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Using cognitive-behavioral therapy to manage tiredness after a brain injury

Submission date
05/12/2023

Recruitment status
No longer recruiting

Registration date
11/12/2023

Overall study status
Completed

Last Edited
21/06/2024

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Fatigue is a very common symptom following a brain injury and can have a big impact on people' s quality of life while they are trying to recover. It is therefore important to try and reduce fatigue, to help people have more energy to do the things important to them.
Cognitive behavioural therapy (CBT) is a form of talking therapy. Some research studies have found that CBT is effective in treating symptoms of fatigue in people with a brain injury. However, other studies have found mixed results, which suggests we need to better understand CBT therapy. We would like to explore which aspects of CBT might be most effective and which parts might not be. Most research has previously focused on assessing the effectiveness of a 'package' of CBT, rather than the distinct components.
The primary aim of this project is to evaluate the effectiveness of CBT for managing fatigue after an acquired brain injury. We would also like to know which aspects in particular are helpful, to support health services to develop more personalised and time-efficient CBT programmes to improve patients' lives.

Who can participate?
Anyone with a brain injury, that has symptoms of fatigue after their brain injury. Participants should not have had previous CBT exposure for fatigue management in the past. Participants should not be involved in other psychological interventions.

What does the study involve?
CBT therapy for the management of fatigue post brain injury. Participants will have to complete some questionnaires and rate their fatigue levels throughout their engagement with CBT therapy. Participants need to attend 6 therapy sessions and a follow up appointment.

What are the possible benefits and risks of participating?
Participants may reduce their experience of fatigue following their brain injury with the use of psychological techniques.
A risk could possibly be some psychological distress due to the type of conversations which will take place during the intervention. Regular supervision and check-ins with the participants will be monitoring potential risks and a risk management plan is in place to secure all participants are safe.

Where is the study run from?
Poole Community Health Clinic (UK)

When is the study starting and how long is expected to run for?
September 2023 to April 2024

Who is funding the study?
University of Southampton (UK)

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
326412

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 326412

Study information

Scientific Title
Cognitive behavioural therapy for the management of fatigue after acquired brain injury

Study objectives
The primary aim of this project is to evaluate the effectiveness of CBT for managing fatigue after an acquired brain injury. The study will explore which aspects of a CBT package in particular are most helpful, to support health services to develop more personalised and time-efficient CBT programmes to improve patients lives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/09/2023, South West - Central Bristol Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8000; centralbristol.rec@hra.nhs.uk), ref: 23/SW/0090

Study design
Single case experimental design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Management of fatigue after acquired brain injury

Interventions
Cognitive behavioural therapy will be provided to all participants of the study.

As this is a single case experimental design study, all participants will receive the same intervention which is cognitive behavioural therapy.

Timeframe of intervention.
Baseline Assessment (set of questionnaires measuring fatigue, anxiety, depression, overall health).Participants complete the baseline assessment/set of questionnaires and start recording their fatigue levels.

2-3 weeks gap. During this time, participants record their fatigue levels on a daily basis. Participants continue to record their fatigue levels throughout the intervention on a daily basis.

First therapy session
Assessment session (understanding how fatigue is impacting participant physically, emotionally and cognitively, goal setting).

Second therapy session
Formulation (bringing all the information together to make more sense of participant's experience of fatigue and overall health).

Baseline assessment (set of questionnaires measuring fatigue, anxiety, depression, overall health and therapeutic alliance).

Third therapy session
Relaxation techniques (mindfulness, breathing exercises).

Fourth therapy session
Pacing (focus on finding out more about how active or inactive a participant).

Baseline assessment(set of questionnaires measuring fatigue, anxiety, depression, overall health and therapeutic alliance).

Fifth therapy session
Cognitive restructuring (beliefs about brain injury, negative thinking styles and strategies to shift those).
Sixth therapy session
Summary (the aim is to consolidate learning).

4 weeks gap

Follow up session.
Baseline assessment(set of questionnaires measuring fatigue, anxiety, depression, overall health and therapeutic alliance).
End of intervention.

Overview:
Participants will then attend 6 therapy sessions of cognitive behavioural therapy (participants will be recording their fatigue levels throughout the intervention on a scale of 0-10).

There will be a gap of 2-3 weeks between the first baseline appointment and the assessment appointment. There will be a 2-3 week-gap between the formulation and relaxation therapy appointment. There will be a week-gap between relaxation and pacing sessions. There will be a 2-3 week gap between pacing and cognitive restructuring sessions. There will be a week-gap between cognitive restructuring and summary sessions. There will be a 4-week gap between summary and follow up sessions.

The same initial set of questionnaires administered at the first baseline assessment will be completed at various points during the intervention to capture change (one at the beginning, one after formulation session, one after pacing session and one at the follow up).

After completing the 6 therapy session, participants will continue to record their fatigue levels for 4 weeks, and then attend a follow up session.
This will be the end of the intervention.

Intervention Type
Behavioural

Primary outcome(s)
1. Fatigue will be measured by completing daily fatigue ratings (Salman et al., 2013). Participants will be asked to use a visual analogue scale (from 0 meaning not tired to 10 meaning extremely tired) on a daily basis throughout the intervention.
2. Fatigue will be measured using the Modified Fatigue Impact Scale (MFIS), (Ghajarzadeh et al., 2012) at all baseline assessments (4 in total).
3. Fatigue will be measured using the Visual Analogue Scale to Evaluate Fatigue Severity (VAS-F), (Shahid et al., 2011) at all baseline assessments (4 in total).

Key secondary outcome(s))
1. Overall health will be measured with the SF-36 questionnaire, (Lins & Carvalho, 2016) at all baseline assessments (4 in total).
2. Depression will be measured with the Patient Health Questionnaire-9, (Sun et al., 2019) at all baseline assessments (4 in total).
3. Anxiety will be measured with the General Anxiety Disorder-7 (GAD-7; Spitzer et al., 2006) at all baseline assessments (4 in total).
4. Therapeutic alliance will be measured with the Working Alliance Inventory, (Tatman & Love, 2010) in three baseline assessments (3 in total, not in the very first baseline assessment).

Completion date
17/04/2024

Eligibility

Key inclusion criteria
1. An adult
2. Have an acquired brain injury
3. Experience fatigue
4. Have not experienced CBT before
5. Don’t have any significant problems with communication or thinking skills

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
90 years

Sex
All

Total final enrolment
4

Key exclusion criteria
1. Not able to engage with talking therapies
2. Had CBT in the past
3. Do not have a brain injury
4. Participants are involved with other psychological therapies

Date of first enrolment
20/11/2023

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Poole Community Health Clinic
Shaftesbury Road
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BH15 2NT

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
University/education

Funder Name
University of Southampton

Alternative Name(s)
University of Southampton UK

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Datasets generated during and/or analysed during the study are not expected to be made public to avoid identifying the participants.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	28/08/2023	06/12/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3	25/09/2023	06/12/2023	No	No