Author’s response to reviews

Title: Understanding Implementation Fidelity in a Pragmatic Randomized Clinical Trial in the Nursing Home Setting: A Mixed-Methods Examination

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Version: 1 Date: 19 Aug 2019

Author’s response to reviews:

Jeremy Grimshaw, Peter Juni, Tianjing Li, Shaun Treweek
Editors-in-Chief

Trials

August 19, 2019

Re: TRLS-D-19-00369R1: Understanding Implementation Fidelity in a Pragmatic Randomized Clinical Trial in the Nursing Home Setting: A Mixed-Methods Examination
Dear Drs. Grimshaw, Juni, Li, & Treweek:

Thank you for considering this manuscript for publication in Trials. We appreciate the thoughtful suggestions of the Reviewers. Below are our responses to these comments and a description of our revisions to the manuscript. Attached please find a “track changes” version of the revised manuscript; the “Lines” referred to in this letter correspond to the revisions in this version. We believe the revisions have strengthened the paper considerably and we hope you find the paper suitable for publication.

Reviewer #1:

1) The background section could benefit from some further details of the trial setting and purpose - e.g. an explanation of what 'advance care planning' means, why is this a problem, why is a video providing education needed and what is it designed to change/do.

To address this concern, we have added the following language in the Background section (p. 6, Lines 124-132):

“ACP, the process through which clinicians determine patients’/families’ preferred treatment decisions prior to treatment needs, most appropriately result in advance directives (e.g., do-not-hospitalize, do-not-resuscitate). Nursing homes are required to engage in this process; however, evidence reveals deficiencies in meeting this mandate.(8-17) Video decision support tools have been developed to standardize information about and provide visualization of treatment decisions and to obviate literacy and language barriers inherent to traditional advance care planning. While such tools have ameliorated advance care planning in small RCTs across a number of settings,(18-25) pRCTs could substantiate the benefit of the tools’ broad uptake in real-world settings including in nursing homes.”

2) It is not currently clear how the results relate to the '3 key lessons' in the discussion. While it seems very sensible to suggest that a 'flexible fidelity' approach is important for pragmatic RCTs (i.e. where core elements of an intervention are delivered alongside the purposeful adaptation of non-essential intervention features), it is not clear to me how this relates to the findings reported in the results. Which aspects of the video education programme were considered core and which could be adapted?
We have added the following language at various points throughout the Discussion section (p. 19, Lines 419-421):

“As modified CFIF domains (i.e., moderating factors of fidelity outcomes) supported these three lessons in an overlapping manner, domain-specific findings will be embedded throughout the following discussion of each lesson.”

Flexible fidelity paragraph:

p. 19, Lines 427-428: “The need for such adaptability at the individual and organizational levels is apparent from our and others’ findings, especially those findings related to Participant Responsiveness and Context.”

pp. 19-20, Lines 430-432: “Such an approach could foster positive Participant Responsiveness in these stakeholders which was at times lacking in PROVEN’s low adherence facilities.”

p. 20, Lines 435-437: “Given challenges in PROVEN’s low adherence facilities associated with local resources, organizational needs related to Context also emerged as an important consideration for adaptation.”

Reciprocal facilitation paragraphs:

p. 20, Lines 442-444: “Our findings regarding Participant Responsiveness, Recruitment, and Strategies to Facilitate Implementation point to another lesson for fidelity in pRCTs: the value of reciprocal facilitation.”

p.20: Lines 447-449: “PROVEN participants’ more negative Participant Responsiveness to the intervention in low adherence facilities may highlight the need for engaging all stakeholders from the initial planning stages of pRCTs onward.”
p. 21, Lines 457-459: “Facilitation in the opposing direction, from leadership team to Champion, can also play a critical role in fidelity for pRCTs by addressing Participant Responsiveness, Recruitment, and Strategies to Facilitate Implementation issues.”

Organizational readiness paragraph:

p. 21, Lines 474-476: “In line with other studies, PROVEN’s findings (i.e., related to Recruitment and Context) highlight another lesson about fidelity in pRCTs: the need to assess organizational and Champion readiness and to adapt accordingly.“

To address the question about the program’s core components, we have added the following language in the Methods section (pp. 7-8, Lines 152-161):

The core components of the intervention included 1) offering the video to patients/families and 2) doing so within specified time parameters. At each intervention facility, one or two ACP Champions were designated as the individual(s) charged with delivering the intervention. As per the implementation protocol, they were instructed to offer a video to all newly admitted or readmitted patients (or their family members) within 7 days of admission and to all long-stay patients (length of stay > 100 days) every 6 months or upon change in status over an 18-month implementation period. Consistent with a pragmatic trial, other elements of the program were customizable to real-world demands (e.g., which videos were offered, to whom they were offered, which mode of administration was offered/used). ACP practices continued as per usual in control facilities.

3) It is stated on p8 that "for the purposes of this report, adherence was measured using the cumulative VSR completion rates for long-stay patents only" whilst the trial was designed to target both long-stay and newly admitted patients. Was there low adherence across both types of patients within the sites designated as 'low adherence facilities', and similarly for 'high adherence facilities' was adherence high across both types of patients? Were there differences in the qualitative data for how champions considered the implementation of the video programme for these 2 different types of patients? It would be useful to be able to read a brief rationale for why implementation for long-stay patients was the focus here.

We have changed the text to now read (p. 9, Lines 187-190):
“To be consistent with PROVEN’s focus on long-stay patients within its primary trial outcome, adherence in this report was measured using the cumulative VSR completion rates for long-stay patients only (to the exclusion of rates for short-stay patients). “

4) Details on the rationale behind exclusion of facilities with a zero adherence rate would be helpful.

We have changed the text to now read (p. 12, Lines 251-255):

“Within each HCS, NHs in the top (high adherence) and bottom (low adherence) quintiles of adherence rates based on the Video Status Reports were identified. Facilities with an adherence rate of zero were excluded; these facilities were disengaged from the program for a wide variety of reasons (e.g., pending closures, administrative upheavals) to the extent that feedback from the Champions would not have been informative.

5) Perhaps better to use numbers rather than percentages for description of interviewees. Also it is stated that 89% were social workers - what were the professions of the other participants?

We have changed the text to now read (p. 13, Lines 279-282):

“A total of 33 Champion interviews were conducted and analyzed from among these 28 facilities (5 facilities had two Champions). The Champions were female (33/33) and mostly social workers (29/33). The four additional Champions’ professions fell within administrative roles (N=2) and nursing roles (N=2).”

6) The manuscript uses rather a lot of abbreviations which reduce its readability. It would be beneficial to readers if these could be reduced where possible.

We have replaced the following abbreviations with full text:

EMR=electronic medical record
HCS=health care system
MDS=Minimum Data Set
Reviewer #2:

General comments:

1) The main comment I have is really about the use of 'videos offered' as the sole measure of fidelity, and the basis for the fidelity scores which ranked centres as high/low. This seems quite a simplistic measure and I'm not sure it's the best way to rank centres - however, provision of the intervention protocol/logic model to elucidate core components and intended mechanisms of change may validate this choice.

2) My second comment is in relation to the mixed methods approach taken - I really like this approach being used to exploring fidelity, but more detail needed about specific MMR approach in line with guidance for best practice of mixed methods in health research.

3) Final main comment is in relation to the reporting of methods and results - currently reads a bit opaque in places, would suggest more detail and/or provision of further supplementary info to enhance transparency and understanding of what was done.
We have endeavored to answer these three points in detail as raised more specifically in the “Specific comments” below.

Specific comments:

1) Abstract
   a) Make aim of this study clearer (at present only trial aim clear)

   b) Not very clear what ‘tentative Champion recruitment efforts' mean - clarify

   c) Not very clear what ‘Champions supplementing ACP conversations with the video' means - suggest clarifying. Or perhaps supplementing the video with conversations regarding ACP makes more sense if that’s what's meant?

   d) Again, not very clear what 'Champions valuing leadership team facilitation' means without having read the full study. Could benefit from clarifying

The revised abstract addressing Comments 1a-d is provided below:

Background: The PRagmatic trial Of Video Education in Nursing homes (PROVEN) is amongst the first large pragmatic randomized clinical trials (pRCTs) to be conducted in U.S. nursing homes (N=119 intervention, N=241 control across two health care systems). The trial aims to evaluate the effectiveness of a suite of videos to improve advance care planning (ACP) for nursing home patients. This report uses mixed methods to explore optimal and sub-optimal conditions for implementation fidelity within a pRCT in nursing homes.

Methods: PROVEN’s protocol required (a) designated facility Champion(s) to offer an ACP video to long-stay patients every 6 months during the 18-month implementation period. Champions completed a “Video Status Report” (VSR) within electronic medical records each time a video was offered. VSR data was used to derive facility’s adherence rates (i.e., cumulative video offer). Fifteen-month qualitative Champion interviews were purposively sampled from facilities within the highest and lowest (i.e., top and bottom quintiles) adherence rates. Two researchers analyzed interview data thematically using a deductive approach based upon a revised Conceptual Framework for Implementation Fidelity’s (CFIF’s) six domains. Matrices were developed to compare coded narrative by domain across facility adherence status.
Results: Twenty-eight interviews involving 33 Champions were analyzed. Different patterns were observed across high versus low adherence facilities for five CFIF domains. Low adherence nursing homes had limited implementation resources (Context), perceived negative patient/family responsiveness to the program (Participant Responsiveness), and reticence by Champions in offering videos (Recruitment). High adherence nursing homes displayed more perceived patient/family willingness to engage in the program (Participant Responsiveness), Champions supplementing video showing with ACP conversations (Quality of Delivery), strategic approaches to recruitment (Recruitment), and Champions’ appreciation of external facilitation (Strategies to Facilitate Implementation).

Conclusions: Critical lessons for pRCT implementation in nursing homes emerged from this report: 1) flexible fidelity (i.e., delivering core elements of an intervention while permitting adaptation of non-core elements) should serve as the gold standard; 2) reciprocal facilitation (i.e., early and ongoing stakeholder engagement in research design and, reciprocally, researchers’/organizational leaders’ ongoing support of implementation) is vital; and 3) organizational and Champion readiness should be formally assessed early and throughout implementation to facilitate remediation.

2) Background:

a) Line 98 - NIHBCC guidance focused on strategies to enhance as well as assess fidelity, which is a subtle but important aspect; suggest rephrasing this line to 'the National Institutes of Health Behavior Change Consortium proposed recommended practices for ensuring and assessing fidelity within this context'. Also, the reference provided is for the 2004 consortium paper, so unclear where 1999 comes into play - suggest clarifying or removing.

As recommended, we have changed the text to now read (p. 5, Lines 101-102):

“The National Institutes of Health Behavior Change Consortium proposed recommended practices for ensuring and assessing fidelity within this context.”

We have also removed “1999”.

b) Justification for the use of mixed methods is quite limited, and doesn't address many of the key points recommended in best practice for mixed methods research (Cresswell et al 2018 NIH OBSSR guidance) (e.g. how will integrating qual and quant provide more insight and enable the whole to be 'greater than the sum of the parts', eg relative strengths and weaknesses of each, explicitly describing the approach to integration (e.g. connecting/building/merging/embedding etc), priority of quant v qual etc - suggest addressing this
The manuscript’s Introduction (p. 5, Lines 108-113) currently justifies the use of mixed methods. Given the critical nature of this paragraph to the logic of the Introduction - we retain that paragraph there and - to avoid redundancy - do not repeat the content in the Methods section. Below is the relevant paragraph:

“Mixed methods study designs are a valuable approach to help decipher the “why” and “how” of success or failure in achieving fidelity within pRCTs.(6) Qualitative analysis can unearth the influence of context and setting and contribute to the interpretation of quantitative results related to intervention fidelity. The integration of these research methods can identify strategies to ameliorate or avoid conditions where an intervention’s core elements are not delivered as intended or emulate conditions where they are.”

To supplement this paragraph, however, we have added the following language in the Methods section: (p. 11, Lines 246-248):

“This mixed methods report followed a sequential explanatory design and integrated PROVEN’s quantitative and qualitative data at the methods level. This was done by connecting the two datasets through the sampling framework.(29)”

c) Some overlap between some of the more detailed information about PROVEN given in intro and again in methods - suggest keeping in same place

We have changed the text to now read (p. 6, Lines 114-119):

This report aims to use mixed methods to further our understanding of factors influencing fidelity to implementation within the context of pRCTs by leveraging data from the PRagmatic trial Of Video Education in Nursing homes (PROVEN). PROVEN is one of the largest pRCTs to be conducted in nursing homes and implements an advance care planning (ACP) video education program in intervention facilities.
3) Methods:

a) The trial was due to be completed in May 2019 - has that happened? If so suggest updating the wording here. Also, was the fidelity evaluation before the trial was completed and all data available? Would the findings be much different if the sites hadn't been sampled until the end? Are the data to be used to change what happens in the trial? This would be important information to provide.

We have changed the text to now read (p. 7, Lines 145-146):

“The trial began in March 2016 and was completed in May 2019.”

We believe the suggestion for further explanation refers to the mixed methods analysis of fidelity characteristics. Accordingly, we have added text to address this concern (p. 11, Lines 246-250):

“This mixed methods report followed a sequential explanatory design and integrated PROVEN’s quantitative and qualitative data at the methods level. This was done by connecting the two datasets through the sampling framework. Sites were sampled and mixed methods analysis conducted toward the later end of the trial, thus the results of this report were not shared with sites during the implementation process.”

However, if this suggestion asks for clarification regarding the use of adherence data and its use throughout the trial - we note that this information is provided at:

pp. 8-9, Lines 180-186: “The research team was able to link VSR data to MDS data to determine the proportion of new admissions and long-stay residents had VSR completed, implying a video was offered, as per protocol. During the implementation period, HCS leadership provided Champions with monthly feedback reports which included their facility’s adherence (“video offer”) rate; these reports were reviewed at regular telephone group and individual conference calls with HCS leadership and/or research team members.”

b) Would be helpful to provide implementation protocol mentioned as supplementary file. This would be also helpful in elucidating from the outset what the core components of the intervention were
We attach with this resubmission a toolkit we provided to Champions (“Additional File 2”) and a toolkit we provided to facilities (“Additional File 3”). These toolkits provide a comprehensive overview of the implementation protocol.

We have also changed the text to now read (pp. 7-8, Lines 152-161):

“The core components of the intervention included 1) offering the video to patient/families and 2) doing so within specified time parameters. At each intervention facility, one (or two) ACP Champion(s) (most often a social worker) was/were designated as the individual(s) charged with delivering the intervention. As per the implementation protocol, they were instructed to offer a video to all newly admitted or readmitted patients (or their family members) within 7 days of admission and to all long-stay patients (length of stay > 100 days) every 6 months or upon change in status over an 18-month implementation period. Consistent with a pragmatic trial, other elements of the program were customizable to real-world demands (e.g., which videos were offered, to whom they were offered, which mode of administration was offered/used). ACP practices continued as per usual in control facilities.”

c) 'Conducted in a fashion that was typical for any new quality improvement program being introduced into their systems' - could you briefly explain this? Perhaps could do this in implementation protocol supplementary file? Also would be helpful to provide interview topic guides.

We have changed the text to now read (p. 7, Lines 168-171):

“In contrast to a traditional RCT, the ACP Video Program roll-out and ongoing implementation was primarily led by the HCS corporate leadership, that is, in a fashion that was typical for any new quality improvement program being introduced into their systems. “

We submitted the interview guide with the initial submission but are happy to do so again (please see “Additional File 1” within the resubmission).
d) Why was the VSR adherence rate (e.g. high fidelity) the video 'offer' rate, and not the video 'shown' rate (data also collected)? As if the aim of the overall trial is to determine the effectiveness of the video for ACP, then these fidelity data are not as useful as the 'video shown' rate. E.g. if the trial finds no effectiveness and fidelity was high, then it doesn't necessarily mean that the videos were actually ineffective, as it could just mean that the videos were offered but not shown. I acknowledge that even if the videos were all shown, it doesn't mean that patients actually watched/engaged with them (treatment receipt), but gives slightly more certainty than just videos offered?

We chose to analyze Champion adherence based on rates of administering/offering (e.g., treatment delivery) the intervention as we are exploring in this paper the behaviors and experiences of Champions related to implementation processes. Treatment receipt is more appropriate for measuring the trial’s effectiveness which is not the aim of this paper but will be of a future PROVEN paper.

e) As mentioned by the authors, fidelity is a multicomponent construct, beyond just delivery/adherence at a basic level according to both the CFIF (original and modified) and the NIHBCC. It’s therefore not clear why ‘Only the CFIF component of "content" captured in the measure of adherence is considered in this report’ (p186). This goes back to my previous point that I'm not sure if basing the fidelity score for each site only on videos offered (basic content adherence) and not the other aspects of fidelity (as conceptualised by either CFIF or NIHBCC) gives the full picture of fidelity. Suggest adding this, or strongly justifying why not done, and acknowledging as a limitation. Also, the authors note that in this intervention the participants refer to patients, and family members as well as champions. Would a more indepth understanding of the factors influencing fidelity have been achieved if they were also interviewed about it? I imagine quite time restrictive so probably not possible, but something to be perhaps considered in the limitations.

Prior to beginning our work, we found targeted use of CFIF adherence elements validated in a study by Augustsson et al (2014). The authors wrote: “In the current study, only the components of content and frequency were applicable due to the intervention design.”

Similarly, there are a number of reasons - innate to the intervention’s design - as to why only “content”(controlling for “frequency) is appropriate for calculating the adherence score. We now see the need to provide elaboration on this point.
To summarize, from the four types of baseline adherence (i.e., content, frequency, duration, and coverage), “content” (controlling for frequency) is the closest to an objective, consistent, and stable measure of adherence to this singular (vs. multi-component) intervention (that being the binary nature of its delivery: yes, it was offered vs. no, it was not). We controlled for “frequency” with the “content” adherence measure by calculating the cumulative rate of videos EVER being offered to patients (thus, avoiding double-counting of multiple offers over time to any one patient - a possibility within the specified program protocol). “Duration” - that is, how long the active ingredients were delivered - would be an inconsistent and unstable measure of bottom-line adherence; the temporal distance from the initial video offer to the ultimate video offer varied across patients - depending upon various parameters related to their status. “Coverage” would also be an inconsistent and unstable measure; the number of videos out of the suite of videos offered in each instance (“dosage”) was up to the discretion of the Champion so varied by patient.

To explicate briefly these points in the text, the language now reads (p. 10, Lines 208-218):

“According to CFIF,(9) implementation fidelity is a multi-component construct that represents adherence (the “bottom-line” measurement of fidelity) and associated moderators. Adherence includes the following components: content (the intervention’s “active ingredients”), frequency (how often the active ingredients were delivered), duration (how long the active ingredients were delivered), and coverage (how much of the active ingredients were delivered). Given the intervention’s design, only the CFIF component of “content” which controlled for “frequency” (i.e., the cumulative VSR completion rate reflecting whether or not a video was ever offered to each patient as per protocol) is relevant to this report. “Duration” and “coverage” represented unstable measures to include in the adherence score given their potential variation across patients/family members.”

To address the concern about the lack of patient/family perspective in this work, we have changed the text to now read (p. 22, Lines 488-490):

“The limitations of this work should be noted. First, conducting qualitative interviews with patients and family members, in addition to Champions, could have provided valuable triangulation of our findings. Such an effort was beyond the scope of this study, however.”
f) The analysis procedure in the Methods section is quite opaque, and needs detail. For example, would be helpful to provide the actual adherence rates /quintile cut-offs from the VSR reports, e.g. in a table, to get a sense of how good/bad the high/low sites were overall. Additionally, more info re interviews needed - were interviews conducted in all sites? And only selected sites analysed? It would be very helpful for transparency to provide the structured codebook developed as supplementary file What are 'positive and negative cases of codes within the data'? line 233. Who took part in the consensus meetings to reconcile coding?

We have inserted a new table (named Table 1) to provide the requested details on overall adherence rates. This table can be found on p. 28.

To address several of the other points, we have changed the text to now read:

p. 9, Lines 195-197: “An experienced research assistant conducted semi-structured telephone interviews with Champions from all intervention facilities to gather their perceptions of the implementation experience at 4 months, 9 months, and 15 months into implementation.”

Line, p.: “Only interviews from these high and low adherence NHs were analyzed. Analysis was done deductively across the two facility classifications to identify differential factors influencing fidelity as established by the six modified CFIF constructs.”

p. 12, Lines 258-262: “Two researchers (J.A.P. and L.R.B.), blinded to facility adherence status (i.e., “high” or “low”), developed a structured codebook and independently coded all data by blocks of text through an iterative process. Coders actively identified instances where themes were verified or refuted within the data. Consensus meetings between J.A.P. and LR.B. were periodically held to reconcile individual coding decisions.“

We also attach the structured codebook within this resubmission as “Additional File 4”.

4) Results:

a) Did any themes encountered not fit within the CFIF domains?

Since this analysis was conducted deductively (and not with a hybrid inductive/deductive approach), we did not pursue identification of whether additional themes outside of the CFIF domains were present.

b) I really like Table 1 - but I think the explanation re paired convergent/divergent/unpaired belongs in the methods to explain how the mixed methods integration was conducted.
We have changed the text to now read (p.12, Lines 263-270):

“When coding was complete, J.A.P. was unblinded to facility adherence status and developed matrices to compare coded narrative by CFIF domain across “high” versus “low” adherence facilities, in order to identify any similarities and/or differences in implementation factors. These themes were then assessed according to the following classifications: 1. Paired-convergent: the theme was represented in both high and low adherence facilities with similar findings, 2. Paired-divergent: the theme was represented in both high and low adherence facilities but with contrasting findings, and 3. Unpaired: the theme was represented in a high or low adherence facility, but not both.”

We accordingly adjusted the text at p. 13 Lines 284-286 in the Results section to more briefly state:

“Table 2 organizes the themes within CFIF domain across three columns according to the classifications mentioned above: 1) Paired-convergent, 2) Paired-divergent, and 3) Unpaired.”

c) A lot of the results section reads very thinly - e.g. the participant responsiveness findings are very interesting, but not much 'meat on the bones' as described in the results section. Any more information from the interviews as to why participants were or weren't as engaged/responsive in certain settings? Would be helpful to get a sense of how widespread the themes identified are across the NHs - could be added to a table/table 1?

The question as to why participants varied in responsiveness by certain settings is an interesting one. Given our deductive approach to analysis, however, we were limited to analyzing how data fell within the Conceptual Framework for Implementation Fidelity (CFIF) domains. The reviewer’s comment points to a future line of research that could be pursued with inductive or hybrid (both inductive and deductive) qualitative analysis: the nuance existing across high/low adherence facilities within each CFIF domain.

As for the suggestion to quantitize the themes identified (i.e., perhaps in a table) - we believe that such an exercise would not add but detract from the qualitative analysis in that: 1) it would inappropriately emphasize quantity over salience of themes and 2) it would inappropriately treat the qualitative data as plural and divisible which we would argue it is not.*


d) The finding re Quality of Delivery is really interesting - but think it could be explored more in the context of adaptation, especially given the key finding of the study about 'flexible fidelity'.
I.e. was it intended in the protocol that a conversation would be had by Champions with patients? How often did this happen? What was the potential additional effectiveness of the intervention by addition of this conversation? If the intervention is found effective, how do we know if it's the video or the conversations? Again, exploring views of patients and family members could have helped elucidate this. It's not clear from the outset what the core elements of the intervention are or the intended mechanisms of change - perhaps if the intervention protocol is provided as recommended in the background comments then this could be made clear here.

Champions were trained to use the videos as a catalyst to ACP conversations. (Additional File #2). However, whether or not the videos were followed up with such conversation cannot be reported as associated data were not collected.

We are not measuring trial effectiveness in this report but rather implementation fidelity; thus, while the question of whether effectiveness could be due to the video vs. ACP conversations is valid, it is not relevant to this particular work.

We have added the limitation of not qualitatively exploring patient/family perspectives as part of our work. This language has been added to p. 22, Lines 488-490 - as mentioned above under Reviewer 2’s Comment 3e.

We have added language about the core elements of the intervention to pp. 7-8, Lines 152-161 - as mentioned above under Reviewer 2’s Comment 3b.

We also attach with this resubmission the toolkits we provided to Champions and facilities as “Additional File 2” and “Additional File 3”. They provide a comprehensive overview of the implementation protocol.

5) Discussion:

a) It's surprising that the study mentioned on line 397 is not described in the background - e.g. what was done already in relation to studying implementation of PROVEN, and why this study is needed - ‘quantitative analysis of PROVEN discovered that a facility characteristic associated with adherence was Champion engagement (i.e., degree of attendance on ongoing coaching calls'
Thank you for pointing this omission out. We have added this work as reference #6 in the Introduction at (p. 5, Lines 105-107):

“Moreover, while factors influencing implementation fidelity have been studied in traditional RCTs, study of these factors in pRCTs is nascent.(4, 6)”

Sincerely,

Jennifer A. Palmer, MS, PhD