Northern Clinical Psychosocial Rehabilitation Program
Club 84

Project Description

A 12 week pilot study targeted for adult consumers within a community mental health rehabilitation setting to implement a Personal Safety Tool for self-management and crisis management

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Government of South Australia
SA Health

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Project Title

Public title

A 12 week pilot study targeted for adult consumers within a community mental health rehabilitation setting to implement a Personal Safety Tool for self-management and crisis management.

Scientific title

A pilot study on the use of a Personal Safety Tool for self-management and crisis management within a clinical mental health rehabilitation setting.

Version Number: 2

Project Team Roles and Responsibilities

All investigators and key project team members listed below are affiliated with the Northern Adelaide Local Health Network (NALHN), Northern Mental Health Services.

Project Team:

Role	Name	Position	Service	Responsibilities
Project Sponsor	Michelle Oliver	Team Leader/ Senior Occupational Therapist (OT)	Northern Clinical Psychosocial Rehabilitation Program: Club 84	> Facilitate approval > Support strategic direction of project > Ongoing communication and progression to Clinical Governance > Ongoing supervision and support to Project Leads
Project Leads	Anna Francis	OT		> Establishing working parties and meetings with relevant participants > Coordinate the project team and assign work tasks > Opening project on NALHN Quality improvement register through the NALHN intranet > Conduct project planning activities > Reviewing current literature and forming literature review > Forming and implementing communication plan > Supporting recruitment phase of project > Forming consent forms and completing collaboratively with participants > Supporting implementation phase of project > Monitor and drive project progress > Provide relevant stakeholders with project status updates and provide in-service > Implementing pre and post evaluation methods > Providing weekly debriefing to participant group > Ongoing updating of data base and adhering to confidentiality requirements > Complete full evaluation/analysis highlighting outcomes and plans for future implementation
	Amily Daw	Senior OT		

Working Party	Name	Position	Service	Responsibilities
	Michelle Oliver	Team Leader/ Senior Occupational Therapist (OT)	Northern Clinical Psychosocial Rehabilitation Program: Club 84	> Responsible for supporting the Project Leads with the development and implementation of the Project Plan. > Provide advice and information and resources to assist in delivery of key project outcomes related to project goals and objectives.
	Amily Daw	Senior OT	Northern Clinical Psychosocial Rehabilitation Program: Club 84	
	Anna Francis	OT	Northern Clinical Psychosocial Rehabilitation Program: Club 84	
	Ryan Kelly	OT	Northern Clinical Psychosocial Rehabilitation Program: Club 84	
	Laura Withers	OT	Northern Clinical Psychosocial Rehabilitation Program: Club 84	
	Deanne Clayton	Peer Specialist	Northern Clinical Psychosocial Rehabilitation Program: Club 84	
	Bronwyn Fisher	Peer Specialist	North- East Clinical Psychosocial Rehabilitation Program: The Gully	
	Chloe Strand	Consumer	Northern Clinical Psychosocial Rehabilitation Program: Club 84	
	Sharon Tennant	Consumer/ volunteer	Northern Clinical Psychosocial Rehabilitation Program: Club 84	

Resources

Resources necessary for the project to be conducted

- IT facilities SA Health, NALHN. Pass code secure and meets confidentiality requirements of mental health act. Range of existing sensory tools which are available at the Northern Clinical Psychosocial Rehabilitation Program, ‘Club 84’.

Funding/ support being sought or secured

- The pilot will be cost neutral.

Background

Literature review

Project leads have reviewed a number of research articles and have liaised with services globally regarding current use and effectiveness. This has provided supporting evidence to justify the need to pilot the use of implementing a Personal Safety Tool Pilot study within community mental health rehabilitation setting.

At present there is not a Personal Safety Tool being utilised at the Northern Clinical Psychosocial Rehabilitation Program to support consumers self-management and self-awareness when in distress or in crisis.
It has been discovered that other Occupational Therapists across Northern Mental Health services are using various Personal Safety Tool highlighting limited continuity of the use and access of the Personal Safety Tool across services.

Personal Safety Tools have been well established in many inpatient and community mental health settings. An example of this is highlighted in a study conducted at The Mercy Psychiatric Unit in Werribee, Victoria where individualised Personal Safety Tool's were collaboratively completed with consumers and staff. The aim was to help both consumers and staff to identify triggers and early warning signs to highlight signs of distress. The plan then offers practical suggestions for sensory and calming strategies that are easily available. (Chalmers at al. 2012).
The use of sensory tools guided by someone (often a clinician or peer-worker) who is trained in sensory modulation as a clinical intervention (Te Pou o te Whakaaro Nui 2011). This presses on us to consider the need for a site specific Personal Safety Tool at the Northern Clinical Psychosocial Rehabilitation to support greater self-management and capacity in consumers in managing their symptoms and overall mental health care.

In the first instance we are wanting to conduct an overall a six-month pilot study of the Personal Safety Tool at the Northern Clinical Psychosocial Rehabilitation however, in order to conduct a Personal Safety Tool pilot we are first seeking endorsement and support for establishing a time-limited Implementation Working Party to progress this pilot to a site specific crisis management tool and report on the evaluations at the end of the specific period of the pilot.

References

- Personal Safety Tool (Cooley Dickinson Hospital, 2006)
- Chalmers, A, Harrison, S, Mollison, K, Molloy, N and Gray, K 2012, 'Establishing sensory-based approaches in mental health in-patient care: A multidisciplinary approach', Australasian Psychiatry, vol. 20, no. 35, pp. 35-39.
- Te Pou o te Whakaaro Nui, 2011, *Sensory modulation in mental health clinical setting: A review of the literature*, Auckland. Te Pou o te Whakaaro Nui

Rationale and justification:

Personal Safety Tools are consumer-centered and drawing from the principles of recovery and trauma informed care. These principles help to foster increased safety and resiliency throughout engagement in rehabilitation and upon independent living in the community. The Personal Safety Tool aims to support consumers who are distressed and agitated to regain a sense of calm by using a range of individualised sensory strategies and tools to moderate sensory input and support self-regulation.

At present there is not a Personal Safety Tool being utilised at the Northern Clinical Psychosocial Rehabilitation Program to support consumers self-management and self-awareness when in distress or in crisis. Consumers have identified challenges in self-managing their symptoms during crisis and consequently contact or present to mental health crisis services and emergency departments on multiple occasions. It has been explored and noted that other Occupational Therapists across Northern Mental Health services are using various versions of Personal Safety Tool's, highlighting limited continuity of the use and access of the Personal Safety Tool's across services.

Project Leads will work collaboratively with 10-12 participants to complete a PST as part of a 12 week pilot study. The Personal Safety Tool will adopt a strengths based approach and promote greater self-management, self-awareness and empowerment in participants managing their symptoms and health care. Participants will be made aware that their Personal Safety Tool is a working document and they will be provided a copy for their reference. If outcomes are positive the PST will be considered for ongoing use in practice at the Northern Clinical Psychosocial Rehabilitation Program.

Research questions, Aim, Objectives, Hypothesis

Research questions:
Are Personal Safety Tools effective in the reduction of crisis presentations in a community mental health setting?

Aim:
The Personal Safety Tool aims to support consumers who are distressed and agitated to regain a sense of calm by using a range of individualised sensory strategies and tools to moderate sensory input and support self-regulation. Clinical and non-clinical staff at the Northern Clinical Psychosocial Rehabilitation Program will work collaboratively with consumers to complete a Personal Safety Tool to be included in their Mental Health Care Plan. The Personal Safety Tool will adopt a strengths based approach and promote greater self-management, self-awareness and empowerment in consumers managing their symptoms and health care.

Objectives:

- Self-management of various mental health conditions (personality disorders, anxiety, schizophrenia, obsessive Compulsive disorder and post-traumatic stress disorder) assessed by Sensory Modulation
- Adopts self-management approach though supporting consumers to identify their individualised coping strategies to manage symptoms of their mental health.
- Reduction in Emergency Department presentations and readmissions.
- Aligning with the National Framework for Recovery Oriented Mental Health Services

- Utilising least restrictive approach and aligning with Trauma Informed Care and Practice principles.
- Consumers in community mental health setting self-managing their symptoms in crisis situations
- Potential for the Personal Safety Tool to be used across different mental health sites which supports Continuity of communication and consumer care.
- Strengthen partnerships between Occupational Therapists within northern public mental health services and establish greater flow through of information across services. This will in turn support continuity of communication and consumer care.

Hypothesis:
Adult consumers with a mental health diagnosis will have increased skills in self-management and reduce likelihood of crisis presentations through utilising a Personal Safety Tool.

Expected outcomes

The Personal Safety Tool aims to support adult consumers within a community mental health setting who are distressed and agitated to regain a sense of calm through identifying their triggers, early warning signs and using a range of individualised sensory strategies and tools to self-soothe and self-regulate.

The Personal Safety Tool will adopt a strengths based approach and promote greater self-management in consumers managing their symptoms and mental health care. The Personal Safety Tool will work to reduce emergency department presentations, inpatient admissions and length of care in hospital. The Personal Safety Tool adopts recovery and trauma informed care principles. It additionally aligns with the Mental Health act and supports least restrictive approach e.g. reducing need for restraint and seclusion.

The pilot study will work to strengthen partnerships between Occupational Therapists within northern public mental health services and establish greater flow through of information across services. This will in turn, support continuity of communication and consumer care.

Project Design

Research project setting

- Activities of the project including research, development and implementation will take place at the Northern Clinical Psychosocial Rehabilitation Program.
- Utilisation of the Personal Safety Tool by Consumers over the duration of this pilot study will be at the Northern Clinical Psychosocial Rehabilitation Program, potentially inpatient setting, and participant homes and within their community.

Methodological approach

- Interventional/Clinical Trials Research Method
- Rationale behind decision for this method is due to with people via active participation including the capturing of data relating to these people.
- Development of the Personal Safety Tool was rationalised based on review of the evidenced based research, literature and consultation with consumers, experiences with consumers.

Participants

Description and number

- Participants aged 18-65 with a mental health diagnosis within a clinical mental health rehabilitation setting. 10-12 Participants will be selected for the pilot study. Even distribution of male, female and age has been considered when review demographic reports at the Northern Clinical Psychosocial Rehabilitation Program.

Inclusion and exclusion criteria

- Key inclusion 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
- Key exclusion criteria
    - Poor judgement / insight
    - Cognitive impairment impacting on decision making / ability to make informed consent

Sample size and statistical and power issues

- 10-12 Participants will be selected for the pilot study.
- Even distribution of male, female and age has been considered when review demographic reports at the Northern Clinical Psychosocial Rehabilitation Program.

- Due to restraints in population size the pilot study will be restricted in sample size. This is predicted to potentially decrease the power of pilot statistics but will not likely impact the credibility of the data and outcomes produced.

Participant recruitment strategies and timeframes

Whether screening takes place before or after consent,

- Screening will take place before the consent process

Who initially approaches the participants?

- Recruitment will be an informal process approx. 6 months prior and potential participants will be approached face-to-face by either of the project leads during presentation at the Northern Clinical Psychosocial Rehabilitation Program or by appointment at this location.

How much time does a potential participant have to consider participation?

- Project leads have been providing in-service and updates to potential participants at the Northern Clinical Psychosocial Rehabilitation Program about the project for approximately 6months.
- The potential participants will have up until 18th to 29th September 2017 to consider participation to complete pre-evaluation and develop individualised Personal Safety Tool. This will be a total of five weeks to consider participation from recruitment stage to commencing the pilot study.

How do participants receive the recruitment documentation?

- Project Leads will provide recruitment documentation to participants during the recruitment phase between periods 1st to 15th September 2017. This will outline a brief summary of the pilot study including proposed objectives in addition to a timeline when the study is planned to commence and end, contact details and participant expectations during the project study.

Whether the profile and number of projected participants are appropriate to answer the research question?

- Yes, the project leads have weighed up the maximum capacity of participants they can afford to have in the study given time constraints and total number of consumers meet the inclusion criteria.

Whether the recruitment strategy is fair and promotes distributive justice?

- To ensure a fair and equitable distribution of participants i.e. age, sex and diagnosis demographics, a demographic report has been used to break down age and gender profiles

The potential for undue influence, coercion or exploitation

- The project leads will adhere to the Confidentially Act which safeguards participants from any undue influence, coercion or exploitation through the project process
- Project leads will consider utilising Club 84 Peer-specialist (lived experience worker) to support the recruitment process. This aims to reduce any possible apprehension and /or pressure that participants may experience to participate in the study (e.g. prevent authoritarian approach). Provide opportunity for potential participants to debrief or express concerns to a peer / non-clinical staff.
- Consumers will be approached by the project leads in a private setting during the recruitment phase.

- Participation in the project will be voluntary this will be made clear in the consent forms and recruitment documentation, in addition to their rights being made clear to opt out at any stage.

Whether any payments or in-kind contributions are being offered to participants,

- Project Leads will adhere to the National Standards for MH Service
- And provide in-kind contributions to participants, in ways of tea/ coffee and food where appropriate.
- Participants will also be offered transport support to support participation in the project process if necessary, to ensure consumers will not be out of pocket financially.

The exclusion of specific groups, who would otherwise be eligible to participate in and may wish to be included in this project,

- N/A, as the Project will only be targeting the consumer group at the Northern Clinical Psychosocial Rehabilitation Program.
- Any issues related to the inclusion or exclusion of people whose primary language is other than English, and
- Consumers will not be excluded whose primary language is other than English, the use of interpreting services will be made available.

The potential for 'over-surveying' one or more groups/populations.

- N/A, as the Project will only be targeting the consumer group at the Northern Clinical Psychosocial Rehabilitation Program, therefore all participants will be surveyed equally.
- The project leads have taken into consideration a range of pre and post evaluation methods to ensure content meets needs and skill levels of consumers, and is not perceived as overwhelming or could impact on their stress levels.
- In addition, both project leads have significant experience working with the participant demographic and skills in evaluating various groups/ projects. This prior experience will be drawn upon to further ensure this process is not perceived as overwhelming or could impact on their stress levels.

Consider the value of "arms-length" recruitment where it could be perceived that the researcher has an unequal and/or dependent relationship with prospective participants.

- The project leads will ensure that participants are treated equally and fairly through working to consider and meet the Mental Health standards (e.g. standard 1 rights and responsibilities, standard 3 Consumer and Carer participation and standard 10 Delivery of Care).
- Project leads are trained mental health clinicians working within a diverse consumer group who may also experience comorbid cognitive impairment or trauma background/attachment challenges. Project Leads have strategies in place to mitigate risks around the potential of participants developing unequal and or dependent relationships including communication strategies, appropriate relationships and social engagement. If there are any concerns relating unequal and/or dependent relationship with prospective participants Project Leads will liaise with Project Sponsor and or participant treating mental health team/doctor for management and planning. Approach/es to provision of information to participants and or consent

Research activities

Participation commitment

- Project leads to support participants to develop an individualised Personal Safety Tool.

- Weekly engagement with Project Leads throughout a 12 week period. This will involve weekly face to face debriefing and phone calls.
- Participants to utilise their developed Personal Safety Tool during the 12 week pilot study.
- Participate in pre and post evaluation and ongoing review with Project Leads.

Project duration

- It is predicted that the Personal Safety Tool study will run over a 6 month period.
- Planning phase- 8 week period
- Implementation phase- 12 week period
- Evaluation phased- 2 week period
- Dissemination phase- 2 week period

Patient follow-up

- **Weekly engagement with Project Leads throughout a 12 week period**.
  - Project leads will aim for weekly face to face contact with participants to debrief and provide questionnaire and self-rating scales. It is expected that this will take between 15-30 minutes.
  - If participants are unable to attend face to face appointments project leads will provide phone call as an alternative.
  - Project leads will notify participants that phone calls will be required as an alternative if face to face appointments are not achievable for the participant that week.

  Access to help for participants distressed by involvement will include:
  - Individual debriefing with project leads
  - Club 84 staff (Peer support (1), Activity Supervisor (1), other Occupational Therapists (3)
  - Team Leader/Senior Occupational Therapist
  - Treating Care Coordinator through Northern Community Mental Health Service and/or Psychiatrist. All participants are linked in with a Care Coordinator or Psychiatrist through Northern Community Mental Health Service, where they receive primary mental health support
  - Mental Health Triage 24/7 crisis phone service. This is a state wide service. All consumers at Club 84 are oriented and aware how to contact this service.
  - Lifeline phone support
  - Emergency Department (This is a last resort and all other support options will be encouraged and explored prior)
  - Provide consumer feedback pamphlet to support opportunities for participants to report any feedback or complaints if they wish.
- **Evaluation**- pre and post evaluations will be completed by participants with Project Lead support as well as informal evaluations in form of questionnaires during weekly debriefing.
- **Closure**- This will be offered at the end of the 12 week pilot study. 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 debrief will be offered to participants at the end of the pilot study to discuss outcomes and ensure there has been no adverse effects and provide any necessary support.
- **Dissemination**- If project outcomes are used for publishing/research purposes participants will have the opportunity to access research outcomes. This would be offered via letter notifying that research has been completed.
- **Post pilot study 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.

Data collection/gathering

Techniques

- Data will be collected through both qualitative and quantitative measures.
- Sensory modulation/crisis management based self-rating scales and questionnaires which will be completed weekly during one on one debriefing with participants. Informal conversations with participants in regards to the pilot study will be documented and considered as a qualitative measure.
- Statistics through mental health crisis phone contacts (medical records), review of medical records and emergency department presentations.

Impact of and response to participant withdrawal

- Participation in the project will be voluntary this will be made clear in the consent forms and recruitment documentation, in addition to their rights being made clear to opt out at any stage.
- Data of participants who opt-out/withdrawal for more than 50% of the pilot study will become null and void.

Data Management

- Data of the Personal Safety Tool's Pilot will be stored on a passcode secure electronic data base, which only project leads will have access too. Hard copies will be stored securely in case notes in a locked compactus.
- The Personal Safety Tool's will be accessible, only via consent from the participant for other mental health clinicians involved in their care via the Community Based Information System (CBIS) which is passcode secure data base and only assessable by mental health clinicians involved in the participants care. All public health documentation aligns with the Privacy Act.
- The Personal Safety Tool's will be available to external nominated supports by the consumer, with their consent or at the participant's discretion.
- Only project leads will have access to identified data. If project pilot outcomes are to be used for research purposes, participants will be made aware of this during the consent process and will be informed that all data collected from the pilot study and their personal information will be de-identified and represented in numeric form.
- 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.
- Any information that needs to be destroyed will be shredded through the locked confidential bin.
- All participants will be offered consent to sign which will highlight storage, access and destruction of information data.
- Data will be archived electronically securely on a passcode protected data base which only Project Leads will have access to.
- 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 analysis

Matching and sampling strategies

Project Leads will be exploring both qualitative and quantitative measures for all data (as below):

Qualitative
Changes in self-rated distress/crisis management and self-management of symptoms

Quantitative
Changes in Emergency Department presentations, contacts to mental health crisis management services and readmissions to inpatient and length of stay from statistics (medical record)

The results from the pre- and post- data will be collected and analysed using statistical tests to determine if there is significance in the effectiveness of the Personal Safety Tool. This will be represented through t-tests and significance is indicative with scores less than 0.05. However, if there is a high level of drop-outs in the study Project Leads will examine and compare the frequencies and mean scores of the pre and post data without using statistical tests to determine any change in participant scores in self-rated distress/crisis management and self-management of symptoms.

Accounting for potential bias, confounding factors and missing information

- Risk of bias will be reduced through ensuring participants complete their individualised Personal Safety Plan 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.
- Participation in the project will be voluntary this will be made clear in the consent forms and recruitment documentation, in addition to their rights being made clear to opt out at any stage.
- Data of participants who opt-out/withdrawal for more than 50% of the pilot study will become null and void.

Statistical power calculation

- The pilot study has a small population size (n=10-12).
- Due to the small sample size Project Leads have considered and acknowledge that the statistical power calculation may not be useful for analysing data and outcomes.
- With this acknowledged by Project Leads it has been considered that utilising statistical tests such as t-tests will be utilised to measure change in pre and post data.

Data linkage

What linkages are planned or anticipated?

- Project Leads currently have no plans to link with other databases.
- This will be considered during the evaluation/analysis phase of the project.

Outcome measures

Data will be collected through a range of outcome measures including:

- Sensory modulation/crisis management based self-rating scales which will be completed weekly during one on one debriefing with participants
- Statistics mental health crisis phone contacts, review of medical records and emergency department presentations.

Results, Outcomes and Future Plans

Plans for return of results of research to participants

- If project outcomes are used for publishing/research purposes participants will have the opportunity to access research outcomes. This would be offered via a letter to notifying pariticpants that research has been completed.
- Potential future use of the data will be stipulated in the consent form and disucssed with participants.

Plans for dissemination and publication of project outcomes

- Potential publication or data being used for research purposes will be discussed and highlighted on consent forms for participants.
- All data will be de-identified.
- Nil ethical concerns relating to planned or possible use of information/data in this project.
- If there is any adverse reactions due to dissemination from participants this will be managed accordingly by project leads and support from team leader/project sponsor and support can be sought from treating psychiatrist/mental health team if required.

Other potential uses of the data

- There are no other potential uses of the data at this stage.

Project closure processes

- This will be offered at the end of the 12 week pilot study. Project leads will continue advising participants of progression of the project and timeline for completion to deter any apprehnesiion of cessation of the project and offer support as needed.
  One on one debrief will be offered to participants at the end of the pilot study to discuss outcomes and ensure there has been no adverse effects and prodive any necessary support.

Plans for sharing and or future use of data and follow up research

- If project outcomes are favourable reseach data collected will be used as the supporting body of evidence to justify the need and endorsement of a formalised Personal Safety Tools being utilised within community mental health settings.
- Potential for research data to be referenced in other work relating to sensory modulation and mental health.

Contact Persons

Project Leads

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This document has been reviews and endorsed by SQCAG* for consumers and the community XXXX 20XX.

*SA Health Safety and Quality Community Advisory Group.

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