

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Facilitating mental health research for patients, clinicians and researchers; a mixed methods study
AUTHORS	Robotham, Dan; Waterman, Samantha; Oduola, Sheri; Papoulias, Constantina; Craig, Thomas; Wykes, Til

VERSION 1 - REVIEW

REVIEWER	Peter Watson Medical Research Council UK
REVIEW RETURNED	21-Jan-2016

GENERAL COMMENTS	<p>Some of the frequencies of replies to questions would appear to be missing with the apparent consequence of summation errors in the results and other descriptions of frequencies need, in my view, clarifying. I also find the results contradictory with seemingly significant negative aspects flagged by clinicians who still seem to find the use of C4C worthwhile so would need to know more specifically what aspects they found/would potentially find worthwhile. I am not clear how straightforward in terms of time and possible cost the suggested improvements would be such as those highlighted in the discussion (to the existing register of over 7,000 participants) to inform clinicians and screen out unsuitable participant.</p> <p>Page 6, line 41. There are 17 investigator participants comprising a range of 18 mental health problems (4 dementia, 4 psychosis, 1 ADHD, 1 personality disorder, 2 depression, 2 obsessive compulsive disorder with four non-specific = 18 studies as given on page 7, line 54) so my understanding of this is that at least one of the investigator participants is involved in more than one study which are look at more than one mental health problem. Is this correct?</p> <p>Page 7. Looking at the sample of responses it does appear that the staff approached did not have the information or training to be able to help the mystery shoppers which is flagged in the discussion (page 9) although this emphasises the lack of information rather than any possible training required. I wonder how much extra work would be involved in any training and/or giving of up-to-date relevant information to augment the existing information on the 7,851 people (page 4, line 27) already on the register.</p> <p>Did any of the staff report back (page 6 lines 55-56) as they said they would with the information requested by the mystery shoppers in Phase 1? I am not quite clear how many shoppers staff said they would report back to. Is this 21-11 (Yes) = 10 clinicians who said they would report back to each of their shoppers? Where would such information be recorded? Presumably this information could be</p>
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	<p>added to the existing database?</p> <p>Page 7, line 23 Presumably the 52% relates to the 52 people entering Phase 2(a)? I would put in the frequency here to be consistent with the more informative frequencies mentioned later in this paragraph.</p> <p>Page 7 lines 26-28. There are 52 people in Phase 2a (page 6, line 33) but on lines 26-28 on page 7 only replies from 43 of these 52 appear to be mentioned with regard to choosing what studies they participated in (30 agreeing+ 1 disagreeing + 12 neutral=43). On a similar theme in the next sentence (page 7, lines 29-30) on being informed about research a total of 29+12+0= 41 replies are given which is also less than the 52 total possible replies. Did some people refuse to reply to these questions? If so, the non-reply rate would appear quite high and should be discussed.</p> <p>Page 7, lines 38-43. Are the people mentioning 'too many phone calls', 'prefer not being called', 'not feeling safe on the register' and following part of the 7 people mentioned on line 38 who disliked being on the register? If not, would it not make sense to add these to the 7 who disliked being on the register given the strength of their opinions?</p> <p>Page 7 lines 54-57. 6 of the 18 studies did not recruit any participants at all via the register yet two recruited 116 participants between them. Why were some studies more successful at recruitment than others? Does this have ramifications for how to improve the usefulness of the register?</p> <p>Page 8, lines 25-28. I find the results here confusing with most investigators thinking C4C worthwhile and all prepared to recommend it yet in the next sentence less than half think it faster than other methods and only 6 of the 18 said it helped recruit more participants than other methods and on page 7, line 14 'all staff' appeared to lack knowledge about research opportunities and the register. I wonder, therefore, what aspects of C4C would make the investigators think C4C worthwhile and would make them recommend it to colleagues and if they are better off using this as opposed to pre-existing 'other methods'. Not sure what 'other methods' mentioned here (line 28) refers to.</p> <p>Page 8. I assume that since means and sds are given in Table 1 there was no skewness in the distributions of the C4C usefulness measures. Were there any gender differences in responses?</p> <p>Given there are 29 men and 23 women (page 6, line 32) in Phase 2a did you consider comparing responses between genders here? I wonder, perhaps naively, if you have any thoughts about tailoring C4C differently for different ages groups and genders. I know, for example, that shopping behaviour does differ between males and females since a shopping element is implied in phase 1 not least in using mystery shoppers.</p>
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REVIEWER	Jennifer Funderburk Center for Integrated Healthcare, United States
REVIEW RETURNED	18-Feb-2016

GENERAL COMMENTS	<p>Manuscript Title: Providing opportunities to participate in mental health research</p> <p>This manuscript examines the utility of a “consent for contact” register as a method for facilitating recruitment into mental health research. The idea is appealing as it reduces the need for individual clinicians to actively help with recruitment of every research study and allows researchers to present the information about the study to willing patients. As there is research demonstrating recruitment biases, it is possible this method may help address those challenges. However, below are some suggestions that may improve the manuscript:</p> <ol style="list-style-type: none"> 1) It seems the goals of this manuscript is to conduct a program evaluation of the consent for contact register from various perspectives: investigator and patient. It might help to clearly present that as the point as I’m not sure the data that you obtained really answers whether it increased opportunities for patients to learn about research as that might be better answered by the reach of the program (e.g., number of agreements versus declines as well as the number asked, etc.) 2) As a result, it might significantly improve the paper if you actually used a theoretical framework for program evaluation like REACH to structure the three phases of the study. It would help you frame the questions and likely identify potential gaps in information you didn’t obtain (e.g., you don’t know if there are demographic differences that remain between those who consent to CCR and those who don’t as past research suggests that there are factors that potentially bias participation that would be an important gap to fill in the future) 3) The manuscript was difficult to follow as all three phases had different targets. I think it might be helpful to restructure it into 3 different participants/materials/procedures/results sections if allowable. In addition, it felt as if you couldn’t provide as much detail on each phase as a result of putting them all in one article. Consider increasing the length and providing more detail or dropping one piece for another article. 4) The use of the “mystery shopper” was interesting although it was confusing to include it in the design paragraph when most people likely would not understand what you are talking about. Either drop it from there or move up your description of it would help reduce any misunderstanding about it. 5) Questions related to the methods/results: <ol style="list-style-type: none"> a. can you quantify and describe in some ways the advertising/training that was conducted in the sites that the mystery shoppers went and asked clinicians about the CCR? b. Was there more than one site that they went to and were there differences in those sites on levels of marketing for CCR conducted? c. How do you know that the mystery shopper actually asked the clinician? How close in time between the appointment and the training did the mystery shopper go? d. You need to provide more details on the measures for all of the phases and how you exactly used them in the analysis. e. How was the qualitative data collected and rated etc? Were audiotapes used? Did raters examine open-ended questions for themes? Was there a systematic process, please describe it? f. 712 research opportunities to only 612 patients seems odd. g. Paragraph under phase 2a all of the numbers don’t make sense.
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	<p>Why are there so many research opportunities to only 612 patients. That is a high number and if I'm interpreting it correctly those patients must have received a lot of phone calls. Please clarify as I don't think I am interpreting it correctly. Why is it that only 30 agreed when there is a larger n of 412. More clarity would be helpful.</p> <p>h. Regarding the investigators, more information if you have it on their other recruitment methods and the rates of success may help better evaluate the CCR.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer 1 requests:

1) Some of the frequencies of replies to questions would appear to be missing with the apparent consequence of summation errors in the results and other descriptions of frequencies need, in my view, clarifying.

- We have corrected these, as highlighted by this reviewer in the comments below.

2) I also find the results contradictory with seemingly significant negative aspects flagged by clinicians who still seem to find the use of C4C worthwhile so would need to know more specifically what aspects they found/would potentially find worthwhile. I am not clear how straightforward in terms of time and possible cost the suggested improvements would be such as those highlighted in the discussion (to the existing register of over 7,000 participants) to inform clinicians and screen out unsuitable participant.

- We have changed the order of the final paragraph in the results section. It now presents the positive remarks first (including the table), and then the negative remarks. We think these seemingly contradictory remarks are understandable given the context. Researchers tend to use a variety of approaches to recruit participants, and are opportunistic (C4C is just one of the potential methods they will use). We are not aiming to compare C4C with other tried and tested recruitment methods, we merely want to assess whether C4C's has been useful and has made a difference. We have added two sentences in the Discussion section which refer to researchers' opportunistic nature and how C4C can be used as a supplementary recruitment method.

Regarding the comment about the cost implications of suggested improvements in the discussion. We have changed the wording (in the discussion) to clarify that we would only be expecting clinicians to verify for those people on their own caseload. Whether clinicians engage with this will depend on the individual, but this is a potential solution for the future and a way in which clinicians can engage with C4C.

3) Page 6, line 41. There are 17 investigator participants comprising a range of 18 mental health problems (4 dementia, 4 psychosis, 1 ADHD, 1 personality disorder, 2 depression, 2 obsessive compulsive disorder with four non-specific = 18 studies as given on page 7, line 54) so my understanding of this is that at least one of the investigator participants is involved in more than one study which are look at more than one mental health problem. Is this correct?

- Yes this is correct – one clinician was involved in two studies which had used C4C. Clarified in the 'results/sample characteristics' section.

4) Page 7. Looking at the sample of responses it does appear that the staff approached did not have the information or training to be able to help the mystery shoppers which is flagged in the discussion (page 9) although this emphasises the lack of information rather than any possible training required. I wonder how much extra work would be involved in any training and/or giving of up-to-date relevant information to augment the existing information on the 7,851 people (page 4, line 27) already on the register.

- It is true to say that staff lacked information about up-to-date research projects. At present, the

research register is linked to the clinical records system. But the register is not available to clinicians in routine practice. We think that redeveloping the 'front end' of a clinical record system to incorporate 'possible research opportunities' is the only way to keep clinicians informed. This is highlighted in the second-last paragraph of the Discussion section. We have rewritten this paragraph to make it more explicit.

5) Did any of the staff report back (page 6 lines 55-56) as they said they would with the information requested by the mystery shoppers in Phase 1? I am not quite clear how many shoppers staff said they would report back to. Is this 21-11 (Yes) = 10 clinicians who said they would report back to each of their shoppers? Where would such information be recorded? Presumably this information could be added to the existing database?

- We have clarified this by rewriting the first paragraph under the 'Results\Phase 1' section. This now states how many shoppers reported that clinicians would feed back to them. Unfortunately we do not know whether any of the clinicians made good on their promise to feedback at a later date, we did not follow up the mystery shoppers in the long term.

6) Page 7, line 23 Presumably the 52% relates to the 52 people entering Phase 2(a)? I would put in the frequency here to be consistent with the more informative frequencies mentioned later in this paragraph.

- We have changed these to frequencies as recommended.

7) Page 7 lines 26-28. There are 52 people in Phase 2a (page 6, line 33) but on lines 26-28 on page 7 only replies from 43 of these 52 appear to be mentioned with regard to choosing what studies they participated in (30 agreeing+ 1 disagreeing + 12 neutral=43). On a similar theme in the next sentence (page 7, lines 29-30) on being informed about research a total of 29+12+0= 41 replies are given which is also less than the 52 total possible replies. Did some people refuse to reply to these questions? If so, the non-reply rate would appear quite high and should be discussed.

- We have clarified this. These lower numbers were due to some people answering 'don't know' to these questions.

8) Page 7, lines 38-43. Are the people mentioning 'too many phone calls', 'prefer not being called', 'not feeling safe on the register' and following part of the 7 people mentioned on line 38 who disliked being on the register? If not, would it not make sense to add these to the 7 who disliked being on the register given the strength of their opinions?

- Yes, these are the same people. We have clarified in the text.

9) Page 7 lines 54-57. 6 of the 18 studies did not recruit any participants at all via the register yet two recruited 116 participants between them. Why were some studies more successful at recruitment than others? Does this have ramifications for how to improve the usefulness of the register?

- We have since looked at the data and realised that those studies which were more successful in recruiting had simpler recruitment criteria. Investigators experienced difficulties when patients were being screened according to more complex criteria such as current medication, primary diagnosis, etc. A sentence has been added into section 2b, and another sentence in the discussion section.

10) Page 8, lines 25-28. I find the results here confusing with most investigators thinking C4C worthwhile and all prepared to recommend it yet in the next sentence less than half think it faster than other methods and only 6 of the 18 said it helped recruit more participants than other methods and on page 7, line 14 'all staff' appeared to lack knowledge about research opportunities and the register. I wonder, therefore, what aspects of C4C would make the investigators think C4C worthwhile and would make them recommend it to colleagues and if they are better off using this as opposed to pre-existing 'other methods'. Not sure what 'other methods' mentioned here (line 28) refers to.

- The reviewer is referring to two sets of stakeholders here. By 'all staff', we actually meant clinical

staff as opposed to research investigators. We have amended this to 'all clinical staff' to avoid such confusion.

Investigators can see the potential of C4C even though it may not have been useful as a major recruitment method for them. As discussed above (point 2).

11) Page 8. I assume that since means and SDs are given in Table 1 there was no skewness in the distributions of the C4C usefulness measures. Were there any gender differences in responses?

- These are the responses from the research investigators. We have tested these four results for skewness, none were skewed (i.e., none greater than +1 or less than -1).

Regarding the gender variable, the sample in Phase 2b was not equal on gender, there were more females. It would be difficult to test this with such a sample and this was not an aim of the study.

Anecdotally, we do not think it would affect results.

12) Given there are 29 men and 23 women (page 6, line 32) in Phase 2a did you consider comparing responses between genders here? I wonder, perhaps naively, if you have any thoughts about tailoring C4C differently for different age groups and genders. I know, for example, that shopping behaviour does differ between males and females since a shopping element is implied in phase 1 not least in using mystery shoppers.

- The participants recruited in phase 2a are different to the shoppers recruited in phase 1 (we have attempted to clarify this in the Method section). It seems that the original manuscript was confusing for the reader; the stages are now presented explicitly throughout the Method and Results sections. As for a comparison of gender for phase 2a, this would be an interesting concept to look at with a bigger sample. We did not consider it as an objective in this study.

Reviewer 2 requests:

This manuscript examines the utility of a "consent for contact" register as a method for facilitating recruitment into mental health research. The idea is appealing as it reduces the need for individual clinicians to actively help with recruitment of every research study and allows researchers to present the information about the study to willing patients. As there is research demonstrating recruitment biases, it is possible this method may help address those challenges. However, below are some suggestions that may improve the manuscript:

1) It seems the goals of this manuscript is to conduct a program evaluation of the consent for contact register from various perspectives: investigator and patient. It might help to clearly present that as the point as I'm not sure the data that you obtained really answers whether it increased opportunities for patients to learn about research as that might be better answered by the reach of the program (e.g., number of agreements versus declines as well as the number asked, etc.)

- We agree with the reviewers' comments on readability (having read the manuscript again with fresh eyes). We have changed the title to better reflect the aims of the paper. This paper is about facilitating research within mental health settings (both for research investigators and participants). Changes have been made throughout to reflect this. Research opportunities for patients are still an important part of the paper, but are no longer presented as the central aim.

2) As a result, it might significantly improve the paper if you actually used a theoretical framework for program evaluation like REACH to structure the three phases of the study. It would help you frame the questions and likely identify potential gaps in information you didn't obtain (e.g., you don't know if there are demographic differences that remain between those who consent to CCR and those who don't as past research suggests that there are factors that potentially bias participation that would be an important gap to fill in the future)

- We have not been able to find the REACH framework (except in relation other fields, which do not seem relevant to this paper). As stated above, we realise there were problems with the general

readability and have attempted to address this.

We accept the reviewers' comments about the C4C register not being completely representative. It only represents those who choose to be informed about research. Nonetheless, there are 8000 people on the register (a significant proportion of the local clinical population), and 72% of those who are asked agree to join the register. Potentially, this makes it more representative than other methods of recruitment (such as clinician referral).

3) The manuscript was difficult to follow as all three phases had different targets. I think it might be helpful to restructure it into 3 different participants/materials/procedures/results sections if allowable. In addition, it felt as if you couldn't provide as much detail on each phase as a result of putting them all in one article. Consider increasing the length and providing more detail or dropping one piece for another article.

- We think that segmenting the design and results section in this way would make it more complex. However, we agree that the manuscript could be clearer. For this reason we have made the segmentation much more explicit throughout, so the study reads 'phase 1, phase 2a, phase 2b throughout the method and results.

4) The use of the "mystery shopper" was interesting although it was confusing to include it in the design paragraph when most people likely would not understand what you are talking about. Either drop it from there or move up your description of it would help reduce any misunderstanding about it.

- We have added a descriptive sentence about mystery shopper methods (and their place in observational research) into the design section to clarify this. We have also standardised the language elsewhere in the document, such as the 'Participants' section.

5) Questions related to the methods/results:

a. Can you quantify and describe in some ways the advertising/training that was conducted in the sites that the mystery shoppers went and asked clinicians about the CCR?

- We have added some information into the Introduction section, including information on the training, (page 4) and have reported any differences in the teams visited in the 'Results/Sample Characteristics' section (page 7 first paragraph).

b. Was there more than one site that they went to and were there differences in those sites on levels of marketing for CCR conducted?

- Please see 5a above. There were several different sites/teams visited by the shoppers, see 'Results/Sample Characteristics' section. For the record, we have also added to the 'Method/Participants' section to clarify that shoppers were recruited through a mixture of convenience/snowball and purposive sampling in order to get a spread of clinical teams. There were differences in the way C4C was promoted across different teams (Results/Sample Characteristics); three of those teams which were visited by shoppers had received a part-time member of staff to promote C4C in the team. However, only one shopper visited the team after such activity had taken place.

c. How do you know that the mystery shopper actually asked the clinician? How close in time between the appointment and the training did the mystery shopper go?

- We have added a sentence in the 'procedure' section stating how long after the training the shopper completed the task. We cannot confirm whether the mystery shopper actually asked the clinician. We have to trust the shopper in that regard.

d. You need to provide more details on the measures for all of the phases and how you exactly used them in the analysis.

- Copies of the measures are attached as supplementary files, as the editor requested. A sentence has been added to the manuscript (Method/Materials) which states "(copies are available under

Supplementary Information)”.

e. How was the qualitative data collected and rated etc.? Were audiotapes used? Did raters examine open-ended questions for themes? Was there a systematic process, please describe it?

- We have reworded the process in the ‘procedure’ section. The only qualitative data collected was in response to open-ended questions on the form. All interviews were structured (questionnaire-based). The audio recording in phase 2b was used to assist notetaking, rather than as the basis for a transcript. Given the small volume of qualitative statements, thematic analysis is most appropriate. Nonetheless, the quotes provide indicative insights and are included in the analysis. We have provided copies of the questionnaires we used (as an appendix).

f. 712 research opportunities to only 616 (sic.) patients seems odd.

- We don’t think this is odd, since some (a minority) participants took part in multiple research studies. We would expect this to happen.

g. Paragraph under phase 2a all of the numbers don’t make sense. Why are there so many research opportunities to only 616 (sic.) patients. That is a high number and if I’m interpreting it correctly those patients must have received a lot of phone calls. Please clarify as I don’t think I am interpreting it correctly. Why is it that only 30 agreed when there is a larger n of 412. More clarity would be helpful.

- I think this confusion was caused by the fact that we had quoted contextual figures in the results section, rather than the discussion section. The first sentence in this paragraph referred to the number of participants on the register itself, not the number of people we interviewed in our sample. For this reason, we have removed this sentence referring to “712 research opportunities for 616 patients” and put it into the discussion, where it helps frame the ‘wider context’ of the study.

h. Regarding the investigators, more information if you have it on their other recruitment methods and the rates of success may help better evaluate the CCR.

- We have added this data on other recruitment rates which investigators used. This has been added into the first paragraph under ‘Results\Phase 2b’. We did not collect information on relative success rates of these methods as we were not aiming to compare across different methods.

VERSION 2 – REVIEW

REVIEWER	Peter Watson Medical Research Council UK
REVIEW RETURNED	23-Mar-2016

GENERAL COMMENTS	<p>Facilitating mental health research for patients, clinicians and researchers; a mixed methods study bmjopen-2016-011127.R1</p> <p>Page 7 lines 38-39. I wonder how many of the five mystery shoppers who said that staff were going to report back to them with relevant information actually received this information?</p> <p>Page 8, line 5. 52 patients are interviewed of which 15 reported taking part in research prior to joining the register and 18 for the first time since joining the register. What about the remaining 19 (= 52 - (15+18))?</p> <p>Page 8, lines 19-25. 7 people are mentioned as disliking the register but only six reasons for not disliking it are given. This suggests that not all the dislikers gave a reason for not disliking being on the register. Is this correct? Do the 6 reasons quoted for not disliking being on the register come from 6 different people?</p>
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	<p>Page 8, line 36. 194 participants are recruited in 19 studies which would appear to give a mean of $194/19 = 10.21$ in each study rather than the mean of 11 a quoted. The SD quoted here may be worth checking as well.</p> <p>Page 9, Table 1. Presumably the higher the score (for C4C) the more useful it is regarded? These scores could be discussed in a sentence or two here. I am not sure, for example, if a score of 5.5 out of 10 for the valuable rating in Table 4 is exactly a glowing endorsement especially given the efforts that would be required to use the register on updating and linking records? I suspect a more meaningful table would have given scores on how valuable C4C was on particular studies and we could then see which studies C4C benefitted and therefore in what recruitment contexts as I suspect from the discussion and the lack of recruitment to some studies (line 39 of page 8) that the C4C is hit and miss rather than consistently useful across studies as implied by the use of a mean score in Table 1.</p> <p>Page 9, lines 26-28. Less than half (quoted as N=9) of the investigators (quoted as 17 on line 22 of page 7) are mentioned as agreeing C4C was faster than other recruitment rates. Presumably you mean MORE than half as $9 > 17-9 = 8$. You could, therefore, say "However, barely half of the investigators..."</p> <p>I am still not clear why there are such divisions in investigator perceptions of the success of the C4C as reported in lines 26-29 on page 9. From reading the discussion (page 10, lines 6-9) I would assume that investigators working on studies with less stringent eligibility criteria were the ones who found C4C more useful. On page 8 line 39, it states as many as 6 of the 17 investigators (quoted on line 22 of page 7) did not recruit any participants using the register which, given this high proportion of almost a third, could be referred to in the discussion to give a more complete view of its usefulness in practice.</p> <p>Page 10, line 44. The usefulness of the register is suggested as underestimated because of the efforts required by researchers. One could argue that any register can only be useful in practice if it is practical for people to use in a real world setting and so the use referred to in this line is a potential, theoretical usefulness rather than one that might (ever) be realised in a real world setting.</p> <p>I suspect that C4C can be useful in certain limited settings where there are less stringent recruitment criteria (as mentioned in the discussion although there are no figures to back this up reported in the paper) and therefore it would be more informative to see any sort of numerical detail of how unstringent a recruitment setting needs to be to get a feel for when C4C can work effectively as there are clearly situations where it has no effect on recruitment at all and people may well not want to put the effort in to adopting this system for no, or little, reward.</p>
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REVIEWER	Jennifer Funderburk VA Center for Integrated Healthcare, USA
REVIEW RETURNED	12-Apr-2016

<p>GENERAL COMMENTS</p>	<p>This is a second submission of an article and I applaud the authors as they were very responsive to the reviewers and editorial requests. Overall, the manuscript is much clearer and easier to read. However, I still feel there are additional changes that can be made to improve the manuscript.</p> <p>1) One area the manuscript could be developed more is in the discussion section presenting a more balanced view of the C4C. Reviewing the difference between using a C4C register with its strengths and weaknesses as opposed to other methods that currently exist would be useful and how it complements and adds to other approaches would be good. The authors seem to heavily focus on the positive data, neglecting additional discussion of some of the potential patient barriers as well as the concern I would have which is a health system only allowing researchers to use this one method and eliminate other recruitment processes.</p> <p>2) Another area that would help audience members who may be considering developing a C4C within their own system is more information about the amount of effort that went into its creation. This doesn't have to be an involved discussion in the introduction, but some additional details in the introduction helping the readers understand: How much training occurred? What exactly was placed in the medical record to facilitate the C4C or was it in a separate system (i.e., was it one question that the provider checked a box)? Are patients asked at every visit? How does it exactly work basically?</p> <p>3) In addition, more specifics about those who agree to participate compared to those in the system would be helpful to identify the potential diversity of the program: What are the demographics of those who are agreeing to join and how do they compare to other studies conducted in the local area? What were recruitment rates in studies prior to the implementation of this registrar? And what was the typical recruitment process or some examples prior to this implementation?</p> <p>4) Another question that came up when I was contemplating the methods is if a majority of the clinicians asked by the mystery shopper were not directed to the C4C, then how are you getting people to enroll? What is actually happening? Are other members of the healthcare teams asking them and understand what C4C is even though the clinicians don't clearly understand?</p>
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VERSION 2 – AUTHOR RESPONSE

Reviewer 1 requests:

1. Page 7 lines 38-39. I wonder how many of the five mystery shoppers who said that staff were going to report back to them with relevant information actually received this information?

Unfortunately we do not know whether any of the clinicians actually fed back to shoppers at a later date, this information was not collected as shoppers were not followed up in the long term. We have added a sentence in the final paragraph of the document (under 'Strengths and Limitations').

2. Page 8, line 5. 52 patients are interviewed of which 15 reported taking part in research prior to joining the register and 18 for the first time since joining the register. What about the remaining 19 (= 52 - (15+18))?

Yes this is correct. We have added a sentence to clarify this in the appropriate place in the 'results' section.

3. Page 8, lines 19-25. 7 people are mentioned as disliking the register but only six reasons for not disliking it are given. This suggests that not all the dislikers gave a reason for not disliking being on the register. Is this correct? Do the 6 reasons quoted for not disliking being on the register come from 6 different people?

There was one missing, we have now added. We have also rearranged this paragraph to show the numbers of people making each comment (which adds up to seven; one person per comment).

4. Page 8, line 36. 194 participants are recruited in 19 studies which would appear to give a mean of $194/19 = 10.21$ in each study rather than the mean of 11 a quoted. The SD quoted here may be worth checking as well.

Correct, the mean and SD have been amended accordingly.

5. Page 9, Table 1. Presumably the higher the score (for C4C) the more useful it is regarded? Yes, we have added a sentence to explain. These scores could be discussed in a sentence or two here. I am not sure, for example, if a score of 5.5 out of 10 for the valuable rating in Table 4 is exactly a glowing endorsement especially given the efforts that would be required to use the register on updating and linking records? I suspect a more meaningful table would have given scores on how valuable C4C was on particular studies and we could then see which studies C4C benefited and therefore in what recruitment contexts as I suspect from the discussion and the lack of recruitment to some studies (line 39 of page 8) that the C4C is hit and miss rather than consistently useful across studies as implied by the use of a mean score in Table 1.

We partially agree and have made amendments. Rather than presenting individual scores for each study, we have devised three categories based upon whether studies recruited participants or did not recruit. The three categories are 'recruited 10 or more participants', 'recruited 1-9 participants' and 'did not recruit any participants'. A sentence describing the results in the table has been added to the results paragraph above the table, as suggested. The sample is too small to run interpretative statistics, but it can give an indication of the relative usefulness in relation to recruitment.

6. Page 9, lines 26-28. Less than half (quoted as N=9) of the investigators (quoted as 17 on line 22 of page 7) are mentioned as agreeing C4C was faster than other recruitment rates. Presumably you mean MORE than half as $9 > 17-9 = 8$. You could, therefore, say "However, barely half of the investigators..."

Actually, it is half (9 out of 18). This has been amended in the text.

There was a bit of confusion in the previous version of the document due to there being 18 investigators and 19 studies. We have clarified this and updated the numbers accordingly in the final paragraph under 'Results/Sample Characteristics'. This point has also been amended in the Abstract,

7. I am still not clear why there are such divisions in investigator perceptions of the success of the C4C as reported in lines 26-29 on page 9. From reading the discussion (page 10, lines 6-9) I would assume that investigators working on studies with less stringent eligibility criteria were the ones who found C4C more useful. On page 8 line 39, it states as many as 6 of the 17 investigators (quoted on line 22 of page 7) did not recruit any participants using the register which, given this high proportion of almost a third, could be referred to in the discussion to give a more complete view of its usefulness in practice.

Please see our answer to comment #5 above. We have improved Table 1 and to show perceived usefulness by recruitment outcome. As you can see from these results, investigators who recruited no

participants from C4C did not rate it as being useful or valuable. However, they still seemed to see how the system could be useful in future. The results suggest that they would be likely to use the system again in future. We have amended the fourth paragraph of the discussion section to reflect these findings.

8. Page 10, line 44. The usefulness of the register is suggested as underestimated because of the efforts required by researchers. One could argue that any register can only be useful in practice if it is practical for people to use in a real world setting and so the use referred to in this line is a potential, theoretical usefulness rather than one that might (ever) be realised in a real world setting.

OK, we have deleted the final sentence of the discussion section.

9. I suspect that C4C can be useful in certain limited settings where there are less stringent recruitment criteria (as mentioned in the discussion although there are no figures to back this up reported in the paper) and therefore it would be more informative to see any sort of numerical detail of how unstringent a recruitment setting needs to be to get a feel for when C4C can work effectively as there are clearly situations where it has no effect on recruitment at all and people may well not want to put the effort in to adopting this system for no, or little, reward.

We've alluded to the fact that investigators find C4C deferentially useful depending upon their experience with it. The fourth paragraph of the discussion now mentions this, and the last sentence of this paragraph refers to the fact that investigators might like to think about their own context before using C4C.

Reviewer 2 requests:

1. One area the manuscript could be developed more is in the discussion section presenting a more balanced view of the C4C. Reviewing the difference between using a C4C register with its strengths and weaknesses as opposed to other methods that currently exist would be useful and how it complements and adds to other approaches would be good. The authors seem to heavily focus on the positive data, neglecting additional discussion of some of the potential patient barriers as well as the concern I would have which is a health system only allowing researchers to use this one method and eliminate other recruitment processes.

C4C is designed to work alongside other recruitment methods. It was not designed to be a sole/exclusive system. As we found, most investigators were using alongside other recruitment methods. We have deleted a few words from the discussion which may have led to an assumption that C4C would subsume other recruitment methods.

In response to the comments of Reviewer #1, we have added to the analysis by looking specifically at those studies which did not manage to recruit from C4C. In light of this, we have edited the fourth paragraph of the 'Discussion' section. This addition shows that C4C is not always useful to research investigators. However, even when it is not useful investigators still see that it might be useful in future.

2. Another area that would help audience members who may be considering developing a C4C within their own system is more information about the amount of effort that went into its creation. This doesn't have to be an involved discussion in the introduction, but some additional details in the introduction helping the readers understand: How much training occurred? What exactly was placed in the medical record to facilitate the C4C or was it in a separate system (i.e., was it one question that the provider checked a box?)? Are patients asked at every visit? How does it exactly work basically?

Information about the creation of C4C is listed in the introduction, with reference to three papers (references 5, 6, 7). These papers explain the process of setting up a C4C register and providing training (with patient/service user involvement). We have made this connection to previous papers more explicit in the 'introduction' here; we have reorganised the second paragraph, and re-referenced the key paper on technical/procedural development. The mechanics behind C4C are complex, and we feel that it is better to refer to this elsewhere rather than attempting to explain them in this paper.

3. In addition, more specifics about those who agree to participate compared to those in the system would be helpful to identify the potential diversity of the program: What are the demographics of those who are agreeing to join and how do they compare to other studies conducted in the local area? What were recruitment rates in studies prior to the implementation of this registrar? And what was the typical recruitment process or some examples prior to this implementation?

To indicate the diversity of the programme we have added recruitment and demographic statistics into the 'introduction' section (final paragraph). We have added comparable information in the first paragraph of the discussion section to show the demographics of individuals who were actually recruited through this process. We don't have demographic information of those who did not take part in studies.

The demographic information we have comes from an anonymous electronic patient health record. The record does not store data on research participation unless they have come through the C4C system. Therefore we cannot access similar data for other studies in the local area.

4. Another question that came up when I was contemplating the methods is if a majority of the clinicians asked by the mystery shopper were not directed to the C4C, then how are you getting people to enroll? What is actually happening? Are other members of the healthcare teams asking them and understand what C4C is even though the clinicians don't clearly understand?

Some clinicians/teams are enrolling lots of people, others are enrolling less. It varies across teams. The Trust is large so we would expect quite a lot of variation across different clinical teams. Staff turnover is high, which also increases variability (although C4C is on the induction programme for all staff). Furthermore, staff may not remember about C4C (have added a sentence in the discussion to emphasise this problem). This is why we think it is important to integrate C4C into clinicians' daily lives, by providing pop-ups on their clinical record system whenever they see patients who may be suitable for a particular study. This itself is a technical/logistical challenge. We describe this potential solution in the 'Discussion' section.

To clarify, the dedicated C4C team (described in the introduction, paragraph 2) does also directly enrol patients within the clinical teams; we have added a few words into the Introduction about this (paragraph 2).

VERSION 3 – REVIEW

REVIEWER	Peter Watson Medical Research Council UK
REVIEW RETURNED	25-May-2016

GENERAL COMMENTS	<p>Facilitating mental health research for patients, clinicians and researchers; a mixed methods study. bmjopen-2016-011127.R2</p> <p>The investigator participants and studies on page 7 have totals which are now correctly broken down with the percentages removed from the results on pages 7 and 8 making the results much clearer which was the main concern.</p>
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	I might ask how many of the 27 (page 8, line 9) who had taken part in a study since being put on the research register would have done so if they had not been on the register. I suspect given 18 participated for the first time in a study since joining the register (abstract page 3, line 32) the register is helping to boost recruitment on some studies but it is clear more help is needed to make it effective such as providing clinicians with updates on local studies as is suggested.
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REVIEWER	Jennifer S. Funderburk VA Center for Integrated Healthcare
REVIEW RETURNED	13-Jun-2016

GENERAL COMMENTS	The authors have revised the manuscript based on the reviewers comments and I think this has strengthened the manuscript overall. My only remaining suggestion is related to the authors statement that this method may be useful in certain circumstances to help improve recruitment. If the authors have the data to describe the types of research studies/eligibility criteria (e.g., clinical trials, studies focused on substance use, studies focused on individuals with specific diagnoses) that were more likely to have used this recruitment method versus those who didn't to present this information to complement the self-report findings you present from the investigators. This would also allow you to help make recommendations on when this method may be the most valuable to consider as an investigator.
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VERSION 3 – AUTHOR RESPONSE

Reviewer #1 comment:

I might ask how many of the 27 (page 8, line 9) who had taken part in a study since being put on the research register would have done so if they had not been on the register. I suspect given 18 participated for the first time in a study since joining the register (abstract page 3, line 32) the register is helping to boost recruitment on some studies but it is clear more help is needed to make it effective such as providing clinicians with updates on local studies as is suggested.

Our response:

We have no way of knowing how many of the 27 would have taken part in a study if they were not on the register. We agree with the reviewer's comment that C4C is improving recruitment for some studies but less with others. This is similar to the comment made by Reviewer #2 below.

Reviewer #2 comment:

My only remaining suggestion is related to the authors' statement that this method may be useful in certain circumstances to help improve recruitment. If the authors have the data to describe the types of research studies/eligibility criteria (e.g., clinical trials, studies focused on substance use, studies focused on individuals with specific diagnoses) that were more likely to have used this recruitment method versus those who didn't to present this information to complement the self-report findings you present from the investigators. This would also allow you to help make recommendations on when this method may be the most valuable to consider as an investigator.

Our response:

We have added some extra detail on those three studies which were most successful at recruiting.

This shows the reader that recruitment can be done in a variety of different populations using this method. With the data we have, we feel that it would be difficult to compare test these variables against recruitment success. This extra contextual information has been added to the second paragraph of the section entitled 'Results/Phase 2b'