







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

<b>Submission date</b> 22/11/2016	<b>Recruitment status</b> No longer recruiting	 Retrospectively registered
		 Protocol not yet added
<b>Registration date</b> 22/11/2016	<b>Overall study status</b> Completed	 SAP not yet added
		 Results added
<b>Last Edited</b> 04/05/2018	<b>Condition category</b> Signs and Symptoms	 Raw data not yet added
		 Study completed

## Plain English Summary

### 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 Enfermería  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Protocol/serial number**  
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 hypothesis**  
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

### **Condition**

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

## **Overall study end date**

01/05/2016

# **Eligibility**

## **Participant 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

**Participant exclusion criteria**

Patients suffering from hallucinations, delirium or other psychotic symptoms.

**Recruitment start date**

01/11/2014

**Recruitment end date**

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**

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28905

**Study participating centre**  
**Complejo Hospitalario Palmplona**  
Calle de Irunlarrea, 3  
Palmplona  
Navarra  
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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  
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37007

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## Sponsor information

**Organisation**  
Universidad de Cantabria

**Sponsor details**  
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**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 summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	02/05/2018		Yes	No