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Cupping therapy combined with SSRIs in patients with depression

Submission date
06/03/2018

Recruitment status
No longer recruiting

Registration date
27/03/2018

Overall study status
Completed

Last Edited
07/11/2022

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
Depression is one of the most common psychiatric disorders, affecting 8-20% of the worldwide population during their lives. Selective serotonin reuptake inhibitors (SSRIs) are first-line pharmacotherapy for depressive disorders. But there is still a large portion of patients failed to achieve a full response and suffered from relapse and side effect. As an alternative non-drug therapeutic technique, cupping therapy may offer a option to enhance the efficacy of SSRIs. Cupping therapy is based on the Traditional Chinese Medicine theory and has been practiced for thousands of years. The WHO's definition of cupping is a therapeutic method involving the application of suction by creating vacuum. According to ancient TCM classic, depression is a consequence of “brain shen disorder” and “unbalance of qi and blood”. Cupping therapy on the back is considered to regulate Du and Bladder meridian. Du meridian is directly connected to brain and can regulate “brain shen”. The acu-points of wuzang-shu (BL13, BL15, BL18, BL20, BL23) on the Bladder meridian are key points to restore “qi and blood”. So cupping therapy on Du meridian and wuzang-shu acu-pionts is considered to be beneficial to relief depression by regulating “brain shen” and rebalance “qi and blood”. The aim of this study is to explore the effect of using cupping therapy to help patients with depression.

Who can participate?
Patients aged from 18 to 65 are welcomed to participate.

What does the study involve?
Participants will be divided into two groups. One will receive SSRIs while the other will receive SSRIs combined with cupping therapy.

What are the possible benefits and risks of participating?
Possible benefits include less depressive experience and less side effects. The risk of taking part is minimal. Cupping therapy is a very safe treatment when given by well-trained doctors. Occasionally people having cupping therapy may feel faint or have a temporary pain during treatment.

When is the study starting and how long is it expected to run for?
The study starts from 1/1/2017 and lasts for 3 years in Beijing Hospital of TCM (single center study).

Who is funding the study?
Beijing Municipal Administration of Hospitals (China)

Who is the main contact?
Ms. Jiang is the main contact. The e-mail address is jiangmolin1104@sina.com.

Contact information

Type(s)
Scientific

Contact name
Ms Molin Jiang

Contact details
Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University, No. 23 Backstreet Gallery, Dongcheng District
Beijing
China
100010
0086-010-52176757
jiangmolin1104@sina.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PZ2017014

Study information

Scientific Title
An 8-week randomised controlled trial with 16-week follow-up of cupping therapy combined with SSRIs in patients with depression

Study objectives
Adjuvant cupping therapy provides both short-term and long-lasting enhancement of the antidepressant effect of selective serotonin reuptake inhibitors (SSRIs), as well as reduction of side effects.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Research Ethical Committee of Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University, 05/05/2017, 2017BL-012-02.

Study design
Single-centre interventional randomised 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 below to request a patient information sheet: jiangmolin1104@sina.com

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

Interventions
Participants are randomly assigned to one of two groups: SSRIs alone (control group) or combined with cupping therapy (treatment group).

Control group: Participants will receive SSRIs orally for 8 weeks, including sertraline, fluoxetine, paroxetine, fluvoxamine, citalopram and escitalopram. The dosage will depend on the participant's situation according to the guideline. During 16 weeks of follow-up, participants are asked to continue taking SSRIs.

Treatment group: Participants will receive SSRIs as for the control group as well as cupping therapy. The cupping therapy includes three steps:
1. Flash-cupping. Suction (vacuum) will be created in the cup using a flame. Then the cup will be applied to the du and bladder meridians and quickly moved away.
2. Moving-cupping. The cup applied to the back will be moved back and forth along the du and bladder meridians several times.
3. Retain-cupping. After the cup has been moved away, flaming heat will be used again to create a vacuum in the cup. Then the cup will be applied to the wuzhangshu acu-point and retained for 5 min.
The cupping therapy will be once a week for 8 weeks in total.

Intervention Type
Mixed

Primary outcome measure
Clinical response rate defined as ≥50% reduction from baseline on 17-item Hamilton Rating Scale for Depression (HAMD-17 measured at 8 weeks (endpoint) and 24 weeks (follow-up point).

Secondary outcome measures
1. Change from baseline in HAMD-17 score from baseline at weeks 2, 4, 8 (endpoint) and week 24 (follow-up).
2. Change from baseline in each of five factor scores on HAMD-17 score from baseline at weeks 2, 4, 8 (endpoint) and week 24 (follow-up).
3. Safety and tolerability measured by Treatment Emergent Symptom Scale (TESS) when patients visit the doctor.

Overall study start date
01/01/2017

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Diagnosis of depression using the International Classification of Disease (10th version) (ICD-10)
2. Aged 18-65 years
3. Moderate or severe depression with a score of ≥17 on HAMD-17
4. Current treatment with SSRIs or no medication
5. No cupping therapy during the previous 2 weeks
6. Patients agree to participant in this trial and assign the informed consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
60

Total final enrolment
72

Key exclusion criteria
1. Difficulty in communication
2. Severe suicidal risk (HAMD-17 suicidal item score=4)
3. History of dementia
4. History of bipolar disorder, schizophrenia or have obvious psychotic symptoms.
5. History of alcohol or drug abuse within 12 months
6. Pregnancy or lactation

Date of first enrolment
01/06/2017

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University
Backstreet Gallery No. 23 in Dongcheng District
Beijing
China
100010

Sponsor information

Organisation
Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University

Sponsor details
No. 23, Backstreet Gallery, Dongcheng District
Beijing
China
100010
0086-010-52176813
bjzykyc@163.com

Sponsor type
Government

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type
Not defined

Funder Name
Beijing Municipal Administration of Hospitals

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 22/11/2021:
Planned publication in a high-impact peer-reviewed journal.

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Previous publication and dissemination plan:
We plan to publish a trial protocol in about 6 months after the registration and trial results in approximately 1 year after the trial.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request