

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

|                                        |                                                               |                                                      |
|----------------------------------------|---------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>27/06/2023   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                               | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>01/07/2023 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                               | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>30/06/2023       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |
|                                        |                                                               | <input type="checkbox"/> 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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**Contact details**

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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**

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

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

**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 measure**

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)

## **Secondary outcome measures**

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

## **Overall study start date**

01/06/2022

## **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

## **Age group**

Adult

## **Sex**

Both

## **Target number of participants**

84

## **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

**Sponsor details**

16150 Kubang Kerian

Kelantan

George Town

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16150

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jepem@usm.my

**Sponsor type**

University/education

**Website**

<https://www.usm.my/index.php/en/>

**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

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

## Intention to publish date

01/11/2023

## 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