The feasibility and acceptability of using objective measures to evaluate the Macmillan Physical Activity Behaviour Change Care Pathway

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01. Background to the Macmillan approach

In this chapter, we provide a brief description of the Macmillan Physical Activity Behaviour Change Care Pathway and how the objective measure feasibility study aligns to the overall evaluation.

The Macmillan Physical Activity Behaviour Change Care Pathway (or the ‘Move More’ service as it is more commonly known) is an evidence-based service providing tailored, one-on-one support to help people living with cancer (PLWC) to become more active. The pathway was developed and implemented by Macmillan Cancer Support to promote physical activity, health, fitness and quality of life for people affected by cancer, and to increase their ability to lead an active and independent life and reduce their reliance on clinical services. To assess changes in physical activity levels as a result of this programme, self-report measures of physical activity were used. However, these proved to be limited as physical activity behaviour can be very difficult to recall and report accurately from the point of view of the service users themselves and can also be subject to bias. As such it is possible that the effectiveness of the programme may have been underrepresented due to recall difficulties, or even exaggerated due to over-reporting of physical activity.

The resultant misclassification of physical activity from self-report measures is a particular limitation when evaluating interventions which aim to increase physical activity. It is possible that the effectiveness of physical activity interventions that are evaluated with self-report measures (such as the Macmillan Physical Activity Behaviour Change Pathway) could be exaggerated due to over-reporting of physical activity, or that important small changes in activity which occur as a result of an effective intervention may be missed due to the lack of precision in the chosen measurement methods.

The solution to the above limitations of self-report measures of physical activity is to use objective measures of physical activity such as accelerometers which are worn on the wrist (like a wrist watch). Accelerometers measure acceleration caused by movement of the body on 3 different axes and are able collect accurate and detailed information on habitual physical activity over a number of days. Accelerometers are also able to detect small changes in physical activity (which may be missed by self-report measures) and could potentially allow a more precise evaluation of the Macmillan Physical Activity Behaviour Change Care Pathway in the future. However, whether it is feasible to use accelerometers in people affected by cancer who are participating in the Physical Activity Behaviour Change Care Pathway is unknown. It is also necessary to determine whether the use of accelerometers to assess physical activity is acceptable to people affected by cancer. The objective of this study therefore was to assess whether it is feasible to use accelerometers to evaluate the effectiveness of the Macmillan Physical Activity Behaviour Change Care

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Pathway and to also assess the acceptability of these measurements to people affected by cancer. This will inform subsequent evaluation of this programme and similar physical activity interventions in cancer patients.

The solution is to use objective measures of physical activity, called accelerometers, which are worn on the body (for example, like a wrist watch) and collect accurate and detailed information on habitual physical activity over a number of consecutive days. Unlike pedometers they measure intensity as well as frequency of activity. Accelerometers are also able to detect small changes in physical activity (which may be missed by self-report measures) and could potentially allow a more widespread evaluation of the Macmillan Physical Activity Behaviour Change Care Pathway in the future. However in order to inform a more widespread evaluation, the feasibility of using accelerometers for collecting physical activity data from people affected by cancer needs to be established. It is also necessary to determine whether the use of accelerometers to assess physical activity is acceptable to people affected by cancer.

The process evaluation was formative and the services have adjusted and developed what they do as the evaluation has progressed. Furthermore, services have interpreted and delivered aspects of the Physical Activity Behaviour Change Care Pathway differently

**Outcome measures**

The aims of this study were to examine the feasibility and acceptability of the use of objective measures of physical activity in cancer patients enrolled in the Macmillan Physical Activity Care Pathway. Specific project objectives were to examine:

**Feasibility**

- The ease and effectiveness of using the postal service for the return of accelerometers and questionnaires to investigators
- The training requirements for MacMillan healthcare professionals to initialise and distribute accelerometers and the subsequent support required
- The time necessary for management and processing of accelerometer files by investigators

**Acceptability:**

- Adherence to the measurement protocol, as measured by examination of accelerometer data to determine the proportion of each day of the nine day measurement period in which that the accelerometer was worn as instructed
- Acceptability of the use of wrist worn accelerometers to study sample, as measured using a self-report questionnaire
02. Evaluation methodology

In this chapter we set out the approach that was adopted for the feasibility study.

Methods

Independent of this research, people affected by cancer at different stages of their individual treatment journey either self-referred, or were referred by health professionals (including: Cancer Nurse Specialists, consultants, oncologists, general practitioners, practice nurses, occupational therapists and physiotherapists), to the Macmillan Physical Activity Behaviour Change pathway.

For the proposed research a convenience sample of approximately 60 participants were targeted for recruitment from two Macmillan centres (30 from each site). Convenience sampling was employed in order to meet the participant recruitment rate necessary to ensure completion of data collection and analysis within the projects limited timeframe (originally 7 months from January 2017) and budget. Convenience sampling is entirely appropriate for a feasibility study, where no inferential statistical analyses are being undertaken. All people affected by cancer who enrolled on the Macmillan Physical Activity Behaviour Change Care Pathway programme in the Luton and Lincolnshire areas were invited to participate at their initial enrolment visit. There was no other inclusion or exclusion criteria for this study.

At their enrolment visit a participant information sheet (detailing the measurement protocol and precisely what participation would involve) was provided which participants were able to consider for at least 7 days. At their next scheduled visit (at least 7 days later) participants were able to confirm their intention to participate in the study. All those wishing to participate signed their informed consent.

Measurement protocol

Macmillan Healthcare Professionals provided a GENEActiv accelerometer (Active Insights, Kimbolton, Cambridgeshire, UK) for participants to wear on their wrist continuously for 9 days. They were provided with a set of instructions which detailed the key points and some frequently asked questions regarding accelerometer wear (see Appendix A). At the end of this 9 day period participants completed a short questionnaire designed to assess the acceptability of the accelerometer measurement protocol (See Appendix B). Both the questionnaire and the accelerometer were returned to investigators at the University of Exeter using a prepaid envelope which was provided.

At a scheduled visit 6 months after enrolment in the Macmillan Physical Activity Behaviour Change Care Pathway participants who had completed the baseline measurement were given a second accelerometer to wear on their wrist for a 9 day period and to complete the
same short acceptability questionnaire. They subsequently returned both the questionnaire and the accelerometer to investigators at the University of Exeter using a prepaid envelope via second class post.

**Data handling and analyses**

Accelerometer data was downloaded using manufacturer’s software and descriptive analysis performed in the statistics package R using the GGIR package. Only days in which participants wore the monitor for 16 hours or more on at least 5 days were included in estimates of average daily physical activity. Data covering at least 16 hours of any measured day is likely to include almost all if not all waking activity, and 5 measurement days are sufficient to provide estimates of habitual physical activity. Descriptive data were extracted for mean minutes of moderate to vigorous physical activity (MVPA – physical activity equivalent to an energy expenditure of ≥ 3 x resting metabolic rate) in bouts of; ≥ 5 seconds, ≥ 60 seconds, ≥ 5 minutes and ≥ 10 minutes.
03. Results

In this Chapter we explore the feasibility of accelerometer measurement and the training requirements required for healthcare professionals to participate in the project.

Feasibility of accelerometer measurement and the training required for healthcare professionals

Key Finding: The training provided can be considered appropriate and successful.

A study investigator (Pulsford) visited the Macmillan Healthcare Professionals that would be involved in the collection of physical activity data at sites in Luton and Lincolnshire to provide training on how to initialise the accelerometers, and to outline the information needed to inform conclusions regarding feasibility. Training consisted of a 30 minute talk describing the function of the GENEActiv accelerometer devices and specific guidance on the steps for initialising the devices. Macmillan staff then practiced initialising the accelerometers under supervision, with additional guidance from step-by-step written and illustrated instructions. These instructions were provided for Macmillan staff reference in both hard copy and electronically. After Macmillan staff felt comfortable with the process of initialising the accelerometers and all questions had been addressed, training was provided on how to best standardise instructions for research participants regarding accelerometer wear, and subsequently, a bespoke online accelerometer management spreadsheet which would allow Macmillan staff to record the date that each accelerometer was given to a participant, the date it was returned to investigators in Exeter and the date accelerometers were received back in Luton/Lincolnshire following data extraction, cleaning and charging in Exeter. In total training lasted approximately 40 minutes. During the data collection, investigators from Exeter contacted each site periodically (approximately every 3 months) to update on progress and discuss any issues arising.

This training was deemed to be appropriate and successful for the following reasons: firstly Macmillan Healthcare Professionals from the sites at Luton and Lincolnshire did not report any problems with initialising or distributing the accelerometers. In addition, upon inspection of the accelerometer data there were no evident examples of accelerometers being initialised incorrectly. No ongoing support was requested by Macmillan staff or required during the data collection.

The accelerometer management process was only partly successful. Individual devices assigned to each participant were logged with their id number and then the same device used for that participant’s follow-up measure. However, the dates when accelerometers were given out to participants was not recorded on a number of occasions (they were added later by investigators based on the time stamp from the accelerometer), and the date that devices
were received after data extraction cleaning and charging in Exeter were not recorded at any stage despite email reminders from investigators in Exeter. This impacted investigators assessment of feasibility as described below.

**The ease and effectiveness of using the postal service for the return of accelerometers and questionnaires to investigators**

*Key Finding: It is feasible to use the postal service to distribute and collect accelerometer data within the Macmillan Physical Activity Care Pathway*

Participants returned the accelerometers and completed acceptability questionnaires via second class post to investigators in Exeter. Following extraction of data, charging and cleaning of the accelerometers they were then retuned in batches to Macmillan healthcare professionals again via the post. We can conclude that this method was effective.

Given the geographic distances between study sites this was arguably the most practical and cost-effective method possible to move accelerometers from participants to investigators in Exeter and then back to Macmillan sites in Luton and Lincolnshire. While the use of recorded delivery may have provided greater insurance against loss of accelerometers (and data) these additional steps would necessitate participants paying for postage and possibly claiming the money back from investigators which would likely impact recruitment and adherence, and would also have significant implications for the cost of data collection (recorded deliver costing approximately twice the cost of standard second class delivery) and therefore would have been beyond the scope of this project.

We are unable to provide firm conclusions about the average time taken from the accelerometer being worn by the participant to the accelerometer being available to Macmillan Healthcare Professionals for subsequent data collection as the required data was not adequately collected. The precise dates that accelerometers were given out to participants were not always recorded and the dates that monitors were received from Exeter (following data extraction, cleaning and charging in Exeter) were not recorded at any point during the study. More information is required here, however given that recorded activity data remains on devices until downloaded, and that the data is not in any way affected by delays in the participants returning the device we can still conclude that postal distribution and collection of accelerometers is feasible. It is also useful to note that the software programme used to analyse accelerometer data has features for discriminating between human movement and acceleration recorded while in transit, so any devices returned before data collection had finished could still be analysed.
The time necessary for management and processing of accelerometer files by investigators

Key Finding: The time necessary for management and processing of accelerometer files is predictable and acceptable.

Each data file can be extracted from the accelerometer using the manufacturer’s software in approximately 40 minutes. However, while this is not an inconsiderable amount of time, this task is not an intensive one, rather data extraction can be started and then left to run without continuous attention. Accelerometer data files were analysed as described above in two batches: first baseline (40 files) and then follow-up data (20 files). Data processing in GGIR takes approximately 8-12 hours for each batch of accelerometer files, and subsequent data checking and computation of accelerometer metrics took approximately 4 hours per batch. While the time necessary for data checking and computation of metrics will depend on the data quality and the metrics required, the time necessary for the initial stages of data download and analysis are predictable and (we consider) not unduly labour intensive.

Physical activity estimates from baseline and follow-up

As this study was concerned only with feasibility and acceptability we don’t have adequate statistical power to undertake any inferential analyses or to determine precise changes in physical activity behaviour between baseline and follow-up. Nevertheless, the physical activity estimates are provided below as examples of the information on physical activity behaviour that can be obtained using this measurement method. Estimates of average daily physical activity at baseline and follow-up, and difference in physical activity between baseline and follow-up is presented in table 1.

<table>
<thead>
<tr>
<th>Baseline</th>
<th>N</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean minutes per day MVPA ≥15 second bouts</td>
<td>38</td>
<td>90.9</td>
<td>48.1</td>
<td>14.0</td>
<td>221.0</td>
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<tr>
<td>Mean minutes per day MVPA ≥60 second bouts</td>
<td>38</td>
<td>41.6</td>
<td>33.6</td>
<td>0.3</td>
<td>160.7</td>
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<tr>
<td>Mean minutes per day MVPA ≥ 5 minute bouts</td>
<td>38</td>
<td>20.6</td>
<td>23.8</td>
<td>0.0</td>
<td>112.2</td>
</tr>
<tr>
<td>Mean minutes per day MVPA ≥10 minute bouts</td>
<td>38</td>
<td>1.1</td>
<td>5.1</td>
<td>0.0</td>
<td>31.0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Follow up</th>
<th>N</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean minutes per day MVPA ≥15 second bouts</td>
<td>18</td>
<td>104.9</td>
<td>53.2</td>
<td>22.5</td>
<td>210.7</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>Mean</td>
<td>Std. Dev.</td>
<td>Min</td>
<td>Max</td>
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<td>--------------------------------</td>
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<td>-----</td>
</tr>
<tr>
<td>Mean minutes per day MVPA ≥60 second bouts</td>
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<td>48.7</td>
<td>34.8</td>
<td>3.1</td>
<td>123.2</td>
</tr>
<tr>
<td>Mean minutes per day MVPA ≥ 5 minute bouts</td>
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<td>22.5</td>
<td>20.5</td>
<td>0.6</td>
<td>64.4</td>
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<tr>
<td>Mean minutes per day MVPA ≥10 minute bouts</td>
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<td>10.5</td>
<td>0.0</td>
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<td>Mean minutes per day MVPA ≥15 second bouts</td>
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<td>26.0</td>
<td>-15.0</td>
<td>74.7</td>
</tr>
<tr>
<td>Mean minutes per day MVPA ≥60 second bouts</td>
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<td>9.4</td>
<td>17.2</td>
<td>-8.3</td>
<td>42.4</td>
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<tr>
<td>Mean minutes per day MVPA ≥ 5 minute bouts</td>
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<td>4.7</td>
<td>9.7</td>
<td>-8.1</td>
<td>29.7</td>
</tr>
<tr>
<td>Mean minutes per day MVPA ≥10 minute bouts</td>
<td>16</td>
<td>-0.1</td>
<td>0.5</td>
<td>-1.5</td>
<td>1.1</td>
</tr>
</tbody>
</table>

Table 1: Estimates of average daily moderate-vigorous (MVPA) physical activity (minutes) at baseline and follow-up, and difference in physical activity between baseline and 6 month follow-up.

Acceptability of accelerometer measurement and adherence to guidance on continuous wearing of the accelerometer; measured by examination of the number of valid hours of wear per day computed by the accelerometer software’s non-wear algorithm.

Key Finding: The recruitment target was not achieved but adherence to the measurement protocol in those who participated was very good, and the data provided would allow precise assessment of physical activity and changes in physical activity which result from the intervention.

The project’s recruitment target of 60 participants was not achieved despite an extension in the projects timeline from 7 months to 15 months. Forty participants provided accelerometer data at baseline, 29 from Lincolnshire and 11 from Luton. We are unable to draw any definitive conclusions about the recruitment rate achieved as the two sites recruited differently (predominantly individual consultations in Luton, and within group sessions in Lincolnshire) and information regarding participants who chose not to participate was not collected. In addition, while it was intended that all patients referred to the Macmillan Physical Activity Care Pathway would be invited to participate we are aware that on occasion decisions were taken not to invite certain patients to participate. We are unaware how often this occurred and information regarding the rationale for these decisions was not recorded.

Adherence to guidelines for continuous wear amongst participants was very good. Of 40 participants who provided baseline data 38 participants had at least 5 days of ≥ 16 hours of
wear per day and were included in the baseline analysis. The mean number of hours each day the accelerometer was worn at baseline was 21.6 (SD 5.3) and the mean number of days with at least 16 hours of wear was 7.9 (SD 2.1). Twenty participants provided follow up data, (17 from Lincolnshire and 3 from Luton) and 18 participants had at least 5 days of ≥ 16 hours of wear per day and were included in the follow up analysis. The mean number of hours each day the accelerometer was worn at follow up was 23.0 (SD 2.9) and the mean number of days with at least 16 hours of wear was 8.6 (SD 0.9). Seventeen participants provided both baseline and follow up data, (15 from Lincolnshire and 2 from Luton) but 1 participant from Luton did not have a sufficient number of valid days at baseline to be included. All other 16 participants had at least 5 days and ≥ 16 hours of wear per day and were included in descriptive analyses of the difference in physical activity levels between baseline and follow up. Overall the adherence to the measurement protocol and the quantity of the physical activity data (>5 days with > 16 hrs of accelerometer wear) provided by almost all participants across measurement points in this study would allow good and precise estimates of habitual physical activity and the ability to detect even small changes in physical activity which result from the intervention.

Twenty out of 40 participants were lost to follow-up. We have information on the reasons for withdrawal on 5 participants from Lincolnshire (2 passed away, 2 had significant changes in their health status, and 1 relocated) but no other information on participants lost to follow-up was collected.

**Acceptability of the use of wrist worn accelerometers to study sample, as measured using a self-report questionnaire**

*Key Finding: The assessment of physical activity using accelerometers within the Macmillan Physical Activity Care Pathway is acceptable to this patient group.*

The acceptability was completed by 37 of 38 participants at baseline. Of these 21 completed an acceptability questionnaire at 6 month follow-up. In brief the questionnaire data demonstrates that the use of accelerometers to assess physical activity within the Macmillan Physical Activity Care Pathway is acceptable to this patient group. At both measurement points over 90% of participants agreed that the measurement protocol was acceptable and that they did not mind wearing the accelerometer. In addition, no participants felt that wearing the accelerometer was ‘a hassle’ and only approximately 8% and 4% at baseline and follow-up respectively reported that the accelerometer was uncomfortable. Data from these baseline and follow-up questionnaires is presented in figures 1 and 2.
Figure 1: The acceptability of assessing habitual physical activity using wrist-worn accelerometers in cancer patients enrolled in the Macmillan Physical Activity Behaviour Change Pathway. Baseline data collected using 5 point Likert scales and responses presented as proportion of sample (n=37)

Figure 2: The acceptability of assessing habitual physical activity using wrist-worn accelerometers in cancer patients enrolled in the Macmillan Physical Activity Behaviour Change Pathway. Follow-up data (6 months after baseline measures) collected using 5 point Likert scales, responses presented as proportion of sample (n=21)
**04. Conclusions and recommendations**

*In this Chapter we draw together key findings from the feasibility study. We make a series of recommendations for research and practice*

**Conclusions**

The findings of this feasibility study allow us to conclude that the assessment of physical activity using accelerometers within the Macmillan Physical Activity Care Pathway is very feasible. The training required for Macmillan Healthcare Professionals to collect the data using accelerometers was simple, did not require an undue input of time from investigators and no difficulties with the data collected were observed or reported. The distribution or accelerometers via the postal service is also simple and feasible and the time necessary for investigators to process and analyse the data is predictable and is not prohibitive. We are also able to conclude that assessment of physical activity using accelerometers within the Macmillan Physical Activity Care Pathway is acceptable to patients. Adherence to guidelines for the wearing of the accelerometers was very good and participant’s reported that wearing the accelerometers for 9 days was acceptable within their daily lives. The accelerometer data highlights that participants accumulate most of their daily moderate to vigorous physical activity in bouts of activity less than 1-minute in duration. Less than 3-minutes per day of moderate to vigorous physical activity is undertaken in the recommended minimum bout length of 10-minutes. The results of this study would suggest that the high prevalence of physical activity found in the main study, based on self-reports, is likely to reflect an over reporting of moderate to vigorous intensity physical activity rather than true level of physical activity.

**Recommendations for research and practice**

Given the accepted limitations of the use of self-report measures for evaluating the effectiveness of physical activity interventions, and the apparent feasibility and acceptability of the use of objective measures in this patient group, where possible future intervention evaluation studies should aim to assess changes in physical activity with objective rather than subjective measures of physical activity. There is a clear cost implication for this, but this should be evaluated against the quality of the data provided; the reduced sample size required to measure a given difference in behaviour as a result of measurement precision; and the risk of being unable to detect often small but clinically important intervention related changes in physical activity due to limitations in the self-reporting of physical activity behaviours. Further, if the per-person costs of administering, entering and analysing the self-reported data were available it is likely that overall costs would be comparable.
Given the low number of people with complete data at baseline and follow up in this study and the main study, we would strongly recommend that people responsible for the delivery of interventions should not be responsible for the collection of primary outcome data.

Training and ongoing support should be provided for research partners actively involved in collecting physical activity data using accelerometers. However, the process of initialising accelerometers is very simple so this training need not be too time-intensive.

Should the geographical spread of participants in future evaluations prevent face-to-face distribution and collection of accelerometers, sending accelerometers in standard class post using prepaid padded envelopes is a useful and practical alternative.

Analysis of accelerometer data requires some expertise, however given the importance of best practice in data processing and analysis the relatively limited time required to analyse the data this should not be considered a barrier.

Further investigation is necessary to understand rates of participant recruitment and reasons for participant withdrawal within evaluations of physical activity interventions for individuals living with cancer.
05. References