Author’s response to reviews

Title: Rationale and methods of an Evaluation of the Effectiveness of the Community Paramedicine at Home (CP@home) program for frequent users of emergency medical services in multiple Ontario regions: a study protocol for a randomized controlled trial

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Claudia Buntrock
Associate Editor
Trials

Dear Editor,

Thank you for allowing us the opportunity to respond to the peer review comments. We appreciate the comments made by the reviewers and have edited our article and responded to each of the comments indicating the nature of corresponding changes made in the revised manuscript. We have attached our response to each of the comments as supplementary information, a clean copy of the manuscript, and a copy with track changes based on the original manuscript.

Thank you very much and we hope these revisions satisfy each of the comments made by the reviewers.
Kind regards,

Gina Agarwal et al

Reviewer 1

1. I am pleased to see that members of the paramedic service are among the project team and co-authors. Involvement in research by those with expertise and experience to complement academic roles increases the relevance and quality of research. The perspective of patients would further strengthen the make-up of the research team. The target population for this study will potentially include harder-to-reach populations - individuals with chronic physical and mental health conditions who make frequent calls to emergency services for needs which are not met by existing primary and community services. By involving public and patient members who share characteristics with the harder-to-reach populations, the research team can benefit from their input into understanding how this proposed study addresses the needs of harder to reach patients. Public and patient involvement (PPI) is increasingly required by funders and publishers. Could the authors consider how PPI can support this study.

Thank you very much for your positive review. Regarding involving the patient population in the research, our funder (Canadian Institute of Health Research) did not require this. We are interested in the perspectives of the patient population and members of our team have published an article in the Health Promotion Practice journal regarding this population. We have incorporated what we have learned about this population through our research experience in the intervention and research process. As part of the evaluation, we are conducting focus groups to further inform us about the perspectives of this population. Also as part of our KT, we plan to involve patient groups and family to help us interpret the results of our research. One thing we wanted to avoid, is to include patient representatives who have become professional patients because we believe they are not representative of the true patient population. We have noticed this shift among patient representative organizations.

2. Related to this point, the authors note that recruitment could be challenging but report they are confident the target numbers will be reached. However, the easiest to reach patients will most likely be those recruited and patients with the more challenging needs, arguably the greatest needs, may persist in needing to use emergency services. This risks widening inequity and inequality among patients. Could the authors consider this issue and how they will use data about participant characteristics to explore the reach of this service. PPI (noted above) is arguably one route to help address this potential issue.

As with any study, recruitment may be an issue. Based on our experience with this population and similar population, we believe we will be able to recruit enough participants to make an impact on the population. Baseline data of participants will be collected through de-identified secondary data sources so we will be able to analyze as to whether we are reaching our target population or if we are missing the population with greatest needs. Since we are following
a rigorous randomization process, we believe intervention and control participants will be balanced. Furthermore for our research outcomes, we are conducting an intention to treat analysis so we are looking at the effect of the intervention at the population level. If we are not reaching the population with greatest needs, this will show in our analysis results and we could explore this further then.

3. How generalisable will these results be beyond the Canadian setting? Questions of widening scope of paramedic practice, avoiding hospital admissions, over-demand for emergency ambulance and emergency department services are internationally relevant. Could you consider generalisability.

We added a few lines in the “KT and implications” section regarding the generalizability of our study. As you have correctly indicated, over-demand for EMS and ED is a problem for many countries, primarily developed ones with active paramedic sector in their health system. Our team has been involved with the International Roundtable for Community Paramedicine (IRCP) and we believe our results could be utilized by the IRCP member countries.

4. P7 - could the authors provide a reference for their two pronged approach to reducing unnecessary healthcare utilisation, or say if this is an approach they have developed.

We have added a reference regarding comprehensive management and the two-pronged approach.

5. Primary and secondary outcome measures - are the number of patients conveyed also counted? Apologies if I missed this.

Yes, the number of transports, ED visits, and referrals to the family doctors and community resources will be counted.

6. Process outcomes - how are participant satisfaction data collected? Are the views of carers also collected? If not, why not? How are the interviews conducted and data recorded?

In the last paragraph of the data gathering procedures, we indicated that the participants of CP@home will be asked to complete self-administered electronic surveys during the last visit. The surveys will be in the same tablets that contain the CP@home database. Selected participants and paramedics will also be invited to participate in Key Informant Interviews. We have added a little more details to the Data Gathering Procedures section.

7. It is possible that the target participants respond to human contact generated by the CP@home intervention as much, or maybe more, than the clinical elements of the intervention. How will the authors understand how the intervention is working? How will they know whether attention and
visits are the characteristics which affect emergency calling behaviour rather than clinical input? This is important since it could mean that the intervention may be delivered by people in other roles, at least to some of the population. This could have implications for resources and management.

We have considered this. Based on our experience, we know that a certain proportion of the high users, especially the seniors, are socially isolated. We do not intend to separate the human interaction from the clinical elements of the intervention. However, some of our assessment tools to assess social isolation and we have referrals to community resources dedicated to help individuals with social isolation problems. Furthermore, in the analysis we can separate this subgroup to see how if there is a difference in the outcomes of those who are socially isolated or not. In our experience in a similar project, we have learned that community residents respond differently to paramedics in uniform compared to lay individuals. This has been documented in literature regarding the effects of intervention implementers in uniform.

8. P14 - could the authors clarify the referral process - are appointments automatically made for participants or do they need to follow up advice given by paramedics.

In this RCT, appointments are made automatically unless the participant decides not to participate anymore. The duration between appointments will vary based in availability of participants and whether participants need more time to implement the plan/advice agreed upon during the previous visit. The schedule for the next visit is agreed upon at the end of each visit. We have added these clarification in our protocol.

9. I can't see any information about data being collected from other services providing care or treatment to the CP@home participants as a result of the paramedics' input. While use of emergency services may reduce, input from other services is likely to increase, so currently proposed health care resource utilisation costs will not provide an accurate assessment if the whole service input is not counted. Could the authors respond to this please?

We do plan to link the information of the CP@home participants to our administrative database that collects health care utilization information. This includes the number of primary care visits. We will also monitor community referrals. These are written in our Data Gathering Procedures. We do anticipate that there will be an increase in other healthcare use, and it is actually one of our aims to increase appropriate healthcare resource use.

10. Could the authors provide some references for their analysis and health economics methods.

We have added a reference to our health economic analysis: http://healtheconomics.utoronto.ca/wp-content/uploads/1493-2720-2-PB3.pdf
11. P17 L378. What are 'assertions' which will be analysed along with themes. It is not a term I am familiar with.

We have replaced assertions with opinions.

Reviewer 2

1. There were a few discrepancies in patient criteria and outcomes between the NCT register and this manuscript. Please update and correct to have one consistent version.

Thank you for your comment. We have corrected our inclusion criteria and patient outcomes. We have changed this based on the advise of our senior statistician.

2. The sample calculation did not take account of potential drop-outs. This study needs 522 out of 1450 patients, which is considerably high with 36% of total potential patients in the region.

Since we are using administrative data for our primary outcome. We do not believe there will be a significant number of dropouts in our study. We are primarily conducting intention-to-treat analysis and therefore all participant outcomes will be included in the analysis based on the original randomization.

3. What if most participants prefer the intervention (CP@home) and refuse to participate?

We have added information to our protocol that we have sought a waiver of consent because our primary outcome will be aggregate data from administrative data sources. This was approved by our Research Ethics Board. We will not be consenting participants before randomization. Participants randomized to the intervention group can opt-out from participating in the program. When intervention participants agree to participate, then they will be consented and informed about the research.

4. Page 12, Line 266: the cited reference does not contain the number for the resource savings of $1626.0 per participant. The correct reference might be Agarwal, G. 2017 BMC Emergency Medicine. doi.org/10.1186/s12873-017-0119-4

We have corrected this reference. Thank you for bringing this to our attention.

5. Page 12-14: Could the authors make the inclusion/exclusion criteria more clear: 1) if a participant makes EMS calls during the intervention phase; 2) what if a participant is hospitalised; 3) any existing/new health conditions (i.e. uncontrolled epilepsy, sickle cell disease or certain mental disorders)
We have made modifications to our inclusion criteria. If participant makes an EMS call during the intervention, this does not change participant inclusion or assignment. Participant is re-assessed during the visits following the same protocols and adjustments to the care plan will be made as needed. If the participant is hospitalised, prior to the first visit, he will still be contacted upon discharge. If there is a new medical condition, this will be noted in the assessment and care plans will be adjusted but this does not change participant inclusion or assignment.

6. How to prevent/eradicate the effects of CP@Clinic, which has been implemented in the same region?

CP@home is intended to complement CP@clinic. There may be participants of CP@clinic who may be included in CP@home, though this may not be a significant proportion. If they remain frequent EMS callers, then a more focused intervention, which is CP@home, may be needed. We cannot totally eradicate the effect of CP@clinic. But through the rigorous randomization process, we expect the effect of CP@clinic to be balanced out between the intervention and control groups.