

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Examining the Effectiveness of Group Cognitive Behavioural Therapy for the Treatment of Unipolar Depression in Malaysia: A Randomized Controlled Trial

#### Protocol summary

##### Summary

Goals: 1. To examine effectiveness of GCBT in treatment of depression 2. To compare effectiveness of GCBT with Relaxation training and treatment as usual controls 3. To determine changes to depressive symptoms and negative cognitions when undergoing treatment 5. To determine effects of cohesion on treatment outcome  
Study Design: 3X3 repeated measures MANOVA IV1: Treatment groups (i.e. GCBT, Relaxation, Control) IV2: Assessment time points (i.e. Pre-treatment, Mid-treatment, Post-treatment) DV: BDI-M, DAS-M, ATQ-M, Visual analogue scale (Proxy for cohesion) Target population: The inclusion criteria for the current study was that participants must have been diagnosed with major depressive disorder in the past two weeks by a psychiatrist, between the ages of 18 to 60 years, is currently receiving pharmacotherapy treatment, able to understand Bahasa Malaysia and have no co-morbid diagnosis of major psychiatric (e.g. schizophrenia, bipolar disorder) or medical disorders (e.g. cancer, HIV). Sample Size: Current analysis showed that a total sample size of 159 was required to ensure that enough power was available to limit the chances of Type II error. For the purposes of the current assessment, an estimated 210 participants would be selected to account for potential losses through dropouts and fatigue.

#### General information

##### Acronym

Effectiveness of Group CBT

##### IRCT registration information

IRCT registration number: **IRCT2014102219631N1**

Registration date: **2014-11-12, 1393/08/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-11-12, 1393/08/21

##### Registrant information

###### Name

Joel Low

###### Name of organization / entity

University Putra Malaysia

###### Country

Malaysia

###### Phone

+60 12 300 3385

###### Email address

gs29978@mutiara.upm.edu.my

##### Recruitment status

###### Recruitment complete

##### Funding source

University grant from University Putra Malaysia

##### Expected recruitment start date

2013-06-01, 1392/03/11

##### Expected recruitment end date

2014-05-30, 1393/03/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Examining the Effectiveness of Group Cognitive Behavioural Therapy for the Treatment of Unipolar Depression in Malaysia: A Randomized Controlled Trial

##### Public title

Examining the Effectiveness of Group Cognitive Behavioural Therapy for the Treatment of Unipolar

Depression in Malaysia: A Randomized Controlled Trial

## Purpose

Treatment

## Inclusion/Exclusion criteria

The inclusion criteria for the current study was that the participants must have been diagnosed with major depressive disorder in the past two weeks by a psychiatrist, between the ages of 18 to 60 years, is currently receiving pharmacotherapy treatment for unipolar depression, be able to understand Bahasa Malaysia and no co-morbid diagnosis of major psychiatric (e.g. schizophrenia, bipolar disorder) or medical disorders (e.g. cancer, HIV).

## Age

From **18 years** old to **60 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **210**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

University Putra Malaysia Ethics committee

##### Street address

University Putra Malaysia, 43400 Serdang, Selangor

##### City

Serdang

##### Postal code

43400

#### Approval date

2012-11-01, 1391/08/11

#### Ethics committee reference number

04-02-12-2126RU

## Health conditions studied

### 1

#### Description of health condition studied

Unipolar Depression

#### ICD-10 code

F32.2

#### ICD-10 code description

Severe depressive episode without psychotic symptoms

## Primary outcomes

### 1

#### Description

Depressive symptoms

#### Timepoint

Pre, Mid & Post-treatment

#### Method of measurement

Beck Depression Inventory-Malay

### 2

#### Description

Negative Automatic Thoughts

#### Timepoint

Pre, Mid & Post-treatment

#### Method of measurement

Automatic Thought Questionnaire-Malay

### 3

#### Description

Dysfunctional Beliefs

#### Timepoint

Pre, Mid & Post-treatment

#### Method of measurement

Dysfunctional Attitude Scale-Malay

### 4

#### Description

Cohesion

#### Timepoint

Pre, mid and post-treatment

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention: Group Cognitive Behavioural Therapy

#### Category

Treatment - Other

### 2

#### Description

Placebo Control: Relaxation Training

**Category**

Placebo

**3**

**Description**

Control: Treatment as usual

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Hospital Kajang

**Full name of responsible person**

Sister Tillah

**Street address**

Jalan Semenyih, Bandar Kajang, 43000 Kajang,  
Selangor

**City**

Kajang

**2**

**Recruitment center**

**Name of recruitment center**

Hospital Serdang

**Full name of responsible person**

Head Nurse

**Street address**

Hospital Serdang, Jalan Puchong, 43000 Kajang,  
Selangor Darul Ehsan.

**City**

Serdang

**3**

**Recruitment center**

**Name of recruitment center**

Hospital Kuala Lumpur

**Full name of responsible person**

Head Nurse

**Street address**

Jalan Pahang, 50586 Kuala Lumpur, MALAYSIA

**City**

Kuala Lumpur

**4**

**Recruitment center**

**Name of recruitment center**

Hospital Tengku Ampuan Rahimah

**Full name of responsible person**

Head Nurse

**Street address**

Jalan Langat, 41200 Klang, Selangor

**City**

Klang

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

University Putra Malaysia

**Full name of responsible person**

Dr Firdaus Mukhtar

**Street address**

University Putra Malaysia

**City**

Serdang

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

University Putra Malaysia

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

University Putra Malaysia

**Full name of responsible person**

Joel Low

**Position**

Researcher/Masters of Clinical Psychology

**Other areas of specialty/work**

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## Person responsible for updating data

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**Web page address**  
<http://www.upm.edu.my>

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**  
*empty*  
**Study Protocol**  
*empty*  
**Statistical Analysis Plan**  
*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*  
**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*