

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Improving Advance Care Planning for English- and Spanish-speaking Older Adults: study protocol for the PREPARE randomized controlled trial
AUTHORS	Sudore, Rebecca; Barnes, Deborah; Le, Gem; Ramos, Roberto; Osua, Stacy; Richardson, Sarah; Boscardin, John; Schillinger, Dean

VERSION 1 - REVIEW

REVIEWER	Bernard J. Hammes, PhD Gundersen Health System La Crosse, WI USA
REVIEW RETURNED	29-Mar-2016

GENERAL COMMENTS	This article provides a detailed description of a sophisticated trial of an intervention to improve preparation of adult subjects for advance care planning. It is an important contribution and I strongly recommend its publication.
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REVIEWER	Arianne Brinkman-Stoppelenburg Department of Public Health Erasmus MC Rotterdam The Netherlands
REVIEW RETURNED	14-Apr-2016

GENERAL COMMENTS	<p>This is a well thought out study on an important topic. As the authors state, advance care planning, including the completion of advance directives are less common in ethnic minority groups. The authors clearly know the literature and have drawn appropriately on the experience in this field in the design of the study. The study is carefully designed with the input from both a patient and a clinical advisory board. However, I have a few comments:</p> <ul style="list-style-type: none">- The study's research question(s) are not mentioned in the abstract.- In the paper, study hypotheses are formulated, but no research questions. In the study hypotheses I miss the relation to the patient population.- This also relates to the aim of the study. Is this to test the PREPARE website in elderly people? Or to test it in Spanish speaking elderly? This could be made more clear.- I can imagine that it is more difficult to recruit patients (and surrogates) from ethnic minorities. Are special efforts made to include this patients category?- A drop out of 15% seems rather low.- As is stated in the introduction "Ethnic minorities are also more likely to prefer aggressive treatment, mistrust advance directives and
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	<p>have non-autonomous views on decision making'. Is this taken into account in the intervention?</p> <p>- Regarding the outcomes: there are many secondary outcomes. It is not always clear which validated questionnaires are used, e.g. regarding the ACP behavior change processes.</p> <p>Furthermore, do the investigators also study whether patients' preferences , which are stated in the advance directives, are met? Completion of an advance directive is an important outcome, but in the end, the most important outcome of Advance Care Planning may be whether patient's wishes and preferences are met.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer #1:

No comments to address

Reviewer #2:

1. The study's research question(s) are not mentioned in the abstract.

RESPONSE: Thank you for bringing this to our attention. We have added the main research aim in the Introduction section of the abstract.

“The aim of this trial is to determine the efficacy of PREPARE to engage diverse English- and Spanish-speaking older adults in a full spectrum of ACP behaviors.”

2. In the paper, study hypotheses are formulated, but no research questions. In the study hypotheses I miss the relation to the patient population.

RESPONSE: Thank you for this suggestion. We have added the primary research aims in the last paragraph on page 8. We have clarified in the aims and the hypotheses that we are focused diverse older adults with chronic illness.

“The aims of this study are to (1) To determine the efficacy of PREPARE to engage diverse, older patients with chronic illness in advance care planning (ACP) compared to controls (AD only) and (2) To determine whether PREPARE efficacy varies by race/ethnicity, literacy, clinician-patient language concordance, and patient's desired role in decision making.”

3. This also relates to the aim of the study. Is this to test the PREPARE website in elderly people? Or to test it in Spanish speaking elderly? This could be made more clear.

RESPONSE: As above, we now clarify in our abstract and on page 8 that our population includes both English- and Spanish-speaking older adults with chronic illness. We also describe the population in more detail in the Study Setting and Eligibility Criteria sections on page 9.

4. I can imagine that it is more difficult to recruit patients (and surrogates) from ethnic minorities. Are special efforts made to include this patients category?

RESPONSE: This is a great point and we fully agree. We have gone to great lengths to ensure our team is appropriately trained and our study materials are appropriate for recruiting diverse, vulnerable populations. We have added a paragraph on the top of page 12 to further explain our methods for recruitment in diverse populations.

“Diverse, vulnerable populations are often difficult to recruit for research studies. We employed several strategies to enhance our recruitment. First, we attempted to hire individuals who had experience with diverse populations and individuals who were bilingual (native Spanish-speaking) and bicultural. Furthermore, we conduct extensive sensitivity training with all research staff and require staff to use approved study scripts when speaking to patients. These study scripts and all study materials used for recruitment have been vetted, updated and approved by both our patient advisory and clinical advisory boards. All materials and study scripts are written at a 5th grade reading level and are provided to patients in their preferred language (i.e., English or Spanish).”

5. A drop out of 15% seems rather low.

RESPONSE: For our sample size calculations, we used an anticipated drop out rate of 15% because this was the drop out rate we observed for our prior RCT of the easy-to-read advance directive. This AD study also had several follow-up interviews, and was conducted among diverse English- and Spanish-speaking older patients at the same clinical sites used in this study. Therefore, we have based the 15% off our own experience with this same patient population. In the current study, we are also using similar successful retention methods that have worked in this prior study including reminder calls, letters, following up with emergency contacts provided by participants, meeting patients during their clinic visits, and continuing to provide reimbursements for each follow-up interview.

6. As is stated in the introduction “Ethnic minorities are also more likely to prefer aggressive treatment, mistrust advance directives and have non-autonomous views on decision making’. Is this taken into account in the intervention?

RESPONSE: As we describe in the methods and in reference #27, we did extensive formative work to create an ACP tool that met the needs of our target population. Information included in PREPARE from this formative work with the community resulted in PREPARE focusing on communication, rather than only written advance directives. In addition there is tailored information for individuals who prefer not to make their own medical decisions or want their family involved in decision making. See this description on page 13 and reference #27:

“To ensure PREPARE was easy to read and understand, we used clear health communication principles (e.g., targeting text to the 5th grade reading level) and used extensive formative research and cognitive interviewing with the target population (i.e., racially and ethnically diverse older adults with limited health literacy and English proficiency) to ensure PREPARE content is acceptable to individuals from diverse cultural backgrounds.”

7. Regarding the outcomes: there are many secondary outcomes. It is not always clear which validated questionnaires are used, e.g. regarding the ACP behavior change processes.

RESPONSE: Please refer to Table 2 where we attempted to provide extensive documentation regarding the sources of the survey questions, validity and reliability information for each construct, and the timing of the survey measures for both primary and secondary outcomes.

8. Furthermore, do the investigators also study whether patients’ preferences, which are stated in the advance directives, are met? Completion of an advance directive is an important outcome, but in the end, the most important outcome of Advance Care Planning may be whether patient’s wishes and preferences are met.

RESPONSE: We absolutely agree with the reviewer that the care aligned with patients’ preferences at

the end of life is of utmost importance. However, because we are trying to move ACP upstream from the end of life, we purposefully included and recruited individuals from general primary care clinics. These individuals have to have chronic illness, but be well enough to enroll in our study and engage in follow-up interviews. As we discussed in the background, while advance directives often focus on CPR and mechanical ventilation, they often do not prepare patients for ongoing decision making. For the current study, focused on upstream ACP, we focus on whether PREPARE helped patients actually engage in the ACP process and make better informed medical decisions with less decisional conflict and regret. We do not anticipate that many of our patients will die (none have died yet) and therefore, attempting to measure whether their end of life care matched their advance directive form cannot, regrettably, be a main focus of this study. We agree that value aligned care is the gold standard. Therefore, if PREPARE is found to be efficacious, we will be applying for additional grant funding to either follow our current enrolled patients over time or enroll patients near the end of life to assess care consistent with their advance directives.

VERSION 2 – REVIEW

REVIEWER	Bernard "Bud" Hammes Gundersen Health System USA
REVIEW RETURNED	11-May-2016

GENERAL COMMENTS	This is a re-review of this paper. The other reviewer had a list of comments that the authors have fully and clearly addressed. I have no additional comments or concerns. The paper is ready for publication.
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REVIEWER	Arianne Brinkman-Stoppelenburg Department of Public Health Erasmus MC Rotterdam Netherlands
REVIEW RETURNED	17-May-2016

GENERAL COMMENTS	This is an interesting and well thought out study that is suitable for BMJ open.
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