

PEER REVIEW HISTORY

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ARTICLE DETAILS

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| TITLE (PROVISIONAL) | Evaluation of the Choosing Wisely Australia® 5 Questions resource and a shared decision-making preparation video: Protocol for an online experiment |
| AUTHORS | Muscat, Danielle; Chang, Edward; Thompson, Rachel; Cvejic, Erin; Tracy, Marguerite; Zadro, Joshua; Smith, Jessica; Lindner, Robyn; McCaffery, Kirsten |

VERSION 1 – REVIEW

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| REVIEWER | J Jull Queen's University, Canada |
| REVIEW RETURNED | 27-Aug-2019 |

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| GENERAL COMMENTS | <p>Thank you for the opportunity to review this well written and thought out study protocol. I understand that this study protocol has received ethics review and that a methodologist has been involved as part of the team. I have a few outstanding issues with the proposal as it is written.</p> <p>1) Emphasis on preparation for shared decision making (SDM) versus participation in SDM: The study title leads the reader to think that there might be a direct link between the use of the 5 Questions and SDM - and in the study protocol it is clear in the aim (although in some places it could be clarified) that the 5 Questions are considered to have potential to prepare people for SDM. While the authors have done an overall excellent job with consistent words - care needs to be taken in the protocol for consistent wording (eg. focus on knowledge, intentions, self-efficacy identified in the figure but not in the text).</p> <p>2) The consideration of health literacy - Nutbeam's definition is (appropriately) used although in the proposal is it not acknowledged that the study is limited to functional health literacy and not inclusive of the more comprehensive definition by Nutbeam (functional, relational, critical). Explaining why there is a limited view on health literacy would be helpful and why it is important to take the particular focus on health literacy would be helpful.</p> <p>Other thoughts - might participants be concerned with their categorization according to health literacy? Has the NVS assessment been used to assess people online?</p> <p>3) I wondered about the patient/public/knowledge user involvement - the pilot study is promising with the qualitative interview study with a sub-set of health consumers (is there a citation for this study?). It seems that there is a strong emphasis on the researcher conduct and leadership in this study and inclusion of patients/members of the public or other knowledge user groups (those who will use or be impacted by the outcomes of the research) is limited. This is more of</p> |
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| | <p>a comment but as there is a health equity component to the work that is being done raise this as a point for consideration by the authors. Greater engagement of patients/members of the public/knowledge users may help to mitigate potential challenges of the study (for example, recruitment, drop outs).</p> <p>4) Qualitative study - will all of the comments be used in the analysis, why will this be done (be explicit - what this adds). Will software be used to manage the data?</p> <p>5) Subgroup analysis - I am not qualified to comment on the power calculations and recommend that another reviewer with experience in this study design and statistical analysis check this study (although it seems a methodologist is a member of the team). I wondered why there is no plan for subgroup analysis with demographic data (age, sex et cetera) and if this is feasible given the proposed sample size - or - if the data could be collected and if inadequate to analyze for this study could be used in another, future study with pooled data (is that the intent of the demographic data collection). Again, as this study is concerned with health equity issues it seems appropriate to consider subgroups. Why the CONSORT Equity extension has not be considered for the reporting of this study.</p> <p>6) Miscellaneous comments: -limitations of study design - would ask for comments on by a methodologist -who are "Consumer Reports"? -p8 line 22 - is it findings from focus group testing (is the word "group" missing from this sentence) by Choosing Wisely Australia? and why were the findings "not sufficient"? -p9 line 3 - what does "adapted slightly" mean? and by who? -well done with table 1</p> <p>Overall a well done paper that will make an important contribution to the literature on preparing people to participate in SDM.</p> |
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| REVIEWER | Lixin Song University of North Carolina-Chapel Hill, North Carolina, USA |
| REVIEW RETURNED | 02-Sep-2019 |

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| GENERAL COMMENTS | <p>This manuscript is a well-written protocol of a randomized controlled trial that aims to examine the effectiveness of the Choosing Wisely Australia 5 Questions resource to support patient question-asking and participation in shared decision-making. The study addresses an integral issue related to quality of care and patient satisfaction. Overall the trial is well designed. The only and major concern is the use of study participants who are "healthy volunteers" recruited online to represent/test "patient question-asking and etc" and use of hypothetical scenario to deliver the intervention. Online volunteers are often younger than the real patient population who have multiple comorbid conditions. It is unclear how the use of such a study population and hypothetical scenario can help inform the intervention implementation in the real world. Although the researchers have mentioned these issues in the limitation section, stronger rationale is needed to justify the decisions why this population and hypothetical scenarios are used and how the evidence obtained from this study can inform clinical practice in the real world.</p> |
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Thank you for the opportunity to review this well written and thought out study protocol. I understand that this study protocol has received ethics review and that a methodologist has been involved as part of the team. I have a few outstanding issues with the proposal as it is written.

1) Emphasis on preparation for shared decision making (SDM) versus participation in SDM: The study title leads the reader to think that there might be a direct link between the use of the 5 Questions and SDM - and in the study protocol it is clear in the aim (although in some places it could be clarified) that the 5 Questions are considered to have potential to prepare people for SDM. While the authors have done an overall excellent job with consistent words - care needs to be taken in the protocol for consistent wording (eg. focus on knowledge, intentions, self-efficacy identified in the figure but not in the text).

Thank-you for your comment. To address this, we have made the following changes to the manuscript:

- Changed the title *from* 'Effectiveness of the Choosing Wisely Australia® 5 Questions resource to support patient question-asking and participation in shared decision-making (EQUIP-SDM): Protocol for a randomised controlled trial' *to* 'Evaluation of the Choosing Wisely Australia® 5 Questions resource and a shared decision-making preparation video: Protocol for an online experiment'.
- Removed Figure 1 from the manuscript.

2) The consideration of health literacy - Nutbeam's definition is (appropriately) used although in the proposal is it not acknowledged that the study is limited to functional health literacy and not inclusive of the more comprehensive definition by Nutbeam (functional, relational, critical). Explaining why there is a limited view on health literacy would be helpful and why it is important to take the particular focus on health literacy would be helpful.

Other thoughts - might participants be concerned with their categorization according to health literacy? Has the NVS assessment been used to assess people online?

We recognise that the focus on functional health literacy does not account for communicative and critical-level skills. However, the use of the NVS provides a validated instrument to score and categorise participants according to their level of health literacy in an online study in an automated way. This measure is widely used and has been used previously in online studies. See, for example: Ayre, J et al. "Randoized trial of planning tools to reduce unhealthy snacking: implications for health literacy." *PLoS One* 2019: e0209863.

We also considered it important to assess participants' 'objective' health literacy skills (rather than self-reported health literacy) as it has been argued that self-reported measures assess participants' confidence in their capacity to comprehend and use health materials, rather than their actual ability, and that, conceptually, feelings of perceived confidence (i.e. self-efficacy) differs from health literacy (i.e. skills). Measures of communicative and critical health literacy skills are rarely objective measures of participants' skills.

We have added the following to the 'Strengths and Limitations' section of the manuscript:

"The measure of health literacy used in this study focuses on functional health literacy, but enables automatic scoring and categorisation of participants in an online setting." We have

also included this sentence in the 'Demographic and health data collection' section of the manuscript:

“The NVS has been used in other online studies [37], and is an objective performance-based measure of health literacy skills.”

Participants are made aware in the Participant Information Sheet that this study concerns populations with different levels of literacy, and are reminded that they may stop completing the online survey at any point if they do not wish to continue. They are not provided with a personal assessment of their own literacy. In our previous studies, no concerns have been expressed by participants about the use of these measures in an online setting.

3) I wondered about the patient/public/knowledge user involvement - the pilot study is promising with the qualitative interview study with a sub-set of health consumers (is there a citation for this study?). It seems that there is a strong emphasis on the researcher conduct and leadership in this study and inclusion of patients/members of the public or other knowledge user groups (those who will use or be impacted by the outcomes of the research) is limited. This is more of a comment but as there is a health equity component to the work that is being done raise this as a point for consideration by the authors.

Greater engagement of patients/members of the public/knowledge users may help to mitigate potential challenges of the study (for example, recruitment, drop outs).

Thank-you for this important comment. We appreciate that qualitative interviews do not represent researcher conduct and leadership in this study. We have now moved the information about the unpublished pilot study to the beginning of the ‘Methods’ section on page 8. The ‘Patient Involvement’ section of the manuscript has also been modified to better reflect the nature of consumer involvement in this project:

“A consumer was involved in the study design. The consumer helped select outcomes and outcome measures, develop and refine the intervention, and will inform the interpretation of results and dissemination of findings. Our study protocol was also presented to a Choosing Wisely Australia Board Meeting, with specific feedback sought from the two Consumer Board Members.”

4) Qualitative study - will all of the comments be used in the analysis, why will this be done (be explicit - what this adds). Will software be used to manage the data?

Based on our previous work, data will be presented as counts and percentages. This is now noted in the ‘Qualitative data analysis’ section of the manuscript. Therefore, all comments will be used in the analysis, and basic statistical software will be used to manage the data.

5) Subgroup analysis - I am not qualified to comment on the power calculations and recommend that another reviewer with experience in this study design and statistical analysis check this study (although it seems a methodologist is a member of the team). I wondered why there is no plan for subgroup analysis with demographic data (age, sex et cetera) and if this is feasible given the proposed sample size - or - if the data could be collected and if inadequate to analyze for this study could be used in another, future study with pooled data (is that the intent of the demographic data collection). Again, as this study is concerned with health equity issues it seems appropriate to consider subgroups.

Why the CONSORT Equity extension has not be considered for the reporting of this study.

We have included the following in the ‘Quantitative data analysis’ section of the manuscript: *“Any significant interactions will be followed-up by sub-group analyses based on potentially relevant demographic variables.”*

Although we feel that it is important to include underrepresented groups (i.e. participants with lower levels of health literacy), improving equity outcomes is not the primary focus of this experimental study.

6) Miscellaneous comments:

a. Who are "Consumer Reports"?

Consumer Reports are an independent non-profit product-testing organization. Consumer Reports is considered the “consumer communicator” partner on the *Choosing Wisely* campaign in the United States. This has been clarified in the introduction:

“As part of the original Choosing Wisely campaign, Consumer Reports (an independent non-profit product-testing organisation) partnered with the ABIM Foundation and developed five questions for patients to ask healthcare providers to support better conversations about unnecessary tests, medications and procedures.[3]”

b. P8 Line 22 - Is it findings from focus group testing (is the word "group" missing from this sentence) by Choosing Wisely Australia? and why were the findings "not sufficient"?

The Choosing Wisely Australia 2017 Report referenced in the above sentence states the following: “Focus testing with Australian consumers has identified that, while there is strong support for the use of the 5 Questions resource, people do not always feel they have permission to ask questions.” As such, we have not included the word ‘group’ into our manuscript. We have, however, provided an additional sentence explaining what is meant by ‘not sufficient’:

“Despite its potential, focus testing by Choosing Wisely Australia suggested that the 5 Questions resource alone may not be sufficient for enabling patient question-asking as people may continue to feel that they do not have permission to ask questions.[4]”

c. P9 Line 3 - What does "adapted slightly" mean? and by who?

Minor changes were made to the phrasing of questions by Choosing Wisely Australia, an initiative of NPS Medicinewise Ltd. Please see the table below and underlined text.

| Consumer Reports five questions | Choosing Wisely Australia® five questions |
|---|--|
| 1. Do I really need this test or procedure? | 1. Do I really need this <u>test, treatment or procedure</u> ? |
| 2. What are the risks? | 2. What are the risks? |
| 3. Are there simpler, safer options? | 3. Are there simpler, safer options? |
| 4. What happens if I don't do anything? | 4. What happens if I don't do anything? |
| 5. How much does it cost? | 5. <u>What are the costs?</u> |

We have clarified this using a footnote on Box 1.

d. Well done with Table 1

Thank-you

- 7) Overall a well done paper that will make an important contribution to the literature on preparing people to participate in SDM.

Thank-you

Reviewer: 2

This manuscript is a well-written protocol of a randomized controlled trial that aims to examine the effectiveness of the Choosing Wisely Australia 5 Questions resource to support patient question-asking and participation in shared decision-making. The study addresses an integral issue related to quality of care and patient satisfaction. Overall the trial is well designed. The only and major concern is the use of study participants who are "healthy volunteers" recruited online to represent/test "patient question-asking and etc" and use of hypothetical scenario to deliver the intervention. Online volunteers are often younger than the real patient population who have multiple comorbid conditions. It is unclear how the use of such a study population and hypothetical scenario can help inform the intervention implementation in the real world. Although the researchers have mentioned these issues in the limitation section, stronger rationale is needed to justify the decisions why this population and hypothetical scenarios are used and how the evidence obtained from this study can inform clinical practice in the real world.

Thank-you for this important comment. We have added the following rationale to the 'Objectives' section of the manuscript: *"Our overall objective is to better understand the potential of the Choosing Wisely Australia 5 Questions resource and a newly-developed shared decision-making preparation video for facilitating shared decision-making and reducing the use of unnecessary tests, medications and procedures. As this study represents the world's first evaluation of both interventions, we intend to deliver them online to a community sample using hypothetical vignettes. Participants are asked to imagine being in a specific clinical scenario and proximal cognitive-affective outcomes are assessed following randomisation to different interventions. We consider demonstrating evidence of impact in cognitive and affective outcomes an important first step before embarking on evaluation in the health care setting."*

As noted above, we have also changed the title to 'Evaluation of the Choosing Wisely Australia® 5 Questions resource and a shared decision-making preparation video: Protocol for an online experiment', and have replaced the word 'effectiveness' with 'impact' throughout the manuscript.

VERSION 2 – REVIEW

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| REVIEWER | Lixin Song University of North Carolina-Chapel Hill, USA |
| REVIEW RETURNED | 20-Oct-2019 |
| GENERAL COMMENTS | The researchers have adequately addressed my previous concerns. |