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The effect of group cognitive behavior combined hypnotherapy on neuroendocrine and physical symptoms in patients with anxiety disorders

Submission date
27/06/2023

Recruitment status
No longer recruiting

Registration date
01/07/2023

Overall study status
Completed

Last Edited
30/06/2023

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
Anxiety disorders are one of the common clinical psychological disorders that threaten human mental health and account for a large proportion of psychiatric inpatients. For decades, people have devoted themselves to finding various indicators to accurately measure and objectively evaluate anxiety disorders, and the main indicators are divided into two kinds: psychological indicators, which are generally evaluated with various scales and are characterized by directness and subjectivity; and physiological indicators, which are measured with various instruments and are characterized by indirectness and objectivity. Although the causes of anxiety disorders are still unclear, they are all related to various psychological and physiological indicators.
At present, there are relatively few studies on the correlation between somatic symptoms and endocrine function in anxiety disorders at home and abroad, but there are more studies on the psychological treatment of anxiety disorders. Cognitive therapy and hypnotherapy are both commonly used and widely recognized psychological interventions in clinical practice, and combining the two may provide a new perspective for alleviating somatic symptoms and improving neuroendocrine levels in patients with anxiety disorders.

Who can participate?
Patients with anxiety disorder

What does the study involve?
Participants will be randomly allocated into two groups (intervention and control). The control group will receive regular medication and care. The intervention group will undergo a 6-week cognitive combined with hypnosis group psychotherapy. The program includes understanding anxiety and finding a safe place, finding cognitive biases, identifying automatic thoughts, accepting imperfections, and learning self-hypnosis to experience relaxation, self-mastery, and relapse prevention. Both the intervention and control groups will complete three questionnaires and blood tests for neuroendocrine levels before and after treatment.

What are the possible benefits and risks of participating?
The intervention group participants may experience some emotional fluctuations or trigger past trauma experiences during the intervention process. The intervention effect may also fluctuate or decay due to individual differences or external factors, affecting the participants' confidence in their condition and psychological treatment. The intervention content may also be inconsistent with the participant's personal values or cultural background, causing cognitive or emotional conflicts. There is a very small probability of accidental events or emergencies during the intervention process, which require timely response measures or referral to other professionals. Their benefit is participants can improve their psychological state or problems by learning and applying cognitive behavioral and hypnosis skills, and improve their self-efficacy and quality of life. The control group participants may miss an effective opportunity to improve their mental health level or solve their psychological troubles, or face more challenges and pressures in the absence of professional guidance and support. Their benefit is that they can avoid possible adverse effects that may occur during the psychological intervention process, such as emotional fluctuations, trauma experiences, and effect fluctuations.

Where is the study run from?
Universiti Sains Malaysia (Malaysia)

When is the study starting and how long is it expected to run for?
June 2022 to December 2024

Who is funding the study?
Universiti Sains Malaysia (Malaysia)

Who is the main contact?
Hanyue Zhang, hanyuezhang83@gmail.com

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Study information

Scientific Title

A study on the intervention of cognitive combined hypnotherapy on somatic symptoms and neuroendocrine levels in patients with jaundice filtration

Study objectives
Cognitive combined with hypnotherapy has a positive effect on somatic symptoms and neuroendocrine levels in patients with anxiety filtration

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/04/2023, Ethics Committee of Universiti Sains Malaysia (Kubang Kerian, Kelantan, Kubang Kerian, 16150, Malaysia; +609 - 767 3000/2354/2362; jepem@usm.my), ref: USM/JEPeM /22120758

Study design
Single-center double-blind randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anxiety disorders

Interventions
All participants will be assigned to group cognitive hypnotherapy (GCBH) or standard treatment (ST) in a 1:1 ratio using a computerized block randomization algorithm. All patients will receive general medical care and anxiolytics. Patients in the experimental group will receive a 6-week group cognitive hypnosis intervention. The topics are understanding anxiety and finding a safe place, finding cognitive biases, identifying automatic thoughts, accepting imperfections, and learning self-hypnosis to experience relaxation, self-management and relapse prevention. The control group will receive only conventional medication and care.

Intervention Type
Behavioural

Primary outcome(s)
Measured at baseline week 0 and after treatment at week 6:
1. Anxiety levels in patients with anxiety disorders measured using the Hamilton Anxiety Inventory (HAMA) and Self-Assessment Scales for Anxiety (SAS)
2. Somatic symptoms in patients with anxiety disorders measured using the Somatization Symptom Checklist (SSS)

Key secondary outcome(s))
Neuroendocrine levels (plasma cortisol [COR], serum triiodothyronine [T3], thyroid hormone [T4] and thyroid stimulating hormone [TSH]) measured using blood samples at baseline week 0 and after the intervention at week 6

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. ICD-10 diagnosis of generalized anxiety disorder, social anxiety disorder and panic disorder
2. Anxiety disorder lasting more than 3 months but not more than 3 years
3. Ability to express and understand simple Chinese characters
4. Informed consent and voluntary participation in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients with major psychiatric disorders such as depression and bipolar disorder
2. Patients at serious risk of suicide and self-injury
3. Patients with serious cardiovascular diseases such as severe hypertension, diabetes, hyperlipidemia
4. Patients who have had substance dependence or abuse, such as alcohol or drug dependence
5. Pregnant women

Date of first enrolment
01/05/2023

Date of final enrolment
01/05/2024

Locations

Countries of recruitment
China

Study participating centre
Nanjing Brain Hospital
Nanjing Jiangsu Province

Nanjing
China
210000

Sponsor information

Organisation
Universiti Sains Malaysia

ROR
https://ror.org/02rgb2k63

Funder(s)

Funder type
University/education

Funder Name
Universiti Sains Malaysia

Alternative Name(s)
University of Science, Malaysia, Universiti Sains Malaysia (USM), Universiti Sains Malaysia | George Town, Malaysia | USM, usmofficial1969, University Sains Malaysia (USM), University Sains Malaysia, Science University of Malaysia, USM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
In order to comply with the GDPR and the Data Protection Act 2018, personal data will be deleted as soon as it is no longer required for research.

All study data (e.g. online questionnaires, blood test results) will be stored on university-owned computers which will be downloaded to study team members for analysis. Anonymous data will be shared after posting in response to internal and external requests or as part of posting.

Name and email address of the investigator/institution that should be contacted to access the dataset: Hanyue Zhang (hanyuezhang83@gmail.com)
Types of data that will be shared: Raw behavioral data in .csv and .mat files
Date of availability: data will only be shared when the results are published together with the corresponding scientific paper
Is the participant's consent required and obtained: Obtained
Comments on data anonymization: data will be completely anonymized

IPD sharing plan summary

Stored in non-publicly available repository, Available on request