Randomised control trial of a novel digital system to provide contextualised data feedback to augment physical activity behaviour change in a free-living environment as part of cardiac rehabilitation

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Funding Acknowledgements: Type of funding sources: Public hospital(s). Main funding source(s): Liverpool University Hospitals NHS Foundation Trust

Background: Physical activity (PA) is a core component of cardiac rehabilitation (CR) and is crucial for enhancing cardiovascular (CV) fitness[1]. In the UK, CR programmes involve 1-2 hours of face-to-face contact per week over 6-8 weeks, implying that 98-99% of the intervention period is currently unmonitored and not optimised for potential positive lifestyle interventions. Consequently, CR staff are blind to PA that occurs outside of the clinical setting, which could be of too low or high intensity and/or duration, according to the Association of Certified Physiotherapists in Cardiac Rehabilitation (ACPICR) guidelines[2]. A previous pilot study showed a novel digital system to be feasible, acceptable and effective for CR patients[3], making it a promising intervention to assess in a randomised control trial (RCT).

Purpose: To conduct a RCT to examine whether contextualised data feedback delivered using a novel digital service, in conjunction with usual care (UC) promotes positive PA behavioural change, with direct comparison to UC alone.

Methods: This prospective, parallel group, open-label, RCT enrolled 130 patients eligible for CR and consisted of an 8-week intervention period with follow-up at 8-weeks. The intervention group received the novel digital CR service plus UC, with the control group receiving UC alone. The primary outcome was changes in PA to achieve the ACPICR guidelines. Both groups wore a PA monitor to collect minute-level energy expenditure data that underwent processing using a patented method to extract the specific PA metrics required for analysis. The secondary outcome was changes in CV fitness between pre and post assessments, measured using Incremental Shuttle Walk Test (ISWT).

Results: Patient characteristics are shown in Table 1. Adherence to data collection was good, with an average of 37 complete days (≥768 minutes per day) of PA data per person. Fifty-six intervention group patients and 49 control group patients were analysed for the primary outcome. A significant difference (p<0.025) in the probability of achieving the ACPICR ‘Daily Activity’ guideline was found between groups, with the intervention group more likely to achieve the guideline at week-8 versus control. Despite Covid-19 challenges, pre and post ISWT measurements were obtained for 33 intervention group patients and 37 control group patients. No significant differences between groups were found. However, the average improvement seen in the intervention group, +89 metres (m), exceeded the minimum clinically important difference for the ISWT (+70 m), and was more than double that seen in the control group, +44 m.

Conclusion: This RCT builds on previous evidence supporting the use of the novel digital service in CR[3]. Engagement with, and completion of, the digital CR service was excellent. Participation was associated with statistically significant improved PA in relation to ACPICR guidelines and clinically important increases in CV fitness versus UC alone.

**Table 1: Participant demographic characteristics at baseline assessment**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total (n=130)</th>
<th>Group 1; intervention (n=65)</th>
<th>Group 0; control (n=65)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male sex</td>
<td>100 (77)</td>
<td>49 (75)</td>
<td>51 (79)</td>
</tr>
<tr>
<td>Age (y)</td>
<td>60 (9.8)</td>
<td>60 (8.8)</td>
<td>60 (10.7)</td>
</tr>
<tr>
<td>Body mass (kg)</td>
<td>90.1 (20.6)</td>
<td>91.8 (23.1)</td>
<td>88.4 (17.9)</td>
</tr>
<tr>
<td>Body Mass Index (kg/m²)</td>
<td>30.3 (6.1)</td>
<td>30.3 (6.4)</td>
<td>30.3 (5.7)</td>
</tr>
<tr>
<td>Deprivation Decile (IMD)</td>
<td>3.6 (2.5)</td>
<td>3.8 (2.6)</td>
<td>3.3 (2.4)</td>
</tr>
</tbody>
</table>

Abbreviations: y years, kg kilograms, m metres, IMD Index of multiple deprivation. 

a. Data are expressed as mean (SD) for continuous data, or N (%) for categorical data.

b. N = 129 for Body Mass Index; N = 128 for Deprivation Decile (two postcodes could not be matched using IMD postcode lookup tool from UK Ministry of Housing, Communities and Local Government; N = 130 for all other variables.

Table 1