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

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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
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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
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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
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Person responsible for updating data

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Email
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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