PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Protocol for a feasibility study: A brief self-compassion intervention for adolescents with type 1 diabetes and disordered eating
AUTHORS	Boggiss, Anna Lynette; Consedine, Nathan; Jefferies, Craig; Bluth, Karen; Hofman, Paul; Serlachius, Anna Sofia

VERSION 1 – REVIEW

REVIEWER	Dr. Dennis Görlich University of Münster, Germany
REVIEW RETURNED	14-Oct-2019

GENERAL COMMENTS	The authors submitted a well written and concise study protocol of a randomized pilot trial that compares a self-compassion intervention for adolescents with T1 diabetes and disordered eating. The proposed study is registered at the Australian New Zealand Clinical Trials registry (ANZCT). Overall the submitted study protocol covers all relevant information including the SPIRIT checklist. With respect to the already published study registration at the ANZCTR authors should double-check information given there with the submitted manuscript. At least the included minimal age differs (12 vs 13 years). Exclusion reasons (4) and (5) from the trial registry are not mentioned in the manuscript [(4) children with untreated hypothyroidism, and (5) children recently (in previous 48 hours) diagnosed with DKA or severe hypoglycaemia.]. Also statistical analysis plan differs. While the submitted manuscript describes the use of t-tests, the registration information additionally mentioned correlation analyses and a 2x2 mixed ANOVA with the group variable and data from two assessments. Please clarify which approach will be used when and which will be your major analysis strategy and sensitivity analyses. Authors state that in the analysis the statistical assumptions will be checked, but no alternative analyses are proposed if assumptions (e.g. normality) is not given. The main aim of this pilot trial (according to the manuscript) is to assess feasibility and acceptability as well as the generation of prior information about the effect size of the intervention to afterwards plan a fully powered RCT. The trial registration lists "efficacy" as type of primary endpoints. A pilot trial usually can not prove efficacy and the description in the manuscript seems to be much more appropriate. While the main outcome DEPS-R usually

	is an "efficacy" outcome, the main parameters listed to assess feasibility and acceptability seems to be major here. The anticipated sample size (10 adolescents per study arm ; Total = 20) seems to be fine in the pilot-setting, but no further assessment about how well the anticipated effect size for the primary outcome (DEPS-R), that will be used in the planning of the full RCT can be estimated, is given. In other words, how accurately can your prior information be estimated from the trial? Patient and public Involvement: Please check capitalized words. Study procedures: Blinding will not be applied (according to the study registration). The SPIRIT statement item was answered n/a. I would rather suggest to explicitly add this important information (open trial with no blinding). Outcome measures: The authors state that "qualitative data" will be used to refine the intervention content. I would be very careful to adjust content and then use the effect size of the estimated from data from the old intervention. Adjustment can only be made carefully and should not have any effect on the outcome parameters. Overall, I recommend to publish the protocol in BMJ Open after all raised points and issues are resolved.

REVIEWER	Dr Madeleine Ferrari Australian Catholic University, Australia
REVIEW RETURNED	06-Dec-2019

GENERAL COMMENTS	This protocol outlines an important pilot study which will make a valuable contribution to existing literature. This clinical trial targets a high-risk and vulnerable population, and presents a strong rationale for the novel intervention. The study is well considered and well designed.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 comments

Comment 1: With respect to the already published study registration at the ANZCTR authors should double-check information given there with the submitted manuscript. At least the included minimal age differs (12 vs 13 years). Exclusion reasons (4) and (5) from the trial registry are not mentioned in the manuscript [(4) children with untreated hypothyroidism, and (5) children recently (in previous 48 hours) diagnosed with DKA or severe hypoglycaemia.].

Response: We have updated the ANZCTR registration to include and justify our reducing the minimal age from 13 to 12. Exclusion reasons 4 and 5 have been added to the manuscript (see page 7 of 'main document – marked copy').

Comment 2: Also statistical analysis plan differs. While the submitted manuscript describes the use of t-tests, the registration information additionally mentioned correlation analyses and a 2x2 mixed ANOVA with the group variable and data from two assessments. Please clarify which approach will be

used when and which will be your major analysis strategy and sensitivity analyses.

Response: The ANZCTR registration was updated to remove the 2x2 mixed ANOVA and replace it with an independent samples t-tests. Correlation analyses were added to the manuscript. Our main analysis strategy is also clarified in the manuscript. See comments below and page 14 of 'main document – marked copy'.

"Pearsons correlations will be used to explore the relationships between the different outcome measures, demographic characteristics, disease characteristics, and current insulin regimen".

"An independent samples t-test will be conducted at post-intervention (see time 2, Figure 1) and will be our main analysis to test our hypothesis for differences between the intervention group and waitlist control group in disordered eating behaviour, diabetes-related distress, stress, self-care behaviours and self-compassion.

Comment 3: Authors state that in the analysis the statistical assumptions will be checked, but no alternative analyses are proposed if assumptions (e.g. normality) is not given.

Response: We have amended the paper to describe the non-parametric tests which will be utilised if assumptions are not met (see below and page 14 of 'main document – marked copy').

"If the parametric assumptions are not met, the Mann-Whitney test will compare the two groups at time 2 and Wilcoxon signed-ranks test will analyse possible within group improvements."

Comment 4: The main aim of this pilot trial (according to the manuscript) is to assess feasibility and acceptability as well as the generation of prior information about the effect size of the intervention to afterwards plan a fully powered RCT. The trial registration lists "efficacy" as type of primary endpoints. A pilot trial usually cannot prove efficacy and the description in the manuscript seems to be much more appropriate. While the main outcome DEPS-R usually is an "efficacy" outcome, the main parameters listed to assess feasibility and acceptability seems to be major here.

Response: The ANZCTR registration was altered to include feasibility and acceptability as the primary outcome and "efficacy outcomes" were re-phrased in the manuscript to provide "effect size estimates" (see changes in red font through pages 4, 11, 14 and 17). The term 'pilot study' has also been changed to 'feasibility study' throughout the manuscript to remain clear in the primary aim of the study (see changes in red front through. See changes in red font through pages 1 - 4, 7 and 11. For example, "this protocol paper describes a feasibility study designed to evaluate the feasibility, acceptability, and estimate of the effect of a brief self-compassion intervention for adolescents with type 1 diabetes (T1D) and disordered eating behaviours".

Comment 5: The anticipated sample size (10 adolescents per study arm; Total = 20) seems to be fine in the pilot-setting, but no further assessment about how well the anticipated effect size for the primary outcome (DEPS-R), that will be used in the planning of the full RCT can be estimated, is given. In other words, how accurately can your prior information be estimated from the trial?

Response: Although the feasibility trial is underpowered to find a significant effect for disordered eating behavior, the results will give us an indication of the effect size for this measure. No other intervention studies have measured disordered eating as an outcome, hence our trial would provide some indicators of the magnitude of the effect to allow us to estimate the required sample size for a future RCT. We would estimate the effect size based on the means, standard deviations and sample size in order to calculate a Cohen's d, which we would then use to calculate our required sample size.

This has been clarified in the manuscript by adding the following statement to the data analysis sub-heading on page 14: “These effect size estimates will also allow us to estimate the required sample size for a future RCT. Mean differences, standard deviations and sample size will be used to calculate an estimated Cohen’s d for the effect of the intervention on disordered eating behaviour, which we will then use to calculate our required sample size”.

Comment 6: Patient and public Involvement: Please check capitalized words.

Response: Capitalised words were an error and were removed, see changes in red font on page 15 of ‘main document – marked copy’.

Comment 7: Study procedures: Blinding will not be applied (according to the study registration). The SPIRIT statement item was answered n/a. I would rather suggest to explicitly add this important information (open trial with no blinding).

Response: The following sentence was added in the study procedure section to address this comment, “As the first author (A.B) is responsible for both recruitment and teaching the program, blinding is not possible” (see page 11 of ‘main document – marked copy’). Item 17A of the SPIRIT statement was also amended.

Comment 8: Outcome measures: The authors state that "qualitative data" will be used to refine the intervention content. I would be very careful to adjust content and then use the effect size of the estimated from data from the old intervention. Adjustment can only be made carefully and should not have any effect on the outcome parameters.

Response: Thank you for highlighting a concern in refining the intervention content so much so that it may have a differing effect in the full RCT. It is unlikely such substantial changes will be implemented if the program is shown to be acceptable and indicates possible improvements to outcome measures. For example, entire activities will not be removed however we may amend examples used based on feedback from participants to ensure age-appropriateness. Any changes made will be designed to increase efficacy and although direct comparison would become problematic, the effect size will become arguably more conservative.

Reviewer 2

The reviewer made no edit suggestions.

Formatting amendments

Comment 1: Please re-upload your supplementary files in PDF format.

Response: Supplementary files have been uploaded in PDF format.

Comment 2: Figure/s should not be embedded. Please remove all your figures in your main document and upload each of them separately under file designation ‘Image' (except tables and please ensure that figures are in better quality or not pixelated when zoomed in). They can be in TIFF, JPG or PDF format. Make sure that they have a resolution of at least 300 dpi and at least 90mm x 90mm of width. Figures in document, excel and powerpoint format are not acceptable.

Response: Figure 1 have been uploaded separately in PDF format. Table 1 was moved from the final page to be embedded into the document on page 9.

VERSION 2 – REVIEW

REVIEWER	Dennis Görlich Westfälische Wilhelms-Universität Münster, Germany
REVIEW RETURNED	02-Jan-2020

GENERAL COMMENTS	Thank you for answering the raised points and issues. I do not have any additional questions.