**Appendix 7.** **Participant Information Sheet/Consent Form for Consumers**

The University of Newcastle

**Participant Information Sheet/Consent Form**

|  |  |
| --- | --- |
| **Title** | Exploring the treatment of post-stroke fatigue and low mood disorders: A qualitative study of patients’ and health professionals’ perspectives and preferences in Australia |
| **Short Title** | Perspectives and Preferences for Post-Stroke Treatment |
| **Ethics Reference Number** | **H-2025-0124** |
| **Study Sponsor** | The University of Newcastle |
| **Coordinating Principal Student Researcher** | Yuanchen Liang |
| **Principle Supervisor****Co-lead researcher****Full oversight of research process** | Prof Beata Bajorek |
| **Co-Supervisor****Associate researcher****Full oversight of research process** | Prof Christopher Levi |

**What is the study about?**

This study aims to explore the types of treatments that people may prefer for managing post-stroke fatigue and/or low mood conditions (e.g., depression, anxiety, apathy = low motivation). These preferences may relate to medications, psychological therapies, lifestyle changes, or alternative remedies.

**Do I have to Participate?**

Participation in this study is voluntary. You can choose not to participate, and you may withdraw at any time without consequences. If you decide to withdraw after starting, you may request that your data not be used, provided this request is made **within 7 days** after your interview.

**Who is conducting and funding this study?**

We are a team from the University of Newcastle, Hunter Medical Research Institute, and Hunter New England Local Health District, consisting of:

* Yuanchen (Chloe) Liang: PhD candidate (the student researcher)
* Prof. Beata Bajorek: Clinical Academic Pharmacist
* Prof. Christopher Levi: Clinical Academic Physician

**Who is being asked to participate?**

We are inviting stroke survivors aged 18 years+ living in Australia, as well as informal carers (such as family, friends, neighbours) who support someone affected by stroke-related fatigue or mood disorders.

You can choose to participate via phone, video call (internet – Zoom or Teams online), or in person if you are based in Sydney or Newcastle —whichever is most convenient for you. For in-person interviews, you must be located in Sydney or Newcastle. Interviews will be conducted in private rooms at accessible public venues such as:

In Newcastle: Newcastle City Library (Laman Street), Wallsend Library (Bunn Street), or the Hunter Medical Research Institute (HMRI, Kookaburra Circuit, New Lambton Heights).

In Sydney: venues may include City of Sydney Library (Haymarket), Marrickville Library, or Green Square Library.

These venues offer appropriate privacy for interviews.

Should you require assistance with English language translation or face communication difficulties (e.g., aphasia post-stroke), you are welcome to bring a family member, friend, or informal caregiver to help you during the interview.

**What does participation involve?**

During the interview, a brief scenario will be presented to you on the screen or page. It will describe a particular treatment option (what it is, what is involved in using it). You will then be asked how you feel about it as a possible treatment option for people with post-stroke fatigue or low mood, and what you like or do not like about it. If you choose to take part in both interviews (fatigue and low mood), the total time required will be approximately 60–90 minutes (30–45 minutes per interview). The interviews will be audio-recorded to ensure that we do not miss any of your comments. Immediately after the interview, we will transcribe the discussion and remove any details that could identify you before deleting the recording. If desired, we can provide you with a copy of this anonymous summary.

Your name and contact details may be known to the student researcher (interviewer) for communication and scheduling purposes, and during the interview. This information will be kept secure. Your personally identifying information will never be shared outside of the research team.

Each participant will be assigned a unique Participant Identification (ID) number. A separate, securely stored Master File will contain the link between your name and your ID number. This Master File will only be used for two purposes: (1) to locate and remove your interview data if you choose to withdraw from the study (withdrawal is possible at any time, including up to 7 days after your interview), and (2) to enable us to share any summary findings or reports with you if requested. The Master File will be stored separately from your de-identified interview transcript and other research data to protect your confidentiality.

If you choose an online interview, we will send you a Zoom or Microsoft Teams link via email or phone. You will receive a document describing these scenarios (called 'vignettes') via email or in the postal mail before the interview. These help you consider different treatment approaches and are only used to support your discussion. If you are unable to access email, we can explain the vignettes over the phone.

You will be given the opportunity to review your interview transcript and confirm or amend your responses. The transcript will be sent to you by email or post, depending on your preferred method. You will then have 7 days to review the transcript and make any changes.

**What are the possible risks?**

We don’t expect anything bad to happen because you join this study. But, if you often feel very tired or down, talking about your experiences during the interview might make you feel uncomfortable or worried. Please remember, we are not here to judge you. We just want to understand the problems you’ve faced and what you think about treatments after a stroke. If you want to take a break or stop the interview at any time, just let us know. Also, if you need it, we can help you get in touch with a counsellor or other support services.

Interview transcription will be carried out by the student researcher (YL) and, depending on how frequently interviews are scheduled, by a professional transcription service, called **Transcript Divas**. This external service will not have access to any identifying information beyond the audio**.**

If you experience emotional upset or distress during or after the interview, we will pause or stop, you may wish to contact Lifeline (13 11 14), Beyond Blue (1300 22 4636), and recommend that you contact your usual GP or healthcare provider.

**What Support Will I Receive to Participate?**

If you take part in an interview, you’ll receive an AUD $50 as compensation for your time. You can choose to receive this as an electronic Gift card or printed gift card. For in-person interviews, snacks and drinks will be provided.

**What are the potential costs of taking part?**

Participation in this study is free. If you attend an interview in person, you may incur travel or parking costs. Additionally, if you choose to return any forms (e.g., Participant Information Sheet and Consent Form, Withdrawal Form) via postal mail to the student researcher, you may incur standard postage costs. To help cover these expenses, you will receive a $50 AUD gift card as a reimbursement.

**What about the privacy?**

Your personal information will stay confidential throughout the study. We take your privacy seriously and will only use your data for research purposes. If you have any concerns about how your data is used, feel free to talk to the student researcher (YL).

**Transcript Divas** adheres to strict privacy and data protection standards. Their confidentiality policy can be viewed at: <https://www.transcriptdivas.com.au/transcription-privacy-policy-confidentiality/>. You can find Zoom and Microsoft Teams privacy information at www.zoom.us/privacy and [*www.microsoft.com/en-us/trust-center*](http://www.microsoft.com/en-us/trust-center).

The results may be published or presented, your identity will not be disclosed under any circumstances. Your data will only be shared with your approval.

**What if I want to withdraw from the study?**

Participation in this study is voluntary. You can choose not to participate, and you may withdraw without consequences. You can withdraw from the study up to 7 days after your interview. After this period, your transcript will have been de-identified and data may have already been analysed. However, any personal information that could identify you will be deleted and will not be included in the analysis. To withdraw, please inform the student researcher (YL) verbally, by email, post (if you complete the withdrawal form), or phone.

* If you decide to withdraw after starting, you may request that your data not be used, provided this request is made **within** **7 days** after your interview.
* You can inform the researcher by email, phone, post (if you complete the withdrawal form), or in person. It’s not mandatory for you to complete the withdrawal form for your request to be valid. If you choose to complete the form, it can help clarify your preferences, but it is not required.
* If you withdraw **after the 7-day period**, your data may have already been analysed and cannot be removed from the findings. However, any identifiable information will be deleted and not used.

Please note: At all stages, your withdrawal form will be handled respectfully, and no further contact will be made unless requested.

 **What happens when the research study ends?**

The interview data will be analysed and published in scientific journals and may also be presented at research meetings or presentations. Your identity will not be revealed, but we might use some anonymous quotes from your interview.

**Further information/concerns/questions and who to contact**

**Principal Supervisor**

|  |  |
| --- | --- |
| Name | Beata Bajorek |
| Email | Beata.Bajorek@newcastle.edu.au |

 **Principle student researcher**

|  |  |
| --- | --- |
| Name | Yuanchen (Chloe) Liang |
| Position | PhD research candidate |
| Telephone | +61 0452 619 472 |
| Email | yunchen.liang@uon.edu.au |

If you have concerns about your rights as a participant, you may contact the University of Newcastle Human Research Ethics Office at human-ethics@newcastle.edu.au or call (02) 4921 6333.

Any concerns raised will be treated confidentially and investigated. You will be informed of the outcome.

You will be given a copy of this form to keep.

**Consent Form – for Consumers (patients and/or informal carers)**

|  |  |
| --- | --- |
| **Title:** | Exploring the treatment of post-stroke fatigue and low mood disorders: A qualitative study of patients’ and health professionals’ perspectives and preferences in Australia |
| **Short Title** | Perspectives and Preferences for Post-Stroke Treatment |
| **Ethics Reference Number** | H-2025-0124  |
| **Study Sponsor** | The University of Newcastle |
| **Principal Student Researcher** | Yuanchen Liang |
| **Principle Supervisor****Co-lead researcher****Full oversight of research process** | Prof Beata Bajorek |
| **Co-Supervisor****Associate researcher****Full oversight of research process** | Prof Christopher Levi |

I am taking part as a:

|  |  |
| --- | --- |
| * Person who has had a stroke.
	+ Person who has had post-stroke fatigue.
	+ Person who has had a post-stroke low mood disorder:
		- Depression
		- Anxiety
		- Apathy
 | * Family member/friend/neighbour who provides informal care or support to a stroke survivor
 |

I have read the Participant Information Sheet, or someone has read it to me, to understand the study.

I understand the purposes, procedures and risks of the research described in the study.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I agree to participate in this research study as described and understand that I am free to withdraw the participation at any time during the research study without any consequences.

I am aware that I can contact the study team at any time by:

* + emailing the Principal Student Researcher Yuanchen/Chloe at: Yuanchen.liang@uon.edu.au

I understand that I will be given a signed copy of this document to keep on behalf of the participant.

I indicate my agreement as follow:

|  |  |
| --- | --- |
| I AGREE to participate in ONE OR BOTH of the following ways:(I may change my mind about participation at any time) | * Interview on potential treatment for FATIGUE after stroke
* Interview on potential treatment for LOW MOOD DISORDERS after stroke
 |
| I AGREE to have my voice recorded if I choose to be interviewed  | * Yes
* No
 |
| I **Understand** and **AGREE** that the details I provide will be presented in a way that does **NOT** personally identify me. | * Yes
 |
| I request that my **carer\* or a family member\*** assists, supports, translate, or interprets for me during the interview | * Yes
* No
 |
| I would like to be contacted at the end of the study about the Study Findings | * Yes
* No
 |
| I prefer to be contacted by:  | * Telephone……………
* Email…………………
 |

|  |
| --- |
|  Name of Participant (Print): Date: |
| Signature: | Date: |

**\* The personal details provided on this Consent Form will only be used for the purposes of communication during the study processes, i.e., to arrange a time for interview, to provide a copy of the study findings, where requested. These details will, otherwise, be separated from the information collected through interview.**

**Declaration by Researcher†**

I have given a verbal explanation of this study; its procedures and risks and I believe that participant has understood that explanation.

|  |
| --- |
|  |
|  | Name of Researcher (Print): |  |  |
|  |  |
|  | Signature: |  |  Date: |  |  |

**Form for Withdrawal of Participation**

|  |  |
| --- | --- |
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| **Co-Supervisor****Associate researcher****Full oversight of research process** | Prof Christopher Levi |

You can withdraw from the study up to 7 days after your interview. After this period, your transcript will have been de-identified and data may have already been analysed. However, any personal information that could identify you will be deleted and will not be included in the analysis. To withdraw, please inform the student researcher (YL) verbally, by email, post (if you complete the withdrawal form), or phone.

I wish to withdraw from taking part in the above research study and understand that such withdrawal will not affect the relationship with research team or The University of Newcastle.

|  |  |
| --- | --- |
| Name of Participant (Print): |  |
| Signature: | Date: |

|  |  |
| --- | --- |
| Name of Researcher (Print) |  |
| Signature: |  Date: |