PEER REVIEW HISTORY

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**ARTICLE DETAILS**

<table>
<thead>
<tr>
<th>TITLE (PROVISIONAL)</th>
<th>Qualitative evaluation of a complex intervention to implement health promotion activities according to health-care attendees and health professionals: EIRA study (phase II)</th>
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</thead>
<tbody>
<tr>
<td>AUTHORS</td>
<td>Pons-Vigués, Mariona; Berenguera, Anna; Coma-Auli, Núria; March, Sebastià; Pombo, Haizea; Masluk, Barbara; Pulido-Fuentes, Montserrat; Rodriguez, Carmela; Bellón, Juan A.; Pujol-Ribera, Enriqueta</td>
</tr>
</tbody>
</table>

**VERSION 1 - REVIEW**

| REVIEWER           | Chidinma A. Ibe  
|                   | Johns Hopkins University School of Medicine, Division of General Internal Medicine |
| REVIEW RETURNED    | 09-Aug-2018 |

**GENERAL COMMENTS**

This article describes an interesting and necessary qualitative process evaluation of a multilevel intervention. My overall impressions regarding its preparation for publication are outlined below:

1. The background section should include more information about, and the importance of, the use of process evaluations in trials. (pgs. 6 and 7)

2. The qualitative methods used, as well as the diversity of perspectives obtained, is commendable. It is good that the authors were able to solicit input from various stakeholders engaged with this initiative.

3. Page 8: The recruitment strategies employed require more detail. It describes the overall sample selection approach, but not the specific strategies used to solicit involvement in this study. Doing so could help contextualize the limitations of this study, including why the authors were not able to obtain feedback from those who were not as well-engaged in the study.

4. The results are written in a manner that is too general - so much so that I strongly recommend that the authors spend time rewording some of the statements, because they are written in a manner that is more suitable for a white paper than for publication in a peer-reviewed journal. For instance, several times the authors stated that the specific set of respondents were “happy” or some other feeling. The authors should refrain from assigning such value-based impressions of the respondents' feedback and report the findings in a more neutral manner (for instance, on page 15, bottom paragraph, it could state "Health-care attendees reported high satisfaction with the study because the project provided..."
professionals with sufficient time to listen to their needs and preferences."

4. With respect to the results, the authors should refrain from saying "most" or the "majority" and should provide a percentage of the respondents who had that particular belief. This will strengthen the results section by properly characterizing the extent to which those beliefs were held among those who were queried.

In general, this is an interesting study that requires further specification before it is ready for publication.

<table>
<thead>
<tr>
<th>REVIEWER</th>
<th>Åsa Hörnsten</th>
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<tr>
<td></td>
<td>Professor Department of Nursing Umeå University Sweden</td>
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<tr>
<td>REVIEW RETURNED</td>
<td>15-Oct-2018</td>
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</tbody>
</table>

| GENERAL COMMENTS | The interviews of attendees are stated to be 14 in the abstract and 13 in the main text. The result from this process evaluation is very positive. Possibly it is an effect from pre understandings of those involved in analysis. You get answers in the way you ask... A more inductive analysis would have given a more varied picture. Despite this, it is a well written paper with a large data collection, but it could have been explained better. The triangulation for example and the group discussions among professionals. The involvement of researchers could also have been discussed more critically. |

**VERSION 1 – AUTHOR RESPONSE**

**Reviewer 1 - Reviewer Name: Chidinma A. Ibe**

Institution and Country: Johns Hopkins University School of Medicine, Division of General Internal Medicine

Please state any competing interests or state ‘None declared’: None

This article describes an interesting and necessary qualitative process evaluation of a multilevel intervention. My overall impressions regarding its preparation for publication are outlined below:

1. The background section should include more information about, and the importance of, the use of process evaluations in trials. (pgs. 6 and 7).

**ANSWER:** Following the reviewer’s recommendation, we have added more information about the process evaluation in the background section:

A key question in evaluating a complex intervention is actual effectiveness. However, the process itself is also important: what happens, how, when and why. The process evaluation in trials explores the implementation of an intervention, assesses its quality and fidelity, clarifies causal mechanisms and identifies contextual factors associated with variation in outcomes [4,12]. Qualitative methodology has a unique role in understanding the implementation process of an intervention [13]. Interestingly, qualitative research can be used concurrently with a pilot trial, for instance to optimise recruitment and informed consent strategies, to identify acceptability of the intervention, to provide insights into processes of change and to help interpret findings [14]. Accordingly, the qualitative evaluation of the intervention implementation process is able to identify determinants of clinical practice such as barriers and facilitators that influence the adoption of organizational and professional change [Nilsen 2011]. This qualitative evaluation facilitates understanding of how and why the different components of the intervention are successfully or unsuccessfully implemented; it also contributes to identify predictive
factors of success and generates useful knowledge for advancing the implementation of scientific evidence [Palinkas 2011]. In addition, the qualitative methodological perspective might transcend the main limitations of the quantitative approach that prevails in clinical trials, and provides essential information on the evaluation of interventions, since it involves the different stakeholders, which actively convey their experiences, opinions, needs and suggestions for improvement.

Added references:

2. The qualitative methods used, as well as the diversity of perspectives obtained, is commendable. It is good that the authors were able to solicit input from various stakeholders engaged with this initiative.

ANSWER: Thank you for your comment.

3. Page 8: The recruitment strategies employed require more detail. It describes the overall sample selection approach, but not the specific strategies used to solicit involvement in this study. Doing so could help contextualize the limitations of this study, including why the authors were not able to obtain feedback from those who were not as well-engaged in the study.

ANSWER: Following the reviewer’s recommendation, we have added more information about the recruitment process in the methods section:

PHC professionals from participating PCC and assistant researchers were selected by means of opportunistic sampling [16]. The site investigator of each PCC contacted all professionals who participated in the EIRA study to book group interviews 2-3 months after the beginning of recruitment (February 2015 in 3 centres) and at the end of the intervention (summer of 2015 in the 7 centres of the intervention group). The decision of PHC professionals to participate in the group interviews was voluntary. For health-care attendees we applied theoretical sampling based on a prior definition of participants’ characteristics to obtain optimal variety and discursive wealth [16]. Fifteen informant profiles emerged from the discursive variants sex, age, educational level and type of intervention (the approach to the first component of the intervention was decided by the participant). Next, two of these profiles were randomly allocated to each PCC included in the intervention group of the EIRA Project; one PCC had 3 profiles. At the end of the intervention (summer 2015), the site investigator of each PCC contacted by phone the health-care attendees participating in the EIRA project who met the specific informant profile for the PCC to explain the objectives of the qualitative evaluation and invited them to participate in an interview. The voluntary aspect of participation was also emphasized to health-care attendees.

Moreover, we have modified the following sentence in the limitations:
Also, the voluntary character of participation of health care attendees and professionals might have biased the results towards a positive view of the intervention and of health promotion.

Although participants of this qualitative study and of the EIRA Project comprise people from various geographical origins, the contribution of particularly vulnerable individuals (female carers, immigrants and people with precarious employment) remains inadequate. This subpopulation probably lack sufficient time and need more attention regarding health promoting behaviour. More research is needed to further understanding of vulnerable patients.

4. The results are written in a manner that is too general - so much so that I strongly recommend that the authors spend time rewording some of the statements, because they are written in a manner that is more suitable for a white paper than for publication in a peer-reviewed journal. For instance, several
times the authors stated that the specific set of respondents were “happy” or some other feeling. The authors should refrain from assigning such value-based impressions of the respondents’ feedback and report the findings in a more neutral manner (for instance, on page 15, bottom paragraph, it could state “Health-care attendees reported high satisfaction with the study because the project provided professionals with sufficient time to listen to their needs and preferences.”)

ANSWER: Following the reviewer’s recommendation, we have reviewed the results and the discussion in the new version of the manuscript.

5. With respect to the results, the authors should refrain from saying “most” or the “majority” and should provide a percentage of the respondents who had that particular belief. This will strengthen the results section by properly characterizing the extent to which those beliefs were held among those who were queried.

ANSWER: While some Computer-Assisted Qualitative Data Analysis Software (CAQDAS) provide statistics on the proportion and number of times a text assigned to a specific code appears, we believe that the use of percentage of respondents is more suited to analytic designs for quantitative methodology. In our experience, counting events and stressing those more frequent compromises the analysis of qualitative data because it might falsely convey objectivity and distract from the essence of qualitative research, i.e., in-depth knowledge and interpretation of the phenomenon under study. Accordingly, in this manuscript we resolved to use “most” and “majority” instead of specific percentages of respondents.

In general, this is an interesting study that requires further specification before it is ready for publication.

ANSWER: We are grateful to the reviewers for their comments, which have undoubtedly contributed to improve the manuscript.

Reviewer: 2 - Reviewer Name: Åsa Hörnsten

Institution and Country: Professor, Department of Nursing, Umeå University, Sweden

Please state any competing interests or state 'None declared': None declared

ANSWER: We are grateful to the reviewers for their comments, which have undoubtedly contributed to improve the manuscript.

The interviews of attendees are stated to be 14 in the abstract and 13 in the main text.

ANSWER: In the abstract, we specify the total number of data collection techniques: (1) techniques with health professionals; (2) and techniques with health-care attendees. The sentence in the methods section where 13 semi-structured individual interviews are mentioned refers only to health-care attendees. However, the study also includes one semi-structured individual interview with a health professional. As a result, the total 14 computed individual interviews are included in the abstract.

<table>
<thead>
<tr>
<th>Primary Health Care professionals</th>
<th>Health-care attendees</th>
<th>Total number of techniques Information in the abstract</th>
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<tbody>
<tr>
<td>3 discussion groups in February 2015 and 6 discussion groups at the end of the intervention (summer of 2015)</td>
<td></td>
<td>9 discussion groups</td>
</tr>
<tr>
<td>1 individual interview with a community agent</td>
<td>13 individual interviews</td>
<td>14 semi-structured individual interviews</td>
</tr>
<tr>
<td>1 triangular group</td>
<td></td>
<td>1 triangular group</td>
</tr>
<tr>
<td>2 documentary techniques in February and 4 in summer</td>
<td></td>
<td>6 documents</td>
</tr>
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</table>
We have added the following sentence in the methods section of the new version of the manuscript to avoid confusion:
In total, data collection techniques consisted of 14 semi-structured individual interviews, 9 discussion groups, 1 triangular group and 6 documents.

The result from this process evaluation is very positive. Possibly it is an effect from pre understandings of those involved in analysis. You get answers in the way you ask...

ANSWER: In addition to the positive evaluations, the manuscript also shows a wide range of disapproved aspects of the intervention which require development before the intervention is to be deployed to other health centres. One of the objectives of this investigation on implementation, which is the basis of this qualitative evaluation, is to identify barriers to implementation of the EIRA intervention with the aim to improve it.

We have nonetheless added the following sentence in the discussion:
Although the authors of the current evaluation are also members of the EIRA research team, positive and negative information on the intervention was rigorously collected to deepen understanding on the components that need improvement (see Table 5).

A more inductive analysis would have given a more varied picture.

ANSWER: Even though this research took into account the conceptual model of outcomes for implementation research proposed by Proctor et al., only the dimensions of the model that emerged inductively from the data were considered: acceptability, appropriateness and feasibility, sustainability and penetration (changes implemented).

Despite this, it is a well written paper with a large data collection, but it could have been explained better. The triangulation for example and the group discussions among professionals. The involvement of researchers could also have been discussed more critically.

ANSWER: We have clarified these aspects in the new version of the manuscript:

Conversational techniques were used for PHC professionals: 3 discussion groups in February 2015 and 6 discussion groups at the end of the intervention, in the summer of 2015; 1 triangular group (a meeting of 3 people to discuss a topic with the aim of ascertaining the range and intensity of their views) [17]; and 1 individual interview with a community agent. In addition, we collected the written reports of 6 professionals who could not attend the discussion groups because of scheduling conflict (2 documentary techniques in February and 4 in summer).

The discussion groups took place in the PCC with one moderator and one observer, and lasted between 90 and 120 minutes. Semi-structured individual interviews took place in a setting accessible for the health-care attendees and lasted between 15 and 60 minutes. The field work was carried out in each region by qualified interviewers with experience in qualitative research.

To guarantee quality and rigour we adhered to the following recommendations [22,23]: description of the intervention, the context, the participants and the research process; methodological adequacy; working with different actors; triangulation of techniques (comparison of data obtained by means of different information collection techniques) and analysis (contrasting and comparing the data analyses performed by different analysts to strengthen the credibility and confirmability of the study results); and reflexivity of the interdisciplinary research team. Sufficient data were collected to meaningfully answer the research question.

Although the authors of the current evaluation are also members of the EIRA research team, positive and negative information on the intervention was rigorously collected to deepen understanding on the components that need improvement (see Table 5).
GENERAL COMMENTS
An acceptable qualitative evaluation of a pilot. Very positive. It would though have strengthened the trustworthiness of the analysis if some negative experiences also would have been presented.

VERSION 2 – REVIEW

REVIEWER
Asa Hörnsten
Department of Nursing Umeå University SWEDEN

REVIEW RETURNED
13-Nov-2018

GENERAL COMMENTS
An acceptable qualitative evaluation of a pilot. Very positive. It would though have strengthened the trustworthiness of the analysis if some negative experiences also would have been presented.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 2 - Reviewer Name: Åsa Hörnsten
Institution and Country: Professor, Department of Nursing, Umeå University, Sweden
Please state any competing interests or state 'None declared': None declared

An acceptable qualitative evaluation of a pilot. Very positive. It would though have strengthened the trustworthiness of the analysis if some negative experiences also would have been presented.

ANSWER: In addition to the positive evaluations, the manuscript also shows a wide range of disapproved aspects of the intervention which require development before the intervention is to be deployed to other health centres. It is possible to read negative experiences in almost every section of the results. For example, (acceptability section): "However, they remained critical and underscored that the project was too ambitious, too long, somehow unclear and unorganized, which led to confusion during implementation. They specifically highlighted difficulties in the approach to risk of depression. Moreover, in some primary care teams tension emerged between professionals that participated and their non-participating colleagues”.

Moreover, Table 5 shows the discourses and suggestions for improving the intervention according to participating health care attendees and professionals. Specifically, participants reported suggestions on a varied range of aspects: training, organisation and coordination, recruitment, individual intervention, group intervention, community intervention, patient information leaflets, SMS, webpage, online case report form, evaluation of the intervention (Assistant researchers) and project dissemination.

As we explained in the discussion section, “although the authors of the current evaluation are also members of the EIRA research team, positive and negative information on the intervention was rigorously collected to deepen understanding on the components that need improvement”.

We have nonetheless added the following sentence in the discussion:

“The authors guarantee the accuracy, transparency and honesty of the data and information contained in the study”