Author's response to reviews

Title: Qualitative observation instrument to measure the quality of parent-child interactions in young children with type 1 diabetes mellitus.

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

April 3, 2014

I kindly request that you reconsider our enclosed manuscript for publication in *BMC Pediatrics*, entitled:

‘Qualitative observation instrument to measure the quality of parent-child interactions in young children with type 1 diabetes mellitus’

The present paper describes the development, usability, reliability and preliminary validity of a qualitative observation instrument to measure the quality of parent-child interactions in young children (0-7 years) with type 1 diabetes mellitus.

We already have submitted our manuscript to *BMC Pediatrics* and received comments on our manuscript from reviewers. Based on their comments, we have revised our manuscript and hereby resubmit our manuscript. Below, you will find the comments of the reviewers and our answers on their concerns.

We were able to address all of the issues the reviewers suggested and believe that our manuscript will suite BMC Pediatrics. With the qualitative observation instrument, researchers, pediatricians, diabetes-nurses or psychologists are able to test whether parent-child interactions are associated with outcomes like glycemic control or psychosocial functioning. Furthermore, they could evaluate interventions aimed at optimizing the quality of parent-child interaction in families who have problems during diabetes-management. This could help improve the parent-child interactions during diabetes-management tasks in families with a young child with type 1 diabetes.

I hope that you will find this manuscript of interest for the readers of your journal. If you would like more information, please feel free to contact me.

Sincerely yours,

Esther E. Hartman
Reviewer 1:

1. I think the distinction between existing research with older youth with diabetes and the sparse research on younger youth with diabetes could be made clearer. For example, the added sentence refers to "youth with T1DM" - do the authors mean older youth?

   To make the distinction clearer, we added the age range in our revised manuscript:
   P 11, L10-11: Also, as youth (11-18 years) with T1DM...
   P 16, L23-24: This could be due to the fact that the hypotheses were based on research with youth (11-18 years) with T1DM [6].

2. The distinction between significant correlations and correlations "in the expected direction" could be made clearer - I would suggest relabeling the latter category as "non-significant trends" to distinguish between which results are significant and which are promising but not actually significant results.

   The reviewer suggests relabeling the correlations ‘in the expected direction’ into ‘non-significant trends’. We have changed this in our revised manuscript on the following pages:
   P5, L7: and between |.10| and |.23| for non-significant trends
   P11, L15: significant or non-significant trend
   P15, L11-12, L24: and 13 non-significant trends..., ... higher were non-significant trends...
   P16, L22-23: statistically significant or showed promising but not significant trend. The correlations between the SDQ questionnaire and the OKI-DO domains almost all showed non-significant trends...

3. I appreciate the authors rephrasing the results as "encouraging" - I suggest using this term in the conclusions section of the abstract rather than saying that results support usability, etc.

   We have changed the formulation of the conclusions in the abstract as was suggested by the reviewer. P5, L4-6: The present study showed encouraging indications for the usability and inter-rater reliability (weighted kappa was 0.73) of the qualitative observation instrument. Furthermore, promising indications for the preliminary validity of the observation instrument for diabetes-specific situations were found...

4. Thank you for clarifying that the data from only ONE parent was used in the observation and analysis. The demographic characteristics of that parent should be specified in the table, rather than all participating parents, so the reader has an accurate understanding of whose data are being interpreted.

   The reviewer is right that we should only include the characteristics of the observed parents in the table. Therefore, we adjusted table 1 (P25) and changed the results section describing the characteristics of the parents (P 11, L25-28, P12, L1-3). Of the 74 mothers and 3 fathers that were observed, 67 mothers (91%) and 3 fathers (100 %) completed the form with the (socio)demographic characteristics and SDQ [25]. Most mothers (83%) and fathers
(100%) were cohabiting or married/registered partners (7% of the mothers and 0% of the fathers were single). Half of the participating mothers (50%) had a higher educational level (i.e., approximately 12 years of formal education), while all fathers (100%) had a Bachelor’s or Master’s degree (i.e., approximately 15 years of formal education).

Reviewer 2:

1. In page 4, line 17 I would suggest to write the statement “this is approximately 10% of the total population of children with T1DM aged 0-7 years in the Netherlands [25]” as part of the discussion instead of the methodology.

Like the reviewer suggests, we have relocated this sentence to the discussion section (P17, L9-10): (this is approximately 10% of the total population of children with T1DM aged 0-7 years in the Netherlands [43])

2. In page 4, line 24, I would suggest to specify that "the sociodemographic questionnaire was designed specifically for this study” as it is not a validated questionnaire.

Like the reviewer suggests, we have added the statement that the sociodemographic questionnaire is not a validated questionnaire on P8, L18-21: Furthermore, parents were asked to fill out a questionnaire with (socio)demographic characteristics (i.e., gender of the child, age of the child, marital status parents, and educational levels of both parents) and clinical characteristics (i.e., treatment regimen, times they monitored their child’s blood glucose level a day (average), and years since diagnosis), specifically designed for this study.

3. In page 7, in line 28, I would suggest to report in the methodology that HbA1c was measured closest to the home visit (in the paper it is reported in the results).

The reviewer is right that this should be mentioned in the methods section, rather than the results section. Therefore, we have relocated it to the methods section (P8, L21-23): Glycosylated hemoglobin (HbA1c), measured closest to the home-visit, was locally determined at the hospital the child was treated and extracted from the medical record.

4. In the methodology, an explanation about how the sample size was selected and calculated could improve the understanding.

In the discussion section, we explain that our sample size was lower than anticipated, P17, L5-8: Our sample size was lower than anticipated. Unfortunately, we were not able to include the 120 families we aimed to include [3]. Despite a participation rate of 64% (70% was expected), we included 77 families (this is approximately 10% of the total population of children with T1DM aged 0-7 years in the Netherlands [43]), although 15 hospitals participated in our study instead of 7 [3]. The reviewer wants us to be clearer about our sample size in the methodology section. Therefore, we explained in more detail how the sample size was selected and calculated on P8, L1-13: At first, all infants, toddlers and (pre)school children (aged 0-7 years) treated for
T1DM and their parents were recruited from Kidz&Ko, a partnership between seven pediatric diabetes clinics, and Diabeter, a national center for pediatric and adolescent diabetes care and research. Due to a small sample size, we also recruited all children (0-7 years) with T1DM from 7 other hospitals in the Netherlands (Isala Clinics Zwolle, Amphia Hospital Breda, Franciscus Hospital Roosendaal, Academic Hospital Maastricht, Medical Spectrum Twente Enschede, Zorg Groep Twente Almelo/Hengelo, Atrium Medical Center Heerlen). In these 15 hospitals, 138 young children with T1DM were treated. Parents who lacked basic proficiency in Dutch were excluded, as well as children who were mentally disabled and/or had Down syndrome, or were diagnosed with an Autism Spectrum Disorder (total families excluded: n=17). Of the 121 eligible parents of children with T1DM, 77 families (64%) agreed to participate. Reasons for not participating were: not willing to be videotaped (n=18), a recent hospitalization of the child (n=3), loss of a family member (n=1) or personal reasons (n=22).