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# 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



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# 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

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Keywords: patient participation, decision making, shared decision making, health literacy, question prompt list, medical overuse

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## Abstract

**Introduction:** Choosing Wisely, an international effort to reduce low value care worldwide, encourages patients to ask their doctors questions to support evidence-based shared decision-making. In Australia, Choosing Wisely has developed a 5 Questions resource to help reduce low value care.

**Aims:** The primary aim of this study is to evaluate the effectiveness of the Choosing Wisely Australia 5 Questions resource and a video designed to prepare patients for question-asking and participation in shared decision-making on a) self-efficacy to ask questions and participate in shared decision-making, b) intention to participate in shared decision-making and c) a range of secondary outcomes. The secondary aim of this study is to determine whether health literacy modifies the effects of the interventions.

**Methods:** We will use 2x2x2 between-subjects factorial design (preparation video: yes, no x Choosing Wisely 5 questions resource: yes, no x health literacy: adequate, inadequate). Participants will be recruited by an online market research company, presented with a hypothetical non-specific low back pain scenario, and randomised to study groups stratified by health literacy.


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**Analysis:** Quantitative primary and secondary outcome data will be analysed as intention-to-treat using appropriate regression models (i.e., linear regression for continuous outcomes, logistic regression for dichotomous categorical outcomes).

**Ethics and dissemination:** Ethical approval for this study was obtained from the University of Sydney Human Research Ethics Committee (protocol number: 2018/965). The results from this work will be disseminated through peer-reviewed international journals, conferences and updates with collaborating public health bodies. Resources developed for this study will be made available to patients and clinicians following trial completion.

**Study registration:** This trial has been registered with the Australia New Zealand Clinical Trials Registry (trial number: 376477).

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**Strengths and limitations of this study**

- This is the first study to assess the relative effectiveness of the Choosing Wisely Australia 5 Questions resource, both alone and in combination with an additional video intervention designed to support and build patients' confidence to ask questions compared to no intervention, and explore whether health literacy impacts intervention effectiveness.
- We will randomly allocate participants, conceal allocation, blind study statisticians and aim to recruit 1432 participants to achieve at least 80% power.
- The main limitation of this study is reduced ecological validity and the limited generalisability of the findings due to a) online recruitment and use of 'healthy volunteers', b) the use of a hypothetical scenario, and c) delivering the interventions in a way that diverges from how they would be/are delivered in the real world.
- However, this design allows us to achieve a high response and follow-up rate with adequate representation of people with limited health literacy in a factorial design requiring a large sample.

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# 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

Unnecessary and potentially harmful services account for a significant proportion of total health expenditure.[1] The need to eliminate unnecessary medical care, decrease waste and reduce overdiagnosis has received increasing attention from health systems in the past decade. One initiative that has gained momentum worldwide is Choosing Wisely®.[2] Launched in April 2012 by the American Board of Internal Medicine (ABIM) Foundation, the Choosing Wisely campaign has now been adapted and implemented in more than 20 countries worldwide. The campaign seeks to encourage clinicians and patients to talk about medical tests and procedures that may be unnecessary, and in some instances, can cause harm.[2] While acknowledging that it is often challenging to have conversations about unnecessary tests and treatments, leaders of the campaign consider communication between clinicians and patients during routine clinical encounters a key mechanism for change.[2]

As part of the original Choosing Wisely campaign, Consumer Reports developed five questions for patients to ask healthcare providers to support better conversations about unnecessary tests, medications and procedures.[3] The questions are publically available and have been promoted for use nationally and



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internationally. The five questions were adapted slightly by Choosing Wisely Australia® (see Box 1) and have been disseminated in several forms and languages, including as a one-page downloadable resource, '*5 Questions to Ask Your Doctor*' (hereafter referred to as the 5 Questions resource), that lists the questions and provides additional guidance in their rationale and use (see Appendix A). Annual evaluation surveys conducted by Choosing Wisely Australia suggested that, in 2015 and 2016, 8% of health care consumers were aware of the 5 Questions resource and, in 2017, it was the organisation's most commonly downloaded material (4).

**Box 1. The Choosing Wisely Australia® 5 questions**

1. Do I really need this test, treatment or procedure?
2. What are the risks?
3. Are there simpler, safer options?
4. What happens if I don't do anything?
5. What are the costs?

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The 5 Questions resource has been promoted for its "potential to facilitate better conversations between healthcare providers and consumers".[4] However, it has yet to be formally evaluated, and the precise expected mechanism of action for its effect on the use of low value care has not been investigated. Notwithstanding,



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question prompt lists of this kind are typically regarded as a strategy for facilitating shared decision-making [5] and thus, improved shared decision-making is an obvious potential mediator of the hypothesised effect of the 5 Questions resource on the use of care (see Figure 1).

--- Figure 1 ---

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.[4] In response to this, Choosing Wisely Australia has developed accompanying resources (e.g., posters featuring local hospital staff,[4] a video illustrating how to have conversations with health professionals [6]) that address some potential barriers to the impact of the 5 Questions resource (e.g., the social unacceptability of active participation, patient concerns about healthcare providers' reactions and possible retribution). However, other elements proposed as critical for preparing patients in advance of exposure to a shared decision-making intervention (e.g., explaining that there are two experts in the encounter (healthcare provider *and* patient), challenging attitudes that there are universally right and wrong decisions)[7, 8] remain unaddressed by these resources. An intervention that addresses all elements considered critical for patient preparation may enhance the effectiveness of the 5 Questions resource and may also, on its own, be beneficial.

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The effectiveness of the 5 Questions resource may also depend on patients' health literacy;[9] that is, "the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health"[10]. Adults with lower health literacy have worse health outcomes (e.g. increased hospital admissions and readmissions;[11] poorer chronic disease outcomes [12] and increased mortality [13]), and importantly ask fewer questions when seeing healthcare providers.[14] Previous research shows that interventions that are tailored to an individuals' health literacy level can support more effective communication and potentially reduce health inequalities for people with lower health literacy.[15-17] However, intervention developers often fail to tailor the design of their interventions to adults with lower health literacy and rarely evaluate their impact in this group.

***Objectives***

The primary aim of this study is to evaluate the effectiveness of the Choosing Wisely Australia 5 Questions resource and a newly-developed video designed to prepare patients for question-asking and build their confidence to participate in shared decision-making on a) self-efficacy to ask questions and participate in shared decision-making, b) intention to participate in shared decision-making and c) a range of secondary outcomes. The secondary aim of this study is to determine whether health literacy modifies the effects of the interventions.

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## Methods

### *Study design and setting*

We will use 2x2x2 between-subjects factorial design (preparation video: yes, no x Choosing Wisely 5 questions resource: yes, no x health literacy: adequate, inadequate). This design will enable us to assess the relative effectiveness of different interventions, both alone and in combination compared to no intervention. This design will also allow us to explore whether health literacy impacts the effectiveness of these interventions.

This study will be conducted online using the Qualtrics survey platform. Randomisation will be undertaken via an automated function in the survey platform using an equal allocation ratio and stratification by participant health literacy (adequate, inadequate), yielding four trial arms in each health literacy subgroup: (1) preparation video alone, (2) 5 Questions resource alone, (3) preparation video and 5 Questions resource, and (4) no intervention. Participants will not be blinded to their assigned intervention.

### *Participants, recruitment, and consent*

To be eligible to take part, potential participants must be aged 18 years or older; be an Australian citizen or permanent resident; and possess sufficient self-assessed English language skills to complete questionnaires in English.

Participants will be identified, pre-screened for eligibility, and invited to consider participation by Dynata, a market research company with a database of



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600,000 people willing to be involved in online research. Dynata uses a points system whereby points are earned for completion of surveys which can be redeemed for items such as gift vouchers, donations to charities or cash. If participants agree and are interested in being part of the study, they will be directed to an online survey hosted in Qualtrics. The first page of the survey will display the downloadable Participant Information Statement (see Appendix B). In line with the Australian National Statement on Ethical Conduct in Human Research, 2007 (updated 2018), we have received ethical approval to regard completion of the questionnaire as an indication of consent. Participants are also required to select 'Yes, I would like to participate' to enter the survey.

During the study, all participants will be presented with a hypothetical healthcare scenario that asks them to imagine being in a situation where they have non-specific low back pain and stable pain/symptoms (See Box 2). Non-specific low back pain describes pain between the inferior border of the twelfth rib and lower gluteal folds that is not caused by a serious or specific underlying pathology.[18] Back pain was the eighth most frequently managed problem Australian general practice in 2015 [19] and non-specific low back pain accounts for approximately 90% of low back pain cases.[20] Routine imaging for non-specific low back pain has been shown to have more harms than benefits, and furthermore many medical treatments provide little-to-no benefit over placebo.[21, 22]

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**Box 2. Hypothetical back pain scenario**

"You have had lower back pain for about one month; it has not improved or become worse. You did not have an accident to cause the pain; it just began and has not gone away.

You go to your doctor to get advice on what is causing it and what can help with the pain.

The doctor recommends that you have a scan to help figure out what is causing the pain, and gives you a prescription for some medicine."

***Interventions***

*Preparation video*[1]

We developed a short video (3 minutes) intended to prepare patients for question-asking and shared decision-making. Our rationale for this choice of intervention included that multimedia formats can be a successful tool in engaging and educating patients with low health literacy and encouraging or modifying patient behaviour [23-25] and that videos featuring real people have been found to be more effective than those which only provide graphically presented information

[1] In communications with participants, this intervention was referred to as the 'Introduction to shared decision making' video



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with voice overs.[23] The video script (Appendix C) was developed through an iterative process and was intended to integrate the recommendations for effective preparation as outlined by Joseph-Williams and colleagues.[8] The transcript was developed with reference to the Listenability Style Guide which outlines principles to make spoken discourse more comprehensible and ease the cognitive burden of listening (e.g. repetition of ideas; simple and common idioms; vivid analogies; use of questions to focus the listener's attention).[26] The readability level of the script was also checked and adjusted until a grade five readability level was achieved.

*Choosing Wisely Australia 5 Questions resource*[2]

The Choosing Wisely Australia 5 Questions resource is a one-page document co-branded by Choosing Wisely Australia and NPS Medicinewise that lists the Choosing Wisely Australia 5 questions (see Box 1 above) and provides additional guidance in their rationale and use (see Appendix A). This resource has a readability score of 9.4.

*Implementation of interventions*

The interventions will be displayed to participants within the survey platform. To ensure intervention exposure, a timer has been added to the pages displaying the video (3 minutes) and 5 Questions resource (1 minute), preventing

[2] In communications with participants, this intervention was referred to as the Choosing Wisely Questions



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participants from progressing to the next survey page until the specified time has elapsed. In the preparation video and 5 Questions resource arm, the video will be presented before the 5 Questions resource. Participants will not be prevented from exposure to any other care or interventions prior to or during the study.

***Data Collection***

Study data will be collected via surveys administered immediately before ('Pre'), immediately after ('Post'), and two weeks after ('Follow-up') exposure to the relevant intervention(s) (see Figure 2). All outcomes will be assessed by participant self-report with the exception of proactive intervention use, which will be assessed using observational methods (see Outcomes and Measures).

--- Figure 2 ---

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### *Outcomes and Measures*

Primary and secondary outcomes for the study, as well as measurement instruments and analysis metrics, are shown in Table 1. Outcomes and measures were refined following a pilot study (n=164). Unpublished pilot data are available from the authors upon request.

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Table 1.

*Outcomes and measurement*

| | Outcome | Measure | Pre | Post | Follow-up |
|---|---|---|---|---|---|
| Primary | Self-efficacy to ask questions | Single item adapted from Bandura's self-efficacy theory.[27] Participants are asked to rate their degree of confidence to ask questions of their healthcare provider by recording a number from 0 (Cannot do at all) to 100 (Highly certain can do). | x | x | x |
| | Self-efficacy to be involved in healthcare decision-making | Single item adapted from Bandura's self-efficacy theory.[27] Participants are asked to rate their degree of confidence to be involved in decisions with their healthcare provider by recording a number from 0 (Cannot do at all) to 100 (Highly certain can do). | x | x | x |
| | Self-efficacy to ask questions and be involved in healthcare decision-making | Composite measure based on two individual items (see above). | x | x | x |
| | Intention to engage in shared decision-making | Validated, three-item scale (Cronbach alpha = 0.8; [28]) measuring participants' (i) likelihood of engaging in shared decision-making, from very unlikely (−3) to very likely (+3), (ii) odds of engaging in shared decision-making, from very | x | x | x |

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| | | weak (−3) to very strong (+3) and (iii) agreement with the statement 'I intend to engage in shared decision-making', from total disagreement (−3) to total agreement (+3). Total scores will be rescaled on a scale of 0-6 and the sum of the items divided by three to derive the total score of intention. | | | |
| Secondary | Intention to follow the treatment plan recommended by the doctor without further questioning | A single item on a 10-point scale, adapted from previous research,[29] assessing hypothetical intention to follow the treatment plan recommended by the doctor without further questioning: 'Which best describes your intention to follow the treatment plan recommended by the doctor without asking further questions?' (1 = 'Definitely will not' to 10 = 'Definitely will'). | x | x | x |
| | Knowledge of patient's rights in regards to shared decision-making | Four questions adapted from Halaway et al [30] and applied to the Australian Charter of Healthcare Rights.[31] Participants were asked to indicated "Yes", "No" or "Unsure" to show whether they think the following are patient rights: a) right to talk about questions, concerns and costs regarding diagnosis and treatment; b) right to be given information about your condition and treatment options in word you understand; c) right to be included in choices | x | x | |

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| | about your care. A foil question will be included to detect if participants are arbitrarily selecting 'yes' to all questions. Scores are dichotomised into a) all questions correct, or b) not all questions correct. | |
| Attitude toward shared decision-making | 3-item scale adapted from Dormandy et al.,[32] assessing participants' perceptions of shared decision-making as beneficial/not beneficial, worthwhile/not worthwhile and important/unimportant. Each item has seven response options, forming a scale from 3 to 21. Higher scores indicate less positive attitudes towards shared decision-making. Participants responding with the highest possible score on all three questions will be classified as having positive attitudes. | x |
| Preparedness for shared decision-making | Modified, 8-item version of the Preparation for Decision Making Scale (PrepDM).[33] The PrepDM scale was developed to assess a patient's perception of how useful a decision support intervention is in preparing the respondent to communicate with their practitioner at a consultation visit and to make a health decision. Items are scored on a likert scale 1-5, from 'Not at all' (1) to 'A great deal' (5), with higher scores indicating higher | x |

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| | | | |
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| | perceived level of preparation for decision-making. Items will be summed and the total score divided by 8.[33] | | |
| Acceptability (*Arms 1-3 only*) | Adapted from Shepherd et al,[34] participants asked to rate if they would a) recommend the [intervention] to others and b) use the [intervention] again on a four-point scale from 1 (Definitely not) to 4 (Yes, definitely).[34] Recommendations are dichotomised into would recommend (3 and 4) and would not recommend (1 and 2). | x | |
| Proactive Intervention Use (*Arms 1-3 only*) | We will assess the proportion of participants who click on a link to their intervention. | x | x |
| Healthcare questions | Participants will be asked to write down 5 questions that they would ask the doctor given the hypothetical healthcare scenario. The content of individual responses will be analysed via content analysis using inductive and deductive approaches (see below). The mean number of questions that map onto the Choosing Wisely 5 Questions will be calculated. | x | x |

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*Demographic and health data collection*

In addition to the primary and secondary outcomes, participants will be asked to report their age, gender, Australian state of residence, language spoken at home, education status, employment status, private health insurance status and confidence in filling out medical forms (35). Participants will also be asked to indicate who is usually involved in healthcare decision-making related to their health, and about their experience and perceived knowledge of low back pain. Health literacy will be assessed by the Newest Vital Sign (NVS),[36] with participants categorised as inadequate (score 0-3 on NVS) or adequate literacy (score 4-6 on NVS). We will also administer a single-item measure of self-reported health literacy for the purposes of describing the sample.

**Analysis**

*Quantitative data analysis*

The study statistician will be blinded to the intervention allocation of participants and their level of health literacy until after completion of analyses; a research assistant who has no other involvement in the trial will remove all group identifiers prior to analysis. Quantitative primary and secondary outcome data will be analysed as intention-to-treat using appropriate regression models (i.e., linear regression for continuous outcomes, logistic regression for dichotomous categorical outcomes). Dichotomous variables representing the study factors (preparation video:

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provided, not provided; Choosing Wisely Australia 5 questions resource: provided, not provided; health literacy: adequate, inadequate) and their interactions will be included in models as between-subjects fixed effects, controlling for pre-intervention values (where available). Outcome data collected during the immediate post- and follow-up survey will be analysed in separate models.

***Missing data***

The use of an online survey platform minimises the risk of missing data; participants are required to provided responses to each question before moving on to subsequent items. As such, data is only missing in cases where participants discontinue prior to providing responses for outcome measures. Participants who discontinue the study before completion of the (immediate) post-intervention survey will be excluded from all analyses. Multiple imputation will be used [37] to impute occasional cases of missing data (e.g. some outcome measures incomplete) or for missing responses for participants who complete the initial (pre- and post-) surveys, but do not return to complete the 2-week follow-up survey. If multiple imputation of missing data is utilised, sensitivity analyses will be performed comparing the outcome from complete-case with imputed analyses.

***Sample size***

Sample size estimates were derived based on the primary outcome of intention score, with the estimates of effect based on previously published values [28] and refined



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considering pilot data. For each stratified analysis arm (i.e., inadequate health literacy, adequate health literacy), a sample of n=162 subjects per intervention group is expected to provide approximately 80% power to detect a small main effect (effect size of 0.10 or greater) of the Choosing Wisely Australia questions resource; and over 80% power to detect small main effects (effect sizes 0.20 or larger) of the preparation video intervention, and their interaction, at a p-value of 0.05 in primary analyses. As such, we aim to recruit a total sample size of N=1432 (i.e., 716 with inadequate health literacy and 716 with adequate health literacy; with n = 179 participants randomly allocated to each intervention group [preparation video alone, Choosing Wisely Australia 5 questions resource alone, both Choosing Wisely questions and preparation intervention, and control]). This will allow for a drop-out of approximately 10% of participants who discontinue the study before completing the (immediate) post-intervention survey measures.

***Qualitative data analysis***

Assessment of healthcare questions deemed by participants as important to ask in their hypothetical scenario will be analysed via content analysis.[38] Coding will first be done deductively based on concepts embodied in the Choosing Wisely Australia 5 Questions resource.[39] Two double-blind coders will review all data and code any questions that fit broadly into 1 of 5 categories: Do I really need this test, treatment or procedure? What are the risks? Are there simpler, safer options? What happens if I don't do anything? What are the costs?[40, 41] Any discrepancies



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will be resolved through discussion between coders. Remaining responses will be coded inductively with categories derived from the data.[40] Inductive codes will be collected to form coding sheets and categories freely generated and grouped through the abstraction process.[40] The coding scheme will revised over an iterative process of discussion and revision to ensure all themes are captured.

## Ethics and dissemination

### *Ethical approval and trial registration*

Ethical approval for this study was obtained from the University of Sydney Human Research Ethics Committee (protocol number: 2018/965). This trial has been registered with the Australia New Zealand Clinical Trials Registry (trial number: 376477).

### *Data storage and management*

After enrolment, a unique identifier will be assigned to each study participant. Any participant identifiers will be removed before the data are archived for storage. Data will be downloaded as spreadsheets and stored on password protected computers which are encrypted per university policy. Listed investigators will have access to the final study dataset.

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### *Dissemination and data sharing*

To enhance reporting transparency, this study will be reported in accordance with the Consolidated Standards of Reporting Trials Statement and Checklist. The results from this work will be published as a full-length, peer-reviewed manuscript and presented at national and international meetings. The results from this work will also be disseminated through collaborating public health bodies. Any protocol modification will be communicated during dissemination activities. Resources developed for this study will be made available to patients and clinicians following trial completion.

### *Patient involvement*

We performed a pilot study of the intervention (n=164), and included a further qualitative interview study with a sub-set of health consumers (n=25) to refine our interventions and outcome measures. A consumer has been involved in the study design, selecting outcomes and developing the intervention, and will continue to inform the analysis and dissemination of findings.

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## Author contributions

Authorship decisions adhered to ICMJE recommendations. DM, KM and JKS conceived the original idea for this trial, and this was further developed by EHC, RT, EC, MT, JZ and RL. DM and JKS wrote the first draft of this protocol manuscript, and this was edited by all other authors. EC provided valuable input regarding trial design and analytical considerations, and performed the sample size calculations for the trial. All authors contributed to and approved the final version of the manuscript.

## Funding statement

The study was funded by a National Health and Medical Research Council (NHMRC; help@nhmrc.gov.au) Program Grant (APP1113532). NPS MedicineWise gave permission for investigators' use of the Question Prompt List leaflet without charge. EC was supported by a Sydney Medical School Summer Research Scholarship and KM is supported by an NHMRC Principle Research Fellowship (1121110). Neither the NHMRC nor Sydney Medical School had any role in the design of this study. They will not have a future role in the conduct or write-up of the study or in the decision to submit the findings for publication. A representative of Choosing Wisely Australia (RL) contributed to the design of this study and will have a future role in the conduct and write-up of the study. NPS MedicineWise will not have a role in the decision to submit the study findings for publication.

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## Competing interests

Robyn Lindner is an employee NPS MedicineWise which facilitates Choosing Wisely Australia. The University of Sydney owns IP on the video and DM, MT, KM and RT are contributors to the intellectual property.

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**List of Figures**



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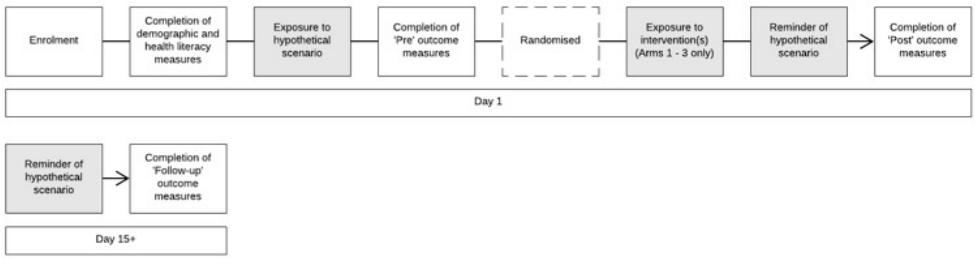
Possible mechanism of action for effect of Choosing Wisely Australia® 5 Questions resource on use of unnecessary tests, medications and procedures

157x26mm (150 x 150 DPI)




Time schedule of enrolment, interventions, and assessments

270x81mm (72 x 72 DPI)

# Appendix A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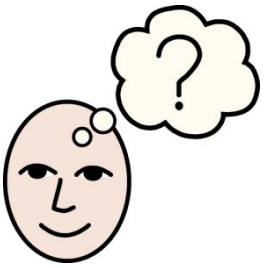
# Appendix B

## Helping people to choose wisely: Evaluating methods for shared decision making in populations with different levels of literacy

**What is the study about?**



We are doing a research study to try to work out what is the best way of helping people to work with their doctor to decide what to do about their health. It can be hard to think of questions on the spot or you might feel like your questions aren't good enough. This study will look at some tools that help people feel more confident to ask their doctor questions and to explain their point of view and what they think is important.

**Who is carrying out the study?**

We are from the School of Public Health at the University of Sydney. Our names are:

- Danielle Muscat
- Jessica Smith
- Erin Cvejic
- Josh Zadro
- Kirsten McCaffery
- Edward Hoi-Fan Chang
- Marguerite Tracy
- Rachel Thompson

**What will happen if I say that I want to be in the study?**

You can decide if you want to take part in the study or not. Please read this sheet carefully so that you can make up your mind about whether you want to take part. Completing a question in the online survey is an indication of your consent to take part in the study.

You may stop completing the online survey at any point if you do not wish to continue, and we will not use your answers. You do not have to give a reason for not taking part. Once you have submitted your survey anonymously, your responses cannot be withdrawn.

If you decide that you want to be in our study, we will ask you to:

1. Complete questions online. For example, about your age, gender, language spoken at home, and answer some questions about a food label.
2. Watch a video or read some information about asking health questions.
3. Read a made-up scenario and pretend that you are visiting a doctor about a sore back.

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4. Complete questions online about patient rights, how you feel about asking the doctor questions, and what you think of the tool provided to you in the study.
5. Write some questions you would want to ask the doctor in the pretend situation.
6. We will send you a follow-up survey one month later which will repeat some of the questions from the first study. This will likely take 5 minutes to complete. We will also provide you with a link to the information or health questions that you received so that you can download them if you would like to.

**Will anyone else know what I say in the study?**

All of the information that we have about you from the study will be private. It will be stored in password-protected files on password-protected computers owned by the University of Sydney. We will write a report about the study and show it to other people but no one will know that you were in the study.

**How long will the study take?**

The study will take about 20 minutes.

**Are there any good things about being in the study?**

This study may help you think more about the questions you can ask when you visit the doctor. It can be helpful to understand more about your treatment options.

**Are there any bad things about being in the study?**

This study will take up some of your time, but we don't think it will be bad for you or cost you anything.

**By giving your consent to take part in this study you are telling us that you:**

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as described above.
- ✓ Agree to the use of your personal information for the research purposes described above.

**What if I want more information about the study or my involvement in it?**

You can contact the researcher: Danielle Muscat

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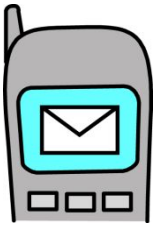
- Call: (02) 9351 7819
- Email: danielle.muscat@sydney.edu.au

You are also able to email and request a summary of the final findings be sent to you at the end of the study.

**What if I am not happy with the study or the people doing the study?**



The ethical aspects of this study have been approved by the HREC of the University of Sydney [Project Number 2018/965].
If you are not happy with how we are doing the study or how we treat you, then you can:

- Call the university on +61 2 8627 8176 or
- Write an email to human.ethics@sydney.edu.au

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Appendix C

Table A.

*Preparation video text and justification*

| Script text | Speaker | Development reference(s) |
|---|---|---|
| *When you visit a doctor, you are in a safe environment with a professional and it's a great time to ask any questions you might have, share information about yourself, discuss your options (or choices) for testing and treatment and make a decision together. This is called shared decision making.* | Patient | - Choosing Wisely Australia video 'The Word on the Street (extended)'.[42]<br>- Shared decision-making definitions in Hoffmann et al (2014) (43) and Charles et al.[44]<br>- Joseph-Williams et al., recommendation that materials should inform patients about shared decision making—what it is, what to expect, and why it is appropriate.[8] |
| *Yes, making decisions with your doctor may seem scary but remember - were experts too! We know what is most important to us, and our values, preferences and experiences.* | Patient | - Joseph Williams et al recommendation that materials should explain that there are two experts in the clinical encounter and should also build patients' belief in their ability to take part.[8] |
| *Shortly, we'll talk about why shared decision making is important and how it can help you make the right decisions about your health.* | Healthcare professional | - Patient Education Materials Assessment tool requirement to clearly and completely state the material's purpose to the listener.<br>- Listenability Style Guide recommendation to provide advanced sign-posting. |
| *The Australian Charter for Healthcare rights says that everyone has the right to be included in decisions and choices about their care. What that means is that we should be informed about serv ices, treatment options and costs in a clear and open way.* | Patient | - Australian Charter of Healthcare Rights, developed by the Australian Commission on Safety and Quality in Healthcare in 2008.[31] |

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| | | |
|---|---|---|
| *Asking your doctor questions is one way to make this happen and can help you to make decisions that you are happy with.* | Patient | - Choosing Wisely – 'Unofficial' film clip.[45] |
| *There are benefits and harms, or 'pros' and 'cons', to every treatment. Asking questions and sharing decisions with your doctor can be helpful to understand the options offered to you and their benefits and harms.* | Healthcare professional | - Choosing Wisely – 'Unofficial' film clip.[45]<br>- Informed Medical Decisions Foundation video.[46]<br>- Joseph Williams et al recommendation that materials should challenge attitudes that there are right and wrong decisions.[8] |
| *For some things these harms may even outweigh their benefits. For example, body scans and imaging (like doing X-rays or MRIs) for small things may actually be more harmful than useful, and sometimes it's better to 'wait and watch'.* | Healthcare professional | - Choosing Wisely video 'The Word on the Street (extended)'.[42] |
| *Sometimes there are no right or wrong choices as two treatments may have similar benefits and harms. In those instances, sharing your preferences and beliefs may help you and the doctor to choose the best treatment for you.* | Healthcare professional | - Joseph-William's recommendation to address patient assumptions that there is always a right and wrong decision. |
| *You may be nervous, or even scared, but it is ok to ask questions. It's good to work with your doctor to understand your options and in fact research shows* | Patient | - The use of repetition as a tool for audiovisual materials targeted to people with low health literacy is also referenced in the Listenability Style Guide (LSG).[26] |

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Appendix C

| | | |
|---|---|---|
| *that asking questions makes it easier to make decisions that are right for you.* | | - Joseph-Williams's recommendation that materials should build patients' belief in their ability to take part.[8]<br>- |
| *Just think, if you had to move to a new house or buy a new car, there are a lot of options, with different pros and cons, and your own personal preferences would be very important to consider. So, what about making decisions about your health?* | Patient | - The questions were also influenced by two Shared Decision Making informational videos.[46,47]<br>- The question asking style and use of analogies is also referenced in the Listenability Style Guide (LSG).[26] |
| *Asking questions and talking to your doctor can also help you to better understand what is happening. You know how sometimes you leave a doctor's appointment and you don't really understand what has been said? It's not a great feeling is it? You should be comfortable with what is being prescribed and why.* | Patient | - Choosing Wisely Australia (39), particularly the "Tumbleweed– Find the right questions to ask your doctor" video.[48]<br>- The use of questions as a tool for audio-visual materials targeted to people with low health literacy is also referenced in the Listenability Style Guide (LSG).[26] |
| *We want to work with you to make the best decisions and know more about your health. We want you to ask questions.* | Healthcare professional | - Joseph Williams' recommendations that materials should redefine perceptions of a good patient and reassure patients that participation will not result in retribution and should also confirm that clinicians want patient participation.[8]<br>- The use of repetition as a tool for audio-visual materials targeted to people with low health literacy is also referenced in the Listenability Style Guide (LSG).[26]<br>- PEMAT-A/V item by providing the viewer with a clear action to take whilst also addressing them directly to maximise the actionability of message. |

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Appendix C

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|---|---|---|
| *We're happy to answer your questions, so together we can work out what is right for you.* | Healthcare professional | - Joseph Williams's recommendation that materials should confirm that clinicians want patient participation.[8]<br>- The use of repetition as a tool for audio-visual materials targeted to people with low health literacy is also referenced in the Listenability Style Guide (LSG).[26] |
| *So remember – ask your questions. We're listening. Let's share decisions together.* | Healthcare professional | - Choosing Wisely video resource.[49] |

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Addressed on page number |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 3 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | |
| Protocol version | 3 | Date and version identifier | |
| Funding | 4 | Sources and types of financial, material, and other support | 28 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1,28 |
| | 5b | Name and contact information for the trial sponsor | 28 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | 28 |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | n/a |

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| | | | |
|---|---|---|---|
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 5-8 |
| | 6b | Explanation for choice of comparators | 5-8 |
| Objectives | 7 | Specific objectives or hypotheses | 8 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 8 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 8 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 9 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 10-11 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | n/a |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 19 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 19 |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 14-17 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | 12 |



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| | | | |
|---|---|---|---|
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 19 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 9 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 8 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 8 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 8 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 8,18 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | n/a |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 14-17 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 19 |



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| | | | |
|---|---|---|---|
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 18 |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 18 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 18,19 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 18,19 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | n/a |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | n/a |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | n/a |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | n/a |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 20 |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | 20-21 |



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| | | | |
|---|---|---|---|
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | ___9_____ |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | ___n/a_____ |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 21, Appendix B |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | ___28_____ |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | ____28_____ |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | ____n/a_____ |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | ____21_____ |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | _____28_____ |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | _____21_____ |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | ___Appendix B__ |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | ____n/a_____ |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.



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BMJ Open

# Evaluation of the Choosing Wisely Australia® 5 Questions resource and a shared decision-making preparation video: Protocol for an online experiment



| | |
|---|---|
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| Primary Subject Heading: | Communication |
| Secondary Subject Heading: | Patient-centred medicine, Public health |
| Keywords: | patient participation, decision making, shared decision making, health literacy, question prompt list, medical overuse |
| | |



SCHOLARONE™
Manuscripts

# Evaluation of the Choosing Wisely Australia® 5 Questions resource and a shared decision-making preparation video: Protocol for an online experiment

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Keywords: patient participation, decision making, shared decision making, health literacy, question prompt list, medical overuse

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## Abstract

**Introduction:** Choosing Wisely, an international effort to reduce low value care worldwide, considers communication between clinicians and patients during routine clinical encounters a key mechanism for change. In Australia, Choosing Wisely has developed a 5 Questions resource to facilitate better conversations. The primary aim of this study is to evaluate the impact of the Choosing Wisely Australia 5 Questions resource and a video designed to prepare patients for question-asking and participation in shared decision-making on a) self-efficacy to ask questions and participate in shared decision-making, b) intention to participate in shared decision-making and c) a range of secondary outcomes. The secondary aim of this study is to determine whether health literacy modifies the effects of the interventions.

**Methods and analysis:** We will use 2x2x2 between-subjects factorial design (preparation video: yes, no x Choosing Wisely 5 questions resource: yes, no x health literacy: adequate, inadequate). Participants will be recruited by an online market research company, presented with a hypothetical non-specific low back pain scenario, and randomised to study groups stratified by health literacy. Quantitative primary and secondary outcome data will be analysed as intention-to-treat using appropriate regression models (i.e., linear regression for continuous outcomes, logistic regression for dichotomous categorical outcomes).


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**Ethics and dissemination:** Ethical approval for this study was obtained from the University of Sydney Human Research Ethics Committee (protocol number: 2018/965). The results from this work will be disseminated through peer-reviewed international journals, conferences and updates with collaborating public health bodies. Resources developed for this study will be made available to patients and clinicians following trial completion.

**Study registration:** This trial has been registered with the Australia New Zealand Clinical Trials Registry (trial number: 376477).

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**Strengths and limitations of this study**

- This is the first study to assess the relative impact of the Choosing Wisely Australia 5 Questions resource, both alone and in combination with an additional video intervention designed to support and build patients' confidence to ask questions compared to no intervention, and explore whether health literacy modifies the impact of interventions.
- We will randomly allocate participants, conceal allocation, blind study statisticians and aim to recruit 1432 participants to achieve at least 80% power.
- The main limitation of this study is reduced ecological validity and the limited generalisability of the findings due to a) online recruitment and use of 'healthy volunteers', b) the use of a hypothetical scenario, and c) delivering the interventions in a way that diverges from how they would be/are delivered in the real world.
- However, this design allows us to achieve a high response and follow-up rate with adequate representation of people with limited health literacy in a factorial design requiring a large sample.
- 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.

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**Evaluation of the Choosing Wisely Australia® 5 Questions resource and a shared decision-making preparation video: Protocol for an online experiment**

Unnecessary and potentially harmful services account for a significant proportion of total health expenditure.[1] The need to eliminate unnecessary medical care, decrease waste and reduce overdiagnosis has received increasing attention from health systems in the past decade. One initiative that has gained momentum worldwide is Choosing Wisely®.[2] Launched in April 2012 by the American Board of Internal Medicine (ABIM) Foundation, the Choosing Wisely campaign has now been adapted and implemented in more than 20 countries worldwide. The campaign seeks to encourage clinicians and patients to talk about medical tests and procedures that may be unnecessary, and in some instances, can cause harm.[2] While acknowledging that it is often challenging to have conversations about unnecessary tests and treatments, leaders of the campaign consider communication between clinicians and patients during routine clinical encounters a key mechanism for change.[2]

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] The questions are publically available and have been promoted for

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use nationally and internationally. The five questions were adopted by Choosing Wisely Australia® (with some minor phrasing changes; see Box 1) and have been disseminated in several forms and languages, including as a one-page downloadable resource, '*5 Questions to Ask Your Doctor*' (hereafter referred to as the 5 Questions resource), that lists the questions and provides additional guidance in their rationale and use (see Appendix A). Annual evaluation surveys conducted by Choosing Wisely Australia suggested that, in 2015 and 2016, 8% of health care consumers were aware of the 5 Questions resource and, in 2017, it was the organisation's most commonly downloaded material (4).

**Box 1. The Choosing Wisely Australia® 5 questions**

1. Do I really need this test, treatment or procedure?[a]
2. What are the risks?
3. Are there simpler, safer options?
4. What happens if I don't do anything?
5. What are the costs?[b]

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[a] Original Consumer Reports question: Do I really need this test or procedure?
[b] Original Consumer Reports question: How much does it cost?

The 5 Questions resource has been promoted for its "potential to facilitate better conversations between healthcare providers and consumers".[4] However, it has yet to be formally evaluated, and the precise expected mechanism of action for



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its effect on the use of low value care has not been investigated. Notwithstanding, question prompt lists of this kind are typically regarded as a strategy for facilitating shared decision-making [5] and thus, improved shared decision-making is an obvious potential mediator of the hypothesised effect of the 5 Questions resource on the use of care.

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] In response to this, Choosing Wisely Australia has developed accompanying resources (e.g., posters featuring local hospital staff,[4] a video illustrating how to have conversations with health professionals [6]) that address some potential barriers to the impact of the 5 Questions resource (e.g., the social unacceptability of active participation, patient concerns about healthcare providers' reactions and possible retribution). However, other elements proposed as critical for preparing patients in advance of exposure to a shared decision-making intervention (e.g., explaining that there are two experts in the encounter (healthcare provider *and* patient), challenging attitudes that there are universally right and wrong decisions)[7, 8] remain unaddressed by these resources. An intervention that addresses all elements considered critical for patient preparation may enhance the impact of the 5 Questions resource and may also, on its own, be beneficial.[7, 8]

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The impact of the 5 Questions resource may also depend on patients' health literacy;[9] that is, "the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health"[10]. Adults with lower health literacy have worse health outcomes (e.g. increased hospital admissions and readmissions;[11] poorer chronic disease outcomes [12] and increased mortality [13]), and importantly ask fewer questions when seeing healthcare providers.[14] Previous research shows that interventions that are tailored to an individuals' health literacy level can support more effective communication and potentially reduce health inequalities for people with lower health literacy.[15-17] However, intervention developers often fail to tailor the design of their interventions to adults with lower health literacy and rarely evaluate their impact in this group.

***Objectives***

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



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demonstrating evidence of impact in cognitive and affective outcomes an important first step before embarking on evaluation in the health care setting. Our primary aim is to assess the impact of the interventions on participants' a) self-efficacy to ask questions and participate in shared decision-making, b) intention to participate in shared decision-making and c) a range of secondary outcomes. Our secondary aim is to determine whether health literacy modifies the impact of the interventions.

## Methods

The study methods have been informed by an unpublished pilot study of the intervention (n=164), which included a qualitative interview study with a sub-set of health consumers (n=25) to refine the interventions and outcome measures. Data collection is planned to start in October 2019 and finish in November 2019.

### *Study design and setting*

We will use 2x2x2 between-subjects factorial design (preparation video: yes, no x Choosing Wisely 5 questions resource: yes, no x health literacy: adequate, inadequate). This design will enable us to assess the relative impact of different interventions, both alone and in combination compared to no intervention. This design will also allow us to explore whether health literacy modifies the impact of these interventions.

This study will be conducted online using the Qualtrics survey platform. Randomisation will be undertaken via an automated function in the survey platform

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using an equal allocation ratio and stratification by participant health literacy (adequate, inadequate), yielding four trial arms in each health literacy subgroup: (1) preparation video alone, (2) 5 Questions resource alone, (3) preparation video and 5 Questions resource, and (4) no intervention. Participants will not be blinded to their assigned intervention.

***Participants, recruitment, and consent***

To be eligible to take part, potential participants must be aged 18 years or older; be an Australian citizen or permanent resident; and possess sufficient self-assessed English language skills to complete questionnaires in English.

Participants will be identified, pre-screened for eligibility, and invited to consider participation by Dynata, a market research company with a database of 600,000 people willing to be involved in online research. Dynata uses a points system whereby points are earned for completion of surveys which can be redeemed for items such as gift vouchers, donations to charities or cash. If participants agree and are interested in being part of the study, they will be directed to an online survey hosted in Qualtrics. The first page of the survey will display the downloadable Participant Information Statement (see Appendix B). In line with the Australian National Statement on Ethical Conduct in Human Research, 2007 (updated 2018), we have received ethical approval to regard completion of the

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questionnaire as an indication of consent. Participants are also required to select 'Yes, I would like to participate' to enter the survey.

During the study, all participants will be presented with a hypothetical healthcare scenario that asks them to imagine being in a situation where they have non-specific low back pain and stable pain/symptoms (See Box 2). Non-specific low back pain describes pain between the inferior border of the twelfth rib and lower gluteal folds that is not caused by a serious or specific underlying pathology.[18] Back pain was the eighth most frequently managed problem Australian general practice in 2015 [19] and non-specific low back pain accounts for approximately 90% of low back pain cases.[20] Routine imaging for non-specific low back pain has been shown to have more harms than benefits, and furthermore many medical treatments provide little-to-no benefit over placebo.[21, 22]

**Box 2. Hypothetical back pain scenario**

"You have had lower back pain for about one month; it has not improved or become worse. You did not have an accident to cause the pain; it just began and has not gone away.

You go to your doctor to get advice on what is causing it and what can help with the pain.



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The doctor recommends that you have a scan to help figure out what is causing the pain, and gives you a prescription for some medicine."

***Interventions***

*Preparation video*[1]

We developed a short video (3 minutes) intended to prepare patients for question-asking and shared decision-making. Our rationale for this choice of intervention included that multimedia formats can be a successful tool in engaging and educating patients with low health literacy and encouraging or modifying patient behaviour [23-25] and that videos featuring real people have been found to be more effective than those which only provide graphically presented information with voice overs.[23] The video script (Appendix C) was developed through an iterative process and was intended to integrate the recommendations for effective preparation as outlined by Joseph-Williams and colleagues.[8] The transcript was developed with reference to the Listenability Style Guide which outlines principles to make spoken discourse more comprehensible and ease the cognitive burden of listening (e.g. repetition of ideas; simple and common idioms; vivid analogies; use of questions to focus the listener's attention).[26] The readability level of the script was also checked and adjusted until a grade five readability level was achieved.

[1] In communications with participants, this intervention was referred to as the 'Introduction to shared decision making' video



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*Choosing Wisely Australia 5 Questions resource*[2]

The Choosing Wisely Australia 5 Questions resource is a one-page document co-branded by Choosing Wisely Australia and NPS Medicinewise that lists the Choosing Wisely Australia 5 questions (see Box 1 above) and provides additional guidance in their rationale and use (see Appendix A). This resource has a readability score of 9.4.

*Implementation of interventions*

The interventions will be displayed to participants within the survey platform. To ensure intervention exposure, a timer has been added to the pages displaying the video (3 minutes) and 5 Questions resource (1 minute), preventing participants from progressing to the next survey page until the specified time has elapsed. In the preparation video and 5 Questions resource arm, the video will be presented before the 5 Questions resource. Participants will not be prevented from exposure to any other care or interventions prior to or during the study.

***Data Collection***

Study data will be collected via surveys administered immediately before ('Pre'), immediately after ('Post'), and two weeks after ('Follow-up') exposure to the relevant intervention(s) (see Figure 1). All outcomes will be assessed by participant

[2] In communications with participants, this intervention was referred to as the Choosing Wisely Questions



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self-report with the exception of 'Indicator of proactive intervention use' (see Outcomes and Measures).

--- Figure 1 ---

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### *Outcomes and Measures*

Primary and secondary outcomes for the study, as well as measurement instruments and analysis metrics, are shown in Table 1. Outcomes and measures were refined following a pilot study (n=164). Unpublished pilot data are available from the authors upon request.

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Table 1.
*Outcomes and measurement*

| | Outcome | Measure | Pre | Post | Follow-up |
|---|---|---|---|---|---|
| Primary | Self-efficacy to ask questions | Single item adapted from Bandura's self-efficacy theory.[27] Participants are asked to rate their degree of confidence to ask questions of their healthcare provider by recording a number from 0 (Cannot do at all) to 100 (Highly certain can do). | x | x | x |
| | Self-efficacy to be involved in healthcare decision-making | Single item adapted from Bandura's self-efficacy theory.[27] Participants are asked to rate their degree of confidence to be involved in decisions with their healthcare provider by recording a number from 0 (Cannot do at all) to 100 (Highly certain can do). | x | x | x |
| | Self-efficacy to ask questions and be involved in healthcare decision-making | Composite measure based on two individual items (see above). | x | x | x |
| | Intention to engage in shared decision-making | Validated, three-item scale (Cronbach alpha = 0.8; [28]) measuring participants' (i) likelihood of engaging in shared decision-making, from very unlikely (−3) to very likely (+3), (ii) odds of engaging in shared decision-making, from very | x | x | x |

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| | | | | | |
|---|---|---|---|---|---|
| | | weak (−3) to very strong (+3) and (iii) agreement with the statement 'I intend to engage in shared decision-making', from total disagreement (−3) to total agreement (+3). Total scores will be rescaled on a scale of 0-6 and the sum of the items divided by three to derive the total score of intention. | | | |
| Secondary | Intention to follow the treatment plan recommended by the doctor without further questioning | A single item on a 10-point scale, adapted from previous research,[29] assessing hypothetical intention to follow the treatment plan recommended by the doctor without further questioning: 'Which best describes your intention to follow the treatment plan recommended by the doctor without asking further questions?' (1 = 'Definitely will not' to 10 = 'Definitely will'). | x | x | x |
| | Knowledge of patients' rights in regards to shared decision-making | Four questions adapted from Halaway et al [30] and applied to the Australian Charter of Healthcare Rights (second edition).[31] Participants were asked to indicate "Yes", "No" or "Unsure" to show whether they think the following are patient rights: a) ask questions and be involved in open and honest communication; b) make choices with your healthcare provider; c) include the people that you want in planning and decision-making; d) get clear information about your condition, including the possible benefits and risks of | x | x | |

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| | | |
|---|---|---|
| | different tests and treatments. A foil question will be included to detect if participants are arbitrarily selecting 'yes' to all questions. Scores are dichotomised into a) all questions correct, or b) not all questions correct. | |
| Attitude toward shared decision-making | Three-item scale adapted from Dormandy et al.,[32] assessing participants' perceptions of shared decision-making as beneficial/not beneficial, worthwhile/not worthwhile and important/unimportant. Each item has seven response options, forming a scale from 3 to 21. Scores will be recoded such that higher scores indicate more positive attitudes towards shared decision-making. Participants responding with the highest possible score on all three questions will be classified as having positive attitudes. | x |
| Preparedness for shared decision-making | Modified, 8-item version of the Preparation for Decision Making Scale (PrepDM).[33] The PrepDM scale was developed to assess a participants' perception of how useful a decision support intervention is in preparing them to communicate with their practitioner at a consultation visit and to make a health decision. Items are scored on a likert scale 1-5, from 'Not at all' (1) to 'A great deal' (5), with higher scores indicating higher perceived level | x |

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| | | | |
|---|---|---|---|
| | of preparation for decision-making. Items will be summed and the total score divided by 8.[33] | | |
| Acceptability (*Arms 1-3 only*) | Adapted from Shepherd et al.,[34] participants are asked to rate if they would a) recommend the [intervention] to others and b) use the [intervention] again on a four-point scale from 1 (Definitely not) to 4 (Yes, definitely).[34] Recommendations are dichotomised into would recommend (3 and 4) and would not recommend (1 and 2). | x | |
| Indicator of proactive intervention use (*Arms 1-3 only*) | We will assess the proportion of participants who click on a link to their intervention. | x | x |
| Healthcare questions | Participants will be asked to write down 5 questions that they would ask the doctor given the hypothetical healthcare scenario. The content of individual responses will be analysed via content analysis using inductive and deductive approaches (see below). The mean number of questions that map onto the Choosing Wisely 5 Questions will be calculated. | x | x |

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*Demographic and health data collection*

In addition to the primary and secondary outcomes, participants will be asked to report their age, gender, Australian state of residence, language spoken at home, education status, employment status, private health insurance status and confidence in filling out medical forms [35]. Participants will also be asked to indicate who is usually involved in healthcare decision-making related to their health, and about their experience and perceived knowledge of low back pain. Health literacy will be assessed by the Newest Vital Sign (NVS),[36] with participants categorised as inadequate (score 0-3 on NVS) or adequate literacy (score 4-6 on NVS). The NVS has been used in other online studies [37], and is an objective, performance-based measure of health literacy skills. We will also administer a single-item measure of self-reported health literacy for the purposes of describing the sample.

**Analysis**

*Quantitative data analysis*

The study statistician will be blinded to the intervention allocation of participants and their level of health literacy until after completion of analyses; a research assistant who has no other involvement in the trial will remove all group identifiers prior to analysis. Quantitative primary and secondary outcome data will be analysed as intention-to-treat using appropriate regression models (i.e., linear

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regression for continuous outcomes, logistic regression for dichotomous categorical outcomes). Dichotomous variables representing the study factors (preparation video: provided, not provided; Choosing Wisely Australia 5 questions resource: provided, not provided; health literacy: adequate, inadequate) and their interactions will be included in models as between-subjects fixed effects, controlling for pre-intervention values (where available). Outcome data collected during the immediate post- and follow-up survey will be analysed in separate models. Any significant interactions will be followed-up by sub-group analyses based on potentially relevant demographic variables.

***Missing data***

The use of an online survey platform minimises the risk of missing data; participants are required to provide responses to each question before moving on to subsequent items. As such, data is only missing in cases where participants discontinue prior to providing responses for outcome measures. Participants who discontinue the study before completion of the (immediate) post-intervention survey will be excluded from all analyses. Multiple imputation will be used [38] to impute occasional cases of missing data (e.g. some outcome measures incomplete) or for missing responses for participants who complete the initial (pre- and post-) surveys, but do not return to complete the 2-week follow-up survey. If multiple imputation of missing data is utilised, sensitivity analyses will be performed comparing the outcome from complete-case with imputed analyses.

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### *Sample size*

Sample size estimates were derived based on the primary outcome of intention score, with the estimates of effect based on previously published values [28] and refined considering pilot data. For each stratified analysis arm (i.e., inadequate health literacy, adequate health literacy), a sample of n=162 subjects per intervention group is expected to provide approximately 80% power to detect a small main effect (effect size of 0.10 or greater) of the Choosing Wisely Australia questions resource; and over 80% power to detect small main effects (effect sizes 0.20 or larger) of the preparation video intervention, and their interaction, at a p-value of 0.05 in primary analyses. As such, we aim to recruit a total sample size of N=1432 (i.e., 716 with inadequate health literacy and 716 with adequate health literacy; with n = 179 participants randomly allocated to each intervention group [preparation video alone, Choosing Wisely Australia 5 questions resource alone, both Choosing Wisely questions and preparation intervention, and control]). This will allow for a drop-out of approximately 10% of participants who discontinue the study before completing the (immediate) post-intervention survey measures.

### *Qualitative data analysis*

Assessment of healthcare questions deemed by participants as important to ask in their hypothetical scenario will be analysed via content analysis.[39] Coding will first be done deductively based on concepts embodied in the Choosing Wisely

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Australia 5 Questions resource.[40] Two double-blind coders will review all data and code any questions that fit broadly into 1 of 5 categories: Do I really need this test, treatment or procedure? What are the risks? Are there simpler, safer options? What happens if I don't do anything? What are the costs?[41, 42] Any discrepancies will be resolved through discussion between coders. Remaining responses will be coded inductively with categories derived from the data.[41] Inductive codes will be collected to form coding sheets and categories freely generated and grouped through the abstraction process.[41] The coding scheme will revised over an iterative process of discussion and revision to ensure all themes are captured. Based on our previous work, data will be presented in the form of frequencies expressed as percentages and actual numbers of key categories. We will also report category names, definitions and data examples.

## Ethics and dissemination

### *Ethical approval and trial registration*

Ethical approval for this study was obtained from the University of Sydney Human Research Ethics Committee (protocol number: 2018/965). This trial has been registered with the Australia New Zealand Clinical Trials Registry (trial number: 376477).

### *Data storage and management*

After enrolment, a unique identifier will be assigned to each study participant. Any participant identifiers will be removed before the data are archived for



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storage. Data will be downloaded as spreadsheets and stored on password protected computers which are encrypted per university policy. Listed investigators will have access to the final study dataset.

### *Dissemination and data sharing*

To enhance reporting transparency, this study will be reported in accordance with the Consolidated Standards of Reporting Trials Statement and Checklist. The results from this work will be published as a full-length, peer-reviewed manuscript and presented at national and international meetings. The results from this work will also be disseminated through collaborating public health bodies. Any protocol modification will be communicated during dissemination activities. Resources developed for this study will be made available to patients and clinicians following trial completion.

### *Patient involvement*

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 the analysis 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.

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## Author contributions

Authorship decisions adhered to ICMJE recommendations. DM, KM and JKS conceived the original idea for this trial, and this was further developed by EHC, RT, EC, MT, JZ and RL. DM and JKS wrote the first draft of this protocol manuscript, and this was edited by all other authors. EC provided valuable input regarding trial design and analytical considerations, and performed the sample size calculations for the trial. All authors contributed to and approved the final version of the manuscript.

## Funding statement

The study was funded by a National Health and Medical Research Council (NHMRC; help@nhmrc.gov.au) Program Grant (APP1113532). NPS MedicineWise gave permission for investigators' use of the Question Prompt List leaflet without charge. EC was supported by a Sydney Medical School Summer Research Scholarship and KM is supported by an NHMRC Principle Research Fellowship (1121110). Neither the NHMRC nor Sydney Medical School had any role in the design of this study. They will not have a future role in the conduct or write-up of the study or in the decision to submit the findings for publication. A representative of Choosing Wisely Australia (RL) contributed to the design of this study and will have a future role in the conduct and write-up of the study. NPS MedicineWise will not have a role in the decision to submit the study findings for publication.

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## Competing interests

Robyn Lindner is an employee NPS MedicineWise which facilitates Choosing Wisely Australia. The University of Sydney owns IP on the video and DM, MT, KM and RT are contributors to the intellectual property.

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**List of Figures**



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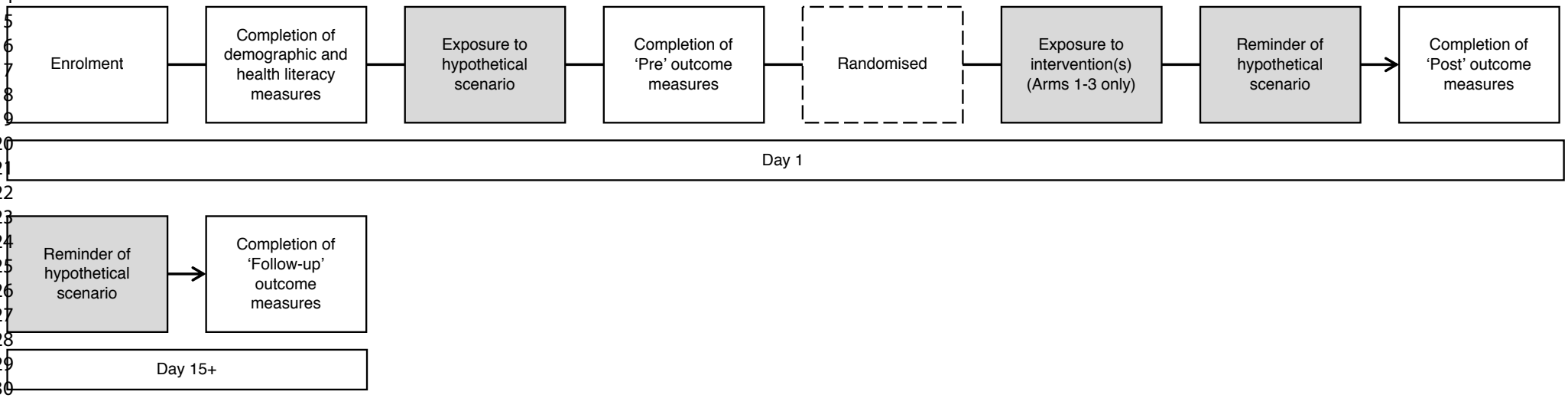
Enrolment
Completion of demographic and health literacy measures
Exposure to hypothetical scenario
Completion of 'Pre' outcome measures
Randomised
Exposure to intervention(s) (Arms 1-3 only)
Reminder of hypothetical scenario
Completion of 'Post' outcome measures
Day 1
Reminder of hypothetical scenario
Completion of 'Follow-up' outcome measures
Day 15+

## Appendix A


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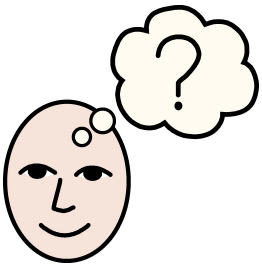
# Appendix B

## Helping people to choose wisely: Evaluating methods for shared decision making in populations with different levels of literacy

**What is the study about?**



We are doing a research study to try to work out what is the best way of helping people to work with their doctor to decide what to do about their health. It can be hard to think of questions on the spot or you might feel like your questions aren't good enough. This study will look at some tools that help people feel more confident to ask their doctor questions and to explain their point of view and what they think is important.

**Who is carrying out the study?**

We are from the School of Public Health at the University of Sydney. Our names are:

- Danielle Muscat
- Jessica Smith
- Erin Cvejic
- Josh Zadro
- Kirsten McCaffery
- Edward Hoi-Fan Chang
- Marguerite Tracy
- Rachel Thompson

**What will happen if I say that I want to be in the study?**

You can decide if you want to take part in the study or not. Please read this sheet carefully so that you can make up your mind about whether you want to take part. Completing a question in the online survey is an indication of your consent to take part in the study.

You may stop completing the online survey at any point if you do not wish to continue, and we will not use your answers. You do not have to give a reason for not taking part. Once you have submitted your survey anonymously, your responses cannot be withdrawn.

If you decide that you want to be in our study, we will ask you to:

1. Complete questions online. For example, about your age, gender, language spoken at home, and answer some questions about a food label.
2. Watch a video or read some information about asking health questions.
3. Read a made-up scenario and pretend that you are visiting a doctor about a sore back.
4. Complete questions online about patient rights, how you feel about asking the doctor questions, and what you think of the tool provided to you in the study.
5. Write some questions you would want to ask the doctor in the pretend situation.
6. We will send you a follow-up survey one month later which will repeat some of the questions from the first study. This will likely take 5 minutes to complete. We will also provide you with a link to the information or health questions that you received so that you can download them if you would like to.

**Will anyone else know what I say in the study?**

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All of the information that we have about you from the study will be private. It will be stored in password-protected files on password-protected computers owned by the University of Sydney. We will write a report about the study and show it to other people but no one will know that you were in the study.

**How long will the study take?**

The study will take about 20 minutes.

**Are there any good things about being in the study?**

This study may help you think more about the questions you can ask when you visit the doctor. It can be helpful to understand more about your treatment options.

**Are there any bad things about being in the study?**

This study will take up some of your time, but we don't think it will be bad for you or cost you anything.

**By giving your consent to take part in this study you are telling us that you:**

- ✓ Understand what you have read.
- ✓ Agree to take part in the research study as described above.
- ✓ Agree to the use of your personal information for the research purposes described above.

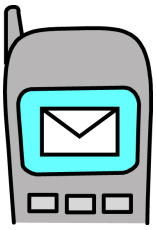
**What if I want more information about the study or my involvement in it?**

You can contact the researcher: Danielle Muscat

- Call: (02) 9351 7819
- Email: danielle.muscat@sydney.edu.au

You are also able to email and request a summary of the final findings be sent to you at the end of the study.

**What if I am not happy with the study or the people doing the study?**



The ethical aspects of this study have been approved by the HREC of the University of Sydney [Project Number 2018/965].
If you are not happy with how we are doing the study or how we treat you, then you can:

- Call the university on +61 2 8627 8176 or
- Write an email to human.ethics@sydney.edu.au

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Appendix C

Table A.
*Preparation video text and justification*

| Script text | Speaker | Development reference(s) |
|---|---|---|
| *When you visit a doctor, you are in a safe environment with a professional and it's a great time to ask any questions you might have, share information about yourself, discuss your options (or choices) for testing and treatment and make a decision together. This is called shared decision making.* | Patient | - Choosing Wisely Australia video 'The Word on the Street (extended)'.[1]<br>- Shared decision-making definitions in Hoffmann et al (2014)[2] and Charles et al.[3]<br>- Joseph-Williams et al., recommendation that materials should inform patients about shared decision making—what it is, what to expect, and why it is appropriate.[4] |
| *Yes, making decisions with your doctor may seem scary but remember - were experts too! We know what is most important to us, and our values, preferences and experiences.* | Patient | - Joseph-Williams et al., recommendation that materials should explain that there are two experts in the clinical encounter and should also build patients' belief in their ability to take part.[4] |
| *Shortly, we'll talk about why shared decision making is important and how it can help you make the right decisions about your health.* | Healthcare professional | - Patient Education Materials Assessment tool requirement to clearly and completely state the material's purpose to the listener.[5]<br>- Listenability Style Guide recommendation to provide advanced sign-posting.[6] |
| *The Australian Charter for Healthcare rights says that everyone has the right to be included in decisions and choices about their care. What that means is that we should be informed about serv ices, treatment options and costs in a clear and open way.* | Patient | - Australian Charter of Healthcare Rights, developed by the Australian Commission on Safety and Quality in Healthcare.[7] |
| *Asking your doctor questions is one way to make this happen and can help you to make decisions that you are happy with.* | Patient | - Choosing Wisely – 'Unofficial' film clip.[8] |

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Appendix C

| | | |
|---|---|---|
| *There are benefits and harms, or 'pros' and 'cons', to every treatment. Asking questions and sharing decisions with your doctor can be helpful to understand the options offered to you and their benefits and harms.* | Healthcare professional | - Choosing Wisely – 'Unofficial' film clip.[8]<br>- Informed Medical Decisions Foundation shared decision making animated short.[9]<br>- Joseph Williams et al., recommendation that materials should challenge attitudes that there are right and wrong decisions.[4] |
| *For some things these harms may even outweigh their benefits. For example, body scans and imaging (like doing X-rays or MRIs) for small things may actually be more harmful than useful, and sometimes it's better to 'wait and watch'.* | Healthcare professional | - Choosing Wisely video 'The Word on the Street (extended)'.[1] |
| *Sometimes there are no right or wrong choices as two treatments may have similar benefits and harms. In those instances, sharing your preferences and beliefs may help you and the doctor to choose the best treatment for you.* | Healthcare professional | - Joseph-Williams et al., recommendation to address patient assumptions that there is always a right and wrong decision. |
| *You may be nervous, or even scared, but it is ok to ask questions. It's good to work with your doctor to understand your options and in fact research shows that asking questions makes it easier to make decisions that are right for you.* | Patient | - Listenability Style Guide recommendation to use repetition as a tool for audiovisual materials targeted to people with low health literacy.[6]<br>- Joseph-Williams et al., recommendation that materials should build patients' belief in their ability to take part.[8] |
| *Just think, if you had to move to a new house or buy a new car, there are a lot of options, with different pros and cons, and your own personal preferences would be very important to consider. So, what about making decisions about your health?* | Patient | - Informed Medical Decisions Foundation shared decision making animated short.[9]<br>- Bupa Health UK – 'What is shared decision making?' video [10]<br>- Listenability Style Guide recommendation to incorporate questions and use of analogies.[6] |

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Appendix C

| | | |
|---|---|---|
| *Asking questions and talking to your doctor can also help you to better understand what is happening. You know how sometimes you leave a doctor's appointment and you don't really understand what has been said? It's not a great feeling is it? You should be comfortable with what is being prescribed and why.* | Patient | - Choosing Wisely Australia Tumbleweed– Find the right questions to ask your doctor" video.[11]<br>- Listenability Style Guide recommendation to incorporate questions.[6] |
| *We want to work with you to make the best decisions and know more about your health. We want you to ask questions.* | Healthcare professional | - Joseph Williams et al., recommendations that materials should redefine perceptions of a good patient and reassure patients that participation will not result in retribution and should also confirm that clinicians want patient participation.[4]<br>- Listenability Style Guide recommendation to use repetition as a tool for audiovisual materials targeted to people with low health literacy.[6]<br>- PEMAT recommendation to provide the viewer with a clear action to take whilst also addressing them directly to maximise the actionability of message.[5] |
| *We're happy to answer your questions, so together we can work out what is right for you.* | Healthcare professional | - Joseph Williams et al., recommendation that materials should confirm that clinicians want patient participation.[4]<br>- Listenability Style Guide recommendation to use repetition as a tool for audiovisual materials targeted to people with low health literacy.[6] |
| *So remember – ask your questions. We're listening. Let's share decisions together.* | Healthcare professional | - Choosing Wisely video resource – Stethoscope - We're listening.[12] |

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Appendix C

## References

1 Choosing Wisely Australia. The Word on the Street (extended). 2017 http://www.choosingwisely.org.au/resources/videos/the-word-on-the-street-interviews-about-interacti/wisely-australia-the-word-on-the-street-(extended (accessed 19 Jul 2019).

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3 Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango). *Soc Sci Med* 1997;44(5):681-92.

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6 Rubin DL. Listenability Style Guide. In: Worthington DL, Bodie GD, eds. The Sourcebook of Listening Research: Methodology and Measures. Hoboken, NJ: John Wiley & Sons, Inc. 2017:361-371.

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8 Choosing Wisely Australia. Choosing Wisely - 'unofficial' film clip. 2014 http://www.choosingwisely.org.au/resources/videos/other-choosing-wisely-videos/unofficial (accessed 19 Jul 2019).

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10 Bupa Health UK. What is shared decision making? 2017 https://www.youtube.com/watch?v=eAaTnGkbpPc (accessed 19 Jul 2019).

11 Choosing Wisely Australia. 'Tumbleweed' - Find the right questions to ask your doctor. 2017 https://www.youtube.com/watch?v=G_1M_evOYF8 (accessed 19 Jul 2019).

12 Choosing Wisely Australia. Stethoscope - We're listening. 2017 http://www.choosingwisely.org.au/resources/videos/other-choosing-wisely-videos/stethoscope (accessed 19 Jul 2019).

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SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

| Section/item | Item No | Description | Addressed on page number |
|---|---|---|---|
| **Administrative information** | | | |
| Title | 1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | 2a | Trial identifier and registry name. If not yet registered, name of intended registry | 3 |
| | 2b | All items from the World Health Organization Trial Registration Data Set | |
| Protocol version | 3 | Date and version identifier | |
| Funding | 4 | Sources and types of financial, material, and other support | 28 |
| Roles and responsibilities | 5a | Names, affiliations, and roles of protocol contributors | 1,28 |
| | 5b | Name and contact information for the trial sponsor | 28 |
| | 5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | 28 |
| | 5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | n/a |

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| | | | |
|---|---|---|---|
| **Introduction** | | | |
| Background and rationale | 6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 5-8 |
| | 6b | Explanation for choice of comparators | 5-8 |
| Objectives | 7 | Specific objectives or hypotheses | 8 |
| Trial design | 8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) | 8 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | 9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 8 |
| Eligibility criteria | 10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 9 |
| Interventions | 11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 10-11 |
| | 11b | Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) | n/a |
| | 11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) | 19 |
| | 11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 19 |
| Outcomes | 12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 14-17 |
| Participant timeline | 13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | 12 |



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| | | | |
|---|---|---|---|
| Sample size | 14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 19 |
| Recruitment | 15 | Strategies for achieving adequate participant enrolment to reach target sample size | 9 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: | | | |
| Sequence generation | 16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 8 |
| Allocation concealment mechanism | 16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 8 |
| Implementation | 16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 8 |
| Blinding (masking) | 17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 8,18 |
| | 17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | n/a |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection methods | 18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 14-17 |
| | 18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 19 |



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| | | | |
|---|---|---|---|
| Data management | 19 | Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | 18 |
| Statistical methods | 20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 18 |
| | 20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 18,19 |
| | 20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 18,19 |
| **Methods: Monitoring** | | | |
| Data monitoring | 21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | n/a |
| | 21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | n/a |
| Harms | 22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | n/a |
| Auditing | 23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | n/a |
| **Ethics and dissemination** | | | |
| Research ethics approval | 24 | Plans for seeking research ethics committee/institutional review board (REC/IRB) approval | 20 |
| Protocol amendments | 25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) | 20-21 |



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| | | | |
|---|---|---|---|
| Consent or assent | 26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | ___9_____ |
| | 26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | ___n/a_____ |
| Confidentiality | 27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 21, Appendix B |
| Declaration of interests | 28 | Financial and other competing interests for principal investigators for the overall trial and each study site | ___28_____ |
| Access to data | 29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | ____28_____ |
| Ancillary and post-trial care | 30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | ____n/a_____ |
| Dissemination policy | 31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | ____21_____ |
| | 31b | Authorship eligibility guidelines and any intended use of professional writers | _____28_____ |
| | 31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | _____21_____ |
| **Appendices** | | | |
| Informed consent materials | 32 | Model consent form and other related documentation given to participants and authorised surrogates | ___Appendix B__ |
| Biological specimens | 33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | ____n/a_____ |

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.



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