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A study exploring the practicality and effectiveness of relaxation therapy plus autohypnotherapy for patients with breast and lung cancer undergoing radiotherapy

Submission date 14/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 19/05/2010	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/06/2019	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

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
R0584

Study information

Scientific Title
A feasibility study of relaxation therapy plus autohypnotherapy for patients with thoracic or breast cancer undergoing radiotherapy

Acronym
HYPREL

Study objectives
The aims are:
1. To develop a programme of cue-controlled relaxation and auto hypnosis (RELHYP) in order to facilitate predictable, regular, gentle breathing during planning and radiotherapy
2. To obtain preliminary evidence of feasibility and effectiveness
3. To validate an automated system for quantifying movement during planning radiotherapy
4.To obtain information about the effect size of the intervention to inform the design of a definitive randomised controlled trial (RCT)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hull and East Yorkshire Research Ethics Committee approved on the 17th September 2007 (ref: 07/H1304/109)

Study design
Phase II randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied

Lung cancer, oesophageal cancer or breast cancer

Interventions
Patients will be randomised to radiotherapy treatment as usual or HYPREL.

HYPREL will consist of a standard, protocolised intervention consisting of:
1. Training in progressive muscular relaxation and cue controlled relaxation by means of audio recordings. Commencing on Day 1, patients will be asked to practice at least once daily until the completion of radiotherapy. They will keep a diary record as in previous studies.
2. Four sessions of protocolised live training in hypnotherapy consisting of training in autohypnosis (Spiegel eye roll technique, anchoring); rehearsal in imaguo, and ego strengthening.

The timing of sessions will be:
Sessions 1 and 2: between days 8 and 14 (in the OHC)
Session 3: day 15 (in the CT planning suite (rehearsal in vivo)
Session 4 (booster): day 42 (mid point of radiotherapy)

Intervention Type
Other

Phase
Phase II

Primary outcome measure
During radiotherapy, the frequency and amplitude of chest wall movement will be measured during RT1, RT10, and RT15 (last fraction of treatment for breast cancer) or RT20 (last fraction of treatment for thoracic cancer) using the Varian RPM system. This is an established system with an integrated software package for data retrieval and processing. It involves no direct patient contact. An infra-red camera is used to track a pair of reflective markers that are mounted on the front face of a small box which is placed on the patients chest. Apart from the placement of this box, the use of this equipment has no impact on the standard treatment. The motion of these markers acts as a surrogate for that of the chest itself and is used to measure its amplitude and frequency. The regularity of the breathing cycle of each patient will be characterised by the mean and standard deviation established over 40 breathing cycles.

Secondary outcome measures
1. Differences between groups in the frequency and amplitude of chest wall movement at other time points
2. Between-group differences in Mood Rating Scale (MRS), Brief State Anxiety Inventory (BSAI), Patient Satisfaction Questionnaire (PSQ) and Functional Assessment of Cancer Therapy (FACT) scores at all time points following randomisation

Overall study start date
18/07/2008

Completion date
30/04/2010

Eligibility

Key inclusion criteria
1. Treatment to include at least 15 - 20 fractions of radical radiotherapy to the thorax or breast
2. Lung cancer, oesophageal cancer or breast cancer
3. Male or female
4. Age at least 18 years
5. Eastern Cooperative Oncology Group (ECOG) performance status of 0 - 1
6. Able to complete questionnaires
7. Able and willing to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Thirty patients (30)

Key exclusion criteria
1. Unable to lie supine for medical reasons
2. History of functional psychosis

Date of first enrolment
18/07/2008

Date of final enrolment
30/04/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Rehabilitation
Kingston upon Hull
United Kingdom
HU3 2PG

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

Sponsor details
Hull Royal Infirmary
Anlaby Road
Kingston upon Hull
England
United Kingdom
HU3 2JZ

Sponsor type
Hospital/treatment centre

Website
http://www.hey.nhs.uk/ShowContent.aspx?PageID=7

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Charity

Funder Name
Dimbleby Cancer Care (UK) (ref: YLD035)

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