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AIM2Change: making the changes that matter to you

Submission date
07/02/2023

Recruitment status
No longer recruiting

Registration date
20/02/2023

Overall study status
Completed

Last Edited
21/10/2024

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Childhood obesity levels continue to rise, and as this usually leads to obesity in adulthood the condition has significant costs to individuals, the NHS and society. The team in Bristol has run a weight-management clinic for young people (YP) for 20 years, with many losing weight. Those who do not lose weight, and their families, were asked what the barriers were that stopped them from making changes to their diet and activity levels. They answered that they felt lost, did not feel motivated to change, and preferred the clinic to take charge of their weight loss. This study aims to develop a new program to help YP (aged 11-18 years) in Bristol's weight management clinic develop their motivation to manage their weight using Acceptance and Commitment Therapy (ACT). The program will help young people engage with the choices and changes they want to make, set their own targets, and lose weight.

Who can participate?
YP with obesity aged between 11 and 18 years old

What does the study involve?
The approach is person-centred, focusing on understanding and accommodating the views of the people who will use the intervention, to improve its relevance, and outcomes for them and to increase participation in and adherence to the programme. The team will collaborate individually with 10 to 12 YP with obesity to design the ACT programme (with their parents' help if they wish). An initial framework for the programme has been created, which will be further developed with each young person over seven online sessions. This will ensure that the proposed treatment is acceptable, age-appropriate, and useful to YP in the future when it is tested in a later study. Each session will comprise 45 minutes of ACT with our health psychologist, followed by a 15-minute person-centred 'think aloud' interview with the qualitative researcher to gain immediate feedback on the session and develop with the YP any changes or additions they think are necessary to improve the intervention for use with YP.

Patient and Public Involvement (PPI): When designing the study, supported by the charity Obesity UK, YP within the target age range and adults with obesity were consulted. The PPI contributors felt the ACT approach to weight management was "a new way to consider" the problem and for the young people it felt "empowering, hopeful and for the whole person". A lay

co-applicant and volunteers from diverse ages and backgrounds were recruited to the team to form an advisory group for guidance throughout.

What are the possible benefits and risks of participating?
By taking part participants will have a novel opportunity to help design this new programme of care for the Care of Childhood Obesity clinic in the short term, and the team plans to test this intervention in clinics around the UK in the future. It is hoped that participants will learn new ways to approach their weight management and improve their psychological well-being through the experience of the intervention through the co-development process. Please note there is no guarantee of weight loss during this study. There are no physical risks or burdens during the study. Acceptance and Commitment Therapy teaches us to understand difficult feelings, which may lead to emotional discomfort, but our health psychologist will support participants through the process of experiencing and understanding these feelings. The clinic care team will also support participants throughout.

Where is the study run from?
Bristol Royal Hospital for Sick Children (UK)

When is the study starting and how long is it expected to run for?
July 2022 to December 2023

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Elanor Hinton, elanor.hinton@bristol.ac.uk (UK)

Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
317533

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 317533, CPMS 54210

Study information

Scientific Title
AIM2Change: Helping adolescents to increase their intrinsic motivation to change weight; a co-development of a new Acceptance and Commitment Therapy (ACT)-based treatment for tier 3 paediatric weight management

Acronym
AIM2Change

Study objectives
The aim is to co-develop an Acceptance and Commitment Therapy (ACT)-based programme with members of the clinical population of young people with obesity as an intervention to increase intrinsic motivation for weight management, using a qualitative and person-based approach.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/11/2022, North West - Greater Manchester (GM) East Research Ethics Committee (Meeting held by video-conference via Zoom; +44 (0)2071048306; gmeast.rec@hra.nhs.uk), ref: 22/NW/0337

Study design
Co-development qualitative interview study

Primary study design
Other

Secondary study design

Study setting(s)
Hospital, Internet/virtual

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Young people with lived experience of obesity who attend a tier 3 paediatric weight management clinic

Interventions
The aim is to develop an Acceptance and Commitment Therapy (ACT) programme for young people accessing tier-three weight management services. The intervention will be developed with the patient group themselves. Participants will receive versions of the therapeutic content, and help to provide feedback that will shape the programme and its content. The intervention aims to increase the patient's own motivation for making and sustaining change to lifestyle by exploring what drives them as a person, and understanding what they want their life to be about. The approach is person-centred and focuses on the experiences of the clinical population to guide the research outcomes.
The principal objectives are to:
(i) assess which components of the proposed intervention are valued by young people;
(ii) co-develop additional activities to meet patient experiences;
(iii) produce the intervention manual and training documents;

Secondary outcomes from the research process include;
(i) explore the potential of online delivery;
(ii) produce the protocol for future feasibility trials.

Recruitment and consent:
Recruitment will be at the Care of Childhood Obesity (CoCO) clinic, at Bristol Royal Hospital for Children. A diverse sample will be recruited of up to 15 young people, who need additional help with their weight management beyond the current multidisciplinary team offering, alongside their parents/carers. During routine clinic appointments, young people who are not losing weight under the clinics' current approach will be introduced to the research concept by the Consultant Endocrinologist - Professor Julian Hamilton-Shield or Dr Dinesh Giri. The patient an information pack will be offered at that meeting, and that includes a contact number and email address for Jennifer Cox, the Health Psychologist delivering the co-development sessions. Jennifer Cox holds an honorary contract with the University Hospital Bristol and Weston Trust. When possible, Jennifer Cox will attend clinic appointments to meet the young people in person and answer any questions. The young people will be given 24 hours to consider their participation. If the family has provided Jennifer Cox with contact details during the clinic appointment, Jennifer Cox will contact them not earlier than 24 hours after the clinic appointment. The family are also able to contact Jennifer Cox via the number or email address provided. Consent will be received via an online link. Online appointments will be scheduled, for those who wish to proceed, at a time that is convenient for them.

The young person and their parent (should the young person wish them to attend) will meet for seven one-hour sessions that will comprise 45 minutes of therapy development time, and a 15-minute interview. During the therapy development, activities from the template programme will be delivered and discussed with changes and suggestions from the young person shaping the activities. The interview section gives the chance for the young person to reflect on the activities and the session with a third party to enable objective feedback to be given.

The sessions will be delivered online, at a time to suit the participant. These sessions will be delivered on a secure online platform, Microsoft Teams, to minimise visits to the clinic, saving time and travel costs. To ensure equal access, the budget will include funds for data usage and tablets to borrow.
The personal circumstances of the young person will be considered to find a suitable space for the sessions, and if it is not available at home, a private room on site in Bristol will be found.

If a participant decides to leave the research process before the end, every attempt will be made to understand this as fully as possible by asking the independent qualitative interviewer, as opposed to the therapist, to run a short session to capture the reasoning behind their decision (an ‘exit interview’).

A three-hour-long final consensus meeting will be held for the young people, their parents /carers (if needed for support by the young people), applicants and the steering group at the end of the project. Whilst the young people will have shared their experiences with the researcher, this meeting may involve the young people sharing with a much wider group of people, therefore the decision has been taken to conduct this meeting online to reduce the pressure that may be felt at speaking out. During the consensus meeting, the programme details will be finalised with a chance to discuss any differences in opinion. The CUBE methodology will be used to establish the participants' perception of their experience in 4 domains: their contribution, voice, agenda and potential to change intervention. Once the young person has experienced the intervention over the seven-week period and provided their thoughts and

opinions through the interviews and the consensus meeting, that is the end of their involvement in the study. They will continue to receive their normal care through the CoCO clinic.

Intervention Type
Other

Primary outcome measure
Co-development of an adapted intervention during online sessions with young people measured using person-centred 'think aloud' interviews with a qualitative researcher after each of the 7 therapy sessions and a consensus meeting at the end of the co-development period

Secondary outcome measures
Other desired outcomes include the following measured using person-centred 'think aloud' interviews with a qualitative researcher after each of the 7 therapy sessions and a consensus meeting at the end of the co-development period:
1. Co-development of additional activities/sessions with the young people
2. An understanding of patient perceptions of online delivery in this peri-COVID pandemic
3. Developed intervention manuals and training documents ready to be used in a feasibility trial

Overall study start date
04/07/2022

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Aged from 11 to 18 years old
2. Patients attending the Care of Childhood Obesity Clinic at Bristol Royal Hospital for Sick Children
3. Body mass index of >95th percentile

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
15

Total final enrolment
14

Key exclusion criteria
Complex communication difficulties that would significantly impede meaningful engagement with the intervention

Date of first enrolment
07/12/2022

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Royal Hospital for Sick Children
Care of Childhood Obesity Clinic
Upper Maudlin Street
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BS2 8BJ

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.uhbristol.nhs.uk/

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Findings will be shared initially with study participants and PPI advisory group. A comprehensive plan for dissemination will be developed with the public co-applicant and advisory group, which is anticipated to include sharing the findings with the NHS England children and young people obesity group, Health Integration Teams, through an open-access publication in a high-impact journal, relevant conferences (e.g., UK Congress of Obesity), Bristol Childhood Obesity webinar series, and through Obesity UK.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be stored in the University of Bristol Data Repository, where it will be made available to other researchers. All requests for access to the anonymised transcription will be assessed by a University of Bristol data access committee to check they are authentic research requests.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Preprint of initial intervention development work which led to the Research for Patient Benefit grant for this study	06/09/2023	08/02/2023	No	No
HRA research summary			28/06/2023	No	No
Basic results		21/10/2024	21/10/2024	No	No
Protocol file	version 1.3	03/01/2023	21/10/2024	No	No