Author’s response to reviews

Title: Improving engagement with healthcare in hepatitis C: a randomised controlled trial of a Peer Support intervention

Authors:

Helen Stagg (helen.stagg@ed.ac.uk)
Julian Surey (j.surey@ucl.ac.uk)
Marie Francis (marie.francis@ucl.ac.uk)
Jennifer MacLellan (jennifer.maclellan@ndm.ox.ac.uk)
Graham Foster (g.r.foster@qmul.ac.uk)
André Charlett (andre.charlett@phe.gov.uk)
Ibrahim Abubakar (i.abubakar@ucl.ac.uk)

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Dear Dr. Samuel,

Thank you for your review of our paper ‘Improving engagement with healthcare in hepatitis C: a randomised controlled trial of a Peer Support intervention’. Our responses to the reviewers are below and changes are tracked within the paper. Two additional changes to our supporting statements have also been made.

EDITOR

1) Under the declaration 'Ethics approval and consent to participate', please clarify (as in the Method) that the participants provided 'written' informed consent.

Thank you, this has been corrected to include the word ‘written’ on line 374.
2) Please note that the declaration 'Consent for publication' refers to the publication of material that would enable participants to be identified (for further information, please see (https://www.biomedcentral.com/getpublished/editorial-policies#consent+for+publication). If such material is not present in the manuscript, please change the response to 'Not applicable'.

This has been corrected on line 378.

3) Above the list of declarations, please add the heading 'Declarations'.

This has been added on line 371.

4) In Additional file 2, the end of the follow-up period is listed as 29th April 2016, but this is absent from the main text. Please edit/clarify this.

This has been added on line 207 of the methods.

REVIEWER 1

5) This paper reports on findings from a randomised controlled trial (RCT) assessing the efficacy of peer support as a means of engaging people experiencing homelessness and drug dependence with healthcare services for hepatitis C (HCV). The primary outcome of interest was successful engagement with clinical hepatitis services. Potential participants were recruited via relevant outreach services in London, UK, and, after confirmatory testing, those identified with chronic infections were randomised into either 'peer support' or 'standard of care' arms. The authors conclude that indeed, peer support can improve the engagement of patients with chronic HCV with healthcare services.

The paper is refreshingly well written and the study very clearly explained (even if much of the detail is appended as supplementary material). Moreover, the matter of peer support is an important one, not least in ensuring that 'no one is left behind' in our collective determination to achieve HCV 'elimination'.

We thank the reviewer for these very positive comments.

6) Nonetheless, despite the undoubted academic quality of the paper I have one principal reservation. Why, in this era, when the benefits of 'peer support' among people who inject drugs have been so widely and convincingly demonstrated (see for example, the 2012 WHO 'Guidance' document) was an RCT considered necessary? Why, when, as the authors themselves point out, there is no shortage of observational data and qualitative evidence - including experiential knowledge from both clinicians and service users -
attesting to the effectiveness of peer support? Is it simply that 'evidence' from RCTs is necessarily privileged over and above other forms of evidence? If so, this would seem somewhat ironic in light of the recent 'Cochrane Controversy' concerning the absence of (so-called) 'gold standard' RCT evidence supporting the efficacy of direct acting antivirals.

We take the reviewer’s point. Within the financial constraints of the UK’s National Health Service it is very difficult to get new interventions adopted unless the evidence base is sufficiently secure, which would usually require randomised controlled trial data followed by a health economics analysis to assess if the intervention was cost-effective. It is not enough to know that the intervention works, it also needs to be proven to save money that would otherwise be spent on another part of the health system relevant to these individuals e.g. providing them with liver transplants. A health economics analysis is not possible without a reliable effect estimate on which it can be based. Such is the nature of national healthcare systems with budgetary constraints.

7) I would also make an additional point. I find the paper's representation of the 'underserved and vulnerable' (p.4) troubling. Terms like 'chaotic lifestyle factors' may inadvertently contribute to othering people already experiencing significant social stigmatisation, not least by implying that they find themselves in their current circumstances somehow as a result of their own making. This is not to suggest that we in any way gloss over the extent (and accompanying risks) of such disadvantage, but rather that we be clear about the determining influence of boarder social-structural factors (the criminalisation of drug use, chronic unemployment, shortage of public housing etc.). In other words, the social determinants of health.

We agree and have edited our language to be less judgemental. Please see lines 63-87, 119, 344.

8) These concerns aside, I congratulate the authors on a fine piece of academic writing. Epistemological reservations notwithstanding, if such trials help strengthen the involvement of peers in the provision of much needed care and support for people who inject drugs experiencing social disadvantage - including in treatment for chronic HCV - then good luck!

Thank you very much for this positive comment. We will be working to ensure that our findings are used to benefit such individuals; there is no value in research that is not used to ensure positive impact.

REVIEWER 2

9) This paper describes the first RCT of a peer worker intervention to support engagement of marginalised people into BBV health services, so far as I am aware. It is important as
these services are expanding worldwide and evidence of their effectiveness is critical to understanding their value. The study is well designed and the analysis and reporting is generally clear. The usual care is a fairly cold distant referral, but this sits within the range of ‘usual care’ I think and is a valid comparator given the aim of the study is to test the benefit of the peer intervention. The limitation of an unblinded study is acknowledged and I think unavoidable. The paper is well written. There are a couple of abbreviations not defined e.g. LFU (I presume lost to follow up?)

We thank the reviewer for these very positive comments. We have checked through the manuscript and ensured that all abbreviations are defined where they are mentioned in the main text and in the additional files, as well as ensuring that they are all in the abbreviations list.

10) I have only minor concerns:

The peer worker is key to these services my experience, but the peer intervention was not well described, nor was the peer training. What is that individual's demographic profile and does it match that of your clients? What training is provided? What supervision? Is the person paid? Full-time or part-time?

I downloaded the additional file 2 and most of these questions were not answered there, but even so, this paper evaluates the benefit of an intervention that is unusual and novel. It must be described in more than three lines! I know the reader was referred to detailed descriptions elsewhere but a brief description might lengthen the paper a little but make it a complete piece of work. I would request this be added.

We completely agree with this point and have added the additional details requested into additional file 2 (line 34 onwards), as well as a point about the sex distribution into the discussion (line 335).

11) Minor points:

Should cite Walsh et al 2006 as the first use of peer intervention for HCV (not my paper!) could cite work by Treloar et al who were the second to report on this.

We are always happy to cite more relevant literature. Could the reviewer give a fuller citation for these two papers, please e.g. the journal? We already cite two papers by Treloar et al. (references 15 and 21) and a 2008 publication by Norman et al. on which Walsh is second author (reference 14), but are struggling to find Walsh 2006. Many thanks.

12) There are too many significant figures in the stats: e.g. 18.09% increase in engagement. 18% is quite sufficient!
Thank you; this been revised throughout the text (including in additional file 5) to one decimal place for the absolute measures/percentages. For odds ratios, quoting to two decimal places has been retained, as an ‘industry standard’.

Yours faithfully,

Dr. Helen Stagg

Centre for Global Health Research, Usher Institute of Population Health Sciences and Informatics, The University of Edinburgh, MacKenzie House, 30 West Richmond Street, Edinburgh, EH8 9DX, UK; 0131 6 511447; helen.stagg@ed.ac.uk