Protocol

FULL/LONG TITLE OF THE STUDY
AIM2Change: Helping **A**dolescents to increase their **I**ntrinsic **M**otivation **to change** weight; a co-development of a new Acceptance and Commitment Therapy based treatment for tier 3 paediatric weight management

SHORT STUDY TITLE / ACRONYM

AIM2Change: making the changes that matter to you.

PROTOCOL VERSION NUMBER AND DATE

Version 1.3 13/01/23

RESEARCH REFERENCE NUMBERS

IRAS Number:	317533
SPONSORS Number:	CH/2022/7329
FUNDERS Number:	NIHR203605

This protocol has regard for the HRA guidance and order of content

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

.....

Date:
...../...../.....

Name (please print):

.....

Position:

.....

Chief Investigator:

Signature:

.....

Date:
..13..../.01.../..23
....

Name: (please print)

.....ELANOR HINTON.....

LIST of CONTENTS

KEY STUDY CONTACTS

Insert full details of the key study contacts including the following

Co- Chief Investigator	Julian Hamilton Shield J.P.H.Sheild@bristol.ac.uk +441173420159
Co- Chief Investigator and Study Co-ordinator	Elanor Hinton, Elanor.hinton@bristol.ac.uk +44 117 455 4558
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Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	NIHR: National Institute for Health and Care Research
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Committees	Steering group – Led by Julian Hamilton Shield, as above PPI group, led by Elanor Hinton and Gail Thornton, as above.
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STUDY SUMMARY

Study Title	AIM2Change: Helping **A**dolescents to increase their **I**ntrinsic **M**otivation **to change** weight; a co-development of a new Acceptance and Commitment Therapy based treatment for tier 3 paediatric weight management
Internal ref. no. (or short title)	AIM2Change: making the changes that matter to you.
Study Design	Co-development
Study Participants	Young people aged between 11-18 years who have attended the tier three weight management service, the Care of Childhood Obesity clinic at Bristol Children's Hospital without losing weight after eight months at the service.
Planned Size of Sample (if applicable)	10 -12 young people and their parents/carers
Follow up duration (if applicable)	N/A
Planned Study Period	18 months
Research Question/Aim(s)	To: i. assess which components of the proposed intervention are relevant to and valued by young people. ii. co-develop additional activities/sessions with the young people iii. explore the potential of online delivery in this peri-COVID pandemic. iv. produce the intervention manual and training documents

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NIHR RFPB Grant (NIHR203605)	£149,743.00
NIHR BRC Diet & Physical Activity Theme, within Bristol Medical School and UHBW NHS FT	Providing support in kind, computers, desk space etc.

ROLE OF STUDY SPONSOR AND FUNDER

The study is funded by an 18-month NIHR Research for Patient Benefit Grant. The funder reviewed the proposed study design, conduct and the data analysis plan prior to funding being granted. They will not review conduct, data analysis and interpretation, manuscript writing and dissemination of the results.

The University Hospitals Bristol and Weston are the sponsor, with Amelia Lowe, Research & Innovation being our named sponsor contact. The named contact reviewed the proposed study design, conduct and the data analysis plan prior to submission for funding and reviewed this protocol before formally agreeing to sponsor the project.

The research team will now control the final decision making on the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. Reports will be provided to the funder annually and to the sponsor as requested during the course of the project.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Steering Group:

The steering group will comprise an external collaborator (Dr Nikki Davis, Consultant Paediatric Endocrinologist & Diabetes Specialist, University Hospital Southampton NHS Foundation Trust to who will chair the committee and help provide independent oversight of and expert guidance on the progress and conduct of the study (and if results warrant, will help provide continuity between this co-development study and preparation for future trials). One of Obesity UK's directors (Kenneth Clare) to share knowledge of the national obesity landscape from a patient perspective, and at least two young people and their parent/carers. The steering group will meet at four milestones during the project, in addition to attending the consensus meeting, and will guide the strategic direction of this research and monitor progress, compliance, and data quality.

PPI Advisory Group:

The PPI lead (EH) and GT have budgeted and planned to ensure the lay voice is prominent and integrated. Contributors to the initial PPI sessions have been invited to form an advisory group comprising young people with (YP) obesity and parents of YP with obesity to meet online. We will extend recruitment more widely to increase PPAG diversity, by recruiting from Obesity UK, local health integration teams and community groups, other YP obesity services such as SHINE (Sheffield), and other charities, such as National Voices.

Planned contributions and meetings:
Three PPAG meetings are planned, designed for the following:
(1) initial thoughts on project and review of participant-facing documentation;
(2) discussion of initial findings and help interpret results;
(3) contributing to the final report, publications, and design of the future trial.

At each stage, the advisory group's feedback will be incorporated into the research processes. The PPAG will also advise on dissemination and take part in PPI evaluation.

Support for members:
Meetings of the advisory group will be held securely online. We will provide instructions on how to join the meetings and help individuals get set up. GT will proactively offer support and induction for the project specifically and PPI more generally. We recognise that this could be a sensitive area for some YP, so will continue to liaise with others who support them. Additionally, GT has employment experience of sensitive management of emotional discussions and of working with young people and will provide responsive facilitation of the group and emotional support as required. We have budgeted for payment for their contribution (£25/per person).

PPI Lead and coordination:
The CI (EH) is also PPI lead, keeping the PPI at the heart of the project management. She is supported by GT who has considerable experience of co-ordinating and participating in PPI on successful NIHR grants.

Evaluation of impact:
We have embedded PPI evaluation and impact assessment in our project. We will use an online tool designed for this purpose (The CUBE) to evaluate the experience of PPI for the advisory group and to capture impact on the project.

PROTOCOL CONTRIBUTORS

Dr Elanor Hinton will lead the day-to-day management and delivery of the project. She will supervise the Research Associate and contribute to design and analysis. She will manage the budget, chair meetings with co-applicants and liaise with the steering group. She will provide NIHR reports and other dissemination of the findings. She will take the role of PPIE lead for this proposal and will be partnered with the public co-applicant in supporting PPI throughout the project.

Professor Julian Hamilton Shield will provide insight on childhood obesity and its treatment goals, service provision and the future need to operationalise an intervention in multiple sites in feasibility and RCT settings. He will act as a mentor for the lead (EH) and will contribute to management and steering group and consensus meetings.

Ms Gail Thornton (Public contributor) has lifelong lived experience of obesity and overweight and an understanding of the potential psychological components that contribute to the maintenance of obesity. She has a BSc. in psychology and a master's degree in psychological research methods. Her role will include ensuring the project as a whole, but also the documentation, intervention itself and interpretation of the results, are in keeping with the aims of being acceptable and relevant to young people living with obesity from diverse socioeconomic and ethnic backgrounds and to ensure that their voice is heard throughout.

Dr Aidan Searle is a qualitative methodologist with the NIHR BRC Nutrition Theme. Dr Searle also has a background in Health Psychology and has Chartered Psychologist status. His experience includes: the lived experience of health conditions, delivery of health services, practitioner-patient communication, behaviour change theory and intervention development. He will lead on the design, implementation, and analysis of the qualitative interviews.

Dr Jennifer Cox (Research Associate) is a Chartered, HCPC registered, Health Psychologist trained in ACT. Jennifer completed her PhD at the CoCO clinic, which includes a qualitative paper that has informed this intervention. Dr Cox will be responsible for intervention development, recruitment, delivery of therapy, data analysis, interpretation, and dissemination.

Dr Dinesh Giri is a Consultant Paediatric Endocrinologist at the CoCO clinic with considerable experience in supporting patients with obesity. He will be responsible for recruitment.

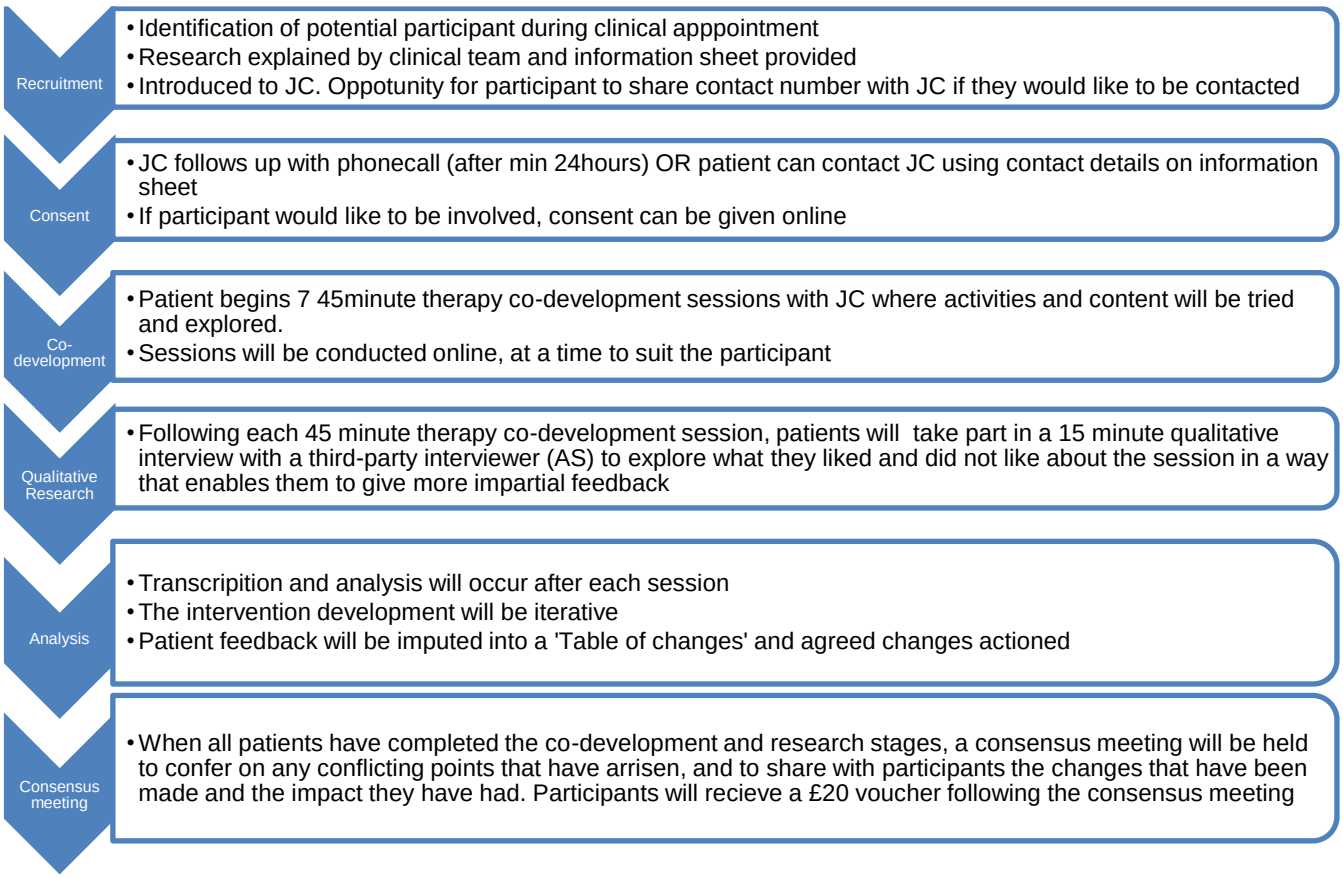
Dr Claire Semple is a Specialist Clinical Psychologist (CoCO clinic) who will be responsible for the clinical safeguarding of the participants throughout the intervention and will advise on ACT programme development through her extensive experience of ACT in other clinical areas and working with young people managing overweight.

All elements of protocol design, and public facing documents (e.g. PIS) have had PPI input, through the involvement of Ms Gail Thornton, who has also reviewed and contributed to all elements of the protocol design. The original research concept arose from qualitative interviews with service users and their parents/carers, and four PPI groups were run prior to applying for funding, which contributed to, and changed our research proposal. We have now conducted two further PPI sessions during which the contributors viewed and commented on public facing documentation.

The sponsor has reviewed all of the documentation to ensure that the documentation and plans are in line with their policy but the sponsor and the funder have not been involved in the research design.

KEY WORDS: Acceptance and Commitment Therapy, paediatric, weight management, tier 3 services, adolescents

STUDY FLOW CHART



Project Gant Chart – Grant began on the 4th July 2022.

Activity	Planned start in month	Planned duration (in months)																		
			1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**
Management meeting 1	1	<1																		
Steering group meeting 1 (Project start)	1	1																		

Prepare documents with PPI Co-applicant and PPI group and submit application for HRA and REC approval	1	4																		
PPI Meeting 1 (welcome, documentation review & CUBE evaluation	2	<1																		
Management meeting 2	5	<1																		
Recruitment and iterative intervention co-development sessions with YP	5	9																		
Deductive analysis of qualitative interview transcripts	6	8																		
Management meeting 3	9	<1																		
Steering group meeting 2 (Project monitoring)																				
Management meeting 4	14	<1																		
PPI Meeting 2 (discussion of findings & interpretation, & CUBE evaluation)	14	1																		
Consensus meeting with Participants, Co-applicants & Steering group	14	<1																		
Finalisation of intervention manual and training documents	14	2																		
Preparation and submission of manuscript for publication	15	4																		

Preparation of final report for funder and development of feasibility trial grant application (RfPB Tier 2)	16	3																		
Management meeting 5	17	<1																		
PPI Meeting 3 (input into paper, report, & future trial & final CUBE evaluation)	17	<1																		
Preparation of PPI impact and evaluation report	17	2																		
Steering group meeting 3 (Project outputs)	17	<1																		

STUDY PROTOCOL

AIM2Change: Helping **A**dolescents to increase their **I**ntrinsic **M**otivation **to change** weight; a co-development of a new Acceptance and Commitment Therapy based treatment for tier 3 paediatric weight management

1 BACKGROUND

The rise of obesity continues in England with 6.3% of children aged 11 leaving primary school with severe obesity (BMI >99.6th percentile) and 22% of boys and 21% of girls aged 13-15 years classified as obese (BMI >95th percentile)[4,5]. Obesity in childhood is not just a predictor for morbidity in adulthood but has significant co-morbidities in childhood[6,7]. Despite the obvious need for urgent action, theory based behavioural interventions for severe obesity are marked by only modest improvement in weight status and high levels of attrition[8]. The Care of Childhood Obesity (CoCO) Clinic in Bristol is currently the only NHS England/CCG funded tier 3 service for children with morbid obesity, with a multidisciplinary team (MDT) including consultant endocrinologists, psychologist, nurse, social worker, and dietitians. NHS England has recognised the need to promote equitable access to MDT-led services and plans to replicate the CoCO service in 14 further regional centres across the country in 2021/22, to be known as Complications Related to Excess Weight (CEW) clinics. Often, children attending the clinic have BMI scores above 50, profound, life threatening conditions including severe sleep apnoea, fatty liver disease or Type 2 diabetes, with disorders of mood and self-esteem. Obesity is becoming increasingly socially patterned with the poorest and least enfranchised families and certain ethnicities at most risk[4]. These under-served groups do attend the clinic but many are unable to successfully commit fully to making changes in food choice, portion size, cooking from scratch, snacking, and decreased sedentary time. The present COVID pandemic has amplified the additional risk conferred by obesity on health outcomes in YP.

Despite its success in addressing morbid obesity and its complications[9], many young people (YP) in the CoCO clinic still struggle to make positive changes to their weight management. Qualitative reviews based on families' experiences of the CoCO clinic were conducted in 2009 and 2019, which examined reasons for lack of improvement to BMI[10,11]. A combination of complex lives and an external locus of control resulted in YP and parents feeling they lacked competency and motivation to make meaningful change[11] . These findings were interpreted in the context of Self-Determination Theory (SDT [12,13]) which comprises three components of Autonomy, Competence and Relatedness, which, if experienced together, elicit the intrinsic motivation necessary to enact behaviour change. Indeed, a study of the correlates of SDT and physical activity in children demonstrated that children's motivation is based on intrinsic motivation and is a target for behavioural interventions in YP[14] .

Our qualitative review identified and interpreted patient issues in the context of SDT[11]. SDT posits that intrinsic motivation is present in activities that are naturally satisfying and fulfilling (i.e. enacting a positive behaviour can in itself be perceived as a reward). By freeing themselves from external pressures and developing intrinsic motivation, individuals begin to accept their challenges and commit to making changes in their behaviour. As one of our PPI contributors commented: "to have that moment where you think I need to do this for me". Acceptance and Commitment Therapy (ACT;[15]) is an action-oriented approach that stems from traditional Cognitive Behavioural Therapy[16]. The premise of ACT is that individuals learn to recognise patterns of avoidance and interference from emotional responses and learn to accept that these deeper feelings are appropriate responses to certain situations that should not prevent them from committing to desired actions. Recent reviews have concluded that ACT can be successfully applied to help YP with health issues[17,18]. Figure 1 describes how SDT and ACT are brought together in the intervention.

A recent systematic review found that ACT was effective in improving weight-related health behaviours and psychological wellbeing in adults living with obesity and in some studies this was associated with greater weight loss than standard care[19]. We are now collaborating with the review authors Dr Maiz and Ms Iturbe to conduct a scoping review of the use of ACT for weight-management in YP (pre-registered protocol: https://osf.io/9teha), Ms Iturbe is currently a visiting postgraduate student to Bristol who is helping complete the review and work on preparation for this project. Inclusion criteria for the scoping review are as follows: adolescents between 11 and 18 years; ACT incorporated in the intervention; weight management as outcome. Screening of 165 abstracts has resulted in the inclusion of two feasibility studies[20,21], two trial protocols[22,23], and one study designed to develop a new paediatric obesity treatment platform incorporating ACT[24]. This preliminary work thus far indicates that ACT for weight management is deemed acceptable by adolescents with some reduction in BMI and improvements in aspects of psychological wellbeing over the course of the intervention period[20,21,24]. However, each of these studies differ in their aims (e.g. emphasising psychological wellbeing over weight loss[22]) and methodologies (e.g. group therapy over individual sessions [20]), suggesting that further research is necessary to determine the efficacy of ACT in the context of psychological wellbeing and weight management in YP. Therefore, this proposal to co-develop a person-based ACT-based intervention for weight-management in YP is novel in that it will draw on evidence synthesis, PPI, and with YP at the heart of its development.

To prepare the initial ACT programme, we have applied the COM-B framework of intervention development [25], which focuses on whether an intervention develops individuals' Capability, Opportunity and Motivation to enact and sustain change in the relevant target Behaviours. The experience of the clinic staff (JHS, DG, CS), direct observation (JC) and qualitative service review (JC, AS, EH) has informed the COM-B process, and demonstrated that the proposed ACT programme will provide the framework to deliver effective Motivational Behaviour Change Techniques to increase intrinsic motivation. The process of developing this intervention has been documented in a publication that has been submitted for publication[38].

This proposal seeks to co-develop a person-based programme, based on ACT, to increase intrinsic motivation in YP who have not responded to the MDT-led approach (Figure 1 for link between SDT and ACT). Applying 'participatory design', to consider patients as the 'experts of their own experience', is not a new concept in itself[26], but has not yet been regularly applied to projects co-designing interventions with young people. Indeed, a concurrent systematic review is assessing the use of participatory design for obesity management with young people[27]. Initial findings from this review are that this approach is novel, creative, and welcomed by the young people, and that further evaluative work is required (Willmott, unpublished communications). We believe that co-developing an ACT-informed weight-management programme with the young people themselves has the potential to precisely address the difficulties of those not yet benefitting from current 'multi-disciplinary, standard behaviour change interventions'. The first step, through this application, is using cutting-edge, behavioural change person-based techniques to work with YP to develop an acceptable programme to ensure that the next phase, a feasibility study across two sites, is successful. The programme could then be implemented nationally across tier 3 services and modified for tier 2 adjunctive care.

The population being included are therefore patients (aged 11- 18) already accessing tier 3 weight management services, who are not seeing weight change from their current treatment.

2 RATIONALE

The research proposal aims to co-design an ACT based intervention to support patients who are not currently progressing at the CoCO clinic. Currently, these patients would remain with the clinic for 18 months but may not lose any weight. The patient's weight may create both health and wellbeing difficulties, both in the immediate and the long-term, and this may be compounded by the sense of 'failure' that may occur from not achieving the goals the CoCO clinic set for them.

A service review identified that this patient group had a lack of self-determination, and ACT is known to support connection to intrinsic motivations[29]. (ACT is currently used successfully in adult weight management[19] and has been adapted for young people[1]. Currently, there is no specific weight management adaption for young people in a weight management context. The proposed work therefore addresses a gap in the literature. The proposed work was presented to four PPI groups, who approved and amended the proposal. This preliminary work is summarised in an intervention development paper that is currently under revie[38].

The research will continue in this patient-led way, continuing to co-develop the intervention with up to 15 people and their parents/guardians. We considered this an important process, to ensure the finalised intervention is of value and meaning to the target audience. This co-development process is

very much in line with the new MRC guidelines for iterative, patient led intervention development and evaluation.

By the end of this 18-month period, we intend to have an intervention manual produced, that could be trialled across the new CEW-clinics across the UK. If successful, the intervention could be adapted for other audiences (e.g., Tier 2 weight management, younger children) offering the intervention a wide potential scope for impact. We have started building our network of contacts within tier 2 and 3 services around the UK to facilitate this process.

3 THEORETICAL FRAMEWORK

Figure 1. The theoretical framework for the AIM2Change study in visual form

Process of intervention selection completed to date.

Qualitative review Cox et al. (2020)

COM-B & APPEASE criteria

Systematic review

PPI

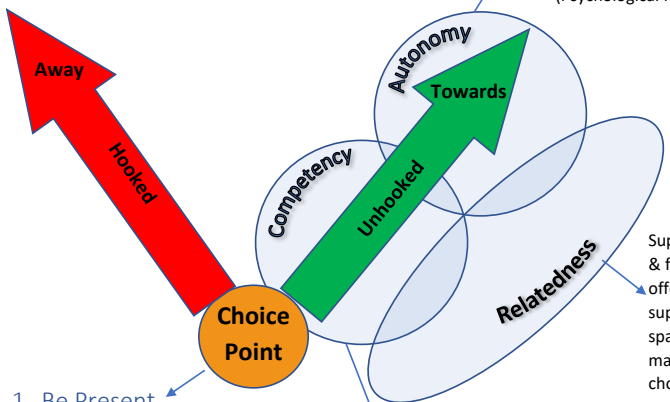
Person based approach to intervention design.

ACT to improve self-determination.

Planned work to be completed during the grant period.

Behaviours that are inconsistent with the **VALUES** YP would like to stand for, and ultimately move the YP away from their goals.

These typically include coping strategies that may relieve discomfort in the short-term (i.e., comfort eating) but long-term are detrimental.



3. Do what matters

Developing the ability to take control of behaviours and act in ways that are in line with the **VALUES** chosen by the YP, that lead to the life they want to be living.

(Psychological flexibility)

Supported by clinicians & family/friends who offer unconditional support and enable the space and time for YP to make autonomous choice.

1. Be Present

ACT Sessions will developing the YP's awareness, so they **notice** the moments where they have choice over their behaviours, and help them live in the present moment

2. Open up

ACT Sessions will develop skills in opening up to experiencing, **accepting and 'unhooking'** from feelings and sensations without acting on them.

Seven weekly hour long sessions of ACT therapy, delivered to participants.

Integrated with qualitative interviews to hear patients experiences in line with the Person-Based Approach (PBA) development.

Planned work to be completed during the grant period

Feasibility trial

Multi-centred full trial

4 RESEARCH QUESTION/AIM(S)

The aim is to co-develop an ACT 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. This approach aims to empower the young people to be part of making positive changes and does not stigmatise or attribute blame to them as responsible for their weight difficulties.

4.1 Objectives

The objectives are to:

v. assess which components of the proposed intervention are relevant to and valued by young people.
vi. co-develop additional activities/sessions with the young people
vii. explore the potential of online delivery in this peri-COVID pandemic.
viii. produce the intervention manual and training documents

4.2 Outcome

The desired outcomes are:

i. an adapted intervention that responds to what is relevant and valued by young people.
ii. co-developed additional activities/sessions with the young people.
iii. an understanding of patient perceptions of online delivery in this peri-COVID pandemic.
iv. developed intervention manuals and training documents ready to be used in a feasibility trial.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

Co-development of Intervention:
The seven-session ACT programme will be delivered by the Research Associate (JC) to the young person in the four months in between their consultant appointments to avoid contamination. These sessions will be delivered on an NHS secure online platform, such as 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. Personal circumstances of the young person will be considered to find suitable space for the sessions, and if it is not available at home, a private room on site in Bristol will be found.
Qualitative 'think aloud' cognitive interviews based on the person-based approach to intervention development[2] will be conducted for approximately 15 minutes with participants at the end of each session to gain an inductive understanding of the comprehensibility, acceptability, and value of intervention components. We will also ask participants to consider the length of each session and of the programme as a whole. This iterative approach to qualitative research can also provide rich data on the contextual factors that may influence young people's engagement with the intervention or the process of enacting weight loss behaviours in the context of their lives, their values and prior experiences[2]. There are two primary paradigms with regard to the 'think aloud' approach[32]: one paradigm is founded on the view that the facilitator intervenes as little as possible during the

interview process. The other paradigm is rooted in the practice of intensive interviewing with follow-up probes (e.g., can you tell me in your own words what the question is asking). As this approach encourages participants to verbalise thoughts while answering questions, we feel it is possible that follow-up probes may also be included in the interviews with young people if they are reticent to engage with the 'pure' think-aloud approach. However, an experienced qualitative researcher will facilitate these interviews (AS) and they will be recorded on Microsoft Teams and transcribed verbatim. Think aloud interviews also allow the researchers to observe participants involved in the development of the intervention following each session expressing their thoughts out loud, thus giving valuable insights into their experiences and views of the intervention while they are salient for the participant. This approach has been shown to be useful in the context of developing an intervention to improve breathing in individuals with asthma as it provided insights into every aspect of the intervention ensuring it is feasible and acceptable to participants[33].

The interviews will be analysed iteratively and managed using the software Nvivo. If common themes for change are found, then modifications will be made to the sessions for the next participants. If no consensus is found, no changes will be made. This iterative process will be repeated until all participants have completed the programme. Suggested changes will inform the evaluation of the intervention using a 'Table of Changes', that will begin with the PPI sessions on the initial design of the programme. A Table of changes provides a novel and efficient approach to the analysis and criteria of intervention development regarding feasibility, acceptability and refinement[34]. Comments relating to the intervention will be classified according to whether a particular component is likely to impact on or be a precursor to behaviour change. Tabulating the qualitative data in this way will serve to refine the contents of the sessions in a young person-based, responsive process.

A consensus meeting will be held for the young people, their parents/carers (if needed for support by the young people), applicants and steering group including to young PPI members. 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. Through structured discussions and voting on the Table of Changes, agreement will be reached on the sessions and activities to form the programme to take forward to a trial. This meeting will inform the development of the training manual, such that future therapists could deliver the intervention with fidelity ensured. ACT posits that there is no one-size-fits-all approach to therapy, and so the resulting manual will contain different activities to meet each objective, to enable therapy to be tailored to age, preferences, and socio-economic circumstances.

Consideration of health economics of the intervention
Input from our health economic collaborator (RK) will be sought at key milestones in the project, through invitation to the following management meetings: meeting one to ensure we keep economic viability in mind from the start, meeting four prior to finalisation of the intervention, and meeting 5 during preparation of reports and feasibility trial design. RK will provide advice on viability in this study, including the affordability and cost-effectiveness of the intervention, and contribute to the development of the protocol for the future feasibility trial.

6 STUDY SETTING

Participants will be recruited from the Care of Childhood Obesity clinic at Bristol Royal Hospital for Children, or one of the CoCO service's outreach clinics (e.g. Southmead Hospital, Bristol). The research has been designed based on feedback from patients and their families (Cox et al. 2019), and therefore it is an appropriate next-step to conduct this co-development research piece with this patient group. The research is a single centre study. The site requirements are that they run tier three weight management services for children and young people.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

- Age range. 11-18

7.1.2 Exclusion criteria

- (During this initial development) people with complex communication difficulties that would significantly impede meaningful engagement with the intervention.

7.2 Sampling

We will aim to recruit from diverse socioeconomic and ethnic groups, using the clinic team's knowledge of their patients to ensure young people disadvantaged by low income and other social and ethnicity factors are proportionately represented in our participant sample.

7.2.1 Size of sample

We will recruit up to 15 patients and their parents/carers. It is considered that this will give sufficient data to meet saturation, whilst remaining achievable within the 9-month recruitment period. All parents will be consented for their own participation as well as that of their young people.

7.2.2 Sampling technique

Purposive sampling will be used as we will aim to recruit from diverse socioeconomic and ethnic groups, using the clinic team's knowledge of their patients to ensure young people disadvantaged by low income and other social and ethnicity factors are proportionately represented in our participant sample.

7.3 Recruitment

Recruitment will be at the CoCO clinic, Bristol Royal Hospital for Children (with JHS, DG & CS), or one of the CoCO service's outreach clinics (e.g. Southmead Hospital, Bristol). We will recruit up to 15 young people, who need additional help with their weight management beyond the current MDT offering, alongside their parents/carers to support the young people in the process. We will aim to recruit from diverse socioeconomic and ethnic groups, using the clinic team's knowledge of their patients to ensure young people disadvantaged by low income and other social and ethnicity factors are proportionately represented in our participant sample. There are around 166 patients actively engaged in the clinic. A recent audit of patients revealed 58% of young people would meet our inclusion criteria. Patients will be identified by their clinical team (JHS, CS, DG) and those eligible will be invited to take part. To meet our target of up to 10-12 young people to participate in the intervention co-development, we will aim to recruit 15 young people based on an estimated 20% drop-out rate. For those that decide to drop out we will ask the reason why, for our understanding for future trials.

7.3.1 Sample identification

The patients' existing clinical team (JHS, CS, DG) will identify potential participants during their routine clinical appointment. No other member of the research team will have access to the patients' identifiable personal data. The clinical team will introduce the study to any patient that meets the inclusion criteria, based on their age and progress at their current clinic appointment.

Each young person participating in the co-development process will be given a voucher as a 'Thank you' for their contribution to the research element of the project. This will be given after their attendance at the consensus meeting.

7.3.2 Consent

During the patients' routine clinic appointment, patients who meet the inclusion criteria will be invited to take part in the research by their usual clinician. An age-appropriate written information sheet will be offered to both young people and their parents and they will be introduced to the RA/Therapist JC and given an opportunity to ask any questions. They may, if they would like, share a contact number with JC for her to ring them at least 24 hours later for them to ask any more questions. They may also/alternatively contact JC using the contact details provided on the information sheet.

After a minimum of 24 hours, consent can be given to participate, using an online link shared with participants following the phone call.

As we will be seeking consent for children and young people under the age of 16, their parents will need to conduct the consent, however we will also ask the children and young people to sign an assent form, and the research will not be conducted unless both parties have signed.

All information sheets have been reviewed by a PPI group of the target users' age to ensure that the materials are appropriate and accessible.

8 ETHICAL AND REGULATORY CONSIDERATIONS

The research offers no clear benefit to patients as the work is in its preliminary stages. We propose that ACT has the potential to have a substantial impact for young people who need help with their weight management, with benefits beyond weight management into holistic wellbeing and lifestyle improvement which may sustain into adulthood. Participant therefore may benefit from these effects but this cannot be guaranteed.

The specific needs of the population have been considered through working with PPI groups, the patients feedback themselves via qualitative interviews, and the involvement of their clinical team in this intervention development. Due to the person-based co-development approach to research, the patients individual needs will continue to inform and shape the intervention.

The patients dignity and privacy have been considered throughout the research process. All research will be informed, consented to and anonymised to ensure dignity is upheld.

8.1 Assessment and management of risk

If the research team come into information that has safeguarding implications, the information would be escalated through the CoCO clinics usual procedures. Dr Clare Semple, clinical psychologist is the safeguarding lead on the research team and concerns would be passed to her. The clinic MDT also includes a clinical nurse specialist and social worker, who are used to managing safeguarding

concerns so if Dr Semple was not available, the information would be escalated to them, and they would respond in the same way as if a safeguarding concern arose in one of their clinic appointments.

The Sponsor does not anticipate any requirement for safety reporting in this study as no adverse events relating to the study are expected. Should any adverse events occur that are considered related to the study intervention, they will be recorded and reported in accordance with UHBW's Research Safety Reporting SOP.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

The study will be performed subject to favourable opinion/ authorisation/permission or equivalent from all necessary regulatory and other bodies. This includes but is not limited to REC, HRA, NHS Trusts. Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.

Once approvals have been given, all correspondence with the REC will be retained. It is the Chief Investigator's responsibility to produce the annual reports as required. The Chief Investigator will notify the REC of the end of the study. An End of Study report will be submitted (due to the duration of study being <2 years). If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

Before any site can enrol patients into the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place. The sponsor will run local capability and capacity review and approval at the same time as HRA submission.

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

This study will be conducted in accordance with:

- The principles of Good Clinical Practice, as set out in the International Conference for Harmonisation of Good Clinical Practice (ICH GCP) guidelines
- The UK Policy Framework for Health and Social Care Research.

Amendments

The PI, Dr Elanor Hinton will be responsible for the decision to amend the protocol, alongside Prof. Julian Hamilton Shield. All amendments will be sent to the Sponsor for review prior to submission who will decide if the amendment is substantial or non-substantial.

New protocols will be numbered V1.1, V1.2 and the PI (EH) will be responsible for documenting and circulating the most up-to-date versions of the protocol. A share file will be kept updated with the most up-to-date documentation for all of the research team to refer to. All previous versions will be also kept in a shared file for history tracking and reference.

Substantive changes will be communicated to stakeholders via email.

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

If applicable, other specialist review bodies (e.g. Confidentiality Advisory Group (CAG)) need to be notified about substantial amendments in case the amendment affects their opinion of the study.

Amendments also need to be notified to the national coordinating function of the UK country where the lead NHS R&D office is based and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site. Note that some amendments that may be considered to be non-substantial for the purposes of REC still need to be notified to NHS R&D (e.g. a change to the funding arrangements).

8.3 Peer review

This Research proposal was developed by the core research team and improved by additional collaborators to benefit from their expertise. The application went on to be independently reviewed by Research Design Service South West which included expert review by 3 reviewers including a lay person. Through the application for funding, the research proposal was also reviewed by the NIHR funding committee and their external peer reviewers.

8.4 Patient & Public Involvement

PPI is active at every stage of the research process for the AIM2Change study. Due to having a PPI representative on the research team, and an ongoing PPI group there is PPI involvement in management and oversight of the research, undertaking the research, the analysis of results and dissemination.

To include the voice of young people and people with experience of obesity from the outset, we conducted four online PPI sessions with support from Obesity UK and the NIHR ARC West: two groups of young people (12-18 years, one group with obesity; 11 in total), and two adult groups with lived experience of obesity (9 in total). The groups included a range of socio-economic backgrounds, genders, ethnicities, and localities. We outlined preliminary ideas for the project, demonstrated possible programme materials, tried out examples of the tasks/games that could be adapted for the ACT sessions and explained some of the concepts. Groups gave feedback about the concepts, design and implementation of such an adapted programme, and importantly, they suggested improvements to the project so that it was appropriate and acceptable to its young participants (e.g. "use examples relevant to the young person", "run it individually not in a group"). The PPI groups unanimously supported the project and the idea of co-production. They felt our approach was worthwhile and "felt different" and "a new way to consider this". They recounted negative experiences of weight management and said by contrast this proposed programme provided life-skills and developed all-round well-being ("empowering, hopeful and for the whole person", "you take responsibility for you"). The groups' feedback has contributed to the study design and specific changes have been made, for example (i) ensuring all images used in programme materials are representative and diverse, and (ii) participants will **choose** whether they want to be accompanied in sessions. One of the participants is

now a co-applicant (GT). She has attended all team meetings since accepting this role, actively contributed to the development of the research plans, with a particular but not exclusive focus on the participant pathway and on PPI and has reviewed and helped write the grant application at both stages.

PPI Advisory Group:
The PPI lead (EH) and GT have budgeted and planned to ensure the lay voice is prominent and integrated. Contributors to the initial PPI sessions have been invited to form an advisory group comprising young people (YP) with obesity (five) and parents of YP with obesity (three) to meet online. We will extend recruitment more widely to increase PPAG diversity, by recruiting from Obesity UK, local health integration teams and community groups, other YP obesity services such as SHINE (Sheffield), and other charities, such as National Voices.
Planned contributions and meetings:

Three PPAG meetings are planned, designed for the following: (1) initial thoughts on project and review of participant-facing documentation; (2) discussion of initial findings and to help interpret results; (3) contributing to the final report, publications, and design of the future trial. At each stage, the advisory group's feedback will be incorporated into the research processes. The PPAG will also advise on dissemination and take part in PPI evaluation. Whilst the PPAG will advise on the outcome from the table of changes, the RDS advise that the PPAG would not attend the consensus meetings, to keep PPI separate from the consensus process. The and the young people who sit on the steering group will be in attendance during the consensus meetings.

To date, two separate 'initial' PPI meetings have been held. In the first meeting 4 YP living with obesity and 6 parents of young people living with obesity joined an online call to be introduced to the study and give feedback on the PISs. These contributors were recruited from all over the UK to increase representation and diversity. In the second meeting, 4 YP from a local community project were also introduced to the approach to be taken in this study and they also gave feedback on the PISs.

Support for members:
Meetings of the advisory group will be held securely online. We will provide instructions on how to join the meetings and help individuals get set up. GT will proactively offer support and induction for the project specifically and PPI more generally. We recognise that this could be a sensitive area for some YP so will continue to liaise with others who support them. Additionally, GT has employment experience of sensitive management of emotional discussions and of working with young people and will provide responsive facilitation of the group and emotional support as required. We have budgeted for payment for their contribution (£25/session/per person).

PPI Lead and coordination:
The CI (EH) is also PPI lead, keeping the PPI at the heart of the project management. She is supported by GT who has considerable experience of co-ordinating and participating in PPI on successful NIHR grants.

Evaluation of impact:
We have embedded PPI evaluation and impact assessment in our project. We will use an online tool designed for this purpose (The CUBE[36]) to evaluate the experience of PPI for the advisory group and to capture impact on the project.

8.5 Protocol compliance

To record protocol compliance, a log of the patient journey for each patient has been created on

Excel, and will updated weekly by the RA and overseen by the co-PI checked monthly and fed to the steering group before every meeting.

Accidental protocol deviations can happen at any time. It is imperative that they are reported to the CI and sponsor immediately. Deviations from the protocol that are found to be frequently recurring are not acceptable and will require immediate action and could potentially be classified as a serious breach. If protocol deviations occur, management will meet to discuss how to ensure they do not happen again.

8.6 Data protection and patient confidentiality

The data will be stored in a de-personalised anonymous manner, to remove identifiable data (locations, addresses, clinician names, etc) and pseudonyms will be used to describe patients. Only this non-identifiable data will be shared to allow for audit, quality control and analysis. Only non-identifiable data will be used in publications, shared open access or transferred to co-investigators.

The study will be monitored in accordance with UHBW's Monitoring SOP. All study related documents will be made available on request for monitoring and audit by UHBW, the relevant Research Ethics Committee and for any other regulatory authorities. This is standard practice and patients/carers will consent to this in the study consent form.

All documents will be stored securely and only accessible by study staff and authorised personnel. Data will be collected and retained in accordance with the General Data Protection Regulation. All data will be stored on password protected UoB computers and servers, with access protected to only designated individuals.

The original recordings will be deleted once transcription is complete. Study documents (paper and electronic) will be retained in a secure location during and after the study has finished. All essential documents, including patient records and other source documents will be retained for a period of 25 years following the end of the study.

The data custodian is Dr Elanor Hinton.

8.7 Indemnity

No equipment has been provided for the purpose of the study.

This is an NHS-sponsored research study. If there is negligent harm during the clinical trial when the NHS body owes a duty of care to the person harmed, NHS Indemnity covers NHS staff, medical academic staff with honorary contracts, and those conducting the trial. NHS Indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm. Ex-gratia payments may be considered in the case of a claim.

8.8 Access to the final study dataset

The research team, collaborators and steering group will have access to the full, non-identifiable dataset. De-personalised, data may be made available by requests to Jennifer.cox@bristol.ac.uk . The consent forms offer the opportunity for patients to consent to their data involvement in secondary analysis, and it is clear that this is an optional choice for them.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

Data ownership:
The data arising from this study will be owned by the sponsor.

Dissemination:
The study will be registered on the ISRCTN and published in the research summaries database on the HRA website. On completion of the study, the data will be analysed and tabulated, and a final study report will be prepared. This report will be accessed via the HRA website.
Findings will be shared initially with study participants and the 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.

Outputs:
The primary output will be the intervention manual, which will provide sufficient information for a therapist to deliver the intervention initially in a feasibility trial. A second key output will be a protocol and tier 2 application to the RfPB scheme for a feasibility trial to estimate recruitment, retention, adherence and acceptability and fidelity of the intervention across two sites. The feasibility study will also allow us to test our proposed method to determine the extent to which the key components of SDT (autonomy, competency, and relatedness) have been elicited through participation in the intervention.

Anticipated impact:
The development of this ACT-based intervention with and for young people living with obesity has the potential to have a substantial impact for young people across the UK who need help with their weight management. The PPI sessions conducted so far have revealed that this holistic approach to increasing intrinsic motivation and positive changes towards personal goals is new to the target population and that it could have benefits beyond weight management. Increasing intrinsic motivation of young people to manage their weight will not only reduce their obesity and associated co-morbidities as young people, but also decrease their chances of remaining obese into adulthood. If the intervention is deemed feasible, the findings will be used to inform a future definitive multicentre trial across England within the CEW clinics, funded by the NIHR HTA award system.

Acknowledgements:
The funder and supporting organisations including Obesity UK will be acknowledged within all publications and dissemination reports.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship of the final study report will be given in line with the International Committee of Medical Journal Editors. It is anticipated that first author will be allocated to the primary writer and contributor of each paper, with the final named author being EH as the trial PI.

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11. APPENDICIES

11.1 Appendix 1- Required documentation

Patient information sheets (three versions; 11-15 years, 16+ years, parent/guardian).
Online consent form parent/guardian
Online assent form – young person <16
Online consent for – young person 16+

11.2 Appendix 2 – Schedule of Procedures (Example)

Procedures	**Visits (insert visit numbers as appropriate)**									
	Screening	**Follow up phone call**	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 5**	**Week 6**	**Week 7**	**Once all ppts complete**
Information sheets given	x									
Opportunity to ask questions	x	x								
Informed consent		x								

Co-development therapy session			x	x	x	x	x	x	x	
Qualitative interview			x	x	x	x	x	x	x	
Review of future trial measures									x	
Consensus meeting										x
Sharing outcomes of the research										x

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.3	10Jan23	Elanor Hinton	Change 1: Following further discussions around safeguarding participants in our study, we would like to amend the text of one of the points in the consent form and the corresponding text in the patient information sheets. This is to clarify the possible range of people who might be contacted if concerns are raised, to cover both working hours (9-5), when the patients clinic team would be contacted, and early evening when online appointments may also occur, as after school time is likely to be when the majority of intervention development sessions are scheduled. Change 2: Updated the protocol text to allow for approach of potential participants at the Care of Childhood Obesity (University Hospital Bristol & Weston NHS Trust) run outreach clinic which is held at Southmead Hospital rather than Bristol Royal Hospital for Children.