**Participant Information Sheet/Consent Form**

**Health/Social Science Research** –*Person responsible providing consent*

|  |  |
| --- | --- |
| **Title** | Exploring the unmet rehabilitation needs of stroke survivors in Australia: A qualitative study |
| **Protocol Number** | 2024/ETH01885 |
| **Project Sponsor** | St Vincent’s Health Network Sydney |
| **Coordinating Principal Investigator** | Dr Lauren Christie |
| **Site Principal Investigator** | Dr Lauren Christie |
| **Associate Investigator(s)** | Professor Natasha Lannin  Ms Kate Makroglou  Dr Christine Shiner  Dr Kate Scrivener  Maddison Smith  A/Prof Erin Godecke  Kelvin Hill  Dr Angela Dos Santos |
| **Location** | St Vincent’s Health Network Sydney |

**Part 1 What does participation involve?**

**1 Introduction**

This Participant Information Sheet/Consent Form tells the participant about the research project. It explains the processes involved with taking part. Knowing what is involved will help the participant decide if they want to take part in the research. Please read this information carefully. Ask questions about anything that the participant doesn’t understand or want to know more about. Participation in this research is voluntary. If the participant doesn’t wish to take part, they don’t have to.

**What is the research about?**

The participant is invited to take part in this research project, which is aiming to investigate the unmet rehabilitation needs of stroke survivors in Australia. This research will ask the participant for their feedback on the care they received immediately after their stroke, during rehabilitation and after discharge from the hospital. We are specifically interested in what the participant’s main needs are as a stroke survivor and how these needs were or were not met by healthcare services.

**Who is doing the research?**

This research is being undertaken by Dr Lauren Christie, and the Allied Health Research Unit. This research has been funded by St Vincent’s Health Australia Health Equity Program and is sponsored in Australia by St Vincent’s Health Network, Sydney. A portion of these funds are allocated to researchers who are part of the Allied Health Research Unit and associated with this project.

**Why have we asked the participant to take part?**

The participant has been invited because they have experienced a stroke in the last 10 years and have completed some form of inpatient or outpatient rehabilitation for stroke.

**2 What is the purpose of this research?**

There are currently gaps in our knowledge concerning how health services are meeting the needs of stroke survivors in Australia. A recent report revealed that many stroke survivors experience challenges that can persist for years after stroke. However, these needs may not be met by rehabilitation and support services. The outcomes of this project will provide key insights into the specific unmet needs of stroke survivors who have received care at St Vincent’s Health Network, Sydney and the broader community. The participant’s participation in this project and feedback about rehabilitation for stroke will help us to support stroke survivors.

**3 What does participation in this research involve?**

A member of the research team will contact the participant and ask them some basic questions to make sure they’re eligible to participate. If these questions show that the participant meets the requirements, then they will be able to start the research project. If the questions show that they cannot be in the research project, the research coordinator will discuss other options with them, including checking if they require additional support from a health professional.

If the participant is eligible and provides consent, they will be invited to complete an online survey. We can help the participant complete this survey over the phone or in person. The survey will ask them some basic information about themselves, their stroke and their experience of care in rehabilitation. After they complete the survey, the participant will attend a one-on-one interview (45 minutes) to provide their feedback on the support they received in rehabilitation after stroke. This interview will either be conducted face to face at St Vincent’s Hospital Sydney or online, depending on the participant’s preference and availability.

A summary of the interview findings from all study participants will also be emailed to the participant to read and comment on to ensure all important points regarding unmet stroke rehabilitation needs have been captured. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way.

**Will the participant be paid?**

Yes, the participant will be offered a $50.00 gift card once they complete the study to reimburse them for the time spent completing the survey and/or any expenses they incur to attend the interview. The gift card is provided by the Coles-Myer group.

**4 Other relevant information about the research project**

We are recruiting stroke survivors who have completed some form of inpatient or outpatient rehabilitation for stroke. Rehabilitation may have taken place through St Vincent’s Health Network, Sydney but we are also recruiting in the broader community and regional areas. About 15-20 people will take part in this project.

**5 Does the participant have to take part in this research project?**

Participation in any research project is voluntary. If the participant does not wish to take part, they do not have to. If the participant decides to take part and later changes their mind, they are free to withdraw from the project at any stage. Their decision whether to take part or not to take

part, or to take part and then withdraw, will not affect their relationship with professional staff or their relationship with St Vincent’s Health Network, Sydney.

If the participant decides they want to take part in the research project, they will be asked to sign the consent section of this form. By signing it they are telling us that they:

* Understand what they have read
* Consent to take part in the research project
* Consent to be involved in the research described
* Consent to the use of their personal and health information as described.

They will be given a copy of this Participant Information and Consent Form to keep.

**6 What are the possible benefits of taking part?**

We cannot guarantee or promise that the participant will receive any benefits from this research; however, the project provides an opportunity to contribute to stroke survivorship research which may be appealing for them as a person who has experienced stroke. Information gathered from this research may improve our understanding of the unmet rehabilitation needs stroke survivors face and how health services can be improved.

**7 What are the possible risks and disadvantages of taking part?**

There is a potential risk for discomfort and/or distress related to reflecting on their experience of stroke and the risk of inconvenience related to the time taken to participate in the interview. We do not anticipate that this will happen and the participant will have the opportunity to withdraw from the study at any time if they do not want to continue.

If the participant does experience discomfort or distress, we will discuss this with them and refer them to support services such as:

* StrokeLine: [strokeline@strokefoundation.org.au](mailto:strokeline@strokefoundation.org.au) or 1800 787 653, Monday to Friday 9 am to 5 pm
* Beyond Blue: [www.beyondblue.org.au](http://www.beyondblue.org.au) or 1300 22 46 36, 24 hours a day, 7 days a week
* Lifeline: ph. 13 11 14, 24 hours a day, 7 days a week

In addition, the participant may consider talking to their GP or specialist heath care team for personalised clinical support. If the participant is eligible for Medicare, they can access subsidised psychology support through their GP.

**8 What if the participant withdraws from this research project?**

If the participant does consent to participate, they may withdraw at any time. If they decide to withdraw from the project, please notify a member of the research team before they withdraw. A member of the research team will inform the participant if there are any special requirements linked to withdrawing. If they do withdraw, they will be asked to complete and sign a ‘Withdrawal of Consent’ form; this will be provided to them by the research team.

If the participant decides to leave the research project, the researchers will not collect additional personal information from them, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. The participant should be aware that data collected up to the time they withdraw will form part of the research project results. If they do not want their data to be included, they must tell the researchers when they withdraw from the research project.

**9 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

* Loss of funding; the study team no longer has the resources required to conduct the study procedures
* Limited participants; limited number of participants meet the inclusion criteria,
* Lead Investigator/s leaving the organization.

**10 What happens when the research project ends?**

When the research project ends, the data collected will be used to inform improvements of stroke rehabilitation systems at St Vincent’s Health Network. If the participant would like to, they can receive a summary of the results when the research project is completed by ticking the box in the consent form below.

**Part 2 How is the research project being conducted?**

**11 What will happen to information about the participant?**

By signing the consent form the participant consents to the research team collecting and using personal information about them for the research project. Any information obtained in connection with this research project that can identify them will remain confidential. The participant’s name and any identifying information will be replaced with a code.

The personal information that the research team collects and uses is demographic data, information about the participant’s stroke, the participant’s personal experience of rehabilitation after stroke and unmet needs related to stroke recovery.

We will collect audio recordings of the interviews so we can transcribe them. By agreeing to take part in the research, the participant consents to the research team collecting and using this information for the research project. The participant’s information will be collected and managed using REDCap electronic data capture tools hosted by St Vincent’s Health Network. REDCap (Research Electronic Data Capture) is a secure, web based application designed to support data capture for research studies.

All audio-recordings, transcripts, information and analysed data will be securely stored and password protected electronically on a secure St Vincent’s Health Network server. Only the project research team will have access to data collected in this study. Any written information collected from the participant will be de-identified, meaning any personal details that can identify them will be removed. This data will be maintained securely for 5 years from the time of publication. The participant’s information will only be used for the purpose of this research project and it will only be disclosed with their permission, except as required by law.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified.

In accordance with relevant Australian and/or New South Wales and other relevant laws, the participant has the right to request access to the information about them that is collected and stored by the research team. They also have the right to request that any information with which they disagree be corrected. Please inform the research team member named at the end of this document if the participant would like to access their information

**12 Complaints and compensation**

If the participant suffers any distress or psychological injury as a result of this research project, they should contact the research team as soon as possible. They will be assisted with arranging appropriate treatment and support.

**13 Who has reviewed the research project?**

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

The ethical aspects of this research project have been approved by the HREC of St Vincent’s Hospital Sydney and the Aboriginal Health and Medical Research Council Human Research Ethics Committee.

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

**14 Further information and who to contact**

If the participant has any complaints or questions about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then they may contact one of the following people.

Name: Lauren Christie

Position: Principal Investigator

Telephone: +61 436 853 797

Email: lauren.christie@svha.org.au

**Complaints contact person**

Name Research Office Manager

Position Research Office Manager

Telephone 02 8382 4960

Email [SVHS.Research@svha.org.au](mailto:SVHS.Research@svha.org.au)

**Local Research Office contact (Research Governance Officer)**

Name Research Governance Officer

Position Research Governance Officer

Telephone 02 8382 4960

Email [SVHS.Research@svha.org.au](mailto:SVHS.Research@svha.org.au)

**Thank you for taking the time to consider this study.**

**If the participant wishes to take part in it, please sign the attached consent form.**

**This information sheet is for them to keep.**

**Consent Form (Patient participant) –** *Person responsible providing consent*

|  |  |
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| **Location** | St Vincent’s Health Network Sydney |

**Declaration by Person Responsible**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

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

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

I freely agree to the participant taking part in this research project as described and understand that I am free to withdraw them at any time during the project without affecting their future care.

I understand that I will be given a signed copy of this document to keep.

**Please tick the appropriate boxes:**

* **I would prefer to participate in an in-person interview**
* **I would prefer to participate in an online interview**
* **I would like to receive a summary of the research findings once the project is complete by email.**
* **My contact details to arrange the interview are:**

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|  | | | | | | | |
|  | Name of Participant (please print) | |  |  | |  |  |
|  | Name of Person Responsible  (please print) | |  |  | |  |  |
|  | Relationship of Person Responsible to Participant | |  |  | |  |  |
|  | | | | | | | |
|  | Signature of Person Responsible |  | | | Date |  |  |
|  | | | | | | | |

**Declaration by Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the person responsible for the participant has understood that explanation.

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|  | | | | | | |
|  | Name of Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† An appropriately qualified member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

**Form for Withdrawal of Participation –** *Person responsible providing consent*

|  |  |
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| **Location** | St Vincent’s Health Network Sydney |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine care, or my relationships with the researchers or St Vincent’s Health Network.

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|  | | | | | | | |
|  | Name of Participant (please print) | |  |  | |  |  |
|  | Name of Person Responsible  (please print) | |  |  | |  |  |
|  | Relationship of Person Responsible to Participant | |  |  | |  |  |
|  | | | | | | | |
|  | Signature of Person Responsible |  | | | Date |  |  |
|  | | | | | | | |

In the event that the participant’s decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

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**Declaration by Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the person responsible for the participant has understood that explanation.

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| --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |
|  | Name of Researcher (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project. Note: All parties signing the consent section must date their own signature.