PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Protocol for a process evaluation of a cluster randomised controlled trial to improve management of multi-morbidity in general practice: The 3D study
AUTHORS	Mann, Cindy; Shaw, Ali; Guthrie, Bruce; Wye, Lesley; Man, Mei-See; Hollinghurst, Sandra; Brookes, Sara; Bower, Peter; Mercer, Stewart; Salisbury, Chris

VERSION 1 - REVIEW

REVIEWER	Jamie Murdoch University of East Anglia United Kingdom
REVIEW RETURNED	09-Feb-2016

GENERAL COMMENTS	This protocol for a process evaluation of the 3D trial is of a good standard and suitable for publication. On the whole there is an excellent data collection plan which utilises both quant and qual data to understand key processes of implementation and the team have clearly considered the different levels of implementation that may affect delivery. However I have a few comments (mainly about the observations of consultations) that might be helpful for the study team. The first two are the only ones I think are a requirement for publication. The last three I think are not necessary but if feasible would greatly enhance the team's evaluation of implementation and two out of the three could be done as secondary analyses with the data the team already propose to collect. 1. The authors foreground context as a key focus of the study. If so I think the protocol would be improved by a definition of what counts as context and how the authors view or plan to investigate the theoretical relationship between the intervention, context and outcomes. 2. Although I can see the team will characterise all practices at the beginning and end of the study, and will interview staff at the end to understand maintenance of the intervention, I think it would be a good idea to spread observations and recordings of consultations across duration of the study to understand how the relationship between context and the intervention may change over time and so may lead to important changes in its delivery. Perhaps this is the intention, and if so, this could be made clearer in Table 1. 3. I think a key focus of the evaluation should be how, in intervention practices, information collected by the nurse at the first appointment is subsequently used by the GP in the second appointment, in particular to follow the trajectory of what the patient reported in appointment 1 to how this was later understood, used and acted on by the GP in appointment 2. 4. If feasible I think findings could be strengthened by obtaining qualitative observational and interactional data of nurse/GP

	consultations in usual care practices to identify a clear distinction in the delivery of patient-centredness between the 3D intervention and usual care. 5. While the proposed framework approach to analysing the qualitative data will probably capture broad issues of implementation across practices, in order to fully assess the implementation of a patient-centred intervention with additional template, it would be beneficial to analyse patient-provider-EPR interactions using an approach based on conversation analysis. How are patient-centred styles enacted within ongoing interactions? How do GPs/nurses bring the template into the consultation interaction and how does it organise communication between patient and GP/nurse? What are the consequences for how consultations proceed and responded to by patients?

REVIEWER	Juliane Koeberlein University of Wuppertal Germany
REVIEW RETURNED	11-Feb-2016

GENERAL COMMENTS	1) To achieve a closer look into the implementation process the authors intend to collect data from case study practices. Only intervention practices will be sampled as case studies. If it is possible there should be also a few case study practices sampled from the control practices to get a better feeling for usual care processes which could not fully describe by quantitative data. 2) Authors intend to sample 4 care studies to achieve a sample that encompasses heterogeneity. I am not sure if a sample of 4 practices generates sufficient heterogeneity. This “power calculation” should be explained in detail. 3) p. 8 line 22/23: authors describe that practices will be sampled and enrolled before or soon after they have received their training. In my opinion first interviews should urgently take place before any training to achieve a real baseline statement. 4) Strengths and weaknesses of the planned process evaluation approach should be discussed.

REVIEWER	Ingmar Schäfer Department of Primary Medical Care, University Medical Center Hamburg-Eppendorf, Germany
REVIEW RETURNED	19-Feb-2016

GENERAL COMMENTS	The authors are to be congratulated for conducting an interesting study on an important topic. The protocol for the supplementing process evaluation comprises an impressive variety of analysis steps and contains useful information on aims, design and analysis of the qualitative and quantitative measures. However, I have some issues with the protocol paper that the authors should consider. I will present my comments as I go through the manuscript. 1. Introduction pg. 3 ln. 33-34: “… as multimorbidity becomes more prevalent.” This statement lacks some explanation and should at least be substantiated by a reference. 2. Introduction, Process evaluation pg. 4 ln. 44 - pg. 5 ln. 32. This chapter contains a lengthy general explanation about what process

	evaluation is and how it is conducted. It contains much useful information to the reader who is not familiar with this evaluation design, but the chapter is also redundant as most of these points are specified later in the context of the study. In order to provide a concise manuscript the authors should reflect if this chapter is really needed or if it could be deleted if the necessary information was introduced in short form in the later chapters of the manuscript. 3. Process Evaluation Methods, Case studies, Sampling and recruitment pg. 8 ln. 3-10. The heterogeneity of intervention implementation needs to be more clearly defined, especially regarding which indicators are used and by which method similarity is assessed. 4. pg. 8 ln. 27-29. Please include information on how is “failing to adopt or deliver elements of the intervention” defined. 5. pg. 8 ln. 29-30. Please state how is an “interesting organisation of care” defined. 6. pg. 8 ln. 41-42. Please specify which “scores on measures relating to patient-centered care at baseline” will be used. 7. Process Evaluation Methods, Case studies, Case study data collection pg. 10 ln. 11-13. Please list all the “quality and outcome framework data” that are collected. 8. pg. 10 ln.14-15. Please list all the “continuity measures” that are collected. 9. pg. 10 ln. 30. Please include information on how the training is observed. 10. pg. 10 ln. 32. Please specify by which guiding questions the impression of practice and ease of study setup will be assessed. 11. pg. 10 ln. 33-34. Please state how “key role” is defined. 12. pg. 10 ln. 35-38. Please specify by which guiding questions practice context, views of the training etc. will be assessed. 13. pg. 12 ln. 10. Please include the questions that will guide the discussion of the consultation.

VERSION 1 – AUTHOR RESPONSE

Response to reviewers
Manuscript ID bmjopen-2016-011260
Many thanks to all three reviewers for their very helpful comments. We have responded to these comments as below and are confident that the paper is improved by these clarifications and minor changes.
Reviewer 1.
We appreciate the commendation of the overall design of the process evaluation and the recognition that what can be achieved is inevitably constrained by available resources.
1. Thank you for pointing out that there should be a clearer indication of what counts as context. This has been addressed by adding ‘and form the context to be evaluated’ to the end of the sentence at the end of an existing paragraph on p5 which describes the context to be evaluated.

How the theoretical relationship between the intervention, context and outcomes will be investigated has been clarified in the analysis section on p14:
'Quantitative and qualitative data about usual care in all trial practices will be used to assess similarity of care at baseline to the intervention and to assess whether this changes over the course of the trial. A baseline description of the practice and of its usual care for patients with multimorbidity will allow comparison of care across practices and across areas. By repeating this at the end of the trial it will also allow us to assess whether usual care has changed over the course of the trial, and feed into interpretation of results by facilitating comparison of care provided by intervention and usual care practices. If there is a clear trend towards initiatives that are very similar to 3D, any improvements in care resulting from 3D may be matched by those that occur as a result of 'secular trends'. It is also expected that the various components of the intervention may not be uniformly implemented across practices, in part due to differences in context e.g. nurse roles, baseline arrangements for LTC care and whether the practice has their own pharmacist, and that this may be reflected in differences in outcomes. Therefore variation in outcomes by practice will be compared with variation in practice characteristics to generate hypotheses about any associations observed.'
2. We agree that how observation is spread over the whole period of the trial is an important consideration that is at least partially addressed by our design. Due to variation in the time that practices have started to deliver the intervention, observations and consultation recordings will in fact be spread across a time span of about 8 months and will include both some first reviews and some second reviews. Changes in practice context may affect delivery and reach by affecting the rate at which reviews are arranged (which we observed in the pilot phase) but are less likely to affect the content of them (delivery by clinicians) as this is dependent on the intervention template. The rate of reviews will be tracked by monthly searches run in each intervention practice. This is referred to in point a) in table 5.
3. Thank you for pointing out that knowing how the information collected by the nurse is subsequently used by the GP in the second part of each review would be valuable. We do in fact propose to investigate this when a selection of patient records at the end of the trial is examined. Point h has been added to table 3 to clarify this.
4. We agree that it would be desirable to include one or more usual care practices as case studies but this is dependent on the availability of resources. Reference to this has been made in the new strengths and weaknesses section at the beginning of the paper but the process evaluation design is consistent with the peer-reviewed funding application and the ethics approved protocol in the planned amount of data that will be collected. There is also a statement in the second paragraph under 'sampling and recruitment' that some flexibility will be retained that may be used in this way. The modified sentence on p7 'If resources allow, a usual care practice may also be recruited as a case study to provide a comparison to care provided in intervention practices and to check whether findings from case study practices are reflective of the intervention, and not simply due to evolving usual care' addresses this point.
5. We agree that analysis of the interactions is important to evaluate a patient-centred approach. This analysis will be informed by a Conversation Analysis approach as well as by insights from the patient involvement group. This point has been clarified in the analysis section p14 'Evaluation of the patient-centredness of the interactions will be based on an analysis of the interactions, informed by a Conversation Analysis approach' and a reference added. A second sentence has been added to the end of the first paragraph on p15 'This group will also provide the patient perspective on indicators of patient-centred behaviour to inform analysis of interactions in the consultation recordings'.
The experience of using the template will also be explored in the interviews. During the pilot interviews clinicians reflected on how it affected patient-centredness.
Reviewer 2.
1. Thank you for your point that it would be helpful to get a better feeling for care processes in usual care practices than quantitative data will provide, which we accept. Because of this, we are in fact collecting quite detailed information through direct contact with staff in each usual care and intervention practice and this has been made clearer in table 1. A usual care practice will be sampled

as a case study if resources allow as we agree that this would potentially be helpful to understanding the difference the intervention might make. Please also see response to point 4 above.
2. Thank you for asking for clarification about the sampling strategy. We have now modified the description of the sampling strategy on p7 to clarify that we are not aiming in our sample to represent the entire variety of participating practices but to sample purposively based on the aims of the process evaluation to investigate adoption, delivery and maintenance of the intervention. We anticipate that our sampling strategy, will achieve sufficient heterogeneity to provide examples of relatively poor and relatively good adoption, delivery and maintenance and will allow us to identify barriers and facilitators to implementation and to generate hypotheses about factors that may be associated with differing outcomes. The answer to point 4 above also to some extent addresses this point, in that resources are inevitably limited to funding the original peer-reviewed proposal.
3. Thank you for pointing out the importance of obtaining a statement of practices' baseline situation. Sufficient information for sampling is not available however, until after training. Paragraph 2 of the sampling and recruitment section has been modified to clarify this point.
4. Thank you for pointing out the omission of a discussion of strengths and weaknesses. This has now been added at the beginning of the paper.
Reviewer 3
Thank you for the positive comments and for pointing out where more information is needed.
1. A reference about increasing prevalence of multimorbidity has been added to the statement in the first paragraph on p3
2. As you point out, a general explanation of the need for process evaluation was included for the benefit of readers not familiar with process evaluation but we accept that this could be more concise. We have accordingly tried to achieve this by removing some sentences in the process evaluation section of the introduction and the section on design considerations in Process Evaluation Methods.
3. Thank you for pointing out that we need to be clearer about what we mean by heterogeneity of implementation. This has been clarified as described in the response to reviewer 2 point 2 and we have also added a couple of sentences to the first paragraph in the sampling and recruitment section to clarify what we mean by poor implementation with reference to fig 1 which describes the intervention ingredients.
4. Again thank you for prompting clarification of what we mean by adoption and delivery. This has been clarified and a reference to fig 1 has been added in paragraph 1 of the sampling and recruitment section. 'Adoption includes the steps described in Fig 1 under 'Practices organisation of care', such as allocating a usual GP, and delivery includes the components listed in Fig 1 under 'Clinicians conduct of reviews', e.g. provision of a health plan.'
5. We agree that 'an interesting organisation of care' was unclear. This has now been deleted and better explanation of what would prompt sampling of additional practices has been added instead.
6. The scores on measures of patient-centred care at baseline may not after all be used in sampling so this has been deleted.
7. Thank you for pointing out the need to explain what is meant by Quality and Outcome Framework data. A reference has now been added.
8. Similarly the need to explain how continuity is to be understood. Again a reference has been added.
9. Information at c) in Table 2 on how the training is to be observed has now been included
10. More detail of what is meant by the impression of the practice and ease of study set-up has been added at d) in Table 2
11. 'Key role' has been deleted at e) in Table 2 and the roles have been specified instead
12. The guiding questions to be used in obtaining information about practice context etc. have been described more clearly at e) in Table 2.
13. Some indication of what will be considered when discussing the consultations has now been added to b) in Table 4. Specific questions will depend on the content of individual consultations and will aim to elucidate the observed interaction between patient and clinician and how they responded to each other so are not included in the protocol.

VERSION 2 – REVIEW

REVIEWER	Jamie Murdoch University of East Anglia, UK
REVIEW RETURNED	14-Mar-2016

GENERAL COMMENTS	I am satisfied the authors have adequately addressed all my comments and therefore recommend this article for publication.

REVIEWER	Ingmar Schäfer University Medical Center Hamburg-Eppendorf, Department of Primary Medical Care, Germany
REVIEW RETURNED	01-Apr-2016

GENERAL COMMENTS	Thank you for giving response to my comments and revising the manuscript accordingly. I have no further concerns with this paper.