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Comparing the effects of live versus recorded relaxation on mood, coping, and quality of life on patients with cancer

Submission date 17/03/2010	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 07/05/2010	**Overall study status** Stopped	
Last Edited 16/10/2015	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R0578

Study information

Scientific Title
A pragmatic, randomised controlled trial of the effects of live relaxation on mood, coping, and quality of life on patients with cancer

Acronym
LIVEREL

Study objectives
1. In patients attending the Oncology Health Centres for the first time, what is the relative effectiveness of live relaxation "LIVEREL" and recorded relaxation "RECREL" (i.e. "treatment as usual" including audio recorded relaxation as part of support within the Oncology Health Centres) on mood, coping and quality of life?
2. What is the relative cost-effectiveness of LIVEREL and RECREL?
3. What are the immediate effects of live versus recorded relaxation instructions on blood pressure and pulse rate?

If patients randomised to LIVEREL have significantly higher relaxation scores on the Mood Rating Scale than those randomised to RECREL, we would conclude that the beneficial effects of LIVEREL was due to the extra social contact and/or the effects of live feedback on performance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hull & East Riding Local Research Ethics Committee approved on the 18th of September 2007 (ref: 07H1304/110)

Study design
Single centre prospective pragmatic randomised active controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied

Various cancers; colorectal, gynaecological cancer (ovarian, endometrial, cervical) lung, or prostate

Interventions

All interventions will be carried out in the Oncology Health Centres at Castle Hill and Princess Royal Hospitals, Kingston upon Hull (House of Commons, 2004; Walker et al., 2003 a and b). Patients will be randomised to one of two interventions:

1. Patients randomised to RECREL will be taught progressive muscular relaxation and cue-controlled relaxation (Hutchings et al., 1980), with imagery of the patients choice, by means of audio recordings based on scripts used in our previous studies of patients with breast cancer, colorectal cancer, and lymphoma, and with healthy volunteers (Johnson et al., 1996; Ratcliffe et al., 1995, Walker et al., 1999a). Each therapist will record these scripts in his/her own voice. Patients will be asked to practice once daily at home for 8 weeks (daily diary records to be kept). To control for patient contact, they will receive three audio recorded training sessions (progressive muscular relaxation, with or without guided imagery) at weeks, 1, 2 and 4 in the Oncology Health Centres.

2. Patients randomised to LIVEREL will receive the same audio recordings and will be given identical instructions to practice daily at home for 8 weeks. In addition, they will be given three sessions of live training (40 minutes) at weekly intervals from our clinical nurse specialists (behavioural oncology).
An external consultant skilled in these methods will assess the competency of each of the nurses and their ability to adhere to the protocol. In addition, to ensure protocol adherence, a random sample of live sessions will be observed by a clinical psychologist during the study period.
All patients will be invited to attend, or telephone, one of the Oncology Health Centres whenever they wish, and they will receive treatment as usual in the Centres when they attend (House of Commons, 2004; Walker et al., 2003 a and b). This includes access to the Clinical and Research Nurse Specialists (Behavioural Oncology) and, if indicated clinically, the clinical psychologists. All patients with clinically significant problems will receive treatment according to current local practice and any psychosocial or psychopharmacological interventions will be documented. They will also have access to other support services.
Records of telephone and other contact with the Centres will be kept (using the contact cards used in previous studies).

Intervention Type

Other

Phase

Phase III

Primary outcome measure

Relaxation scale score on the Mood Rating Scale (MRS), (Anderson et al., 2000; Johnson et al., 1996; Walker et al., 1997; Walker et al., 1999; Wesnes et al., 1997b), measured at 8 weeks

Secondary outcome measures

1. Functional Assessment of Cancer Therapy: General version (FACT-G) (Cella et al., 1993)
2. Hospital Anxiety and Depression Scores (HADS) (Hermann, 1997; Walker et al., 1999; Zigmond & Snaith, 1983)
3. Mood Rating Scale (MRS) (remaining scales) (Anderson et al., 2000; Johnson et al., 1996;

Walker
et al., 1997; Walker et al., 1999; Wesnes et al., 1997)
4. Brief Profile of Mood States (Cella et al, 1987)
5. EuroQol (EQ-5D) (Brooks, 1996; EuroQoL Group, 1990)
6. Health Service Use (HSU)
7. Social Support Questionnaire (SSQ)
8. Patient Satisfaction Questionnaire (PSQ) (Walker et al., 1999)
All secondary outcomes will be measured at 4 and 12 weeks.

Overall study start date
01/01/2008

Completion date
01/07/2011

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. At least 18 years of age
2. Histologically confirmed colorectal cancer, gynaecological cancer (ovarian, endometrial, cervical) lung, or prostate cancer.
3. Accessing the Oncology Health Service for the first time

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
156

Key exclusion criteria
1. WHO performance status 2, 3 and 4;
2. Clinically significant cognitive impairment or dementia
3. Inability to complete Quality of Life questionnaires
4. Inability or unwillingness to give informed consent
5. History of functional psychosis.

Date of first enrolment
01/01/2008

Date of final enrolment
01/07/2011

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Hull & 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

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hull & East Yorkshire Hospitals NHS Trust (UK) - Endowment Funds

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 expected to be made available