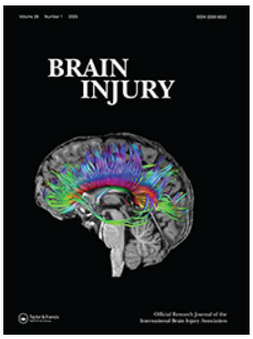

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Effectiveness of a psychoeducational program for caregivers of persons with acquired brain injury: a randomized controlled trial (EDUCA-V)

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ABSTRACT

Objective: To assess the effectiveness of a psychoeducational intervention program (PIP) compared to standard attention in reducing caregiver burden after the intervention (at 4 months) and at follow-up (at 8 months).

Methods: A multicenter, evaluator-blind, randomized controlled trial. The experimental group received a PIP intervention consisting of 10 weekly group sessions, while the control group received standard attention. The primary outcome was measured as the change scores from baseline on the caregiver's burden (ZBI). The secondary outcomes evaluated included caregiver mental health (GHQ-28), anxiety (STAI), and depression (CES-D). Trial registration: ISRCTN16513116.

Results: The sample comprised 76 informal caregivers (41 allocated in the intervention condition and 35 in the control). The caregiver's burden (ZBI) did not show significant differences between groups at 4 months or 8 months. There were favorable and significant changes in the caregiver's mental health (GHQ) and depression (CES-D) at 4 months in the PIP group. There were no significant differences between groups in anxiety during the trial.

Conclusions: The PIP intervention group reported positive effects on general mental health and depression after the intervention but not at follow-up. We need more studies which interventions follow expert recommendations and can sustain positive results over time.

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Acquired brain injury; caregiver burden; depression; mental health; psychoeducation, randomized controlled trial, EDUCA V trial

Introduction

Acquired brain injury (ABI) caused by cerebrovascular accidents, cranioencephalic trauma, cerebral anoxia, tumors and brain infections has become one of the leading causes of severe dependency in developed countries (1). Surviving patients often have significant physical, cognitive, and psychological sequelae leading to long-term care and dependency (2,3).

Most patients who have suffered from ABI live at home with a family member who takes care of them (4). Caregivers play an essential role in the recovery process, working together with the rehabilitation teams (5,6). However, even after rehabilitation, severe ABI can have a marked impact on the capabilities of the affected person and entail an enormous repercussion on his or her significant social circle (family, friends, relatives). In the chronic phase of the disease, family caregivers who spend more time caregiving experience higher levels of distress (7).

The caregiver is exposed to continuous wear and tear that reflects in poorer physical health, higher levels of anxiety, depression and stress, poorer quality of life, and reduced enjoyment of social relationships (8,9). This phenomenon is known as caregiver burden (10). Three main contributing factors have been traditionally proposed to explain caregiver burden: First, the specific characteristics of the patient (level of autonomy in carrying out activities of daily living, physical and cognitive limitations and behavioral disorders); second, factors linked to the socio-family environment (financial burden and reorganization of the family structure) (11); third, the lack of knowledge and preparation to cope with the task of caregiving (12). It is estimated that 50% of carers suffer from some psychological disorder; anxiety, depression, somatization and insomnia are the most prevalent (13). The caregiver's psychological distress can negatively impact the quality of care and the patient's recovery (14,15).

A wide range of interventions for caregivers of people with ABI has been proposed (16–20). These interventions include psychoeducational programmes (21), skills training (22,23), emotional support (24), or psychotherapy (25) applied in different delivery formats (face-to-face, written, telephone, or web-based). The effectiveness of these interventions is unclear, as they use different interventions, designs (experimental or quasi-experimental) and methodologies. For example, studies that use face-to-face interventions, although their cost is supposed to be higher (due to the necessity for additional

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resources), have yielded favorable outcomes for caregivers with depression, problem-solving, and distress levels (22,26). Studies that combine different components in the intervention (psychoeducation plus skill building) seem more effective than interventions that only apply psychoeducational strategies (27). Studies that apply tailored interventions have shown the most beneficial results in reducing depressive symptoms (22,28). Despite we can find studies with a wide range of number of sessions, the evidence supports the recommendation of approximately 5 to 9 sessions for the intervention, with sufficient power to detect significant results (27). Finally, studies whose interventions are focused on the caregiver were more likely to provide benefits than those that targeted the caregiver/survivor dyad or the survivor only (27).

Systematic reviews and meta-analyses of non-pharmacological interventions show mixed results regarding their effectiveness for informal caregivers of people with ABI. These reviews conclude that more high-quality research – including well-designed and adequately powered randomized controlled clinical trials – is needed to confirm the effectiveness of psychological interventions for informal caregivers (27,29,30).

The EDUCA initiative was developed with two primary aims: to enhance the understanding of caregiver burden and to create innovative psychoeducational interventions to support informal caregivers of individuals with different chronic illnesses. Through various randomized controlled trials, a significant amount of experience and positive results have been gained in addressing the burden of caregivers for individuals with mental illnesses such as dementia, schizophrenia, and intellectual disability (31–34). In this new study, we have attempted to address the gaps identified in previous research. We have planned high-quality research using an experimental (single-blind) design and developed a new psychoeducative intervention program (PIP). This new intervention combines some of the approaches that have shown better results in previous studies and are recommended in literature reviews: focusing on the challenges of informal caregivers of people with ABI through a group face-to-face multilayer intervention that combines psychoeducation, skills building and emotional support through 10 sessions.

The primary objective of this new study is to evaluate the effectiveness of a standardized group psychoeducational intervention program (PIP) compared to standard care in reducing caregiver burden. Secondary objectives include evaluating the impact of the PIP on caregivers' mental health, anxiety, and depression. The evaluation will be conducted at the end of the trial (4 months since baseline) and during the follow-up period (8 months since baseline).

Following these objectives, the EDUCA-V trial hypothesized that informal caregivers assigned to the PIP condition would experience a lower burden at four and eight months post-intervention than caregivers placed in the control condition (standard attention). After intervention and at follow-up, it was hypothesized that caregivers in the PIP condition would exhibit a significant improvement in mental health state (well-being, depression, and anxiety) compared to those allocated to the control condition (standard attention).

Methods

Design

The study was an interventionist, multicentre, evaluator-blind, randomized controlled trial with individual randomization to either of two conditions: PIP or standard care.

Procedure

Nine Spanish rehabilitation centers collaborated to recruit the sample. Each rehabilitation center had two independent investigators: one therapist for administering the PIP and one evaluator for outcome assessment. Evaluators were blinded to the allocated intervention. A central research committee was responsible for supervising the proper completion of trial procedures and adherence to protocol. Participants were recruited via advertisements on research sites and phone calls to potential participants (those who could meet the selection criteria based on the recruiter's criteria). They were informed about the aim of the study, the randomization process, the potential benefits of the intervention, the voluntary nature of participation, the anonymity of data processing, and the freedom to refuse their participation without stating reasons. A written informed consent was signed before their inclusion in the study. The Ethical and Scientific Research Committees of Navarra (Project 2015/54), Spain, along with the Ethical Committee of each participating research center, approved the study. The study procedures were carried out in agreement with the Declaration of Helsinki.

Participants

To qualify for participation in the study, caregivers had to meet the following requirements: (i) males or females (18+ years); ii) be caring for a person with ABI (traumatic brain injury, stroke, anoxia, brain tumor or encephalitis; (iii) be an informal (unpaid) caregiver; iv) spend a minimum of 4 hours/week caring for the care-receiver. The patient with BI should be: i) over 16 years of age, ii) resident in the community, iii) receiving appropriate outpatient rehabilitation, iv) being stable clinically, v) and the time since the BI had to be more than 3 months.

Those caregivers who did not have the time to attend the weekly intervention sessions or had received a standardized intervention comparable to the one administered in the trial within the past year were excluded from participating in the study. Exclusion criteria for patients were: i) having been cared for in a respite care unit during the last 30 days or ii) living in professionally supervised housing.

The central research committee established the criteria for ending the trial before completion as (i) caregiver decision, (ii) transition of the patient being cared for from outpatient to inpatient status or residential care, and (iii) protocol deviations.

Interventions

Caregivers randomized to the intervention arm received their usual treatment plus a Psychoeducational Intervention

Program (PIP). PIP intervention was developed by a group of experts in ABI (psychologists and psychiatrists). Firstly, based on their experience in clinical practice with patients and caregivers and available evidence, they reached a consensus on the interests, needs, difficulties and emotional hardships caregivers of people with ABI faced. Secondly, following the structure and format of previous interventions (31–34), they created a new intervention focused on the reality and needs of caregivers of people with BI.

Caregivers underwent training in cognitive and behavioral skills and received standardized information regarding the clinical progression of the disease. The program aimed to enhance caregivers' overall caregiving abilities, communication skills, and ability to seek and enjoy pleasant events while teaching them relaxation techniques and how to seek support. The PIP was an interactive program that required active participation from caregivers, including role-playing and applying newly learned skills to solve conflicts. The PIP used cognitive-behavioral techniques to help caregivers identify and challenge negative beliefs and develop new coping mechanisms for the demands of caregiving. The program consisted of 10 weekly group sessions, each lasting 90–120 minutes, with a 15-minute break included in each session to prevent fatigue or lack of focus.

Each session of the PIP followed a consistent structure, starting with a review of the previous week's homework tasks, then an introduction to the topic at hand and exercises to practice the newly acquired knowledge or skills. The program was administered by professionals with clinical experience in BI (psychologists) trained in applying the PIP. The therapist and the caregiver were provided with manuals to guide them through the program. Table 1 shows the contents and details of each session.

Strategies to improve participant fidelity were implemented. One such strategy involved sending phone notifications to remind participants of the time and date of the next session. The intervention's application is fully described per the TIDieR proposal (35) (see Supplementary materials).

Caregivers randomized to the control arm received the only usual treatment provided by their outpatient center, which included periodic interviews and information regarding the clinical course of the person with ABI.

Data collection and outcome assessment

The Educa-V trial included three visits: baseline, post-intervention (approximately four months after the trial began), and follow-up (approximately eight months since the inception of the trial). To mitigate the possibility of researcher bias or similar biases, all outcomes were measured using self-reported scales administered by a researcher blinded to the intervention allocation. The assessments took place in the rehabilitation centers from January 2019 to September 2019.

Primary outcome measure

The primary hypothesis related to caregiver burden was tested using the original and well-known Zarit Burden Interview of

Table 1. Contents of the psychoeducational intervention program (PIP).

Sesion	Content	Topics developed
1	To know who we are	Information about EDUCA project (aims and related issues). General information about brain damage. The importance of our needs, care and self-care Strengthen the interpersonal relationship within the group.
2	My life has changed	Adapting to change. How it can affect our daily living. Evaluating our rights and compromises.
3	Take care of oneself	How do I feel? Self-care in the caregiver. Learning to take care of oneself. Changing routines.
4	Stress & well-being	Tension, emotion & stress. Coping with stress. Relaxation technique: Relaxation by breathing.
5	Importance of thinking	Identifying beliefs & changing negative beliefs. Relaxation by mental distraction.
6	Improving my communication	The effective communication. How to talk with the health services. Relaxation by imaginary.
7	Understanding behavior problems	ABC of behavior. How to manage behavior problems. To make a plan to change behavior. Relaxation by muscular relaxation.
8	Approaching demandings situations	Improving the situation. Strategies for managing behavior. Demanding situations. Relaxation by imaginary.
9	Importance of pleasant activities	Pleasant activities and mood. Identifying & planning pleasant activities. Relaxation by imaginary.
10	Planning the future	Worries about the future. Assistance, health services & laws. About the future. Wrapping summary and program evaluation by the caregivers.

22 items (ZBI-22) (10). This scale is widely used in the assessment of the subjective caregiver burden (30). It has been used in different clinical contexts, such as dementia, severe mental illness, cancer, palliative care or intellectual disabilities (36–38). The total score is obtained by summing the individual scores of the 22 items. Each item is rated on a 5-point Likert scale, ranging from 0 (never) to 4 (nearly always). The total score can range from 0 to 88. Higher scores indicate a more significant caregiver burden. The Zarit Burden Interview (ZBI-22) has been shown to have good psychometric properties, including high internal consistency, test-retest reliability, and construct validity in various caregiving contexts (39–42). The Spanish version was used in this study (43).

Secondary outcome measures

Secondary hypotheses were related to mental health state, depression, and anxiety.

Caregivers' mental health was assessed using the General Health Questionnaire (GHQ-28) (44). The GHQ-28 comprises 28 items divided into four subscales: somatic symptoms, anxiety/insomnia, social dysfunction, and severe depression. Respondents are asked to rate the frequency with which they experience each symptom on a four-point Likert scale, ranging from 0 ('not at all') to 3 ('much more than usual'). The subscale scores are summed to provide a total score that ranges from 0 to 84, with higher scores indicating worse mental health. The Spanish validation was used in this study (45).

Caregivers' Depressive symptoms were assessed with the Center for Epidemiologic Studies Depression Scale (CES-D) (46). The CES-D is a 20-item scale that rates the frequency of depressive symptoms over the past week. It includes a four-point scale ranging from 0 (rarely or none) to 3 (most or all of the time). The items cover a range of symptoms, including sadness or hopelessness, loss of appetite or overeating, sleep disturbances, low self-esteem, and difficulty concentrating. The total score on the CES-D scale can range from 0 to 60, with higher scores indicating more severe depressive symptoms. Scores above 16 indicate possible depression, while scores above 22 suggest a high likelihood of depression. We used the Spanish validation of CES-D (47).

To assess the caregivers' anxiety, we selected the State-Trait Anxiety Inventory (STAI) (48). The STAI scale consists of two separate 20-item questionnaires: state anxiety (how anxious a person feels at a specific moment) and trait anxiety (how anxious a person generally feels in their daily life). Each item is rated on a 4-point Likert scale ranging from 1 (not at all) to 4 (very much so). Range scores of each subtest vary from 20 to 80. Higher scores indicate greater anxiety. We used the Spanish validation (49).

In addition, and to avoid alternative explanations for the possible changes in caregiver outcome scores, information about the clinical status of the patients with ABI was collected using the Glasgow Outcome Scale (GOS) (50) and the Neuropsychiatric Inventory (NPI) (51) at each visit. The Glasgow Outcome Scale (GOS) is a neurological assessment tool for classifying patients after traumatic brain injury. The Neuropsychiatric Inventory (NPI) is a widely used tool for assessing 12 common neuropsychiatric symptoms (delusions, hallucinations, agitation/aggression, depression/dysphoria, anxiety, elation/euphoria, apathy/indifference, disinhibition, irritability/lability, aberrant motor behavior, sleep and nighttime behavior, and appetite and eating abnormalities).

Sample size

A sample size of 200 caregivers was determined for the study, assuming a baseline score of 22 on the ZBI scale with a standard deviation of 15. A moderate effect size (standardized mean difference = 0.40) was expected for inter-group comparisons on the ZBI scale. This sample size was calculated to achieve 85% power at a 5% alpha level with a randomized allocation of caregivers in a 1:1 ratio.

Randomization

The randomization process was conducted by an independent biostatistician in each research site using a password-protected database and block randomization, with block sizes ranging from 1 to 4. The 'Randomizer v. 0.4.0' module of Jamovi statistical software was used to generate the sequence. The randomization process was blinded for all site investigators involved in the study. Only the central research committee had this information. The study coordinator informed each participant of the randomization results via phone call. The assignment generation of the participants was maintained during the entire study. No switching from one group to another was allowed. This was considered a protocol violation (exclusion criterion for exclusion from the study). Participants and the interventionist were aware of the group assignment. Only the researchers responsible for evaluating the participants at four and eight months were blinded to the group assignment.

Statistical methods

Continuous variables were presented using means and standard deviations, while categorical variables were reported as frequencies and percentages. To examine the main outcomes, between-group analyses on change scores from baseline (visit #1) to post-intervention (visit #2) and follow-up (visit #3) were conducted. Results are reported using mean differences, standard deviations, and/or 95% confidence intervals (CI), as well as standardized effect sizes (SMD). Data were analyzed using a mixed linear model for repeated measures (MLM) on complete cases (CC), which included caregivers who provided complete information at visits #2 and #3 (52). The interaction term of intervention by visit was tested to evaluate the effect of the intervention. SMD scores can be interpreted following Cohen's cutoff points (values around 0.2 indicating a small effect, values around 0.5 indicating a medium effect, and values around 0.8 indicating a large effect) (53). Analyses were performed with Stata v14 (StataCorp, College Station, TX, 2015), Jamovi v2.3. (The Jamovi project, 2022) and R Core Team (2021). R: A Language and environment for statistical computing. (Version 4.1).

Results

Recruitment and losses

Sample recruitment took place from January to March 2019. A total of 76 caregivers were recruited to participate. Forty-one participants were assigned to the PIP arm, while 35 were to the control arm. Figure 1 shows the trial flowchart. The median recruitment by research site was 8 (range 5 to 15).

At visit #2, 8 participants (19%) were lost in the intervention group and 5 participants (14%) in the control group, with no significant difference found between the groups (Fisher exact test, $p = 0.761$). At visit #3, there were no losses in the intervention group, while 4 participants (13%) discontinued their participation in the control group. The difference in drop-outs at visit #3 was statistically significant (Fisher exact test, p-value = 0.046). All sample losses were caused by the caregiver's voluntary decision not to continue with the study (they argued lack of time, loss of interest, etc.).

Sample description

Overall, caregivers were predominantly women (35 [85%] and 30 [87%] in the PIP and control arm, respectively) caring for their husbands or parents, with a mean age of 58.6. years (11.3) in the PIP group and 59.7 years (12.8) in the control group. Their education level was medium (high school) to high (university degree), and most of them had no paid occupation (unemployed, studying, housewife, retired or disabled). They had been in the role of caregivers for about 5–7 years.

According to care aspects, almost all carers reported spending more than 28 hours per week caring for their family members (without external help or minimal financial help). The average score in the ZBI showed mild to moderate burden (54). The CES-D scores indicated that caregivers of both groups were slightly above the cutoff point (>16) (55). Table 2 shows the caregivers' baseline socio-demographic and clinical details by arm.

No significant demographic or clinical baseline differences were found in the comparison between participants who dropped out of the study (at visits 2 or 3) and those who completed it.

Table 3 shows the sociodemographic and clinical details of the ABI sample. The majority of patients were men around 54 (14.5) years old. They had a primary diagnosis of ABI caused by stroke (17 patients [41%] in the PIP group and 17 patients [47%] in the control group) or secondary to head trauma. Most patients were legally capacitated (60 of the total sample [79%]).

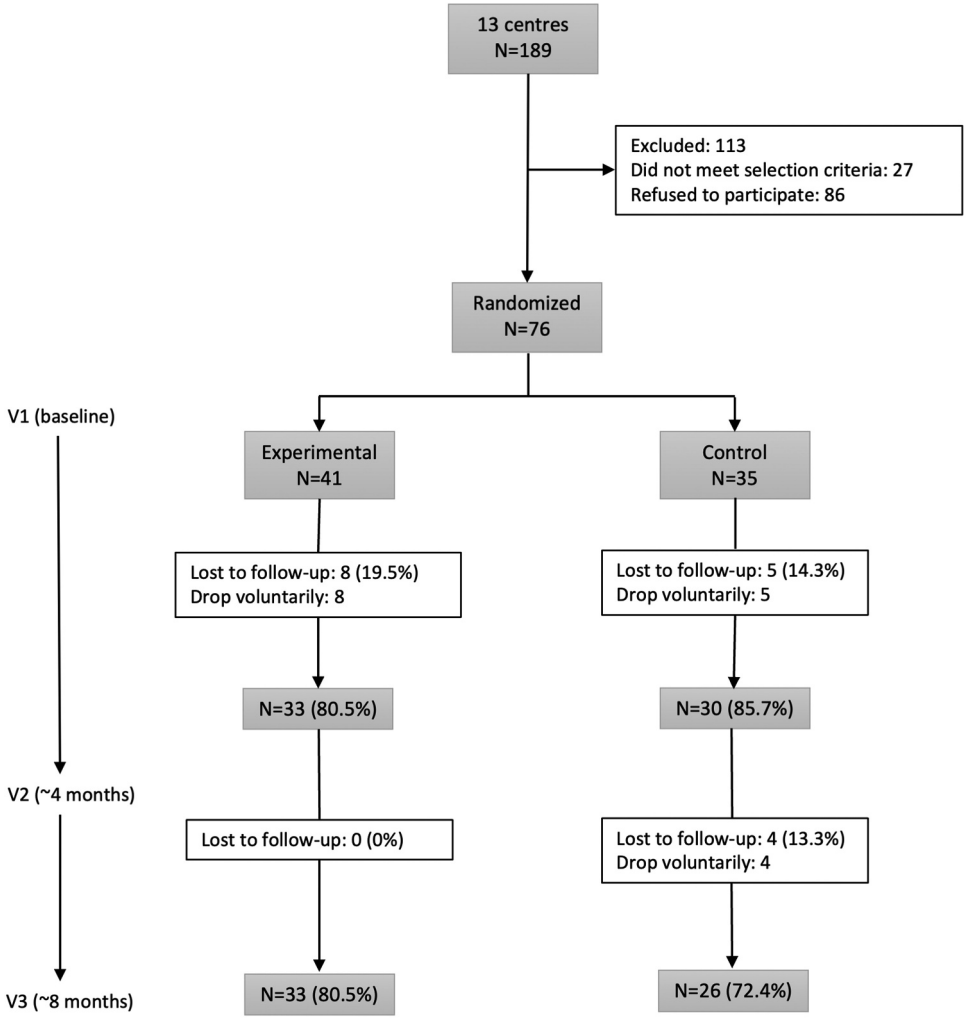


Figure 1. Trial flowchart.

Table 2. Sociodemographic and baseline clinical data for caregivers.

Variables	Total ($N = 76$)	PIP ($n = 41$)	Control ($n = 35$)	p-value
Age, mean (SD)	59.2 (12.1)	58.6 (11.3)	59.7 (12.8)	.691
Female gender, n (%)	65 (85.5)	35 (85.4)	30 (85.7)	.965
Time of care (months), mean (SD)	81.64 (73.88)	85.06 (78.4)	76.7 (68.7)	.608
Hours of care (weekly), n (%)				
<28 hours	7 (9.2)	2 (4.8)	5 (14.3)	.157
≥28 hours	69 (90.8)	39 (95.1)	30 (85.7)	
Education level, n (%)				
Without degree	1 (1.3)	0	1 (2.7)	.682
Primary	13 (17.1)	8 (19.5)	5 (14.3)	
Secundary (high school)	38 (50)	20 (48.8)	18 (51.5)	
College, university	24 (31.6)	13 (31.7)	11 (31.5)	
Marital status, n (%)				
Single	9 (11.9)	3 (7.3)	6 (17.1)	.534
Married	59 (77.6)	32 (78.1)	27 (77.1)	
Separated/divorced	3 (3.9)	2 (4.9)	1 (2.9)	
Widow/er	5 (6.6)	4 (9.7)	1 (2.9)	
Relation to patient, n (%)				
Couple	44 (58.7)	24 (60)	20 (57.1)	.665
Parent	16 (21.3)	9 (22.5)	7 (20)	
Son/daughter	11 (14.6)	6 (15)	5 (14.3)	
Brother/sister	2 (2.7)	1 (2.5)	1 (2.9)	
Other	2 (2.7)	0	2 (5.7)	
External assistance provided, n (%)				
Professional	13 (18.6)	10 (25)	3 (10)	.270
Financial	16 (22.8)	8 (20)	8 (26.7)	
None	41 (58.6)	22 (55)	19 (63.3)	
Working situation, n (%)				
Working	19 (25.3)	12 (30)	7 (20)	.694
Unemployed	10 (13.3)	4 (10)	6 (17.1)	
Studing	1 (1.3)	1 (2.5)	0	
Housewife	14 (18.7)	8 (20)	6 (17.1)	
Retired	26 (34.7)	12 (30)	14 (40)	
Disabled	5 (6.7)	3 (7.5)	2 (5.71)	
ZBI score, mean (SD)	33.22 (17.47)	35.63 (16.87)	32 (17.96)	.200
GHQ-28 score, mean (SD)	32.18 (15.53)	32.73 (17.21)	31.52 (13.45)	.741
Somatic symptoms	8.94 (4.39)	8.68 (4.31)	9.26 (4.54)	.572
Anxiety and insomnia	10.78 (5.29)	10.48 (5.63)	11.14 (4.89)	.594
Social dysfuntion	8.58 (3.66)	8.85 (3.55)	8.26 (3.82)	.492
Depression	3.86 (5.01)	4.70 (5.92)	2.85 (3.46)	.111
CES-D score, mean (SD)	17.07 (8.58)	17.51 (8.76)	16.57 (8.47)	.637
STAI score, mean (SD)				
State	25.27 (13.92)	26.04 (15.02)	24.37 (12.66)	.603
Trait	24.07 (10.98)	24.09 (11.81)	24.05 (10.09)	.987

ZBI: Zarit Burden Interview; GHQ-28: General Health Questionnaire-28 items; CES-D: Center for Epidemiologic Studies-Depression Scale; STAI: State-Trait Anxiety Inventory.

Table 3. Sociodemographic and clinical description of the ABI sample at baseline.

Variables	Total ($N = 76$)	PIP ($n = 41$)	Control ($n = 35$)	p-value
Age, mean (SD)	54.5 (14.5)	52.8 (14.8)	56.2 (14.2)	.317
Male gender, n (%)	52 (68.4)	27 (65.9)	25 (71.4)	.602
Cause of ABI, n (%)				
Stroke	34 (44.2)	17 (41.5)	17 (47.2)	.076
Traumatism	17 (22.1)	13 (31.7)	4 (11.1)	
SF	13 (16.9)	4 (9.8)	9 (25)	
Brain Tumour	8 (10.4)	6 (14.6)	2 (5.6)	
Infection	2 (2.6)	0	2 (5.6)	
Anoxia	1 (1.3)	0	1 (2.8)	
Other	2 (2.6)	1 (2.4)	1 (2.8)	
Legally incapacitated, n (%)				
No	60 (79)	31 (75.6)	29 (82.9)	.394
Partial	3 (3.9)	1 (2.4)	2(5.7)	
Total	13 (17.1)	9 (22)	4 (11.4)	
Glasgow Outcome Scale (GOS), mean (SD)	3.2 (0.47)	3.2 (0.46)	3.2 (0.53)	.994
Neuropsychiatric Inventory (NPI), mean (SD)				
Severity	16.17 (15.33)	18.79 (17.31)	13.01 (12.05)	.104
Distress	8.70 (9.15)	10.37 (10.02)	6.82 (7.75)	.093

Glasgow Outcome Scale scores indicated a severe disability with a permanent need for help with daily living (3.2; SD = 0.47). Neuropsychiatric Inventory (NPI) shows low scores. The most frequent and severe symptoms were irritability, apathy, depression, agitation and appetite, and eating abnormalities. These symptoms were also most distressing to the caregivers.

Primary outcome

Table 4 and Figure 2 show the ZBI change scores from baseline (visit #1) to post-intervention (visit #2) and follow-up (visit #3). The complete case analyses were not significant at 4 and 8 months since trial inception (SMD = 0.06; CI 95% [−7.04; 5.33] and SMD = −0.22: CI 95% [−0.74; 0.30]). The mixed linear model for repeated measures analysis did not reveal a significant interaction of the intervention arm by time (p-value = 0.277).

Secondary outcomes

Table 4 and Figure 3 also display the change scores of GHQ-28, CES-D and STAI from the baseline. For the GHQ-28 (total score), the analysis showed a large and significant effect favoring the PIP intervention group at four months (SMD = 0.76; CI 95% [0.23; 1.29]). This positive effect disappears at follow-up (8 months). The MLM analysis shows a statistically significant interaction of the intervention arm by time (p-value = 0.007) for the total score. The subscales of somatic symptoms, anxiety & insomnia and social dysfunction showed similar positive results at 4 months (SMD = 0.83; SMD = 0.60; SMD = 0.68, respectively). Although these positive results were not sustained over time (visit #3), MLM analysis showed significant effects (p-value = 0.07; $p = 0.04$ and p-value = 0.015, respectively). There were no significant effects on the depression subscale at any time.

In the analysis for the CES-D at 4 months, the PIP arm experienced a reduction in depression, while the control group increased its punctuations. Statistical comparisons by arm showed medium and significant effect size (SMD = 0.56 [0.04; 1.07]) at this endpoint.

Once again, the change score at 8 months since inception shows a loss of the positive effects obtained al post-intervention (SMD = 0.12; CI 95% [−0.38 to 0.63]). The MLM analysis was not significant (p-value = 0.103).

STAI-State subscale change scores at 4 and 8 months showed mean differences near 5 points. However, they did not reveal statistically significant results (SMD = 0.24; CI 95% [−0.25;0.74] and SMD = 0.22; CI 95%[−0.29; 0.74]). The MLM analysis was not significant (p-value = 0.386). STAI-Trait subscale did not detect relevant changes.

None of the variables related to the clinical status of patients with ABI (GOS and NPI) showed significant changes during the study. GOS at 4 and 8 months showed SMD = −0.172 (p-value = 0.525) and −0.274 (p-value = 0.382) respectively. NPI severity showed SMD = −2.76 (p-value = 0.292) at 4 months and SMD = 0.30 (p-value = 0.262) at 8 months. NPI distress at visit #2 (post-intervention) showed higher values but was also insignificant (SMD = 0.47; p-value = 0.07).

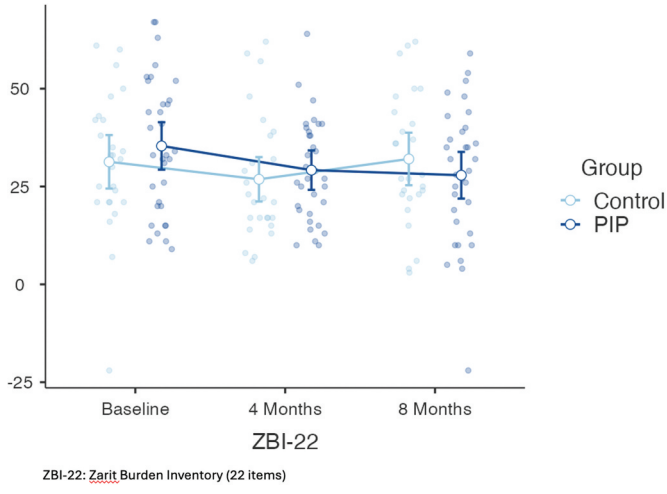


Figure 2. Effectiveness results for the primary outcome (Zarit Burden Interview).

Discussion

Caring for a person with acquired brain injury for long periods can compromise the caregiver's health, leading to increased levels of psychological distress, anxiety, or depression. Based on a sample of 76 nonprofessional Spanish careers, the study's primary objective was to evaluate the effectiveness of a manualized psychoeducational programme in reducing caregiver burden. The recruited sample showed medium to moderate levels of burden at baseline. The results obtained during the three visits did not allow us to reject the null hypothesis (there were no differences between groups). The comparison showed a null effect size in the post-treatment phase (SMD = 0.06), and a small effect size at the last visit (SMD = −0.22). These results are consistent with those reported in other studies with caregivers of people with ABI (16,17,19,56). Based on this and our prior experience with other experimental studies involving samples of various chronic diseases (such as Alzheimer's, schizophrenia, and intellectual disabilities), we have detected that caregiver burden (as evaluated by the Zarit Burden interview), appears to be a psychological construct with low sensitivity to change in response to this type of interventions (31–34).

Results obtained at baseline on the secondary variables show subclinical values. The results of the secondary measures obtained during the three visits partially support the alternative hypothesis of differences between groups. Levels of distress and depression, measured by the GHQ-28 and CES-D, respectively, indicate that the psychoeducational intervention produces positive effects on the experimental group in the acute phase of the intervention (4 months). However, these beneficial effects appear to be diluted at the 8-month visit. It is not appropriate to compare these results to other studies due to different study designs (26), different intervention strategies (56), or delivery formats (57). Possibly, booster sessions during the follow-up period could lead to a maintenance of these effects.

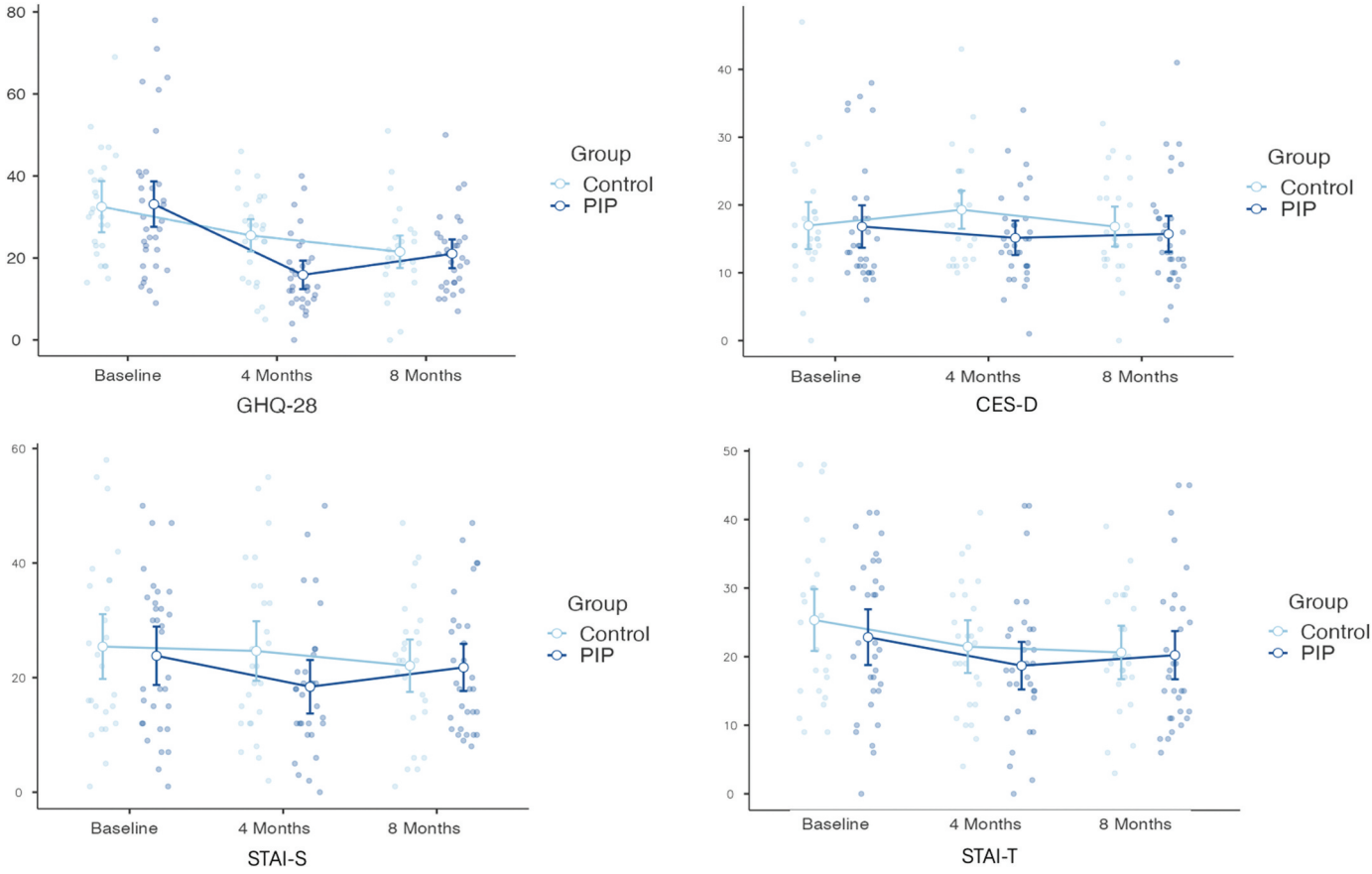
Finally, the anxiety variable (STAI) did not show significant changes in the two subscales (state or trait) or any assessment points. Studies with specific interventions to diminish anxiety and reduce emotional stress in caregivers have found that practising these new skills for longer periods is necessary to obtain benefits (58).

Table 4. Efficacy outcomes (change scores from baseline).

	Visit 2 (4 months since baseline)				Visit 3 (8 months since baseline)				
Outcomes	PIP ($N = 33$)	Control ($N = 30$)	Mean Difference (95% CI)	SMD (95% CI)	PIP ($N = 32$)	Control ($N = 26$)	Mean Difference (95% CI)	SMD (95% CI)	p-value [a]
ZBI-22, mean (SD)	−4.90 (14.11)	−5.76 (9.86)	−0.85 (−7.04;5.33)	0.06 (−0.56;0.42)	−1.93 (8.90)	−4.34 (12.79)	−2.40 (−8.12;3.31)	−0.22 (−0.74;0.30)	.277
GHQ-28, mean (SD)	−17.24 (17.39)	−5.63 (12.02)	11.60 (4;19.21)	0.76 (0.23;1.29)	−12.09 (15.13)	−11 (13.03)	1.09 (−6.13;8.57)	0.07 (−0.43;0.59)	.007
Somatic Symptoms	−4.96 (4.55)	−1.33 (4.14)	3.63 (1.43;5.83)	0.83 (0.28;1.36)	−3.42 (4.69)	−3.23 (4.77)	0.19 (−2.29;2.67)	0.04 (−0.47;0.55)	.007
Anxiety & Insomnia	−5.63 (5.54)	−2.6 (4.26)	3.03 (0.52;5.54)	0.60 (0.08;1.23)	−4.18 (5.74)	−4.15 (5.75)	0.02 (−2.99;3.04)	0.01(−0.5;0.51)	.040
Social Dysfunction	−3.81 (4.62)	−1 (3.93)	2.81 (0.75;4.87)	0.68 (0.15;1.20)	−2.09 (3.65)	−2.03 (3.97)	0.05 (−1.94;2-04)	0.01 (−0.5;0.52)	.015
Depression	−2.81 (5.15)	−0.7 (3.76)	2.11 (−0.17;4.41)	0.46 (−0.04;0.97)	−2.39 (4.17)	−1.57 (3.11)	.81 (−1.15;2.78)	0.21 (−0.30;0.73)	.290
CES-D, mean (SD)	−1.66 (7.33)	2.6 (7.88)	4.26 (0.43;8.10)	0.56 (0.04;1.07)	−1.09 (5.96)	−0.14 (1.75)	0.94 (−2.97;8.57)	0.12 (−0.38;0.63)	.103
STAI, mean (SD)									
State	−5.03 (18.23)	−0.03 (22.49)	4.99 (−5.27;15.27)	0.24 (−0.25;0.74)	−5.40 (18.39)	−0.76 (23.21)	4.63 (−6.30;15.57)	0.22 (−0.29;0.74)	.386
Trait	−3.39 (15.05)	−3.03 (17.58)	0.36 (−7.86;8.58)	0.02 (−0.47;0.51)	−4.15 (14.62)	−3.88 (18.01)	0.27 (−8.31;8.85)	0.01 (−0.50;0.53)	.777

PIP: Psychoeducational Intervention Program; SMD: Standardized Mean Difference; ZBI: Zarit Burden Inventory (22 items); GHQ-28: General Health Questionnaire Scaled (28 items); CES-D: Center for Epidemiologic Studies – Depression Scale; STAI: State-Trait Anxiety Inventory.

[a] p-values for the interaction of intervention by time from the mixed linear model for repeated measures.



GHQ-28: General Health Questionnaire Scaled (28 items); CES-D: Center for Epidemiologic Studies – Depression Scale; STAI-S: State-Trait Anxiety Inventory (State); STAI-S: State-Trait Anxiety Inventory (Trait).

Figure 3. Effectiveness results for the secondary outcomes (GHQ-28, CES-D, and STAI).

The patients' status in terms of both functional impairment (GOS) and severity of psychiatric and behavioral disturbances (NPI) remained stable throughout the study. This allows us to exclude alternative explanations related to the patient's condition.

Although these results are not conclusive, they partially support the application of this type of intervention to reduce caregiver distress and depression. While these results reflect some benefits, we still need more research to understand better the reasons for variability in caregiver experience and preparedness for the long caregiving task (12). In this regard, and according to previous systematic reviews (27,29,30), we detected a significant paucity of studies using solid methodological approaches.

Limitations and strengths of the research

Despite the attempt to produce a methodologically relevant study with high internal validity (where causal inferences can be made), it is important to recognize that this study has important limitations that must be considered.

First, the sample recruitment procedure could have been more successful. Previous calculations determined a sample size of 200 participants. We recruited 38% of the estimated sample. Despite attempts to recruit a larger sample, many participants were reluctant to participate, citing time constraints, lack of interest in attending the sessions, or random assignment to the intervention as reasons for their refusal. Similarly, some centers declined their initial participation in the study or could not disseminate the study successfully. This issue could affect the representation of the population of caregivers of people with ABI and the internal validity of the results.

Second, the randomization process and the duration of the study have led to a substantial attrition bias in both groups, with an approximate dropout rate of 25%. Although no differences were found between completers and non-completers at baseline, it is plausible that caregivers facing more challenging circumstances (such as lack of time, lack of support, or high levels of distress) may have declined to participate. On the other hand, this attrition bias was significantly higher (p-value < 0.05) in the control group. Participants may have experienced a greater loss of interest in the study by not receiving the PIP intervention.

Third, as in previous EDUCA studies with similar non-pharmacological interventions, it is tough to keep participants and professionals blinded about their inclusion in different study arms. This limitation may have influenced the caregivers' self-perception and their responses.

Fourthly, it is essential to note that caregivers and patients involved in this study were concurrently receiving routine clinical care (regular meetings with the staff, ongoing follow-up, and management of each case) at their respective centers.

This circumstance could have contributed to a ceiling effect, limiting the possibility of observing substantial improvements.

Finally, we tried to assess caregivers' acceptance, opinion, fidelity, and adherence to the intervention using a qualitative questionnaire in the caregiver's manual. However, most of them did not report this information. Including mixed methods research (quantitative and qualitative data) could be an important source of information that would increase the depth of understanding of the effect of the intervention by exploring the subjective experiences, meanings, and social contexts of informal care.

The findings of this study and its limitations should be integrated into the existing body of evidence and considered in developing new healthcare strategies that target the support and assistance of caregivers for individuals with acquired brain injury (ABI).

Conclusions

This study assessed the effectiveness of a psychoeducational intervention for caregivers of individuals with acquired brain injury (ABI). While some positive effects on mental health, particularly in reducing distress and depression, were observed at four months post-intervention, these benefits were not sustained over time. The intervention did not significantly reduce caregiver burden or anxiety. It is important to note that this research was subject to several limitations (including a relatively small sample size and the potential for attrition bias) that could potentially impact the validity and generalizability of the findings. This study underlines the complexity of care for patients with ABI and highlights the need to develop and rigorously evaluate new interventions that follow experts' recommendations.

Availability of data and materials

Due to ethical and legal constraints, the data are unsuitable for public deposition and only available upon request with the signature of a data privacy form. To request the data, readers may contact the corresponding author.

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Author contributions

MMC, AIDP, JIQ, RS, and EPC conceived the study and developed the protocol. NA, MP carried out the data collection and coordinated the study. EGF and PB performed data analysis. EGF wrote the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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