Mobile health (mHealth) applications with children in treatment for obesity: A randomised feasibility study

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Submitted on behalf of members of the H2020 BigO Project.

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Background
The W82GO Service delivers evidence-based obesity treatment to families of children and adolescents with obesity (BMI≥85th percentile) and has a positive impact on obesity1. Smartphone mHealth apps can augment treatment by helping children with obesity to reduce rate of eating and monitor physical activity2, 3.

Aim
To evaluate, using a randomised design, the feasibility and acceptability of a mHealth intervention to reduce eating rate and track physical activity among children in treatment for obesity.

Methods

Recruitment
New and review patients in W82GO Service
Children and teens 9-16 years, BMI≥85th percentile

Informed consent

Baseline measures*
Followed by randomisation

Control
4 weeks
Usual care at W82GO

Intervention
Eating Behaviour Treatment with Mandolean®
4 weeks
Plus usual care at W82GO

Post-intervention Measures*
Study End

Table 1: Participant characteristics and Child Behaviour Checklist (CBCL) results at baseline

<table>
<thead>
<tr>
<th>PARTICIPANT CHARACTERISTICS &amp; BASELINE MEASURES</th>
<th>INTERVENTION</th>
<th>CONTROL</th>
<th>COMPLETED STUDY</th>
<th>DID NOT COMPLETEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>T and E (%)</td>
<td>n=8</td>
<td>n=12</td>
<td>n=13</td>
<td>n=8</td>
</tr>
<tr>
<td>Male / female n</td>
<td>3/5</td>
<td>4/8</td>
<td>4/6</td>
<td>5/3</td>
</tr>
<tr>
<td>Mean age, years</td>
<td>13.1±2.3</td>
<td>13.5±2.3</td>
<td>13.3±2.7</td>
<td>13.5±1.3</td>
</tr>
<tr>
<td>Baseline BMI, kg/m²</td>
<td>31.6±6.9</td>
<td>35.2±8.9</td>
<td>32.1±6.7</td>
<td>33.1±4.6</td>
</tr>
<tr>
<td>Baseline BMI SDS (SD)</td>
<td>3.0±2.27</td>
<td>3.0±2.60</td>
<td>3.0±0.56</td>
<td>3.0±0.37</td>
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</tbody>
</table>

Child Behaviour Checklist (CBCL) Total T-score

- Externalising behaviour T-score mean±SD
  - 75.2±6.6* 71.6±4.7 69.0±3.9* 67.9±5.6**

- Internalising behaviour T-score mean±SD
  - 64.3±6.2* 57.6±7.5 56.4±3.5 60.3±9.2

* Mean T-score score significantly different between intervention and control groups at baseline (p<0.05)
** Mean T-score at baseline significantly different between participants who completed the study and non-completers (p<0.05)

Results

90% wore smartwatch at baseline
30% wore smartwatch post-intervention
Low exposure post-intervention explained by:
Total attrition (n=8), Technical issues (n=3), Incompatible phone (n=2), Watch strap broke (n=1)

The BigO ecosystem creates heatmaps based on intensity of physical activity logged by smartwatch users.

Figure 1: Clinical study protocol for mHealth intervention among children in treatment for obesity.

*Baseline & post-intervention measures: anthropometry, questionnaires (Parent CBCL, Child Peds QL, Child Piers-Harris), rate of eating using Mandolean®, physical activity levels with smartwatch and myBigO app.

Process Measures:
- Feasibility: recruitment and retention.
- Fidelity: adherence to randomisation and study procedures.
- Acceptability: objective measures of app engagement, system usability scale (SUS) surveys and verbal feedback.

Ethical permission: granted by the research ethics committee at Children’s Health Ireland, Temple St., Dublin.

Figure 2: Summary of selected process measures arising from randomised feasibility study in terms of feasibility, fidelity and acceptability.

Conclusions
Results indicated that protocol amendments would be necessary for any future study and technical usability studies are needed to understand use in our patient group.

Future research should examine the influence of behaviour and emotional measures on study engagement and acceptability.

References
1. O’Malley et al. (2012) Obesity Facts. 5(S1):46
3. Cooper et al. (2015) JMIP, 13:113
4. O’Malley et al. (2012) Obesity Facts. 5(S1):46
6. Cooper et al. (2015) JMIP, 13:113

Acknowledgments
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SUS Acceptability Measure

Figure 3 Mean System Usability Scale (SUS) scores for Mandolean® and Smartwatch with standard error bars categorised for total, intervention and control groups. SUS score ≥80 considered above average acceptability.