

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

Submission date 05/12/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/12/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/06/2024	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English Summary

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?
Alexandros Zouloumis, alexandros.zouloumis@nhs.net

Contact information

Type(s)

Scientific, Principal Investigator

Contact name

Dr Birgit Gurr

Contact details

Shaftesbury Rd, Poole BH15 2NT
Poole
United Kingdom
BH15 2NT
+44 1202 683363
dhc.community.braininjury@nhs.net

Type(s)

Public

Contact name

Mr Alexandros Zouloumis

ORCID ID

<http://orcid.org/0009-0003-0250-8780>

Contact details

University of Southampton
Building 44
Highfield Campus
Southampton
Southampton
United Kingdom
SO17 1BJ
+44 (0)23 8059 5000
az4n21@soton.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

326412

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 326412

Study information

Scientific Title

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

Study hypothesis

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

Secondary study design

Single case experimental design

Study setting(s)

Hospital, Workplace

Study type(s)

Treatment

Participant information sheet

See study outputs table

Condition

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 measure

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).

Secondary outcome measures

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).

Overall study start date

27/09/2023

Overall study end date

17/04/2024

Eligibility

Participant 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

Age group

Adult

Lower age limit

18 Years

Upper age limit

90 Years

Sex

Both

Target number of participants

7

Total final enrolment

4

Participant 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

Recruitment start date

20/11/2023

Recruitment end date

31/01/2024

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Poole Community Health Clinic
Shaftesbury Road

Poole
United Kingdom
BH15 2NT

Sponsor information

Organisation

University of Southampton

Sponsor details

University Road
Southampton
Southampton
England
United Kingdom
SO17 1BJ
+44 (0)23 8059 5000
rgoinfo@soton.ac.uk

Sponsor type

University/education

Website

<http://www.southampton.ac.uk/>

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

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

Intention to publish date
31/12/2024

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
Protocol file	version 3	25/09/2023	06/12/2023	No	No