Government of South Australia
SA Health

Northern Mental Health Service
Clinical Psychosocial Rehabilitation Program
'Club 84'
84 Yorktown Road
Elizabeth Park SA 5113
Telephone: 7485 4500 Fax: 7485 4511

# Participant Information Sheet/Consent Form
## Interventional Study

Northern Clinical Psychosocial Rehabilitation Program, Club 84

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|---|---|
| **Title** | A 12 week research project targeted for adult consumers within an adult rehabilitation setting to implement a Personal Safety Tool for self-management and crisis management |
| **Short Title** | Personal Safety Tool Research Project |
| **Protocol Number** | AD02737 |
| **Project Sponsor** | Michelle Oliver (Team Leader/Occupational Therapist) |
| **Coordinating Principal Investigator/ Principal Investigator** | Amily Daw and Anna Francis (Project Leads and Occupational Therapists) |
| **Location** | Northern Clinical Psychosocial Rehabilitation Program- 84 Yorktown Road, Elizabeth Park, SA 5113 |

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# Part 1 What does my participation involve?

### 1 Introduction

You are invited to take part in this research project. This research project has been developed to support participants at Club 84 who have a mental health diagnosis or emerging mental illness. A Personal Safety Tool has been developed for this research project and is used as a form of sensory intervention. This tool will aim to assist you to identify what you are like when you are well, what situations cause you distress and the signals of your distress. The Personal Safety Tool will offer individualised practical suggestions for self-soothing and calming during crisis situations.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the intervention and processes involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a family member, friend, carer, mental health support or your doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

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

- Understand what you have read.
- Consent to take part in the research project.
- Consent to participate in completing and using a Personal Safety Tool with Project Leads support.
- Consent to the use of your personal and health information as described.

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

## 2 What is the purpose of this research?

The aim of the research project is to assist you to identify what you are like when you are well, what situations cause you distress and the signals of your distress. The Personal Safety Tool will offer individualised practical suggestions for self-soothing and calming strategies during crisis situations. At present there is not a Personal Safety Tool being utilised at Club 84. This highlights the need to implement and trial the use of Personal Safety Tools as a form of crisis management within a mental health community rehabilitation setting. The research project aims to support you to implement a Personal Safety Tool to help you self-manage your symptoms, identify helpful coping strategies and reduce chance of crisis and feelings of distress.

The research project will aim to trial the effectiveness of Personal Safety Tool over a 12 week period. If outcomes determine that it is beneficial it will be considered for ongoing use for consumers at Club 84. The research project will additionally assist Club 84 staff to better understand your needs and help you to feel safe and in control during stressful situations.

If research project outcomes are proven to be beneficial, the Personal Safety Tool may be considered for use across other community mental health settings and contribute towards future education and research. The research project aims to additionally support better communication across public mental health services and improve continuity of consumer care.

Personal Safety Tools have been well established in many inpatient and community mental health settings internationally. Project Leads have extensively reviewed recent literature relating to Personal Safety Tools within mental health and it is evidenced to be an effective intervention tool in reducing distress and crisis presentations.

Project Leads have consulted and worked alongside Club 84 consumers, staff and volunteers and in addition Peer Workers from Club 84 and The Gully (North East Psychosocial Rehabilitation Program) to develop the Personal Safety Tool. This tool has further been presented to management and endorsed for use in this research project.

This research has been initiated by Project Leads, Anna Francis (Occupational Therapist) and Amily Daw (Senior Occupational Therapist).

## 3 What does participation in this research involve?

To participate in the Personal Safety Tool research project you will need to sign this consent form.

- Waiving consent:
    - Project Leads will not consider waiving consent as a part of the research project. At any stage participants choose to revoke their consent form they will no longer be able

to participate in the research project. Project Leads will however maintain a duty of care in follow up and debriefing to participants who revoke consent.

Screening for eligibility

- Participants eligible for the research project have been carefully screened by Project Leads by meeting the following criteria:
  - Adult 18-65 years
  - Mental Health Diagnosis including:
  - Borderline Personality Disorder
  - Anxiety
  - Schizophrenia
  - Personality Disorder
  - Dissociative identity disorder
  - Obsessive Compulsive Disorder
  - Post-Traumatic Stress Disorder
  - Registered consumer with Northern Community Mental Health Services
  - Registered consumer with the Northern Clinical Psychosocial Rehabilitation Program
  - Minimum age 18 Years - Maximum age 65 Years
  - Gender Both males and females

- There will be no control group as a part of this research project. All participants involved in the research project will all be utilising the same interventions and procedures.

**Procedures**

It is predicted that the Personal Safety Tool study will run over a 6 month period. It will divided into 4 separate phases:

- Planning phase- 8 week period
  - Recruitment and consent to be completed.
  - Participants will undertake a pre-evaluation with Project Leads.
- Implementation phase- 12 week period
  - Project Leads will work to support participants to develop an individualised Personal Safety Tool.
  - Ongoing support, review and evaluations offered to participants by Project Leads including questionnaires, semi structured interviews and self-rating scales.
  - Participants will engage in weekly face to face debriefing and phone calls with Project Leads.
- Evaluation/closure phase- 2 week period
  - Post-evaluation at the end of the 12 week period to determine key outcomes.
  - Further debriefing and support will be offered by Project Leads.
  - Closure:
    This will be offered at the end of the 12 week research project. Project Leads will continue advising participants of progression of the project and timeline for completion to deter any apprehension of cessation of the project and offer support as needed.
  - One on one debriefing will be offered to participants at the end of the research project to discuss outcomes and ensure there has been no adverse effects and provide any necessary support.
- Dissemination phase- 2 week period
  - Please refer to below.

**Patient follow-up**

- Weekly engagement with Project Leads throughout a 12 week period. This will involve weekly scheduled face to face debriefing sessions (15-30 minutes) and weekly phone calls.
- Dissemination- If project outcomes are used for publishing/research purposes participants will have the opportunity to access research outcomes. This would be advised via letter notifying that research has been completed.
- Post research project follow-up with participants in the form of a semi-structured interview- This is predicted to be 12 months after the final evaluation/analysis is completed.

Reimbursement/costs:

- There are no additional costs associated with participating in this research project, nor will you be paid.
- In-kind contributions will be offered to participants, in ways of tea/ coffee and food where appropriate.
- Participants will be offered transport support if required to allow for participation in the project process.

How the research will be monitored:

- Project Leads will monitor participants on a weekly basis though regular communication strategies such as face to face contact, telephone calls, debriefing.

The commitment required by the participant:

- Participants will be required to understand and agree to the terms stated in this consent form and sign accordingly.
- Participants will be required to participate in the pre and post evaluation measures (self-rating scale and questionnaire) with Project Lead support.
- Participate in weekly face to face or phone contact with Project Leads over the 12 week period (approx. 15-30 minutes per week) to complete evaluation measures (self-rating scale and questionnaire) and face to face debriefing if necessary.
- Participate in any follow up appointments after the 12 week research project.
- Participants to actively use developed Personal Safety Tool during the 12 week period to support evaluation and measuring outcomes.

Bias:

- Risk of bias will be reduced through ensuring participants complete their individualised Personal Safety Tool with only Project Lead face to face support and not influenced by other participant's answers.
- Project Leads will empower participants to formulate their own answers and not answer questions for the on the Personal Safety Tool.
- Project Leads have considered risks of bias in data collection. Therefore, the use of both qualitative and quantitative data has been selected.
- Participants will be completing weekly self-rating scales which will be completed in numerical form and there is minimal risk of researchers incorrectly interpreting results.

## 4 What do I have to do?

- Participants will not be expected or requested to make any lifestyle changes.
- Participants will be recommended to maintain their current mental and physical health management plan and care e.g. medications, medical reviews and contact with health services.
- If possible, participants will need to notify Project Leads of any changes to their mental state or capacity to participate in the research study. Please note Project Leads will support ongoing monitoring of participants mental health through reviewing medical records and liaising with mental health supports as required.

## 5 Other relevant information about the research project

- Sample size and location:
  - There will be 10-12 participants taking part in the research project at Club 84.

- Services involved:
  - The research project will be only conducted with participants engaging at Club 84.

- Cultural considerations:
  - Participants will not be excluded whose primary language is other than English, the use of interpreting services will be made available if required.

## 6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not effect your engagement at Club 84 and mental health care and treatment. It will additionally not effect your relationship with Project Leads, Club 84 staff or other mental health supports.

## 7 What are the alternatives to participation?

- Current engagement will not change at the Northern Clinical Psychosocial Rehabilitation Program by undertaking this research project. The research project is an additional Occupational Therapy based intervention that is being trialled.

## 8 What are the possible benefits of taking part?

- It is predicted that participants will gain a greater awareness and self-management of their symptoms to prevent crisis and feelings of distress.
- Participants will gain greater insight of their personal sensory based strategies to manage in distress.
- Reduction in crisis presentations e.g. contacts to Mental Health Triage, presentations to Emergency Departments and inpatient readmissions/length of stay in care.
- Potential for the Personal Safety Tool to be used within Club 84 post-trial as part of practice if outcomes are proven beneficial.

## 9 What are the possible risks and disadvantages of taking part?

The Personal Safety Tool has low risks associated with its development and use, however Project Leads have completed a risk assessment and detailed the potential participant related risk below. This risk has been deemed unlikely to occur and strategies have been considered and listed below to minimise impact.

There may be risks associated with this research study that Project Leads do not expect or have not predicted. It is important and your responsibility to inform the Project Leads or your mental health supports immediately about any concerns or negative symptoms you may experience.

| **Potential Risk:** | **Risk likelihood rating:** | **Strategy to manage risk:** |
|---|---|---|
| Potential for development and ongoing use of the Personal Safety Tool to trigger participants to experience negative mental health symptoms. | Unlikely to occur | - Project leads to provide ongoing contact through weekly face to face meetings and phone contacts.<br>- Project Leads to provide debriefing as required. Project Leads are trained mental health clinicians/Occupational Therapists.<br>- Project Leads to make environmental considerations e.g. advising participants of nearby exits.<br>- Project Leads can liaise with additional mental health supports if required for more assertive follow up. |

## 10 What if new information arises during this research project?

- Sometimes during the course of a research project, new information becomes available about the interventions which are being studied. If this happens, your Project Leads will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your Project Leads will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

- Also, on receiving new information, your Project Lead's might consider it to be in your best interests to withdraw you from the research project. If this happens, they will explain the reasons and arrange for your regular health care to continue.

## 11 Can I have other treatments during this research project?

- Participants will be recommended to maintain their current mental and physical health management plan and care e.g. medications, medical reviews and contact with health services. Participants are encouraged to notify Project Leads or mental health supports if there is any significant changes to their mental or physical health management that may impact on their participation in the research project.

## 12 What if I withdraw from this research project?

- If you decide to withdraw from the project, please notify Project Leads before you withdraw. This notice will allow Project Leads to support closure from the research project and support and establish any additional mental health supports.

- If you do withdraw your consent during the research project, the Project Leads will not collect additional personal information from you, 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. If you withdraw, data will only be utilised as part of the data analysis and results by participants who have completed 50% of participation (6 weeks) in the research project. If you do not want Project Leads to do this, you must tell them before you join the research project.

- If participants are discharged from Club 84 during the 12 week research project they will not be able to continue in the research project. Project Leads will include participant's current progress utilising the Personal Safety Tool and involvement in the research project within their discharge summary. Additionally, Project Leads will devise a management plan liaising with relevant supports for follow up.

- If participants mental state deteriorates during the research project and impacts on their capacity to engage, Project Leads will use their clinical judgement and negotiate with the participant and relevant mental health supports to discuss plans for withdraw or ongoing engagement in the research project.

- Project Leads will support participants to opt in and opt out of the research project at any time if they request. Opting in of the research project will only be permitted if participants have completed the pre-evaluation, and if this is prior to week 6 of the research project. This will support a 50% of participation of the study to increase credibility and analysis.

## 13 Could this research project be stopped unexpectedly?

- It is not predicted that the research project will be stopped unexpectedly.
  This unlikely event may occur if:
  - Participants present with adverse effects from utilising their Personal Safety Tool.
  - Project Leads are unable to meet work roles and responsibilities due to unforeseen circumstances.

## 14 What happens when the research project ends?

- Project Leads will provide one on one face to face post-trial meeting's with all participants to discuss outcomes and success of the project. This appointment time with be offered via letter. This is predicted to be completed during the dissemination phase (four weeks post the research project).

- If outcomes support use of the Personal Safety Tool participants will be supported and encouraged to continue utilising their Personal Safety Tool at Club 84.

- Once Project Leads have completed the final analysis of the research project (predicted early November 2017) participants will be offered with a summary of the results. Project Leads will consider presenting outcomes within the Club 84 community through a consumer forum.

- If the Personal Safety Tool is endorsed by management to be used on an ongoing basis at Club 84 participants will be notified via letter, face to face or phone call.

- If project outcomes are used in the future for publishing/research purposes participants will be notified via letter. If used for research purposes participants data from the research project will be de-identified.

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

### 15 What will happen to information about me?

- Data collected or used:

    - Data will be collected through both qualitative and quantitative measures.
    - Only Project Leads will have access to identified data during the initial data collection phase.
    - During the data analysis phase Project Leads will ensure data is de-identified.

- Data storage and access:

    - Data from the research project will be stored on a passcode secure electronic data base, which only project leads will have access to. Hard copies will be stored securely in case notes in a locked compactus at Northern Community Mental Health Service.
    - Project Leads and primary mental health supports will be able to access participants Personal Safety Tool via hard copy and through the Community Based Information System (CBIS) which is passcode secured. Participant information will only be accessible by mental health clinicians involved in the participants care.
    - Any hard copy personal information will be stored securely in locked case notes/compactus. Other copies will be scanned and stored on secure/passcode protected electronic data base which Project Leads can only access.
    - Any information that needs to be destroyed will be shredded through the locked confidential bin.
    - All storage, destruction and access of clinical and personal information meet and align with the Privacy Act, Confidentiality requirements and Mental Health Act and Standards.

- Data storage

    - It is predicted that the data will be stored for no longer than 5 years, which meets SA Health requirements.
    - Copies of the participants Personal Safety Tool will be stored and archived in case notes at Northern Community Mental Health Service.

- Future use of data:

    - There is the potential that data collected from the research study may be utilised for future research in supporting sensory based interventions and promoting self-management for consumers within adult mental health settings. If used for research purposes data will be de-identified.

- Data storage continued:
  - By signing the consent form you consent to the Project Leads collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Identifiable information will be stored on a password secure computer system only accessible to the Project Leads. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

- Additional health information relating to participants will be sought from their health records:
  - Information about you may be obtained from your health records (e.g. in-patient admissions, contact with crisis services, Emergency Department presentations) held at Club 84 and Northern Community Mental Health Service for the purpose of this research. By signing the consent form you agree to the Project Leads accessing health records if they are relevant to your participation in this research project.

- Potential for publication of results
  - 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 you cannot be identified, except with your permission. All personal information and data will be de-identified.

- Recording of participation noted in health records:
  - Information about your participation in this research project may be recorded in your health records. This can be accessed by primary mental health supports involved in your care.

- Accessing own information/data:
  - In accordance with relevant Australian and/or South Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the Project Leads named at the end of this document if you would like to access your information.
  - Any information obtained for the purpose of this research project and for the future research described in Section 15 that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

## 16 Complaints and compensation

  - If you suffer any negative effects as a result of this research project, you should contact the Project Leads as soon as possible and you will be assisted with arranging appropriate supports.
  - Relevant information can be provided to participants by Project Leads and Project Sponsor relating to formal complaint processes.

## 17 Who is organising and funding the research?

- Organising

  - This research project is being conducted by SA Health/ Northern Mental Health/ Northern Clinical Psychosocial Rehabilitation Program- Club 84

## 18 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 The Queen Elizabeth Hospital Human Research Ethics Committee (TQEH/LMH/MH)

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.

## 19 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any concerns which may be related to your involvement in the project (e.g. any negative effects), you can contact the **Project Leads** on **7485 4500**.

If you have a mental health emergency please call the **Mental Health Triage** (24 hour Crisis and Emergency Assistance) on **13 14 65**

**Clinical contact person(s)**

| | |
|---|---|
| Name | Anna Francis |
| Position | Occupational Therapist |
| Telephone | 7485 4500 |
| Email | Anna.Francis@sa.gov.au |

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|---|---|
| Name | Amily Daw |
| Position | Occupational Therapist |
| Telephone | 7485 4500 |
| Email | Amily.Daw@sa.gov.au |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

| | |
|---|---|
| Name | Alison Barr |
| Position | NALHN Research Governance Officer |
| Telephone | 8182 9346 |
| Email | Alison.Barr@sa.gov.au |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

**Reviewing HREC approving this research and HREC Executive Officer details**

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|---|---|
| Reviewing HREC name | Heather O'Dea |
| HREC Executive Officer | HREC Executive Officer |
| Telephone | 8222 6841 or 8222 4139 |
| Email | Heather.odea@sa.gov.au |

**Local HREC Office contact (Single Site -Research Governance Officer)**

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|---|---|
| Name | Alison Barr |
| Position | NALHN Research Governance Officer |
| Telephone | 8182 9346 |
| Email | Alison.Barr@sa.gov.au |

# Consent Form

| | |
|---|---|
| **Title** | A 12 week research project targeted for adult consumers within an adult rehabilitation setting to implement a Personal Safety Tool for self-management and crisis management |
| **Short Title** | Personal Safety Tool Research Project |
| **Protocol Number** | AD02737 |
| **Project Sponsor** | Michelle Oliver (Team Leader/Occupational Therapist) |
| **Coordinating Principal Investigator/ Principal Investigator** | Amily Daw and Anna Francis (Project Leads and Occupational Therapists) |
| **Location** | Northern Clinical Psychosocial Rehabilitation Program- 84 Yorktown Road, Elizabeth Park, SA 5113 |

**Declaration by Participant**

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 give permission for my doctors, other health professionals, hospitals and/or mental health services outside of Club 84 to release information to Project Leads concerning my mental illness, care and treatment for the purposes of this project. I understand that such information will remain confidential.

In addition, I give permission for Project Leads to release information to relevant primary mental health supports (such as GP, private and public Psychiatrist and Care Coordinator) concerning my mental illness, care and treatment for the purposes of this project.

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

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

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

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

**Declaration by Study Doctor/Senior Researcher†**

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

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior 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

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|---|---|
| **Title** | A 12 week research project targeted for adult consumers within an adult rehabilitation setting to implement a Personal Safety Tool for self-management and crisis |
| **Short Title** | Personal Safety Tool Research Project |
| **Protocol Number** | AD02737 |
| **Project Sponsor** | Michelle Oliver (Team Leader/Occupational Therapist) |
| **Coordinating Principal Investigator/ Principal Investigator** | Amily Daw and Anna Francis (Project Leads and Occupational Therapists) |
| **Location** | Northern Clinical Psychosocial Rehabilitation Program- 84 Yorktown Road, Elizabeth Park, SA 5113 |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my engagement at Club 84.

Name of Participant (please print) _____

Signature _____ Date _____

Description regarding verbal withdraw:

**Declaration by Study Doctor/Senior Researcher†**

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

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

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