SingHealth

RESEARCH STUDY PROTOCOL

PROTOCOL TITLE: Enhancing patient wellbeing through integration of social prescribing, transitional care, and place-based care in community hospitals settings

PROTOCOL NUMBER:

VERSION NUMBER: 1.1

VERSION DATE: 01 September 2026

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PROTOCOL SIGNATURE PAGE

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Declaration of Investigator

I confirm that I have read the above-mentioned protocol and its attachments. I agree to conduct the described study in compliance with all stipulations of the protocol, regulations and ICH E6 Guideline for Good Clinical Practice (GCP).

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Name of Principal Investigator: Assoc. Prof Lee Kheng Hock

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Signature of Principal Investigator:

_____

Date:

_____

Name of Study Site: Outram Community Hospital, Sengkang Community Hospital

Note:
- This page should be signed with wet-ink signature or digital signature. Do not paste digital image of a wet-ink signature.
- Signed copies of this signature page should be stored in the study file and in the respective study site's investigator file.

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1. BACKGROUND AND RATIONALE

Traditional Healthcare and Social Determinants

Traditional healthcare systems have historically focused on clinical interventions, often with limited attention to the broader social determinants of health (SDOH) that significantly influence patient outcomes. Poor care transitions remain a critical challenge in healthcare delivery, contributing to increased readmissions, suboptimal outcomes, and fragmented care experiences. Evidence indicates that inadequate discharge planning and limited patient self-management following hospital discharge are key drivers of avoidable rehospitalisation and emergency department utilisation.

Care transitions, defined as the movement of patients between healthcare settings or levels of care represent particularly vulnerable periods. During these transitions, breakdowns in communication and coordination can compromise patient safety and continuity of care. Consequently, the quality-of-care transitions has emerged as a key performance indicator globally, reflecting increasing recognition that poorly managed transitions contribute substantially to preventable adverse outcomes.

Evolution of Social Prescribing

In response to the limitations of purely biomedical models of care, social prescribing has emerged as an innovative approach to addressing the wider determinants of health. Social prescribing connects patients to community-based, non-clinical services that support social, emotional, and practical needs. Traditional models typically involve referrals to voluntary and community sector organisations, with the aim of improving wellbeing and reducing healthcare utilisation.

Evidence suggests that social prescribing can enhance mental health, reduce social isolation, and improve quality of life and healthcare experiences. However, these models frequently operate parallel to, rather than integrated within, clinical care pathways. As a result, traditional social prescribing alone may be insufficient to address the complex and multi-layered needs of patients during critical care transitions.

Place-based Care at SingHealth Community Hospitals: An Integrated Extension

Place-based Care (PBC) at SingHealth Community Hospitals represents a significant evolution of these approaches, addressing the limitations of fragmented care by integrating social prescribing with structured transitional care. Within community hospital settings, PBC encompasses five core domains: coordinated specialist outpatient follow-ups, linkage to community resources, medication adherence support, primary care transition planning, and caregiver education and self-care empowerment.

This integrated model shifts the conventional discharge process from a primarily episodic and medically driven approach to a comprehensive, person-centred care pathway that incorporates both clinical and social assessment, coordinated care planning, supported transition, and structured follow-up. By embedding social prescribing within the continuum of care, PBC aims to improve both clinical outcomes and patient experience during vulnerable transition periods.

Implementation in the Singapore Healthcare Context

PBC has been implemented across SingHealth community hospitals through Wellbeing Care Coordinators (WBCs), who systematically identify high-risk patients using structured screening approaches and coordinate

care across hospital and community settings. This implementation is situated within Singapore's evolving healthcare landscape, characterised by rapid population ageing, sustained pressure on hospital capacity, and a growing emphasis on community-based care under national initiatives such as HealthierSG (SingHealth Group Communications, 2023; Nah et al., 2024).

Community hospitals play a pivotal role within this continuum, providing intermediate care between acute hospitalisation and community reintegration. Integrating PBC within this setting presents a critical opportunity to address both clinical and social needs during care transitions, with the potential to improve patient outcomes while optimising healthcare resource utilisation (Ministry of Health Singapore, 2017).

Evidence Base and Research Gaps

There is an increasing body of evidence supporting the effectiveness of both social prescribing and transitional care interventions when implemented independently. Social prescribing has been associated with improvements in mental health, social connectedness, and patient-reported outcomes, while structured transitional care programmes have demonstrated benefits in care coordination, patient satisfaction, and reduced hospital utilisation.

The Care Transition Measure (CTM-15), validated in Singapore's multi-ethnic population, provides a robust and reliable tool for assessing care transition quality from the patient perspective. Its strong psychometric properties and association with clinically relevant outcomes make it particularly suitable for evaluating integrated transitional care interventions (Bakshi et al., 2012).

Despite these advances, significant gaps remain. There is limited evidence evaluating integrated models that combine social prescribing with comprehensive transitional care, particularly within Asian healthcare settings. While individual intervention components have been studied, the synergistic effects of combining social and clinical care remain poorly understood. In addition, evidence on implementation processes and contextual factors influencing the success and sustainability of such models is limited.

Study Rationale and Innovation

This study addresses the critical need for a rigorous evaluation of PBC as an integrated model of care within community hospital settings. By employing a pragmatic parallel cluster randomised controlled trial design, the study will generate robust evidence on the effectiveness of PBC in real-world practice while minimising contamination at the ward level. The cluster-based design is appropriate given that the intervention is delivered at the ward level and cannot be implemented at the individual patient level without risk of spillover effects.

The use of validated outcome measures, including the CTM-15 as the primary outcome, will enable comprehensive assessment of care transition quality alongside broader outcomes related to patient wellbeing and healthcare utilisation. In addition, the study incorporates a mixed-methods approach, guided by the Practical, Robust Implementation and Sustainability Model (PRISM), to provide insights into implementation processes, mechanisms of action, and contextual factors influencing effectiveness (McCreight et al., 2019; Rabin et al., 2022).

Findings from this study will inform policy and service planning decisions regarding the scaling and sustainability of integrated social prescribing models within Singapore’s healthcare system and contribute to the international evidence base on complex transitional care interventions.

2. HYPOTHESIS AND OBJECTIVES

Primary Objective

This study aims to evaluate the effectiveness of SingHealth Community Hospitals place-based care (PBC), an integrated model combining social prescribing with structured transitional care support, in improving care transition quality compared to standard community hospital care.

Primary Hypothesis

We hypothesise that care transition quality during intervention periods will be superior to that during control periods, as measured by the CTM-15 at 3 weeks post-discharge.

This improvement reflects enhanced performance across key domains targeted by PBC, including coordination of specialist outpatient follow-ups, community resource linkage, medication adherence support, primary care transition planning, and caregiver and self-care competency.

Secondary Objectives

- To assess patient-centred outcomes by evaluating the impact of PBC on patient wellbeing (EQ5D-5L), medication adherence (MARS-5), and patient experience.
- To examine healthcare utilisation patterns, including emergency department visits, unplanned readmissions within 90 days post-discharge and adherence to specialist outpatient clinic appointments.
- To evaluate the effectiveness of PBC in facilitating meaningful engagement with community resources within 60 days post-discharge.
- To understand implementation processes using the PRISM framework, including identification of barriers, facilitators, and contextual factors influencing PBC implementation across community hospital settings.
- To assess caregiver burden following discharge using the 8-item Preparedness for Caregiving Scale (PCS).
- To refine and validate the PBC logic model by identifying key mechanisms of action and contextual influences on intervention effectiveness.

Secondary Hypotheses

We hypothesise that, compared to the control group, the intervention group will be associated with:

- Improved patient wellbeing and quality of life over the 6-month follow-up period
- Enhanced medication adherence at 21 days, 90 days, and 6 months post-discharge
- Increased engagement with community resources within 60 days post-discharge

- Reduced emergency department visits/unplanned readmissions within 90 days post-discharge
- Improved adherence to scheduled specialist outpatient clinic appointments
- Greater caregiver preparedness during the early post-discharge period
- High acceptability and feasibility of PBC among patients, caregivers, and healthcare providers

Outcome	Source & Instrument	Data Collection Timepoint
Primary Outcome		
Care Transition Quality	CTM-15	T1
Secondary Outcomes		
Patient Wellbeing	EQ5D-5L	T0, T1, T2, T3
Medication Adherence	5-item Medication Adherence Report Scale (MARS-5)	T1, T2, T3
Community Resource Engagement (Within 60 days Post-Discharge)	Study PREMs	T0, T2, T3
Patient Satisfaction	SCH PREMs	T2
Emergency Department Visits and Unplanned Readmissions (Within 90 days Post-Discharge)	eHINTS, Patient Self-Reported	T2
SOC Appointments Adherence	Patient Self-Reported	T2, T3
Caregiver Burden	8-item Preparedness for Caregiving Scale (PCS)	3 – 6 weeks Post-Discharge

Table 1. Primary and secondary outcomes in evaluation of the PBC

Timepoints
T0: Baseline
T1: 21 days (or 3 weeks) post-discharge
T2: 90 days after discharge
T3: 6 months after discharge

3. EXPECTED RISKS AND BENEFITS

3.1. Expected risks to subjects.

Questionnaires and semi-structured interviews
Some of the questionnaires and/or semi-structured interview questions might make participants feel uncomfortable. They may refuse to answer any of the questions and/or take a break at any time during the study.

Personal privacy and confidentiality
This study uses information that may affect participants' privacy. To protect their confidentiality, the research study team will only use unique codes, assigned to each participant, when identifying data collected from them. As there will be a link between the code and participants' identifiable information, there is still a possibility of data breach, which is when data is seen or used without permission. While the chances of this is very small, it is not zero.

3.2. Expected benefits to subjects.

There are no direct benefits to subjects from their participation in this study. However, subjects' participation will contribute evidence on the effectiveness, implementation, and acceptability of PBC in community hospital settings and may inform future improvements to transitional and community-based care.

4. STUDY POPULATION

4.1. List the number and nature of subjects to be enrolled.

The study will recruit approximately 720 patient participants across Outram Community Hospital (OCH) and Sengkang Community Hospital (SKCH), accounting for anticipated attrition and modest variation in ward-level recruitment (see Section 8.1). Participants will be recruited continuously from participating wards throughout the study period and will receive care according to their ward's randomised allocation. Patients admitted to intervention wards will receive place-based care (PBC), while those admitted to control wards will receive standard community hospital care.

In addition, approximately 80–100 primary informal caregivers will be recruited for the caregiver burden assessment. Eligible caregivers will be identified through participating patients and invited to complete the Preparedness for Caregiving Scale (PCS), providing a complementary assessment of caregiver outcomes during the post-discharge transition period.

For the qualitative component, 30 patient participants (approximately 15 per trial arm, with representation from both sites) will be purposively sampled from the 720 trial participants. Up to 10 caregivers will be sampled from the caregiver cohort.

In addition, data will be collected from healthcare professionals and stakeholders using a combination of focus group discussions (FGDs) and/or individual semi-structured interviews, depending on participant availability and scheduling constraints. Up to three FGDs will be conducted, each comprising 5–6 participants (approximately 15–18 participants in total). These will include programme leaders, senior clinicians, Healthier SG coordinators, community partners, and healthcare administrators with strategic oversight of PBC implementation.

4.2. Inclusion and Exclusion Criteria for Recruitment

Patient Participants (Quantitative Component)

Eligible patients will be recruited from participating wards and will receive care according to their ward's randomised allocation. Patients admitted to wards assigned to the intervention group will receive PBC ("PBC-exposed patients"), while those admitted to wards assigned to the control group will receive standard community hospital care ("control patients").

Patients must meet all the following inclusion criteria:

1. Aged **50 years and above** at the time of recruitment
2. With expected discharge to the community
3. Able to converse in **English, Mandarin, or Malay**
4. Able to provide **informed consent**
5. Able to complete study questionnaires

Patients will be excluded if they are:

1. Planned for hospice discharge.
2. Planned for **nursing home placement, transitional shelter or care facilities.**

Eligibility for study participation extends beyond enrolment. Participants must continue to satisfy all inclusion criteria and remain free of any exclusion criteria from enrolment until discharge. Participants who become ineligible during this period may be discontinued from further study participation in accordance with the study protocol.

Interview Participants (Qualitative Component)

Participants for the qualitative component will be recruited from Outram Community Hospital (OCH) and Sengkang Community Hospital (SKCH), including patients, programme implementers, clinicians, and key stakeholders.

All qualitative participants must meet the following general inclusion criteria:

1. Aged **21 years and above** at the time of recruitment
2. Able to understand and converse in **English**
3. Able to provide **informed consent**

Eligibility Criteria by Participant Group

Participants will be purposively sampled to capture a range of perspectives across the following groups:

1. Intervention group patients: Patients admitted to wards randomised to the intervention group and receiving PBC
2. Control group patients: Patients admitted to wards randomised to the control group and receiving standard community hospital care
3. Programme implementers: Individuals with at least three months of experience delivering PBC interventions, including Wellbeing Care Coordinators and Healthier SG team members
4. Clinicians: Healthcare professionals directly involved in patient care related to PBC, including physicians, nurses, and allied health professionals
5. Key stakeholders: Individuals with strategic or organisational oversight of PBC implementation, including programme leaders, senior clinicians, Healthier SG coordinators, community partners, and healthcare administrators with at least one month of relevant experience

4.3. Recruitment Process

The study team will work closely with PBC programme administrators at Outram Community Hospital (OCH) and Sengkang Community Hospital (SKCH) to identify and recruit patients, programme implementers, clinicians, and key stakeholders. WBC will identify eligible patients during the first week of admission based on predefined criteria and refer potential participants to the study team on a weekly basis.

A study team member will contact referred patients during their second week of admission to arrange a face-to-face meeting. During this meeting, at least two study team members will assess eligibility using the demographic and screening form. Upon confirmation of eligibility, written informed consent will be obtained prior to commencement of data collection.

Data collection for patient participants will be conducted at four predefined timepoints: baseline (T0, during admission), 3 weeks post-discharge (T1; ±7 days), 90 days post-discharge (T2; ±14 days), and 6 months post-discharge (T3; ±14 days). This schedule enables assessment of both short-term and longer-term outcomes across the care transition period, with T1 aligned to the primary outcome measure of care transition quality (CTM-15).

Patient and caregiver interviews will be conducted approximately 3–6 weeks after discharge, after participants have had sufficient opportunity to experience the transition from hospital to home and any early post-discharge support. Intervention and control participants will be interviewed within the same post-discharge window.

Data collection for programme implementers, clinicians, and key stakeholders will be conducted at a single timepoint (approximately mid-study), subject to participant availability. A window period of ±7 or ±14 days (as specified above) will be permitted for all follow-up assessments to accommodate scheduling constraints.

Where applicable, patients will be asked to identify their primary informal caregiver involved in their post-discharge care. Identified caregivers will be approached at T1 for consent and invited to complete a caregiver burden assessment approximately two weeks thereafter.

5. STUDY DESIGN AND PROCEDURES/METHODOLOGY

5.1. Methods and Study Design

This protocol has been developed in accordance with the SingHealth Centralised Institutional Review Board (CIRB) Research Study Protocol requirements and is guided by the SPIRIT 2025 statement for randomised trial protocols (Chan et al., 2025) (Figure 1). The study is further underpinned by the Practical, Robust Implementation and Sustainability Model (PRISM), which informs the embedded process evaluation and ensures consideration of implementation feasibility, sustainability, and real-world applicability (McCreight et al., 2019; Rabin et al., 2022).

This study will employ a pragmatic parallel cluster randomised controlled trial (cRCT) design, in which clusters (wards) are randomised to either the intervention group (place-based care [PBC]) or the control group (standard community hospital care) for the duration of the study. The design and analysis plan follow key methodological considerations for cluster randomised trials (Hemming and Taljaard, 2023).

The unit of randomisation is the ward (which is a naturally-occurring cluster). A total of 12 wards across Outram Community Hospital (OCH) and Sengkang Community Hospital (SKCH) will be included in the study. Wards will be allocated in a 1:1 ratio, with 6 wards assigned to the intervention group and 6 wards assigned to the control group. Where feasible, stratified randomisation by hospital site and ward type will be applied to ensure a balanced distribution of clusters across study arms.

Randomisation will be conducted using a computer-generated allocation sequence developed by an independent statistician. Once assigned, clusters will remain in their allocated group throughout the study period. Any modifications due to operational, safety, or feasibility considerations will be formally documented and justified.

The study will recruit approximately **720 participants** across both sites. Based on the sample size calculation in Section 8.1, this corresponds to approximately 60 recruited participants per ward and an expected 576 participants with primary-outcome data at T1 after allowing for 20% attrition. Individual participants will not be randomised; instead, patients admitted to each ward will receive the care model assigned to that ward. Patients admitted to intervention wards will receive PBC, while those admitted to control wards will receive standard community hospital care.

The sample size reflects the cluster-randomised design and accounts for within-ward correlation as well as the small number of clusters available for randomisation. While a larger number of wards would improve statistical efficiency, the proposed 12-ward design represents a pragmatic balance between methodological rigour and operational feasibility within the participating hospitals.

Follow-up assessments will be conducted at the following timepoints:
- T0: Baseline
- T1: 21 days post-discharge (±7 days)
- T2: 90 days post-discharge (±14 days)
- T3: 6 months post-discharge (±14 days)

The quantitative component will utilise validated instruments to assess study outcomes. The primary outcome, care transition quality, will be measured using the Care Transition Measure (CTM-15) at T1.

Secondary outcomes include patient wellbeing (EQ-5D-5L) measured longitudinally from T0 to T3, medication adherence (MARS-5) assessed at T1 to T3, and patient satisfaction (PREMs) measured at T1. Additional outcomes include community resource engagement, emergency department visits, and adherence to specialist outpatient clinic appointments, derived from a combination of patient reported experience measures, patient self-report and administrative data.

Recruitment will be monitored by ward and site to support balanced cluster sizes and representation across age, sex, ethnicity, and Clinical Frailty Scale categories. Eligibility will not be altered to achieve demographic quotas.

Caregiver Recruitment and Data Collection

Where applicable, patients will be asked to identify their primary informal caregiver during admission. Initial engagement will take place in the ward setting, where study team members will introduce the study and provide an overview of caregiver participation. Caregivers who express interest will be contacted at approximately 3 weeks post-discharge (aligned with the patient's T1 timepoint) for formal recruitment and consent.

Following consent, caregivers will complete the Preparedness for Caregiving Scale (PCS) to assess caregiver burden during the early post-discharge period. A purposive subsample will additionally be invited to participate in semi-structured interviews at approximately 3–6 weeks after discharge, conducted either via secure telephone or virtual inteview (e.g. Zoom) or face-to-face at a location convenient to the participant.

These interviews will explore caregiving experiences, including adaptation to the caregiving role, interactions with the patient, challenges encountered, and perceived support needs during care transitions.

Process Evaluation

Process measures will also be collected to evaluate implementation of PBC, including intervention reach, fidelity, acceptability, and feasibility. These will be assessed using recruitment and retention rates, delivery of key intervention components, patient experience measures, and qualitative data on barriers and facilitators.

PRISM Domain	Measure	Data Source
Reach	Recruitment rate	Study logs
Fidelity	Delivery of PBC components	DCF
Acceptability	Patient experience	PREMs, qualitative data
Feasibility	Retention, barriers	Logs + qualitative data

Qualitative Methodology

The qualitative component will employ a combination of semi-structured interviews and focus group discussions (FGDs) with five key stakeholder groups: PBC-exposed patients, pre-intervention patients,

programme implementers, clinicians, and key stakeholders (including programme leaders, senior clinicians, Healthier SG coordinators, community partners, and healthcare administrators).

A total of 30 semi-structured interviews comprising approximately 15 participants from the intervention arm and 15 from the control arm, with representation from both hospital sites. The proposed sample size is guided by the principle of information power (Malterud et al., 2016) rather than statistical power. The focused aim of the qualitative component, recruitment of participants with direct experience of the care transition, use of a PRISM-informed interview guide and in-depth individual interviews are expected to provide sufficient information power to identify major patterns and contrasting experiences across the trial arms.. For programme implementers, clinicians, and key stakeholders, data will be collected using a combination of focus group discussions and/or semi-structured individual interviews, depending on participant availability, scheduling constraints, and feasibility.

Specifically:

- Up to three FGDs comprising 5–6 participants each will be conducted where feasible
- Where participants are unable to attend FGDs due to clinical or operational commitments, individual semi-structured interviews will be offered as an alternative

Data collection and analysis will proceed iteratively. The adequacy of the sample will be reviewed throughout data collection based on the richness and diversity of the data, the extent to which major themes are sufficiently developed, and whether additional interviews continue to provide substantively new insights. Additional interviews may be conducted if the planned sample does not provide sufficient information power. The study is not intended to establish saturation independently within every hospital-by-trial-arm subgroup; comparisons at these levels will be exploratory.

Quantitative Methodology

Our quantitative methodology will employ validated questionnaires to evaluate primary and secondary outcome measures. T1 visit assessments have a window period of ±7 days, while a window period of ±14 days is allowed for all the other follow-up visit assessments to accommodate scheduling needs.

	Study Period inside Community Hospital			Study Period outside Community Hospital		
	Allocation	**Enrolment**	**Baseline**	**Post-discharge**		
TIMEPOINT	***Allocation is done via cluster randomization and determined before patient admits to the ward.***	t_0 *(0 day)*	t_0 *(0 day)*	t_1 *(21 days after discharge)*	t_2 *(90 days)*	t_3 *(180 days)*
WINDOW PERIOD		***NA***	***NA***	***± 7 days***	***+14 days***	***+14 days***
ENROLMENT:						
Demographics, CFS, Living Arrangement		X				
Inclusion and Exclusion Criteria		X				
Informed consent		X				
INTERVENTION:						
PBC (for intervention wards only)		X	X	Ongoing following up as clinically indicated		
ASSESSMENTS:						
Primary Outcome:						
CTM-15				X		
Secondary Outcome:						
MARS-5				X	X	X
EQ5D-5L			X	X	X	X
PREMs - Community Resource Engagement			X		X	X
PREMs - Participant Satisfaction				X		
ED Use/ Unplanned Admissions					X	
SOC Appointment Adherence					X	X
Caregiver PCS				3 – 6 weeks post-discharge		
QUALITATIVE INTERVIEWS:						
Patient / Caregiver Interviews				3 – 6 weeks post-discharge		

Professional/ Stakeholder Interviews or FGDs	Mid Study

Abbreviations: CFS=Clinical Frailty Score, PBC=Place-based Care, CTM-15=Care Transition Measure, MARS-5=Medication Adherence Report Scale, ED=Emergency Department, SOC=Specialist Outpatient Clinic, PCS=Preparedness for Caregiving Scale, FGD=Focus Group Discussion

Figure 1. SPIRIT figure for the schedule of enrolment, interventions, and assessments.

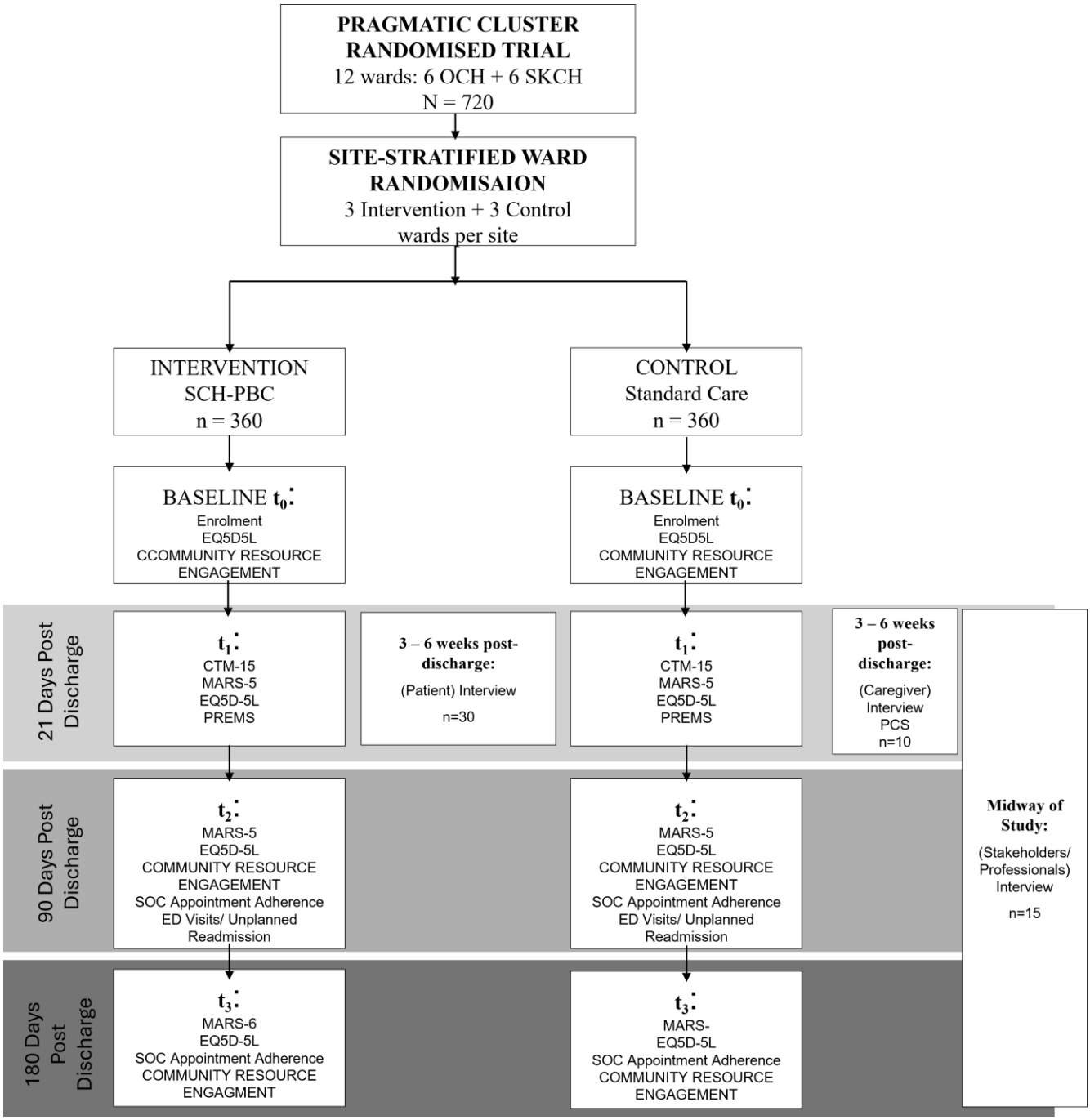


Figure 2 Study flowchart.

Primary Outcome Justification:

The CTM-15 is the primary outcome measure for this study and aligns closely with the five core domains of the PBC intervention: specialist outpatient clinic (SOC) follow-up coordination, community resource linkage, medication adherence support, primary care transition planning, and caregiver and self-care capability. The CTM-15 is a validated 15-item instrument that assesses the quality-of-care transitions from the patient's perspective, capturing key domains such as medication management, understanding of the care plan, preparation for self-care, and coordination across healthcare settings.

The CTM-15 has been validated in Singapore's multi-ethnic population by Bakshi et al. (2012), demonstrating strong psychometric properties, with Cronbach's alpha values of 0.87 for the English version and 0.82 for the Chinese version. The validation study also demonstrated its ability to discriminate between patients with different post-discharge outcomes, with significant differences observed between patients with and without emergency department visits (mean difference: 4.7 points) and rehospitalization (mean difference: 3.9 points). These findings support its suitability for evaluating comprehensive transitional care interventions such as PBC.

The CTM-15 will be administered at T1 (3 weeks post-discharge), which represents an appropriate timepoint for capturing patients' overall care transition experience while maintaining recall accuracy. This timing is consistent with the Singapore validation study, which administered the CTM-15 approximately 3 weeks after discharge, and allows sufficient time for patients to experience key transitional care components while minimising recall bias (Bakshi et al., 2012). Where patients are unable to complete the questionnaire, proxy respondents (e.g., spouse, child, family member, or other informal caregiver) will be permitted. Respondent type (patient versus proxy) and the proxy's relationship to the patient will be recorded in the Data Collection Form (DCF). This will allow reporting of respondent characteristics and enable prespecified sensitivity analyses to examine whether study findings differ according to respondent type.

Secondary Outcomes Rationale

The secondary outcomes are selected to capture key components of the PBC intervention. Community resource engagement within 60 days post-discharge reflects the effectiveness of community linkage. This is measured through a study specific PREM that was informed by the NHS England Social Prescribing Common Outcomes Framework and the PRISM framework. Medication Adherence Report Scale (MARS-5), assessed at multiple timepoints, evaluates the sustainability of adherence support. Adherence to SOC appointments reflects the effectiveness of follow-up coordination. Patient wellbeing will be assessed using the EQ-5D-5L, a generic health-status measure with evidence supporting the relevance of its dimensions in Singapore (Rabin and de Charro, 2001; Lee et al., 2020). Patient satisfaction and emergency department visits offer additional perspectives on care quality and healthcare utilisation.

5.2. Intervention condition

Patients admitted to wards allocated to the intervention group will receive PBC. The intervention comprises five key domains: Wellbeing Care Coordination, HealthierSG integration, community resource linkage, care transition support, and ongoing monitoring. The intervention is delivered by a multidisciplinary team.

5.3. Control Condition

Patients admitted to wards allocated to the control group will receive standard community hospital care throughout the study period.

This parallel cluster design enables comparison of outcomes between intervention and control groups while minimizing contamination and maintaining operational feasibility.

6. SAFETY MEASUREMENTS

6.1. Definitions

Serious adverse event (SAE) in relation to human biomedical research, means any untoward medical occurrence as a result of any human biomedical research which:

- results in or contributes to death
- is life-threatening
- requires in-patient hospitalization or prolongation of existing hospitalization
- results in or contributes to persistent or significant disability/incapacity or
- results in or contributes to a congenital anomaly/birth defect
- results in such other events as may be prescribed

Adverse event (AE) in relation to human biomedical research means any untoward medical occurrence as a result of any human biomedical research which is NOT serious. Adverse event can be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease possibly/ probably/ definitely associated with the participant in the human biomedical research.

6.2. Collecting, Recording and Reporting of Serious Adverse Events (SAEs) to CIRB

The reporting requirements will be in accordance with the reporting requirements published on CIRB website at the time when the event took place. Only related SAEs (definitely/ probably/ possibly) will be reported to CIRB. Related means there is a reasonable possibility that the event may have been caused by participation in the research.

The investigator is responsible for informing CIRB after first knowledge that the case qualifies for reporting. Follow-up information will be actively sought and submitted as it becomes available. Related AEs will not be reported to CIRB. However, the investigator is responsible to keep record of such AEs cases at the Study Site File.

6.3. Safety Monitoring Plan

The trial will be monitored by an independent data and safety monitoring board comprising clinical experts and a biostatistician. The board will conduct a single interim review of unblinded safety and effectiveness data after approximately 100 participants have completed the T1 primary outcome assessment. To ensure

participant safety, all intervention-related adverse events will be systematically recorded throughout the study duration.

6.4. Complaint Handling

Complaints will be recorded by the research study team member, and the PI will be notified within 24 hours.

7. DATA ANALYSIS

7.1. Data Quality Assurance

To ensure data quality and reliability, several quality assurance measures will be implemented. These include standardized training for all study members, conducting random data quality checks, weekly data quality audits, and monitoring of inter-rater reliability.

7.2. Data Entry and Storage

All physical source documents will be securely stored in locked cabinets at SCH, with access strictly limited to authorized personnel. Trained study members will record data in password-protected Excel files. Electronic medical records, accessed only with explicit patient consent, will be maintained in password-protected files. The electronic data will not contain research participant identifiers. Identification code linking electronic data and research participants will be stored separately. Following study completion, all data will be retained for a seven-year period, after which it will be disposed of in accordance with established policies.

Once the transcribing of semi-structured interviews and FGD is completed, the audio will be deleted from the storage drive. The transcribed files will be saved in the study team's OneDrive, which will be password-protected, encrypted and kept under lock-and-key within the department. The files will only be accessible to study team members.

8. SAMPLE SIZE AND STATISTICAL METHODS

8.1. Determination of Sample Size

The sample size calculation is based on care-transition quality measured using the CTM-15 at 21 days post-discharge (T1; ±7 days). Each item is scored on a 1–4 Likert scale and transformed to a 0–100 scale, with higher scores indicating better quality of care transitions.

A between-group difference of 6 points on the CTM-15 was selected as the target effect, with an assumed standard deviation of 15 points, consistent with SDs of 14.7 (English) and 15.4 (Chinese) reported in the Singapore validation of the CTM-15 among patients discharged from two tertiary hospitals (Bakshi et al., 2012). This difference of 6 points exceeds the between-group differences observed in the Singapore validation study between patients with and without rehospitalisation (3.9 points) or emergency department use (4.7 points) and corresponds to a standardised effect size of 0.40 (Bakshi et al., 2012). These known-groups differences support the clinical relevance of the selected target but should not be interpreted as a formally established minimally important difference.

Because the intervention is delivered and randomised at ward level, the calculation accounts for clustering and unequal ward-level sample sizes. The unequal-cluster design effect was calculated as $1 + \{[(1 + CV^2)m] - 1\} \times ICC$, where m is the mean number of participants with primary-outcome data per ward, CV is the coefficient of variation of cluster size, and ICC is the intracluster correlation coefficient (Eldridge et al., 2006; Rutterford et al., 2015). Given the small, fixed number of clusters (12 wards; 6 per arm, stratified by hospital

site), the calculation follows Hemming et al. (2011) and uses a t-distribution with $2(k - 1) = 10$ degrees of freedom, where k is the number of clusters per arm, rather than a standard normal approximation.

An ICC of 0.02 was selected as the primary planning assumption. Empirical ICC studies show substantial variation across outcomes and settings; values in the vicinity of 0.02 occur within reported distributions, but no ward-level ICC specific to the CTM-15 was identified (Adams et al., 2004; Thompson et al., 2012; Korevaar et al., 2021). Accordingly, 0.02 should be regarded as a lower-end plausible planning assumption rather than a directly validated CTM-15 ICC. A cluster-size CV of 0.25 was assumed, representing modest ward-level variation. Balanced per-ward recruitment caps will be used to keep cluster sizes as similar as operationally feasible. Historical ward-level recruitment data should be reviewed before trial initiation to confirm that a CV of approximately 0.25 is reasonable. If local data do not support either assumption, the recruitment target should be reassessed. Sensitivity to ICC values from 0.01 to 0.05 is shown in Table 2.

Under the primary assumptions—12 wards, a 6-point difference, SD of 15 points, ICC of 0.02, cluster-size CV of 0.25, two-sided $\alpha = 0.05$, and 80% power—approximately 413 participants with T1 data are required. For operational planning this is rounded to 420 with T1 data; allowing for 20% attrition gives a minimum recruitment requirement of approximately 528 participants (44 per ward). Following discussion with the programme leadership, the planned operational recruitment target is 720 participants (60 per ward; 360 per arm). Assuming 20% attrition, approximately 576 participants (48 per ward) will contribute T1 data. Under the primary assumptions, this target provides approximately 86% power. The larger target improves precision and resilience to attrition and modest departures from the planning assumptions; it does not change the prespecified target effect.

Table 2. Sensitivity of statistical power to the assumed ICC at the planned target (720 enrolled; 576 expected with T1 data; cluster-size CV = 0.25; 6-point difference; SD = 15 points; 12 wards).

ICC	Design effect	Statistical power
0.01	1.50	94%
0.02 (primary assumption)	2.00	86%
0.03	2.50	78%
0.04	3.00	71%
0.05	3.50	64%

The planned sample of 720 participants is intended to improve precision, facilitate balanced recruitment across wards (60 per ward), and provide additional protection against attrition and modest departures from the planning assumptions.. Power is sensitive to the true ICC, as shown in Table 2; consequently, the observed ICC and the realised coefficient of variation in ward-level sample sizes will be reported. Enrolment is powered on the primary endpoint. Six-month secondary outcomes (EQ-5D-5L, MARS-5, and specialist outpatient clinic appointment adherence etc) will be estimated with lower precision because of cumulative attrition.

To minimise loss to follow-up, Wellbeing Care Coordinators and the study team will maintain regular contact with participants, and follow-up assessments may be conducted by telephone where in-person visits are not feasible.

Caregiver burden will be assessed as an exploratory, cross-sectional secondary outcome among consenting primary caregivers of enrolled participants; given the exploratory nature of this component, a formal sample size calculation was not performed, and the achieved sample will depend on caregiver availability and consent rates. Based on feasibility considerations and anticipated participation rates, approximately 80–100 primary informal caregivers are anticipated for the Preparedness for Caregiving Scale (PCS) assessment.

8.2. Randomization and Blinding

Randomisation

Baseline assessments will be conducted for all participants prior to exposure to the intervention, consistent with standard practice for establishing pre-intervention characteristics in cluster randomised trials (Eldridge et al., 2016).

Randomisation will be performed at the ward (cluster) level and stratified by hospital site. The 12 participating wards comprise 6 wards at Outram Community Hospital (OCH) and 6 wards at Sengkang Community Hospital (SKCH). Within each site, wards will be randomly allocated in a 1:1 ratio to the intervention or control group (3 intervention: 3 control at OCH; 3 intervention : 3 control at SKCH), rather than randomising all 12 wards as a single pool. Stratifying by hospital site at the point of randomisation, rather than adjusting for it post hoc, helps ensure balanced representation of both sites across study arms and avoids the risk that a pooled randomisation of only 12 clusters could, by chance, concentrate one hospital disproportionately in one arm, a meaningful risk given the small number of clusters (Kahan & Morris, 2012). Hospital site is correspondingly included as a fixed effect in the primary analysis model (section 8.3), consistent with analysing according to the stratification variables used at allocation. The randomisation sequence will be generated using a computer-based randomisation procedure, applied separately within each site stratum, by an independent statistician who is not involved in participant recruitment, intervention delivery, or outcome assessment, in line with CONSORT guidance for the reporting of cluster randomised trials (Campbell et al., 2012). Where feasible, further stratification by ward type will also be applied within each site.

Patients admitted to OCH and SKH are assigned to the wards according to standard clinical workflows and based on clinical needs and bed availability. As such, individual participants are not directly randomised; instead, each participant receives the care model assigned to the ward to which they are admitted, with patients in intervention wards receiving PBC and patients in control wards receiving standard care throughout the study period. Because ward assignment precedes and is independent of trial enrolment, this reduces the risk of selection or identification bias that can arise in cluster trials where recruiters are aware of a cluster's allocation before approaching individual participants (Giraudeau & Ravaud, 2009). Nonetheless, as clinical and bed-availability criteria for ward assignment are determined independently of this study, any systematic differences in how patients are triaged to the wards over the study period should be monitored.

To minimise confounding by calendar time of discharge, recruitment duration will be kept approximately balanced across wards; wards recruiting substantially faster or slower than the cohort average will be flagged for review, with coordinator capacity reallocated toward under-recruiting wards to maintain balance.

Blinding

Due to the nature of the intervention and its implementation at the ward level, blinding of participants, clinical staff, and research personnel is not feasible, consistent with the inherent constraints on blinding in cluster randomised trials of ward-based care models (Campbell et al., 2012).

Outcome measurement approaches differ in their exposure to this constraint and are addressed accordingly. For outcomes derived from electronic health records, standardised data extraction procedures will be applied by trained study personnel following predefined protocols, minimising subjective judgement in outcome ascertainment (Karanicolas et al., 2010).

To mitigate the resulting risk of assessment bias, patient-reported outcomes will be collected using standardised, validated instruments administered via a fixed interview script, minimising scope for interviewer-introduced variation in how questions are asked or probed (Karanicolas et al., 2010). Interviewers will receive structured training on neutral administration and will not be informed of the study hypotheses regarding expected direction of effect.

Data analysts conducting the primary and prespecified secondary analyses will be blinded to treatment allocation until the analysis dataset is finalised, at which point allocation will be unblinded for interpretation and reporting.

8.3. Statistical and Analytical Plans

Quantitative and qualitative data will be analysed separately using methods appropriate to each data type. For the quantitative component, descriptive statistics will be used to summarise baseline characteristics and outcome measures derived from the Data Collection Form (DCF).

Analyses will be conducted using generalised linear mixed-effects models (GLMMs) to account for the hierarchical structure of the data, including clustering at the ward level and repeated measurements over time. The models will incorporate fixed effects for intervention status and hospital site, as well as random effects for hospital wards and, where appropriate, participant-level repeated measures. The primary estimand is the individual-level intervention effect on CTM-15 score at T1. Primary and secondary models will additionally include age, Clinical Frailty Scale, and baseline EQ-5D-5L, and living arrangement as prespecified covariates. Age is included as a standard demographic covariate consistent with convention in trials of older adults, Clinical Frailty Scale and baseline EQ-5D-5L reflect their established role as prognostic and equity-relevant patient characteristics in care transition research; and living arrangement is included given its direct relevance to a person-centred bridging care intervention specifically designed around the post-discharge support environment, consistent with CONSORT/SPIRIT guidance on covariate-adjusted analysis in randomised trials (Kahan et al., 2014). As randomisation ensures balance on these covariates in expectation, their inclusion is not required for unbiased estimation of the treatment effect; any resulting gain in precision depends on the actual association between these covariates and CTM-15 and is not assumed in the sample size calculation.

The primary model will use a Kenward–Roger degrees-of-freedom adjustment or a comparably valid small-sample correction, as uncorrected mixed models and conventional generalised estimating equations may have inflated type I error when only a small number of clusters are randomised (Leyrat et al., 2018). Sensitivity analyses will examine alternative small-sample corrections and assumptions regarding missing data.

All analyses will follow the intention-to-treat principle, whereby participants will be analysed according to the intervention status of their ward at the time of admission, regardless of intervention completion. The primary outcome analysis will assess differences in care transition quality, measured using the CTM-15 at T1.

Secondary outcomes, include patient wellbeing (EQ-5D-5L), medication adherence (MARS-5), community resource engagement, patient satisfaction, emergency department visits, and specialist outpatient clinic appointment adherence. Continuous outcomes will be analysed using linear mixed-effects models, while

binary or count outcomes will be analysed using generalised mixed-effects models such as logistic or Poisson regression.

Exploratory subgroup analyses will assess effect modification by Clinical Frailty Scale category and living arrangement using treatment-by-subgroup interaction terms. These analyses will be interpreted cautiously because the trial is not powered for interaction effects.

Given the role of hospital site as a stratification factor in randomisation, treatment effects will be descriptively summarised by site to assess consistency of direction and magnitude; given the limited number of clusters per site per arm (3 vs. 3), this is not presented as a formal interaction test, which would be substantially underpowered to detect true effect modification.

Sensitivity analyses will assess the effect of missing data and analytical assumptions. Where appropriate, multiple imputation under a missing-at-random assumption will be used, with additional analyses under plausible departures from that assumption. CTM-15 analyses will also be repeated among patient respondents only. A per-protocol analysis will be conducted using prespecified adherence criteria based on documented receipt of core PBC components.

All continuous variables will be summarised using means and standard deviations or medians and interquartile ranges as appropriate; categorical variables will be summarised using counts and percentages. Effect estimates will be reported with 95% confidence intervals. Analyses will be conducted in Stata version 18 or later, using two-sided $\alpha = 0.05$ for the primary outcome.

For the qualitative component, interview and focus group data will be analysed using thematic analysis conducted by trained researchers, supported by qualitative data analysis software NVivo 14 to organise the data. Researchers will first familiarise themselves with the transcripts prior to coding. An iterative hybrid coding approach will be adopted, combining deductive coding guided by the PRISM framework with inductive coding to capture emergent themes. Analytical rigour will be enhanced through regular coder discussions and investigator triangulation, and interview guides may be refined iteratively in response to emerging insights.

Following completion of the separate analyses, quantitative and qualitative findings will be triangulated to provide an integrated interpretation of the effectiveness and implementation of PBC. Integrated findings will be synthesised and reported in the final study report.

9. DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

The investigators and SCH will permit study-related monitoring, audits, and/or IRB review and regulatory inspection(s), providing direct access to source data/document.

10. QUALITY CONTROL AND QUALITY ASSURANCE

Data safety which includes both soft and hard copies data collected will be monitored by the study team members throughout the study. Everyone in the research team will be assigned roles to perform and everyone will adhere to his or her responsibilities throughout the research process. Each member of the research study team that is involved in data collection will be briefed about the process.

Data will be collected by delegated study members with training and standardised protocols in place to ensure homogeneity and data quality control. The PI will physically check all data collected from each participant before it is translated onto the electronic encrypted document. Research data will be stored on institution-approved secure systems with access restricted to authorised study personnel only.

11. ETHICAL CONSIDERATIONS

This study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with the Good Clinical Practice and the applicable regulatory requirements. This final Study Protocol, including the final version of the Participant Information and Consent Form, must be approved in writing by the Centralised Institutional Review Board (CIRB), prior to enrolment of any patient into the study. The principal investigator is responsible for informing the CIRB of any amendments to the protocol or other study-related documents, as per local requirement.

11.1. Confidentiality of Data and Patient Records

All physical source documents will be securely stored in locked cabinets at SCH, with access strictly limited to authorized personnel. Trained study members will record data in password-protected Excel files. Electronic medical records, accessed only with explicit patient consent, will be maintained in password-protected files. The electronic data will not contain research participant identifiers. Identification code linking electronic data and research participants will be stored separately. Following study completion, all data will be retained for a seven-year period, after which it will be disposed of in accordance with established policies.

12. PUBLICATIONS

All study participants will provide written informed consent prior to participation. The SingHealth Centralized Institutional Review Board will provide oversight of the study, including review of protocol amendments, monitoring of adverse events, and conducting annual reviews. To ensure broad dissemination of our findings, we will present results at relevant international conferences in social prescribing and gerontology and publish in peer-reviewed scientific journals.

13. RETENTION OF STUDY DOCUMENTS

All physical source documents will be securely stored in locked cabinets at SCH, with access strictly limited to authorized personnel. Trained study members will record data in password-protected Excel files. Electronic medical records, accessed only with explicit patient consent, will be maintained in password-protected files. The electronic data will not contain research participant identifiers. Identification code linking electronic data and research participants will be stored separately. Following study completion, all data will be retained for a seven-year period, after which it will be disposed of in accordance with established policies.

14. FUNDING AND INSURANCE

This work is supported by SingHealth Fund – SCH with a planned duration of 12 months from 1 June 2026 to 30 June 2028. Institutional indemnity and insurance arrangements will apply in accordance with SingHealth policy.

15. AUTHOR CONTRIBUTIONS

LKH, AKLF, CPCY, MWSJ and CJT conceived and designed the study and the intervention. ROHS, QXN and MWSJ designed the statistical plan. QXN, MWSJ, and CJT drafted the manuscript. LKH solicited the funding. All authors read and approved the final manuscript.

16. CONFLICT OF INTEREST

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

List of Attachments

Appendix 1 – References

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