patients and teenagers and young adults (16 to 24 Year olds).

What does the study involve?
In Arm 1, patients will be assessed by a trained complementary therapist to create a personalised treatment programme, which may include massage (hand and foot), aromatherapy, reflexology, Indian head massage, reiki, relaxation, visualisation, guided imagery, and mindfulness. If hypertension persists at study visits 3 and 4, participants will be reviewed by the medical and nursing team and may be transferred to standard care. Arm 2 participants will receive standard care only, involving a review by the nursing team, discussions about their well-being, repeated blood pressure checks, and if necessary, referral to the medical team for further evaluation and potential home blood pressure monitoring or medication.

What are the possible benefits and risks of participating?
This is the first study to look at using complementary therapy for WCHS and the findings from this research will show if complementary therapy is an effective treatment for white coat hypertension. The findings from this research may lead to a change in how WCHS is managed with the NHS; with the aim of improving patient’s experiences of being on an early phase clinical trial.

Taking part may mean your appointment will last longer, and you may want to consider this when talking to the research nurse about this study.

Where is the study run from?
Newcastle upon Tyne Hospitals NHS Foundation Trust

When is the study starting and how long is it expected to run for?
July 2023 to January 2026

Who is funding the study?
Newcastle upon Tyne Hospitals NHS Foundation Trust

Who is the main contact?
Dr Ben Hood, ben.hood@nhs.net

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327774

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Newcastle R & D number - 10527

Study information

Scientific Title
A randomised control trial, evaluating the effect of a personalised complementary therapy intervention for the management of white coat hypertension syndrome within early phase oncology clinical trial patients

Acronym
PRECISE

Study objectives
This research will examine the impact of a personalised complementary therapy intervention for the management of 'White Coat Hypertension' within early-phase oncology clinical trial patients. Cancer patients that take part in early-phase clinical trials have advanced cancer; a type of cancer that is terminal. In many cases these set of patients have exhausted all NHS treatment options available to them and are sometimes offered the opportunity to take part in an early phase clinical trial; to get access to an experimental cancer treatment.
Research shows that advanced cancer patients have a lot of anxiety, as a consequence of disease burden. Research also shows that advanced cancer patients anxiety levels increase when attending hospital appointments, in particular clinical trial appointments. Further research has also shown that increased anxiety levels make patients' blood pressure rise, when they are attending these type of appointments. This is often called white coat hypertension; which, if untreated increases patients risk of heart attack and stroke.
Personalised complementary therapy is used within the NHS to support cancer patients; making them feel more relaxed and reduce their anxiety levels. Within our clinical team we have witnessed at first hand the impact complementary therapy has, and believe it does have a positive impact on anxiety and white coat hypertension.
To date there has been no clinical research to examine if complementary therapy is an effective treatment for anxiety and white coat hypertension.

The primary objectives of this research are:
1. To investigate if personalised complementary therapy is an effective intervention in the management of anxiety and white coat hypertension
2. To investigate if personalised complementary therapy is more effective than current gold standard practices for the management of white coat hypertension
3. To investigate what the rates of white coat hypertension are amongst early-phase cancer clinical trial patients

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/08/2023, London - Riverside Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8023; riverside.rec@hra.nhs.uk), ref: 23/LO/0701

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Medical and other records

Study type(s)
Other, Quality of life, Efficacy

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

Health condition(s) or problem(s) studied
White coat hypertension

Interventions
Patients will be randomised into two study arms using electronic Recap 1:1 randomisation. The interventions last 1 hour with no follow-up activities.

Arm 1
Patients randomised to arm 1; the complementary therapy arm, will be assessed by a trained complementary therapist, to create a personalised complementary therapy treatment programme. Participants will either receive massage, including hand and foot, aromatherapy, reflexology, Indian head massage, and reiki, or relaxation, visualisation, guided imagery and mindfulness.

In addition, if hypertension persists at study visits 3 and 4; arm 1 participants would be reviewed by the medical and nursing team and a decision would be made to transfer the participant to a standard of care.

Arm 2
Arm 2 participants will receive a standard of care only.
Standard of care - Review by the nursing team; discussion with patients around how they are feeling (BP repeated after discussion). At the next visit, if BP is still high, the patient is to be referred to the medical team. This would include a detailed medical history and physical exam; to examine possible causes of elevated BP, such as undiagnosed hypertension or drug-related. If no obvious cause is found, consider home BP monitoring (at least twice daily for 7 days). At the next appointment, if BP continued to be raised a medical decision would be made – either to medicate the patient with anti-hypertension medication, and/or refer the patient to their general practitioner.

Intervention Type
Behavioural

Primary outcome measure
1. Blood pressure measured using a sphygmomanometer at pre and post-complementary therapy, and pre and post-standard-of-care visits
2. Anxiety measured using the Generalized Anxiety Disorder (GAD-7) scale at every visit, before any intervention of standard of care treatment for WCH or GAD

Secondary outcome measures
The rate of white coat hypertension syndrome measured using data collected in patient medical records at visit one and visit two, as part of screening

Overall study start date
01/07/2023

Completion date
01/01/2026

Eligibility

Key inclusion criteria
1. Men or women 16 years and above
2. Confirmed diagnosis of advanced cancer
3. Confirmed GAD-7 score of 10 or above and / or 1WCH (1 WCHA criteria: A discrepancy of more than 20/10 mmHg between clinic and median daytime BP (NICE, 2022))

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Previous confirmed diagnosis of hypertension
2. Unconfirmed WCH
3. Patients receiving a treatment with known cardio toxicity that effects BP

Date of first enrolment
14/10/2023

Date of final enrolment
01/10/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

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+44 (0)1912824519
Nuth.nuthsponsorship@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Newcastle upon Tyne Hospitals NHS Foundation Trust

Alternative Name(s)
Newcastle upon Tyne Hospitals NHS Trust

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/01/2027

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication