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

Submission date
01/04/2019

Recruitment status
No longer recruiting

Registration date
08/04/2019

Overall study status
Completed

Last Edited
20/09/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
N/A

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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

ROR
https://ror.org/052g8jq94

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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?
Results article		01/09/2020	20/09/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes