CONFIDENTIAL

Protocol Number	X21-0166 & 2021/ETH01006
Coordinating Principal Investigator	Dr Andrew McDonald
Signature:	
	Date: 18 October 2023
Protocol Authors (Co-investigators)	Mark Harris Andrew Simpson Andrew Baillie Catherine Spooner Michelle Cunich Lisa Parcsi Kizzy Yang (nee Searle) Ben Harris-Roxas Owen Hutchings Nathalie Hansen Beatriz Lopez Portillo Silvia Rojas Padilla Peri O'Shea Fleur Harrison Leonie Oakes Joel Keep
Protocol Version Number	11
Protocol Date	18/10/2023
Sponsor (if applicable)	Sydney Local Health District
Proprietary Notice (if applicable)	N.A.

Ethics Statement:

The study will be conducted in accordance with the *National Statement on Ethical Conduct in Human Research* (2007) (Link to National Statement) , the *CPMP/ICH Note for Guidance on Good Clinical Practice* (Link to CPMP/ICH) and consistent with the principles that have their origin in the Declaration of Helsinki. Compliance with these standards provides assurance that the rights, safety and well-being of trial participants are respected.

Contents

SUMMARY

Protocol Title	Shared Health Arrangements Research & Development (SHAReD) study
Intervention	Online shared-care software for communication between mental health services, GPs and their shared patients.
Objectives	The primary objectives of the SHAReD study are: 1. Does the implementation of an online shared care plan (the intervention) improve the frequency and quality of **primary and preventive care** received by study participants in intervention sites compared to participants in sites with usual care 3 months after their reported usual shared care ? The secondary objectives are: 2. Does the intervention better **integrate care** between mental health services and general practice compared with usual care 3 months after their reported usual shared care ? 3. Does the intervention improve **consumer health risks and service use** compared with usual care 3 months after their reported usual shared care? 4. What are the main costs and health outcomes associated with the intervention and usual care situations, is the intervention more **cost-effective** compared to usual care, and are there any costs avoided (saved) 3 months after their reported usual shared care?
Study design	Pragmatic trial with the unit of randomisation being four of the five Adult Community Mental Health 'Core' Teams in Sydney Local Health District (SLHD). Pairs of teams (matched by service type and consumer population) randomised to early or late intervention 3 months after their reported usual shared care.
Planned sample size	500 consumers and their shared-care GPs
Selection criteria	Inclusion criteria are: 1. People who are clients of the SLHD Adult Community Mental Health 'Core' Teams in Canterbury, Croydon, Camperdown and Marrickville and the GPs that these consumers nominate. 2. Age: 18+ years 3. Engaged in shared care or willing to commence a shared care arrangement before participating in a baseline survey. 4. Intervention group: Has a GP engaged in shared care who consents to participate in the study and to have the electronic care plan installed. 5. Willing to provide informed consent and willingness to participate and comply with the study requirements. Exclusion criteria

	Unable to give informed consent. Unable to speak English or a language not supported by the study.
Study Procedure	1.SLHD Adult Community Mental Health 'Core' Teams with be randomised to – 1 of Canterbury or Croydon and 1 of Camperdown or Marrickville will be randomly allocated to the intervention group and the other will receive delayed intervention 2.500 People with severe mental illness (PWSMI) who have contact with these teams and who are identified as suitable by the Core team staff member who is their care coordinator during routine visits will be given written information about the study. With the consumer's permission, care coordinators will provide the research team with contact details of consumers who are interested in participating in the study. 3.A research officer will contact these potential participants to explain the study, answer any questions, and obtain informed consent. 4.Participant consumers will be asked to approach their GP to be part of the project OR consent to the research team doing so on their behalf to recruit GPs to the study. 5.If GPs provide consent to participate in the study, they and their patient are enrolled in the study and an appointment is made to install the INCA shared care software in the GP practice's computer and arrangements will be made to train the GP in its use and a baseline survey is conducted with the consumers and their shared-care GPs. 6.Consumers in the intervention group will have their physical health care coordinated through an online shared care plan. 7.Consumers in the comparison group will receive usual care. 8.If GPs withdrew consent to participate in the study, their patient will remain enrolled in the study and will be able to participate in a repeat interview 3 months after their reported usual shared care. 9.Consumer and GP participants will participate in a repeat interview 3 months after their reported usual shared care. If any consumer does not have a shared care appointment/follow-up since baseline, they will be invited to participate in the repeated interview three months after 30 June 2023 (i.e., 3 months after the deadline for the intervention to be implemented). 10.With consent and approval, relevant health service use and clinical data will be extracted from medical records held by GPs, datasets held by SLHD, HealtheNet (including MBS/PBS items), and the NSW Ministry of Health (ICOD). 11.A subset of consumers will be invited to participate in a qualitative interview after 3 months of their reported usual shared care. 12.A subset of SLHD mental health clinicians (Care Coordinators and shared care clinicians) and GPs will be interviewed after the intervention period.

Statistical considerations	Sample size calculation Assuming 20% change, a sample size of 91 per group is required to detect a change from 30 to 50% in primary outcomes based on $\alpha = 0.05$, $1-\beta = 0.8$. Assuming a design effect due to clustering of 2, a total sample of 360 is required (180 in each group). Analysis plan For analysis of differences between the intervention and usual care alternatives, linear or generalised multi-level mixed models will be estimated depending on the type of outcome in question. Intra-class correlations will be calculated to compare the amount of variance associated with design features as individual participants are nested within care coordinators who are nested within community mental health teams, and those same participants are also nested within GPs who may also be nested within medical centres, which will occur before selecting random effects for these models. As well as an analysis of completers, defined as those consumers, care coordinators and GP triads that complete an online shared care plan, an intention to treat (ITT) analysis will also be completed for this study. For the ITT analysis, those who have dropped out will be treated using a variety of sensitivity analyses. Further, baseline predictors and intervention features of both the SHAReD (e-shared care) and usual care situations will be added to multi-level models to identify effects of these characteristics on outcomes. Qualitative analyses (predominantly deductive but inductive coding will also be applied to detect new and emerging themes) will also be undertaken. All relevant costs such as implementation costs and healthcare usage [hospitalisations, GP care, specialists, allied health, and prescribed medication, and the multiple outcomes such as interactions with the health system, engagement, preventive tests undertaken, clinical measures and quality of life for participants in the intervention and usual care groups will be quantified, and tests of significance will be undertaken on these data. These results will be used in a cost-consequence analysis (CCA). A comprehensive within-trial cost-effectiveness study will also be conducted provided effectiveness has been demonstrated, with the main effects/benefits consisting of satisfactory completion of an online shared care plan, reduction in consumer cardiometabolic risk, and avoiding unplanned hospitalisations. A cost-utility evaluation will be conducted if effectiveness in relation to quality of life has been demonstrated, to provide a ranking of the alternatives (e-shared care, usual care) on the basis of the amount of resources (costs) used to gain an extra quality adjusted life year (QALY) by receiving the SHAReD intervention. All the necessary effects/benefits and costs (direct medical, consumer costs for medical care and any indirect costs) will be identified, counted and valued using established methods. A range of incremental cost-effectiveness ratios (ICERs) will be calculated such as the incremental cost for an extra QALY gained, cost for an unplanned hospitalisation that was avoided. Sensitivity analysis will be conducted and some results presentations graphically.

Time Period of Data Collection	Mental health service consumers and their GPs will start to be recruited as soon as ethics approval is obtained (1 July 2021) and baseline data will be collected as soon as possible after recruitment. Recruitment and baseline data collection is expected to take 3 months. Follow-up data collection will be conducted 3 months after the consumer has had their usual shared care.
Duration of the Study	3 years
Funding (if applicable)	$998,755
Funder	Translational Research Grants Scheme, NSW Health

Protocol Version Control box

Protocol Version Number	Date	Summary of Changes
1	25 May 2021	NA
2	2 Jul 2021	Various in response to ethics review
3	20 Jul 2021	Various in response to ethics review
4	22 March 2022	Addition of team member approved by ethics (Stella Jun) 1.1 and 3 Removal of telehealth as part of the intervention – both groups will use telehealth 4.4 and 7 monitoring of telehealth use has been added as an indicator of integrated care. 4.4 3-month period removed from 2ndry outcome 8.2 Additional information on the economic evaluation requiring (section 7) access to additional hospital data Update to start and finish dates (Table 2) Removal of consumer outcome variables: Patient Activation Score, HLQ Domain and consumer travel expenses (Table 10)9.4 Clarification that changes in work practice will be explored in the qualitative interviews 9.5 Addition of SLHD health data
5	8 July 2022	1. Appendix 10.1 and 10.2 Michael Moore replaced by Nathalie Hanson, Sharedstudy@unsw.edu.au added as a contact for further information

		2. Appendix 10.2 Addition of reimbursement to GPs added to GP participant information 3. Appendix 10.5 Brief simple information for consumers (new) 4. Appendix 10.6 Script for explaining the participant information document to consumers (new) 5. Appendix 11.6 GP verbal consent (new) 6. Appendix 15.2 Letter to GP from consumer(new)` 7. Appendix 15.3 One-page study information for GPs (new) 8. Extension of study to 3 years noted 9. Protocol amendments: i. Addition of $100 reimbursement to GPs ii. Addition of exclusion criterion regarding language spoken by the consumer iii. Addition of GP exclusion criterion: No EMR iv. Addition of verbal consent for GPs v. Clarify how Letter to GP from consumer will be sent
6	25 Aug 2022	1. Appendix 3 Consumer survey 12 months changed to 9 months 2. Appendix 10.1 Consumer PIS 12 months changed to 9 months 3. Appendix 10.2 GP participant information: Change to details of reimbursement to GPs 4. Appendix 10.5 Brief information for consumers 12 months changed to 9 months 5. Appendix 15.3 One-page study information for GPs- Change to details of reimbursement 6. Protocol amendments: a. Change to details of reimbursement to GPs b. 12 months changed to 9 months where applicable due to shortened follow-up period (change to 9 months already approved by ethics)
7	8 Sep 2022	1. Revisions to the following so consumers engage in baseline regardless of GP consent to participate in the study 1. Appendix 10.1 Consumer PIS 2. Appendix 10.6 Consumer PIS script 3. Protocol: flow chart

		2. Appendix 3 Consumer survey: additional questions re choice and pattern of use of GPs, some rewording to allow for multiple GPs
8	15 Dec 2022	1. Modification to economic evaluation 2. Addition of detail regarding the GP recruitment process, including Appendix 15.4 GP telephone recruitment & interview script 3. Revision of detail in the protocol regarding the consumer recruitment process to be consistent with the text for GP recruitment (also some recruitment details moved from 6.4 to 5.3)
9		Addition of team member: Beatriz Lopez Portillo (replaced Stella Jun)
10	21/07/2023	1. Addition of team member: Silvia Rojas Padilla (Health Economic Research Officer, USYD) & Dr Peri O'Shea (Research Officer, UNSW) 2. Removal of team member: Xue (Snow) Li who leaves the project 31 August 2023 3. Appendix 3 Consumer survey: questions were deleted to avoid burden on consumers 4. Appendix 4 GP Survey: questions were modified to consider Providers in both groups (i.e., intervention and comparison) 5. Appendix 6 Consumer qualitative interview: questions were modified 6. Appendix 7 Providers qualitative interview: questions were modified to consider Providers in both groups (i.e., intervention and comparison) 7. Appendix 10.1 Consumer PIS: changes to research staff and contact for further information and to reflect changes in protocol 8. Appendix 10.2 GP PIS: Information for GPs modified to include all GPs in the follow-up phase 9. Appendix 10.3 Mental Health Service Provider PIS & 10.4 Carer PIS: changes to research staff and contact for further information 10. Appendix 12 Research Data Management Plan was modified to reflect the DTA with UNSW and USYD 11. Appendix 16. Guide to assist care coordinators informing consumers whose GPs did not consent of the implications for their participation in the study (new) 12. Appendix 17. Follow up Recruitment Advertisement (new)

		13. Appendix 17.1a Script to call consumer for follow up survey and interview (new) 14. Appendix 17. 1b Script to invite consumers face-to-face to participate in follow up survey and interview (new) Protocol amendments: a. 9 months changed to 3 months due to shortened follow-up period b. Changes to inclusion criteria and study procedure to include the follow-up of consumers whose GPs withdrew consent after baseline or declined after the consumer consented to the study c. Changes to study procedure to include follow-up date for consumers who did not have a shared care appointment/follow-up after baseline d. Changes to study procedure to include data extraction sources such as HealtheNet e. Changes to study procedure to include the possibility of MHS staff creating the shared care plan for GPs to review f. Health economic assessment updated to reflect changes in study protocol g. Updated Figure 1 intervention flow chart after revision with Shared Care Clinicians (MHS staff) h. Start and finish dates have been amended i. Telehealth was deleted as a secondary point j. Study flow chart updated to reflect changes to study protocol (i.e., change in the follow up timeframe) k. Changes to schedule of participant surveys and interviews to be consistent with changes in study protocol and procedure l. Changes to study visits and procedures to be consistent with changes in study protocol and procedure
11	18/10/2023	1. Addition of team members: Fleur Harrison, Leonie Oakes and Joel Keep as Research Officers, UNSW 2. Modification to the RDMP section 'Data Retention & Disposal' to reflect a) change on date for disposing of the shared data

		with CPHCE, UNSW & University of Sydney, and b) changes on the process to confirm deletion 3. Modification to GP audit/HealtheNet timeframe to reflect the 6-month period post-intervention, compared to 6-month pre-intervention, and same 6-month period in previous year for season effect 4. Removal of outcomes to GP audit/HealtheNet since they are not likely to change in reduced timeframe and have insufficient power with the reduced sample: a. GP-recorded influenza vaccination in past 9 months b. Patient Absolute Cardiovascular Disease Risk score c. GP-recorded health risk levels in past 9 months

1. BACKGROUND AND INTRODUCTION

1.1. DISEASE/PROPOSED INTERVENTION BACKGROUND

The problem

People with severe mental illness (PWSMI) have a 13-30-year shorter life expectancy than the general population. [1–3] This is largely attributed to high rates of modifiable cardiometabolic risk factors such as smoking, hyperlipidaemia, hypertension, obesity, diet and sedentary lifestyle,[4,5] which translates to high rates of chronic disease. As a result, PWSMI are six times more likely to die of cardiovascular disease and four times more likely to die of respiratory disease than the general public.[6] The annual economic cost of premature comorbidity in this population necessitates better integrated care; primary care is considered ideal for managing multimorbidity.[7,8] PWSMI have poor uptake of preventive care and proactive use of primary care due to a number of provider issues (e.g. stigma, poor communication) and consumer issues (e.g. cognitive difficulties, low health literacy).[9] The higher mortality rate among PWSMI also requires urgent attention. The costs of treating PWSMI and premature death among people of PWSMI in Australia in 2016 was $15 billion.[10]

The intervention

An online shared care plan will facilitate coordinated and planned care of consumers of mental health services "consumers" including management of risk factors and referral to allied health services and other relevant programs. It will be adapted from one used for consumers with long-term cancer patients in St George and the existing Mental Health Shared Care Checklist used in the SLHD Living Well Living Longer (LWLL program).[11] It will be based on the existing shared care plan used by SLHD, which is a paper form. The use of the existing shared care plan ensures the study is testing the difference between paper and online shared care plans rather than differences in the content of the plans. Functional specifications developed in consultation with mental health services (MHSs), general practitioners (GPs) and consumers in SLHD. The online shared care plan a) is interactive so the GP and MHS can review, edit and add to it (the consumer can view it); b) generates automated reminders for GPs, care coordinators and consumers; and c) enables MHSs to monitor completion and evaluate outcomes. The MHS care coordinators and peer support workers will assist the consumers and any nominated carers to access the INCA software and review their plans.

The RPA Virtual Hospital at SLHD will be available across all four teams. It will be used in the intervention for:

1. people who do not have a GP or not able to get to a GP - RPA VIRTUAL will fill the GP role
2. teleconsultations involving the GP, mental health care coordinator (MHC) and the consumer. This will save the MHC going with a patient to the GP.

The tasks for the consumer, the GP and the MHS in the intervention are presented in Figure 1.

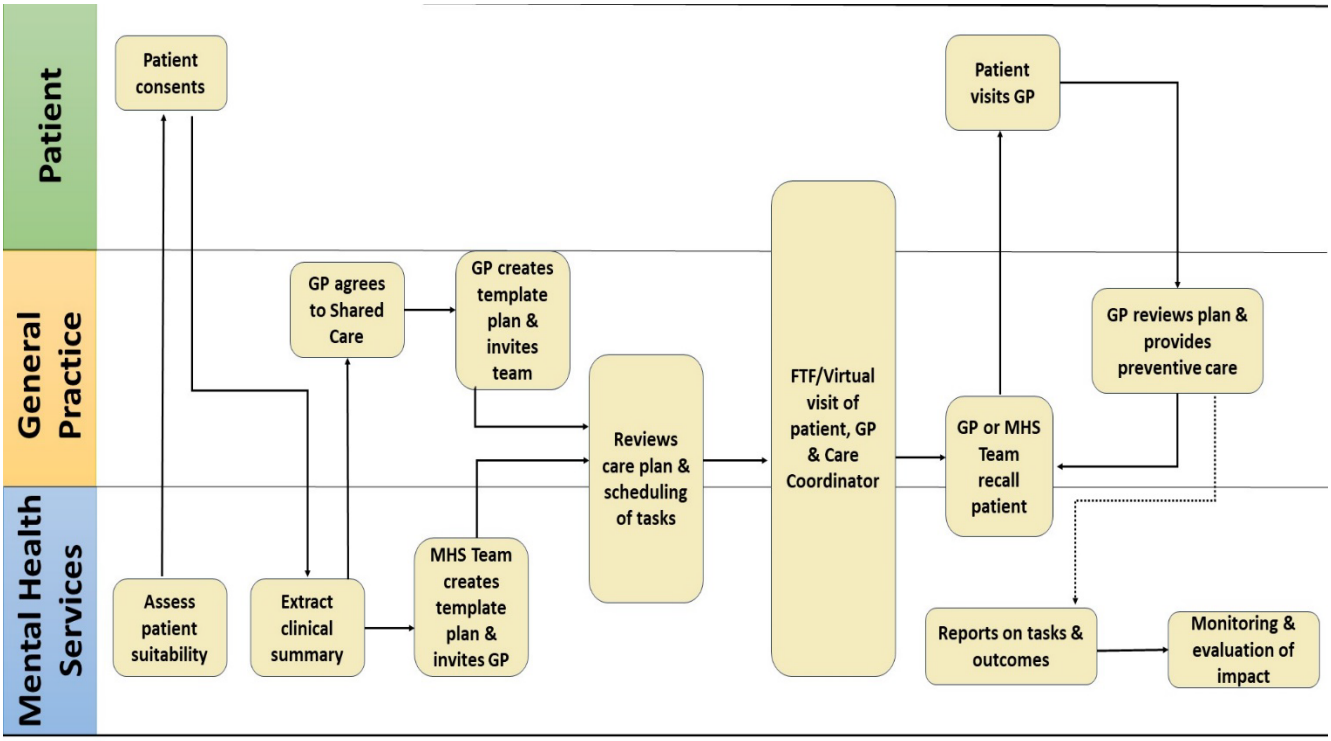

Figure 1 Intervention flow chart

Context

SLHD has five Adult Community Mental Health 'Core' Teams. The four largest teams will be involved in the study: 2 in Western Sector, 2 in Eastern Sector.

Table 1 Mental health teams in the study

Western Sector Teams	Eastern Sector Teams
Canterbury	Camperdown
Croydon	Marrickville

The SLHD Living Well Living Longer shared care program used the ACI clinical redesign process in partnership with CESPHN to develop a collaborative model of shared care with GPs.[12] This has engaged over 330 GPs in providing shared care to over 1000 PWSMI, 736 of which remain active with the MHS at most recent count. Of those active shared care consumers, 512 have received a verified annual physical health check with their GP.

These innovations require change to existing routines in both MHSs and general practice, facilitated by quality improvement activities led by clinical champions.

Training and support will be provided on using the shared care software to the implementation teams, in collaboration with the existing GP shared care liaison clinicians within Sydney Local Health Service (SLHD)'s MHS, and CESPHN field support staff. Separately they will provide training and support to GP practices upon installing the

shared care software. This training will also address redesign of routine practices and be provided to medical staff, care coordinators and peer support workers. The training and redesign elements will be informed by our previous research providing both training and quality improvement in general practice in the prevention and management of long-term conditions and care of vulnerable populations.[13,14] This includes the importance of interactive and peer learning. It is also consistent with the education and practice support program of partner CESPHN.

There are challenges in organising initial and review shared care consultations for PWSMI in general practice, with this requiring considerable time from the care coordinator and strong engagement from the consumer. Telehealth has been shown to enable better access to a range of health services.[15] Telehealth consultations involving consumers, GPs and mental health providers have been increasingly used since the COVID pandemic and can be used in this trial to facilitate shared care.

1.2. RATIONALE FOR PERFORMING THE STUDY

Communication between GP and MHS presents an ongoing challenge, with no shared electronic records system. Phone calls are often impractical, and emails are rarely utilised due to privacy concerns, therefore services typically rely on fax or mail, with no verification that the person receiving the update either reviews it or uploads it to their own electronic record for further transparency.

Research with other long-term conditions suggests that effective sharing of care requires an interactive information system allowing team members to confirm acceptance of their roles, notify when tasks are due, track that tasks are completed and share information and results.[16,17] Online shared-care systems can improve appropriate health-service use and reduce hospitalisations and have been demonstrated as feasible for conditions such as cancer and diabetes.[18–22] Their adaptation to shared care of PWSMI has not yet been demonstrated.

The interactive online shared-care plan has been used for two years in cancer shared care in St George Hospital and evaluated for its feasibility and acceptability to providers and consumers in that context.[23,24] A pilot study of its use with consumers on Clozapine is being developed in SE Sydney. Preliminary findings are that it is acceptable to consumers and providers and significantly enhances the consistency of care provided in general practice. However, it does require changes to work practices in both mental health services and general practice.

The innovation to be trialled solves key challenges in shared and integrated care of PWSMI. If successful, it will improve the quality of preventive care received by PWSMI through better communication and coordination between general practice and MHSs. If successful, the intervention will be rolled out across the SLHD and CESPHN.

2. HYPOTHESIS

1. After 3 months, the intervention will improve the frequency and quality of primary and preventive care received by study participants in intervention sites compared to participants in sites with usual care.
2. After 3 months, the intervention will better integrate care between mental health services and general practice compared with usual care.
3. After 3 months, the intervention will improve consumer health risks and service use compared with usual care.
4. After 3 months, the intervention will demonstrate cost-effectiveness compared to usual care (i.e. the situation without the intervention) and *cost avoidance* (i.e. there will be reduced costs in the intervention group).

3. STUDY OBJECTIVES / AIMS

Aim: To investigate the adaptability, replicability and effectiveness of an online shared care plan in NSW Health mental health and primary care settings.

PRIMARY OBJECTIVES
Primary research question:

1. After 3 months, does the intervention improve the frequency and quality of **primary and preventive care** received by study participants in intervention sites compared to participants in sites with usual care?

SECONDARY OBJECTIVES
Secondary research questions:

2. After 3 months, does the intervention better integrate care between mental health services and general practice compared with usual care?
3. After 3 months, does the intervention improve consumer health risks and service use compared with usual care?
4. After 3 months, what are the main differences in the costs and various outcomes between the SHAReD intervention and usual care groups? If effectiveness has been demonstrated: is the SHAReD intervention more cost-effective compared to usual care, and are there any costs avoided due to the intervention?

4. STUDY DESIGN

4.1. DESIGN / STUDY TYPE

This is a pragmatic cluster randomised controlled trial. The unit of randomisation is the team. The teams are four of the five Adult Community Mental Health 'Core' Teams in SLHD (Table 1). Randomisation will be stratified by sector (Eastern and Western): One team from each sector will be randomised to the intervention group, the other team will be allocated to the comparison group. The comparison group Teams will receive the intervention after the 3-month data collection is complete.

As there are only two teams per sector in the study, randomisation will be done by a person independent from the study by flipping a coin.

4.2. EXPECTED PARTICIPANT NUMBERS

We aim to recruit 500 consumers and expect 400 to remain in the study at 3-month follow-up (20% loss to follow up). Power calculation: Assuming 20% change in the frequency and quality of primary and preventative care received by participants, a sample size of 91 per group is required to detect a change from 30 to 50% in primary outcomes based on $\alpha = 0.05$, $1-\beta = 0.8$. Assuming a design effect due to clustering of 2, a total sample of 360 is required (180 in each group).

4.3. TIME PERIOD OF THE STUDY

Table 2 Start and finish dates

Task	Start Date	End Date
Management/advisory structures	04/2021	07/2021
Staff Recruited (Research Manager)	06/2021	07/2021
Functional specifications and care plan template	04/2021	12/2021
Development of cost and consumer outcomes questionnaires (and database)	04/2021	12/2021
Ethics approval	04/2021	07/2021
Trial commencement/Recruitment	03/2022	12/2022
Trial completion	04/2023	06/2023
Evaluation reporting	01/20234	04/2024
Translation/dissemination	05/2024	06/2024

4.4. ENDPOINTS

PRIMARY ENDPOINTS

Differences between the intervention and comparison groups in changes in the frequency and quality of preventive care from their reported usual shared care to 3-months:

1. Increased % of consumers for whom each health risk is measured and recorded over the preceding 3 months*
2. Increased % consumers who have been vaccinated against influenza over the preceding 3 months
3. Decreased % consumers with high CVD risk who have not received a prescription for either an anti-hypertensive or lipid lowering drug.
4. Increased % consumers who report advice/referral for smoking cessation, diet education and physical activity over the preceding 3 months.

* Health risks are itemised in Table 3.

SECONDARY ENDPOINTS

Differences between the intervention and comparison groups in changes from their reported usual shared care to 3-months:

5. Increased % MHS consumers have a care plan (GPMP and TCA) in last 3 months
6. Increased consumer rating of extent to which providers (MH & GP) are working to a common care plan in the past 3 months
7. Improved quality of communication between MHSs and GPs in last 3 months
8. Reduced number of ED attendances and hospitalisations in last 3 months
9. Increased number of visits to GP in last 3 months
10. Improved consumer experience of providers (MH & GP) working to a common (shared) care plan in the past 3 months (qualitative analysis)
11. Increased scores on Domain 1 (Feeling understood and supported by healthcare providers) and Domain 7 (Navigating the healthcare system) of the Health Literacy Questionnaire
12. Increased score on Patient Activation Measure (PAM-13)
13. Improved diet and physical activity behaviours
14. Reduced Absolute Cardiovascular Disease Risk score **
15. Reduced diabetes risk score using AUSDRISK ***
16. Improved levels of most recently recorded results from health risk screening*
17. Reduced costs of hospitalisations in last 3 months
18. Reduced out of pocket costs of participants
19. Improvements in Quality of Life as assessed by the EQ5D-5L.

* Health risks are itemised in Table 3.

** Information needed for CVD risk score is provided in Table 4

*** Information needed for AUSDRISK score is provided in Table 5.

Table 3 Health risks

Health risks	Units/options	Normal range/goals
Systolic & diastolic blood pressure (BP)	mmHg	<130/85 mm Hg
Weight and height (height 'ever recorded') - for body mass index (BMI)	Weight: kg Height: cm BMI: Weight/Height*Height	reduced BMI for those above healthy weight
Lipids: - total cholesterol (TC), - Low-density lipoprotein (LDL), - High-density lipoprotein (HDL), - triglycerides (TG)	mmol/L	TC <5.5 mmol/L HDL > 1.0mmol/L
Fasting blood glucose (FBG)	mmol/L	3.0 - 6.0 mmol/L
Glycated haemoglobin (HbA1c)	mmol/mol	15-42 mmol/mol
smoking status	Y/N	N
alcohol consumption	number of drinks each week	Max 10 drinks per week
waist circumference	cm	<94 cm men < 80cm women
Kidney function test: - Estimated Glomerular Filtration Rate (eGFR) - microalbuminuria	eGFR - GFR number microalbumin: mg	eGFR <60 mL/min/1.73 m2? Less than 30 mg is microalbumin

Table 4 Information needed for CVD risk score

Elements	Units/options
Gender	M/F
Age	years
Systolic blood pressure	mmHg
Smoking status	Y/N
Total cholesterol	mmol/L
HDL cholesterol	mmol/L
Diabetes	Y/N
ECG shows left ventricular hypertrophy (LVH)	Y/N/unknown

Table 5 Information needed for AUSDRISK score

Elements	Units/options
Age	Years
Gender	M/F
Country of birth	Australia/ Asia, Middle East, North Africa, Sth Europe / Other
Aboriginal, Torres Strait Islander, Pacific Islander or Maori descent	Y/N
Family history of diabetes	Y/N
Past high glucose	Y/N
Hypertension treatment (medication for high blood pressure)	Y/N
Smoking status	Y/N
Fruit and veg every day	Y/N
Physical activity 2.5 hours per week	Y/N
Waist circumference	cm

4.5. SITES

Site Name/s	The study site is Sydney LHD. Teams involved in the study will be four adult Community Mental Health 'Core' Teams at Canterbury, Croydon, Camperdown and Marrickville
Site Contact/Investigator	Andrew McDonald
PHO	**YES**
If a non-PHO is an EEA in place?	**N.A.**
Study Procedures	Procedures have been developed in consultation with site team leaders and staff and will be the consistent across all four mental health teams. The number of active consumers with each team varies from 278 to 448. It is anticipated that each team will recruit approximately one-quarter of the total sample, with larger teams recruiting slightly more than smaller sites. Care coordinators at each team will identify and approach potential study participants. They will be given written information to give to the consumer. With the consumer's permission, care coordinators will provide the research team with contact details of consumers who are interested in participating in the study. A research officer will contact these potential participants to explain the study, answer any questions, and obtain informed consent. In intervention sites, participant consumers will be asked to approach their GP to be part of the project or consent to the research team doing so on their behalf to recruit GPs to the study. For consumers in the intervention group, if GPs provide consent to participate in the study, they and their patient are enrolled in the study and an appointment is made to install the shared care software in the practice's computer and arrangements will be made to train the GP in its use. Consumers in the comparison group will receive usual care. If their GP decline to be involved in the study, these consumers will remain enrolled in the study for intention-to-treat analysis. Consumer participants will participate in a baseline survey which is repeated 3 months after their usual shared care appointment, or 3 months after 30 June for those consumers who did not attend their shared care appointment. These interviews will be conducted via telephone, online or face-to-face, depending upon the preference of each consumer. All consumers will be invited to participate in a qualitative interview after the 3-month survey. Care Coordinators and GPs will also be interviewed after the intervention period.

	All survey and interview data, and data extracted from HealtheNet (including MBS/PBS items) and medical records will be entered into a SLHD REDCap data base. De-identified data from external repositories (ICOD) will be saved in secure password protected OneDrive files at UNSW Sydney. Data for the economic studies will be saved in secure password protected OneDrive files for assembling and analysis at The University of Sydney, and outputs (during and post analysis stage) will be stored on the SLHD REDCap.

5. STUDY PARTICIPANTS

5.1. INCLUSION CRITERIA

1. Consumers from SLHD Adult Community Mental Health 'Core' Teams in Canterbury, Croydon, Camperdown and Marrickville.
2. Age: 18+ years
3. Engaged in shared care or willing to commence a shared care arrangement before the baseline survey.
4. Intervention group: Has a GP engaged in shared care who consents to participate in the study and to have the electronic care plan installed
5. Willing to provide informed consent and willingness to participate and comply with the study requirements.

5.2. EXCLUSION CRITERIA

Consumers:

1. Unable to give informed consent.
2. Unable to speak English or a language supported by the study.

GPs:

1. No EMR

5.3 RECRUITMENT

1. Who will be recruited?

Consumers of mental health services in SLHD and their GPs will be recruited to the study. Specifically:

- Adult consumers of the SLHD Adult Community Mental Health 'Core' Teams in Canterbury, Croydon, Camperdown and Marrickville in shared-care arrangements with their GP (or willing to commence shared care arrangements).
- The consumer's general practitioner engaged in shared care with the mental health service.

RECRUITMENT OF CONSUMERS

2. How will participants be identified and recruited?

1. SLHD Mental Health Care Coordinators or Shared Care Clinicians ("Clinicians") will introduce the study to the consumer. This could be face-to-face at the clinic (before or during a consultation) or via telephone if the consumer is not visiting the mental health facility during the recruitment period. Interested consumers will be asked whether they agree to see or be contacted by a researcher and, if so, ascertain the appropriate method of contact, e.g. telephone, letter, email or face to face. This verbal approval to be contacted by the researcher and the contact details of the consumer and their GP will be noted by the Clinician in an Excel database in a SLHD MS Teams folder.

   The Clinician will provide consumers with a package of information about the study and the researcher's role in the study that contains a short, easy-read information sheet (Appendix 10.5) and a more detailed Information for Participants (Appendix 10.1) that consumers can discuss with significant others (e.g. family, carer, kinship group, support worker).

2. When possible, a researcher will be based at the clinic. If so, interested consumers will be introduced to the researcher. Clinicians will also provide the researcher with the name of the consumer's GP. GP name is necessary at this time so informed consent can be given by the consumer for the researchers to contact that GP.

   When a researcher is not at the clinic or is not available, interested consumers will be noted in an Excel Database in a SLHD MS Teams folder and this information will be used by the research team to contact that consumer.

3. Will the potential participants be screened?

SLHD Mental Health Care Coordinators will identify if consumers meet eligibility requirements.

The mental illness of consumers will be assessed by the Mental Health Care Coordinators to determine if they have capacity to consent at the time prior to referring to the research team.

Mental Health Care Coordinators will not approach people who are known to have existing guardianship arrangements around medical decision making (for example, people with cognitive impairment or intellectual disability that are sufficient to prevent informed consent).

4. What is the impact of any relationship between researchers and potential participants on recruitment?

Research staff are employed separately to the health services. Research staff will have no prior relationship with consumers. The initial approach about participation will be made by Mental Health staff not directly involved in the research.

5. How will the recruitment strategy facilitate obtaining the consent of participants?

Research staff will be trained to able to build rapport with mental health service consumers and to be flexible in the recruitment process. It is anticipated that referral to the study by a care co-ordinator will engender trust in the value of the research project. All efforts will be made to minimise participant burden. Consumers will be invited to consult or include carers, support/peer workers or any other trusted person if they would like their assistance with the consent process.

6. How will the recruitment strategy ensure that participants can make an informed decision about participation?

The researcher will verbally explain the information provided on the participant information sheet. A script has been prepared to ensure all key points are addressed and appropriate language is used (Appendix 10.6)

An easy-read information sheet will be available for consumers to read and discuss with significant others (e.g. family, carer, kinship group, support worker) who can assist in deciding whether or not to consent to participating in the study (Appendix 10.5).

7. Are there any risks associated with the recruitment strategy for potential participants or for the viability of the project?

The nature of this study is nonintrusive and there should be no significant risk to participants ' physical or mental health. Information about the study will be provided at arms-length from the research by clinical mental health workers who are not involved in the research.

Recruitment and data collection will be via telephone or online meeting (e.g. Zoom) or in community mental health service settings. No recruitment or data collection will involve inpatients in acute hospital settings.

The information and consent process are flexible allowing for verbal consent if the consumer prefers. Consumers can withdraw from the study at any time.

While the interview and focus questions will not be seeking information about the participants ' mental illness history or previous traumatic events, there is a risk that any discussion about events and behaviours could trigger past trauma. To minimise risk and ensure support, a protocol will be developed with mental health services. The information sheet includes information about mental health support they can access after the interview if issues arise: their care coordinator and their GP. Participants can choose to take a support person into the interview with them.

Data collection with PWSMI in supported environments decreases risk to the researchers relative to interviewing in participants ' homes. Other strategies to mitigate risk to the research officer consistent with the UNSW Fieldwork Guideline (HS406) include: maintaining communication, debriefing, and accessing the Employee Assistance Program if necessary. The research officers engaged to conduct data collection will have experience in data collection with health-service consumers from disadvantaged groups and will receive specific training in data collection with people with mental illness.

Psychological support will be available if consumers become distressed via their mental health team or out of hours services.

Where consumers are admitted to hospital subsequent to approach or recruitment (for physical or mental health issues), we will arrange assessment as soon as possible after discharge, if that is acceptable to the consumer.

8. Consistency with the requirements outlined in National Statement 4.5.5-11 regarding having respect for participants with a cognitive impairment, an intellectual disability, or a mental illness.

- Only consumers with the capacity to consent will be invited to participate in the study
- Where the mental illness is temporary or episodic, an attempt will be made to seek consent at a time when the condition does not interfere with the person's capacity to give consent.
- The process of seeking the person's consent will include discussion of any possibility that his or her capacity to consent or to participate in the research may vary or be lost altogether. The participant's wishes about what should happen in that circumstance will be followed.
- The capacity of the consumer to consent to the research will be assessed his/her mental health care coordinator, who is qualified to judge the capacity of their patients. Where there are any concerns, this will be discussed with the consumer's treating psychiatrist.
- Care coordinators will advise the research team of any changes in the participant's capacity to consent and to participate in the research.
- Care has been taken in the design of the interviews and will be taken in the training of interview staff to ensure that the interview does not increase consumer's discomfort or distress and to ensure that, if this were to occur, that the interview would be stopped and the consumer supported and referred appropriately.

RECRUITMENT OF GPS

1. After a consumer has consented to participate in the study (which includes consent to the research team contacting their GP about study participation), the research team will contact the consumer's GP. The name of the GP and their practice will be confirmed with the consumer.
2. If feasible, a letter from the consumer is posted to the GP informing that the consumer has consented to be in the study and inviting the GP to be in the study (Appendix 15.2). The letter states: *"The research team will contact you shortly or you can contact the Research Manager, Stella Jun".*
3. The GP contact details are recorded by the MH clinician in an Excel database on the SLHD MS Teams folder and shared with the research team.
   - 3.1 Intervention group: Details of GPs who decline will not be retained after data collection has completed. They will be retained during the data collection period because consumers are known to change GPs and this information is likely to be necessary to follow up.
   - 3.2 Comparison group: Details of GPs who decline but whose consumers consent to participate, will be retained. They will be retained because consumers will receive their usual shared care (no need for the GP to install the electronic care plan), and this information is likely to be necessary to follow up.
4. The research team will use a script when they contact the GPs (Appendix 15.4).
5. GPs can consent verbally (Appendix 11.6) or by signing a written consent form (Appendix 11.3). GPs will be offered reimbursement for their participation in the study ($100 shopping voucher or cash for participating in each component of the study). Recruitment materials include a letter of invitation from the head of the mental health service in the LHD (Appendix 15.1), a letter from the GP's patient informing the GP that s/he has consented to be in the study and inviting the GP to also consent to be in the study (Appendix 15.2), GP participant information abbreviated (Appendix 15.3) and in full (Appendix 10.2).

9. What happens if a GP does not want to participate?

If a GP does not want to participate in the trial, neither they nor their patients who are engaged with the mental health service (MHS) will be given access to the online shared-care tool. Consumers of these GPs can still provide baseline data for the study and will be followed up for the study. Communication between the GP and the MHS will continue as usual, which is generally via letters and faxes.

10. How will participants be recruited to the qualitative interview?

Participants from both groups will be invited to participate in semi-structured qualitative interviews. This will include consumers and their carers, and health care providers (including MHS staff and GPs).

Consumers will be invited to express interest in themselves and/or their carers being interviewed for the study via an invitation within the consumer survey. Contact details will be requested so the study team can contact the consumer and/or their carer.

The research team will contact the consumers who expressed interest and any carers who were nominated by consumers to recruit them to the qualitative interviews.

GPs will be invited to express interest in being interviewed for the study via an invitation within the GP survey. A similar process to that for consumers will be used to contact those GPs who expressed interest in being interviewed.

Mental health service care coordinators who have facilitated consumer recruitment to the study will be invited to express interest in being interviewed via a letter of invitation sent to them by the Principal Investigator, Dr Andrew McDonald (Appendix 13). The letter of information will include a Participant Information sheet (Appendix 10.3) and consent forms for care coordinators (Appendix 11.4). A similar process to that for consumers will be used to ensure that a broader consumer and Provider perspective on shared care is captured.

11. How will participants be reimbursed for their time and expenses for participation in the study?

Consumers will be reimbursed for their time and expenses participating in the baseline survey, follow-up survey and qualitative interview via a $20 gift voucher per occasion of participation (maximum $60 per consumer across the course of the study). This amount was deemed reasonable as the survey is designed to be short in duration and additional travel should not be necessary as interviews are expected to be conducted via telephone, zoom, or face-face at the mental health service.

GPs will be reimbursed for their time and expenses participating in the research study via a $100 shopping voucher (or cash whichever GP prefers) for participating in each of the following components of the study including 1) Baseline survey (15 min), 2) Follow up survey (15 min), 3) Data extract (just access to computer), 4) INCA installation/training (intervention group now and comparison group 3 months after their usual shared care appointments, i.e., 3 months after 30 June 2023) and 5) Qualitative interview (20-30 minutes). Each GP receives total 5, $100 payment over the study period.

5.4 CONFOUNDERS

Any baseline differences between clients seen by intervention and comparison teams in demographic or socioeconomic characteristics and mental health condition may act as potential confounders. These will be assessed in the analysis and, if necessary, adjustment made in analyses.

Another potential confounding factor could be that patients will accumulate around the GPs with the most engagement in the study who have the shared eMR (electronic medical record) installed early on. MHS case coordinators will be asked to monitor whether any consumers have changed GPs as a result of the trial and inform the study investigators if this happens. We cannot stop consumers from changing GPs, but we can only monitor if this happens. Our experience with this consumer group is that changing GPs is unlikely unless a consumer is dissatisfied with their existing GP.

5.5 STUDY LIMITATIONS

Study limitations may include:

- Inability to conduct RCT at individual level due to practical constraints of doing so.
- Reliance on self-report for some measures.
- Reliability of routinely collected data from general practice clinical records.

6. STUDY PROCEDURES

6.1. STUDY FLOW CHART

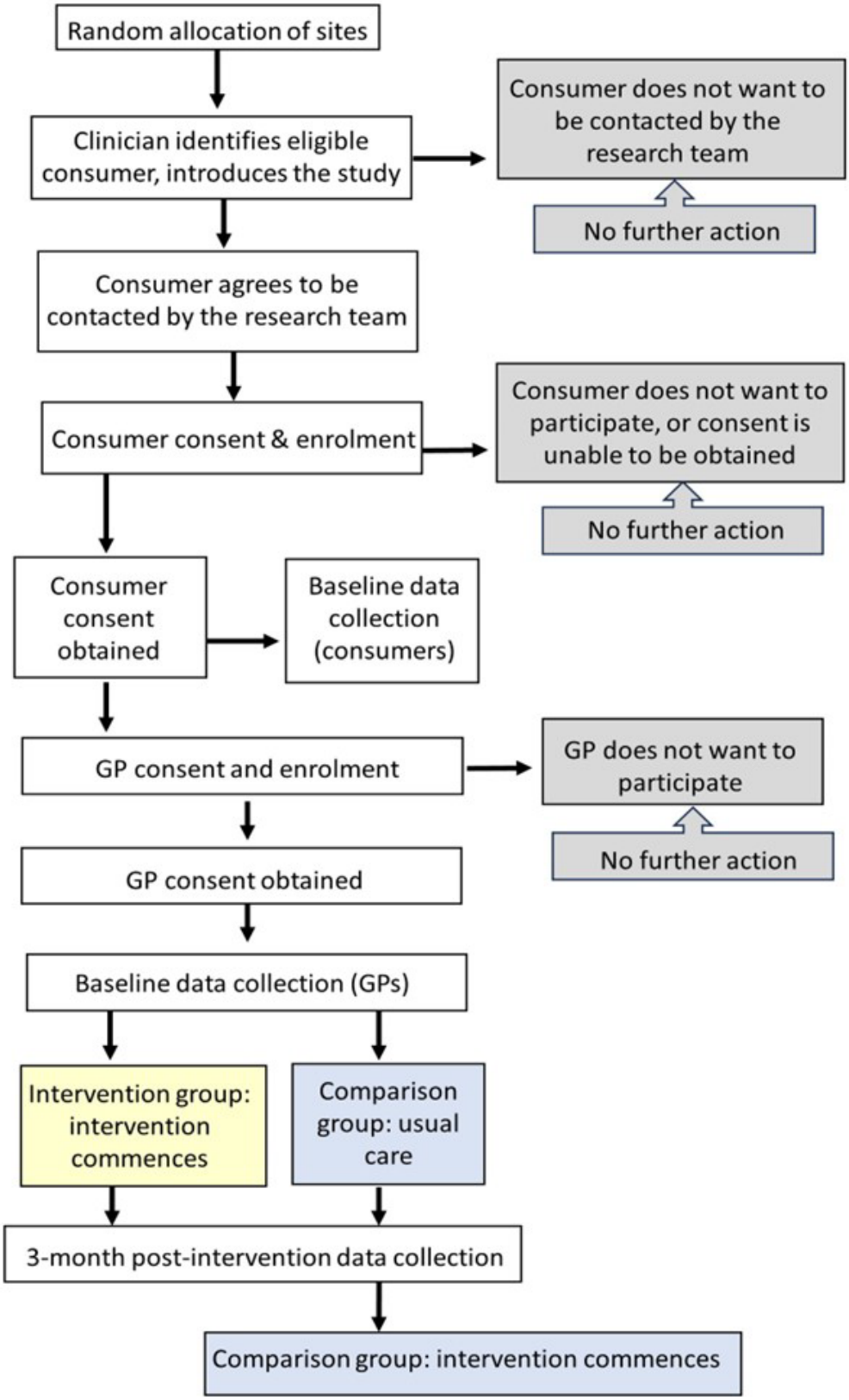

Figure 2 Study flow chart

6.2. INVESTIGATION PLAN

The schedule of surveys and qualitative interviews with study participants is presented in Table 6.

Table 6 Schedule of participant surveys and interviews

		Baseline survey	3-month after usual shared care survey	3-month after usual shared care qualitative interview
Consumers	Intervention	✓	✓	✓
	Comparison	✓	✓	✓
Carers	Intervention			✓
	Comparison			✓
GPs	Intervention	✓	✓	✓
	Comparison	✓	✓	✓
MHS	Intervention			✓
	Comparison			✓

The schedule of visits and procedures is presented in Table 7.

Table 7 Study visits and procedures

	Observation			Treatment					Follow up
Study procedures	Enrolment via MHS	GP phone contact	Consumer survey interview	MHS creates online shared care plan before GP Visit 1	GP Visit 1 To create/review online shared care plan ideally with MHS	MHS reviews care plan initially and as needed	Other GP visits as required (optional telehealth with MHS)	Annual physical health check by GP	Consumer survey interview and qualitative interview
Invitation to participate	X								
Participant Consent	X								
Telephone/face-face interview			X						X
GP Agrees		X							
Care plan developed				X	X	X			
Care plan implemented and reviewed					X		X	X	

If consumers consent, the research team will approach their GP to participate. If the GP agrees a summary of the consumer's previous care is sent and the GP is assisted to download and install the software for the e-care plan. The GP or the MHS staff create the standard care plan (depending on workload of the GP). If the GP creates the standard care plan, they invite the mental health team to edit or join the plan. If the MHS staff creates the shared care plan, they invite the GP to edit or join the plan. Then, the care coordinator reviews the care plan and makes adjustments to suit the consumer's individual care and include other providers involved in the care. Next, the consumer is invited and attends the GP. At each visit the tasks in the care plan are completed by the GP with or without involvement of the mental health team by telehealth. Results of tests are uploaded into the care plan. The consumer is able to view the care plan but not to edit it. The care coordinator is able to review the care plan and check if tasks have been performed and results of these. Consumer and provider are sent reminder for follow up visits.

6.3. STUDY PROCEDURE RISKS

Confidentiality/privacy of data

Precedence Healthcare, the developers of the INCA software for online shared care plans, have put in place best-practice data storage and encryption procedures for medical data in Australia. This includes the storage of data on Sydney-hosted servers and SSL encryption across all databases, websites, sub-domains and company emails. Furthermore, all participants will sign up to the shared care software's Privacy Policy and Terms of Use which outline the type of information that is provided and how it will be handled throughout the trial to assess this risk themselves when they sign up for the trial. For the purposes of independence, bias minimisation and confidentiality, all consumer data provided by the software owners (from the software platform) to the investigators will be de-identified."

Other risks

Further study risks and their management are described in Table 8.

Table 8 Study risks and their management

Project phase	Description of risk	Risk mitigation strategy
Recruitment	Consumer feels pressured to be involved and/or concerned about consequences for their own treatment or care.	Initial approach at arm's length by mental health staff not involved in the study. Consumer can then elect to participate or not. During the recruitment interview, the research officer will emphasise that non-participation in the study will not impact their relationship with the MHS or their GP.
Recruitment	Inviting consumers to the study will take time for the care coordinators	Consultation meetings have been conducted with mental health staff to ensure their role is acceptable and not overly burdensome
Recruitment	There could be a variety of reasons why a GP may choose not to participate, such as time commitment and variability of PC skills and having to learn to use a software programme.	The trial is based upon our experience of working with GPs to install the same software package (different shared care template) for working with cancer specialists and their cancer patients. This experience identified that the software was easy to use and worked seamlessly with existing clinical software. In fact, it saved time for the GPs as they no longer needed to send letters or faxes to specialist services. Even so, training was provided (and will be provided in this study) by the research team and the software company. In addition, a position has been funded to ensure GPs are adequately supported to use the new software.
Interviews	Consumer/carer research participant feels uncomfortable about engaging in the interview.	Consumer reminded that they can withdraw at any stage or take a break.

Interviews	Emotional responses activated during the interview	If participants become distressed during the interview, researchers will provide basic support and inform the care coordinator that the consumer was feeling distressed and might need follow up. If this happens out of hours, the researcher will ask the consumer if there is somebody they should call who can provide support e.g., support worker, GP or carer. If the researcher is concerned about a participant's safety out of hours, they will contact the mental health line 1800-011-511. Support information is also provided on the PISCF.
Intervention	Consumer feels uncomfortable with information being shared between health care providers or participating in consultations via telehealth	Participants are reminded that participation in shared care and/or telehealth consultations is voluntary and they may withdraw at any time.
Intervention	Care plan does not meet all consumer's needs or their condition becomes more acute.	Consumers can access the care plan and ask their GP or the care coordinator to make changes to add additional roles or actions. GPs are informed how they can quickly escalate care if the consumer's condition becomes more acute or unstable.
Intervention	Adverse event due to a task in the care plan being missed	Care coordinator will regularly review incomplete care plan tasks. Any adverse event thought to be associated with tasks not completed in the care plan will be regularly reviewed by an independent safety and monitoring committee.

Independent Safety and Monitoring Committee

Given the nature of the intervention and the short duration of the trial adverse events are unlikely. However, in case an adverse event does arise as a result of the intervention or the data collection, an Independent Safety and Monitoring Committee (ISMC) will be established with three people to monitor adverse events linked to the trial.

The Project Steering Committee will report to the ISMC via an online meeting if an adverse arises or, if not, every 6 months. Adverse events will be identified via the SLHD incident management system (IMS) and GPs in the intervention arm of the trial.

About ten adverse events occur each week across the five mental health teams in SLHD. Two of these teams will receive the intervention so less than five adverse events might normally occur. These events are reported to and managed by the SLHD IMS. Dr Andrew McDonald, Principal Investigator and Director of Clinical Services (SLHD Mental Health) will receive weekly reports of adverse events and identify those consumers who are enrolled in the intervention arm of the trial. He will review those reports to ascertain if the incident might be related to the trial. This might require some enquiries to be made by Dr McDonald. If, in his professional judgement, he thinks there is any possibility that the incident was related to the intervention, he will then refer it to the ISMC for discussion and direction. A meeting would be scheduled for within a week. In the meantime, the SLHD normal process for incident management will also occur.

GPs in the intervention arm of the trial will be asked (via the GP Participant Information Sheet, Appendix 10.2) to notify the care coordinator of any adverse events related to the trial. The care coordinator will enter an IMS+ notification that goes through the above process.

6.4. PARTICIPANT RECRUITMENT AND SCREENING

Will participants be screened?	YES
If yes, what data will be collected? (NB, if participant is not eligible, will data collected be destroyed or kept?) This should be mentioned in PIS/CF)	Age, ability to give consent, in shared care or willing to enter shared care arrangement, language
Who will make initial contact with participants?	Care Coordinators and Shared Care Clinicians ("Clinicians") at participating mental health services will verbally introduce the study to the consumer during a consultation.
Who will perform the consent process? How will this be carried out?	A research officer will explain the contents of the participant information form using a script (Appendix

Will participants be screened?	YES
If yes, what data will be collected? (NB, if participant is not eligible, will data collected be destroyed or kept?) This should be mentioned in PIS/CF)	Age, ability to give consent, in shared care or willing to enter shared care arrangement, language
Who will make initial contact with participants?	Care Coordinators and Shared Care Clinicians ("Clinicians") at participating mental health services will verbally introduce the study to the consumer during a consultation.
	10.6) and answer any questions the consumer might have.
Will participants be consented verbally/explicitly/using eConsent?	Explicit or verbal
Will participants be given 24 hours to consider participating?	YES
Review of existing databases or databanks (please identify the database/databank and the custodian)	SLHD hospital records(SLHD), HealtheNet (eMR SLHD), ICOD (New South Wales Ministry of Health), GP records (private practice). De-identified data will be stored in ReDCap of the SLHD

Will participants be screened?	YES
If yes, what data will be collected? (NB, if participant is not eligible, will data collected be destroyed or kept?) This should be mentioned in PIS/CF)	Age, ability to give consent, in shared care or willing to enter shared care arrangement, language
Who will make initial contact with participants?	Care Coordinators and Shared Care Clinicians ("Clinicians") at participating mental health services will verbally introduce the study to the consumer during a consultation.
Review of clinic files (please include who will be reviewing these files, for example a research coordinator).	LHD mental health clinic files will not be reviewed by the research team.
Advertisements (please include where the advertisement will be placed for example, in a newspaper, poster in a clinic or hospital foyer, radio announcements, website etc.)	A recruitment advertisement will be placed in clinic waiting rooms, inviting consumers to contact a member of the clinical team to discuss the study (Appendix 5)
Information Letter to Medical practitioners	YES (Appendix 10.2)
Explain how potential participants will be screened for the study	Clinician will assess suitability for study criteria

Will participants be screened?	YES
If yes, what data will be collected? (NB, if participant is not eligible, will data collected be destroyed or kept?) This should be mentioned in PIS/CF)	Age, ability to give consent, in shared care or willing to enter shared care arrangement, language
Who will make initial contact with participants?	Care Coordinators and Shared Care Clinicians ("Clinicians") at participating mental health services will verbally introduce the study to the consumer during a consultation.
Any other potential recruitment methods.	-

6.5. PARTICIPANT ENROLMENT

Potential participants will be enrolled into the study after the informed consent process has been completed and the participant has been assessed to meet all the inclusion criteria and none of the exclusion criteria. Study participants will receive a study enrolment number and this will be documented on all study documents.

6.6. INFORMATION AND CONSENT

All potential study participants will be provided with a comprehensive information sheet about the research (Appendix 8) and they will be required to provide written consent (Appendix 11) (or verbal consent if they have literacy difficulties Appendix 11.2) before being able to participate in the study.

SLHD templates have been used to develop the information and consent forms.

6.7 WAIVER OF CONSENT

Not applicable

6.8. END OF STUDY TREATMENT/WITHDRAWAL PROCEDURE

Participants may withdraw from the study at any time. If they decide to withdraw from this research project, they will need to notify a member of the research team (details provided in the participant information sheet) and they will be asked to complete withdrawal form. If they do not want to complete a withdrawal form, the research team will try to ascertain the reason for withdrawal, whether there are any problems that need to be followed up, and whether the existing data and secondary data can be used.

Withdrawn participants will not be replaced.

After the intervention, GPs who wish to continue to use this online shared care plan will need to pay an annual fee (currently estimated to be $60 per practice per annum). Alternatively, the online shared care plan can be exported as a text document (pdf format) and used in the same way that existing care plans are used by GPs and mental health services and saved within their medical record software.

6.9. PARTICIPANT WITHDRAWAL

Participants may withdraw from the study for the following reasons: participant has chosen to withdraw from the study, protocol violation, or participant has experienced an adverse event.

If a participant withdraws from the study, the research team will not collect additional health information about that person, although 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 the participant does not want their data to be included, they must tell the researchers when they withdraw from the project.

The consumer will be coded as ‘withdrawn – existing data to be used ’or ‘withdrawn – existing data not to be used’.

7. OUTCOMES AND DATA SOURCES

Table 9 Outcomes and their data sources

Concept	Primary Outcomes	Data source
1 Preventive care	GP-recorded screening of health risks 6-month period post-intervention* (May-October 2023) compared with the 6-month periods: • Pre-intervention (November 2022-April 2023) • In the previous year (May-October 2022) **"intervention" = shard care plan in Inca (May-June 2023)*	GP records
	GP-recorded prescription of antihypertensive or lipid lower medications 6-month period post-intervention* (May-October 2023) compared with the 6-month periods: • Pre-intervention (November 2022-April 2023) • In the previous year (May-October 2022) **"intervention" = shard care plan in Inca (May-June 2023)*	GP records & HealtheNet
	Consumer-reported advice/referral from GP for smoking cessation, diet and physical activity in last 6 months	Consumer survey

Concept	Secondary Outcomes	Data source
1 Preventive care	GP-recorded care plans: GPNP and Team Care, mental health 6-month period post-intervention* (May-October 2023) compared with the 6-month periods: • Pre-intervention (November 2022-April 2023) • In the previous year (May-October 2022) **"intervention" = shard care plan in Inca (May-June 2023)*	GP records
2 Integration of care	Consumer assessment of extent to which providers (MH & GP) are working to a common care plan in last 6 months	Consumer survey
	Provider reported quality of communication between MHSs and GPs in last 6 months	Provider survey and qualitative interviews

Concept	Secondary Outcomes	Data source
3 Health service use	ED use and hospitalisations for primary care preventable conditions and other conditions 6-month period post-intervention* (May-October 2023) compared with the 6-month periods: • Pre-intervention (November 2022-April 2023) • In the previous year (May-October 2022, to check for seasonal effect) **"intervention" = shard care plan in Inca (May-June 2023)*	SLHD eMR (Appendix 14), Integrated Care Outcomes Database (ICOD)
	GP visits 6-month period post-intervention* (May-October 2023) compared with the 6-month periods: • Pre-intervention (November 2022-April 2023) • In the previous year (May-October 2022, to check for seasonal effect) **"intervention" = shard care plan in Inca (May-June 2023)*	GP records EMR Report (CMH011 Document Audit)
	Number of consumers engaged in Mental Health Shared Care arrangements and applicable outcomes, GP contact details	EMR Reports (AMH Current Clients; AMH Metabolic Monitoring) (Appendix 14),
	Consumer experience of providers (MH & GP) working to a common care plan in last 2 years	Consumer and carer qualitative interviews
4 consumer health risks	Consumer health literacy score in last 6 months	Consumer survey
	Consumer health risk behaviours in las 6 months	
	Consumer diabetes risk score on AUSDRISK in last 6 months***	

Concept	Secondary Outcomes	Data source
5 Cost-consequence and cost-effectiveness	Costs of hospitalisations and other healthcare services avoided 6-month period post-intervention* (May-October 2023) compared with the 6-month periods: • Pre-intervention (November 2022-April 2023) • In the previous year (May-October 2022, to check for seasonal effect) **"intervention" = shard care plan in Inca (May-June 2023)*	Hospitalisations data, SLHD Healthcare Use (especially hospitalisations, length of stay, procedures) and Cost data using medical record numbers, Consumer survey, eMR Reports 'AMH Current Clients', 'CMH011 Document Audit', and 'AMH Metabolic Monitoring', SLHD Targeted Activity & Reporting System (STARS)
	Consumer quality of life score on EQ5D-5L in last 6 months	Consumer survey

* See Table 3
** See Table 4
*** See Table 5

8. STATISTICAL CONSIDERATIONS

8.1. SAMPLE SIZE OR POWER CALCULATION

We aim to recruit 500 consumers and expect 400 to remain in the study at 9-month follow-up (20% loss to follow up). Power calculation: Assuming 20% change, a sample size of 91 per group is required to detect a change from 30 to 50% in primary outcomes based on $\alpha = 0.05$, $1-\beta = 0.8$. Assuming a design effect due to clustering of 2, a total sample of 360 is required (180 in each group).

8.2. PROVIDE A DETAILED ANALYSIS PLAN

Quantitative analysis

The fidelity and tailoring of the intervention to participants' needs will be assessed by analysing records, provider and consumer interviews 3 months after their usual shared care appointments. We will compare outcomes over 3 months after intervention between SHAReD intervention and comparison groups with linear or generalised multi-level mixed models including age, sex and key independent variables that are found to be significantly different between groups at baseline. Intra-class correlations will be calculated to compare the amount of variance associated with design features such as individual participants nested within care coordinators who are nested within community mental health teams, and those same participants are also nested within GPs who could also be nested within medical centres, before selecting random effects for these statistical models. As well as an analysis of completers (defined as those consumers, care coordinator and GP who

consented and are engaged in shared care), an intention to treat (ITT) analysis will also be included for this project. For the ITT analysis, those who drop out of the study (defined as consumers who were discharged of shared care or who withdrew consent) will be treated using a variety of sensitivity analyses including multiple imputation for the missing values on key measures resulting from them dropping out of the study. Sensitivity analyses will assess unmeasured variation.

Qualitative analyses

This will evaluate the experience of participants, carers and providers, barriers to implementation, conditions for sustainability and translation. Qualitative data will be managed and coded using NVivo 11 analysis software (QSR International). Two researchers will review each transcript and develop coding aligned with the Theoretical Domains Framework and Normalisation Process Theory.[25,26] Coding will be predominantly deductive but inductive coding will also be applied to detect new and emerging themes.

Data combining and cost analyses

Secondary data from GP records, and SLHD eMR data (including hospitalisations, ED visits and ambulatory care records, associated costs, documentation audit report and metabolic report) as well as information from SLHD Targeted Activity & Reporting System (STARS) will be obtained and merged with the consumer survey data within the SLHD by AI Beatriz Lopez Portillo/AI Andrew Simpson. GP records will be used to answer research questions 1 and 2 – quantitative analysis is described above. SLHD's patient data from the eMR (including hospitalisation, ED visits, ambulatory data, documentation audit and metabolic monitoring) as well as information from STARS and cost information will be used to answer research questions 3 and 4. These analyses of the resulting combined and de-identified dataset are described below.

The merged SLHD administrative data (micro-level data) will be from a 6-month period post-intervention (May-October 2023, considering the intervention as having a shared care plan in Inca between May and June 2023) compared with the 6-month periods, a) pre-intervention (November 2022-April 2023) and b) in the previous year (May-October 2022, to check for seasonal effect). The data will be analysed as part of the healthcare cost component (in the larger health economic evaluation).

The healthcare usage (such as hospitalisations, ED visits, ambulatory care and GP care) data will firstly be grouped in a meaningful way e.g., for hospitalisations, summarised by ARDRGs, diagnoses and average length of stay. Costs will be summarised too e.g., for hospitalisation costs, these will be described in terms of main components such as 'Medical', 'Nursing' and 'Allied Health' costs occurring during admissions. We will calculate the total and mean utilisation of healthcare services and costs (and undertake further econometric analyses) for those in the SHAReD intervention, usual care, and combined (SHAReD and comparison) groups. These summary statistics (and later modelled estimates) will be included in the cost component of the economic evaluation. Additionally, it will be informative to measure the healthcare costs of SMI from the viewpoint of the SLHD/NSW health system, expressed as average total costs of SMI treatment per person under the alternative care situations. The SHAReD care group may be broken down into several subgroups for the analysis, and based on the degree to which they completed the intervention (e.g. their adherence to the shared e-plan, how many times they were engaged with the essential components

of the intervention and what they received, the quality of SHAReD care delivery, and participant acceptability and responsiveness to the intervention).[27] All costs will be expressed in 2023 Australian dollars.

Econometric methods commonly used to address issues associated with healthcare usage and cost variables such as problems of heteroscedasticity and skewness will be applied in this study. [28] These methods will be used to estimate the total (and differences in/incremental) costs (and costs specific to single and multiple health conditions, health risks, cardiometabolic outcomes) associated with the SHAReD care situation versus usual care adjusted for several participant and system-level characteristics. Various econometric methods will be explored such as log- transformed ordinary least squares models, GLMs (and may be those for repeated measures/panel data too) and survival (duration) models, with "goodness of fit" and other statistical measures used to make decisions about the models. [29]

There may be missing data especially from the survey or general practice or as a result of merging data. This will be addressed by multiple imputation in the analysis.

To address confounding, variables with baseline differences between SHAReD intervention and usual care will be included in the final multivariate regression analysis.

To manage any risk that merging databases of non-identifiable data could subsequently result in the individuals being identified, data will be de-identified after combining the SLHD eMR data and costs with consumer survey data and stored securely (see section 12 of protocol). Only data with more than five individual responses will be released.

Costing component and the economic evaluation

An economic evaluation of the online shared care intervention (SHAReD) compared to usual care will be undertaken using the healthcare viewpoint. All relevant healthcare resources and health effects/benefits for the intervention and usual care groups will be identified, accurately counted and valued.

The healthcare resources used for delivering the SHAReD intervention and usual care will be identified, collected/estimated by researchers or clinicians delivering care, and valued. For the SHAReD intervention group, these will consist of the time of clinicians to develop the SHAReD care training program for staff, consumers and GPs; the materials used during the training (e.g. printing, travel time); the time of the facilitators to provide the staff training; and estimates of the time involved in general practice from encounter data and tasks (setting up care plan, making changes to or updating the care plan, communication with Mental Health team); essential infrastructure used; new technology purchased and used; training and supervision time for SHAReD participants and GPs; key medical treatments as per the description of the SHAReD intervention (such as medical tests, pathology, and medications); and consumables. The eMR reports such as CMH011 Document Audit, AMH Current Clients and AMH Metabolic Monitoring may be accessed by AI Beatriz Lopez Portillo and AI Andrew Simpson to identify any relevant healthcare items and costs. For both groups, the occurrence of hospital admissions, Emergency Department visits and other health service usage (such as ambulatory care) will be measured and valued. These data will be sought from the SLHD's

patient data collection using medical record numbers (and eMR) and associated SLHD costings during the study. Costs attributable to the research will not be considered. Estimates of how the work of clinicians (and thus costs) has changed from the situation without the SHAReD intervention will also be explored during the focus groups. Variations in healthcare usage (such as hospitalisations and other medical treatment sought) and costs occurring later in the study (and up to 3 months post completion of the intervention) will be sought from SLHD eMR reports and the SLHD Performance Unit for cost of ED presentations and hospitalisations. The mean costs in the SHAReD intervention and usual care groups will be compared in addition to the mean health effects/benefits such as the care plan completion rate, quality of care received, clinical metrics, hospital admissions (and readmissions), hospital length of stay, and score on the utility-based and disease-generic quality of life measure (EQ5D-5L). [30,31]

Having data on both the healthcare resource utilisation (costs) and health effects/benefits for the different groups will allow us to undertake a detailed cost-consequence analysis (CCA) – a first step for the economic assessment. CCA is a widely used form of economic assessment and recommended for reporting on health interventions with significant complexity and when there are multiple effectiveness measures such as programs/models of care seeking to address a range of clinical outcomes (Drummond et al 2005), and broad-reaching programs that have a range of health and non-health related effects needing to be quantified and assessed (NICE 2017). For this initial step of the economics work, the relevant costs and multiple outcomes will be calculated and presented in a disaggregated way which enables decision-makers to assess the relative importance of each component to the context they face. The comparator will consist of those consumers who did not receive the SHAReD intervention. Descriptive analysis will be used to estimate the total and mean costs (and standard deviations) associated with the intervention and usual care, as well as the effectiveness information (outcomes) and reported in a disaggregated manner.

A within-trial economic evaluation of the SHAReD intervention compared to usual care will be conducted if effectiveness has been demonstrated. The mean costs and health effects/benefits will be used to generate the incremental cost for a one-unit improvement in the health effect of interest (e.g. an extra Quality Adjusted Life Year [QALY]) for the SHAReD group compared to the usual care group. We will assemble several ICERs such as the incremental cost for each care plan completed, the reduction in cases with cardiometabolic risk (and separate risk factors), unplanned hospital admissions avoided, and a gain in QALYs among the SHAReD group compared with the usual care group. The results of the evaluation will be used to determine the within-trial cost-effectiveness (and utility) of the SHAReD intervention i.e. whether it offered value for money.

The results will be shown graphically on a cost-effectiveness plane.[32] Thus, the cost-effectiveness plane will show the differences in healthcare costs and health effects/benefits between the SHAReD intervention and usual care groups in two dimensions, with the healthcare costs plotted against health effects/benefits. We will use the bootstrap method, which is a re-sampling method used to estimate basic statistics on a population through sampling the dataset with replacement, to create 10,000 random samples and then use these samples to establish a statistical distribution for the costs and health effects/benefits (means and standard deviations) in the intervention and control groups, as well as to generate confidence intervals for the applicable ICER .[33] Various sensitivity

analyses will be undertaken. We will also generate a cost-effectiveness acceptability curve to summarise the impact of uncertainty on the results of the evaluation, expressed as the main ICER in relation to possible values of the cost-effectiveness threshold.[34] Values for thresholds will be determined by considering what is meaningful for the healthcare provider.

Health related quality of life will be collected using the EuroQol five dimensions, 5 levels questionnaire (i.e. EQ5D5L), which is a reliable and validated utility-based and disease-generic quality of life measure used for medical decision-making in Australia and elsewhere. The cost-effectiveness study will use QALYs gained as one of the main health effects based on the EQ5D5L questionnaires administered at baseline, during, and at completion of the trial. Factors for changes in the quality of life (including the various domains, visual analogue score, overall score and QALYs) of study participants over time will also be explored using a range of econometric methods, such as difference in difference models, generalised linear mixed models (GLMMs) for repeated measures /panel data and other panel data methods.

The effects of the SHAReD intervention on employment and other activities undertaken by participants (and costed out) will be examined using summary statistics and logistic/probit models.

The economic evaluation will apply established principles and methods for undertaking cost-effectiveness (and cost-utility) analyses, consistent with the National Health and Medical Research Council's (NHMRC) economic evaluation guidelines.[35]

9. DATA COLLECTION

9.1 Overview of forms for each data collection
Types of data and their respective forms (if applicable) are listed below, followed by a description of the procedures for data collection.

1. Existing (secondary) consumer data:
    a. general practice records extracted via PenCat and Polar
    b. SLHD Data from the Integrated Care Outcomes Database (ICOD) (Specific items in Appendix 1)
    c. ED Presentations, hospitalisations and medical treatment data using medical record numbers from the SLHD Performance Unit (Appendix 14)
    d. EMR Reports (Area Mental Health (AMH) Current Clients; CMH011 Document Audit; AMH Metabolic Monitoring) (Appendix 14)
    e. STARS Report (Community Ambulatory MH Report) (Appendix 14)
2. Quantitative data from:
    a. Consumer questionnaire (Appendix 3)
    b. Provider questionnaire (Appendix 4)
3. Qualitative data via interviews with:

a. Consumers and carers (Appendix 6)

b. Providers. (Appendix 7).

9.2 Consumer quantitative interviews

Survey interviews will be conducted with both intervention and comparison consumers at baseline and 3 months after their usual shared care (or 30 June 2023 if they did not have a shared care plan). The interview schedule components and their sources are summarised in Table 9.

Table 10 Sources of questions in the consumer survey

Outcomes	**Source of questions**
Consumer-reported advice/referral from GP for smoking cessation, diet and physical activity in last 6 months	Questions developed by CPHCE in previous research [32,33]
Consumer assessment of extent to which providers (MH & GP) are working to a common care plan in last 6 months	Question developed by CPHCE, informed by research on interprofessional teamworking in primary and community care settings[34]
Health literacy (Feeling understood and supported by healthcare providers)	Health Literacy Questionnaire (HLQ) (Domain 1)[35]
Current health risk behaviours	Questions developed by CPHCE
Absolute Cardiovascular Disease Risk	Australian Absolute Cardiovascular Disease Risk [37]
Diabetes risk	AUSDRISK [38]
Quality of life	EQ5D-5L[28,29]
Costs	Out-of-pocket costs

Accommodation of mental illness: Interviews will be usually conducted by telephone or video conferencing. Carers or support workers will be asked to assist if the participants agree. The interview questions will use plain English and graphic images. Where participants are judged by treating staff to be unable to understand or answer questions remotely the interviews will be conducted in person, with arrangements to ensure the safety of the consumer and research team. In person interviews will be conducted in a location such as health service and respecting social distancing in accordance with the COVID-19 plan of the SLHD. Carers or support workers will be asked to assist if the participant wishes.

The study procedure is flexible allowing interviews to be postponed if the participant is distressed or acutely ill. If participants become distressed during the interview, researchers will provide basic support and inform the care coordinator that the consumer was feeling distressed and might need follow up. If this happens out of hours, the researcher will ask the consumer if there is somebody they should call who can provide support e.g., support worker, GP or carer. If the researcher is concerned about a participant's safety out of hours, they will contact the mental health line 1800-011-511.

Assessment of participants 'degree of mental illness: The mental illness of participants will have been assessed by the SLHD mental health services.

Assessment of whether participants 'mental illness increases their susceptibility to discomfort or distress. The SLHD Care Coordinator will assess if the consumer participants have increased susceptibility to discomfort or distress and advise the consumer if they think participation in the study is appropriate at this time.

9.3 Provider (GP) interviews

Survey interviews will be conducted with GPs in the intervention and comparison groups at baseline and 3 months after consumers had had their usual shared care appointment (or 30 June 2023 if consumers didn't have a shared care appointment). The survey assesses engagement with the intervention (based on Normalisation Process Theory),[27] their confidence and practices including the quality of communication.

9.4 Qualitative interviews

The interviews with consumers, their carers and health care providers will explore their experiences with shared care and identify barriers and enablers to successful implementation, sustainability and translation. This will include questions around the changes in work, reflecting on the situation before and during the SHAReD intervention. These interviews will be conducted by telephone or video conferencing unless this is judged, by treating staff, to be unsuitable. In the latter case, in-person interviews will be arranged as described for the quantitative interviews.

The qualitative interviews will be conducted by research staff already employed by, or recruited by, the Centre for Primary Health Care and Equity (CPHCE). Interviewers will be recruited to the study if they have existing supervised experience with qualitative data collection with vulnerable populations and with health care professionals. In addition to existing experience, the interviewers will be given specific training to ensure they understand the specific needs of this study and of mental health service consumers, mental health service providers and GPs. Training will employ peer learning (more experienced researchers involved with teaching less experienced researchers) and will be cofacilitated by the academic and the SLHD investigators as well as people with lived experience from the SLHD.

Transcribers who are not listed investigators on the ethics application will be asked to sign a confidentiality agreement before being provided with access to recordings.

Study participants will not be asked to review their individual transcripts, but will be sent a summary of the results of the qualitative interviews for their comment.

9.5 Administrative health data collection within SLHD

Routine and administrative health data for study participants, maintained by the SLHD, for the purpose of measuring and valuing crucial outcomes and costs will be collected. The ambulatory data are contained in the electronic medical records reports: AMH Current Client, AMH Metabolic Monitoring and CMH011 Document Audit, and STARS report (Community Ambulatory MH Report); and ED visits, hospitalisations and costs associated with these stays from medical record numbers in SLHD.

10. PUBLICATION & INTELLECTUAL PROPERTY

The Project Steering Committee will be responsible for developing publication procedures and resolving authorship issues.

A plain-English summary report will be provided to participants.

11.ETHICS

11.1. INVESTIGATOR AUTHORISATION PROCEDURE

The conduct of this study will commence once the initial approval process has been completed through Ethics and Governance authorisation for SLHD.

11.2. Detail any waivers of consent sought, SLHD Privacy Compliance Form submitted

Not applicable

11.3. PROTOCOL AMENDMENTS

Updated documents will only be implemented once they have been reviewed and approved by an Ethics Committee and if applicable Governance Officer for each site.

12.CONFIDENTIALITY AND STORAGE AND ARCHIVING OF STUDY

See Appendix 12: The Research Data Management Plan.

13. REFERENCES

1 World Health Organization. Meeting report excess mortality in persons with severe mental disorders. WHO Headquarters, Geneva, 18-20 November 2015. Geneva: WHO, 2015 https://www.who.int/mental_health/evidence/excess_mortality_meeting_report.pdf.

2 Walker ER, McGee RE, Druss BG. Mortality in mental disorders and global disease burden implications: a systematic review and meta-analysis. *JAMA Psychiatry* 2015; **72**: 334–41.

3 National Mental Health Commission. Equally Well Consensus Statement: Improving the physical health and wellbeing of people living with mental illness in Australia. Sydney: NMHC, 2016 http://www.mentalhealthcommission.gov.au/our-work/equally-well.aspx.

4 De Hert M, Correll CU, Bobes J, *et al.* Physical illness in patients with severe mental disorders. I. Prevalence, impact of medications and disparities in health care. *World Psychiatry* 2011; **10**: 52–77.

5 Morgan VA, Waterreus A, Jablensky A, *et al.* People living with psychotic illness 2010. Report on the second Australian national survey. Canberra: Commonwealth of Australia, 2011 https://www.health.gov.au/internet/main/publishing.nsf/Content/717137A2F9B9FCC2CA257BF0001C118F/$File/psych10.pdf.

6 Mental Health Commission of NSW. Physical health and mental wellbeing: evidence guide. Sydney: Mental Health Commission of NSW, 2016 https://nswmentalhealthcommission.com.au/sites/default/files/publication-documents/Physical%20health%20and%20wellbeing%20-%20final%208%20Apr%202016%20WEB.pdf.

7 Firth J, Siddiqi N, Koyanagi A, *et al.* The Lancet Psychiatry Commission: a blueprint for protecting physical health in people with mental illness. *Lancet Psychiatry* 2019; **Published online July 16, 2019**. DOI:10.1016/S2215-0366(19)30132-4.

8 Inquiry report - Mental Health Productivity Commission. https://www.pc.gov.au/inquiries/completed/mental-health/report (accessed March 17, 2022).

9 RANZCP. The Economic Cost of Serious Mental Illness and Comorbidities in Australia and New Zealand. Royal Australian and New Zealand College of Psychiatrists (RANZCP), 2016.

10 Corrigan PW, Druss BG, Perlick DA. The impact of mental illness stigma on seeking and participating in mental health care. *Psychol Sci Public Interest* 2014; **15**: 37–70.

11 Simpson, A., Garcelon, L., Tippett, R., Clenaghan, P., Rimmer, P., Nolan, M., Parcsi, L., McDonald, A. GP & Mental Health Shared Care: Formalising Relationships to Improve Consumer Health Outcomes. Melbourne, 2029.

12 Song HJ, Harris M, Li F-Y, Green J, Knight A. Connecting General Practitioners Through a Peer-Facilitated Community of Practice for Chronic Disease Care. *The Annals of Family Medicine* 2020; **18**: 179–179.

13 Hespe C, Rychetnik L, Peiris D, Harris M. Informing implementation of quality improvement in Australian primary care. *BMC Health Services Research* 2018; **18**: 287.

14 SLHD. SLHD RPA Virtual Hospital - Home. https://www.slhd.nsw.gov.au/RPA-Virtual-Hospital/ (accessed May 22, 2021).

15 Schütze H, Chin M, Weller D, Harris MF. Patient, general practitioner and oncologist views regarding long-term cancer shared care. *Family practice* 2018; **35**: 323–9.

16 Emery JD, Shaw K, Williams B, *et al.* The role of primary care in early detection and follow-up of cancer. *Nature reviews Clinical oncology* 2014; **11**: 38–48.

17 Kooij L, Groen WG, Harten WH van. The Effectiveness of Information Technology-Supported Shared Care for Patients With Chronic Disease: A Systematic Review. *Journal of Medical Internet Research* 2017; **19**: e7405.

18 Harris M, Taggart J, Chin M, Liaw W. Electronic shared care plan for long term care of cancer patients. 2019; published online Oct 21. https://cphce.unsw.edu.au/research/prevention-and-management-long-term-conditions/electronic-shared-care-plan-long-term-care.

19 Zhao Y, Brettle A, Qiu L. The Effectiveness of Shared Care in Cancer Survivors—A Systematic Review. *International Journal of Integrated Care* 2018; **18**: 2.

20 Smith SM, Cousins G, Clyne B, Allwright S, O'Dowd T. Shared care across the interface between primary and specialty care in management of long term conditions. *Cochrane Database of Systematic Reviews* 2017. DOI:10.1002/14651858.CD004910.pub3.

21 van Dongen JJJ, van Bokhoven MA, Daniëls R, van der Weijden T, Emonts WWGP, Beurskens A. Developing interprofessional care plans in chronic care: a scoping review. *BMC Family Practice* 2016; **17**: 137.

22 Snoswell CL, Taylor ML, Comans TA, Smith AC, Gray LC, Caffery LJ. Determining if Telehealth Can Reduce Health System Costs: Scoping Review. *Journal of Medical Internet Research* 2020; **22**. DOI:10.2196/17298.

23 Yu H. Cancer Shared e-Care Plan Report. ; : 40.

24 Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation Science* 2012; **7**: 37.

25 Normalization Process Theory | Normalization Process Theory. http://www.normalizationprocess.org/ (accessed May 24, 2021).

26 EuroQol. EQ-5D-5L. 2017; published online April 18. https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/.

27 Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S. A conceptual framework for implementation fidelity. *Implement Sci* 2007; **2**: 40.

28 Kilian R, Matschinger H, Löeffler W, Roick C, Angermeyer MC. A comparison of methods to handle skew distributed cost variables in the analysis of the resource consumption in schizophrenia treatment. *J Ment Health Policy Econ* 2002; **5**: 21–31.

29 Mihaylova B, Briggs A, O'Hagan A, Thompson SG. Review of statistical methods for analysing healthcare resources and costs. *Health Econ* 2011; **20**: 897–916.

30 Herdman M, Gudex C, Lloyd A, *et al.* Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of life research* 2011; **20**: 1727–36.

31 Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. Methods for the Economic Evaluation of Health Care Programmes, Fourth Edition. Oxford, New York: Oxford University Press, 2015.

32 Cohen DJ, Reynolds MR. Interpreting the Results of Cost-Effectiveness Studies. *Journal of the American College of Cardiology* 2008; **52**: 2119–26.

33 Campbell MK, Torgerson DJ. Bootstrapping: estimating confidence intervals for cost-effectiveness ratios. *QJM: An International Journal of Medicine* 1999; **92**: 177–82.

34 Fenwick E, Marshall DA, Levy AR, Nichol G. Using and interpreting cost-effectiveness acceptability curves: an example using data from a trial of management strategies for atrial fibrillation. *BMC Health Services Research* 2006; **6**: 52.

35 Thorogood, M. and Y. Coombes. Evaluating Health Promotion: Practice and Methods. Oxford University Press https://oxford.universitypressscholarship.com/view/10.1093/acprof:oso/9780199569298.001.0001/acprof-9780199569298 (accessed May 22, 2021).

14. LIST OF APPENDICES

1. **SLHD Data from the Integrated Care Outcomes Database (ICOD)**
2. **MBS and PBS data (specific items)**
3. **Consumer survey questionnaire**
4. **Provider (GP) questionnaire**
5. **Recruitment advertisement**
6. **Consumer qualitative interview guide**
7. **Providers qualitative interview guide**
8. **Consumer invitation letter**
9. **Consumer expression of interest form**
10. **Participant information sheets:**
    - 10.1. **Information for consumers**
    - 10.2. **Information for GPs**
    - 10.3. **Information for Mental Health Service providers**
    - 10.4. **Information for carers**
    - 10.5. **Brief information for consumers (separate versions for a) intervention and b) control groups)**
    - 10.6. **Script for explaining study information to consumers**
11. **Consent forms:**
    - 11.1. **Written consent form for consumers**
    - 11.2. **Verbal consent form for consumers**
    - 11.3. **Consent form for GPs**
    - 11.4. **Consent form for Mental Health Service providers**
    - 11.5. **Consent form for carers**
    - 11.6. **Verbal consent form for GPs**
12. **Data management plan**
13. **Letter of invitation to care coordinators**
14. **ED Presentations, hospitalisation and medical treatment data using medical record numbers from the SLHD Performance Unit**
15. **GP recruitment**
    - 15.1. **GP invitation letter from Mental Health Service**
    - 15.2. **GP invitation letter from consumer**
    - 15.3. **Brief information for GPs**

15.4. GP telephone recruitment & interview script

16. Guide to assist care coordinators informing consumers whose GPs did not consent of the implications for their participation in the study

17. Follow-up Recruitment Advertisement

17.1a Script to call consumer for follow up survey and interview

17.1b Script to invite consumers face-to-face to participate in follow up survey and interview