ISRCTN32511542 https://doi.org/10.1186/ISRCTN32511542

Physical activity level as an outcome measure for use in cancer cachexia trials: a feasibility study

Submission date 05/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/12/2007	**Overall study status** Completed	
Last Edited 17/08/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
Version 1.1

Study information

Scientific Title

Study objectives
Patients with lung or upper-gastrointestinal cancer will find the wearing of an activity monitor over one week acceptable. This has been defined as 80% of patients finding the device acceptable, demonstrated by them wearing the monitor 80% of the time.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Oxfordshire Research Ethics Committee A Study on the 8th March 2007 (ref: 07/Q1604/16).

Study design
Non-randomised, unblinded single-group design

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Palliative care in cancer patients

Interventions
Use of an ActivPAL free-living activity monitor (PAL technologies, Glassgow, UK) to assess free-living activity over one week. There is no control group in this trial, the activity monitors will be used for a period of one-week and, as we are assessing acceptability as a primary endpoint, there is no follow-up beyond this period.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Percentage acceptability of assessing physical activity level with an ActivPAL monitor over one week in patients with lung or upper gastro-intestinal cancer.

Key secondary outcome(s))
1. Correlation between the stepping component and the non-stepping component of the activity score

2. Limits of agreement between the measured stepping component of the activity score and an estimate of the stepping component based on step count; step count for each participant multiplied by the mean 'activity per step' calculated from all participants

All secondary endpoints will be assessed retrospectively, after one week, using the data uploaded from the activity monitors.

Completion date
01/05/2008

Eligibility

Key inclusion criteria
1. Diagnosis of lung or upper-gastrointestinal cancer
2. Eastern Cooperative Oncology Group performance status of 0 - 2
3. Adequate understanding of verbal and written English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex

Key exclusion criteria
1. Currently receiving chemo-radiation therapy
2. Less than four weeks post surgery

Date of first enrolment
01/08/2007

Date of final enrolment
01/05/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Macmillan Reader in Palliative Medicine and Medical Oncology
Nottingham

United Kingdom
NG5 1PB

Sponsor information

Organisation
University of Nottingham (UK)

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (UK) (Ref: C18598/A8211)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2010		Yes	No