

# Determining the effectiveness of a structured group dynamic relaxation-training programme on reducing anxiety and depression symptoms

<b>Submission date</b> 01/04/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/04/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/09/2021	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Studies have persistently shown that anxiety disorders cause morbidity, increased use of health care services, decreased work productivity, work absence and will possibly be one of the leading causes of disability in the twenty-first century. In the treatment of anxiety disorders, psychopharmacological interventions with benzodiazepines and selective serotonin reuptake inhibitors (SSRI) have shown their efficacy. Non-pharmacologic interventions may be proposed as an alternative option, with the aim to reduce perceived anxiety and stress and to increase the sense of well being in the general population and relaxation – meditation techniques represent one of the most important alternatives in anxiety intervention worldwide.

The aim of the present study is to determine the effectiveness of an intensive four-week structured group relaxation-training program (sophrology's dynamic relaxation) on anxiety and depression symptoms in primary care patients with moderate and high anxiety levels.

### Who can participate?

Patients with moderate and high anxiety levels aged between 18 and 70 years.

### What does the study involve?

Participants attend 12 one-hour sessions over a 4 week period. The intervention group will participate in the dynamic relaxation program called "well-being and sophrology" and the control group will participate in a cognitive program based on physical and mental health recommendations.

### What are the possible benefits and risks of participating?

Possible benefits are the improvement of anxiety and depression symptoms. No risks expected as a result of participation.

### Where is the study run from?

Medical Health Care Centre "Serraparera", Cerdanyola, Barcelona.

When is the study starting and how long is it expected to run for?  
May 2015.

Who is funding the study?  
Investigator-initiated and funded.

Who is the main contact?  
Koen van Rangelrooij  
koen@sofrologia.com

**Study website**  
N/A

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
Nil known

## Study information

**Scientific Title**  
Effectiveness of a structured group relaxation-training programme based on sophrology's dynamic relaxation techniques for primary care patients with moderate and high anxiety levels: a randomised controlled trial

**Study objectives**

The Dynamic relaxation programme (sophrology) is more effective than a physical and mental health recommendations programme in patients with moderate and high anxiety levels.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 20/10/2015, the University Review Board of the Autonomous University of Barcelona (CEIm – Parc de Salut MAR, Dr. Aiguader, 88, 08003, Barcelona; 93 316 06 77; ceic-psmar@imim.es), ref: 2015/6141/I.

**Study design**

Interventional and experimental study design, single centre, randomized controlled trial,

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

**Health condition(s) or problem(s) studied**

Anxiety

**Interventions**

Both programs covered a total of 12 one-hour sessions over 4 weeks (3 sessions a week). The intervention group followed the structured dynamic relaxation program called “well-being and sophrology” and the control group a cognitive program based on physical and mental health recommendations (PMHR). Simple random sampling was used. Two physicians, two nurses and a psychologist from the Medical Health Care Centre guided both the sophrology intervention and the PMHR (Physical and Mental Health Recommendations) control programme.

**Intervention Type**

Behavioural

**Primary outcome measure**

Anxiety was measured using the Hospital Anxiety Depression Scale (HADS) and the State-Trait Anxiety Inventory (STAI) at the beginning of the first and the last session of the training programme.

**Secondary outcome measures**

N/A

**Overall study start date**

16/03/2015

**Completion date**

19/06/2015

## **Eligibility**

**Key inclusion criteria**

1. A score >7 for the Hospital Anxiety Depression Scale - anxiety subscale
2. 18 to 70 years of age

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

70 patients

**Total final enrolment**

70

**Key exclusion criteria**

1. Initiated or changed pharmacological, behavioural or any other therapy during the programme
2. Presented uncontrolled mental illness
3. Planned to participate in other therapies or similar programmes such as Yoga, Mindfulness, meditation, acupuncture, or other
4. During the programme suffered from important stressful life events
5. Not able to participate for linguistic, cultural or physical problems
6. Could not attend sessions regularly (<80% attendance)

**Date of first enrolment**

04/05/2015

**Date of final enrolment**

22/05/2015

## **Locations**

**Countries of recruitment**

Spain

**Study participating centre**  
**Medical Health Care Centre "Serraparera"**  
Carrer Diagonal, s/n,  
Cerdanyola del Valles  
Spain  
08290

## Sponsor information

**Organisation**  
Autonomous university Barcelona

**Sponsor details**  
Plaza Cívica.  
08193 Bellaterra (Cerdanyola del Vallès)  
Bellaterra  
Spain  
08193  
+34 93 581 11 11  
informacio@uab.cat

**Sponsor type**  
University/education

**Website**  
[www.uab.cat](http://www.uab.cat)

**ROR**  
<https://ror.org/052g8jq94>

## Funder(s)

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded

# Results and Publications

## Publication and dissemination plan

Planned publication in the “Journal of Psychosomatic Research”, the Spanish journal “Psiquiatría y Salud Mental” or another high impact peer-reviewed journal.

## Intention to publish date

15/04/2019

## Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/09/2020	20/09/2021	Yes	No