Author's response to reviews

Title: Implementation of a self-management support approach (WISE) across a health system. A process evaluation explaining what did and didn't work for organisations, clinicians and patients

Authors:

Anne Kennedy (a.kennedy@soton.ac.uk)
Anne Rogers (a.e.rogers@soton.ac.uk)
Carolyn Chew-Graham (c.a.chew-graham@keele.ac.uk)
Thomas Blakeman (t.m.blakeman@manchester.ac.uk)
Robert Bowen (robert.a.bowen@manchester.ac.uk)
Caroline Gardner (caroline.j.gardner@manchester.ac.uk)
Victoria Lee (victoria.lee@manchester.ac.uk)
Rebecca Morris (Rebecca.morria@manchester.ac.uk)
Joanne Protheroe (j.protheroe@keele.ac.uk)

Version: 3 Date: 13 March 2014

Author's response to reviews: see over
Dear Editors

Thank you for your helpful consideration of our paper. We have now addressed your editorial comments and those of the four reviewers and have considerably revised the paper.

Response to reviewers:

Editorial comments

One of the principal reviewer concerns is that the intervention does not appear to be evidence-based. This could have a number of implications. For example, if the intervention is ineffective and clinicians (or organization stakeholders) recognized this then the finding that implementation failed is not surprising or all that interesting. This is in light of definitions of evidence-based practice that include the veracity of research evidence and the application of clinician judgment. If clinicians or organizations believe that a practice is not evidence-based, then it follows that implementation would be limited. Indeed, it could be an ethical breach for a clinician to utilize an approach lacking evidence. Following from this and as noted by one of the reviewers, results are analyzed as a failure of implementation rather than a failure of the intervention itself. Thus, the data analysis needs to be more nuanced and considering the role of both the intervention and the implementation. The authors should consider whether the data can be re-analyzed with a focus on the lack of intervention effectiveness (in conjunction with, or rather than, implementation failure) as the primary issue. This is critical to understanding the relevance of this study to the implementation of evidence-based interventions.

Response

We have now cut the paper considerably.

We agree that it is essential to make clear the evidence base of the intervention and the consequential message to the clinicians entering training. The components of the intervention were all evidenced based and we have flagged this up with reference to key papers which demonstrate this (to training, materials and approach). Moreover much of this evidence was established in a context where there local clinicians would have been aware of this (the key trials were conducted in the North West health economy for example [1-7]). This is now more clearly established in the text.

We have added a sentence to reinforce our view that the evidence base is good for the components of the intervention (p5 and p18). We do acknowledge that the intervention had not been trialled in full in primary care, only in secondary care and now state that more clearly. We do not believe that the WISE intervention posed an ethical breach for clinicians – we think the issue is around implementation of self-care support in a primary care setting. This was an ‘as good as it gets’ approach to SMS in terms of reach and integrating patients, clinicians and organisations. This is what we stated in the main trial paper:
We set out to implement a practice-based training programme to enhance outcomes through enhanced self-management, which involved a number of steps:

1. Engaging a high proportion of practices with the programme
2. Delivering training to a high proportion of clinicians and other staff
3. Ensuring training was relevant and acceptable
4. Encouraging implementation of the training in routine practice
5. Enhancing shared decision making and self-management
6. Improving outcomes

Our data shows that steps 1-3 were largely achieved, but we suggest that the intervention failed at step 4, and consequently failed to generate changes at steps 5 and 6. Ensuring that training was acceptable at step 3 required considerable compromise in restricting the length and content of training to match the time that practices were willing to devote. This necessarily limited the intensity of the intervention and our ability to subsequently add reinforcement and ensure fidelity. More success may have been achieved if that had not been the case, but that may have led to lower levels of practice engagement.

A common complaint in health services research is that effective interventions are often not feasible, and feasible interventions often not effective. Many published self-management trials are conducted in atypical contexts with selected, volunteer samples. Our study took proven components of self-management support and tested whether we could implement these as a comprehensive package in routine primary care practice using existing educational structures, applied to an entire local health economy. We sought to sensitise our intervention to the particular nature of primary care, providing a structure and tools to allow practitioners to introduce self-management support into time-limited consultations, to enhance partnerships with patients, and to encourage behavior change.‘[8]

(We attach the trial paper published in the British Medical Journal). We have now added more details to the discussion to consider intervention effectiveness in terms of implementation in primary care (p18).

Reviewer 1

Major Revisions

The paper is very well written and interesting but it is very long at 9,243 words excluding the abstract and the references. I have just checked the word limit on the author instructions and it does say a max of 6,000 and in exceptional circumstances 8,000. The introduction and the results sections in particular could be reduced in length.

The research question is important and well defined and of interest as self-management approaches such as this, whilst evidence based are often poorly implemented in practice. A detailed exploration of why this might be the case is of value to health service managers, health professionals and policy makers. The qualitative and quantitative methods used by the team seem to be appropriate to the research question although see point below about methods. The methods are very detailed and include some items that are not discussed in the results section. To reduce the length of the paper, I think the authors should just include the methods that relate to the findings that they will discuss. For
example:
- Collation of documents generated by the training, these included: Training notes (written by the trainers after each training session); patient journey maps created during training; reflections on what the practice does well and on challenges and problems to achieve change; action plans and steps to change identified by the practices; and logos designed by each practice as an ice-breaking task. These provide context concerning engagement in training but are not included in this paper.

If this is not going to be reported in detail then perhaps it could be excluded from the methods.

Response
We have removed this and the text of the document has been considerably shortened.

The authors use the NPT constructs as their framework and this is detailed in Table 1 and related to organisational, professional and patient levels. This is useful and I wanted the results section to expand on this. The text in the results section is organised under the health system, professional and patient headings but it was not clear to me how this related to the NPT constructs. I would like to see headings that relate to the NPT constructs used in the text, further subheadings such as those used in the results are fine to guide the reader through but it would help the reader to relate back to the NPT constructs.

Response
We have now related the overarching analysis section of the results to NPT constructs (p16-17).

Minor revisions
Overall, I think the discussion and conclusion bring the findings together well. The figure 2 pie charts, in colour, were useful although the response rate is low (48%) although not unusually so for research such as this in primary care. I would arrange them in the same way for each item (guidebook, Prism, Salford web) – the PRISM ones are in a slightly different order which was confusing at first glance.

Response
The figure has been amended.

Reviewer 2

Major Compulsory Revisions
Nevertheless, lack of organizational commitment to an evidence-based practice is often cited as a barrier to EBP implementation, so in this respect the study offers little insight into the challenges involved in implementing evidence-based approaches. This raises the question of the rationale for doing this study. How does an evaluation of the failure to successfully impact patient outcomes through the implementation of WISE add to our understanding of implementation in general or implementation of SMS interventions in particular? The authors should consider adding a discussion of what it would take to successfully implement...
SMS in primary care settings based on this experience.

Response
The organisational commitment was not altogether lacking – there was strong commitment from the top, problems were at the practice and professional level and we feel this is of interest and hope this version of the paper provides clearer insights.

We have added to the discussion to highlight what the failure of WISE implementation adds to understanding of implementation of SMS in primary care (p18). We have added a sentence to the conclusion about what is needed to successfully implement SMS for patients (p19):

Finally, self-management requires resources which extend beyond the immediacy of the practices implicating the need for links to broader networks of care. It is possible to extend systems of resources which involve other agents but this requires programmatic change.

Second, given the rapidly changing structure of health care in the UK at the time this study was conducting, it isn’t clear why the systems level context of implementation was not made an explicit focus of this process evaluation. The authors reference the “outer context” of the CFIR model, but the outer context of the broader systems changes occurring during the time the RCT was conducted and how these changes may have affected patient-provider relations and provider attitudes towards SMS and/or innovations in practice needs some elaboration.

Response
Had we the foreknowledge to predict the scale of the political change which occurred during the lifespan of this long research project, we could have built this into the process evaluation. Such a focus would have meant a different approach and protocol and we had to deliver on what the original funding had approved. We did not have the time or resources to follow a new track.

Third, more detail is required concerning the interviews conducted. Including some of the questions from the interview guide that were asked of participants is recommended, as well as a description of duration of the interviews and who conducted them. More detail is also required of the procedures for data analysis. What framework was used to develop themes based on the codes? Was a grounded theory approach or a phenomenological approach used in identifying themes? The authors should at least provide citations that describe the approach taken to analyzing the data.

Response
More detail has been added about the interviews. An appendix outlining the interview questions has now been included. A citation about the analysis approach has been added (p7)

Finally, the statement on p. 24 that WISE was viewed by practitioners as having “no perceived relevance or use in providing self-management support because of the biomedical focus of chronic disease management” is unclear. What is it about WISE that is inconsistent with the biomedical focus?
Response
This has been clarified by the following statement (p16):
‘Practice nurses performed the prioritised biomedical monitoring tasks related to QOF and could not readily *differentiate* this from self-management support.’

Minor Essential Revisions
First, it appears that the study could have provided an opportunity to validate some of the perspectives of various stakeholders in the implementation process through triangulation, but there is little evidence in the manuscript that this was, in fact, done by the authors. For instance, when a trainer is cited that there appears to have been little interest in among practitioners in WISE, was this confirmed in interviews with the practitioners? As another example, the authors state that “the involvement in a research project was deliberately downplayed because of the known difficulties of getting GPs to engage with or value research possibly because of the potential challenge to their professional identity as autonomous practitioners or competing priorities.[50]” Was this confirmed in interviews with the practitioners?

Response
Added a quote and linked the indifference of clinicians to the opinions of the trainers (p 12-13). The second suggestion for triangulation has now been removed from the text in order to shorten the paper. We have added at the end of the discussion that both clinicians and patients reported problems with PRISMS (p19).

Second, the fact that the majority of patients viewed their relationship with their primary care provider as ambivalent or negative raises the question of the generalizability of the findings. Is this typical of patient-provider relationships in the UK or elsewhere?

Response
Yes, we feel that this view is common amongst people who live in areas of high deprivation such as where the trial and process evaluation took place. We have added a reference to add weight to this finding (p17).

‘This accords with findings that social deprivation is linked to trust and confidence in GPs’ (reference Croker JE, Swancutt DR, Roberts MJ, Abel GA, Roland M, Campbell JL: *Factors affecting patients trust and confidence in GPs: evidence from the English national GP patient survey*. *BMJ Open* 2013, 3)

Reviewer 3

Major compulsory revisions:
1. The paper could be further strengthened mainly by placing some of the key findings within the context of emerging implementation literature focused on dissemination and implementation of self-management and behavior health change programs, particularly regarding the importance of using bottom-up as
well as top-down implementation strategies (e.g., see Proctor, et al.) as well as the public health literature regarding tailoring and marketing health behavior change (e.g., see work by Resnicow, et al.). Also, to what extent did patient perceptions regarding the utility of the self-management materials might have been confounded by psychiatric symptoms?

**Response**

We have now added a reference and table to clarify the implementation strategy (table 1 and p4). Psychiatric symptoms could well have confounded perceptions of self-management materials, but the aim of the training was for clinicians to tailor support to individual need so this should have been accounted for (see table 1 which now clarifies this approach). Anxiety and depression were measured in the RCT, but nothing was found to have any effect on patient outcomes.

2. Additional detail needs to be provided on the qualitative analyses—particularly regarding how codes were identified and what the iterative process for coding involved and whether theme saturation was obtained (see page 11)

**Response**

A reference has been added and this section re-written (p7)

The interviews were transcribed and then read and coded by members of the research team (based on the questions in table 2) who provided written comments and interpretations of exemplar quotes [9]. These were collated to create a wall-chart based on NPT constructs. A team-based iterative process drawing on the quantitative data allowed an understanding of the implementation at each level. Discussions within the team then contributed to the final overarching analysis.

3. The study mentions that the WISE intervention did not result in any changes in patient outcomes. What about specific measures of provider uptake of the intervention components? It would be helpful to know in general which components were adopted or not adopted and the level of fidelity (e.g., completion of training, number of patients getting self-management materials, assessment of self-management activities used by patients)

**Response**

Details of fidelity to training have been added (p 11). The pie charts indicate which tools were adopted. The main trial paper reports:

> Across the 12 months of the study, similar percentages of intervention and control patients reported each type of support, including receiving a guidebook (25% vs. 24%) and encouragement to use community programmes (19% vs. 20%) and patient support groups (11% vs. 12%). This indicates that there was no effect of the training on tailoring access to support for patients. 5% of both intervention and control patients reported using PRISMS which is difficult to explain but indicates that PRISMS forms were not adopted for use with patients in consultations. We have added a sentence outlining this, (p12):

> ‘The RCT findings showed no difference between groups in accessing each type of support indicating the training had no effect on improving support for patients’
4. Some context regarding access to GP clinics, especially wait times for appointments etc. would be helpful in order to better understand patient resistance to receiving self-management materials as well as the role of the doctor-patient relationship.

Response
We did not collect data on this and it appears to vary widely within and between practices despite national guidelines on waiting times for appointments. Whilst waiting time is undoubtedly a factor in patient dissatisfaction with access to primary care – we feel the main finding was the patients’ views that primary care consultations were not a legitimate place for self-management support to occur, additionally, due to the necessity of reducing the word count, there is no space to expand on this possible explanation for patient resistance to receiving self-management support.

5. Elaborate on the finding (page 17) that practices were more receptive to training but for “the wrong reasons” (e.g., socializing) especially within the context of the literature on provider communities of practice. Also, contextually. It would be helpful to determine the extent to which the providers had prior experience in team-building functions, especially those that involved implementing new processes or quality improvement studies.

Response
We have elaborated on these findings in the discussion and added references concerning quality improvement studies and team building in primary care (p18). Unfortunately, due to the disbanding of the PCTs it is not possible to retrospectively determine whether team-building training was a priority for providers. From the findings of this study, it seems that WISE training was completely different to any other training practice staff had been involved in.

Minor essential revisions:
The paper, especially in the introduction section tended to use a number of long and complex sentences (e.g., “Evaluation frameworks designed to establish the extent of the fostering of the implementation of research into practice also recognise contextual elements of the whole system which need to be taken into consideration.”) Please edit this section for brevity.

Response
The paper has been extensively edited and this sentence has been removed.

Reviewer 4
- Major Compulsory Revisions
Although the topic is an important one, and the perspectives of the clinicians/team members are interesting, there appear to be significant, fundamental, problems with this manuscript that would require reanalysis and major revision if they were to be adequately addressed. These are detailed below:
1) The most important problem originates with the classification of the
intervention being implemented as an “evidence-based practice (EBP).” It appears that this is not the case, thus the purpose for the trial itself—to test the intervention.

Response
This problem has been a tension for publications related to WISE and is obviously of interest to the journal Implementation Science. We contend that the various components of the complex WISE intervention were evidence based and have added a sentence and references to justify this (p5 and p18). However, as outlined in the response to the editor, we acknowledge that the whole practice training element of WISE had not been trialled in primary care and have amended the paper accordingly.

2) Once it was designated as an EBP, the authors proceed to analyze and interpret the results as a failure of implementation of processes they believe should lead to improvements in clinical practice/outcomes. Yet the intervention as described seems weak and not likely to be effective, particularly when compared to known effective interventions designed to improve self-management of chronic disease.

Response
As explained earlier, the training intervention was changed following formative evaluation to ensure reach and engagement of practices during implementation we feel strongly that we did succeed in this – had the training been of a longer duration and more didactic with close monitoring of practitioners, then we would not have recruited as many practices as we did (indeed we failed to gain access to practices post training to conduct observations). We have added a challenge to the results (p18):
‘The challenge is to show how an intervention of greater intensity or duration could enhance effectiveness without compromising reach.’

3) Given this point of view, results are analyzed as a failure of implementation rather than a failure of the intervention itself. Many of the quotes provided could be interpreted as evidence that the intervention was perceived as so weak as to be ineffective, thus not worth implementing. I would interpret this as a failure of the intervention rather than a failure of implementation.

Response
We disagree, rather than being a weak intervention, it was robust and pragmatic. We feel it is the nature of current primary care practice and the lack of fit with the patient’s daily life that means self-management support is not workable in primary care. We feel this is an important message and have made changes to the overarching analysis, discussion and conclusions to get this across more clearly.

4) It is possible the data could be re-analyzed and re-interpreted, but to do so, the intervention and its components would need to be more carefully described and compared to existing effective interventions and relevant theory, so that the reader understands the strengths and weaknesses of this intervention compared to others. Then the qualitative data could be re-analyzed from the standpoint of this comparative framework.
Response
We have added table 1 to provide more detail about the intervention and the implementation strategy. The overarching analysis now links more clearly to NPT.

5) The Methods section is limited and much detail is needed.
   a. No information is provided about how the data were managed, coded, or analyzed other than that interviews were recorded.

Response
More detail has now been added (p7)

b. Surveys were used but information is not provided regarding response rate. Practices were defined as “trained” but there is no information about what that really means in terms of the proportions of staff trained etc.

Response
Response rate for the survey (48%) is given on figure 3. Details have been added about % of staff trained (p11)

c. Little information is provided describing participants and their roles.

Response
Table 1 now provides more information

d. No information is provided about how differences in interpretation or coding (was coding done?) were identified, assessed, or resolved.

Response
We trust that the phrase ‘a team-based iterative process’ encompasses this (p7)

6) Some of the context is particular to the NHS; this may be understand by those familiar with NHS details but explanation would be helpful for those less well-versed in system characteristics (e.g., the distinction between Clinical Professional Directorate and Commissioning Directorate).

Response
We have removed the term ‘clinical professional directorate’

7) Under “Acceptability and utility of the training” the authors indicate that there was “good attendance” but do not define what that means.

Response
We have now added more detail (p11)

8) The Discussion and Conclusions begin from the assumption that the intervention was evidence-based and that the intervention failed, thus would need to be reworked if a re-analysis was completed.

Response
The overarching analysis, discussion and conclusion have been re-worked
Reference List


