University of Southampton

ERGO II Ethics application form – Psychology Committee

1. Applicant Details

1.1 Applicant name	**Alexandros Zouloumis**
1.2 Supervisor	**Dr Warren Dunger**
1.3 Other researchers / collaborators (if applicable): *Name, address, email*	**Dr Birgit Gurr BIRGIT.GURR@nhs.net** **Juan Mertel Morillo J.Mertel-Morillo@soton.ac.uk**

2. Study Details

2.1 Title of study	CBT intervention for the management of fatigue post ABI
2.2 Type of project	**Doctorate project**

2.3 Briefly describe the rationale for carrying out this project and its specific aims and objectives.
Fatigue is a common consequence following ABI reported by 50-70% of ABI survivors. Studies have found that CBT therapy has been efficacious in treating fatigue symptoms in ABI survivors by reducing fatigue levels (Ymer et. al., 2020). Other studies have found mixed results following CBT for fatigue management (Ali et. al., 2021). Further evidence is required to determine the effectiveness of CBT for the treatment of fatigue post brain injury. Interventions based on CBT principles has proven to be effective however research has mainly focused on the effectiveness of "therapy packages" consisting of multiple CBT-components rather than on the distinct CBT- components (Heuvel et. al., 2022). The primary aim of this project is to evaluate the effectiveness of CBT therapy in the management of fatigue post brain injury as there is no conclusion as to whether CBT can be effective. Another aim is to evaluate the relevant core components of a CBT intervention for fatigue management post ABI as this knowledge can lead to personalised CBT programs that required less time to reach a recovery outcome.

2.4 Provide a brief outline of the basic study design. Outline what approach is being used and why.
The design of the study will be single case experimental design (Ford et al., 2022). Given the timeframes of a thesis project, a single case experimental design can provide flexible,

rigorous, and cost-effective approaches that can be used in personalized interventions to identify the optimal treatment for an individual patient.

2.5 What are the key research question(s)? Specify hypotheses if applicable.

Is CBT therapy effective for the management of fatigue post ABI?
What component of a CBT therapy intervention is most effective for the management of fatigue post ABI?

3. Sample and setting

3.1 Who are the proposed participants and where are they from (e.g. fellow students, club members)? List inclusion / exclusion criteria if applicable.

Participants will be recruited from a brain injury community NHS service.

Inclusion criteria are:

- Adult (18+)
- A diagnosed ABI,
- Self-reported experience of fatigue,
- No previous experience of CBT

Exclusion criteria:

- Severe post ABI injuries,
- Difficulty in engaging in talking therapy (language impairments due to ABI),
- Severe cognitive impairment
- Lacking mental capacity to consent to engage in research
- Current involvement in other talking therapies in the service

3.2. How will the participants be identified and approached? Provide an indication of your sample size. If participants are under the responsibility of others (e.g., parents/carers, teachers) state if you have permission or how you will obtain permission from the third party).

Principal investigator is going to identify and approach patients/potential participants. Patients will be informed about the study by the principal investigator, and should they wish to engage in the study screening progress, only then the referral will be made.
Participants will be informed what information will be included and copied into the referral letter, as per standard service procedures. Consent will be obtained from the patient to access identifiable personal information prior to their enrolment in the study.
After initial contact with potential participants, principal investigator will share the contact details with chief investigator to be contact them by telephone to explain the study.

Given the design of the project and following university guidelines the minimum number of participants required for a single case experimental design study is 3 participants, but the aim is to recruit 7 participants.

3.3 Describe the relationship between researcher and sample. Describe any relationship e.g., teacher, friend, boss, clinician, etc.

Chief researcher (trainee clinical psychologist) will be the main therapist. This is a doctorate thesis project.

3.4 How will you obtain the consent of participants?

All participants will be recruited through a brain injury community NHS service. Participants will be referred by a clinician, who's care they are already under. The referrer will provide a referral letter, including some of the patient's medical information and items listed on inclusion/exclusion criteria. The principal investigator (clinical supervisor) will review referrals and selected referrals will be discussed with the Chief Investigator (trainee clinical psychologist).
The Chief investigator will then contact potential participants to discuss the study and obtain tehri consent. Consent forms will be given to all participants of the study. All participants will be asked to complete a written consent form (either online or face to face). Participants will complete the consent forms by themselves.
Participants will be provided a written information sheet and provided an opportunity to ask any questions, made aware of their rights to withdraw.

3.5 Is there any reason to believe participants may not be able to give full informed consent? If yes, what steps do you propose to take to safeguard their interests?

Yes.

The participants of the study will have an ABI. This can be a reason to suspect they might lack capacity to consent. The study will not recruit anyone who lacks capacity (this is one of the exclusion criteria of the study).

The chief researcher will check whether participants have the capacity to consent. This can be done by explaining the project to participants to check their understanding of the information given, whether they are able to retain the information to weigh up the benefits of participating and whether they are able to make the decision to engage.

4. Research procedures, interventions and measurements

4.1 Give a brief account of the procedure as experienced by the participant. Make it clear who does what, how many times and in what order. Make clear the role of all assistants and collaborators. Make clear the total demands made on participants, including time and travel.

Recruiting/identifying participants

Consultant neuropsychologist (principal investigator) will invite patients from ward/community team to participate and share participants' information sheet to inform them about the purpose of the study.
If they consent (written consent will be required), their contact details will be passed on to the chief researcher (trainee clinical psychologist) who will contact them by telephone to complete an initial screen and ensure they meet inclusions/exclusion criteria. Participants will have the chance to ask questions and will be given will be given 48 hours to decide whether they want to take part in the study.

Consent forms will be given to all participants of the study. All participants will be asked to complete a written consent form (either online or face to face). Participants will complete the consent forms by themselves.
Participants will be provided a written information sheet and provided an opportunity to ask any questions, made aware of their rights to withdraw. Participants will be given the option to drop out at any time of the research (but not 2 weeks after data collection).

Participants will be given participants' information sheet to read and will have the chance to ask questions.

Timeline
The active/therapy phase of the study should take place between October 2023 and April 2024. The project will be written up by May 2024 to meet thesis submission deadline.

Procedure

Participants will be invited to take part in a study that will require active participation for 18 weeks. During this time, they will be asked to complete some questionnaires and attend psychotherapy sessions at Poole Brain Injury Community Clinic. They will need to attend 6 sessions in total over 18 weeks period and record their fatigue levels with the use of a Likert scale daily.
After completing the active phase of therapy (6 sessions), they will be contacted again two weeks later to compete some questionnaires.

Please read the outline bellow.

Phase one/ start of intervention
Participants will complete some questionnaires/set of batteries that will take approx 45min. (GAD-7, PHQ-9, SF36 , MFIS, VAS-F, and MoCA). Participants start recording their fatigue levels with the use of the Likert Scale daily.

Phase two/ therapy sessions
Two weeks after completing the questionnaires/set of batteries, participants will be invited to attend their first therapy session. The first therapy session will be an assessment.
A week after session 1, participants will attend their second therapy session. This session will be formulation and psychoeducation.
Two weeks after attending the first and second appointment, participants will complete the same questionnaires/set of batteries they had completed at the beginning of the intervention (apart from MoCA). This will take approx 45 minutes.

Two weeks after, participants will attend their third therapy session. This will be CBT relaxation techniques. Two weeks after completing this session, participants will complete the same questionnaires/set of batteries they had completed at the beginning of the intervention (apart from MoCA) and the WAI. This will take approx 45 minutes.

Two weeks after, participants will attend their fourth therapy session. This will be based on CBT pacing and behavioural techniques. Two weeks after completing this session, participants will complete the same questionnaires/set of batteries they had completed at the beginning of the intervention (apart from MoCA) and the WAI. This will take approx 45 minutes.

Two weeks after, participants will attend their fifth therapy sessions. This will be CBT-cognitive restructuring. Two weeks after completing this session, participants will complete the same questionnaires/set of batteries they had completed at the beginning of the intervention (apart from MoCA) and the WAI. This will take approx 45 minutes.

Two weeks after, participants will attend their sixth and final therapy session. This will be relapse prevention. Two weeks after completing this session, participants will complete the same questionnaires/set of batteries they had completed at the beginning of the intervention (apart from MoCA) and the WAI. This will take approx 45 minutes.

Participants will be contacted two weeks later (after completing therapy) and will be asked to repeat the same questionnaires/set of battery that will take approximately 45min (apart from MoCA), the WAI and answer what session has been most effective/helpful. This will be completed online.

After this, participants will be given debriefing form and be offered the opportunity to ask questions about the study.

This will signal the end of the active phase of this research project.

Timeline	Intervention	Aims
November 2023	Baseline Assessment	Completion of outcome measures. GAD-7 PHQ-9 SF36 MFIS VAS-F Daily fatigue diary (Likert scale 0-10)

		Which session has been more effective according to the patient (there will be a list of all the sessions and participants can tick the relevant choice)?
2-3 weeks later/ first session	Assessment	To gain a shared understanding of how fatigue is affecting the patient.
Second session	Formulation/Brief Psychoeducation	Education on the impact of brain injury/ how fatigue can affect daily living
Third session	CBT- relaxation techniques	relaxation techniques (5-4-3-2-1, diaphragmatic breathing, progressive muscle relaxation techniques) for the management of fatigue
Fourth session	CBT -Pacing/Behavioural changes in everyday activities	Learning the importance of pacing/resting in the management of fatigue
Fifth session	CBT – cognitive restructuring	Identify unhelpful thinking styles/challenging negative thinking patterns
Sixth session	Relapse prevention	Consolidation of knowledge

End of the study.
Definition: as this project is a clinical trial, there will be a follow up appointment with all participants a month after completing the intervention. This will be phone call to collect the final data (completion of questionnaires).
The end of the study will therefore be the date of the last contact with the last participant at the follow up meeting.

4.2 Will the procedure involve deception of any sort? If yes, what is your justification?
N/A Participants will be told that they will be offered treatment for fatigue post ABI based on CBT principles.

4.3. Detail any possible (psychological or physical) discomfort, inconvenience, or distress that participants may experience, including after the study, and what precautions will be taken to minimise these risks.
One potential risk for taking part in this study could be an increase in participants fatigue due to travelling to the service to receive treatment. To reduce any further fatigue caused by travelling, the option of attending the intervention online will be offered to all participants. Also, to reduce burden I could offer the option to clients to record the content

of the sessions (to be able to listen to them again at their homes to reduce fatigue in session).

Moreover, there is a possibility for participants to be distressed due to the nature of conversations we will be having in therapy (ABI related questions, reflections on life before injury etc).
To manage/minimise burden: I am a trainee clinical psychologist with experience working with distress, I will be supervised by qualified clinical psychologists and will be discussing clinical cases regularly in supervision to monitor participants' risk/distress and will follow the risk procedure for the NHS service.
Debrief forms will be given to all participants explaining the outcome of the study and telephone contact will be available to answer any questions that might arise after participating in the project.

4.4 Detail any possible (psychological or physical) discomfort, inconvenience, or distress that YOU as a researcher may experience, including after the study, and what precautions will be taken to minimise these risks. If the study involves lone working please state the risks and the procedures put in place to minimise these risks (please refer to the lone working policy).

I will be working with people with ABI who are struggling with mood, fatigue, life. As a trainee clinical psychologist, I have some experience working with people in distress and I will utilise my clinical skills (self-care, exercise, breathing exercises) to minimise any discomfort/inconvenience. Most importantly, I will have regular supervision to help me manage any possible distress/discomfort.

4.5 Explain how you will care for any participants in 'special groups' e.g., those in a dependent relationship, are vulnerable or are lacking mental capacity), if applicable:

N/A

4.6 Please give details of any payments or incentives being used to recruit participants, if applicable:

Participants will be reimbursed for their time and travel to the service to receive their treatment in the form of vouchers. All participants will receive a £50 voucher at the end of the study once all data has been collected.
Participants will also have the option to engage in therapy online. In this case, there wont be any payments for their involvement.

5. Access **and storage of data**

5.1 How will participant confidentiality be maintained? Confidentiality is defined as non-disclosure of research information except to another authorised person.

Confidential information can be shared with those already party to it and may also be disclosed where the person providing the information provides explicit consent. Consider whether it is truly possible to maintain a participant's involvement in the study confidential, e.g. can people observe the participant taking part in the study? How will data be anonymised to ensure participants' confidentiality?
Participants' involvement and information collected about them during the course of the research will be kept strictly confidential. Only members of the research team and responsible members of the University of Southampton may be given access to data for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential. The referring clinician and GP will be notified of participation in research, as per standard medical care. We would like to share the formulation letter with GP and referring clinician, as per standard clinical practice. In addition, the only other time we would have to breach confidentiality and speak to GP or emergency services, if we believe that the person is at risk to self or to others, or if they are at risk from others. Data will be pseudonymised, where participant data will be linked using a code until the data collection is finished. Only the chief researcher, Alexandros Zouloumis, will know the code assignment. Since this study will have a small sample size (approximately 7 participants), some information can be identifiable, but only by the main researchers in the team. Personal data will be handled securely during collection, analysis, storage and transfer by using encryption and password protected access, or lockable cabinets for hard data, that are placed in locked rooms. Personal data and consent forms will be kept separate from non-identifiable data. The information is kept on password protected computers/laptops, that only the researcher has access to.

5.2 How will personal data and study results be stored securely during and after the study. Who will have access to these data?
All data and study results will be stored in NHS service and in NHS laptops. The people who will have access to the data and results are the main researcher, and the clinical/academic supervisors.

5.3 How will it be made clear to participants that they may withdraw consent to participate? Please note that anonymous data (e.g. anonymous questionnaires) cannot be withdrawn after they have been submitted. If there is a point up to which data can be withdrawn/destroyed e.g., up to interview data being transcribed please state this here.
Although participants can withdraw at any time during the active phase of the study. Any data collected up to the point of withdrawal will be used in the study.

6. Additional Ethical considerations

6.1 Are there any additional ethical considerations or other information you feel may be relevant to this study?
N/A