ISRCTN15875290 https://doi.org/10.1186/ISRCTN15875290

PERCEPT - myeloma transplant prehab study

Submission date
11/02/2019

Recruitment status
No longer recruiting

Registration date
13/02/2019

Overall study status
Completed

Last Edited
18/03/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
People with the blood cancer myeloma who undergo chemotherapy are not routinely prescribed exercise or physical activity advice as part of their treatment and many are even told to rest or not to exercise because of pain and bone disease related to their cancer. Yet research studies tell us that exercising before, during and after cancer treatment can be beneficial and that excessive rest or being inactive can have detrimental effects on wellbeing. As the medical treatment for cancer gets better and more people are surviving, it is important that people have other 'therapies' to help them prepare for and potentially combat the side effects of their cancer treatment. This maybe especially important for myeloma patients who are receiving an intensive treatment called stem cell transplant. The primary aim of this study is to evaluate the feasibility of delivering a physiotherapist-led exercise and behaviour change intervention before and during stem cell transplant treatment in people with myeloma. Secondary objectives are to investigate the possible effect of the intervention on a range of measures including fatigue, quality of life, physical activity and functional capacity.

Who can participate?
Patients with myeloma who are having stem cell transplant treatment at University College Hospital

What does the study involve?
Participants are randomly allocated one of two groups: an exercise intervention group and a usual care control group. The exercise group undertake individually tailored aerobic and resistance exercise with behaviour change support during three phases of their treatment. In phase 1, for 6-8 weeks before they come into hospital for their stem cell transplant they are asked to exercise three times per week. They are asked to take part in one session a week with a physiotherapist in a gym and complete two other sessions at home. In phase 2, during their hospital stay, immediately after their stem cell transplant, the exercise participants are offered supervised exercise sessions with a physiotherapist three times per week. In phase 3, for 3 months after they leave hospital the participants are asked to continue exercising at home three times per week. They receive weekly phone or Skype support from a physiotherapist to promote and support continuation or return to independent exercise in the post-transplant period.

What are the possible benefits and risks of participating?
The results of this study may help improve the experience of people with myeloma undergoing

stem cell transplant and lead to further large-scale research into the role of exercise as part of the transplant treatment pathway.

Where is the study run from?
University College London Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2018 to September 2021 (updated 03/11/2021, previously: March 2021; updated 10/08/2020, previously: November 2020)

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Orla McCourt
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
40801

Study information

Scientific Title

Pilot randomised controlled trial of a physiotherapist-led exercise intervention delivered prior to and during stem cell transplant in patients with myeloma

Acronym
PERCEPT

Study objectives
The primary objective of this study is to evaluate the feasibility of delivering an exercise and behaviour change intervention prior to and during the usual autologous stem cell transplant treatment pathway in people with myeloma. Secondary objectives are to investigation of the possible effect of the intervention on a range of measures including fatigue, quality of life, physical activity and functional capacity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/03/2019, NHS Health Authority Research Ethics Committee - Camden and Kings Cross (Tel: +44 (0)207 972 2561; Email: nrescommittee.london-camdenandkingscross@nhs.net), ref: 19/LO/0204

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Physical, Rehabilitation

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
This pilot randomised, single site trial will involve participants with myeloma undergoing autologous stem cell transplantation (ASCT). This trial has two arms; an exercise intervention arm and a usual care control arm. Eligible participants will be randomised to an exercise intervention group or usual care control group.

Participants randomised to the exercise intervention arm will be asked to undertake a partly supervised, physiotherapist led, individually tailored exercise programme for up to 8 weeks prior to their transplant as an outpatient, which will be continued during hospitalisation for transplant treatment. The exercise programme will be carried out three time per week. Following discharge from hospital, the participants in the exercise intervention arm will be offered weekly telephone support from a physiotherapist to promote and support continuation or return to independent exercise in the post transplant period (for up to 3 months).

Assessments will be conducted at four timepoints: baseline assessment 4-6 weeks prior to ASCT, and follow up assessments on day before or day of transplantation, on discharge from hospital and three months' post ASCT. Assessments will involve questionnaires regarding fatigue, quality

of life (QOL), exercise self-efficacy, physical activity, accelerometery and physical assessments including a walk test, sit to stand test and handheld dynamometry. In the final follow up participants will also complete a questionnaire on health and social care usage and approximately 20 participants will participant in qualitative interviews.

Intervention Type
Behavioural

Primary outcome(s)
The feasibility of the intervention including:
1. Percentage uptake (recruitment rate)
2. Adherence to the intervention and acceptability of receiving the intervention (including any deviation from exercise protocol)
3. Attrition due to the intervention, loss to follow-up and adverse event rate
These will be assessed by extracting data from screening and recruitment logs, attendance at supervised exercise training sessions and review of independent exercise log book records and review of adverse events;

Key secondary outcome(s))
The following measures will be taken at four timepoints (at baseline 6-8 weeks before transplant, around day of their transplant, on discharge from transplant hospital admission and 3 months following date of transplant):
1. Fatigue, measured using the Functional Assessment of Chronic Illness Therapy (FACIT-F)
2. Quality of life, measured using the European Organisation for Research and Treatment of Cancer QOL Questionnaire (EORTC QLQ-C30 and myeloma specific module QLQ- MY20), Functional Assessment of Cancer Therapy Bone Marrow Transplantation scale (FACT- BMT) and EuroQol-5D
3. Frailty, measured using the International Myeloma Working Group Frailty Assessment outcome measure
4. Physical activity and sedentary time, measured using ActivPAL accelerometers
5. Functional capacity, measured using the six minute walk test, hand held dynamometry and a timed 30 second sit to stand test
6. Self-reported physical activity behaviour and self-efficacy, measured using the short form International Physical Activity Questionnaire (IPAQ-SF) and Exercise Self-Efficacy Scale (ESES)
7. Resting blood pressure and heart rate
8. Height and weight
9. Blood count and markers of immune system function, measured using blood samples

The following measures will be taken at the final timepoint only (3 months following date of transplant):
1. Health and social care service use in the acute post-transplant period, including transplant hospital admission, using a questionnaire and medical record review
2. Qualitative interviews with a purposeful sample of up to 20 study participants

Completion date
27/09/2021

Eligibility

Key inclusion criteria

1. Adult patients referred to the UCLH transplant multidisciplinary team (MDT) and awaiting autologous stem cell transplant as treatment for myeloma
2. Clinically able to carry out an exercise training programme on a regular basis
3. Patients must have a good command of written and spoken English
4. Willing and able to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Patients with known spinal instability, spinal cord compression or neurological deficits
2. Those who have had recent (within six weeks) spinal surgery or other surgery for pathological fractures
3. Abnormal resting ECG and/or unstable angina
4. Those deemed unsuitable to partake by the MDT
5. Unable or unwilling to undertake an exercise programme on a regular basis

Date of first enrolment
26/05/2019

Date of final enrolment
09/10/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London Hospitals NHS Foundation Trust
London
United Kingdom
NW1 2BU

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: ICA-CDRF-2017-03-067

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/02/2023	22/02/2023	Yes	No
Results article	results from embedded qualitative semi-structured interview study	17/04/2023	26/04/2023	Yes	No
Results article	Qualitative results	09/08/2023	18/03/2025	Yes	No
Protocol article	protocol	29/01/2020	03/02/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Protocol adaptations following COVID-19 pandemic	08/04/2022	11/04/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes