PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Evaluating the provision of Further Enabling Care at Home (FECH+) for informal caregivers of older adults discharged home from hospital – protocol for a multicentre randomised controlled trial
AUTHORS	Hill, Anne-Marie; Moorin, Rachael; Slatyer, Susan; Bryant, Christina; Hill, Keith; Waldron, Nicholas; Aoun, Samar; Kamdar, Ami; Grealish, Laurie; Reberger, Caroline; Jones, Cindy; Bronson, Mary; Bulsara, Max; Maher, Sean; Claverie, Tracey; Moyle, Wendy

VERSION 1 – REVIEW

REVIEWER	Heli Vaartio-Rajalin Åbo Akademi University/Health sciences, Finland
REVIEW RETURNED	26-Nov-2020

GENERAL COMMENTS	The theme of the study is very actual and has an international relevance. However, the Abstract includes some flaws (patient over 70 years or over 80 years as in keywords? The organization names should be anonymized in order to follow the research ethics - also in the main text; and all the instruments to be applied are not clarified such as in Table 2). Furthermore, in Abstract You use the concept of effectivity in Aim, when in the main text the Aim is related to efficacy, and in hypotheses self-efficacy - these are not synonymous. So what is the Aim? The study design is well described but I would like to read a further developed description of the instruments chosen - why these instruments? How do they fit into Aim (and what is the Aim)? The instruments should be added into Figure 1. And how many nurses are going to be involved into FECH+ intervention? How can it affect the intervention and its results? In addition, the Informed Consent material should be described better, and the list of references should be rewritten (year of publication is missed in some references, and the style varies).

REVIEWER	David Levine Brigham and Women's Hospital / Harvard Medical School; USA
REVIEW RETURNED	03-Jan-2021

GENERAL COMMENTS	GENERAL COMMENTS Thank you for the opportunity to review this manuscript. The authors should be congratulated for proposing to study a very important and understudied area. The authors seem to have already begun their protocol, and so my comments purposefully focus on reconcilable areas. In general, I feel the authors could better make the case for why they believe a telephone-based post-discharge intervention based on only 6 telephone calls will be effective. I also wonder, given Australia's robust Hospital in the Home infrastructure, if a subgrouping of patients who received their acute care at home instead of in the

	traditional hospital could be examined. Please see my specific comments below. SPECIFIC COMMENTS Introduction • The authors note references 10-13 as "evidence that providing supportive programs can reduce the adverse consequences of caregiving for older adults." However, reference 10 notes, "the effect of caregiver support interventions is small and also inconsistent." Reference 11 is the lead author's own pilot for FECH. Reference 12 analyzes digital mental health tools, which are not proposed in this study, and mostly notes there are few. Reference 13 describes the HRQOL of dyads, not an intervention to support the dyad. In light of this, the authors could better make their case. • Reference 20's findings are striking and cause the reader to question why FECH+ will be successful. There are multiple trials like FECH that have sadly failed (most recently, for example: Schnipper and Samal et al, J Hosp Med, 2020). • The authors' pilot data are a strength. Aims and Hypotheses • The authors could better rationalize their choice of HRQOL as the primary outcome, as opposed to readmission, for example. Participants • Could the authors explain the discrepancy between the ANZCTR registration and this manuscript with respect to "providing unpaid support?" This eligibility criterion is not noted in the registration. Outcome Measures • Could the authors explain the discrepancy between the ANZCTR registration and this manuscript with respect to primary outcome? The registration notes co-primary outcomes; the manuscript does not. Perhaps their reporting of economic analyses separately explains this? • The authors are wise to comment on the suitability for telephone administration of the BADLI. However, it seems odd that only this tool is called out, whereas the others are not. Will the others not be administered by telephone? Statistical analysis plan • The authors could cite their multiple imputation method. • Will the tests be performed 2-sided? This is not stated. • The authors' power calculation does not seem to account for their repeated measures analysis. To my knowledge, G*Power is not capable of this. See https://bmcmedresmethodol.biomedcentral.com/articles/10.1186/1471-2288-13-100. Trial status • The authors note that recruitment commenced August 2020 yet the ANZCTR registration notes a recruitment status of "not yet recruiting." Could this discrepancy be reconciled?

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 comments	Thank you for your time and helpful comments to improve the manuscript.

3	However, the Abstract includes some flaws (patient over 70 years or over 80 years as in keywords	As stated is correct. The inclusion criteria for our trial is aged 70 years and over. We have no upper age limit for exclusion. For the Keywords the authors have used MeSH browser terms. These are: **"Aged" (MeSH scope notes stated this is aged 65 and older)** **"Aged, 80 and over"** Checking keywords from multiple records in PubMed confirms both of these keywords these are used consistently for trials that focus on older adults. These metadata will ensure that the protocol is found on searches of older adults. To avoid any confusion authors have removed the MeSH term "Aged, 80 years and over.
4	Furthermore, in Abstract You use the concept of effectivity in Aim, when in the main text the Aim is related to efficacy, and in hypotheses self-efficacy - these are not synonymous. So what is the Aim?	Thank you for identifying this discrepancy. We have clarified the wording of the aim in the Abstract to use the word "efficacy" as opposed to a trial design of "effectiveness"(1). The Aim is now as stated in the abstract and repeated in the introduction (*see inserted highlighted word correction in abstract).* 1. Schwartz JS. Health services research: translating discovery and research into practice and policy. In: Robertson D, Williams GH, eds. Clinical and Translational Science: principles of human research. 2nd ed. Boston: Elsevier 2017: page 113. Self-efficacy is used in the secondary outcomes and is used in the context of a secondary hypothesis explaining the proposed mechanism of the intervention. i.e. will there be improvement in caregiver self-efficacy in the intervention group? To clarify, in the secondary aims authors have inserted the word caregiver prior to the word self-efficacy where this is stated *(see inserted highlighted word prior to self-efficacy in Aims and hypotheses section.)*
5	The organization names should be anonymized in order to follow the research ethics - also in the main text;	Authors have aimed to follow research guidelines for transparency and included names of participating organisations and locations of the research which are also available publicly on the trial registry website where our trial is registered.

		If any query, authors are agreeable to adhere to Editor feedback if change is requested. See other examples in BMJ open of published protocols that identify the organisations. http://dx.doi.org/10.1136/bmjopen-2020-042475 http://dx.doi.org/10.1136/bmjopen-2020-037457
6	and all the instruments to be applied are not clarified such as in Table 2).	See response to comment 7 below.
7	The study design is well described but I would like to read a further developed description of the instruments chosen - why these instruments? How do they fit into Aim (and what is the Aim)?	Authors have provided more information about of some instruments in the outcome procedure section being mindful of word count (*see inserted highlighted text in the outcome section of the methods*). Each instrument has also been referenced so that readers can obtain further information as interested. The instruments have been chosen to measure the constructs of interest that can assist to explain the causal mechanism of the intervention. We have added some text to explain this at the beginning of the secondary outcomes (*see inserted highlighted text in the beginning of the secondary outcomes in the outcome section of the methods).* We have also added linking text to explain the hypotheses at the end of the introduction that explain why these outcomes should be measured *(see sentence in paragraph 4 of the introduction just prior to the Aims and hypotheses section beginning "Secondary aims will assist to explore….").* Re how they fit into the aims - The instruments measure each of the outcomes that will evaluate the primary and secondary aims. Each outcome is matched by an instrument – to clarify for the reader the outcomes have been matched to the aims in this section *(see inserted aim number against each outcome and its relevant tool).*
8	And how many nurses are going to be involved into FECH+ intervention? How can it affect the intervention and its results?	Authors have clarified that two to three nurses will be employed for each site. We have also clarified that training is provided for all nurses as a group and regular monitoring of data is being undertaken to maintain fidelity of

		intervention delivery (*see highlighted text in Methods: sub section of training).*
9	In addition, the Informed Consent material should be described better	Thank you - authors have now added supplementary online files of plain language statements and consent forms for the reader *(see supplementary material).*
10	List of references should be rewritten (year of publication is missed in some references, and the style varies	Authors have re-checked the reference list for any inaccuracies and made corrections. Word and year corrections have been highlighted. Any small punctuation errors have been corrected without highlighting. Authors are happy to make any further edits if the reviewer specifies (*see highlighted text in references).*
Reviewer 2 comments		Thank you for your time and helpful comments to improve the manuscript.
11	In general, I feel the authors could better make the case for why they believe a telephone-based post-discharge intervention based on only 6 telephone calls will be effective.	Authors have firstly clarified that the original FECH program was a telephone intervention hence our reasoning is partially based on the pilot trial. (*see inserted phrase first sentence of paragraph 4 of the introduction*). We have also added text that explains the FECH program in the pilot trial achieved a moderate effect size and was clinically significant (*see inserted text paragraph 4)* providing evidence for evaluating its efficacy. Finally. we have added some background research showing some evidence that telephone interventions for caregivers can have positive impact and relevant references for the reader (*see highlighted text in paragraph 4 in introduction and new references highlighted in reference section)*. *(Also see response to comment 13 and 14 below).*
12	I also wonder, given Australia's robust Hospital in the Home infrastructure, if a subgrouping of patients who received their acute care at home instead of in the traditional hospital could be examined	Authors agree it would be useful but are not able to include this as part of the present trial. We chose to focus on patients who had been admitted and this approach is supported by the service providers in our trial. We are unable to change the participating sites at this stage of project development.
13	The authors note references 10-13 as "evidence that providing supportive programs can reduce the adverse consequences of caregiving for older adults."	*See also response to comments 11 and 14.* Authors were intending to make the case for our study by emphasising that the evidence is sparse and that although there are some positive results such as our pilot trial, there are no conclusive studies that demonstrate an effective

	However, reference 10 notes, "the effect of caregiver support interventions is small and also inconsistent." Reference 11 is the lead author's own pilot for FECH. Reference 12 analyzes digital mental health tools, which are not proposed in this study, and mostly notes there are few. Reference 13 describes the HRQOL of dyads, not an intervention to support the dyad. In light of this, the authors could better make their case.	replicable intervention. Therefore, further research is required. We have aimed to clarify and explain this rationale by making the following adjustments: The word limited has been added to emphasise the overall findings of studies published to date. "There is <u>limited</u> evidence…." *(see inserted highlighted word first sentence of paragraph 3 in the introduction)*. We have brought up a sentence from later in the paragraph to link the gaps in evidence to gaps in evidence specific to the after-discharge period (s*ee highlighted second sentence in the third paragraph which has been transferred up).* We have added text from a recent reference that explains some of the gap in evidence, demonstrating the mechanism behind the lack of effectiveness. Feelings of helplessness and lack of information contribute to stress which is what the intervention addresses (*See highlighted inserted text in introduction paragraph 4 and new reference Lilleheie et al,2021 highlighted in reference list*). Reference 12: We intended to show there is limited evidence overall, no matter which type of program is provided. We have inserted a phrase to clarify this (*see inserted phrase in first sentence in paragraph 3 in the introduction*). We believe that the authors of this study in noting there are few effective interventions strengthen the rationale for designing and evaluating new and novel interventions. Our pilot trial demonstrates our work to fill this gap. To address relevancy, reference 13 has been replaced by an article reporting an *evaluation of a program for caregivers to support a patient being discharged from hospital*. Caregivers attended a face-to-face caregiver training prior to discharge and received two telephone checks after hospital discharge that ended after 14 days of hospital discharge (Hendrix et al.2020) (*see reference 13 in*

		the reference list)
14	Reference 20's findings are striking and cause the reader to question why FECH+ will be successful. There are multiple trials like FECH that have sadly failed (most recently, for example: Schnipper and Samal et al, J Hosp Med, 2020).	Authors agree that the systematic review findings of Smith et al demonstrated only low-quality evidence for some benefit in reducing caregiver burden and anxiety. Again, we believe this demonstrates the need for more trials to be conducted and note that authors of this review also reach this conclusion (as we state). We have now overtly stated this at the end of paragraph 3 to summarise that this gap in evidence requires more research (*see highlighted last sentence in paragraph 3*). Authors will evaluate if FECH + will be successful based on the strength of our pilot data and past evidence about interventions delivered to caregivers. This is the reason for conducting the trial and in Australia this gap in evidence-based care for this population was deemed to be of sufficient urgency to fund our trial. While there are other trials that have not demonstrated efficacy, authors are evaluating a new intervention. While we note the reference of Schnipper et al., that study focuses on adults rather than older adults and does not focus on carers. We are aiming to provide an intervention that improves carers' preparedness to care and reduces their stress and evaluate if this in turn improves their quality of life.
15	The authors could better rationalize their choice of HRQOL as the primary outcome, as opposed to readmission, for example.	Authors sought to use a tool that directly measured the impact of the intervention on caregivers' quality of life. While readmission is a suitable measure for health care services to evaluate whether they are providing adequate health care such that discharged patients do not return, it can be substantially influenced by factors beyond the control of the caregiver. Hence this outcome this does not evaluate how the caregiver is coping at home and what impact the discharge is having on their physical and mental health and overall wellbeing. We believe that improved health related quality of life of carers is likely to be associated with improved ability to sustain the caregiving role longer term which is an important outcome in its own right.

		We have added a short explanation to justify our choice of this outcom (*see highlighted sentences in paragraph 4 related to HRQOL).* We have also added detail about HRQOL and its constructs for the reader in the outcomes measures section to more overtly demonstrate the problems carers face and the way AQOL-8D captures these constructs *(see inserted highlighted text in paragraph 1 in outcome measures - methods section).*
16	Could the authors explain the discrepancy between the ANZCTR registration and this manuscript with respect to "providing unpaid support?" This eligibility criterion is not noted in the registration.	Authors used the phrase to clarify the Australian system for an international readership. We sought to explain the difference between caregivers who are family/ friends and professional paid care workers from a health care organisation. To ensure consistency we have removed the word from this sentence but clarified further in text following *(see inserted text in participant section of the methods)*
17	Could the authors explain the discrepancy between the ANZCTR registration and this manuscript with respect to primary outcome? The registration notes co-primary outcomes; the manuscript does not. Perhaps their reporting of economic analyses separately explains this?	Yes - the primary outcomes are both clinical and economic. We stated the clinical outcome separately to the economic outcome. Authors have now clarified for the reader by adding text in the primary aims section clarifying that the economic outcome is also a primary outcome *(see highlighted text in primary aims - introduction section).*
18	The authors are wise to comment on the suitability for telephone administration of the BADLI. However, it seems odd that only this tool is called out, whereas the others are not. Will the others not be administered by telephone	Yes, authors are administering all tools including baseline assessment by telephone. We inadvertently emphasised this tool but have clarified this for the reader to state that we previously found it feasible to effectively administer these tools by phone in our pilot trial. (*See inserted text in outcomes section after secondary outcome measures described).*
19	The authors could cite their multiple imputation method.	Authors have provided a citation (Stern et al). (*See highlighted citation in the statistical analysis section and in the reference number 48 in the references).*

20	Will the tests be performed 2-sided? This is not stated.	All statistical tests will be two-sided. *See highlighted inserted text in methods statistical analysis section.*
21	The authors' power calculation does not seem to account for their repeated measures analysis. To my knowledge, G*Power is not capable of this. See https://bmcmedresmethodol.biomedcentral.com/articles/10.1186/1471-2288-13-100.	We used a Simple Random Sample design with an effect size we expect to see. This design will give a higher sample size than we require using a Repeated Measures Design. This project will have a high drop-out rate and so we prefer to keep a larger sample size in order to be adequately powered and also to take care of any secondary analyses. The power calculation has been repeated with PASS software - this produced the same sample size.
22	The authors note that recruitment commenced August 2020 yet the ANZCTR registration notes a recruitment status of "not yet recruiting." Could this discrepancy be reconciled?	Authors have sent two requests for the updates to be placed onto the trial registry website but, as with other aspects of research, the registry has experienced significant time delays due to COVID 19. The trial has ethics approvals and was able to commence as soon as public health regulations for COVID19 allowed Australian hospitals and Universities to do so. We seek to publish our protocol in a timely manner so the trial is in the public domain.