

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### **A randomized controlled trial on the effectiveness of Brain Injury Family Intervention (BIFI) in improving psychological well-being of Traumatic Brain Injury (TBI) caregivers at two government hospitals in Malaysia**

#### **Protocol summary**

##### **Study aim**

To assess the effectiveness of Brain Injury Family Intervention (BIFI) in reducing emotional distress, reducing burden of care, fulfilling caregiver's needs, and increasing life satisfaction among Traumatic Brain Injury (TBI) caregivers in selected government hospitals.

##### **Design**

Single blinded two armed group randomized controlled trial with 100 participants from 2 government hospitals. Self-reported questionnaires will be collected at baseline, immediately after intervention program, 3 months and 6 months follow-up.

##### **Settings and conduct**

It will be conducted at Sungai Buloh Hospital and Cheras Rehabilitation Centre in Malaysia. Randomization of participants will be done using a computer generated sets of random allocation. Only investigator knows which treatment will be allocated to the groups.

##### **Participants/Inclusion and exclusion criteria**

Traumatic Brain Injury (TBI) caregivers must be Malaysian or Permanent Resident of Malaysia. Their age must be 18 and above to be eligible to participate. Traumatic Brain Injury (TBI) caregivers with any type of races/ethnicity (Malay, Chinese, Indian and others) and gender will be included. The participants must be able to read or write in Bahasa Malaysia or English. Participants could be parents, spouses, siblings, sons/daughters or relatives. They must have been caring for Traumatic Brain Injury (TBI) patients for > 3 month post injury, time spend for caring activities is at least 2 hours per day. The exclusion criteria include paid caregiver. The injury which is not due to Traumatic Brain Injury (TBI) will be excluded.

##### **Intervention groups**

The intervention group will be involve in Brain Injury Intervention Program (BIFI) program. It is scheduled for 5 sessions in 5 weeks. Each session will take about 90 - 120

minutes.

##### **Main outcome variables**

The primary end-point is the Traumatic Brain Injury (TBI) caregiver's emotional distress.

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20180809040746N1**

Registration date: **2018-09-01, 1397/06/10**

Registration timing: **prospective**

Last update: **2018-09-01, 1397/06/10**

Update count: **0**

##### **Registration date**

2018-09-01, 1397/06/10

##### **Registrant information**

##### **Name**

Siti Aminah Omar

##### **Name of organization / entity**

The Universiti Teknologi MARA

##### **Country**

Malaysia

##### **Phone**

+60 3-6126 7206

##### **Email address**

siti\_aminah@salam.uitm.edu.my

##### **Recruitment status**

**Not yet recruiting**

##### **Funding source**

##### **Expected recruitment start date**

2639-11-22, 2018/09/01

##### **Expected recruitment end date**

2640-11-22, 2019/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A randomized controlled trial on the effectiveness of Brain Injury Family Intervention (BIFI) in improving psychological well-being of Traumatic Brain Injury (TBI) caregivers at two government hospitals in Malaysia

**Public title**

The effectiveness of Brain Injury Family Intervention (BIFI) in improving psychological well-being of Traumatic Brain Injury (TBI) caregivers at two government hospitals in Malaysia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

TBI caregivers must be Malaysian or Permanent Resident of Malaysia. TBI caregivers with any type of races/ethnicity (Malay, Chinese, Indian and others) Participants could be parents, spouses, siblings, sons/daughters or relatives. The participants must be able to read or write in Bahasa Malaysia or English. The caregivers must have been caring for TBI patients for > 3 month post injury. Time spend for caring activities is at least 2 hours per day.

**Exclusion criteria:**

The exclusion criteria include paid caregiver or formal caregiver. The injury which is not due to TBI will be excluded.

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization of participants will be done using a computer generated sets of random allocation.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Single blind RCT will be implemented where only principle investigator knows which treatment will be allocated to the groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

National Medical Research Register of Ministry of Health Malaysia

**Street address**

Jalan Rumah Sakit

**City**

Bangsar

**Postal code**

59000

**Approval date**

2639-11-21, 2018/08/30

**Ethics committee reference number**

42951

**Health conditions studied****1****Description of health condition studied**

Traumatic brain Injury (TBI) caregivers

**ICD-10 code**

S06.2

**ICD-10 code description**

Diffuse traumatic brain injury

**2****Description of health condition studied**

Traumatic Brain Injury caregivers

**ICD-10 code**

S01

**ICD-10 code description**

Open wound of head

**3****Description of health condition studied**

Traumatic Brain Injury caregivers

**ICD-10 code**

S06.3

**ICD-10 code description**

Focal traumatic brain injury

**4****Description of health condition studied**

Traumatic Brain Injury caregivers

**ICD-10 code**

S07

**ICD-10 code description**

Crushing injury of head

## Primary outcomes

### 1

#### Description

Emotional distress

#### Timepoint

Baseline, immediately after intervention program, 3 months and 6 months follow-up

#### Method of measurement

Beck Depression Inventory, Positive and Negative Affect Schedule

## Secondary outcomes

### 1

#### Description

TBI caregiver's burden level

#### Timepoint

Baseline, immediately after intervention program, 3 months and 6 months follow-up

#### Method of measurement

Caregiver Strain Index

### 2

#### Description

TBI caregiver's needs

#### Timepoint

Baseline, immediately after intervention program, 3 months and 6 months follow-up

#### Method of measurement

Family Needs Questionnaire

### 3

#### Description

TBI caregiver's life satisfaction

#### Timepoint

Baseline, immediately after intervention program, 3 months and 6 months follow-up

#### Method of measurement

Satisfaction With Life Scale

## Intervention groups

### 1

#### Description

Intervention group: The participants will be involved in BIFI program and also treatment as usual (TAU). It will be scheduled for 5 sessions in 5 weeks. Each session will take for about 90 - 120 minutes

#### Category

Behavior

### 2

#### Description

Control group: Participants will receive Treatment -As-Usual (TAU) at their respective hospitals

## Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hospital Rehabilitasi Cheras

##### Full name of responsible person

Dr Norazlina Abd Aziz

##### Street address

Jalan Yaacob Latif

##### City

Cheras

##### Postal code

56000

##### Phone

+60 3-9145 3400

##### Email

abdulaziznorazlina@yahoo.com

##### Web page address

<http://www.hrc.moh.gov.my>

### 2

#### Recruitment center

##### Name of recruitment center

Hospital Sungai Buloh

##### Full name of responsible person

Dr Akmal Hafizah Zamli

##### Street address

Jalan Hospital

##### City

Sungai Buloh

##### Postal code

47000

##### Phone

+60 3-6145 4333

##### Email

dr.akmal@moh.gov.my

##### Web page address

<http://hsgbuloh.moh.gov.my/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Universiti Teknologi MARA

##### Full name of responsible person

Dean of Faculty of Medicine

##### Street address

Jalan Hospital

##### City

Sungai Buloh

##### Postal code

47000

##### Phone

+60 3-6126 7001

**Email**

zamrin7680@salam.uitm.edu.my

**Web page address**

https://medicine.uitm.edu.my

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Universiti Teknologi MARA

**Proportion provided by this source**

50

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Universiti Teknologi MARA

**Full name of responsible person**

Siti Aminah Omar

**Position**

Lecturer/ Clinical Psychologist

**Latest degree**

Master

**Other areas of specialty/work**

Clinical Psychology

**Street address**

Jalan Hospital

**City**

Sungai Buloh

**Province**

Selangor

**Postal code**

47000

**Phone**

+60 3-6126 7206

**Email**

city\_min@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Universiti Teknologi MARA

**Full name of responsible person**

Siti Aminah Omar

**Position**

Lecturer/clinical psychologist

**Latest degree**

Master

**Other areas of specialty/work**

Clinical Psychology

**Street address**

Jalan Hospital

**City**

Sungai Buloh

**Province**

Selangor

**Postal code**

47000

**Phone**

+60 3-6126 7206

**Email**

city\_min@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Universiti Teknologi MARA

**Full name of responsible person**

Siti Aminah Omar

**Position**

Lecturer/clinical psychologist

**Latest degree**

Master

**Other areas of specialty/work**

Clinical psychology

**Street address**

Jalan Hospital

**City**

Sungai Buloh

**Province**

Selangor

**Postal code**

47000

**Phone**

+60 3-6126 7206

**Email**

city\_min@yahoo.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

No - There is not a plan to make this available