PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Enhancing peer-support experience for patients discharged from acute psychiatric care: Protocol for a randomized controlled pilot trial
AUTHORS	Urichuk, Liana; Hrabok, Marianne; Hay, Katherine; Spurvey, Pamela; Sosdjan, Daniella; Knox, Michelle; Fu, Allen; Surood, Shireen; Brown, Robert; Coulombe, Jeff; Kelland, Jill; Rittenbach, Katherine; Snaterse, Mark; Abba-Aji, Adam; Li, Xin-Min; Chue, Pierre; Greenshaw, Andrew; Agyapong , Vincent

VERSION 1 – REVIEW

REVIEWER	Mark Salzer Temple University (Philadelphia; USA)
REVIEW RETURNED	03-Mar-2018

GENERAL COMMENTS	Much of the research on peer support interventions is undermined by the lack of structured interactions. People are simply asked to "provide peer support." More detail is needed about what exactly the peers are going to do in their face-to-face visits and exactly what the nature of the text messages will be. In its current state these interventions cannot be replicated. There is some attention paid to providing incentives to peers and they are planning to gather data from peers, but their approach to addressing these questions is not well described. Data analysis pertaining to the data from the peers and other mental health professionals is not described.

REVIEWER	Steve Gillard St George's, University of London, United Kingdom
REVIEW RETURNED	13-Mar-2018

GENERAL COMMENTS	This is a timely and potentially important piece of work which could complement other similar trials taking place internationally. While a great deal of thought has gone into aspects of the design, there are some issues with the design that are problematic and require the protocol to be re-framed somewhat, as discussed below. A good, concise overview of the literature and rationale for the study is given. There appear to be two discrete interventions taking place, EPSS, and interactive and daily text messaging. This is a four arm trial which will enable the effects of the two interventions to be considered separately and together, statistically, but this will make delivery of the trial complicated and will make it extremely hard to avoid contamination; a) there needs to be some way of capturing and considering in the analysis the incidence of peer workers in the

	EPSS only arm contacting participants by text (even where this contact is for purposes of confirming appointments only rather than of an explicitly interactive nature – e.g. peer workers will find it hard not to reply to texts where support is clearly requested), and b) EPSS is described as 'incorporating' the text messaging, so the challenges to peer workers of delivering EPSS minus text messaging (i.e. some parts of the manual but not other parts) need to be considered. In addition, phone calls are mentioned as part of EPSS and it is not made clear if peer workers can telephone participants in the EPSS only arm (perhaps daily) while not sending text messages. There appears to be a third intervention at work here, which is an incentivisation approach for peer workers. First of all this raises the ethical question of whether or not peer workers are adequately paid for their work, and second it raises a methodological question of whether or not it is appropriate for there to be an intervention designed to effect delivery of the intervention in the same study that is testing the effect of the intervention. Clarity is also required on whether or not all participants in the study are offered membership of EPSS. If participants randomised not to receive EPSS are made members of EPSS then there is a contamination issue; if they are not there is a methodological issue as different arms of the trial will be differently incentivised which will inevitably lead to differences between groups at follow up. As such the study appears over complicated and it seems doubtful that observed effects can be adequately disaggregated and interpreted. The aims of the study are given as evaluating the effectiveness of EPSS (p5). However on page 7 the study is referred to as a pilot study and no primary outcome is nominated or power calculation given. The hypotheses tests around the different arms of the study are therefore inappropriate as there is no way of adequately addressing them, notwithstanding the over-complexity of the design as discussed above. To note, the abstract similarly incorrectly states that the study will evaluate effectiveness and should be re-written to reflect the proposed changes below. 'Effectiveness' of peer worker (table 3 page 9) seems to refer to process data (e.g. number of contacts, texts etc), data that it is very important to collect in all arms as noted above in order to try and assess contamination. Measures put in place around blinding are commendable. Given that this is a pilot study it might be opportune to test whether or not it might be practicable to put additional measures in place to further protect the blind (e.g. primary outcome self-completed by participant and placed in envelope at start of follow-up interview). Given the points raised above the protocol should be explicitly re-framed as a either a feasibility trial, perhaps with an exploratory component around outcomes, and have a stated set of aims that is appropriate to the study design (rather than hypothesis tests and aims that cannot be addressed. There need to be clear feasibility questions around rate of recruitment as completing screening, consent, data collection, randomisation and commencing the intervention within one week of discharge is incredibly hard to do and recruitment rates will impact on the scope and feasibility of any subsequent definitive trial. There also need to be questions and a clear methodological approach for testing the feasibility of delivering a four arm trial without contamination because without this publication of a subsequent trial might be difficult and will compromise the quality that the team are clearly trying to achieve.

	The intervention(s) should be simplified too; all peer workers should be properly incentivised to do their work and this should not be described as an active ingredient of the intervention. Instead there should be a feasibility aim around successfully retaining peer workers. As noted above a set of aims around protecting blind assessment would be important and beneficial, as well as a question around completeness of follow-up questions. Qualitative work with both participants and peer workers might usefully be included and the methods described to help address feasibility questions. As implicit in the paper, specific questions around effect sizes, selection of primary outcome and power calculation for future study should be made an explicit aim of the study.

VERSION 1 – AUTHOR RESPONSE

Reviewers' Comments to Author:

Reviewer: 1
Reviewer Name: Mark Salzer
Institution and Country: Temple University (Philadelphia; USA)
Competing Interests: None Declared

Much of the research on peer support interventions is undermined by the lack of structured interactions. People are simply asked to "provide peer support." More detail is needed about what exactly the peers are going to do in their face-to-face visits and exactly what the nature of the text messages will be. In its current state these interventions cannot be replicated.
As suggested by the reviewer, the nature of the interaction between the peer support workers and the patients have been described. We have also described the content of the supportive text messages. Please see Page 7, Lines7-16.

There is some attention paid to providing incentives to peers and they are planning to gather data from peers, but their approach to addressing these questions is not well described.

We thank the reviewer for this observation. As suggested we have now described more clearly how we plan to evaluate the effectiveness of the incentives to be provided to peer support workers participating in the study. Please see Page 10, Lines 1-11 and see Table 3.

Data analysis pertaining to the data from the peers and other mental health professionals is not described.

As suggested we have now described the data analysis plan more clearly with respect to for the peers and mental health professionals. Please see Page 10, Lines 13-25.

Reviewer: 2
Reviewer Name: Steve Gillard
Institution and Country: St George's, University of London, United Kingdom
Competing Interests: None declared

This is a timely and potentially important piece of work which could complement other similar trials taking place internationally.
We thank the reviewer for acknowledging the timeliness and potential importance of our proposed study
While a great deal of thought has gone into aspects of the design, there are some issues with the design that are problematic and require the protocol to be re-framed somewhat, as discussed below.

A good, concise overview of the literature and rationale for the study is given.
There appear to be two discrete interventions taking place, EPSS, and interactive and daily text messaging. This is a four arm trial which will enable the effects of the two interventions to be considered separately and together, statistically, but this will make delivery of the trial complicated and will make it extremely hard to avoid contamination; a) there needs to be some way of capturing and considering in the analysis the incidence of peer workers in the EPSS only arm contacting participants by text (even where this contact is for purposes of confirming appointments only rather than of an explicitly interactive nature – e.g. peer workers will find it hard not to reply to texts where support is clearly requested), and b) EPSS is described as 'incorporating' the text messaging, so the challenges to peer workers of delivering EPSS minus text messaging (i.e. some parts of the manual but not other parts) need to be considered.
We thank the reviewer for this observation. We will like to clarify that the peer support workers participating in the EPSS are not precluded from interacting with patients via text messages. This interaction is separate from the automated daily supportive text messages which is delivered to patients via an online application. There is therefore no possibility for contamination. We have clarified this in the proposal. Please see Page 7, Lines 17-39.

In addition, phone calls are mentioned as part of EPSS and it is not made clear if peer workers can telephone participants in the EPSS only arm (perhaps daily) while not sending text messages.
We thank the reviewer for this observation. We have now clarified that patients inthe EPSS arm of the study will be offered opportunity for interactive text messages and phone calls to patients. Please see page 7 , Lines 21-25

There appears to be a third intervention at work here, which is an incentivisation approach for peer workers. First of all this raises the ethical question of whether or not peer workers are adequately paid for their work, and second it raises a methodological question of whether or not it is appropriate for there to be an intervention designed to effect delivery of the intervention in the same study that is testing the effect of the intervention.
The study is not investigating the pay and remuneration offered peer support workers but we acknowledge that it is an important factor contributing to attrition of peer workers globally. One aspect of the goals of the study is to assess the impact of the incentives on the attrition rates for peer support workers. We therefore believe that our study methods are sound.

Clarity is also required on whether or not all participants in the study are offered membership of EPSS.
We have provided this clarification. Please see Page 7, Lines 40-43
If participants randomised not to receive EPSS are made members of EPSS then there is a contamination issue; if they are not there is a methodological issue as different arms of the trial will be differently incentivised which will inevitably lead to differences between groups at follow up. As such the study appears over complicated and it seems doubtful that observed effects can be adequately disaggregated and interpreted.
We thank the reviewer for this observation. We respectfully disagree with the reviewer that there are methodological issues with not offering affiliate membership to patients enrolled in the supportive text message only and control arms of the study. This is because enrolment on the EPSS as affiliate

members is part of the peer support intervention designed into the EPSS. Please see Page 4, Lines 13-19 and Lines 32-34.

The aims of the study are given as evaluating the effectiveness of EPSS (p5). However on page 7 the study is referred to as a pilot study and no primary outcome is nominated or power calculation given.

We have nominated two primary outcomes (Please see Page 5, Lines 6-13 and Page 9 Lines 10 &11) and provided reason for not providing power and sample size calculations for this pilot study. Please see Page 7, Lines 45-49.

The hypotheses tests around the different arms of the study are therefore inappropriate as there is no way of adequately addressing them, notwithstanding the over-complexity of the design as discussed above.

We have clarified that the hypothesis if for the full study and not the pilot study. Please see Page 5, Lines 30. We have also clarified that the data from the pilot study will be used for effect and sample size estimation which will guide a future highly powered study. Please see Page 10, Lines 14-17. To note, the abstract similarly incorrectly states that the study will evaluate effectiveness and should be re-written to reflect the proposed changes below.

'Effectiveness' of peer worker (table 3 page 9) seems to refer to process data (e.g. number of contacts, texts etc), data that it is very important to collect in all arms as noted above in order to try and assess contamination.

As indicated above, there is no possibility for contamination as the phone numbers of patients in the peer support only arm of the study will not be entered in the online application designed to deliver daily supportive text messages. Furthermore, interactive text messages between peer workers and patients are considered as part of the services that peer workers offer.

Measures put in place around blinding are commendable. Given that this is a pilot study it might be opportune to test whether or not it might be practicable to put additional measures in place to further protect the blind (e.g. primary outcome self-completed by participant and placed in envelope at start of follow-up interview).

We thank the reviewer for the suggestion. However, as we anticipate most assessments to be over the phone, it may not be practical to incorporate this approach. Please see Page 10, Lines 1-5.

Given the points raised above the protocol should be explicitly re-framed as a either a feasibility trial, perhaps with an exploratory component around outcomes, and have a stated set of aims that is appropriate to the study design (rather than hypothesis tests and aims that cannot be addressed. There need to be clear feasibility questions around rate of recruitment as completing screening, consent, data collection, randomisation and commencing the intervention within one week of discharge is incredibly hard to do and recruitment rates will impact on the scope and feasibility of any subsequent definitive trial.

We thank the reviewer for the suggestion. As suggested by the reviewer, we have reframed the aims and objectives of the study. We have also clarified that our hypothesis is for the full study and added supporting details in the statistical analysis section. Page 5, Lines 2-34.

There also need to be questions and a clear methodological approach for testing the feasibility of delivering a four arm trial without contamination because without this publication of a subsequent trial might be difficult and will compromise the quality that the team are clearly trying to achieve.

The intervention(s) should be simplified too; all peer workers should be properly incentivised to do their work and this should not be described as an active ingredient of the intervention. Instead there should be a feasibility aim around successfully retaining peer workers.

We thank the reviewer for these suggestions. As stated previously, we do not anticipate contamination as interactive text messages between peer workers and patients are part of the EPSS and the automated daily supportive text messages intervention require that patients' phone numbers are entered into the program data base. Please see Page 7, Lines 17-39.
Furthermore, one of our goals is to compare attrition rates for peer workers with historical attrition rates for peer workers in the zone in the year prior to implementing EPSS. Please see Page 10, Lines 13-25.

As noted above a set of aims around protecting blind assessment would be important and beneficial, as well as a question around completeness of follow-up questions.
We have incorporated the reviewer's suggestions into the study aims and objectives. Please see Page 5, Lines 18-20, Page9, Lines 13-16 and Page10 Lines1-11.

Qualitative work with both participants and peer workers might usefully be included and the methods described to help address feasibility questions.
We thank the reviewer for the suggestion. Our study includes limited qualitative work involving peer workers and mental health therapist. As suggested by the reviewer we have included focus group workshop for a cross section of patients in the four arms of the study to enable us obtain qualitative data from patients. Please see Page 10, Lines 1-11.

As implicit in the paper, specific questions around effect sizes, selection of primary outcome and power calculation for future study should be made an explicit aim of the study.

We have made the changes suggested by the reviewer. Please see Page 5, Lines 2-13.