Author's response to reviews

Title:A pilot study to determine the short term effect of milk with differing glycaemic property on sleep among toddlers: A randomized controlled trial

Authors:

Snigdha Misra Dr (snigdha_misra@imu.edu.my)
Geok Lin Khor Prof (geoklin_khor@imu.edu.my)
Shamsul Haque Dr (shamsul@monash.edu.my)
Peter Mitchell Prof (Peter.Mitchell@nottingham.edu.my)
David Benton Prof (d.benton@swansea.ac.uk)

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Author's response to reviews: see over
**Reviewer's comments**

<table>
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<th>Sl. No.</th>
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| Editorial | This is an interesting study but some aspects of methodology were not adequately described | - Line 128- study design A double-blind randomised control trial (between subjects) design was adopted  
- The main outcome measure was sleep, measured using the actiwatch. Outcome measures were recorded at the end of the trial period. |
| | • Study design, outcome variables and parameters. | - Polysomnography, is a test used to diagnose sleep disorders. It is generally used to determine the night time sleep patterns. Polysomnography was not included in the study as our main aim was to assess the impact of the carbohydrate type on the sleep patterns of toddlers. |
| | • Specifically, it is important to know why polysomnography was not included in the study. | |
| Reviewer 1 | the text lacks scientific writing and several sections need to be Re-written. English editing is necessary. | Revised |
| Abstract | Should be rewritten according to the following comments  
Introduction Lines 69-73: The use of references is needed  
**Lines 78-87**: Revision is needed. The mechanism should be described in a clear manner in one paragraph.  
**Line 88 and elsewhere**: Sometimes capital letters are used and sometimes not. This should be uniform throughout the text.  
Line 91 and elsewhere: Terms should be abbreviated the first time they appear in text (eg GI, CHO). Also there is no need to use so many abbreviations throughout the text.  
**Issues that need to be considered**: The point that the authors want to make is not clearly addressed through the introduction. The hypothesis is not backed in the introduction. | - Complied  
**Lines 83-90** |
| Methods | Main methodological issues are: | - Complied  
- Complied  
- Complied  
- Lines 120-141 |
• The milk formulas are not iso-caloric and it seems that apart from differing GI, the two formulas are also low and high in carbohydrate. This has to be discussed.

• There is no information for daily diet from dietary analysis or standardization of meals.

• As it is mentioned in introduction food timing is another important factor in sleeping patterns. However, timing of feedings is not mentioned and maybe not controlled.

• Polysomnography could have produced more quality data.

Line 147: Why breastfeeding toddlers were allowed in the study since babies and toddlers who breastfeed have totally different feeding and sleeping patterns from formula fed? This has to be discussed.

Line 157: This is mentioned above.

The milk formulas were isocaloric. The main difference between the two products was that the HGI milk product contained added sugars contributing to a higher level of total carbohydrate (71.7%). While, LGI milk product had no added sugars. The total CHO of the LGI product was close to regular fresh milk (38.8%), thereby contributing to a lower GI value. (Lines 201-206)

• The meals provided to the toddlers were not isocaloric. All the day care centres followed a standardised menu.

• The timing of the feed was controlled. All the toddlers were provided with the test feed 3 times per day, at the day care centres. However, the toddlers were also provided with the test milk if needed at home. But the timing of the feed was not controlled, if given at home.

• Polysomnography, is a test used to diagnose sleep disorders. It is generally used to determine the night time sleep patterns. Actigraphy was used as it captures both-the day time sleep and night time sleep without restricting the child’s freedom of movement. Moreover, it was easy to monitor the sleep during the day time at the child care centres and also at night at home. It was less burdensome on the child care providers as well as the parents. The toddlers seemed to be well adapted to wearing the actigraph watches.

• Toddlers who were breastfed only during the night were also included in the study. The mothers reported that the toddlers were breast fed during the night to gradually wean from breast feeding. It was considered unethical to abstain the toddlers from breast feeding at night. (Lines 177-181)
This paragraph should be titled “Test products” giving more information on the milk formulas tested (eg composition/ingredients of the two products).

Which ingredient increased GI of the HGI formula?

How many ml consumed in total?

Questionnaires etc used in the study should be added to the study Design

Were there children above 2 y? This is not mentioned elsewhere.

Analysis of the method “Actigraphy” is too extended, while information on the actual outcomes is not given.

The age range of the children was 14-24 months. Children above the age of 2 years were not included in the study.

Complied

Confidentiality of the ingredients used is to be maintained as this product is currently available in the market.

Added sugars increased the GI of HGI

About 180 ml of milk was consumed per feed. The total amount consumed per day ranged from 540 ml-720 ml.

A questionnaire was used to collect information on the complementary feeding practices of the toddlers. The questions asked were; type of food and beverages consumed, amount of food and the age at which the foods were introduced. However, the information obtained is beyond the scope of the present paper. (Lines 196-170)

Complied

The age range of the children was 14-24 months. Children above the age of 2 years were not included in the study.

Complied

There is no need for such an extensive overview of socio-demographic data since they appear in Table. Use either text or table.

Use units.

Issues that need to be considered: Was there any power calculation done?

To the best of our knowledge, data on toddlers’ sleep pattern was unavailable. Hence, as a pilot study, 70 subjects were suggested to arrive at a power of 90%. Due to a high non-response rate, only 56 toddlers could be recruited for the study.

Per scoop information reflects the macronutrients present.

Results

Complied

Complied. TST (hrs), SOL(mins), WASO(mins), SE(%)
• Is there a mistake in Iron and Zinc values for LGI formula?
• Table 2: Too extended. In most indices only Mean ± SD would be enough for all tables.
• Table 3: Again too extended. It seems that there were some malnourished / Under nourished children. This should be discussed.
• Additionally, it would be interesting if BMI categories were associated with sleeping duration and the other sleep related indices.
• Table 4: Not needed
• Table 5: Units are missing so it is impossible for someone to interpret the data!
• However, if total sleep is in hours it seems that 7 hours is too little for toddlers. Is it only nocturnal sleep time? This has to be clear.
• Figure 1: Check for editing mistakes

Reviewer 2
Major Compulsory Revisions
Abstract
• Background
• Last sentence should be expunged
• Methods
• Is the consent written or just informed. What about consent from your hospital
• Results
• Sample size is small
• Introduction
• What is the justification for this study?
• The introduction is ling and verbose

• Table 1: no mistake
• Complied
• Complied
• This is beyond the scope of the objective. Our main aim was to determine the difference in sleep patterns among the groups fed with differing GI milk.
• Has been removed.
• Complied
• 7 hours is the total sleep time (diurnal and nocturnal)
• Complied

• Written consent was obtained as mentioned under ethical considerations
• Small sample size is due to the high non response rate
• Many milk products for growing children which are commercially available have a high level of added sugars. The added sugars in the long run may contribute to Obesity and other non-communicable diseases. There have been claims that high carbohydrates induces better sleep pattern. Hence the present study was designed to understand if the milk products with lower GI can have a better outcome among children.
Authors should quote studies by Chinawa et al on sleep studies
b, JM Chinawa, BF Chukwu, HA Obu. Sleep practices among medical students in Pediatrics Department of University of Nigeria Teaching Hospital, Ituku/Ozalla, Enugu, Nigeria

**Methods**

- Toddlers with underlying health complications and with continued breast feeding throughout the study period were excluded. (What are these complications?)
- What is the components of this milk, does this component affect glycaemic control or nutritional status on some children with cow milk allergy?
- Did you validate this questionnaire
- Anthropometry
  - The children were weighed with minimum clothing to the nearest 10g (this is not ideal)
  - What are the sensitivities and specificities of the weighing scale and instrument the authors used to measure the height of children?
  - So much emphasis on actiware software

**Anthropometry**

- The children were weighed with minimum clothing to the nearest 10g (this is not ideal)
- What are the sensitivities and specificities of the weighing scale and instrument the authors used to measure the height of children?
- So much emphasis on actiware software

**Discussion**

- First paragraph looks more like report of results than discussion
- When the author tried to compare their studies with others, they did a simple comparison without really doing a thorough critique
- (SDpooled) for two groups of size n and with means \([23] x_-\). The effect size thus 278 obtained was 0.32, which indicates that there is a moderate effect of the LGI
- These studies were conducted among older children with a different outcome. Hence may not be suitable in the present context
- Breast milk has a GI of 20. It may have an effect on the sleep patterns. Hence, breast fed toddlers were excluded.
- Underlying health conditions included-known conditions of allergy, bronchitis, etc
- The components of the products would not be disclosed as the product is commercially available. The issue on glycaemic control is beyond the scope of the study
- The questionnaire was not validated. Questions pertaining to complementary feeding and breast feeding practices were asked, which is not presented in this context. *(Lines 196-170)*
- Complied
product 279 group over the HGI group, despite the modest sample size. Further studies are
- 280 suggested with a larger population to affirm the trends noticed in the present study.
- Are these statements really necessary? It is more like data analysis or results, not discussion.
- In general, the discussion should be rewritten.

**Conclusion**
- The conclusion is too long, this should be made succinct.

**References**
- Some of the references cited are very old
- References are not uniform; some are Vancouver while some are not
- Minor revisions
- It is expedient to send this article to an English editing service
- Level of interest: An article of limited interest
- Quality of written English: Needs some language corrections before being published

| Complied | Complied | Complied | Complied |