

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 13/06/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr James Illingworth

Contact details
Research and Development Department
Hull University Teaching Hospitals NHS Trust
Office 14, 2nd Floor Daisy Building
Castle Hill Hospital
Cottingham
United Kingdom
HU16 5JQ
+44 (0)1482 461903
James.Illingworth@hey.nhs.uk

Additional identifiers

Protocol serial number
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)

Primary study design

Interventional

Study design

Phase II randomised controlled trial

Study type(s)

Treatment

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 imago, 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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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**

United Kingdom

England

Study participating centre**Institute of Rehabilitation**

Kingston upon Hull

United Kingdom

HU3 2PG

Sponsor information**Organisation**

Hull and East Yorkshire Hospitals NHS Trust (UK)

ROR

<https://ror.org/01b11x021>

Funder(s)**Funder type**

Charity

Funder Name

Dimbleby Cancer Care (UK) (ref: YLD035)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration