Rosemary Bryant AO
Research Centre

Addressing safety, quality, and cost of care through a telehealth outpatient transitional care model: the TTOMMI trial

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Statement of Compliance

This document is a protocol for a research project. This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the
NHMRC National Statement on ethical Conduct in Human Research (2007).

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SYNOPSIS

Title:	Addressing safety, quality, and cost of care through a telehealth transitional care model – the TTOMMI trial
Short Title:	The TTOMMI trial
Design:	Pragmatic randomised control trial (pRCT)
Study Centres:	The Queen Elizabeth and Royal Adelaide Hospitals, and the University of South Australia
Hospital:	The Queen Elizabeth and Royal Adelaide Hospitals, Central Adelaide Local Health Network
Study Question:	Does a transitional model of care using a telehealth intervention decrease hospital readmission in patients with multimorbidity
Study Aim:	The aim of this study is to develop and test a transitional model of care to optimally support people living with multimorbidity, post-hospital discharge, via telehealth, and ensure continuity of care between the secondary (acute) and primary healthcare sectors to minimise direct contact with hospital services
Primary Objectives:	1. Assess impact of intervention on 1 month readmission post- discharge
Secondary Objectives	1. Calculate a cost analysis on the transitional service model of care 2. Evaluate the patient experience with continuity of care and the transition service 3. Assess patients' symptom burden pre and post transitional support service intervention 4. Evaluate patients' quality of life, self-efficacy, and symptom management, pre and post intervention
Inclusion Criteria:	• Adult inpatients at Royal Adelaide Hospital and The Queen Elizabeth Hospital in participating units and wards • Sufficient cognitive function and English language skills to be able to provide informed consent and complete assessments. (although interpreters are readily available in the inpatient setting, the main components of this intervention are via telehealth in the transition period after discharge Therefore although we will be able to communicate with the participant's family regarding their care and needs whilst in hospital, interpreter services may not be available via telehealth post-discharge. Also, given that the informed consent form and some written assessments are in English, they need to have adequate English language skills to provide written informed consent). • Ability to engage in telehealth • Presence of multimorbidity defined as :a history of a either diabetes with cardiovascular disease, OR comorbidity in at least 3 of the following illness domains: o Diabetes: type 1 or type 2 o Cardiovascular disease: symptomatic atherosclerotic disease (ischemic heart disease, cerebrovascular disease, peripheral vascular disease, symptomatic valvular heart disease or

	atrial fibrillation ○ Chronic cardiac failure ○ Psychiatric illness including mood or anxiety disorders ○ Respiratory disease including chronic obstructive airways disease, asthma, or interstitial lung disease ○ Kidney disease resulting in chronic renal impairment with creatinine clearance <30 ml/min ○ Current active malignancy
Exclusion Criteria:	• Patients living in or likely to be discharged to high level residential aged care facility • *Patients enrolled particularly comprehensive management programs on discharge from the TQEH, e.g., heart failure outreach service, COPD pulmonary rehabilitation or receiving disability or community psychiatric services including care coordination.* • Patients followed up through other CALHN services providing community outreach such as patients who are homeless • Patients with a current history of illicit drug or alcohol dependence which may interfere with ability to engage with the program • Patients with palliative intent and likely to have a life expectancy of less than 6 months • Patients due for elective readmission within 2 weeks of current hospital discharge
Number of Planned Participants:	200
Investigational product:	None
Safety considerations:	Low risk: discomfort with some types of questions related to mood, cognition, or personal issues for patients
Statistical Methods:	Linear regression analyses will be conducted to estimate effects of the intervention on primary and secondary outcomes. A hospital fixed effects model will be used to account for stratification at the hospital level. Sensitivity analyses will be performed to assess the robustness of the findings.

SUMMARY

Background

People with multimorbidity have high health service use and require access to an array of home and health support services. Increased communication and coordination of healthcare between the secondary and primary healthcare sectors has been shown to decrease hospital readmissions and increase primary healthcare use among this population.

A feasibility study was recently completed, which trialled a nurse-led transition care coordinator role to improve the quality of transitional care post-discharge, for people with multimorbidity who are at risk of hospital readmission. These patients typically have complex care needs requiring coordinated healthcare support beyond their admission diagnosis. It was proposed that a nurse coordinator role could be a cost-effective intervention to reduce readmission rates among this group of patients. The nurse coordinator performed a transition and risk assessment, then provided transition support over a six-week period post-discharge. The overall aim of this project was to test the feasibility of the service for people with multimorbidity and staff at Central Adelaide Local Health Network (CALHN).

The feasibility study proved successful, demonstrating evidence of acceptability, feasibility, fidelity and sustainability from both patients and staff. Results suggested promising effects on care coordination, patient experience, and hospital readmission rates could be demonstrated through a larger trial. Significantly, the study highlighted that there is currently no process within CALHN for assessing or managing risk of readmission among people with multimorbidity, despite international evidence that transitional care is associated with reduced rehospitalisation rates. The feasibility study also demonstrated that the transition coordinator (TC) role supported people with multimorbidity as they transferred back to their home and community.

Aim

The aim of this study is to develop and test a transitional model of care to support people living with multimorbidity following discharge from hospital. A follow up transition coordination service via telehealth with home and healthcare supports will be provided to embed continuity of care between the secondary (acute/hospital) and primary healthcare sectors. The objective is to minimise further direct contact with hospital services and to improve the patient transition experience.

Method

In the proposed transitional care service, the TC will play a key liaison role between multidisciplinary clinical disciplines and the patient, including liaison with the patient's GP. The TC will holistically assess each patient for risk of hospital readmission, collaboratively develop a transition plan with the patient, communicate with their GP, and provide telephone follow-up care coordination for up to six weeks post-discharge. Telephone calls with the patient will be structured in a therapeutic conversation to monitor the patient's symptoms, mental health, other healthcare needs and provision of effective support services. A multidisciplinary case discussion will occur around 4 weeks post- discharge in preparation for handover to the general practitioner and other specialist providers. The TC will have a final consultation with the patient after the multidisciplinary case discussion (4-6 weeks post-discharge), to inform the patient of any outcomes or actions.

Participants will be contacted 3 months after discharge from the transition service, to identify whether they have had ongoing interactions with their general practitioner, and the outcome of referrals to other services such as clinical psychology or My Aged Care. Participants will also be invited to complete a questionnaire at 3 months post-discharge, assessing patient care coordination (Patient Continuity of Care Questionnaire), symptom burden (the Edmonton Symptom Assessment System – Revised) and quality of life (EuroQol-5D-3L).

The patients will be followed up for one year after discharge through SA Health's patient administration systems to document subsequent readmission and outpatient interactions within SA health. This will be to document the potential costs of readmission for subsequent studies. There will be a final continuity of care questionnaire at 12 months, and then no further contact with the patient required.

INTRODUCTION

Due to increasing life expectancy and improvements in healthcare, the prevalence of multimorbidity (i.e., the presence of 2 or more chronic conditions) is rising. People with multimorbidity have health outcomes characterised by functional decline, decreased quality of life, and increased mortality.[1] Multimorbidity is also costly for health systems and society, due to associations with high hospital readmission rates,[2] high healthcare utilisation,[3, 4] and decreased productivity.[5-7] These challenges are perpetuated because health systems are designed for acute and critical illness episodes, and do not effectively address the needs of people with multimorbidity. This population often receive fragmented health services, leaving them vulnerable to receiving inadequate care at the point of transition between the secondary (acute, hospital) and primary healthcare sectors, and at risk of preventable hospital readmission.

Historically, the health system has been underpinned and strengthened by the primacy of the single disease model of illness.[8] However, there is consensus that the single disease model is unsuitable for people with multimorbidity and coordinated models of care at the primary/secondary inter-health sector interface are required to reduce care fragmentation and support positive patient experiences.[9-11]

Several transition interventions have been trialled to reduce high short term readmission rates, [12, 13] however, no discrete intervention or bundle of interventions has been found to reliably reduce rehospitalisation. Some interventions which have been found to be useful include a transition coach, home visits, post-discharge telephone calls. A transition coach engages with the patient throughout the hospitalisation as well as after discharge. Pre-discharge visits in these interventions focused on disease-specific education and the completion of a social needs assessment, and post-discharge contacts focused on medication adherence, appropriate ambulatory follow-up, and symptom monitoring[14].

Patients with multimorbidity often have polypharmacy and are frequently readmitted due to medication misadventure. Depression and anxiety are also common in patients with multimorbidity and may be associated with worse outcomes. Hence, interventions such as home medication reviews, and mental health care plans, which are available through Commonwealth Government funding, may also be useful in reducing readmission in patients with multimorbidity.

The COVID-19 pandemic has required many organisations to implement telehealth as a way of delivering care. Many services which were previously only provided face to face, or through outpatients, have now been successfully transitioned to a telehealth service. There are still issues with telehealth delivery, including device and internet capabilities at the consumer end, the unfamiliarity of the user interface, and uncertainty regarding the cost effectiveness at the provider end.

Although intensive interventions including multidisciplinary care, and home visits have been shown to reduce short term readmissions, they may not be cost effective in all settings, and are difficult to implement across an organisation. Low intensity interventions such as phone calls are easy to implement, however, have not been shown by themselves to impact on readmission rates[15]. What is needed is a low-cost intervention which combines multiple interventions into a coordinated package, which can be delivered without requiring face to face or outpatient consultations, and which if successful, can be readily spread across an organization.

A recent feasibility study (Telehealth Transition of Multimorbid Individuals [TTOMMI] study) conducted at the Royal Adelaide Hospital demonstrated acceptability, feasibility, and usefulness of a transition care coordination service for both patients and staff. Moving forward, the aim of this pragmatic randomised control study is to develop and test a transitional model of care to optimally support people living with multimorbidity, via telehealth, and decrease hospital readmissions. The study is expected to commence 1 July 2023, and complete 1 February 2025.

STUDY PURPOSE

The main purpose of this study is to implement a transitional model of care to minimise unnecessary hospital admissions and emergency department presentations for patients with multimorbidity. The research study is being implemented initially at the Queen Elizabeth, and then the Royal Adelaide Hospitals. This is because the Central Adelaide Local Health Network (CALHN) does not have embedded transition care coordination pathways, protocols, or services. This is significant because transition coordination between the primary and secondary healthcare sectors has been shown to decrease hospital readmissions and increase primary healthcare use.[16]

AIM AND HYPOTHESIS

The aim of this study is to develop and test a transitional model of care to optimally support people living with multimorbidity, post-hospital discharge, via telehealth, and ensure continuity of care between the secondary (acute) and primary healthcare sectors to minimise direct contact with hospital services. We hypothesise that the provision of a transition support service, post-hospital discharge, for patients with multimorbidity will decrease the short-term hospital readmission rate for that patient cohort.

METHODS

Study design and schedule

The study design is a multi-centre pragmatic randomised control trial (pRCT) of patients with multimorbidity. As this is a pRCT, real-world clinical practices, patient flow, and operations will be considerations within the research design elements. A mixed methods approach using quantitative and qualitative data collection methods will be employed. The study setting will be multi-centre, commencing at the Queen Elizabeth Hospital (TQEH), and progressing to the Royal Adelaide Hospital (RAH), Central Adelaide Network (CALHN). Between 3 and 6 medical units and wards will be included.

Randomisation

The randomisation will be at the level of the individual patient. We will go from ward/unit to ward/unit to get the nursing staff to make referrals, but then the patients themselves will be randomised 1:1 to intervention or control. As part of the information provision during the consent discussion, patients will be advised of the randomisation process and its implications.

Participants

The eligible population will be adult inpatients 18 years of age and over that fulfill all inclusion criteria and do not meet any of the exclusion criteria (see Table 1). The patient population was selected as previous work by our team had demonstrated that this population had an approximate 25-30% 28-day readmission rate.

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria

• Inpatients (ward or emergency department)
• Sufficient cognitive function and English language skills to provide informed consent and complete assessments. (Although interpreters are readily available in the inpatient setting, the main components of this intervention are via telehealth in the transition period after discharge Therefore although we will be able to communicate with the participant's family regarding their care and needs whilst in hospital, interpreter services may not be available via telehealth post-discharge. Also, given that the informed consent form and some written assessments are in English, they need to have adequate English language skills to provide written informed consent).
• Ability to engage in telehealth
• A history of either diabetes with cardiovascular disease, or comorbidity in at least 3 of the following illness domains:
  ○ Diabetes: type 1 or type 2
  ○ Cardiovascular disease: symptomatic atherosclerotic disease (ischemic heart disease, cerebrovascular disease, peripheral vascular disease, symptomatic valvular heart disease or atrial fibrillation
  ○ Chronic cardiac failure
  ○ Psychiatric illness including mood or anxiety disorders
  ○ Respiratory disease including chronic obstructive airways disease, asthma, or interstitial lung disease
  ○ Kidney disease resulting in chronic renal impairment with creatinine clearance ≤30 ml/min
  ○ Current active malignancy.
	• Patients living in or likely to be discharged to high level residential aged care facility
	• Patients enrolled in a comprehensive management program on discharge, e.g., formal rehabilitation program, rehabilitation in the home, heart failure outreach service, COPD pulmonary rehabilitation, hospital in the home, or receiving disability or community psychiatric services including care coordination
	• Patients followed up through other local health network (LHN) services providing community outreach such as patients who are homeless
	• Patients with a current history of illicit drug or alcohol dependence which may interfere with ability to engage with the program
	• Patients with palliative intent and likely to have a life expectancy of less than 6 months
	• Patients due for elective readmission within 2 weeks of current hospital discharge
	• Insufficient cognitive function or English language skills to provide informed consent and complete assessments.

Identification and recruitment of participants

Several procedures will be used to identify and recruit participants for the trial intervention. For the intervention ward(s):

- Ward staff, patient flow and bed management meetings will be attended by the Research Project Manager to brief staff explain on all aspects of the research and introduce the TCs and their role.
- Emails and flyers will be sent by Dr. Kate Davis to medical, nursing, pharmacy and allied health leads as well as relevant clinical staff. These communiques will again explain all aspects of the research and introduce the TCs and their role.
- Study criteria will be entered into Sunrise and a trial list created to triage potential participants into a patient list. The TCs (CALHN employees) or CALHN Research Investigator (Kate Davis,

Associate CALHN employee, with sunrise access permissions in accordance with CALHN policy) will review the list daily and follow up with relevant treating clinicians.

- Additionally, a referral process will be set up in Sunrise. Staff on the study wards can independently make a referral to the TCs through the Sunrise system. However, the first approach to the patient will be by a treating clinician (ward nurse or treating physician), who will seek the patient's permission to be approached by a CALHN Investigator or TC, who will then follow patients up.
- Trial wards will be rounded daily, and nursing/medical staff liaised with to identify patients.
- Huddles will be attended, and nursing/medical staff liaised with to identify patients.

Access to patient information will only be available for SA Health staff. Researchers who are not SA Health staff will only be able to view deidentified information which has been entered into case report forms.

Consent process

Dr Davis, or TCs will obtain participants' informed consent. Only the participants will provide informed consent. Prior to approaching patients on the ward, the clinical team managing the patient will first be consulted and permission granted for a research team member to then approach the patient. This will ensure that discussion of the research is appropriate with the identified patient. If the person is receptive, the TC will discuss the study and all procedures with them. The patient will then be invited to participate in the study. If they are open to the invitation, the participant information sheet and a consent form will be left with the patient for 24 hours. Patients will be advised to consult with a partner, significant other, or close family member regarding their consent to participate in the research, and to contact the TC to discuss or clarify any aspects of the research. The patient will then be approached 24 hours later to confirm willingness to take part in the study. Written, informed consent will be obtained by The TCs (CALHN employees) or CALHN Research Investigator, Dr Kate Davis, for all participants to ensure that they understand the study requirements, risks, and benefits.

Once the participant has provided consent (which will include discussing the protocol with family members) we will reach out to multiple members of the participant's health care team which will include their family, carers, general practitioner, and practice nurse. These individuals will be invited collaborate in the participant's care but will not be explicitly consented. People will then be approached in person by the TCs (CALHN employees) or CALHN Research Investigator (Dr Kate Davis) and invited to hear about the transition service study.

The patient population will have multimorbidity and may even be frail, and collaboration with family or significant others may be required/ongoing. Therefore, to balance the patient's agency with their desire for family/significant other involvement, consultation, and discussion with the patients in relation to this will be ongoing.

We would like to waive consent for the TCs (both will be RN's, Level 2, and CALHN employees) to initially access potential participants' information on Sunrise. This initial access would enable assessment of potential participants' eligibility for the study. We formally request the CALHN HREA to waive the necessity for consent at this point (to view potential participants' MR, at this 'screening of MR for eligibility stage'). The justification for this is that the risks associated with this are low. The benefits of accessing the potential participants' information for the study, if eligible, exceeds the risk of the TCs reviewing the patient's medical history without prior

consent. It would be impractical to consent all of the participants who need to be reviewed in order to see whether they should be approached for the study, i.e., the time taken to see, explain and consent patients (for permission to review their medical record) would be inordinate. To protect the patient's privacy the details of the participants who are accessed will be documented on paper, then will be discarded through the confidential bins when no longer needed. The following points also apply:

a. There is no known or likely reason for thinking that participants would not consent if they were asked
b. There is sufficient protection of their privacy
c. There is an adequate plan to protect the confidentiality of data
d. The waiver is not prohibited by State, federal, or international law.

Waiver of Consent

The information below addresses the justification required when requesting a waiver of consent. These point demonstrates that the TTOMMI trial project meets all requirements of Chapter 2.3.10 of the NHMRC National Statement on Ethical Conduct in Human Research (2007):

1. *Involvement in the research carries no more than low risk.*

   Response: Involvement in the research carries no more than low risk because there is no anticipated harm or discomfort for participants associated with taking part. However, there are four possible low/minor risks, including:

   1. TCs accessing potential patients' medical information during the screening process for participant eligibility, without their prior consent (thus this waiver for consent at this point).
   2. The additional contact and healthcare interactions which the patients receive as part of the care transition service.
   3. The conduct of the questionnaires and the inconvenience and discomfort associated with answering the questions.
   4. The potential for creating dependency in the relationship between the TC and participant

The first risk will be managed through SA Health permission to the waiving of consent for this procedure (for rationale -see above). Secondly, the new and ongoing home/healthcare services the patient receives during the transition intervention will be provided through professional health support services. The patient will not be exposed to any additional risk other than that which people would normally incur when routinely accessing these services. The other anticipated inconvenience is tiring during assessment, or questionnaire completion. Patients will be offered breaks and comfort rests where appropriate.

b) *The benefits from the research justify any risks of harm associated with not seeking consent*
   Response: The benefits include minimising unnecessary contact, potential interactions, stress or confusion with patients, as well as not wasting patients' time. Unnecessary, because during the 'screening for eligibility process' a majority of patients will be found to be ineligible (this was the case in the feasibility study).

c) It is impracticable to obtain consent, and the rationales for this are addressed below including the following points:

   ►Why is it impractical to gain consent?

   ►Time period

►How many records will be accessed?

►Are there limitations to resources?

►Mortality rates

►Lost to follow up

It is impracticable to obtain consents because of the volume of patients required to screen each day, and the additional time and cost this would take for the researchers. The additional time and cost would not contribute to improved ethical outcomes; therefore, the additional time would be unnecessary, inordinate and preclude meeting study timelines. Impracticability of obtaining consent particularly relates to the quantity of patient medical records that require scrutiny during the screening for eligibility, the age of patents is an issue as far as some maybe quite elderly or frail and additional unnecessary contact with researchers could be stressful. The accessibility of records is not an issue, however the limitations to resources, is an issue as stated above, the additional time required would be unjustifiably costly. The mortality rate of participants will not be affected and the inability to contact participants due to access to contact details or due to likelihood of contact details having changed due to time or due to characteristics of participant groups, is irrelevant.

d) *There is no known or likely reason for thinking that participants would not have consented if they had been asked.*
Response: There is no known or likely reason for thinking that participants would not have consented if they had been asked, however as discussed in point c (above) obtaining consent is impracticable.

e) There is sufficient protection of their privacy
Response: To protect the patient's privacy the details of the participants who are accessed will be documented on paper, then will be discarded through the confidential bins when no longer needed.

f) There is an adequate plan to protect the confidentiality of data, including:

►What format are they storing data in?

►Where is data being stored?

►Who will have access to identifiable data?

►Will data be re-identifiable?

►Which investigator is responsible for de-identifying data?

►Are you using REDCap?

Response: Professor Sepehr Shakib and the two Transition Coordinators (CALHN employees) will be the only researchers/clinicians accessing patients' medical admission data for the purposes of screening at this point. These researchers/employees are obliged to comply with SA Health patient privacy and confidentiality policies (Privacy Policy Directive Policy No.: D0445).

g) *In case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)*
Response: Patients who are screened and found to be ineligible for the study will not be followed up in any way. Any documentation or listing of these patients' details (documentation will be on paper) will be discarded through the confidential bins when no longer needed. Information will be made available to patients consenting to and taking part in the research, as discussed in section 'Dissemination of program

outcomes'.

h) *The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled*

Response: There will be no entitlement for these patients, as they are not participating in the research and their details will be confidentiality discarded (following discernment of ineligibility during the screening process).

i) *The waiver is not prohibited by State, federal, or international law.*

Response:

The consent waiver being applied for is only applicable at the point of screening for study eligibility and is not prohibited by State, federal, or international law.

Data access

Access to participants medical record will require accessing data through Sunrise. Table 2 below lists the data source, software and related information to be accessed as part of the study.

Table 2. Access to existing data

Access to existing data table	
Name/Description of data	CALHN Electronic Medical Records
Data Custodian	CALHN
Database Name	Sunrise
Agency Type	State
Data Collection Format	Identifiable

Intervention

The intervention involves a transitional care service, based on the transition care model developed by Naylor and colleagues.[17,18] The intervention components were informed by the following: literature on transitional care; the study team's prior experience in delivering nurse-led models of care for people with multimorbidity; previous consumer/participant feedback from the feasibility study; and, the Foundations Framework for developing and reporting models of care for multimorbidity.[19] The intervention will be provided by registered nurses referred to as Transition Coordinators (TCs). The TC's role is supported by Naylor's transitional model, which requires the provision of:

> a broad range of time-limited services designed to ensure health care continuity, avoid preventable poor outcomes among at-risk populations, and promote the safe and timely transfer of patients from one level of care to another or from one type of setting to another.[20]

Each participant in the study will have a 'primary transition coordinator' who will have responsibility to provide care coordination and continuity of care for that participant's transition. However, the information will be carefully documented and handed over in case of unavailability of the primary transition coordinator, to a 'secondary transition coordinator'.

Transition care coordination involves three stages: inpatient baseline assessment, risk of readmission and transition planning, transitional care coordination, and handover to the general practitioner. Successful transition coordination requires that when patients are discharged from hospital General Practitioners (GPs) are notified (phone call) within 24 hours of discharge, and an appointment made for patient review in a timely manner. It will be the TCs responsibility to provide the GP with information regarding the time critical nature of the appointment. We will test this as part of our intervention. Figure 1 represents the intervention components,

aligned to the key areas in Stokes' framework: clinical focus, organisation of care delivery, and support for model delivery.

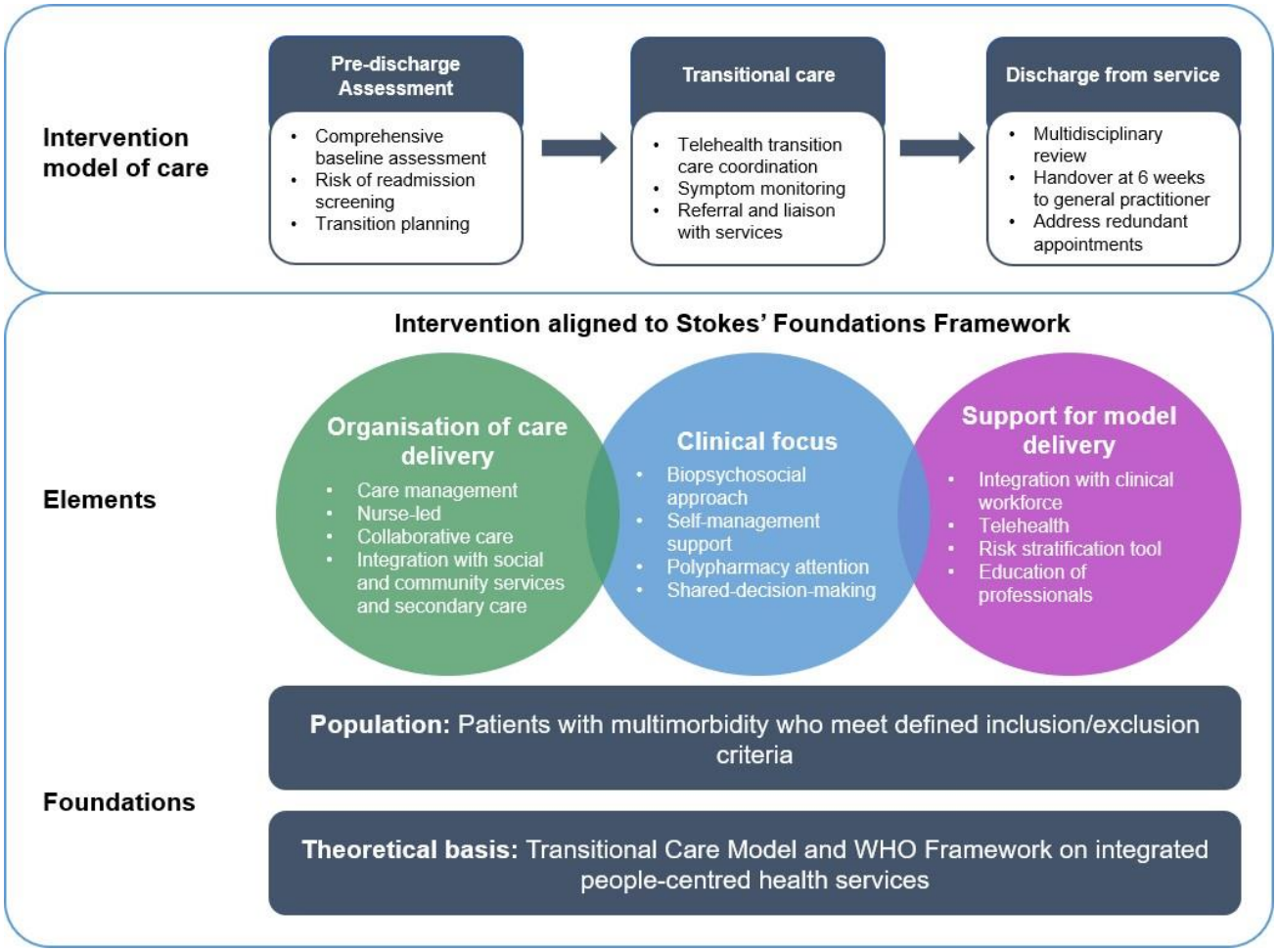

Figure 1. The intervention components, aligned to the key areas in Stokes' framework.

Baseline assessment and planning

At baseline, the TC will assess the participant demographics, frailty, activities of daily living, cognitive function, depression and anxiety, mobility, health literacy, medication management, comorbidities, nutrition, end-of-life planning, and risk of re-hospitalisation. Next, the TC will develop a Transition Action Plan (TAP) with the patient, identifying services required on discharge (e.g., meals assistance, medication review, psychology). The TAP will be reviewed with the patient prior to discharge, entered into the patient's medical notes, and communicated to the GP (within 24 hours of discharge). The TC will ensure a post-discharge GP appointment within 2 weeks of discharge, preferably within the first week, and organize a home medication review if appropriate. The process of transition patient assessment, care planning and communication is anticipated to take between 2 and 3 hours. Within the research context, the assessment and planning time are fundamental in establishing a therapeutic, sensitive, and trusting relationship between the TC and patient, without burdening the patient. The patient will be provided with the choice to self-select the technology used for communication. The post-hospital discharge care coordination follow

up appointments will be via Telehealth, using telephone, or iPad/app (provided). If the patient self-selects 'iPad/app', technology training and support will be provided, and the technology and process trialled in hospital, prior to discharge. Telehealth appointments will be conducted using the HealthDirect app, which is used across SA health for video telehealth consultations and supported by SA Health ICT services. Given that HealthDirect is already used by SA Health it has all of the necessary security and confidentiality requirements for the purpose of video telehealth consultations. There will be no video or audio data recorded as part of the telehealth consultations hence there are no anticipated issues regarding data storage and security.

Transitional care coordination

Following discharge, the TC will provide transition coordination via telehealth for up to 6 weeks, as indicated by patients' clinical stability. The TC will contact the patient post-discharge at 48 hours, then 1 week later, then 4 weeks later. Clinical assessment by the TC may indicate more frequent phone calls monitoring or intervention are required. During telehealth calls, the TC will review: the TAP, symptoms, appointments attended, medication management, and domestic and health services required/accessed. The TC will undertake appropriate actions (e.g., service referral or follow-up, patient education, liaison with healthcare providers) to coordinate the transition of the patient back to primary care. This will particularly involve liaison with the general practitioner team including the practice nurse involved in the patient's chronic disease care planning. A multidisciplinary case discussion will be held approximately 4- 6 weeks post-discharge between the TC and clinical team.

Handover

The TC holds a final telephone consultation with the patient at 6-10 weeks post-hospital discharge, completes a final assessment, and discharges the patient from the transitional care service. The TC then provides the patient's GP with a letter summarising the issues identified, actions taken, and recommendations for ongoing care.

Outcomes

Primary

- Rate of representation to hospital (emergency department or hospital admission) within 3 months of discharge from index admission

Secondary outcomes

Health care utilisation

- Rate of representation to hospital (emergency department or hospital admission) within 1, 6 and 12 months of discharge from index admission
- Overall length of hospital stay within 1, 3, 6 and 12 months of discharge from index admission
- Cost of transition service model of care

Patient outcomes

- Patient-reported symptom burden
- Patient symptom management/self-efficacy
- Quality of life

- Patient experience, satisfaction, and perceived continuity of care

Organisation of care

- Implementation of components of transitional care model
- Implementation of transition action plan for all patients

Data collection

Data collection will require the collection of patient assessment and medical record data, as well as questionnaire responses. Figure 2 depicts the data collection required at certain time points (e.g., in-patient screening, through to 3-month discharge from the transition service and follow up surveys). Table 3 provides details on the data collection tools. Again, the TC will be sensitive to the patient, continuing rapport thought the research, without burdening the patient.

Table 3. Data collection instruments, purpose, and validation

Instrument	**Primary use/purpose**	**No. of items**
Patient Continuity of care questionnaire (PCCQ)	PCCQ measures patient perceptions of factors central to continuity of care. The questionnaire subscales correspond to the theoretical components of continuity of care that have been proposed in the literature, namely informational, relational and management continuity.	41
Edmonton Symptom Assessment System – Revised (ESAS-r)	The ESAS-r assesses symptom burden.	9
EQ5D3L	EQ5D3L is a preference-based measure of health status that assesses patient experience of health at a point in time, for clinical, population, health and economic evaluation surveys.	5

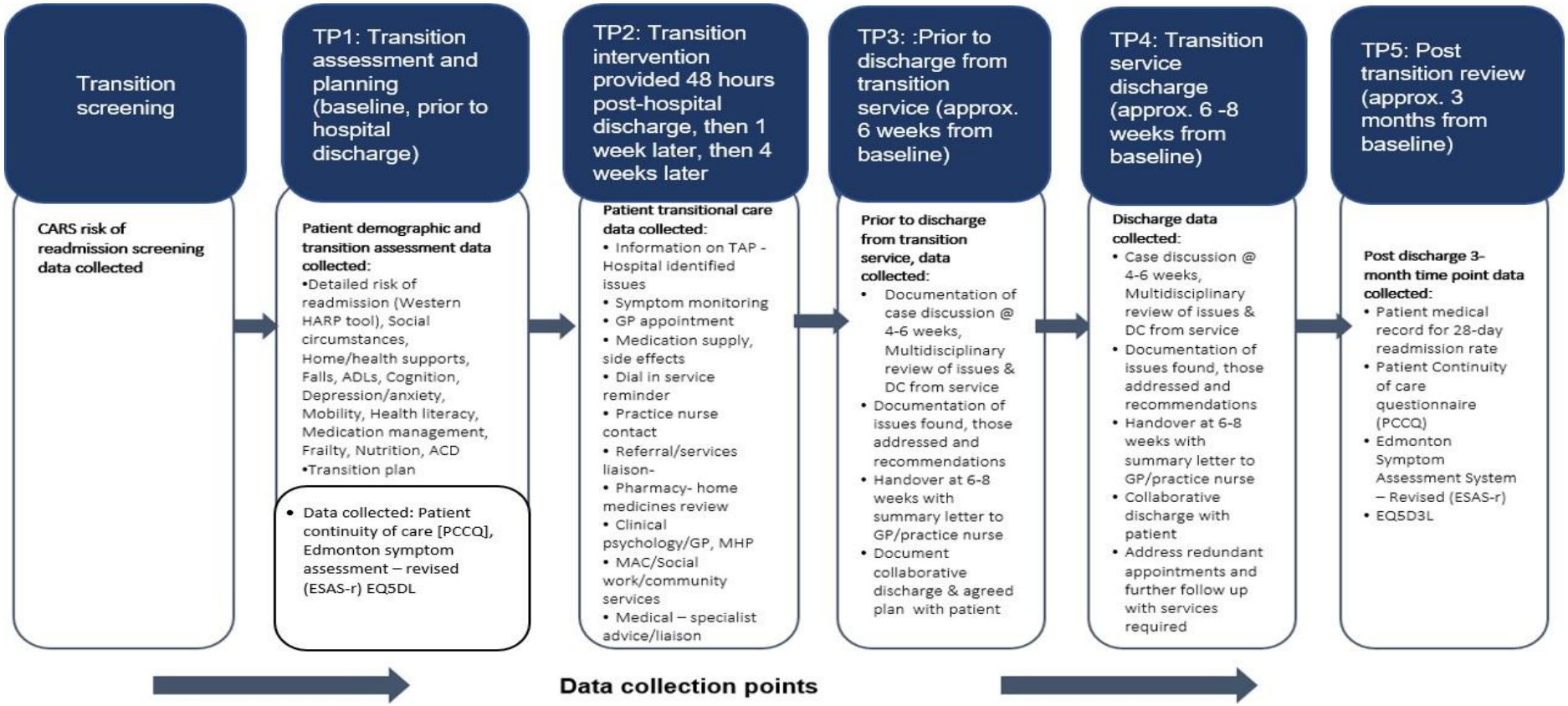

Figure 2. Time points (TP) aligned with data collection, phone calls, interventions, and other relevant details

PARTICIPANT SAFETY AND WITHDRAWAL

Risk management and safety

Involvement in the research carries no more than low risk.

Involvement in the research carries no more than low risk because there is no anticipated harm or discomfort for participants associated with taking part. However, there are four possible low/minor risks, including:

1. TCs or Dr Davis accessing potential patients' medical information during the screening process for participant eligibility, without their prior consent (thus this waiver for consent at this point).
2. The additional contact and healthcare interactions which the patients receive as part of the care transition service.
3. The conduct of the questionnaires and the inconvenience and discomfort associated with answering the questions.
4. The potential for creating dependency in the relationship between the TC and participant.

There is no anticipated harm or discomfort associated with taking part in this research. However, the four possible minor risks listed above will be mitigated in the following ways. The first risk will be managed through SA Health permission to waive consent for this procedure (for rationale -see above). Secondly, the additional or new and ongoing home/healthcare services the patient receives during the transition intervention will be provided through professional health support services. The patient will not be exposed to any additional risk other than that which people would normally incur when routinely accessing these services. The other anticipated inconvenience is tiring during assessment, or questionnaire completion. Patients will be offered breaks and comfort rests where appropriate.

Lastly, the patient and TC relationship will be established as a collaborative one throughout the intervention. To initially affirm the patient's agency, the transition action plan will be developed collaboratively with the patient. Part of the study is to enable patients' self-efficacy, and this will be achieved through education, support and coaching during phone calls, along with decreasing support and phone calls as the intervention progresses, and the patient's independence increases. Lastly, patients' will be prepared for completion of the intervention, through collaborative discussion and agreement of their transition discharge status and the communication and handover of this to their GP and Practice nurse. When discharged from the transition service, patients will not be left without support, but ongoing healthcare and supports will be coordinated through their primary healthcare provider.

The benefits from the research justify any risks of harm associated with not seeking consent.

The benefits include minimising unnecessary contact, potential interactions, stress or confusion with patients, as well as not wasting patients' time. These interactions maybe unnecessary, because during the 'screening for eligibility process' a majority of patients will be found to be ineligible (this was the case in the feasibility study).

It is impracticable to obtain consent, and the rationales for this are addressed below including the following points:

►Why is it impractical to gain consent?
►Time period
►How many records will be accessed?
►Are there limitations to resources?
►Mortality rates
►Lost to follow up

It is impracticable to obtain consent at this point in the research because of the volume of patients required to screen each day, and the additional time and cost this would take for the researchers. The additional time and cost would not contribute to improved ethical outcomes; therefore, the additional time would be unnecessary, inordinate and preclude meeting study timelines. Impracticability of obtaining consent particularly relates to the quantity of patient medical records that require scrutiny during the screening for eligibility. The age of patents is an issue as far as some may be quite elderly or frail and additional unnecessary contact with researchers could be stressful. The accessibility of records is not an issue, however the limitations to resources, is an issue as stated above, the additional time required would be unjustifiably costly. The mortality rate of participants will not be affected and the inability to contact participants due to access to contact details or due to likelihood of contact details having changed due to time or due to characteristics of participant groups, is irrelevant.

There is no known or likely reason for thinking that participants would not have consented if they had been asked.

There is no known or likely reason for thinking that participants would not have consented if they had been asked, however as discussed above, obtaining consent is impracticable.

There is sufficient protection of their privacy.
To protect the patient's privacy the details of the participants who are accessed will be documented on paper, then will be discarded through the confidential bins when no longer needed.

In case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media).
Patients who are screened and found to be ineligible for the study will not be followed up in any way. Any documentation or listing of these patients' details (documentation will be on paper) will be discarded through the confidential bins when no longer needed. Information will be made available to patients consenting to and taking part in the research, as disused in section titled 'Dissemination of program outcomes', page 22. However, information will be made available to patients consenting to and taking part in the research, as disused in the section headed

The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled.

There will be no entitlement for these patients, as they are not participating in the research and their details will be confidentiality discarded (following discernment of ineligibility during the screening process).

The waiver is not prohibited by State, federal, or international law.

The consent waiver being applied for is only applicable at the point of screening for study eligibility and is not prohibited by State, federal, or international law.

Protocol deviations

A ‘serious breach’ is a breach of Good Clinical Practice or a breach of the protocol that is likely to affect to a significant degree the safety or rights of a trial participant, or the reliability and robustness of the data generated in the clinical trial. The principal investigator will use continuous vigilance to identify and report any suspected breaches to the sponsor within 72 hours of becoming aware of the event and report any serious breaches confirmed by the sponsor as occurring at the site to their institution (research governance office) within 72 hours of being notified of the serious breach.

Handling of withdrawals

Patients are free to withdraw from the project at any time, or for any reason, or the investigator deems it is in the participant’s best interest to do so. If they do withdraw consent during the research project, any personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. Patients will be advised that data collected by the study team up to the time of withdrawal will form part of the research project results. The patient’s readmission data will also be collected from SA health information systems for the trial’s primary endpoint. All information will be managed in compliance with the Australian Code for the Responsible Conduct of Research (2018), the University of South Australia ownership and retention of data policy and a created data management plan in line with UniSA procedure requirements.

ANALYSIS

Sample size estimation & justification

The main aim of a sample size calculation will be to determine the number of participants needed to detect a clinically relevant effect of the transitions service intervention. (Charan and Biswas 2013) . As discussed above the patient population has been selected to have a high baseline readmission rate, and these patients are known to have a high proportion of preventable readmissions attributed to poor care coordination. Our previous data has demonstrated that a similar group of patients (those with diabetes and cardiovascular disease (HREC/18/CALHN/120)) have a 25-30% representation rate within 28 days of discharge. As this intervention is anticipated to be up to 6 weeks, and the effect is expected to help prevent representations beyond this time, our primary endpoint will be to evaluate representation to the emergency department or readmission within 3 months.

Our previous study demonstrated that approximately 40% of patients had a representation by 3 months. The readmission rate in this study may be higher due to enrolment of patients with greater multimorbidity, and the exclusion of patients already receiving other CALHN services.

We anticipate that the enrolment of approximately 200 patients over 18 months will be feasible and provide us with sufficient sample size to achieve the primary outcome with the likely baseline readmission rate in the control group and absolute reduction in the intervention group (Table 4). Given that the primary endpoint will be derived from SA health information systems, and the study has an intention-to-treat approach, there will be need to consider a larger sample size for consideration of withdrawals, drop-outs, or loss to follow up.

Table 4. Sample size per group by baseline readmission rate and absolute reduction in readmission with 80% power and α=0.05

	Baseline readmission rate in control group at 3 months		
Absolute reduction in readmission rate in intervention group	35%	40%	45%
15%	136	150	160
20%	70	79	86
25%	40	47	52

Statistical methods to be undertaken

An intent-to-treat approach will be used. Linear regression analyses will be conducted to estimate effects of the intervention on primary and secondary outcomes. A hospital fixed effects model will be used to account for stratification at the hospital level. Sensitivity analyses will be performed to assess the robustness of the findings.

DATA SECURITY AND HANDLING

Data management and storage

There is an adequate plan to protect the confidentiality of data.

Dr Kate Davis will be the Study Data Manager and responsible for ensuring there is an adequate plan to protect the confidentiality of data. The plan will outline systematic steps for data handling and record keeping of collected data and will be lodged in accordance with University of South Australia policies and procedures, and SA Health Patient Privacy and Confidentiality Policies (Privacy Policy Directive Policy No.: D0445).

All hard copy documents including signed participant consent forms will be secured at RBRC, University of South Australia, in a locked office and filing cabinet. These will then be scanned and stored in the same secured network location as the other evaluation data. All data will be stored electronically on a secure password protected network drive. These data will only be accessible to the named investigators.

The data will be stored for a minimum of 15 years post publication of findings, consistent with national guidelines and UniSA policy and procedures guidelines for general research. Written approval will be obtained from the CALHN executive and UniSA Research Dean of Clinical and Health Sciences to destroy the data after the minimum period has elapsed. The digital data will be destroyed by UniSA Research Data Management Services.

Confidentiality and security

Other data management issues are addressed below including:

►*What format are they storing data in? AND where is data being stored?*

Electronic survey data will be initially stored through licensed software such as REDCAP, a secure web application for surveys, until the end of the survey collection period. At the end of the collection period the survey data will be exported and deleted from the online survey platform. Deidentified survey data

and deidentified clinical data will be securely stored on a University of South Australia server.

Questionnaire instruments completed in paper format will be directly entered at completion into an electronic database managed by the data manager at the applicable program site. Access to the database on the UniSA network drive will be limited to the researchers. For analysis purposes, the data will be non-identifiable, and no identifiable individual data will be published. Data access beyond those managed at CALHN will be limited to the investigators.

►*Who will have access to identifiable data?*

Dr Kate Davis and the Transition Coordinators

►*Will data be re-identifiable?*

All identifiers will be removed from the dataset by the TCs or Dr Davis, and re-identified with a replacement code, after patients are discharged from the Transition Care Service. (e.g., name, postcode, date of birth). Re- identification will later be possible through reference to a master copy of data that contains identifiers of study participants, aligned with the non-identifiable participant's code. As data manager, Dr Davis will have responsibility for security of the identifiable data, and re-identifiable (coded) data.

►*Which investigator is responsible for de-identifying data?*

Dr Kate Davis

►*Are you using REDCap?*

Yes

Dissemination of program outcomes

It is important to disseminate research results to the healthcare community and research participants. This will be achieved through academic journal publication, conference, and internal institutional publication. A copy of the published articles related to the research will be sent to participants upon request. Articles will be either mailed by post or emailed as requested by participants.

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