Effectiveness of Brain Injury Family Intervention (BIFI) in Improving Psychological Well-Being of Traumatic Brain Injury Caregivers in Malaysia: A Randomized Controlled Trial

Siti Aminah Omar[1,2], Nor Sheereen Zulkefly[2] & Firdaus Mukhtar[2*]

[1]Department of Psychiatry, Faculty of Medicine, Universiti Teknologi MARA, Malaysia

[2]Department of Psychiatry, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, Malaysia

DOI: https://doi.org/10.47772/IJRISS.2026.100500706

Received: 11 May 2026; Accepted: 16 May 2026; Published: 11 June 2026

ABSTRACT

Objective: Traumatic Brain Injury (TBI) is a major cause of death and disability worldwide, with a global incidence of approximately 69 million annually[1]. Following a TBI, family members often assume caregiving roles. Despite their critical role in supporting individuals with TBI, this group remains underserved in nursing and healthcare settings. In Malaysia, there are limited structured-supported programs within nursing and healthcare settings targeting the psychological well-being of these caregivers. This study assessed the effectiveness of the Brain Injury Family Intervention (BIFI) in improving the psychological well-being of TBI caregivers in selected Malaysian hospitals.

Methods: This study was a two-armed, single-blinded randomized controlled trial conducted at Hospital Sungai Buloh and Hospital Rehabilitasi Cheras, Malaysia. One hundred TBI caregivers were randomly assigned to either an intervention group, which participated in the psychologist-led BIFI program over 5 sessions (90-120 minutes each), or a control group receiving usual care. Eligible participants were caregivers aged 18 and older caring for TBI patients for over three months post-injury.Outcomes measured included emotional distress (Beck Depression Inventory-BDI), caregiver burden (Caregiver Strain Index- CSI), and life satisfaction (Satisfaction With Life Scale- SWLS), assessed at pre-test, post-test, 3-month, and 6-month follow-ups.

Results: This study showed significant improvements in emotional distress (F (1.97, 193.38) = 446.01, $p < 0.05$) and caregiver burden (F (1, 97) = 89.17, $p < 0.05$) in the intervention group compared to the control group at post-intervention and at the 3-month and 6-month follow-ups. However, there were no significant changes in caregivers' life satisfaction in either group.

Conclusions: This study demonstrated the effectiveness of the BIFI program in improving the psychological well-being of TBI caregivers, with sustained outcomes up to six months. The findings support the integration of structured psychoeducational programs into TBI care protocols.

Keywords: traumatic brain injury (TBI), caregiver burden, randomized controlled trial, psychological well-being, Malaysia

INTRODUCTION

Traumatic brain injury (TBI) is recognized as a primary contributor to mortality and disability worldwide. In 2021, approximately 37.93 million prevalent cases of TBI were reported globally[2,3]. Past studies indicated that the global incidence rate of traumatic brain injury (TBI) has increased from 200 per 100,000 population to 346 per 100,000 population annually [4,5]. The precise occurrence rates were anticipated to be elevated, particularly in developing countries [6]. Another study [1] highlighted that Southeast Asia and Africa were among the highest contributors to TBI cases. Furthermore, it was reported that low- and middle-income countries (LMICs), such

as Malaysia, Vietnam, and Thailand, had a reporting rate for TBI that was three times higher than that of high-income countries [7].

In Malaysia, the average cost of care per patient for mild TBI was RM11,041.35 (USD 2707.34), RM32,550.00 (USD 7981.26) for moderate TBI, and RM36,917.86 (USD 9052.26) for severe TBI [8]. The expenses associated with treatment for traumatic brain injury (TBI) were perceived as excessive when compared to the net income of Malaysians, which stood at RM37,900 (USD 9178) in 2016 [8]. This economic burden was particularly concerning given that TBI frequently led to significant loss of function, resulting in long-term disabilities that greatly diminished patients' quality of life [9]. Such disabilities severely limited their ability to work, ultimately leading to reduced employment opportunities and increased financial hardship for both the individuals and their families [10]. The economic burden of TBI not only affected the victims but also extended to caregivers who had to provide ongoing support [11]. As TBI patients navigated their new reality, they often became reliant on their caregivers for daily activities, emotional support, and assistance in managing their health needs [5].

Additionally, in Malaysia, caregiving activities have consistently involved family participation [12]. After the incident of TBI, the obligation of caregiving for TBI patients would fall under their family member's responsibility. As the event was sudden, most of them were not prepared mentally and physically. Furthermore, these caregiving activities require full-time commitment, financial obligation, and social responsibility [13–15]. Consequently, many caregivers may experience poor psychological well-being, such as distress, anxiety, burden, poor quality of life, and self-dissatisfaction [16–18].

If caregivers are struggling with their own health, it raises an important question: who will provide the necessary care for the patients? Studies have shown that a caregiver's psychological well-being significantly influences not only their ability to support patients but also impacts the patients' overall recovery [19–21]. Research has shown that the intervention programs that were tailored for TBI caregivers had a significant benefit on TBI patients [22,23]. These studies also supported the idea that a caregiver's psychological well-being is important in ensuring the successful long-term care of TBI patients.

Nurses play a crucial role in the early identification of caregiver distress, acting as key frontliners in the healthcare system. Their involvement is essential in facilitating support for the management of caregivers of individuals with traumatic brain injury (TBI). Nevertheless, there remains a notable scarcity of structured, nursing-supported intervention programs aimed at enhancing the psychological well-being of caregivers in the Malaysian context [11,12,24–27]. Extensive research has been conducted in Western countries; however, such programs remain limited in Malaysia. Therefore, implementing a structured intervention program would help caregivers improve their quality of life [28]. This would also result in better service and care management of TBI cases [23,28]. Several studies implemented a psychological treatment program for TBI caregivers based on an existing module by Kreutzer [22,23,29,30]. This module is known as the Brain Injury Family Intervention (BIFI) [31]. To the best of the authors' knowledge, this study is among the first to use a standardized intervention program focusing on TBI caregivers in Malaysia.

This study introduced the Brain Injury Family Intervention (BIFI) for TBI caregivers in Malaysia, utilizing a randomized controlled trial (RCT) to evaluate its effectiveness. The program aimed to enhance the caregivers' psychological well-being and equip them with the necessary skills to manage their emotions and caregiving tasks effectively. Additionally, the study sought to inform the development of organized support systems within the Malaysian healthcare system, complementing existing programs such as the "Return to Work Program." The primary objective was to assess the effectiveness of BIFI in improving the psychological well-being of TBI caregivers compared to usual care.

METHODS

This was a prospective, parallel-group, single-blind randomized controlled trial with a 1:1 allocation ratio, comparing the BIFI intervention to standard care. This trial was registered in the Iranian Registry of Clinical Trials (IRCT20180809040746N1) on 1 September 2018 (https://irct.behdasht.gov.ir/trial/33286).

Study location

Hospital Sungai Buloh (HSB) and Hospital Rehabilitasi Cheras (HRC) were selected as the study settings as they are the primary hospitals in dealing with head injury patients. The study population was TBI caregivers who attended the Neuro Rehabilitation outpatient follow-up clinic at selected hospitals. The primary sampling population in this study was TBI caregivers of patients with TBI. Although the patients themselves were not the participants, limited demographic and clinical information about them (e.g., age, gender, injury severity, and education level) was collected through their caregivers. This information was used to describe the caregiving context and support the interpretation of related outcomes. All analyses and interventions focused solely on the caregivers.

Study population

The sampling frame consisted of the registration lists of TBI caregivers and patients who attended the rehabilitation follow-up clinics at Hospital Sungai Buloh (HSB) and Hospital Rehabilitasi Cheras (HRC) on the recruitment day. The study began collecting data in December 2018 and was completed in December 2020.

Sample size calculation

Sample size estimation was based on the formula for the clinical superiority trials [32]. The formula is $N = 2(Z_{1-\alpha} + Z_{1-\beta})^2 \times S^2 / (\delta - \delta_0)^2$. The sample size was calculated with the power of the study 80% ($Z_{1-\beta}$=0.845) and a significant level α at 0.05 with 95% confidence interval $Z_{1-\alpha}$=1.96, δ^2=9.355 (SD pooled); Depression (BDI score) $\delta - \delta_0$=5.86 (mean difference), with 25 % dropout rate and a medium-sized effect of 0.60. A total of 50 participants were required for each group in this study.

Randomization

TBI caregivers who were eligible and consented to participate were numbered coded before randomization. A simple random sampling method, computer-generated random sampling, assigned participants to either the intervention or control group. The procedure followed the 1:1 allocation format. The randomization process was carried out by the co-investigator.

Statistical analysis

All statistical analyses were conducted using IBM SPSS Statistics (Version 27). Descriptive statistics summarized participants' sociodemographic profiles and baseline characteristics, with continuous data presented as means and standard deviations (SD) and categorical variables reported in frequencies and percentages.

Independent samples t-tests and chi-square tests compared demographic and baseline characteristics between intervention and control groups. Significant baseline differences were noted and treated as covariates in subsequent analyses.

To evaluate the effectiveness of the BIFI intervention over time, a repeated measures ANOVA compared outcome variables (emotional distress, caregiver burden, life satisfaction, and family needs) at four time points (pre-, post-, 3-month, and 6-month follow-up). Mauchly's Test of Sphericity assessed the assumption of sphericity, with the Greenhouse-Geisser correction applied when violated. Between-group comparisons were included as between-subjects factors, and ANCOVA was used for significant baseline differences. A p-value < 0.05 was considered statistically significant, with effect sizes (Cohen's d or partial eta squared) reported to interpret practical significance. There were no missing data as all participants completed all assessments at each time point.

Study procedure

All screening procedures based on inclusion and exclusion criteria were completed prior to the intervention program, conducted by co-investigators who ensured the correct diagnosis of potential participants with Traumatic Brain Injury (TBI). Only caregivers of patients with confirmed TBI participated. Interested caregivers were invited into a separate room for a detailed explanation, provided with a participant information sheet, and given time to consider their involvement. Those who chose to participate signed a consent form before completing a questionnaire.

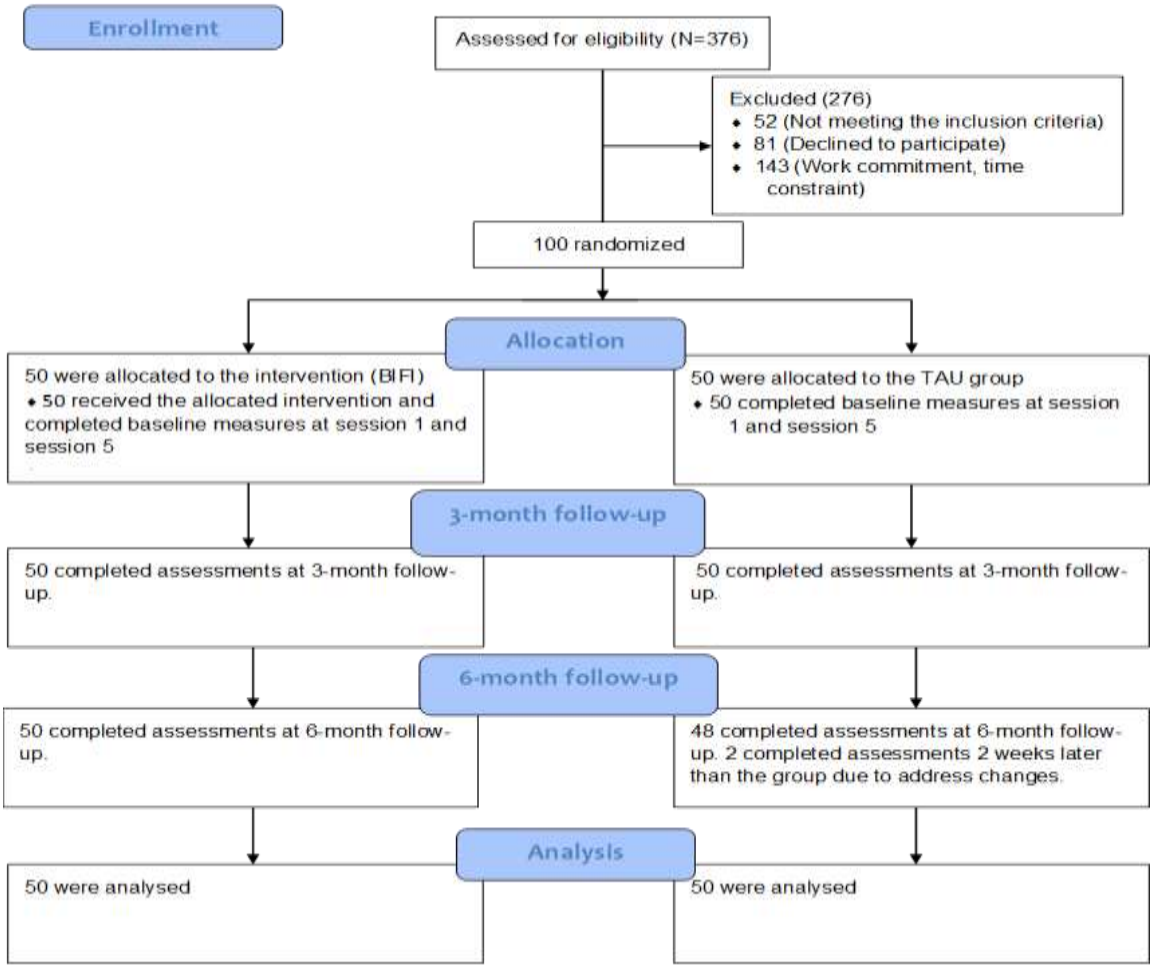
The program was conducted in either Bahasa Melayu or English, depending on caregivers' preferences, and involved small groups of 10. A clinical psychologist served as the principal investigator. Caregivers completed self-rated questionnaires (BDI, CSI, and SWLS) at the start (T1) and after the intervention (T2), along with follow-ups at 3 months (T3) and 6 months (T4). Each session ran for 90-120 minutes over 5 weekends, requiring full attendance and completion of homework, which was reviewed by the principal investigator.

Control group caregivers (TAU) completed questionnaires during clinic visits, with a similar timeline for responses. Questionnaires were mailed to them with a one-week deadline for return. Both groups continued to receive standard TBI rehabilitation care throughout the study period.

Trial reporting

This trial was reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The CONSORT checklist has been submitted as a supplementary file. No adverse events were identified during the study period. Participants were monitored throughout the intervention for any signs of psychological distress. The CONSORT flow diagram illustrating participant recruitment, randomization, allocation, follow-up, and analysis is presented in Figure 1.

Figure 1: Research Flowchart



Inclusion and exclusion criteria

Eligible participants were TBI caregivers who met the following criteria.

Inclusion Criteria:

- Malaysian or Permanent Residents of Malaysia.
- Aged 18 and above.
- Any ethnicity (Malay, Chinese, Indian, and others)
- Able to read and write in Bahasa Malaysia or English.
- Family caregiver (parent, spouse, sibling, son/daughter, or relative) of the individual with TBI.
- Primary caregiver
- Living together with the individual with TBI.
- Caring for more than 3 months post-injury [33].
- Spending a minimum of two hours per day on caregiving activities [34].

Exclusion Criteria

- Paid caregivers or formal caregivers
- Caregivers of patients with injuries other than TBI.
- Individuals with prior neurological or psychiatric disorders, learning disabilities.
- Individuals with previous head injuries.

Contamination bias

To prevent contamination bias, several measures were implemented. A clear separation between intervention and control groups was established, with the intervention taking place in a different building and on separate days. All staff received training in strict protocols to prevent information sharing, and data collection utilized structured instruments at predefined time points. Weekly team meetings ensured compliance. Participants were blinded and instructed not to share information between groups until the study's completion.

Blinding

Blinding was implemented in this study to reduce bias and ensure the validity of the findings. All caregivers and co-investigators were blinded to group allocation. However, the principal investigator was not blinded due to her active role in coordinating intervention sessions. Despite this, the principal investigator did not participate in data collection, thereby reducing the risk of bias. Specific co-investigators were assigned tasks for data collection. Significant effort was made to maintain the research objectives.

Measures

Sociodemographic information of TBI caregivers and clinical information of TBI patients

All sociodemographic information about caregivers of individuals with traumatic brain injury (TBI) was collected through self-report questions. This information included age, gender, ethnicity, religion, marital status, education level, employment status, financial status, and the amount of time spent on caregiving. For clinical information regarding TBI patients, details such as the time since the injury and the severity of the injury were obtained from the patients' medical records.

Beck Depression Inventory (BDI)

The BDI scale measures emotional distress (depression) using a 21-item questionnaire with a four-point Likert scale (0 to 3), with scores ranging from 0 to 63 and higher scores indicating greater severe depression. The BDI Malay has been translated and validated for the Malaysian population, with internal consistency (Cronbach's α) ranging from 0.71 to 0.91 and good construct validity [35].

Caregiver Strain Index (CSI)

The Caregiver Strain Index is a self-report questionnaire. It has 13 items that measure burden level related to the provision of care [36]. It also measures 5 related domains such as employment, financial, social, time, and physical. The maximum score of CSI is 13. This score can be divided into 'having strain' (score of >7) and 'no strain' (score of <7) [36]. There is no age limit to use the test**.** The CSI has been translated into the Malay language [37]. The Cronbach's alpha coefficient for the 13-item CSI-M was 0.79, which indicated that the scale had good internal consistency reliability [37]

Satisfaction with Life Scale (SWLS)

Satisfaction with Life Scale (SWLS) was designed to assess life satisfaction [38]. The SWLS consisted of five items. Life satisfaction was measured using a 7-point Likert scale score ranging from "strongly disagree" to "strongly agree." The range of scores is between 5 to 35. Those who scored 20 are considered neutral. Scores between 5-9 indicated extremely dissatisfied with life. While scores between 31-35 indicated extremely satisfied with life. The SWLS showed excellent internal consistency ($\alpha = 0.84$)[38,39] . The SWLS has been translated and validated in the Malaysian population [40]. Results showed that the Malay SWLS had good internal consistency (Cronbach's a = 0.83) [40].

Brain Injury Family Intervention Module

BIFI was used as the main tool in the intervention program. It is a structured module developed by Prof Dr. Jeffry Kreutzer and colleagues from Virginia Commonwealth University, USA. It was designed as an intervention module guide for TBI caregivers. This module is based on Cognitive Behavior Therapy and Family Systems Theories [41]. The development of this module was funded by the National Institute on Disability and Rehabilitation Research (NIDRR). To achieve the desired goals, the BIFI was designed to be implemented in a five-session format. Each session can include two or three topics. It will take 90 – 120 minutes per session. The sessions are recommended to be implemented individually. However, it can also be implemented in a group format. BIFI was recommended to be delivered in a designated format, with a discussion of earlier topics, which will facilitate the discussion of later topics.

Cultural Adaptation of the Brain Injury Family Intervention Module

The BIFI manual has undergone a process of assessment and translation [42]. This process was necessary to ensure the treatment's fidelity. It included backward and forward translation, content review, and revision. The authors invited a panel of experts to assist in this process. Two clinical psychologists, 1 certified translator, and 2 rehabilitation physicians were involved. All of the panelists had more than five years of working experience. The module was modified based on their feedback. The expert first suggested using simpler Malay. The expert also recommended using universal images for local adaptation. Finally, a revised version of the BIFI manual was adapted to suit the Malaysian population.

Pilot study

A pilot study was conducted to assess the functionality and feasibility of the BIFI program with ten TBI caregivers from Hospital Sungai Buloh, of whom nine completed all five sessions. Feedback indicated a need for extending the discussion period by 30 minutes, as the original 90 to 120 minutes was deemed insufficient.

Caregivers suggested integrating some homework into the sessions due to time constraints at home. Consequently, the program was adjusted to allow for flexibility, enabling caregivers to complete tasks during sessions or at home.

Initially held on weekdays, the program was expanded to weekends to accommodate caregivers' schedules, allowing them to choose sessions and groups as needed. Attendance was monitored to ensure all caregivers completed the program. Additionally, caregivers requested the option to bring their patients, leading to approval for patients to wait in a nearby area with a designated nurse. During implementation, only one caregiver brought a patient for a single session.

Ethics of the study

Ethics approval was obtained from the National Medical Research Register (NMRR-18-2253-42951-IIR) for the study conducted at the Ministry of Health settings.

Informed consent

Before determining whether to participate, the investigator outlined the potential risks and benefits of participation, and the information leaflet was distributed at this point. Participants were also allowed to ask the investigator any questions they had regarding the study before deciding whether or not to participate. Once this process was complete, they were required to sign a consent form.

Privacy and confidentiality

No personal identifying details, such as names and contact details, were recorded on the questionnaire. It appeared only on the consent form. The questionnaires were linked to the consent forms by a unique code appearing on both documents. No digital record was kept of the personal identifying details, and these details were not included in the data file. The write-up of the findings will also not include any such details.

Honorarium and incentives

The caregivers were provided with incentives during the study period. Both the intervention and control groups received RM 100 (USD 24) for completing questionnaires at four points: T1 (Baseline), T2 (immediately after the program), T3 (3 months follow-up), and T4 (6 months follow-up).

Publication policy

The results of this study are intended to be published in academic or medical journals or presented at academic conferences. Data access was restricted to the research team only. All data is collected anonymously. The participants could not be identified in any report or publication resulting from this study. Before publication, approval will be obtained from the Medical Research and Ethics Committee Malaysia (MREC) and the Ministry of Health Malaysia.

RESULTS

Table 1 shows a summary of the sociodemographic information of TBI caregivers and a comparison between the intervention group and the control group. Frequencies and percentages were used for all categorical data, while mean and standard deviation were used for all continuous data.

Table 1: Sociodemographic Information Caregiver and Comparison Between Intervention Group and Control Group

Sociodemographic Information Caregiver	**Intervention Group (n = 50)**	**Control Group (n = 50)**	**Total Sample (N = 100)**	**p-value**
Age[a] (years), mean (SD)	40.14 (8.048)	39.56 (8.389)	39.85 (8.184)	$p = 0.725$
Gender[b], n (%)				
Male	14 (28.0%)	16 (32.0%)	30 (30.0%)	$p = 0.663$
Female	36 (72.0%)	34 (68.0%)	70 (70.0%)	
Ethnicity[c], n (%)				
Malay	30 (60.0%)	35 (70.0%)	65 (65.0%)	$p = 0.731$
Chinese	13 (26.0%)	8 (16.0%)	21 (21.0%)	
Indian	6 (12.0%)	6 (12.0%)	12 (12.0%)	
Other	1 (2.0%)	1 (2.0%)	2 (2.0)	
Religion[c], n (%)				
Islam	30 (60.0%)	35 (70.0%)	65 (65.0%)	$p = 0.645$
Buddha	12 (24.0%)	7 (14.0%)	19 (19.0%)	
Hindu	6 (12.0%)	6 (12.0%)	12 (12.0%)	
Christian	2 (4.0%)	2 (4.0%)	4 (4.0%)	
Marital Status[c], n (%)				
Married	47 (94.0%)	39 (78.0%)	86 (86.0%)	$p = 0.096$
Single	2 (4.0%)	8 (16.0%)	10 (10.0%)	
Divorced	0 (0.0%)	2 (4.0%)	2 (2.0%)	
Widowed	1 (2.0%)	1 (2.0%)	2 (2.0%)	
Education Level[c], n (%)				
Postgraduate	1 (2.0%)	2 (4.0%)	3 (3.0%)	$p = 0.276$
Degree	10 (20.0%)	11 (22.0%)	21 (21.0%)	
Diploma	12 (24.0%)	14 (28.0%)	26 (26.0%)	
SPM/STPM	17 (34.0%)	20 (40.0%)	37 (37.0%)	
Secondary Level	5 (10.0%)	3 (6.0%)	8 (8.0%)	
Primary Level	5 (10.0%)	0 (0.0%)	5 (5.0%)	
Employment Status[c], n (%)				
Government Sector	15 (30.0%)	10 (20.0%)	25 (25.0%)	$p = 0.345$
Private Sector	7 (14.0%)	8 (16.0%)	15 (15.0%)	
Self-Employed	12 (24.0%)	13 (26.0%)	25 (25.0%)	
Unemployed	1 (2.0%)	0 (0.0%)	1 (1.0%)	
Pensioner	1 (2.0%)	5 (10.0%)	6 (6.0%)	
Part Time Work	2 (4.0%)	5 (10.0%)	7 (7.0%)	
Housewife/Househusband	12 (24.0%)	8 (16.0%)	20 (20.0%)	
In Full Time Education	0 (0.0%)	1 (2.0%)	1 (1.0%)	
Financial Status[c], n (%)				
Less than RM 1000	14 (28.0%)	8 (16.0%)	22 (22.0%)	$p = 0.205$
RM 1001 to RM 3000	11 (22.0%)	20 (40.0%)	31 (31.0%)	
RM 3001 to RM 5000	16 (32.0%)	13 (26.0%)	29 (29.0%)	
RM 5001 to RM 10000	9 (18.0%)	8 (16.0%)	17 (17.0%)	
More than RM 10000	0 (0.0%)	1 (2.0%)	1 (1.0%)	
Duration of caregiving[c], n (%)				
2 years	23 (46.0%)	25 (50.0%)	48 (48.0%)	$p = 0.407$

3 years	25 (50.0%)	20 (40.0%)	45 (45.0%)	
4 years	2 (4.0%)	5 (10.0%)	7 (7.0%)	

[a]Independent T-test for; [b]Chi Square; [c]Fisher – Freeman - Halton Exact Test;

Table 1 (Continued)

Sociodemographic Information Caregiver	**Intervention Group (n = 50)**	**Control Group (n = 50)**	**Total Sample (N = 100)**	***p*-value**
Part Time Work	2 (4.0%)	5 (10.0%)	7 (7.0%)	
Housewife/Househusband	12 (24.0%)	8 (16.0%)	20 (20.0%)	
In Full Time Education	0 (0.0%)	1 (2.0%)	1 (1.0%)	
Financial Status[c], n (%)				
Less than RM 1000	14 (28.0%)	8 (16.0%)	22 (22.0%)	$p = 0.205$
RM 1001 to RM 3000	11 (22.0%)	20 (40.0%)	31 (31.0%)	
RM 3001 to RM 5000	16 (32.0%)	13 (26.0%)	29 (29.0%)	
RM 5001 to RM 10000	9 (18.0%)	8 (16.0%)	17 (17.0%)	
More than RM 10000	0 (0.0%)	1 (2.0%)	1 (1.0%)	
Duration of caregiving[c], n (%)				
2 years	23 (46.0%)	25 (50.0%)	48 (48.0%)	$p = 0.407$
3 years	25 (50.0%)	20 (40.0%)	45 (45.0%)	
4 years	2 (4.0%)	5 (10.0%)	7 (7.0%)	

[a]Independent T-test for; [b]Chi Square; [c]Fisher – Freeman - Halton Exact Test;

The mean age for the respondents in the intervention group was 40.14 and the standard deviation was 8.048 years old. The mean age for respondents in the control group was 39.56, the standard deviation was 8.389 years, and there was no statistically significant difference between the intervention group and control group ($p = 0.725 > 0.05$). The majority of the respondents from both groups were female (intervention = 36, 72.0%, control = 34, 68.0%). Most respondents were Malay (intervention = 30, 60.0%, control = 35, 70.0%).

Overall, at baseline, respondents in both intervention and control groups showed similar distribution with all of the variables not significantly different ($p = 0.663 > 0.05$ and $p = 0.731 > 0.05$). More than half of the respondents were married (86.0%) from both groups (intervention = 47, 94.0%, control = 39, 78.0%). There was no difference between-group in terms of marital status ($p = 0.096 > 0.05$).

Table 1 also shows that most of the respondents possessed SPM from both groups (intervention = 17, 34.0%, control = 20, 40.0%). In terms of employment status, most of the respondents worked in the government sector (intervention = 15, 30.0%) and in the control group, most of the respondents were self-employed (13, 26.0%). Most of the respondents (20, 40.0%) had a monthly income between RM 1001 to RM 3000 which were respondents from the control group and for the intervention group, the respondents had a monthly income between RM 3001 to RM 5000 (16, 32.0%).

Overall, at baseline, respondents in both intervention and control groups showed similar distribution with all of the variables not significantly different ($p = 0.280 > 0.05$, $p = 0.345 > 0.05$, and $p = 0.205 > 0.05$). Half of the respondents cared for a TBI patient for almost 2 years for the control group (25, 50.0%) and cared for a TBI patient for almost 3 years for the intervention group (25, 50.0%). There was no significant difference in how long they had been caring for TBI patients between the intervention and control group ($p = 0.407 > 0.05$).

Table 2 shows the sociodemographic information of TBI patients and the comparison between the intervention group and the control group. Frequencies and percentages were used for all categorical data, while mean and standard deviation were used for all continuous data.

Table 2: Sociodemographic Information of TBI Patient and Comparison Between Intervention Group and Control Group

Sociodemographic Information of TBI Patient	**Intervention Group (n = 50)**	**Control Group (n = 50)**	**Total Sample (N = 100)**	**p-value**
Age[a] (years), mean (SD)	31.20 (10.172)	34.36 (11.371)	32.78 (10.850)	$p = 0.146$
Gender[d], n (%)				
Male	48 (96.0%)	44 (88.0%)	92 (92.0%)	$p = 0.269$
Female	2 (4.0%)	6 (12.0%)	8 (8.0%)	
Education Level[c], n (%)				
Degree	12 (24.0%)	5 (10.0%)	17 (17.0%)	$p = 0.227$
Diploma	15 (30.0%)	20 (40.0%)	35 (35.0%)	
SPM/STPM	21 (42.0%)	20 (40.0%)	41 (41.0%)	
Secondary Level	2 (4.0%)	4 (8.0%)	6 (6.0%)	
Primary Level	0 (0.0%)	1 (2.0%)	1 (1.0%)	

[a]Independent T-test for; [c]Fisher – Freeman - Halton Exact Test; [d]Fisher's Exact Test

The mean age for the respondents in the intervention group was 31.20, and the standard deviation was 10.172 years. The mean age for respondents in the control group was 34.36 and the standard deviation was 11.371 years, and it was not statistically significantly different between the intervention group and the control group ($p = 0.146 > 0.05$). The majority of the respondents from both groups were male (intervention = 48, 96.0%, control = 44, 88.0%). Most of the respondents possessed SPM from both groups (Intervention $n = 21$, 42.0%, Control $n = 20$, 40.0%) and for the control group had the highest proportion of Diploma holders (20, 40.0%). Overall, at baseline, respondents in both Intervention and Control groups showed similar distribution with all of the variables not statistically different ($p = 0.269 > 0.05$ and $p = 0.227 > 0.05$).

Table 3 shows the clinical information and comparison between the intervention group and the control group. Frequencies and percentages were used for all categorical data.

Table 3: Clinical Information of TBI Injury and Comparison Between Intervention Group and Control Group

Clinical Information	**Intervention (n = 50)**	**Control (n = 50)**	**Total Sample (N = 100)**	**p-value**
Cause of TBI[d], n (%)				
MVA	49 (98.0%)	45 (90.0%)	94 (94.0%)	$p = 0.204$
FALL	1 (2.0%)	5 (10.0%)	6 (6.0%)	
Severity of Injury[d], n (%)				
Moderate	1 (2.0%)	5 (10.0%)	6 (6.0%)	$p = 0.204$
Severe	49 (98.0%)	45 (90.0%)	94 (94.0%)	

[d]Fisher's Exact Test was used for variables with expected cell counts less than 5

The majority of respondents in both the intervention and control groups sustained TBI primarily due to motor vehicle accidents (MVA), with 98.0% in the intervention group and 90.0% in the control group. A smaller proportion experienced TBI from falls, accounting for 2.0% in the intervention group and 10.0% in the control group. The p-value of $p = 0.204 > 0.05$ indicates that the differences in the cause of TBI between the intervention and control groups are not statistically significant.

In terms of injury severity, severe injuries were predominant in both groups, with 98.0% in the intervention group and 90.0% in the control group classified as severe. Moderate injuries were less common, with 2.0% in the intervention group and 10.0% in the control group. The *p*-value of $p = 0.204 > 0.05$ suggests no statistically significant difference in the severity of injury between the intervention and control groups. Table 4 shows the baseline emotional distress, the burden of care and life satisfaction comparison between the intervention group and the control group**.**

Table **Error! No text of specified style in document.**: Baseline Emotional Distress, Burden of Care, and Life Satisfaction Comparison Between Intervention Group and Control Group

Variable	**Intervention Group (*n* = 50)**	**Control Group (n = 50)**	**Total Sample (N = 100)**	**Mean Difference (95% CI)**	**t-test p-value**
Beck Depression Inventory (BDI), mean (SD)	36.12 (6.974)	34.16 (6.535)	35.14 (6.796)	1.960 (-0.722, 4.642)	$t = 1.450$ $p = 0.150$
Burden Level (CSI), mean (SD)	11.42 (1.458)	10.20 (1.678)	10.81 (1.680)	1.220 (0.596, 1.844)	$t = 3.880$ $p = 0.001$
Life Satisfaction (SWLS), mean (SD)	19.00 (3.130)	19.64 (2.554)	19.32 (2.860)	-0.640 (-1.774, 0.494)	$t = -1.120$ $p = 0.265$

Several notable findings emerged when comparing the intervention and control groups. The Beck Depression Inventory (BDI) scores were slightly higher in the intervention group, with a mean of 36.12 (SD = 6.974) compared to 34.16 (SD = 6.535) in the control group. However, this difference was not statistically significant, as indicated by a mean difference of 1.960 (95% CI: -0.722, 4.642) and a *p*-value of $0.150 > 0.05$, suggesting that both groups had similar levels of depression.

When examining the burden level using the Caregiver Strain Index (CSI), the intervention group had a higher mean score of 11.42 (SD = 1.458) compared to 10.20 (SD = 1.678) in the control group. The mean difference was 1.220 (95% CI: 0.596, 1.844), with a significant *p*-value of $0.001 < 0.05$, indicating that the intervention group experienced a greater burden.

Life satisfaction, measured by the Satisfaction with Life Scale (SWLS), was slightly lower in the intervention group (mean = 19.00, SD = 3.130) compared to the control group (mean = 19.64, SD = 2.554), but this difference was not significant, with a mean difference of -0.640 (95% CI: -1.774, 0.494) and a *p*-value of $0.265 > 0.05$.

Emotional Distress Outcomes

The repeated measure ANOVA was employed to assess the significant difference between mean scores of depression level between the intervention group and control group at pre-, post, 3-month follow-up, and 6-month follow-up. The results of this analysis are shown in **Table 5** and **Table 6**:

Table 5: Comparison of Depression Level Between Intervention and Control Group at Pre, Post, 3-Month Follow-Up and 6-Month Follow-Up

Variable	**Treatment group**	**N**	**Mean**	**Std. Deviation**
Depression Level Pre	Intervention Group	50	36.12	6.974
	Control Group	50	34.16	6.535
Depression Level Post	Intervention Group	50	13.72	2.382
	Control Group	50	34.56	6.462
Depression Level 3-month follow-up	Intervention Group	50	14.48	2.341
	Control Group	50	35.14	6.562
Depression Level 6-month follow-up	Intervention Group	50	29.32	5.744
	Control Group	50	36.26	6.461

Table 6: Mauchly's Test of Sphericity for Depression Level

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Depression Level	0.219	146.728	5	**0.001***	0.658	0.678	0.333

*Significance Level at $p < 0.05$

A repeated measure analysis of variance (ANOVA) was conducted to assess the significant difference between mean scores of depression level between intervention and control group at pre, post, 3-month follow-up and 6-month follow-up. Mauchly's Test of Sphericity indicated that the assumption of sphericity had been violated, (χ^2 (5) = 146.728, $p < 0.05$). Consequently, the Greenhouse-Geisser correction was applied (refer to Table 7). The multivariate test revealed a significant difference between mean scores of depression level between the intervention and control group at pre-, post, 3-month follow-up, and 6-month follow-up (F (1.97, 193.38) = 446.01, $p < 0.05$). The mean depression level decreased significantly from pre-intervention (Mean = 36.12) to post-intervention (Mean = 13.72). This reduction was sustained at the 3-month follow-up (Mean = 14.48), although there was an increase by the 6-month follow-up (Mean = 29.32). In contrast, the control group's mean depression levels remained relatively stable throughout the study, showing only minor fluctuations. The partial eta squared value of 0.82 indicates a large effect size, showing that the intervention accounted for 82% of the variance in depression level. This indicated that the hypothesis was supported as there were significant differences in the mean scores of depression levels between the intervention and control group at pre-, post, 3-month follow-up, and 6-month follow-up.

Table 7: Test of Within-Subjects Effects for Depression Level

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Depression Level * Group	Sphericity Assumed	9326.22	3	3108.74	446.01	**0.001***	0.82
	Greenhouse-Geisser	9326.22	1.97	4726.21	446.01	**0.001***	0.82
	Huynh-Feldt	9326.22	2.03	4584.9	446.01	**0.001***	0.82
	Lower-bound	9326.22	1	9326.22	446.01	**0.001***	0.82

*Significance Level at $p < 0.05$

Table 8 presents the mean differences in depression levels between the intervention and control groups, adjusting for multiple comparisons using the Bonferroni method. The results indicated that there was a significant difference between the groups, with p-value = 0.001, $p < 0.05$.

Table 8: Mean Differences in Depression Level Between Groups

Variable	(I) Treatment group	(J) Treatment group	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval for Difference	
						Lower Bound	Upper Bound
Depression Level * Group	Intervention Group	Control Group	-11.620*	1.049	**0.001***	-13.703	-9.537
	Control Group	Intervention Group	11.620*	1.049	**0.001***	9.537	13.703

Based on estimated marginal means

* The mean difference is significant at the 0.05 level.

Caregiver Burden Outcomes

Homogeneity of Variance

Parametric statistical analyses require the homogeneity assumption to be met before they can be utilised. In the case where an unequal number of subjects in groups exists, the requirement to ensure homogeneity of variance across groups is especially important. Thus, the Levene's Test was performed to test the homogeneity of variance of data in the study before applying statistical tests. Table 9 shows the results of Levene's Test of caregiver burden at post, 3-month follow-up and 6-month follow-up.

Table 9: Levene's Test of Equality of Variance at post, 3-month follow-up and 6-month follow-up

Test	Levene's Statistics	df	df	Significance
Caregiver Burden Post	0.331	1	98	0.566
Caregiver Burden 3-Month Follow Up	0.004	1	98	0.947
Caregiver Burden 6-Month Follow Up	1.797	1	98	0.183

*The significance at the 0.05 Level.

From Table 9 above, the Levene's test of equality of variances was conducted to assess the assumption of homogeneity of variances for the post-test, 3-month follow-up and 6-month follow-up caregiver burden. The results indicated that the variances were equal across the intervention group and control group for caregiver burden post ($p = 0.566$), caregiver burden 3-month follow-up ($p = 0.947$) and caregiver burden 6-month follow-up ($p = 0.183$), as the significance values were greater than 0.05 ($p > 0.05$). This indicates that the assumption of equal variances was satisfied.

Post Intervention Caregiver Burden

Given the baseline differences in caregiver burden between groups ($p = 0.001$), ANCOVA was employed to control for pre-test scores as a covariate in all subsequent caregiver burden analyses.

A one-way ANCOVA was conducted to identify the difference in the post-intervention caregiver burden between the intervention group and the control group, after controlling for pre-(baseline) caregiver burden. The results of this analysis are shown in Table 10:

Table 10: Test of Between-Subjects Effects of Caregiver Burden at Post Intervention

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	1263.675	2	631.838	786.103	0.001	0.942
Intercept	3.299	1	3.299	4.105	0.046	0.041
CSI ScoreT1	66.515	1	66.515	82.755	0.001	0.460
Group	**1238.336**	**1**	**1238.336**	**1540.680**	**0.001**	**0.941**
Error	77.965	97	0.804			
Total	6158.000	100				
Corrected Total	1341.640	99				

*The Mean Difference is Significant at the 0.05 Level.

As presented in Table 10, when holding constant the pre-test caregiver (covariate), there was a significant difference in the post-test caregiver burden between the intervention group and the control group (F (1, 97) = 1540.680, $p = 0.001 < 0.05$). The partial $\eta^2 = 0.941$ indicated a large effect size.

3-Month Follow-up Caregiver Burden

The one-way ANCOVA was employed to identify the difference in the 3-month follow-up caregiver burden between the intervention group and the control group, after controlling for pre- (baseline) caregiver burden. The results of this analysis are shown in Table 11. As presented in Table 11, when holding constant the pre-test caregiver (covariate), there was significant difference in the 3-month follow-up caregiver burden between the intervention group and the control group (F (1, 97) = 1248.871, $p = 0.001 < 0.05$). The partial $\eta^2 = 0.928$ indicated a large effect size.

Table 11: Test of Between-Subjects Effects of Caregiver Burden at 3-month follow-up

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	1069.503	2	534.751	649.547	0.001	0.931
Intercept	19.639	1	19.639	23.855	0.001	0.197
CSI ScoreT1	32.663	1	32.663	39.675	0.001	0.290
Group	**1028.156**	**1**	**1028.156**	**1248.871**	**0.001**	**0.928**
Error	79.857	97	0.823			
Total	6162.000	100				
Corrected Total	1149.360	99				

*The Mean Difference is Significant at the 0.05 Level.

6-Month Follow-Up Caregiver Burden

The one-way ANCOVA was conducted to identify the difference in the 6-month follow-up caregiver burden between the intervention group and the control group, after controlling for pre- (baseline) caregiver burden. The results of this analysis are shown in Table 12 below:

Table 12: Test of Between-Subjects Effects of Caregiver Burden at 6-month follow-up

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	103.776	2	51.888	59.058	0.001	0.549
Intercept	35.723	1	35.723	40.660	0.001	0.295
CSI ScoreT1	62.816	1	62.816	71.496	0.001	0.424
Group	**78.340**	**1**	**78.340**	**89.165**	**0.001**	**0.479**
Error	85.224	97	0.879			
Total	9598.000	100				
Corrected Total	189.000	99				

*The Mean Difference is Significant at the 0.05 Level

As presented in Table 12, after controlling for the pre-test caregiver (covariate), a significant difference in 6-month follow-up caregiver burden was observed between the intervention group and the control group (F (1, 97) = 89.165, $p = 0.001$, $p < 0.05$). The partial $\eta^2 = 0.479$ indicated a large effect size.

Life Satisfaction Outcomes

The repeated measure ANOVA was conducted to examine the significant difference between mean scores of life satisfaction between the intervention and control group at pre-, post-, 3-month follow-up, and 6-month follow-up. The results of this analysis are shown in Table 13 below:

Table 13: Comparison of Life Satisfaction Between Intervention and Control Group at Pre, Post, 3-Month Follow-Up and 6-Month Follow-Up

Variable	Treatment group	N	Mean	Std. Deviation
Life Satisfaction Pre	Intervention Group	50	19.00	3.130
	Control Group	50	19.64	2.554
Life Satisfaction Post	Intervention Group	50	19.22	2.802
	Control Group	50	19.64	2.464
Life Satisfaction 3-month follow-up	Intervention Group	50	19.00	2.828
	Control Group	50	19.72	2.259
Life Satisfaction 6-month follow-up	Intervention Group	50	18.98	2.803
	Control Group	50	19.52	2.764

A repeated measure analysis of variance (ANOVA) was conducted to assess the significant difference between mean scores of life satisfaction between the intervention and control group at pre-, post, 3-month follow-up, and 6-month follow-up. Mauchly's Test of Sphericity indicated that the assumption of sphericity had been violated, (χ^2 (5) = 55.077, $p < 0.05$) (refer to Table 14). Consequently, the Greenhouse-Geisser correction was applied (refer to Table 15). The multivariate test revealed no significant difference between mean scores of life satisfaction between the intervention and control group at pre-, post, 3-month follow-up, and 6-month follow-up (F (2.24, 219.20) = 1.12, p = 0.332). The partial eta squared value of 0.01 indicates a small effect size, showing that the intervention accounted for 1% of the variance in life satisfaction. This did not support the hypothesis that there were significant differences in the mean scores of life satisfaction between the intervention and control groups at pre-intervention, post-intervention, 3-month follow-up, and 6-month follow-up.

Table 14: Mauchly's Test of Sphericity for Life Satisfaction

Within Subjects Effect	Mauchly's W	Approx. Chi-Square	df	Sig.	Epsilon[b]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Life Satisfaction	0.566	55.077	5	**0.001***	0.746	0.772	0.333

*Significance Level at $p < 0.05$

Table 15: Test of Within-Subjects Effects on Life Satisfaction

Source		Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Life Satisfaction * Group	Sphericity Assumed	1.26	3	0.42	1.12	0.340	0.01
	Greenhouse-Geisser	1.26	2.24	0.56	1.12	0.332	0.01
	Huynh-Feldt	1.26	2.32	0.54	1.12	0.333	0.01
	Lower-bound	1.26	1.00	1.26	1.12	0.292	0.01

*Significance Level at $p < 0.05$

DISCUSSION

The current investigation revealed that the BIFI effectively enhanced the psychological well-being of TBI caregivers in the intervention group compared to the control group receiving treatment as usual (TAU) at pre-, post-, 3-month follow-up, and 6-month follow-up.

The result of this study found that the BIFI was able to reduce the depression level immediately after treatment, at 3-month follow-up, and 6-month follow-up compared to the control group. The mean depression level showed a significant difference immediately after the intervention, at the 3-month follow-up, and at the 6-month follow-up. Despite an increase in the mean score at the 6-month follow-up, the overall changes remained significant.

This finding was consistent with a previous study that investigated the effectiveness of family intervention, but for Acquired Brain Injury (ABI)/Traumatic Brain Injury (TBI) and Spinal Cord Injury (SCI) which demonstrated a significant improvement in symptoms of depression up to 8 months follow-up [43]. Additionally, the BIFI showed efficacy in alleviating caregiver burden at post-intervention, as well as at the 3-month and 6-month follow-ups. An elevation in scores was noted at the 6-month follow-up, but the scores remained significant.

The present study somewhat aligns with the earlier research, which demonstrated a significant reduction in the mean burden score pre- and post-intervention; however, no significant differences were observed at the 3-month follow-up [23]. The authors attributed the insignificant differences to the limited sample size, single-center recruiting, and absence of a booster between the follow-ups. The current study successfully addressed the issues by using a meticulous sample size calculation, integrating multi-center settings, and implementing boosters between follow-ups. Moreover, the findings in this study also supported a previous study that found that family interventions were able to reduce burden levels among ABI/TBI and SCI caregivers at post-treatment and 8-month follow-up [43].

The findings provide an interesting insight, indicating that the BIFI did not lead to improvements in life satisfaction among caregivers. This aligns with a previous study which reported that many caregivers felt satisfied with their lives, despite the challenges they faced caring for TBI patients [25]. It is important to approach these results with a thoughtful perspective. The mean scores for all participants fell between 19.00 and 19.64, where scores from 15 to 19 suggest a level of satisfaction that is somewhat below average, while a score of 20 indicates a neutral stance. Since the scores were close to this neutral point, it seems likely that significant improvements in life satisfaction were challenging to achieve.

The lack of significant improvement in life satisfaction among caregivers warrants further exploration. Caregivers might not be unhappy with their lives, but they may not fully understand what constitutes happiness or well-being in their situation. In Malaysia, especially among Malay Muslim caregivers, cultural norms may discourage them from expressing dissatisfaction since caregiving is often seen as a religious and moral duty[44,45]. Additionally, the Satisfaction with Life Scale (SWLS) primarily assesses cognitive evaluations of life satisfaction, which may overlook emotional aspects[46]. This could limit its ability to reflect real changes in the lives of caregivers from collectivist cultures. Future research should consider using culturally adapted tools or mixed methods to better understand the experiences of Malaysian caregivers of individuals with traumatic brain injury.

Nurses are uniquely positioned to identify early signs of distress and burden among TBI caregivers[47]. However, targeted training is essential to equip nurses with the skills to recognize these signs effectively. For instance, a Malay caregiver may not openly report feelings of distress and might instead focus on the spiritual aspects of their caregiving experience. Integrating routine caregiver psychological screening into standard nursing assessment protocols at TBI rehabilitation clinics would ensure early identification and timely referral to appropriate support programs. These findings suggest that a structured program such as BIFI can empower nurses to deliver evidence-based psychoeducational support to TBI caregivers[47,48]. Through a Training of Trainers approach, nurses could be equipped with the skills needed to identify early signs of distress, prevent unnecessary deterioration of caregiver psychological well-being, and provide culturally sensitive care[48].

The present healthcare strategy in Malaysia, focusing on TBI patients is effective but may not be comprehensive. The current programs, such as the "Return to Work" initiative and regular follow-ups, are crucial for facilitating

the reintegration of TBI patients into society and tracking their progress. This management can be further optimized by incorporating an additional curriculum, like BIFI, for the caregivers.

Existing healthcare professionals such as clinical psychologists, occupational therapists, and other rehabilitation therapists can be trained to use the BIFI and implement the program in the TBI population. However, proper training is essential for competency and accountability purposes.

Strengths and Limitations

This study demonstrates several key strengths that highlight the importance of its findings. It is, to the authors' knowledge, the first randomized controlled trial (RCT) in Malaysia that specifically targets caregivers of individuals with traumatic brain injury (TBI) through an intervention program. While previous research has predominantly focused on rehabilitation programs for TBI patients, this study conclusively addresses a significant gap in the literature by introducing an intervention program tailored specifically for TBI caregivers.

Furthermore, the present study utilized the BIFI, which is founded on the established CBT and family functioning theoretical model developed by Kreutzer et al. in 2002. The structured component and advantages of this module were further supported by the results of the study.

Additionally, the study also included a longer follow-up period (6 months) compared to the previous studies [23]. In addition, a booster session was incorporated between the 3-month and 6-month follow-ups. This study confirmed that BIFI was effective up to the 6-month follow-up.

While the findings of the present study are promising, it is important to acknowledge its limitations. The study only included 2 study settings - Hospital Sungai Buloh and Hospital Rehabilitasi Cheras - which may limit the representativeness of the population to those in Klang Valley only. To improve the comprehensiveness of the findings, it would be beneficial to extend the sample to include those in rural areas. Additionally, the current study utilized self-report questionnaires to assess the program's effectiveness. Potential bias in reporting could have influenced the study's results.

One limitation of this study is the lack of accurate data regarding the time elapsed since the injury occurred. Some caregivers were unable to provide the exact date or year of the injury. This reliance on memory can result in potential inaccuracies. Research has shown that recall bias can lead to either an underestimation or an overestimation of the actual effects [49].

Clinical and Policy Implications

Essentially, the findings in this study can be a solid justification for policymakers to consider the inclusion of the BIFI in the current guidelines. This improvement will encourage a comprehensive approach to the management of the TBI population. It is recommended that policymakers inform all the relevant healthcare stakeholders of the information and resources available for the TBI populations.

Future Research Directions

First, future studies should consider replicating the present study on a larger scale. As mentioned earlier, the study settings might not be enough to generalize the data to the larger population. It is strongly recommended to expand the sampling across states. It is hoped that this effort will lead to a better understanding and more accurate data interpretation.

Second, the next recommendation is to modify and expand this program module to other types of acquired brain injuries, such as stroke. This is because the stroke population falls under the same umbrella as TBI, but in a different category. Certain clinical outcomes of stroke patients overlap with those of TBI patients. Consequently, the impact on caregivers is also the same. By expanding the module to other caregivers it could improve and inform strategies for better outcomes.

Finally, future researchers can further assess the effectiveness of BIFI in improving the psychological well-being of TBI caregivers by using digital telehealth or an online approach. Digital telehealth or online approaches are currently trending and could reach a larger number of participants. Additionally, it is not time-consuming, provides easy access to resources, and is cost-effective.

CONCLUSIONS

This study examined the effectiveness of the BIFI program in improving the psychological well-being of caregivers for individuals with traumatic brain injury (TBI) in Malaysia. The findings showed significant improvements in emotional distress and caregiver burden. However, no significant changes were observed in the life satisfaction outcomes. This lack of change may be attributed to cultural factors within the current population, where caregiving roles are viewed as a religious obligation, moral duty, and responsibility.

These findings have important implications for nursing practice, particularly regarding the implementation of a structured psychoeducational support program for TBI caregivers. Through a Training of Trainers approach, nurses can help bridge the gap between early intervention and long-term support for this population. Integrating the BIFI program into existing TBI nursing care protocols could enhance the overall management of the TBI caregivers across acute, rehabilitation, and community settings. Future research should further explore the needs of caregivers and how Malaysian culture influences the caregiving experience. Ultimately, this study provides a valuable evidence base for improving the psychological well-being of TBI caregivers and advancing family-centered nursing care in Malaysia.

Abbreviations

α	**Alpha**
β	Beta
%	Percentage
ABI	Acquired Brain Injury
ADL	Activities of Daily Living
ANOVA	Analysis of Variance
ANCOVA	Analysis of Covariance
APA	American Psychological Association
BDI	Beck Depression Inventory
BIFI	Brain Injury Family Intervention
CBT	Cognitive Behavior Therapy
CONSORT	Consolidated Standards of Reporting Trials
CSI	Caregiver Strain Index
HRC	Hospital Rehabilitasi Cheras
HSB	Hospital Sungai Buloh
LMICs	low- and middle-income countries
MVA	Motor Vehicle Accident
MREC	Medical Research and Ethics Committee Malaysia

NMRR	National Medical Research Register
NIDRR	National Institute on Disability and Rehabilitation Research
RCT	randomized controlled trial
RM	Ringgit Malaysia
SCI	Spinal Cord Injury
SD	Standard Deviation
SPM	Sijil Pelajaran Malaysia
STPM	Sijil Tinggi Pelajaran Malaysia
SWLS	Satisfaction with Life Scale
TAU	treatment as usual
TBI	Traumatic Brain Injury
USD	United States Dollar
WHO	World Health Organization

Ethics Declaration

All procedures performed in the studies involving human participants were in accordance with the ethical standards of the national research committee and with the 1964 Helsinki Declaration.

Consent to Participate

Informed consent was obtained from all participants included in the study.

Consent to Publish

Participant provided consent for anonymized data and relevant findings to be published in this manuscript. No identifying information is included in the published material.

ACKNOWLEDGEMENTS

This study acknowledges the contributions of Universiti Putra Malaysia, Universiti Teknologi MARA, the Ministry of Health Malaysia, the investigators, doctors, nurses, and all participants involved. Special thanks to Professor Dr Jeffrey Kreutzer and his team for aiding and supporting the study (founders of the Brain Injury Family Intervention module - Virginia Commonwealth University, Richmond, United States).

Author Contributions

SAO- Conceptualization, methodology, validation, formal analysis, investigation, data curation, writing (original draft), writing (review and editing), visualization, project administration, and funding acquisition.

FM- Conceptualization, resources, writing (review & editing) and supervision.

NSZ – Writing (review & editing) and supervision.

Funding Declaration

This study was funded by Universiti Teknologi MARA (grant number: 600-IRMI/MyRA/5/3/LESTARI [036/2017]).

Competing Interest

The authors declare no competing interests.

Data Availability Statement

The data of this study are available upon request and subject to approval from the Ministry of Health Malaysia, Universiti Putra Malaysia, and Universiti Teknologi MARA.

REFERENCES

1. Dewan, M. C., Rattani, A., Gupta, S., Baticulon, R. E., Hung, Y. C., Punchak, M., Agrawal, A., Adeleye, A. O., Shrime, M. G., Rubiano, A. M., Rosenfeld, J. V., & Park, K. B. (2019). Estimating the global incidence of traumatic brain injury. Journal of Neurosurgery, 130, 1080–1097. https://doi.org/10.3171/2017.10.JNS17352
2. Yan, J., Wang, C., & Sun, B. (2025). Global, regional, and national burdens of traumatic brain injury from 1990 to 2021. Frontiers in Public Health, 13. https://doi.org/10.3389/fpubh.2025.1556147
3. Zhong, H., Feng, Y., Shen, J., Rao, T., Dai, H., Zhong, W., & Zhao, G. (2025). Global Burden of Traumatic Brain Injury in 204 Countries and Territories From 1990 to 2021. American Journal of Preventive Medicine, 68, 754–763. https://doi.org/10.1016/j.amepre.2025.01.001
4. Bryan-Hancock, C., & Harrison, J. (2010). The global burden of traumatic brain injury: preliminary results from the Global Burden of Disease Project. Injury Prevention, 16(Supplement 1), A17–A17. https://doi.org/10.1136/ip.2010.029215.61
5. Huang, X. F., Ma, S. F., Jiang, X. H., Song, R. J., Li, M., Zhang, J., Sun, T. J., Hu, Q., Wang, W. R., Yu, A. Y., & Li, H. (2024). Causes and global, regional, and national burdens of traumatic brain injury from 1990 to 2019. Chinese Journal of Traumatology - English Edition, 27, 311–322. https://doi.org/10.1016/j.cjtee.2024.03.007
6. Johnson, W. D., & Griswold, D. P. (2017). Traumatic brain injury: a global challenge. The Lancet Neurology, 16(12), 949–950. https://doi.org/10.1016/S1474-4422(17)30362-9
7. Berwick, D., Bowman, K., & Matney, C. (2022). Traumatic Brain Injury: A Roadmap for Accelerating Progress (2022). In Traumatic Brain Injury. https://doi.org/10.17226/25394
8. You, X., Liew, B. S., Rosman, A. K., Dcsn, Musa, K. I., & Idris, Z. (2018). The estimated cost of surgically managed isolated traumatic head injury secondary to road traffic accidents. Neurosurgical Focus, 44(5), E7. https://doi.org/10.3171/2018.1.FOCUS17796
9. Formisano, R., Longo, E., Azicnuda, E., Silvestro, D., D'Ippolito, M., Truelle, J. L., von Steinbüchel, N., von Wild, K., Wilson, L., Rigon, J., Barba, C., Forcina, A., & Giustini, M. (2017). Quality of life in persons after traumatic brain injury as self-perceived and as perceived by the caregivers. Neurological Sciences, 38(2), 279–286. https://doi.org/10.1007/s10072-016-2755-y
10. Carlozzi, N. E., Sander, A. M., Choi, S. W., Wu, Z., Miner, J. A., Lyden, A. K., Graves, C., & Sen, S. (2022). Improving outcomes for care partners of persons with traumatic brain injury: Protocol for a randomized control trial of a just-in-time-adaptive self-management intervention. PLoS ONE, 17(6 June). https://doi.org/10.1371/journal.pone.0268726
11. Arulsamy, A., & Shaikh, M. F. (2020). Current status of traumatic brain injury research in Malaysia: A systematic review. Neuroscience Research Notes, 3(4), 1–21. https://doi.org/10.31117/neuroscirn.v3i4.52
12. Azman, A., Jali, N. A., Jamir Singh, P. S., Abdullah, J. M., & Ibrahim, H. (2020). Family roles, challenges and needs in caring for traumatic brain injury (TBI) family members: a systematic review. Journal of Health Research, 34(6), 495–504. https://doi.org/10.1108/JHR-07-2019-0138
13. D'Ippolito, M., Aloisi, M., Azicnuda, E., Silvestro, D., Giustini, M., Verni, F., Formisano, R., & Bivona, U. (2018). Changes in Caregivers Lifestyle after Severe Acquired Brain Injury: A Preliminary Investigation. BioMed Research International. https://doi.org/10.1155/2018/2824081
14. Harding, R., Gao, W., Jackson, D., Pearson, C., Murray, J., & Higginson, I. J. (2015). Comparative Analysis of Informal Caregiver Burden in Advanced Cancer, Dementia, and Acquired Brain Injury. Journal of Pain and Symptom Management, 50(4), 445–452.

https://doi.org/10.1016/j.jpainsymman.2015.04.005
15. Nonterah, C. W., Jensen, B. J., Perrin, P. B., Stevens, L. F., Cabrera, T. V., Jiménez-Maldonado, M., & Arango-Lasprilla, J. C. (2013). The influence of TBI impairments on family caregiver mental health in Mexico. Brain Injury, 27(11), 1287–1293. https://doi.org/10.3109/02699052.2013.812243
16. Saban, K. L., Griffin, J. M., Urban, A., Janusek, M. A., Pape, T. L.-B., & Collins, E. (2016). Perceived health, caregiver burden, and quality of life in women partners providing care to Veterans with traumatic brain injury. Journal of Rehabilitation Research and Development, 53(6), 681–692. https://doi.org/10.1682/JRRD.2015.07.0143
17. Sander, A. M., Hanks, R. A., Ianni, P. A., Boileau, N. R., Kratz, A. L., Hahn, E. A., Tulsky, D. S., & Carlozzi, N. E. (2019). Sociocultural Factors Influencing Caregiver Appraisals Following Traumatic Brain Injury. Archives of Physical Medicine and Rehabilitation, 100(4), S58–S64. https://doi.org/10.1016/j.apmr.2018.08.193
18. Tam, S., McKay, A., Sloan, S., & Ponsford, J. (2015). The experience of challenging behaviours following severe TBI: A family perspective. Brain Injury, 29(7–8), 813–821. https://doi.org/10.3109/02699052.2015.1005134
19. Kelly, A., Ponsford, J., & Couchman, G. (2013). Impact of a family-focused intervention on self-concept after acquired brain injury. Neuropsychological Rehabilitation, 23(4), 563–579. https://doi.org/10.1080/09602011.2013.795903
20. Niemeier, J. P., Kreutzer, J. S., Marwitz, J. H., & Sima, A. P. (2019). A Randomized Controlled Pilot Study of a Manualized Intervention for Caregivers of Patients With Traumatic Brain Injury in Inpatient Rehabilitation. Archives of Physical Medicine and Rehabilitation, 100(4S), S65–S75. https://doi.org/10.1016/j.apmr.2018.07.422
21. Shepherd-Banigan, M. E., Shapiro, A., McDuffie, J. R., Brancu, M., Sperber, N. R., Van Houtven, C. H., Kosinski, A. S., Mehta, N. N., Nagi, A., & Williams, J. W. (2018). Interventions That Support or Involve Caregivers or Families of Patients with Traumatic Injury: a Systematic Review. Journal of General Internal Medicine, 33(7), 1177–1186. https://doi.org/10.1007/s11606-018-4417-7
22. Gan, C., Gargaro, J., Kreutzer, J. S., Boschen, K. A., & Wright, F. V. (2010). Development and preliminary evaluation of a structured family system intervention for adolescents with brain injury and their families. In Brain Injury, 24(4), 651–663. https://doi.org/10.3109/02699051003692142
23. Kreutzer, J. S., Marwitz, J. H., Sima, A. P., & Godwin, E. E. (2015). Efficacy of the Brain Injury Family Intervention: Impact on Family Members. Journal of Head Trauma Rehabilitation, 30(4), 249–260. https://doi.org/10.1097/HTR.0000000000000144
24. Hassan, S. T. S., Khaw, W. F., Rosna, A. R., & Husna, J. (2011). Traumatic brain injury: Caregivers' problems and needs. Journal of the Nepal Medical Association, 51(181), 53–55. https://pubmed.ncbi.nlm.nih.gov/22335097/
25. Mazlan, M., Ghani, S. Z. S. A., Tan, K.-F., & Subramanian, P. (2016). Life satisfaction and strain among informal caregivers of patients with traumatic brain injury in Malaysia. Disability and Rehabilitation, 38(22), 2198–2205. https://doi.org/10.3109/09638288.2015.1123307
26. Ludin, S. M., & Othman, H. (2019). The Family Caregivers' Needs on Care At Home With Severe Traumatic Brain Injury Survivors: A Review. The Malaysian Journal of Nursing, 11(02), 69–76. https://doi.org/10.31674/mjn.2019.v11i02.008
27. Othman, H., Ludin, S. M., Saidi, S., & Awang, M. S. (2021). The needs of traumatic brain injury survivors' caregivers and the implication required during the covid-19 pandemic: Public health issues. Journal of Public Health Research, 10. https://doi.org/10.4081/jphr.2021.2205
28. Baker, A., Barker, S., Sampson, A., & Martin, C. (2017). Caregiver outcomes and interventions: A systematic scoping review of the traumatic brain injury and spinal cord injury literature. Clinical Rehabilitation, 31(1), 145–160. https://doi.org/10.1177/0269215516639357
29. Meixner, C., O'Donoghue, C. R., & Hart, V. (2017). Impact of the Brain Injury Family Intervention (BIFI) training on rehabilitation providers: A mixed methods study. NeuroRehabilitation, 40(4), 545–552. https://doi.org/10.3233/NRE-171441
30. Kreutzer, J. S., Marwitz, J. H., Godwin, E. E., & Arango-Lasprilla, J. C. (2010). Practical approaches to effective family intervention after brain injury. Journal of Head Trauma Rehabilitation, 25(2), 113–120. https://doi.org/10.1097/HTR.0b013e3181cf0712
31. Kreutzer, J. S., Stejskal, T. M., Ketchum, J. M., Marwitz, J. H., Taylor, L. A., & Menzel, J. C. (2009). A

preliminary investigation of the brain injury family intervention: Impact on family members. Brain Injury, 23(6), 535–547. https://doi.org/10.1080/02699050902926291

32. Zhong, B. (2009). How to calculate sample size in randomized controlled trial? Journal of Thoracic Disease, 1(1), 51–54. https://doi.org/10.3978/j.issn.2072-1439.2009.02.02
33. Vasipalli, S. S., Sadayandi, R. A., Rajasegaran, R., Nagaraju, N., Ravi, S., & Sudarsan, K. (2025). Stress and quality of life in caregivers of patients with traumatic brain injury: A cross-sectional study. Journal of Neurosciences in Rural Practice, 16(1), 76–83. https://doi.org/10.25259/JNRP_398_2024
34. Gordon, R., Simpson, G. K., & Paasila, J. M. (2023). Hours and costs of formal and informal care following traumatic brain injury and spinal cord injury sustained through motor vehicle accidents: A cross- sectional study. Journal of Rehabilitation Medicine, 55. https://doi.org/10.2340/JRM.V55.5368
35. Mukhtar, F., & Oei, T. P. S. (2008). Exploratory and confirmatory factor validation and psychometric properties of the Beck Depression Inventory for Malays (BDI-Malay) in Malaysia. Malaysian Journal of Psychiatry, 17(1).
36. Robinson, B. (1983). Validation of a Caregiver Strain Index. Journal of Gerontology, 38, 344–348.
37. Othman, Z., & Siongteck, W. (2014). Validation of malay caregiver strain index. Eastern Journal of Medicine, 19, 102–104.
38. Diener, E., Emmons, R. A., Larsen, R. J., & Griffin, S. (1985). The Satisfaction with Life Scale. Journal of Personality Assessment, 49(1), 71–75.
39. Mustapha, M. (2015). Subjective Well-being among Malaysian Students [Doctoral dissertation, University of Plymouth].
40. Swami, V., & Chamorro-Premuzic, T. (2009). Psychometric evaluation of the Malay satisfaction with life scale. Social Indicators Research, 92(1), 25–33. https://doi.org/10.1007/s11205-008-9295-7
41. Patterson, J. M. (1988). Families experiencing stress. I. The family adjustment and adaptation response model. II. Applying the FAAR model to health-related issues for intervention and reasearch. Family Systems Medicine, 6(2), 202–237. https://doi.org/10.1037/h0089739
42. Omar, S. A., Zulkefly, N. S., & Mukhtar, F. (2024). The Effectiveness of Brain Injury Family Intervention in Improving the Psychological Well-Being of Caregivers of Patients With Traumatic Brain Injury: Protocol for a Randomized Controlled Trial. JMIR Research Protocols, 13(1). https://doi.org/10.2196/53692
43. Soendergaard, P. L., Arango-Lasprilla, J. C., Wolffbrandt, M. M., Dornonville de la Cour, F. L., Biering-Sørensen, F., & Norup, A. (2023). Investigating the Effectiveness of a Family Intervention after Acquired Brain or Spinal Cord Injury: A Randomized Controlled Trial. Journal of Clinical Medicine, 12(9). https://doi.org/10.3390/jcm12093214
44. Hofstede, G. (2001). Culture's Consequences: Comparing Values, Behaviors, Institutions, and Organizations Across Nations (2nd ed.). Sage Publications.
45. Sumari, M., Baharudin, D. F., Khalid, N. M., Ibrahim, N. H., & Ahmed Tharbe, I. H. (2020). Family functioning in a collectivist culture of Malaysia: A qualitative study. The Family Journal, 28(4), 396–402.
46. Pavot, W., & Diener, E. (1993). Review of the Satisfaction With Life Scale. Psychological Assessment, 5(2), 164–172. https://doi.org/10.1037/1040-3590.5.2.164
47. Shepherd-Banigan, M., Kaufman, B. G., Decosimo, K., Dadolf, J., Boucher, N. A., Mahanna, E. P., Bruening, R., Sullivan, C., Wang, V., Hastings, S. N., Allen, K. D., Sperber, N., Coffman, C. J., & Van Houtven, C. H. (2020). Adaptation and Implementation of a Family Caregiver Skills Training Program: From Single Site RCT to Multisite Pragmatic Intervention. Journal of Nursing Scholarship, 52(1), 23–33. https://doi.org/10.1111/jnu.12511
48. Nexø, M. A., Kingod, N. R., Eshøj, S. H., Kjærulff, E. M., Nørgaard, O., & Andersen, T. H. (2024). The impact of train-the-trainer programs on the continued professional development of nurses: a systematic review. BMC Medical Education, 24(1), 1–15. https://doi.org/10.1186/s12909-023-04998-4
49. Althubaiti, A. (2016). Information bias in health research: Definition, pitfalls, and adjustment methods. In Journal of Multidisciplinary Healthcare (Vol. 9, pp. 211–217). Dove Medical Press Ltd. https://doi.org/10.2147/JMDH.S104807