Progressive muscle relaxation technique in the care of anxiety and pain in the cancer patient

Submission date	Recruitment status	Prospectively registered		
22/11/2016	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
22/11/2016	Completed	[X] Results		
Last Edited 04/05/2018	Condition category Signs and Symptoms	[] Individual participant data		

Plain English summary of protocol

Background and study aims

Cancer patients often suffer from emotional distress such as anxiety or depression. The presence of these symptoms in combination with the physical symptoms of cancer, such as pain and nausea (feeling sick), can have a negative effect on overall quality of life. Progressive muscle relaxation is a technique which involves relaxing muscles through a two-step process: Tensing specific muscle groups followed by releasing the tension and noticing the feeling when relaxing the muscles. This exercise can be an effective way to lower overall tension and stress levels, and help people to relax when they are feeling anxious. The aim of this study is to find out whether this muscle relaxation technique can help reduce levels of anxiety and pain in cancer patients, leading to an improved quality of life.

Who can participate?

Adult cancer patients experiencing anxiety, muscle tension, sleeping difficulties, sadness, or anxiety attacks

What does the study involve?

Participants attend a single session where they learn the muscle relaxation technique. The session takes place in a comfortable room with a trained instructor, either individually or in groups. After the session, participants are encouraged to perform the technique at home at least once a day for the duration of the study. At the start of the study and then every week for a month, participants complete a number of questionnaires to assess their anxiety, pain and nausea levels. In addition, they are asked about their medication use at the same times.

What are the possible benefits and risks of participating?

There are no direct benefits or risks involved with participating in this study.

Where is the study run from?

Hospital Universitario Marques de Valdecilla and nine other hospitals in Spain.

When is the study starting and how long is it expected to run for? February 2014 to May 2016

Who is funding the study? Investigator initiated and funded

Who is the main contact? Dr Paula Parás-Bravo

Contact information

Type(s)

Scientific

Contact name

Dr Paula Parás-Bravo

Contact details

Universidad de Cantabria Escuela de Enfermeria Avenida de Valdecilla s/n santander Spain 39008

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Proyecto tesis

Study information

Scientific Title

Is the muscle relaxation technique capable of improving the quality of life of cancer patients with anxiety and pain?

Study objectives

The progressive muscle relaxation technique in its abbreviated version reduces symptoms of anxiety and pain in cancer patients, leading to improved quality of life.

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. Ethical Committee of Cantabria, 29/05/2014, ref: 2014.097
- 2. Alcorcon Hospital Ethics Committee, 03/11/2014
- 3. Ethical Committee Fuenlabrada Hospital, 03/12/2014

- 4. Ethical Committee Getafe Hospital, 26/06/2014, ref: A13-14
- 5. Ethical Committee Puerta Del Hierro Hospital, 27/07/2014, ref: Huph Pi92/14
- 6. Ethical Committee Instituto Catalan Oncologia Badalona, 14/11/2014, ref: Jacobson 01/2014
- 7. Ethical Committee Instituto Catalan Oncologia Hospitalet, 10/09/2014, ref: Acta 15-14
- 8. Ethics Committee Salamanca Hospital, 18/07/2014
- 9. Sierrallama Hospital Ethics Committee, 01/08/2014, ref: 2014.097
- 10. Committee Etica Complex Hospitalario Navarra, 01/02/2015, ref: Pyto 2015/14

Study design

Non-randomised study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Anxiety, pain and nausea in cancer patients

Interventions

All participants receive a guided session in order to learn abbreviated progressive muscle relaxation training by following Bernstein and Borkovec. These sessions are conducted individually or in groups, according to the patients' condition. All researchers who perform the intervention are fully trained regarding the selection criteria, information provided to participants, data collection procedures and application of the technique in order to unify criteria and reduce possible inter-examiner bias. All researchers receive a written guidance document for the relaxation session. The patients perform the technique in a sitting position in rooms furnished with armchairs, cushions, pleasant lighting and an overall quiet environment. Each session last approximately 60 minutes and is divided into the following 4 parts:

- 1. An explanation regarding the characteristics of the abbreviated progressive muscle relaxation training by Bernstein and Borkovec
- 2. Application of a relaxation session
- 3. Answering possible questions
- 4. Data collection using the self-administered FACT-G questionnaire and the data collection notebook.

At the end of the session, patients are provided with information regarding the intervention consisting of a brief description of the session, based on text and images, in order to support the performance of this technique at their respective homes. Participants are advised to perform the technique at home at least once a day for the duration of the study.

Participants are followed up weekly for one month.

Intervention Type

Behavioural

Primary outcome measure

- 1. Quality of life is measured using the FACT-G (Functional Assessment of Cancer Therapy General) questionnaire at baseline and weekly for four weeks (1 month)
- 2. Anxiety is measured using a visual analogue scale (VAS) at baseline and weekly for four weeks (1 month)
- 3. Pain is measured using a visual analogue scale (VAS) at baseline and weekly for four weeks (1 month)
- 4. Nausea is measured by asking participants a yes/no question about their nausea levels at baseline and weekly for four weeks (1 month)

Secondary outcome measures

- 1. Analgesic use is measured through patient interviews at baseline and weekly for four weeks (1 month)
- 2. Anxiolytic use is measured through patient interviews at baseline and weekly for four weeks (1 month)
- 3. Hypnotics use is measured through patient interviews at baseline and weekly for four weeks (1 month)
- 4. Antidepressant use is measured through patient interviews at baseline and weekly for four weeks (1 month)

Overall study start date

01/02/2014

Completion date

01/05/2016

Eligibility

Key inclusion criteria

- 1. Age 18 years and over
- 2. Cancer patients
- 3. Experiencing anxiety, muscle tension, sleeping difficulties, sadness, or anxiety attacks
- 4. Provision of consent to participate

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

272

Key exclusion criteria

Patients suffering from hallucinations, delirium or other psychotic symptoms.

Date of first enrolment

01/11/2014

Date of final enrolment

01/10/2015

Locations

Countries of recruitment

Spain

Study participating centre

Hospital Universitario Marques de Valdecilla

Av. Valdecilla, 25 Santander Spain 39008

Study participating centre Hospital Fundación Alcorcon

Calle Budapest, 1 Madrid Spain 28922

Study participating centre

Hospital Universitario Fuenlabrada Calle Camino del Molino, 2

Fuenlabrada Madrid Spain 28942

Study participating centre Hospital Universitario de Getafe Carr. Madrid - Toledo, Km 12,500 Madrid Spain 28905

Study participating centre Complejo Hospitalario Palmplona

Calle de Irunlarrea, 3 Palmplona Navarra Spain 31008

Study participating centre Hospital Sierrallana

Barrio de Ganzo, s/n Cantabria Spain 39300

Study participating centre Hospital Universitario de Salamanca

Paseo de San Vicente, 88-182 Castilla y Leon Spain 37007

Study participating centre Instituto Catalan de Oncologia, Hospitalet

Hospital Duran i Reynals Avinguda de la Granvia, 199-203 Barcelona Spain 08908

Study participating centre Instituto Catalan de Oncologia, Badalona

Hospital Duran i Reynals Avinguda de la Granvia, 199-203 Barcelona Spain 08908

Study participating centre Hospital Universitario Puerta del Hierro

Calle Manuel de Falla, 1 Madrid Spain 28222

Sponsor information

Organisation

Universidad de Cantabria

Sponsor details

av. Valdecilla sn Santander Spain 39008

Sponsor type

University/education

ROR

https://ror.org/046ffzj20

Funder(s)

Funder type

Not defined

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal

Intention to publish date

31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/05/2018		Yes	No