Participant Information Sheet for Young Stroke Survivors

Project title:

Making the invisible visible: A feasibility evaluation of the co-designed Talking Heads psychoeducation package for young survivors of stroke

Instructions

This **Participant Information Sheet and Consent Form tells you about the research project**. You can then decide if you want to take part.

Please **read this document**. It is formatted to be easy for people with communication and cognitive difficulties to read and understand.

Ask questions about anything that you don't understand or want to know more about. You might want to **talk about it with a relative, friend or local doctor.**

Participation **is voluntary.**

If you want to take part in the research project, you will be asked to **sign the consent form**. By signing it you are telling us that you:

- ✓ Understand what you have read
- ✓ Consent to take part in the research

1. What is this project about?

Having a stroke at a younger age can be confusing. **Getting the right information is very important.** But many young stroke survivors **cannot find the information they need.**

We have created an online information package **specifically for younger people who have had strokes.**

We did this by talking to other young stroke survivors, their family members, and health professionals. **They told us what information they needed and how we should deliver it.**

We want to test the information package. We want to know if it is helpful, easy to understand, and easy to use. **We will use the information to improve it.**

The **Talking Heads** information package provides information on **'invisible difficulties' that affect young stroke survivors.**

The information is designed to help people **understand their stroke, learn new strategies to manage, and know how to find more help.**

The package covers **six topics:**

1. Fatigue
2. Brain fog
3. Feeling overwhelmed
4. Grief and loss
5. Finding meaning, enjoyment, and hope
6. Sex, relationships and intimacy

The package includes **written tipsheets, short videos and podcasts.** These resources will be **on a website for participants to access whenever they like.**

The package also **includes 3 optional online information sessions**. These sessions will be **facilitated by a clinician** and a **person with young stroke.**

The clinician will provide advice. The person with young stroke will share their story and experiences. Participants will be able to **ask questions and talk to other people with young stroke.**

2. Who is conducting this study?	
Professor Dana Wong La Trobe University, Melbourne	
Ms Michaela Grech La Trobe University, Melbourne	
Dr Nick Sathananthan La Trobe University, Melbourne	
Dr Toni Withiel Royal Melbourne Hospital	
Professor Emma Power University of Technology, Sydney	
Professor Ian Kneebone University of Technology, Sydney	

Associate Professor Rene Stolwyk Monash University, Melbourne	
Associate Professor Eirini Kontou University of Nottingham, United Kingdom	
Mr Adrian O’Malley Physical Disability Council of New South Wales	
Ms Brooke Conoley La Trobe University	
Ms Maddy Green La Trobe University	
The project has been **funded** by the **Tim Glendinning Memorial Grant** through the **Stroke Foundation**.	

3. Who can participate?

You can participate in this study if:

- You had a **stroke/TIA between the ages of 18 – 45**
- Your **stroke** happened more than one month ago and **less than 10 years ago**
- You **live in Australia**
- You have an **internet-compatible device**
- You want **information and support for 'invisible difficulties'**

You can participate **by yourself**. You can also participate with a family member, partner, or friend.

We aim to include people from all over Australia. We also want to include people **with memory or thinking difficulties** and people with **aphasia.**

We can provide support for you to access the internet.

4. Do I have to take part in this study?

Participation in this study is **voluntary** and you can **withdraw at any time.**

If you withdraw**, you can ask us not to use your data.** This will **not be possible** once the study has finished.

Stopping **will not affect** your current or future treatment,

research involvement or relationship with your care team.

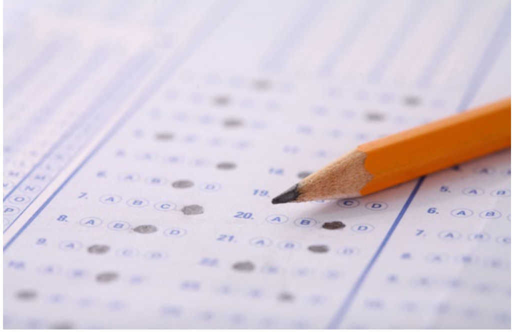
5. What will I be asked to do?

If you choose to participate, you will do **the following tasks** in this order**:**

1) We will contact you (phone or Zoom) to **check that you are eligible** to participate, and to **explain the study** to you.

2) You will complete a **20-minute screening interview** through telehealth (phone or Zoom).

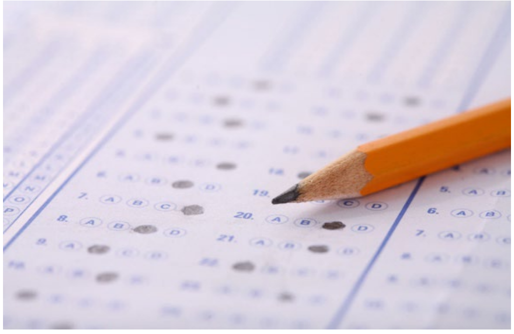
3) You will **complete** **<u>online</u>** **questionnaires** about your mood, wellbeing, goals, and unmet needs. **We can help you complete the questionnaires**. A family member or friend can also help you. The questionnaires **will take 30 – 60 minutes.**



4) You will be **given access** to the Talking Heads information package for **12 weeks.**

   You will **access the tipsheets, videos, and podcasts through a website**. You will **access the online information sessions through Zoom.** We will tell you when these will be held.

You choose how you use the package. **We will automatically track** how people use it.



5) After 12 weeks, you will complete **the same <u>online</u> questionnaires** about your mood, wellbeing, goals, and unmet needs.

6) You will **complete an <u>interview</u>** over Zoom about your experience of using the package. We will ask you to provide feedback on the information package.

   The **interview will take 30 – 60 minutes. We will record the interview** with your permission.

You can **continue with your usual lifestyle and care** throughout this project. There is **no cost** to participate. **You will not be paid** for participating.

6. How do I participate with a family member, partner, or friend?

We will ask if you want to participate with someone else **when we first contact you.**

They will also receive access to the information package.

Family members/friends **will complete their own online questionnaires**. You can **complete the final interview together, or separately**.

7. Are there any risks associated with this study?

You **may experience strong emotions** throughout the study.

The online questionaires will ask about your mood, wellbeing, and the impact of your stroke. You may find some of the questions **stressful or upsetting**. You can skip these questions, take a break, or stop immediately. If this happens, we will offer you support.

You may **talk about emotional topics** during your **final interview** (e.g., your experience of stroke). You can decline to answer any question, or stop the interview at any time. If this happens, we will offer you support.

There are also **several services you can contact** for additional support **at any point** while participating:

Helpline	Helpline phone number	Hours available	About the helpline
Stroke Foundation	**03 9670 1000**	Monday to Friday, 9am to 5pm	First point of call when dealing with a distressed stroke survivor or relative.
Stroke Foundation StrokeLine	**1800 787 653**	Monday to Friday, 9am to 5pm.	Information and advice on stroke prevention, treatment, recovery, and support.
Carers Australia	**1800 242 636**	Monday to Friday, 8:30am to 4:30pm	Provides information and counselling to carers.

8. What are the possible benefits?

We cannot promise you any direct benefits from this research. You **may experience individual benefits**. Using the information package may improve your **understanding** of and **confidence** in managing post-stroke challenges.

Participating in the research **may** help us understand how to deliver information about hidden challenges to young stroke survivors. **This might benefit other young stroke survivors.**

9. What information will I have to give?

We will collect your **demographic information.** We will ask you about your age, gender/sex, education level, cultural identity, and where you live.

We will collect information **about your stroke. We may ask for permission to access your medical records** to find out information about your stroke.

We will collect information about the **impact of your stroke.** We will ask you about stroke symptoms, cognitive (memory/thinking) and language difficulties, and daily living.

We collect information **about your mood, wellbeing, health literacy, and goals.** You will complete questionnaires to provide this information.

We will collect information about **your perspective and experience of using the Talking Heads information package.**

10. What will happen to information about me?

We will **store your information securely for at least 7 years**. The storage, transfer and destruction of your data will be undertaken in accordance with the Research Data Management Policy .

Talking heads website usage will be tracked by Google Analytics. It collects non-identifiable information about website use (such as pages visited, time spent on the site). This information is **anonymised** so you can't be identified by Google. The data may be **stored securely** on Google servers located outside Australia for a limited period before being deleted.

The information you provide will **remain confidential**. We **will not use your name or identify you** in any way. We **will not share** your information. Only the research team can read the information.

The results of the study may appear in **journal publications** or **conference presentations** related to this project. **We will not use your name or identify you in any way** in these publications and presentations.

Your information **will only be used for this project** unless you give us permission to use it for other projects. You have the right to request access to your information collected and stored by the research team.

If you withdraw**, you can ask us not to use your data.** This will **not be possible** once the study has finished.

11. Will I hear about the results of the study?

We will send you a **summary of overall interview results** once they have been analysed. You will be able to check whether our analysis represents your views and perspectives.

We will send you **summary of the findings from the whole project** once it has finished.

12. What if I change my mind?

You can choose to withdraw from participating in the study at any time up **UNTIL** we analyse the data. Data analysis will begin four-weeks after the final interviews.

If you decide to withdraw, you can let us know by either:

1. Emailing us: talkingheads@latrobe.edu.au
2. Calling us: 03 9479 1679

If you decide to withdraw it will **NOT** affect your relationship with La Trobe University, the research team, or any health services you have accessed or may access in the future.

13. Research compliance

Research involving humans in Australia is reviewed by an independent group of people on a Human Research Ethics Committee (HREC).

This study has been approved by the HREC of La Trobe University. The approval number is HEC25554.

If you are concerned about the way this study is being conducted or you wish to **make a complaint** about any part of this study, please contact the La Trobe Human Ethics Committee:

Ethics and Research Governance Manager Phone: 03 9479 1443
Email: humanethics@latrobe.edu.au

14. Further information and who to contact

Please contact the research team to discuss the study

Email: talkingheads@latrobe.edu.au

Phone: 03 9479 1679

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Professor Dana Wong can discuss the study with you

Email: d.wong@latrobe.edu.au

Phone: 03 9479 5079