ISRCTN13325606 https://doi.org/10.1186/ISRCTN13325606

Clinical hypnosis to improve subjective well-being and quality of life in individuals with depression

Submission date
11/08/2022

Recruitment status
No longer recruiting

Registration date
16/09/2022

Overall study status
Completed

Last Edited
10/02/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The purpose of this study was to test the effectiveness of clinical hypnosis to improve subjective well-being and quality of life in people with depression. Developing appropriate modules for use in the clinical practice of treating depression, as well as developing standard operating procedures for governance in health facilities.

Who can participate?
Adults who have symptoms of depression

What does the study involve?
The design of this study used a randomized controlled trial to prove the effectiveness of clinical hypnosis in improving subjective well-being and quality of life before and after the intervention. During the intervention process, it will also be recorded through biofeedback and salivary component biomarkers to determine the dynamics and changes in physiological changes that occur due to the intervention. The data will then be analyzed and integrated into a single unit to answer research questions.

What are the possible benefits and risks of participating?
The advantages that participants get are, first, increasing knowledge about the treatment of depressive symptoms. Second, participants receive direct treatment to improve subjective well-being and quality of life. There is no significant risk that may occur to the participants.

Where is the study run from?
Faculty of Psychology Universitas Gadjah Mada (Indonesia)

When is the study starting and how long is it expected to run for?
June 2019 to February 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Mr Baskoro
danangsetyobudibaskoro@gmail.com

Contact information

Type(s)
Scientific

Contact name
Mr Danang Baskoro

Contact details
Bulaksumur
Caturtunggal
Kec. Depok
Kabupaten Sleman
Daerah Istimewa
Yogyakarta
Indonesia
55281
+62 0274 588688
danangsetyobudibaskoro@gmail.com

Type(s)
Scientific

Contact name
Mr Danang Baskoro

Contact details
Bulaksumur
Caturtunggal
Kec. Depok
Kabupaten Sleman
Daerah Istimewa
Yogyakarta
Indonesia
55281
+62 0274 588688
danangsetyo86@mail.ugm.ac.id

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Clinical hypnosis to improve subjective well-being and quality of life in individuals with depression

Study objectives
Clinical hypnosis can improve subjective well-being and quality of life in individuals with depression

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/12/2019, Medical and Health Research Ethics Committee (MHREC) Faculty of Medicine, Public Health, and Nursing Universitas Gadjah Mada - Dr Sardjito General Hospital (Bulaksumur Yogyakarta 55281, Indonesia; +62 (274) 588688; info@ugm.ac.id), ref: KE/FK/1413 /EC/2019

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Depression

Interventions
The design of this study used a randomized controlled trial to prove the effectiveness of clinical hypnosis in improving subjective well-being and quality of life before and after the intervention. During the intervention process, biofeedback and salivary component biomarkers will also be

recorded to determine the dynamics and changes in physiological changes that occur due to the intervention. The data will then be analyzed and integrated into a single unit to answer research questions.

Participants who register are selected based on the inclusion criteria. Researchers conducted an examination to ensure the eligibility of participants. After being judged worthy and meeting the specified number of 75 participants, randomization was carried out to avoid bias from confounding variables.

Randomization was performed on participants to be grouped into three groups, namely 25 participants were in the clinical hypnosis group, 25 participants were in the relaxation group and 25 others were in the control group. Interventions are carried out individually by clinical psychologists who have competence in clinical hypnosis.

The clinical hypnosis group was given the clinical hypnosis intervention in two sessions with a duration of 90-100 minutes (not including the installation of equipment), where the distance between the first and second sessions was a minimum of one week and a maximum of two weeks. In the clinical hypnosis group, they will also be given homework assignments, namely doing self-hypnosis with guidance through audio and recorded every day in a journal.

The relaxation group was given the intervention for two sessions with a duration of 30-45 minutes (not including the installation of equipment), where the distance between the first and second sessions was a minimum of one week and a maximum of two weeks.

While the control group was not given therapeutic treatment. The control group participants still came to the laboratory and met with research assistants to conduct questions and answers about everyday topics for 30 minutes. The control group will be given treatment after the experiment is complete.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 10/02/2025:

Subjective Well-Being
1. Subjective wellbeing measured using the Personal Well-being Index (PWI) consisting of seven mandatory items, including standard of living, life achievement, personal health, personal relationships, personal safety, social relationships, future security, and two additional items that have been adapted to the Indonesian culture at baseline and 14 days

Quality of Life
2. Quality of Life (QoL) measured using the WHOQOL-BREF scale which measures the quality of life of individuals based on four domains, namely physical health, psychological, social relationships, and the environment at baseline and 14 days

Positive and Negative Emotions
3. Positive and negative emotions measured using the Expanded Form of Positive and Negative Affects Schedule (PANAS-X), which contains 60 items with a Likert scale that specifically measures positive and negative emotions as well as other emotions at baseline, two hours (after therapy), and 14 days

Depression
4. Depression of participants measured using the Patient Health Questionnaire (PHQ-9). The PHQ-9 scale has 9 items, with 4 answer choices using a Likert scale at baseline and 14 days

_____

Previous primary outcome measure:

Subjective Well-Being
1. Subjective wellbeing measured using the Personal Well-being Index (PWI) consisting of seven mandatory items, including standard of living, life achievement, personal health, personal relationships, personal safety, social relationships, future security, and two additional items that have been adapted to the Indonesian culture at baseline and 14 days

Quality of Life
2. Quality of Life (QoL) measured using the WHOQOL-BREF scale which measures the quality of life of individuals based on four domains, namely physical health, psychological, social relationships, and the environment at baseline and 14 days

Positive and Negative Feelings
3. Positive and negative feelings measured using the Expanded Form of Positive and Negative Affects Schedule (PANAS-X), which contains 60 items with a Likert scale that specifically measures positive and negative emotions as well as other emotions at baseline, two hours (after therapy), and 14 days

Depression
4. Depression of participants measured using the Patient Health Questionnaire (PHQ-9). The PHQ-9 scale has 9 items, with 4 answer choices using a Likert scale at baseline and 14 days

Secondary outcome measures

Current secondary outcome measures as of 10/02/2025:

Biofeedback
1. Physical condition measured using heart rate variability (HRV), and galvanic skin response (GSR) during the hypnosis process. HRV and GSR use a tool made by CV Amakusa Instrumentation Technology called GSR AIT - 06.

Biomarkers
2. Salivary cortisol biomarkers and alpha-amylase levels in saliva measured using standard ELISA procedures in a laboratory at baseline and then 14 days

_____

Previous secondary outcome measures:

Biofeedback
1. Physical condition measured using electroencephalogram (EEG), heart rate variability (HRV), and galvanic skin response (GSR) during the hypnosis process. The specifications of the EEG tool used are Digital Brain Electric Activity Mapping, Contec™ brand, Model: KT88-3200. While HRV and GSR use a tool made by CV Amakusa Instrumentation Technology called GSR AIT - 06.

Biomarkers
2. Salivary cortisol biomarkers and alpha-amylase levels in saliva measured using standard ELISA procedures in a laboratory at baseline and then 14 days

Overall study start date
16/06/2019

Completion date
15/02/2023

Eligibility

Key inclusion criteria
1. Aged 21 – 50 years old
2. Symptoms of depression
3. Willing to follow COVID-19 health procedures and all series of offline research activities as evidenced by signing informed consent
4. Do not have conditions that prevent them from following the course of therapy, do not have problems understanding instructions, comorbid with other physical and psychological illnesses that do not allow Clinical Hypnosis intervention, such as schizophrenia, attention disorders and so on
5. Not currently involved in other psychotherapy/research

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
75

Key exclusion criteria
1. 20 years old and under or 51 years old and over
2. No symptoms of depression
3. Unwilling to follow COVID-19 health procedures and the entire series of offline research activities
4. Have conditions that prevent them from following the course of therapy, have problems capturing instructions, comorbid with other physical and psychological illnesses that do not allow clinical hypnosis intervention, such as schizophrenia, attention disorders and so on
5. Involved in psychotherapy/other research

Date of first enrolment
10/08/2022

Date of final enrolment

31/08/2022

Locations

Countries of recruitment
Indonesia

Study participating centre
Faculty of Psychology Universitas Gadjah Mada
Jl Socio Humanities of Bulaksumur
Karang Malang Caturtunggal
Kec. Depok
Sleman Regency, Yogyakarta Special Region
Indonesia
55281

Sponsor information

Organisation
Gadjah Mada University

Sponsor details
Bulaksumur
Caturtunggal
Kec. Depok
Kabupaten Sleman
Daerah Istimewa
Yogyakarta
Indonesia
55281
+62 0274 588688
info@ugm.ac.id

Sponsor type
University/education

Website
https://ugm.ac.id/en

ROR
https://ror.org/03ke6d638

Funder(s)

Funder type
University/education

Funder Name
Universitas Gadjah Mada

Alternative Name(s)
Gadjah Mada University, UGM

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Indonesia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
04/05/2023

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