Author’s response to reviews

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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Author’s response to reviews:

Dear editor,

Thank you for the opportunity to revise our manuscript. Below we provide a detailed response to the reviewers’ comments in their reports.

Associate editor report: please add a section to the discussion which reflects on the implications for implementation science as a field. This could involve implications re: the conduct of process evaluations alongside complex interventions, on methodological aspects, on the use of frameworks for process evaluation, and/or on conducting multinational process evaluations (and appropriate references where relevant). The process evaluation literature is an increasingly vibrant one and demonstrating how this work contributes to the extant literature as it relates specifically to implementation science would help to draw generalizable principles that may be of interest to a broader set of readers.

Response: Guided by the comments of reviewer 2, we elaborated the discussion by

- comparing our findings to findings of process evaluations of other complex interventions;

- by reflecting more on challenges in doing a multinational process evaluation study in the complex LTC setting;

- by elaborating more on our choice for structuring the process evaluation study according to the RE-AIM framework;

- and by relating our findings and thoughts on future dissemination of the PACE Programme to the fidelity-adaptation debate – a debate that is increasingly recognized within implementation research studies of complex interventions.

See our responses to reviewer #2.
We think that these elaborations contribute to draw generalizable principles of interest to a broader set of readers.

Reviewer reports:

Reviewer #1: This paper presents a process evaluation that was conducted as part of a larger cluster randomized controlled trial of the PACE "Steps to Success" program. The authors used mixed-methods to conduct the process evaluation focusing on implementation of the PACE program in the larger trial and were guided by the RE-AIM Framework.

Overall, this is a well-written paper that is clear and easy-to-follow. The authors present a comprehensive and robust process evaluation exploring various facets of implementation (reach, adoption, maintenance, etc.), using complementary quantitative and qualitative methods. Major feedback is presented below, as well as minor comments.

Comment: Background: Further clarification on the clinical intervention (PACE program) vs the implementation intervention (i.e., implementation strategy/strategies) would be helpful. As-is, it is unclear what exactly was part of the clinical intervention (everything in Figure 1; what were the 'core components' of the clinical intervention - all 6 steps?) vs the implementation intervention/strategies (e.g., use of a 'champion' - the PACE coordinator; as well as training sessions that were delivered over 12 months). When specifying the implementation strategies used, it would be helpful if the authors could map them onto a framework (e.g., the ERIC framework by Powell et al.). Also, if there is a website for the PACE program that could be included, that would be helpful to reference in case readers wish to learn more about the program/implement it at their organization. As a researcher who focuses on hospice/end-of-life/palliative care, some evidence showing concordance of the PACE program with clinical practice guidelines for palliative care (and/or evidence of the original clinical intervention showing positive effect on health outcomes) would be useful.

Response: The reviewer is right that all 6 steps were key components of the PACE Steps to Success Programme (as is described in the paper). However, a differentiation between clinical intervention and implementation strategies is not applicable, as the PACE Steps to Success Programme is designed as a holistic multicomponent one-year train-the-trainer program. Training PACE coordinators as local champions is actually as much a central feature of the Program as the content of the six steps.

To further clarify this and to refer to evidence showing concordance with clinical practice guidelines, we added the following sentences to the introduction:

"The PACE Steps to Success Programme is a one-year multicomponent train-the-trainer programme for nursing homes that aims to stepwise implement a palliative care approach into the day-to-day routines in nursing homes. …"
The intervention was based on the ‘Route to Success in Long-term Care Facilities’, a palliative care intervention developed in the UK.9,10 The Route to Success builds upon the well-known palliative care intervention ‘Gold Standards Framework’ (GSF), which aims to improve palliative care within primary care and was later adapted for use in long-term care facilities.11,12 The program is described in detail elsewhere8, and information packages in various languages are available from the website of the European Association for Palliative Care.13"

Comment: Methods: Some discussion of the timeline and triangulation between the quantitative and qualitative methods would be helpful. For example, were quantitative data analyzed first? Did results of quantitative analyses inform qualitative data collection (i.e., was the team able to tailor interview guides/discussion guides based on quantitative results they were seeing so that they could ask targeted questions)?

Response: The time at which measures were collected is described in the text as well as in Table 2.

Qualitative data collection (interviews) took place at month 13-15. Researchers who performed the interviews were instructed to take notice of the answers on the questions of the evaluation questionnaire, which were collected in month 8, and prepare some targeted questions that they could bring in if needed.

We added to the methods:

"Researchers in each country were trained in conducting these qualitative interviews, and were supported by the first and last authors (MOV and HRP) during monthly online meetings. They were instructed to take notice of the nursing home staff’s answers on the evaluation questionnaires, which were collected a few months earlier, and prepare some targeted questions that they could bring in if needed."

Comment: Methods/Results/Discussion: Overall, the methods used by the authors were comprehensive and rigorous. However, I had some concerns about their measure of implementation. Implementation was measured at the level of the implementation strategy (how many educational sessions were delivered/attended), but not at the level of the clinical intervention (once trained, how were LTCF PACE coordinators implementing each of the 6 steps in the PACE model?). My main concerns about this approach are that although this measures implementation of the implementation strategy, it does not measure implementation of the PACE model at the LTCFs. Quantitatively/systematically assessing implementation of the PACE model itself may have shed additional light on the main results of the trial which showed little effect on patient outcomes. If such data are presented as part of a separate publication, a reference to the publication for further details would be helpful to the reader.

Additionally, the data collected from LTCF staff (PACE coordinators) seemed to focus only on the perceived effectiveness of the country instructors, not the PACE program itself. If the authors
have any data that would point to implementation of the PACE model itself, that would be helpful to include. The barriers/facilitators section speaks to this some (e.g., resistance of staff members to use PACE documents), but additional data would be helpful, as it would help paint a more comprehensive picture of where the "voltage drop" occurred in the trial, since the authors note there were no effects on patient outcomes (symptom burden in last week of life). As-is, the reader is left to wonder if it was one of several issues: ineffective clinical intervention? Suboptimal implementation of/ineffective trainings (trainings given to PACE coordinators by country trainers)? Poor implementation of the PACE program itself, despite an effective clinical intervention and effective implementation intervention. If such data were not collected, acknowledging this as a limitation may be appropriate.

Response: We can alleviate the concerns of the reviewer, because – as the reviewer frames it – implementation on the level of implementation strategies as well as on the level of the PACE steps were evaluated. The latter one is called Adoption in the RE-AIM framework.

According to the RE-AIM framework, Implementation was operationalized as ‘the extent to which the intervention was implemented as intended’. We investigated this by analyzing the structured diaries that country trainers completed on a weekly basis during the 12 months of the intervention, in which they kept track of all the activities they performed regarding the PACE Steps to Success Programme, to see how many sessions were delivered, in what order and what time. Additionally, we examined the quality of the trainings by involving the appreciation of care staff members towards the programme and trainer’s teaching competencies.

In addition, Adoption was measured as the number of PACE documents (Looking and Thinking Ahead documents from step 1, and pain and depression assessments from step 4) that were completed and archived at the end of the consolidation period (month 12). This merely reflects the adoption of the PACE steps at the LTCFs.

Factors affecting Adoption are described in the results section. These factors concerned: the content of documents, the organization of daily care practice, resistance to use documents, the target group and stimuli from others.

Comment: Discussion: In the Discussion, the authors mention that the barriers/facilitators map onto CFIR. Some formal mapping would be helpful, if possible. For example, noting that PACE Program/way of delivery maps onto the characteristics of the intervention domain, people working with PACE maps onto the characteristics of individuals domain, as well as linking other findings to specific constructs.

Response: As requested, we made the mapping of the PACE categories onto CFIR more explicit, by describing:

"The three categories described above largely correspond with the domains in the Consolidated Framework For Implementation Research (CFIR)27, with the first category ‘the PACE Programme itself and its way of delivery’ mapping onto the CFIR domain ‘characteristics of the
Comment: Minor Comments

* Line 229 - "the proportion of residents for who had a completed pain and/or depression assessment" - I believe "for" should be deleted

* Line 309 - "so that he/she could incorporate examples from own practice" - I believe "his/her" should be placed in between "from" and "own"

* Line 319 - consider "intention to maintain" instead of "intention to maintenance"

Response: Thank you for pointing us to these errors. We have revised them accordingly.

Reviewer #2: 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:

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

Response: We changed the sentence.

Comment: 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".

Response: The reviewer is right that the paper reporting about the effectiveness study is under review elsewhere. Because it is not published yet, we actually prefer to not show any information on trial effectiveness in this paper, and removed the few sentences about it. If the editor wishes that information on the effectiveness of the trial is included in this paper, we would like to ask
for some more time until the other paper has been published. Then, we can add detailed information on the effectiveness of the trial if wished.

Comment: 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.

Response: We have included the definitions of the RE-AIM domains as used in the process evaluation study in a Box (Box 1).

"The process evaluation followed the RE-AIM framework to structure the different implementation factors namely Reach, Effectiveness, Adoption, Implementation, and Maintenance23 (see Box 1 for a definition of each of these domains)."

Comment: 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.

Response: We changed 'efficacy' into 'effectiveness' throughout the paper.

Comment: 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.
Response: We agree with the reviewer that effectiveness and implementation are closely interwoven, and that process evaluation studies can help to optimize the intervention as well as the implementation process.

We changed the sentences into the following:

"These five domains interact to determine the overall impact of a health intervention programme. This means that an evidence-based intervention could still have low overall impact if it is poorly implemented. Process evaluation studies allow for insight into how interventions and the process of implementation can be optimized, to aid future dissemination.23"

Comment: 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?

Response: The paper describes that the criteria for high, medium and low levels of Reach, Adoption, Implementation and intention to Maintenance were established during a consensus meeting with the PACE consortium and that they were based on key elements of the program, before the results were analysed.

The criteria were thus not based on the distributions but based on the content of the PACE programme. The cut-off score for a high level of Reach is indeed somewhat lower (70%) than for Adoption (80%). This is because we considered a mean attendance rate of (almost) 100% not to be realistically achievable in practice, because of sickness/holiday of staff or staff who must stay on the ward, while a rate of 100% Adoption (percentage of residents with an ACP document completed and archived) is more easily achievable in practice.

We added to the text:

"Before the results were analysed, we established criteria for high, medium and low levels of Reach, Adoption, Implementation and intention to Maintenance during a consensus meeting with the PACE consortium, based on key elements of the program. For example, Reach was rated ‘high’ if the mean attendance rate on all six training sessions was 70% or higher, ‘medium’ if 30-69% and ‘low’ if below 30%. Cut-off scores for Adoption were somewhat higher than for Reach, because we thought that higher rates on Adoption would be more easily achievable in practice (see Table 1 for the full list of criteria)."
Comment: (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?

Response: Unfortunately, we are not able to answer the reviewers’ questions. Because we aimed for clear and simple attendance lists that PACE coordinators could easily fill in, the attendance lists only asked for the number of care staff members attending each session and the total number of care staff members working in the LCTF at that moment. Care staff members were defined as nurse aids, certified nursing assistants and registered nurses, but not separately rated in the attendance lists. The attendance lists for step 3 (multidisciplinary review meeting) and step 6 (reflective debriefing sessions) additionally asked whether GPs, community nurses or other persons attended these, as allied health providers were particularly invited to attend these sessions.

Comment: 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).

Response: All steps are equally important within the PACE Program, and there are no steps that are more critical because they are prerequisite for other steps (although attending step 1 could raise enthusiasm for attending the other steps as well – we found in the qualitative data).

We agree however with the reviewer that one average attendance rate does not provide a complete picture. Indeed, the patterns described by the reviewer (drop in attendance rate after 2 steps or mediocre attendance across all steps) were seen in the LTCFs. Of course we could present the attendance rates per step per LCTF, but that is too much data to digest easily. Therefore, we chose to have one average attendance rate and to also present additional information and explanations that were found through the qualitative interviews.

However, if the editor would like us to present the separate attendance rates per step per LCTF, we are willing to describe this in a Supplementary file.

Comment: 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?

Response: For the same reason as described above (no step being a prerequisite for other steps) it did not matter so much if staff members were only exposed to certain parts of the intervention. Moreover, country trainers encouraged staff members and PACE coordinators to share what they learned between the training sessions with staff members who could not attend, and from the qualitative information we know that this was done regularly. In addition, we asked managers in the qualitative interviews whether staff turnover influenced the implementation, but the majority indicated that this barely played a role.

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

Response: OK, we deleted these words.

Comment: 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.

Response: For 2 LTCFs in Belgium, not all 6 attendance lists (from the 6 steps) were received from the PACE coordinator, so their mean attendance rate could not be calculated. However, based on the attendance lists we did receive, information from the country trainer and from the (group) interviews, we could estimate their level of Reach as Medium. This is described in a note at Figure 4.

Comment: 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.

Response: Appendix Figure 5 is accompanied by the following notes, which will hopefully provide answers to the reviewer’s questions:

Notes: (1) For 1 LTCF in The Netherlands, no report was received from the PACE coordinator, but the level of Adoption could be estimated as Low, based on information from the (group) interviews. (2) Due to high resident turnover the proportion in some LTCFs exceeds 100% as it was calculated as ‘number of residents with document divided by number of beds’. 

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

Response: No, we did not focus on LTCFs that score high or low on all domains. We have thought of one measure capturing the levels of all domains, and to relate this to the effectiveness study, but this was too complicated. Because the different domains are differently important in each LTCF in influencing the level of Effectiveness, no such measure would realistically capture the overall implementation.

Comment: 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.

Response: The reviewer is right that many of the barriers and facilitators were identified in earlier research. That is why they (the 3 categories in which they are bundled) map so well onto the Consolidated Framework for Implementation Research (see comment of reviewer 1).

Of course, most of these aspects were taken into account before the trial started (e.g. we tried to seek well-qualified trainers, motivated PACE coordinators and supporting managers), but still came out as barriers. That is because the intervention took place in a complex setting and in the real world, in which many aspects changed along the way (PACE coordinators left or became ill, managers had to deal with reorganizations etc.).

Also, because of the cluster randomized controlled trial, we had to constantly seek balance between generalizing the intervention across the seven countries as much as possible and tailoring it to local contexts. Now that the PACE Program proved effective on some of the study outcomes, the intervention can contextualized better in future implementations. This also means that LTCFs can add the materials and tools to their own electronic system (which is different in the countries and LTCFs, therefore we provided materials on paper in the trial), which care staff is used to work with and which will make it easier to attach the materials to a certain resident.
We elaborated on this in the discussion:

"Although the barriers and facilitators we identified may not be all novel\textsuperscript{29}, and most of them were even taken into account before we started the trial (e.g. we defined a set of criteria for the selection of country trainers and PACE coordinators, we tried to motivate managers and deliver clear materials), the practicalities of realizing them still appeared to be a challenge (e.g., identifying and retaining persons who fitted the selection criteria and stayed in post for the duration of the study, translating and culturally adapting a programme that is originally from England). The nursing home context is described as a particularly difficult one in which to implement change and improvement, because of issues related to staff turnover, high workload, low numbers of registered nurses and an institutional environment that continually shifts and transforms.\textsuperscript{29,30} The international scope of the study added another layer of complexity. As described, country-specific as well as facility-specific challenges were omnipresent. …"

Comment: 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):


- Use of the PARIHS framework to evaluate the implementation process: https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-8-28


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 theDelivery, 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:
Response: We thank the reviewer for mentioning all these studies. We added a paragraph which we compared our findings to other process evaluations of complex interventions.

"The three categories described above largely correspond with the domains in the Consolidated Framework For Implementation Research (CFIR)27, with the first category ‘the PACE Programme itself and its way of delivery’ mapping onto the CFIR domain ‘characteristics of the intervention’; the second category ‘people working with the PACE Programme’ mapping onto the CFIR domain ‘characteristics of individuals’; and the third category ‘contextual factors’ mapping onto the two CFIR domains ‘inner and outer setting’. These are not isolated categories, but interrelate with each other in a way that corresponds to the findings from a realist process evaluation within the Facilitating Implementation of Research Evidence (FIRE) study performed in care homes.28 This study suggested an interplay between mechanisms relating to the alignment and fit of the intervention with staff members’ needs, expectations and work setting, prioritization of the topic of the intervention and engagement of staff with the intervention, which, in combination influenced staff’s ability to learn over time and ultimately implement practice changes.28 Indeed, we found that the level of implementation was largely dependent on whether LTCFs prioritized their involvement in the PACE programme, which included release of resources (e.g. dedicated time for PACE coordinators, budget to reimburse staff attending training) and other forms of managerial support, often resulting in collective engagement and motivation of staff to develop their roles around palliative care."

In addition, we added some sentences on the fidelity-adaptation debate that is increasingly recognized within complex interventions and implementation research studies where context is an important mediating factor.

"Closely monitoring the fit between the programme and the context, as well as monitoring the adaptations made to the programme and attempting to understand why they occurred and how they may influence the functioning of the intervention is important in further guiding the dissemination of the PACE Programme.22 In addition, it is important to ensure that the programme remains consistent with its underlying theories. This corresponds with an approach often heard in the ‘fidelity-adaptation debate’ – a debate that is increasingly recognized within implementation research studies of complex interventions where context is an important mediating factor – stating that it may be more helpful to reframe the idea of fidelity away from adherence to delivery of all intervention components towards alignment with theories underpinning the intervention.22,30,38 This approach provides a more flexible framework for assessing fidelity, and includes being able to contextualize an intervention to specific circumstances whilst still being faithful to its underlying theory.20"

Lastly, we elaborated on our choice for structuring the process evaluation according to the RE-AIM framework:
"Whereas other studies sometimes only report ‘fidelity’ as a single measure for degree of overall implementation, we structured our process evaluation according to the RE-AIM framework which enabled us to capture a more complete picture. Although many approaches to evaluation of intervention implementation exist, we considered the RE-AIM framework to be the best fit, because it clearly acknowledges that each RE-AIM dimension provides a target for the intervention. However, the RE-AIM framework also has its limitations, one being that it is initially developed to assess the implementation of complex public health interventions rather than being specific to LTCFs; therefore we slightly adapted the framework to fit this specific context."