Reviewer's report

Title: Evaluating the implementation of the PACE Steps to Success Programme in long-term care facilities in seven countries according to the RE-AIM framework

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Reviewer: Matthias Hoben

Reviewer's report:

Process evaluations of complex interventions are key to understanding how and why (or why not) a complex intervention worked. Unfortunately, such process evaluations are rarely published. Therefore this paper is a potentially important addition to the literature. The approach that was implemented - a program to improve palliative care practices in long term care - is highly needed and a process evaluation to better understand how this intervention was implemented and experienced by participants is an important research topic. However, there are several concerns that I think the authors need to address:

Abstract, line 7: "..., which aim was" - consider revising to "..., whose aim was"

Introduction, line 66 and following: I understand that details on study methods and effectiveness of PACE are (or will be) published elsewhere. However, a few more details on how "quality of the end-of-life care given to residents" was defined and measured are needed here. Quality of end-of-life care is a very broad concept. I would appreciate if the authors could elaborate a bit on which outcomes they assessed to measure this concept. Also, again while I understand that the authors have their effectiveness study under review somewhere else and they can't compromise that submission by reporting actual effectiveness results in this process paper, I would appreciate a definition of what the authors consider a "small effect size".

Process evaluation: I suggest that the authors briefly define each of the 5 RE-AIM domains early on (could be done in a table or figure). The authors explain in the methods section how they measured each of the five domains, but until then readers who are not familiar with the Re-AIM framework have no idea what each of the 5 domains actually mean.

Process evaluation, line 79 and following: In their trial protocol the authors state that the PACE study was a pragmatic trial and while they don't make this statement in this paper, it is still obvious that this was a trial of quite some pragmatic nature. Therefore, I think the term "efficacy" is not accurate, since it usually reflects whether an intervention works under highly controlled, more laboratory-like conditions. Effectiveness (as actually used by the authors in the introductions) seems more appropriate. The Re-AIM framework allows for both options. Please revise throughout the paper. Furthermore, I think the statement that PACE 'performed well' on this domain contradicts what the authors state in the introduction - i.e. that effect sizes were small and for some outcomes no effects were found. There is some evidence for the effectiveness of PACE but I am not sure if that is enough to say PACE 'performed well'. Please consider to word more carefully. Also, rather than saying 'despite the fact that we found effects overall
impact may have been small if implementation was poor’ I think it would make more sense to say something like ‘better understanding the other four RE-AIM domains - such as poor implementation - will help to determine why the overall effectiveness was rather small or why we found no effects for some of the study outcomes’. The current version neglects the fact that a certain implementation fidelity and intervention effectiveness are closely interwoven - and the small overall impact the authors mention is actually reflected by the small effect sizes (rather than overall impact being distinct from the small effect sizes as implied by the current wording). Finally, consider amending the last sentence in this paragraph (lines 81-82). Not only can process evaluation help to optimize the intervention itself, but also to optimize the implementation process and uptake.

Data collection, tab. 1: Reflecting on the definitions of the RE-AIM domains and the descriptions in table 1 of how they are operationalized, I have a few questions:

(a) generally, I wonder how the authors decided and justified the cut-off scores/criteria for high/medium/low levels of each RE-AIM domain. This applies especially the first two domains (reach & adoption), which are both based on proportions. Why are the cut-offs for these two proportions different? Were they determined based on distributions or are there any qualitative/content-based criteria the authors applied?

(b) REACH: Why did the authors just focus on attendance rates? Part of the definition of the REACH domain also is the representativeness of participants. The authors just refer to LTC staff, but the provider groups working in these facilities are quite heterogeneous. They include care aides (or nursing assistants), regulated nurses, allied health providers, clinical educators/specialists, managers, ... Was there any participant group that was over-/under-represented? Were certain provider groups more likely to attend than others? Was attendance of certain groups more critical than attendance of other groups? Furthermore, how meaningful is it to average attendance rates across the six steps? What if in a facility attendance was very high at the first few steps and dropped off later on while in another facility attendance was relatively constant but rather mediocre across all six steps. Both facilities will likely have a medium attendance rate when averaging across the six steps. However, one would expect quite a different effect in both facilities. In other words, are there workshops that are more critical to attend than other ones (e.g. early steps are critical because they are a prerequisite for subsequent steps). Finally, how important would it be that roughly the same people attend all the sessions? If there is a facility with high turnover but the staff members who were working there (despite the fact that they were new ones in each step) were likely to participate, the mean attendance rate would be high. However, staff members only were exposed to certain parts of the intervention. Would that matter?

Data collection, line 129: Consider deleting the phrase "Here to,"

Results, Reach, lines 179 and following: The authors state that attendance rates ranged from 4% to 81%. However, appendix fig. 4 suggests that there were 2 facilities in Belgium (#s 4 & 6) with no attendance at all. Please clarify.
Results, Adoption, lines 221 and following: The authors state that adoption rates ranged from 6% to 186%. However, appendix fig. 5 suggests that there was 1 facility in The Netherlands (# 3) with no adoption at all. Also, it is unclear how adoption rates &gt; 100% are possible. Regardless of resident turnover, should not the total N of residents (no matter if they left at some point or if new residents were included) be the denominator and should not the number of residents among this total number of residents with documents available be the denominator? If that is the case, rates &gt; 100% are impossible. Please clarify.

For later: do they focus on facilities that have high/low ratings in all domains?

Discussion, recommendations of how to improve PACE, lines 401 and following: Many of the barriers the authors identified are well known. Can the authors please discuss why minimal amount of documentation, provision of clear materials and ensuring that trainers are well qualified are things they could not have taken into account before carrying out PACE? Also, I am unclear why using electronic documentation instead of paper-based documentation would be an improvement. I would think that documentation in general (regardless whether it is on paper or electronic) is a barrier. The same is true for the barriers related to PACE participants. The relevance of managers for intervention and implementation success is not a novel finding. The same is true for the finding that PACE coordinators need to be motivated and need to have enough time and other resources. Every available model on factors influencing implementation processes will include these factors. Finally, the need to tailor interventions to local contexts, ensure appropriate timing, etc. also were well-known facts during the development of the PACE program. Please discuss why these factors were not taken into account for the intervention and implementation design.

Generally, the discussion falls short of comparing the findings of this process evaluation to process evaluations of other complex interventions. Examples to consider are (among many others):

- The process evaluation of the FIRE study:
  https://implementationscience.biomedcentral.com/articles/10.1186/s13012-018-0811-0 and

- Use of the PARIHS framework to evaluate the implementation process:

- Use of the Normalization Process Theory to evaluate intervention implementation:
  https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-8-96 or
  https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-7-106

I recommend that the authors also critically discuss possible limitations of the RE-AIM framework and how other approaches to assessing fidelity and implementation success compare to the RE-AIM framework. For example the Delivery, Receipt and Enactment framework (references see below) differentiates more finely grained what is simply called 'adoption' and 'implementation' in the RE-AIM framework.


Other frameworks include the Normalization Process Theory or the fidelity assessment framework published by Carroll:


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