Author’s response to reviews

Title: SKIP (Supporting Kids with diabetes In Physical activity): Feasibility of a randomised controlled trial of a digital intervention for 9-12 year olds with type 1 diabetes mellitus.

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Author’s response to reviews:

Dear Editorial Team,

Many thanks for taking the time to review this manuscript - we are aware that submission is after the original deadline, although given that the request came at the time of our institutional Christmas closure we did not receive reviewer's comments until January. We had requested a brief extension although did not receive a reply. We are however ready to submit in advance of our requested extension and hope that our revised manuscript is acceptable to you.

We have endeavoured to address all comments wherever possible and believe that the quality of the manuscript has improved as a result. Our responses are below:

Technical Comments:

Comment: Please change 'Introduction' to "Background".

Response: We have made this change.
Editor Comments:

In addition to the referee comments, please address the following editorial points:

1. Please add the date of registration to the ISRCTN under your abstract.

Response 1. This has been added.

2. Ethics approval and consent to participate: please add the full name of the IRB that approved your study.

Response 2. This has been added: East Midlands - Nottingham 2 Research Ethics Committee (07.06.2016; Ref: 16/EM/0223).

3. CONSORT statement. In accordance with BioMed Central editorial policies (http://www.biomedcentral.com/submissions/editorial-policies#standards+of+reporting), could you please ensure your manuscript reporting adheres to CONSORT guidelines (http://www.consort-statement.org/downloads) for reporting randomised controlled trials. This is so your methodology can be fully evaluated and utilised. Can you please include a completed CONSORT checklist as an additional file when submitting your revised manuscript.

Response 3. We have now included the relevant CONSORT checklist.

Reviewer reports:

Frida Sundberg (Reviewer 1):

Comment 1: Line 89; introducing the broader age group "children and young people (CYP)" when the study exclusively includes children aged 9-12 years is unnecessary and confusing. This paper is about children not adolescents or young adults. The discussion on sharing of treatment responsibiltys with parents is not in the scope of this paper and contributes to the confusion.

Using "diabetics" as a noun (line 94) is abandoned by most journals.

The statement that interventions must be "inexpensive" (line 98) is provocative. Cost effective might be easier to understand?

The general statement of "CYP" using technology (line 101) is rather vague with refererral to the young age group children 9-12 years.

Response 1: We have removed the term “children and young people” from the text and from the abbreviations. We have replaced the term “diabetics” to “children with diabetes”, Page 5, line 94.
On Page 5, Line 97 we have changed the wording from “inexpensive” to “cost-effective”. Reference to CYP on Page 5, Line 100 has been replaced with more specific reference to “children”.

Comment 2: Line 118; East Midlands NHS University Hospitals. For a foreign reader, please add nationality. UK I assume?
Response: This information has been added to Page 6, Line 118.

Comment 3: Line 125: It could have been more appropriate to refer to study participants as children or study participants rather than patients
Response 3: We use the term “participants” throughout to refer to those who participated in the study. On Line 125, the term “patients” is used because we are referring to all individuals approached (who were all patients of the clinics) to participate, with some later becoming participants and others not. It would therefore not be appropriate to refer to these individuals as participants and is appropriate to use the term patients.

Comment 4: Line 130 the sentence "Written Participants completed questionnaires... " was hard for me to follow.
Response 4: “written” was a typo and has now been deleted, Page 6 Line 130.

Comment 5: Line 132 the description "a Polar Active physical activity wristwatch" is to vague to be part of a methods description. Model, brand, manufacturer, manufacturing country. A short description whether it was blinded or provided feedback to the user would be helpful.
Response 6: We have added details.

Comment 6: Line 141 "a questionnaire" on what?
Response 6: Page 7 Line 144, we have added the sentence “on usual care” to clarify this.

Comment 7: Line 167: whom did the interviews? One interviewer or more? What was the relation between the interviewer and the informant? Where and under what circumstances where the interviews performed?
Response 7: We have added this information to Page 8, Line 169-171
Comment 8: Line 173 "Body composition" - what measurements were used?

Response 8: We state on Page 8, Line 178 that this measurement was taken from the child’s medical notes. We have added that the measure used was body mass index calculated from directly measured height and weight.

Comment 9: Line 187 what does the sentence "total usual care score was similar between sites..." mean?

Response 9: Page 7, Line 145-146. We have added a line here explaining how the overall usual care score was calculated.

Comment 10: Line 189+191 the abbreviations NUH and UHL are introduced without explanation

Response 10: Page 6, Line 119. We have added a line here to introduce these abbreviations.

Comment 11: Several questionnaires were used and results reported in the tables. Most of this data was not reflected in the discussion. It could be possible to either reduce the uncommented data or to deepen the discussion on the data on several aspects as fear of hypo, perceived health and so on.

Response 11: We feel it would be too lengthy and result in an article that would be difficult to digest if individual comment was made on all measured outcomes including those with non-significant findings. We therefore decided to discuss in detail those findings which showed to be significant but feel that it is still important to leave the additional data in the table to provoke further thought and investigation.

Comment 12: Table 2: there are unexplained abbreviations in the headers av "INT" (intervention group?) and abbreviated names of questionnaires. Each table should be possible to read and understand separately. There is too much data in the table. Data that is not reflected in the discussion might be regarded as redundant. Which findings are regarded as important enough to report? And there are no information in the tables on what differences that are significant.

Response 12: We have added a key explaining these abbreviations underneath the table. In attempting to write as concise an article as possible it is not appropriate to discuss in detail the results for every measured outcome and so we have selected the most important ones to discuss in detail. We still feel that it is appropriate and important to provide all results in the table as the taking of these measurements must be mentioned given that this is a feasibility study. It would be confusing to mention that measurements were taken, without providing outcomes for these measurements. We feel that presenting them in a Table is the most concise and appropriate approach for both transparency and to encourage further consideration of findings.
Comment 13: Table 3 It might be more appropriate to report BMI_SDS (Z-scores) rather than raw BMI as it changes with age and onset of puberty. There is no information on Tanner Staging. The information on insulin delivery is confusing: MDI:pump:pen is not the normal categories. MDI vs pump would be a more common description. Does "self-monitoring" refer to capillary glucose monitoring by "finger-pricking"? What does parent "without qualifications" mean? Level of school/professional education? Is it necessary for the understanding of the manuscript to know all these steps of incomes or would it be possible to cluster data to reduce redundant information not commented on in the discussion? Is the information necessary overall?

Response 13: The information presented regarding insulin delivery and self-monitoring was presented in the same form to participants and so reflects exact responses to the exact wording of the questionnaire responded to by participants. Level of school education is already presented in its collapsed form though we have clarified the description to “without formal educational qualifications” in order to clarify. We have also now clustered the data for family income to only include three categories.

Comment 14: Table 3 Percentage data is presented with a very uneven level of certainty "100.0%" "98%" "87.8%". It is a bit confusing.

Response 14: We believe this is actually in reference to Table 4 as these percentages appear in this table. We have now amended the presented percentages to include one decimal place for all percentages apart from 100% which is presented as 100% as not higher (i.e. 100.1%) is possible.

Comment 15: Table 5; too much data. What is necessary and what is redundant? It is unsatisfactory to have data on delta (changes), please give absolute numbers instead. HbA1c should be presented both as % and mmol/mol in accordance with international agreements. Insulin doses could have been presented as U/kg but is hard to interpret in this age group due to onset of puberty. What do you mean with "HbA1c aim low/high accuracy"? There are unexplained abbreviations in the table as HFS do. The table need to be possible to read alone.

Response 15: The absolute numbers are presented in Table 2 and so it would be repetitive to include them here too. The change scores are appropriate for the analysis used and presented in this table. With regards to HbA1c we have added both % and mmol/mol as requested to Table 2. We do not feel it would be appropriate to add this to Table 5 as Table 5 presents the comparative analysis and so results would be the same regardless of the given unit, however we agree that these data should be provided and so we have added to Table 2. We have added a key to Table 5 to explain the abbreviations and the other uncertainties presented in this comment.

Freya MacMillan (Reviewer 2):

General comment: * This intervention targets an important, under researched target group. The paper is written well. At present, it is not clear of the novelty of the intervention however. To
highlight this, a critique of the literature on lifestyle focused intervention through technology for this target group is required. E.g. have there been any other website based, or app based interventions etc in this target group? What did they find? How is your intervention different? What specifically is this paper adding to the literature? What is the research question being answered as part of this research? This literature also needs to be referred back to throughout the discussion section to highlight the novelty and any similarity/differences with your intervention.

General response: We have recently published a systematic review that looks at the impact of technology-based interventions across multiple behaviours associated with self-management of T1DM. Therefore we have referenced this review (which includes 30 studies) rather than replicating information about the individual studies. This provides a rationale for the focus on physical activity intervention and the study aim is described immediately following. We have referred back to the review in the discussion.

Minor comments:

Comment 1: Line 58 in abstract: 'at the end' rather than 'of the end.'
Response 1: Descriptive analysis was undertaken OF the end-of-study questionnaire. We have added “” to clarify that this is the name of a questionnaire.

Comment 2: Do not use the term 'diabetics' (not politically correct) - it is 'people/person with diabetes'
Response 2: We have changed this to “children with diabetes”

Comment 3: Intro: Final sentence of first para - should parents not be targeted too, seeing as earlier in this paragraph you mention the importance of parental involvement?
Response 3: Undoubtedly parental role is important and the parents were involved in the study i.e. parents contributed similarly to data collection and were encouraged to take part in the intervention via the ‘Parent Zone’ and by encouraging their child to participate. However, children were targeted primarily as the objective of the intervention was to help develop independence of the child.

Comment 4: Intro: Diet has not been mentioned anywhere. The focus of the paper is physical activity but diet needs to be acknowledged, at least as an important part of managing diabetes.
Response 4: Intervention participants received access to the STAK-D website the content of which has been described elsewhere (9). However, we have now referred to diet in the brief description of STAK-D: “STAK-D combined behaviour change techniques including physical activity goal setting, feedback and increasing knowledge with the aim of increasing participant’s
self-efficacy for diabetes self-management (e.g. confidence around management of physical activity alongside diet, and regular blood glucose self-monitoring)”. We have added this to the discussion in the limitations in the context of the general information provided within the STAK-D content.

Comment 5: Line 108: ‘in a RCT’ rather than 'and a RCT.'

Response 5: Page 5 Line 109: We have attempted to clarify this sentence. Evaluation of the feasibility and acceptability of the RCT itself was an aim of the study in addition to evaluating feasibility and acceptability of the intervention. We have therefore left the sentence as ‘and a RCT’ but added information in an attempt to clarify.

Comment 6: Methods: Line 139 - how was 'usual care' measured? This is not clear.

Response 6: We have added details on Page 7, Lines 147-149 to further explain how usual care was measured.

Comment 7: Line 156 - is this correct? That you had a burden questionnaire to measures the burden in completing questionnaires. Or did you mean a burden questionnaire to measure the burden of participating in the online intervention?

Response 7: This is correct. As it was also an aim of the study to examine feasibility and acceptability of the RCT, this includes acceptability of the measures. The burden questionnaire therefore asked about the burden of completing the measures in order to indicate acceptability.

Comment 8: Line 179 - '…with their 95%' rather than 'with its 95%.'

Response 8: Page 9 Line 188. We have made this change.

Comment 9: Add the cut points targets you used to define feasible and acceptable

Response 9: This information is provided on Page 8, Lines 164-166 and on Page 11, Lines 231-232.

Comment 10: The interview questions need to be included in the methods or an associated table/appendix - what was asked?

Response 10: The interview followed an open format and so concrete questions were not used. We have included the interview guide as an additional document.
Comment 11: Results, line 190: 'residential' what?
Response 11: Page 9, Line 199. We have clarified this by changing to ‘residential retreats’.

Response 12: Page 10, Line 210. We have made this change.

Comment 13: Line 205 - what were the demographic and clinical characteristics that were collected (these need stated in the methods section).
Response 13: Given that a full methods paper has been previously published and readers are directed towards this paper on Page 6 Line 113, we do not feel it appropriate to repeat in full all measures. We have clarified on Page 6 Line 113-114 that full details of the demographic and clinical measures taken are provided in this paper.

Comment 14: Line 245 - this first sentence should be in the methods section.
Comment 14: We have moved this line to the Methods section, Page 7, Line 151-152.

Comment 15: Line 279 - Second sentence should be in methods.
Response 15: We have moved this line to the Methods section, Page 9, Line 194-196.

Comment 16: Discussion - Line 357 - is chronically 'ill' an acceptable term? Would 'individuals with a chronic condition' be better to use here?
Response 16: Page 16, Line 370-371. We have made this change.

Comment 17: Line 360 - 'collect' rather than 'collection.' What were the targets for your data collection and why were these values set?
Response 17: Page 17, Line 373. We have corrected this typo.

Comment 18: Line 365 - are these completion rates CYP with t1d? If not, please refer to studies specifically in CYP with t1d
Response 18: Yes they were.
Comment 19: Line 402 - short term improvements in what?

Response 19: These are already described in the original manuscript, in the sentence immediately following (self-reported sedentary behaviour and parent-reported physical health).

Comment 20: Line 416 - why were aspects of the intervention withdrawn - what was the reasoning behind this?

Response 20: Our published protocol specified that these feedback elements would continue for the 8-week intervention period (although children were encouraged to continue using STAK-D through to 6-month follow-up. This information has been added in and referenced.

Comment 21: Limitations - there are others. Why was the Polar Active watch used - is this popular with young people? Small sample size for the quant part too. Diet was not measured and could impact on clinical markers

Response 21: Yes, prior research had shown that children preferred the Polar Active activity watch (PAW) to other monitors. The PAW has a comfortable, waterproof watch-style design and digital display features provided instant feedback, and was shown to be better accepted by children compared to other research-grade monitors – this information has been added in and referenced (38). The intervention was focused primarily on physical activity rather than overall self-management of T1DM; nevertheless, the educational content provided within STAK-D included self-management and wellbeing approaches, and provided guidance on the importance of regular blood glucose monitoring, and managing physical activity around diet. The sample was small, limiting the conclusions that can be drawn, although it was sufficient to address our feasibility aims. We have added this information into the limitations.

Peter Memiah (Reviewer 3):

Well structured descriptive paper - showing mean changes. Excellent articulation of the study.

A few things to note- on the tables CSAPPA Adequacy score shows a pvalue of 1?

Response 22: This value was rounded up from 0.996. Although not a likely value it is correct and is likely due to the fact that responses were discrete and the data was not perfectly normally distributed.

CPHQ Physical score baseline to 8 week follow up was the only significant variable- what was it about this test? in the discussion- provide a sentence of other studies that have utilized the same assessment
Response 23: Thank you for this comment. We have added a short section to address this on Page 19, Line 435-439.

The attrition of 49 at baseline to 38—even though this is better than most studies - is such across the health facility system? - you mention it as a limitation- can you provide further information on the facilities?

Response 24: Follow-ups were largely completed using home visits and so the facilities are unlikely to have had an effect. While it was the case that many follow-up visits could be and subsequently were completed during the patients regular clinic, the researcher was required to make independent contact with the patient prior to them attending any clinic to gain ongoing consent for them to complete follow-up measures in the clinic. The main factor influencing attrition was therefore, the researcher’s ability to make contact with the participant to arrange the follow-up (then further factors such as participant attendance/non-attendance etc. came into play). The majority of missed follow-ups were the result of non-response to multiple phone calls and text messages to arrange it to which facilities have little effect. The lack of response to phone calls is however, in line with statistics regarding non-attendance of participants to out-patient clinics.

Thank you for your review of our response and revised submission. If anything further is required, please do not hesitate to let us know.

Kind regards, The authors.