PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	What is the impact of research champions on integrating research in mental health clinical practice? A quasi experimental study in South London, UK.
AUTHORS	Oduola, Sherifat; Wykes, Til; Robotham, Dan; Craig, Thomas

VERSION 1 – REVIEW

REVIEWER	Felicity Callard Durham University, United Kingdom I am Chair of the Oversight Committee for the clinical research database that the authors discuss in their paper -- this could be seen as a competing interest, since I have an interest in disseminating research employing this database. This committee gave approval for the research discussed in the paper to go ahead. I have had no interaction with any of the authors about their paper during the conception or writing of their paper.
REVIEW RETURNED	03-May-2017

GENERAL COMMENTS	I am primarily a qualitative researcher. While I have of course assessed the quantitative data, you should ensure that the other reviewer(s) have done a more careful checking of this element of the paper to ensure it is robust.

REVIEWER	Jutta Bleidorn Institute for General Practice Medical School Hannover Germany
REVIEW RETURNED	17-May-2017

GENERAL COMMENTS	1)Please check again the research question at the end of introduction. It seems unclear, maybe some words are missing -?

REVIEWER	Paul Wallace University College London United Kingdom I am a former Specialty Cluster Lead fro the NIHR Clinical Research Network
REVIEW RETURNED	18-May-2017

GENERAL COMMENTS

GENERAL COMMENTS:

Generally this is a sound paper describing important research findings, but it needs quite a lot of attention to grammar and syntax.

There is a lack of clarity / consistency about the definition of the primary sampling unit – was it the borough or the mental health team?

More information is needed about how the RCs were recruited and subsequently supervised, as well as how they were allocated to the different intervention teams.

Critically we need more information about how c4c was recorded and by whom.

Some attention needs to be given to Figure 1 – the y axis should be labelled as percentage and the numbers in each group should appear in the title or the key. The inclusion of (p<0.001) is meaningless and should either be removed or properly annotated.

The conclusion that the effect is not sustained cannot be justified by the data which you have collected and therefore should be omitted.

SPECIFIC COMMENTS

1. Is the research question or study objective clearly defined?

The research question and objectives are clear, though the description in paragraph 2 page 2 is in need of editing.

2. Is the abstract accurate, balanced and complete?

The abstract is generally accurate balanced and complete, but the final paragraph of the conclusions is not justified by the research findings and should be omitted.

3. Is the study design appropriate to answer the research question?

The study design is generally appropriate, though some aspects need to be clarified (see below)

The introduction should make reference to the NIHR Clinical

Research Network, where employment if research staff/champions has been a feature since its inception in 2006.

4. Are the methods described sufficiently to allow the study to be repeated?

The methods are generally satisfactorily described but in places the writing lacks precision and/or clarity and is in need of revision (see below). The authors should re-write the section describing the intervention, making it clear how the RC s were recruited, how they were supervised and how their time was allocated between the intervention teams. Further information should be supplied about the level of commitment/support offered by each of the intervention teams (ie to costs, training, supervision etc).

5. Are research ethics (e.g. participant consent, ethics approval) addressed appropriately?

Yes

6. Are the outcomes clearly defined?

The authors should provide more information about c4c, the key outcome measure. This is clearly a measure of the numbers/proportions of eligible patients recorded as having given their agreement to be included on the register of patients willing to be approached for research participation. The authors should clarify how agreement was sough in the intervention and control teams, who recorded the c4c outcome, and whether it was recorded electronically or manually. Information about the reliability of this measure should be given separately from the reference to the paper by Callard et al.

7. If statistics are used are they appropriate and described fully?

I am not a statistician, but the statistics appear to me to be generally appropriate. However greater clarity is needed about the primary sampling unit which is currently unclear. Is it the borough or the mental health team? It would appear from the results setting out 10 intervention sites and 5 control sites that it was the teams, but this needs to be clarified.

8. Are the references up-to-date and appropriate?

Yes

9. Do the results address the research question or objective?

In general the results address the research question. However additional information should be provided about how many patients (if any) were discharged from the control sites.

10. Are they presented clearly?

Yes, though I suggest some changes to Figure 1 (see below)

11. Are the discussion and conclusions justified by the results

In general the discussions and conclusions are justified. However, the second para is not justified – the lack of difference in c4c recruitment does not reflect challenges to recruitment as stated. Rather it suggests that there were no substantial differences in this activity between the intervention and control units prior to the recruitment of the RCs. The last paragraph of the main findings section suggests that the study findings indicate that RC roles need to be sustained over time. While this intuitively makes sense, there is insufficient evidence from the study to justify this conclusion.

12. Are the study limitations discussed adequately?

The strengths and limitations of the study are generally well discussed. However it would be helpful if the authors could include a critical appraisal of the principal outcome measure (see below)

13. Is the supplementary reporting complete (e.g. trial registration; funding details; CONSORT, STROBE or PRISMA checklist)?

None needed

14. To the best of your knowledge is the paper free from concerns over publication ethics (e.g. plagiarism, redundant publication, undeclared conflicts of interest)?

Yes

15. Is the standard of written English acceptable for publication?

The standard of English is occasionally unsatisfactory and the paper would benefit from careful review and amendment to improve both syntax and clarity. Eg: “ In this study and as demonstrated by Callard, individuals were not recruited to research studies but a research register so that researchers can approach them and invite them to research studies"

VERSION 1 – AUTHOR RESPONSE

1. Please revise your title to state the research question, study design, and setting (location).
We have changed the title to reflect our research question

2. Please ensure the reference section is fully up to date with the relevant literature.
We have included additional references and have updated the reference list

Reviewer 2 request
1. Please check again the research question at the end of introduction. It seems unclear; maybe some words are missing -?
We have rephrased the research question for clarity

Reviewer 3 request
1. The research question and objectives are clear, though the description in paragraph 2 page 2 is in need of editing.
As above (Reviewer 2)

2. The abstract is generally accurate balanced and complete, but the final paragraph of the conclusions is not justified by the research findings and should be omitted.
We have omitted the referenced paragraph as recommended.

3. The study design is generally appropriate, though some aspects need to be clarified (see below). The introduction should make reference to the NIHR Clinical Research Network, where employment if research staff/champions has been a feature since its inception in 2006.
We have acknowledged and included the NIHR Clinical Research Network in our reference list

4. The methods are generally satisfactorily described but in places the writing lacks precision and/or clarity and is in need of revision (see below). The authors should re-write the section describing the intervention, making it clear how the RC s were recruited, how they were supervised and how their time was allocated between the intervention teams. Further information should be supplied about the level of commitment/support offered by each of the intervention teams (ie to costs, training, supervision etc).
We have reorganised the order of the intervention section. This now states how research champions were recruited, allocated to teams and the supervision arrangements that were in place for them. Information on training and cost is also included.

5. The authors should provide more information about c4c, the key outcome measure. This is clearly a measure of the numbers/proportions of eligible patients recorded as having given their agreement to be included on the register of patients willing to be approached for research participation. The authors should clarify how agreement was sough in the intervention and control teams, who recorded the c4c outcome, and whether it was recorded electronically or manually. Information about the reliability of this measure should be given separately from the reference to the paper by Callard et al.
We have clarified who sought patient consent in both the intervention (research champion and clinicians) and comparison group (clinicians). Responses were recorded electronically. We have also referenced other previous studies that have used C4C as outcome measure to justify its reliability.

6. I am not a statistician, but the statistics appear to me to be generally appropriate. However greater clarity is needed about the primary sampling unit which is currently unclear. Is it the borough or the

mental health team? It would appear from the results setting out 10 intervention sites and 5 control sites that it was the teams, but this needs to be clarified.
We have clarified that our sampling unit was the participating teams

7. In general the results address the research question. However additional information should be provided about how many patients (if any) were discharged from the control sites.
We have clarified that there were no patients discharged from the comparison group during the study period.

8. Yes, though I suggest some changes to Figure 1
We have amended the figure as suggested.

9. In general the discussions and conclusions are justified. However, the second para is not justified – the lack of difference in c4c recruitment does not reflect challenges to recruitment as stated. Rather it suggests that there were no substantial differences in this activity between the intervention and control units prior to the recruitment of the RCs. The last paragraph of the main findings section suggests that the study findings indicate that RC roles need to be sustained over time. While this intuitively makes sense, there is insufficient evidence from the study to justify this conclusion.
We have rephrased the second paragraph of the main findings section. We have also removed the last paragraph of the conclusion as suggested.

10. The strengths and limitations of the study are generally well discussed. However it would be helpful if the authors could include a critical appraisal of the principal outcome measure (see below)
We have included an appraisal of how our outcome measure related to other studies in the field.

11. The standard of English is occasionally unsatisfactory and the paper would benefit from careful review and amendment to improve both syntax and clarity. Eg: “ In this study and as demonstrated by Callard, individuals were not recruited to research studies but a research register so that researchers can approach them and invite them to research studies"
We agree with the reviewer on clarity. We have clarified this by rephrasing the sentence. We believe it now reads better and clearer. We have also edited the whole paper addressing the grammatical and syntax issues

VERSION 2 – REVIEW

REVIEWER	Felicity Callard Durham University, United Kingdom As specified previously, I am Chair of the Oversight Committee for the database mentioned in this study (CRIS). However, I have had no contact with the authors in their development and write-up of this study.
REVIEW RETURNED	20-Jun-2017

GENERAL COMMENTS	I am somewhat baffled, since it does not appear that the details from my previous review reached the authors. I am satisfied with the changes that the authors have made in relation to the specific requests set out by the editor, but cannot see evidence of the authors responding to the comments/suggestions which I provided in my initial peer review. I am therefore repasting the entirety of my initial review review (though I acknowledge that some of these

issues might have been resolved in the new draft). There are certain suggestions that still need to be addressed.

Peer review of first submission (not R1 revised draft):

Investing in clinical staff to embed research in mental health clinical services: a quasi-experimental study

This is a clearly structured paper that provides an important demonstration of the value of embedding ‘research champions’ in services to support the process of research. I have requests for some revisions, which I lay out below:

- The syntax and punctuation can be patchy – and some of the logic within the paragraphs is therefore difficult to follow. Please ensure that the paper is edited carefully to ensure that each statement is substantiated and that sentence structure is tight.
- Introduction and conclusion – the paper is currently concisely written. While this brings benefits, it means that some of the issues are not adequately laid out. In the introduction, the sentence “However, the challenge is not solely related to the actual recruitment of participants as emerging evidence suggest that patients are willing to participate in research with the understanding that they have autonomy over their participation [5] and are reassured of confidentiality of their personal information” is hard to follow – what is the logic here? That more focus needs to be put on guaranteeing autonomy and confidentiality? Likewise, the sentence that starts “Ultimately, of course, the requirement to take and record consent” is difficult to follow – the list of what follows contains heterogeneous things that are difficult for the reader to parse. Also, one of the key difficulties that you don’t really mention is that there may be inequalities (age, gender, SES, ethnicity) in who gets to participate/who is more readily approached – with knock on effects in terms of the scientific robustness of findings, etc.
- Explanation of C4C – while it’s fine to refer to other publications, readers would find it helpful if there were slightly more information about how C4C works – particularly important to make explicit that the first approach has to be by a member of the clinical team (and I assume that therefore the research champions fall into this category).
- P.4 The wording could be made more explicit: ‘C4C signup’ actually means a yes OR a no in response to the C4C approach (rather than saying yes to being on the register). It is important – not least because of the outcome measure selected – to clarify that there are two distinct issues here (one: increasing rates of participant recruitment in studies (which is likely to be increased by maximizing those consenting to C4C); the other, increasing rates at which patients are asked to consent or not to be contacted (your outcome measure, which could theoretically mean that all those approached decline to C4C) – they don’t necessarily operate in lock-step with one another!).
- P.7 Why were gender and age captured but not ethnicity (especially given the existing literature indicating that there can be inequalities in participation in relation to ethnicity)? And do you have anything more to say about gender and age in the concluding sections of the paper; it’s odd to mention that these data were captured, but then not really to reflect on them further.
- Conclusions / Limitations – my main requirements relate to these sections. Crucially, I think you need to address three outstanding questions:

	o But what if much higher rates of approaching service users to C4C doesn't necessarily result in a much higher rate of those consenting? Would this matter for you? (Particularly in relation to how you set things up in the introduction – where you place emphasis on failure to recruit to target and on time.) Did you track the rates of yes/no consent/refuse? I don't think you necessarily need to report these, but you do need to defend whether it matters that you haven't presented them, and whether the specifics do matter to you. o Are the hugely increased rates of approach in the intervention groups in part due to how the research champions were being evaluated? In short, were they given (hard and/or soft) targets when recruited into this role? And did they know that their success/rate of recruitment would be used in research studies / potentially used to justify making these roles more likely in future? If both these were the case, this would be significant in explaining the high ORs that you report – since the RCs would have been highly incentivized in relation to maximizing numbers of C4C approaches. And you would certainly need to mention this in your concluding comments as regards what is essential when embedding RCs into a service. o Further reflection on who was being approached – you briefly address the question of those considered to be higher functioning (and you should cite Patel et al, here http://bmjopen.bmj.com/content/7/3/e013113.info), but don't consider other potential inequalities (around gender, ethnicity, age). Your study can't necessarily answer this, but these issues should be mentioned. References The reference list is currently not adequate. I list two references below that I know of off-hand (in addition to Patel et al), but you need to do a quick review to check you have caught major publications from the past few years. (The more recent references seem to derive from your own research group/contacts; there are undoubtedly other, key references that should be included). Overcoming barriers to recruiting ethnic minorities to mental health research: a typology of recruitment strategies, BMC Psychiatry https://bmcpsychiatry.biomedcentral.com/articles/10.1186/s12888-015-0484-z Barriers and opportunities for enhancing patient recruitment and retention in clinical research: findings from an interview study in an NHS academic health science centre, Health Research Policy & Systems https://health-policy-systems.biomedcentral.com/articles/10.1186/1478-4505-13-8

REVIEWER	Professor Paul Wallace University College London I am a former Specialty Cluster Lead with the NIHR Clinical Research Network
REVIEW RETURNED	23-Jun-2017

GENERAL COMMENTS	Accept

VERSION 2 – AUTHOR RESPONSE

Reviewer 1 request

But what if much higher rates of approaching service users to C4C doesn’t necessarily result in a much higher rate of those consenting? Would this matter for you? (Particularly in relation to how you set things up in the introduction – where you place emphasis on failure to recruit to target and on time.) Did you track the rates of yes/no consent/refuse? I don’t think you necessarily need to report these, but you do need to defend whether it matters that you haven’t presented them, and whether the specifics do matter to you.

Response: We did not track the rates of yes/no in this study, as it is beyond the scope of this paper to test how patients’ responses translate to actual participation. However, we had acknowledged in the Conclusion section that the increased number of patients approached for C4C may also increase their participation in clinical studies.

Are the hugely increased rates of approach in the intervention groups in part due to how the research champions were being evaluated? In short, were they given (hard and/or soft) targets when recruited into this role? And did they know that their success/rate of recruitment would be used in research studies / potentially used to justify making these roles more likely in future? If both these were the case, this would be significant in explaining the high ORs that you report – since the RCs would have been highly incentivized in relation to maximizing numbers of C4C approaches. And you would certainly need to mention this in your concluding comments as regards what is essential when embedding RCs into a service.

Response: It is plausible that having targets for the RCs may have increased the rates of approach, however the C4C implementation programme require all clinicians in the Trust to ask a proportion of their patients about C4C regardless of the intervention. We have added the following sentence “clinicians are required to ask a proportion of patients on their caseload per month, which is regularly reviewed and discussed in team meetings”, under ‘Recruitment as usual’ in the Methods section.

Further reflection on who was being approached – you briefly address the question of those considered to be higher functioning (and you should cite Patel et al, here https://emea01.safelinks.protection.outlook.com/?url=http%3A%2F%2Fbmjopen.bmj.com%2Fcontent%2F7%2F3%2Fe013113.info&data=01%7C01%7Csherifat.oduola%40kcl.ac.uk%7C0b38c0225a5348bd43f208d4c1ffedf0%7C8370cf1416f34c16b83c724071654356%7C0&sdata=H%2FJNxIobZuMdx53RsfIvD3orMVSokZDVQ5uQ9%2FcNYEg%3D&reserved=0), but don’t consider other potential inequalities (around gender, ethnicity, age). Your study can’t necessarily answer this, but these issues should be mentioned.

Response: We have cited Patel et al. 2017 as suggested. We have also tested the gender and age differences in the patient responses and there were no difference. We have added the following: ‘there were no differences in the number of asked C4C, by gender (men 31.3%; women 31.7% X2 = 0.05, df = 1 p=0.82); or by age (mean 46.6; 95% CI = 45.90 – 47.43, p = 0.24)’ to the Results section and this is further discussed in Discussion sections.

VERSION 3 – REVIEW

REVIEWER	Felicity Callard Durham University, United Kingdom I am the chair of the governance committee for the anonymised database referred to in this paper. This committee approved the application relating to the research reported in this paper. However, I have had no direct contact with any of the authors in developing their paper.
REVIEW RETURNED	16-Jul-2017

GENERAL COMMENTS	Thank you for addressing these requests for minor changes (which I think were for some reason left off the last collation of reviewer comments).