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Effectiveness of sophrology (a mind-body method) on patients with anxiety

Submission date
06/06/2022

Recruitment status
No longer recruiting

Registration date
28/06/2022

Overall study status
Completed

Last Edited
29/06/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
According to the World Health Organisation (WHO), anxiety and mood disorders are the largest cause of human disability in the world and more than 260 million people suffer from an anxiety disorder. Anxiety and depression have a significant economic impact: it has been estimated that the cost in lost productivity on the global economy is about US$ 1 trillion annually. In line with the proposal of the Committee of Permanent Representatives, the European Social Affairs Council calls for the adoption of a new EU strategic framework on health and safety at work for the period 2021-2027, amongst others, relating to psychosocial risks and stress at work, which are among the most difficult and most urgent problems mentioned in this document.
This study is in line with a previous study which assessed the effectiveness of the structured stress management program "sophrology and wellbeing" (SW) in reducing anxiety and depression symptoms in patients with a moderate or high level of anxiety. The aim of this second study is to investigate if a stress management sophrology training program based on two 1-hour sessions a week for 4 consecutive weeks is as effective at reducing anxiety and depression as the previous program based on three 1-hour sessions a week for 4 consecutive weeks.

Who can participate?
Patients aged between 18 and 70 years with anxiety and depression symptoms

What does the study involve?
Participants are randomly allocated to the sophrology and wellbeing program or a theory-based control program consisting of healthy habits recommendations. Anxiety and depression symptoms are measured before and after the interventions.

What are the possible benefits and risks of participating?
The possible benefits of participation in this study are the reduction of anxiety and depression symptoms.

Where is the study run from?
Autonomous University of Barcelona (Spain)

When is the study starting and how long is it expected to run for?
May 2015 to November 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Koen van Rangelrooij, koen@sofrocay.com

Contact information

Type(s)
Scientific

Contact name
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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 Caycedian sophrology in patients with moderate and high anxiety levels: a second prospective randomized controlled study

Study objectives
The stress management sophrology and wellbeing program based on two 1-hour sessions a week is less effective at reducing anxiety and depression symptomatology than the three 1-hour sessions a week program for 4 consecutive weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/10/2015, Ethics Committee: "Investigación Clínica Parc de Salut MAR" (CEIm – Parc de Salut MAR, Dr. Aiguader, 88, 08003, Barcelona, Spain; +34 (0)93 316 06 77; ceic-psmar@imim.es), ref: 2015/6141/I

Study design
Prospective controlled randomized study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Moderate and high anxiety levels

Interventions
Patients are randomly assigned into two groups of 35 participants following simple randomization. Following the list of selected patients, every multiple of seven is called by telephone (patient 7,14, 21, etc) and alternately assigned to the intervention group or the control group until the number of 35 participants is reached for each group. The sample size is based on medical and statistical considerations.

The sophrology group receive the structured Sophrologie & wellbeing (SW) intervention for 4 consecutive weeks at a rate of two weekly sessions of 1 hour each (theory and practical). The first half of the program is dedicated to a theoretical part (50%) and the other half to practising sophrology techniques (50%), which consist of training in relaxation techniques, breathing exercises, as well as imaging and mental programming techniques (for the past, present, future and personal values). At the end of each session the group receive a summary of the theoretical part and a digital recording of the practised sophrology technique. They are motivated to train daily and to apply what they learn in everyday life and are instructed to know how to manage stress properly and develop a more serene and positive attitude.

The control group receive the exclusively theory-based Healthy Habit Program (HHP) intervention for 4 weeks, also with two 1-hour sessions per week. The program consists of a theoretical part similar to the SW program, and a more interactive part on promoting healthy habits in the face of stress. This interactive part consists of informative videos and/or specialized lectures on the topics covered in the theoretical part. At the beginning of the intervention, participants are informed of the possibility to continue with the sophrology program once the HHP intervention ends.

The programs are administered in two different classrooms, at the same time and on the same days of the week at the primary health care centre facilities. The team of trainers, four health care professionals and Caycedian sophrologists duly train in the SW intervention and impart the interventions to both groups (sophrology and control).

Statistical analyses are performed using SPSS 27th version (IBM Corp.). Descriptive statistics including mean and standard deviation of the HADS and STAI scores for the sophrology and control group are used to describe the different variables used in this study. Repeated measures for the analysis of variance (ANOVA) are used to compare pre- and post-intervention scores for

the sophrology and control group (between-groups and within-group intervention effect). The student (t) test is used to compare the basal scores for both groups and to detect possible initial differences between the two groups. The p-value under 0.05 is considered statistically significant for all data analyses. Pre-post Cohen's (d) effect sizes (ES) are used to measure the effect size in the sophrology and control groups.

Intervention Type
Behavioural

Primary outcome(s)
1. Anxiety and depression symptoms measured using the Hospital Anxiety Depression Scale (HADS) at baseline and after 4 consecutive weeks
2. State and trait anxiety levels measured using the State-Trait Anxiety Inventory (STAI) at baseline and after 4 consecutive weeks

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/11/2017

Eligibility

Key inclusion criteria
1. Scored ≥8 points on the HAD-Anxiety subscale
2. Older than 18 years and younger than 70 years
3. Expressed a formal wish to take part in the research
4. Not presenting any of the exclusion criteria
5. Read and signed an informed consent document

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Key exclusion criteria

Patients were excluded from the study if they:
1. Started, changed or increased any pharmacological therapy during the program
2. Suffered from an acute state of severe mental illness (major depression, bipolar disorder and schizophrenia, etc)
3. Planned to participate in other therapies or similar programs such as yoga, meditation, acupuncture or similar during the study
4. Suffered, during the program, from important stressful life events, which could produce a bias in the assessments of the study
5. Were not able to participate because of linguistic, cultural or physical problems

Date of first enrolment
01/06/2017

Date of final enrolment
14/06/2017

Locations

Countries of recruitment
Spain

Study participating centre
Serraparerra Primary Health Care Centre
Carrer diagonal s/n
Cerdanyola del Valles
Spain
08290

Sponsor information

Organisation
Autonomous University of 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 datasets generated and analysed during the current study will be available upon request from Koen van Rangelrooij (koen@sofrocay.com).

IPD sharing plan summary
Available on request