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Body and Cancer: a randomised phase III study in cancer patients undergoing chemotherapy - a supervised group exercise intervention versus standard care

Submission date
05/07/2007

Registration date
13/08/2007

Last Edited
02/11/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
BCIII

Study objectives
The hypothesis to be tested is that the outcomes - health benefits - in the intervention group is better than in the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from:
1. The Scientific Committees of the Copenhagen and Frederiksberg municipalities on the 24th June 2003 (ref: 01-273/00)
2. The Danish Data Protection Agency on the 1st August 2003 (ref: 2000-41-0-149)

Study design
Single-centre randomised prospective open label trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Oncological and haematological cancer patients undergoing chemotherapy

Interventions
Cancer patients will be recruited from the Copenhagen University Hospital, Department of Oncology, Department of Haematology and from The Herlev Hospital, Department of Oncology.

After informed consent and baseline measures randomisation (Clinical Internet Trial Management System [CITMAS]). Data is anonymised using an ID-code and administrative data is kept in a separate database.

The intervention group:
The exercise intervention included four components:
1. Physical exercise (resistance and cardiovascular/fitness training)
2. Relaxation training
3. Body awareness training
4. Massage

The intervention took place in a specially designed workout room located at the Copenhagen University Hospital and was carried out over a six-week period, nine hours per week, in the mornings. Patients came in especially to participate in the exercise programme. On Mondays, Wednesdays and Fridays, the patients participated in physical exercise for 1.5 hours followed by 0.5 hours of relaxation. On Tuesdays, the programme included 1.5 hours of body awareness training followed by 0.5 hours of relaxation. Finally, on Mondays and Fridays, the patients received 0.5 hours of massage.

The different components of the programme constituted a total package, which implied that the patients could not select one activity in preference of another. Seven to ten patients of mixed gender were included in each group. Physiotherapists and a cancer nurse specialist supervised the programme. Pre-exercise screening was performed every second day before the high-intensity physical training.

If one of the following criteria were met, the patient was excluded from the physical training component of the programme on that specific day:
1. Diastolic blood pressure less than 45 mmHg or greater than 95 mmHg
2. Pulse at rest greater 100 beats per minute
3. Temperature greater than 38°C
4. Respiration frequency greater than 20 (number of respirations per minute)
5. Infection requiring treatment with antibiotics
6. Ongoing bleeding
7. Fresh petechiae
8. Bruises
9. Thrombocytes less than 50 x 10^9/l
10. Leucocytes less than 1.0 x 10^9/l

Heart rate was continuously monitored and measured by means of a wireless heart rate transmitter worn by the patients.

Control group:
Patients assigned to the control group received usual care from the health care team and completed outcome measures on the same time frame as the intervention group (no supervised exercise during a six-week period).

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Fatigue measure: European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30), measured at baseline, after six weeks and after three months.

Secondary outcome measures
1. Improvement in muscular strength, aerobic fitness measured using One Repetition Maximum (1RM), Maximal oxygen uptake (VO2max), measured at baseline and after six weeks
2. Improvement in quality of life measured using QLQ-C30, Functional Assessment Cancer Therapy-Anaemia (FACT-An), measured at baseline, after six weeks and after three months
3. Improvement in general well-being measured using Medical Outcomes Study 36-item Short Form (MOS SF-36), measured at baseline, after six weeks and after three months
4. Reduction in anxiety and depression measured using Hospital Anxiety and Depression Scale (HADS), measured at baseline, after six weeks and after three months
5. Physical activity level I - IV measured using the Saltin Scale, measured at baseline, after six weeks and after three months

Overall study start date
01/10/2003

Completion date
01/03/2007

Eligibility

Key inclusion criteria
1. World Health Organization (WHO) performance stage score zero to one
2. A diagnosis of cancer (one month previously), admitted to hospital for out-patient chemotherapy
3. Received at least one series of chemotherapy
4. Previously undergone surgery and/or radiotherapy
5. Age 18 to 65 years inclusive
6. Residence in the Greater Copenhagen Council
7. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
250

Key exclusion criteria

1. Brain metastases
2. Bone metastases
3. Thrombocytopenia
4. Cardiovascular symptoms-cardial insufficiencies
5. No recent myocardial infarct
6. Normal blood pressure

Date of first enrolment
01/10/2003

Date of final enrolment
01/03/2007

Locations

Countries of recruitment
Denmark

Study participating centre
The University Hospitals Centre for Nursing and Care Research (UCSF)
Copenhagen
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DK-2100

Sponsor information

Organisation
The University Hospitals Centre for Nursing and Care Research (UCSF) (Denmark)

Sponsor details
The Copenhagen University Hospital
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Sponsor type
Hospital/treatment centre

Website
http://www.ucsf.dk/

ROR
https://ror.org/05bpbnx46

Funder(s)

Funder type
Charity

Funder Name
The Danish Cancer Society (Denmark)

Funder Name
The Lundbeck Foundation (Denmark)

Funder Name
The Novo Nordic Foundation (Denmark)

Funder Name
The Ministry of Culture Committee on Sports Research (Denmark)

Funder Name
The Copenhagen University Hospital (Denmark)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/10/2009		Yes	No