Author’s response to reviews

Title: Implementing cardiovascular disease prevention guidelines to translate evidence-based medicine and shared decision making into general practice: Theory-based intervention development, qualitative piloting and quantitative feasibility

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Author’s response to reviews:

Dear Dr Presseau,

Thank you for the opportunity to revise and resubmit this paper. We have made substantial changes to the manuscript in response to the helpful comments of the editor and reviewers, including:

1. revised background including a new summary table for our earlier research on this topic that informed the intervention;
2. more detail about the theory-based BCW process we used in text and a new summary table;
3. explaining our focus on the new decision aid component of the intervention for feasibility testing rather than the audit and feedback component that was already familiar to GPs;
4. clarifying methods including how the survey measures relate to feasibility outcomes;
5. restructuring the methods and results around 5 stages to make them easier to follow;
6. discussing broader implications of the process we used; and
7. additional appendix using TIDIER checklist.

Please note we would like to change the corresponding author to first author Dr Carissa Bonner if the paper is accepted for publication, as she is soon returning from maternity leave; both authors have emailed their confirmation for this change.

We have addressed each point below. Page numbers are as per the clean copy uploaded as a supplementary file.
Associate Editor’s report:

1. Please clarify what n=113/25 refers to in the abstract.

We have removed this from the abstract and explained more clearly in the methods:

Page 11: “The working prototype (version 1) was demonstrated at the national GP17 conference in October 2017 via a 30 minute presentation with a question/answer session (attended by n=113 delegates); and a conference stall where 25 GPs tested the first website prototype on a tablet, of which 16 completed a written feedback form.”

2. What is a ‘star’ rating? (abstract)

We have removed this from the abstract and explained more clearly in the methods:

Page 8: “Conference data included notes from verbal discussion with stall visitors and a brief written feedback form from attendees with open responses and an overall acceptability rating out of 10.”

3. Please add a section to the discussion that considers broader implications of this work for the field of implementation science

We have added a paragraph discussing the implications of the theory-based approach we used:

This study aimed to develop, pilot and evaluate the feasibility of a new online platform for the Australian CVD prevention guidelines that links existing strategies (risk calculator, audit and feedback) with a new patient decision aid to help GPs identify relevant guideline-based recommendations (for both medication and lifestyle change) and communicate this to patients. This paper outlines the results of a theory-based intervention development process, and piloting/feasibility research for the new decision aid component that was not previously available to Australian GPs.

4. Consider using the TIDIER checklist as part of more transparent reporting of the intervention

We have added this as a supplementary appendix file.

5. Clarify if the outer ring (policy categories) were used within the BCW and if not, why not.

This was explained where the delivery mode was specified as guidelines in the previous version. We have now added a table that summarises the outcomes of the BCW process including the outer ring to more clearly explain this.

Page 10: “In terms of the BCW framework [28], the intervention targets GPs during consultations and uses education, training and persuasion functions to address: psychological capability (decision aid to improve knowledge of applicable guidelines and communication skills; supported by audit and feedback), physical opportunity (by providing the first CVD prevention decision aid based on
Australian guidelines and updated evidence), and reflective motivation (by addressing GP concerns through case studies that show how absolute risk can be assessed and communicated; linked to decision aid and part of audit and feedback). It uses multiple behaviour change techniques (information about health consequences, feedback on behaviour, instruction on how to perform a behaviour, action planning, social comparison) delivered via the policy category of guidelines, using an online format for wide accessibility and flexible/sustainable implementation. See Table 2.

6. The uncontrolled pre-post design of the piloting should be discussed in the limitations section.

We have added this to the limitation section and explained why this approach was used in the methods.

Page 19: “The main limitation of the current study is the use of a pre-post design to maximise end user feedback, rather than a randomised trial design which will be the next stage of the project”

7. Avoid language such as ’slight nonsignificant’; it is either statistically significant or it is not.

We have removed the nonsignificant results as recommended by a reviewer, and instead focused on the three main feasibility outcomes.

8. Table 1's formatting is not clear (currently across 3 different pages)

Table 1’s formatting has been amended to fit on 1 page (now Table 3).

9. Was a logic model developed for the intervention? if so, it would help to include this

We did not develop a logic model for intervention effects/mediators for this development stage, but will do so for the next stage of evaluation. We have now added further explanation and a table that summarises the behavioural targets in terms of BCW components (psychological capability, physical opportunity and reflective motivation).

Page 10: “In terms of the BCW framework [28], the intervention targets GPs during consultations and uses education, training and persuasion functions to address: psychological capability (decision aid to improve knowledge of applicable guidelines and communication skills; supported by audit and feedback), physical opportunity (by providing the first CVD prevention decision aid based on Australian guidelines and updated evidence), and reflective motivation (by addressing GP concerns through case studies that show how absolute risk can be assessed and communicated; linked to decision aid and part of audit and feedback). It uses multiple behaviour change techniques (information about health consequences, feedback on behaviour, instruction on how to perform a behaviour, action planning, social comparison) delivered via the policy category of guidelines, using an online format for wide accessibility and flexible/sustainable implementation. See Table 2.”

10. Consider using published tools to justify the selection of the theoretical approaches used

We have provided additional information about the theory-based BCW process in this version, and why we chose it. We did not use a published tool to select a specific theory.

Page 7: “Stage 1: The first step was to clearly articulate the problem and solutions in behavioural terms, to address the issues identified in the Healthy Heart Study. We used the Behaviour Change Wheel (BCW) framework because it synthesises multiple health behaviour theories and models to guide the
development of rigorous interventions [28]. According to this framework, behaviour can be attributed to three determinants of behaviour: opportunity (physical and social), capability (physical and psychological), and motivation (automatic and reflective). The framework outlines a process to identify the most important behavioural barriers, the best target population for behaviour change, evidence-based behaviour change techniques, and the most feasible delivery mode.”

11. How was the n=123 in the feasibility study decided?

We aimed to maximise end user feedback within our project budget, oversampling at baseline (n=123) aiming for 100 participants after 1 month (n=98). This is now explained in the methods section.

Page 8: “A pre-post design was used to maximise feedback from ~100 end users within the project budget, with oversampling at baseline (n=123) to achieve adequate numbers at follow-up (n=98).”

12. Table 2 would be improved if baseline and follow-up participants were the same n=98; the different n's may account for the descriptive differences. I suggest presenting the participants that completed both measures in Table 1 to compare like with like, and also allow you to describe attrition (i.e 20%) between baseline and follow-up.

We have amended the table headings to more clearly identify the relevant sample size. Our measures of potential efficacy (guideline-based recommendation) and acceptability (intended use) are based on the baseline sample of 123; while the measure of demand (actual use over 1 month) is based on the follow-up sample of 98. In the new manuscript, Table 4 describes the participant characteristics at each time point; Table 5 refers only to baseline outcomes with n=123 before and after using the decision aid.

13. The methods for the quantitative feasibility study should clarify the main intended behavioural outcome and process variables, and how they were assessed (providing the questionnaire as an appendix is helpful but not sufficient. please clarify specifically which intended constructs and variables were the focus, and why those specifically). It would help to disentangle factors that are outcome measures (behaviour) from constructs targeted by the intervention, from variables that indicate fidelity (e.g. website use). This would also help to streamline the reporting of the results of the quantitative feasibility study.

We have clarified this in the amended abstract, methods and results sections. The focus of the quantitative study was on the following feasibility measures: potential efficacy (guideline-based recommendation), acceptability (intended use) and demand (actual use over 1 month). The added detail on the BCW process we used explains the behavioural targets of the intervention more clearly, including a new Table 2.

Abstract Page 2: “Stage 5 was a feasibility study to evaluate potential efficacy (guidelines-based recommendations for each risk category), acceptability (intended use) and demand (actual use over 1 month) amongst GPs.”

Method Page 8: “Stage 5: A feasibility study to assess acceptability (intended use after initial viewing), demand (actual use after 1 month) and potential efficacy (improved knowledge of recommended interventions for each risk category as per guidelines) [22] was conducted.”

Results: see new subheadings for each outcome and new table column headings.
14. The low, medium, high risk case analysis is not described in the methods and so comes as a surprise in the results. Why split an already small sample in this way?
The analysis was done this way to match the Australian guidelines, as this was the delivery mode. We have now explained this more clearly in the methods under ‘setting’:

Page 7: “The guidelines target General Practitioners (GPs) who can be accessed free of charge under the Medicare system. They are based on the 5 year Framingham model of absolute CVD risk, with different recommendations for:

• low risk (<10%): no medication with lifestyle change (smoking, diet, exercise) as needed;
• moderate risk (10-15%): lifestyle change initially, unless extra risk factors are present or lifestyle change is ineffective (in which case medication should be considered); and
• high risk (>15%): both blood pressure/cholesterol lowering medication and lifestyle change.”

15. Results of the quantitative feasibility study would be clearer if presented descriptive stats first, followed by inferential stats. At present it is very difficult to follow the flow of the results.

We agree the structure of the initial manuscript was confusing, and have amended the methods and results sections to follow 5 stages:

This project identified barriers that had not been addressed in previous trials, including: psychological capability (lack of knowledge about how risk factors relate to medication and lifestyle guidelines, and difficulty understanding/explaining absolute CVD risk); physical opportunity (lack of access to updated evidence and risk communication tools that match Australian guidelines); and reflective motivation (concerns about how to apply guidelines to challenging patient scenarios) [16, 17]. More detailed Framework Analysis had been conducted in 1 GP interview study and 2 patient think aloud studies prior to this stage (see Table 1); so thematic analysis for this stage was limited to notes taken during the interviews (CB and MF) and from audio recordings, to identify areas to improve.

16. Why present the results for only those who reported using the risk assessment? Why not present for all?

Use of the risk assessment tool is the only way that users could access the decision aid, so we were interested in feedback only from those who actually viewed the intervention. We have now made it clearer which outcomes were measured at baseline and followup and who was included.

17. Table 3 lacks clarity and focus, which is compounded by the table split across 2 pages. Clarify which outcomes/process/fidelity measures are being reported on, and present data for both pre and post. Also, remains unclear why the sample is split in three. Why only likelihood to prescribe presented (all variables tested should be included)? Clarify if the % reported in the table are based on the same n pre and post.

We have reformatted this table to fit on 1 page and explained the use of low/moderate/high risk categories in the methods under ‘setting’.

Page 7: “The guidelines target General Practitioners (GPs) who can be accessed free of charge under the Medicare system. They are based on the 5 year Framingham model of absolute CVD risk, with different recommendations for:

• low risk (<10%): no medication with lifestyle change (smoking, diet, exercise) as needed;
• moderate risk (10-15%): lifestyle change initially, unless extra risk factors are present or lifestyle change is ineffective (in which case medication should be considered); and
• high risk (>15%): both blood pressure/cholesterol lowering medication and lifestyle change.”
Reviewer reports:

Reviewer #1: This manuscript reports on the design, piloting, and feasibility assessment of an intervention to address barriers to CVD guideline adherence. The authors should be commended on the considerable amount of work reflected in this manuscript, however there are several major issues that require attention which I have outlined below. With thoughtful revisions, this article has the potential to appeal to a broad audience.

Thank you for your positive comments and helpful suggestions.

Major Revisions

18. The authors present the intervention as based in COM-B theory, however the theory is mentioned at the beginning of the methods and not again until the discussion. Please clearly link components of the intervention to the theoretical construct they operationalize, and the corresponding barrier they are targeting.

We have added more explanation and a table summarising the outcome of the BCW process we followed, which more clearly explains the behavioural barriers as well as the content and format of the intervention (Table 2).

Page 10: “In terms of the BCW framework [28], the intervention targets GPs during consultations and uses education, training and persuasion functions to address: psychological capability (decision aid to improve knowledge of applicable guidelines and communication skills; supported by audit and feedback), physical opportunity (by providing the first CVD prevention decision aid based on Australian guidelines and updated evidence), and reflective motivation (by addressing GP concerns through case studies that show how absolute risk can be assessed and communicated; linked to decision aid and part of audit and feedback). It uses multiple behaviour change techniques (information about health consequences, feedback on behaviour, instruction on how to perform a behaviour, action planning, social comparison) delivered via the policy category of guidelines, using an online format for wide accessibility and flexible/sustainable implementation. See Table 2.”

19. I also found the presentation of both the methods and the results confusing at times. I would suggest organization via consistent subheadings across these two sections would be useful (perhaps by stage or by intervention content).

We agree the structure of the initial manuscript was confusing, and have amended the methods and results to follow 5 stages:

Page 6: “The methods involved 5 different stages:
1. Intervention development based on BCW process
2. Co-design of content with GPs
3. GP conference feedback on prototype
4. GP and patient interview feedback on functional website
5. Feasibility study with GPs using website over 1 month”

Specific comments according to sections are included below:
Background

20. The first paragraph of the background is repeated throughout subsequent paragraphs and can be removed altogether. The second paragraph on CVD prevention guidelines provides unnecessary detail and should be shortened to 2-3 sentences to help focus the background quickly. For example: Evidence and guidelines are well-established (references), but adherence in practice remains suboptimal (references). The current approach focus on … therefore there is a need to … The detail on previous work done to assess barriers (currently in the methods) belongs in the introduction to help the reader understand the rationale for the study and how this intervention targets known barriers. Be sure to link explicitly to the underlying theory here.

We have shortened the background information and moved the details of our previous research to the introduction as suggested, summarised in new Table 1. We have also explained this research in terms of our theoretical framework:

Page 5: “This project identified barriers that had not been addressed in previous trials, including: psychological capability (lack of knowledge about how risk factors relate to medication and lifestyle guidelines, and difficulty understanding/explaining absolute CVD risk); physical opportunity (lack of access to updated evidence and risk communication tools that match Australian guidelines); and reflective motivation (concerns about how to apply guidelines to challenging patient scenarios)”

21. Methods (Page 7, starting on line 47) - Much more detail is required here. The BCW framework should be introduced at the beginning of the intervention section. Please provide explicit examples of the deficits in psychological capability, physical opportunity, and reflexive motivation targeted by the intervention content.

We have provided more detail about this framework in the methods, with the addition of a table outlining the results of the BCW process:

Page 9-10: “Completing the Behaviour Change Wheel process (summarised in Table 2) identified the need to develop a new tool for GPs to use with their patients in consultations, with the following key features (see Figure 1-2 for screenshots of main features, and Appendix 1-2 for TIDIER checklist and more detailed intervention content):

1. Interactive CVD risk calculator that combines CVD risk assessment and management algorithms to help GPs identify risk category guidelines [1, 27], based on best practice risk communication principles and patient perceptions of existing CVD risk calculators [23, 25, 32];
2. Personalised patient decision aid that shows the effect of different medication (blood pressure, cholesterol, aspirin), lifestyle (smoking, diet, exercise) and supplement (antioxidants, omega-3, multivitamins) interventions on individual CVD risk to help GPs discuss the benefits and harms of different options [19], based on updated evidence reviews and International Patient Decision Aid Standards to support shared decision making [33]; and
3. Self-directed audit & feedback including cases that GPs find challenging for CVD risk assessment and communication [16, 17], and comparison of management to guidelines [27], using evidence-based behaviour change techniques [34]; based on existing audit and feedback tools familiar to GPs.”

Page 10: “In terms of the BCW framework [28], the intervention targets GPs during consultations and uses education, training and persuasion functions to address: psychological capability (decision aid to improve knowledge of applicable guidelines and communication skills; supported by audit and
feedback), physical opportunity (by providing the first CVD prevention decision aid based on Australian guidelines and updated evidence), and reflective motivation (by addressing GP concerns through case studies that show how absolute risk can be assessed and communicated; linked to decision aid and part of audit and feedback). It uses multiple behaviour change techniques (information about health consequences, feedback on behaviour, instruction on how to perform a behaviour, action planning, social comparison) delivered via the policy category of guidelines, using an online format for wide accessibility and flexible/sustainable implementation. See Table 2.”

22. Methods (Page 7, line 59) - you mention that screenshots illustrating features are provided in Appendix 1. Please revise this Appendix to explicitly link features to BCTs and highlight the exact content operationalizing the BCT.

We have provided more detail about this with the addition of a table outlining the results of the BCW process - please see response above.

23. Methods (Page 8, section on qualitative piloting) - Were the recording for the ASK-GP sessions transcribed? How was all your qualitative data analyzed? More detail is needed on the approach. Additionally, it is misleading to provide the n for the number of conference delegates at the session (113) when you only collected data from n=16 GPs? Please clarify the type of data collected from the presentation and how many GPs it represents.

We have clarified these numbers and provided an explanation of the analysis approach.

Methods Page 8: “More detailed Framework Analysis had been conducted in 1 GP interview study and 2 patient think aloud studies prior to this stage (see Table 1); so thematic analysis for this stage was limited to notes taken during the interviews (CB and MF) and from audio recordings, to identify areas to improve.”

Results Page 11: “The working prototype (version 1) was demonstrated at the national GP17 conference in October 2017 via a 30 minute presentation with a question/answer session (attended by n=113 delegates); and a conference stall where 25 GPs tested the first website prototype on a tablet, of which 16 completed a written feedback form.”

24. Methods (Page 9, line 9) - the authors mention the use of the Theory of Planned Behaviour in their baseline survey. Please justify why TPB was used over other theories.

The TPB manual was used to obtain a validated measure of self efficacy rather than using the TPB as the theoretical approach – so we have removed this term in the paper to avoid confusion. We have provided additional information about the theory-based BCW process in this version:

Audit and feedback programs on this topic were already available to GPs, but there were no available tools to assist GPs with communicating Australian absolute risk guidelines to patients. Systematic reviews of existing online CVD risk communication tools (73 risk calculators and 25 decision aids) found none that met Australian guidelines, used best practice risk communication formats, followed international patient decision aid standards for presenting all management options in a balanced way, or met the needs of people with lower health literacy [20].

25. Results (Page 9, section on qualitative piloting) - please highlight the main points of feedback and subsequent changes to the intervention in the text Results (Page 11, paragraph 2) - Several non-
significant results are presented here. If results are non-significant, they do not need to be highlighted in the text. Alternatively, if they are CLINICALLY meaningful (i.e., they changed the behaviour of several GPs) then please re-frame appropriately.

We have removed the non-significant findings for secondary outcomes and have focused instead on the 3 main feasibility outcomes. The focus of the quantitative study was on the following feasibility measures: potential efficacy (guideline-based recommendation), acceptability (intended use) and demand (actual use over 1 month). We have not yet assessed the effectiveness of the intervention in clinical practice so can make no claims about the GPs’ actual behaviour; although we are planning this for the next stage using a randomised design in clinical practice as explained in the discussion. We have clarified the feasibility outcomes in the amended abstract, methods and results sections.

26. Discussion (Page 12, first paragraph) - The authors should discuss the utility of applying theory to inform intervention development. Was it helpful? Consider how the results of the study compare to similar intervention that have/have not used theory.

Although we cannot yet comment on effectiveness in practice compared to interventions that were not based on a theoretical framework, the process did enable us to identify new behavioural barriers overlooked in earlier trials. We have added a paragraph on this to the discussion:

Page 18: “More broadly, this project illustrates how the theory-based Behaviour Change Wheel framework can be used to identify behavioural barriers to the use of guidelines, and develop an evidence-based intervention to address these barriers. Our earlier work had explored the problem of CVD guideline use in terms of capability, opportunity and motivation [16], which enabled us to identify new behavioural barriers that previous trials had not specifically addressed [14, 15]. This approach helped us to identify three evidence-based interventions to address those gaps (risk calculator, decision aid, audit and feedback), integrate all three into one intervention using a feasible online format, and develop/test the component that was not previously available to Australian GPs (decision aid). The co-design of the combined intervention with end users through the iterative development process resulted in a website that appears to be acceptable to users, and can now be tested for effectiveness in a clinical setting using strategies that GPs themselves have identified.”

27. Discussion (Page 12, Line 48) - A&F was mentioned in the methods and not again until the discussion. Given that it is one of two intervention strategies employed, please make results relating to it more explicit (or provide an explanation as to why there are no results). I'm left wondering whether there were iterative improvements to the A&F and how participants experienced it. Organizing your results according to the intervention strategies would be one way to streamline things.

The A&F component was not explicitly tested in this study as this was already available and familiar to GPs; we focused on testing the new decision aid component within the online guideline delivery mode. This is now explained more clearly in the Aim section and throughout the paper.

Aim Page 5: “This study aimed to develop, pilot and evaluate the feasibility of a new online platform for the Australian CVD prevention guidelines that links existing strategies (risk calculator, audit and feedback) with a new patient decision aid to help GPs identify relevant guideline-based recommendations (for both medication and lifestyle change) and communicate this to patients. This paper outlines the results of a theory-based intervention development process, and piloting/feasibility research for the new decision aid component that was not previously available to Australian GPs.”
Discussion Page 18: “This approach helped us to identify three evidence-based interventions to address those gaps (risk calculator, decision aid, audit and feedback), integrate all three into one intervention using a feasible online format, and develop/test the component that was not previously available to Australian GPs (decision aid).”

Minor Revisions

Abstract

28. Background: The objective would be more clearly stated as "This paper outlines the development, qualitative piloting, and quantitative feasibility assessment of…”

We have amended as suggested.

29. Methods: Please separate out the reference to the GP conference session and stall

We have explained this more fully in the manuscript and removed from the abstract.

30. Results: What does the average star rating represent (e.g., overall satisfaction? Utility?). If it just satisfaction, I would remove this from the abstract as it is not compelling or central to your results. Instead, please highlight the changes that were made in response to usability testing.

We have explained the rating in the manuscript under methods and focused on the feasibility testing in the abstract as suggested.

Abstract Page 2: “Stage 5 was a feasibility study to evaluate potential efficacy (guidelines-based recommendations for each risk category), acceptability (intended use) and demand (actual use over 1 month) amongst GPs…. Stage 2-4 improved the content and format of the intervention based on qualitative feedback from GP and patient user testing over three rounds of website development. Stage 5 suggested potential efficacy with improved identification of hypothetical high risk patients (from 29% to 78%) and recommended medication (from 59% to 87%) after viewing the website. Acceptability and demand were high, with most GPs (89%) indicating they would use the website in the next month, and 72% reported using it again after one month. Open feedback identified a need for integration with medical software and practice nurse activities.”

Methods Page 8: “Conference data included notes from verbal discussion with stall visitors and a brief written feedback form from attendees with open responses and an overall acceptability rating out of 10.”

31. Conclusion: No need to re-state what the project did in the abstract conclusion. Instead, focus on the implications of the results and the next steps (i.e., outstanding barriers to be addressed).

We have amended as suggested.

Methods

32. Page 8 - references to the number of participants in each phase belongs in the results section Please provide more detail about the healthcare setting in Australia for international readers. How is primary care organized and delivered?
We have provided more detail about the Australian context under setting:

Page 7: “The guidelines target General Practitioners (GPs) who can be accessed free of charge under the Medicare system. They are based on the 5 year Framingham model of absolute CVD risk, with different recommendations for:

• low risk (<10%): no medication with lifestyle change (smoking, diet, exercise) as needed;
• moderate risk (10-15%): lifestyle change initially, unless extra risk factors are present or lifestyle change is ineffective (in which case medication should be considered); and
• high risk (>15%): both blood pressure/cholesterol lowering medication and lifestyle change.”

33. Page 8, Line 33 - Were prompts used during the think-aloud interviews? Please provide more detail about this process.

We have provided more detail about the concurrent think aloud process used.

Page 8: “This involved a concurrent protocol where users were asked to think aloud as they used the website, followed by prompting for feedback by the interviewer (CB).”

34. Page 8 - Include one general statement about ethics that lists all relevant institutions (no need to separate by phase as it is confusing to the reader and does not add value).

We have amended as suggested.

35. Page 9, first sentence - What is TKW?

We have removed this referral to TKW to avoid confusion – this is the name of the GP recruitment company we used.

36. Page 9, Line 21 - "…website usage assessed…" - please clarify if this was self-reported use or objective usage data.

We have clarified it was self-report.

Results

37. Page 10, Line 3 - please separate out the reference to the conference presentation and the stall.

We have amended as suggested.

38. Page 10, Line 12 - how many conference attendees provided in-depth user feedback?

We have provided more detail about this:

Page 11: “The working prototype (version 1) was demonstrated at the national GP17 conference in October 2017 via a 30 minute presentation with a question/answer session (attended by n=113 delegates); and a conference stall where 25 GPs tested the first website prototype on a tablet, of which 16 completed a written feedback form.”

39. Page 10, Line 54 - the most common sources for what? Guideline exposure?
We have clarified this as follows, and removed results that were only meaningful in Australia.

Page 14: “At baseline (n=123), almost all (95%) reported using absolute CVD risk calculators, most commonly the National Vascular Disease Prevention Alliance website (www.cvdcheck.org.au; 33%) and risk calculators within practice software (Best Practice 29%; Medical Director 20%). A lower proportion (72%) of GPs had seen the national CVD prevention guidelines.”

40. Page 11, Line 47 - Please remove the results on the number of GPs who did not suggest any changes as this is likely an artifact of not wanting to respond to the survey. Instead, lead with the number of GPs who had constructive feedback. The overarching goal of the paper is to illustrate how you responded to feedback in a systematic way to improve the intervention.

We have amended the open feedback results as suggested. Please see Table 3 for details of how we responded to feedback at each stage.

Page 14: “In required open feedback, improvements were suggested by 48% and 40% of GP feedback at baseline and follow-up respectively. Of all suggested improvements at baseline, improving access (e.g. via Practice Software integration) was most common (49%) followed by formatting changes (31%; e.g. colour and font) and content changes (19%; e.g. more instructions, different website design features, additional risk factor/effect estimates beyond the scope of the guidelines). Similarly, of all suggested improvements at follow-up, improving formatting was most common (58%) followed by improving access (40%) and content changes (20%).”

Discussion

41. Page 13, beginning on Line 21 - The three suggestions from GPs need to be mentioned in the results text (in addition to the table) to facilitate the discussion. During what stage did these suggestions emerge (it appears like Version 3?) and why were they not addressed as part of this study?

We have highlighted these results in text as well as the table and explained why they were not addressed.

Abstract Page 3: “Open feedback identified a need for integration with medical software and practice nurse activities.

Results Page 12: No major content issues were identified in version 3 testing, but there were some suggestions for implementation to improve accessibility: linking the risk calculator to GP practice software, involving practice nurses, and creating a patient/consumer version of the website that is easier to understand without GP consultation. These issues could not be addressed within the project budget for intervention development.”

Results table 3: “Implementation suggestions still need to be addressed:
1. auto-population of risk factors from patients’ electronic record;
2. low health literacy version of decision aid; and
3. pre-consultation access to risk calculator/decision aid”
Reviewer #2:
Thank you for the opportunity to review this manuscript. Using both qualitative and quantitative methods, the authors aimed to develop, pilot and evaluate the feasibility of a multi-faceted complex intervention to increase GP's use of Australian cardiovascular disease (CVD) prevention guidelines. There are strengths to this manuscript with potential for contributions to the literature and to the public health issue of overtreatment of low CVD risk patients and under-treatment of high CVD risk patients as a result of current approaches. First, the intervention is grounded in the Behavior Change Wheel which targets patient and GP identified barriers to the adoption of absolute risk for the assessment and treatment of CVD. Second, the authors integrated two evidence-based strategies as key features of their intervention, namely 1) audit and feedback to increase GPs' use of guidelines and change prescribing behaviours, and 2) patient decision aid to improve doctor-patient communication.

However, there are opportunities to strengthen this manuscript. First, greater explanation about how the intervention was developed, its content and its intended use for GPs and patients would be beneficial. Second, more methodological details are required for both the qualitative and quantitative components. Third, the way in which GP/patient and implementation barriers were determined and the differences between the two are difficult to decipher throughout the manuscript.

Thank you for your helpful comments which we have addressed as follows:

Background

42. Page 4, Line 38 - "The current approach to CV prevention…” Suggest re-phrasing to the current recommended approach, as it is my understanding that the recommended approach (absolute risk assessment) is not being used in clinical practice.

We have removed this section.

43. The authors highlight the consequences of the current utilized approach vis-à-vis the over and under use of medications. Since CVD prevention (and the authors' intervention) is also focused on lifestyle modifications, could the authors provide a comment on the consequences related to non-pharmacological interventions as well? I suggest it is important to set the stage with the consequences related to both pharmacological and non-pharmacological interventions since the piloted intervention focuses on 9 options that fall within both of these categories.

We agree and have explained this more clearly with guideline recommendations for low, moderate and high risk patients included, under setting:

Page 7: “The guidelines target General Practitioners (GPs) who can be accessed free of charge under the Medicare system. They are based on the 5 year Framingham model of absolute CVD risk, with different recommendations for:

• low risk (<10%): no medication with lifestyle change (smoking, diet, exercise) as needed;
• moderate risk (10-15%): lifestyle change initially, unless extra risk factors are present or lifestyle change is ineffective (in which case medication should be considered); and
• high risk (>15%): both blood pressure/cholesterol lowering medication and lifestyle change.”

44. Page 5, Line 9-10 - "Absolute risk guidelines" - It is unclear whether these are absolute risk guidelines or clinical practice guidelines that recommend an absolute risk approach.
We have clarified this as follows:

Page 4: “Despite the availability of clinical guidelines based on risk calculators”

45. Given the intervention is grounded in the Behaviour Change Wheel (BCW), suggest adding a few sentences describing the framework in greater detail which may be helpful for readers who may not be familiar with it.

We have provided greater detail about this approach:

Page 7: “Stage 1: The first step was to clearly articulate the problem and solutions in behavioural terms, to address the issues identified in the Healthy Heart Study. We used the Behaviour Change Wheel (BCW) framework because it synthesises multiple health behaviour theories and models to guide the development of rigorous interventions [28]. According to this framework, behaviour can be attributed to three determinants of behaviour: opportunity (physical and social), capability (physical and psychological), and motivation (automatic and reflective). The framework outlines a process to identify the most important behavioural barriers, the best target population for behaviour change, evidence-based behaviour change techniques, and the most feasible delivery mode.”

46. The authors attribute GP barriers to the use of absolute CVD risk guidelines to three determinants of behaviour. Please provide a reference for this statement. The source of these determinants is unclear on two levels: 1) the determinants themselves (are these determinants stipulated by the BCW?), and 2) how the three specific determinants (i.e opportunity, capability and motivation) were determined for the GPs in this context. The authors provide examples of each determinant, but actually defining them would be helpful.

We have clarified this with references to our earlier work that identified the behavioural barriers (see new Table 1) and more detail about the BCW approach in the methods (please see response above).

47. Page 6 - line 17. Reference 26 is not the correct reference. I believe the authors intended to reference:

Thank you for this correction, this section has been revised with the new background.

Aim

48. The proposed interventions aimed to address implementation barriers across opportunity capability, and motivation, yet these are presented as GP/patient behavioral barriers to the use of evidence based CVD guidelines in the background (p.5). The labels "behavioral" and "implementation" barriers seem to be used interchangeably throughout the manuscript, yet I see these as distinctly different. The behavioral barriers are related to the use of absolute CVD risk guidelines, yet are the
implementation barriers are related to the intervention or the use of absolute risk? If both are referring to the use of absolute CVD risk, then I suggest make this clearer.

We agree that this was unclear and have amended it throughout the manuscript. We now refer to behavioural barriers in relation to the use of absolute risk guidelines; and implementation barriers in terms of what still needs to be done to embed our intervention into clinical practice.

Methods

49. I appreciate the complexity of this intervention. The supplementary information provided in the appendices is helpful. It would be useful to introduce and further describe Figures 1 and 2 in the text or in an accompanying legend. Greater explanation about how the intervention was developed, its content and its intended use for GPs and patients would be beneficial. Despite numerous reads, I am left somewhat unclear about how this intervention is meant to be used by GPs and by patients. Is it meant as a learning/training tool that GPs use on their own time to exercise their knowledge about prescribing for low, medium and high risk patients (use of hypothetical patients), or it is meant to be used during an encounter with patients? Or both?

We have provided much more explanation of the intervention development, content and intended use in the revise manuscript based on the BCW process we followed, summarised in the new results section for Stage 1 and new Table 2.

Page 9-10: “Completing the Behaviour Change Wheel process (summarised in Table 2) identified the need to develop a new tool for GPs to use with their patients in consultations, with the following key features (see Figure 1-2 for screenshots of main features, and Appendix 1-2 for TIDIER checklist and more detailed intervention content):

1. Interactive CVD risk calculator that combines CVD risk assessment and management algorithms to help GPs identify risk category guidelines [1, 27], based on best practice risk communication principles and patient perceptions of existing CVD risk calculators [23, 25, 32];

2. Personalised patient decision aid that shows the effect of different medication (blood pressure, cholesterol, aspirin), lifestyle (smoking, diet, exercise) and supplement (antioxidants, omega-3, multivitamins) interventions on individual CVD risk to help GPs discuss the benefits and harms of different options [19], based on updated evidence reviews and International Patient Decision Aid Standards to support shared decision making [33]; and

3. Self-directed audit & feedback including cases that GPs find challenging for CVD risk assessment and communication [16, 17], and comparison of management to guidelines [27], using evidence-based behaviour change techniques [34]; based on existing audit and feedback tools familiar to GPs.”

Page 10: “In terms of the BCW framework [28], the intervention targets GPs during consultations and uses education, training and persuasion functions to address: psychological capability (decision aid to improve knowledge of applicable guidelines and communication skills; supported by audit and feedback), physical opportunity (by providing the first CVD prevention decision aid based on Australian guidelines and updated evidence), and reflective motivation (by addressing GP concerns through case studies that show how absolute risk can be assessed and communicated; linked to decision aid and part of audit and feedback). It uses multiple behaviour change techniques (information about health consequences, feedback on behaviour, instruction on how to perform a behaviour, action planning, social comparison) delivered via the policy category of guidelines, using an online format for wide accessibility and flexible/sustainable implementation. See Table 2.”
50. Throughout the manuscript, there is emphasis on the benefits of audit and feedback to influence GP's prescribing behaviours. Yet since CVD prevention and management also include non-pharmacological interventions, might there be room to balance out this emphasis to include pharmacological prescribing behaviours and the provision of recommendations for non-pharmacological interventions as well?

We agree and have clarified that the guidelines recommend non-pharmacological interventions as opposed to medication for low risk patients, under setting. We have also clarified in the introduction that this paper focuses on the new decision aid component (with both medication and lifestyle options), rather than the audit and feedback component since this was already available to GPs.

Introduction Page 5: “Audit and feedback programs on this topic were already available to GPs, but there were no available tools to assist GPs with communicating Australian absolute risk guidelines to patients. Systematic reviews of existing online CVD risk communication tools (73 risk calculators and 25 decision aids) found none that met Australian guidelines, used best practice risk communication formats, followed international patient decision aid standards for presenting all management options in a balanced way, or met the needs of people with lower health literacy [18] … This study aimed to develop, pilot and evaluate the feasibility of a new online platform for the Australian CVD prevention guidelines that links existing strategies (risk calculator, audit and feedback) with a new patient decision aid to help GPs identify relevant guideline-based recommendations (for both medication and lifestyle change) and communicate this to patients.”

Methods Page 7: “The guidelines target General Practitioners (GPs) who can be accessed free of charge under the Medicare system. They are based on the 5 year Framingham model of absolute CVD risk, with different recommendations for:
• low risk (<10%): no medication with lifestyle change (smoking, diet, exercise) as needed;
• moderate risk (10-15%): lifestyle change initially, unless extra risk factors are present or lifestyle change is ineffective (in which case medication should be considered); and
• high risk (>15%): both blood pressure/cholesterol lowering medication and lifestyle change.”

51. A key feature of the intervention is a Patient Decision Aid that shows the effect of different medications and lifestyle interventions on individual CVD risk. What are the options presented in the patient decision aid? How is this feature intended to be used and accessed by GPs vs patients? What features of this shared decision-making resource were intended to 'help GPs communicate guidelines to patients" (p. 6) and which features were intended for patients? What about its role in improving doctor-patient communication?

At this stage we identified GPs as the most suitable target for behaviour change so it is aimed at them for use during a consultation with a patient – this has now been explained in the manuscript with a summary in Table 2. We are in the process of creating a consumer/patient version of the decision aid for which we have just received funding. We have now specified the decision aid options more clearly in text, as shown in the existing Figure.

Page 9-10: “Completing the Behaviour Change Wheel process (summarised in Table 2) identified the need to develop a new tool for GPs to use with their patients in consultations,

... Personalised patient decision aid that shows the effect of different medication (blood pressure, cholesterol, aspirin), lifestyle (smoking, diet, exercise) and supplement (antioxidants, omega-3, multivitamins) interventions on individual CVD risk to help GPs discuss the benefits and harms of
different options [19], based on updated evidence reviews and International Patient Decision Aid Standards to support shared decision making [33].

52. Page 7 - lines 47-50. What is the difference between psychological capability, physical opportunity, and reflective motivation and the terms used in the background (i.e. capability, opportunity and motivation)? Are these any different, and if so how?

We have explained these terms more consistently in terms of the BCW framework.

Background Page 5: This project identified barriers that had not been addressed in previous trials, including: psychological capability (lack of knowledge about how risk factors relate to medication and lifestyle guidelines, and difficulty understanding/explaining absolute CVD risk); physical opportunity (lack of access to updated evidence and risk communication tools that match Australian guidelines); and reflective motivation (concerns about how to apply guidelines to challenging patient scenarios) [16, 17].

Methods Page 7: According to this framework, behaviour can be attributed to three determinants of behaviour: opportunity (physical and social), capability (physical and psychological), and motivation (automatic and reflective).

Results Page 10: “In terms of the BCW framework [28], the intervention targets GPs during consultations and uses education, training and persuasion functions to address: psychological capability (decision aid to improve knowledge of applicable guidelines and communication skills; supported by audit and feedback), physical opportunity (by providing the first CVD prevention decision aid based on Australian guidelines and updated evidence), and reflective motivation (by addressing GP concerns through case studies that show how absolute risk can be assessed and communicated; linked to decision aid and part of audit and feedback).

53. Generally, the qualitative piloting and quantitative feasibility methods require greater detail.

We have provided more detail in this version; please see amended text with new subheadings for 5 stages in Methods:

Page 6: “The methods involved 5 different stages:
1. Intervention development based on BCW process
2. Co-design of content with GPs
3. GP conference feedback on prototype
4. GP and patient interview feedback on functional website
5. Feasibility study with GPs using website over 1 month”

Qualitative piloting:
54. Who delivered the presentation session at GP2017 and who hosted the room stall? How was the interview guide developed? What type of qualitative analysis was conducted? How was the analysis conducted and by whom?

We have provided more detail in this version; please see amended text in Methods:

Methods Page 8:
Stage 3: The website user interface was piloted at an Australian national conference for General Practitioners in 2017 (GP17) via a presentation and question/answer session (CB); and a tablet placed in an exhibition room stall (CB). Conference data included notes from verbal discussion with stall visitors and a brief written feedback form from attendees with open responses and an overall acceptability rating out of 10.

Stage 4: After the GP17 conference, the website content was developed iteratively based on semi-structured “think aloud” user interviews [29] to improve acceptability. More detailed Framework Analysis had been conducted in 1 GP interview study and 2 patient think aloud studies prior to this stage (see Table 1); so thematic analysis for this stage was limited to notes taken during the interviews (CB and MF) and from audio recordings, to identify areas to improve. Interviews were conducted at the University of Sydney, via Skype or at the participants’ residence/workplace, and were audio-recorded to supplement field notes on intervention features to improve. This involved a concurrent protocol where users were asked to think aloud as they used the website, followed by prompting for feedback by the interviewer (CB).

Quantitative feasibility study:
55. The authors aimed to assess demand and potential efficacy of the intervention. It is unclear how these outcomes were assessed. In the description of the baseline survey, other variables were collected such as use of guidelines and risk calculators, self-efficacy, intended use of website. The follow-up survey repeated these same questions. Yet, it is unclear how these data are related to the demand and potential efficacy feasibility outcomes outlined above.

The focus of the quantitative study was on the following feasibility measures: potential efficacy (guideline-based recommendation), acceptability (intended use) and demand (actual use over 1 month). Our measures of potential efficacy (guideline-based recommendation) and acceptability (intended use) are based on the baseline sample of 123; while the measure of demand (actual use over 1 month) is based on the follow-up sample of 98. We have more clearly explained this throughout the manuscript in the revised version including new subheadings for the results text/tables that focus on these aspects.

Abstract Page 2: “Stage 5 was a feasibility study to evaluate potential efficacy (guidelines-based recommendations for each risk category), acceptability (intended use) and demand (actual use over 1 month) amongst GPs.”

Methods Page 8: “Stage 5: A feasibility study to assess acceptability (intended use after initial viewing), demand (actual use after 1 month) and potential efficacy (improved knowledge of recommended interventions for each risk category as per guidelines) [22] was conducted.”

Results: see subheadings for each outcome and new table column headings.
56. The authors state that the follow-up surveys were sent in 3 batches. What does this mean, and what is the justification for doing so?

We have explained this as follows.

Page 9: “The 4 minute follow-up survey was sent in 3 batches 1 month after completion of the baseline survey to standardise the follow-up period (range: 4-6 weeks).”

Results
57. Please begin this section by describing the participants who participated in the qualitative piloting. The number of delegates and GPs who participated in each component of the qualitative study is currently provided in the methods section, but I think this would better fit in results.
We have moved this information as suggested.

58. Page 10 - Lines 52-57. It is not immediately clear what most common sources is referring to and for whom (particularly as the sentence leads with GPs who had not seen the guidelines).

We have clarified this as follows, and removed results that were only meaningful in Australia.

Page 14: “At baseline (n=123), almost all (95%) reported using absolute CVD risk calculators, most commonly the National Vascular Disease Prevention Alliance website (www.cvdcheck.org.au; 33%) and risk calculators within practice software (Best Practice 29%; Medical Director 20%). A lower proportion (72%) of GPs had seen the national CVD prevention guidelines.”

59. In the quantitative feasibility study section, results are sometimes presented as proportions (%) and sometimes as n without denominators.

We have amended this section to be more consistent, with the sample size clearly stated for each outcome.

60. I am not familiar with the way in which the paired t-test results are presented (t71). Further, the CONSORT statement for feasibility trials (2010) states that any estimates of effect should be reported using 95% confidence intervals - not p values - because pilot trials/studies are not powered for testing hypotheses about effectiveness.

We are no longer presenting t-test results because they were nonsignificant, to address reviewer comments. We have replaced p-values with 95% confidence intervals for the categorical data that were analysed using Pearson’s Chi-squared test.

61. Page 11 - lines 47: 26% and 29% of GP feedback - does this represent the proportion of total feedback, or the proportion of GPs? If the latter, suggest removing feedback.

This section has been removed for clarity, and the paragraph was amended to address other reviewer feedback.

Discussion

62. On page 13, the authors present GP and patient suggestions for implementation offered in the context of this study that will be addressed in future work. Since these suggestions are findings from this study, I suggest these could appear in the results.

We have highlighted these results in text as well as the table and explained why they were not addressed.

Abstract Page 3: “Open feedback identified a need for integration with medical software and practice nurse activities.

Results Page 12: No major content issues were identified in version 3 testing, but there were some suggestions for implementation to improve accessibility: linking the risk calculator to GP practice software, involving practice nurses, and creating a patient/consumer version of the website that is easier to understand without GP consultation. These issues could not be addressed within the project budget for intervention development.”
Results table 3: “Implementation suggestions still need to be addressed:
1. auto-population of risk factors from patients’ electronic record;
2. low health literacy version of decision aid; and
3. pre-consultation access to risk calculator/decision aid”

Strengths and Limitations
63. Nine patients were included in the qualitative piloting, which is a much smaller proportion than the number of GPs who provided feedback. No patients were included in the feasibility study.

We have provided more details about our previous studies that focused on patients (see new Table 1); but agree this is a limitation even though our target audience is GPs for this intervention. We have clarified our focus on GPs for the intervention and previous research with patients as follows:

Introduction Page 5: “The Healthy Heart Study aimed to identify and understand behavioural barriers to CVD prevention guidelines in Australia through research with 400 GPs and 600 patients/consumers in 2011-2018 (see Table 1). This project identified barriers that had not been addressed in previous trials, including: psychological capability (lack of knowledge about how risk factors relate to medication and lifestyle guidelines, and difficulty understanding/explaining absolute CVD risk); physical opportunity (lack of access to updated evidence and risk communication tools that match Australian guidelines); and reflective motivation (concerns about how to apply guidelines to challenging patient scenarios) [16, 17].”

Aim Page 5: “This study aimed to develop, pilot and evaluate the feasibility of a new online platform for the Australian CVD prevention guidelines that links existing strategies (risk calculator, audit and feedback) with a new patient decision aid to help GPs identify relevant guideline-based recommendations (for both medication and lifestyle change) and communicate this to patients.”

Methods Page 8: More detailed Framework Analysis had been conducted in 1 GP interview study and 2 patient think aloud studies prior to this stage (see Table 1); so thematic analysis for this stage was limited to notes taken during the interviews (CB and MF) and from audio recordings, to identify areas to improve.

Results Page 9: “Completing the Behaviour Change Wheel process (summarised in Table 2) identified the need to develop a new tool for GPs to use with their patients in consultations”

Discussion Page 19: “The main limitation of the current study is the use of a pre-post design to maximise end user feedback, rather than a randomised trial design which will be the next stage of the project; and the use of GP self report rather than GP-patient interactions within a consultation.”