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Realist evaluation of a complex integrated care program: a study protocol

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Abstract

Introduction

Due to the lack of acceptable methods of evaluation for complex integrated care programs, the net benefits of such interventions and understanding of how these are achieved remain uncertain. This leads to difficulties in the development, implementation, adaptation and scaling up of similar interventions. In this study, we evaluate an integrated care network, the National University Health System (NUHS) Regional Health System (RHS), consisting of acute hospitals, step down care, primary care providers, social services, home care and community partners using a theory driven realist evaluation approach. We examine the implementation fidelity and effectiveness of its constituting programs and gather evidence to inform future interventions within NUHS-RHS. By using a realist approach that balances the needs of context-specific evaluation with international comparability, this study carries the potential to address current research gaps.

Methods and Analysis

The context, mechanism and outcomes of the NUHS-RHS are examined using a convergent parallel mixed method study. First, the context and working mechanisms that underpin the NUHS-RHS will be assessed through ethnographic observations of events, interviews with stakeholders and surveys. Second, implementation fidelity and outcomes of specific programs of the NUHS-RHS will be assessed through program document reviews, ethnographic observations of the conduct of program activities, structured interviews with program team members and healthcare users and prospective surveys with healthcare users. Data collected will be analysed according to the formula used in realist evaluation, findings on the context, mechanisms and implementation fidelity will be used to explain the outcomes.

Ethics and dissemination

The National Healthcare Group, Singapore, Domain Specific Review Board (DSRB) reviewed and approved this study protocol. Study results will be published in international peer reviewed journals and presented at conferences and internally to NUHS-RHS and Ministry of Health, Singapore.

Keywords: Realist Evaluation, Integrated Care, Mixed Methods Evaluation

Strengths and limitations of this study

- This study provides the first opportunity to holistically evaluate the NUHS-RHS, and one of the first to conduct a comprehensive evaluation of a new integrated care network in the context of South-East Asia.
- By adopting a theory-driven realist evaluation approach, findings from this study are expected to generate contextually relevant evidence for improving efficiency and effectiveness of integrated care in Singapore and similar health system. It is also expected to yield policy-relevant insights for national-level decision makers as they continue to monitor and refine integrated care models for Singapore over the coming years.
- The use mixed methods in this study allows us to draw on the strengths of both qualitative and quantitative methods, while overcoming the limitations of either methods if used alone. This enhances the credibility of the evaluation findings and allows for generation of in-depth insights.
- In designing this evaluation, relevant stakeholders including program team members, healthcare managers and policymakers were engaged, this provide confidence that the evaluation efforts are relevant and findings are likely to be adopted for improvement in current models and for development of future initiatives.
- While mixed methods design has been advocated for the evaluation of complex healthcare interventions, it is a relatively new method in comparison to the RCTs commonly used in the evaluation of medical interventions. Due to the lack of familiarity on the use of mixed methods in the field of health and healthcare research, this study design may draw criticism for not being as rigorous as the typical Randomized Controlled Trial (RCT).
- The use of mixed methods design increases complexity especially in terms of data analysis. Nonetheless, we strive to reach optimal integration of data at multiple levels – study design, methods, interpretation and reporting – using the convergent parallel mixed methods approach which connects and merges methods and findings.
- As participation in the evaluation efforts is voluntary and only individuals who are able or have proxies who are able to provide informed consent are included in this evaluation effort, we also recognize that selection bias may be introduced in this study. To account for selection bias, demographic information including age, gender, ethnicity and role (for healthcare providers) are collected and will be compared between responders and non-responders

Introduction

Across the world, rapidly aging populations and increasing demand for healthcare services call for a paradigm shift from disease-centered healthcare provision to more holistic, people centered care [1]. People centered care involves putting people and communities, not diseases as the focus of health systems. It highlights the importance of empowering people to take charge of their health, takes into account holistic needs of a person and seeks to provide quality care timely and appropriately [2]. Integrated care supports people centered care by coordinating healthcare services in a way that ensures people receives a continuum of care at the different levels and sites of care within the health system according to their needs. As characterized by Valentijn et al., care integration can take place on many dimensions: at the micro-level clinical level, the meso-level professional or organizational level and the macro or systemic level [3]. As such, the types of interventions that qualify under the wide umbrella of "integrated care" vary tremendously, as do the settings in which they are introduced and their attendant benefits and costs. Moreover, introducing integrated care often calls for complex, multi-component programs that involve many stakeholders, sometimes with conflicting perspectives and interests. When implemented successfully, integrated people centered health services can be more effective, cost less, improve patient engagement and better prepared to respond to increasing demands for healthcare services [4].

However, despite these growing needs and the availability of basic design principles related to integrated care, the development and implementation of such care models remains challenging. In every instance, there is a need for healthcare providers and organizations to understand which care models work, for whom and how they work in the unique setting in which integrated care is planned for a particular population. Current evaluations such as the "gold-standard" Randomized Controlled Trial (RCT) design rarely adequately or even explicitly address the context-specific drivers behind implementation outcomes and their relationship to the underlying program theory, making it difficult to interpret their findings in light of other programs in different settings. As a result, few evaluation strategies are widely-accepted as appropriate, and to date, the net benefit of integrated care interventions and understanding of how these are achieved remains empirically uncertain. It is therefore essential to develop comprehensive, rigorous and practical methods to evaluate person-centered integrated care programs, not to just inform the selection of effective and efficient interventions but also to facilitate improvement and scaling-up.

Realist evaluation, as first suggested by Pawson and Tilley, is a theory-driven based approach used to assess interventions which are assumed to be embedded in a social reality that influences how the intervention is implemented and how various actors in that reality respond to it [5]. A realist program theory specifies not only the outcomes are linked to the intervention, but also what mechanisms generate the outcomes and what features of the context affect them. The context-mechanism-outcome (CMO) configuration is used as the main structure for analysis, with the goal of identifying both causal mechanisms and contextual factors associated with variation in outcomes [6]. As such, a realist evaluation should include a theory-driven formative evaluation [7], process evaluation [8] as well as outcomes evaluation, and should avoid the rigorously successionist format of experimental design. Pawson and Tilley argue that an intervention can only achieve successful outcomes if appropriate ideas are applied to the right context with appropriate social and cultural conditions. Realist evaluation is increasingly applied to the evaluation of complex healthcare interventions as it seeks to provide a more explicitly and in-depth understanding of what works, for whom and in what circumstances [5].

Singapore is typical of many other countries with a rapidly aging population that is accompanied by an increasing prevalence of chronic and complex illnesses [9] . Designed with an emphasis on providing episodic care within acute hospitals in a largely disease specific manner and controlling infectious disease in a young population, Singapore's health system now faces the challenge of ensuring appropriate care and long-term fiscal sustainability for a long-lived population at increasing risk of multiple chronic diseases[10]. In addition, having already reached the highest levels of efficiency in the world[11], simple or easy fixes to increase performance while keeping costs low are increasingly rare. A radical change in vision and strategy is therefore needed, requiring complex systems-level interventions that break down existing siloes to refocus on prevention, primary care, and community-based management. Such interventions will need to be built on a strong foundation of integrated care.

Therefore, in 2012, the Ministry of Health (MOH) Singapore launched a major initiative to reorganize healthcare at the national level into six clusters or Regional Health Systems (RHS) to foster care integration [12]. This was recently reorganized in 2017, into three integrated clusters to better meet future healthcare needs [13]. Every RHS comprises of a network each led by a major public hospital working in close partnership with health care providers (primary care providers, community hospitals, nursing homes, home care and day rehabilitation providers) and social care providers (including Senior Activity Centers, Grassroots organizations and Social Service Offices) within the same geographical region. Each RHS has the mandate and funding support to design and implement integrated care programs that leverage this network to provide healthcare beyond the hospital to the community, value-driven healthcare and holistic care across the entire care continuum in a cost-effective way [14]. To support this common vision, every RHS was tasked to implement programmes identified by the MOH to be of priority and held accountable for same outcomes jointly agreed on between the MOH and the RHSes throughout the country. Following this lead, each RHS implemented the priority programs tailored to the unique needs and demographic of the population in which it serves as well as the different strengths of community partners within its network. Other programs unique to respective RHSes were also developed and implemented accordingly.

In this study, we propose to take advantage of a unique opportunity to document and evaluate the formation and implementation of a multi-pillared regional integrated care network. This evaluation study began in June 2016 at the National University Hospital System (NUHS)- RHS, the RHS at the western part of Singapore. The evaluation will be conducted using a realist evaluation approach, which seeks to test and refine the program theory while assessing whether and how the program succeeds in the local setting, in order to generate important insights not just for Singapore but for the wider field of integrated care research.

Specific Aims

The specific aims of the evaluation are

(i) To examine the nature and working mechanisms of the NUHS Regional Health System (RHS) as an integrated care network;

(ii) To examine the implementation fidelity and effectiveness of its constituent programs;

(iii) To gather evidence to inform future interventions targeted at individuals with multiple chronic conditions.

Research Questions

In accordance with the aims of the evaluation, this study is designed to answer the following research questions at two levels i.e. the level of RHS and level of its individual programs respectively:

1. **Level of RHS**: How does the NUHS-RHS work to achieve its intended outcomes according to various stakeholders involved?
2. **Program Level**:
    a. Have the NUHS-RHS programs been implemented as intended? What are the moderating factors and barriers in the implementation of the programs?
    b. What are the effects of the NUHS-RHS programs on healthcare utilization, healthcare outcomes and care experiences?
    c. What are the effects of NUHS-RHS programs on healthcare cost?

Methods and Analysis

Considering the developmental nature of the NUHS-RHS, this evaluation is designed primarily as a formative evaluation which incorporates outcome valuation principles [15]. Evaluation findings will be used to further improve the health system as it continues to develop. The realist evaluation approach is adopted to provide the overall methodological guide. Beyond the assessment of whether the NUHS-RHS has achieved its intended outcomes, this evaluation is also designed to answer how and why NUHS-RHS and its constituting interventions work, or do not work, by examining the context (C), mechanism (M) and outcomes (O) of the NUHS-RHS.

A logic model depicted in Figure 1 provides the graphical description of the NUHS-RHS and how it is expected to work to achieve its intended outcomes. It is used as the basis of evaluation and as a guiding tool to focus our evaluation activities. This logic model is designed in collaboration with the RHS strategic planning office together healthcare providers.

As illustrated under activities on Figure 1, programs (P1-6) describes the MOH priority programs implemented nationally. The NUHS-RHS Integrated Interventions and Care Extension (P1) program aims to help patients with complex conditions who were admitted at least three or more times a year through a holistic case management. NUHS Transition Care Program (P2) was implemented to enable patients to transit smoothly from hospital to homes through a multidisciplinary team to ensure continuity of care. Appropriate Sitting of Care (P3 and P4) aims to ensure appropriate sitting of patients who are medically stable and deemed to not required specialist care from acute hospital to the community through partnership with primary and community care providers. Health Promotion and Disease Management (P5) focuses on health education, early detection of chronic diseases and timely interventions to prevent development of chronic illnesses as well as slow down the deterioration of diseases. Strengthening of primary and community care within the NUHS-RHS (P6) is achieved through cross deployment of skilled manpower from the acute hospital to the partnering primary and community

care providers so as to improve the capability and confidence of the partners of the NUHS-RHS. Leveraging on tele-health and IT enablers, the Carehub aims to provide a single point of contact through individual's continuum of care post hospital discharge. The Primary Care Network (PCN) brings together a group of family physicians and community partners to create a support network for patients with chronic medical conditions in the community [16].

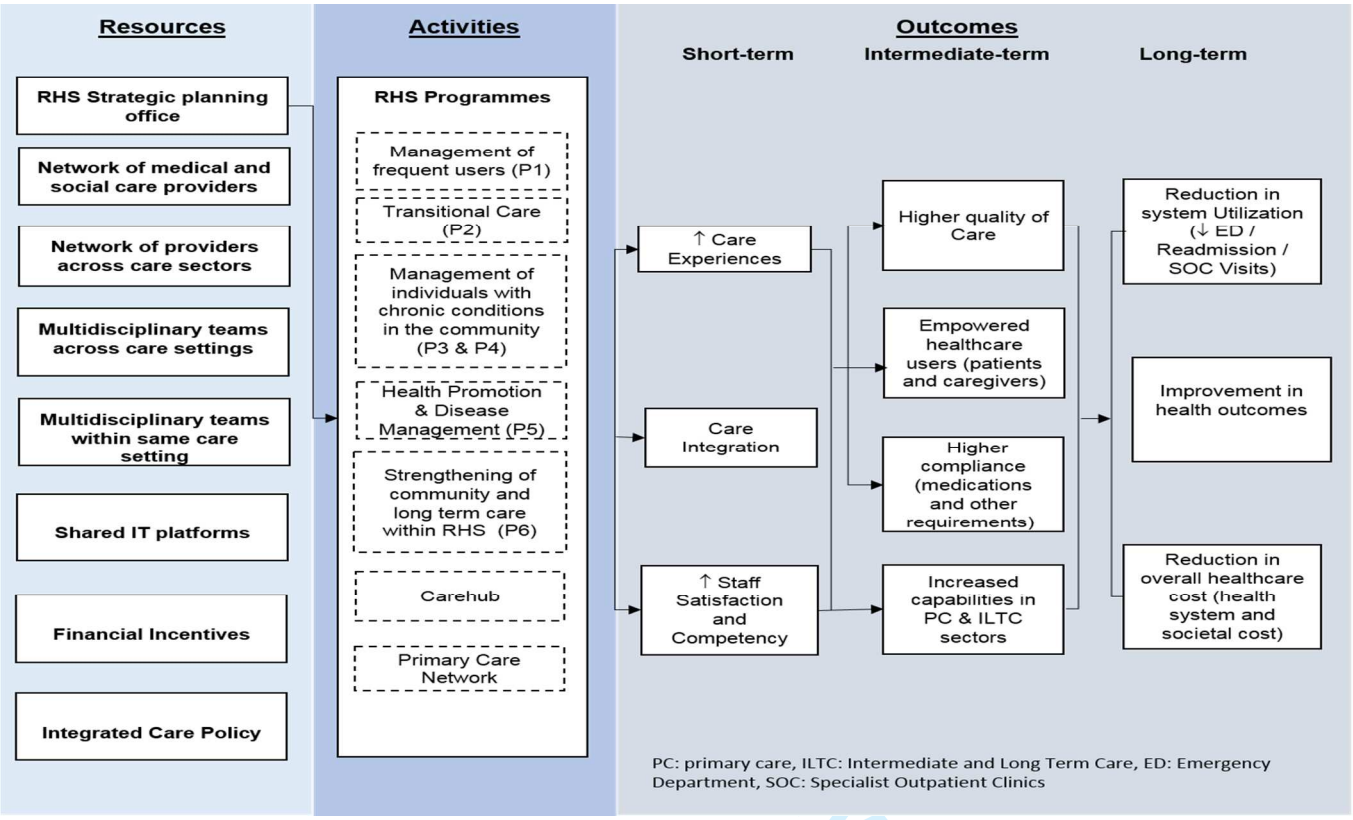

Figure 1: Logic model of NUH-RHS

Prioritization of NUHS-RHS Programs for Evaluation

As the number of programs undertaken under the purview of the NUHS-RHS is large, programs were prioritized for evaluation in consultation with stakeholders including healthcare providers and administrators, based on (i) maturity of program, (ii) urgency for evaluation, (iii) complexity of programs and (iv) scientific importance.

Program maturity was assessed based on the duration of program implementation. A program that had been implemented for a longer duration was considered to more mature and given higher priority than one which was recently implemented. Programs nearing the end of their funding period were also given higher priority for evaluation, as evaluation was essential to inform the future development of the program. Complexity was determined by assessing the number of dimensions of integrated care as defined previously (clinical, professional, organizational, systematic, normative and functional integration) [3]. A program that set out to

integrate care in more dimensions was considered to be more complex than one which integrated care in fewer dimensions.

Finally, scientific importance was examined by a knowledge gap analysis conducted by reviewing available published articles relevant to these programs on PubMed. A program with the least number of relevant articles was considered to be of greatest scientific importance. According to these criteria, MN and HJMV ranked various NUHS-RHS programs as low, medium and high priority for evaluation. Through the priority-setting process, four programs, P1, P2, P3 and P4, were identified to be the best candidate programs for evaluation.

Study Design

A convergent parallel mixed methods study will be conducted at two levels (Figure 2). First, the context and working mechanisms that underpin the NUHS-RHS as a whole will be assessed through ethnographic observation of management meetings, interviews with stakeholders and surveys to assess the level of integration from providers' perspectives. Second, implementation fidelity and outcomes of the four specific programs will be assessed. Overall fidelity of the respective NUHS-RHS programs will be examined through program document reviews, ethnographic observations of program activities and structured interviews with program team members and healthcare users. Structured interviews with the beneficiaries of the programs and time series analysis of the changes in outcomes associated with the various programs will be conducted.

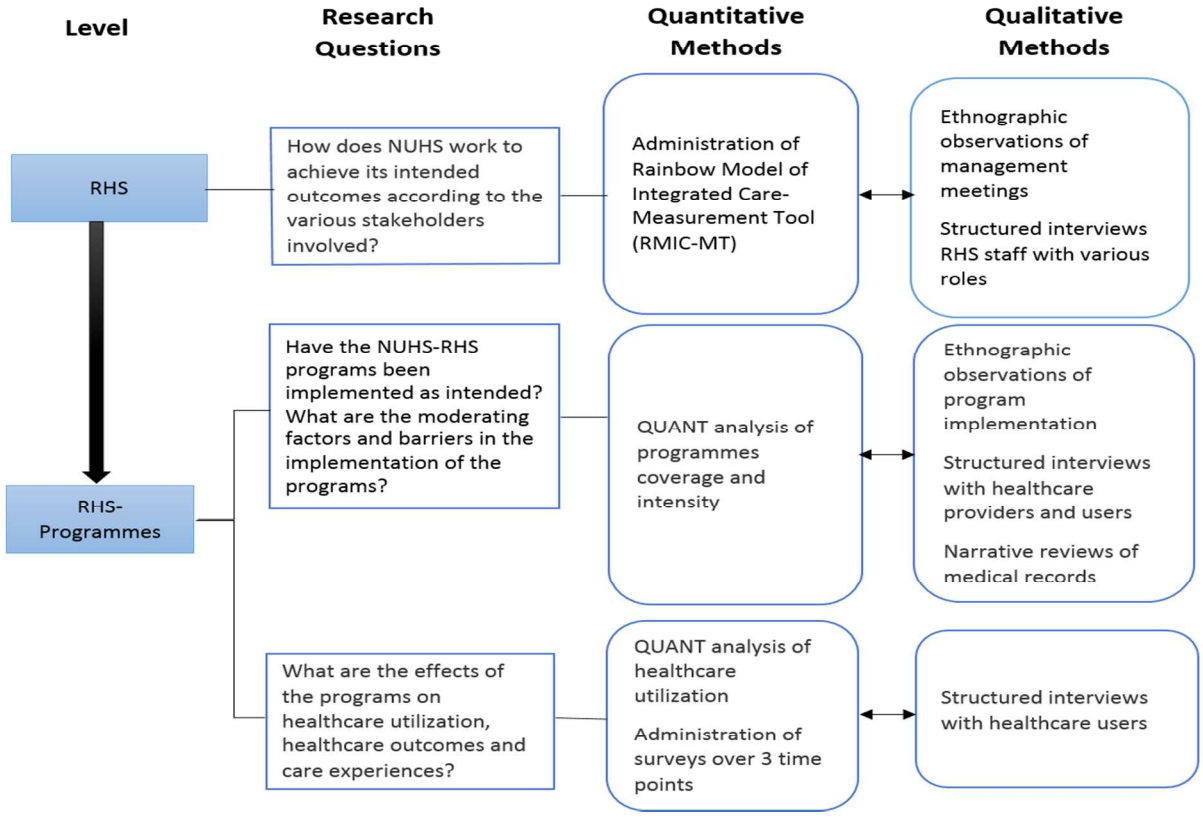

Figure 2: Convergent Parallel Mixed Methods Design of NUHS-RHS Evaluation

Study population

Two distinct groups of study participants – healthcare providers/managers and healthcare users – are selected based on defined criteria in this study. Healthcare providers/managers who are a part of the governance, planning and implementation of the programs are invited to take part in structured interviews and to complete the online Rainbow Model of Integrated Care (RMIC) survey [17], while healthcare users, including patients or proxies (caregivers), are invited for structured interviews or prospective surveys over three time points. Interactions between healthcare providers and healthcare users will be observed.

Study Procedures

Research Question 1: How does NUHS-RHS work to achieve its intended outcomes from the perspectives of various stakeholders involved?

Measures

The RMIC [3], a comprehensive framework for care integration has been adopted to guide data collection and analysis to answer research question 1. Developed through a systematic literature review and validated by international Delphi panels, the RMIC describes six dimensions of care integration (clinical, professional, organizational, functional and normative integration) across different levels within a health system needed to provide a continuous, comprehensive and coordinated delivery of services to the individual and population [18]. Based on the RMIC, the working mechanism of the NUHS-RHS will be examined through ethnographic observations of team meetings and interviews with healthcare providers, and administration of the RMIC measurement tool (MT) adapted to Singapore [17 19]. Observation notes will be taken and interviews will be audio recorded and transcribed. Tested and validated in Singapore, the RMIC-MT was developed to measure the extent of care integration from the healthcare providers' perspectives. It consists of 62 items grouped into eight factors of integrated care related to person-focused and population-based care, clinical integration, professional, organizational, systematic, functional and normative integration. The RMIC-MT uses a four point Likert scale ranging from "never" to "all the time" and an additional option of "not sure/don't know" [17].

Analysis

Observation notes and interview transcripts will subsequently be thematically coded by two independent researchers using a two-step approach. The first step consists of a deductive analysis, where units of data are coded according to the RMIC. This will be followed by an inductive analysis, where new themes or unexpected findings are elicited through coding and categorizing.

Incomplete RMIC-MT will be excluded from analysis and missing data will be imputed with median score of each item. Then, the RMIC-MT will be scored according to the eight dimensions of RMIC as described above and as

the total score of integrated care. The extent of integrated care within NUHS will be compared against the extent of integrated care in other health systems in which the RMIC-MT has been administered. After which, data collected qualitatively and through the RMIC-MT would be merged according to the RMIC to answer research question 1.

Research Question 2: Have the programs been implemented as intended? What are the moderating factors for the implementation of the programs?

Measures

The modified version of the Conceptual Framework of Implementation Fidelity (CFIF) [20] highlights important mechanisms and moderating factors for implementation of complex interventions, and is adopted to guide data collection and analysis to answer research question 2. Content, frequency and dose of program implementation and the moderating factors affecting implementation fidelity, including participant responsiveness, intervention complexity, comprehensiveness of policy description, strategies to facilitate implementation, quality of delivery, recruitment and context will be assessed. Data will be gathered through reviews of program documents, medical records, structured interviews healthcare providers and observations of actual delivery of interventions as described in Table 1.

	Specific component	Data sources
Adherence	Content	Ethnographic observation, medical records review and interview with program team members
	Frequency / duration	Medical records review, interview with program team members and healthcare users
	Coverage	Program databases, interview with program team members
moderating factors	Participant responsiveness	Ethnographic observation, interview with program team members and healthcare users and possibly medical records review (if recorded)
	Intervention complexity	Program documents (protocols, guidelines)
	Comprehensiveness of policy description	Program documents (protocols, guidelines)
	Strategies to facilitate implementation	Interview with program team members
	Quality of delivery	Interview with healthcare users
	Recruitment	Program database, interview with program team members

	Context	Interview with program team members

Table 1: Assessment of Implementation Fidelity of NUHS-RHS programs

Program documents including guidelines and databases will be reviewed by evaluators. Program guidelines will be examined to provide an understanding of the planned activities for each program and the proposed mechanisms of achieving targeted outcomes. The number of eligible patients referred, response rate, reasons for non-enrolment into the programs, frequency of program delivery as well as duration of enrolment will be retrieved from the existing program databases to determine the coverage, frequency and duration of respective programs. Furthermore, medical records of patients enrolled into the programs will be reviewed to provide a comprehensive picture of patient's healthcare journey from enrolment to discharge. Medical records will be proportionately sampled based on the number of healthcare providers that are able to provide referrals within each program and the time point at which patients are enrolled into the programs.

Healthcare providers (physicians, nurses, and other allied health professionals), and healthcare managers (care coordinators and healthcare administrators) who are involved in the planning, development and implementation of the four programs are invited to participate in face-to-face structured interviews. Written informed consent and demographic information including their age, gender, duration of involvement and roles will be collected prior to the interviews. Guided by the CFIF, content of interventions and moderating factors, which may have contributed or hampered the implementation of the interventions, will be assessed during interviews. All interviews will be audio-recorded, transcribed verbatim and coded thematically.

Two sessions of ethnographic observations (induction and follow up) for each study participant will be randomly conducted at patients' homes and/or through phone calls depending on where and how the interventions are provided. We expect to observe two sessions each for approximately 30 participants from each program and informed consent will be obtained from participants. Content of care delivery, interactions between healthcare professionals and users together patients' responses to the service will be observed. For each session, field notes will be taken, findings will be written in narratives and analyzed thematically.

Analysis

Data from the various sources will subsequently be analyzed according to the modified version of the CFIF. The extent of which the intervention components were implemented will be rated on a 5-points Likert scale ranging from never to always by two independent evaluators. Potential moderating factors which affect the implementation of the programs will be assessed by examining participant responsiveness, comprehensiveness of protocols/guidelines, support available to facilitate recruitment and implementation, quality of service delivery and context (patient, professionals, organizational, political and economic factors).

Questions 3: What are the effects of the programs on healthcare utilization, healthcare outcomes and care experiences?

Measures

The Chronic Care Model (CCM) identifies the community, the health system, self-management support, delivery system design, decision support and clinical information systems as key elements of a health system that are essential to provide good quality chronic care [21]. Healthcare utilization, healthcare outcomes and patients reported experiences and outcomes associated with the NUHS-RHS programs will be assessed through review of clinical indicators, structured interviews and administration of surveys as described below, to identify alignment with the CCM.

The effect of the program on healthcare utilization will be measured by analyzing the number of admissions, Emergency Department (ED) attendance, number of specialist outpatient clinic (SOC) attendances, average bed days, for patients enrolled from the start of the programs. To capture the potentially evolving nature of the programs and their effects, data will be collected over various time points with respect to their respective date of enrollment program– 12 months before (T-12), 9 months before (T-9), 6 months before (T-6), 3 months before (T-3), date of enrolment (T0), 3 months after (T3), 6 months after (T6), 9 months after (T9), 12 months after (T12) and 15 months after (T15). Demographic information (gender, age, race, comorbidity and socio-economic status) will also be retrieved for all patients.

Clinical indicators at various time points for all patients who are enrolled and decline will be extracted from the existing NUHS-RHS databases. In reference to the point of patients' enrolment into the programs, clinical indicators at T-12, T-9, T-6, T-3, T0, T3, T6, T9, T12 and T15 will be extracted. In addition, 8-item Morisky Medication Adherence Scale (MMAS-8) will be used to assess patients' compliance to prescribed medications [22]. The MMAS-8 is a structured self-report measure of medication-taking behaviour that has been widely used in various cultures and is considered a gold standard of measurement [23].

The effect of the programs on patient- reported outcomes, patients' quality of life, care experience and self-efficacy will be assessed using validated survey instruments over 3 time points, at the starting point, mid-way and the end of the program. Quality of life of patients will be assessed using the EuroQol- 5 Dimension (EQ-5D) instrument. The EQ-5D consists of 5 items, which recognizes the fundamental importance of independent physical, emotional and social functioning, as part of a more holistic view of health. It has been validated in Singapore and is a common measure used to assess quality of life as the result of healthcare interventions [24]. Patients' perception of the quality of care received will be examined using the Patient Assessment of Care for Chronic Conditions (PACIC) [25]. The PACIC seeks to understand the frequency with which various aspects of care patients with chronic conditions received from their healthcare providers aligned with components of the Chronic Care Model (CCM). The healthcare providers include regular doctors, nurse, care coordinators, allied health providers and others. PACIC has been widely validated and used at various healthcare settings across the world [26-29].

Patients' experience of care continuity will be assessed using the CCAENA (Continuity of care between care levels) questionnaire. The CCAENA consists of 29 items and assesses continuity of care across different levels from the patients' perspectives [30]. The components covered by the CCAENA include the relationships between patient and primary care providers, and between specialists and primary care providers. Finally, self-efficacy is measured using the Patient Activation Measure (PAM), which consists of 13 items will be used to measure patient knowledge, skill, and confidence for self-management [31].

Complementary to the quantitative analysis of outcomes, a more in-depth understanding of healthcare users' perception of healthcare quality, including why and how it has worked, or did not work, will be explored qualitatively through interviews with healthcare users. Healthcare users including patients and their family members who have had experiences with the programs for at least 3 months are invited to take part in face to face interviews. Interviews are structured according to the program logic model, and key components of the Chronic Care Model (CCM) [21]. Perception of the level of care integration as well as recommendations for improvement to the programs will also be elicited during the interviews. Potential participants will be recruited through care coordinators and will be screened against the selection criteria by the study team prior to the interviews. Only those who are eligible and are willing to be audio recorded will be interviewed. Written informed consent and demographic information will be attained from the participants before proceeding with the interviews. Interviews will be conducted in English, Chinese or Malay at the patients' homes or at NUHS. Notes will be taken during observations and all interviews are audio recorded, transcribed verbatim and will be imported to Atlas.ti 7.0 for analysis.

Analysis

To examine the effects of the NUHS-RHS programs on healthcare utilizations, healthcare outcomes and care experiences, interrupted time series analysis (ITSA) will be conducted for all programs. In addition, difference in difference (DID) analysis will be conducted for those with comparison groups [32 33]. Proposed to be more flexible compared to the traditional randomized controlled trials analysis, the ITSA is conducted to estimate the changes associated with the introduction of interventions over time. To estimate changes in the above outcomes, time series regression that includes data from patients enrolled into the programs 1 year prior to and after referral to the programs will also be run. The model will have 3 main parameters: 1. Estimation of the annual trend in healthcare utilization (i.e. hospital admission, SOC attendances, ED attendances and average bed days) and clinical indicators one year before until the introduction of the programs 2. Estimation of changes in all outcomes associated with introduction of the programs; 3. The trend change in outcomes associated with each year. For each outcome, we will apply a generalized estimating equation model clustering by the combination of age, sex, and comorbidity score with robust standard errors and an autoregressive correlation matrix. We will report rate ratios (RRs) calculated from the parameter estimations, which represent population-averaged rates. DID analysis will subsequently be performed to estimate the impact of the programs by comparing differential effects

in the outcomes between intervention and comparison groups. Sensitivity analyses will be performed and confounding effects will be accounted for.

Observation notes and interview transcripts will be thematically coded by two independent researchers using a two-steps approach. The first step consists of a deductive analysis, where units of data are coded according to the CCM. This will be followed by an inductive analysis, where new themes or unexpected findings are elicited through coding and categorizing. If the interviews were conducted in other languages beside English, these will be transcribed and the analysis will be conducted by a researcher that is fluent in that language. The relevant quotes representative of the analysis will then be translated into English. Subsequently, data collected through prospective surveys and interviews with healthcare users will be merged using the CCM as a framework.

Research Question 4: What are the effect of NUHS-RHS programs on healthcare cost?

Measures

Six categories of costs including (i) development costs (ii) program implementation costs (iii) healthcare utilization costs (inpatient, outpatient and community) (iv) productivity costs incurred to patients and/or caregivers (v) travel costs borne by patients for travelling to receive care and (vi) caregiving cost will be collected [34]. Costs categories (i), (ii), (iii) are considered costs related to the healthcare system whereas categories (iv)-(vi) take into account costs from the societal perspective.

Development costs include costs incurred during the development of the NUHS-RHS and their respective programs. The program implementation costs take into account costs related to the implementation of the programs including the manpower costs, travel costs, costs of equipment, and costs of materials used for patient and caregiver training and costs associated with multidisciplinary team meetings. The development and implementation costs will be systematically collected using WHO's CostIt instrument [35] and will be divided by the number of clients included into the programs to obtain per patient cost.

The cost of healthcare utilizations (hospital inpatient, outpatient services, primary and community care services), productivity costs (estimated based on absence from paid employment due to illness or providing care), travel costs (distance to healthcare providers and expenses incurred related to providing care to enrolled patients) and caregiving costs (cost related to the hire of domestic helpers, costs related to improvement in home environment and costs of caregiver training) will be collected using routinely collected hospitals data and a cost questionnaire administered to participants at T0 and T12 where each participant will be asked to recall his/her expenses 3 months prior to the time of the interview.

Analysis

After, differences in costs according to their categories before and after enrollment in NUHS-RHS programs will be analyzed using paired Wilcoxon tests. The difference will be considered statistically significant if the p-value < 0.05. Paired analysis will be adjusted by age, gender and number of co-morbidities at baseline. To estimate the cost-effectiveness of the right-site care programs, changes in quality of life as measured in Quality adjusted life years (QALYs) obtained based on the EQ-5D will be used as the measure of program effectiveness and incremental cost-effectiveness ratio (ICER) will be computed. The ICER will be estimated based on changes in health system and societal costs divided by the mean of changes in QALYs. The program will be considered

cost effective if the ICER is lower than Singapore-specific thresholds. Currently, in the absence of a formal nationally-accepted threshold, we will adapt a default threshold consistent with WHO CHOICE benchmarks of approximately $60-75000 per QALY[36] The appropriate cost-effectiveness thresholds will be reviewed and updated to be consistent with national best practice at the time of completion of the analysis.

Data Integration

Finally, to provide an overall evaluation of the NUHS-RHS taking into consideration various perspectives, qualitative and quantitative data obtained from various stakeholders including the program team members and patients/proxies will be integrated. The study team will first analyze the data collected for the individual research questions 1-4, using the respective guiding conceptual framework for each research question. Assessment of the fit of data integration will be conducted by examining the coherence of findings from various methods used, as suggested by Fetters et al [37]. Next, study findings from research questions 1 and 2 on the context and working mechanism of NUHS-RHS and implementation fidelity of the programs will be used to explain the outcomes for research questions 3 and 4, using the CMO formula of the realist evaluation method. A few potential CMO configurations will then be proposed and discussed (for validation purposes) through 2-3 focus group discussions comprising of 8-10 different stakeholders each. This approach is expected to enable the study team to make firm recommendations.

Ethics and dissemination

Data collection for this study was started in June 2016 and is expected to continue until June 2019. The National Healthcare Group, Singapore, Domain Specific Review Board reviewed and approved this study protocol Board (DSRB Ref: 2016/00410 and 2016/00914). Written informed consent forms are obtained from participants (healthcare providers and users) included for interviews and surveys. To maintain confidentiality of the research participants, identifiable information obtained from research participants are kept securely under password protection. A unique respondent identification is assigned to each study participant so that data can be processed anonymously. Waiver of informed consent was obtained for analysis of retrospective data collected as part of the hospital and Ministry of Health (MOH) routine data collection and no identifiable data are known by the researchers. Study results will be written up and published in international peer reviewed journals and will be presented at national, international conferences and internally at NUHS-RHS and the MOH, Singapore

Mitigation of Potential Risks and Limitations

While mixed methods design has been advocated for the evaluation of complex healthcare interventions, it is a relatively new method in comparison to the RCTs commonly used in the evaluation of medical interventions. Due to the lack of familiarity on the use of mixed methods in the field of health and healthcare research, this study design may draw criticism for not being as rigorous as the typical RCT. Furthermore, we acknowledge that the use of mixed methods design also increases complexity. Nonetheless, we strive to reach optimal integration of data at multiple levels – study design, methods, interpretation and reporting – using the convergent parallel mixed methods approach which connects and merges methods and findings.

Furthermore, as participation in the evaluation efforts is voluntary and only individuals who are able or have proxies who are able to provide informed consent are included in this evaluation effort, we also recognize that selection bias may be introduced in this study. To account for selection bias, demographic information including age, gender, ethnicity and role (for healthcare providers) are collected and will be compared between responders and non-responders. Given the prospective nature of some of our data collection methods, difficulties in following up with respondents are also anticipated. To minimize the numbers lost to follow up, research appointments are scheduled at participants' time and place of convenience in collaboration with participants' care coordinators. In the event when loss to follow is inevitable due to death, survival analysis will be conducted to account for the missing data.

In addition, it must be acknowledged that as much as it was intended for the delivery of care to be consistent, variability in the extent of how care was provided exists, especially across different disease specific subprograms and also within individual sub-program. To account for such variability, subgroup analysis will be conducted and adjustments based on the number of care providers within a subprogram will also be made.

Discussion

Singapore is in the early phase of developing new integrated care models. Notwithstanding the scope of more general design principles of integrated care, development and implementation of integrated care requires adaptation to the context, needs of the local population and the capacity and capability of local healthcare providers. To the best of our knowledge, this study provides the first opportunity to holistically evaluate the NUHS-RHS, and one of the first to conduct a comprehensive evaluation of a new integrated care network in the context of South-East Asia.

Given the complex nature of integrated care programs and the research questions of this study, mixed method research was adopted to provide a holistic and in-depth evaluation to generate insights applicable for various stakeholders. The use of both quantitative and qualitative methods in the validation and confirmation of findings will allow us to draw on the strengths of both methods, while overcoming the limitations of either methods if used alone. This enhances the credibility of the evaluation findings and allows for generation of in-depth insights.

This study carries significant implications for the health system and society in Singapore as well as for the field of integrated care internationally. By ensuring the rigor of this evaluation and adopting a realist approach, findings from this study are expected to generate contextually relevant evidence for improving efficiency and effectiveness of the NUHS-RHS as it develops and also to inform future initiatives of the NUHS. It is also expected to yield policy-relevant insights for national-level decision makers as they continue to monitor and refine the RHS model for Singapore over the coming years. In designing this evaluation, stakeholders including program team members, healthcare managers and policymakers were engaged to help evaluators understand the context in which the programs were implemented, how interventions have been delivered, to define objectives, evaluation questions and outcomes which are relevant to the stakeholders and to identify constraints to the feasibility of implementation of the evaluation itself. Various potential pitfalls in evaluation design and

implementation have been collectively identified and risk management strategies put into place wherever possible. This provides confidence that the evaluation efforts are rigorous, relevant and has the potential to provide insights for program improvement as well as provide evidence to support policy decisions to scale-up/down activities within NUHS. Engagement of stakeholders early in the evaluation efforts is also expected to increase the likelihood that recommendations will be adopted to improve the relevant components of the existing care models and define future new care models. On the other hand, the involvement of stakeholders may exert pressure to act on preliminary findings. Understanding these dynamics will also be of interest as part of the evaluation itself.

Like NUHS, other integrated care networks within Singapore and abroad are experimenting with new integrated care models. However, the findings from existing research of the (cost-)effectiveness of integrated care are to a major extent inconsistent because of the variations in the strategic outcomes, methods of implementation, contexts (i.e. system and policy) and/or applied evaluation measures. Examples include next generation accountable care organisations in the United States [38], integrated care pioneers and vanguard sites in England [39] [40], population health management pilots in the Netherlands [41], integrated care pilots in Belgium [42] and theintegrated care demonstrators in Australia [43]. This study provides an opportunity to fill some of the gaps in current research by evaluating the NUHS-RHS and its constituent programs using a rigorous and comprehensive design that balances the needs of context-specific evaluation with international comparability. Wherever possible, steps such as using internationally validated instruments for evaluation of chronic disease are taken, to allow for meaningful international comparisons that can increase collective knowledge about the restructuring of chronic care models towards advancing integrated care.

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Authors' contributions
SAT, TW and HJMV initiated the study and HJMV conceptualized the study. HJMV and MN designed and constructed the first draft of study protocol. ST, SHW, KMF, SAT, TW and JY reviewed study protocol and provided feedback for the refinement of the protocol. MN, PS, AL, XYL, ST, SHW and KMF are involved in data collection and MN, PS, XYL and FS will be involved in data analysis related to this study. MN wrote up the first draft and final version of the manuscript. All authors read, provided suggestions for revision and approved the final manuscript.

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Data sharing statement
For access to the data set, a formal request should be sent to the corresponding author. The request will only be considered when the primary results of the study have been published

Competing Interests
ST, SHW, KMF, SAT and TW are a part of the NUHS-RHS strategic planning office which is involved in the planning and development of programmes under the purview of the NUHS-RHS.

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Realist evaluation of a complex integrated care program using a mixed method study protocol

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Realist evaluation of a complex integrated care program using a mixed method study protocol

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Abstract

Introduction

The lack of understanding on how complex integrated care programs achieve their outcomes due to the lack of acceptable methods leads to difficulties in the development, implementation, adaptation and scaling up of similar interventions. In this study, we evaluate an integrated care network, the National University Health System (NUHS) Regional Health System (RHS), consisting of acute hospitals, step down care, primary care providers, social services and community partners using a theory driven realist evaluation approach. This study aims to examine how and for whom the NUHS-RHS works to improve healthcare utilisations, outcomes, care experiences and reduce healthcare costs. By using a realist approach that balances the needs of context-specific evaluation with international comparability, this study carries the potential to address current research gaps.

Methods and Analysis

This evaluation will be conducted in three research phases: 1. development of initial program theory (IPT) underlying the NUHS-RHS; 2. testing of program theory using empirical data; 3. refinement of IPT. IPT was elicited and developed through reviews of program documents, informal discussions and in-depth interviews with relevant stakeholders. Then, a convergent parallel mixed method study will be conducted to assess context (C), mechanisms (M) and outcomes (O) to test the IPT. Findings will then be analyzed according to the realist evaluation formula of CMO in which findings on the context, mechanisms will be used to explain the outcomes. Finally, based on findings gathered, IPT will be refined to highlight how to improve the NUHS-RHS by detailing what works (outcome), as well as how (mechanisms) and under what conditions (context).

Ethics and dissemination

The National Healthcare Group, Singapore, Domain Specific Review Board (DSRB) reviewed and approved this study protocol. Study results will be published in international peer reviewed journals and presented at conferences and internally to NUHS-RHS and Ministry of Health, Singapore.

Keywords: Realist Evaluation, Integrated Care, Mixed Methods Evaluation

Strengths and limitations of this study

- This study provides the first opportunity to holistically evaluate the NUHS-RHS, and one of the first to conduct a comprehensive evaluation of a new integrated care network in the context of South-East Asia.
- By adopting a theory-driven realist evaluation approach, findings from this study are expected to generate contextually relevant evidence for improving efficiency and effectiveness of integrated care in Singapore and similar health system. It is also expected to yield policy-relevant insights for national-level decision makers as they continue to monitor and refine integrated care models for Singapore over the coming years.
- The use mixed methods in this study allows us to draw on the strengths of both qualitative and quantitative methods, while overcoming the limitations of either methods if used alone. This enhances the credibility of the evaluation findings and allows for generation of in-depth insights.
- In designing this evaluation, relevant stakeholders including program team members, healthcare managers and policymakers were engaged, this provide confidence that the evaluation efforts are relevant and findings are likely to be adopted for improvement in current models and for development of future initiatives.
- While realist evaluation and mixed methods design have been advocated for the evaluation of complex healthcare interventions, it is a relatively new method in comparison to the RCTs commonly used in the evaluation of medical interventions. Due to the lack of familiarity on the use of mixed methods in the field of health and healthcare research, this study design may draw criticism for not being as rigorous as the typical Randomized Controlled Trial (RCT).
- The use of mixed methods design increases complexity especially in terms of data analysis. Nonetheless, we strive to reach optimal integration of data at multiple levels – study design, methods, interpretation and reporting – using the convergent parallel mixed methods approach which connects and merges methods and findings.
- As participation in the evaluation efforts is voluntary and only individuals who are able or have proxies who are able to provide informed consent are included in this evaluation effort, we also recognize that selection bias may be introduced in this study. To account for selection bias, demographic information including age, gender, ethnicity and role (for healthcare providers) are collected and will be compared between responders and non-responders

Introduction

Across the world, rapidly aging populations and increasing demand for healthcare services call for a paradigm shift from disease-centered healthcare provision to more holistic, people centered care [1]. People-centered care involves placing people and communities at the focus of health systems not diseases. It highlights the importance of empowering people to take charge of their health, takes into account holistic needs of a person and seeks to provide quality care timely and appropriately [2]. Integrated care supports people-centered care by coordinating healthcare services in a way that ensures people receive a continuum of care at the different levels and sites of care within the health system, according to their needs. The World Health Organization (WHO)'s framework of people centered integrated care describes the complexity of such interventions and the need to involve various stakeholders in their execution. Complex multi-component delivery strategies are also typically recommended[1].

As characterized by Valentijn et al., care integration can take place on many dimensions: at the micro-level clinical level, the meso-level professional or organizational level and the macro or systemic level [3]. The types of interventions that qualify under the wide umbrella of "integrated care" vary tremendously, as do the settings in which they are introduced and their attendant benefits and costs. Moreover, introducing integrated care often calls for complex, multi-component programs that involve many stakeholders, sometimes with conflicting perspectives and interests. When implemented successfully, integrated people centered health services can be more effective, cost less, improve patient engagement and better prepared to respond to increasing demands for healthcare services [4].

However, despite these growing needs and the availability of basic design principles related to integrated care, the development and implementation of such care models remains challenging. In their systematic review, Suter et al identified ten universal principles for successful health systems integration including (i) comprehensive services across the continuum of care, (ii) person-centerness, (iii) collaboration between organisations (iv), standardized care delivery through interprofessional teams, (v) performance management, (vi) information systems, (vii) organizational culture, (viii) professional integration, (ix) good governance and (x) financial management [5]. Furthermore, it is acknowledged that successful implementation of integrated care requires an effective composition of interventions at the micro-, meso- and macro-levels[6 7]. However, the multifaceted interplay between the building blocks of integrated care and the influence of various contextual factors on outcomes render the development of a simple and standardized implementation model impossible [8]. In every instance, there is a need for healthcare providers and organizations to understand which care models work, for whom and how they work in the unique setting in which integrated care is planned for a particular population so as to facilitate implementation and ensure longer term sustainability in a longer term [9].

Current evaluations such as the "gold-standard" Randomized Controlled Trial (RCT) design rarely adequately or even explicitly address the context-specific drivers behind implementation outcomes and their relationship to the underlying program theory, making it difficult to interpret their findings in light of other programs in different settings. As a result, few evaluation strategies are widely-accepted as appropriate, and to date, the net benefit of integrated care interventions and understanding of how these are achieved remains empirically uncertain. It is therefore essential to develop comprehensive, rigorous and practical methods to evaluate person-centered integrated care programs, not to just inform the selection of effective and efficient interventions but also to facilitate improvement and scaling-up. In the evaluation of such complex interventions, the Medical Research Council (MRC) argues for the importance of process evaluation in conjunction with outcome evaluation, to account for variability in implementation[10]. The MRC's process evaluation framework guides evaluators to understand the implementation processes (what is implemented and how), mechanisms of intervention (how the delivery of the intervention produces change) and contextual factors that affect implementation and outcomes [11].

Singapore is typical of many other countries with a rapidly aging population that is accompanied by an increasing prevalence of chronic and complex illnesses [12] . Designed with an emphasis on providing episodic care within acute hospitals in a largely disease specific manner and controlling infectious disease in a young population, Singapore's health system now faces the challenge of ensuring appropriate care and long-term fiscal

sustainability for a long-lived population at increasing risk of multiple chronic diseases[13]. In addition, having already reached the highest levels of efficiency in the world[14], simple or easy fixes to increase performance while keeping costs low are increasingly rare. A radical change in vision and strategy is therefore needed, requiring complex systems-level interventions that bring about changes of organizational, policy, power and financing structures and break down existing siloes within the healthcare system to refocus on prevention, primary care, and community-based management. Such interventions will need to be built on a strong foundation of integrated care.

In 2012, the Ministry of Health (MOH) Singapore launched a major initiative to reorganize healthcare at the national level into six clusters or Regional Health Systems (RHS) to foster care integration [15]. This was recently reorganized in 2017, into three integrated clusters to better meet future healthcare needs [16]. Every RHS comprises of a network each led by a major public hospital working in close partnership with health care providers (primary care providers, community hospitals, nursing homes, home care and day rehabilitation providers) and social care providers (including Senior Activity Centers, Grassroots organizations and Social Service Offices) within the same geographical region. Each RHS has the mandate and funding support to design and implement integrated care programs that leverage this network to provide healthcare beyond the hospital to the community, value-driven healthcare and holistic care across the entire care continuum in a cost-effective way [17]. To support this common vision, every RHS was tasked to implement programs identified by the MOH to be of priority and held accountable for same outcomes jointly agreed on between the MOH and the RHSes throughout the country. Following this lead, each RHS implemented the priority programs tailored to the unique needs and demographic of the population in which it serves as well as the different strengths of community partners within its network. Other programs unique to respective RHS were also developed and implemented accordingly.

In this study, we propose to take advantage of a unique opportunity to document and evaluate the formation and implementation of a multi-pillared regional integrated care network. This evaluation study began in June 2016 at the National University Hospital System (NUHS)- RHS, the RHS at the western part of Singapore. This study aims to examine how and for whom the NUHS-RHS, as an integrated care network, works from healthcare providers' and healthcare users' perspectives to improve healthcare utilization, health outcomes and care experiences as well as to reduce healthcare costs.

Methods and Analysis

Considering the developmental nature of the NUHS-RHS, this evaluation is designed primarily as a formative evaluation which incorporates outcome valuation principles [18]. Considering the developing nature of the NUHS-RHS and its constituent programs, the evaluation findings will be used to facilitate modifications to existing NUHS-RHS programs as well as to provide evidence to support the increased likelihood of future success.

The evaluation will be conducted using a realist evaluation approach [19], which seeks to test and refine the program theory while assessing whether and how the program succeeds in the local setting, in order to generate important insights not just for Singapore but for the wider field of integrated care research. Realist evaluation is increasingly applied to the evaluation of complex healthcare interventions as it seeks to provide a more explicit and in-depth understanding of what works, for whom and in what circumstances and has been recommended for the evaluation of integrated care interventions[20 21]. It is a theory-driven approach in which interventions are assumed to be based on theories but are also active, flexible to changes and embedded in a social reality that influences how the intervention is implemented and how various actors in that reality respond to it [19]. A realist program theory specifies not only which outcomes are linked to the intervention, but also what mechanisms generate the outcomes and what features of the context affect them. The context-mechanism-outcome (CMO) configuration is used as the main structure for analysis, with the goal of identifying both mechanisms (what and how components of interventions result in changes) and contextual factors (features of the conditions which influence the mechanisms of interventions) are associated with variation in outcomes [22 23]. Pawson and Tilley

argue that an intervention can only achieve successful outcomes if the appropriate ideas are applied to the right context with appropriate social and cultural conditions[22]. A realist evaluation therefore includes a theory-driven formative evaluation [24], process evaluation [25] as well as outcomes evaluation, and avoids the rigorously successionist format of experimental design.

This evaluation will be conducted in three research phases according to the framework for realist evaluation outlined by Pawson and Tilley (Figure 1) [22]: 1. development of initial program theory underlying the NUHS-RHS; 2. testing of program theory using empirical data; 3. refinement of initial program theory.

Phase 1: Development of Initial Program Theory (IPT)

This evaluation began with first eliciting the IPT which subsequently formed the basis of the evaluation, focus the evaluation activities and determined the appropriate study design, data collection and analysis methods. First, program-related documents of the NUHS-RHS which describe the rationales, components of interventions and program protocols were reviewed to identify the underlying assumptions about how the respective programs are expected to work to achieve their intended outcomes. Ethnographic observations were then conducted to verify and obtain additional information to comprehensively describe the theory of change underlying the NUHS-RHS programs.

Subsequently, key stakeholders involved in the planning, development and implementation of the NUHS-RHS programs were engaged through group discussions to identify: (i) factors which influence the implementation of the programs, (ii) initial observations on how and for whom the programs work, (iii) objectives of evaluation and (iv)outcomes which are relevant to the stakeholders. In collaboration with the RHS strategic planning office, a logic model (Figure 2), a tool that describes logical linkages among program resources, activities, and intended outputs, audiences, and short-, intermediate-, and long-term outcomes [26] related to the establishment of NUHS-RHS was drafted to depict IPT underlying the NUHS-RHS. To ensure the accuracy of the IPT, the logic model was circulated to stakeholders who were previously engaged for further inputs. After which, refinement to the IPT was made.

As illustrated under activities on Figure 2, programs (P1-6) describes the MOH priority programs implemented nationally. The NUHS-RHS Integrated Interventions and Care Extension (P1) program aims to help patients with complex conditions who were admitted at least three or more times a year through a holistic case management. NUHS Transition Care Program (P2) was implemented to enable patients to transit smoothly from hospital to homes through a multidisciplinary team to ensure continuity of care. Appropriate Sitting of Care (P3 and P4) aims to ensure appropriate sitting of patients who are medically stable and deemed to not required specialist care from acute hospital to the community through partnership with primary and community care providers. Health Promotion and Disease Management (P5) focuses on health education, early detection of chronic diseases and timely interventions to prevent development of chronic illnesses as well as slow down the deterioration of diseases. Strengthening of primary and community care within the NUHS-RHS (P6) is achieved through cross deployment of skilled manpower from the acute hospital to the partnering primary and community care providers so as to improve the capability and confidence of the partners of the NUHS-RHS. Leveraging on tele-health and IT enablers, the Carehub aims to provide a single point of contact through individual's continuum of care post hospital discharge. The Primary Care Network (PCN) brings together a group of family physicians and community partners to create a support network for patients with chronic medical conditions in the community [27].

Phase 2: Testing of Program Theory using Empirical Data

Prioritization of NUHS-RHS Programs for Testing of Program Theory

As the number of programs undertaken under the purview of the NUHS-RHS is large, programs were selected for the testing of the IPT in consultation with stakeholders including healthcare providers and administrators, based on: (i) maturity of program, (ii) urgency for evaluation, (iii) complexity of programs and (iv) scientific importance.

Program maturity was assessed based on the duration of program implementation. A program that had been implemented for a longer duration was considered to more mature and given higher priority than one which was recently implemented. Programs nearing the end of their funding period were also given higher priority for evaluation, as evaluation was essential to inform the future development of the program. Complexity was determined by assessing the number of dimensions of integrated care as defined previously (clinical, professional, organizational, systematic, normative and functional integration) [3]. A program that set out to integrate care in more dimensions was considered to be more complex than one which integrated care in fewer dimensions.

Finally, scientific importance was examined by a knowledge gap analysis conducted by reviewing available published articles relevant to these programs on PubMed. A program with the least number of relevant articles was considered to be of greatest scientific importance. According to these criteria, MN and HJMV ranked various NUHS-RHS programs as low, medium and high priority for evaluation. Through the priority-setting process, four programs (P1, P2, P3 and P4) were identified to be the best candidate programs for evaluation.

Study Participants

Two distinct groups of study participants – healthcare providers/managers and healthcare users – are selected based on defined criteria in this study. Healthcare providers/managers who are a part of the governance, planning and implementation of the programs are invited to take part in structured interviews and to complete the online Rainbow Model of Integrated Care (RMIC) survey [28], while healthcare users, including patients or proxies (caregivers), are invited for structured interviews or prospective surveys over three time points. Interactions between healthcare providers and healthcare users will be observed

Study Design

Given the complexity of integrated care programs being evaluated and a range of perspectives in which this study tries to capture, a convergent parallel mixed methods study will be undertaken to test the IPT developed in phase 1. Using the convergent parallel strategy, both quantitative and qualitative data will be collected concurrently. Components will be given equal weight and two datasets will be analyzed, compared and merged through iterative cycles of validation and confirmation of findings [29].

Evaluation of implementation, context and mechanisms

Implementation fidelity, context and mechanisms that underpin the NUHS-RHS as a whole will be assessed according to the modified version of the Conceptual Framework of Implementation Fidelity (CFIF) [30]. The CFIF provides a framework to assess content, frequency and dose of program implementation and the moderating factors affecting implementation fidelity of complex interventions. Moderating factors including participants' responsiveness, intervention complexity, comprehensiveness of policy description, strategies to facilitate implementation, quality of delivery, recruitment and context will be assessed. Data will be gathered through reviews of program documents, medical records, structured interviews healthcare providers and observations of actual delivery of interventions as described in Table 1.

Program documents including guidelines and databases will be reviewed by evaluators. Program guidelines will be examined to provide an understanding of the planned activities for each program and the proposed mechanisms of achieving targeted outcomes. The number of eligible patients referred, response rate, reasons for non-enrolment into the programs, frequency of program delivery as well as duration of enrolment will be retrieved from the existing program databases to determine the coverage, frequency and duration of respective programs. Furthermore, medical records of patients enrolled into the programs will be reviewed to provide a comprehensive picture of interactions between healthcare providers' and users throughout a patient's healthcare journey from enrolment to discharge. Medical records will be proportionately sampled based on the number of healthcare providers that are able to provide referrals within each program and the time point at which patients are enrolled into the programs.

Healthcare providers (physicians, nurses, and other allied health professionals), and healthcare managers (care coordinators and healthcare administrators) who are involved in the planning, development and implementation of the four programs are invited to participate in face-to-face structured interviews. Written informed consent and demographic information including their age, gender, duration of involvement and roles will be collected prior to the interviews. Guided by the CFIF, content of interventions and moderating factors, which may have contributed or hampered the implementation of the interventions, will be assessed during interviews. All interviews will be audio-recorded, transcribed verbatim and coded thematically.

Two sessions of ethnographic observations (induction and follow up) for each study participant will be randomly conducted at patients' homes and/or through phone calls depending on where and how the interventions are provided. We expect to observe two sessions each for approximately 30 participants from each program and informed consent will be obtained from participants. Content of care delivery, interactions between healthcare professionals and users together patients' responses to the service will be observed. For each session, field notes will be taken, findings will be written in narratives and analyzed thematically.

Data Analysis

Data from the various sources will be given equal weightage and will subsequently be integrated at data analysis stage guided by the modified version of the CFIF using the triangulation protocol methodology [31]. The extent of which the intervention components were implemented will be rated on a 5-points Likert scale ranging from never to always by two independent evaluators. Potential moderating factors which affect the implementation of the programs will be assessed by examining participant responsiveness, comprehensiveness of protocols/guidelines, support available to facilitate recruitment and implementation, quality of service delivery and context (patient, professionals, organizational, political and economic factors). Analysis will also take into account other emergent themes not defined by the CFIF.

Table 1: Evaluation of implementation fidelity, context and mechanism underlying NUHS-RHS programs

	Specific component	**Data sources**
Adherence	Content	Ethnographic observation, medical records review and interview with program team members
	Frequency / duration	Medical records review, interview with program team members and healthcare users
	Coverage	Program databases, interview with program team members
Moderating factors	Participant responsiveness	Ethnographic observation, interview with program team members and healthcare users and possibly medical records review (if recorded)
	Intervention complexity	Program documents (protocols, guidelines)
	Comprehensiveness of policy description	Program documents (protocols, guidelines)
	Strategies to facilitate implementation	Interview with program team members
	Quality of delivery	Interview with healthcare users
	Recruitment	Program database, interview with program team members
	Context	Interview with program team members

Evaluation of outcomes

Healthcare utilization and health outcomes

Healthcare utilization, health outcomes and patient-reported experiences and outcomes associated with the NUHS-RHS programs will be assessed through review of clinical indicators, structured interviews and administration of surveys as described below, to identify alignment with the Chronic Care Model (CCM) [32]. The CCM identifies the community, the health system, self-management support, delivery system design, decision support and clinical information systems as key elements of a health system that are essential to provide good quality chronic care [32].

The effect of the program on healthcare utilization will be measured by analyzing the number of admissions, Emergency Department (ED) attendance, number of specialist outpatient clinic (SOC) attendances, average bed days, for patients enrolled from the start of the programs. To capture the potentially evolving nature of the programs and their effects, data will be collected over various time points with respect to their respective date of enrollment program– 12 months before (T-12), 9 months before (T-9), 6 months before (T-6), 3 months before (T-3), date of enrolment (T0), 3 months after (T3), 6 months after (T6), 9 months after (T9), 12 months after (T12) and 15 months after (T15). Demographic data (gender, age, race, comorbidity and socio-economic status) will also be retrieved for all patients.

Clinical indicators at various time points for all patients who are enrolled and decline will be extracted from the existing NUHS-RHS databases. In reference to the point of patients' enrolment into the programs, clinical indicators at T-12, T-9, T-6, T-3, T0, T3, T6, T9, T12 and T15 will be extracted. In addition, the 8-item Morisky Medication Adherence Scale (MMAS-8) will be used to assess patients' compliance to prescribed medications [33]. The MMAS-8 is a structured self-report measure of medication-taking behaviour that has been widely used in various cultures and is considered a gold standard of measurement [34].

The effect of the programs on patient- reported outcomes, patients' quality of life, care experience and self-efficacy will be assessed using validated survey instruments over three time points, at the starting point, mid-way and the end of the program. Quality of life of patients will be assessed using the EuroQol- 5 Dimension (EQ-5D) instrument. The EQ-5D consists of 5 items, which recognizes the fundamental importance of independent physical, emotional and social functioning, as part of a more holistic view of health. It has been validated in Singapore and is a common measure used to assess quality of life as the result of healthcare interventions [35]. Patients' perception of the quality of care received will be examined using the Patient Assessment of Care for Chronic Conditions (PACIC) [36]. The PACIC seeks to understand the frequency with which various aspects of care patients with chronic conditions received from their healthcare providers aligned with components of the Chronic Care Model (CCM). The healthcare providers include regular doctors, nurse, care coordinators, allied health providers and others. PACIC has been widely validated and used at various healthcare settings across the world [37-40].

Patients' experience of care continuity will be assessed using the CCAENA (Continuity of care between care levels) questionnaire. The CCAENA consists of 29 items and assesses continuity of care across different levels from the patients' perspectives [41]. The components covered by the CCAENA include the relationships between patient and primary care providers, and between specialists and primary care providers. Finally, self-efficacy is

measured using the Patient Activation Measure (PAM), which consists of 13 items will be used to measure patient knowledge, skill, and confidence for self-management [42].

Complementary to the quantitative analysis of outcomes, a more in-depth understanding of healthcare users' perception of healthcare quality, including why and how it has worked, or did not work, will be explored qualitatively through interviews with healthcare users. Healthcare users including patients and their family members who have had experiences with the programs for at least 3 months are invited to take part in face to face interviews. Interviews are structured according to the program logic model, and key components of the Chronic Care Model (CCM) [32]. Perception of the level of care integration as well as recommendations for improvement to the programs will also be elicited during the interviews. Potential participants will be recruited through care coordinators and will be screened against the selection criteria by the study team prior to the interviews. Only those who are eligible and are willing to be audio recorded will be interviewed. Written informed consent and demographic information will be attained from the participants before proceeding with the interviews. Interviews will be conducted in English, Chinese or Malay at the patients' homes or at NUHS. Notes will be taken during observations and all interviews are audio recorded, transcribed verbatim and will be imported to Atlas.ti 7.0 for analysis.

Data-analysis

An interrupted time series analysis (ITSA) will be conducted for all programs to examine the effects of the NUHS-RHS programs on healthcare utilization, health outcomes and care experiences. In addition, difference in difference (DID) analysis will be conducted for those with comparison groups [43 44]. Proposed to be more flexible compared to the traditional randomized controlled trials analysis, ITSA is conducted to estimate the changes associated with the introduction of interventions over time. To estimate changes in the above outcomes, time series regression that includes data from patients enrolled into the programs 1 year prior to and after referral to the programs will also be run. The model will have 3 main parameters: 1. Estimation of the annual trend in healthcare utilisation (i.e. hospital admission, SOC attendances, ED attendances and average bed days) and clinical indicators one year before until the introduction of the programs 2. Estimation of changes in all outcomes associated with introduction of the programs; 3. The trend change in outcomes associated with each year. For each outcome, we will apply a generalized estimating equation model clustering by the combination of age, sex, and comorbidity score with robust standard errors and an autoregressive correlation matrix. We will report rate ratios (RRs) calculated from the parameter estimations, which represent population-averaged rates. DID analysis will subsequently be performed to estimate the impact of the programs by comparing differential effects in the outcomes between intervention and comparison groups. Sensitivity analyses will be performed and confounding effects will be accounted for.

Observation notes and interview transcripts will be thematically coded by two independent researchers using a two-steps according to the integrated approach as described by Bradley et al [45]. We have selected this approach as this study adopts an existing CCM framework, but we would like to ensure completeness of findings by assuring other emergent themes not previously described in the CCM are also considered. The first step consists of a deductive analysis, where units of data are coded according to the CCM. This will be followed by an inductive analysis, where new themes or unexpected findings are elicited through coding and categorizing. If the interviews were conducted in other languages beside English, these will be transcribed and the analysis will be conducted by a researcher that is fluent in that language. The relevant quotes representative of the analysis will then be translated into English. Subsequently, data collected through prospective surveys and interviews with healthcare users will be merged using the CCM as a framework.

Care Integration

The extent of care integration with the NUHS-RHS will be assessed through the administration of the RMIC measurement tool (MT) adapted to Singapore [28 46]. Tested and validated in Singapore, the RMIC-MT was developed to measure the extent of care integration from the healthcare providers' perspectives. It consists of 62 items grouped into eight factors of integrated care related to person-focused and population-based care, clinical

integration, professional, organizational, systematic, functional and normative integration. The RMIC-MT uses a four point Likert scale ranging from "never" to "all the time" and an additional option of "not sure/don't know" [28].

Data-analysis

Incomplete RMIC-MT will be excluded from analysis. The "not sure/don't know" option will be considered as missing data and will be imputed with median score of each item. The RMIC-MT will be scored as described previously by Nurjono et al. in which the average score for respective dimensions of RMIC and overall care integration will be computed. A higher score on the RMIC-MT is considered to reflect a greater extent of care integration. The RMC was developed through a systematic literature review and validated by international Delphi panels. [3] It describes six dimensions of care integration (clinical, professional, organizational, functional and normative integration) across different levels within a health system needed to provide a continuous, comprehensive and coordinated delivery of services to the individual and population. Furthermore, the degree of integrated care within NUHS will be compared to the degree of integrated care in other health systems (Netherlands and Australia) in which the RMIC-MT has been administered.

Healthcare cost

To examine the effect of NUHS-RHS programs on healthcare costs, six categories of costs including (i) development costs (ii) program implementation costs (iii) healthcare utilisation costs (inpatient, outpatient and community) (iv) productivity costs incurred to patients and/or caregivers (v) travel costs borne by patients for travelling to receive care and (vi) caregiving cost will be collected [47]. Cost categories (i), (ii), (iii) are considered related to the healthcare system whereas categories (iv)-(vi) take into account costs from the societal perspective.

Development costs include costs incurred during the development of the NUHS-RHS and their respective programs. The program implementation costs take into account costs related to the implementation of the programs including the manpower costs, travel costs, costs of equipment, and costs of materials used for patient and caregiver training and costs associated with multidisciplinary team meetings. The development and implementation costs will be systematically collected using WHO's CostIt instrument [48] and will be divided by the number of clients included into the programs to obtain per patient cost.

The cost of healthcare utilisations (hospital inpatient, outpatient services, primary and community care services), productivity costs (estimated based on absence from paid employment due to illness or providing care), travel costs (distance to healthcare providers and expenses incurred related to providing care to enrolled patients) and caregiving costs (cost related to the hire of domestic helpers, costs related to improvement in home environment and costs of caregiver training) will be collected using routinely collected hospitals data and a cost questionnaire administered to participants at T0 and T12 where each participant will be asked to recall his/her expenses 3 months prior to the time of the interview.

Data-analysis

Differences in costs by category before and after enrollment will be analyzed using paired Wilcoxon tests. The difference will be considered statistically significant if the p-value < 0.05. Paired analysis will be adjusted by age, gender and number of co-morbidities at baseline. To estimate the cost-effectiveness of the right-site care programs, an incremental cost-effectiveness ratio (ICER) will be computed using changes in Quality-adjusted life years (QALYs) attributable to the program as the primary measure of program effectiveness, divided by changes in costs costs measured both from the health system and societal perspectives. The program will be considered cost effective if the ICER is lower than Singapore-specific thresholds. Currently, in the absence of a formal nationally-accepted threshold for societal costs, we will adapt a default threshold consistent with WHO CHOICE benchmarks of approximately $60-75000 per QALY[49] The appropriate cost-effectiveness thresholds will be reviewed and updated to be consistent with national best practice at the time of completion of the analysis.

Phase 3: Refinement of Initial Program Theory

Finally, to provide an overall evaluation of the NUHS-RHS taking into consideration various perspectives, qualitative and quantitative data obtained from various stakeholders including the program team members and patients/proxies will be integrated through the process of triangulation at the data interpretation stage when both quantitative and qualitative data have been analysed separately [31]. The triangulation protocol will be adopted to guide data integration by first producing a convergence coding matrix according to the guiding conceptual frameworks to display findings emerging from each component followed by consideration of where there is agreement, partial agreement, silence or dissonance between findings from different data sources. Assessment of the fit of data integration will be conducted by examining the coherence of findings from various methods used, as suggested by Fetters et al [50]. Data on context, mechanisms and outcomes will be gathered and analyzed guided by respective frameworks as described in phase 2. These will then be linked according to the realist evaluation CMO formula in which findings on context and mechanisms will used to explain outcomes observed. A few potential CMO configurations will then be proposed and discussed (for validation purposes) through 2-3 focus group discussions comprising of 8-10 different stakeholders each. After which, the initial program theory will be refined to highlight how to improve the NUHS-RHS by detailing what works (outcome), as well as how (mechanisms) and under what conditions (context).

Ethics and dissemination

Data collection for this study was started in June 2016 and is expected to continue until June 2019. The National Healthcare Group, Singapore, Domain Specific Review Board reviewed and approved this study protocol Board (DSRB Ref: 2016/00410 and 2016/00914). Written informed consent forms are obtained from participants (healthcare providers and users) included for interviews and surveys. To maintain confidentiality of the research participants, identifiable information obtained from research participants are kept securely under password protection. A unique respondent identification is assigned to each study participant so that data can be processed anonymously. Waiver of informed consent was obtained for analysis of retrospective data collected as part of the hospital and Ministry of Health (MOH) routine data collection and no identifiable data are known by the researchers. Study results will be written up and published in international peer reviewed journals and will be presented at national, international conferences and internally at NUHS-RHS and the MOH, Singapore

Mitigation of Potential Risks and Limitations

While realist evaluation approach and mixed methods design have been advocated for the evaluation of complex healthcare interventions, they are relatively new in comparison to the RCTs commonly used in the evaluation of medical interventions. Due to the lack of familiarity on the use of realist evaluation and mixed methods in the field of health and healthcare research, this study design may draw criticism for not being as rigorous as the typical RCT. Furthermore, we acknowledge that the use of mixed methods design also increases complexity. Nonetheless, we strive to reach optimal integration of data at multiple levels – study design, methods, interpretation and reporting – using the convergent parallel mixed methods approach which connects and merges methods and findings.

Furthermore, as participation in the evaluation efforts is voluntary and only individuals who are able or have proxies who are able to provide informed consent are included in this evaluation effort, we also recognize that selection bias may be introduced in this study. To account for selection bias, demographic information including age, gender, ethnicity and role (for healthcare providers) are collected and will be compared between responders and non-responders. Given the prospective nature of some of our data collection methods, difficulties in following up with respondents are also anticipated. To minimize the numbers lost to follow up, research appointments are scheduled at participants' time and place of convenience in collaboration with participants' care coordinators. In the event when loss to follow is inevitable due to death, survival analysis will be conducted to account for the missing data.

In addition, it must be acknowledged that as much as it was intended for the delivery of care to be consistent, variability in the extent of how care was provided exists, especially across different disease specific subprograms

and also within individual sub-program. To account for such variability, subgroup analysis will be conducted and adjustments based on the number of care providers within a subprogram will also be made.

Discussion

Singapore is in the early phase of developing new integrated care models. Notwithstanding the scope of more general design principles of integrated care, development and implementation of integrated care requires adaptation to the context, needs of the local population and the capacity and capability of local healthcare providers. To the best of our knowledge, this study provides the first opportunity to holistically evaluate the NUHS-RHS, and one of the first to conduct a comprehensive evaluation of a new integrated care network in the context of South-East Asia using a realist evaluation approach.

This study carries significant implications for the health system and society in Singapore as well as for the field of integrated care internationally. By ensuring the rigor of this evaluation and adopting a realist approach, findings from this study are expected to generate contextually relevant evidence for improving efficiency and effectiveness of the NUHS-RHS as it develops and also to inform future initiatives of the NUHS. It is also expected to yield policy-relevant insights for national-level decision makers as they continue to monitor and refine the RHS model for Singapore over the coming years. In designing this evaluation, stakeholders including program team members, healthcare managers and policymakers were engaged to help evaluators understand the context in which the programs were implemented, how interventions have been delivered, to define objectives, evaluation questions and outcomes which are relevant to the stakeholders and to identify constraints to the feasibility of implementation of the evaluation itself. Various potential pitfalls in evaluation design and implementation have been collectively identified and risk management strategies put into place wherever possible. This provides confidence that the evaluation efforts are rigorous, relevant and has the potential to provide insights for program improvement as well as provide evidence to support policy decisions to scale-up/down activities within NUHS. Engagement of stakeholders early in the evaluation efforts is also expected to increase the likelihood that recommendations will be adopted to improve the relevant components of the existing care models and define future new care models. On the other hand, the involvement of stakeholders may exert pressure to act on preliminary findings. Understanding these dynamics will also be of interest as part of the evaluation itself.

Like NUHS, other integrated care networks within Singapore and abroad are experimenting with new integrated care models. However, the findings from existing research of the (cost-)effectiveness of integrated care are to a major extent inconsistent because of the variations in the strategic outcomes, methods of implementation, contexts (i.e. system and policy) and/or applied evaluation measures. Examples include next generation accountable care organisations in the United States [51], integrated care pioneers and vanguard sites in England [52 53], population health management pilots in the Netherlands [54], integrated care pilots in Belgium [55] and theintegrated care demonstrators in Australia [56]. This study provides an opportunity to fill some of the gaps in current research by evaluating the NUHS-RHS and its constituent programs using a rigorous and comprehensive design that balances the needs of context-specific evaluation with international comparability. Wherever possible, steps such as using internationally validated instruments for evaluation of chronic disease are taken, to allow for meaningful international comparisons that can increase collective knowledge about the restructuring of chronic care models towards advancing integrated care.

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Authors' contributions

SAT, TW and HJMV initiated the study and HJMV conceptualized the study. HJMV and MN designed and constructed the first draft of study protocol. ST, SHW, KMF, SAT, TW and JY reviewed study protocol and provided feedback for the refinement of the protocol. MN, PS, AL, XYL, ST, SHW and KMF are involved in data collection and MN, PS, XYL and FS will be involved in data analysis related to this study. MN wrote up the first draft and final version of the manuscript. All authors read, provided suggestions for revision and approved the final manuscript.

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Data sharing statement

For access to the data set, a formal request should be sent to the corresponding author. The request will only be considered when the primary results of the study have been published

Competing Interests

ST, SHW, KMF, SAT and TW are a part of the NUHS-RHS strategic planning office which is involved in the planning and development of programs under the purview of the NUHS-RHS.

Figure legends

Figure 1: Realist evaluation processes and research phases according to Pawson and Tilley

Figure 2: Logic model of NUHS-RHS

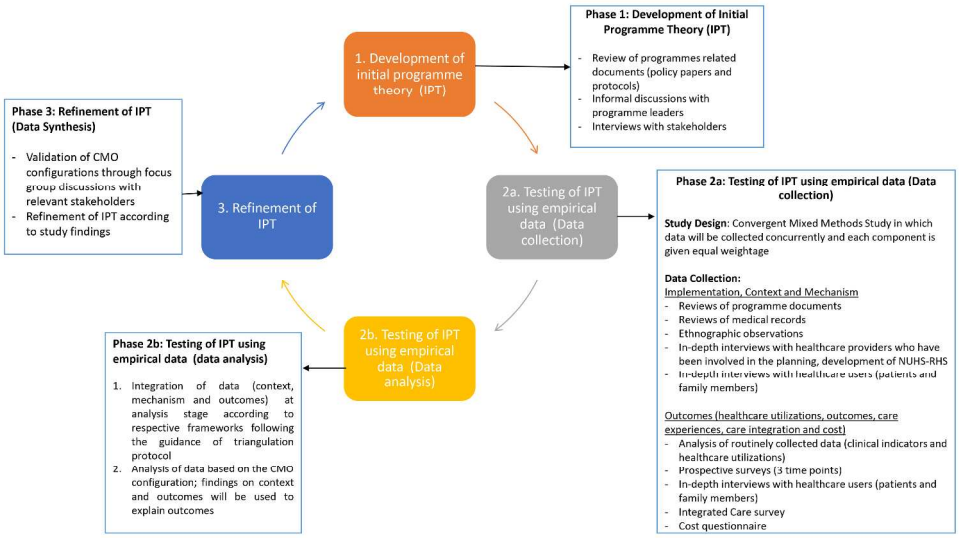

Figure 1: Realist evaluation processes and research phases according to Pawson an d Tilley

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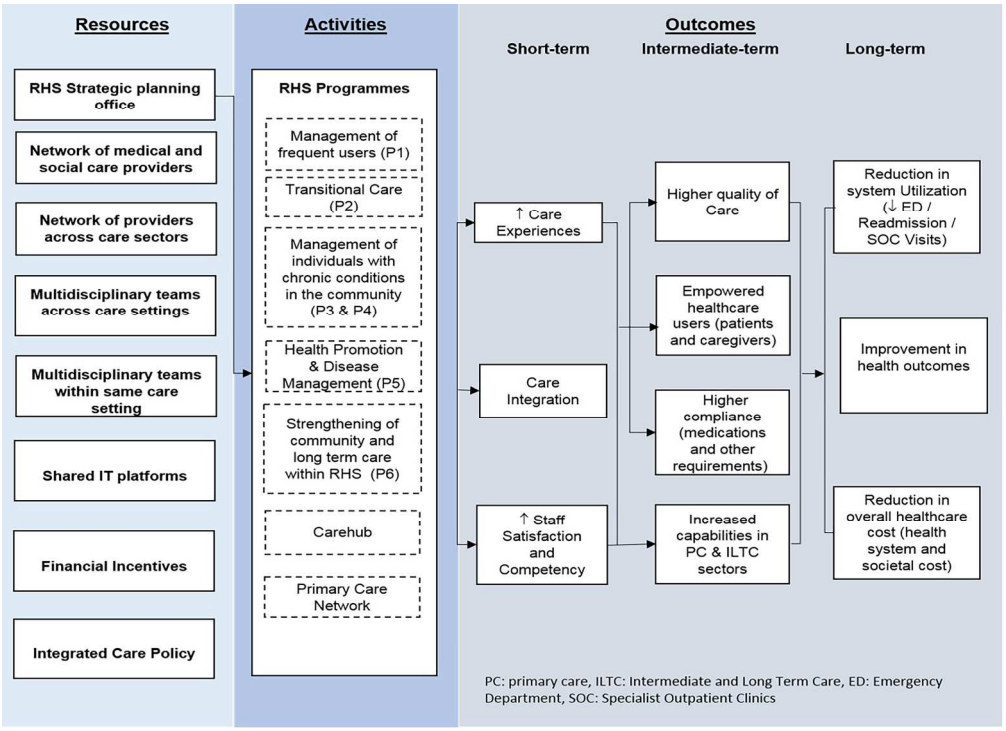

Figure 2: Logic model of NUHS-RHS

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Realist evaluation of a complex integrated care program: protocol for a mixed methods study

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Realist evaluation of a complex integrated care program: protocol for a mixed methods study

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Abstract

Introduction

The lack of understanding of how complex integrated care programs achieve their outcomes due to the lack of acceptable methods leads to difficulties in the development, implementation, adaptation and scaling up of similar interventions. In this study, we evaluate an integrated care network, the National University Health System (NUHS) Regional Health System (RHS), consisting of acute hospitals, step down care, primary care providers, social services and community partners using a theory driven realist evaluation approach. This study aims to examine how and for whom the NUHS-RHS works to improve healthcare utilisations, outcomes, care experiences and reduce healthcare costs. By using a realist approach that balances the needs of context-specific evaluation with international comparability, this study carries the potential to address current research gaps.

Methods and Analysis

This evaluation will be conducted in three research phases: 1. development of initial program theory (IPT) underlying the NUHS-RHS; 2. testing of program theory using empirical data; 3. refinement of IPT. IPT was elicited and developed through reviews of program documents, informal discussions and in-depth interviews with relevant stakeholders. Then, a convergent parallel mixed method study will be conducted to assess context (C), mechanisms (M) and outcomes (O) to test the IPT. Findings will then be analyzed according to the realist evaluation formula of CMO in which findings on the context, mechanisms will be used to explain the outcomes. Finally, based on findings gathered, IPT will be refined to highlight how to improve the NUHS-RHS by detailing what works (outcome), as well as how (mechanisms) and under what conditions (context).

Ethics and dissemination

The National Healthcare Group, Singapore, Domain Specific Review Board (DSRB) reviewed and approved this study protocol. Study results will be published in international peer reviewed journals and presented at conferences and internally to NUHS-RHS and Ministry of Health, Singapore.

Keywords: Realist Evaluation, Integrated Care, Mixed Methods Evaluation

Strengths and limitations of this study

- This study is one of the first study to holistically evaluate a new integrated care network in the context of South-East Asia.
- Using a theory-driven realist evaluation approach, findings from this study are expected to generate contextually relevant evidence for improving efficiency and effectiveness of integrated care as well as informing policy decisions in Singapore and similar health systems.
- The use mixed methods in this study allows us to draw on the strengths of both qualitative and quantitative methods, enhancing the credibility of the evaluation findings and allows for generation of in-depth insights.
- Inclusion of relevant stakeholders in the design of the evaluation provides confidence that the evaluation efforts are relevant and findings are likely to be adopted for improvement in current models and for development of future initiatives.
- Realist evaluation and mixed methods design are relatively new methods in comparison to the Randomized Controlled Trials (RCTs) commonly used in the evaluation of medical interventions. Therefore, this study design may draw criticism for not being as rigorous as the typical RCT.
- The use of mixed methods design increases complexity in data analysis. We plan to reach optimal integration of data at multiple levels by connecting and merging methods, findings and interpretation.
- We acknowledge selection bias associated with voluntary participation and selection of individuals who are able to provide informed consent this study. To account for this, demographic information including age, gender, ethnicity and role (for healthcare providers) are collected and will be compared between responders and non-responders

Introduction

Across the world, rapidly aging populations and increasing demand for healthcare services call for a paradigm shift from disease-centered healthcare provision to a more holistic, people centered care [1]. People-centered care involves placing people and communities at the focus of health systems not diseases. It highlights the importance of empowering people to take charge of their health, takes into account holistic needs of a person and seeks to provide quality care timely and appropriately [2]. Integrated care supports people-centered care by coordinating healthcare services in a way that ensures people receive a continuum of care at the different levels and sites of care within the health system, according to their needs. The World Health Organization (WHO)'s framework of people centered integrated care describes the complexity of such interventions and the need to involve various stakeholders in their execution. Complex multi-component delivery strategies are also typically recommended[1].

As characterized by Valentijn et al., care integration can take place on many dimensions: at the micro-level clinical level, the meso-level professional or organizational level and the macro or systemic level [3]. The types of interventions that qualify under the wide umbrella of "integrated care" vary tremendously, as do the settings in which they are introduced and their attendant benefits and costs. Moreover, introducing integrated care often calls for complex, multi-component programs that involve many stakeholders, sometimes with conflicting perspectives and interests. When implemented successfully, integrated people centered health services can be more effective, cost less, improve patient engagement and better prepared to respond to increasing demands for healthcare services [4].

However, despite these growing needs and the availability of basic design principles related to integrated care, the development and implementation of such care models remains challenging. In their systematic review, Suter et al identified ten universal principles for successful health systems integration including (i) comprehensive services across the continuum of care, (ii) person-centerness, (iii) collaboration between organisations (iv), standardized care delivery through interprofessional teams, (v) performance management, (vi) information systems, (vii) organizational culture, (viii) professional integration, (ix) good governance and (x) financial management [5]. Furthermore, it is acknowledged that successful implementation of integrated care requires an effective composition of interventions at the micro-, meso- and macro-levels[6 7]. However, the multifaceted interplay between the building blocks of integrated care and the influence of various contextual factors on outcomes render the development of a simple and standardized implementation model impossible [8]. In every instance, there is a need for healthcare providers and organizations to understand which care models work, for whom and how they work in the unique setting in which integrated care is planned for a particular population so as to facilitate implementation and ensure longer term sustainability [9].

Current evaluations such as the "gold-standard" Randomized Controlled Trial (RCT) design rarely adequately or even explicitly address the context-specific drivers behind implementation outcomes and their relationship to the underlying program theory, making it difficult to interpret their findings in light of other programs in different settings. As a result, few evaluation strategies are widely-accepted as appropriate, and to date, the net benefit of integrated care interventions and understanding of how variable outcomes are achieved remains empirically uncertain. It is therefore essential to develop comprehensive, rigorous and practical methods to evaluate people-centered integrated care programs, not to just inform the selection of effective and efficient interventions but also to facilitate improvement and scaling-up. In the evaluation of such complex interventions, the Medical Research Council (MRC) argues for the importance of process evaluation in conjunction with outcome evaluation, to account for variability in implementation[10]. The MRC's process evaluation framework guides evaluators to understand the implementation processes (what is implemented and how), mechanisms of intervention (how the delivery of the intervention produces change) and contextual factors that affect implementation and outcomes [11].

Singapore is typical of many other countries with a rapidly aging population that is accompanied by an increasing prevalence of chronic and complex illnesses [12] . Designed with an emphasis on providing episodic care within acute hospitals in a largely disease specific manner and controlling infectious disease in a young population, Singapore's health system now faces the challenge of ensuring appropriate care and long-term fiscal

sustainability for a long-lived population at increasing risk of multiple chronic diseases[13]. In addition, having already reached the highest levels of efficiency in the world[14], simple or easy fixes to increase performance while keeping costs low are increasingly rare. A radical change in vision and strategy is therefore needed, requiring complex systems-level interventions that bring about changes of organizational, policy, power and financing structures and break down existing siloes within the healthcare system to refocus on prevention, primary care, and community-based management. Such interventions will need to be built on a strong foundation of integrated care.

In 2012, the Ministry of Health (MOH) Singapore launched a major initiative to reorganize healthcare at the national level into six clusters or Regional Health Systems (RHS) to foster care integration [15]. This was recently reorganized in 2017, into three integrated clusters to better meet future healthcare needs [16]. Every RHS comprises of a network each led by a major public hospital working in close partnership with health care providers (primary care providers, community hospitals, nursing homes, home care and day rehabilitation providers) and social care providers (including Senior Activity Centers, Grassroots organizations and Social Service Offices) within the same geographical region. Each RHS has the mandate and funding support to design and implement integrated care programs that leverage this network to provide healthcare beyond the hospital to the community, value-driven healthcare and holistic care across the entire care continuum in a cost-effective way [17]. To support this common vision, every RHS was tasked to implement programs identified by the MOH to be of priority and held accountable for same outcomes jointly agreed on between the MOH and the RHSes throughout the country. Following this lead, each RHS implemented the priority programs tailored to the unique needs and demographic of the population in which it serves as well as the different strengths of community partners within its network. Other programs unique to respective RHS were also developed and implemented accordingly.

In this study, we propose to take advantage of a unique opportunity to document and evaluate the formation and implementation of a multi-pillared regional integrated care network. This evaluation study began in June 2016 at the National University Hospital System (NUHS)- RHS, the RHS at the western part of Singapore. This study aims to examine how and for whom the NUHS-RHS, as an integrated care network, works from healthcare providers' and healthcare users' perspectives to improve healthcare utilization, health outcomes and care experiences as well as to reduce healthcare costs.

Methods and Analysis

Considering the developmental nature of the NUHS-RHS, this evaluation is designed primarily as a formative evaluation which incorporates outcome valuation principles [18]. The evaluation findings will be used to facilitate modifications to existing NUHS-RHS programs as well as to provide evidence to support the increased likelihood of future success.

The evaluation will be conducted using a realist evaluation approach [19], which seeks to test and refine the program theory while assessing whether and how the program succeeds in the local setting, in order to generate important insights not just for Singapore but for the wider field of integrated care research. Realist evaluation is increasingly applied in the evaluation of complex healthcare interventions as it seeks to provide a more explicit and in-depth understanding of what works, for whom and in what circumstances and has been recommended for the evaluation of integrated care interventions[20 21]. It is a theory-driven approach in which interventions are assumed to be based on theories but are also active, flexible to changes and embedded in a social reality that influences how the intervention is implemented and how various actors in that reality respond to it [19]. A realist program theory specifies not only which outcomes are linked to the intervention, but also what mechanisms generate the outcomes and what features of the context affect them. The context-mechanism-outcome (CMO) configuration is used as the main structure for analysis, with the goal of identifying both mechanisms (what and how components of interventions result in changes) and contextual factors (features of the conditions which influence the mechanisms of interventions) are associated with variation in outcomes [22 23]. Pawson and Tilley

argue that an intervention can only achieve successful outcomes if the appropriate ideas are applied to the right context with appropriate social and cultural conditions[22]. A realist evaluation therefore includes a theory-driven formative evaluation [24], process evaluation [25] as well as outcomes evaluation, and avoids the rigorously successionist format of experimental design.

This evaluation will be conducted in three research phases according to the framework for realist evaluation outlined by Pawson and Tilley (Figure 1) [22]: 1. Development of initial program theory underlying the NUHS-RHS; 2. Testing of program theory using empirical data; 3. Refinement of initial program theory.

Phase 1: Development of Initial Program Theory (IPT)

This evaluation began with first eliciting the IPT which subsequently formed the basis of the evaluation, focus the evaluation activities and determined the appropriate study design, data collection and analysis methods. First, program-related documents of the NUHS-RHS which describe the rationales, components of interventions and program protocols were reviewed to identify the underlying assumptions about how the respective programs are expected to work to achieve their intended outcomes. Ethnographic observations were then conducted to verify and obtain additional information to comprehensively describe the theory of change underlying the NUHS-RHS programs.

Subsequently, key stakeholders involved in the planning, development and implementation of the NUHS-RHS programs were engaged through group discussions to identify: (i) factors which influence the implementation of the programs, (ii) initial observations on how and for whom the programs work, (iii) objectives of evaluation and (iv)outcomes which are relevant to the stakeholders. In collaboration with the RHS strategic planning office, a logic model (Figure 2), a tool that describes logical linkages among program resources, activities, and intended outputs, audiences, and short-, intermediate-, and long-term outcomes [26] related to the establishment of NUHS-RHS was drafted to depict IPT underlying the NUHS-RHS. To ensure the accuracy of the IPT, the logic model was circulated to stakeholders who were previously engaged for further inputs. After which, refinement to the IPT was made.

As illustrated under activities on Figure 2, programs (P1-6) describes the MOH priority programs implemented nationally. The NUHS-RHS Integrated Interventions and Care Extension (P1) program aims to help patients with complex conditions who were admitted at least three or more times a year through a holistic case management. NUHS Transition Care Program (P2) was implemented to enable patients to transit smoothly from hospital to homes through a multidisciplinary team to ensure continuity of care. Appropriate Sitting of Care (P3 and P4) aims to ensure appropriate sitting of patients who are medically stable and deemed to not required specialist care from acute hospital to the community through partnership with primary and community care providers. Health Promotion and Disease Management (P5) focuses on health education, early detection of chronic diseases and timely interventions to prevent development of chronic illnesses as well as slow down the deterioration of diseases. Strengthening of primary and community care within the NUHS-RHS (P6) is achieved through cross deployment of skilled manpower from the acute hospital to the partnering primary and community care providers so as to improve the capability and confidence of the partners of the NUHS-RHS. Leveraging on tele-health and IT enablers, the Carehub aims to provide a single point of contact through individual's continuum of care post hospital discharge. The Primary Care Network (PCN) brings together a group of family physicians and community partners to create a support network for patients with chronic medical conditions in the community [27].

Phase 2: Testing of Program Theory using Empirical Data

Prioritization of NUHS-RHS Programs for Testing of Program Theory

As the number of programs undertaken under the purview of the NUHS-RHS is large, programs were selected for the testing of the IPT in consultation with stakeholders including healthcare providers and administrators, based on: (i) maturity of program, (ii) urgency for evaluation, (iii) complexity of programs and (iv) scientific importance.

Program maturity was assessed based on the duration of program implementation. A program that had been implemented for a longer duration was considered to more mature and given higher priority than one which was recently implemented. Programs nearing the end of their funding period were also given higher priority for evaluation, as evaluation was essential to inform the future development of the program. Complexity was determined by assessing the number of dimensions of integrated care as defined previously (clinical, professional, organizational, systematic, normative and functional integration) [3]. A program that set out to integrate care in more dimensions was considered to be more complex than one which integrated care in fewer dimensions.

Finally, scientific importance was examined by a knowledge gap analysis conducted by reviewing available published articles relevant to these programs on PubMed. A program with the least number of relevant articles was considered to be of greatest scientific importance. According to these criteria, MN and HJMV ranked various NUHS-RHS programs as low, medium and high priority for evaluation. Through the priority-setting process, four programs (P1, P2, P3 and P4) were identified to be the best candidate programs for evaluation.

Study Participants

Two distinct groups of study participants – healthcare providers/managers and healthcare users – are selected based on defined criteria in this study. Healthcare providers/managers who are a part of the governance, planning and implementation of the programs are invited to take part in structured interviews and to complete the online Rainbow Model of Integrated Care (RMIC) survey [28], while healthcare users, including patients or proxies (caregivers), are invited for structured interviews or prospective surveys over three time points. Interactions between healthcare providers and healthcare users will be observed

Study Design

Given the complexity of integrated care programs being evaluated and a range of perspectives in which this study tries to capture, a convergent parallel mixed methods study will be undertaken to test the IPT developed in phase 1. Using the convergent parallel strategy, both quantitative and qualitative data will be collected concurrently. Components will be given equal weight and two datasets will be analyzed, compared and merged through iterative cycles of validation and confirmation of findings [29].

Evaluation of implementation, context and mechanisms

Implementation fidelity, context and mechanisms that underpin the NUHS-RHS as a whole will be assessed according to the modified version of the Conceptual Framework of Implementation Fidelity (CFIF) [30]. The CFIF provides a framework to assess content, frequency and dose of program implementation and the moderating factors affecting implementation fidelity of complex interventions. Moderating factors including participants' responsiveness, intervention complexity, comprehensiveness of policy description, strategies to facilitate implementation, quality of delivery, recruitment and context will be assessed. Data will be gathered through reviews of program documents, medical records, structured interviews healthcare providers and observations of actual delivery of interventions as described in Table 1.

Program documents including guidelines and databases will be reviewed by evaluators. Program guidelines will be examined to provide an understanding of the planned activities for each program and the proposed mechanisms of achieving targeted outcomes. The number of eligible patients referred, response rate, reasons for non-enrolment into the programs, frequency of program delivery as well as duration of enrolment will be retrieved from the existing program databases to determine the coverage, frequency and duration of respective programs. Furthermore, medical records of patients enrolled into the programs will be reviewed to provide a comprehensive picture of interactions between healthcare providers' and users throughout a patient's healthcare journey from enrolment to discharge. Medical records will be proportionately sampled based on the number of healthcare providers that are able to provide referrals within each program and the time point at which patients are enrolled into the programs.

Healthcare providers (physicians, nurses, and other allied health professionals), and healthcare managers (care coordinators and healthcare administrators) who are involved in the planning, development and implementation of the four programs are invited to participate in face-to-face structured interviews. Written informed consent and demographic information including their age, gender, duration of involvement and roles will be collected prior to the interviews. Guided by the CFIF, content of interventions and moderating factors, which may have contributed or hampered the implementation of the interventions, will be assessed during interviews. All interviews will be audio-recorded, transcribed verbatim and coded thematically.

Two sessions of ethnographic observations (induction and follow up) for each study participant will be randomly conducted at patients' homes and/or through phone calls depending on where and how the interventions are provided. We expect to observe two sessions each for approximately 30 participants from each program and informed consent will be obtained from participants. Content of care delivery, interactions between healthcare professionals and users together patients' responses to the service will be observed. For each session, field notes will be taken, findings will be written in narratives and analyzed thematically.

Data Analysis

Data from the various sources will be given equal weightage and will subsequently be integrated at data analysis stage guided by the modified version of the CFIF using the triangulation protocol methodology [31]. The extent of which the intervention components were implemented will be rated on a 5-points Likert scale ranging from never to always by two independent evaluators. Potential moderating factors which affect the implementation of the programs will be assessed by examining participant responsiveness, comprehensiveness of protocols/guidelines, support available to facilitate recruitment and implementation, quality of service delivery and context (patient, professionals, organizational, political and economic factors). Analysis will also take into account other emergent themes not defined by the CFIF.

Table 1: Evaluation of implementation fidelity, context and mechanism underlying NUHS-RHS programs

	Specific component	**Data sources**
Adherence	Content	Ethnographic observation, medical records review and interview with program team members
	Frequency / duration	Medical records review, interview with program team members and healthcare users
	Coverage	Program databases, interview with program team members
Moderating factors	Participant responsiveness	Ethnographic observation, interview with program team members and healthcare users and possibly medical records review (if recorded)
	Intervention complexity	Program documents (protocols, guidelines)
	Comprehensiveness of policy description	Program documents (protocols, guidelines)
	Strategies to facilitate implementation	Interview with program team members
	Quality of delivery	Interview with healthcare users
	Recruitment	Program database, interview with program team members
	Context	Interview with program team members

Evaluation of outcomes

Healthcare utilization and health outcomes

Healthcare utilization, health outcomes and patient-reported experiences and outcomes associated with the NUHS-RHS programs will be assessed through review of clinical indicators, structured interviews and administration of surveys as described below, to identify alignment with the Chronic Care Model (CCM) [32]. The CCM identifies the community, the health system, self-management support, delivery system design, decision support and clinical information systems as key elements of a health system that are essential to provide good quality chronic care [32].

The effect of the program on healthcare utilization will be measured by analyzing the number of admissions, Emergency Department (ED) attendance, number of specialist outpatient clinic (SOC) attendances, average bed days, for patients enrolled from the start of the programs. To capture the potentially evolving nature of the programs and their effects, data will be collected over various time points with respect to their respective date of enrollment program– 12 months before (T-12), 9 months before (T-9), 6 months before (T-6), 3 months before (T-3), date of enrolment (T0), 3 months after (T3), 6 months after (T6), 9 months after (T9), 12 months after (T12) and 15 months after (T15). Demographic data (gender, age, race, comorbidity and socio-economic status) will also be retrieved for all patients.

Clinical indicators at various time points for all patients who are enrolled and decline will be extracted from the existing NUHS-RHS databases. In reference to the point of patients' enrolment into the programs, clinical indicators at T-12, T-9, T-6, T-3, T0, T3, T6, T9, T12 and T15 will be extracted. In addition, the 8-item Morisky Medication Adherence Scale (MMAS-8) will be used to assess patients' compliance to prescribed medications [33]. The MMAS-8 is a structured self-report measure of medication-taking behaviour that has been widely used in various cultures and is considered a gold standard of measurement [34].

The effect of the programs on patient- reported outcomes; patients' quality of life, care experience and self-efficacy will be assessed using validated survey instruments over three time points, at the starting point, mid-way and the end of the program. Quality of life of patients will be assessed using the EuroQol- 5 Dimension (EQ-5D) instrument. The EQ-5D consists of 5 items, which recognizes the fundamental importance of independent physical, emotional and social functioning, as part of a more holistic view of health. It has been validated in Singapore and is a common measure used to assess quality of life as the result of healthcare interventions [35]. Patients' perception of the quality of care received will be examined using the Patient Assessment of Care for Chronic Conditions (PACIC) [36]. The PACIC seeks to understand the frequency with which various aspects of care patients with chronic conditions received from their healthcare providers aligned with components of the Chronic Care Model (CCM). The healthcare providers include regular doctors, nurse, care coordinators, allied health providers and others. PACIC has been widely validated and used at various healthcare settings across the world [37-40].

Patients' experience of care continuity will be assessed using the CCAENA (Continuity of care between care levels) questionnaire. The CCAENA consists of 29 items and assesses continuity of care across different levels from the patients' perspectives [41]. The components covered by the CCAENA include the relationships between patient and primary care providers, and between specialists and primary care providers. Finally, self-efficacy is

measured using the Patient Activation Measure (PAM), which consists of 13 items will be used to measure patient knowledge, skill, and confidence for self-management [42].

Complementary to the quantitative analysis of outcomes, a more in-depth understanding of healthcare users' perception of healthcare quality, including why and how it has worked, or did not work, will be explored qualitatively through interviews with healthcare users. Healthcare users including patients and their family members who have had experiences with the programs for at least 3 months are invited to take part in face to face interviews. Interviews are structured according to the program logic model, and key components of the Chronic Care Model (CCM) [32]. Perception of the level of care integration as well as recommendations for improvement to the programs will also be elicited during the interviews. Potential participants will be recruited through care coordinators and will be screened against the selection criteria by the study team prior to the interviews. Only those who are eligible and are willing to be audio recorded will be interviewed. Written informed consent and demographic information will be attained from the participants before proceeding with the interviews. Interviews will be conducted in English, Chinese or Malay at the patients' homes or at NUHS. Notes will be taken during observations and all interviews are audio recorded, transcribed verbatim and will be imported to Atlas.ti 7.0 for analysis.

Data-analysis

An interrupted time series analysis (ITSA) will be conducted for all programs to examine the effects of the NUHS-RHS programs on healthcare utilization, health outcomes and care experiences. In addition, difference in difference (DID) analysis will be conducted for those with comparison groups [43 44]. Proposed to be more flexible compared to the traditional randomized controlled trials analysis, ITSA is conducted to estimate the changes associated with the introduction of interventions over time. To estimate changes in the above outcomes, time series regression that includes data from patients enrolled into the programs 1 year prior to and after referral to the programs will also be run. The model will have 3 main parameters: 1. Estimation of the annual trend in healthcare utilisation (i.e. hospital admission, SOC attendances, ED attendances and average bed days) and clinical indicators one year before until the introduction of the programs 2. Estimation of changes in all outcomes associated with introduction of the programs; 3. The trend change in outcomes associated with each year. For each outcome, we will apply a generalized estimating equation model clustering by the combination of age, sex, and comorbidity score with robust standard errors and an autoregressive correlation matrix. We will report rate ratios (RRs) calculated from the parameter estimations, which represent population-averaged rates. DID analysis will subsequently be performed to estimate the impact of the programs by comparing differential effects in the outcomes between intervention and comparison groups. Sensitivity analyses will be performed and confounding effects will be accounted for.

Observation notes and interview transcripts will be thematically coded by two independent researchers using a two-steps according to the integrated approach as described by Bradley et al [45]. We have selected this approach as this study adopts an existing CCM framework, but we would like to ensure completeness of findings by assuring other emergent themes not previously described in the CCM are also considered. The first step consists of a deductive analysis, where units of data are coded according to the CCM. This will be followed by an inductive analysis, where new themes or unexpected findings are elicited through coding and categorizing. If the interviews were conducted in other languages beside English, these will be transcribed and the analysis will be conducted by a researcher that is fluent in that language. The relevant quotes representative of the analysis will then be translated into English. Subsequently, data collected through prospective surveys and interviews with healthcare users will be merged using the CCM as a framework.

Care Integration

The extent of care integration with the NUHS-RHS will be assessed through the administration of the RMIC measurement tool (MT) adapted to Singapore [28 46]. Tested and validated in Singapore, the RMIC-MT was developed to measure the extent of care integration from the healthcare providers' perspectives. It consists of 62 items grouped into eight factors of integrated care related to person-focused and population-based care, clinical

integration, professional, organizational, systematic, functional and normative integration. The RMIC-MT uses a four point Likert scale ranging from "never" to "all the time" and an additional option of "not sure/don't know" [28].

Data-analysis

Incomplete RMIC-MT will be excluded from analysis. The "not sure/don't know" option will be considered as missing data and will be imputed with median score of each item. The RMIC-MT will be scored as described previously by Nurjono et al. in which the average score for respective dimensions of RMIC and overall care integration will be computed. A higher score on the RMIC-MT is considered to reflect a greater extent of care integration. The RMC was developed through a systematic literature review and validated by international Delphi panels. [3] It describes six dimensions of care integration (clinical, professional, organizational, functional and normative integration) across different levels within a health system needed to provide a continuous, comprehensive and coordinated delivery of services to the individual and population. Furthermore, the degree of integrated care within NUHS will be compared to the degree of integrated care in other health systems (Netherlands and Australia) in which the RMIC-MT has been administered.

Healthcare cost

To examine the effect of NUHS-RHS programs on healthcare costs, six categories of costs including (i) development costs (ii) program implementation costs (iii) healthcare utilisation costs (inpatient, outpatient and community) (iv) productivity costs incurred to patients and/or caregivers (v) travel costs borne by patients for travelling to receive care and (vi) caregiving cost will be collected [47]. Cost categories (i), (ii), (iii) are considered related to the healthcare system whereas categories (iv)-(vi) take into account costs from the societal perspective.

Development costs include costs incurred during the development of the NUHS-RHS and their respective programs. The program implementation costs take into account costs related to the implementation of the programs including the manpower costs, travel costs, costs of equipment, and costs of materials used for patient and caregiver training and costs associated with multidisciplinary team meetings. The development and implementation costs will be systematically collected using WHO's CostIt instrument [48] and will be divided by the number of clients included into the programs to obtain per patient cost.

The cost of healthcare utilisations (hospital inpatient, outpatient services, primary and community care services), productivity costs (estimated based on absence from paid employment due to illness or providing care), travel costs (distance to healthcare providers and expenses incurred related to providing care to enrolled patients) and caregiving costs (cost related to the hire of domestic helpers, costs related to improvement in home environment and costs of caregiver training) will be collected using routinely collected hospitals data and a cost questionnaire administered to participants at T0 and T12 where each participant will be asked to recall his/her expenses 3 months prior to the time of the interview.

Data-analysis

Differences in costs by category before and after enrollment will be analyzed using paired Wilcoxon tests. The difference will be considered statistically significant if the p-value < 0.05. Paired analysis will be adjusted by age, gender and number of co-morbidities at baseline. To estimate the cost-effectiveness of the right-site care programs, an incremental cost-effectiveness ratio (ICER) will be computed using changes in Quality-adjusted life years (QALYs) attributable to the program as the primary measure of program effectiveness, divided by changes in costs costs measured both from the health system and societal perspectives. The program will be considered cost effective if the ICER is lower than Singapore-specific thresholds. Currently, in the absence of a formal nationally-accepted threshold for societal costs, we will adapt a default threshold consistent with WHO CHOICE benchmarks of approximately $60-75000 per QALY[49] The appropriate cost-effectiveness thresholds will be reviewed and updated to be consistent with national best practice at the time of completion of the analysis.

Phase 3: Refinement of Initial Program Theory

Finally, to provide an overall evaluation of the NUHS-RHS taking into consideration various perspectives, qualitative and quantitative data obtained from various stakeholders including the program team members and patients/proxies will be integrated through the process of triangulation at the data interpretation stage when both quantitative and qualitative data have been analysed separately [31]. The triangulation protocol will be adopted to guide data integration by first producing a convergence coding matrix according to the guiding conceptual frameworks to display findings emerging from each component followed by consideration of where there is agreement, partial agreement, silence or dissonance between findings from different data sources. Assessment of the fit of data integration will be conducted by examining the coherence of findings from various methods used, as suggested by Fetters et al [50]. Data on context, mechanisms and outcomes will be gathered and analyzed guided by respective frameworks as described in phase 2. These will then be linked according to the realist evaluation CMO formula in which findings on context and mechanisms will used to explain outcomes observed. A few potential CMO configurations will then be proposed and discussed (for validation purposes) through 2-3 focus group discussions comprising of 8-10 different stakeholders each. After which, the initial program theory will be refined to highlight how to improve the NUHS-RHS by detailing what works (outcome), as well as how (mechanisms) and under what conditions (context).

Ethics and dissemination

Data collection for this study was started in June 2016 and is expected to continue until June 2019. The National Healthcare Group, Singapore, Domain Specific Review Board reviewed and approved this study protocol Board (DSRB Ref: 2016/00410 and 2016/00914). Written informed consent forms are obtained from participants (healthcare providers and users) included for interviews and surveys. To maintain confidentiality of the research participants, identifiable information obtained from research participants are kept securely under password protection. A unique respondent identification is assigned to each study participant so that data can be processed anonymously. Waiver of informed consent was obtained for analysis of retrospective data collected as part of the hospital and Ministry of Health (MOH) routine data collection and no identifiable data are known by the researchers. Study results will be written up and published in international peer reviewed journals and will be presented at national, international conferences and internally at NUHS-RHS and the MOH, Singapore

Mitigation of Potential Risks and Limitations

While realist evaluation approach and mixed methods design have been advocated for the evaluation of complex healthcare interventions, they are relatively new in comparison to the RCTs commonly used in the evaluation of medical interventions. Due to the lack of familiarity on the use of realist evaluation and mixed methods in the field of health and healthcare research, this study design may draw criticism for not being as rigorous as the typical RCT. Furthermore, we acknowledge that the use of mixed methods design also increases complexity. Nonetheless, we strive to reach optimal integration of data at multiple levels – study design, methods, interpretation and reporting – using the convergent parallel mixed methods approach which connects and merges methods and findings.

Furthermore, as participation in the evaluation efforts is voluntary and only individuals who are able or have proxies who are able to provide informed consent are included in this evaluation effort, we also recognize that selection bias may be introduced in this study. To account for selection bias, demographic information including age, gender, ethnicity and role (for healthcare providers) are collected and will be compared between responders and non-responders. Given the prospective nature of some of our data collection methods, difficulties in following up with respondents are also anticipated. To minimize the numbers lost to follow up, research appointments are scheduled at participants' time and place of convenience in collaboration with participants' care coordinators. In the event when loss to follow is inevitable due to death, survival analysis will be conducted to account for the missing data.

In addition, it must be acknowledged that as much as it was intended for the delivery of care to be consistent, variability in the extent of how care was provided exists, especially across different disease specific subprograms

and also within individual sub-program. To account for such variability, subgroup analysis will be conducted and adjustments based on the number of care providers within a subprogram will also be made.

Discussion

Singapore is in the early phase of developing new integrated care models. Notwithstanding the scope of more general design principles of integrated care, development and implementation of integrated care requires adaptation to the context, needs of the local population and the capacity and capability of local healthcare providers. To the best of our knowledge, this study provides the first opportunity to holistically evaluate the NUHS-RHS, and one of the first to conduct a comprehensive evaluation of a new integrated care network in the context of South-East Asia using a realist evaluation approach.

This study carries significant implications for the health system and society in Singapore as well as for the field of integrated care internationally. By ensuring the rigor of this evaluation and adopting a realist approach, findings from this study are expected to generate contextually relevant evidence for improving efficiency and effectiveness of the NUHS-RHS as it develops and also to inform future initiatives of the NUHS. It is also expected to yield policy-relevant insights for national-level decision makers as they continue to monitor and refine the RHS model for Singapore over the coming years. In designing this evaluation, stakeholders including program team members, healthcare managers and policymakers were engaged to help evaluators understand the context in which the programs were implemented, how interventions have been delivered, to define objectives, evaluation questions and outcomes which are relevant to the stakeholders and to identify constraints to the feasibility of implementation of the evaluation itself. Various potential pitfalls in evaluation design and implementation have been collectively identified and risk management strategies put into place wherever possible. This provides confidence that the evaluation efforts are rigorous, relevant and has the potential to provide insights for program improvement as well as provide evidence to support policy decisions to scale-up/down activities within NUHS. Engagement of stakeholders early in the evaluation efforts is also expected to increase the likelihood that recommendations will be adopted to improve the relevant components of the existing care models and define future new care models. On the other hand, the involvement of stakeholders may exert pressure to act on preliminary findings. Understanding these dynamics will also be of interest as part of the evaluation itself.

Like NUHS, other integrated care networks within Singapore and abroad are experimenting with new integrated care models. However, the findings from existing research of the (cost-)effectiveness of integrated care are to a major extent inconsistent because of the variations in the strategic outcomes, methods of implementation, contexts (i.e. system and policy) and/or applied evaluation measures. Examples include next generation accountable care organisations in the United States [51], integrated care pioneers and vanguard sites in England [52] [53], population health management pilots in the Netherlands [54], integrated care pilots in Belgium [55] and theintegrated care demonstrators in Australia [56]. This study provides an opportunity to fill some of the gaps in current research by evaluating the NUHS-RHS and its constituent programs using a rigorous and comprehensive design that balances the needs of context-specific evaluation with international comparability. Wherever possible, steps such as using internationally validated instruments for evaluation of chronic disease are taken, to allow for meaningful international comparisons that can increase collective knowledge about the restructuring of chronic care models towards advancing integrated care.

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Authors' contributions

SAT, TW and HJMV initiated the study and HJMV conceptualized the study. HJMV and MN designed and constructed the first draft of study protocol. ST, SHW, KMF, SAT, TW and JY reviewed study protocol and provided feedback for the refinement of the protocol. MN, PS, AL, XYL, ST, SHW and KMF are involved in data collection and MN, PS, XYL and FS will be involved in data analysis related to this study. MN wrote up the first draft and final version of the manuscript. All authors read, provided suggestions for revision and approved the final manuscript.

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Data sharing statement

For access to the data set, a formal request should be sent to the corresponding author. The request will only be considered when the primary results of the study have been published

Competing Interests

ST, SHW, KMF, SAT and TW are a part of the NUHS-RHS strategic planning office which is involved in the planning and development of programs under the purview of the NUHS-RHS.

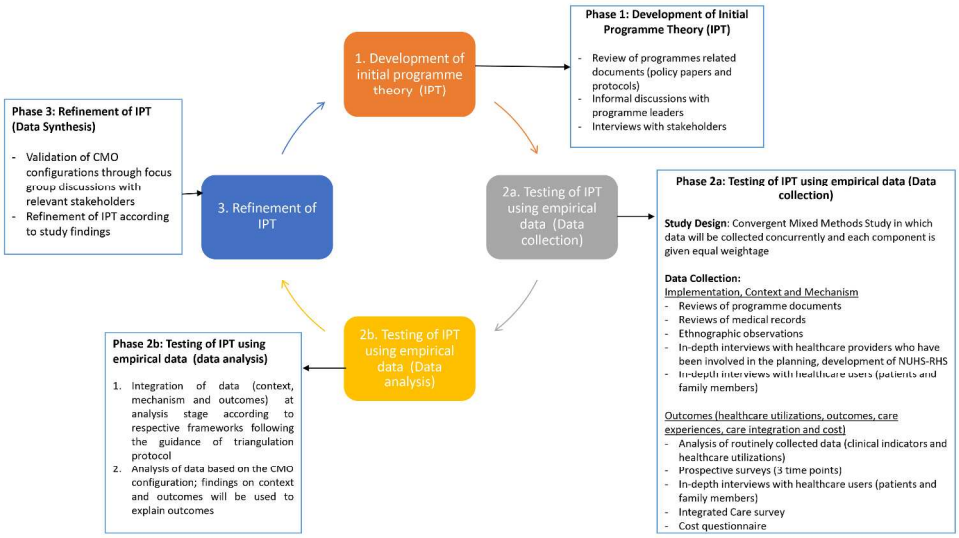

Figure 1: Realist evaluation processes and research phases according to Pawson an d Tilley

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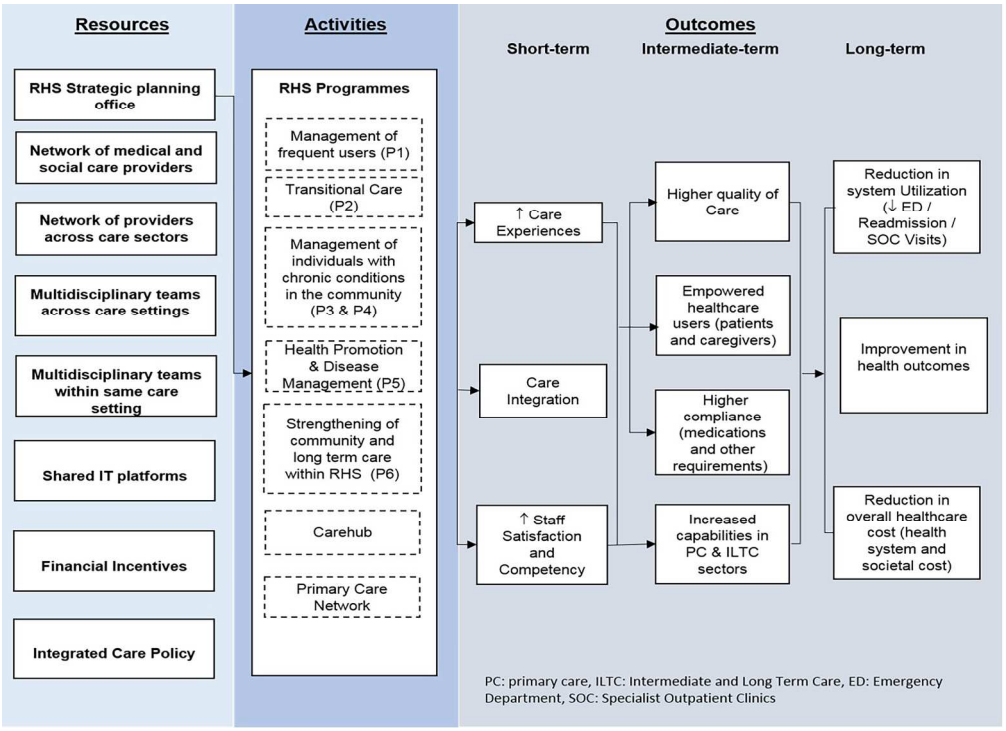

Figure 2: Logic model of NUHS-RHS

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