BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<u>http://bmjopen.bmj.com</u>).

If you have any questions on BMJ Open's open peer review process please email <u>editorial.bmjopen@bmj.com</u>

BMJ Open

Evaluating a novel Integrated Community of Care (ICoC) for patients from an urbanized low-income community in Singapore using the Participatory Action Research (PAR) methodology: A Study Protocol

Journal:	BMJ Open
Manuscript ID	bmjopen-2017-017839
Article Type:	Protocol
Date Submitted by the Author:	19-May-2017
Complete List of Authors:	Low, Lian Leng; Singapore General Hospital, Family Medicine and Continuing Care; Duke-NUS Medical School Maulod, Adlina; Duke-NUS Medical School Lee, Kheng Hock; Singapore General Hospital, Family Medicine and Continuing Care; Duke-NUS Medical School
Primary Subject Heading :	Health services research
Secondary Subject Heading:	General practice / Family practice, Geriatric medicine, Health policy, Qualitative research
Keywords:	Low-income community, Action Research, Integrated Care, Community- based care, Transitional care

SCHOLARONE[™] Manuscripts

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Title: Evaluating a novel Integrated Community of Care (ICoC) for patients from an urbanized low-income community in Singapore using the Participatory Action Research (PAR) methodology: A Study Protocol

Authors

Lian Leng Low^{1, 2}* (low.lian.leng@singhealth.com.sg)

Adlina Maulod³ (ad.maulod@duke-nus.edu.sg)

Kheng Hock Lee^{1, 2} (lee.kheng.hock@singhealth.com.sg)

Affiliations

¹ Department of Family Medicine & Continuing Care, Singapore General Hospital, Singapore

² Family Medicine, Duke-NUS Medical School, Singapore

³ Centre for Aging Research and Education, Duke-NUS Medical School, Singapore

* Corresponding authors

Dr Lian Leng Low, Academia Level 4, Department of Family Medicine & Continuing Care, 20 College

Road, Singapore 169856, Singapore General Hospital. Telephone +65-63265872, Email:

low.lian.leng@singhealth.com.sg

Word Count

5131 words

<u>Abstract</u>

 Objectives: Poorer health outcomes and disproportionate healthcare utilization in socioeconomically disadvantaged patients is well established. However there is sparse literature on effective integrated care interventions that specifically target these high-risk individuals. The Integrated Community of Care (ICoC) is a novel care model that integrates hospital-based transitional care with health and social care in the community for high-risk individuals living in socially deprived communities. This study aims to evaluate the effectiveness of the ICoC in improving acute hospital utilization and investigate the implementation process and its effects on clinical outcomes using a mixed-methods participatory action research (PAR) approach.

Methods and Analysis: This is a single-centre prospective, controlled, observational study performed in the SingHealth Regional Health System. A total of 250 eligible patients from an urbanized low-income community in Singapore will be enrolled during their index hospitalization. Our PAR model combines two research components: quantitative and qualitative, at different phases of the intervention. Outcomes of acute hospital utilization and health related quality of life are compared to controls, at 30 days and one year. The qualitative study aims at developing a more context-specific social ecological model of health behaviour. This model will identify how influences within one's social environment: individual, interpersonal, organizational, community and policy factors affect people's experiences and behaviors during care transitions from hospital to home. Knowledge on the operational aspects of ICoC will enrich our evidence-based strategies to understand the impact of the ICoC. The blending of qualitative and quantitative mixed methods recognizes the dynamic implementation processes as well as the complex and evolving needs of community stakeholders in shaping outcomes.

Ethics and Dissemination: Ethics approval was granted by the SingHealth Centralized Institutional Review Board (CIRB 2015/2277). The findings from this study will be disseminated by publications in peer-reviewed journals, scientific meetings, and presentations to government policy makers.

Trial registration number: NCT02678273

Key words: Low-income community; action research; integrated care; community-based care; transitional care

Article Summary

Strengths and Limitations of study

- 1. The Integrated Community of Care (ICoC) is a novel care model that integrates hospitalbased transitional care with health and social care in the community for high-risk individuals living in socially deprived communities.
- Study utilized a mixed method participatory action research (PAR) methodology to evaluate the effectiveness of a complex intervention program for a high-risk urbanized low-income community.
- 3. A randomized controlled trial design is not possible for this study.

Background

Elderly⁽¹⁾, socioeconomically disadvantaged and socially isolated patients such as those residing in public rental housing are at highest risk of ill health. Low socioeconomic status (SES) is well recognized as an independent risk factor for various adverse health outcomes, such as readmission

BMJ Open

risk ⁽²⁻⁴⁾ and hospital utilization⁽⁵⁾. In Singapore, public rental housing is an area-level measure of SES and is independently associated with increased readmission risk and being a frequent hospital admitter and emergency department (ED) user.⁽⁶⁾ The reasons behind these poor outcomes include poor knowledge of personal health status, inappropriate health behaviors ⁽⁷⁾, inability to navigate the complicated healthcare system ^(3, 8), lower health literacy and misalignment between patient and care team with regard to goals of care ⁽⁹⁾. These factors for poor outcome are common among residents of rental flats in Singapore. In addition, such residents are more likely to have comorbidities, poor social support, more likely to suffer from mental health conditions and more likely to be on anti-depressant treatment ^(6, 10). The confluences of these factors in a sub-population of patients who tend to live together in socially deprived communities create challenges as well as opportunities to improve the health of the population.

While there is abundant literature highlighting the poorer health outcomes and disproportionate healthcare utilization in socioeconomically disadvantaged patients, there is sparse literature on integrated care interventions that specifically target these high-risk individuals. Englander et al (11) described the implementation of a nurse and pharmacist-led multicomponent transitional care program which included coaching and education; home visits for highest risk patients; provision of 30 days of medications for low-income adults who were uninsured or on public insurance. However, the intervention did not reduce 30-day readmission rates or emergency department re-attendances. The authors concluded that the diverse needs of this population were too overwhelming for a nurse and pharmacist-based intervention. In Singapore, community-based initiatives led by social work professionals and para-professionals have been described ⁽¹²⁾. However, the program faced similar problems and was hampered by the lack of a multi-disciplinary healthcare team to address complex health and social needs across different settings of care. Three reviews on effectiveness of transitional care trials by Hansen ⁽¹³⁾, Kansagara ⁽¹⁴⁾, and Kriplani ⁽¹⁵⁾ independently concluded that transitional care interventions must be comprehensive, going beyond single component intervention. Integrating medical and social care across settings that span the different phases of care from hospitalization, discharge planning to post-discharge surveillance. The programs also need the flexibility to respond to individual needs.

In Singapore, it is estimated that 900,000 citizens living in the city state will be 65 years or older by 2030 and at least 50,000 (5.3%) would be staying in rental housing.⁽¹⁶⁾ A shift from a hospital centric model of care to a community centric model of care is widely accepted as a strategy that will enable us to provide sustainable and cost-effective care for our rapidly aging population. In response to this need, many new models of care were developed and tested for effectiveness. The Integrated Community of Care (ICOC) is a novel model of integrated care developed by the Singapore General Hospital that was designed to bring together best practices in transitional care ⁽¹⁷⁻²⁰⁾. This care model provides multidisciplinary transitional care, which fully integrates health, and social care across the full cycle of care for high-risk individuals living in socially deprived communities.

The aim of this evaluation is to answer the following questions while providing feedback to key decision makers over the 2 years of the project: (1) What is the overall effectiveness of the ICoC program in improving acute hospital utilization? (2) What are the different components of the ICoC programme: their structure, their stakeholders (targeted patients and practitioners), their operating process and their effects on clinical outcomes? (3) What are the strengths and aspects to improve of each programme from the perspective of the concerned stakeholders in view of a better services integration? (4) What characteristics of the patients and the ICoC programme contribute to positive impacts on use of services, quality of life, patient activation and patient experience with care?

Methods/Design

Study Site

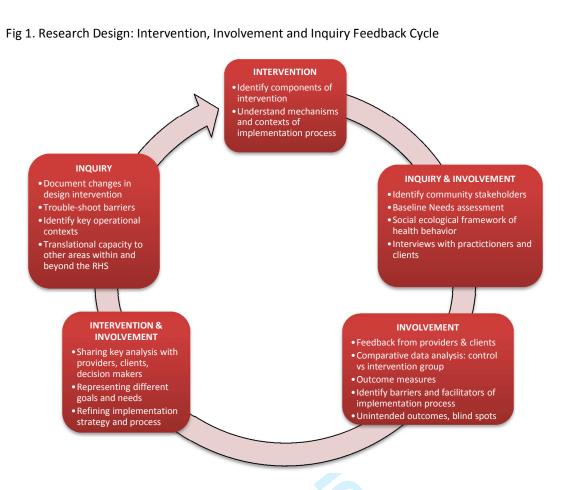
Adopting a population health approach, the Ministry of Health Singapore has been advocating for the transformation of our health care system from a hospital centric to a community centric. In 2011, public healthcare delivery was re-organized into regional health systems (RHS). The aim of which was to organize regional health assets into an integrated structure that will promote care integration of care across the care continuum. There is to be vertical and horizontal integration of healthcare institutions. In addition, the regional health systems will work to integrate health and social care by working closely with social care agencies within each region. Six RHSs were created, each being responsible to integrate care for a specific geographic region in Singapore. Each RHS is anchored by a tertiary hospital, supported by a community hospital providing intermediate and rehabilitation care and complete with linkages to primary care and long term care services in the region. In 2014, the Singapore Health Services (SingHealth) RHS was officially launched and consisted of primary to tertiary care institutions that account for the care of nearly a million residents in Singapore.

Conceptual Framework for Evaluation

The strategy of using multidisciplinary case management that we have adopted for our model of care have been widely used in many care integration programs aimed at reducing health care utilization and improve quality of care for frail older adults with multimorbidities .⁽²¹⁾ The evaluation of this model of care is challenging because it contains multiple components. For example, the medical, social and personal care components may act both independently of each other and interdependently in affecting the outcome of patient care. The assessment of individual components of intervention becomes complicated.⁽²²⁾ This creates a need for a novel adaptation of the mixed method strategy of evaluation. In addition to quantitative studies of outcome, our multidisciplinary research team will also use participatory action research (PAR) as part of the overall evaluation of the effectiveness of the ICOC program. PAR has been defined as "systematic inquiry, with the participation of those affected by the problem being studied, for the purposes of education and action or effecting social change".⁽²³⁾

In Singapore, the recent and rapid transformation of health services delivery for the aging population had created unprecedented shifts in the power relationship between users, policy makers and service providers in the healthcare system. In such circumstances the use of PAR is preferable as a research method because it is driven not only by the learning objectives of investigators but also by the circumstances and contexts of the community involved. Sandberg et al notes that in complex cases, intervention may affect important factors that were not planned for and not measured by quantitative methods. Rather, these factors could be better accounted for through qualitative methods.⁽²²⁾ In this regard, PAR is intended to be both highly localized and comparative. Investigation of the programme structure, its operating processes and stakeholders' experiences can be captured through qualitative methods while the comparative assessment of health outcomes between the intervention and control group will be valuably complemented through quantitative research methods.

The combination of both quantitative and qualitative methods of research will facilitate a more comprehensive assessment of the ICoC, particularly to understand the multiple outcomes of the program in terms of what works, for what and for whom. The PAR includes a learning component, which will synergize the 3 "Is" of <u>Intervention</u> (Action), <u>Involvement</u> (Participation in the Community) and <u>Inquiry</u> (Research) into a feedback cycle. The 3 Is mutually augment each other to contribute to the social transformation of integrated elderly care. The approach requires the co-partnership of stakeholders, implementation teams and research units to collect data, reflect upon findings of outcomes and refine the intervention process further to develop and achieve better delivery and results of ICoC.



Research Design

The ICoC study is a single-centre prospective, controlled, observational study performed in the SingHealth Regional Health System. (24, 25) Participatory action research with community-dwelling socially-at-risk elderly Singaporeans has the potential to explore some of the complex health and social problems that poor and socially-isolated elderly face, while also contributing to individual and community capacity building. Additionally, PAR has been found to be an appropriate process for evaluating patient-centred models of care. Nolan & Hazelton (1996) found similarities in nursing processes with PAR, particularly through the steps of assessment, planning, implementation, evaluation and replanning⁽²⁶⁾. PAR has also been engaged successfully to facilitate improvements in healthcare services (Hart and Bond, 1995)⁽²⁷⁾. The mixed-methods PAR approach to the ICoC model is significant to health systems research because it attempts to triangulate both medical practitioners' and elderly patients' perspectives of intervention delivery. In this regard, our evaluation method is designed to be sensitive to outcomes beyond only the intended hypothesis. Additionally, while evaluation studies utilizes quantitative data to measure intervention outcomes, a qualitative approach may address issues with regards to using a single metric of examining hospital admissions, which have been found to be less suitable for complex and vulnerable patients where many other factors contribute to the need for hospitalization.⁽²⁸⁾

Study Aims and Hypotheses

Our participatory action research (PAR) model combines two research components, quantitative and qualitative, at different phases of the intervention. The primary <u>objective</u> of the <u>quantitative</u> study is

to evaluate the effectiveness of the ICoC program in achieving a significant reduction in the proportion of patients in the intervention group with unscheduled hospital readmissions within 30 days of the index discharge date relative to controls. The secondary aims of this study are to evaluate the effectiveness of the ICoC program in achieving (i) a lower proportion of patients in the intervention group with three or more unscheduled hospital readmissions within one year of index discharge; (ii) a lower emergency department attendance rate in the intervention group at 30 days, and one year from index discharge; (iii) a lower specialist outpatient clinic attendance rate in the intervention group at 30 days, and one year from index discharge; (iv) Improving health related quality of life in the intervention group relative to baseline as measured by the EQ-5D at 30 days, and one year compared to the control group.

For the quantitative study, we hypothesize that the ICoC program will significantly reduce the proportion of patients who had an unscheduled readmission within 30 days of index discharge, compared to the control group. The secondary hypotheses are that the ICoC program can significantly reduce hospital readmissions at one year; emergency department and specialist outpatient clinic attendance rate at 30 days, and one year compared to the control group; and health related quality of life at 30 days, and one year compared to baseline.

The qualitative study aims at developing a more context-specific social ecological model of health behavior.⁽²⁹⁾ We propose a social ecological framework of health behavior in the manner below:

- a. Care recipients' and caregivers' conditions and experiences (individual level)
- b. Interactions between elderly patient, caregivers and healthcare providers (interpersonal level)
- c. Elderly's and caregivers' access to experiences with service use and health care delivery (institutional/ organizational level)
- d. Elderly patients' connections with and support from the community (community level)
- e. How public initiatives and access to other healthcare programmes affect the experience of transitional care post-discharge (policy level)

This model helps to identify how influences within one's social environment: individual, interpersonal, organizational, community and policy factors affect people's experiences and behaviors during care transitions from hospital to home. The knowledge of how this model operates on the ground will enrich our evidence-based strategies to understand the impact of the ICoC. The blending of qualitative and quantitative mixed methods recognizes the dynamic implementation processes as well as the complex and evolving needs of community stakeholders in shaping outcomes. The PAR operates on a feedback loop that is sensitive to changes experienced by practitioners and patients in real-time. In this project, both the implementation and research team work in tandem to evaluate and improve the intervention on-the-go.

Inclusion and Exclusion Criteria

Patients are eligible if they:

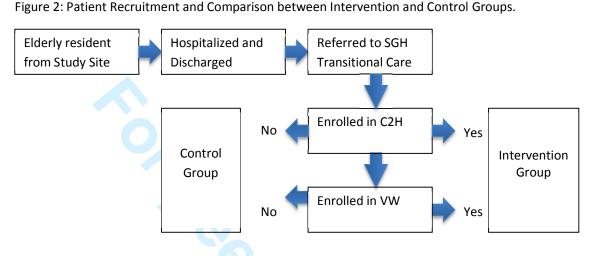
1) Age \geq 60 years at time of recruitment

2) Staying in public rental housing in Blocks 51, 52 Chin Swee or Block 5 Banda Street in Singapore

We will exclude patients who decline our program or dementia patients who are incapable of independent living and do not have a caregiver. Patients who have mild dementia and are capable of independent living or have a caregiver are suitable to be enrolled into the ICoC program, which will support care in the community. Patients in the intervention group will be recruited during their first admission (thereby known as the index admission) upon study commencement. Based on the

BMJ Open

electronic medical records, close to 180 unique patients were admitted to SGH in 2014. Assuming a low 5% rejection and exclusion rate (confirmed by our feasibility study), the recruitment period is estimated to be take 1.5 years. Recruitment will close when the sample size of 250 is reached. Control patients will be identified retrospectively at the end of the study period and data extracted from the SGH patient database using the index admission as the start date.



For the qualitative component, the research team will purposively extract a sample size of 40 elderly patients/ clients based on the sample of 300 elderly residents who are enrolled in C2H intervention programme and who are also under the supervision of the VW. The elderly patients/ clients are recruited into the study through referrals from medical and care team, where we hope to get a representative sample in terms of gender, age, ethnicity, health and physical status and living arrangements. The research team will also be interviewing 10 community practitioners who are providing care in the study site.

The ICoC intervention program (Figure 3)

1. SGH Transitional Care (TC) team for care transitions of hospitalized residents

The SGH TC team (comprising a senior family physician and a medical officer) is a dedicated service that will provide inpatient care or co-management with specialists for all enrolled patients, with emphasis on comprehensive discharge planning, formulation of a care plan post-discharge and proper hand-over care to the community virtual ward and C2H teams. This intervention incorporates the best principles in transitional care that includes both pre-discharge and post-discharge components (27-29). The hand-over care will be executed via a daily half-hour video conferencing meeting between the three teams.

2. Community Virtual Ward (VW) for coordinating community care and home-based primary care

The community-based VW team comprises of a staff nurse and resident physician seconded by SGH to provide continuing community care, home-based primary and nursing care to enrolled patients. This intervention is supported by strong evidence for home-based primary care and continuing care for frail elders (24, 25). The team's responsibilities include: (i) comprehensive geriatric assessment; (ii) continuing care and at least weekly surveillance of discharged patients for up to one month post-discharge; (iii) monitoring at risk patients for compliance to the prescribed care plans and medications; (iv) health promotion and education to enrolled patients; (v) developing patient-specific action plans for patients with high risk diseases such as heart failure and diabetes and (vi)

coordinating and integrating the primary, transitional and social care for enrolled patients; and (vii) hand-over care to community service providers for long term follow up upon stabilization of patients and according to clinical protocol. The community VW team is physically located in the community.

3. Care Closer to Home (C2H) team for social case management and home help

Since October 2014, the C2H is a program by the Agency for Integrated Care comprising a case manager, a social work assistant and five nursing aides to put in place health, personal and social services, e.g. medication management, home help services to assist with basic activities of daily living e.g. showering to help seniors to age in place. To date, the program has enrolled close to 300 residents. AIC closely supports and provides professional guidance for the C2H program.

All three components of the ICoC program will be provided to enrolled patients. To ensure this, we have harmonized our inclusion and exclusion criteria for entry into all three components.

Figure 3: Conceptual Model of Care for the ICoC Program



Integrated Community of Care

Control group participants

 The control group of approximately 1100 participants will receive current hospital standard of care when they are hospitalized. Patients will be managed by their specialists in charge depending on their admitting diagnoses. Patients may be referred to the SGH THC program and/or various community services on discharge if deemed necessary by their specialists. Continuing care post-discharge may be provided at the specialist outpatient clinics or a primary care provider identified by the hospital specialist. The community VW and C2H teams would not be available for control group patients.

Data Collection strategies to Measure Outcomes

Basic Characteristics

Intervention Group: The research team will take informed consent from the intervention group participants and interview them for demographic, socioeconomic status, medical comorbidities and

health-related quality of life (EQ-5D). This information will be verified with SingHealth's Electronic Health Intelligence System (eHIntS) system, which is a data warehouse capturing detailed demographic, socioeconomic and clinical data.

Control Group: Control group patients will be retrieved from the eHIntS system. A waiver of patient consent will be sought from the centralized institutional review board for extraction of de-identified routinely collected information. Similar demographic, socioeconomic status and medical comorbidities data (predictors used for propensity scores calculation listed in Annex 1) will be collected for both groups to allow calculation of propensity scores as a basis for comparability. We have shown in our previous study (22) that these data can be extracted from our data warehouse for inclusion in a propensity score model.

Outcome Measures at 30 days and one-year

The research team and the ICoC team will follow up with study participants for the primary and secondary outcomes at 30 days, and one year (Table 1). An unscheduled readmission is defined as a readmission for a non-elective indication. Unscheduled readmission at 30 days (short-term outcome) is a universally accepted indicator of transitional care quality and one year outcomes (long-term outcome) is chosen to reflect the quality of community and continuing care. The research team will conduct a face-to-face survey interview at 30 days and one year to repeat the EQ-5D scales. Healthcare utilization data of intervention and control group participants will be extracted from SingHealth's eHIntS system and merged with Ministry of Health (MOH)'s Omnibus data resource. This will ensure complete and accurate healthcare utilization outcomes and overcome the issue of cross utilization.

A checklist will be developed to measure fidelity to components of ICoC program and ensure standardization of intervention. The nature (routine/emergency) and number of home visits e.g. doctor/nurse/C2H will be retrieved from the clinical documentation notes.

Variable	Method of Collection	Baseline	Follow-up (30 days)	Follow-up (One year)
Demographic, Socio-economic	Questionnaire,			
status, Health information and prior	EQ-5D, eHIntS			
healthcare utilization, Abbreviated		х		
Mental Test, Modified Barthel Index,		^		
Instrumental activities of daily living,				
health related quality of life				
Primary Outcome Measure –	eHIntS,			
Unscheduled hospital readmission	Omnibus		Х	A
within 30 days of index discharge				
Secondary Outcome Measures –	EQ-5D, eHIntS,			
Unscheduled hospital readmissions	Omnibus			
at one year; Emergency department				
attendances, specialist outpatient			Х	Х
clinic attendances and health				
related quality of life at 30 days and				
one year				

Table 1: Data collection sources at Baseline, 30 days and One Year outcomes for participants

Sample Size calculation

The primary aim is to evaluate the effectiveness of the ICoC program in achieving a significant reduction in the proportion of patients in the intervention group with unscheduled hospital readmissions within 30 days of the index discharge date relative to controls. Data from a previous study shows a historical 30-day re-admit rate of 17.5% for patients in the three proposed Intervention HDB blocks and 16.8% in the Control blocks. The prospectively recruited sample size for the Intervention will be n1 = 250 and, based on 2014 data, we anticipate about n2 = 1100 patients in the Control group. The figure shows the proposed sample sizes will provide \geq 80% power using a two-sided Fisher's exact test (α =0.05) to detect the following range of differences (unadjusted) in 30-day re-admit rates between Control (P2) vs. Intervention (P1): 18.0 vs. 10.7, 17.0 vs. 9.9, 16.0 vs. 9.1, 15.0 vs. 8.3, 14.0 vs. 7.5 and 13.0 vs. 6.7. Targeted reductions in Intervention group readmission rates range from 40.5–48.5% and would certainly be considered clinically meaningful. In our virtual ward study, we achieved 33% reduction in 30-day readmission rates and it is likely this can be improved with additional home visits and social care case management. Control and Intervention 30-day re-admission rates will also be compared using logistic regression using propensity scores to adjust for effects of confounders.

Qualitative Data Collection Design and Strategies

The qualitative research component of the PAR will be conducted in three phases.

Phase 1: Intervention & Involvement

1a. Understanding mechanisms and contexts of intervention (Practitioners and Patients)

The research team will engage in 'go-along' interviews to understand the complexities around integrated care in a low-income rental neighbourhood. The "go-along" combines both participant observation and interview methods and will be conducted with VW nurses and the C2H team (n=10) as they go about their daily care-rounds around the study site. Data collected will provide information in terms of patient/clients' receptivity to medical intervention, relationship between practitioners and their elderly patients/clients. The objective of go-along interviews is to capture the practitioners' perspective of the barriers and facilitators in the implementation of ICoC to their patients/ clients. Research team will document processes in which medical practitioners understand, implement and apply appropriate practices of care to the elderly residents in low-income rental dwelling. For triangulation, the research team will conduct content analysis of practitioners' case summaries over the period of intervention to trace the chronology and outcome of individualized interventions.

1b. Elderly Residents' Qualitative Needs Assessment based on Case Summaries and Complementary Quantitative Study

Based on case summaries by community practitioners, research team will work with implementation team to identify and categorically group elderly residents based on complexity of case and specific health conditions. Medical team and nurses will refer 40 cases/ elderly residents to the research team for Phase 2b of in-depth semi-structured/ informal interviews. Elderly residents will be grouped according to similarities in terms of case complexity (1st strata) followed by whether they show improvements in health behavior or not.

Phase 2: Action Learning through Involvement and Inquiry

2a. Interpreting, explaining, translating and refining identified problems, priorities and strengths in concert with key community members- clinicians, nurses, resident leaders and elderly residents (n=10). Through focus group discussions, the aim of this phase is to: 1) to understand how

 practitioners define care and how their vision of care is being expressed through their practices and 2) to obtain a profile of "complex" cases and how practitioners manage these issues.

2b. ICoC User Experience (n=40 based on referral in Phase 1b)

Research team will establish rapport with elderly residents in intervention group and conduct indepth interviews to explore the experiences and attitudes of older people who are in the intervention group (VW and C2H). Objective is to gain an understanding of the strengths and weaknesses of community care from the perspective of recipients in the study site.

Upon approval from the IRB, participants are invited to participate in research study through case referrals by nurses and community health partners. Upon receiving referrals, research team will administer Montreal Cognitive Assessment – Singapore (MoCA - Singapore) screener to determine participants' eligibility and whether elderly respondents are cognitively impaired and if they would require a professional or lay proxy (if applicable) to respond to questions on their behalf. Research team will obtain consent from the elderly respondent/ their proxy and inform them that participation in the study is voluntary and care services will not be withdrawn should they decide to not participate or withdraw from the study. After obtaining consent, interviews will largely follow a life history format, where research team will ask about their personal histories to get to know them better and to gain rapport. When comfort is established through repeated interactions (following nurses around and being a familiar face), the research team will begin asking about the recipient's feedback on care services (refer to interview guide). Sessions will be about max. 30 mins each time so as to not tax the elderly resident and will continue until all questions in the guide have been completed.

Phase 3. Inquiry and Intervention

Data analysis and findings from phase 1 and 2 will provide feedback on the delivery of the intervention. These findings will be analyzed together with the post-30 days and post 1 year quantitative outcome measures to identify which mechanisms of the intervention has been successful and which ones require improvements. Additionally, the objective of Phase 3 is to also highlight unintended outcomes of the intervention that clients and practitioners consider as beneficial to their experiences. The team will further analyze implications of findings and translational capacity to other low-income rental community-dwelling areas in Singapore.

Statistical Analysis

Quantitative Data Analysis



The secondary aim 1 analysis will use Fisher's exact test and logistic regression and compare groups on proportions of patients with three or more unscheduled hospital readmissions within one year of index discharge. Secondary aims 2 and 3 will involve Poisson regression analysis on numbers of visits per three-month and one-year intervals, and aim 4 will involve standard analysis of variance methods to compare quality of life scores. All analyses will incorporate propensity score adjustment. All analyses will be performed using SAS V9.4 software (SAS© Cary, NC, USA).

All in-depth interviews with key personnel and focus group discussions will be audiotaped and transcribed and uploaded onto qualitative software database nVivo 11. While 'go-along' interviews with nurses and case workers and interviews with more cognitively-impaired elderly recipients will not be audio-recorded due to the long duration of such sessions and difficulty in capturing speech respectively. Written notes will be used instead to record such observations and conversations and will be type- written once fieldwork for the day is over. Typed written notes will be uploaded onto

nVivo 11. The research team will use nVivo to code responses for emergent themes regarding practitioner and client/patient (provider-user) experience of the ICoC programme.

Ethics and Dissemination

Informed consent for participation in the ICoC intervention programme will be taken from each enrolled patient. Informed consent to participate in the research study will be taken another time for patients/ clients who have been referred to research team and also practitioners who will be interviewed and/or participating in focus group discussions. SingHealth Centralized Institutional Review Board (CIRB 2015/2277) approved this study.

Findings will be disseminated by publications in peer-reviewed journals, scientific meetings, and presentations to policy makers and practice partners.

Status of the study

The ICoC program is expected to last 2 years, from July 2016 to June 2018.

Discussion

It is increasingly recognized that non-biological determinants of health such as social, environmental and individual behaviors impact significantly on health outcomes.^(30, 31) These non-biological determinants of health interact in a complex relationship a person's biological health determinants such as gender, age, inherited and acquired health conditions. Therefore, quality healthcare alone cannot achieve optimal outcomes in health. The ICoC program is the first step to achieving optimal health in a high-risk population by systematically addressing biological, social and individual risk factors for poor health. Components of the ICoC program will address social determinants of health such as social connectedness, loneliness; individual behaviors such patient activation, locus of control and environmental determinants such as access to health services and facilities. Policy changes and intervention (the ICoC program in this case) that can modify health seeking behavior and affect delivery of healthcare services may affect health determinants and health outcomes. Implementing a complex ICoC intervention program and understanding the complex interaction between determinants, policy and outcomes therefore require an innovative approach to evaluation such as the participatory action research (PAR) model.

The findings from ICoC program will directly inform policy makers on the feasibility of implementation and effectiveness of integrating traditional silos of practice on reducing acute hospital utilization. This has direct policy implications on the funding model and quantum to support such a program. In the short to medium term, the study will develop a novel model of integrated care that shifts care from a hospital centric system to an integrated community centric system for high-risk communities. In the long term, the study has policy implications on the feasibility and effectiveness of empanelment of high-risk communities to a community based integrated care team supported by the regional health system. The systematic inquiry, with the participation of those affected by the problem being studied, will enable the ICoC program and policy makers to understand the complex interaction between health determinants, intervention and health outcomes. This knowledge will facilitate design of better interventions of the ICoC program.

BMJ Open

However, our study has potential limitations. Firstly, a randomized controlled trial design would have been most rigorous for evaluation of the ICoC program. However, we had wanted to evaluate the effectiveness of the synergism achieved by all three components of the ICoC program. The restriction of the C2H program to the three intervention blocks precluded us from randomizing the rental housing blocks or patients for intervention. We will minimize bias in the statistical comparison of the intervention and control groups by using propensity scores to balance baseline covariates. Second, this study is limited to a single rental housing community, so generalizability to other rental housing communities would be unknown. If results from the ICOC program are promising, we intend for this model of care to be propagated to other rental housing communities throughout RHS and Singapore.

In summary, this is the first study to develop a novel integrated community of care that integrates hospital-based transitional care with health and social care in the community for high-risk individuals living in socially deprived communities. The IcoC program will be rigorously evaluated using a participatory action research methodology. The study findings will directly inform policy makers on the feasibility of implementation and effectiveness of integrating traditional silos of practice on reducing acute hospital utilization, and the funding model and quantum to support such a program.

Study status: At the point of manuscript submission, the enrollment of participants is ongoing.

Contributorship Statement: LLL, AM and LKH conceived and designed the study. LLL and AM wrote the first draft of the paper, and all authors critically revised the paper and gave final approval for publication.

Acknowledgements: We would like to acknowledge the SingHealth Regional Health System Office, staff from the Singapore General Hospital Office of Integrated Care and Associate Professor Angelique Chan from Duke-NUS Medical School Centre for Aging Research and Education for their support.

Funding Statement: This study is supported by the SingHealth Regional Health System and Duke-NUS Medical School Centre for Aging Research and Education. No additional grant funding was obtained.

Data Sharing statement: Details of ongoing data collection (indicators and outcomes) is available from the corresponding author at low.lian.leng@singhealth.com.sg

Competing interests: The authors declare that they do not have competing interests.

<u>References</u>

1. Lim E, Matthew N, Mok W, Chowdhury S, Lee D. Using hospital readmission rates to track the quality of care in public hospitals in Singapore. BMC health services research. 2011;11(Suppl 1):A16.

2. Krumholz HM, Bernheim SM. Considering the role of socioeconomic status in hospital outcomes measures. Annals of internal medicine. 2014;161(11):833-4.

3. Arbaje AI, Wolff JL, Yu Q, Powe NR, Anderson GF, Boult C. Postdischarge environmental and socioeconomic factors and the likelihood of early hospital readmission among community-dwelling Medicare beneficiaries. The Gerontologist. 2008;48(4):495-504.

4. Hu J, Gonsahn MD, Nerenz DR. Socioeconomic status and readmissions: evidence from an urban teaching hospital. Health affairs (Project Hope). 2014;33(5):778-85.

 5. Filc D, Davidovich N, Novack L, Balicer RD. Is socioeconomic status associated with utilization of health care services in a single-payer universal health care system? International journal for equity in health. 2014;13(1):115.

6. Low LL, Win W, Ng MJM, Tan SY, Liu N, Lee KH. Housing as a social determinant of health in Singapore and its association with readmission risk and increased utilization of hospital services. Frontiers in Public Health. 2016;4.

7. Kangovi S, Barg FK, Carter T, Long JA, Shannon R, Grande D. Understanding why patients of low socioeconomic status prefer hospitals over ambulatory care. Health affairs (Project Hope). 2013;32(7):1196-203.

8. Kangovi S, Levy K, Barg FK, Carter T, Long JA, Grande D. Perspectives of older adults of low socioeconomic status on the post-hospital transition. Journal of health care for the poor and underserved. 2014;25(2):746-56.

9. Kangovi S, Barg FK, Carter T, Levy K, Sellman J, Long JA, et al. Challenges faced by patients with low socioeconomic status during the post-hospital transition. Journal of general internal medicine. 2014;29(2):283-9.

10. Wee LE, Yong YZ, Chng MW, Chew SH, Cheng L, Chua QH, et al. Individual and area-level socioeconomic status and their association with depression amongst community-dwelling elderly in Singapore. Aging & mental health. 2014;18(5):628-41.

11. Englander H, Michaels L, Chan B, Kansagara D. The care transitions innovation (C-TraIn) for socioeconomically disadvantaged adults: results of a cluster randomized controlled trial. Journal of general internal medicine. 2014;29(11):1460-7.

12. Shum E, Lee CE. Population-based healthcare: the experience of a regional health system. Annals of the Academy of Medicine, Singapore. 2014;43(12):564-5.

13. Hansen LO, Young RS, Hinami K, Leung A, Williams MV. Interventions to reduce 30-day rehospitalization: a systematic review. Annals of internal medicine. 2011;155(8):520-8.

14. Kansagara D, Chiovaro JC, Kagen D, Jencks S, Rhyne K, O'Neil M, et al. So many options, where do we start? An overview of the care transitions literature. Journal of hospital medicine : an official publication of the Society of Hospital Medicine. 2016;11(3):221-30.

15. Kripalani S, Theobald CN, Anctil B, Vasilevskis EE. Reducing hospital readmission rates: current strategies and future directions. Annual review of medicine. 2014;65:471-85.

16. Singapore DoS. Population Trends 2015 2015 [updated 30 Sep 2015; cited 2015 8 Dec]. Available from: <u>http://www.singstat.gov.sg/publications/publications-and-papers/population-and-population-structure/population-trends</u>.

17. Naylor MD, Aiken LH, Kurtzman ET, Olds DM, Hirschman KB. The care span: The importance of transitional care in achieving health reform. Health affairs (Project Hope). 2011;30(4):746-54.

18. Low LL, Vasanwala FF, Ng LB, Chen C, Lee KH, Tan SY. Effectiveness of a transitional home care program in reducing acute hospital utilization: a quasi-experimental study. BMC health services research. 2015;15:100.

19. Lee KH, Low LL, Allen J, Barbier S, Ng LB, Ng MJM, et al. Transitional care for the highest risk patients: findings of a randomised control study. International journal of integrated care. 2015;15(4).

20. Low LL, Tan SY, Ng MJM, Tay WY, Ng LB, Balasubramaniam K, et al. Applying the Integrated Practice Unit Concept to a Modified Virtual Ward Model of Care for Patients at Highest Risk of Readmission: A Randomized Controlled Trial. PloS one. 2017;12(1):e0168757.

21. Althaus F, Paroz S, Hugli O, Ghali WA, Daeppen JB, Peytremann-Bridevaux I, et al. Effectiveness of interventions targeting frequent users of emergency departments: a systematic review. Annals of emergency medicine. 2011;58(1):41-52.e42.

22. Sandberg M, Jakobsson U, Midlov P, Kristensson J. Case management for frail older people - a qualitative study of receivers' and providers' experiences of a complex intervention. BMC health services research. 2014;14:14.

23. Blair T, Minkler M. Participatory action research with older adults: key principles in practice. The Gerontologist. 2009;49(5):651-62.

24. Low LL, Liu N, Wang S, Thumboo J, Ong ME, Lee KH. Predicting frequent hospital admission risk in Singapore: a retrospective cohort study to investigate the impact of comorbidities, acute illness burden and social determinants of health. BMJ open. 2016;6(10):e012705.

25. Low LL, Liu N, Wang S, Thumboo J, Ong MEH, Lee KH. Predicting 30-Day Readmissions in an Asian Population: Building a Predictive Model by Incorporating Markers of Hospitalization Severity. PloS one. 2016;11(12):e0167413.

26. Nolan A HL. The Practicing Nurse. Sydney: W.B. Saunders Bailliere Tindall, Sydney; 1996.

27. Hart E BM. Action Research for Health and Social Care: A Guide to Practice: Open University Press, Buckingham; 1995.

28. Roland M, Dusheiko M, Gravelle H, Parker S. Follow up of people aged 65 and over with a history of emergency admissions: analysis of routine admission data. BMJ (Clinical research ed). 2005;330(7486):289-92.

29. McLeroy KR, Bibeau D, Steckler A, Glanz K. An ecological perspective on health promotion programs. Health education quarterly. 1988;15(4):351-77.

30. Evans RG, Stoddart GL. Producing health, consuming health care. Social science & medicine (1982). 1990;31(12):1347-63.

31. Dahlgren G, Whitehead M. Policies and strategies to promote social equity in health. Stockholm: Institute for future studies. 1991.

STROBE Statement—Checklist of items that should be included in reports of cohort studies	?S
--	----

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract Page 1
		(b) Provide in the abstract an informative and balanced summary of what was done
		and what was found Page 2
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported Pages 2-3
Objectives	3	State specific objectives, including any prespecified hypotheses Page 3
Methods		
Study design	4	Present key elements of study design early in the paper Page 4 onwards
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection Page 4 onwards
Participants	6	(<i>a</i>) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Page 6
		(b) For matched studies, give matching criteria and number of exposed and unexposed Page 9
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable Page 8-9
Data sources/	8*	For each variable of interest, give sources of data and details of methods of
measurement		assessment (measurement). Describe comparability of assessment methods if there is more than one group Pages 9
Bias	9	Describe any efforts to address potential sources of bias Page 9
Study size	10	Explain how the study size was arrived at Page 10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why Page 11
Statistical methods	12	(<i>a</i>) Describe all statistical methods, including those used to control for confounding Page 11
		(b) Describe any methods used to examine subgroups and interactions Not applicable in our study.
		(c) Explain how missing data were addressed Not applicable in our study.
		(d) If applicable, explain how loss to follow-up was addressed We are able to
		retrieve utilization data from our electronic health record system.
		(<u>e</u>) Describe any sensitivity analyses Not applicable in our study.
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed No results are available yet.
		(b) Give reasons for non-participation at each stage No results are available yet.
		(c) Consider use of a flow diagram No results are available yet.
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders No results are available yet.
		(b) Indicate number of participants with missing data for each variable of interest Nor results are available yet.
		(c) Summarise follow-up time (eg, average and total amount) No results are availabl yet.

BMJ Open

Outcome data	15*	Report numbers of outcome events or summary measures over time No results are available yet.
Main results	16	(<i>a</i>) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were
		adjusted for and why they were included No results are available yet.
		(b) Report category boundaries when continuous variables were categorized No results are available yet.
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period. No results are quickly used.
Other analyses	17	meaningful time period No results are available yet. Report other analyses done—eg analyses of subgroups and interactions, and
Other analyses	17	sensitivity analyses No results are available yet.
Discussion		
Key results	18	Summarise key results with reference to study objectives No results are available yet.
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or
		imprecision. Discuss both direction and magnitude of any potential bias Page 12-13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,
		multiplicity of analyses, results from similar studies, and other relevant evidence
		Pages 12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results Page 12-13
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if
		applicable, for the original study on which the present article is based Page 14

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

BMJ Open

Evaluating a novel Integrated Community of Care (ICoC) for patients from an urbanized low-income community in Singapore using the Participatory Action Research (PAR) methodology: A Study Protocol

Journal:	BMJ Open
Manuscript ID	bmjopen-2017-017839.R1
Article Type:	Protocol
Date Submitted by the Author:	10-Jul-2017
Complete List of Authors:	Low, Lian Leng; Singapore General Hospital, Family Medicine and Continuing Care; Duke-NUS Medical School Maulod, Adlina; Duke-NUS Medical School Lee, Kheng Hock; Singapore General Hospital, Family Medicine and Continuing Care; Duke-NUS Medical School
Primary Subject Heading :	Health services research
Secondary Subject Heading:	General practice / Family practice, Geriatric medicine, Health policy, Qualitative research
Keywords:	Integrated Care, Community-based care, Transitional care, Low-income elderly community, participatory action research

SCHOLARONE[™] Manuscripts

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Title: Evaluating a novel Integrated Community of Care (ICoC) for patients from an urbanized low-income community in Singapore using the Participatory Action Research (PAR) methodology: A Study Protocol

Authors

Lian Leng Low^{1, 2}* (low.lian.leng@singhealth.com.sg)

Adlina Maulod³ (ad.maulod@duke-nus.edu.sg)

Kheng Hock Lee^{1, 2} (lee.kheng.hock@singhealth.com.sg)

Affiliations

¹ Department of Family Medicine & Continuing Care, Singapore General Hospital, Singapore

² Family Medicine, Duke-NUS Medical School, Singapore

³ Centre for Aging Research and Education, Duke-NUS Medical School, Singapore

* Corresponding authors

Dr Lian Leng Low, Academia Level 4, Department of Family Medicine & Continuing Care, 20 College

Road, Singapore 169856, Singapore General Hospital. Telephone +65-63265872, Email:

low.lian.leng@singhealth.com.sg

Word Count

5131 words

<u>Abstract</u>

 Introduction: Poorer health outcomes and disproportionate healthcare utilization in socioeconomically disadvantaged patients is well established. However there is sparse literature on effective integrated care interventions that specifically target these high-risk individuals. The Integrated Community of Care (ICoC) is a novel care model that integrates hospital-based transitional care with health and social care in the community for high-risk individuals living in socially deprived communities. This study aims to evaluate the effectiveness of the ICoC in improving acute hospital utilization and investigate the implementation process and its effects on clinical outcomes using a mixed-methods participatory action research (PAR) approach.

Methods and Analysis: This is a single-centre prospective, controlled, observational study performed in the SingHealth Regional Health System. A total of 250 eligible patients from an urbanized low-income community in Singapore will be enrolled during their index hospitalization. Our PAR model combines two research components: quantitative and qualitative, at different phases of the intervention. Outcomes of acute hospital utilization and health related quality of life are compared to controls, at 30 days and one year. The qualitative study aims at developing a more context-specific social ecological model of health behaviour. This model will identify how influences within one's social environment: individual, interpersonal, organizational, community and policy factors affect people's experiences and behaviors during care transitions from hospital to home. Knowledge on the operational aspects of ICoC will enrich our evidence-based strategies to understand the impact of the ICoC. The blending of qualitative and quantitative mixed methods recognizes the dynamic implementation processes as well as the complex and evolving needs of community stakeholders in shaping outcomes.

Ethics and Dissemination: Ethics approval was granted by the SingHealth Centralized Institutional Review Board (CIRB 2015/2277). The findings from this study will be disseminated by publications in peer-reviewed journals, scientific meetings, and presentations to government policy makers.

Trial registration number: NCT02678273

Key words: Low-income elderly community; participatory action research; integrated care; community-based care; transitional care

Article Summary

Strengths and Limitations of study

- 1. The Integrated Community of Care (ICoC) is a novel care model that integrates hospitalbased transitional care with health and social care in the community for high-risk individuals living in socially deprived communities.
- Study utilized a mixed method participatory action research (PAR) methodology to evaluate the effectiveness of a complex intervention program for a high-risk urbanized low-income community.
- 3. A randomized controlled trial design is not possible for this study.

Introduction

Elderly, socioeconomically disadvantaged and socially isolated patients such as those residing in public rental housing are at highest risk of ill health. Low socioeconomic status (SES) is well recognized as an independent risk factor for various adverse health outcomes, such as readmission

 risk ⁽¹⁻³⁾ and hospital utilization⁽⁴⁾. In Singapore, public rental housing is an area-level measure of SES and is independently associated with increased readmission risk and being a frequent hospital admitter and emergency department (ED) user.⁽⁵⁾ The reasons behind these poor outcomes include poor knowledge of personal health status, inappropriate health behaviors ⁽⁶⁾, inability to navigate the complicated healthcare system ^(2, 7), lower health literacy and misalignment between patient and care team with regard to goals of care ⁽⁸⁾. These factors are common among residents of rental flats in Singapore. To qualify for heavily subsidized rental housing from the government, the gross household income must be very low at 1,500 Singapore dollars per month. The median household income in Singapore is 8,290 Singapore dollars per month ⁽⁵⁾. In addition, such residents are more likely to have comorbidities, poor social support, more likely to suffer from mental health conditions and more likely to be on anti-depressant treatment ^(5, 9). The confluences of these factors in a subpopulation of patients who tend to live together in socially deprived communities create challenges as well as opportunities to improve the health of the population.

While there is abundant literature highlighting the poorer health outcomes and disproportionate healthcare utilization in socioeconomically disadvantaged patients, there is sparse literature on integrated care interventions that specifically target these high-risk individuals. Englander et al. (10) described the Care Transitions Intervention (C-TraIn) program, a nurse and pharmacist-led multicomponent transitional care program conducted at an urban academic medical centre in Portland, Oregon. The C-TraIn program included coaching and education; home visits for highest risk patients; provision of 30 days of medications for low-income adults who were uninsured or on public insurance. However, the intervention did not reduce 30-day readmission rates or emergency department re-attendances. The authors concluded that the diverse needs of this population were too overwhelming for a nurse and pharmacist-based intervention. In Singapore, community-based initiatives led by social work professionals and para-professionals have been described ⁽¹¹⁾. However, the program faced similar problems and was hampered by the lack of a multi-disciplinary healthcare team to address complex health and social needs across different settings of care. Three reviews on effectiveness of transitional care trials by Hansen⁽¹²⁾, Kansagara⁽¹³⁾, and Kriplani⁽¹⁴⁾ independently concluded that transitional care interventions must be comprehensive, going beyond single component intervention. Integrating medical and social care across settings that span the different phases of care from hospitalization, discharge planning to post-discharge surveillance. The programs also need the flexibility to respond to individual needs.

In Singapore, it is estimated that 900,000 citizens living in the city state will be 65 years or older by 2030 and at least 50,000 (5.3%) would be staying in rental housing.⁽¹⁵⁾ A shift from a hospital centric model of care to a community centric model of care is widely accepted as a strategy that will enable us to provide sustainable and cost-effective care for our rapidly aging population. In response to this need, many new models of care were developed and tested for effectiveness. The Integrated Community of Care (ICOC) is a novel model developed by the Singapore General Hospital that was designed to bring together best practices in transitional care ⁽¹⁶⁻¹⁹⁾. This care model provides multidisciplinary transitional care, which fully integrates health and social care for high-risk individuals living in socially deprived communities. The ICoC program is the first step to achieving optimal health in a high-risk population by systematically addressing biological, social and individual risk factors for poor health. Components of the ICoC program will address social determinants of health such as social connectedness, loneliness; individual behaviors such patient activation, locus of control and environmental determinants such as access to health services and facilities.

The aim of this evaluation is to answer the following questions while providing feedback to key decision makers over the 2 years of the project: (1) What is the overall effectiveness of the ICoC program in improving acute hospital utilization? (2) What are the different components of the ICoC programme: their structure, their stakeholders (targeted patients and practitioners), their operating

process and their effects on clinical outcomes? (3) What are the strengths and aspects to improve of each programme from the perspective of the concerned stakeholders in view of a better services integration? (4) What characteristics of the patients and the ICoC programme contribute to positive impacts on use of services, quality of life, patient activation and patient experience with care?

Methods/Design

Study Site

Adopting a population health approach, the Ministry of Health Singapore has been advocating for the transformation of our health care system from a hospital centric to a community centric. In 2011, public healthcare delivery was re-organized into regional health systems (RHS). The aim of which was to organize regional health assets into an integrated structure that will promote care integration of care across the care continuum. There is to be vertical and horizontal integration of healthcare institutions. In addition, the regional health systems will work to integrate health and social care by working closely with social care agencies within each region. Six RHSs were created, each being responsible to integrate care for a specific geographic region in Singapore. Each RHS is anchored by a tertiary hospital, supported by a community hospital providing intermediate and rehabilitation care and complete with linkages to primary care and long term care services in the region. In 2014, the Singapore Health Services (SingHealth) RHS was officially launched and consisted of primary to tertiary care institutions that account for the care of nearly a million residents in Singapore.

Intervention and Control

The ICoC intervention program (Figure 1)

1. SGH Transitional Care (TC) team for care transitions of hospitalized residents

The SGH TC team (comprising a senior family physician and a medical officer) is a dedicated service that will provide inpatient care or co-management with specialists for all enrolled patients, with emphasis on comprehensive discharge planning, formulation of a care plan post-discharge and proper hand-over care to the community virtual ward and C2H teams. This intervention incorporates the best principles in transitional care that includes both pre-discharge and post-discharge component ^(13, 19). The hand-over care will be executed via a daily half-hour video conferencing meeting between the three teams.

2. Community Virtual Ward (VW) for coordinating community care and home-based primary care

The community-based VW team comprises of a staff nurse and resident physician seconded by SGH to provide continuing community care, home-based primary and nursing care to enrolled patients. This intervention is supported by strong evidence for home-based primary care and continuing care for frail elders ^(20, 21). The team's responsibilities include: (i) comprehensive geriatric assessment; (ii) continuing care and at least weekly surveillance of discharged patients for up to one month post-discharge; (iii) monitoring at risk patients for compliance to the prescribed care plans and medications; (iv) health promotion and education to enrolled patients; (v) developing patient-specific action plans for patients with high risk diseases such as heart failure and diabetes and (vi) coordinating and integrating the primary, transitional and social care for enrolled patients; and (vii) hand-over care to community service providers for long term follow up upon stabilization of patients and according to clinical protocol. The community VW team is physically located in the community.

3. Care Closer to Home (C2H) team for social case management and home help

Since October 2014, the C2H is a program by the Agency for Integrated Care comprising a case manager, a social work assistant and five nursing aides to put in place health, personal and social services, e.g. medication management, home help services to assist with basic activities of daily living e.g. showering to help seniors to age in place. To date, the program has enrolled close to 300 residents. AIC closely supports and provides professional guidance for the C2H program.

All three components of the ICoC program will be provided to enrolled patients. To ensure this, we have harmonized our inclusion and exclusion criteria for entry into all three components.

Control group participants

The control group of approximately 1100 participants from other rental housing blocks in our regional health system will receive current hospital standard of care when they are hospitalized. Patients will be managed by their specialists in charge depending on their admitting diagnoses. Patients may be referred to the SGH THC program and/or various community services on discharge if deemed necessary by their specialists. Continuing care post-discharge may be provided at the specialist outpatient clinics or a primary care provider identified by the hospital specialist. The community VW and C2H teams would not be available for control group patients.

Figure 1: Conceptual Model of Care for the ICoC Program

Conceptual Framework for Evaluation

The strategy of using multidisciplinary case management that we have adopted for our model of care has been widely used in many care integration programs aimed at reducing health care utilization and improve quality of care for frail older adults with multimorbidities.⁽²²⁾ The evaluation of this model of care is challenging because it contains multiple components. For example, the medical, social and personal care components may act both independently of each other and interdependently in affecting the outcome of patient care. The assessment of individual components of intervention becomes complicated, creating the need for a novel adaptation of a mixed-method strategy of evaluation. Thus, our multidisciplinary research team combines the use of both quantitative and qualitative methods through a participatory action research (PAR) approach as part of the overall evaluation of the effectiveness of the ICOC program.

PAR has been defined as "systematic inquiry, with the participation of those affected by the problem being studied, for the purposes of education and action or effecting social change".⁽²³⁾ In Singapore, the recent and rapid transformation of health services delivery for the aging population had created unprecedented shifts in the power relationship between users, policy makers and service providers in the healthcare system. Participatory action research with community-dwelling socially-at-risk elderly Singaporeans has the potential to explore some of the complex health and social problems that poor and socially-isolated elderly face, while also contributing to individual and community capacity building. Additionally, PAR has been found to be an appropriate process for evaluating patient-centred models of care. Nolan & Hazelton found similarities in nursing processes with PAR, particularly through the steps of assessment, planning, implementation, evaluation and replanning⁽²⁴⁾. PAR has also been engaged successfully to facilitate improvements in healthcare services ⁽²⁵⁾.

A mixed-methods PAR approach will facilitate a more comprehensive assessment of the ICoC, particularly to understand the multiple outcomes of the program in terms of what works, for what and for whom. In this regard, PAR is intended to be both highly localized and comparative.

Investigation of the programme structure, its operating processes and stakeholders' experiences can be captured through qualitative methods while the comparative assessment of health outcomes between the intervention and control group will be valuably complemented through quantitative research methods. Our preferred approach is driven not only by the learning objectives of investigators but also by the circumstances and contexts of the community involved.

Research Design

The ICoC study is a single-centre prospective, controlled, observational study performed in the SingHealth Regional Health System. ^(26, 27) Drawing upon established trends in PAR praxis ^(28, 29), our research design similarly includes a learning component, that we have conceptualized as a synergy between the 3 "Is" of <u>Intervention</u> (Action), <u>Involvement</u> (Participation in the Community) and <u>Inquiry</u> (Research) into a feedback cycle (Figure 2). The 3 Is mutually augment each other to contribute to the social transformation of integrated elderly care. The approach requires the co-partnership of stakeholders, implementation teams and research units to collect data, reflect upon findings of outcomes and refine the intervention process further to develop and achieve better delivery and results of ICoC.

Figure 2. Research Design: Intervention, Involvement and Inquiry Feedback Cycle

The mixed-methods PAR approach to the ICoC model is significant to health systems research because it attempts to triangulate both medical practitioners' and elderly patients' perspectives of intervention delivery. In this regard, our research design intends to capture sensitivity to outcomes beyond only the intended hypothesis. Additionally, while evaluation studies utilizes quantitative data to measure intervention outcomes, a qualitative approach may address issues with regards to using a single metric of examining hospital admissions, which have been found to be less suitable for complex and vulnerable patients where many other factors contribute to the need for hospitalization.^{(30) (31)}

Study Aims and Hypotheses

Our participatory action research (PAR) model combines two research components, quantitative and qualitative, at different phases of the intervention. The primary <u>objective</u> of the <u>quantitative</u> study is to evaluate the effectiveness of the ICoC program in achieving a significant reduction in the proportion of patients in the intervention group with unscheduled hospital readmissions within 30 days of the index discharge date relative to controls. The index admission and index discharge dates are defined as the date of the patient's first admission to the hospital and discharge from the hospital respectively. The secondary aims of this study are to evaluate the effectiveness of the ICoC program in achieving (i) a lower proportion of patients in the intervention group with three or more unscheduled hospital readmissions within one year of index discharge; (ii) a lower emergency department attendance rate in the intervention group at 30 days, and one year from index discharge; (iv) Improving health related quality of life in the intervention group relative to baseline as measured by the EQ-5D at 30 days, and one year compared to the control group.

The qualitative study aims at developing a more context-specific social ecological model of health behavior.⁽³²⁾ We propose a social ecological framework of health behavior in the manner below:

a. Care recipients' and caregivers' conditions and experiences (individual level)

- b. Interactions between elderly patient, caregivers and healthcare providers (interpersonal level)
- c. Elderly's and caregivers' access to experiences with service use and health care delivery (institutional/ organizational level)
- d. Elderly patients' connections with and support from the community (community level)
- e. How public initiatives and access to other healthcare programmes affect the experience of transitional care post-discharge (policy level)

This model helps to identify how influences within one's social environment: individual, interpersonal, organizational, community and policy factors affect people's experiences and behaviors during care transitions from hospital to home. The knowledge of how this model operates on the ground will enrich our evidence-based strategies to understand the impact of the ICoC. The PAR operates on a feedback loop that is sensitive to changes experienced by practitioners and patients in real-time. In this project, both the implementation and research team work in tandem to evaluate and improve the intervention on-the-go.

Sample Size calculation

Data from a previous study shows a historical 30-day re-admit rate of 17.5% for patients in the three proposed Intervention HDB blocks and 16.8% in the Control blocks. The prospectively recruited sample size for the Intervention will be 250 and, based on 2014 data, we anticipate about 1100 patients in the Control group. The figure shows the proposed sample sizes will provide \geq 80% power using a two-sided Fisher's exact test (α =0.05) to detect the following range of differences (unadjusted) in 30-day re-admit rates between Control vs. Intervention: 18.0 vs. 10.7, 17.0 vs. 9.9, 16.0 vs. 9.1, 15.0 vs. 8.3, 14.0 vs. 7.5 and 13.0 vs. 6.7. Targeted reductions in Intervention group readmission rates range from 40.5–48.5% and would certainly be considered clinically meaningful. In our previously published virtual ward study ⁽¹⁹⁾, we achieved 33% reduction in 30-day readmission rates and it is likely this can be improved with additional home visits and social care case management.

Inclusion and Exclusion Criteria

Patients are eligible if they:

1) Age \geq 60 years at time of recruitment

2) Staying in public rental housing in Chinatown area in Singapore

We will exclude patients who decline our program or dementia patients who are incapable of independent living and do not have a caregiver. Patients who have mild dementia and are capable of independent living or have a caregiver are suitable to be enrolled into the ICoC program, which will support care in the community. Patients in the intervention group will be recruited during their first admission upon study commencement (Figure 3). Based on the electronic medical records, close to 180 unique patients were admitted to Singapore General Hospital (SGH) in 2014. Assuming a low 5% rejection and exclusion rate (confirmed by our feasibility study), the recruitment period is estimated to be take 1.5 years (1st August 2016 to 31st January 2018). Recruitment will close when the sample size of 250 is reached. Control patients will be identified retrospectively at the end of the study period and data extracted from the SGH patient database using the index admission as the start date.

Figure 3: Patient Recruitment and Comparison between Intervention and Control Groups.

For the qualitative component, the research team will purposively extract a sample size of 40 elderly patients/ clients based on the sample of 300 elderly residents who are enrolled in C2H intervention programme and who are also under the supervision of the VW. The elderly patients/ clients are recruited into the study through referrals from medical and care team, where we hope to get a representative sample in terms of gender, age, ethnicity, health and physical status and living arrangements. The research team will also be interviewing 10 community practitioners who are providing care in the study site.

Data Collection strategies to Measure Outcomes

Basic Characteristics

Intervention Group: The research team will take informed consent from the intervention group participants and interview them for demographic, socioeconomic status, medical comorbidities, abbreviated Mental Test, and modified Barthel Index, instrumental activities of daily living and health-related quality of life (EQ-5D). These information will allow the investigators to characterize and identify needs in our intervention group patients better.

Control Group: Control group patients will be retrieved from the eHIntS system. A waiver of patient consent will be sought from the centralized institutional review board for extraction of de-identified routinely collected information. Similar demographic, socioeconomic status and medical comorbidities data (predictors used for propensity scores calculation listed in Appendix A supplementary file) will be collected for both groups to allow calculation of propensity scores as a basis for comparability. We have shown in our previous study ⁽²⁷⁾ that these data can be extracted from our data warehouse for inclusion in a propensity score model. Information such as abbreviated mental test, modified barthel index, instrumental activities of daily living and health related quality of life will not be available for the control group,

Outcome Measures at 30 days and one-year

The research team and the ICoC team will follow up with study participants for the primary and secondary outcomes at 30 days, and one year (Table 1). An unscheduled readmission is defined as a readmission for a non-elective indication. Unscheduled readmission at 30 days (short-term outcome) is a universally accepted indicator of transitional care quality and one year outcomes (long-term outcome) is chosen to reflect the quality of community and continuing care. The research team will conduct a face-to-face survey interview at 30 days and one year to repeat the EQ-5D scales. Healthcare utilization data of intervention and control group participants will be extracted from SingHealth's eHIntS system and merged with Ministry of Health (MOH)'s Omnibus data resource. This will ensure complete and accurate healthcare utilization outcomes and overcome the issue of cross utilization. Similarly, predictors of 30-day readmission that will be used for propensity score matching will be available from eHIntS and Omnibus databases.

A checklist will be developed to measure fidelity to components of ICoC program and ensure standardization of intervention. The nature (routine/emergency) and number of home visits e.g. doctor/nurse/C2H will be retrieved from the clinical documentation notes.

Table 1. Data collection sources at Baseline	, 30 days and One Year outcomes for participant	S
Tuble 11 Bata concetion sources at Basenne	, se days and one real outcomes for participant	-

Variable	Method of Collection	Baseline	Follow-up (30 days)	Follow-up (One year)
Demographic, Socio-economic status, Health information and prior healthcare utilization, Abbreviated Mental Test, Modified Barthel Index, Instrumental activities of daily living, health related quality of life	Questionnaire, EQ-5D, eHIntS	х		
Primary Outcome Measure – Unscheduled hospital readmission within 30 days of index discharge	eHIntS, Omnibus		x	
Secondary Outcome Measures – Unscheduled hospital readmissions at one year; Emergency department attendances, specialist outpatient clinic attendances and health related quality of life at 30 days and one year	EQ-5D, eHIntS, Omnibus		x	x

Qualitative Data Collection Design and Strategies

The qualitative research component of the PAR will be conducted in three phases.

Phase 1: Intervention & Involvement

1a. Understanding mechanisms and contexts of intervention (Practitioners and Patients)

The research team will engage in 'go-along' interviews to understand the complexities around integrated care in a low-income rental neighbourhood. The "go-along" combines both participant observation and interview methods and will be conducted with VW nurses and the C2H team (n=10) as they go about their daily care-rounds around the study site. Data collected will provide information in terms of patient/clients' receptivity to medical intervention, relationship between practitioners and their elderly patients/clients. The objective of go-along interviews is to capture the practitioners' perspective of the barriers and facilitators in the implementation of ICoC to their patients/ clients. Research team will document processes in which medical practitioners understand, implement and apply appropriate practices of care to the elderly residents in low-income rental dwelling. For triangulation, the research team will conduct content analysis of practitioners' case summaries over the period of intervention to trace the chronology and outcome of individualized interventions.

1b. Elderly Residents' Qualitative Needs Assessment based on Case Summaries and Complementary Quantitative Study

Based on case summaries by community practitioners, research team will work with implementation team to identify and categorically group elderly residents based on complexity of case and specific health conditions. Medical team and nurses will refer 40 cases/ elderly residents to the research team for Phase 2b of in-depth semi-structured/ informal interviews. Elderly residents will be grouped according to similarities in terms of case complexity (1st strata) followed by whether they show improvements in health behavior or not.

Phase 2: Action Learning through Involvement and Inquiry

2a. Interpreting, explaining, translating and refining identified problems, priorities and strengths in concert with key community members- clinicians, nurses, resident leaders and elderly residents (n=10). Through focus group discussions, the aim of this phase is to: 1) to understand how practitioners define care and how their vision of care is being expressed through their practices and 2) to obtain a profile of "complex" cases and how practitioners manage these issues.

2b. ICoC User Experience (n=40 based on referral in Phase 1b)

Research team will establish rapport with elderly residents in intervention group and conduct indepth interviews to explore the experiences and attitudes of older people who are in the intervention group (VW and C2H). Objective is to gain an understanding of the strengths and weaknesses of community care from the perspective of recipients in the study site.

Once the Institutional Review Board (IRB) has given ethics approval to conduct the research, the investigators will invite residents in the intervention group to participate in research study through case referrals by nurses and community health partners. Due to the nature of the User Experience research which requires substantial feedback from participants, nurses and community health partners will only refer elderly clients who are able to respond to questions without requiring a proxy. Research team will obtain consent from the elderly respondent and inform them that participation in the study is voluntary and care services will not be withdrawn should they decide to not participate or withdraw from the study. After obtaining consent, the qualitative research team will build rapport of elderly participants further through regular interactions facilitated by frequent house visits with community nurses and health partners. When comfort and trust has been established between the research team and participants, investigators will conduct interviews following a life history format. We will ask about their personal histories to gain a deeper and better understanding of their current circumstances and health behaviors. We will also seek their feedback as recipients of the care intervention. Interviews will be carried out over multiple sessions and visits, instead of a block session, so as to not tax elderly participants. Each session would last about approximately 30 minutes and will continue until all questions in the interview guide (Appendix B supplementary file) have been satisfactorily completed.

Phase 3. Inquiry and Intervention

Data analysis and findings from phase 1 and 2 will provide feedback on the delivery of the intervention. These findings will be analyzed together with the post-30 days and post 1 year quantitative outcome measures to identify which mechanisms of the intervention has been successful and which ones require improvements. Additionally, the objective of Phase 3 is to also highlight unintended outcomes of the intervention that clients and practitioners consider as beneficial to their experiences. The team will further analyze implications of findings and translational capacity to other low-income rental community-dwelling areas in Singapore.

Analysis

Quantitative Data Analysis

To analyze our primary aim, Control and Intervention 30-day re-admission rates will be compared using logistic regression using propensity scores to adjust for effects of confounders.

The secondary aim 1 analysis will use Fisher's exact test and logistic regression and compare groups on proportions of patients with three or more unscheduled hospital readmissions within one year of index discharge. Secondary aims 2 and 3 will involve Poisson regression analysis on numbers of visits per three-month and one-year intervals, and aim 4 will involve standard analysis of variance

 methods to compare quality of life scores. All analyses will incorporate propensity score adjustment. All analyses will be performed using SAS V9.4 software (SAS© Cary, NC, USA).

Qualitative Data Analysis

All in-depth interviews with key personnel and focus group discussions will be audiotaped and transcribed and uploaded onto qualitative software database nVivo 11. While 'go-along' interviews with nurses and case workers and interviews with elderly recipients with speech difficulties (eg. slow speech, inaudible voice) will not be audio-recorded due to the anticipated long duration of such sessions and difficulty in capturing speech respectively. Written notes will be used instead to record such observations and conversations and will be type- written once fieldwork for the day is over. Typed written notes will also be uploaded onto NVivo 11. The research team will use NVivo to code responses for theoretical and emergent themes regarding practitioner and client/patient (provider-user) experience of the ICoC programme.

The team will analyze data, by coding for broad themes that correspond to influences at the individual, interpersonal, organizational, community and policy level according to the social ecological framework of health behavior, while simultaneously code for emergent themes. The combination of both deductive and inductive analytical approaches will provide further granularity for the evaluation of the ICoC intervention programme. Data will be independently coded by two qualitative analysts and codings will be compared for agreement through NVivo, to achieve interrater reliability.

Ethics and Dissemination

Informed consent for participation in the ICoC intervention programme will be taken from each enrolled patient. Informed consent to participate in the research study will be taken another time for patients/ clients who have been referred to research team and also practitioners who will be interviewed and/or participating in focus group discussions. SingHealth Centralized Institutional Review Board (CIRB 2015/2277) approved this study.

Findings will be disseminated by publications in peer-reviewed journals, scientific meetings, and presentations to policy makers and practice partners.

Status of the study

The ICoC program is expected to last 2 years, from July 2016 to June 2018.

Discussion

It is increasingly recognized that non-biological determinants of health such as social, environmental and individual behaviors impact significantly on health outcomes.^(33, 34) These non-biological determinants of health interact in a complex relationship a person's biological health determinants such as gender, age, inherited and acquired health conditions. Therefore, quality healthcare alone cannot achieve optimal outcomes in health. Policy changes and interventions (the ICoC program in this case) that can modify health seeking behavior and affect delivery of healthcare services may affect health determinants and health outcomes. Implementing a complex ICoC intervention program and understanding the complex interaction between determinants, policy and outcomes therefore require an innovative approach to evaluation such as the participatory action research (PAR) model.

The findings from ICoC program will directly inform policy makers on the feasibility of implementation and effectiveness of integrating traditional silos of practice on reducing acute

hospital utilization. This has direct policy implications on the funding model and quantum to support such a program. In the short to medium term, the study will develop a novel model of integrated care that shifts care from a hospital centric system to an integrated community centric system for high-risk communities. In the long term, the study has policy implications on the feasibility and effectiveness of empanelment of high-risk communities to a community based integrated care team supported by the regional health system. The systematic inquiry, with the participation of those affected by the problem being studied, will enable the ICoC program and policy makers to understand the complex interaction between health determinants, intervention and health outcomes. This knowledge will facilitate design of better interventions and policies that systematically address health determinants and policies in future iterations of the ICoC program.

However, our study has potential limitations. Firstly, a randomized controlled trial design would have been most rigorous for evaluation of the ICoC program. However, we had wanted to evaluate the effectiveness of the synergism achieved by all three components of the ICoC program. The restriction of the C2H program to the three intervention blocks precluded us from randomizing the rental housing blocks or patients for intervention. We will minimize bias in the statistical comparison of the intervention and control groups by using propensity scores to balance baseline covariates. Second, this study is limited to a single rental housing community, so generalizability to other rental housing communities would be unknown. If results from the ICOC program are promising, we intend for this model of care to be propagated to other rental housing communities throughout RHS and Singapore.

Study status: At the point of manuscript submission, the enrollment of participants is ongoing.

Contributorship Statement: LLL, AM and LKH conceived and designed the study. LLL and AM wrote the first draft of the paper, and all authors critically revised the paper and gave final approval for publication.

Acknowledgements: We would like to acknowledge the SingHealth Regional Health System Office, staff from the Singapore General Hospital Office of Integrated Care and Associate Professor Angelique Chan from Duke-NUS Medical School Centre for Ageing Research and Education for their support.

Funding Statement: No grant funding was obtained for this study.

Data Sharing statement: Details of ongoing data collection (indicators and outcomes) is available from the corresponding author at low.lian.leng@singhealth.com.sg

Competing interests: The authors declare that they do not have competing interests.

References

1. Krumholz HM, Bernheim SM. Considering the role of socioeconomic status in hospital outcomes measures. Annals of internal medicine. 2014;161(11):833-4.

2. Arbaje AI, Wolff JL, Yu Q, Powe NR, Anderson GF, Boult C. Postdischarge environmental and socioeconomic factors and the likelihood of early hospital readmission among community-dwelling Medicare beneficiaries. The Gerontologist. 2008;48(4):495-504.

3. Hu J, Gonsahn MD, Nerenz DR. Socioeconomic status and readmissions: evidence from an urban teaching hospital. Health affairs (Project Hope). 2014;33(5):778-85.

BMJ Open

4. Filc D, Davidovich N, Novack L, Balicer RD. Is socioeconomic status associated with utilization of health care services in a single-payer universal health care system? International journal for equity in health. 2014;13(1):115.

5. Low LL, Win W, Ng MJM, Tan SY, Liu N, Lee KH. Housing as a social determinant of health in Singapore and its association with readmission risk and increased utilization of hospital services. Frontiers in Public Health. 2016;4.

6. Kangovi S, Barg FK, Carter T, Long JA, Shannon R, Grande D. Understanding why patients of low socioeconomic status prefer hospitals over ambulatory care. Health affairs (Project Hope). 2013;32(7):1196-203.

7. Kangovi S, Levy K, Barg FK, Carter T, Long JA, Grande D. Perspectives of older adults of low socioeconomic status on the post-hospital transition. Journal of health care for the poor and underserved. 2014;25(2):746-56.

8. Kangovi S, Barg FK, Carter T, Levy K, Sellman J, Long JA, et al. Challenges faced by patients with low socioeconomic status during the post-hospital transition. Journal of general internal medicine. 2014;29(2):283-9.

9. Wee LE, Yong YZ, Chng MW, Chew SH, Cheng L, Chua QH, et al. Individual and area-level socioeconomic status and their association with depression amongst community-dwelling elderly in Singapore. Aging & mental health. 2014;18(5):628-41.

10. Englander H, Michaels L, Chan B, Kansagara D. The care transitions innovation (C-TraIn) for socioeconomically disadvantaged adults: results of a cluster randomized controlled trial. Journal of general internal medicine. 2014;29(11):1460-7.

11. Shum E, Lee CE. Population-based healthcare: the experience of a regional health system. Annals of the Academy of Medicine, Singapore. 2014;43(12):564-5.

12. Hansen LO, Young RS, Hinami K, Leung A, Williams MV. Interventions to reduce 30-day rehospitalization: a systematic review. Annals of internal medicine. 2011;155(8):520-8.

13. Kansagara D, Chiovaro JC, Kagen D, Jencks S, Rhyne K, O'Neil M, et al. So many options, where do we start? An overview of the care transitions literature. Journal of hospital medicine : an official publication of the Society of Hospital Medicine. 2016;11(3):221-30.

14. Kripalani S, Theobald CN, Anctil B, Vasilevskis EE. Reducing hospital readmission rates: current strategies and future directions. Annual review of medicine. 2014;65:471-85.

15. Singapore DoS. Population Trends 2015 2015 [updated 30 Sep 2015; cited 2015 8 Dec]. Available from: <u>http://www.singstat.gov.sg/publications/publications-and-papers/population-and-population-structure/population-trends</u>.

16. Naylor MD, Aiken LH, Kurtzman ET, Olds DM, Hirschman KB. The care span: The importance of transitional care in achieving health reform. Health affairs (Project Hope). 2011;30(4):746-54.

17. Low LL, Vasanwala FF, Ng LB, Chen C, Lee KH, Tan SY. Effectiveness of a transitional home care program in reducing acute hospital utilization: a quasi-experimental study. BMC health services research. 2015;15:100.

18. Lee KH, Low LL, Allen J, Barbier S, Ng LB, Ng MJM, et al. Transitional care for the highest risk patients: findings of a randomised control study. International journal of integrated care. 2015;15(4).

19. Low LL, Tan SY, Ng MJM, Tay WY, Ng LB, Balasubramaniam K, et al. Applying the Integrated Practice Unit Concept to a Modified Virtual Ward Model of Care for Patients at Highest Risk of Readmission: A Randomized Controlled Trial. PloS one. 2017;12(1):e0168757.

20. De Jonge KE, Jamshed N, Gilden D, Kubisiak J, Bruce SR, Taler G. Effects of home-based primary care on Medicare costs in high-risk elders. Journal of the American Geriatrics Society. 2014;62(10):1825-31.

21. Dreiher J, Comaneshter DS, Rosenbluth Y, Battat E, Bitterman H, Cohen AD. The association between continuity of care in the community and health outcomes: a population-based study. Israel journal of health policy research. 2012;1(1):21.

22. Althaus F, Paroz S, Hugli O, Ghali WA, Daeppen JB, Peytremann-Bridevaux I, et al. Effectiveness of interventions targeting frequent users of emergency departments: a systematic review. Annals of emergency medicine. 2011;58(1):41-52.e42.

23. Blair T, Minkler M. Participatory action research with older adults: key principles in practice. The Gerontologist. 2009;49(5):651-62.

24. Nolan A HL. The Practicing Nurse. Sydney: W.B. Saunders Bailliere Tindall, Sydney; 1996.

25. Hart E BM. Action Research for Health and Social Care: A Guide to Practice: Open University Press, Buckingham; 1995.

26. Low LL, Liu N, Wang S, Thumboo J, Ong ME, Lee KH. Predicting frequent hospital admission risk in Singapore: a retrospective cohort study to investigate the impact of comorbidities, acute illness burden and social determinants of health. BMJ open. 2016;6(10):e012705.

27. Low LL, Liu N, Wang S, Thumboo J, Ong MEH, Lee KH. Predicting 30-Day Readmissions in an Asian Population: Building a Predictive Model by Incorporating Markers of Hospitalization Severity. PloS one. 2016;11(12):e0167413.

28. Rahman MA. Some trends in the Praxis of Participatory Action Research. Reason PaB, H., editor. London: Sage; 2008.

29. Chevalier JMaB, D.J. . Participation Action Research: Theory and Methods for Engaged Inquiry. United Kingdom: Routledge 2013.

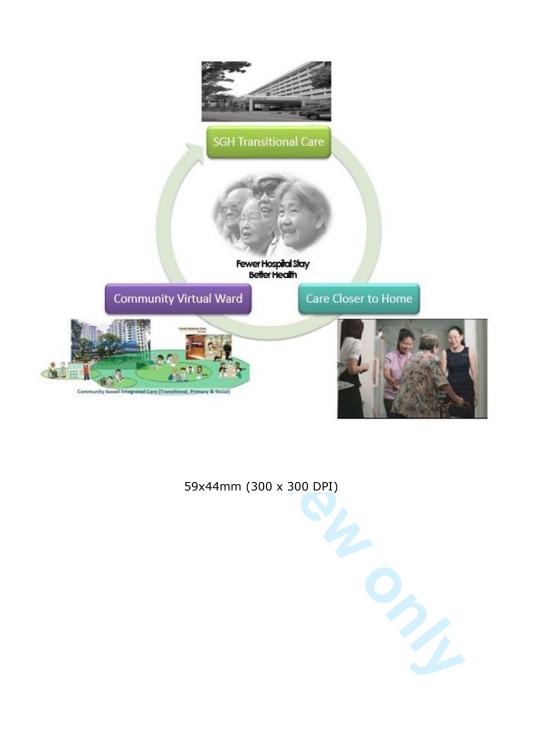
30. Roland M, Dusheiko M, Gravelle H, Parker S. Follow up of people aged 65 and over with a history of emergency admissions: analysis of routine admission data. BMJ (Clinical research ed). 2005;330(7486):289-92.

31. Sandberg M, Jakobsson U, Midlov P, Kristensson J. Case management for frail older people - a qualitative study of receivers' and providers' experiences of a complex intervention. BMC health services research. 2014;14:14.

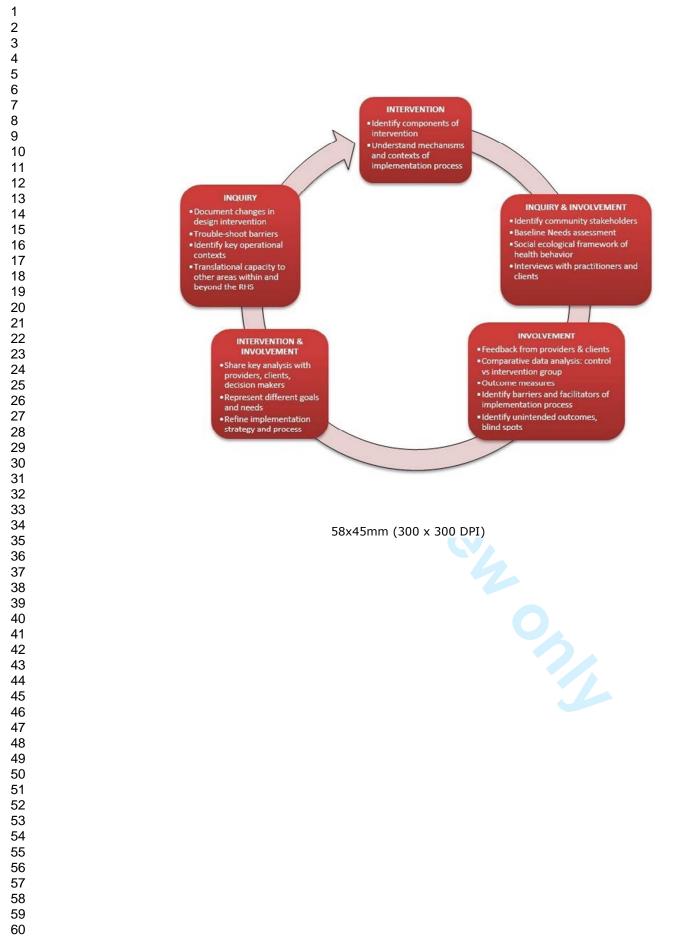
32. McLeroy KR, Bibeau D, Steckler A, Glanz K. An ecological perspective on health promotion programs. Health education quarterly. 1988;15(4):351-77.

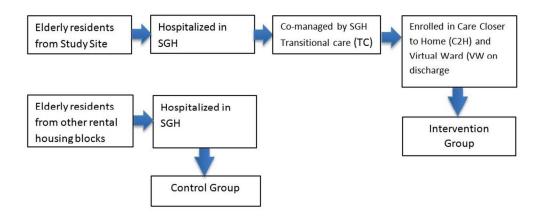
33. Evans RG, Stoddart GL. Producing health, consuming health care. Social science & medicine (1982). 1990;31(12):1347-63.

34. Dahlgren G, Whitehead M. Policies and strategies to promote social equity in health. Stockholm: Institute for future studies. 1991.



For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml





86x35mm (300 x 300 DPI)

Domains	Predictor
Patient demographics	Age
5 1	Gender
	Required financial assistance using Medifund
Past healthcare utilization	Emergency department visits six months before index admission
	Hospital admissions one year before index admission
Index educion	
Index admission	Urgent / Emergency admission
	Stayed in a subsidized ward
	Required inpatient dialysis
	Required intravenous furosemide 40mg and above
	Length of stay
Medical comorbidities	Depression
	History of alcoholism
	Osteoarthritis
	Spine fracture
	Charlson comorbidity index
	Chanson comorbidity index
	Total 15 predictors



Appendix B: Interview Guide with the Elderly Care Recipient

- 1. Introduction/ building rapport
 - a. Establish life history: past employment, family life, social support etc.
- 2. Ask about who has been helping them out with their health, care and medication, physical therapy
- 3. What kind of help have they been receiving? How did they come to be a care recipient?
- 4. Describe the care routine.
 - a. Medicine management
 - b. Hospital admission and post-discharge care
 - c. Social care
 - d. Home cleanliness
 - e. Support and reassurance
 - f. Mental health
 - g. Access to health services
 - h. Information giving/ health literacy
 - i. Connection to other social agencies
 - j. Post-op treatment and follow-up
- 5. Has the care they received met their needs or are there needs that remain unmet?
- 6. What is their relationship with community nurses, health aide workers and case manager? What do they perceive of their services?
- 7. Why do they think they have been allocated care?
- 8. What is their understanding of the role of community care workers?
- 9. Ask to give an account of their health issues, how they perceive their health, how their health affects their life situation or vice-versa, impacts of their health on relationships with others
- 10. What do they think about the help they are receiving? Have they observed any personal changes?
- 11. What have they learned from community care workers?
- 12. Has it improve their life situation or changed the way they think about their health?
- 13. Share about their experiences the last time they were admitted to the hospital. What do they think was the cause of their admission and if they feel the situation could have been avoided
- 14. How confident are they about managing their health? Do they feel that they have more understanding/ information about how to take care of themselves?
- 15. What about the health care they received was most helpful to their everyday life? What do they like best about it? What did they least like about it? How can the services be improved?

BMJ Open

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abst Page 1
		(b) Provide in the abstract an informative and balanced summary of what was do and what was found Page 2
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being report Pages 2-3
Objectives	3	State specific objectives, including any prespecified hypotheses Page 3
Methods		
Study design	4	Present key elements of study design early in the paper Page 4 onwards
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitme exposure, follow-up, and data collection Page 4 onwards
Participants	6	(<i>a</i>) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Page 6
		(b) For matched studies, give matching criteria and number of exposed and unexposed Page 9
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and ef modifiers. Give diagnostic criteria, if applicable Page 8-9
Data sources/	8*	For each variable of interest, give sources of data and details of methods of
measurement		assessment (measurement). Describe comparability of assessment methods if the more than one group Pages 9
Bias	9	Describe any efforts to address potential sources of bias Page 9
Study size	10	Explain how the study size was arrived at Page 10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why Page 11
Statistical methods	12	(<i>a</i>) Describe all statistical methods, including those used to control for confound Page 11
		(b) Describe any methods used to examine subgroups and interactions Not applied in our study.
		(c) Explain how missing data were addressed Not applicable in our study.
		(d) If applicable, explain how loss to follow-up was addressed We are able to
		retrieve utilization data from our electronic health record system.
		(<u>e</u>) Describe any sensitivity analyses Not applicable in our study.
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study,
		completing follow-up, and analysed No results are available yet.
		(b) Give reasons for non-participation at each stage No results are available yet.
		(c) Consider use of a flow diagram No results are available yet.
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) ar
		information on exposures and potential confounders No results are available yet.
		(b) Indicate number of participants with missing data for each variable of interes results are available yet.
		(c) Summarise follow-up time (eg, average and total amount) No results are avai yet.

Outcome data	15*	Report numbers of outcome events or summary measures over time No results are available yet.
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and
		their precision (eg, 95% confidence interval). Make clear which confounders were
		adjusted for and why they were included No results are available yet.
		(b) Report category boundaries when continuous variables were categorized No
		results are available yet.
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a
		meaningful time period No results are available yet.
Other analyses	17	Report other analyses done-eg analyses of subgroups and interactions, and
		sensitivity analyses <mark>No results are available yet.</mark>
Discussion		
Key results	18	Summarise key results with reference to study objectives No results are available yet.
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or
		imprecision. Discuss both direction and magnitude of any potential bias Page 12-13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,
		multiplicity of analyses, results from similar studies, and other relevant evidence
		Pages 12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results Page 12-13
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if
		applicable, for the original study on which the present article is based Page 14

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

BMJ Open

Evaluating a novel Integrated Community of Care (ICoC) for patients from an urbanized low-income community in Singapore using the Participatory Action Research (PAR) methodology: A Study Protocol

Journal:	BMJ Open
Manuscript ID	bmjopen-2017-017839.R2
Article Type:	Protocol
Date Submitted by the Author:	27-Jul-2017
Complete List of Authors:	Low, Lian Leng; Singapore General Hospital, Family Medicine and Continuing Care; Duke-NUS Medical School Maulod, Adlina; Duke-NUS Medical School Lee, Kheng Hock; Singapore General Hospital, Family Medicine and Continuing Care; Duke-NUS Medical School
Primary Subject Heading :	Health services research
Secondary Subject Heading:	General practice / Family practice, Geriatric medicine, Health policy, Qualitative research
Keywords:	Integrated Care, Community-based care, Transitional care, Low-income elderly community, participatory action research

SCHOLARONE[™] Manuscripts

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Title: Evaluating a novel Integrated Community of Care (ICoC) for patients from an urbanized low-income community in Singapore using the Participatory Action Research (PAR) methodology: A Study Protocol

Authors

Lian Leng Low^{1, 2}* (low.lian.leng@singhealth.com.sg)

Adlina Maulod³ (ad.maulod@duke-nus.edu.sg)

Kheng Hock Lee^{1, 2} (lee.kheng.hock@singhealth.com.sg)

Affiliations

¹ Department of Family Medicine & Continuing Care, Singapore General Hospital, Singapore

² Family Medicine, Duke-NUS Medical School, Singapore

³ Centre for Aging Research and Education, Duke-NUS Medical School, Singapore

* Corresponding authors

Dr Lian Leng Low, Academia Level 4, Department of Family Medicine & Continuing Care, 20 College

Road, Singapore 169856, Singapore General Hospital. Telephone +65-63265872, Email:

low.lian.leng@singhealth.com.sg

Word Count

5131 words

<u>Abstract</u>

Introduction: Poorer health outcomes and disproportionate healthcare utilization in socioeconomically disadvantaged patients is well established. However there is sparse literature on effective integrated care interventions that specifically target these high-risk individuals. The Integrated Community of Care (ICoC) is a novel care model that integrates hospital-based transitional care with health and social care in the community for high-risk individuals living in socially deprived communities. This study aims to evaluate the effectiveness of the ICoC in reducing acute hospital utilization and investigate the implementation process and its effects on clinical outcomes using a mixed-methods participatory action research (PAR) approach.

Methods and Analysis: This is a single-centre prospective, controlled, observational study performed in the SingHealth Regional Health System. A total of 250 eligible patients from an urbanized low-income community in Singapore will be enrolled during their index hospitalization. Our PAR model combines two research components: quantitative and qualitative, at different phases of the intervention. Outcomes of acute hospital utilization and health related quality of life are compared to controls, at 30 days and one year. The qualitative study aims at developing a more context-specific social ecological model of health behaviour. This model will identify how influences within one's social environment: individual, interpersonal, organizational, community and policy factors affect people's experiences and behaviours during care transitions from hospital to home. Knowledge on the operational aspects of ICoC will enrich our evidence-based strategies to understand the impact of the ICoC. The blending of qualitative and quantitative mixed methods recognizes the dynamic implementation processes as well as the complex and evolving needs of community stakeholders in shaping outcomes.

Ethics and Dissemination: Ethics approval was granted by the SingHealth Centralized Institutional Review Board (CIRB 2015/2277). The findings from this study will be disseminated by publications in peer-reviewed journals, scientific meetings, and presentations to government policy makers.

Trial registration number: NCT02678273

Key words: Low-income elderly community; participatory action research; integrated care; community-based care; transitional care

Article Summary

Strengths and Limitations of study

- 1. The Integrated Community of Care (ICoC) is a novel care model that integrates hospitalbased transitional care with health and social care in the community for high-risk individuals living in socially deprived communities.
- Study utilized a mixed method participatory action research (PAR) methodology to evaluate the effectiveness of a complex intervention program for a high-risk urbanized low-income community.
- 3. A randomized controlled trial design is not possible for this study.

Introduction

Elderly, socioeconomically disadvantaged and socially isolated patients are at highest risk of ill health. Low socioeconomic status (SES) is well recognized as an independent risk factor for various adverse health outcomes, such as readmission risk ⁽¹⁻³⁾ and hospital utilization⁽⁴⁾. In Singapore, public

rental housing is an area-level measure of SES and is independently associated with increased readmission risk, frequent hospital admission and emergency department (ED) utilisation.⁽⁵⁾ The reasons behind these poor outcomes include poor knowledge of personal health status, inappropriate health behaviors ⁽⁶⁾, inability to navigate the complicated healthcare system ^(2, 7), lower health literacy and misalignment between patient and care team with regard to goals of care ⁽⁸⁾. These factors are common among residents of rental flats in Singapore. To qualify for heavily subsidized rental housing from the government, the gross household income must be 1,500 Singapore Dollars or lower per month. The median household income in Singapore is 8,290 Singapore dollars per month ⁽⁵⁾. In these low SES communities, residents are known to have more comorbidity, poorer social support, more mental health disorders and depression ^(5, 9). The confluences of these factors in a sub-population of patients who tend to live together in socially deprived communities create challenges as well as opportunities to improve the health of the population.

While there is abundant literature highlighting the poorer health outcomes and disproportionate healthcare utilization in socioeconomically disadvantaged patients, there is sparse literature on integrated care interventions that specifically target these high-risk individuals. Englander et al. (10) described the Care Transitions Intervention (C-Train) program, a nurse and pharmacist-led multicomponent transitional care program conducted at an urban academic medical centre in Portland, Oregon. The C-TraIn program included coaching and education; home visits for highest risk patients; provision of 30 days of medications for low-income adults who were uninsured or on public insurance. However, the intervention did not reduce 30-day readmission rates or emergency department re-attendances. The authors concluded that the diverse needs of this population were too overwhelming for a nurse and pharmacist-based intervention. In Singapore, community-based initiatives led by social work professionals and para-professionals have been described ⁽¹¹⁾. However, the program faced similar problems and was hampered by the lack of a multi-disciplinary healthcare team to address complex health and social needs across different settings of care. Three reviews on effectiveness of transitional care trials by Hansen⁽¹²⁾, Kansagara⁽¹³⁾, and Kriplani⁽¹⁴⁾ independently concluded that transitional care interventions must be comprehensive, going beyond a single component intervention. Multi-component interventions integrating medical and social care to span the different phases of care from hospitalization, discharge planning to post-discharge surveillance is required improve the health outcomes of such a high-risk community. The programs also need the flexibility to respond to individual needs. This current gap in caring for such high-risk communities is what our multi-component intervention program aims to address.

In Singapore, it is estimated that 900,000 citizens living in the city state will be 65 years or older by 2030 and at least 50,000 (5.3%) would be staying in rental housing.⁽¹⁵⁾ A shift from a hospital centric model of care to a community centric model of care is widely accepted as a strategy that will enable us to provide sustainable and cost-effective care for our rapidly aging population. In response to this need, many new models of care were developed and tested for effectiveness. The Integrated Community of Care (ICOC) is a novel model developed by the Singapore General Hospital (SGH) that was designed to bring together best practices in transitional care ⁽¹⁶⁻¹⁹⁾, in addition to a Community Virtual Ward to coordinate community care and home-based primary care, and a Care Closer to Home (C2H) team for social case management and home help (fully elaborated under methods). In this care model, the ICoC fully integrates health and social care for high-risk individuals living in socially deprived communities. The ICoC program is the first step to achieving optimal health in a high-risk population by systematically addressing biological, social and individual risk factors for poor health. Components of the ICoC program will address social determinants of health such as social connectedness, loneliness; individual behaviors such patient activation, locus of control and environmental determinants such as access to health services and facilities.

The aim of this evaluation is to answer the following questions while providing feedback to key decision makers over the two years of the project: (1) what is the overall effectiveness of the ICoC program in improving acute hospital utilization? (2) What are the different components of the ICoC programme: their structure, their stakeholders (targeted patients and providers), their operating process and their effects on clinical outcomes? (3) What are the strengths and aspects to improve of each programme from the perspective of the concerned stakeholders in view of a better services integration? (4) What characteristics of the patients and the ICoC programme contribute to positive impacts on use of services, quality of life, patient activation and patient experience with care?

Methods/Design

Study Site

Adopting a population health approach, the Ministry of Health Singapore has been advocating for the transformation of our health care system from a hospital centric to a community centric. In 2011, public healthcare delivery was re-organized into regional health systems (RHS). The aim of which was to organize regional health assets into an integrated structure that will promote care integration of care across the care continuum. There is to be vertical and horizontal integration of healthcare institutions. In addition, the regional health systems will work to integrate health and social care by working closely with social care agencies within each region. Six RHSs were created, each being responsible to integrate care for a specific geographic region in Singapore. Each RHS is anchored by a tertiary hospital, supported by a community hospital providing intermediate and rehabilitation care and complete with linkages to primary care and long term care services in the region. In 2014, the Singapore Health Services (SingHealth) RHS was officially launched and consisted of primary to tertiary care institutions that account for the care of nearly a million residents in Singapore.

Inclusion and Exclusion Criteria

Patients are eligible if they:

- 1) Age \geq 60 years at time of recruitment
- 2) Staying in public rental housing in Chinatown area in Singapore

Chinatown was chosen as the Care Closer to Home (C2H) team had already started a social care case management and home help program in this area since October 2014. We will exclude patients who decline our program or dementia patients who are incapable of independent living and do not have a caregiver. Patients who have mild dementia and are capable of independent living or have a caregiver are suitable to be enrolled into the ICoC program, which will support care in the community. Patients in the intervention group will be recruited during their first admission upon study commencement (Figure 1) on a consecutive sampling basis. Based on the electronic medical records, close to 180 unique patients were admitted to SGH in 2014. Assuming a low 5% rejection and exclusion rate (confirmed by our feasibility study), the recruitment period is estimated to be take 1.5 years (1st August 2016 to 31st January 2018). Recruitment will close when the sample size of 250 is reached. Control patients will be identified retrospectively at the end of the study period and data extracted from the SGH patient database using the index admission as the start date.

Figure 1: Patient Recruitment and Comparison between Intervention and Control Groups.

Intervention and Control

The ICoC intervention program (Figure 2)

60

1. Singapore General Hospital (SGH) Transitional Care (TC) team for care transitions of hospitalized residents

The SGH TC team (comprising a senior family physician and a medical officer) is a dedicated service that will provide inpatient care or co-management with specialists for all enrolled patients, with emphasis on comprehensive discharge planning, formulation of a care plan post-discharge and proper hand-over care to the community virtual ward and C2H teams. This intervention incorporates the best principles in transitional care that includes both pre-discharge and post-discharge component ^(13, 19). The hand-over care will be executed via a daily half-hour video conferencing meeting between the three teams.

2. Community Virtual Ward (VW) for coordinating community care and home-based primary care

The community-based VW team comprises of a staff nurse and resident physician seconded by SGH to provide continuing community care, home-based primary and nursing care to enrolled patients. This intervention is supported by strong evidence for home-based primary care and continuing care for frail elders ^(20, 21). The team's responsibilities include: (I) comprehensive geriatric assessment; (ii) continuing care and at least weekly surveillance of discharged patients for up to one month postdischarge; (iii) monitoring at risk patients for compliance to the prescribed care plans and medications; (iv) health promotion and education to enrolled patients; (v) developing patientspecific action plans for patients with high risk diseases such as heart failure and diabetes and (vi) coordinating and integrating the primary, transitional and social care for enrolled patients; and (vii) hand-over care to community service providers for long term follow up upon stabilization of patients and according to clinical protocol. The community VW team is physically located in the community.

3. Care Closer to Home (C2H) team for social case management and home help

Since October 2014, the C2H is a program by the Agency for Integrated Care (AIC) comprising a case manager, a social work assistant and five nursing aides to put in place health, personal and social services, e.g. medication management, home help services to assist with basic activities of daily living e.g. showering to help seniors to age in place. To date, the program has enrolled close to 300 residents. AIC closely supports and provides professional guidance for the C2H program.

All three components of the ICoC program will be provided to enrolled patients. To ensure this, we have harmonized our inclusion and exclusion criteria for entry into all three components. The ICoC program has been implemented since August 2016.

Control group participants

The control group of approximately 1100 participants from other rental housing blocks in our regional health system will receive current hospital standard of care when they are hospitalized. Patients will be managed by their specialists in charge depending on their admitting diagnoses. Patients may be referred to the SGH TC program and/or various community services on discharge if deemed necessary by their specialists. Continuing care post-discharge may be provided at the specialist outpatient clinics or a primary care provider identified by the hospital specialist. The community VW and C2H teams would not be available for control group patients.

Figure 2: Conceptual Model of Care for the ICoC Program

Conceptual Framework for Evaluation

The strategy of using multidisciplinary case management that we have adopted for our model of care has been widely used in many care integration programs aimed at reducing health care utilization and improve quality of care for frail older adults with multimorbidities.⁽²²⁾ The evaluation of this model of care is challenging because it contains multiple components. For example, the medical, social and personal care components may act both independently of each other and interdependently in affecting the outcome of patient care. The assessment of individual components of intervention becomes complicated, creating the need for a novel adaptation of a mixed-method strategy of evaluation. Thus, our multidisciplinary research team combines the use of both quantitative and qualitative methods through a participatory action research (PAR) approach as part of the overall evaluation of the effectiveness of the ICOC program.

PAR has been defined as "systematic inquiry, with the participation of those affected by the problem being studied, for the purposes of education and action or effecting social change".⁽²³⁾ In Singapore, the recent and rapid transformation of health services delivery for the aging population had created unprecedented shifts in the power relationship between users, policy makers and service providers in the healthcare system. PAR with community-dwelling socially-at-risk elderly Singaporeans has the potential to explore some of the complex health and social problems that poor and socially-isolated elderly face, while also contributing to individual and community capacity building. In the context of our research site, PAR is an appropriate process for evaluating patient-centred models of care, especially since the action research strategies that we are proposing are common to processes in the field of nursing—particularly through the steps of assessment, planning, implementation, evaluation and replanning⁽²⁴⁾. The "PIE method", for instance, has been used among nurses to document patients' progress, where its acronym stands for identifying <u>P</u>roblems, proposing <u>I</u>nterventions and Evaluation⁽²⁵⁾. PAR has also been engaged successfully to facilitate improvements in healthcare services⁽²⁶⁾.

A mixed-methods PAR approach will facilitate a more comprehensive assessment of the ICoC, particularly to understand the multiple outcomes of the program in terms of what works, for what and for whom. In this regard, PAR is intended to be both highly localized and comparative. Investigation of the programme structure, its operating processes and stakeholders' experiences can be captured through qualitative methods while the comparative assessment of health outcomes between the intervention and control group will be valuably complemented through quantitative research methods. Our preferred approach is driven not only by the learning objectives of investigators but also by the circumstances and contexts of the community involved.

Research Design

The ICoC study is a single-centre prospective, controlled, observational study performed in the SingHealth RHS. ^(27, 28) Drawing upon established trends in PAR praxis which emphasizes collective processes of investigation and involvement as well as experimentation grounded in experience and social history ^(29, 30), our research design similarly includes a learning component. We have conceptualized our design in terms of a synergy between the 3 "Is" of <u>Intervention</u> (Action), <u>Involvement</u> (Participation in the Community) and <u>Inquiry</u> (Research) into a feedback cycle (Figure 3). The 3 Is mutually augment each other to contribute to the social transformation of integrated elderly care. The approach requires the co-partnership of stakeholders, implementation teams and research units to collect data, reflect upon findings of outcomes and refine the intervention process further to develop and achieve better delivery and results of ICoC.

Figure 3. Research Design: Intervention, Involvement and Inquiry Feedback Cycle

The mixed-methods PAR approach to the ICoC model is significant to health systems research because it attempts to triangulate both medical providers' and elderly patients' perspectives of intervention delivery. In this regard, our research design intends to capture sensitivity to outcomes beyond only the intended hypothesis. Additionally, while evaluation studies utilizes quantitative data to measure intervention outcomes, a qualitative approach may address issues with regards to using a single metric of examining hospital admissions, which have been found to be less suitable for complex and vulnerable patients where many other factors contribute to the need for hospitalization.^{(31) (32)}

Study Aims and Hypotheses

Our participatory action research (PAR) model combines two research components, quantitative and qualitative, at different phases of the intervention. The primary <u>objective</u> of the <u>quantitative</u> study is to evaluate the effectiveness of the ICoC program in achieving a significant reduction in the proportion of patients in the intervention group with acute hospital readmissions within 30 days of the index discharge date relative to controls. The index admission and index discharge dates are defined as the date of the patient's first admission to the hospital and discharge from the hospital respectively. The secondary aims of this study are to evaluate the effectiveness of the ICoC program in achieving (i) a lower proportion of patients in the intervention group with three or more unscheduled hospital readmissions within one year of index discharge; (ii) a lower emergency department attendance rate in the intervention group at 30 days, and one year from index discharge; (iii) a lower specialist outpatient clinic attendance rate in the intervention group at 30 days, and one year from index discharge; (iv) Improving health related quality of life in the intervention group relative to baseline as measured by the EQ-5D at 30 days, and one year compared to the control group.

The qualitative study aims at developing a more context-specific social ecological model of health behavior.⁽³³⁾ We propose a social ecological framework of health behaviour in the manner below:

- a. Care recipients' and caregivers' conditions and experiences (individual level)
- b. Interactions between elderly patient, caregivers and healthcare providers (interpersonal level)
- c. Elderly's and caregivers' access to experiences with service use and health care delivery (institutional/ organizational level)
- d. Elderly patients' connections with and support from the community (community level)
- e. How public initiatives and access to other healthcare programmes affect the experience of transitional care post-discharge (policy level)

This model helps to identify how influences within one's social environment: individual, interpersonal, organizational, community and policy factors affect people's experiences and behaviours during care transitions from hospital to home. The knowledge of how this model operates on the ground will enrich our evidence-based strategies to understand the impact of the ICoC. The PAR operates on a feedback loop that is sensitive to changes experienced by providers and patients in real-time. In this project, both the implementation and research team work in tandem to evaluate and improve the intervention once primary outcomes have been measured or unintended outcomes have been reported.

Sample Size calculation

Data from a previous feasibility study shows a historical 30-day re-admit rate of 17.5% for patients in the three proposed Intervention HDB blocks and 16.8% in the Control blocks. The prospectively recruited sample size for the Intervention will be 250 and, based on 2014 data, we anticipate about 1100 patients in the Control group. The figure shows the proposed sample sizes will provide ≥80%

power using a two-sided Fisher's exact test (α =0.05) to detect the following range of differences (unadjusted) in 30-day re-admit rates between Control vs. Intervention: 18.0 vs. 10.7, 17.0 vs. 9.9, 16.0 vs. 9.1, 15.0 vs. 8.3, 14.0 vs. 7.5 and 13.0 vs. 6.7. Targeted reductions in Intervention group readmission rates range from 40.5–48.5% and would certainly be considered clinically meaningful. In our previously published virtual ward study ⁽¹⁹⁾, we achieved 33% reduction in 30-day readmission rates and it is likely this can be improved with additional home visits and social care case management.

For the qualitative component, the research team will purposively select a sample size of 40 elderly patients/ clients based on the sample of 300 elderly residents who are enrolled in C2H intervention programme and who are also under the supervision of the VW. The elderly patients/ clients are recruited into the study through referrals from medical and care team based on their health status and case severities (eg. Polypharmacy, multiple comorbidities, frailty). We hope to get a diverse sample in terms of gender, age, ethnicity and living arrangements. The research team will also be interviewing all community health providers (n=10) who are providing care in the study site.

Data Collection strategies to Measure Outcomes

Basic Characteristics

 Intervention Group: The research team will take informed consent from the intervention group participants and interview them for demographic, socioeconomic status, medical comorbidities, abbreviated Mental Test, and modified Barthel Index, instrumental activities of daily living and health-related quality of life (EQ-5D). These information will allow the investigators to characterize and identify needs in our intervention group patients better.

Control Group: Control group patients will be retrieved from the eHIntS system. The eHIntS system is SingHealth's electronic health record system, that integrates information from multiple sources including administrative data (for example, patient demographics), clinical data and ancillary data into our enterprise data warehouse. A waiver of patient consent will be sought from the centralized institutional review board for extraction of de-identified routinely collected information. Similar demographic, socioeconomic status and medical comorbidities data (predictors used for propensity scores calculation listed in Appendix A supplementary file) will be collected for both groups to allow calculation of propensity scores as a basis for comparability. We have shown in our previous study ⁽²⁸⁾ that these data can be extracted from our data warehouse for inclusion in a propensity score model. Information such as abbreviated mental test, modified Barthel index, instrumental activities of daily living and health related quality of life will not be available for the control group.

Outcome Measures at 30 days and one-year

The research team and the ICoC team will follow up with study participants for the primary and secondary outcomes at 30 days, and one year (Table 1). An unscheduled readmission is defined as a readmission for a non-elective indication. Unscheduled readmission at 30 days (short-term outcome) is a universally accepted indicator of transitional care quality and one year outcomes (long-term outcome) is chosen to reflect the quality of community and continuing care. The research team will conduct a face-to-face survey interview at 30 days and one year to repeat the EQ-5D scales. Healthcare utilization data of intervention and control group participants will be extracted from SingHealth's eHIntS system and merged with Ministry of Health (MOH)'s Omnibus data resource. This will ensure complete and accurate healthcare utilization outcomes and overcome the issue of cross utilization. Similarly, predictors of 30-day readmission that will be used for propensity score matching will be available from eHIntS and Omnibus databases.

A checklist will be developed to measure fidelity to components of ICoC program and ensure standardization of intervention and the designed interventions are faithfully adhered to. The nature

 (routine/emergency) and number of home visits e.g. doctor/nurse/C2H will be retrieved from the clinical documentation notes.

Table 1: Data collection sources at Baseline, 30 days and One Year outcomes for participants

Variable	Method of Collection	Baseline	Follow-up (30 days)	Follow-up (One year)
Demographic, Socio-economic	Questionnaire,			
status, Health information and prior	EQ-5D, eHIntS			
healthcare utilization, Abbreviated		х		
Mental Test, Modified Barthel Index,		×		
Instrumental activities of daily living,				
health related quality of life				
Primary Outcome Measure –	eHIntS,			
Unscheduled hospital readmission	Omnibus		Х	
within 30 days of index discharge				
Secondary Outcome Measures –	EQ-5D, eHIntS,			
Unscheduled hospital readmissions	Omnibus			
at one year; Emergency department				
attendances, specialist outpatient 🕥			Х	Х
clinic attendances and health				
related quality of life at 30 days and				
one year				

Qualitative Data Collection Design and Strategies

The qualitative research component of the PAR will be conducted in three phases.

Phase 1: Intervention & Involvement

1a. Understanding mechanisms and contexts of intervention (Providers and Patients)

The research team will engage in 'go-along' interviews with nurses and community healthcare providers to understand the complexities around integrated care in a low-income rental neighbourhood. The 'go-along' combines both participant observation and interview methods and will be conducted with all of the VW nurses and the C2H team (n=10) as they go about their daily care-rounds around the study site. Data collected will provide information in terms of patient/clients' receptivity to medical intervention, relationship between providers and their elderly patients/clients. The objective of go-along interviews is to capture the providers' perspective of the barriers and facilitators in the implementation of ICoC to their patients/ clients. Research team will document processes in which medical providers understand, implement and apply appropriate practices of care to the elderly residents in low-income rental dwelling. For triangulation, the research team will conduct content analysis of providers' case summaries over the period of intervention to trace the chronology and outcome of individualized interventions.

1b. Elderly Residents' Qualitative Needs Assessment based on Case Summaries and Complementary Quantitative Study

Based on case summaries by healthcare providers, research team will work with implementation team to identify and categorically group elderly residents based on complexity of case and specific health conditions. Medical team and nurses will refer 40 cases/ elderly clients with different physical and health status as well as across gender, ethnicity, age and living arrangements to the research

team for Phase 2b of in-depth semi-structured/ informal interviews. Elderly residents will be grouped according to similarities in terms of case complexity (1st strata) followed by whether they show improvements in health behaviour or not.

Phase 2: Action Learning through Involvement and Inquiry

2a. This phase involves interpreting preliminary data, explaining contexts, translating findings and refining identified problems, priorities and strengths together with key community membersclinicians, nurses, resident committee members and elderly residents who are physically and cognitively able to participate and be involved in discussions. Through focus group discussions, the aim of this phase is to: 1) to understand how providers define care and how their vision of care is being expressed through their practices and 2) to understand the background profile of clients and develop case-studies of "complex" cases and how both the providers, resident committee and patients manage these issues.

2b. ICoC User Experience (n=40 based on referral in Phase 1b)

Research team will establish rapport with elderly residents in intervention group and conduct indepth interviews to explore the experiences and attitudes of older people who are in the intervention group (VW and C2H). Objective is to gain an understanding of the strengths and weaknesses of community care from the perspective of recipients in the study site.

Once the Institutional Review Board (IRB) has given ethics approval to conduct the research, the investigators will invite residents in the intervention group to participate in research study through case referrals by nurses and community health providers. Due to the nature of the User Experience research which requires substantial feedback from participants, nurses and community health providers will only refer elderly clients who are able to respond to questions without requiring a proxy. When comfort and trust has been established between the research team and participants, investigators will conduct interviews following a life history format. We will ask about their personal histories to gain a deeper and better understanding of their current circumstances and health behaviours. We will also seek their feedback as recipients of the care intervention. Interviews will be carried out over multiple sessions and visits, instead of a block session, so as to not tax elderly participants. Each session would last about approximately 30 minutes and will continue until all questions in the interview guide (Appendix B supplementary file) have been satisfactorily completed.

Phase 3. Inquiry and Intervention

Data analysis and findings from phase 1 and 2 will provide feedback on the delivery of the intervention. These findings will be analysed together with the post-30 days and post 1 year quantitative outcome measures to identify which mechanisms of the intervention have been successful and which require improvements. Improvements to the intervention will only be implemented and executed only after our primary outcomes have been collected and analysed. Additionally, the objective of Phase 3 is to also highlight unintended outcomes of the intervention that clients and providers consider as beneficial to their experiences. The team will further analyse implications of findings and translational capacity to other low-income rental community-dwelling areas in Singapore.

Analysis

Quantitative Data Analysis

To analyze our primary aim, control and intervention 30-day re-admission rates will be compared using logistic regression using propensity scores to adjust for effects of confounders.

The secondary aim 1 analysis will use Fisher's exact test and logistic regression and compare groups on proportions of patients with three or more unscheduled hospital readmissions within one year of index discharge. Secondary aims 2 and 3 will involve Poisson regression analysis on numbers of visits per three-month and one-year intervals, and aim 4 will involve standard analysis of variance methods to compare quality of life scores. All analyses will incorporate propensity score adjustment. All analyses will be performed using SAS V9.4 software (SAS© Cary, NC, USA).

Qualitative Data Analysis

All in-depth interviews with key personnel and focus group discussions will be audiotaped and transcribed and uploaded onto qualitative software database nVivo 11. While 'go-along' interviews with nurses and case workers and interviews with elderly recipients with speech difficulties (e.g. slow speech, inaudible voice) will not be audio-recorded due to the anticipated long duration of such sessions and difficulty in capturing speech respectively. Written notes will be used instead to record such observations and conversations and will be type-written at the end of each day. Typed written notes will also be uploaded onto NVivo 11. The research team will use NVivo to code responses for theoretical and emergent themes regarding practitioner and client/patient (provider-user) experience of the ICoC programme.

The team will analyse data, by coding for broad themes that correspond to influences at the individual, interpersonal, organizational, community and policy level according to the social ecological framework of health behaviour, while simultaneously code for emergent themes. The combination of both deductive and inductive analytical approaches will provide further granularity for the evaluation of the ICoC intervention programme. Data will be independently coded by two qualitative analysts and codings will be compared for agreement through NVivo, to achieve interrater reliability.

Ethics and Dissemination

Informed consent for participation in the ICoC intervention programme will be taken from each enrolled patient. Participation in the study is voluntary and care services will not be withdrawn should elderly patients decide to not participate or withdraw from the study. After obtaining consent, the qualitative research team will build rapport of elderly participants further through regular interactions facilitated by frequent house visits with community nurses and health providers. Additional informed consent to participate in the research study will be taken for patients/ clients who have been referred to research team and for providers who will be interviewed and/or participating in focus group discussions. SingHealth Centralized Institutional Review Board (CIRB 2015/2277) and National University of Singapore Institutional Review Board (NUS IRB: H-17-035) has approved this study.

Findings will be disseminated by publications in peer-reviewed journals, scientific meetings, and presentations to policy makers and practice providers.

Status of the study

The ICoC program is expected to last 2 years, from July 2016 to June 2018.

Discussion

It is increasingly recognized that non-biological determinants of health such as social, environmental and individual behaviors impact significantly on health outcomes.^(34, 35) These non-biological determinants of health interact in a complex relationship a person's biological health determinants such as gender, age, inherited and acquired health conditions. Therefore, quality healthcare alone cannot achieve optimal outcomes in health. Policy changes and interventions (the ICoC program in

this case) that can modify health seeking behavior and affect delivery of healthcare services may in turn affect health determinants and health outcomes. Implementing a complex ICoC intervention program and understanding the complex interaction between determinants, policy and outcomes therefore require an innovative approach to evaluation such as the PAR model.

The findings from ICoC program will directly inform policy makers on the feasibility of implementation and effectiveness of integrating traditional silos of practice on reducing acute hospital utilization. This has direct policy implications on the funding model and quantum to support such a program. In the short to medium term, the study will develop a novel model of integrated care that shifts care from a hospital centric system to an integrated community centric system for high-risk communities. In the long term, the study has policy implications on the feasibility and effectiveness of empanelment of high-risk communities (assigning individuals to care teams) to a community based integrated care team supported by the regional health system. The systematic inquiry, with the participation of those affected by the problem being studied, will enable the ICoC program and policy makers to understand the complex interaction between health determinants, intervention and health outcomes. This knowledge will facilitate design of better interventions and policies that systematically address health determinants and policies in future iterations of the ICoC program.

Our study has potential limitations. Firstly, a randomized controlled trial design would be most appropriate for evaluating the effectiveness, but it is not always the best design for process indicators. Moreover, we had wanted to evaluate the effectiveness of the synergism achieved by all three components of the ICoC program. The restriction of the C2H program to the three intervention blocks precluded us from randomizing the rental housing blocks or patients for intervention. We will minimize bias in the statistical comparison of the intervention and control groups by using propensity scores to balance baseline covariates. Second, this study is limited to a single rental housing community, so generalizability to other rental housing communities would be unknown. If results from the ICOC program are promising, we intend for this model of care to be propagated to other rental housing communities throughout RHS and Singapore.

Study status: At the point of manuscript submission, the enrollment of participants is ongoing.

Contributorship Statement: LLL, AM and LKH conceived and designed the study. LLL and AM wrote the first draft of the paper, and all authors critically revised the paper and gave final approval for publication.

Acknowledgements: We would like to acknowledge the SingHealth Regional Health System Office, staff from the Singapore General Hospital Office of Integrated Care and Associate Professor Angelique Chan from Duke-NUS Medical School Centre for Ageing Research and Education for their support.

Funding Statement: No grant funding was obtained for this study.

Data sharing statement: Details of ongoing data collection (indicators and outcomes) is available from the corresponding author at low.lian.leng@singhealth.com.sg

Competing interests: The authors declare that they do not have competing interests.

Figure legends:

Figure 1: Patient Recruitment and Comparison between Intervention and Control Groups

Figure 2: Conceptual Model of Care for ICoC program

Figure 3: Research Design Intervention, Involvement and Inquiry Feedback Cycle

References

1. Krumholz HM, Bernheim SM. Considering the role of socioeconomic status in hospital outcomes measures. Annals of internal medicine. 2014;161(11):833-4.

2. Arbaje AI, Wolff JL, Yu Q, Powe NR, Anderson GF, Boult C. Postdischarge environmental and socioeconomic factors and the likelihood of early hospital readmission among community-dwelling Medicare beneficiaries. The Gerontologist. 2008;48(4):495-504.

3. Hu J, Gonsahn MD, Nerenz DR. Socioeconomic status and readmissions: evidence from an urban teaching hospital. Health affairs (Project Hope). 2014;33(5):778-85.

4. Filc D, Davidovich N, Novack L, Balicer RD. Is socioeconomic status associated with utilization of health care services in a single-payer universal health care system? International journal for equity in health. 2014;13(1):115.

5. Low LL, Win W, Ng MJM, Tan SY, Liu N, Lee KH. Housing as a social determinant of health in Singapore and its association with readmission risk and increased utilization of hospital services. Frontiers in Public Health. 2016;4.

6. Kangovi S, Barg FK, Carter T, Long JA, Shannon R, Grande D. Understanding why patients of low socioeconomic status prefer hospitals over ambulatory care. Health affairs (Project Hope). 2013;32(7):1196-203.

7. Kangovi S, Levy K, Barg FK, Carter T, Long JA, Grande D. Perspectives of older adults of low socioeconomic status on the post-hospital transition. Journal of health care for the poor and underserved. 2014;25(2):746-56.

8. Kangovi S, Barg FK, Carter T, Levy K, Sellman J, Long JA, et al. Challenges faced by patients with low socioeconomic status during the post-hospital transition. Journal of general internal medicine. 2014;29(2):283-9.

9. Wee LE, Yong YZ, Chng MW, Chew SH, Cheng L, Chua QH, et al. Individual and area-level socioeconomic status and their association with depression amongst community-dwelling elderly in Singapore. Aging & mental health. 2014;18(5):628-41.

10. Englander H, Michaels L, Chan B, Kansagara D. The care transitions innovation (C-TraIn) for socioeconomically disadvantaged adults: results of a cluster randomized controlled trial. Journal of general internal medicine. 2014;29(11):1460-7.

11. Shum E, Lee CE. Population-based healthcare: the experience of a regional health system. Annals of the Academy of Medicine, Singapore. 2014;43(12):564-5.

12. Hansen LO, Young RS, Hinami K, Leung A, Williams MV. Interventions to reduce 30-day rehospitalization: a systematic review. Annals of internal medicine. 2011;155(8):520-8.

13. Kansagara D, Chiovaro JC, Kagen D, Jencks S, Rhyne K, O'Neil M, et al. So many options, where do we start? An overview of the care transitions literature. Journal of hospital medicine : an official publication of the Society of Hospital Medicine. 2016;11(3):221-30.

14. Kripalani S, Theobald CN, Anctil B, Vasilevskis EE. Reducing hospital readmission rates: current strategies and future directions. Annual review of medicine. 2014;65:471-85.

15. Singapore DoS. Population Trends 2015 2015 [updated 30 Sep 2015; cited 2015 8 Dec]. Available from: <u>http://www.singstat.gov.sg/publications/publications-and-papers/population-and-population-structure/population-trends</u>.

16. Naylor MD, Aiken LH, Kurtzman ET, Olds DM, Hirschman KB. The care span: The importance of transitional care in achieving health reform. Health affairs (Project Hope). 2011;30(4):746-54.

17. Low LL, Vasanwala FF, Ng LB, Chen C, Lee KH, Tan SY. Effectiveness of a transitional home care program in reducing acute hospital utilization: a quasi-experimental study. BMC health services research. 2015;15:100.

18. Lee KH, Low LL, Allen J, Barbier S, Ng LB, Ng MJM, et al. Transitional care for the highest risk patients: findings of a randomised control study. International journal of integrated care. 2015;15(4).

19. Low LL, Tan SY, Ng MJM, Tay WY, Ng LB, Balasubramaniam K, et al. Applying the Integrated Practice Unit Concept to a Modified Virtual Ward Model of Care for Patients at Highest Risk of Readmission: A Randomized Controlled Trial. PloS one. 2017;12(1):e0168757.

20. De Jonge KE, Jamshed N, Gilden D, Kubisiak J, Bruce SR, Taler G. Effects of home-based primary care on Medicare costs in high-risk elders. Journal of the American Geriatrics Society. 2014;62(10):1825-31.

21. Dreiher J, Comaneshter DS, Rosenbluth Y, Battat E, Bitterman H, Cohen AD. The association between continuity of care in the community and health outcomes: a population-based study. Israel journal of health policy research. 2012;1(1):21.

22. Althaus F, Paroz S, Hugli O, Ghali WA, Daeppen JB, Peytremann-Bridevaux I, et al. Effectiveness of interventions targeting frequent users of emergency departments: a systematic review. Annals of emergency medicine. 2011;58(1):41-52.e42.

23. Blair T, Minkler M. Participatory action research with older adults: key principles in practice. The Gerontologist. 2009;49(5):651-62.

24. Nolan A HL. The Practicing Nurse. Sydney: W.B. Saunders Bailliere Tindall, Sydney; 1996.

Timby BK. Fundamental nursing skills and concepts. Philadelphia: Wolters Kluwer Health;
 2017.

26. Hart E BM. Action Research for Health and Social Care: A Guide to Practice: Open University Press, Buckingham; 1995.

27. Low LL, Liu N, Wang S, Thumboo J, Ong ME, Lee KH. Predicting frequent hospital admission risk in Singapore: a retrospective cohort study to investigate the impact of comorbidities, acute illness burden and social determinants of health. BMJ open. 2016;6(10):e012705.

28. Low LL, Liu N, Wang S, Thumboo J, Ong MEH, Lee KH. Predicting 30-Day Readmissions in an Asian Population: Building a Predictive Model by Incorporating Markers of Hospitalization Severity. PloS one. 2016;11(12):e0167413.

29. Rahman MA. Some trends in the Praxis of Participatory Action Research. Reason PaB, H. , editor. London: Sage; 2008.

30. Chevalier JMaB, D.J. . Participation Action Research: Theory and Methods for Engaged Inquiry. United Kingdom: Routledge 2013.

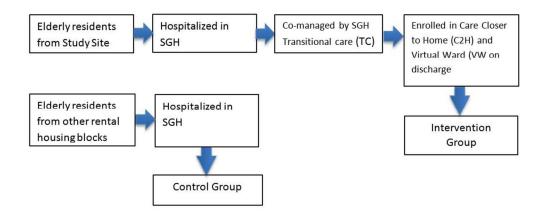
31. Roland M, Dusheiko M, Gravelle H, Parker S. Follow up of people aged 65 and over with a history of emergency admissions: analysis of routine admission data. BMJ (Clinical research ed). 2005;330(7486):289-92.

32. Sandberg M, Jakobsson U, Midlov P, Kristensson J. Case management for frail older people - a qualitative study of receivers' and providers' experiences of a complex intervention. BMC health services research. 2014;14:14.

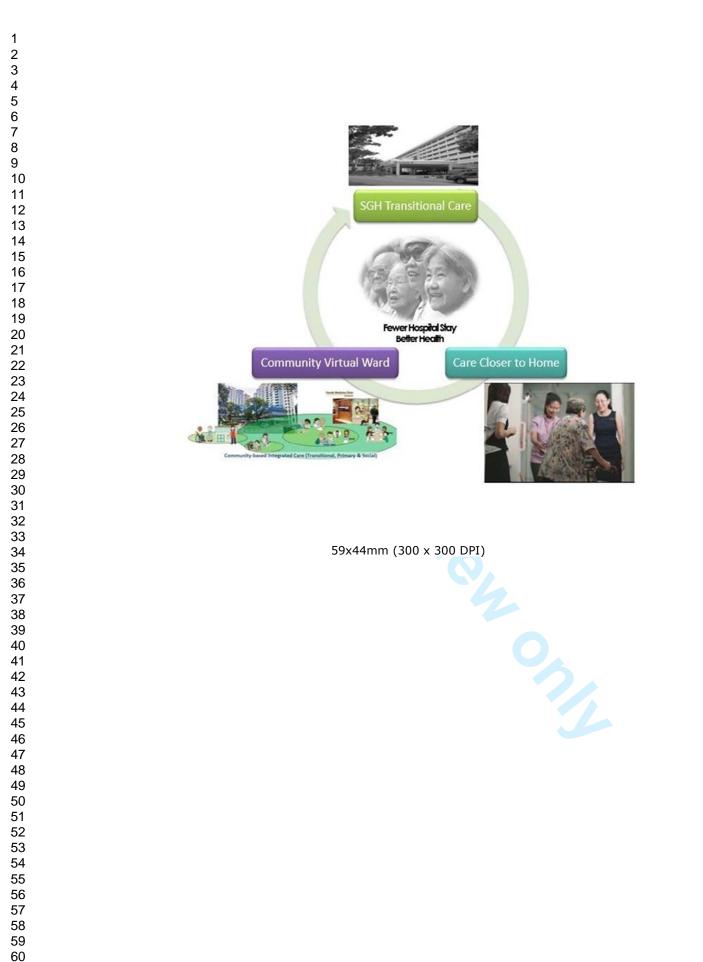
33. McLeroy KR, Bibeau D, Steckler A, Glanz K. An ecological perspective on health promotion programs. Health education quarterly. 1988;15(4):351-77.

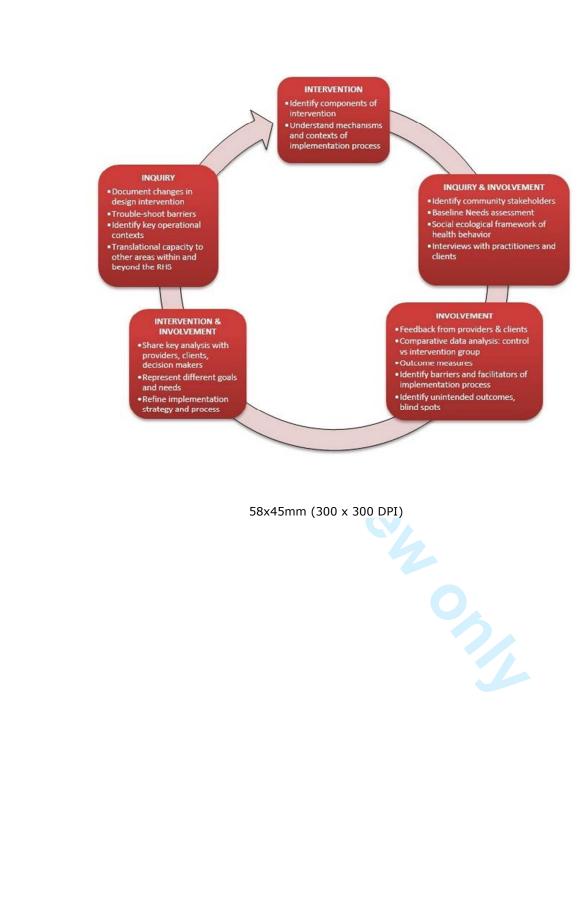
34. Evans RG, Stoddart GL. Producing health, consuming health care. Social science & medicine (1982). 1990;31(12):1347-63.

35. Dahlgren G, Whitehead M. Policies and strategies to promote social equity in health. Stockholm: Institute for future studies. 1991.



86x35mm (300 x 300 DPI)





Domains	Predictor
Patient demographics	Age
5 1	Gender
	Required financial assistance using Medifund
Past healthcare utilization	Emergency department visits six months before index admission
	Hospital admissions one year before index admission
Index educion	
Index admission	Urgent / Emergency admission
	Stayed in a subsidized ward
	Required inpatient dialysis
	Required intravenous furosemide 40mg and above
	Length of stay
Medical comorbidities	Depression
	History of alcoholism
	Osteoarthritis
	Spine fracture
	Charlson comorbidity index
	Chanson comorbidity index
	Total 15 predictors



Appendix B: Interview Guide with the Elderly Care Recipient

- 1. Introduction/ building rapport
 - a. Establish life history: past employment, family life, social support etc.
- 2. Ask about who has been helping them out with their health, care and medication, physical therapy
- 3. What kind of help have they been receiving? How did they come to be a care recipient?
- 4. Describe the care routine.
 - a. Medicine management
 - b. Hospital admission and post-discharge care
 - c. Social care
 - d. Home cleanliness
 - e. Support and reassurance
 - f. Mental health
 - g. Access to health services
 - h. Information giving/ health literacy
 - i. Connection to other social agencies
 - j. Post-op treatment and follow-up
- 5. Has the care they received met their needs or are there needs that remain unmet?
- 6. What is their relationship with community nurses, health aide workers and case manager? What do they perceive of their services?
- 7. Why do they think they have been allocated care?
- 8. What is their understanding of the role of community care workers?
- 9. Ask to give an account of their health issues, how they perceive their health, how their health affects their life situation or vice-versa, impacts of their health on relationships with others
- 10. What do they think about the help they are receiving? Have they observed any personal changes?
- 11. What have they learned from community care workers?
- 12. Has it improve their life situation or changed the way they think about their health?
- 13. Share about their experiences the last time they were admitted to the hospital. What do they think was the cause of their admission and if they feel the situation could have been avoided
- 14. How confident are they about managing their health? Do they feel that they have more understanding/ information about how to take care of themselves?
- 15. What about the health care they received was most helpful to their everyday life? What do they like best about it? What did they least like about it? How can the services be improved?

BMJ Open

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abst Page 1
		(b) Provide in the abstract an informative and balanced summary of what was do and what was found Page 2
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being report Pages 2-3
Objectives	3	State specific objectives, including any prespecified hypotheses Page 3
Methods		
Study design	4	Present key elements of study design early in the paper Page 4 onwards
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitme exposure, follow-up, and data collection Page 4 onwards
Participants	6	(<i>a</i>) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Page 6
		(b) For matched studies, give matching criteria and number of exposed and unexposed Page 9
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and ef modifiers. Give diagnostic criteria, if applicable Page 8-9
Data sources/	8*	For each variable of interest, give sources of data and details of methods of
measurement		assessment (measurement). Describe comparability of assessment methods if the more than one group Pages 9
Bias	9	Describe any efforts to address potential sources of bias Page 9
Study size	10	Explain how the study size was arrived at Page 10
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why Page 11
Statistical methods	12	(<i>a</i>) Describe all statistical methods, including those used to control for confound Page 11
		(b) Describe any methods used to examine subgroups and interactions Not applied in our study.
		(c) Explain how missing data were addressed Not applicable in our study.
		(d) If applicable, explain how loss to follow-up was addressed We are able to
		retrieve utilization data from our electronic health record system.
		(<u>e</u>) Describe any sensitivity analyses Not applicable in our study.
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study,
		completing follow-up, and analysed No results are available yet.
		(b) Give reasons for non-participation at each stage No results are available yet.
		(c) Consider use of a flow diagram No results are available yet.
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) ar
		information on exposures and potential confounders No results are available yet.
		(b) Indicate number of participants with missing data for each variable of interes results are available yet.
		(c) Summarise follow-up time (eg, average and total amount) No results are avai yet.

Outcome data	15*	Report numbers of outcome events or summary measures over time No results are available yet.
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and
		their precision (eg, 95% confidence interval). Make clear which confounders were
		adjusted for and why they were included No results are available yet.
		(b) Report category boundaries when continuous variables were categorized No
		results are available yet.
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a
		meaningful time period No results are available yet.
Other analyses	17	Report other analyses done-eg analyses of subgroups and interactions, and
		sensitivity analyses <mark>No results are available yet.</mark>
Discussion		
Key results	18	Summarise key results with reference to study objectives No results are available yet.
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or
		imprecision. Discuss both direction and magnitude of any potential bias Page 12-13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,
		multiplicity of analyses, results from similar studies, and other relevant evidence
		Pages 12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results Page 12-13
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if
		applicable, for the original study on which the present article is based Page 14

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

BMJ Open

Evaluating a novel Integrated Community of Care (ICoC) for patients from an urbanized low-income community in Singapore using the Participatory Action Research (PAR) methodology: A Study Protocol

Journal:	BMJ Open
Manuscript ID	bmjopen-2017-017839.R3
Article Type:	Protocol
Date Submitted by the Author:	30-Aug-2017
Complete List of Authors:	Low, Lian Leng; Singapore General Hospital, Family Medicine and Continuing Care; Duke-NUS Medical School Maulod, Adlina; Duke-NUS Medical School Lee, Kheng Hock; Singapore General Hospital, Family Medicine and Continuing Care; Duke-NUS Medical School
Primary Subject Heading :	Health services research
Secondary Subject Heading:	General practice / Family practice, Geriatric medicine, Health policy, Qualitative research
Keywords:	Integrated Care, Community-based care, Transitional care, Low-income elderly community, participatory action research

SCHOLARONE[™] Manuscripts

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

Title: Evaluating a novel Integrated Community of Care (ICoC) for patients from an urbanized low-income community in Singapore using the Participatory Action Research (PAR) methodology: A Study Protocol

Authors

Lian Leng Low^{1, 2}* (low.lian.leng@singhealth.com.sg)

Adlina Maulod³ (ad.maulod@duke-nus.edu.sg)

Kheng Hock Lee^{1, 2} (lee.kheng.hock@singhealth.com.sg)

Affiliations

¹ Department of Family Medicine & Continuing Care, Singapore General Hospital, Singapore

² Family Medicine, Duke-NUS Medical School, Singapore

³ Centre for Aging Research and Education, Duke-NUS Medical School, Singapore

* Corresponding authors

Dr Lian Leng Low, Academia Level 4, Department of Family Medicine & Continuing Care, 20 College

Road, Singapore 169856, Singapore General Hospital. Telephone +65-63265872, Email:

low.lian.leng@singhealth.com.sg

Word Count

5131 words

<u>Abstract</u>

 Introduction: Poorer health outcomes and disproportionate healthcare utilization in socioeconomically disadvantaged patients is well established. However there is sparse literature on effective integrated care interventions that specifically target these high-risk individuals. The Integrated Community of Care (ICoC) is a novel care model that integrates hospital-based transitional care with health and social care in the community for high-risk individuals living in socially deprived communities. This study aims to evaluate the effectiveness of the ICoC in reducing acute hospital utilization and investigate the implementation process and its effects on clinical outcomes using a mixed-methods participatory action research (PAR) approach.

Methods and Analysis: This is a single-centre prospective, controlled, observational study performed in the SingHealth Regional Health System. A total of 250 eligible patients from an urbanized low-income community in Singapore will be enrolled during their index hospitalization. Our PAR model combines two research components: quantitative and qualitative, at different phases of the intervention. Outcomes of acute hospital utilization and health related quality of life are compared to controls, at 30 days and one year. The qualitative study aims at developing a more context-specific social ecological model of health behaviour. This model will identify how influences within one's social environment: individual, interpersonal, organizational, community and policy factors affect people's experiences and behaviours during care transitions from hospital to home. Knowledge on the operational aspects of ICoC will enrich our evidence-based strategies to understand the impact of the ICoC. The blending of qualitative and quantitative mixed methods recognizes the dynamic implementation processes as well as the complex and evolving needs of community stakeholders in shaping outcomes.

Ethics and Dissemination: Ethics approval was granted by the SingHealth Centralized Institutional Review Board (CIRB 2015/2277). The findings from this study will be disseminated by publications in peer-reviewed journals, scientific meetings, and presentations to government policy makers.

Trial registration number: NCT02678273

Key words: Low-income elderly community; participatory action research; integrated care; community-based care; transitional care

Article Summary

Strengths and Limitations of study

- 1. The Integrated Community of Care (ICoC) is a novel care model that integrates hospitalbased transitional care with health and social care in the community for high-risk individuals living in socially deprived communities.
- Study utilized a mixed method participatory action research (PAR) methodology to evaluate the effectiveness of a complex intervention program for a high-risk urbanized low-income community.
- 3. A randomized controlled trial design is not possible for this study.

Introduction

Elderly, socioeconomically disadvantaged and socially isolated patients are at higher risk of ill health ⁽¹⁻⁴⁾. Low socioeconomic status (SES) is well recognized as an independent risk factor for various adverse health outcomes, such as readmission risk ^(3, 5, 6) and hospital utilization⁽⁷⁾. In Singapore,

public rental housing is an area-level measure of SES and is independently associated with increased readmission risk, frequent hospital admission and emergency department (ED) utilisation.⁽⁸⁾ The reasons behind these poor outcomes include poor knowledge of personal health status, inappropriate health behaviors ⁽⁹⁾, inability to navigate the complicated healthcare system ^(6, 10), lower health literacy and misalignment between patient and care team with regard to goals of care ⁽¹¹⁾. These factors are common among residents of rental flats in Singapore. To qualify for heavily subsidized rental housing from the government, the gross household income must be 1,500 Singapore Dollars or lower per month. The median household income in Singapore is 8,290 Singapore dollars per month ⁽⁸⁾. In these low SES communities, residents are known to have more comorbidity, poorer social support, more mental health disorders and depression ^(8, 12). The confluences of these factors in a sub-population of patients who tend to live together in socially deprived communities create challenges as well as opportunities to improve the health of the population.

While there is abundant literature highlighting the poorer health outcomes and disproportionate healthcare utilization in socioeconomically disadvantaged patients, there is sparse literature on integrated care interventions that specifically target these high-risk individuals. Englander et al. (13) described the Care Transitions Intervention (C-TraIn) program, a nurse and pharmacist-led multicomponent transitional care program conducted at an urban academic medical centre in Portland, Oregon. The C-TraIn program included coaching and education; home visits for highest risk patients; provision of 30 days of medications for low-income adults who were uninsured or on public insurance. However, the intervention did not reduce 30-day readmission rates or emergency department re-attendances. The authors concluded that the diverse needs of this population were too overwhelming for a nurse and pharmacist-based intervention. In Singapore, community-based initiatives led by social work professionals and para-professionals have been described ⁽¹⁴⁾. However, the program faced similar problems and was hampered by the lack of a multi-disciplinary healthcare team to address complex health and social needs across different settings of care. Three reviews on effectiveness of transitional care trials by Hansen⁽¹⁵⁾, Kansagara⁽¹⁶⁾, and Kriplani⁽¹⁷⁾ independently concluded that transitional care interventions must be comprehensive, going beyond a single component intervention. Multi-component interventions integrating medical and social care to span the different phases of care from hospitalization, discharge planning to post-discharge surveillance is required improve the health outcomes of such a high-risk community. The programs also need the flexibility to respond to individual needs. This current gap in caring for such high-risk communities is what our multi-component intervention program aims to address.

In Singapore, it is estimated that 900,000 citizens living in the city state will be 65 years or older by 2030 and at least 50,000 (5.3%) would be staying in rental housing.⁽¹⁸⁾ A shift from a hospital centric model of care to a community centric model of care is widely accepted as a strategy that will enable us to provide sustainable and cost-effective care for our rapidly aging population. In response to this need, many new models of care were developed and tested for effectiveness. The Integrated Community of Care (ICoC) is a novel model developed by the Singapore General Hospital (SGH) that was designed to bring together best practices in transitional care ⁽¹⁹⁻²²⁾, in addition to a Community Virtual Ward to coordinate community care and home-based primary care, and a Care Closer to Home (C2H) team for social case management and home help (fully elaborated under methods). In this care model, the ICoC fully integrates health and social care for high-risk individuals living in socially deprived communities. The ICoC program is the first step to achieving optimal health in a high-risk population by systematically addressing biological, social and individual risk factors for poor health. Components of the ICoC program will address social determinants of health such as social connectedness, loneliness; individual behaviors such patient activation, locus of control and environmental determinants such as access to health services and facilities.

The aim of this evaluation is to answer the following questions while providing feedback to key decision makers over the two years of the project: (1) what is the overall effectiveness of the ICoC program in improving acute hospital utilization? (2) What are the different components of the ICoC programme: their structure, their stakeholders (targeted patients and providers), their operating process and their effects on clinical outcomes? (3) What are the strengths and aspects to improve of each programme from the perspective of the concerned stakeholders in view of a better services integration? (4) What characteristics of the patients and the ICoC programme contribute to positive impacts on use of services, quality of life, patient activation and patient experience with care?

Methods/Design

Study Site

Adopting a population health approach, the Ministry of Health Singapore has been advocating for the transformation of our health care system from a hospital centric to a community centric. In 2011, public healthcare delivery was re-organized into regional health systems (RHS). The aim of which was to organize regional health assets into an integrated structure that will promote care integration of care across the care continuum. There is to be vertical and horizontal integration of healthcare institutions. In addition, the regional health systems will work to integrate health and social care by working closely with social care agencies within each region. Six RHSs were created, each being responsible to integrate care for a specific geographic region in Singapore. Each RHS is anchored by a tertiary hospital, supported by a community hospital providing intermediate and rehabilitation care and complete with linkages to primary care and long term care services in the region. In 2014, the Singapore Health Services (SingHealth) RHS was officially launched and consisted of primary to tertiary care institutions that account for the care of nearly a million residents in Singapore.

Inclusion and Exclusion Criteria

Patients are eligible if they:

- 1) Age \geq 60 years at time of recruitment
- 2) Staying in public rental housing in Chinatown area in Singapore

Chinatown was chosen as the Care Closer to Home (C2H) team had already started a social care case management and home help program in this area since October 2014. We will exclude patients who decline our program or dementia patients who are incapable of independent living and do not have a caregiver. Patients who have mild dementia and are capable of independent living or have a caregiver are suitable to be enrolled into the ICoC program, which will support care in the community. Patients in the intervention group will be recruited during their first admission upon study commencement (Figure 1) on a consecutive sampling basis. Based on the electronic medical records, close to 180 unique patients were admitted to SGH in 2014. Assuming a low 5% rejection and exclusion rate (confirmed by our feasibility study), the recruitment period is estimated to be take 1.5 years (1st August 2016 to 31st January 2018). Recruitment will close when the sample size of 250 is reached. Control patients will be identified retrospectively at the end of the study period and data extracted from the SGH patient database using the index admission as the start date.

Figure 1: Patient Recruitment and Comparison between Intervention and Control Groups.

Intervention and Control

The ICoC intervention program (Figure 2)

60

1. Singapore General Hospital (SGH) Transitional Care (TC) team for care transitions of hospitalized residents

The SGH TC team (comprising a senior family physician and a medical officer) is a dedicated service that will provide inpatient care or co-management with specialists for all enrolled patients, with emphasis on comprehensive discharge planning, formulation of a care plan post-discharge and proper hand-over care to the community virtual ward and C2H teams. This intervention incorporates the best principles in transitional care that includes both pre-discharge and post-discharge component ^(16, 22). The hand-over care will be executed via a daily half-hour video conferencing meeting between the three teams.

2. Community Virtual Ward (VW) for coordinating community care and home-based primary care

The community-based VW team comprises of a staff nurse and resident physician seconded by SGH to provide continuing community care, home-based primary and nursing care to enrolled patients. This intervention is supported by strong evidence for home-based primary care and continuing care for frail elders ^(23, 24). The team's responsibilities include: (I) comprehensive geriatric assessment; (ii) continuing care and at least weekly surveillance of discharged patients for up to one month postdischarge; (iii) monitoring at risk patients for compliance to the prescribed care plans and medications; (iv) health promotion and education to enrolled patients; (v) developing patientspecific action plans for patients with high risk diseases such as heart failure and diabetes and (vi) coordinating and integrating the primary, transitional and social care for enrolled patients; and (vii) hand-over care to community service providers for long term follow up upon stabilization of patients and according to clinical protocol. The community VW team is physically located in the community.

3. Care Closer to Home (C2H) team for social case management and home help

Since October 2014, the C2H is a program by the Agency for Integrated Care (AIC) comprising a case manager, a social work assistant and five nursing aides to put in place health, personal and social services, e.g. medication management, home help services to assist with basic activities of daily living e.g. showering to help seniors to age in place. To date, the program has enrolled close to 300 residents. AIC closely supports and provides professional guidance for the C2H program.

All three components of the ICoC program will be provided to enrolled patients. To ensure this, we have harmonized our inclusion and exclusion criteria for entry into all three components. The ICoC program has been implemented since August 2016.

Control group participants

The control group of approximately 1100 participants from other rental housing blocks in our regional health system will receive current hospital standard of care when they are hospitalized. Patients will be managed by their specialists in charge depending on their admitting diagnoses. Patients may be referred to the SGH TC program and/or various community services on discharge if deemed necessary by their specialists. Continuing care post-discharge may be provided at the specialist outpatient clinics or a primary care provider identified by the hospital specialist. The community VW and C2H teams will not be available for control group participants.

Figure 2: Conceptual Model of Care for the ICoC Program

Conceptual Framework for Evaluation

The strategy of using multidisciplinary case management that we have adopted for our model of care has been widely used in many care integration programs aimed at reducing health care utilization and improve quality of care for frail older adults with multimorbidities.⁽²⁵⁾ The evaluation of this model of care is challenging because it contains multiple components. For example, the medical, social and personal care components may act both independently of each other and interdependently in affecting the outcome of patient care. The assessment of individual components of intervention becomes complicated, creating the need for a novel adaptation of a mixed-method strategy of evaluation. Thus, our multidisciplinary research team combines the use of both quantitative and qualitative methods through a participatory action research (PAR) approach as part of the overall evaluation of the effectiveness of the ICoC program.

PAR has been defined as "systematic inquiry, with the participation of those affected by the problem being studied, for the purposes of education and action or effecting social change".⁽²⁶⁾ In Singapore, the recent and rapid transformation of health services delivery for the aging population had created unprecedented shifts in the power relationship between users, policy makers and service providers in the healthcare system. PAR with community-dwelling socially-at-risk elderly Singaporeans has the potential to explore some of the complex health and social problems that poor and socially-isolated elderly face, while also contributing to individual and community capacity building. In the context of our research site, PAR is an appropriate process for evaluating patient-centred models of care, especially since the action research strategies that we are proposing are common to processes in the field of nursing—particularly through the steps of assessment, planning, implementation, evaluation and replanning⁽²⁷⁾. The "PIE method", for instance, has been used among nurses to document patients' progress, where its acronym stands for identifying <u>P</u>roblems, proposing <u>Interventions and Evaluation ⁽²⁸⁾. PAR has also been engaged successfully to facilitate improvements in healthcare services ⁽²⁹⁾.</u>

A mixed-methods PAR approach will facilitate a more comprehensive assessment of the ICoC, particularly to understand the multiple outcomes of the program in terms of what works, for what and for whom. In this regard, PAR is intended to be both highly localized and comparative. Investigation of the programme structure, its operating processes and stakeholders' experiences can be captured through qualitative methods while the comparative assessment of health outcomes between the intervention and control group will be valuably complemented through quantitative research methods. Our preferred approach is driven not only by the learning objectives of investigators but also by the circumstances and contexts of the community involved.

Research Design

The ICoC study is a single-centre prospective, controlled, observational study performed in the SingHealth RHS. ^(30, 31) Drawing upon established trends in PAR praxis which emphasizes collective processes of investigation and involvement as well as experimentation grounded in experience and social history ^(32, 33), our research design similarly includes a learning component. We have conceptualized our design in terms of a synergy between the 3 "Is" of <u>Intervention</u> (Action), <u>Involvement</u> (Participation in the Community) and <u>Inquiry</u> (Research) into a feedback cycle (Figure 3). The 3 Is mutually augment each other to contribute to the social transformation of integrated elderly care. The approach requires the co-partnership of stakeholders, implementation teams and research units to collect data, reflect upon findings of outcomes and refine the intervention process further to develop and achieve better delivery and results of ICoC.

Figure 3. Research Design: Intervention, Involvement and Inquiry Feedback Cycle

BMJ Open

The mixed-methods PAR approach to the ICoC model is significant to health systems research because it attempts to triangulate both medical providers' and elderly patients' perspectives of intervention delivery. In this regard, our research design intends to capture sensitivity to outcomes beyond only the intended hypothesis. Additionally, while evaluation studies utilize quantitative data to measure intervention outcomes, a qualitative approach may address the limitations of using a single metric of examining hospital admissions, which have been found to be less suitable for complex and vulnerable patients where many other factors contribute to the need for hospitalization.^{(34) (35)}

Study Aims and Hypotheses

Our participatory action research (PAR) model combines two research components, quantitative and qualitative, at different phases of the intervention. The primary <u>objective</u> of the <u>quantitative</u> study is to evaluate the effectiveness of the ICoC program in achieving a significant reduction in the proportion of patients in the intervention group with acute hospital readmissions within 30 days of the index discharge date relative to controls. The index admission and index discharge dates are defined as the date of the patient's first admission to the hospital and discharge from the hospital respectively. The secondary aims of this study are to evaluate the effectiveness of the ICoC program in achieving (i) a lower proportion of patients in the intervention group with three or more unscheduled hospital readmissions within one year of index discharge; (ii) a lower emergency department attendance rate in the intervention group at 30 days, and one year from index discharge; (iii) a lower specialist outpatient clinic attendance rate in the intervention group at 30 days, and one year from index discharge; (iv) Improving health related quality of life in the intervention group relative to baseline as measured by the EQ-5D at 30 days, and one year compared to the control group.

The qualitative study aims at developing a more context-specific social ecological model of health behavior.⁽³⁶⁾ We propose a social ecological framework of health behaviour in the manner below:

- a. Care recipients' and caregivers' conditions and experiences (individual level)
- b. Interactions between elderly patient, caregivers and healthcare providers (interpersonal level)
- c. Elderly and caregiver's access experiences with service use and health care delivery (institutional/ organizational level)
- d. Elderly patients' connections with and support from the community (community level)
- e. How public initiatives and access to other healthcare programmes affect the experience of transitional care post-discharge (policy level)

This model helps to identify how influences within one's social environment: individual, interpersonal, organizational, community and policy factors affect people's experiences, behaviours and clinical outcomes during care transitions from hospital to home. The knowledge of how this model operates on the ground will enrich our evidence-based strategies to understand the impact of the ICoC. The PAR operates on a feedback loop that is sensitive to changes experienced by providers and patients in real-time. In this project, both the implementation and research team work in tandem to evaluate and improve the intervention once primary outcomes have been measured or unintended outcomes have been reported.

Sample Size calculation

Data from a previous feasibility study shows a historical 30-day re-admit rate of 17.5% for patients in the three proposed Intervention blocks and 16.8% in the Control blocks. The prospectively recruited sample size for the Intervention will be 250 and, based on 2014 data, we anticipate about 1100 patients in the Control group. The figure shows the proposed sample sizes will provide ≥80% power

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

using a two-sided Fisher's exact test (α =0.05) to detect the following range of differences (unadjusted) in 30-day re-admit rates between Control vs. Intervention: 18.0 vs. 10.7, 17.0 vs. 9.9, 16.0 vs. 9.1, 15.0 vs. 8.3, 14.0 vs. 7.5 and 13.0 vs. 6.7. Targeted reductions in Intervention group readmission rates range from 40.5–48.5% and would certainly be considered clinically meaningful. In our previously published virtual ward study ⁽²²⁾, we achieved 33% reduction in 30-day readmission rates and it is likely this can be improved with additional home visits and social care case management.

For the qualitative component, the research team will purposively select a sample of 40 elderly patients/ clients based on the sample of 250 elderly residents who are enrolled in C2H intervention programme and who are also under the supervision of the VW. The elderly patients/ clients are recruited into the study through referrals from medical and care team based on their health status and case severities (eg. Polypharmacy, multiple comorbidities, frailty). Since the qualitative study will be conducted over a year, we derived the sample size (n=40) elderly clients based on feasibility in terms of time, recruitment and limited manpower resources. We projected our sample size based on the concept of information power, which indicates that the more information the sample holds that will be relevant for the actual study, the lower the number of participants needed.⁽³⁷⁾ We appraised the information power of our sample based on the following factors:

- a. Sample specificity: All qualitative participants are elderly clients enrolled in the ICoC and share specific similarities for example, in terms of poor socio-economic status, low-literacy, living alone, mental impairment and difficulties in managing chronic illness. The variations that we intend to represent in our sample would be medical complexities, sex, race, caregiving arrangements and age (60-90 above).
- b. Applying mixed-use of deductive and inductive/ grounded theory approaches necessitate that the sample needs to provide a solid foundation to ground conclusions
- c. Strong quality of dialogue: Experienced research team conducting multiple in-depth interviews with each client will produce rich and meaningful data to evaluate the user perspective of the ICoC intervention
- d. Exploratory and thematic cross-case analysis will be conducted based on in-depth interview responses.

From the factors above, we are confident that our study can obtain sufficient information power with a sample size of 40, without compromising depth and rigour.

The research team will also be interview all community health providers (n=10) who are providing care in the study site.

Data Collection strategies to Measure Outcomes

Basic Characteristics

Intervention Group: The research team will obtain informed consent from the intervention group participants and interview them for demographic, socioeconomic status, medical comorbidities, abbreviated Mental Test, and modified Barthel Index, instrumental activities of daily living and health-related quality of life (EQ-5D). This information will allow the investigators to characterize and identify needs in our intervention group patients better.

Control Group: Control group patients will be retrieved from the eHIntS system. The eHIntS system is SingHealth's electronic health record system, that integrates information from multiple sources including administrative data (for example, patient demographics), clinical data and ancillary data into our enterprise data warehouse. A waiver of patient consent will be sought from the centralized institutional review board for extraction of de-identified routinely collected information. Similar

demographic, socioeconomic status and medical comorbidities data (predictors used for propensity scores calculation listed in Appendix A supplementary file) will be collected for both groups to allow calculation of propensity scores as a basis for comparability. We have shown in our previous study ⁽³¹⁾ that these data can be extracted from our data warehouse for inclusion in a propensity score model. Information such as abbreviated mental test, modified Barthel index, instrumental activities of daily living and health related quality of life will not be available for the control group.

Outcome Measures at 30 days and one-year

The research team and the ICoC team will follow up with study participants for the primary and secondary outcomes at 30 days, and one year (Table 1). An unscheduled readmission is defined as a readmission for a non-elective indication. Unscheduled readmission at 30 days (short-term outcome) is a universally accepted indicator of transitional care quality and one year outcomes (long-term outcome) is chosen to reflect the quality of community and continuing care. The research team will conduct a face-to-face survey interview at 30 days and one year to repeat the EQ-5D scales. Healthcare utilization data of intervention and control group participants will be extracted from SingHealth's eHIntS system and merged with Ministry of Health (MOH)'s Omnibus data resource. The MOH's Omnibus data resource contains national-level healthcare utilization data and will ensure complete and accurate healthcare utilization outcomes and overcome the issue of cross utilization to different healthcare clusters in Singapore. Similarly, predictors of 30-day readmission that will be used for propensity score matching will be available from eHIntS and Omnibus databases.

A checklist will be developed to measure fidelity to components of ICoC program and ensure standardization of intervention and the designed interventions are faithfully adhered to. The nature (routine/emergency) and number of home visits e.g. doctor/nurse/C2H will be retrieved from the clinical documentation notes.

Variable	Method of	Baseline	Follow-up	Follow-up
	Collection		(30 days)	(One year)
Demographic, Socio-economic	Questionnaire,			
status, Health information and prior	EQ-5D, eHIntS			
healthcare utilization, Abbreviated		V		
Mental Test, Modified Barthel Index,		^		
Instrumental activities of daily living,				
health related quality of life				
Primary Outcome Measure –	eHIntS,			
Unscheduled hospital readmission	Omnibus		Х	
within 30 days of index discharge				
Secondary Outcome Measures –	EQ-5D, eHIntS,			
1. Unscheduled hospital	Omnibus			
readmissions at one year;				
2. & 3. Emergency department				
attendances, specialist outpatient			Х	Х
clinic attendances at 30 days and				
one year				
4. Health related quality of life at 30				
days and one year				

Table 1: Data collection sources at Baseline, 30 days and One Year outcomes for participants

Qualitative Data Collection Design and Strategies

The qualitative research component of the PAR will be conducted in three phases.

Phase 1: Intervention & Involvement

1a. Understanding mechanisms and contexts of intervention (Providers and Patients)

The research team will engage in 'go-along' interviews with nurses and community healthcare providers to understand the complexities around integrated care in a low-income rental neighbourhood. The 'go-along' combines both participant observation and interview methods and will be conducted with all of the VW nurses and the C2H team (n=10) as they go about their daily care-rounds around the study site. Data collected will provide information in terms of patient/clients' receptivity to medical intervention, relationship between providers and their elderly patients/clients. The objective of go-along interviews is to capture the providers' perspective of the barriers and facilitators in the implementation of ICoC to their patients/ clients. Research team will document processes in which medical providers understand, implement and apply appropriate practices of care to the elderly residents in low-income rental dwelling. For triangulation, the research team will conduct content analysis of providers' case summaries over the period of intervention to trace the chronology and outcome of individualized interventions.

1b. Elderly Residents' Qualitative Needs Assessment based on Case Summaries and Complementary Quantitative Study

Based on case summaries by healthcare providers, research team will work with implementation team to identify and categorically group elderly residents based on complexity of case and specific health conditions. The medical team and nurses will refer 40 cases/ elderly clients with different physical and health status as well as across gender, ethnicity, age and living arrangements to the research team for Phase 2b of in-depth semi-structured/ informal interviews. Elderly residents will be grouped according to similarities in terms of case complexity (first strata) followed by whether they show improvements in health behaviour or not (second strata).

Phase 2: Action Learning through Involvement and Inquiry

2a. This phase involves interpreting preliminary data, explaining contexts, translating findings and refining identified problems, priorities and strengths together with key community membersclinicians, nurses, resident committee members and elderly residents who are physically and cognitively able to participate and be involved in discussions. Through focus group discussions, the aim of this phase is to: 1) to understand how providers define care and how their vision of care is being expressed through their practices and 2) to understand the background profile of clients and develop case-studies of "complex" cases and how both the providers, resident committee and patients manage these issues.

2b. ICoC User Experience (n=40 based on referral in Phase 1b)

Research team will establish rapport with elderly residents in intervention group and conduct indepth interviews to explore the experiences and attitudes of older people who are in the intervention group (VW and C2H). Objective is to gain an understanding of the strengths and weaknesses of community care from the perspective of recipients in the study site.

Once the Institutional Review Board (IRB) has given ethics approval to conduct the research, the investigators will invite residents in the intervention group to participate in research study through case referrals by nurses and community health providers. Due to the nature of the User Experience research which requires substantial feedback from participants, nurses and community health providers will only refer elderly clients who are able to respond to questions without requiring a proxy. When comfort and trust has been established between the research team and participants,

investigators will conduct interviews following a life history format. We will ask about their personal histories to gain a deeper and better understanding of their current circumstances and health behaviours. We will also seek their feedback as recipients of the care intervention. Interviews will be carried out over multiple sessions and visits, instead of a block session, so as to not tax elderly participants. Each session would last about approximately 30 minutes and will continue until all questions in the interview guide (Appendix B supplementary file) have been satisfactorily completed.

Phase 3. Inquiry and Intervention

Data analysis and findings from phase 1 and 2 will provide feedback on the delivery of the intervention. These findings will be analysed together with the post-30 days and post 1 year quantitative outcome measures to identify which mechanisms of the intervention have been successful and which require improvements. Improvements to the intervention will only be implemented and executed only after our primary outcomes have been collected and analysed. Additionally, the objective of Phase 3 is to also highlight unintended negative consequences or beneficial outcomes of the intervention that clients and providers experience. The team will further analyse implications of findings and translational capacity to other low-income rental community-dwelling areas in Singapore.

Analysis

Quantitative Data Analysis

To analyze our primary aim (Table 1), control and intervention 30-day re-admission rates will be compared using logistic regression using propensity scores to adjust for effects of confounders.

The secondary aim 1 analysis (Table 1) will use Fisher's exact test and logistic regression and compare groups on proportions of patients with three or more unscheduled hospital readmissions within one year of index discharge. Secondary aims 2 and 3 (Table 1) will involve Poisson regression analysis on numbers of emergency department and specialist outpatient clinic visits respectively, per three-month and one-year intervals, and aim 4 (Table 1) will involve standard analysis of variance methods to compare quality of life scores. All analyses will incorporate propensity score adjustment. All analyses will be performed using SAS V9.4 software (SAS© Cary, NC, USA).

Qualitative Data Analysis

All in-depth interviews with key personnel and focus group discussions will be audiotaped and transcribed and uploaded onto qualitative software database nVivo 11. While 'go-along' interviews with nurses and case workers and interviews with elderly recipients with speech difficulties (e.g. slow speech, inaudible voice) will not be audio-recorded due to the anticipated long duration of such sessions and difficulty in capturing speech respectively. Written notes will be used instead to record such observations and conversations and will be type-written at the end of each day. Typed written notes will also be uploaded onto NVivo 11. The research team will use NVivo to code responses for theoretical and emergent themes regarding practitioner and client/patient (provider-user) experience of the ICoC programme.

The team will analyse data, by coding for broad themes that correspond to influences at the individual, interpersonal, organizational, community and policy level according to the social ecological framework of health behaviour, while simultaneously code for emergent themes. The combination of both deductive and inductive analytical approaches will provide further granularity for the evaluation of the ICoC intervention programme. Data will be independently coded by two qualitative analysts and codings will be compared for agreement through NVivo, to achieve interrater reliability.

Ethics and Dissemination

Informed consent for participation in the ICoC intervention programme will be taken from each enrolled patient. Participation in the study is voluntary and care services will not be withdrawn should elderly patients decide to not participate or withdraw from the study. After obtaining consent, the qualitative research team will build rapport of elderly participants further through regular interactions facilitated by frequent house visits with community nurses and health providers. Additional informed consent to participate in the research study will be taken for patients/ clients who have been referred to research team and for providers and stakeholders who will be interviewed and/or participating in focus group discussions. SingHealth Centralized Institutional Review Board (CIRB 2015/2277) and National University of Singapore Institutional Review Board (NUS IRB: H-17-035) has approved this study.

Findings will be disseminated by publications in peer-reviewed journals, scientific meetings, and presentations to policy makers and practice providers.

Status of the study

The ICoC program is expected to last 2 years, from July 2016 to June 2018.

Discussion

It is increasingly recognized that non-biological determinants of health such as social, environmental and individual behaviors impact significantly on health outcomes.^(38, 39) These non-biological determinants of health interact in a complex relationship a person's biological health determinants such as gender, age, inherited and acquired health conditions. Therefore, quality healthcare alone cannot achieve optimal outcomes in health. Policy changes and interventions (the ICoC program in this case) that can modify health seeking behavior and affect delivery of healthcare services may in turn affect health determinants and health outcomes. Implementing a complex ICoC intervention program and understanding the complex interaction between determinants, policy and outcomes therefore require an innovative approach to evaluation such as the PAR model.

The findings from ICoC program will directly inform policy makers on the feasibility of implementation and effectiveness of integrating traditional silos of practice on reducing acute hospital utilization. This has direct policy implications on the funding model and quantum to support such a program. In the short to medium term, the study will develop a novel model of integrated care that shifts care from a hospital centric system to an integrated community centric system for high-risk communities. In the long term, the study has policy implications on the feasibility and effectiveness of empanelment of high-risk communities (assigning individuals to care teams) to a community based integrated care team supported by the regional health system. The systematic inquiry, with the participation of those affected by the problem being studied, will enable the ICoC program and policy makers to understand the complex interaction between health determinants, intervention and health outcomes. This knowledge will facilitate design of better interventions and policies that systematically address health determinants and policies in future iterations of the ICoC program.

Our study has potential limitations. Firstly, a randomized controlled trial design would be most appropriate for evaluating the effectiveness, but it is not always the best design for process indicators. Moreover, we had wanted to evaluate the effectiveness of the synergism achieved by all three components of the ICoC program. The restriction of the C2H program to the three intervention blocks precluded us from randomizing the rental housing blocks or patients for intervention. We will minimize bias in the statistical comparison of the intervention and control groups by using propensity scores to balance baseline covariates. Second, this study is limited to a single rental housing community, so generalizability to other rental housing communities would be unknown. If

results from the ICoC program are promising, we intend for this model of care to be propagated to other rental housing communities throughout RHS and Singapore.

Study status: At the point of manuscript submission, the enrollment of participants is ongoing.

Contributorship Statement: LLL, AM and LKH conceived and designed the study. LLL and AM wrote the first draft of the paper, and all authors critically revised the paper and gave final approval for publication.

Acknowledgements: We would like to acknowledge the SingHealth Regional Health System Office, staff from the Singapore General Hospital Office of Integrated Care and Associate Professor Angelique Chan from Duke-NUS Medical School Centre for Ageing Research and Education for their support.

Funding Statement: No grant funding was obtained for this study.

Data sharing statement: Details of ongoing data collection (indicators and outcomes) is available from the corresponding author at low.lian.leng@singhealth.com.sg

Competing interests: The authors declare that they do not have competing interests.

Figure legends:

Figure 1: Patient Recruitment and Comparison between Intervention and Control Groups

Figure 2: Conceptual Model of Care for ICoC program

Figure 3: Research Design Intervention, Involvement and Inquiry Feedback Cycle

References

1. Low LL, Liu N, Ong MEH, Ng EY, Ho AFW, Thumboo J, et al. Performance of the LACE index to identify elderly patients at high risk for hospital readmission in Singapore. Medicine. 2017;96(19):e6728.

2. Franchi C, Nobili A, Mari D, Tettamanti M, Djade CD, Pasina L, et al. Risk factors for hospital readmission of elderly patients. European journal of internal medicine. 2013;24(1):45-51.

3. Hu J, Gonsahn MD, Nerenz DR. Socioeconomic status and readmissions: evidence from an urban teaching hospital. Health affairs (Project Hope). 2014;33(5):778-85.

4. Lim KK, Chan A. Association of loneliness and healthcare utilization among older adults in Singapore. Geriatrics & gerontology international. 2017.

5. Krumholz HM, Bernheim SM. Considering the role of socioeconomic status in hospital outcomes measures. Annals of internal medicine. 2014;161(11):833-4.

6. Arbaje AI, Wolff JL, Yu Q, Powe NR, Anderson GF, Boult C. Postdischarge environmental and socioeconomic factors and the likelihood of early hospital readmission among community-dwelling Medicare beneficiaries. The Gerontologist. 2008;48(4):495-504.

7. Filc D, Davidovich N, Novack L, Balicer RD. Is socioeconomic status associated with utilization of health care services in a single-payer universal health care system? International journal for equity in health. 2014;13(1):115.

8. Low LL, Win W, Ng MJM, Tan SY, Liu N, Lee KH. Housing as a social determinant of health in Singapore and its association with readmission risk and increased utilization of hospital services. Frontiers in Public Health. 2016;4.

 9. Kangovi S, Barg FK, Carter T, Long JA, Shannon R, Grande D. Understanding why patients of low socioeconomic status prefer hospitals over ambulatory care. Health affairs (Project Hope). 2013;32(7):1196-203.

10. Kangovi S, Levy K, Barg FK, Carter T, Long JA, Grande D. Perspectives of older adults of low socioeconomic status on the post-hospital transition. Journal of health care for the poor and underserved. 2014;25(2):746-56.

11. Kangovi S, Barg FK, Carter T, Levy K, Sellman J, Long JA, et al. Challenges faced by patients with low socioeconomic status during the post-hospital transition. Journal of general internal medicine. 2014;29(2):283-9.

12. Wee LE, Yong YZ, Chng MW, Chew SH, Cheng L, Chua QH, et al. Individual and area-level socioeconomic status and their association with depression amongst community-dwelling elderly in Singapore. Aging & mental health. 2014;18(5):628-41.

13. Englander H, Michaels L, Chan B, Kansagara D. The care transitions innovation (C-TraIn) for socioeconomically disadvantaged adults: results of a cluster randomized controlled trial. Journal of general internal medicine. 2014;29(11):1460-7.

14. Shum E, Lee CE. Population-based healthcare: the experience of a regional health system. Annals of the Academy of Medicine, Singapore. 2014;43(12):564-5.

15. Hansen LO, Young RS, Hinami K, Leung A, Williams MV. Interventions to reduce 30-day rehospitalization: a systematic review. Annals of internal medicine. 2011;155(8):520-8.

16. Kansagara D, Chiovaro JC, Kagen D, Jencks S, Rhyne K, O'Neil M, et al. So many options, where do we start? An overview of the care transitions literature. Journal of hospital medicine : an official publication of the Society of Hospital Medicine. 2016;11(3):221-30.

17. Kripalani S, Theobald CN, Anctil B, Vasilevskis EE. Reducing hospital readmission rates: current strategies and future directions. Annual review of medicine. 2014;65:471-85.

18. Singapore DoS. Population Trends 2015 2015 [updated 30 Sep 2015; cited 2015 8 Dec]. Available from: <u>http://www.singstat.gov.sg/publications/publications-and-papers/population-and-population-structure/population-trends</u>.

19. Naylor MD, Aiken LH, Kurtzman ET, Olds DM, Hirschman KB. The care span: The importance of transitional care in achieving health reform. Health affairs (Project Hope). 2011;30(4):746-54.

20. Low LL, Vasanwala FF, Ng LB, Chen C, Lee KH, Tan SY. Effectiveness of a transitional home care program in reducing acute hospital utilization: a quasi-experimental study. BMC health services research. 2015;15:100.

21. Lee KH, Low LL, Allen J, Barbier S, Ng LB, Ng MJM, et al. Transitional care for the highest risk patients: findings of a randomised control study. International journal of integrated care. 2015;15(4).

22. Low LL, Tan SY, Ng MJM, Tay WY, Ng LB, Balasubramaniam K, et al. Applying the Integrated Practice Unit Concept to a Modified Virtual Ward Model of Care for Patients at Highest Risk of Readmission: A Randomized Controlled Trial. PloS one. 2017;12(1):e0168757.

23. De Jonge KE, Jamshed N, Gilden D, Kubisiak J, Bruce SR, Taler G. Effects of home-based primary care on Medicare costs in high-risk elders. Journal of the American Geriatrics Society. 2014;62(10):1825-31.

24. Dreiher J, Comaneshter DS, Rosenbluth Y, Battat E, Bitterman H, Cohen AD. The association between continuity of care in the community and health outcomes: a population-based study. Israel journal of health policy research. 2012;1(1):21.

25. Althaus F, Paroz S, Hugli O, Ghali WA, Daeppen JB, Peytremann-Bridevaux I, et al. Effectiveness of interventions targeting frequent users of emergency departments: a systematic review. Annals of emergency medicine. 2011;58(1):41-52.e42.

26. Blair T, Minkler M. Participatory action research with older adults: key principles in practice. The Gerontologist. 2009;49(5):651-62.

60

27. Nolan A HL. The Practicing Nurse. Sydney: W.B. Saunders Bailliere Tindall, Sydney; 1996.

28. Timby BK. Fundamental nursing skills and concepts. Philadelphia: Wolters Kluwer Health; 2017.

29. Hart E BM. Action Research for Health and Social Care: A Guide to Practice: Open University Press, Buckingham; 1995.

30. Low LL, Liu N, Wang S, Thumboo J, Ong ME, Lee KH. Predicting frequent hospital admission risk in Singapore: a retrospective cohort study to investigate the impact of comorbidities, acute illness burden and social determinants of health. BMJ open. 2016;6(10):e012705.

31. Low LL, Liu N, Wang S, Thumboo J, Ong MEH, Lee KH. Predicting 30-Day Readmissions in an Asian Population: Building a Predictive Model by Incorporating Markers of Hospitalization Severity. PloS one. 2016;11(12):e0167413.

32. , Rahman MA. Some trends in the Praxis of Participatory Action Research. Reason PaB, H. editor. London: Sage; 2008.

33. Chevalier JMaB, D.J. . Participation Action Research: Theory and Methods for Engaged Inquiry. United Kingdom: Routledge 2013.

Roland M, Dusheiko M, Gravelle H, Parker S. Follow up of people aged 65 and over with a 34. history of emergency admissions: analysis of routine admission data. BMJ (Clinical research ed). 2005;330(7486):289-92.

35. Sandberg M, Jakobsson U, Midlov P, Kristensson J. Case management for frail older people a qualitative study of receivers' and providers' experiences of a complex intervention. BMC health services research. 2014;14:14.

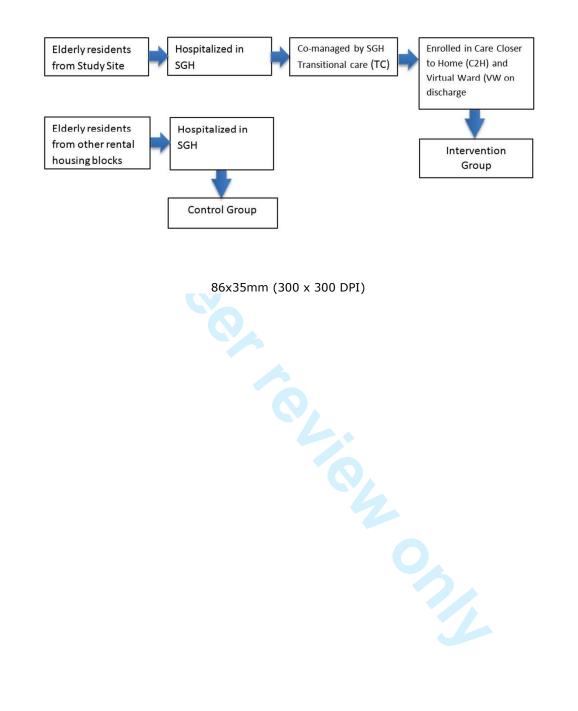
36. McLeroy KR, Bibeau D, Steckler A, Glanz K. An ecological perspective on health promotion programs. Health education quarterly. 1988;15(4):351-77.

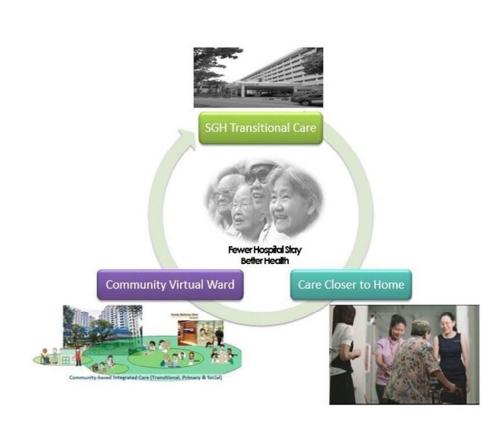
Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided 37. by Information Power. Qualitative health research. 2015.

38. Evans RG, Stoddart GL. Producing health, consuming health care. Social science & medicine (1982). 1990;31(12):1347-63.

Dahlgren G, Whitehead M. Policies and strategies to promote social equity in health. 39. Stockholm: Institute for future studies. 1991.

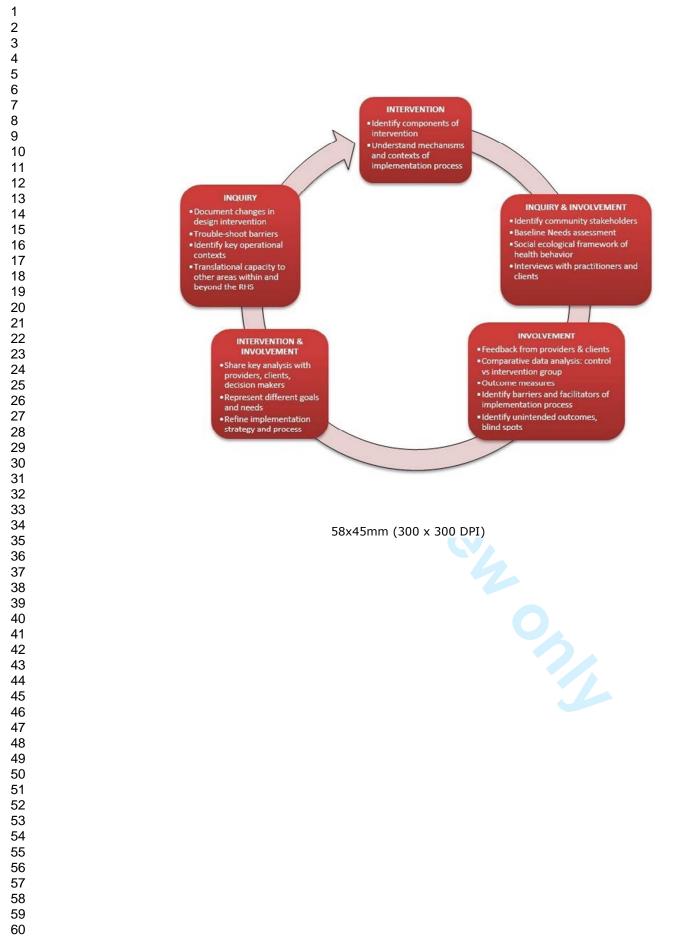
For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml



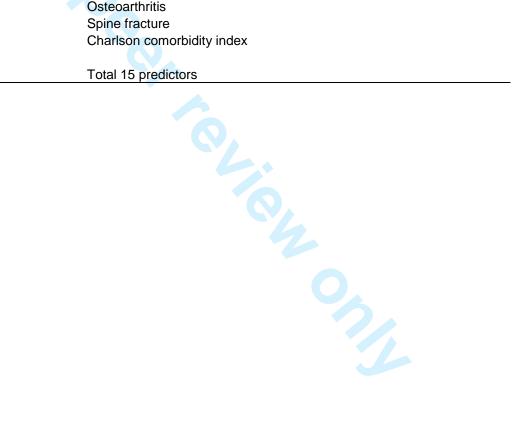


59x44mm (300 x 300 DPI)

For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml



Domains	Predictor
Patient demographics	Age
	Gender
	Required financial assistance using Medifund
Past healthcare utilization	Emergency department visits six months before index admissior
	Hospital admissions one year before index admission
Index admission	Urgent / Emergency admission
	Stayed in a subsidized ward
	Required inpatient dialysis
	Required intravenous furosemide 40mg and above
	Length of stay
Medical comorbidities	Depression
	History of alcoholism
	Osteoarthritis
	Spine fracture
	Charlson comorbidity index
	Total 15 predictors



- 1. Introduction/ building rapport
 - a. Establish life history: past employment, family life, social support etc.
- 2. Ask about who has been helping them out with their health, care and medication, physical therapy
- 3. What kind of help have they been receiving? How did they come to be a care recipient?
 - 4. Describe the care routine.
 - a. Medicine management
 - b. Hospital admission and post-discharge care
 - c. Social care
 - d. Home cleanliness
 - e. Support and reassurance
 - f. Mental health
 - g. Access to health services
 - h. Information giving/ health literacy
 - i. Connection to other social agencies
 - j. Post-op treatment and follow-up
- 5. Has the care they received met their needs or are there needs that remain unmet?
- 6. What is their relationship with community nurses, health aide workers and case manager? What do they perceive of their services?
- 7. Why do they think they have been allocated care?
- 8. What is their understanding of the role of community care workers?
- 9. Ask to give an account of their health issues, how they perceive their health, how their health affects their life situation or vice-versa, impacts of their health on relationships with others
- 10. What do they think about the help they are receiving? Have they observed any personal changes?
- 11. What have they learned from community care workers?
- 12. Has it improve their life situation or changed the way they think about their health?
- 13. Share about their experiences the last time they were admitted to the hospital. What do they think was the cause of their admission and if they feel the situation could have been avoided
- 14. How confident are they about managing their health? Do they feel that they have more understanding/ information about how to take care of themselves?
- 15. What about the health care they received was most helpful to their everyday life? What do they like best about it? What did they least like about it? How can the services be improved?

STROBE Statement—Checklist of items that should be included in reports of cohort studies	?S
--	----

	Item No	Recommendation		
Title and abstract	1	(<i>a</i>) Indicate the study's design with a commonly used term in the title or the abstract Page 1		
		(b) Provide in the abstract an informative and balanced summary of what was done		
		and what was found Page 2		
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported Pages 2-3		
Objectives	3	State specific objectives, including any prespecified hypotheses Page 3		
Methods				
Study design	4	Present key elements of study design early in the paper Page 4 onwards		
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection Page 4 onwards		
Participants	6	 (a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up Page 6 (b) For matched studies, give matching criteria and number of exposed and 		
		unexposed Page 9		
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable Page 8-9		
Data sources/	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there i		
measurement		more than one group Pages 9		
Bias	9	Describe any efforts to address potential sources of bias Page 9		
Study size	10	Explain how the study size was arrived at Page 10		
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why Page 11		
Statistical methods	12	(<i>a</i>) Describe all statistical methods, including those used to control for confounding Page 11		
		(b) Describe any methods used to examine subgroups and interactions Not applicabl		
		(c) Explain how missing data were addressed Not applicable in our study.		
		(d) If applicable, explain how loss to follow-up was addressed We are able to		
		retrieve utilization data from our electronic health record system.		
		(<u>e</u>) Describe any sensitivity analyses Not applicable in our study.		
Results				
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed No results are available yet.		
		(b) Give reasons for non-participation at each stage No results are available yet.		
	14*	(c) Consider use of a flow diagram No results are available yet.(a) Give characteristics of study participants (eg demographic, clinical, social) and		
Descriptive data	14.	information on exposures and potential confounders No results are available yet.		
		(b) Indicate number of participants with missing data for each variable of interest Norresults are available yet.		
		(c) Summarise follow-up time (eg, average and total amount) No results are availably yet.		

BMJ Open

Outcome data	15*	Report numbers of outcome events or summary measures over time No results are available yet.
Main results	16	(<i>a</i>) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included No results are available yet.
		(b) Report category boundaries when continuous variables were categorized No results are available yet.
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period No results are available yet.
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses No results are available yet.
Discussion		
Key results	18	Summarise key results with reference to study objectives No results are available yet.
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias Page 12-13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence Pages 12-13
Generalisability	21	Discuss the generalisability (external validity) of the study results Page 12-13
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based Page 14

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.