Author’s response to reviews

Title: Feasibility, user experiences, and preliminary effect of Conversation Cards for Adolescents© on collaborative goal-setting and behavior change: Protocol for a pilot randomized controlled trial

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Comments

Reviewer 1
It is not clear in the title what the preliminary impact of Conversation Cards for Adolescents (CCA) might be on. We modified our title from: “Feasibility, user experiences, and preliminary impact of Conversation Cards for Adolescents©, a patient-centered communication and behavior change tool: Protocol for a pilot randomized controlled trial” to: “Feasibility, user experiences, and preliminary effect of Conversation Cards for Adolescents© on collaborative goal-setting and behavior change: Protocol for a pilot randomized controlled trial

P2, line 41 - please state which country the national guideline recommendations refer to. We replaced the word “national” with “clinical” since no geographic limitations exist for the implementation of these guideline recommendations (P3, line 1).

P3, line 36 onwards - the abstract states that this is a theory-driven tool. Please could you provide some information about the theoretical background for the CCA. P21, lines 7-34 - the authors may wish to consider if this would be better placed in the introduction section.
We appreciate these suggestions and added details on the theory component to our tool. We also moved the indicated lines to the Introduction section (P4).

P5 Methods - further information about study timings would be helpful, for example when will recruitment end and finish, when will the study be expected to report? Recruitment commenced in March 2019 and will continue until 50 adolescents are reached. We anticipate this to be December 2019, with findings submitted for publication by April 2020. We now include these details in our manuscript (P5, para 2).

P5, lines 56-58 - please could you provide a reference for the statement about the benefits of using a pragmatic RCT approach.
We added references to support our application of the pragmatic approach (P5, para 3).

P6, line 51 - It is stated earlier in text that the population is adolescents with obesity. Please could you clarify the rationale for including participants at or above 85th percentile? CDC states that obesity in children and teens is considered at or above 95th percentile, whilst overweight is at or above 85th percentile.
Thank you for this comment. In fact, since our study commenced in March 2019, we changed our eligibility criteria to include any adolescent irrespective of weight status. This change was based on recommendations from the practicing physicians at the recruiting centre and the research team to support lifestyle change across the weight spectrum of adolescents seeking consultations and to facilitate recruitment. We are transparent about these changes in our updated records on clinicaltrials.gov.

P7, line 21 - please could you provide a justification for 0.2 as an appropriate effect size e.g. is this found in previous studies?
An effect size of 0.2 was informed by Whitehead et al. (2016) who stated that “For a main trial designed with 90% power and two-sided 5% significance, we recommend pilot trial sample sizes per treatment arm of 75, 25, 15 and 10 for standardised effect sizes that are extra small (≤0.1),
small (0.2), medium (0.5) or large (0.8), respectively.” Given that we could not locate previous studies with similar components to our future trial (e.g., primary outcome on collaborative goal-setting, use of a tool, adolescents 13-17y, consultation setting), we agree with your comment and chose to remove mention of effect size in our manuscript. This section now reads:

“Due to a lack of research studies directly comparable to ours, we were unable to use recommendations for pilot trial sample sizes on the basis of effect size for a future primary outcome on collaborative goal-setting [35]. We justify our pilot trial sample size of 50 adolescents with pragmatic considerations. That is, assuming ~85% recruitment of our sample of 50 adolescents, we estimated a margin of error of ± 10% for a 95% confidence interval; this recruitment percentage is derived from similar RCTs conducted in a primary care setting related to pediatric obesity [36, 37].” (P16, para 3).

P8, line 22 - does each member of staff involved in facilitating the study receive one $25 gift card, or is it related to the number of participants they see? Each staff member received one $25 gift card at study commencement irrespective of the number of adolescents they will see. This section now reads:

“...offering gift cards as tokens of appreciation ($25 Visa gift card per adolescent; $25 Amazon gift card per physician and administrative/clinical staff).” (P7, para 2).

P8, randomisation - please clarify whether the person undertaking assessments is aware of each participant's group allocation. This is an open-label trial, so the study coordinator conducting the assessments with adolescents will not be blinded to the allocations. This section now reads:

“The study coordinator, who will undertake study assessments with adolescents, will have access to REDCap® on-site to randomize and provide allocations to adolescents.” (P8, para 1).

P11/12 - Is this study considering what the primary outcome for the full-scale trial might be? The questions under 'Scientific Assessment' on P15 suggest it might be but this is not clear to me. The primary outcome for the full-scale trial is the perception of collaborative goal-setting by adolescents, for which we use an instrument in our pilot trial as well. The feasibility questions on safety are related to issues that may arise from our pilot trial, such as mental health risks in discussing lifestyle and behavior change, as opposed to safety in relation to procedures of a full-scale trial.

P13-14 - there is an ambitious range of questions to be answered. How will the information not addressed by the questionnaires be captured? By involving physicians in qualitatively and quantitatively evaluating our pilot trial, we foresee no issues with getting insight on the identified questions, and to date, have captured most from having the study coordinator be present daily on-site. We now state in our manuscript:

“These evaluations were informed by a modified version of the framework described by Tickle-Degnen (2013) [31] and will either have specific quantifiable thresholds or will be evaluated by
the study coordinator, physicians, and administrative/clinical staff through direct observation and experiences from the trial.” (P11, para 2).

“Program evaluations are best completed in a team approach; we will plan an end-of-study evaluation team meeting (~1h) to discuss feasibility metrics between the research team, physicians, and administrative/clinical staff.” (P17-18).

P16 - providers are asked their opinion on the CCA. However, I had understood that the researcher is using the CCA with the adolescents and then keeps the CCA pack (p9, lines 56-58), so the provider would not be using the CCA. If this is the case, what exposure will the providers have to the CCA to enable them to complete the questionnaires?

The physicians all completed orientation and training sessions using the CCAs. For familiarity/recall, they’re provided with the CCAs for 15 minutes prior to completing the user experience questionnaire and prior to the appointment with their very first participant. This ensures that physicians’ perceptions of the CCAs are not influenced by their encounter itself and their interaction with the adolescent/family. We now indicate:

“All physicians are exposed to the CCAs in the orientation and training sessions, as well as before completing the tool assessments.” (P15, para 1).

P16, lines 44-51 - will the telephone interview be audio-recorded? Also, looking at the interview schedule and from my own experiences, I think it may be unlikely to complete this in 15 minutes.

Yes, the telephone interviews are audio-recorded, and we indicate this in our data analysis section:

“Qualitative data will be audio-recorded, transcribed verbatim using The Comma Police, managed using NVivo 11, and analyzed by two independent reviewers using content analysis [39]; field notes and memos will be documented.” (P17, para 1).

Based on data collection from our first adolescent participants, we were too ambitious in aiming for 15 minutes. We submitted an ethics amendment changing this to 30 minutes.

P17, line 12 - when do the assessments take place for the providers?

The data collection time points are outlined in Tables 2 (adolescents) and 3 (physicians). We now indicate:

“Outcome measures collected at the three time points for adolescents and physicians are indicated in Tables 2 and 3.” (P16, para 2).

P18, lines 53-56 - please could you clarify how adverse events are being recorded and monitored?

We now indicate:
“Participants may experience psychosocial adverse events in relation to making lifestyle changes, which will be recorded and monitored by on-site research, administrative, or clinical staff.” (P18, para 4).

P18, lines 56-58 - please could you explain the consent procedures in more detail? E.g. who will provide assent vs consent?

We now indicate:

“All adolescents, parents, and physicians enrolled in our trial will provide written informed assent (adolescents) and/or consent (parents and physicians).” (P18, para 3).

P19, line 34 - this states that "Our primary aim in evaluating the feasibility of CCAs is to improve adolescent-provider communication related to shared decision-making and goal-setting for pediatric obesity". Please clarify if this refers to your aim for this pilot RCT or for the potential full-scale RCT.

We now state:

“Our primary aim in evaluating the feasibility of CCAs in our pilot trial is to ultimately improve adolescent-provider communication related to shared decision-making and goal-setting for preventing or managing pediatric obesity.” (P19, para 2).

Spirit checklist - this states that item 5d about the committees etc can be found on p22. I cannot locate information about the different committees or management groups involved.

In addition to authors’ contributions, we now include a paragraph on Roles and responsibilities for the end-users involved. Specifically, we state:

“Individuals overseeing the trial include the study coordinator (MK) and principal investigator (GDCB) from the University of Alberta as well as nine physicians (SL, HR, TL, BI, LJ, FN, KT, JLW, MZ) and four administrative/clinical staff from the NECHC. The study coordinator is responsible for managing, monitoring, and evaluating the clinical trial, including capturing data on feasibility and performance measures, soliciting recruitment, administering data collection assessments, and partnering with the NECHC staff to ensure pragmatic delivery and fidelity of the trial. The administrative/clinical staff provide input on day-to-day operations and inform the study coordinator of eligible patients, while physicians guide adolescents through the goal-setting during the clinical appointment and debrief with the study coordinator afterwards.” (P23).

Spirit checklist - this states that item 29 about who will have access to the final dataset is n/a. It is not clear to me why this wouldn't apply to this study.

In the roles and responsibilities section, we now state:

“The final trial data set will only be made available to the research team for performing data analysis.” (P23).

Reviewer 2

Why only a 3-week follow up? Is this not trivial even if it is the sort of duration to test SMART goal attainment? It is very unlikely that many strategies will have an effect on BMI over such a
short time and the study will not tell us whether the behaviour change is maintained. I think the feasibility study needs to check the duration of outcomes that would be relevant for a main ie. large and so expensive, clinical trial.

We thank the reviewer for this relevant and very important comment. We chose a 3-week follow-up period to monitor whether those who used vs didn’t use the cards are able to achieve goal completion within a feasible time period. We agree with the reviewer that the timeframe is likely not adequate to determine whether or not the cards elicit long-term changes in behavior and a concomitant change in BMI. At this point, we want to assess elements of trial feasibility and to explore what types of goals are most commonly chosen by teens, which will guide decisions regarding what outcome measures will be most appropriate for our future RCT, especially since we can’t measure all goals to the same degree of precision. Our long-term plan is to conduct a full-scale RCT within which we’ll evaluate long-term outcomes, including changes in lifestyle behaviors and weight status.

What is the outcome variable on which the power calculation is based (or is it estimate for recruitment?) An effect size of 0.2 is quite low - how big is the main trial intended to be? The recruitment strategies are straightforward and I do not envisage any particular difficulties.

An effect size of 0.2 was informed by Whitehead et al. (2016) who stated that “For a main trial designed with 90% power and two-sided 5% significance, we recommend pilot trial sample sizes per treatment arm of 75, 25, 15 and 10 for standardised effect sizes that are extra small (≤0.1), small (0.2), medium (0.5) or large (0.8), respectively.” Given that we could not locate previous studies with similar components to our future trial (eg, primary outcome on collaborative goal-setting, use of a tool, adolescents 13-17y, primary care), we agree with your comment and chose to remove mention of effect size in our manuscript. This section now reads:

“Due to a lack of research studies directly comparable to ours, we were unable to use recommendations for pilot trial sample sizes on the basis of effect size for a future primary outcome on collaborative goal-setting [35]. We justify our pilot trial sample size of 50 adolescents with pragmatic considerations. That is, assuming ~85% recruitment of our sample of 50 adolescents, we estimated a margin of error of ± 10% for a 95% confidence interval; this recruitment percentage is derived from similar RCTs conducted in a primary care setting related to pediatric obesity [36, 37].” (P16, para 3).

Finally, we agree that the recruitment strategies are straight-forward, and this trial represents the first RCT conducted at this clinical site, so we want to ensure the processes and procedures are acceptable and reasonable to incorporate into this practice-based research, especially when many of our day-to-day activities (recruiting, consenting, collecting research data) will be new to patients, administrative, and clinical staff.

Will the research team check that the goals conform to the SMART standard? Yes, the study coordinator captures the completed goal-setting sheet after each appointment with a participating adolescent. We added the word “fidelity” in addition to documentation purposes. (P9, para 3).
What safety concerns do you have? Although you will check, it is hard to see that there is anything unsafe about the intervention as it stands. Presumably a SMART goal could be unsafe or have unsafe behaviour associated - is this what you mean?

We agree and expect there to be low or negligible risks involved with this trial. However, we also acknowledge that risks are not always monitored in trials; this is particularly true for pediatric trials, so we plan to collect these data to adhere to good clinical practices for trial conduct and reporting. The feasibility questions on safety indicated in our manuscript are related to issues that may arise from our pilot trial, such as mental health risks in discussing lifestyle and behaviour change, as opposed to safety in relation to procedures of a full-scale trial.

How will this give you reliability, validity and trustworthiness of the assessments? How will you assess these?

The feasibility question on reliability, validity, and trustworthiness of the assessments indicated in our manuscript was referring to our use of questionnaires from the literature, which we selected based on good psychometric properties for reliability and validity. Determining reliability, validity, and trustworthiness of our tool is beyond the scope of this trial. Conducting telephone interviews with participants on how the goal-setting activity complemented our tool will provide us with preliminary information on content validity (the extent to which the measurement [goal-setting using our tool] represents goal-achievement [9-point Likert scale in our interview on degree and effort of achievement of goal]).