PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Realist evaluation of a complex integrated care program: protocol for a mixed methods study
AUTHORS	Nurjono, Milawaty; Shrestha, Pami; Lee, Alice; Lim, Xin Ya; Shiraz, Farah; Tan, Shermin; Wong, Shing Hei Thomas; Foo, Kah Mun; Wee, Thomas; Toh, Sue-Anne Ee Shiow; Yoong, Joanne; Vrijhoef, Hubertus

VERSION 1 - REVIEW

REVIEWER	Dominique Tremblay Université de Sherbrooke, Canada
REVIEW RETURNED	02-May-2017

GENERAL COMMENTS	Realist evaluation of a complex integrated care program: a study protocol Page1 of 20 Line 2: Title: Maybe the authors need to think about adding “Mixed methods” into the title to align with the study design and the “Strengths and limitations of this study” arguments. Page 4 of 20 Line 24 to 40: The authors should provide the scientific bases about their argument and the state of science regarding implementation of integrated healthcare services. Line 50: Please define context and causal mechanism concept. Line 57-59: 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. Please clarify the link between complex healthcare interventions and a person-centered intervention program. It remains implicit into the text. Reference number 5 is 1997. Please provide a recent reference with example of using realist evaluation to study complex healthcare interventions. Page 5 of 20 Line 12: Please clarify the nature of complex systems-level interventions and what is meant by “break down existing siloes” Line 50: no specific aim related to context raises questions about how CMO configurations will emerge from the study. Line 52: Please clarify the difference between “causal mechanism” and “working mechanism”.

	Line57: Please clarity what is meant by “implementation fidelity” and “effectiveness” according to realist evaluation. Page 6 of 20 Line 4 to 20: It is difficult to link the 3 specific aims and the research questions according to realist evaluation. Various concepts are used (p. ex. Outcome and Effects). Question 2a is not specific to configurational approach: “What are the moderating factors and barriers in the implementation of the programs?” It remains unclear how the research questions are embedded into realist evaluation approach. Line 27-29: “this evaluation is designed primarily as a formative evaluation”. The reference 15 was not found. However, the definition provided by CDC for formative evaluation does not align with the intervention that is currently implemented and with the research question 2a. Line 37: It would be helpful for the readership to have a definition of what is a logic model. Why this logic model is not used to describe the intervention (Line 17 p. 5 of 20)? This section render the method section difficult to understand. Page 8 of 20 Line 17-29: The authors should provide the scientific bases about the choice of the study design and justify the appropriateness with realist evaluation. Surprisingly, no reference in this section. Line 26-44: It is difficult to understand why ethnographic observations of team meetings and interviews are included into the “Measures” section. Please clarify Data collection for qualitative and quantitative data. Line 32: Fig 2 does not illustrate how Qual and Quan will be integrated and specify the weight of each method. Line 49-54: The authors should provide the scientific bases about the type of analysis for qualitative data. Lien 57-60: Please clarify how the score will be constructed and provide reference. Page 10 of 20 Line 13: “Conceptual Framework of Implementation Fidelity (CFIF) 20 highlights important mechanisms”. It is not clear what are the mechanisms? Please clarify why the moderating factors are considered and not the enabling factors in order to determine “What works” as part of realist evaluation? Page 11 of 20 Line 14: review of medical records of patients raises ethical issues. Please specify which specific data will be collected. Line 45: There is multiple sources of data and this not clear how the analysis will be performed. The authors should clarify how the data will be analyzed and add reference. Page 12 of 20 Line 4: Add research before question 3. Page 14 of 20 Line 17: Please specify the research question 4. Please review main text and Fig 2: no research question 4. . Page 15 of 20 Line 8 Please make explicit into the text and figure the link between context, mechanism, outcomes and the questions. (e.g. Line 17: research questions 1 and 2 on the context and working mechanism while there is no mention of “mechanism” for Q1 and Q2). Data integration should address how quantitative and qualitative date will be integrated (see Cresswell) and then how CMO will be integrated considering the multiple frameworks used. It would be helpful for the readership going beyond the juxtaposition of these frameworks and explain the process of data integration. This would

	be a very significant contribution.

REVIEWER	Dr robin miller Health services management centre University of Birmingham United kingdom
REVIEW RETURNED	08-May-2017

GENERAL COMMENTS	This is an interesting and important study of the implementation of a large scale integrated care programme. My only reservation relates to the deployment of the realist approach and would suggest some amendments or clarifications in regards to this. It is my understanding that one of the benefits / contributions of realism is in building on learning from previous programmes which have used similar mechanism to achieve the connected behaviour change but this is not part of the methodology as yet. I also wondered if the logic model would be better presented in the cmo structure to again underpin this as the underpinning approach.

VERSION 1 – AUTHOR RESPONSE

Page1 of 20
Line 2: Title: Maybe the authors need to think about adding "Mixed methods" into the title to align with the study design and the "Strengths and limitations of this study" arguments.

Response: Thank you for the suggestion, we have revised the title of the manuscript to "Realist evaluation of a complex integrated care program using a mixed method study protocol" to illustrate alignment with study design and the "strengths and limitations of this study".

Page 4 of 20
Line 24 to 40: The authors should provide the scientific bases about their argument and the state of science regarding implementation of integrated healthcare services.

Response: Thank you for the suggestion. We have revised this section (4 of 20) to support our argument and the state of science regarding implementation of integrated healthcare services. It now reads "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-centered, (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. Furthermore, it is acknowledged that successful implementation of integrated care requires an effective composition of interventions at the micro, meso and macro-levels. However, the complex 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. 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. "

Line 50: Please define context and causal mechanism concept.

Response: The concept of context and mechanism has been defined in the revised manuscript on page 5 of 20. It now reads: "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."

Line 57-59: 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. Please clarify the link between complex healthcare interventions and a person-centered intervention program. It remains implicit into the text.

Response: To clarify this link, we have referenced the WHO's framework of people centred integrated care to illustrate the complexity of such intervention. "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" on page 4 of 20, we have also included the recommendation by the Medical Research Council (MRC) to guide the evaluation of complex interventions such as people centered integrated care. It says "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. 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.

Reference number 5 is 1997. Please provide a recent reference with example of using realist evaluation to study complex healthcare interventions.

Response: We have updated the references with more recent references including a systematic review and empirical studies to elaborate how realist evaluation has been widely used in the evaluation of healthcare interventions have been added to the revised manuscript on page 5 of 20.

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Line 12: Please clarify the nature of complex systems-level interventions and what is meant by "break down existing siloes"

Response: This has been clarified in the revised manuscript on page 5 of 20. It now reads "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"

Line 50: no specific aim related to context raises questions about how CMO configurations will emerge from the study.

Response: To provide better clarity, we have revised the aim of the study to explicitly illustrate the

CMO configuration on page 5 of 20. It now reads "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.

Line 52: Please clarify the difference between "causal mechanism" and "working mechanism".

Response: For better clarity, we have standardized the use of term "mechanism" throughout the manuscript without differentiating between causal and working mechanism. In this manuscript, mechanism is defined as what and how components of interventions that result in changes.

Line57: Please clarity what is meant by "implementation fidelity" and "effectiveness" according to realist evaluation.

Response: According to realist evaluation, implementation fidelity seeks to examine the concept of context (the circumstances in which interventions work), and mechanism (how they work) while effectiveness refers to the outcomes of the interventions.

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Line 4 to 20: It is difficult to link the 3 specific aims and the research questions according to realist evaluation. Various concepts are used (p. ex. Outcome and Effects). Question 2a is not specific to configurational approach: "What are the moderating factors and barriers in the implementation of the programs?" It remains unclear how the research questions are embedded into realist evaluation approach.

Response: Thank you for pointing this out. To clarify this, we have revised the aim of the study and highlighted that the research (page 5 of 20) will be conducted in 3 phases on page 6 of 20 according to the realist evaluation approach. It now reads "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. 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 (page 6 of 20).

Line 27-29: "this evaluation is designed primarily as a formative evaluation". The reference 15 was not found. However, the definition provided by CDC for formative evaluation does not align with the intervention that is currently implemented and with the research question 2a.

Response: Thank you for pointing this out, we have revised reference no. 15 to ensure the link is valid. Considering the developmental nature of NUHS RHS, this study was designed as a formative evaluation as defined by CDC in consideration of the developmental nature of NUHS-RHS in which it is looking to modify and improve its existing programs. The evaluation findings will be used to facilitate modifications on existing NUHS-RHS programs as well as to provide evidence to support the increase likelihood of success of NUHS-RHS. We have clarified this on page 5 of 20 of the revised manuscript.

Line 37: It would be helpful for the readership to have a definition of what is a logic model. Why this logic model is not used to describe the intervention (Line 17 p. 5 of 20)? This section render the method section difficult to understand.

Response: Thank you for the suggestion, a definition of a logic model has been included into the revised manuscript on page 6 of 20. In this study, a logic model is defined as “a tool that describes logical linkages among program resources, activities, and intended outputs, audiences, and short-, intermediate-, and long-term outcomes”. For the purpose of this study, the logic model was developed with relevant stakeholders and used to describe the initial programme theory underlying the NUHS-RHS and not to describe the intervention.

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Line 17-29: The authors should provide the scientific bases about the choice of the study design and justify the appropriateness with realist evaluation. Surprisingly, no reference in this section.

Response: Thank you for the suggestion. Under the revised methods section, the justification for the conduct of realist evaluation has been included (page 5 of 20). The justification included says “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. 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. 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. 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. A realist evaluation therefore includes a theory-driven formative evaluation, process evaluation as well as outcomes evaluation, and avoids the rigorously successionist format of experimental design.

To test the initial program theory, a convergent parallel mixed methods study was selected as due to the complexity of integrated care programs being evaluated a range of perspectives in which this study tries to capture the testing of the initial program theory 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 data sets will be analyzed, compared and merged through iterative cycles of validation and confirmation of findings” (page 8 of 20).

Line 26-44: It is difficult to understand why ethnographic observations of team meetings and interviews are included into the “Measures” section. Please clarify Data collection for qualitative and quantitative data.

Response: To clarify the data collection methods, we have included Figure 1 on the revised manuscript to describe the realist evaluation process, including specific procedures (data collection and analysis) at respective phases of realist evaluation.

Line 32: Fig 2 does not illustrate how Qual and Quan will be integrated and specify the weight of each method.

Response: We have revised Figure 1 to include an explanation of how Qual and Quan data will be integrated. 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 according to the triangulation protocol (page 7 of 20).

Line 49-54: The authors should provide the scientific bases about the type of analysis for qualitative data.

Response: On page 10 of 20, we have included a new reference to support the type of analysis we have adopted for this study as well as clarified the reason for the choice. It now reads “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. 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.

Lien 57-60: Please clarify how the score will be constructed and provide reference.

Response: On the revised manuscript, we have clarified that 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 (page 10 of 20).

Page 10 of 20
Line 13: “Conceptual Framework of Implementation Fidelity (CFIF) 20 highlights important mechanisms”. It is not clear what are the mechanisms? Please clarify why the moderating factors are considered and not the enabling factors in order to determine “What works” as part of realist evaluation?

Response: The CFIF provides a guiding framework which has previously shown to be useful in examining implementation fidelity by looking at the adherence to what the program initially intended as well as moderating factors that affect program implementation. Moderating factors encompasses both barriers and enabling factors and the realist evaluation seeks to understand not only what works but also what does not; therefore in this study, we collect data on the moderating factors which include both facilitators and barriers. Furthermore, some factors may act as facilitator as well as barrier. With such consideration, it is important to consider all moderating factors so as to ensure that important moderating factors are not missed out.

Page 11 of 20
Line 14: review of medical records of patients raises ethical issues. Please specify which specific data will be collected.

Response: We have specified on the revised manuscript on page 7 of 20 the specific data to be collected through review of medical records. It now reads: 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.

Line 45: There is multiple sources of data and this not clear how the analysis will be performed.The

authors should clarify how the data will be analyzed and added references.

Response: Thank you for the suggestion. On the revised manuscript, we have clarified how multiple sources of data will be analyzed (page 8 of 20). It now reads: “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. Analysis will also take into account other emergent themes not defined by the CFIF.”

Page 12 of 20
Line 4: Add research before question 3.

Response: Thank you for pointing this out.

Page 14 of 20
Line 17: Please specify the research question 4. Please review main text and Fig 2: no research 4

Response: To provide better clarity, we have restructured the method & analysis section and included headings which illustrate the 3 phases of the study on the revised manuscript:
The new headings include:
1. Development of Initial Program Theory (IPT)
2. Testing of program theory using empirical data
- Prioritization of NUHS-RHS Programs for Testing of Program Theory
- Study Participant
- Study Design
- Evaluation of implementation, context and mechanisms
- Evaluation of outcomes
o Healthcare utilization and health outcomes
o Care Integration
o Healthcare Cost
3. Refinement of Initial Program Theory

This research processes have also been illustrated on Figure 1.

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Line 8 Please make explicit into the text and figure the link between context, mechanism, outcomes and the questions. (e.g. Line 17: research questions 1 and 2 on the context and working mechanism while there is no mention of “mechanism” for Q1 and Q2). Data integration should address how quantitative and qualitative date will be integrated (see Cresswell) and then how CMO will be integrated considering the multiple frameworks used. It would be helpful for the readership going beyond the juxtaposition of these frameworks and explain the process of data integration. This would be a very significant contribution.

Response: Yes, we agree with the reviewers about the importance of explicit illustration of the CMO relevance and data integration. In response to this, we have included additional text to clarify how data integration as part of phase 3 (refinement to the initial programme theory) will be conducted.

The revised now reads” 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. 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. 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 programme 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) (Page 11-12 of 20). "

VERSION 2 – REVIEW

REVIEWER	Dominique Tremblay Université de Sherbrooke, Quebec, Canada
REVIEW RETURNED	07-Jul-2017

GENERAL COMMENTS	This revised version addresses all comments made in the previous manuscript. Thanks to the authors. Please remove the term statistics and add an "s" for mixed method (Title)

REVIEWER	Dr Robin Miller Health Services Management Centre University of Birmingham United Kingdom
REVIEW RETURNED	13-Jul-2017

GENERAL COMMENTS	This is an important protocol as it demonstrated how a realist approach can be used to construct a robust evaluation of a complex programme.

VERSION 2 – AUTHOR RESPONSE

Reviewer 1:
Please remove the term statistics and add an "s" for mixed method (Title)
Thank you for pointing this out, we have removed the term statistics and added an "s" for mixed method.

We hope to have adequately address the comments.