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Service-review and feasibility trial in paediatric weight management

Submission date	Recruitment status	[X] Prospectively registered
12/11/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/12/2018	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/09/2021	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Rates of childhood obesity are increasing, yet little is known about the patient perspective of paediatric weight-management services. A qualitative review of the Bristol based Care of Childhood Obesity (COCO) clinic was run in 2009. Since then, the care pathway has evolved, and it would be advantageous to revisit the questions asked in this review with the current patient group to understand how they perceive the treatment pathway on offer to them. A need for self-management strategies that can be used between appointments has been highlighted as a priority by the 2009 review, and through working with the clinical team. The aim of this study is to assess the acceptability and appropriateness of introducing a phone app, FoodT, to the treatment package. FoodT is a response inhibition brain-training game which supports understanding of which foods should be eaten more often and which should be eaten in moderation. Its use has been seen to result in a decrease in calorie intake, both in laboratory and free-living conditions. The training involves pictures of healthy foods (e.g. fruit, vegetables) that must be responded to (tapped) and pictures of foods high in fat, salt and sugar (HFSS) (e.g., crisps, chocolate, sweets) that must not be tapped.

Who can participate?
Child and adolescent service-users attending a weight management course or program due to excessive weight

What does the study involve?
FoodT is offered as an optional activity for child and adolescent service-users at the Bristol weight-management clinic, and its outreach programme, held in special schools around Bristol. The study lasts 8 weeks and service-users are informed that participation is entirely voluntary for the duration of the trial. The research takes a mixed-methods approach, with the aim to understand how feasible, acceptable and beneficial this app is to service-users and their families. Data is collected through online surveys, questionnaires and optional interviews.

What are the possible benefits and risks of participating?
The app may support participants to make healthier food choices and reduce their snacking. Therefore, playing with the app may support weight-management. The previous work conducted by the research team has shown no evidence of any harm or risk imposed by playing with the

FoodT app. An increase in food craving has been reported in a very small number of cases, less than 1% of ~1000 participants. Participants in this trial will be advised to stop engagement with the app and to contact a member of the research team if they are to experience these cravings. The probability of a serious adverse event is judged to be minimal in this study; a large-scale study with about 100,000 members of the public (using either the FoodT app or a similar web-based training task) has not resulted in any negative events (except for the increase in cravings) being reported. Additionally, the outcome may be that the app will result in no change in eating behaviour for participants, leading to unnecessary time costs.

Where is the study run from?
1. Bristol Royal Infirmary (UK)
2. South Bristol Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2018 to March 2020

Who is funding the study?
European Society for Clinical Nutrition and Metabolism (Luxembourg)

Who is the main contact?
Jennifer Cox
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
39768

Study information

Scientific Title
A feasibility study exploring patient perceptions of a paediatric weight-management programme, and the suitability of introducing a response inhibition training app to the treatment programme

Study objectives
As the trial is a feasibility trial, the trialists are not aiming to prove or disprove a hypothesis. The study aims to understand whether running a large-scale trial, to test the app against a hypothesis, is feasible.
The outcome aim of this research is to understand if the introduction of the FoodT app to treatment as usual in the clinical setting, is feasible and beneficial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central – Berkshire B Research Ethic Committee, 08/11/2018, ref: 242624

Study design
Non-randomised; Interventional; Design type: Treatment, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Childhood obesity

Interventions
There are two strands to this research project. Firstly, a qualitative service review that will be based on interviews with the service users of the COCO clinic and their families. Secondly, a feasibility trial of introducing a response-inhibition based brain-training to the service users

using an app. The participants have the option to participant in one, or both strands of this research project.

Strand one, Service Review: Consenting participants may take part in the service review of the COCO clinic. These participants may include child service-users and their families, and they will be invited to an interview to explore their experiences of the COCO clinic. Questions will be based around their initial experiences of joining the clinic, what elements they find most or least beneficial, and what improvements they would like to see made. Each interview will take between 10-20 mins. The recruitment target is 20 parent-child pairs, as was achieved in Owens et al. (2009).

Strand two - A feasibility trial of the FoodT app:
The child service-users will be engaging with their treatment as usual, and additionally, will be invited to use the FoodT app. The recommended dose is once a day for the first month, then once a week for seven weeks. Each game lasts five minutes. None of the participant's usual treatment will be altered due to participation in the trial, and participants are encouraged to attend clinic appointments as usual.

The methodology for the feasibility trial will take the following pathway, details of each stage will follow below:
A. Consent
B. Interview OR questionnaire
C. Online survey
D. In-app data collection
E. Eight-week intervention phase
F. Interview OR questionnaire
G. Online survey

Baseline qualitative and quantitative data will be collected, and then repeated post-intervention at the eight-week mark. Each participant will be asked to engage in three forms of data collection
1. An interview OR a questionnaire (at stages B and F)
Service-users and their parents/guardians will have the option of either taking part in an interview or filling in a questionnaire. Both will ask questions on the same areas - the initial collection will focus on participants current eating behaviours, goals and motivations, the behaviours they feel are most detrimental to their weight, and how prepared they feel to tackle those behaviours.
The data collection at the eight-week mark will focus on the participants perceptions of the app, how and when they used it, whether they felt it addressed a need and whether they will continue to use it and recommend to others. It will also ask about their perceptions of being involved in the trial (i.e. time taken, acceptability of data collection methods). The decision to offer both a questionnaire or an interview was supported by a young person’s advisory group, a proportion of the group favoured the privacy and ease of answering a questionnaire at home, where as other members of the group felt they could convey their perceptions easier through an interview. The group considered it important to allow this element of choice, to make the research process accessible to all.

2. An online survey developed through Bristol’s University tool (www.onlinesurveys.ac.uk/) (at stages C and G)
The online survey will include computerised measures of food choice, will ask participant to indicate the amount they like foods on a scale for a selection of healthy and unhealthy foods, ask participants to rate how frequently they consume the foods that are included in the training (at

eight-weeks only) and will measure their trait characteristics through a selection of questionnaires; the loss of control of eating scale (LOCES-B), child eating behaviour questionnaire (CEBQ), child binge eating disorder scale (C-BEDS) and child readiness to change scale (at baseline only).

3. Questions asked directly by the app (Stage D)
The app will collect demographic information, ask participants to rate how frequently they consume the foods that are included in the training (once at baseline and once at four weeks), and ask questions on their current levels of craving (each time they play).

Information on interviews (both for the review and the feasibility trial):
All interviews will be conducted by the, PhD student. The interviews will be semi-structured, and the schedule will be tailored for children of different ages. Children will be invited to bring their parents with them into the interview room if they wish. All interviews will take place within a space within University Hospitals Bristol, or the outreach centres. Each interviewee will be given £10 per interview for their time (i.e. £10 for each child and £10 for each parent/guardian, for each interview engaged with). All interviews will be recorded for the purpose of transcription and analysis. Transcription will be carried out only by members of the research team mentioned on the document, primarily the PhD student. Once transcription has taken place, the audio files will be stored away in line with the sponsor, University of Bristol's, data protection guidelines.

The qualitative research will be transcribed and analysed after each participant. Early stage findings will be used to guide the questions asked in the latter participants interviews; to ensure a full picture of participant views, important to the feasibility nature of the trial. The outpatient COCO clinics run roughly weekly, giving the research team time to explore the data between each batch of recruitment, allowing the interview schedule to be adapted as required. A mixed-methods approach has been chose (Hesse-Biber, 2010). This will allow exploration of how the app is used and perceived in the real-world setting. Qualitative data will be used to better understand the quantitative information.

Data collection for the review can occur simultaneously to the feasibility trial. The data collection period is expected to last for 6 months, or until saturation point is met for the qualitative review. The service user review seeks to interview a sample of 20 child service users and their families, as was achieved by Owens et al. (2009), however data collection may be stopped earlier if, or will continue past the 20th, until consensus from the research team is that saturation point has been met, and no new themes are arising.

For the feasibility trial, each participant will be involved with research for an eight-week period, which is the standard period they would wait between appointments at the clinic. As a feasibility trial, powered effect is not expected, therefore, the recruitment target is to recruit 30 participants from the main COCO clinic, and another 30 from the outreach clinics in schools. Due to the nature of this study, it is uncertain how many service users will consent to participation. Interest from service users at the recruitment stage, and retention are two of the outcome measures and will be an important insight into the acceptability of the intervention in this population, key to answering the research question.

Intervention Type
Device

Primary outcome measure
Feasibility measured via:
1. Qualitative interviews and/or questionnaires with staff, patients and their families at the end

of the 12-week trial period
2. Recruitment rates
3. Adherence measured through in-app data collection that reports on frequency of play

Secondary outcome measures
Benefit measured by:
1. Qualitative feedback via interviews and/or questionnaires at the end of the trial period
2. Self-reported consumption frequency of common snack foods (in app & online survey) at the start and end of trial (week 0 and week 12)
3. Food liking measured by a Visual Analogue Scale (VAS) (online survey) at the start and end of trial (week 0 and week 12)
4. Food preference measured using a forced-choice food task (online survey) at the start and end of trial (week 0 and week 12)

Overall study start date
03/12/2018

Completion date
24/03/2020

Eligibility

Key inclusion criteria
1. Attendance at a weight management course or program due to excessive weight
2. Participant gives assent to participate
3. Participants parent/guardian gives consent to their child's participation (if under 16)

Clinic staff will also be recruited for participation in the study to determine feasibility and acceptability from their perspective. The inclusion criteria for staff are:
1. Employment in the obesity or weight management clinic
2. Involvement in the treatment of those using the FoodT app

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80

Total final enrolment
21

Key exclusion criteria
1. Problems with eyesight that cannot be corrected with glasses and prevent the participant from seeing the food images on the phone screen

2. The participant does not speak English or understand written English
3. Concurrent participation in a trial investigating a weight-loss intervention

Date of first enrolment
12/12/2018

Date of final enrolment
24/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Royal Infirmary (BRI)
United Kingdom
BS2 8HW

Study participating centre
South Bristol Hospital
-
United Kingdom
BS14 0DE

Sponsor information

Organisation
University of Bristol

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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Research organisation

Funder Name
European Society for Clinical Nutrition and Metabolism

Alternative Name(s)
ESPEN

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Luxembourg

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 20/09/2021:
Recruitment was cut short due to the COVID-19 pandemic. We had also planned to run a community-based recruitment arm to the study (20+20 young people and their parents), but it was not possible to run the community arm. We are now preparing a publication of the findings to be submitted in early 2022, as well as inclusion in the PhD thesis for Jennifer Cox.

Previous publication and dissemination plan:
Planned publication in a high-impact peer reviewed journal, and as part of a PhD for Jennifer Cox.

Intention to publish date
31/05/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository Open Research Exeter (https://ore.exeter.ac.uk/repository). The anonymised datasets will be stored here once the trial has finished. Consent from participants

will be obtained that explicitly details that the trial information will be made available publicly and to other researchers.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2		10/12/2018	No	Yes
Participant information sheet	version V2		10/12/2018	No	Yes
Participant information sheet	version V2		10/12/2018	No	Yes
Participant information sheet	version V2		10/12/2018	No	Yes