PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Effectiveness of one-to-one volunteer support for patients with psychosis – protocol of a randomised controlled trial
AUTHORS	Priebe, Stefan; Pavlickova, H; Eldridge, Sandra; Golden, Eoin; McCrone, Paul; Ockenden, Nick; Pistrang, Nancy; King, Michael

VERSION 1 - REVIEW

REVIEWER	Magenta Simmons Orygen, The National Centre of Excellence in Youth Mental Health (Australia) I have previously volunteered for a befriending program (for one year in 2004). I have no other competing interests to declare.
REVIEW RETURNED	03-Apr-2016

GENERAL COMMENTS	I have marked review checklist item 4 as a 'no' because the interview schedule has not been made available and would prevent the study from being replicated. This manuscript is a protocol for a randomised trial comparing a 'companion' (befriending) intervention with an active control condition for adults aged 18-65 who have been diagnosed with schizophrenia or related psychotic disorder. This is an important topic given the serious impairment to social functioning seen in those who have been diagnosed with a psychotic disorder. Befriending programs are well intentioned and hold promise to increase social activity for those experiencing social isolation, however they are variable in their approach and have not been well researched. This trial will be a welcome addition to the small yet important field. The manuscript is well written and presented in line with the SPIRIT guidelines (including an attached checklist). Some comments include: 1. Please reconsider the use of the term 'patient' to describe people, particularly when talking about them in general (rather in relation to their time spent when accessing services). If you choose to retain this term then I would recommend providing a context to justify this. For example, the scope of the literature that you are reviewing and the study that you are proposing is limited only to individuals who are currently accessing medical services. I understand it is a commonly used term however this doesn't make it any less problematic. 2. In the abstract and then again in the methods section when you describe the booklet given to both the intervention and control

	groups. You do not specify whether the activities included in the booklet are of a social nature (i.e. would they necessarily involve interactions with other people or could they be undertaken alone or with minimal social contact?). 3. The primary outcome is time spent engaging in social activities per day using a shortened version of the Time Use Survey (TUS). I can see that the original TUS includes activities such as 'time spent in chat rooms', however the way in which we engage with technology has since changed dramatically. It is not clear the degree to which this measure accounts for use of social media and whether or not this would be included as a social activity. Given that approximately two thirds of UK adults own a smartphone and that your sample includes adults as young as 18, some consideration of whether or not this should be included as time spent in social activity is warranted (and some note about this should be included in the manuscript). 4. You note that one limitation of the study is that "there may be different perspectives on what the most relevant outcomes of volunteer support are". You also note that you have undertaken a program of work on this issue so I am left wondering if you know what the different perspectives are. What were the perspectives were of volunteers, participants and coordinators of befriending programs that you have consulted with? Or was this topic not covered in earlier work? Detailing this with reference to previous work would provide a clearer rationale about the choice of primary outcome. 5. The outcomes you are measuring focus on time spent in social activity but don't account for quality of social interaction or satisfaction with social interaction. It is possible that as a result of time spent with volunteers, intervention participants will experience an increase in the enjoyment of social activities and capturing this may allow for a fuller understanding of the impact of the intervention. 6. Another factor to consider when measuring time spent in social activities is the degree to which the participants have initiated the contact or activities themselves. This may be an indicator not only of the effect of the intervention in terms of activation but also of the possible longer term impact of the intervention. 7. The inclusion/exclusion criteria include a large age range, potentially a large range of service use (and therefore time since onset of first episode of psychosis, or FEP, time spent receiving treatment and type of treatment received, including type of antipsychotic medication and related side effects and the degree to which psychological therapies have been focussed on social isolation) and do not exclude based on comorbidity. Age at onset of FEP, length and degree of social isolation and duration of untreated psychosis may also be relevant. Are you collecting these details along with the demographic information or including these elements in the qualitative interview schedule? Do you plan to control for any factors in your analyses? 8. For readers who may be unfamiliar with the area, it may be useful to include some brief information in the background about the difference between peer work and befriending/companionship. It may also be helpful to explain briefly why the term 'befriending' is contentious rather than just acknowledging it.

	9. One limitation of the design not addressed in the manuscript is the possibility of contamination from the intervention group participants to the active control group participants, as they will be seen at the same service. Aside from the possibility of intervention participants becoming more active in seeking out social contact from those around them, including other clients of the service they are attending, and also possibly promoting the benefits of their companion, it is also possible that the staff members of the service may become more focused on increasing social contact as a result of the study and their observations of clients in the intervention arm. Although care has been taken to try and minimise the chances of participants disclosing the group they have been allocated to research staff, it is not clear if the same consideration has not been made for disclosure to other clients and staff members at the service. 10. The description of the qualitative interviews is somewhat vague in the manuscript. It would be helpful if you could include some of the detail described in the supplementary file. 11. You also do not mention how the subset of 20 participants and 20 volunteers will be selected to participate in the qualitative interviews. Is this a random subset? How will you enable representativeness? Will you use purposive sampling? This may be beneficial given the issues raised in point 7 about the diverse sample of participants included in the proposed study. Further, it may be useful to ask the person matching intervention participants with volunteers to rate the degree to which they felt the match was suitable, and to also include some interview probes around this issue for participants and volunteers. 12. Although it is difficult to see a way around this, the attempts that you are making to reduce contact with the volunteer in the week prior to assessments being undertaken may have other unintended effects. It is possible that volunteers may increase contact in the lead up to week in which they are to have no contact and therefore intervention participants may feel satisfied with their level of social contact overall and take a break themselves that week. 13. On page 9 under the subtitle ‘Proposed sample size’ you base your power calculation on an ambition of at least doubling the time spent in social activities each day. Please provide some justification for this. 14. Although the results of each study have not been published as journal articles as far as I am aware, there is a befriending program in Australia (Rainbow Project) that has been evaluated by two separate students at Murdoch University and I include these here only because the results may be of interest to you (although I am unsure of their availability): a. "I wasn't expecting a happy person": identity management in arranged friendships between volunteers and people with "mental health" problems / Rachael Rebecca Dunn. http://prospero.murdoch.edu.au/search~S1?/cDUN+2003/cdun+2003/-3%2C-1%2C0%2CE/frameset&FF=cdun+2003&1%2C2%2C b. A qualitative evaluation of the experiences of persons involved in a small-scale befriending program for psychiatric service users / Thomas David McCarthy. http://prospero.murdoch.edu.au/search~S1?/Xbefriending&searchsc

	ope=1&SORT=D/Xbefriending&searchscope=1&SORT=D&SUBKEY=befriending/1%2C25%2C25%2CB/frameset&FF=Xbefriending&searchscope=1&SORT=D&2%2C2%2C

REVIEWER	Miguel Ruiz-Veguilla Hospital Universitario Virgen del Rocio
REVIEW RETURNED	26-Apr-2016

GENERAL COMMENTS	1. Is the question posed original, important and well defined? The authors have posed an interesting research question: The effectiveness and cost-effectiveness of a one-to-one volunteer support programme for patients with psychosis, referred to as a companion scheme to avoid the potentially misleading term 'befriending'. This issue has not been widely studied in schizophrenia, less still by RCT. 2 Are the methods appropriate and well described, and are sufficient details provided to allow others to evaluate and/or replicate the work? The RCT is well described. The main variables, like Intervention and psychopathology, are of interest. However, the authors did not explain one of the most important variables, the Intervention. In addition, the authors should include an Apathia scale. It would be interesting to see whether the change in socialisation is due a change in aphathia level or not 3. What are the strengths and weaknesses of the methods? The strong point is the method/RCT, which is very good, well designed. The weak points are a) What are they going to do about relapse of patients? What happens when patients relapse or are admitted to hospital? b) The explanation of the intervention. More information about the intervention is necessary. This information would increase the possibility of replicating the results. 6. The following data are required to improve the paper: • Information on the intervention (is it written?) • The authors should include an Apathia scale • More information about the intervention • Answer this question: what happens when a patient relapses?

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Magenta Simmons
Institution and Country: Orygen, The National Centre of Excellence in Youth Mental Health (Australia)
Competing Interests: I have previously volunteered for a befriending program (for one year in 2004). I

have no other competing interests to declare.

I have marked review checklist item 4 as a 'no' because the interview schedule has not been made available and would prevent the study from being replicated.

The qualitative interview schedule has not been decided yet.

This manuscript is a protocol for a randomised trial comparing a ‘companion’ (befriending) intervention with an active control condition for adults aged 18-65 who have been diagnosed with schizophrenia or related psychotic disorder.

This is an important topic given the serious impairment to social functioning seen in those who have been diagnosed with a psychotic disorder. Befriending programs are well intentioned and hold promise to increase social activity for those experiencing social isolation, however they are variable in their approach and have not been well researched. This trial will be a welcome addition to the small yet important field.

The manuscript is well written and presented in line with the SPIRIT guidelines (including an attached checklist). Some comments include:

1. Please reconsider the use of the term ‘patient’ to describe people, particularly when talking about them in general (rather in relation to their time spent when accessing services). If you choose to retain this term then I would recommend providing a context to justify this. For example, the scope of the literature that you are reviewing and the study that you are proposing is limited only to individuals who are currently accessing medical services. I understand it is a commonly used term however this doesn’t make it any less problematic.

We would like to argue for the use of ‘patient’ in the context of the current paper as the current work refers to individuals with psychosis in mental health setting who are referred to volunteering schemes by their caring clinicians. Therefore we believe that the use of the term ‘patient’ is appropriate and makes a clear reference to the target group.
2. In the abstract and then again in the methods section when you describe the booklet given to both the intervention and control groups. You do not specify whether the activities included in the booklet are of a social nature (i.e. would they necessarily involve interactions with other people or could they be undertaken alone or with minimal social contact?).

This has now been included.
More detail has been added to the methods section under Active Control Condition.

3. The primary outcome is time spent engaging in social activities per day using a shortened version of the Time Use Survey (TUS). I can see that the original TUS includes activities such as ‘time spent in chat rooms’, however the way in which we engage with technology has since changed dramatically. It is not clear the degree to which this measure accounts for use of social media and whether or not this would be included as a social activity. Given that approximately two thirds of UK adults own a smartphone and that your sample includes adults as young as 18, some consideration of whether or not this should be included as time spent in social activity is warranted (and some note about this should be included in the manuscript).

This trial has concentrated on a behavioural change excluding social media interaction as this area of research, particularly in individuals with psychosis, is so far not well established. The exclusion of items related to social media has been made explicit in the Methods under the Outcome section.
4. You note that one limitation of the study is that “there may be different perspectives on what the

most relevant outcomes of volunteer support are". You also note that you have undertaken a program of work on this issue so I am left wondering if you know what the different perspectives are. What were the perspectives were of volunteers, participants and coordinators of befriending programs that you have consulted with? Or was this topic not covered in earlier work? Detailing this with reference to previous work would provide a clearer rationale about the choice of primary outcome.

The notion of different perspectives comes from the existing literature. We carried out some work in this area on this topic however its findings are complex and beyond the scope of this paper.

5. The outcomes you are measuring focus on time spent in social activity but don't account for quality of social interaction or satisfaction with social interaction. It is possible that as a result of time spent with volunteers, intervention participants will experience an increase in the enjoyment of social activities and capturing this may allow for a fuller understanding of the impact of the intervention.

The primary outcome is behavioural, however, subjective evaluation has been captured by the subjective quality of life measure which includes items specifically asking about subjective evaluation of one's relationships.
6. Another factor to consider when measuring time spent in social activities is the degree to which the participants have initiated the contact or activities themselves. This may be an indicator not only of the effect of the intervention in terms of activation but also of the possible longer term impact of the intervention.

While a valid point, this is a complex assessment that goes beyond the scope of the trial.

7. The inclusion/exclusion criteria include a large age range, potentially a large range of service use (and
therefore time since onset of first episode of psychosis, or FEP, time spent receiving treatment and type of treatment received, including type of antipsychotic medication and related side effects and the degree to which psychological therapies have been focussed on social isolation) and do not exclude based on comorbidity. Age at onset of FEP, length and degree of social isolation and duration of untreated psychosis may also be relevant. Are you collecting these details along with the demographic information or including these elements in the qualitative interview schedule? Do you plan to control for any factors in your analyses?

We collect information on contact with care provider, medication, and the length of illness. The degree of social isolation is captured by the number of social contacts and engagement in social activities. We will use the length of illness for the subgroup analyses, as has been pre-specified within the statistical analyses plan.

8. For readers who may be unfamiliar with the area, it may be useful to include some brief information in the background about the difference between peer work and befriending/companionship. It may also be helpful to explain briefly why the term 'befriending' is contentious rather than just acknowledging it.

This has now been included in the introduction section.
9. One limitation of the design not addressed in the manuscript is the possibility of contamination from the intervention group participants to the active control group participants, as they will be seen at the same service. Aside from the possibility of intervention participants becoming more active in seeking out social contact from those around them, including other clients of the service they are attending, and also possibly promoting the benefits of their companion, it is also possible that the staff members of the service may become more focused on increasing social contact as a result of the study and their observations of clients in the intervention arm. Although care has been taken to try and minimise

the chances of participants disclosing the group they have been allocated to research staff, it is not clear if the same consideration has not been made for disclosure to other clients and staff members at the service.

Given that we recruited less than 10 patients randomised to the intervention and control condition in 1:1 ratio per clinical team, and there is no involvement of clinicians in the intervention, we expect there would be little potential for contamination. Therefore no additional measures to account for this have been taken.

10. The description of the qualitative interviews is somewhat vague in the manuscript. It would be helpful if you could include some of the detail described in the supplementary file.

The interview schedule has not been developed yet and is likely to be informed by further experience with the trial.

11. You also do not mention how the subset of 20 participants and 20 volunteers will be selected to participate in the qualitative interviews. Is this a random subset? How will you enable representativeness? Will you use purposive sampling? This may be beneficial given the issues raised in point 7 about the diverse sample of participants included in the proposed study. Further, it may be useful to ask the person matching intervention participants with volunteers to rate the degree to which they felt the match was suitable, and to also include some interview probes around this issue for participants and volunteers.

This has been added under the Qualitative data section.

12. Although it is difficult to see a way around this, the attempts that you are making to reduce contact with the volunteer in the week prior to assessments being undertaken may have other unintended effects. It is possible that volunteers may increase contact in the lead up to week in which they are to have no contact and therefore intervention participants may feel satisfied with their level of social contact overall and take a break themselves that week.

The procedure we employed entails postponing a meeting rather than having one earlier. However, even if patient and volunteer did meet twice prior to the assessment, there will be at least a week lag, which we suspect is long enough time to avoid any assessment bias.

13. On page 9 under the subtitle ‘Proposed sample size’ you base your power calculation on an ambition of at least doubling the time spent in social activities each day. Please provide some justification for this.

This is an exploratory trial – our aim was to include length of time that would have social relevance.

14. Although the results of each study have not been published as journal articles as far as I am aware, there is a befriending program in Australia (Rainbow Project) that has been evaluated by two separate students at Murdoch University and I include these here only because the results may be of interest to you (although I am unsure of their availability):

a. "I wasn't expecting a happy person": identity management in arranged friendships between volunteers and people with "mental health" problems / Rachael Rebecca Dunn.http://prospero.murdoch.edu.au/search~S1?/cDUN+2003/cdun+2003/-3%2C-1%2C0%2CE/frameset&FF=cdun+2003&1%2C2%2C

b. A qualitative evaluation of the experiences of persons involved in a small-scale befriending program for psychiatric service users / Thomas David McCarthy.http://prospero.murdoch.edu.au/search~S1?/Xbefriending&searchscope=1&SORT=D/Xbefriending&searchscope=1&SORT=D&SUBKEY=befriending/1%2C25%2C25%2CB/frameset&FF=Xbefriending&searchscope=1&SORT=D&2%2C2%2C

Thank you.

Reviewer: 2
Reviewer Name: Miguel Ruiz-Veguilla
Institution and Country: Hospital Universitario Virgen del Rocio, Spain
Competing Interests: Non conflict of interests

1. Is the question posed original, important and well defined?

The authors have posed an interesting research question: The effectiveness and cost-effectiveness of a one-to-one volunteer support programme for patients with psychosis, referred to as a companion scheme to avoid the potentially misleading term 'befriending'.
This issue has not been widely studied in schizophrenia, less still by RCT.

2 Are the methods appropriate and well described, and are sufficient details provided to allow others to evaluate and/or replicate the work?
The RCT is well described. The main variables, like Intervention and psychopathology, are of interest.
However, the authors did not explain one of the most important variables, the Intervention.
In addition, the authors should include an Apathia scale. It would be interesting to see whether the change in socialisation is due a change in aphathia level or not

The description of the intervention has been revisited.

We feel that the concept of apathy has been captured by the CAINS, which is the most comprehensive scale for negative symptoms.
3. What are the strengths and weaknesses of the methods?
The strong point is the method/RCT, which is very good, well designed.
The weak points are
a) What are they going to do about relapse of patients? What happens when patients relapse or are admitted to hospital?

Patients will be followed-up as long as they have capacity to complete the interviews.

b) The explanation of the intervention. More information about the intervention is necessary. This information would increase the possibility of replicating the results.

The Description of the intervention has been revisited and amended within the Experimental intervention section.
6. The following data are required to improve the paper:
• Information on the intervention (is it written?)
• The authors should include an Apathia scale
• More information about the intervention
• Answer this question: what happens when a patient relapses?

Please see above.

VERSION 2 – REVIEW

REVIEWER	Miguel Ruiz Veguilla HOSPITAL VIRGEN DEL ROCIO.UGC-SALUD MENTAL SPAIN
REVIEW RETURNED	08-Jun-2016

GENERAL COMMENTS	In the revised version of this manuscript,the authors have suitably addressed all the queries raised by this referee.