Author’s response to reviews

Title: Effectiveness of a Community Program for Older Adults with Type 2 Diabetes and Multimorbidity: A Pragmatic Randomized Controlled Trial

Authors:

John J. Miklavcic (miklavcic@chapman.edu)
Kimberly D. Fraser (kdfraser@ualberta.ca)
Jenny Ploeg (ploegj@mcmaster.ca)
Maureen Markle-Reid (mreid@mcmaster.ca)
Kathryn Fisher (fisheka@mcmaster.ca)
Amiram Gafni (gafni@mcmaster.ca)
Lauren E. Griffith (griffith@mcmaster.ca)
Sandra Hirst (shirst@ucalgary.ca)
Cheryl A. Sadowski (cherylas@ualberta.ca)
Lehana Thabane (thabanl@mcmaster.ca)
Jean A. C. Triscott (jean.triscott@ualberta.ca)
Ross Upshur (ross.upshur@utoronto.ca)

Version: 2 Date: 20 Feb 2020

Author’s response to reviews:

February 20, 2020

Re: BGTC-D-19-0064R91 (Response to Peer Review Comments)
Dear Mr. Fabio Salvi,

We would like to thank you for forwarding the peer review comments to us. We have revised the manuscript in response to the reviewer feedback. In our view, responding to the reviewer comments that we received significantly strengthens the manuscript.

Please find our point-by-point response below, which summarizes how we have addressed each of the reviewer’s comments.

We have done our best to address all review comments and look forward to hearing from you soon regarding the revised manuscript.

Sincerely,

Jenny Ploeg, RN, PhD

Point-by-Point Response to Reviewer Comments (BGTC-D-19-0064R91

Reviewer 1

1. Strengths. The reviewer acknowledged a number of study strengths, including the importance of the topic and potential contribution of the work, the inclusion of an exploratory analysis for participants whose mental functioning differed at baseline, and the overall quality of the writing and data presentation. We sincerely thank the reviewer for these comments.

2. Gender. Issue: The reviewer indicated that the impact of a gender imbalance between the groups cannot be known because no subgroup analysis was performed. Response: As noted in the paper, a decision was made a priori to not conduct a subgroup analysis in the event of overall non-significant findings because of the large body of work that discourages subgroup analyses in this scenario (references cited in manuscript). We nevertheless agree with the reviewer that we cannot know the impact that a gender imbalance may have, thus we have included this as a limitation of the study [pg 23].

3. Missing Covariates. Issue: The reviewer indicated that the study did not control for several other covariates that can influence physical functioning and other outcomes, such as physical activity and nutritional intake. Response: Unfortunately, we did not have access to information on these covariates. However, we agree with the reviewer that these are important variables that can influence the outcome(s). We have included this as a limitation of the study [pg. 23].

4. Site Differences. Issue: The reviewer questioned the impact of site differences and whether this was accounted for in the analysis (e.g., weighted procedures, covariate in ANCOVA). Response: While there were differences in the total sessions attended by participants at each site, these reflect participant variation/preferences rather than site variation. The sites
were deliberately chosen because they were similar in terms of primary care service, services pertaining to diabetes care, the skills of the site providers, and the clients served. We have added information on the criteria for selecting PCNs &amp; their similarities in the ‘Participants and Recruitment’ subsection of the paper [pg. 8]. Regarding adjusting the analyses, weighting was not done because there were no known site differences and inclusion of site as a covariate in the ANCOVA was not done because of the non-significant findings (i.e., there were no overall effects and thus no question about confounding factors that might account for the effects, also our primary interest was in the effectiveness of the program rather than the impact of site per se).

Reviewer 2

1. Intervention: Issue: The reviewer indicated that there were few details provided in the manuscript on the intervention and questioned whether this may help to explain the study’s non-significant findings. Response: We had assumed that interested readers would consult the prior publications for detailed information on the intervention; however, we agree with the reviewer that a brief summary of the key features of the intervention should be included in this manuscript. We have provided additional information in the ‘Intervention’ subsection, including the theoretical foundation for the intervention (Bandura’s Social Cognitive Theory), consumer (client) co-design, and provider involvement in the design (which included family physicians and other health care providers) [pg. 9-10]. This additional information illustrates the strong foundation for the intervention and suggests that other reasons are likely to underlie the study’s non-significant findings (already mentioned in the Discussion).

2. Consumer Co-Design: Issue: The reviewer noted that there was no indication of consumer co-design. Response: Older adults and their family caregivers were involved in the co-design of the intervention. We agree that important information was missing from the manuscript and we have added this to the description of the intervention in the ‘Intervention’ subsection [pg. 9-10].

3. Caregivers and Informal Peer Support: Issue: The reviewer indicated that the role of informal peers and carers was unclear. Response: Informal peer support in the study was referring to participants supporting one another in the group sessions, and family caregivers were invited to attend the in-home visits and group sessions. We agree with the reviewer that these roles should be clarified and we have added this information to the description of the intervention in the ‘Intervention’ subsection [pg. 9-10].

4. Medical Doctor Co-Design: Issue: The reviewer asked whether medical doctors were involved in the design of the intervention. Response: Medical doctors were among the health care providers involved with the co-design, and we have added this information to the description of the intervention in the ‘Intervention’ subsection [pg. 9-10]. Care coordination by the RN included collaboration and communication with other PCN providers, which included family physicians, and we have added this to the care coordination component of the intervention in the ‘Intervention’ subsection [pg. 9-10].

5. Clinical Outcomes: Issue: The reviewer indicated that clinical outcomes were not included in the study and questioned whether inclusion of these might have motivated a higher level of engagement of family physicians in the intervention or promotion of self-management in their clients. Response: We do not support the use of clinical outcome measures in this study for three reasons. 1) Medical doctors were involved in the co-design of the intervention (point 4), which included consideration of primary and secondary outcomes. They supported a shift in
focus from provider-centred outcomes to patient-oriented outcomes, such as the quality of life measure (PCS) used in this study. 2) Care coordination by the RN during this study also included collaboration with all PCN providers, which included family physicians, who supported the intervention. 3) Our aim was to focus on outcomes of importance to clients, due to the self-management emphasis of the intervention. Ongoing work in our research unit continues to reveal that clients rarely cite clinical outcomes as motivational factors, others have questioned their relevance (e.g., Wyatt et al., 2014). Recent work on developing PROMs (e.g., PROMIS suite of instruments) is motivated by concerns about the relevance of clinical measures, and other studies focused on older adults with multimorbidity have selected quality of life measures as the primary outcome to highlight their importance (e.g., Salisbury et al., 2018; Boult et al., 2013). We have added support for not focusing on clinical outcomes to the study limitations section that refers to this potential limitation [pg. 22].

6. Competence and Fidelity: Issue: The reviewer indicated that provider competency and intervention fidelity were not discussed or measured. Response: Provider competency was not measured because this would be difficult to accurately assess; however, initial standardized training and routine monthly research team meetings with the interventionists were conducted to monitor implementation, identify challenges related to implementation, and develop solutions to overcome the challenges. We have added a new subsection to the Methods section, entitled “Intervention Training and Fidelity”, to provide more detail on the methods to develop and monitor provider competence and ensure fidelity in the delivery of the intervention [pg. 11-12]. Dose of the intervention, meaning the uptake of in-home visits, is another measure of fidelity to the intervention. As noted in the “Intervention Dose” subsection of the Results, 68 of 70 (97%) of intervention participants received at least one home visit and 61 (87%) attended at least one group session. Participants had an average of 1.8 (median = 2) out of a maximum of 3 home visits and attended an average of 3.7 (median = 4) out of a maximum of 6 group sessions. This is a further indication that the intervention components were delivered (and well received by participants).

7. Follow-up Time: Issue: The reviewer indicated that the follow-up time period (6 months) may be insufficient to change behaviour and see a change in outcomes. Response: We agree with the reviewer and have included this as a limitation of the study [pg. 22-23].

8. Low Uptake: Issue: The reviewer indicated that no explanation was provided for the low uptake rate (22%). Response: While we agree the uptake (recruitment rate) was low, this problem has been cited by a number of other studies on older adult populations with multimorbidity (our population), including the recent 3D trial (Salisbury et al., 2018) and the Guided Care trial (Boult et al., 2013). Response: We have added a paragraph to the Discussion to note this issue and the need for continue research to identify effective recruitment/retention strategies for studies targeting vulnerable older adults [pg. 21].

9. Sample Below Target: Issue: The reviewer indicated that the implication of enrolling less than the necessary sample (e.g., type II error) was not acknowledged. Response: We agree that this should be acknowledged, thus we have included it as a limitation of the study [pg. 22].

Additional Revision (Not Identified by Reviewers, Requested by Authors)

1. Limitation: The original submission included the following limitation: “Due to the complex nature of the intervention, effects cannot be attributed to specific program components
[14]”. We have removed this limitation, because it does not apply to this study (where no overall effects were observed).