

Digital self-management for mental and sexual wellbeing after acquired brain injury (HOPE4ABI): feasibility randomised controlled trial

PARTICIPANT INFORMATION SHEET

We are inviting you to take part in a research study to test a new 8-week online course for people living with acquired brain injury (ABI). Before you decide to take part, it is important you understand why we are doing the research and what it will involve. Please read this information carefully and talk about it with family or friends if you want to.

What is the purpose of the study?

ABI affects people in different ways. Rehabilitation tends to focus on physical and cognitive health – for example, walking and talking. Mental health, sexual wellbeing and relationship problems are often neglected. These issues can be overwhelming and effect other areas of life.

Together with people living with ABI, we designed an online course to support mental and sexual wellbeing (called Hope for ABI, or 'HOPE4ABI'). The purpose of this study is to test HOPE4ABI in randomised controlled trial, or RCT.

Important note: this study is not meant to replace psychological therapy or medical treatment. We aim to help you to manage your own mental and sexual wellbeing. Please contact your GP if you think you need professional advice or support.

Why have I been chosen?

We have invited you because you had an ABI at least 3 months ago. We would like you to take part in the new HOPE4ABI intervention and tell us how you got on afterwards.

What are the benefits of taking part?

The HOPE4ABI course may help you to manage your own mental and sexual wellbeing. You may meet new friends, or learn new skills, or find out something new about yourself.

We will email you a link to questionnaires that measure your wellbeing. We will send you a £10 gift voucher each time you complete the follow up questionnaires – once after the course, and then again after 6 months.

Are there any risks associated with taking part?

The study is online and there is little physical risk of taking part. However, mental and sexual wellbeing can be sensitive issues. You can decide how much to participate in topics that you might find uncomfortable. If you feel emotional or psychological distress at any time, you are welcome to leave the activity, or withdraw from the research entirely. If you want to

discuss your sexual or psychological wellbeing with a professional, please contact your GP or NHS 111.

If we suspect that you may be at risk of harm to yourself or others, we will advise you to contact your GP, NHS 111, or call 999 (in an emergency). We will also write to your GP to inform them, and we may contact emergency services on your behalf if we feel there is an immediate risk to life. If you tell us you have engaged in criminal activity, we will report this to Coventry University Ethics Committee. They will decide on further action and may refer the matter to the police.

Do I have to take part?

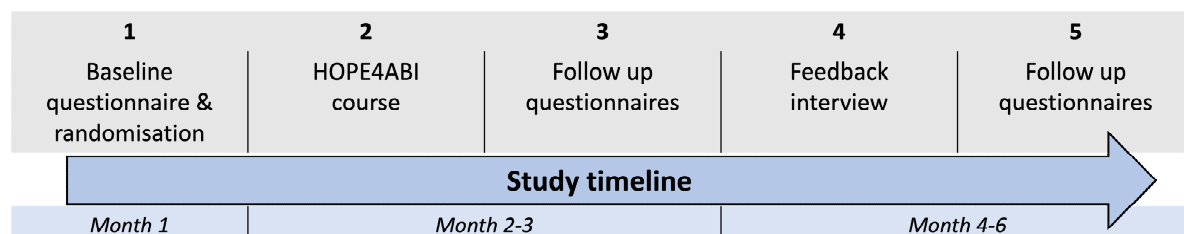
No – it is your choice. If you are unsure, please take time to discuss with your family or friends or ask the researchers if you have any questions.

How do I withdraw from the study?

You can withdraw your participation from the study at any time. You do not need to give a reason, and your rights will not be affected. Just let the research team know, using the contact details on the study website. You can request to withdraw your data from the study until **31/05/2024**, by contacting the research team and quoting your participant ID number. After 31/05/2024, all data will be analysed as a group, and it will not be possible to withdraw your individual data.

What will happen if I decide to take part?

There is a digital consent form on the next page. If you decide to take part, you will need to confirm all the statements to show that you understand your rights and are happy to participate. The diagram below shows the steps you will take through the rest of the study.



1. You will be asked to fill in baseline questionnaires to tell us all about you, including contact details, education, marital status, and some details about your ABI. You will only need to complete this once.

Three short questionnaires will measure your wellbeing: mental wellbeing, quality of life, and sexual wellbeing. This will take you around 15-20 minutes. You will complete these again at the two follow up points so we can compare your answers before and after the course.

Next, the computer will assign you to either: **peer supported** HOPE4ABI, or **self-directed** HOPE4ABI. This is decided at random, like the flip of a coin. You have a 50/50 chance of being put in any group.

2. The 8-week HOPE4ABI course contains a range of self-management tools, tips, and activities. Different formats such as videos, podcasts, and quizzes will be used to cover topics relating to psychological and emotional wellbeing, intimacy, and personal and social relationships. A different topic will be covered each week, with the content being released at the same time every week, e.g. 11am on a Monday. Each week's content will last around 1 hour, but you can work through it at your own pace across the week. All aspects of the course are **optional**.

The **peer-supported** course will offer options for you to interact with other participants (i.e., your peers) and will be guided by a peer 'facilitator' who will oversee your progress and be on hand to answer questions. The **self-directed** course has the same topics and content, but you will have no contact with other participants and there will be no facilitator.

3. A week after your HOPE4ABI course has ended, we will email you a link to the wellbeing questionnaires, plus a short feedback questionnaire about your experience on the course. These will take you around 15-20 minutes to complete. We will then email you a £10 gift voucher as a thank you for completing them.
4. We will invite participants at random to tell us in more detail about your thoughts, opinions, experiences of the study. Interviews will take place on Microsoft Teams at a time that suits you and will last around 30 minutes. Your opinions will help us to make improve the course for future participants.

If you are randomly selected for an interview, we will send you an invitation after the course. You do not have to decide now, and you do not have to say yes. We will send you the relevant information to help you decide at the time.

5. After six months, we will email you a link to the same **wellbeing** questionnaires, plus a few questions including whether you are using what you learned on the course. These will take you around 15-20 minutes to complete. We will email you another £10 gift voucher as a thank you for completing them.

Data Protection and Confidentiality

We will process your data in accordance with the General Data Protection Regulation 2016 (GDPR) and the Data Protection Act 2018. We will not tell anyone that you have taken part in our research and ask everyone to respect the confidentiality of their fellow participants. All information collected about you will be kept strictly confidential. All electronic data will be stored on a password-protected computer file on Coventry University's SharePoint. Your name and contact details will be kept separately from your anonymised questionnaire and interview data, to minimise risk of identification in the event of a data breach. Identifiable data (e.g. name, contact details) will be destroyed at the end of the study period **31/10/2024**. The anonymised data (e.g. questionnaire responses with names removed) will be kept in long-term digital storage for up to 10 years after the trial has ended and will be permanently deleted by **31/10/2034**.

Data Protection Rights

Coventry University is a Data Controller for the information you provide. You have the right to access information held about you, in accordance with the General Data Protection Regulation and the Data Protection Act 2018. For more details, including the right to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk. Questions, comments, and requests about your personal data can also be sent to the Coventry University Data Protection Officer at enquiry.igu@coventry.ac.uk

What will happen with the results of this study?

This study will help us to make sure the research process is suitable, accessible, and appropriate for people with ABI. Next, we aim to run a large-scale RCT to evaluate the effect of HOPE4ABI on mental and sexual wellbeing in a larger group of people with ABI.

We will report results of this study in journal articles, research reports, newsletters, blogs, and presentations. Quotes or key findings will always be made anonymous for reporting purposes.

Making a Complaint

If you are unhappy with any aspect of this research, please contact the research team:

Dr Hayley Wright - ab7764@coventry.ac.uk

Prof Andy Turner – hsx116@coventry.ac.uk

If you still have concerns or wish to make a formal complaint, please write to: Coventry University Ethics Committee, Coventry University, Coventry CV1 5FB; or email ethics.uni@coventry.ac.uk. In your letter please provide information about the research project, give the names of the researchers, and detail the nature of your complaint.