

Feasibility and acceptability of physical activity monitoring as an educational tool in the management of pediatric type 1 diabetes

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Abstract

Introduction

The spontaneous, sporadic and sometimes unpredictable nature of children's physical activity causes fluctuations in blood glucose level and challenges for children with type 1 diabetes. Physical activity monitoring has potential utility. This study aimed to explore the perceptions of physical activity monitoring among healthcare professionals and assess the feasibility and acceptability of using it in the management of paediatric type 1 diabetes.

Methods

Seven healthcare professionals from one paediatric diabetes centre in the UK were involved in a focus group. Data were analysed thematically. Physical activity monitoring using a wrist-worn monitor was tested for feasibility with thirteen children aged 7-11 years with type 1 diabetes. The primary outcome was feasibility (i.e., recruitment, adherence, data completion, adverse events and acceptability). Secondary measures were glycaemic control, parental self-efficacy for diabetes management and parental fear of hypoglycaemia.

Results

Healthcare professionals valued having an awareness of the level, type and intensity of children's physical activity. They identified unmet training and resource needs that would facilitate them being able to give physical activity advice to children and families. Recruitment rate was 20%, adherence to the activity monitoring was good and study completion rate was 62%. No adverse events were reported. Physical activity monitoring was deemed acceptable by parents.

Conclusions

Physical activity monitoring could be a feasible part of routine clinical practice, but further research is needed to understand whether healthcare professionals are best placed to implement it and what impact it has on health outcomes.

Introduction

Physical activity (PA) can benefit blood glucose (BG) control, lipid profile, and body composition in children with type 1 diabetes [1, 2] but figures suggest these children are less active than their peers [3-6]. This is potentially influenced by the challenge of managing BG level before, during and after PA, amplified by the spontaneous, often unpredictable and sporadic nature of children's activity [7, 8]. Children with type 1 diabetes are advised to do at least 60 minutes of moderate-to-vigorous physical activity per day and minimise sedentary time [2]. Children's activity is often characterised by vigorous intensity PA interspersed with light intensity and rest and the timing of activity may be less predictable than in adults [9]. Repeated bouts of vigorous PA in between longer periods of low-to-moderate intensity activity or rest has been shown to produce a lesser fall in BG levels compared with continuous moderate-intensity PA [9]. This results in a challenge of maintaining stable BG levels and the merit of different approach to management that takes into consideration the *intensity* and *timing* of activity rather than just the overall amount (as per traditional step count methods) [9, 10].

Fluctuation in BG level (hypo- and hyperglycaemia) is a side-effect of PA with significant physical symptoms and potential chronic complications [2, 9]. Parents of preadolescent children typically take responsibility for diabetes management and find PA a challenge, have concerns about activity-induced hypoglycaemia (fear of hypoglycaemia) [11, 12], may avoid intensive PA for their child due to fears [11] and perceive a need for support from healthcare professionals (HCPs) or other experts to help manage these difficulties [7, 8].

Healthcare professionals, as trusted sources of care can educate and support parents to have confidence in their ability to manage changes in BG level around PA [8, 13]. However, research findings suggest that paediatric diabetes HCPs perceive a lack of; i) competence, ii) confidence and iii) time to deliver this education in routine clinic appointments [12, 13]. Clinical guidelines in the UK encourage regular PA for children with type 1 diabetes [14], but offer HCPs little advice on how best to do this or how the management of BG levels around PA could be facilitated with available technologies.

Advances in insulin therapy and glucose monitoring devices means that technology plays a larger role in day-to-day diabetes management than perhaps in any other chronic illness [15]. Continuous glucose monitoring (CGM) devices provide information about current glucose concentration and a detailed picture of the pattern of BG throughout the day, enabling people to intervene and prevent hypo-/hyperglycaemia [2]. Objective PA monitoring using accelerometers is another potentially facilitative tool in day-to-day diabetes management, presenting opportunities to discuss and respond to true frequency and intensity of activity rather than parents, children and HCPs relying on recalled estimations of activity. Given the complexity of PA management among children with type 1 diabetes, one approach does not fit all and activity monitoring provides a way of tailoring clinical advice to an individual's behaviour. We have previously found that parents of children with type 1 diabetes in the UK want to see PA monitoring used as part of routine clinical practice to raise awareness about PA and its relationship with BG level [16]. PA monitoring may also facilitate communication between parents and HCPs [8] and so research is needed that explores its potential utility as an educational tool.

Previous research has used PA monitoring as a behaviour change intervention in attempt to find ways of increasing PA level among children with type 1 diabetes, as demonstrated in the UK ActivPals intervention. This found that self-monitoring with a wrist-worn pedometer linked to a smartphone App was regarded as feasible and acceptable by parents of children aged 7-16 years with type 1 diabetes despite no noticeable intervention effect on PA level [17]. The UK web-based STAK-D intervention found that preadolescent children aged 9-12 with type 1 diabetes could self-monitor their behaviour using a PA watch, though engagement was low, technical issues were experienced and no significant change was measured in PA level [18]. One previous study has used PA monitoring as a diabetes self-management tool, rather than a behaviour change tool. That research conducted in Germany assessed the acceptability of using a sensor to monitor PA among adolescents (14-17 years) with type 1 diabetes [19]. The PA sensor (DiaTrace) was integrated into a mobile phone and combined with a CGM. DiaTrace was highly accepted by users, who could monitor their activity in real-time and later visualise PA on graphs. Schiel et al. concluded that DiaTrace could be integrated

into clinical practice easily [19], which warrants further investigation. The aim of this study is to explore whether PA monitoring can be used as a way for HCPs and parents of pre-adolescent children with type 1 diabetes to better manage BG levels.

Objectives

1. To explore paediatric diabetes HCPs' perceptions of PA monitoring in the management of type 1 diabetes via a focus group.
2. To explore whether PA monitoring is feasible and acceptable when used as an educational tool in the management of paediatric type 1 diabetes.

Methods

The research protocol and all study documents were submitted to the Leeds East Research Ethics Committee (UK). Minor revisions were addressed and ethical approval was granted on 14/08/2017 (reference: 17/YH/0224). Health Research Authority approval was sought from a NHS site in the UK and granted on 28/08/2017. The ClinicalTrials.gov registration number is NCT03144869.

The research was concurrent mixed-methods and took two parts: part 1 involved a focus group with HCPs. Part 2 assessed the feasibility and acceptability of PA monitoring as an educational tool. The qualitative data in part 1 and 2 extended the breadth of the inquiry (expansion) and provided depth to the quantitative data (complementarity) [20].

Part 1: Focus group with HCPs

Participants

Paediatric diabetes HCPs (n=17) from one paediatric diabetes centre in the UK were invited to take part in a focus group in October 2017. Invitees included consultants, registrars, nurses, dieticians and psychologists. HCPs were eligible if they worked with children with type 1 diabetes. HCPs were emailed by the clinical investigator with an invitation to take part. Seven HCPs participated; there

were representatives from consultants, registrars, dieticians and nurses, male and female participants with a range of experience in type 1 diabetes from 2-24 years.

Data collection

The focus group was conducted at the place of work and facilitated by the Chief Investigator (HQ). HQ is a researcher in exercise psychology with a research background exploring PA among children with type 1 diabetes. HQ was not known to the HCPs prior to conducting the focus group. Written informed consent was received by the researcher prior to the focus group. The researcher followed a semi-structured interview script based on questions to explore HCPs' perceptions of PA monitoring in the management of paediatric diabetes (as per research objective 1). Questions included: *how much do HCPs know about their patients' PA levels?*; *what resources and training are currently available to help HCPs advise patients about PA?*; and *how useful would PA monitoring be in the management of paediatric type 1 diabetes?*. The focus group was recorded electronically and then transcribed verbatim by an external transcription company under a confidentiality agreement.

Data analysis

All identifiable data were removed from the transcripts. Transcripts were coded using NVivo software to organise the data. Data were analysed thematically using the approach outlined by Braun and Clarke [21]. The researcher looked for items of interest in the data (codes) and grouped common codes into themes. Verbatim quotations were used to illustrate the themes. Identifiers were removed from quotations to protect participant confidentiality.

Part 2: Feasibility and acceptability of PA monitoring

Participants

Children and their parent(s) were recruited from the same paediatric diabetes centre used in part 1. An advertisement was printed in the clinic newsletter and an invitation pack with expression of interest form was posted by the clinic to patients meeting the eligibility criteria (n=63) in January 2018. To be eligible, patients had to meet the following criteria: i) aged 7-11 years, ii) diagnosed with type 1

diabetes for at least 12 months, and iii) consenting parent (parent, carer or legal guardian).

Participants were not eligible if they: i) had a severe co-morbid disability that impacted their physical ability, ii) experienced recurrent hypoglycaemia (BG <4mmol/l daily/<70 mg/dl) or the consultant had concern about diabetes control, iii) unable to communicate in the English language (due to limited resources we were unable to have materials translated). The researcher met interested parents and children at their next clinic appointment to discuss the research and written informed consent was received from parents, and assent from children, prior to data collection.

Physical activity monitoring

The PA monitoring period occurred between meeting the researcher at a routine clinic appointment and the next routine clinic appointment. During the activity monitoring period, children wore a wrist-worn PA monitoring device on the non-dominant wrist like a watch (Runscribe, USA) for up to 5 days. The device had weight 15g and dimensions 35x25x7.5mm; it recorded triaxial accelerometry data at 10 Hz and store it locally in internal non-volatile memory. The advantage of this device over other similar PA monitors was that it stored raw data, rather just the acceleration counts for each epoch. This gave us the opportunity to select our processing algorithms after data were collected to provide the most sensitivity to changes in PA. The PA monitoring device did not have a visual feedback display as we did not intend to influence children's behaviour in this study. After the monitoring period, the PA data was downloaded by the research team, and analysed by dividing the collected data into 15s epochs. This epoch value was chosen as it has been shown that longer epochs, such as 60s, tend to underestimate moderate and vigorous PA in children [22].

The METs of each epoch were estimated using the technique of Hildebrand et al. [23] and then each epoch was categorised as sedentary, low, moderate and vigorous using the widely applied thresholds of 0, 1.5, 3 and 6 METs respectively [24]. The activity levels were then displayed as colour-coded activity plots at 15s resolution over each day in the monitoring period (red = vigorous; green = moderate; blue = light; grey = sitting or sedentary) (see Figure 1 for the illustration of the activity plots received by children and parents). Children and parents were not required to keep a diary of

activities during the monitoring period in attempt to keep the burden to a minimum and not to compromise the ability to determine the acceptability of activity monitoring using a device. Activity plots (Figure 1) and written feedback was prepared for each participant by the researcher. Each feedback report included a day-by-day written summary of the child's PA intensity across the day, addressing times of high and low intensity activity levels and posing questions to ask children and parents to reflect on what they were doing that day and how it may have influenced BG levels. Parents were encouraged to discuss their feedback with their diabetes team.

Figure 1 Activity plot showing one day of activity for male aged 7 (school day)

Data collection

Primary outcome measures

The feasibility study used quantitative data and interviews to evaluate the activity monitoring and the research processes rather than reach conclusions about its effectiveness or impact of the activity monitoring on behavioural or health outcomes. The primary endpoint was feasibility, measured with the following outcomes: recruitment, adherence, retention, data completion, adverse events and acceptability.

Recruitment: The number of eligible participants who consented to participate.

Adherence: The proportion of participants who adhered to the activity monitoring protocol which included having at least 3 days of activity data, as commonly used in studies with children [25]. Adherence of >70% would be deemed acceptable, as used in a similar study [18].

Retention: The number of participants completing the intervention, including all follow-up data collection (follow-up and interview) compared to the number started.

Data completion: Determined by recording the proportion of participants who completed the outcome measures (complete and partial or non-completion with reasons). The feasibility of gathering routinely collected data available in patients' clinic notes was assessed. Feasibility was determined if >85% of the sample had complete clinical records available, as used in a similar study [18].

Adverse events: Occurrence of adverse events was summarised using descriptive statistics. Occurrence of adverse events related to the intervention (e.g., severe hypoglycaemia, accident or injury) was assessed by participant self-report.

Acceptability: User acceptability of the research and intervention processes was assessed by interview with parents. Interviews at follow-up explored participant burden, acceptability of the PA monitor and usefulness of the PA feedback. The aim was to determine appropriateness of PA monitoring for use in a future trial and clinical practice.

Secondary outcome measures

Clinical data: Date of diagnosis, glycaemic control (HbA1c), height and weight measurements- measured by trained nurses as routine at every clinic appointment- were taken from the child's clinic notes, with consent.

Parental self-efficacy for diabetes management: Parental self-efficacy for diabetes management was assessed using the maternal self-efficacy for diabetes scale [26] before activity monitoring took place. The 17-item scale asks parents to rate their level of confidence in independently managing specific tasks related to diabetes management on a 5 point scale 1- not confident at all to 5- very confident without help.

Parental fear of hypoglycaemia: Parental fear of hypoglycaemia was assessed using the parents' Hypoglycemia Fear Survey (HFS) [27] before activity monitoring took place. The HFS is comprised of a 10-item behaviour (B) subscale and a 15-item worry (W) subscale. HFS-B items describe behaviours performed in order to avoid hypoglycaemic episodes and/or their negative consequences (e.g., by limiting exercise or PA). HFS-W items ask about specific concerns about hypoglycaemic episodes (e.g., episodes occurring during sleep, or having an accident).

Data analysis

Secondary endpoints and demographic data were summarised with descriptive statistics. If quantitative data were missing from survey responses, the sample average for that question was calculated (mean imputation method). Interview data were analysed thematically.

Results

Part 1: Focus group with HCPs

This section presents findings from the focus group with HCPs, each subheading represents a theme from the thematic analysis.

Healthcare professionals' awareness of children's physical activity level

HCPs acknowledged that having an awareness of PA type, intensity and duration was important for understanding the influence of the activity on diabetes management. The effect of PA and exercise on BG was described as, "*unpredictable*" and depended on the activity type (e.g., anaerobic and aerobic) or specific activity, for example:

"Swimming ...is very unpredictable because ... for some children they just absolutely love it and their glucose levels will drop. But for some children it's the worst thing in the world and the adrenalin sends their glucose levels shooting up because they just can't stand it and they're really stressed"

The environment and the duration of the activity, as well as the timing of the activity in relation to the last meal were all discussed as influential factors in the unpredictability of PA. The fluctuation in BG as a result of PA was believed to be a barrier to PA, especially the fear hypoglycaemia. For example:

"I think probably for families the big fear is that they're going to go low, and that's probably more their mental barrier to things, or their big anxiety is that they're going to go hypo and are they going to go hypo overnight or afterwards as well."

Children often have a diabetes management plan for Physical Education (PE) lessons in schools. However, HCPs acknowledged that it is difficult to know what PE actually involves and what the

energy expenditure might be, for example, *"One of the difficulties is that PE in school, especially for younger children, is largely not physical activity. It's largely standing around taking turns watching other people."* One HCP hypothesised that, *"actually children expend more energy at playtime than they do in PE lessons"*. The HCPs were also aware of differences in children's activity levels across the week and noticed the difference this can have on BG and required insulin regime.

Healthcare professionals' unmet physical activity training and resource needs

When asked what training they had received in the management of PA for children with type 1 diabetes, the HCPs explained how *"we'd probably like more"* and that their knowledge of the topic was based on experience and self-directed learning rather than formal education or training. HCPs described having a personal responsibility to reflect on past experience, learn from colleagues and voluntarily seek PA-specific education sessions, network meetings, webinars and conferences. The group believed that this meant that, *"It's the motivated [healthcare professionals] that end up turning up"* at such educational opportunities. A lack of time was cited as the main barrier to engaging in such resources.

Perceptions of physical activity monitoring for children with type 1 diabetes

Physical activity monitoring was regarded a learning opportunity for children and parents to recognise patterns in BG changes. The group acknowledged the appeal of any kind of technology for children with type 1 diabetes and their families. However, one HCP questioned whether they would be able to engage all families with PA monitoring; *"we have enormous difficulty getting them to look at their blood sugars which are key to their management of their diabetes, so I'm not sure how much they will engage with looking at something else"* and continued to say that perhaps only the motivated families and children would engage, suggesting that an incentive would be needed. One HCP added that PA monitoring would be useful in the management of insulin basal rate settings, for example;

"You set [basal rate] based on what your average day is. And of course some kids will do PE and walk to school on a Monday, but on Wednesday will do something completely different. So their basal rate settings may change from, will need to

change from a 4,000 step day to a 15,000 step day....for a small proportion of patients that sort of information could be very helpful."

The HCPs believed there is potentially interesting information to be gained from wearing a CGM and a PA monitor at the same time. HCPs also acknowledged an opportunity for PA monitoring to open up the discussion about PA between HCPs and patients. There was discussion around the benefits of having some 'hard evidence' of PA level, complementing a "solution-focussed" approach to diabetes management and action-planning with the family.

Part 2: Feasibility and acceptability study

Figure 2 Recruitment flowchart for Part 2 Feasibility study

Participants

The feasibility study sample consisted of 13 children with type 1 diabetes and their parent(s). Children's age ranged between 7 and 11 (mean = 8.9 years, SD = 1.5). Length of diabetes diagnosis ranged from 15 months to 86 months (mean = 41.1 months, SD = 22.7). Gender distribution was unequal, with females representing 39% of the sample.

Recruitment

The invite to participate in the research was distributed by the clinical team via post to patients on the clinic list who met the inclusion criteria (63 out of ~212 on the clinic list). An expression of interest was received by 17 patients (27% response rate). Informed consent was received by 13 children and parents (20% recruitment rate) (see Figure 2). It took 3 months to reach the target sample.

Adherence: Adherence to the activity monitor was 85% (100% adherence among those also wearing a CGM). Reasons for non-adherence were withdrawal (n=1) and technical problems (n=1). The majority (91%) of children had at least 3 full days of activity data.

Retention: At follow-up, 12 parents were invited for interview and 8 agreed to participate (62%).

Reason for non-completion was 'lost contact with the participant'.

Data completion: Questionnaires were checked for completeness and reasons for missing data explored. A visual scan of the data identified single items as missing at random. All participants had complete clinical records available for use as outcome measures.

Adverse events: No adverse events were reported.

Acceptability

Interviews explored the experience and acceptability of the PA monitoring (average interview duration 9 minutes). Most of the parents were motivated to be involved in the research because they valued the importance of PA and were interested in knowing about their child's PA level. Three parents were encouraged because PA monitoring might help them manage any unplanned PA their children engage in outside of normal daily routine.

Acceptability of the physical activity monitoring

All parents (n=8) said that their child enjoyed wearing the activity monitor. Reasons for liking the activity monitor ranged from it being a "*novelty*" (B1) to it being "*easy to wear*" (B5), liking "*competition*" (A1) and it making the child "*feel important*" (B3). Three parents explained that their child enjoyed being able to show the watch to other children. Some parents described difficulties with the size of the activity monitor wrist strap. Children with smaller wrists experienced the activity monitor falling out of the wrist strap. Parents also had positive feedback about the activity monitor, with only one experiencing worry about losing the activity monitor. Battery life meant that the activity monitor was worn by children for a maximum of 5 days and some parents felt that they would have benefitted from have PA data for a longer length of time (e.g., 2 weeks or more). The timing of the activity monitoring period was determined by when participants were recruited to the study and parents would have preferred a choice of when the monitoring period happened, for example during school term time rather than school holidays or vice versa. Two parents said their child also enjoyed the activity plots, for example: "*he found the print out really useful*" (A1) and, "*he enjoyed the feedback*" (B1). All parents interviewed valued the feedback they received about their child's PA. Whilst the PA activity plots (Figure 1) were received well by most parents, not all found the plots

easy to interpret. Accompanying the graphs with a written summary report was useful for the parent who found the plot difficult to understand.

Perceived impact of physical activity monitoring

All parents reported having better insight into their child's activity patterns, especially during the school day. Three parents felt reassured about PA intensity during the school day. One parent explained, *"I was quite surprised at how active he is at school actually because I thought they did a lot of sitting down... obviously they don't"* (B7). Parents were also surprised by the intensity of some activities and described having a raised awareness of different types and intensities of activity and the influence these have on BG. One parent considered making an adjustment to her child's diabetes management on one day of the week in response to what she had learned about her child's higher than expected activity level during the school day. Though the same parent acknowledged that not all parents would be able to recognise and make those adjustments without support from HCPs.

Other perceived impacts of the activity monitoring included reports of prompted conversations about PA with i) the school nurse (B5), ii) the child (A1, A2) and iii) with the diabetes team in clinic (A3). And although the PA monitor was not intended to promote behaviour change, two parents said that the activity feedback prompted them to encourage their child to be more physically active (B5, B7). Two parents said that their child now wants a similar activity tracker of their own.

Parents' recommendations for future implementation

Parents were interested in having more opportunities to receive PA feedback, especially around times when they find it difficult to manage BG and would benefit from a better understanding of how activity might be influential, such as on holiday, PE in school, and during the school week. One parent believed that having immediate, real-time PA feedback from the watch, rather than retrospective feedback would be more useful.

Two parents wanted to understand how the activity level relates to BG control and diabetes control, with the desire "*for [physical activity monitoring] to run alongside clinics on a regular basis*" (B7). Whilst parents were keen for PA monitoring and activity feedback to be discussed in clinic, they appreciated that there was limited time. An alternative suggestion was to have a seminar to discuss PA level. Parents were realistic about the resource implications, but one did acknowledge that, "*in a perfect world all parents would have the opportunity to try this out*" (A1). One parent suggested that it would be beneficial to involve the school in the PA monitoring in order to understand the impact of certain school-based physical and mental activities on BG level.

Secondary outcome measures

The secondary purpose of this study was to explore the feasibility of collecting outcome measures.

Table 1 Participant outcome data

Clinical data

HbA1c ranged from 37mmol/mol to 70mmol/mol (mean = 56.6 mmol/mol, SD = 10.4) (Table 1).

Based on the 2015 National Institute for Health and Care Excellence (NICE) guidelines recommending HbA1c of ≤ 48 mmol/mol [14], 15% of the sample would be considered to have good diabetes control (NB: the recommendation changed from ≤ 58 mmol/mol to ≤ 48 mmol/mol in 2005, so 62% of the sample would be regarded as in good control if based on NICE 2005 guidelines of ≤ 58 mmol/mol [28]). The clinic mean in 2018 was 59.1 mmol/mol and overall 66.9% patients achieved an HbA1c < 58 mmol/mol.

Parental self-efficacy for diabetes management

Overall, this group of parents demonstrated a high degree of confidence in their ability to manage their child's diabetes. The average response across items was at or above 4 ("somewhat confident without help") for 75% of the respondents. Parents were less confident on the item, "I can adjust my child's management plan to allow for an overnight stay away from home without parents", suggesting that time spent away from their child were perceived as more difficult for parents to manage...

Parental fear of hypoglycaemia

Overall, parents of children in this study scored low on the parent fear of hypoglycaemia survey (mean = 46) out of a possible score of 15-75. Higher scores reflect greater fear of hypoglycaemia. On average, parents scored 25 (mean) out of a possible score of 0–44 on the behaviour subscale and 22 (mean) on the worry subscale out of a possible 0–60. There was a wide range of total scores (32-71).

Discussion

Findings support the results from the existing literature showing that HCPs perceive PA among children with type 1 diabetes to be difficult to manage due to the unpredictability of children's behaviour [8, 12, 13]. There was concern from HCPs about the potential burden of asking children with type 1 diabetes to wear a PA monitor, especially those who already use insulin pumps and CGMs, but this study showed that children are willing to wear a wrist-worn activity monitor with good adherence, which supports other studies in this population [18]. PA monitoring has the potential to benefit parents by raising awareness of their child's PA level and patterns of activity, for example, periods of the day when children are more or less active how this influences BG control. It could be particularly beneficial for times when parents are not with their children and thus have no insight in how physically active their child has been, for example during the school day. This supports previous research exploring the barriers to PA for this population, where parents' involvement in PA decision-making (including insulin administration, BG monitoring) and reluctance to give others this responsibility is said to necessitate their presence during the activity and make it challenging when parents cannot be present [7]. Activity monitoring was regarded a useful way to understand the influence of PA level and intensity on BG level. This may be particularly beneficial when paired with CGM data, which has been explored in lab settings with children [4], but less so in 'real world' settings. This study did not seek to explore the benefits of PA monitoring as a behavioural change intervention, but there were some reports of children wanting their own activity monitor, suggesting that children might be interested in self-monitoring their PA behaviour with commercial PA monitors.

The recruitment rate (20%) was about normal for this population, where rates of 16% [29], 25% [16] and 35% [18] have been found in PA intervention studies. Recruitment took place during patients' routine clinical appointments meaning recruitment may have been quicker had we invited families to make additional visits for research purposes. Adherence to PA monitoring was acceptable among all participants and adherence rate was slightly higher in children using a CGM. Previous PA interventions have reported adherence rates between 50% and 100% [1]. Retention to follow-up (completion rate 62%) was slightly low compared to other studies in this area which have reported retention rates of 67% [29], 76% [18] and 100% [19]. Similar to other studies, we have shown that using PA monitors in children with type 1 diabetes is safe [29], but participants report technical issues with the monitor and some concerns about loss [17, 18]. Feedback from parents in this study suggested that the activity monitoring period needs to be self-selected in order for parents to get the information they desire about their child's PA behaviour, rather than determined by the research timings. It was apparent that parents were particularly interested in PA insights from times when they were not with their child such as during the school day and found PA insights from weekends and school holidays less useful. A longer period of activity monitoring would also be preferred. Future research should consider how longer PA monitoring periods could be used, taking into consideration alternative PA devices..

The findings from this study should be considered in light of the following limitations and unanswered questions. Given that the PA monitoring in this study was delivered by the research team, further research should explore whether PA monitoring is feasible and acceptable when delivered outside of research conditions. Further research needs to clarify who is best placed to collect, process and analyse PA data from monitors and then deliver PA advice, guidance and feedback to children with type 1 diabetes. Adherence to the activity monitoring was acceptable under research conditions, but it is less clear how compliant children and parents would be beyond the study period. Parental hypoglycaemia fear scores and efficacy scores suggest that our sample may have been biased. Having an already confident, engaged sample was a concern raised by the HCPs in the focus group and was

reflected in the sample's mean HbA1c being lower than the clinic average. This suggests a need for future research to explore ways of engaging with families who might benefit the most from extra diabetes management support (i.e., those who lack confidence or have higher HbA1c levels). It would also be useful to explore the following questions: i) what impact PA monitoring has on important health and behavioural outcomes for children with type 1 diabetes and their parents (e.g., PA level)? and ii) can PA monitoring help demonstrate the relationship between PA and BG level when used with CGMs?

Conclusion

This research has demonstrated that PA monitoring among children aged 7-11 years with type 1 diabetes is feasible and acceptable as part of routine clinical practice when delivered by a researcher. The findings suggest that PA data may give HCPs and parents a more complete picture of children's day-to-day activity level and might provide a useful opportunity to open up discussion about PA during routine clinic appointments. There is good potential of PA monitoring to support the clinical management of paediatric type 1 diabetes.

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Author Contributions

HQ conceived of the research idea, secured the funding, led on the conduct of the study and analysis of data and led on the drafting and re-drafting of the manuscript. BH contributed to the analysis of accelerometer data and drafting of the manuscript. NW contributed to the conception of the research idea, supported the conduct of the research and contributed to the drafting of the manuscript. All authors reviewed and approved the final version of the manuscript.

Conflict of interest

There are no known conflicts of interest.

Role of the funder and sponsor

This study was funded by The Children's Hospital Charity located in Sheffield Children's NHS Foundation Trust. Sheffield Children's Hospital NHS Foundation Trust was the study sponsor. The sponsor or funding source had no role in the study design, in the collection, analysis or interpretation of data, in the writing of the report or the decision to submit the article for publication.

Tables

Table 1 Participant outcome data

| ID | Child | Age | Diagnoses (months) | Height (cm) | Weight (kg) | Glycated haemoglobin (HbA1c) | Parental self- efficacy | Parental fear of hypoglycaemia | |
|----|--------|-----|-----------------------|----------------|----------------|--|-------------------------------|-----------------------------------|-------|
| | | | | | | | | Behaviour | Worry |
| A1 | Male | 8 | 70 | 137.0 | 30.4 | 49 | 76 | 24 | 23 |
| A2 | Female | 9 | 23 | 124.0 | 24.5 | 64 | 65 | 23 | 10 |

| | | | | | | | | | |
|-----------------|--------|----|----|-------|------|----|-----|-----|-----|
| A3 | Female | 10 | 55 | 136.6 | 30.6 | 67 | 85 | 23 | 9 |
| A4 | Female | 11 | 49 | 158.5 | 46.0 | 44 | 53 | 27 | 26 |
| A5 | Male | 7 | 20 | 122.0 | 24.7 | 37 | 67* | 23* | 20* |
| A6 | Male | 9 | 61 | 135.8 | 37.7 | 52 | 72 | 29 | 33 |
| B1 ^a | Male | 10 | 19 | 144.9 | 35.2 | 70 | 84 | 35 | 36 |
| B2 | Female | 10 | 15 | 137.4 | 30.8 | 51 | 83 | 19 | 36 |
| B3 | Male | 7 | 28 | 126.5 | 40.9 | 68 | 76 | 21 | 40 |
| B4 | Male | 8 | 23 | 130.5 | 29.1 | 55 | 80 | 28 | 9 |
| B5 | Female | 11 | 86 | 154.5 | 42.7 | 69 | 57 | 21 | 14 |
| B6 | Male | 7 | 53 | 127.1 | 27.6 | 55 | 67 | 28 | 12 |
| B7 | Male | 8 | 32 | 129.0 | 28.3 | 55 | 73 | 18 | 16 |

*missing data - sample average for that question used

^a 'B' indicates CGM users

Figures

Figure 1 Activity graph showing one day of activity for male aged 7 (school day)

Figure 2 Recruitment flowchart for Part 2 Feasibility study

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