Reviewer's report

Title: Effect of guided self-determination youth intervention integrated into outpatient visits versus treatment as usual on glycemic control and life skills: a randomized clinical trial in adolescents with type 1 diabetes

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Reviewer: Sue Channon

Reviewer's report:

The authors are presenting work that takes a model of intervention - guided self-determination - that has been successfully applied in adult diabetes services and adapted it for young people and their families. Having read the protocol paper I was interested to review this results paper as this is an area in which, as the authors identify, there has been a recent run of complex intervention trials with teenagers with type 1 diabetes that have not had any significant findings. Whilst it might be considered that a paper with only one significant finding amongst many outcome measures was not a success in terms of the intervention, it is important for papers such as this to be published: It is building on the body of knowledge in this very difficult clinical area and for those tracking this type of work who have read the protocol paper it is really good to hear the results, albeit disappointing that it hasn’t quite worked out as hoped.

The methods are appropriate and the manuscript does largely comply with the CONSORT guidelines required for an RCT. My main concerns focus on the description of setting and intervention which were less than clear – hence the following specific comments below. I appreciate that with a previously published protocol paper then much of the work goes across the two papers but even taking that into account I would not be able to replicate the intervention as delivered in this study - the content in terms of the reflective sheets are identified but the process in the face to face work is less clear, the context of delivery (including setting) isn’t certain and in neither this paper or the protocol paper are the adaptations from the adult work described. These would be the areas I think need further clarification.

In general the discussion is well balanced and the writing is certainly acceptable, with some rewriting particularly in the latter half of the discussion needed as identified below.

My specific thoughts as I went through the manuscript are as follows:

Background: The background is well described capturing the challenges and descriptions of interventions for young people with diabetes and their families.

Methodology:

This intervention has been adapted from a successful intervention with adults. The theoretical underpinning of the intervention is well described in the protocol paper and briefly captured here. However there appear to be significant
differences between this intervention and the adult study:

Procedural: A two-hour group intervention delivered outside clinic setting by researcher and HCP to a triadic intervention for adolescent, parent and HCP in clinic

Developmental stage: it was not clear how the intervention had been adapted from work with adults to work with young people and their parents in a triad. With the youngest participant being 13 years old it struck me that with an intervention that focusses on autonomy-support and shared decision making (within personal and professional relationships) and competency that there may well be young people for whom this isn’t consistent with their personal developmental stage and also the developmental stage of their family.

To understand the “fit” between intervention and participants it is crucial to understand the adaptations that were made in particular in relation to developmental stage and to include parental role.

Delivery of intervention: HCPs were tested in relation to their delivery of GSDY prior to trial but there is no mention of ongoing measurement of fidelity to the intervention through the progress of the trial. With practitioners delivering both the intervention and the control usual care this seems to be important in terms of establishing whether any result can be ascribed to delivery of the intervention.

I think the idea was that the intervention was delivered as part of routine care – Could the authors clarify what routine contact is as 8 sessions for 30-45 minutes in 12 months (as per control group) seems unlikely to be routine levels of contact? Who would they normally see in routine contact?(just one practitioner?)

Control group – was there any attempt to understand what was covered in these sessions? There needs to be a description of usual care.

Were the sheets sent out in advance or completed in waiting area?

Was there a particular reason why dietetic involvement if it was to happen would only be in the first two sessions for the intervention group but “as needed” for the control group?

I wasn’t clear if all sessions were triadic and parents had an additional two sessions? In the intervention section reference is made to “before each visit the adolescents and parents….“ and then later there is reference to the parental two sessions - this could be made clearer.

Outcomes

The secondary outcomes match the intervention - I think with teenagers it makes it particularly challenging to have HbA1c as the primary outcome in a 12 month study with a psychosocial intervention (rather than say the perceived competence or anther variable that is at the heart of the intervention) but it is rare to find a study that doesn’t so it fits with expectations of studies in diabetes.

In terms of the writing I felt the section on the secondary outcomes section a and the measures would benefit from a re-write - it was a bit jumbled and bringing them together more closely might make it easier to read (and potentially save
some words). I think the definition of improvement in life skills as a composite measure also needs some greater clarity.

Results
The hypotheses are sound but I am not able to comment fully on the appropriateness of the statistical approach as I am unfamiliar with some of the tests.

Visits-sessions: I wasn’t clear quite what was being described - did they come to clinic but not receive the intervention? What defines a completed session? I got thoroughly confused through this section – which may be use of terminology – visits/sessions? This needs clarification although I got the general message that it didn’t go as planned and that the intervention went more off plan that the control group.

Who was in charge of determining whether parents attended or not? (not sure this is clear in methods) In the section on the dietician does the sentence “Each GSDY adolescent completed 1 to 6 visits” mean 1-6 visits to the dietician?

Looking at the numbers it would seem that each practitioner worked with around 5 each in the intervention group? The results control for practitioner but this wasn’t really addressed either in the results or the discussion.

Discussion
Amotivation: the definition of amotivation is slightly buried in the text earlier in the piece – given that it is discussed in detail I think it needs to be clearer or reiterated in more detail actually what it is. It is a little confusing as it is a negative term – does a reduction in amotivation mean they are more motivated? Is this the beginning of a process of engagement?

It is good to put the results in context of three other trials with similar types of findings - I wasn’t sure if the authors made a little too much of the fact that their intervention HbA1c was unchanged (when others went up) but they were tentative so I think it was legitimate.

There is little discussion of the fact that 11 young people did not complete the intervention of which 7 were patient withdrawals - active and passive - compared to 3 non-completers in the control group. Was there a sense that this was quite a demanding intervention?

The deviation from the original protocol is included and the rationale for not following the group approach used in the adult study is well and honestly justified. Given the level of differences between this and the adult study intervention I I wouldn’t go so far as to attribute the different outcome on HbA1c to the completion of the two reflection sheets – seems a bit extreme so I would modify that sentence.

I think the writing gets much harder to follow when the discussion considers amotivation. I didn’t understand why amotivation indicates that the adolescents felt motivated to identify the reasons for self-management in which they believed – this needed to be clarified. In the description of the measure earlier in the paper autonomy is different to amotivation but somehow the young people are now being described as autonomously motivated which I didn’t understand as I didn’t
think there was a significant impact on autonomy. Why does a lack of autonomy support in the parents and HCP responses indicate they are applying pressure? It may be that the parents' responses on questionnaires don’t indicate an increase in autonomy support but they are demonstrating this by enabling the children to attend appointments alone? What is the appropriate amount of autonomy given that there is clear evidence of the positive impact of continued parental involvement across adolescence? It is also a very valid point that maybe the reduced amotivation relates to the sheer fact of higher number of visits — indicating the HCPs commitment to them and their care?

The possible spillover ie contamination between arms is recognised but it also needs to be acknowledged that with no measurement of the fidelity of the intervention there is no way of knowing what was actually occurring in any of the sessions either intervention or control?

I appreciate this is the quantitative paper but a few headlines about the qualitative experience of the participants would be of interest

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests