Author's response to reviews

Title: Reducing stress and supporting positive relations in families of young children with type 1 diabetes: A randomized controlled study for evaluating the effects of the DELFIN parenting program

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Author's response to reviews: see over
Dear Sir or Madam,

Enclosed I send you the revision of the manuscript: “Reducing stress and supporting positive relations in families of young children with type 1 diabetes: A randomized controlled study for evaluating the effects of the DELFIN parenting program. Heike Sassmann, Mira de Hair, Thomas Danne and Karin Lange”.

We thank the reviewers for the careful and thorough review of the paper and the invitation to revise our manuscript. We have made the appropriate changes. Please find below our responses and revisions. We have highlighted revisions in response to the first reviewer in blue, revisions in response to the second reviewer in red.

Please do not hesitate to contact me for comments or queries.

Yours, sincerely

Heike Saßmann
Response to reviewers’ reports
MS: 1281869393716423
Reducing stress and supporting positive relations in families of young children with type 1 diabetes: A randomized controlled study for evaluating the effects of the DELFIN parenting program. Heike Sassmann, Mira de Hair, Thomas Danne and Karin Lange

Referee 1:

We thank the reviewer for the thorough review and the helpful comments on our manuscript. We have taken into account the reviewer’s objections and have revised our manuscript accordingly. Below we have addressed the comments and indicated the respective changes we have made (printed in blue).

1. Be careful not to overestimate the results - … the authors may consider noting that the results suggest initial support for the intervention: The reviewer’s formulation is used in the abstract to make a conclusion of the study outcome without overestimating the results (page 3).

2. How does the current study build on/differ from 2 other interventions? We included these studies (page 5) and discussed the advantages of the telephone-based intervention (Monaghan et al., 2011) in the discussion section (page 13). However, we see some differences in the intentions as well as in the methods between the 2 studies and the DELFIN program which we discuss below:

Both studies point to the importance of supporting parents with children with type 1 diabetes in solving everyday challenges. Monaghan’s et al. (2011) concept is characterized by a telephone-based intervention. Sullivan-Bolyai et al. (2010) are concentrating on social support via instructed laypersons. In contrast the DELFIN program was run by accredited psychotherapists. The lessons were given by focussing on role playing and on the supervision of general parenting behaviour.

The focus of the intervention of Monaghan et al. was on enhancing coping behaviour and diabetes management through the use of cognitive strategies. Sullivan-Bolyai et al. instructed parent mentors to provide social support to parents of newly diagnosed children (particularly to share practical day-to-day management information). In contrast the DELFIN intervention focussed not only on illness-related, but on overall parenting strategies in conflict situations. In addition strategies in order to build a positive relationship with the child were trained.

3. Please provide more information on the feasibility/acceptability of the intervention: We addressed this point on page 12 and included the adherence to session attendance for the families in the paragraph “Satisfaction with the DELFIN program”. We added information about homework adherence and introduced the effects of the supra-regional catchment area of the clinic.

4. It is not clear how the group x time analyses were conducted – it seems that repeated-measures analysis or GLM may be more appropriate: We have done analyses from general linear models as well. The group x time analyses failed to reach statistical significance (page 10-11).
5. *Were the parents of the same children treated independently?* The parents were treated independently. The focus of the intervention was on individual parenting behaviour of mothers or/and fathers. We wanted to know, whether they changed their individual parenting behaviour. While interacting with the child it is possible that the mother changes her parenting behaviour after attending DELFIN, while the father does not.

We agree that there might be an influence between parents and this is a limitation of the study. Due to the small sample size mothers and fathers were not analysed separately. We addressed this point in the discussion section (page 15). This would be an important question to be answered in further multicentre studies. We calculated associations between mothers and fathers, between mothers only and between fathers only in order to obtain some information about possible associations. There were no differences in correlations between those groups.

6. *Inclusion of effect sizes would be helpful in determining potential for improvements in a large scale intervention:* We calculated effect sizes (table 3 and page 11). Effect sizes are moderate to high for the reduction of negative parenting behaviour in the intervention group. The effect sizes of parenting behaviour are higher in the intervention group than in controls. For parents’ stress, depression and anxiety small effect sizes were observed in both groups.

7. *Delivering the intervention during routine clinic visits:* The intervention was indeed time-consuming. However, it would be possible to perform more separate sessions that might be combined with the routine visits in the outpatient centres. The children might participate in a diabetes education course simultaneously.

8. *Please say more about how the intervention targeted parental distress:* We added information in the methods section (DELFIN intervention, page 7). Parental distress should be reduced via cognitive and behavioural interventions. The main focus of the program was on implementing and practising effective behavioural parenting strategies (e. g. how to be consequent; what to say or what to do in conflict situations, how to build a positive relationship with the child). These strategies are supposed to reduce parental stress, anxiety and depression as well as children’s behavioural difficulties. The effectiveness of these general parenting strategies in reducing parents stress and depressive symptoms has been reported in a number of studies on this topic (e. g. refs. 35, 36, 37 and 38).

9. *Please clarify the sentence in the first paragraph of page 5:* We have changed the wording of the sentence, hoping that it is now more understandable. As far as we know there is no manualized program that includes a written manual, which includes all relevant behavioural strategies for resolving conflict situations (not only diabetes specific ones) and to build a positive relationship with the child.

10. *Reframing the paper to focus on feasibility and preliminary efficacy of the intervention:* We emphasized feasibility and the preliminary status of the results (e. g. page 3, page 15).
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Referee 2:

We thank the reviewer for the thorough review and the helpful comments on our manuscript. We have taken into account the reviewer’s objections and have revised our manuscript accordingly. Below we have addressed the comments and indicated the respective changes we have made (printed in red).

1. **Missing data for A1c:** A1c data is provided for each child within the study there are no missings (page 10). Baseline assessments have been completed by 33 families. With n = 33 children with type 1 diabetes. The parents data has been analysed for each parent independently (mothers and fathers have been treated independently). We add the number of children with moderate metabolic control (A1c between 7.5% and 9%) (page 10). We have depicted the changes in metabolic control on page 11 and not in the table.

2. **A more comprehensive delineation of the intervention is needed in order for replication:** We specified the intervention more detailed in the methods section (DELFIN intervention, page 7). There is a hierarchical organization in the program, having the same topics on different levels in the 5 sessions.

3. **Providing the scoring of the instruments:** We have provided the scoring of the instruments at page 8.

4. **Biochemical assay method should be stated:** We included the biochemical assay method for A1c in the section “Measures” – “Biomedical data” (page 9). The method was DCA™, Siemens Healthcare Diagnostics. All analyzes had been conducted in the same laboratory.

5. **Some description regarding the reason for not measuring outcomes immediately after the intervention is warranted:** We addressed this point in the methods section and added information on the delayed assessments after intervention (page 6). We wanted to give the parents opportunities to practice the new skills. The other reason was the biologically slow change of A1c.

6. **Theoretical framework for guiding the study:** The theoretical framework of the DELFIN program is based on principles derived from behaviour therapy. We combined cognitive and behavioural strategies that had been evaluated before in training programs (e. g. refs. 35, 36, 37 and 38). We supplemented the background section in the paper regarding this comment (page 5).

7. **Recommendation of a power calculation:** We performed a power calculation. The required sample size for detecting significant differences in the study groups was N = 64 (n = 32 for each study group). Unfortunately we were not able to recruit more than n = 73 parents and 8 of them dropped out after randomization. Later we lost another 8 parents thus that we could not reach the recommended sample size.
8. **Adherence to session attendance should be included:** We addressed this point on page 12 and included the adherence to session attendance for the families in the paragraph “Satisfaction with the DELFIN program”. We added information about homework adherence and introduced the effects of the supra-regional catchment area of the clinic.

9. **Including the age range in the abstract:** The age range of the children has been included in the abstract (page 3).

10. **Acknowledging the decrease in anxiety and stress in the control group in the abstract:** We corrected the abstract accordingly. The decrease in anxiety and stress in the control group is now mentioned in the abstract (page 3).

11. **Efficacy and outcomes of the 3 programs for German-speaking families mentioned:** We added new references in the background section (page 4). We have also reformulated this point and added information about the current state of these programs. They are focusing on diabetes education not on supporting parenting behaviour.

12. **Including the design in the method section:** The design (randomized controlled group design, with the control group being wait listed) was included in the method section on page 6, first paragraph.

13. **Statement of clear hypotheses:** The hypotheses can be found on page 5, last paragraph.

14. **Indication of the name of the subscale in which the control group improved:** The name of the subscale which improved in the control group can be found on page 10.

15. **Inclusion of the sample size for correlations:** Spearman’s correlations were calculated for the parents of the DELFIN group and we included the sample size (page 26).