

Evaluating the effectiveness of a psychoeducational intervention for caregivers of individuals with acquired brain injury

Submission date 08/11/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/12/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/09/2024	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Caring for a person with acquired brain injury (ABI) is stressful and could increase the risk of developing several health problems. A preventative measure such as a psychoeducational intervention could be useful to decrease the burden associated with caregiving. The main aim of this study is to assess the effectiveness of a psychoeducational intervention for caregivers of people with acquired brain injury (ABI).

Who can participate?

Informal caregivers of ABI patients

What does the study involve?

Participants are randomly allocated into two groups. One group receives the usual support from the day centres where the patient is being treated. The other group receives the same support plus a psychoeducative intervention of 10 sessions lasting 90-120 minutes. It includes information about the disease and training on different cognitive and behavioral skills. The study runs for 8 months. There are three assessment points at the start of the study and after 4 and 8 months.

What are the possible benefits and risks of participating?

Participants will benefit from a reduction in caregiver burden and better know-how about care skills and self-care. This study will be conducted with the highest regard for the safety and well-being of the participants. It is important to note that at no time were participants at any physical, emotional, or health risk by participating in the research. All procedures and activities were designed in such a way that they did not pose a danger to participants.

The only potential risk participants may experience will be discomfort from the time spent in the study. It is understood that their time is valuable, and there is concern about any inconvenience they may experience while participating in the different phases of the research. However, the study would like to express their appreciation for their contribution, as participation is essential to advance knowledge and understanding in this area of study.

Where is the study run from?
Aita Menni Hospital (Spain)

When is the study starting and how long is it expected to run for?
January 2011 to December 2019

Who is funding the study?
Sisters Hospitallers (Spain)

Who is the main contact?
Ana Isabel Domínguez Panchón, aidominguez.aitamenni@hospitalarias.es (Spain)

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Mrs Ana Isabel Domínguez

ORCID ID

<https://orcid.org/0000-0002-4477-0029>

Contact details

Egaña Kalea, 10
Bilbao
Spain
48010
+34 944 43 49 27
aidominguez.aitamenni@hospitalarias.es

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Efficacy of a psychoeducative intervention program versus treatment as usual to prevent or reduce the burden associated with caring for a person with acquired brain injury: a two arm, evaluator blind, multicentre, randomized controlled trial

Acronym

EDUCA-V

Study objectives

1. The caregivers allocated to the psychoeducative intervention program will present less burden at the endpoint (4 months) and at follow-up (8 months) than those allocated to the control condition.
2. The caregivers allocated to the psychoeducative intervention program will present better mental health at the endpoint (4 months) and at follow-up (8 months) than the caregivers allocated to the control condition.
3. The caregivers allocated to the psychoeducative intervention program will present less anxiety at the endpoint (4 months) and at follow-up (8 months) than those allocated to the control condition.
4. The caregivers allocated to the psychoeducative intervention program will present less depression at the endpoint (4 months) and at follow-up (8 months) than those allocated to the control condition.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 10/10/2011, Ethical and Scientific Research Committee of Navarra (Pabellón de Docencia Recinto Hospital de Navarra Irunlarrea, 3, Pamplona, 31008, Spain; +34 848422495; ceic@cfnavarra.es), ref: 74/11

Study design

Two-arm evaluator-blind multicentre randomized controlled trial

Primary study design

Interventional

Study type(s)

Prevention, Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied

The burden associated with acquired brain injury caregiving

Interventions

Randomization: The randomization process will be conducted in each research site using block randomization, with block sizes ranging from 1 to 4. The "Randomizer v. 0.4.0" module of Jamovi will be used to generate the sequence. The randomization process is blinded for all site investigators involved in the study. Only the central research committee had this information. The researchers responsible for evaluating the results were also blinded to the dyad assignment.

Control group: Caregivers allocated to this group will receive the usual support from the day centre where the patients have multifaceted/multi-professional care aimed at improving or maintaining functional, social, and cognitive abilities for as long as possible. The caregiver will receive periodic interviews and information about the situation and clinical course of the patient.

Intervention group: Caregivers allocated to this group are exposed to the same usual care the control group will receive plus a psychoeducative intervention program. This intervention is administered in 10 group sessions of 90-120 minutes each and the sessions were administered

weekly. The caregiver will receive standardized information about the clinical course of schizophrenia and training on different cognitive and behavioral skills to increase care abilities, communicative skills, pleasant events, seeking support, and relaxation.

Intervention Type

Behavioural

Primary outcome(s)

Caregiver burden measured using the Zarit Burden Interview at baseline and 4 and 8 months

Key secondary outcome(s)

The following secondary outcome measures are assessed at baseline and 4 and 8 months:

1. Caregiver's mental health measured using the General Health Questionnaire, 28 items (GHQ-28)
2. Caregiver anxiety measured using the State-Trait Anxiety Inventory (STAI)
3. Caregiver depression measured using the Center for Epidemiologic Studies Depression Scale (CES-D)

Completion date

31/12/2019

Eligibility

Key inclusion criteria

Caregivers:

1. Aged 18 years old and over
2. Be caring for a person with acquired brain injury (ABI) (traumatic brain injury, stroke, anoxia, brain tumour or encephalitis)
3. Be an informal (unpaid) caregiver
4. Spend a minimum of 4 hours/week caring for the care-receiver

Participants with ABI:

1. Aged 16 years old and over
2. Residents in the community
3. Receiving appropriate outpatient rehabilitation
4. Being stable clinically
5. Time since the ABI is more than 3 months

Participant type(s)

Carer

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

99 years

Sex

All

Total final enrolment

76

Key exclusion criteria

Caregivers:

Those who did not have the time to attend the weekly sessions of intervention or had received a standardized intervention comparable to the one administered in the trial within the past year

Participants with ABI:

1. Having been cared for in a respite care unit during the last 30 days
2. Living in professionally supervised housing

Date of first enrolment

01/01/2019

Date of final enrolment

30/03/2019

Locations**Countries of recruitment**

Spain

Study participating centre

Aita Menni Hospital

Egaña Kalea, 10

Bilbao

Spain

48010

Sponsor information**Organisation**

Hermanas Hospitalarias

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hermanas Hospitalarias

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during the current study will be available upon request from Ana I. Domínguez Panchón (aidominguez.aitamenni@hospitalarias.es). Quantitative and qualitative anonymized raw data will be shared for up to 5 years after the end of the trial. Consent from participants was required and obtained. Participants 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. Data anonymisation was performed using dissociated data (using an internal and unique code for each participant). The study procedures were carried out in agreement with the Declaration of Helsinki.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/09/2024	16/09/2024	Yes	No
Participant information sheet			29/11/2023	No	Yes
Participant information sheet			29/11/2023	No	Yes