

Participant Information Sheet

Study Title: Cognitive behavioural therapy for the management of fatigue after acquired brain injury.

Researcher: Alexandros Zouloumis, trainee clinical psychologist
ERGO number: 80267_ Version 2_ 28/08/23

You are being invited to take part in the above research study which is being undertaken by a doctoral student at the University of Southampton.

To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information.

You may like to discuss it with others, but it is up to you to decide whether to take part. If you are happy to participate you will be asked to sign a consent form.

If you decide to participate, your GP will be also informed via letter (optional).

What is the research about?

Fatigue is very common symptom following a brain injury and can have a big impact on people's quality of life whilst 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 for 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.

Why have I been asked to participate?

You have been asked to take part in the study as you have experienced a brain injury and also symptoms of fatigue, which you would like to improve. You have not previously undertaken CBT for fatigue or other difficulties in the past. You are also not involved in other psychological interventions with the service for managing your fatigue.

What will happen to me if I take part?

The main aim of this study is to help you reduce the experience of fatigue following your brain injury with the use of psychological techniques. These techniques will be informed by CBT from previous research with sessions which can take place remotely (online) or in person at the brain injury service in Poole.

You will first be invited to take part by a neuropsychologist from the Dorset Brain Injury Service. They will ask you a few questions via telephone to make sure you are able to participate in the study.

This will include checking you are:

- An adult
- Have an acquired brain injury
- Experience fatigue
- Have not experienced CBT before
- Don't have any significant problems with communication or thinking skills

If you meet our inclusion criteria, we will ask you to complete and sign a consent form to take part in the study.

The next step involves completing some questionnaires about your symptoms. This will include questions about your fatigue, physical and mental health, as well as a brief test of your thinking skills (e.g. memory). You will also be asked to keep a daily log of how fatigued you feel throughout your involvement in the study.

You will then meet with a therapist for an assessment to learn more about your experience of fatigue. This will be followed by six 1-hour sessions of psychological therapy. This will involve learning some new skills for managing fatigue such as relaxation, pacing, and challenging thoughts. You will be asked to complete some tasks outside of these appointments to help you practise the skills at home.

You will be asked to complete some further questionnaires halfway through and again at the end of therapy, to help us evaluate whether anything has changed for you. This will help us to determine whether the intervention has been helpful.

Your therapist may record some sessions using an encrypted Dictaphone. This will be used to ensure the therapist is following the treatment plan and involves a supervisor listening to them and providing feedback to the therapist. You will be asked to consent to do this and have the right to decline.

Are there any benefits in my taking part?

The main benefits of taking part in this study are:

1. You will learn CBT strategies which previous research has found to be effective in managing fatigue. Although we cannot guarantee this will be your experience, we hope this will be beneficial for your recovery.
2. You will be contributing to research which hopes to benefit other people experiencing fatigue following brain injury.
3. You will be reimbursed for your time and any travel costs you may have undertaken with a £50 Amazon voucher at the end of therapy.

Are there any risks involved?

It is possible that you may experience an increase in fatigue from traveling to and from appointments. If so, you have the option of attending your appointments online.

The sessions themselves could be tiring. Timings will be adjusted to suit you and you will be given the option of recording sessions to listen to them later to help consolidate what was discussed.

It is possible that you may experience some distress due to the nature of conversations and how your life has been affected by the brain injury. Your therapist is a trainee clinical psychologist and is trained to have these conversations. They also receive regular support and supervision from qualified clinical psychologists.

The University of Southampton holds the legal responsibility for this project. Insurance is held by the University of Southampton for this study which is proportionate to the potential risk of harm to participants.

What data will be collected?

You will be asked to complete questionnaires about your fatigue, physical and mental health. We will also ask some information about you for the purposes of the study. This includes your ethnicity, gender, age, type of brain injury and how long ago you experienced this.

All collected information will be stored in a locked filing cabinet. This will be later transferred into a spreadsheet which will not include your name or any other identifying information to ensure you information is anonymous.

Will my participation be confidential?

Your participation to this study and every piece of information collected about you during your involvement with this 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 about you 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 these people have a duty to keep your information, as a research participant, strictly confidential.

At the end of the study, your data will be anonymously entered into a spreadsheet which will include no personal identifiers (e.g. name, service, date of birth).

Do I have to take part?

No, it is entirely up to you to decide whether to take part. If you choose to be a participant in this study, you will be asked to sign a consent form.

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights or routine care being affected.

You can withdraw from the study at any time by emailing the main researcher at Alexandros.zouloumis@nhs.net.

Data collected up to the point of withdrawal will be used in the study.

What will happen to the results of the research?

Your personal details will remain strictly confidential and kept within the NHS service. Anonymised data will be analysed at the University of Southampton. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

Where can I get more information?

You can email the main researcher at Alexandros.zouloumis@nhs.net who will be happy to answer any questions you may have regarding the intervention.

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researcher who will do their best to answer your questions. You can email the researcher at Alexandros.zouloumis@nhs.net.

You can also email their Academic Supervisor, Dr Warren Dunger, w.n.dunger@soton.ac.uk

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and [can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/Is/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>](http://www.southampton.ac.uk/assets/sharepoint/intranet/Is/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf)

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 1 years after the study has finished after which time any link between you and your information will be removed.

NHS will keep identifiable information about you from this study for 10 years after the study has finished.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

I want to thank you in advance for taking part in this study.