Children's compliance with wrist worn accelerometry within a cluster randomised controlled trial: Findings from The Healthy Lifestyles Programme (HeLP)

Running heading: Children's Accelerometry Compliance within an RCT

Abstract

Purpose: To assess children's compliance with wrist worn accelerometry during a randomised control trial and to examine whether compliance differed by allocated condition or gender.

Method: 886 children within the Healthy Lifestyles Programme (HeLP) trial were randomly allocated to wear a GENEActiv accelerometer at baseline and 18 month follow up. Compliance with minimum wear time criteria (≥10 hours for 3 week, 1 weekend day) was obtained for both time points. Chi-squared tests were used to determine associations between compliance, group allocation and gender.

Results: At baseline, 851 children had useable data, 830 (97.5%) met the minimum wear time criteria, 631 (74.1%) had data for 7 days at 24 hours/day. At follow up, 789 children had useable data, 745 (94.4%) met the minimum wear time criteria, 528 (67%) children had complete data. Compliance did not differ by gender (baseline; X_2 = 1.66, p = 0.2, follow up; X_2 = 0.76, p = 0.4) or by group at follow up (X_2 = 2.35, p = 0.13).

Conclusion: The use of wrist worn accelerometers and robust trial procedures resulted in high compliance at two time points regardless of group allocation, demonstrating the feasibility of using precise physical activity monitors to measure intervention effectiveness.

Trial registration: ISRCTN 15811706

Background

Assessing children's physical activity (PA) using accelerometry is now common place in cohort studies (1, 2, 3) and randomised control trials.(4, 5) However, researchers still face challenges regarding choice of minimum wear time criteria and participant compliance (i.e. those who meet or exceed the minimum wear criteria), which can substantially affect interpretation of results. Setting a high wear time threshold for inclusion in data analysis tends to improve the precision of PA estimates (6) but often substantially increases the number of data files that have to be excluded from analyses due to missing data. This can result in selection bias, as the sample retained may differ on exposure to the intervention in a clinical trial, the outcome variable or other important covariates.(7, 8) Hence it is desirable to maximise both the retained sample size and the accelerometer wear time period. Recent developments in the design of activity monitors and wear protocols have sought to address these two methodological challenges.(9)

Evidence demonstrates that the use of a waterproof, wrist worn accelerometer, designed to be discrete and minimise discomfort, can reduce periods of non-wear in adults (10) with similar high compliance demonstrated in small samples of children. (11) This, in turn, reduces the need for statistical imputation methods, assumptions regarding missing values (7, 12) and the associated risks of selection bias and misclassification of PA. In addition, there is evidence that implementing a 24 hour wear protocol, albeit with waist worn devices, rather than the more commonly used 'waking hours only' protocol can also increase wear time compliance. (9) It would be expected that the combination of increasing both comfort/convenience/waterproofing and manipulating the wear time protocol should yield higher compliance, in turn leading to more precise estimates of PA across the entire week.

Despite evidence of high compliance at single measurement points (11) with wrist worn devices, evidence regarding compliance over multiple measure periods is limited. Assessing compliance over multiple measures is of particular importance in determining the effectiveness of behavioural interventions in randomised trials. Low compliance with the pre specified accelerometer wear time can exacerbate any loss to follow up; participants may complete all other trial outcomes but are treated as lost to follow up for PA outcomes due to their failure to meet the minimum accelerometer wear time criteria. Howie and colleagues (13) demonstrated a reduction from 89% to 79% compliance with wrist worn devices over 4 measurement points using 10 hours for four days criteria. The authors did not take into consideration the compliance with extended wear time that may be achievable with wrist worn devices, nor whether compliance differed across intervention arm. Despite randomisation prior to participants being allocated to intervention or control groups, if non-compliance with wear time is systematically different by group allocation, bias may be introduced.

The aim of this study was to examine children's compliance with a wrist worn accelerometer at baseline and 18 month follow up within a cluster randomised controlled trial, (5) using both traditional and extended wear time criteria. Secondly, the study aimed to examine whether compliance with follow up measures differed by group allocation (i.e. intervention vs. control groups), and whether compliance was associated with gender.

Methods

Participants

Data from the present study were obtained as part of the Healthy Lifestyles Programme (HeLP), a school based, cluster randomised control trial of a novel obesity prevention programme. (5) The trial involved 32 schools and 53 classes of Year 5 children (aged 9-10 years) across Devon, UK. One Year 5 class from each participating school was randomly selected to receive an accelerometer at baseline (n=886). Data were collected in two phases, with 16 schools in each cohort. Baseline physical activity data were collected in October 2012 and 2013 for Cohort 1 and Cohort 2 respectively. Schools were then randomised to receive HeLP (5) or to the control arm (usual practice). Full details of recruitment and study procedures are provided elsewhere (5, 14) (http://clahrc-peninsula.nihr.ac.uk/research/help-the-healthy-lifestyles-programme). Follow up PA data were collected 18 months post baseline, in June 2014 and 2015 for Cohorts 1 and 2, respectively. Ethical approval for the trial was obtained from the Peninsula College of Medicine and Dentistry in March 2012 (reference number 12/03/140).

Physical activity measurement

Physical activity was assessed using a GENEActiv (ActivInsights Ltd, Kimbolton, UK) tri-axial accelerometer, measuring 43mm x 40mm x 13mm. The GENEActiv was attached to a polyurethane strap, and worn at the wrist, like a watch. It can measure between +/- 8g at a rate of up to 100Hz. During the present study, data were collected at a rate of 85.7Hz.

Anthropometric measures

Children's height was measured using a SECA (hamburg, Germany) stadiometer and recorded to the nearest 0.1cm. Weight was measured using a Tanita Body Composition Analyser SC-330 (U.K ltd., Middlesex UK) and recorded to the nearest 0.1kg. BMI sds were calculated using the Cole (15) BMI reference curves for children. Waist circumference was measured 4cm above the umbilicus using a flexible (non-elastic) tape measure.

Protocol

Prior to distributing the monitors, parents received a reminder letter about the date the GENEActiv would be given to children and the date of removal. Monitors were distributed by HeLP co-ordinators to small groups (~10 per group) of children at a time. Participants were informed about the monitor placement and were asked to wear the monitors on their non-dominant wrist, continuously for a period of eight days, which included one familiarisation day. During these sessions, each child was provided with an information pack, including reminder sheets to display at home, and letters to distribute to sport coaches to prevent removal during extracurricular activities, alongside dates for monitor collection. The devices were collected by HeLP co-ordinators, with follow up visits made to collect any not returned on the planned collection day.

Anthropometric data was collected in a private room by two trained and blinded assessors during a specifically designed lesson relating to measurement (14).

Data analysis

Data were downloaded using GENEActiv PC software version 1.4 and analysed using the GGIR software (16, 17, 18) package for R (*cran.r-project.org*). Data processing included auto calibration using local gravity as a reference (16) and the detection of abnormally high values (16, 19). The raw values from each axis are used to create a vector magnitude ($\sqrt{x^2+y^2+z^2}-1g$) with negative values rounded to zero (20) creating the Euclidean Norm minus one (ENMO; measured in milli-g(mg) units) as reported elsewhere (16, 20.) Data were averaged over 1 second epochs, with the first and final 30 minutes removed from analysis, in order to minimise inclusion of spurious data at the beginning and end of data capture. Non-wear time was apparent if the standard deviation of two axes was less that 13mg and the value range was less than 50mg. Non-wear was assessed over 60 minute windows, using moving increments of 15 minutes. (2, 16) Time spent in different PA intensities were estimated using published accelerometer cut-points. (21)

Compliance was established for the minimum wear criteria of ≥10 hours for ≥ 3 week and 1 weekend day (22) at baseline and 18 month follow up. For data collected at baseline, a compliance matrix was created to report the number and percentage of children meeting multiple valid hours / day combinations. In order to assess compliance with valid hour/day combinations at the 18 month follow up, a further compliance matrix was created which only included those children who met the minimum wear time criteria at baseline, allowing a more thorough examination of any potential impact of non-compliance on the overall loss to follow up within the trial. Compliance with minimum wear criteria at baseline and follow up was also reported by gender for both time-points.

Pearson's Chi-squared test was used to assess whether compliance with minimum wear time was associated with group allocation (intervention vs. control) at the 18 month follow up. Only participants who met the minimum wear time criteria at baseline were included in this analysis. Sensitivity analysis using all available data from the 18 month follow up, irrespective of baseline compliance was also undertaken.

Results

Characteristics of the 886 participants (423 male; 463 female) allocated to receive accelerometry at baseline and 18 month follow up are outlined in table 1.

Baseline

Of the 886 participants; 851 had useable data (n = 409 male); missing data (n=35) were a result of monitor failure (including calibration error), or participant absence during the measurement period; shown in figure 1. Of those with useable data, 830 (97.5%) children met the minimum wear time criteria of ≥10 hours for 3 weekdays and 1 weekend day. Table 2 shows the number and percentage of children complying with varying combinations of valid hours / days. When split by gender, 96.8% (396/409) of males and 98.1% (434/442) of females met the minimum wear time criteria, there was no significant association between gender and compliance at baseline (X_2 = 1.66, p = 0.2).

156 Table 1. Anthropometric and physical activity characteristics at baseline and 18 months

	Baseline Mean (SD)			**18 month follow up** Mean (SD)		
	Whole cohort	**Intervention**	**control**	**Whole cohort**	**Intervention**	**control**
n	886	428	458	861	412	449
Gender (n male)	423	208	215	411	200	211
age (years)	9.7 (0.3)	9.8 (0.3)	9.7 (0.3)	11.3 (0.3)	11.3 (0.3)	11.3 (0.3)
height (cm)	138.3 (6.8)	138.7 (6.9)	137.8 (6.7)	147.7 (7.6)	148.2 (7.7)	147.2 (7.6)
weight (kg)	33.6 (7.5)	34.3 (8.1)	33.0 (7.0)	40.5 (9.8)	41.3 (10.4)	39.8 (9.1)
BMI sds [a]	0.19 (1.2)	0.27 (1.2)	0.11 (1.1)	0.19 (1.2)	0.27 (1.3)	0.12 (1.2)
waist circumference (cm)	61.0 (7.4)	61.7 (7.8)	60.4 (7.0)	64.1 (8.4)	64.6 (9.0)	63.7 (7.9)
Physical Activity characteristics [b]						
n	830	408	422	745	359	386
ENMO (mg)	49.3 (11.1)	49.0 (11.3)	49.6 (10.9)	51.8 (13.4)	52.1 (14.0)	51.5 (13.0)
Total PA[c] (minutes)	183.9 (35.7)	182.7 (36.7)	185.0 (34.7)	198.9 (42.0)	199.7 (43.9)	198.1 (40.2)
Light PA (minutes)	130.3 (24.4)	129.4 (24.7)	131.1 (24.2)	141.3 (27.4)	141.7 (27.8)	141.1 (27.1)
Moderate PA (minutes)	40.2 (11.7)	40.0 (12.1)	40.4 (11.4)	43.8 (14.8)	44.3 (16.2)	43.5 (13.4)

Vigorous PA (minutes)	13.42 (6.2)	13.3 (6.2)	13.5 (6.2)	13.6 (7.5)	13.7 (7.7)	13.5 (7.4)
MVPA (minutes)	53.6 (16.5)	53.3 (16.8)	53.9 (16.2)	57.5 (20.9)	58.0 (22.3)	57.0 (19.4)

PA - physical activity; [a]BMI sds calculated using Standard Deviation Scores were derived for body mass index (BMI), based on the UK 1990 BMI reference curves for children [15] [b]Physical activity characteristics for those who met the minimum inclusion criteria .[c] Total physical activity includes time in light, moderate and vigorous PA.

Table 2. Number (percentage) of children achieving different wear time combinations (days / hours) at baseline

	8 hours n (%)	10 hours n (%)	12 hours n (%)	14 hours n (%)	16 hours n (%)	18 hours n (%)	20 hours n (%)	22 hours n (%)	24 hours n (%)
7 days	812 (95.4)	807 (94.8)	803 (94.4)	800 (94.0)	789 (92.7)	759 (89.2)	751 (88.2)	742 (87.2)	631 (74.1)
6 days	819 (96.2)	818 (96.1)	815 (95.8)	813 (95.5)	808 (94.9)	801 (94.1)	797 (93.7)	791 (92.9)	765 (89.9)
5 days	826 (97.1)	825 (96.9)	824 (96.8)	822 (96.6)	819 (96.2)	814 (95.7)	813 (95.5)	808 (94.9)	802 (94.2)
4 days	840 (98.7)	832 (97.8)	830 (97.5)	830 (97.5)	825 (96.9)	817 (96.0)	816 (95.9)	814 (95.7)	811 (95.3)
3 days	847 (99.5)	843 (99.0)	839 (98.6)	839 (98.6)	835 (98.1)	828 (97.3)	826 (97.1)	824 (96.8)	822 (96.6)
2 days	849 (99.8)	848 (99.6)	847 (99.5)	846 (99.4)	840 (98.7)	838 (98.5)	836 (98.2)	833 (97.9)	829 (97.4)
1 day	851 (100)	851 (100)	851 (100)	851 (100)	850 (99.9)	844 (99.2)	843 (99.1)	842 (98.9)	839 (98.6)

Follow up

At follow up (18 months), 25 children had moved out of area, resulting in 861 children potentially available for follow up measures. Their characteristics are presented in Table 1. Of these 861 children, 789 (91.6%) had useable accelerometer data, and 745 (94.4%) met the minimum wear time criteria; 528 children (67%) achieved 24 hours for 7 days. When split by gender, 93.7% of males (356/380) and 95.1% (389/409) of females met the minimum wear criteria, no significant difference in compliance between gender was apparent at follow up (X_2 =0.76, p = 0.38).

When considering only those participants who had valid baseline data (n=830), 746 were potentially available for follow up; of the 84 children who were not available for follow up measures, 22 had moved out of area, 12 children were absent during the testing period, 4 children failed to return the device, 45 monitors failed or had calibration error and 1 child developed a rash and stopped wearing the accelerometer. Of the original 886 children randomised to participate in physical activity data collection, 705 (79.5%) met the minimum wear time criteria at both baseline and follow up. Analysis by gender showed 79.9% (338/423) of males and 79.2% (367/463) of females meeting the minimum wear criteria at both time points. Table 3 presents compliance for combinations of days and hours at 18 months for only those children who had valid baseline data.

For the 830 participants who had valid baseline data and were followed up at 18 months (n=705), Pearson's chi-squared showed no evidence of a statistical association between allocated group and compliance with minimum accelerometer wear time criteria at follow up; 6.8 % (n=25) in the intervention arm and 4.2 % (n=16) of children in the control arm did not meet minimum valid day criteria (X_2 = 2.35, p = 0.13). Sensitivity analysis using all available data from the 18 month follow up (n=789) also showed no association between group allocation and compliance (X_2 = 1.24, p = 0.27).

Table 3. Number (%) of children achieving wear time combinations (days / hours) at follow up*

	8 hours n (%)	10 hours n (%)	12 hours n (%)	14 hours n (%)	16 hours n (%)	18 hours n (%)	20 hours n (%)	22 hours n (%)	24 hours n (%)
7 days	669 (89.7)	663 (88.9)	660 (88.5)	651 (87.3)	642 (86.1)	607 (81.4)	592 (79.4)	575 (77.1)	499 (66.9)
6 days	690 (92.5)	687 (92.1)	683 (91.6)	675 (90.5)	663 (88.9)	650 (87.1)	646 (86.6)	632 (84.7)	613 (82.2)
5 days	707 (94.7)	702 (94.1)	697 (93.4)	693 (92.9)	686 (92.0)	675 (90.5)	669 (89.7)	664 (89.0)	654 (87.7)
4 days	721 (96.7)	719 (96.4)	714 (95.7)	713 (95.6)	706 (94.6)	696 (93.3)	689 (92.4)	680 (91.2)	674 (90.3)
3 days	731 (98.0)	729 (97.7)	725 (97.2)	721 (96.6)	715 (95.8)	707 (94.8)	703 (94.2)	696 (93.3)	691 (92.6)
2 days	744 (99.7)	744 (99.7)	742 (99.5)	740 (99.2)	734 (98.4)	729 (97.7)	726 (97.3)	717(96.1)	709 (95.0)
1 day	746 (100)	746 (100)	746 (100)	745 (99.9)	741 (99.3)	737 (98.8)	735 (89.5)	733 (98.3)	726 (97.3)

*only children with valid wear time at baseline are included in table 3.

Discussion

The primary aim of this study was to examine children's compliance with accelerometer wear time over two measurement points during a randomised controlled trial. The secondary aim was to assess whether compliance differed by group (intervention/control) allocation and gender. The results demonstrate high compliance with wrist worn accelerometry at both baseline (97.5%) and 18 month follow up (94.4%), with equally high compliance demonstrated by both males and females. Moreover, high rates of compliance were also apparent when assessing whether minimum wear time criteria was met at both time points; 705/886 (82.8%) children had ≥ 10hours of wear time for ≥ 4 days (including 1 weekend day) at both baseline and 18 months. Chi squared tests showed no association between gender and compliance (males vs females) at baseline and follow up. Nor were there associations with group allocation (intervention v control) and compliance with minimum wear time at 18 month follow up. It appears, therefore, that constant wear, avoiding having to remember to put on or activate an accelerometer, using a watch-like wrist-worn device is acceptable to children and, consequently, facilitates reliable data collection.

These findings demonstrate that high levels of compliance at multiple time points can be obtained by combining the use of wrist worn, waterproof accelerometers and a 24 hour wear time protocol within a cluster randomised controlled trial in 9-11year old children. Beyond meeting minimum wear time requirements, extended periods of wear can be achieved; providing more accurate estimates of PA, as the possibility of under or over estimating PA based only on capturing small portions of the day (23) or a limited number of days (24) is reduced. This may be particularly important in children's activity measurement due to the variation in their activity over the day.(25) In addition, very few children were lost due to non-wear, further reducing the impact of missing data and possible selection bias. Baseline compliance in the present study is slightly higher than rates previously reported in samples of children with wrist worn devices; Fairclough et al. (11) reported 89% compliance with ≥ 10 hours for 3 week days and 1 weekend day. Additionally, compliance in the HeLP trial compares favourably to data collected with similar populations within large cohort studies using waist worn monitors. (1, 3, 26, 27, 28). For example the Millennium cohort study reported 67% of children complying with ≥ 10 hours on at least 2 days (3); compliance rates within HeLP for the same criteria were 99.6%. It is likely that higher compliance rates within HeLP are due to monitor placement and trial procedures, as many studies using waist worn devices employ a 'waking time only' protocol (9).

Direct comparison of compliance rates between studies is challenging as the method of detecting non-wear can affect estimates of compliance even when the definition of compliance is the same. In the present study the method of detecting non-wear is based on non-wear algorithms that use the raw acceleration values from all three accelerometer axis (16). Arguably this method is more likely to accurately classify non-wear compared to methods based simply on extended periods of consecutive '0' counts (29). It is not clear whether the latter method leads to a greater under or overestimate of non-wear compared to methods based on raw acceleration.

Assessing the compliance at 18 month follow up using two methods a) as an independent time point and b) by considering rate of compliance at follow up with only those children who had provided 'valid' baseline data, allows for a more in depth view of how non-compliance with accelerometer wear may impact on loss to follow up within large scale trials of behavioural interventions. When the 18 month follow up time point is treated independently, compliance with minimum wear is similar to that observed at baseline (94.4%). Yet considering the rate of compliance across both time points provides important information for planning future trials; these results indicate that high compliance with minimum wear can be achieved at both baseline and follow up, with 79.5% of the original sample having valid data at both time points. Results indicate that the percentage of participants treated as 'lost' due to accelerometer non-compliance is low when using a combination of wrist worn devices, a 24 hour wear protocol and comprehensive trial procedures. These results are encouraging for future trials as previous studies reported a large drop in compliance with a minimum wear time of ≥10 hours for ≥3 days between two time points (from 75% to 56%) when using waist worn devices. (30)

Previously, trials of behavioural interventions assessing physical activity with accelerometers have reported lower compliance in the control group, (31) risking systematic missing data and selection bias. Results from the HeLP trial show that it is possible to achieve very high compliance in both allocated groups (intervention and control); possibly due to the cluster nature of the trial. In turn this allows greater sensitivity to detect potential intervention effects (32) and limited loss to follow up due to missing data. As a result, more precise physical activity estimates are possible, as is the capacity to detect small changes. Consequently, future studies may benefit from a reduction in required recruitment targets. (32)

Estimates of PA are reported to differ by gender in childhood, with males accumulating more MVPA than females (27). It is important to ensure that any observed differences are a result of actual behaviour rather than a consequence of systematic error resulting from differences in wear time compliance between genders. The present study demonstrated no association between gender and compliance with minimum wear time criteria at either measurement point. However it is important that differences in compliance are assessed prior to concluding whether are behavioural differences exist. (32).

Whilst providing important findings regarding compliance, the limitations of this study that arise from device failure should be highlighted. A substantial number of participants' data were lost as a result of device failure; this was particularly noticeable at the 18 month follow up assessment, where data from 48 participants were not able to be recovered from the device, increasing missing data at follow up. The device failure appeared to be a result of battery failure over time; future studies should take into consideration the life span of these devices during the study design and procurement phases.

Using a combination of a waterproof, wrist worn accelerometer and a 24 hour wear protocol means no conclusions can be made as to which factor or which combination of factors were most important in increasing compliance; previously Tudor-Locke et al. (9) demonstrated that increased compliance and wear time with waist-worn devices can be increased using a 24 hour protocol, rather than a wake time only protocol. Alternatively, Fairclough et al. (11) demonstrated higher compliance with wrist placement rather than waist-worn devices. It is clear, however, that combination of the two approaches and robust trial protocols provide the best compliance with accelerometer wear time.

Conclusion

High compliance with accelerometer wear time protocols can be achieved with children participating in a cluster randomised controlled trial at both baseline and follow up and does not differ by group (intervention/control) allocation. Constant wear of waterproof, wrist worn accelerometers alongside robust trial procedures should be utilised in physical activity research to minimise the number of children with missing data at follow up through non-compliance.

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