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Using mHealth apps with children in treatment for obesity: Process outcomes from a feasibility study.

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Corresponding Author:
Grace O'Malley
Phone: +353014028591
Email: graceomalley@rcsi.ie

Abstract

Background: Behaviour change interventions, including diet and physical activity, can significantly improve clinical psychosocial outcomes for children in treatment for obesity. Interventions to address rate of eating, satiety and appetite perceptions have shown promise in eHealth clinical studies.

Objective: To describe process methods for applying a mobile health (mHealth) intervention to reduce rate of eating and monitor physical activity among children in treatment for obesity in a tertiary outpatient setting.

Methods: The study protocol was designed to incorporate two mHealth apps as an adjunct to usual care treatment for obesity. Children and adolescents (9-16 years) with obesity (BMI ?98th centile) were recruited in person from the weight management service at a tertiary healthcare centre in the Republic of Ireland. Eligible participants and their parent(s) received information leaflets and informed consent and assent were signed. Participants completed two weeks of baseline testing including behavioural and quality of life questionnaires, anthropometry, rate of eating by Mandolean® and physical activity level using a smart-watch and myBigO smartphone application (app) with support from a dietetic researcher. Thereafter, participants were randomised to: (1) Intervention: Usual clinical care + Mandolean® training to reduce rate of eating or (2) Control: Usual clinical care. Gender and age group (9.0-12.9 years and 13.0-16.9 years) stratifications were applied. At the end of a 4-week treatment period, participants repeated the 2-week testing period. Process evaluation measures were documented including recruitment, study retention, fidelity parameters, acceptability and user satisfaction with mHealth tools.

Results: Twenty participants were enrolled in the study. An online randomisation system assigned 8 participants to intervention and 12 to control. Attrition was higher among the intervention group (5 of 8 participants; 63%) compared to the control group (3 of 12 participants; 25%). Exposure to planned treatment dose was not met. Intervention participants undertook a median of 1.0 training meal using Mandolean® (25th, 75th Centiles 0, 9.3), which represented 19.2% of planned intervention exposure. Eighteen participants were successfully registered with smartwatches and myBigO, however only 9 of 18 participants (50%) logged physical activity data. Significant differences in psychosocial profile were observed at baseline between the groups (Child Behaviour Checklist (CBCL) Total T-score 71.7±3.1 vs. 57.6±6.6, p<.0001)and in those who completed the planned protocol compared to those who withdrew early (CBCL Total T-score 59.0±9.3 vs 67.9±5.6, p=0.044.)

Conclusions: A high early attrition rate was a key barrier to full study implementation. Low exposure to the experimental intervention was explained by poor acceptability of Mandolean as a home-based tool for treatment. Self-monitoring using myBigO and smartwatch was acceptable among this cohort. Further technical and usability studies, are needed to improve adherence in our patient group in the tertiary setting. High perceived task burden in combination with behavioural issues may have contributed to attrition. mHealth interventions are rapidly progressing, however, we need to be cautious in terms of efficacy, burden to participants and our responsibility to identify vulnerable sub-groups at baseline. Clinical Trial: This was a feasibility study with a randomised design to ascertain the feasibility of a proposed protocol and we did not register as a trial.

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Using mHealth apps with children in treatment for obesity: Process outcomes from a feasibility study.

Authors

Sarah Browne[1,2,3], Tahar Kechadi[4], Louise Tully[1], Mckenzie Dow[3], Shane O'Donnell[4], Gerardine Doyle[5], Grace O'Malley[1,2]

[1]School of Physiotherapy, Division of Population Health Sciences, Royal College of Surgeons Ireland, Dublin 2, Ireland.
[2]W82GO Child and Adolescent Obesity Management Service, Children's Health Ireland, Temple Street, Dublin 1, Ireland.
[3] School Public Health, Physiotherapy & Sports Science, University College Dublin, Dublin 4, Ireland.
[4]Insight Centre for Data Analytics, School of Computer Science, University College Dublin, Dublin 4, Ireland.
[5]UCD Michael Smurfit Graduate Business School, University College Dublin, Dublin 4, Ireland.

Corresponding author: graceomalley@rcsi.ie

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Keywords

Childhood obesity, clinical intervention, mHealth, smartphones, appetite, satiety, rate of eating, wearable accelerometers, smartwatches, physical activity.

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Introduction

Global prevalence rates of childhood obesity were estimated at 7.8% for boys and 5.6% for girls in 2016, and prevalence is increasing in low income countries and communities [1]. Interventions in childhood are critical, as children with obesity experience a range of physical and psychosocial health issues, and are at a high risk of developing chronic disease in adulthood [2]. Diet, physical activity and other behavioural interventions can be effective in terms of change in adiposity, and significant clinically relevant metabolic benefits have been demonstrated with a 0.25 reduction in BMI z-score [3], although meaningful reductions in cardiometabolic markers are observed with reductions of 0.15 [4,5]. Recent Cochrane meta-analyses of behaviour change interventions reported 12-month reductions in BMI z-score of -0.06 among 6-11 year old children [6] and -0.13 units (95% CI -0.21 to -0.05) in 12-17 year old adolescents [7].

There is growing evidence that eating behaviours, not simply driven by food choice, influence energy consumption, appetite and satiety. Fast eating is associated with high body weights [8] and interventions to reduce eating-rate seem to enhance weight loss [9]. Eating food quickly may contribute to blunted responses to normal satiety signals, whereby an individual does not respond to gastric distension and gut peptide release, so that normal appetite suppression pathways are not functioning as expected during fast eating occasions [10,11]. A reduction in eating-rate aimed at reducing portion size and normalising satiety signalling has been recently studied [10-16]. A study with 9-17 year olds found that an eating rate intervention enhanced weight loss at 12-months compared to usual care (change in BMI z-score of -0.27) [16]. Slowing eating-rate can also reduce self-selected portion size with no reduction in post-meal satiety levels among children and teenagers [10,13,16]. A recent review appraises a number of commercial apps targeting appetite regulation [17]. Research driven interventions include real-time technology-assisted tools for meal times include utensils with virbrotactile feedback [12,14] and Mandolean®, a plate scales measuring eating rate with real-time computer or smartphone feedback [13,15,16]. The Mandolean® has shown promise as a childhood obesity treatment [16].

Physical activity in combination with dietary behaviour change, rather than either in isolation, are the recommended components of interventions for childhood obesity [6,7,18]. The use of wearable accelerometers to measure physical activity is the accepted objective means of measurement in free living individuals [19], which can be used to determine energy expenditure and requirements [20] and time spent in higher intensity physical activity determines variation in childhood cardiometabolic risk factors [21]. One of the advantages of mHealth interventions compared to traditional approaches is that data from monitoring tools and participant engagement are provided

objectively.

Despite improved technologies and access to mHealth tools for the purpose of monitoring health status and implementing interventions for health behaviour change [22,23], challenges with adherence and exposure remain [24,25]. Planned exposure, impact and potential outcomes are altered by participant interaction with study tools and technology [13,15,24]. The importance of content, design and testing periods with the target group has been emphasised as a means of enhancing engagement with mHealth apps [24,25]. Reporting process measures is increasingly important as they contribute to moving the field forward and provide for translational accuracy in research and practice [26].

Interventions that improve and expand treatment options for children with obesity are important because of challenges within traditional clinical care including available time and resources that impact access for service users. mHealth tools provide adjunctive options to standard treatment approaches and can be beneficial for patients at home and their clinical team. However engagement with devices and apps can act as a barrier to treatment [13,15,22].

The aim of the current study was to determine the feasibility and acceptability of an intervention using two mHealth apps with children in treatment for obesity in a tertiary outpatient setting. Since diet and physical activity interventions are typically undertaken together, it was of interest to assess the acceptability of Mandolean® in addition to a physical activity monitoring tool.

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Methods

Study Design

This study was conducted to determine the feasibility and acceptability of a proposed mobile-health (mHealth) intervention. The study was not registered as a trial however a randomised design was implemented to ascertain protocol feasibility for a proposed randomised controlled trial. We evaluated the process of using two mHealth smartphone apps with children and adolescents receiving treatment for obesity. Feasibility measures included recruitment rates and procedures, and retention rates. Fidelity encompassed intervention delivery and adherence to randomisation and study procedures. Retrospective acceptability included objective measures (engagement with smartphone apps), and self-reported measures (system usability score surveys and verbal feedback).

Participants

Children and teenagers (9.0-16.0 years), with a diagnosis of clinical obesity (body mass index (BMI) >98th percentile for age and gender) referred to the W82GO Child and Adolescent Obesity Service at Children's Health Ireland at Temple Street, Dublin, Ireland were eligible to participate. Socio-economic position was indicated by the Pobal HP Deprivation Index for Small Areas [27]. Children and teenagers were required to have access to a smartphone (Android OS 6.0 or above phones were compatible with the smartwatch and myBigO at Version0 when used in the feasibility study and both Android and iOS were compatible with Mandolean® which did not undergo further development during the study). Smartphone literacy was assumed, and training was provided on study apps by a researcher at baseline established competency in study tasks. Exclusion criteria included: moderate or severe learning difficulties that would prevent use of smartphone apps or giving informed assent; child having a concurrent serious medical issue; if parent or child/teenager were not proficient in understanding English; refusal by the child to give assent or parents/legal guardians to give informed consent to participate in the project; or if the child lived in Direct Provision (the system of asylum seeker accommodation used in the Republic of Ireland). Pregnancy and use of medications known to affect weight also precluded participation.

Study procedures

Health professionals working within the obesity service informed eligible participants about the study and provided a patient information leaflet to parent(s)/legal guardian(s) and their child. After 3-7 days a researcher phoned the parent/guardian to answer questions and check if they wished to participate. Once written informed consent and child assent was received, a study appointment was

offered for baseline assessment. A single dietetic researcher (SB) implemented the study protocol, co-ordinating and providing communications. All participants met a researcher for scheduled face-to-face and phone communications and were also invited to call or email the researcher outside scheduled reviews. Study contacts at each time point (T), modality and actions/measures for each contact are detailed later. At baseline, the researcher guided participants through a practice meal of their choice (brought to the hospital by participants) using Mandolean® (See Multimedia Appendix 1 for more detailed protocol). When participants completed a meal using Mandolean®, data were available to the research team via a dedicated clinical portal online (Mandobase).

The BigO Project (Big Data Against Childhood Obesity Project) is currently testing the myBigO app and clinical portal [28]. The app aims to gather behavioural data alongside measures of environmental conditions (e.g. urban built environment, infrastructures for physical activity, food marketing) among young people in general and an age-matched clinical cohort with obesity. Aggregation mechanisms are being developed to correlate population behaviors with environmental characteristics for the purpose of highlighting priority public health interventions [29].

All participants registered with myBigO app and were set-up with their smartwatch at baseline and post-intervention. The default for data syncing between smartwatch and myBigO on the smartphone was wireless internet connection (to avoid potential expense by using participants' personal mobile data). To ensure the BigO system received regular accelerometery data, participants and their parent(s) were shown how to check the Bluetooth and internet connection between the smartwatch and phone and they were asked to repeat this process every evening. For consistency, standard verbal, practical and written instructions to take home were provided to participants and their carers (See Multimedia Appendix 2). When participants completed a meal using Mandolean® and wore the smartwatch, the data was available to the research team via online clinical portals (Mandobase and BigO Clinical Portal).

Usual Clinical Care

The W82GO Child and Adolescent Weight Management Service is a multi-disciplinary obesity service which delivers efficacious obesity interventions [30]. Children and adolescents <16 years with BMI>98th percentile are referred to the service by hospital physicians based at Children's Health Ireland at Temple Street. Upon referral, children and their carers are invited to a multidisciplinary clinic and undergo assessment by a paediatric dietitian, a paediatric physiotherapist and a paediatric psychologist. Based on the needs of the child and family, a treatment plan is developed and patients are offered either group-based treatment or treatment delivered in a 1:1, more traditional outpatient setting. Treatment is family-based and was developed using contemporary scientific evidence [30].

Participants allocated to the usual care arm completed baseline testing followed by 4-weeks of usual clinical care and subsequent re-testing (Figure 1).

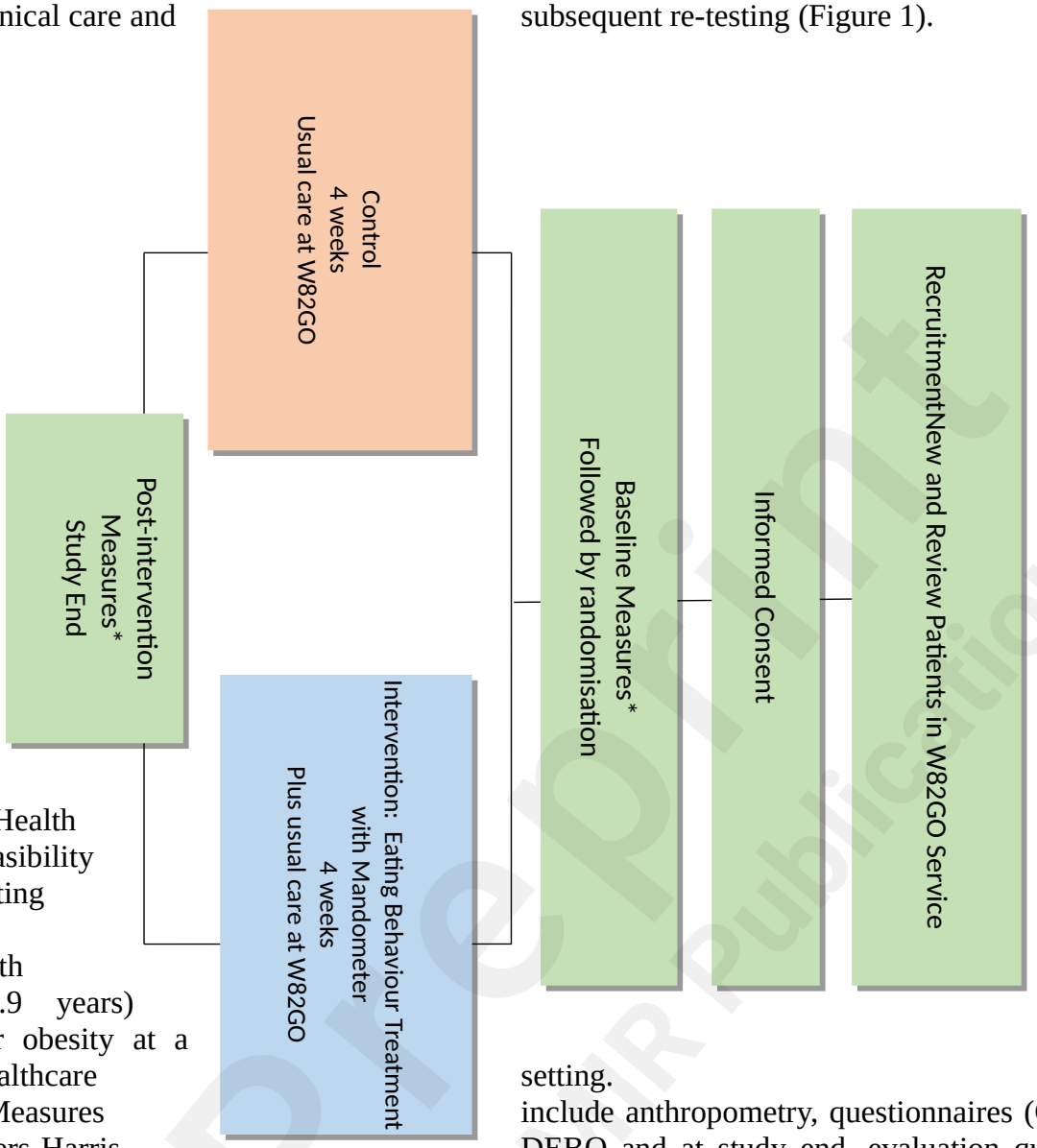

Figure 1 Flow chart of study protocol for an randomised study for an behaviour intervention children (9.0- in treatment tertiary

mHealth feasibility eating

with 16.9 years) for obesity at a healthcare

*Measures Piers-Harris, setting.

include anthropometry, questionnaires (CBCL, Peds QL, DEBQ and at study end, evaluation questionnaires and system usability scales [31]), Rate of eating using Mandolean®, Physical activity levels with smartwatch/accelerometery & myBigO app. See Multimedia Appendix 3 for full description of these measures.

Intervention

Mandolean® was developed at the Section of Applied Neuroendocrinology, Karolinska Institute and the Mando Group AB, Stockholm, Sweden. It consists of a plate scale that is wirelessly connected to a smartphone app with two main functions: (1) measures rate of eating and (2) provides the user with visual feedback on slowing rate of eating. The intervention arm involved usual care with additional training on reducing the rate of eating using Mandolean®. Following randomisation, intervention assigned participants received additional instruction on using the training functions of Mandolean® for at least one meal per day (lunch or dinner or both) over 4 weeks (minimum planned dose

exposure: 28 meals). Using Mandolean® training functions, the patient learns to adopt a typical pattern of eating and satiety by following the displayed 'ideal' rate of eating, which they are aiming to match. The clinician used baseline data (usual portions sizes and rate of eating) to guide a 'training meal' programme for the user. The training aims to teach the patient to eat 280-350 grams in 13-15 minutes and to perceive a level of satiety of 5-6/10 by the end of the meal. A full description of the Mandolean® training procedures is included in Multimedia Appendix 1. Use of Mandolean® in this study integrated a number of behaviour change components, categorised according to the Behaviour Change Technique Taxonomy by Michie et al. [32], including goals and planning, feedback and monitoring, social support, shaping knowledge, comparison of behaviour, repetition and substitutions, and antecedents (See Multimedia Appendix 4 for sub-techniques used).

Sample Size

A sample size of 20 participants was the target, which was considered sufficient to evaluate the process measures in this randomised feasibility study and is in line with similar studies [10,13].

Randomisation

Using an online randomisation service (Sealed Envelope™) participants were randomised to Mandolean® eating behaviour training intervention or control (See Figure 1) by one researcher (SB). Age (9-11.9 years and 12-16.0 years) and gender stratifications were applied and participants' parents were informed of their treatment group by phone after baseline measurements. Participants, therefore, were aware of their study allocation as the intervention required exposure to new eating behaviour training. At this point, further study review appointments were planned (see Table 2).

Outcomes

The Consolidated Standards of Reporting Trials (CONSORT) extension for randomised feasibility studies were used to guide transparency and quality in reporting study measures [33,34] (Multimedia Appendix 5 for CONSORT EHEALTH checklist). Trial process-related outcomes measured in this study addressed feasibility, fidelity and acceptability.

1) Feasibility:
    i) Recruitment process;
    ii) Rates of recruitment to the study;
    iii) Rates of retention and attrition to the study arms.
2) Fidelity:
    i) Adherence to randomisation protocol;
    ii) Appointment attendance (number, modality and duration of study appointments);

iii) Dose delivered (study tasks planned and completed at appointments);
iv) Dose received (training dose in Mandolean® clinical portal) and
v) Adherence to intervention procedures.

3) Acceptability:
i) Participant engagement with Mandolean® app (number of training meals completed);
ii) Participant engagement with BigO physical activity monitoring app (volume of data collected);
iii) Scores from system usability scale (SUS) questionnaires [31];

Qualitative feedback on the open question as part of SUS questionnaire from participants and their carers at the final contact. Data Analysis

Statistical methods for quantitative measures included descriptive frequencies and standard t-test comparisons between intervention and control groups and completer and non-completer groups for baseline age, anthropometry, and questionnaire scores. Qualitative feedback from questionnaires and discussions with users was analysed for content, and categories created for the purpose of presenting key acceptability issues, challenges and facilitators for users and health care professionals.

Ethics

The research protocol was reviewed by the research ethics committee at Temple St. Children's University Hospital and approved on 16/08/2018 (Number 18.013). A pseudonymised patient identification coding system was incorporated and stored in an encrypted file at the clinical site, so that no personal patient information was shared or processed via mHealth apps. Data collected on the apps were locally transformed on the participants' mobile phones and the transformed data, not containing identifiable information, were transmitted and stored to the respective clinical portals (for Mandolean® and BigO).

Results

Participants

Participants were recruited between May 2018 and February 2019. Table 1 describes participant characteristics and baseline assessment measures for intervention and control groups. Five out of eight in the intervention group (63%) and 5 out of 12 in the control group (42%) were categorised as below average socio-economic position (See Multimedia Appendix 6 for further detail). No significant differences between intervention and control groups were noted for mean age, BMI, or BMI SDS. Differences in mean total T-score, externalising behaviour t-score and internalising behaviour t-score for the parent reported child behaviour checklist (CBCL) were observed (See Table 1). A significantly higher score in mean baseline total T-score for CBCL was observed between those who completed the study compared to those who did not, indicating more behavioural issues among those who withdrew. Owing to a high attrition rate, completer and non-completer groups are also presented in Table 1.

Table 1 Characteristics of participants in a randomised feasibility study for a mHealth eating behaviour training intervention at baseline and follow-up.

PARTICIPANT CHARACTERISTICS & BASELINE MEASURES	INTERVENTION n 8	CONTROL n 12	COMPLETED STUDY n 12	DID NOT COMPLETE n 8
Male / female n	3 / 5	6 / 6	4 / 8	5 / 3
Mean age, years (mean ± SD)	13.1±2.3	13.5±2.3	13.3±2.7	13.5±1.5
Baseline BMI, kg/m-2 (mean ± SD)	31.6±3.9	33.2±5.9	32.16±5.7	33.1±4.6
Baseline BMI SDS (mean ± SD)	3.02±0.27	3.04±0.60	3.00±0.56	3.09±0.37
Stage of usual care, weeks (mean ± SD)	40.1±46.2	17.7±16.8	26.9±33.1	26.3±34.6
BASELINE PHYSICAL & PYSCHOSOCIAL HEALTH SELF-REPORT				
Child/Adolescent Self-Report Questionnaires, mean score ±SD				
Physical health PedsQL	74.6±17.1	69.1±15.1	70.5±17.6	72.3±13.3
Psychosocial health PedsQL	49.0±24.87	64.7±20.5	63.3±19.5	51.2±27.5
DEBQ external eating	1.58±0.72	2.00±0.62	2.00±0.56	1.58±0.79
DEBQ emotional eating score	1.29±0.76	1.50±0.53	1.63±0.61	1.09±0.52
DEBQ restrained eating score	1.91±0.81	2.03±0.30	2.08±0.30	1.84±0.79
Parent Self-Report Questionnaire, mean score ±SD				
CBCL Total T-score	71.7±3.1[a]	57.6±6.6[b]	59.0±9.3[g]	67.9±5.6[h]
CBCL Externalising behaviour T-score	67.8±4.7[c]	57.2±7.8[d]	58.2±7.5	65.0±8.7
CBCL Internalising behaviour T-score	64.3±6.2[e]	53.8±8.5[f]	56.1±9.5	60.3±9.2

Pediatric Quality of Life (PedsQL) [35]; Dutch Eating Behaviour Questionnaire (DEBQ) [36]; Child

Behaviour Checklist (CBCL) [37]
Intervention versus control: [ab]mean±SD, t-test for equality of means, equal variances assumed p<.0001; [cd]mean±SD, t-test for equality of means, equal variances assumed p=0.015;[ef]mean±SD, t-test for equality of means, equal variances assumed p=0.01
Completed verus non-completed group: [gh]mean±SD, t-test for equality of means, equal variances assumed p=0.044

Feasibility: rate of recruitment

Children and teenagers were recruited between June 2018 and January 2019. One strategy of recruitment, which involved offering patients and their families study recruitment packs at their first multi-disciplinary assessment appointment for the obesity service, was discontinued during the feasibility study. Families reported mixing up the recruitment pack with usual care information received on the same day and had not read the study information by the time the researcher contacted them some days later by phone. Instead, a researcher or clinician provided a 5-minute information session and study information pack to parents and their children when they were established within the service and followed up with a phone call 3-7 days later. Seventy-two eligible parent-child dyads took recruitment packs for the study and 24 of 72 agreed to participate (33%). Twenty out of 24 (28%) who provided informed consent attended for participation . (See Figure 3 for participant flow through the study.)

Feasibility: retention and attrition.

Three out of 8 participants (25%) in the control arm and 5 out of 12 participants (63%) in the intervention arm withdrew early. Characteristics, participation levels and feedback from children and teenagers who dropped out of the feasibility study before completion are presented in more detail in the Multimedia Appendix 7.

Fidelity: adherence to randomisation protocol

The online randomisation process resulted in males under-represented in the intervention group.

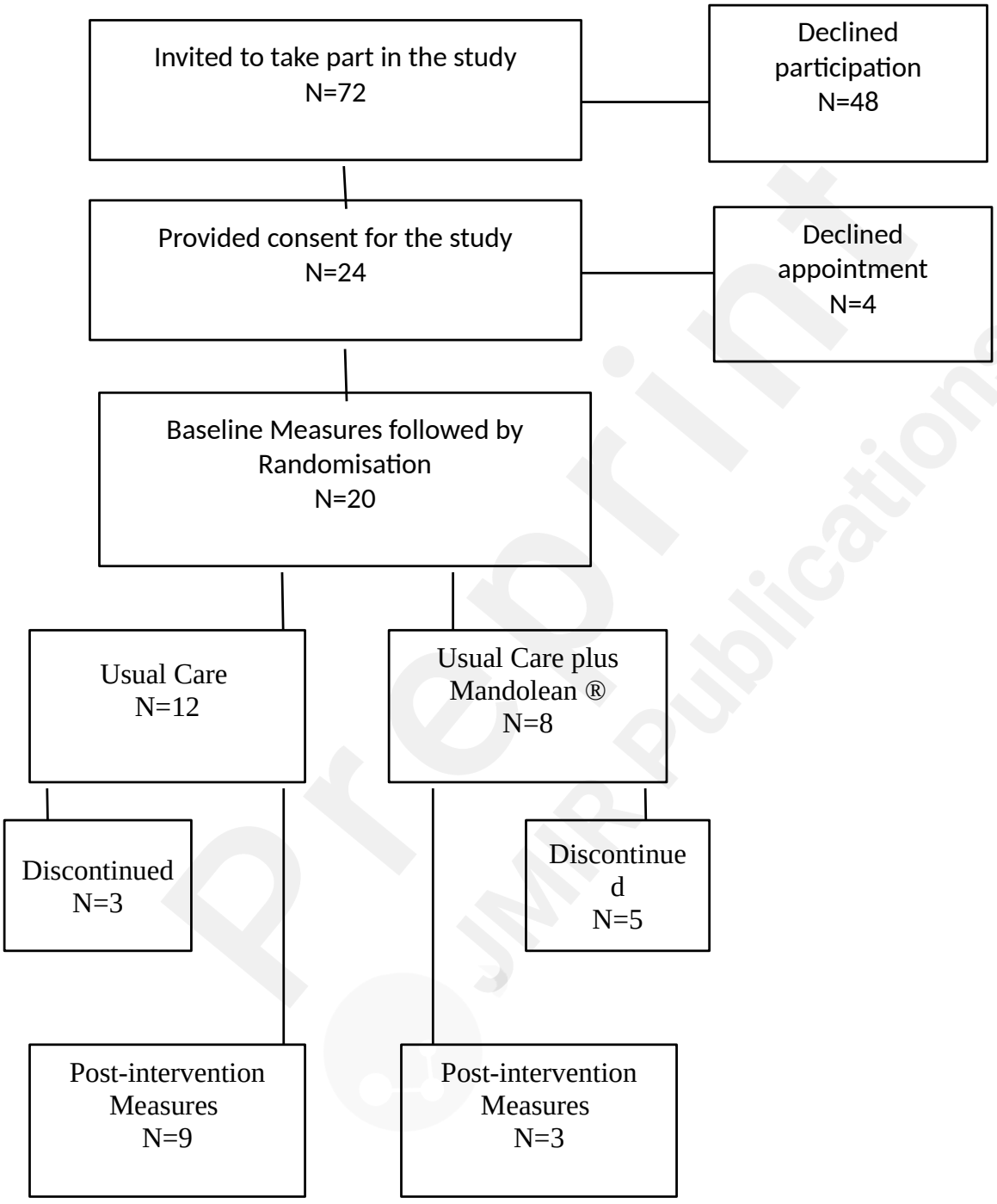

Figure 2 Consolidated Standards of Reporting Trials (CONSORT) diagram for pilot randomised trials

Fidelity: Appointment Attendance

Intervention participants attended study appointments in addition to usual care (Table 2). There was

good adherence to planned face-to-face appointments at T1, however mixed adherence thereafter, with the exception of phone reviews provided by the researcher. Time allocated to study appointments was appropriate. Illness, school and family commitments, competing appointments at the hospital, and living a long distance from hospital (as perceived by families) were barriers to attending appointments. Final reviews were completed by phone for three families who lived at a distance to the hospital in order to minimise absenteeism from school/work.

Fidelity: dose delivered and adherence to intervention procedures

Table 2 shows adherence to intervention protocols at each time point. Reasons for incomplete smartwatch set-up at time-point 1 (T1) included incompatible smartphone (n=5), parent couldn't remember personal account password to complete syncing with the app (n=2), and insufficient time (n=1). Five patients took written instructions for smartphone installation at T1 and completed the process at home on a compatible smartphone belonging to another parent or sibling. Two did not complete Mandolean® set-up at T1 owing to patient time constraints and this was planned for T2, which was completed with one participant, the other did not attend T2 or subsequent appointments. Two patients did not complete questionnaires at baseline, owing to lack of time, and were asked to return by post or at the next appointment, of which one set were returned.

In terms of intervention implementation, of eight patients randomised to Mandolean® treatment four received demonstration and instructions by the researcher in-person, one was provided with instructions over the phone and written instructions by post, three patients did not attend T2 to commence training (See Table 2).

Table 2 Fidelity with planned actions and measures at each time point

Time-point	**T1 0 wk**	**T1a T1+1 wk**	**T2 T1+2 wks**	**T2a T1+4 wks**	**T3 T1+6 wks**	**T4 T1+8 wks**
Planned Mode	**In person**	**Phone**	**Phone/ in person**	**Phone**	**In person**	**In person**
Mode adherence [a] n (%)	20 (100)	16 (80)	17 (85)	12 (60)	8 (40)	9 (45)
Time allocated, minutes	60	15	30	15	30	30
Time allocated adherence n (% of those who attended)	17 (85)	16 (100)	16 (94)	12 (100)	7 (88)	9 (100)
Smartwatch & myBigO set-up n (%)	12 (60)	5 (25)	1 (5)		6 (30)	
Mandolean® app installation	16 (80)					

& baseline meal demonstration n (%)						
Mandolean® intervention training meal demonstration n (%)			4 (50%)			
Intervention verbal instructions n (%)	20 (100)		5 (62.5%)			
Intervention standard instructions n (%)	20 (100)		5 (62.5%)			
Anthropometry n (%)	15 (75)					9 (45)
Socio-demographic data n (%)	20 (100)					
Questionnaires **1. Dutch Eating Behaviour n (%)** **2. Piers-Harris n (%)** **3. CBCL parental questionnaire n (%)** **4. Peds-QL (Quality of Life) n (%)**	19 (95) 19 (95) 19 (95) 19 (95)					
mHealth app usability questionnaires n (%)						11 (55)

[a] Mode adherence expressed as percentage of 20 recruited to study at baseline

Fidelity: dose received

Smartwatch and myBigO app

An early version of myBigO app used here (which accessed accelerometery data via smartwatches) was compatible with Android operating systems 6.0 and above. Of 18 children set-up with smartwatches at baseline, 11 were connected to parents' phones, 1 with a sister's phone and 6 children and adolescents used their own phones.

Available data from the BigO system indicated that, of 18 smartwatches set-up with myBigO, 9 participants (50%) contributed any data. Of those who contributed data, the range was highly variable from 0.3 to 9.2 days (mean 1.6 days ±2.9 days, median 0.2 days IQR 2.0 days). Two participants did not wear the smartwatch at all after baseline set-up (one due to illness and another

was self-conscious about wearing at school) and subsequently dropped out. Two parents deleted myBigO app at some point during the study – one because of lack of space on phone, and the other because father thought child wasn't using the watch/app anymore. One child did not live with the parent who had myBigO and smartwatch set up with a compatible smartphone, and as a result did not sync regularly. Attrition (n=8), poor attendance at T3 (n=2) technical challenges re-syncing watch to phone (n=3) and strap breaking (n=1) were reasons for low usage post-intervention. In addition, self-reported days wearing the watch among users at the post-intervention stage was highly variable. Two reported sensory issues and disliked wearing the watch. A short battery life and forgetting to charge or wear were commonly reported by patients for not wearing as advised.

Mandolean®

All participants completed at least one Mandolean® baseline meal that measured their rate of eating. Three participants completed one baseline meal with the researcher at the hospital canteen and did not complete any at home. The remaining participants successfully completed some baseline measurement meals at home, with a range of usage (2 – 19 meals). Participant engagement with Mandolean® and exposure to the planned intervention are presented in Table 3.

Table 3 Summary statistics for the use of Mandolean® device at baseline (all participants), intervention phase (intervention only), and post-intervention (all participants)

Variable	Baseline meal frequency	Training meals frequency	Post-intervention meals frequency
Number children / teenagers n	20	8	12
Mean	5.7	5.4	4.6
Standard Deviation	5.2	9.2	5.2
Median	5.0	1.0	3.5
25th, 75th Centiles	1.3, 9.0	0, 9.3	0.5, 7.8
Mean meals as % of planned meals (%)	56	19.2	46
Mean unsuccessful meal attempts[a] n (SD)	1.2±2.1	0.5±0.9	1.0±0.8

[a] Unsuccessful meal attempts were meals initiated and therefore registered on the clinical portal system but ultimately did not record rate of eating successfully.

Of eight participants allocated to the intervention training, five received training instructions and three did not engage with the training component. One participant subsequently dropped out of the study before training commenced, therefore the final number exposed to intervention training meals was 4 out of 8 (50% of those randomised to training). Exposure at an individual level represented

7% (12.3 year old male), 14% (9.5 year old female) 39% (15.2 year old female) and 93% 9 (11.6 year old female) of planned intervention.

Acceptability

Participant engagement with Mandolean® and BigO physical activity monitoring app

The findings relating to dose-received presented above indicate poor acceptability as measured through active engagement among users.

Self-report Acceptability Measure: System Usability Scales (SUS)

Mean SUS score results are illustrated in Figure 3. A score of 68 or greater is considered acceptable when assessing user experience of technology [31]. The Mandolean® did not achieve higher than a mean of 68 for the total group or within any sub-group and the smartwatch achieved a mean of 68 or over for all groups. A more detailed table of results is presented in the Multimedia Appendix 8.

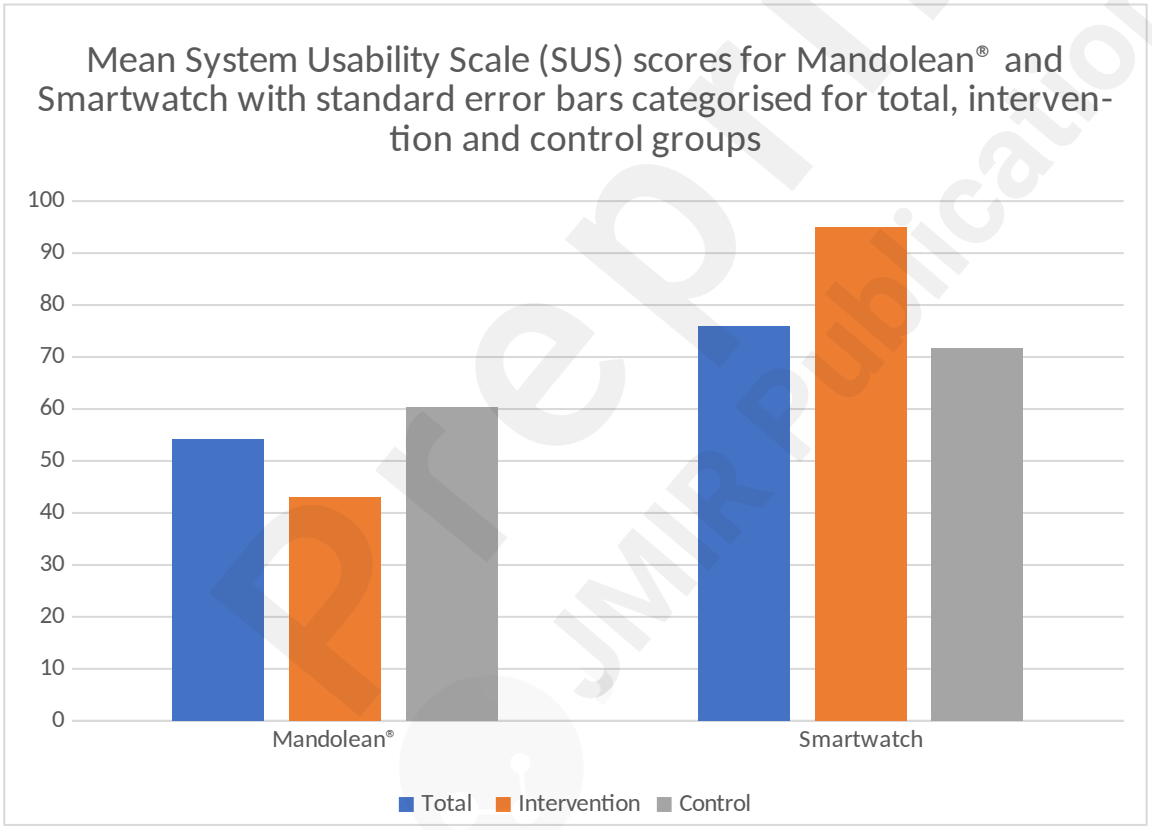

Figure 3 Bar chart showing participants' post-intervention system usability scale (SUS) scores for Mandolean® and Smartwatch for the total group (n=11), intervention (n=4) and control (n=7) groups.

Acceptability: Qualitative feedback from participants and their parents

Qualitative feedback from participants and their parents were categorised for each piece of technology. The main barriers to using Mandolean® were (1) connectivity issues, (2) difficult,

awkward or time consuming to set-up which interfered with family meal times (3) incompatible with family routine (i.e. no regular family meal times, summer holidays, or parental shift work), (4) forgetting to use. A small number of children and parents reported becoming more aware of their speed of eating as a result of using the Mandolean®. Most participants enjoyed wearing the watch, liked the time keeping function and self-monitoring their daily activity levels. The main drawbacks noted were (1) a short battery life, (2) sensory issues, finding the watch uncomfortable and (3) feeling self-conscious at school. Participant quotes and more detail are presented in the Multimedia Appendix 8.

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Discussion

Principal Results

We undertook a study to determine the feasibility and acceptability of a proposed intervention using two mHealth apps with children and adolescents being treated for obesity. The study process was documented thoroughly and, based on observed results, we concluded the need for further technical usability testing in this population. A slow recruitment rate, high attrition rate and low fidelity with planned interventions were the key outcomes informing feasibility. Greater psychosocial issues among the intervention and non-completer groups, observed in the baseline behavioural questionnaire (CBCL) was also note-worthy in this cohort. Although we cannot imply causality about the effect on study engagement or attrition, this finding provides important contextual background about individual and group characteristics, which may have contributed to sub-optimal usage of mHealth tools at home.

In terms of delivering study components, we found the time-points and modes of delivery realistic. Poor fidelity with participant exposure to intervention components, in particular the low number of participants randomised to intervention who attended for the necessary training, and then the low level of engagement with training meals on Mandolean® were the primary barriers to intervention implementation. Adherence with the smartwatch set-up at baseline was, for the majority achieved, while fidelity post-intervention was problematic owing to attrition and non-attendance for reviews.

We considered the high attrition rate as a signal of poor acceptability of the intervention, particularly when a greater number of intervention arm participants opted to leave the study before completion. The poor rating of Mandolean® on the SUS scores supplied further evidence. In contrast, positive feedback about using and understanding the smartwatch and myBigO app were received. Despite the smartwatch being acceptable, the wide range of exposure levels is suggestive of underlying barriers that need to be understood if we are to maximise adherence to mHealth adjuncts to clinical care. Sekhon, Cartwright & Francis propose acceptability as multi-faceted to include seven component constructs: affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy [38]. Applying these constructs to our SUS and qualitative findings, we suggest that technical difficulties, perceived awkwardness and time cost associated with using Mandolean® contributed to a negative attitude among participants and their parent(s). These in turn possibly contributed to feelings of high burden and low confidence about completing the required study tasks. There is also the possibility that the perceived burden associated

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with Mandolean® affected overall study task adherence, including the smartwatch and myBigO.

Comparison with prior work

Our study with Mandolean® differs to previous published work in two technical ways: we used a new mobile tool, with smartphone app interface for Mandolean®, where others plugged it into a computer [15,16] and we had access to objective engagement data from a clinical portal facility which was not available for an earlier clinical study [16]. Compared to a community-based feasibility study that reported process measures we had an older cohort (9-16.0 years versus 6-11.0 years), we recruited in the hospital setting, and we also incorporated an additional mHealth tool to measure physical activity levels [15]. Intervention exposure in a more recent study using smartphones mirrored our findings in that engagement with Mandolean® meals at home amongst teenagers varied considerably within the intervention group from five meals to 80 meals (median 28 meals), out of a planned one meal per day for six months [13]. A study with younger children found that just 19% achieved the minimum expected usage of five meals per week with Mandolean® [15]. These studies and others [39] report engagement issues among children and adolescents when mHealth apps are considered burdensome.

Individual factors contributing to poor adherence with wearing the smartwatch that we found including early attrition, sensory issues, forgetting to charge, forgetting to wear and feeling self-conscious are similar to other studies using wearables devices with young people. Although rigorous research with smartwatches as activity trackers is in its infancy in comparison to traditional accelerometers [40], some of the same adherence issues may apply. For example, Jago et al. [41] reported considerable variability in adhering to a 7-day accelerometer among children, finding that parents would forget to put on the accelerometer, some children found it uncomfortable and some were self-conscious about wearing it at school; however others were excited or interested in wearing it. We found similar barriers among our older group, and facilitators among younger participants. Research with a commercial fitness tracker among adolescents with obesity report a discontinuation rate of 68% before study end that was linked to barriers to physical activity not being addressed by a tracker, seasonality, feelings of activity incompetence, and gradual withdrawal of parental and clinical supports [42]. Our finding that high acceptability of a smartwatch does not translate to adherence is also reported by Phan et al. [42]. The physical activity self-monitoring tool

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available on the smartwatch screen in our study was cited by a number of children and parents as a benefit because they were trying to increase their activity levels. Formal integration of a recognised and important behavioural change techniques of 'self-monitoring' and 'goal setting' [32] could be maximised for future studies with research-led apps such as myBigO and smartwatches. Retention in clinical research, however, is challenging, and we note that a 2-fold study initiation rate may be required in order to achieve meaningful physical activity data for clinicians treating children in treatment for obesity.

While the withdrawal of 63.5% of participants in the intervention arm here is considerably higher than previous studies using Mandolean® [13,15,16], the psychosocial profile of participants has not been described by others and therefore we cannot assume that participants were similar across published trials The most comparable healthcare setting and age group to our own is the study by Ford et al. [16]. They demonstrated high compliance with the intervention, particularly among the Mandolean® arm with 83% attending all study appointments. High intensity contact (14 appointments in 12 months) was reported as a facilitator of retention [16]. Meta-analyses in the wider eHealth literature show attrition rates of 12%-29% [43]. Attrition can depend upon a range of factors known to be influential in clinical care (e.g. school absenteeism, dissatisfaction with care components, demographic factors) [44-46], in addition to factors influencing dropout from eHealth-specific interventions (e.g. registration requirements and male gender) [47-49]. One unique aspect of the current study was the combination of two mHealth tools for measuring both dietary behaviour and physical activity. Our attrition rate, therefore, may not be informative for all mHealth interventions with children and adolescents but certainly contribute insight where high participant engagement is expected among groups with complex health and psychological needs.

The predominant technical issues identified were difficulty connecting scale to phone, Mandolean® failing to recognise the plate when weighing out food, and loss of connection mid-meal, which others also report as a barrier to compliance at home [13,15]. Language like 'annoying', 'cumbersome' and 'time-consuming' reported by Hamilton-Shield et al. [15] reflected the feedback from our participants despite using an updated mobile app version of Mandolean®. We also found a number of other practical challenges similar to Hinton et al. [13] including child impatience during set-up, interruption of the flow of family mealtimes, difficulty with the portion size limit for training meals, and forgetting to use. A minority reported more positively that children adapted quickly to the routine of using Mandolean® at mealtimes, particularly younger participants. In contrast, parents whose teenagers withdrew

from the study early would have preferred them to complete the study. In a community study, by 4-10 weeks some children lost interest and a few parents were tired of using the Mandolean® particularly setting up, dishing food onto a plate, and weighing food [15]. While their trial was a longer duration, we found that these reactions were evident earlier (from two weeks onwards), and in some cases contributed to early withdrawal from the study. Higher behavioural problems among the intervention group at baseline appeared to be a random outcome of allocation. The subsequent high attrition within the group suggests that psychosocial issues in combination with intervention burden discussed above may have played a role in early attrition. Reasons for attrition among children with obesity vary in the intervention literature. Some interventions report no differences between completers and non-completers for behaviour measures using CBCL [50,51]. Others have shown that social competence of 8-14 year old children with overweight or obesity, defined using CBCL, was one of a number of predictors (including lower baseline weight and Caucasian parents) of BMI SDS reduction following a 12 month intervention [45]. Behaviour problems in children from disadvantaged areas has been linked to adherence in other conditions such as Type 1 Diabetes [51]. Behaviour problems are associated with a high risk of overweight and obesity among children, independent of other risk factors such as parental obesity, education, poverty and race [52,53], therefore we expected to find behavioural issues among a substantial number of our participants. Participants here may not be representative of the general population of children and adolescents with obesity for a number of potential reasons including obesity severity that prompted a referral to the specialist paediatric service, varying motivation depending on stage of treatment, and interest in joining research studies based on health status. While patients with known behavioural disorders were ineligible for participation in this study, a self-report tool at baseline assessing psychosocial and behavioural issues detected underlying behavioural issues that may have affected children's ability to partake fully in research tasks (and hence treatment tasks). Based on this experience, we recommend multi-disciplinary baseline assessments to include behavioural measures for similar adjunct interventions with children in treatment for obesity.

This is the first published study in which myBigO with a smartwatch was incorporated into an intervention in a clinical setting. The process outcomes provide some lessons for future research and practice. In order to fully describe the feasibility phase process, we included all participants who attended for a baseline appointment. The slow uptake and early attrition observed indicates that children in treatment for obesity may require greater choice or flexibility in how they contribute data and benefit personally from participation. Different

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approaches to recruitment and deployment need to be explored with different sub-groups including those with psychosocial or behavioural issues and different age groups (children vs. early adolescents vs. mid-adolescents) as they have varied motivations. Greater self-monitoring functionalities and reminders to charge and wear smartwatches may also improve adherence based on barriers reported. Given our challenges with a post-intervention accelerometer period, one unbroken smartwatch exposure may be more realistic and preferable among children in treatment for obesity, reducing the need for extra face to face review appointments. However, clinicians wishing to observe behaviour pre and post-intervention may wish to examine the feasibility of a longer intervention period whereby participants would have time to implement and monitor goals based on baseline measures.

Limitations

This is a feasibility study with a small sample size and short intervention period. Recruitment was limited to children and adolescents attending one specialist paediatric obesity programme, which may have limited recruitment rate and introduced population bias in terms of obesity severity and associated complications, and participant motivation to partake in research. Recruitment rate was also delayed at the study outset by the implementation of the General Data Protection Regulation in the EU and Irish interpretation of the regulation for the purposes of health research. The poor adherence to treatment was evident at early stages, therefore a longer intervention with Mandolean® was unlikely to add additional benefit or knowledge in this group. The intervention group received additional training on Mandolean® that the control group were not exposed to which heightened awareness about behaviours of interest and combined with task burden could well introduce unknown biases. A more structured and validated technical usability study may be of benefit to further understand the challenges children and their families face in using the mobile Mandolean® system. While the SUS has been used previously to evaluate adult user experience with wearable devices [54], the survey has not, to our knowledge, been validated in a paediatric population. However, it does have advantages for use with children as it is short and uncomplicated, it is suitable to use with small samples, provides space for comments and a final score can be interpreted with an established reference standard. The smartwatch with myBigO were at the first stage of feasibility testing in this cohort, and as such the technology will continue to be developed based on user needs. The attrition and engagement measures should be interpreted in the context of a feasibility study with two mHealth apps aimed at children with obesity and as such, not indicative of the performance of either tool used in

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isolation.

Conclusions

Our study explored the process outcomes of using mHealth tools in an obesity treatment study and highlighted challenges and opportunities related to feasibility, fidelity and acceptability. By transparently reporting feasibility using the CONSORT extension guidance [33], we reported potential challenges for mHealth interventions among children with obesity. mHealth interventions are rapidly progressing, however, we need to be cautious in terms of efficacy, burden to participants and our responsibility to identify vulnerable sub-groups at baseline. Challenges include task burden and adherence to complexity in mHealth systems recommended for use at home, particularly among families experiencing behavioural issues. Opportunities noted here include high acceptability of a self-monitoring physical activity system where data is shared between patient and clinician. Children with obesity attending treatment have complex needs and given health service limitations, would benefit from adjuncts to traditional treatment that can be implemented outside of clinical settings. Additional technical and usability studies are recommended to improve our understanding of adherence to treatment.

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Conflicts of Interest

The researchers collaborated with Mando Group AB, Stockholm, Sweden who provided Mandolean® devices for the purpose of the study.

Multimedia Appendices Captions

1. Protocol and process for training participants to use Mandolean®
2. Written standard instructions provided to participants
3. Description of baseline measurements
4. Behaviour Change Techniques incorporated into the intervention
5. CONSORT EHEALTH checklist report
6. Bar chart showing participants' socio-economic position
7. Characteristics and feedback from children and teenagers who dropped out before completion
8. System Usability Scores for Mandolean and Smartwatch, including qualitative comments

1.

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Supplementary Files

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Multimedia Appendixes

Written standard instructions provided to the participants.
URL: https://asset.jmir.pub/assets/233cb88e0dbf882b0881dbdd067319f6.docx

Protocol and process for training participants to use Mandolean.
URL: https://asset.jmir.pub/assets/fa684ca071bcbc585df1ee78441b21a7.docx

Description of baseline measurements.
URL: https://asset.jmir.pub/assets/8d61bb933fb45d7b38daf10acc09bb5c.docx

Behaviour Change Techniques incorporated into the intervention.
URL: https://asset.jmir.pub/assets/51fabd1a1a949a0e7ca40c192b2dc32f.docx

Bar chart showing participants' socioeconomic position.
URL: https://asset.jmir.pub/assets/b54257809bdac15d15949a37b4bdfa24.docx

Characteristics and feedback from children and teenagers who dropped out before completion.
URL: https://asset.jmir.pub/assets/b33fa73a7501e75198d4313306c0f3f7.docx

System usability scores for Mandolean and a smartwatch, including qualitative comments.
URL: https://asset.jmir.pub/assets/ea140b706868516e4a96785537f0404c.docx

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Figures

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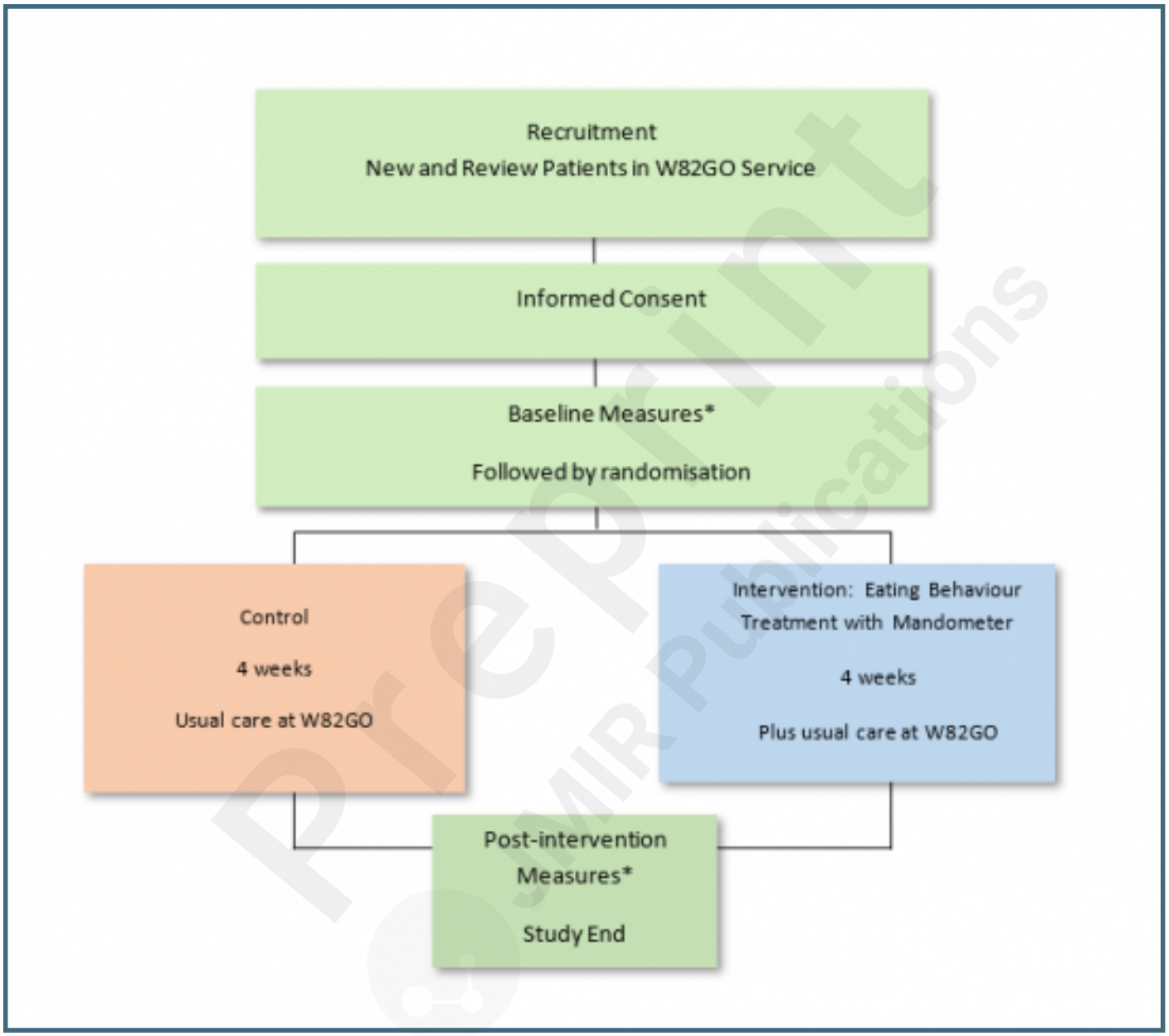
Flowchart of study protocol for a mobile health randomized feasibility study for an eating behavior intervention with children (aged 9.0-16.9 years) in the treatment of obesity in a tertiary health care setting. Baseline and post-intervention measures include anthropometry, questionnaires (Child Behavior Checklist, pediatric quality of life, Piers-Harris, Dutch eating behavior questionnaire, and, at study end, evaluation questionnaires and system usability scales [31]), rate of eating using Mandolean, and physical activity levels with the smartwatch/accelerometerand myBigO app.



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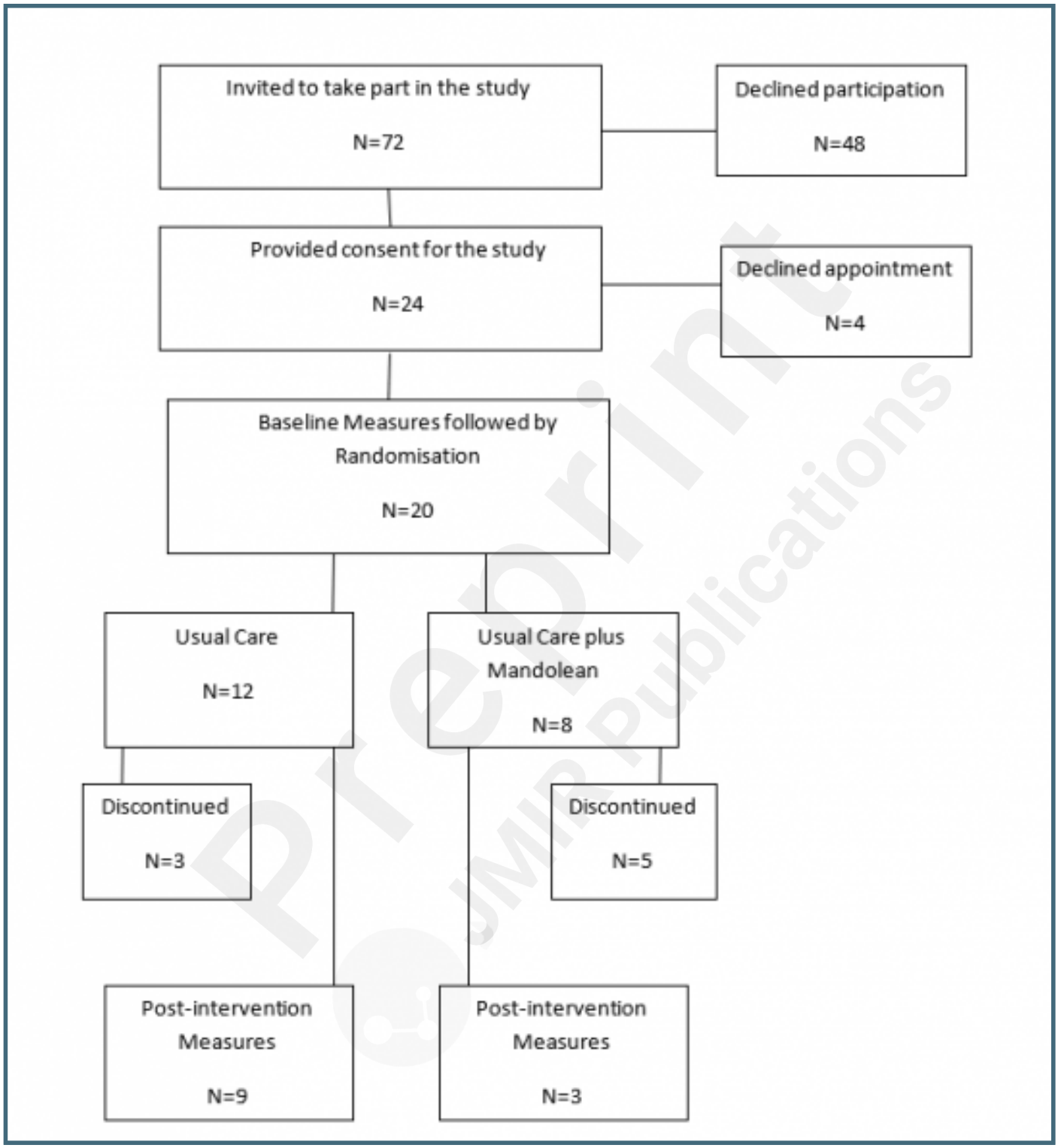
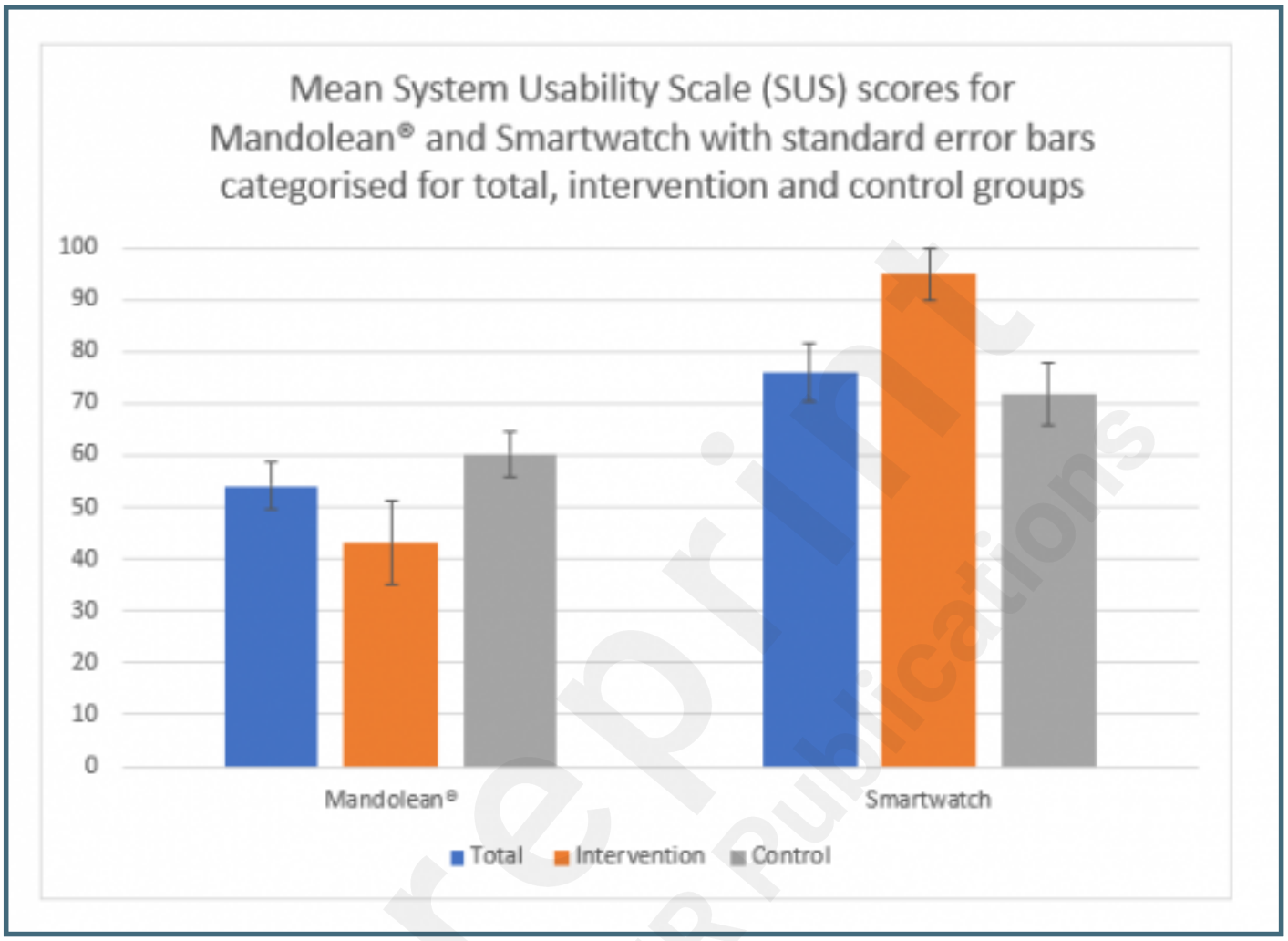
Consolidated standards of reporting trials diagram for pilot randomized trials.



Bar chart showing participants' postintervention System Usability Scale scores for Mandolean and smartwatch for the total (n=11), intervention (n=4), and control (n=7) groups.



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Revised manuscript with tracked changes.
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Multimedia Appendixes

Consolidated standards of reporting trials of electronic and mobile health apps and online telehealth checklist report.
URL: https://asset.jmir.pub/assets/a42898521c80dfde5bc6b70728b8e3b6.pdf

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Author response to editor's comments.
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