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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

Registration date
12/12/2023

Overall study status
Completed

Last Edited
16/09/2024

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Care home

Study type(s)
Prevention, Quality of life, Treatment, Efficacy

Participant information sheet
See study outputs table

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

Secondary outcome measures
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)

Overall study start date
01/01/2011

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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
200

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

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Sponsor information

Organisation
Hermanas Hospitalarias

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Medical Director Manuel Martín Carrasco
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Sponsor type
Hospital/treatment centre

Website
https://www.hospitalarias.es

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hermanas Hospitalarias

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2023

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?
Participant information sheet			29/11/2023	No	Yes
Participant information sheet			29/11/2023	No	Yes
Results article		12/09/2024	16/09/2024	Yes	No