PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Protocol for a process evaluation of a stepped wedge randomised controlled trial to reduce unnecessary hospitalisations of older people from residential aged care: the EDDIE+ study
AUTHORS	Bracci, Ella; Allen, Michelle; Carter, Hannah; Cyarto, Liz; Dwyer, Trudy; Graves, Nicholas; Lee, Xing; Meyer, Claudia; Oprescu, Florin; Harvey, Gillian

VERSION 1 – REVIEW

REVIEWER	Jorgensen, Mikaela Macquarie University, Australian Institute of Health Innovation
REVIEW RETURNED	05-Sep-2022

GENERAL COMMENTS	Thank you to the authors for the opportunity to review this paper, titled "Protocol for a process evaluation of a stepped wedge randomised controlled trial to reduce unnecessary hospitalisations of older people from residential aged care: the EDDIE+ study". The paper outlines a detailed plan for a mixed-methods process evaluation that is being undertaken alongside an RCT. The RCT is a multi-component intervention (EDDIE+) that aims to reduce unnecessary hospital admissions by upskilling staff in 12 RACFs at a single provider in Queensland, Australia. The design, analysis methods and theoretical underpinnings of the process evaluation are well articulated. The tables allow the reader to quickly understand the components of the intervention, elements covered by the process evaluation, and data sources. Well done to the authors - this paper is a great exemplar for conducting a process evaluation. Comments for consideration 1) At the time of completing this review, the process evaluation has already been undertaken (p13 - conducted May-Sep 2022 for an RCT completed May 2022). Protocol papers should generally be reviewed before data collection completes. Could the researchers provide comment? 2) Exclusion of resident voices. Despite being the target of the intervention, the residents themselves are not included in the process evaluation, either through co-design (p16) or as part of the evaluation data collection. Residents who have the cognitive capacity to participate will likely hold opinions on what worked well or less well with the intervention, and what should be considered for implementation in other facilities. Why haven't resident views been sought? Please provide comment in the 'Patient and public

	involvement' section, or include a limitations section outlining the reasons for their exclusion. 3) Generalisability. The process evaluation (and wider RCT) is being conducted with a single provider in Queensland. The RAC stakeholder interview guide does include questions about generalisability to other RAC homes. What are the limitations of conducting this study with a single provider, particularly in trying to understand how and why the intervention might work at scale? Please provide comment in the discussion, or include in a limitations section. 4) Interviewee recruitment. Interviewees will be recruited by email and direct correspondence (p14). Could the researchers clarify who will do the recruiting (i.e. themselves or someone from the provider)? If the former, will email addresses be sent to the researchers with prior participant consent? What does direct correspondence mean here? Please provide further details in this section. 5) Self-efficacy questionnaire analysis. Please describe in more detail the analyses that will be undertaken with the staff self-efficacy questionnaire (p15). Also, how will missing data due to high staff turnover (p3) be treated in any analysis of change over time? 6) Family member/advocate questionnaire. If the evaluation is not yet complete, the researchers could consider including 'N/A' options in this questionnaire. Alternatively, a question could be included on awareness of EDDIE+ and whether or not their family member received hospital avoidance care under the program. 7) Just noting a couple of spelling mistakes - p3 'advocated' should be 'advocates'; Q5 staff questionnaire 'how long have you care for' should be 'cared for'.

REVIEWER	Welmer, Anna-Karin Karolinska Institutet, Department of Neurobiology, Care Sciences and Society
REVIEW RETURNED	01-Dec-2022

GENERAL COMMENTS	Re: Protocol for a process evaluation of a stepped wedge randomised controlled trial to reduce unnecessary hospitalisations of older people from residential aged care: the EDDIE+ study This is a study protocol for a process evaluation of a RCT. As the authors point out, process evaluation is an important part of a project to understand not only if an intervention works but also how and why it may work. Generally, the protocol is well written, and the described methods are reasonable. I however think that some clarifications can be made. 1. The process evaluation will assess the fidelity, acceptability, mechanisms of action and contextual barriers and enablers of the intervention. These concepts are defined quite late in the manuscript. It would be helpful for the reader to have a definition of these concepts already in the introduction. For instance, not all readers may be familiar with the concept fidelity. 2. Fidelity will be assessed as the delivery of the interventions such as number of delivered and attended sessions. So, will the results be shown as the ratio between the number of delivered and attended sessions? What percentage is considered acceptable?

	3. The authors may consider adding analyses of factors associated with better adherence to the intervention, e.g., type of RAC, profession. This can give information on in for whom and in what contexts the intervention works better. 4. Mechanisms will be assessed by a self-efficacy survey pre and post implementation. How long time will there be between the surveys? Is the outcome of this assessments a change score? What is considered an acceptable change? Will the authors consider baseline levels when analyzing change? 5. The quantitative data analyses can be better described. What do the authors mean by inferential analyses (regression analyses, ANCOVA?)? What aims/concepts will be addressed with these analyses? 6. The study will include 12 RAC homes. Approximately, how many respondents will be included in the surveys and interviews? 7. The time plan could be clarified. Is this an ongoing study?

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 Comments	Authors' response
The design, analysis methods and theoretical underpinnings of the process evaluation are well articulated. The tables allow the reader to quickly understand the components of the intervention, elements covered by the process evaluation, and data sources. Well done to the authors - this paper is a great exemplar for conducting a process evaluation.	Thank you for your positive feedback on the paper and helpful suggestions for improvement.
1) At the time of completing this review, the process evaluation has already been undertaken (p13 - conducted May-Sep 2022 for an RCT completed May 2022). Protocol papers should generally be reviewed before data collection completes. Could the researchers provide comment?	Thank you. The protocol paper was submitted whilst data collection was in progress (July 2022); however, as there was a significant time gap to receiving reviewer comments, we have now completed data collection.
2) Exclusion of resident voices. Despite being the target of the intervention, the residents themselves are not included in the process evaluation, either through co-design (p16) or as part of the evaluation data collection. Residents who have the cognitive capacity to participate will likely hold opinions on what worked well or less well with the intervention, and what should be considered for implementation in other facilities. Why haven't resident views been sought? Please provide comment in the 'Patient and public involvement' section or include a limitations section outlining the reasons for their	We agree that the process evaluation would be strengthened with direct resident involvement. Our original intention was to include resident voices, specifically through engagement of the resident panels at individual residential aged care facilities. However, the aged care provider we worked with was not supportive of this at the time of undertaking the study, because of the challenges they were facing during the covid-19 pandemic including restricted access to residential aged care facilities. We have included a commentary on this in the 'Patient and public involvement' section and an

exclusion.	additional limitations section. Future research should address this important concern. The authors felt that having some input from family members could still contribute to the voice of residents while minimising the burden on residents.
3) Generalisability. The process evaluation (and wider RCT) is being conducted with a single provider in Queensland. The RAC stakeholder interview guide does include questions about generalisability to other RAC homes. What are the limitations of conducting this study with a single provider, particularly in trying to understand how and why the intervention might work at scale? Please provide comment in the discussion or include in a limitations section.	Although we are working with one aged care provider in Queensland, we have representation from facilities across a large geographical area, representing metropolitan and rural settings and will be able to identify sites with varying levels of staff turnover. Furthermore, the previous pilot study of the EDDIE intervention was undertaken with a different aged care provider giving us some comparison. However, we acknowledge this is a potential limitation and have added a comment to this effect in a new limitations section.
4) Interviewee recruitment. Interviewees will be recruited by email and direct correspondence (p14). Could the researchers clarify who will do the recruiting (i.e. themselves or someone from the provider)? If the former, will email addresses be sent to the researchers with prior participant consent? What does direct correspondence mean here? Please provide further details in this section.	Thank you. We have added further information to explain the recruitment of interviewees. In brief relevant family members and stakeholders across the 12 RAC homes at the time of the trial were identified by EDDIE+ facilitator, Bolton Clarke investigators and the QUT project team. Once identified, the QUT project team made contact. Once written consent was obtained, interviewee details were passed on to the investigators leading the process evaluation who coordinated a mutual time for the interview.
5) Self-efficacy questionnaire analysis. Please describe in more detail the analyses that will be undertaken with the staff self-efficacy questionnaire (p15). Also, how will missing data due to high staff turnover (p3) be treated in any analysis of change over time?	Thank you. Internal consistency of job-related and team-related self-efficacy will be assessed separately using Cronbach's Alpha. Differences between mean baseline and post intervention scores on the self-efficacy measures will be assessed using t-tests, to determine if there was a statistically significant ($p < .05$) change in job-related self-efficacy and team-related self-efficacy. Linear regression will be used to determine the contribution of staff-related factors including role, experience, age, gender, and location, to changes in job-related and team-related self-efficacy scores. Missing outcome data from staff lost to follow-up will be treated as missing completely at random (MCAR) and handled using complete case analysis (Groenwold et al., 2011).

6) Family member/advocate questionnaire. If the evaluation is not yet complete, the researchers could consider including 'N/A' options in this questionnaire. Alternatively, a question could be included on awareness of EDDIE+ and whether or not their family member received hospital avoidance care under the program.	Thank you for these suggestions. Unfortunately, as the data collection is now complete, we are unable to make the suggested amendments.
7) Just noting a couple of spelling mistakes - p3 'advocated' should be 'advocates'; Q5 staff questionnaire 'how long have you care for' should be 'cared for'.	Thank you. We have made these corrections in the revised manuscript.
Reviewer 2 comments	**Authors' responses**
This is a study protocol for a process evaluation of a RCT. As the authors point out, process evaluation is an important part of a project to understand not only if an intervention works but also how and why it may work. Generally, the protocol is well written, and the described methods are reasonable. I however think that some clarifications can be made.	Thank you for the encouraging feedback and the helpful suggestions to improve the clarity of the manuscript.
1. The process evaluation will assess the fidelity, acceptability, mechanisms of action and contextual barriers and enablers of the intervention. These concepts are defined quite late in the manuscript. It would be helpful for the reader to have a definition of these concepts already in the introduction. For instance, not all readers may be familiar with the concept fidelity.	Thank you. We have introduced these concepts earlier to ensure the reader has an established understanding early on (lines 97-103).
2. Fidelity will be assessed as the delivery of the interventions such as number of delivered and attended sessions. So, will the results be shown as the ratio between the number of delivered and attended sessions? What percentage is considered acceptable?	Thank you. We have indicated that we will calculate the percentage of staff who received training as an indicator of fidelity; however, we have not pre-specified what is an acceptable level.
3. The authors may consider adding analyses of factors associated with better adherence to the intervention, e.g., type of RAC, profession. This can give information on in for whom and in what contexts the intervention works better.	Thank you. we will use linear regressions to determine the contribution of staff-related factors (age, gender, location, role, experience) in relation to job and team-related self-efficacy.
4. Mechanisms will be assessed by a self-efficacy survey pre and post implementation. How long time will there be between the	Thank you. Due to the nature of stepped wedge trials homes with a longer intervention period will have a longer time between baseline and

surveys? Is the outcome of this assessments a change score? What is considered an acceptable change? Will the authors consider baseline levels when analyzing change?	post self-efficacy surveys. The baseline self-efficacy survey was completed immediately prior to the participant's (RN, EN, PCW) first EDDIE+ training session. The post intervention self-efficacy surveys are provided to staff between the final two weeks of the intervention exposure and up to two weeks post trial. The outcome of assessment is not a change score. Analysis will be conducted to determine if there is a statistically significant change in self-efficacy pre and post EDDIE+ intervention, but we have not pre-specified an 'level' of acceptable change.
5. The quantitative data analyses can be better described. What do the authors mean by inferential analyses (regression analyses, ANCOVA?)? What aims/concepts will be addressed with these analyses?	Thank you. Nursing staff and personal care workers completed measures of job related and team related self-efficacy (Riggs et al., 1994) at commencement of the intervention (baseline) and again at completion of the intervention (post). Differences between mean baseline and post intervention scores on both self-efficacy measures will be assessed using t-tests, to determine if there was a statistically significant ($p < .05$) change in job-related self-efficacy and team-related self-efficacy. The self-efficacy data will indicate if the EDDIE+ intervention was successful in upskilling nursing and personal care worker staff to manage sub-acute episodes within the RAC by providing the education, training, decision support tools and diagnostic equipment.
6. The study will include 12 RAC homes. Approximately, how many respondents will be included in the surveys and interviews?	Thank you. For the self-efficacy survey, our aim is to include as many staff as possible that we will match with the pre and post surveys. With regards to the interviews, we are aiming for 30 interviews per different group (staff, resident family members and external stakeholders) (lines 329-330).
7. The time plan could be clarified. Is this an ongoing study?	Thank you. Data collection for the process evaluation took place from May to September 2022. At the time of submitting the protocol paper data collection was in progress (July 2022); however, as there was a time gap to receiving reviewer comments, we have now completed data collection.

VERSION 2 – REVIEW

REVIEWER	Jorgensen, Mikaela Macquarie University, Australian Institute of Health Innovation
REVIEW RETURNED	24-Dec-2022

GENERAL COMMENTS	Thank you to the authors for your responses and the opportunity to review the revised manuscript. I just had one remaining question relating to the self-efficacy questionnaire analysis (#5). Could the authors clarify whether they are proposing to analyse change scores? This is not generally recommended (e.g. see doi.org/10.1093/ije/dyab050).

REVIEWER	Welmer, Anna-Karin Karolinska Institutet, Department of Neurobiology, Care Sciences and Society
REVIEW RETURNED	30-Dec-2022

GENERAL COMMENTS	The authors have done a good job with the revisions. I have no further comments.

VERSION 2 – AUTHOR RESPONSE

Reviewer 1 Comments	**Authors' response**
Thank you to the authors for your responses and the opportunity to review the revised manuscript. I just had one remaining question relating to the self-efficacy questionnaire analysis (#5). Could the authors clarify whether they are proposing to analyse change scores? This is not generally recommended	Thank you for the feedback. With regards to the question about the analysis of the self-efficacy questionnaire, we believe that it is appropriate to analyse the change scores given that we are conducting an intervention study within a randomized controlled trial. We have matched pairs of staff who completed the self-efficacy questionnaire pre and post the EDDIE+ intervention. The paper provided by the reviewer specifically refers to observational studies and points out that "analyses of outcome-change scores do not estimate causal effects except under randomized experimental conditions" (p.1605). The EDDIE+ study satisfies the condition of a randomized controlled trial.
Reviewer 2 comments	**Authors' responses**
The authors have done a good job with the revisions. I have no further comments.	Thank you.