RESEARCH STUDY PROTOCOL

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Protocol Amendment History table

Version	Date	Description of Changes
Version 1	21 March 2025	Initial protocol version.
Version 2	30 June 2025	Protocol revisions and administrative updates.
Version 3	14 October 2025	Previous approved protocol version.
Version 4	20 September 2026	Protocol updated to clarify selected study procedures as implemented, including the randomisation procedure, assignment of AFW modality, and assessment and follow-up timings. Minor administrative and editorial revisions were also incorporated.

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1. BACKGROUND AND RATIONALE

In recent years, social prescribing (SP) has steadily gained prominence in the healthcare landscape owing to its effectiveness in addressing the needs of socially isolated older adults [1]. SP – a form of community referral – was first introduced in the United Kingdom (UK), whereby patients in the primary care setting are linked to a community service that is best suited to provide them with support for their individual social needs upon discharge [2,3]. While the efficacy of SP is limited by participant's interest in the activity offered or their comfort levels around peers belonging to the same activity group [4], many systematic reviews have attested to the benefits of SP programs – ranging from improved physical and mental wellbeing, increased levels of social interaction, and performing day-to-day activities with greater ease [5-11].

SP models encompass an array of interventions that addresses social determinants of health (SDOH) needs [7] ranging from providing more tailored approaches in the form of arts-based activities [12] to physical activities [13]. SDOH refers to non-medical factors that affect health outcomes, such as being able to receive quality healthcare and education, economic and housing certainty, access to nutritious foods, and proper social support [14]. Arts-incorporated SP programs have shown promise in enhancing mental and physical health in older adults – particularly in improving cognition, balance, coordination, and reducing frailty [15,16]. Although previous studies have investigated the effectiveness of arts-incorporated programs in addressing social isolation, however, most of these studies were conducted in Western countries – thereby leaving an underrepresentation of Asian countries in the literature [17]. As cultural differences exist between Western and Eastern populations, this may manifest in how older adults perceive and respond to arts-incorporated interventions and its eventual efficacy in mitigating levels of social isolation. Hence, it is imperative that this research gap is addressed [18].

In Singapore, patients are usually admitted for 21 days to the community hospital (CH), where they undergo short-term rehabilitation administered by a multidisciplinary team [19]. They are also screened and referred to an appropriate SP program (based on their needs assessment) by a well-being coordinator (WBC), who subsequently follows-up with the patient's progress in attending the community resource they are referred to post-intervention [20]. If patients have opted for the SP program, they will be engaged in in-patient SP activities during their stay in the community hospital and continue their participation post-intervention in the community resource they were referred to by their WBC [21].

The Practical, Robust Implementation and Sustainability Model (PRISM) framework integrates perspectives from both program recipients and implementors across different hierarchical levels to examine program effectiveness and implementation while considering contextual factors [22]. Its distinctive feature is the explicit inclusion of an "implementation and sustainability infrastructure" domain, encompassing role definitions, data reporting systems, and communication channels—elements proven crucial in healthcare settings. The framework links these contextual factors to RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) outcomes at both individual and organizational levels [23] and is created to be adaptable – regardless of the settings and interventions. The PRISM framework not only deals with the initial implementation of an intervention, but also considers its sustainability in the long-term – an issue that is largely prevalent in the healthcare sector.

Additionally, we incorporated elements from the Major System Change (MSC) framework into the implementor's interview guide. MSC addresses coordinated, system-wide changes across multiple organisations to improve healthcare delivery, quality, and outcomes, complementing PRISM through its five evaluation domains: decision to change, intervention selection, implementation approach, implementation outcomes, and intervention outcomes [24]. In addition, to evaluate the effectiveness of the arts-incorporated SP program, we have chosen to conduct a randomised controlled trial (RCT) [25]. This is owing to the robust nature of RCTs as a research method in minimizing bias, as randomisation ensures that participant characteristics, both known and unknown, are evenly distributed across groups, enabling any differences in outcomes to be attributed to the study intervention [26]. Furthermore, since there is a lack of RCTs that have been conducted to assess more complex forms of SP interventions (which tend to produce statistically insignificant results), it is hence imperative that our study bridges this gap through our pilot RCT [27,28,29]. We also assess the program's strengths, weaknesses, and areas for improvement as part of the process evaluation [30]. This comprehensive approach helps identify internal and external factors that influence successful implementation and long-term sustainability of complex interventions.

This research protocol outlines the methodology for a mixed method evaluation study of an arts-incorporated SP program (termed as 'Arts for Wellness' (AFW) program) conducted in SingHealth Community Hospitals (SCH) using the PRISM framework.

2. HYPOTHESIS AND OBJECTIVES

Our study aims to examine the effectiveness of an arts-incorporated SP program conducted in Outram Community Hospital (OCH), using an RCT, on older adults' wellbeing in Singapore. We hypothesize that as compared to usual SP care, the AFW program improves patients' mental wellbeing. Concurrently, we will evaluate the process of implementing the program using PRISM framework.

The secondary objectives of our study are:

1) To evaluate whether the arts-incorporated SP program reduces depression, anxiety, social isolation, length of stay in CH, 30-day readmission rates (including unplanned), and improves overall quality of life and wellbeing of patients, and their satisfaction towards their stay in OCH;

2) To understand the patients' perceived barriers and facilitators to participating in the AFW program; and

3) To examine the barriers and facilitators to implementing the AFW program, and perspectives of program recipients and implementors on the effectiveness of AFW program in the OCH.

Findings from this study will help shape future health and social care strategies to support the aging population more effectively. They will also lead to refinement of SP strategies implementation within the clinical and community settings.

3. EXPECTED RISKS AND BENEFITS

3.1. Expected risks to subjects.

Questionnaires, semi-structured interviews, and focus group discussions

Some of the questionnaires and/or semi-structured interview/focus group discussion 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 the knowledge about arts-incorporated SP program in clinical and community settings.

4. STUDY POPULATION

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

A total of 300 patient participants will be recruited from OCH for the quantitative component. These include 200 patients that are enrolled in an arts-incorporated SP intervention and 100 patients that are enrolled in a non-arts-incorporated SP program.

A total of 70 participants will be recruited for the qualitative component. To understand the barriers and facilitators of participating in the AFW program, we will also be sampling 15 arts-incorporated SP intervention patients, 10 healthcare providers (clinicians and WBCs) and 15 caregivers of patients that are enrolled in an arts-incorporated SP intervention. To explore the experience, barriers, and facilitators of conducting the AFW program, we will sample up to 10 program implementors of the SP program and 10 artists of the Arts for Wellbeing (AFW) project and 10 National Arts Council (NAC) stakeholders.

4.2. Inclusion and Exclusion Criteria for Recruitment

Patients who fulfil the following inclusion criteria will be recruited: (1) Aged 50 years and above at time of recruitment; (2) is willing and able to participate in the arts-incorporated program; (3) Able to converse in either English, Mandarin, or Malay; (4) Able to provide informed consent; (5) Able to complete questionnaires.

Our exclusion criteria are patients who are: (1) receiving palliative care; (2) planned for nursing home.

SP intervention patients, program implementors, artists, caregivers, healthcare providers and NAC stakeholders will be recruited from OCH. Patients and caregivers will be invited to participate in semi-structured interviews, and program implementors, artists, healthcare providers and NAC stakeholders will be invited to participate in focus group discussions. Each focus group discussion group will have between three to five participants from the same stakeholder group (i.e. four to six program implementors in one focus group). Additionally, program implementors, artists and NAC

stakeholders will be asked to complete the PSAT. In addition to fulfilling the following inclusion criteria: (1) Aged 21 and above at time of recruitment; (2) Able to understand and converse in English; (3) Able to provide informed consent, the main eligibility criteria for these groups of participants are as follows:

1) SP intervention patients: Has undergone at least 4 sessions of arts-incorporated SP in the community hospital.

2) Program implementors: Has at least three months of experience in SP.

3) Artists: Has been facilitating in the AFW project for at least one month.

4) Caregivers: Is a caregiver of a patient who has undergone at least 4 sessions of arts-incorporated SP in the community hospital.

5) Healthcare providers (clinicians and WBCs): Has patients who have undergone at least 4 sessions of arts-incorporated SP in the community hospital.

6) NAC stakeholders/art director: Has been involved in the AFW project for at least one month.

4.3. Recruitment Process

Our study team will work closely with the SP program administrators in SCH to contact patients, program implementors, artists, and caregivers. The SP program implementors will refer participants to our study team weekly, and a study team member will contact the referred participant to schedule a face-to-face meeting. During the face-to-face meeting, at least two study team members will be present to assess the participant's eligibility using the demographic consent form. Once the study team members have ascertained the participant's eligibility, informed consent will be collected from the participant before commencing data collection.

Data collection sessions for both intervention and control patients will be conducted at four specific time points: at baseline (T0), 4 weeks after baseline (T1), 8 weeks after T1 (T2), and 4 months after T1 (T3), each within ±7 days. Data collection for program implementors, artists, and caregivers will be conducted at a singular time point (around mid-point of the program) – subject to their availability. A window period of ±7 days will be allowed for all follow-up assessments to accommodate scheduling needs.

5. STUDY DESIGN AND PROCEDURES/METHODOLOGY

5.1. Methods and Study Design

This protocol is written in accordance with the SingHealth Centralized Institutional Review Board's Research Study Protocol and guided by the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) reporting guidelines (Figure 1) [31]. We have also drawn upon the PRISM framework to underpin the implementation of the process evaluation. The application of the PRISM framework ensures the feasibility and robustness of interventions to be implemented in the long run.

We will utilize a RCT design to evaluate the effectiveness of the arts-incorporated interventions for seniors undergoing short-term rehabilitation (approximately 21 days) in OCH. In the initial phase of the study, participants were allocated in a 1:1:1 ratio to literary arts, dance, or standard community hospital (CH) care. In a subsequent phase, the randomised comparison was

conducted between the Arts for Wellness (AFW) intervention and standard CH care alone, with AFW modality (literary arts or dance) determined by ward-level scheduling rather than random allocation. Participants receiving AFW will attend four to six arts-incorporated sessions, while control participants will receive standard CH care.

Upon discharge, the intervention group will be invited to participate in 2 virtual sessions of social hour that would be held over Zoom within an 8-week period after the final session of each programme and be linked to community resources, i.e., Active Ageing Center (AAC) which offers arts-incorporated program in the community, while the control group will be linked to community resources with non-arts-incorporated program in the community (Figure 2). Research activities (for example, recruitment, data collection and data analysis) will not be conducted by the AACs. This study will be registered on clinicalTrials.gov.

Our qualitative methodology will employ semi-structured interviews and focus group discussions with six distinct groups: artists, patients, caregivers (including domestic helpers), program implementors, healthcare providers, and NAC stakeholders. We will conduct interviews with 70 participants at their preferred time and location upon obtaining informed consent. A small portion of the program implementors - who are also part of the research team - may be interviewed as they are involved in running the AFW program.

The qualitative interviews will follow interview guides developed by the study team based on the PRISM framework (Appendices 20-25), with elements from the Major System Change framework incorporated into the implementers' interview guide [24]. Semi-structured interviews are expected to last for 45 minutes to 1 hour and focus group discussions are expected to last for 1 hour to 1.5 hours. These interviews will be audio-recorded and transcribed verbatim. All identifiable information will be masked or removed during transcription to ensure participant confidentiality. Our quantitative methodology will employ the use of questionnaires to evaluate primary and secondary outcomes measures.

The primary outcome of this study is patient's mental wellbeing which will be measured using the 14-item Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS). The WEMWBS (Appendix 2) is a validated instrument designed to measure positive mental well-being, encompassing both hedonic (positive affect), and eudaimonic (personal growth) aspects. It has been used in studies conducted in Singapore to assess mental well-being in the Singaporean population [32,33]. WEMWBS is particularly relevant to arts-based social prescribing, as it captures key dimensions of well-being influenced by arts interventions, including emotional resilience, social connectedness, and psychological flourishing. Previously used in other evaluations and studies of social prescribing programs, the WEMWBS will serve as a relevant measure in this study to assess the impact of arts engagement on mental well-being, contributing to the evidence base for arts in healthcare and community settings.

The secondary outcomes are participant satisfaction, depression and anxiety, health-related quality of life, and social isolation. The scales used to measure these outcomes are the Patient Health Questionnaire (PHQ-9) [34,35]; EuroQol 5-Dimensional (EQ5D-5L) [36,37]; General Anxiety Disorder 7-Item (GAD-7) [38,39]; Patient-Reported Experience Measures (PREMS) [40] (Appendices 3-8). We will also be looking at patients' length of stay in the CH and 30-day readmission rates (including unplanned) which would be collected across a 6-month period via the Electronic Health

Intelligence System (eHints), which is SingHealth's platform to consolidate and manage patient data. Table 1 provides a summary of the outcomes and their respective scales.

These scales were piloted on patients (n=30) to gauge the duration and participants' receptivity to the questions, which informed the design of the full-scale study. For this study, apart from the PREMS (which is collected at T1 only), the above-mentioned scales are administered via FormSG at baseline (T0), 4 weeks after baseline (T1), 8 weeks after T1 (T2), and 4 months after T1 (T3), each within a ±7-day window. The same assessment schedule applies to both the intervention and control groups; for AFW participants, T1 corresponds to the post-intervention assessment following completion of the four to six inpatient arts sessions (Table 1). Participants may withdraw from the study or from receiving the study intervention at any time, for any reason.

We would also be using the Program Sustainability Assessment Tool (PSAT) (Appendix 9) which will be administered to program implementors, NAC stakeholders, and artists to assess the sustainability of the arts-incorporated SP program [30] at mid-point of the program. The PSAT is typically used to assess a program's strengths, weaknesses, and areas for improvement that ultimately lead to its sustainability [30].

In addition to the RCT, implementation-related indicators will be collected, including participant perceptions of the program, contextual feasibility, and the experiences of implementors (e.g. artists, program team members), using an appropriate implementation science framework, such as the PRISM and MSC framework. This evaluation will examine the program's delivery mechanisms, contextual influences, and the role of artists as primary implementors. The findings will provide valuable insights into the scalability and sustainability of AFW interventions within the community setting. Table 2 provides a detailed summary of the implementation-related indicators to be collected.

	Enrolment	Allocation	Post-allocation		
TIMEPOINT	***0***	**0**	t_1	t_2	t_3
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Baseline Survey	X				
Allocation		X			
INTERVENTIONS:					
Standard CH care			←	→	
Literary Arts Program			←	→	
Dance Program			←	→	
Social Hour, Take Home Art kit			←	→	
ASSESSMENTS:					
WEMWBS	X	X	X	X	X
PHQ-9	X	X	X	X	X
EQ5D	X	X	X	X	X
GAD-7	X	X	X	X	X
Participant satisfaction			X		
Adherence rates			X	X	X
Any reported adverse events			X	X	X
Qualitative semi-structured interviews (patients, caregivers)				X	
Qualitative interviews (program implementors, artists, NAC stakeholders, clinicians)			←	→	
PSAT*			←	→	

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

WEMBWS, Warwick-Edinburgh Mental Wellbeing Scale; PHQ-9, Patient Health Questionnaire; EQ5D-5L, EuroQol five-dimensional; GAD-7, General Anxiety Disorder 7-Item; eHints, Electronic Health Intelligence System.

\Only collected for artists and program implementors.*

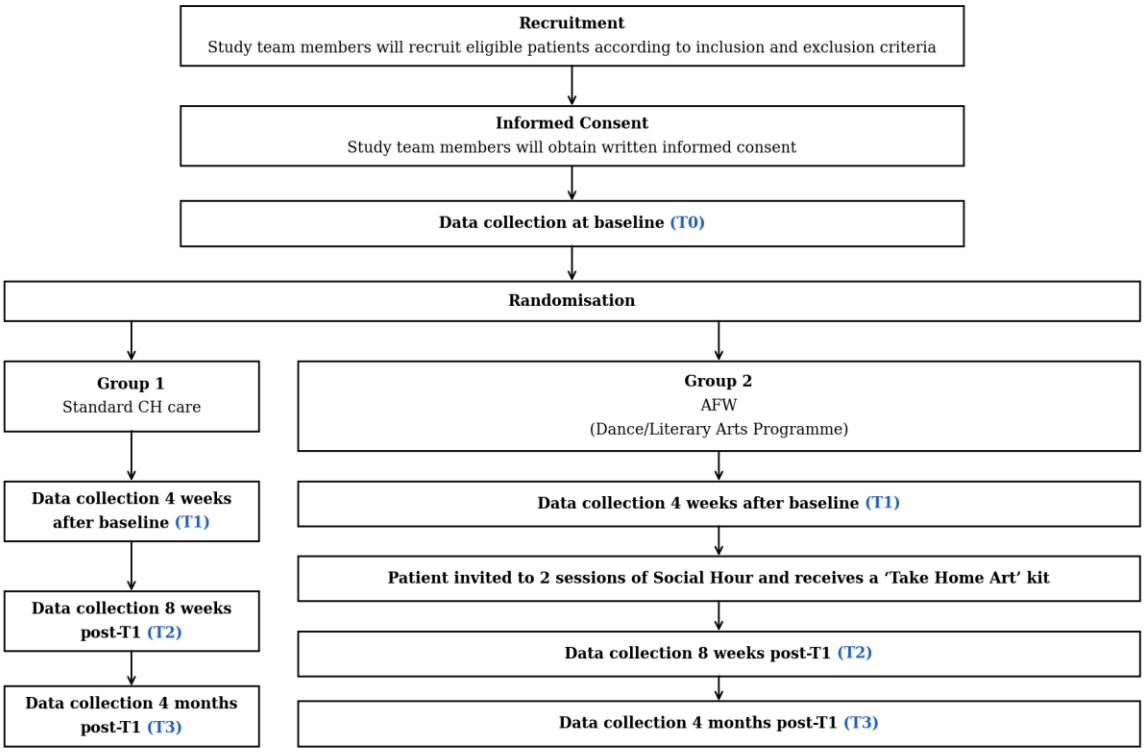


Figure 2. Study flowchart. The protocol initially pursued 1:1:1 allocation, but modality-specific randomisation was subsequently discontinued because the available art form depended on ward scheduling.

5.2. Intervention Group

Participants allocated to AFW received either dance or literary arts according to the programme available on their ward during admission. The programme comprised up to six sessions delivered twice weekly over approximately 3 weeks; because of discharge timing and clinical or operational availability, individual participants could attend fewer than six sessions. The arts-incorporated programs involve the following elements:

1. Literary Arts Program: Improve self-expression through the sharing of stories (in a group setting) of one's name, stories of growing up, retelling a story of courage, and imagining being a superhero.

2. Dance Program: Explore the concepts of *Wiragna* (body awareness, body shape, and body form), *Wirama* (rhythm, tempo, and harmony of movement and music), and *Wirasa* (self-expression through movement).

Participants will be invited for 2 virtual sessions of social hour that would be held over Zoom within 8 weeks upon completing the intervention. Volunteers will assist with less technologically savvy patients at their homes as part of the process. Upon discharge, participants will be linked to arts-incorporated program in the community post-intervention by WBCs, as well as receive a 'Take Home Art' kit (THK). Each THK is unique to its respective art form and is meant to encourage participants to continue engaging in the arts-incorporated activity post-intervention. The THKs are presented to the patients in a package, which comprises of 1) an activity pamphlet detailing activities and instructions, and 2) the required materials for the specific art form. Patients are not required to have

any prior experience in the art forms mentioned above to be eligible for participation. The objective of these interventions is to enhance the wellbeing of seniors in Singapore through the arts-incorporated SP program.

5.3. Control Group

The participants in the control group will receive standard CH care in the community hospital.

Outcome	**Source & instrument**	**Data collection timepoint**
Main primary outcomes		
Mental wellbeing	WEMWBS	T0, T1, T2, T3
Secondary outcomes		
Anxiety and Depression	PHQ-9, GAD-7	T0, T1, T2, T3
Health-related quality of life	EQ5D-5L	T0, T1, T2, T3
Participant satisfaction	Patient's feedback form (AFW PREMS)	T1
Length of stay and 30-day readmission rates (including unplanned)	eHints	6 months pre-and post-intervention

Table 1. Primary and secondary outcomes in the outcomes evaluation of the Arts for Wellness program at Outram Community Hospital.

Table 2. *Process evaluation indicators to be collected for evaluating the Art for Wellness program (AFW) implementation at Outram Community Hospital (OCH).*

PRISM domains	Determinants/ indicators	Tools used to measure indicator(s)	Data source	Time point(s) of data collection
Reach *Defined as representativeness of study participants to individuals who have SDOH needs in OCH*	Proportion and characteristics of eligible patients i. who are enrolled in arts-incorporated SP interventions ii. who finalized plans with WBCs for referral to arts-based activities in the AACs post-intervention iii. who actualized arts-based AAC referrals	Administrative records on numbers and characteristics of eligible patients agreed and those who declined to enroll in SP, SBAR4 form – used by WBCs for documentation plans and resources and focus group discussions with artists and program implementors	SP program implementation team & our study data collection form (DCF) for patients and interviews with artists and program implementors	T0, T1, T2, T3 Mid-point of program onwards
Effectiveness *Defined as the impact of AFW on patient outcomes, including potential negative effects, and variability across subgroups*	Changes in wellbeing, depression and anxiety, health-related quality of life, and social isolation	Scales: WEMWBS, PHQ-9, EQ5D-5L, GAD-7	Patients from OCH	T0, T1, T2, T3
	Participant satisfaction	Patient feedback form (AFW PREMs)	Patients from OCH	T1
	Reasons for success or lack of success of arts-incorporated SP program, any adverse events and/or unintended consequences	Focus group discussions	SP program implementation team, NAC stakeholders, and artists	Mid-point of program onwards
Adoption *Defined as the proportion of wards within OCH, and artists and WBCs who are implementing AFW.*	Percentage of wards in OCH which have the arts-incorporated SP program in place, and numbers and characteristics of artists and WBCs implementing AFW	Administrative records on numbers and characteristics of artists, healthcare providers	SP program implementation team & our study DCF for artists and WBCs	Mid and end point of program check in with implementation team
Implementation *Defined as fidelity to the various elements of AFW including consistency of delivery as intended. It also includes*	Fidelity to the program's protocol including consistency of delivery and quality of intervention across different implementors	Administrative records & Observation worksheet for arts-incorporated SP program sessions	SP program implementation team & Our study team records	Mid and end point check in with implementation team for records & monthly observation (from mid-point of program onwards)

PRISM domains	Determinants/ indicators	Tools used to measure indicator(s)	Data source	Time point(s) of data collection
adaptations made to AFW and implementation strategies.	Adherence to AFW program and adaptations made to implementation process	Focus group discussions	SP program implementation team, NAC stakeholders, and artists	Mid-point of program onwards
	Existing and potential training and support for artists	Focus group discussions	Artists and NAC stakeholders	Mid-point of program onwards
	Clients' use of the intervention and implementation strategies	Administrative records of proportions of patients who joined social hours and used THK Semi-structured interviews for patients from OCH Focus group discussions for SP program implementation team, NAC stakeholders, and artists	Patients from OCH, SP program implementation team, NAC stakeholders, and artists	Patients: T2 Program implementor, NAC stakeholders, and artists: Mid-point of program onwards
Maintenance and sustainability infrastructure *Defined as the extent to which AFW becomes part of the routine organizational practices and policies at the setting level. It is also the long-term effects of AFW on outcomes after it is completed at the individual level.*	Commitment to implement and sustain arts-incorporated intervention in the organization, and which are the factors that can lead to AFW sustainment.	Focus group discussions and PSAT	SP program implementation team, NAC stakeholders, and artists	Mid-point of program onwards
	Reasons for wanting to continue to engage in arts-incorporated SP in the long-term	Semi-structured interviews	Patients and caregivers	T2
	CH length of stay and 30-day readmission rates (including unplanned)	eHints	SP program implementation team	6 months pre- and 6 months post-intervention
Others PRISM contextual factors (institutional)	Perceived barriers and facilitators for adoption of AFW program, and how to enhance adoption	Focus group discussions	SP program implementation team, NAC stakeholders, and artists	Mid-point of program onwards
Patient context	Perceived barriers and facilitators to participating in arts-incorporated SP program in the inpatient setting and in the community	Semi-structured interviews	Patients from OCH (arts-incorporated SP intervention) and caregivers	T2

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 of clinical experts and a biostatistician. The board will conduct a single interim review of un-blinded safety and effectiveness data after 300 participants complete their last follow-up. 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 OCH, 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 transcribing of semi-structured interviews and focus group discussions is completed, the audio will be deleted from the storage drive. Transcripts will be stored on the institution's secure, access-controlled OneDrive and accessible only to authorised study team members.

8. SAMPLE SIZE AND STATISTICAL METHODS

8.1. Determination of Sample Size

The primary aim of this trial is to assess the preliminary effectiveness of arts in social prescribing, with the primary outcome being the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS). Sample size calculation was based on detecting an effect size of 0.26 between groups with 80% power at a significance level of 0.05 for a three-arm trial, which determined that 60 participants per arm would be needed at final analysis. To account for an anticipated 40% attrition rate (derived from ground observations and prior implementation experiences in community-based lifestyle interventions), a total of 300 participants will be recruited. This will comprise 100 participants in each AFW program arm (two arms, total n=200) and 100 participants in the control arm. With this recruitment strategy, even with the expected 40% dropout rate, we will retain approximately 60 participants per arm for final analysis, sufficient to detect the hypothesized effect size of 0.26. [41] During implementation, modality-specific randomisation was discontinued, while the overall 2:1 allocation to AFW versus standard care was maintained. The original three-group calculation is reported here as the basis on which recruitment was planned.

For the qualitative analysis, data collection will continue until data saturation is reached within each group, at which point further data gathering is [42] unlikely to yield additional insights relevant to the research question. Based on previous studies, we anticipate that conducting 70 interviews, comprising 15 patients, 15 caregivers, 10 healthcare providers of patients enrolled in the arts-incorporated social prescribing intervention, 10 program implementors, 10 artists, and 10 NAC stakeholders in the intervention arm will provide a feasible approach to achieving data saturation.

8.2. Randomisation and Blinding

Baseline assessments were completed before allocation. At study initiation, participants were allocated using a computer-generated block randomisation sequence to dance-based AFW, literary arts-based AFW, or standard care in a 1:1:1 ratio. During recruitment, randomisation to a specific AFW modality became operationally impracticable because dance and literary arts programmes were scheduled at ward level and were not concurrently available to all eligible participants. The allocation procedure was subsequently modified such that participants were randomised in an overall 2:1 ratio to AFW plus standard care or standard care alone. Among participants allocated to AFW, the specific

art modality was thereafter determined by the programme available on the ward during the participant's admission rather than by random allocation. The randomisation sequence was generated in R version 4.3.1 (R Foundation for Statistical Computing, Vienna, Austria) by an independent biostatistician who was not involved in participant recruitment or outcome assessment. The allocation sequence was held by personnel independent of participant recruitment. After enrolment and completion of baseline assessment, the research coordinator contacted the personnel holding the allocation sequence to obtain the participant's assignment. Participants, intervention providers, and research coordinators could not be masked to allocation because of the nature of the intervention. Outcomes were self-reported and collected by unmasked research coordinators.

8.3. Statistical and Analytical Plans

In this study, quantitative and qualitative data will be analyzed separately using appropriate methodologies tailored to each data type. Descriptive statistics will summarize baseline characteristics and outcomes from WEMWBS, along with secondary health measures including PHQ-9 (depression), and EQ-5D-5L (health-related quality of life), GAD-7 (anxiety). The PSAT will be used separately to evaluate the program's capacity for long-term sustainability across its eight domains.

The primary analysis will employ adjusted mixed-effects models (MEM). Adjusted MEM will allow us to account for both fixed effects (such as participant demographics, baseline functional status, and intervention type) and random effects (including individual participant variations, artist-specific influences, and group dynamics). This approach is well suited for handling the hierarchical nature of our data and repeated measures over time and offers a more robust approach in handling missing data as compared to traditional approaches.

The analysis will follow an intention-to-treat approach for all participants regardless of completion status. The primary analysis will focus on changes in mental wellbeing, measured by WEMWBS, and differences between the intervention and control groups will be assessed using adjusted MEM. This model will allow for the evaluation of individual trajectories over time, adjusting for baseline differences and potential confounding factors.

Secondary analyses will focus on changes in secondary outcomes, including anxiety (measured by the GAD-7), depression (measured by the PHQ-9), health-related quality of life (measured by the EQ-5D-5L), and 30-day readmission rates (including unplanned) which would be collected via eHints. For these secondary outcomes, adjusted MEM will be used to assess continuous variables, while chi-square tests will be used for categorical outcomes. Subgroup analyses will also be conducted to explore potential variations in outcomes based on age, gender, and baseline health or mental well-being status. Additionally, other secondary analyses may be performed to investigate associations between mental well-being and other health outcomes.

Sensitivity analyses may be conducted to evaluate the impact of missing data. If performed, the baseline observation carried forward (BOCF) method may be used as one alternative for handling missing data, with results from this method compared to those obtained from the adjusted (MEM) to assess the robustness of the findings. Additionally, to check the robustness of the primary outcome findings, a per protocol analysis or Complier Average Causal Effect analysis might be considered.

Results will be presented using means with standard deviations for continuous variables and frequencies with percentages for categorical variables, with 95% confidence intervals reported where appropriate. All statistical analyses will be conducted using Stata version 18, with statistical significance set at $p<0.05$.

For the qualitative portion, thematic qualitative analysis will be conducted by trained researchers using qualitative data analysis software (e.g., NVivo or Dedoose). Researchers will review all transcripts thoroughly to familiarise themselves with the data. An iterative hybrid coding approach will be applied, combining both inductive and deductive techniques. The PRISM framework and elements from the Major System Change (MSC) framework will guide the deductive coding process to facilitate the identification of relevant codes, while an inductive approach will capture emergent insights that extend beyond the predefined constructs of these frameworks [24]. To enhance analytical rigour, coders will participate in iterative discussions, ensuring the validity of interpretations through investigator triangulation. As data coding and analysis occur concurrently with interviews, interview topic guides will be continuously adjusted or refined during the study to accommodate the analysis in an iterative manner.

Following these separate analyses of the quantitative and qualitative data, findings from both data sets will be triangulated to provide a comprehensive understanding of the study outcomes and incorporated into the final report.

9. DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

The investigators and OCH 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.

The trial will be monitored by an independent data and safety monitoring board, comprising of clinical experts and a biostatistician. 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.

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 OCH, 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 OCH, 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 was supported by the National Arts Council for the Enhancing Wellbeing in Seniors through Structured Arts- Based Programs Project (Ref: NAC-SCH Partnership Agreement Dated 8 Jan 2025)

15. AUTHOR CONTRIBUTIONS

[Redacted: contains personally identifiable information (individual contributor initials). Redaction permitted under 42 CFR 11.48(a)(5).]

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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