Author’s response to reviews

Title: Development and feasibility of a wearable infant wrist band for the objective measurement of physical activity using accelerometry

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Version: 2 Date: 15 Jan 2018

Author’s response to reviews:

Reviewers’ comments:

Reviewer #1:

This is an interesting paper which examines the feasibility of an accelerometer for use in infants 3-24 months old. The paper is well written and would be of interest to researchers examining physical activity in young children. I have one small comment which the authors should consider.

Briefly, the authors are using qualitative and quantitative methods to examine the acceptability of the device among mother-child dyads. Since open-ended answers were allowed to the questions asked of mothers, did the authors use a qualitative analysis strategy for developing themes from the responses? If there were few instances of open-ended responses to these questions, then this comment can be disregarded as long as all individual responses are reported in the paper.

Thank you for your feedback. Some of the questions allowed for open-ended responses, yet only a few of the participants chose to complete these open ended responses. We have ensured that all individual responses are reported in the results. If apparent themes were evident, we have reported these themes and the number of participants responding according to each of these themes (Pages 13-14).
Reviewer #2:

The study seems to be conducted very thoroughly and the manuscript reads very well.

My only concern is issues regarding the safety and buttoning, especially only less than half of the mothers (44%) found it secure and safe, and more than one third were worried that their child would unbutton. Also, 34% of the children tried to take the band off, which shows some acceptability issues among children.

While only 44% of mothers reported that they found the buttoning mechanism to be safe and secure, 87% of mothers reported that they were happy with the safety of the band itself (Page 15 lines 5-6). Of those who reported that they did not find the buttoning mechanism to be safe and secure, 40% also reported that they were worried about the child being able to unbutton the band, the majority of whom were mothers of older toddlers as reported in the text (Page 14 lines 12-13). Therefore although there were some concerns about children being able to unbutton the device (although none were reported to be able to do so), most mothers found the band to be safe.

Many mothers reported that their children were curious about the device and were playing with it or biting it (teething) – therefore we believe that the children who had tried to take the band off were likely doing so out of curiosity. Only three mothers reported that they had perceived a negative reaction in from their children, which may have resulted in taking the band off. The majority of children who had tried to take the band off were older than 12 months and it is therefore possible that older toddlers with more autonomy may have taken the band off or may have been exposed to more environments were the bands might be lost (Page 17 lines 9-11). However, while not reported in this paper, the mothers themselves also wore the monitor (in the original Axivity adult band) at the same time as their children, and in 4/6 cases where the child lost their monitor the mother had lost her monitor as well. This indicates that the monitors were lost due to reasons other than the child removing the monitors themselves (ie.: the mother removed the monitors to wash/change and misplaced them or one case of the monitors being stolen which was reported by a mother). Thus it is less likely that these lost monitors point to poor acceptability from the children.

It is not clearly reported how some of the devices were lost. Were the children able to unbutton the device themselves?

Although it was not specifically asked in the questionnaire, none of the mothers reported that their children were able to take the bands off themselves. We did not collect data on how devices were lost, but all children who lost their devices were aged 18-24 months (Page 14 lines...
12-13) and so it is possible that they were able to take the band off themselves and subsequently lost them (Page 17 lines 15-17).

Issues raised by mother such as making their child itchy and hyperactive need to be addressed.

Thank you. While we ensured that the fabric used was hypoallergenic, in future we will need to ensure that mothers are warned to remove the band if any kind of sensitivity reaction occurs (Page 18 lines 11-12). Only one mother reported a physiological reaction to the band, but it is possible that the child (aged 12 months) was simply playing with the band out of curiosity, as was reported to have occurred at least briefly by many mothers.

One mother reported that the band made her child ‘hyperactive’, but as stated in the discussion this could have been misreported due to a language barrier (i.e.: her child was active), or could also be due to the mother reporting what she thought was expected, knowing that the band measured movement. This information has now been removed in the process of shortening the discussion as suggested by reviewer 3.

More work is needed to make the device more acceptable for parents and children.

Neither of the mothers who reported that the band made their child itchy or hyperactive reported being concerned with the safety of the band or with any specific component of the band, and therefore it is difficult to make adjustments to the design to make the device more acceptable based on their responses. However, we have subsequently made adjustments according to the other responses received, i.e.: the band will no longer be used multiple times, and improved stitching techniques and material are now being used in accordance with the concerns raised by the mothers (Page 18). Therefore, according to the feedback received, we have adjusted the band accordingly in order to improve acceptability.

Reviewer #3:

This paper reports a study of mothers' views towards a wristband designed to facilitate objective measurement of physical activity when worn by infants.

The main limitation of the work is that, although presented here as a study of feasibility and acceptability, no a priori feasibility or acceptability criteria are presented. This causes several
problems. First, without pre-specified success criteria, it is not possible to establish whether the wristband was indeed feasible or acceptable. Five relevant dimensions of feasibility and acceptability are described in the Discussion (p15), but success criteria should be specified at an earlier point (e.g. end of Introduction, or in Method). Additionally, many of the dimensions described on p15 are not quantifiable (or at least, not quantified): for example, 'the ability of the band to be worn for at least three days consecutively'. What are the criteria for assessing 'ability' here?

Thank you for raising this valid point. We have now added the success criteria into the introduction. We have also modified the terminology used when describing these criteria so as to allow them to be quantifiable. The criteria are now listed as follows (Page 6):

“The following criteria will be used to determine feasibility and acceptability: 1) the majority of participants (>80%) should wear the band for at least three, but up to seven, days consecutively; 2) the majority of data produced (>80%) should be technically reliable; 3) the band should fit an Axivity AX3 accelerometer; 4) the band should be worn for the required number of days by the majority (>80%) of infants and toddlers between the ages of 3-24 months; and 5) the majority of mothers (>80%) should rate the acceptability of the device as high according to the design specifications - comfort (very comfortable or comfortable), safety (very happy or happy), the buttoning mechanism (easy to unbutton), and drying capability (very quickly or quickly).”

The discussion has now been modified in order to align with these a priori criteria, and in order to quantify whether these criteria were met or not. This section now reads as follows (page 16):

The infant wearable band was considered to be feasible in this context based on a priori criteria: 1) the majority of participants (>95%) wore the band for at least three, but up to seven, days consecutively; 2) the majority of data produced was technically reliable (99% correctly initialised and 100% correctly downloaded); 3) the band was able to fit an Axivity AX3 accelerometer; 4) the band was worn for the required number of days by the majority of infants and toddlers (91% of 3 month infants, 100% of 6 month infants, 100% of 12 month toddlers, 90% of 18 month toddlers and 88% of 24 month toddlers); and 5) the majority of mothers (80-95%) rated the acceptability of the device as high according to the design specifications - comfort (90%), safety (87%), buttoning mechanism (95%), and drying capability (80%).

Second, the Discussion is rather unfocused and overly long, because it describes not only quantifiable feasibility and acceptability outcomes, but also parents' views towards the wristband more broadly.
We have restructured the discussion to fall better in line with the aims of the study. Furthermore, we have cut out some sections that are not relevant for the feasibility and acceptability outcomes, which have shortened the discussion significantly. Some of the findings, while not specifically related to quantifiable feasibility and acceptability outcomes, were considered to be relevant in order to provide contextual information or qualitative feedback, and these have remained in the discussion but have been shortened where possible.

Relatedly, what is the authors’ definition of ‘acceptability’? As I understand it, the term refers to whether potential participants would be willing to receive or engage with a particular treatment - in this case, whether parents would be willing to allow their children to be fitted with the wristband, with the intention for it to be worn for 7 days. Yet, it is not clear whether all of the data presented here are relevant to acceptability. For example, the authors present data on parents’ preference for wristband colour. But what evidence is there that the colour of the wristband is of consequence for the acceptability of the wristband? If none, how do we know that these data are of importance? The same applies to the 'perceptions' and 'comfort' data presented on p14. Similarly, on p17: 'the majority of mothers noticed some form of response … although this was mainly due to curiosity and was not of concern'. If these data are 'not of concern', why report and discuss them?

We agree with your definition of acceptability, however in order to understand the factors that are influencing acceptability in this population we asked questions about colour (which has cultural implications in South Africa), comfort, fabric, ease of use (buttoning mechanism), etc., as these will all determine whether the mother would be willing to let their child wear the band in the future. Therefore, we have reported on these factors in order to fully understand how the bands were perceived and issues that may affect acceptability. We believe that by incorporating questions around these various factors related to acceptability, in conjunction with the wear time data, we have a better understanding of issues that may have affected acceptability and can modify the design accordingly. We have now removed some of the discussion around factors deemed to be irrelevant by the reviewer. Since the questionnaire included some open ended questions, we needed to report on all of the answers received in order to ensure that the reporting of the qualitative data was not biased (and in line with reviewer 1’s comments). Furthermore, although some responses did not seem to cause concerns about the safety of the device, they may have caused concern about acceptability and are hence reported. We have reworded some of these sections for clarity.

Also problematic is the limited nature of some of the data that are provided. For example, we learn that some parents were 'a little worried' or 'very worried' about the safety of the wristband (p13). But no data are available to explain the exact concerns that underpinned these responses.
Furthermore, where qualitative data are provided to explain mothers' concerns, the authors suggest that the data may not be particularly meaningful because of language translation problems, which undermines the credibility of the data. For these reasons, we learn little about how the wristband might be improved to address these concerns.

Unfortunately, it is true that some participants did not provide response elucidating their choices, which limits our ability to understand why certain choices were made. However, by including multiple questions around potential issues affecting acceptability (such as the comfort or buttoning mechanisms), we are more likely to be able to develop a fuller picture of where concern is arising. For this reason, where possible we have taken multiple responses each participant into account in order to better understand acceptability. There was only one instance where we implied that language translation may have been a problem (relating to the word “hyperactive” used by a mother) – although this has since been removed from the manuscript in accordance with the reviewer’s suggestion to shorten the discussion and remove factors that were not relevant to acceptability. In this particular instance, as suggested previously, it may be that the mother was meaning “active” – as in her child was moving a lot. This could have been due to her knowing that the band measures movement. It is not possible that the fabric band could cause hyperactivity and so we were attempting to understand this response in the context of the language used. As mentioned previously, this has now been removed as suggested.

Finally, the Introduction did not provide a very strong rationale for the study. On p5, four studies are mentioned that have involved infants wearing wrist or ankle bands. Why, then, is a new wristband required? The authors argue that 'none [of the four studies] have described the design of the attachments or the feasibility for future use' (p5). This would seem to be an issue of poor reporting in previous studies though, rather than that the wearables used in those studies are necessarily unsuitable.

Thank you. Besides the previous studies not describing the design of the band therefore not allowing reproducibility, they also mentioned various issues with the bands they had used – some of which may have affected the validity of the data acquired (such as the band moving around the waist or falling off multiple times). Furthermore, few tested the feasibility of the data produced from using these devices. It is important to standardise the measurement of physical activity in this population in order to allow data to be comparable between studies and usable for physical activity assessment – and creating a wrist band that can be reproduced for future use allows this to happen. We have now attempted to make this argument clearer by adding some of this detail into the introduction.