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Community health navigator-assisted transition of care from hospital to community: protocol for a randomised controlled trial

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ABSTRACT

Introduction The objective of this parallel group, randomised controlled trial is to evaluate a community health navigator (CHN) intervention provided to patients aged over 40 years and living with chronic health conditions to transition from hospital inpatient care to their homes. Unplanned hospital readmissions are costly for the health system and negatively impact patients.

Methods and analysis Patients are randomised post hospital discharge to the CHN intervention or usual care. A comparison of outcomes between intervention and control groups will use multivariate regression techniques that adjust for age, sex and any independent variables that are significantly different between the two groups, using multiple imputation for missing values. Time-to-event analysis will examine the relationship between seeing a CHN following discharge from the index hospitalisation and reduced rehospitalisations in the subsequent 60 days and 6 months. Secondary outcomes include medication adherence, health literacy, quality of life, experience of healthcare and health service use (including the cost of care). We will also conduct a qualitative assessment of the implementation of the navigator role from the viewpoint of stakeholders including patients, health professionals and the navigators themselves.

Ethics approval Ethics approval was obtained from the Research Ethics and Governance Office, Sydney Local Health District, on 21 January 2022 (Protocol no. X21-0438 and 2021/ETH12171). The findings of the trial will be disseminated through peer-reviewed journals and national and international conference presentations. Data will be deposited in an institutional data repository at the end of the trial. This is subject to Ethics Committee approval, and the metadata will be made available on request.

Trial registration number Australian New Zealand Clinical Trials Registry (ACTRN 12622000659707).

Article Summary The objective of this trial is to evaluate a CHN intervention provided to patients aged over 40 years and living with chronic health conditions to transition from hospital inpatient care to their homes.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Pragmatic randomised controlled trial design with broad inclusion criteria and with an intervention embedded in a real-world healthcare setting.
⇒ Designated community health navigators (CHNs) supported in an established outreach team.
⇒ Participants are not blinded to the treatment arms.
⇒ Contamination may occur from clinic-based or community-based interventions which may duplicate some of the services the CHN may provide.
⇒ The trial will be conducted in one inner urban local health district, and thus, its generalisation to other areas may need to be made with care.

INTRODUCTION

Avoidable hospital readmission occurs when a patient is discharged from an index hospital admission and subsequently has a further, related and unplanned admission, that was potentially preventable.[1] Readmission rates present a challenge in many countries and are an accepted indicator of the quality of hospital care.[2] Unplanned hospital readmission may result due to exacerbation of underlying disease,[3] comorbidity,[4] inadequately planned transitions of care between hospital and the home[5] and failure to follow medication changes made while in hospital.[6] Older patients (>65 years) represent a significant proportion of these readmissions,[2 4] and factors exacerbating readmission include being from a culturally or linguistically diverse (CALD) background, living in poor housing, suffering from functional disability, having admissions prior to the index admission and having a longer length of stay during the index admission.[2] Reducing readmission rates to improve the efficiency and financial sustainability of the healthcare system is a major government priority. Currently, unplanned readmissions cost Australia

approximately A$1.5 billion annually.[7] In New South Wales (NSW) (Australia's most populated state) between 2015 and 2018, readmission rates within 30 days postindex discharge varied between 10% (for ischaemic stroke) and 22% (for cardiac failure).[8]

Standard hospital discharge procedures within NSW hospitals mandate discharge care coordination. This includes liaison with all care providers including the patient's general practitioner (GP) and referral to relevant follow-up services. A detailed discharge summary should be provided to all relevant persons including treating health professionals and the patient and/or their families, which includes medication information, community and GP referral information, follow-up appointments and patient educational resources. Patients are provided with a 2–7-day supply of discharge medications.[9] However, communication and coordination have not always been optimal in Australia contributing to readmission.[10 11]

Strategies aimed at reducing unplanned readmissions have been trialled with variable success. These include improving the interface between hospitals and primary care, the use of GPs and pharmacists to conduct medicine reconciliation and improved discharge planning and follow-up processes.[12] Various models have also been developed which aim to improve the transfer of inpatients back to their homes, including the use of community health workers (CHWs) or community health navigators (CHNs). Within this paper, we use these terms interchangeably. The American Public Health Association describes CHWs as 'frontline public health workers who are trusted members of and /or have an unusually close understanding of the community served'.[13] Particularly within the USA, CHWs have been successfully engaged to improve chronic disease management, particularly hypertension, diabetes and asthma.[14] Internationally, CHWs undertake a variety of roles including helping to navigate health services.[15] Navigation has been shown to reduce admission and readmission rates and improve access to health and social care for disadvantaged groups, especially indigenous and CALD populations.[13 16] In a systematic review of the impact of CHWs on the use of healthcare services in the USA, 42% of the RCTs that measured emergency department (ED) visits, hospitalisations or urgent care visits found that CHW interventions resulted in a decrease in the use of services relative to control groups.[17] In addition, the majority of CHW interventions were cost saving and low cost (less than US$ 1500 per patient per year). Research from Canada indicates that CHWs can play a role in reducing barriers to service access for marginalised populations, help identify emerging needs among communities and aid the health system in preventing families from falling through service gaps.[18]

Trial objectives

This trial aims to evaluate the impact of a CHN intervention provided to patients aged 40 years and above and living with chronic health conditions, to transition successfully from hospital inpatient care to their homes.

Trial setting

The trial will be conducted in Sydney Local Health District (SLHD) in inner urban Sydney, NSW.

Hypotheses

Primary hypothesis

The primary hypothesis is that intervention-group participants will have 50% fewer hospital readmissions (from 20% to 10%), in the first 60 days postdischarge (as this is the duration of the CHN intervention) when compared with the control group.

Secondary hypotheses

In comparison with the control group, intervention group participants will, at 3 months, have higher rates of self-reported medication adherence and improved health literacy. In addition, intervention group participants will, at 6 months postdischarge, report higher rates of patient-centred care and quality of life.

Our hypothesis in relation to the cost of the intervention is that health service use will be more appropriate (higher rates of GP management plans and team care arrangements and fewer ED presentations) and that the total health service cost in the intervention group will be less than the control group at 6 months.

METHODS AND ANALYSIS

Reporting is in accordance with Standard Protocol Items: Recommendations for Interventional Trials [19] (online supplemental file 1).

Study design

This trial will use a parallel-group, pragmatic randomised controlled trial (RCT) design with an embedded qualitative study.

Inclusion criteria

To be eligible, patients must be:

1. Aged 40 years and over,
2. Living within SLHD boundaries
3. Admitted for treatment for a chronic condition(s) (defined as a condition that is long lasting and has persistent effects. They include cardiovascular disease, chronic kidney disease, diabetes, chronic obstructive airway disease, asthma, arthritis, cancer, osteoporosis and mental conditions)[20] or under the SLHD aged care service.
4. Speaking English or any of the five other most commonly spoken languages within SLHD (Arabic, Cantonese, Mandarin, Greek or Italian).

Exclusion criteria

1. Selected for follow-up by any other chronic care programme offered by the SLHD

2. Discharged to residential aged care facilities or rehabilitation facilities, transferred to another SLHD facility or transferred to another hospital or may be too unwell to participate in the study
3. Admitted primarily for COVID-19 diagnosis.
4. Receiving community palliative care services
5. Receiving 7-day postdischarge follow-up from mental health services and may be allocated follow-up from the other healthcare teams
6. Diagnosed with severe cognitive impairment and unable to give verbal consent
7. Patient or their primary carer does not have a landline or a mobile phone contact number available

Sample size

We aim to recruit 460 patients so that approximately 390 patients remain at the 6-month follow-up (based on 3% mortality and 12% loss to follow-up). This was calculated assuming a readmission rate of 20% within 60 days (based on pilot and published data[3 21]) in the control group and a 50% reduction in readmissions due to the intervention, 5% level of significance and 80% power; at least 392 patients (196 in each group) need to be included in the study. Survival analysis of time to readmission would require a similar sample size.[22–24]

Study timeline

Pilot recruitment commenced in November 2022 with the enrolment of nine patients. Due to several delays, this was ceased at the end of 2022 and did not recommence until May 2023. Recruitment will run for approximately 12 months or sooner if the sample size is reached. Follow-up will be conducted at 3 and 6 months postindex discharge. Evaluation will occur in late 2024/early 2025.

Patient screening and recruitment

Patients are screened immediately postdischarge from one of the four public hospitals (Royal Prince Alfred, Balmain, Canterbury and Concord) in SLHD, Australia. SLHD is located in the central/west of Sydney covering 126 km^2 with approximately 740 000 residents. Eligibility is assessed using the NSW Health Patient Flow Portal and the electronic medical record (eMR). The portal includes an integrated care module that has an e-enabled Risk of Hospitalisation (RoH) algorithm that flags patients with a chronic condition at RoH within 12 months (figure 1).

A planned care team member will initially approach eligible patients by telephone and gain permission for research officer (RO) contact. The RO will provide detailed information about the study using a standardised script. Verbal consent to participate will be recorded using an approved Ethics Verbal Consent Template (online supplemental file 2). Once consented, the RO will administer the baseline survey and enter it into an online platform (REDCap). All consenting patients will receive a mailed package containing the patient information sheet, withdrawal of consent form and a copy of the completed verbal consent form.

Allocation and blinding

Consenting patients will be randomly allocated to the intervention or usual care (control) after baseline assessment. Randomisation will be conducted using REDCap with sequence generation via a randomisation sheet preloaded into the software which prevents knowledge of the next allocation. Stratification is based on the hospital site. Blinding will not be used. Patients allocated to the intervention will be informed that they will be contacted by a CHN to arrange a home visit. Those in the control group will be informed that they will not receive the intervention but will receive a follow-up phone call in 3 months.

Context and setting

Three CHN positions are located within the planned care team. This multidisciplinary team is part of an Integrated Care Initiative by the NSW Ministry of Health called the Planned Care for Better Health (PCBH) programme which aims to identify patients at RoH early and strengthen the care provided to them.

Although CHNs are used within international and Australian contexts, the scope of practice, backgrounds and parameters of the role can vary,[25] and the optimal design of the role in different contexts is yet to be established.[26] Within this trial, CHNs have a certificate or higher in community care or aged care (healthcare assistant) and/or experience in a relevant field. Some CHN roles are specifically designed to be representative through shared culture. Although speaking a second language is an advantage in this role, it is not essential given the number of cultural groups within SLHD. The role is designed to build knowledge and interpersonal and communication skills which foster rapport with clients, develop awareness of the unique challenges facing this cohort and demonstrate an ability to use the clinical and social support resources within the SLHD to intervene in the health and social and psychological care of their clients in a meaningful way.

Training and supervision

Training and supervision are essential components underpinning the CHN role. An online training programme (12 modules) has been developed, each comprising a presentation with audio, supporting notes, videos, additional reading materials and a quiz (table 1). Module content is based on previous SLHD programmes,[27] research in general practice[28 29] and stakeholder consultation through a codesign workshop. CHNs undertake modules at their own pace, and group discussion sessions provide an opportunity for the CHNs to reflect on personal experiences with researchers and their supervisor. The CHNs also undertake SLHD mandatory training which incorporates cultural sensitivity and indigenous and aboriginal awareness modules.

Regular and ongoing supervision is provided by the plannned care team leader and supported by clinical nurse consultants (CNCs) and social workers and documented

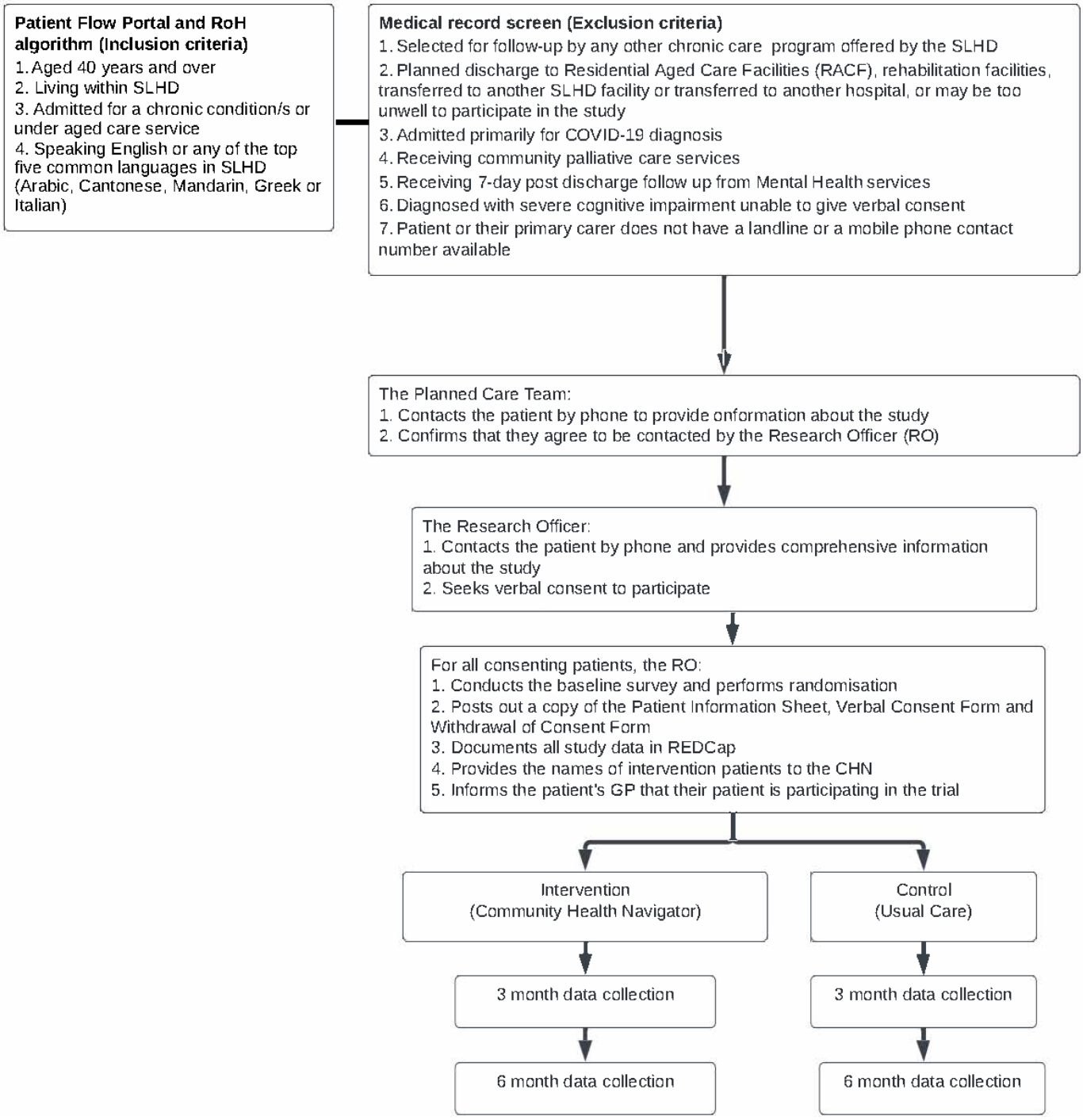

Figure 1 Patient recruitment process.

through SLHD supervision forms and agreements. Supervision includes:

1. Daily huddles with clinical support initially, reduced (second daily) as the CHN builds competence and confidence
2. Weekly case conferences/meetings for debriefing and extended to fortnightly when the CHNs feel established. Fortnightly team case conference with a geriatrician attending every second session
3. 6weekly one-on-one supervision sessions with the team leader used to debrief and discuss individual case management

The CHN intervention

The key element to the CHN intervention (figure 2) is that initial contact is made by the planned care team within 72 hours of hospital discharge with follow-up by the CHN as soon as possible after that.

The specific roles of the CHN will include:

1. Building patient understanding of their health condition and confidence in self-management.
2. Identification of problems in the living environment impacting the patient's health and well-being, such as fall risk and social isolation.

Table 1 Training modules

Module 1	Understanding the Australian healthcare system
Module 2	Introduction to chronic disease
Module 3	Preventive healthcare—risk and protective factors
Module 4	Social determinants of health
Module 5	Community health navigator: roles and responsibilities
Module 6	Cultural mediation and language
Module 7	Communication and self-management
Module 8	Community resources
Module 9	Client need assessment and problem identification
Module 10	Professional responsibilities and boundaries
Module 11	Medicines and medication adherence
Module 12	Access to healthcare

3. Checking medicines against the discharge summary and reconciling these through contact with their GP or pharmacist.
4. Developing a management/action plan that will form the basis of the interaction going forward. This will recognise the limitations of the CHN role but allow linking with more clinically focused care if required.
5. Liaising with the patient's GP, family and carers.

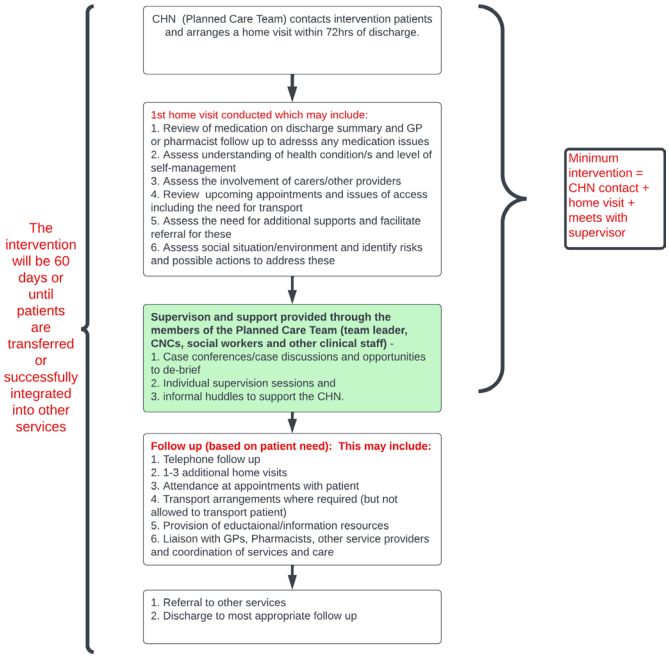

Figure 2 The community health navigator intervention. CHN, community health navigator; CNCs, clinical nurse consultants; GP, general practitioner.

6. Linking to appropriate health and community services to provide ongoing support.

Usual care

Usual care is an appropriate comparator in pragmatic trials.[30] Patients allocated to usual care will be informed that they will not receive assistance from the CHN, but will continue to receive the care they would normally receive posthospitalisation (GP, hospital outpatient or specialist appointments) where scheduled.

Interface with primary care

The GPs (where this is known) for all consenting patients will be informed that their patient is participating in the trial. The CHN will attempt to link patients without a GP to these services. The CHN will provide a letter to the GP of all intervention patients which highlights the main issues requiring management postdischarge. The CHN will also assist the patient in developing a list of questions for the GP that the patient can take with them to the consult.

Fidelity

Procedures for monitoring adherence to intervention protocol by the CHNs will be collected and documented throughout the trial. We will assess the number of home visits, the number of phone contacts, the types of support provided by the CHN and the types of referrals made. The fidelity and tailoring of the intervention to patient needs will be assessed by analysing documentation on the eMR and collected by the CHN. Qualitative data will be used to assess the facilitators and barriers to the fidelity of the intervention from a CHN perspective. Each CHN will receive the same training and supervision to ensure they perform their role with consistency. They will routinely report on their activities which will be reviewed to ensure ongoing fidelity within the intervention.

Outcomes and outcome measures

Primary outcome

Reduced unplanned hospital readmission (all cause) is defined as 50% fewer readmissions (from 20% to 10%) in the first 60 days postdischarge (as this is the duration of the CHW intervention). Data on the index admission for intervention and control patients will be determined from routinely available hospital eMR data and the Patient Flow Portal. Matching records in the 60 days after the index admission from all hospital admissions, within the state of NSW, will be extracted from the NSW Admitted Patient Data Collection (APDC) by the NSW Centre for Health Record Linkage (CHeReL) using a probabilistic linkage procedure, which guarantees false positive rates <0.5% and false negative rates <0.1%.[31] This will include patients who deviate or are lost to follow-up.

Secondary outcomes

Secondary outcomes for the intervention and control patients will be collected by the RO at designated timepoints through telephone follow-up. For patients

preferring to do online follow-up questionnaires, this option will be provided.

The following outcomes (continuous variables) will be assessed at baseline and 3 months:

1. Change in patient-reported medication adherence (measured by the Adherence to Refills Medication Scale)[32]
2. Change in patient-reported health literacy (measured by three domains of the Health Literacy Questionnaire): Domain 4, social support for health; Domain 7, navigating the health system; and Domain 9, understanding health information well enough to know what to do[33]
3. Patient experience of hospital discharge measured through a subset of questions based on the NSW Bureau of Health Information patient surveys: surveyshttps://www.bhi.nsw.gov.au/nsw_patient_survey_programp

The following outcomes (continuous variables) will be assessed at baseline and 6 months:

1. Change in patient-reported quality of life (measured by the EuroQol 5-Dimension 5-Level questionnaire)[34 35]
2. Change in patient-reported assessment of chronic illness (measured by the Patient Assessment of Chronic Illness short form adapted)[36 37]

Linked data

Initial patient consent will include consent to link the admission and trial survey data to hospital-use data (inpatient and ED use) through the APDC available through NSW CHeReL following appropriate ethics application through NSW Population and Health Services Research Ethics Committee.

An economic analysis will measure the cost of the intervention and health service use in the intervention and control groups over 6 months following index discharge, using individually linked Medicare Benefits Schedule (MBS) (including care plans) and Pharmaceutical Benefits Scheme (PBS) data from Services Australia. Our hypothesis is that health service use will be more appropriate (higher proportion of team care arrangements and fewer ED presentations) and that the total cost in the intervention group will be less than the control group at 6 months. Patient consent to link to medical claims through MBS and dispensing of medications on the PBS will be sought at the 6-month follow-up and be undertaken in accordance with the Commonwealth Department of Human Services which governs the ethical and collection processes relating to these data. The benefit of the intervention will be primarily measured by a gain in quality-adjusted life years (QALYs) in the intervention group as compared with the control group. An economic evaluation will be carried out on 'intent-to-treat' basis based on the cost utility framework. The main outcome will be additional costs incurred for QALY gain under CHN intervention compared with usual care (control group). This will be presented as incremental cost-effectiveness ratio (ICER)—incremental cost divided by incremental QALY gain. Further non-parametric bootstrapping will be used as part of sensitivity analysis to check the reliability of results by measuring the uncertainty in the estimate of ICER.

Analytical plan and data management

Baseline characteristics and baseline outcome measures will be compared between the intervention and control groups to assess if there is any selection bias. Our primary analysis to measure the effect of the intervention will be on an intention-to-treat basis in which outcomes will be compared between the group of patients allocated to the control and the group allocated to the intervention irrespective of having any CHN visits. To measure the effect of the intervention against the unplanned readmission within 60 days of discharge from the index hospitalisation, we will do a time-to-event analysis. As a sensitivity analysis, we will do per-protocol analysis for the primary and secondary outcomes—comparing no intervention and intervention as per figure 2. We will use difference-in-difference method to measure the effect of the intervention against the secondary outcomes, patient-reported medication adherence, patient-reported health literacy, patient-reported quality of life and patient-reported assessment of chronic illness. A comparison of outcomes between intervention and control groups will use multivariate regression techniques that adjust for age, sex and any independent variables that are significantly different between the two groups, using multiple imputation for missing values. Baseline characteristics of those lost to follow-up will be analysed. Demographics of non-participants and reasons for dropout will be collected to assess bias.

Data will be managed according to the principles of the Australian Code for the Responsible Conduct of Research. A Research Data Management plan for the project has been established and will be reviewed regularly using the University of New South Wales (UNSW) platforms. All research data will be classified according to the UNSW Classification Standards and handled in accordance with UNSW data handling guidelines. Research data obtained will be stored on a UNSW-supported platform which is secured, managed and backed up centrally. Data will be archived using UNSW's Data Archive.

Qualitative study

The aim of the qualitative study is to explore the perceptions of project stakeholders (patients, health professionals and the CHNs themselves) about the role of CHNs in supporting patients to transition from the hospital to the community and to identify barriers and facilitators to the role.

Specifically, we aim to:

1. Understand how stakeholders view the help of the CHNs with the transition following hospital discharge
2. Determine what factors supported transition and if there were any challenges; and

3. Determine which aspects the CHNs considered supported their onboarding and facilitation into the role, as well as clarifying any challenges they faced when undertaking the role

Data will be generated via semistructured interviews conducted with:

- 16–20 intervention patients conducted by telephone. We will attempt to obtain a diverse sample (age, gender and ethnicity).
- 5–10 health professionals working within the planned care team. These interviews will be conducted using an online platform such as TEAMS.
- All three CHNs including any that leave the role. These interviews will be conducted individually or in small groups via an online platform such as TEAMS.

A sample of intervention patients will be approached 2–3 weeks after discharge from the CHN intervention. The interview will occur as soon as practical after this contact. The interview may include the patient's carer if requested. At the interview, the researcher will go through the information sheet and confirm verbal consent for the participants. A copy of the verbal consent form will be posted to the participant(s). The timeframe for contact has been chosen to aid the recall of the intervention by the patients. Research suggests that optimally, interviews should be done at a time when meaningful change is anticipated or as close as possible to the patient exiting the trial.[38]

The focus of the interviews will be on their experience of follow-up care by the CHN. Thus, control patients will not be interviewed as they have had no contact with the CHN.

All relevant health professionals from the planned care team (the team leader, CNCs, social workers, etc) who were involved in supervising or liaising with the CHNs will be approached to participate. Written consent will be gained once the information sheet has been provided and the person has had an opportunity to consider their participation.

We will approach all CHNs to participate in the qualitative study. A CHN information sheet will be provided, and written consent will be received prior to the collection of any data. CHNs will be asked to complete 'reflections' every month using a series of prompt questions. The CHN will be under no obligation to provide these data, and the content will not be disclosed to their supervisors. These aim to elicit routine issues and challenges and will be reviewed prior to finalising the interview questions. The consent form will cover the collection of reflective notes and interviews.

Data collection and analysis

Separate semistructured interview guides will be employed for patients/carers, healthcare providers and CHNs. A trained researcher will pilot the instruments and conduct the interviews. All interviews will be audio recorded and professionally transcribed. All participant information will be deidentified, and only group data will be reported. Reflexive thematic analysis described by Braun and Clarke[39 40] will be used. Preliminary data analysis will generate initial themes and issues of interest, and this will guide additional analysis of the material. Data management and analysis will be undertaken using NVivo 12 qualitative analysis software.

Safety monitoring and trial management

The trial will be overseen and governed by a management committee comprising the principal investigators (PIs), clinicians, academics, policymakers, study team members and planned care team representatives. This committee is responsible for directing processes, making trial modifications and communicating findings.

Although the intervention is considered to have minimal risks, any adverse events will be monitored by an independent safety and monitoring committee convened for this purpose and comprising independent members (a GP, a consumer and an SLHD representative). At designated times during the trial, the committee will convene with the Chief Investigator and the trial coordinator to discuss any adverse events that have been identified via the SLHD processes for reporting of incidents. The committee will determine if the incident is linked to the intervention and/or data collection procedures and provide advice about trial modifications or any other unforeseen events including whether the trial should be discontinued.

Patient and public involvement

Health Consumers NSW is a partner in the trial and contributed to the trial proposal and development. During phase one, three consumers participated in a codesign workshop used to develop the CHN role. Within phase two, consumers will be involved in the development of resources and also to provide feedback on the patient/carer interview guide. Consumers who participate in the trial will be interviewed to gain their 'lived experience' of the intervention. A consumer also sits on the ISMC.

Confidentiality and access to data

All patient information will be treated confidentially, and only the data custodians and the research team will have access to it. Deidentified data will be stored on the secure drives of the Centre for Primary Health Care and Equity (CPHCE) at the UNSW, Sydney, for 15 years after completion of the study. Identification codes will be stored separately in a password-protected file in CPHCE. Following publication, only the Principal Investigator and the head of departments will have access to all study material. Deidentified data will be available for analysis only on site at SLHD and CPHCE or by request directly to the Principal Investigator.

DISCUSSION

This trial will test a CHN intervention integrated within an existing health service that is designed to support the patient's transition from the hospital back to the

community. Through a robust randomised controlled design, we aim to determine if providing an intervention by a CHN for patients with long-term condition(s) and social and/or psychological vulnerability generates reductions in unplanned hospital readmission (60 days) and improves medication adherence, health literacy, quality of life, experience of healthcare and health service use (including the cost of care) compared with usual care.

The trial is underpinned by a multi-stakeholder partnership of health planners, hospital clinicians and discharge care providers, primary care providers and consumer groups who will guide the study process and evaluation. These stakeholders have joined with us in codesigning this study to evaluate the effectiveness and cost of CHN follow-up of patients after discharge as a key strategy in preventing rehospitalisation.

This trial will also help to identify facilitators and barriers to the implementation of the role in a real-world health setting. If found to be effective, the trial will have important implications for policy regarding the development of CHN roles in the Australian health system including codesigning of their training, accreditation, supervision and funding.

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Contributors SMP contributed to the project design including patient recruitment and data collection, drafting and revising of the manuscript for submission. PA contributed to the study design and conducted reviews of the drafts, including the final version of the manuscript. BH-R contributed to the conceptualisation of intervention and study during planning and codesign phases and contributed to the manuscript. MCW contributed to the study design and reviewing and commenting on drafts of the manuscript. MB contributed to the design of the study during planning phase, focusing on the sample size calculations and the data collection, and reviewing of drafts of the manuscript including the final draft. FD-N contributed to the design of the study during planning phase and reviewing drafts of the manuscript and the final draft. SJ contributed to the study design and reviewing and commenting on drafts of the manuscript. AS contributed to the conceptualisation of research design focusing on the feasibility in terms of economic evaluation and writing the economic evaluation methodology in the manuscript. RHO contributed to the study design and collection of data, reviewing of the manuscript and signing off of the final version. JC contributed to the design of the study particularly recruitment of subjects and the training and supervision of the CHWs and contributed to the earlier versions of the manuscript and signing off of the final version. EH was involved in the design and planning of study, input to drafts and review of final manuscript. FH contributed to the design of the study during planning phase and reviewing drafts of the manuscript and the final draft. MH led the design and planning of the study and was involved in drafting and reviewing of the protocol, reviewing of drafts and final version of the manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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