ENHANCE - Evaluating the NHs englANd Complications of Excess weight clinics for children and young people

Version	Date	Author	Notes on Revision
1.0	20.12.23	C Homer	Version submitted with stage 2 application
2.0	31.01.24	C Homer	Version submitted post award (not ethics approved)
3.0	16.10.24	C Woodward	Updates six months after project start including track changes
3.1	16.10.24	C Woodward	Updates six months after project clean version
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3.3	24.01.25	C Woodward	Updates 1 year after project start clean version
3.4	11.08.25	C Woodward	Project updates including track changes
3.5	08.10.25	C Woodward	NIHR minor amendments – clean version

1. SUMMARY OF RESEARCH

1.1 Background: 2.9% of 4-5 year old and 5.8% of 10-11 year old children are currently living with severe obesity in England [1], significantly impacting on physical and psychosocial health [2]. Severe obesity prevalence varies geographically and is more prevalent in children from deprived areas and certain ethnic groups [3]. Providing support to children and young people (CYP) living with obesity and their families can improve quality of life, prevent mortality and morbidity, and reduce ongoing health needs. Addressing obesity in CYP is therefore a public health priority, yet there is currently limited evidence on, and provision of, effective Tier 3 weight management for CYP in England [4]. Consequently, and to fulfil the NHS Long Term Plan recommendations [5], NHS England (NHSE) commissioned 21 Tier 3 Complications of Excess Weight (CEW) clinics, which aim to deliver holistic support to CYP, aged 2-17 years old, living with severe or complex forms of obesity (LSCO), using different models of care, tailored to local population needs. Evaluation of these clinics is required to develop the evidence base, optimise care, and support future delivery and commissioning.

1.2 Project aims: 1) To undertake a co-produced, comprehensive mixed methods clinical and economic evaluation of the CEW clinics, which develops the evidence base and understanding of optimal models of care, and 2) to contribute to the national CEW clinic framework development to support future roll out and commissioning by 2025/26.

1.3 Research questions and methods: The project brings together a multi-disciplinary team of leading academics, providing expertise in child health, diabetes, obesity, nutrition, physical activity, coproduction, public health, psychology, service evaluation, behaviour change, health economics, implementation, and social sciences, to deliver the evaluation through a comprehensive programme of work packages (WP):

WP1: Project management, coproduction, public and patient involvement and engagement (PPIE) and dissemination will: 1) facilitate coproduction with all stakeholders and embed insights from CYP and their families/caregivers across every WP; 2) co-ordinate dissemination and communication to include patient facing illustrative journal-style summaries, infographics, a project website, social media feeds, lay summaries, short films, conference presentations, reports and journal articles; 3) contribute to the development of the national CEW framework to support future commissioning activity; 4) provide overarching project management and cohesive cross-site working.

WP2: Mapping the delivery and workforce models of CEW clinics will use a combination of documentary review, surveys, process mapping, semi-structured interviews and focus groups with commissioners and NHS / CEW staff to answer the following research questions (RQ): RQ1 What care is being delivered across the clinics and what services are provided at each clinic? RQ2 What different workforce models are used? RQ3 What are the cross-organisational or integrated models of care across the patient pathways? RQ4 What measures and data sources are required to assess programme outcomes and impacts at different levels and timelines? RQ5 How do the CEW clinics influence and contribute to inequalities in access, experience and outcomes?

WP3: Exploring the views and experiences of CYP and their families attending CEW clinics will be underpinned by a realist informed approach using surveys, interviews and focus groups with CYP and families. These findings will be aligned to, and integrated with, quantitative process and outcome data from the CEW national dataset. This WP will address: RQ6 What do CYP and families perceive to be the barriers and facilitators to service engagement and commitment over time? and RQs 4-5 (above).

WP4: Clinical and economic data evaluation will include assessment of service user demographics, analysis of clinical, quality-of-life and cost outcomes over time, and an economic evaluation of each CEW delivery model. This will address: RQ7 What are the demographic and clinical characteristics of CYP referred to CEW clinics, and how do they compare to the general population of children living with obesity? RQ5 (above), and RQ8 What is the cost-effectiveness of the programmes of care?

WP5: *Triangulation*. A triangulation protocol will be co-developed to bring together the findings and display them in a convergence coding matrix to address the final RQ9: What models of care work (or don't work) for whom, why and in what context?

1.4 Anticipated delivery timeframe and impact: The project will be delivered between December 2023 and September 2026, and will inform the national CEW clinic framework development to support future roll out and commissioning by 2025/26. It will also address a significant evidence gap in understanding the optimum delivery models of CEW clinics in terms of clinical and quality-of-life outcomes, acceptability by CYP and families, and cost effectiveness. Findings will inform national service development and will be shared internationally.

2 BACKGROUND AND RATIONALE

2.1 What is the problem being addressed?

The impact of severe obesity in children and young people (classified as Body Mass Index (BMI) >99.6th UK90 centile is significant and is affecting a growing number of CYP in England. Current data indicate that 2.9% (n=126,701) of 4–5 year-olds, and 5.8% (n=227,314) of 10–11 year-olds were living with severe obesity in 2022 [1]. Notably, the prevalence amongst 10-11 year olds has almost doubled since 2007 (3.2%). Perhaps most concerning are the disparities in severe obesity, where almost 1 in 10 children aged 10-11 years from the most deprived areas of England live with severe obesity, compared to only 1 in 50 children from the least deprived areas. Obesity is also more prevalent amongst black and many ethnic minority populations.

The physical, mental, social, and economic consequences of severe obesity in childhood are well documented and interlinked. There is strong evidence to suggest that childhood obesity is associated with the development of type 2 diabetes, hypertension, hyperlipidaemia, and coronary heart disease in adulthood [6, 7] and can result in early onset pre-diabetes and diabetes, dyslipidaemia, high blood pressure, metabolic syndrome, metabolic associated fatty liver disease, and sleep apnoea [8]. Furthermore, children with overweight, obesity, and severe obesity were 11%, 18%, and 39% more likely to access mental health support respectively compared to healthy weight peers [9]. The direct costs of obesity to the NHS, which include costs associated with childhood obesity, are currently estimated at £6.1b per year, and anticipated to rise to £9.7b per year by 2050 [10]. Considering this, and the strong continuation of obesity from child to adulthood, urgent effective and equitable interventions are required. Trying to offset these trajectories through a comprehensive approach, which includes person-centred, holistic, and long-term support, could therefore have far reaching individual, societal, and economic implications [11, 12].

2.2 Why this research is needed now?

The most recent audit of weight management services in England found that only 9% of local areas provide specialist support for CYP living with severe obesity [13]. In light of this, there have been increasing calls for better weight management provision in England [14], particularly those which address the complex biopsychosocial aetiology of obesity. In 2019, the publication of the NHS Long Term Plan stated that 1000 children per year would be provided access to weight management services to treat "*severe complications related to their obesity, such as diabetes, cardiovascular conditions, sleep apnoea and poor mental health*" [5]. This ambition is expected to be achieved through the NHSE funded CEW clinics.

The CEW clinics provide an opportunity to develop, deliver, and evaluate innovative and holistic specialist support for CYP LSCO. In 2021, NHSE began commissioning 21 CEW clinics across England (with a further nine additional clinics announced July 2023 and nine in 2024). Evaluation of these clinics (n=39) is therefore required to develop the evidence base, understand optimal models of care, contribute to the national CEW clinic framework development, support future roll out and commissioning activity.

2.3 What does the current evidence suggest?

A rapid scoping review of the published evidence between 2015 and July 2023 through PubMed (using search terms related to children and young people with severe obesity [population], weight management [intervention], and systematic reviews [study design]) identified 32 reviews. However, few were applicable to specialist Tier 3, multi-disciplinary services in England.

Based on our review, the evidence base around weight management support for CYP LSCO is weak [15-17]. Brown et al. (2017) [15] examined the evidence base for Tier 3 specialist weight management interventions in children aged 2-18 years and concluded that whilst studies demonstrated a reduction in BMI

Standardised Deviation Score (SDS) , they were often heterogenous in content, challenging to synthesise, and average in quality. Of note, few studies looked at provision for children <10 years old and seldom report, in detail, intervention components and content. Deciphering and measuring what may, and may not, be effective is therefore difficult to establish [16, 18]. There were however several consistencies in what authors deemed to be critical factors to supporting CYP living with obesity or severe obesity. Firstly, many suggest that a tailored approach is required based on individual need, representing a movement away from a one-size fits all approach [19-22]. Secondly, given the complex and chronic nature of obesity, a long term and holistic supportive approach is required [19, 21, 23, 24]. Given the potential for widened inequalities, it is critical to consider the cost and accessibility of care across the socio-demographic spectrum [16, 17]. Several reviews concluded that multi-component, multi-disciplinary approaches are warranted to address the dietary, physical activity, social, psychological, and cultural determinants of obesity [17, 18, 23-25], and should consider including other family members or peers depending on the patient's age [16, 17, 21, 22, 25].

Multiple reviews point towards future recommendations for supporting CYP LSCO. A recent scoping review [22] investigated what is known about the perspectives of families and children who receive care in clinic-based child obesity treatment and concluded that data are lacking on the clinic-based treatment of children with severe obesity, and few studies report on non-maternal perspectives. The authors recommend that clinical practice must be tailored to individual family needs, while future research should concentrate on identifying missing variables which impact successful treatment outcomes through more rigorous qualitative studies, standardized outcome measures, focus on children with severe obesity, and fathers' and siblings' perspectives. The need for greater access to medically supervised multi-component interventions has given promising results across psychosocial health outcomes, including quality of life, self-esteem, body image, and symptoms of depression, anxiety, and eating disorders [23]. They also suggest that a broader range of physiological and psychosocial outcomes should be used to assess the impact of interventions. Our recent systematic review (Ells et al, under review) of pharmacotherapy for CYP also points towards some promising outcomes for some of the new generation GLP-1 agonists. Cardel *et al.* (2020) also advocate for significant resources, scientific rigour, and high-quality care for specialist weight management services that is like that for other chronic health conditions, which would require "*comprehensive centres that offer specialised treatment*".

The CEW clinics have been designed around this emerging evidence base and will help address many existing knowledge and implementation gaps. It is therefore imperative that a comprehensive, multi-methodological evaluation is undertaken to understand the context of service delivery, how services are delivered, how they work and who they work for, whether they are effective (across a range of metrics), and whether they represent good value for money. Such an evaluation provides the opportunity to build the evidence base, to guide the deployment of public funds and resources, and fundamentally benefit the health and wellbeing of CYP LSCO.

3. AIM & OBJECTIVES

3.1 Aims: 1) To undertake a co-produced, comprehensive mixed methods clinical and economic evaluation of the CEW clinics, which develops the evidence base and understanding of optimal models of care, and 2) to contribute to the national CEW clinic framework development to support future roll out and commissioning by 2024/25.

3.2 Objectives (associated Work Packages - WP):

A. Work with NHSE to co-produce an evaluation and share emerging learning to inform the development of the National CEW Clinic Framework, and future commissioning (WP1).
B. Map and evaluate different CEW clinic delivery models, including a focus on the CEW workforce and local delivery pathways (WP2).
C. Explore the perspectives of CYP and their families, engaged or not, in the different CEW delivery models (WP3).
D. Examine service user demographics, analyse clinical, quality-of-life and cost outcomes over time, and conduct an economic evaluation for the different CEW delivery models and how these vary by population groups (WP4).
E. Triangulate learning from objectives A-D to understand what worked, what did not, for whom, in what context and why, and how the programme could be improved in the future (WP5).

4. RESEARCH PLAN & METHODS

4.1 Research design and theoretical framework

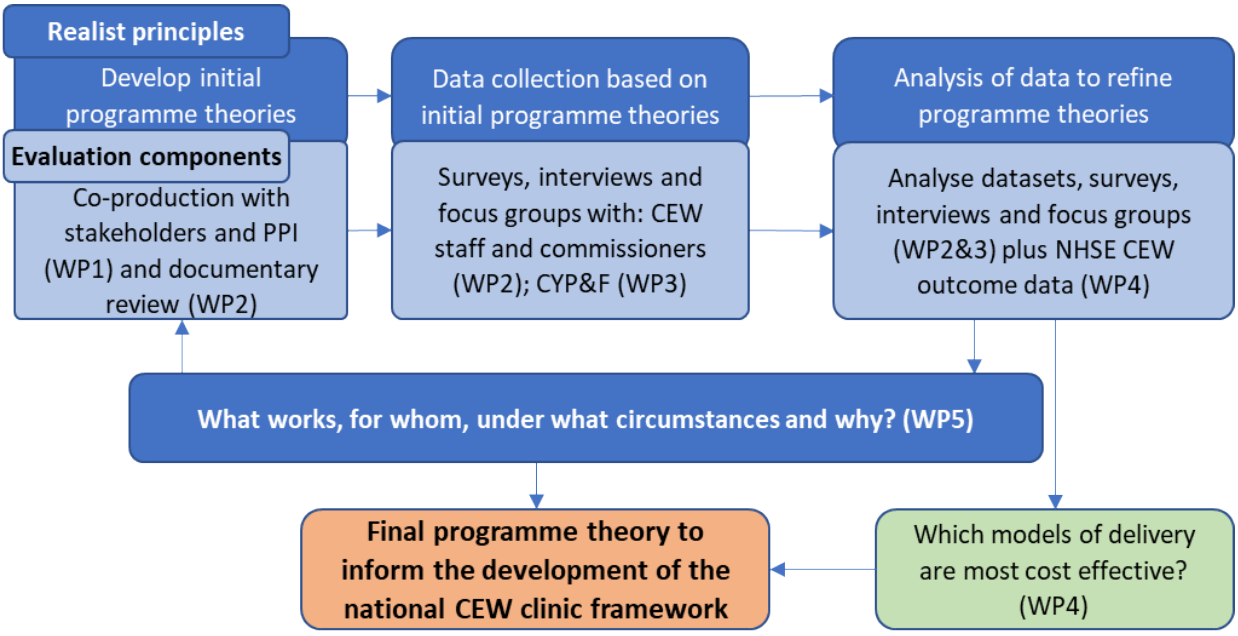
We propose a comprehensive and co-produced [26] evaluation, informed by the MRC guidance on process evaluation of complex interventions [27], and developed in line with the 2019 NIHR carbon reduction guidelines. Whilst we have presented a comprehensive research plan and methods, the co-production approach will provide scope to adapt our proposal following consultation with NHSE, local stakeholders, and the CEW delivery board. We feel this flexible co-produced approach is critical in ensuring the methods are tailored to the needs and expectations of key stakeholders and provide opportunities to tailor the evaluation to real-time developments (such as new sites and MedTech developments). We will also produce a full breakdown of costs for each WP, to provide budgetary transparency and flexibility. This will provide NIHR with the opportunity to tailor both the methodology and budget to meet the programme's stakeholder requirements and budgetary expectations (through conversation and agreement with the evaluation team).

Our structured evaluation plan includes several interlinked WPs that will address the aims and objectives stated above, and the research questions outlined below, drawing on several theoretical frameworks. The evaluation is built on the methods used in the Re:Mission study (PI – LE), and was constructed using the RE-AIM checklist [28] the MRC complex intervention guidance [29], and is underpinned by a realist evaluation approach in order to understand what works, for whom, in what respects, to what extent, in what contexts, and how [30] (see figure 1). We will also draw on behaviour change theories [31] and normalisation process theory [32].The relevant EQUATOR network [33] reporting guidelines (COREQ, STROBE and CHEERS) will also be applied to qualitative, observational and economic components respectively.

4.2 Research questions (and associated work packages – WP)

1. What care is being delivered across the clinics and what services are provided at each clinic (medical, dietary, behavioural, physical, psychological and social)? (WP2)
2. What different workforce models are used (including leadership, multidisciplinary team configuration and skill set / training of team members)? (WP2)
3. What are the cross-organisational or integrated models of care across the patient pathways (examining CEW clinics as part of a networked model of care including the impact of availability of existing community weight management services on efficacy and demand at CEW clinics)? (WP2)
4. What measures and data sources are required to assess programme outcomes and impacts at different levels and timelines (including patient experience, engagement rates, range of health and wellbeing outcomes, reduction of medical complications related to excess weight, social measures and other impacts such as school attendance/attainment?) (WP2 & 3)
5. How do the CEW clinics influence and contribute to inequalities in access, experience and outcomes? This will include factors such as (but not limited to) economic deprivation, autism and special educational needs and disabilities, ethnic minority communities, and digital exclusion? (WP2,3 & 4)
6. What do children and families perceive to be the barriers and facilitators to service engagement and commitment over time (including perceptions of new models of care, strategies to improve access and uptake of services and following up those not engaging with services)? (WP3)
7. What are the demographic and clinical characteristics of CYP referred to CEW clinics and how do they compare to the general population of children living with obesity? (WP4)
8. What is the cost-effectiveness of the programmes of care? (WP4)
9. What models of care work (or don't work) for whom, why and in what context? (WP5)

Figure 1: An illustration explaining how the study is underpinned by a realist informed approach



4.3 Project work packages: methodologies, sample, context, data collection & analysis

WP1: Project management, coproduction, public and patient involvement (PPI) and dissemination *(months 1-32) – led by Homer and Ells, supported by Sharman, Researcher 2 (E Ioannou) and all clinical and WP leads.* This WP will:

- Provide oversight for WPs 2-5 to ensure the project is delivered to time, specification, and budget.
- Coordinate and deliver our ambitious programme of lived experience PPIE activity, led by Sharman.
- Facilitate co-production between the NIHR, stakeholders, and CEW delivery sites, and regular meetings with NHSE to ensure findings inform real time learning, service development and future commissioning.
- Lead the production of the final NIHR synopsis and work with the NIHR library to coordinate the publication of associated manuscripts.
- Coordinate and deliver a comprehensive programme of dissemination and communication co-produced with our PPIE team. This will include regular interim reports, a patient facing interactive illustrated journal-style summary, infographics, a project website, social media feeds, lay summaries, short films, conference presentations and journal articles. We will work with Nifty Fox to develop creative outputs to ensure we maximise reach, engagement and impact through design innovation, and inclusive and widely accessible creative media.

WP2: Mapping the workforce and delivery models of CEW clinics *(months 1-24) - led by Nobles, supported by Matu, Researcher 1(Marwood), Homer, Ells, Wright, and Sharman, to address objective B; RQs 1-5.*

- *Rationale*: CEW clinics were commissioned to test *novel* approaches for supporting CYP LSCO. There are 21 clinics in operation across the country (a further nine clinics announced July 2023) with different workforce and delivery models. To that end, this WP (split across four sub-packages) will use a mixed-methods design to understand the national policy picture surrounding the initial 21 CEW clinics, before examining, in depth, the local planning, workforce, implementation, and adaptation of CEW clinics, to create a nuanced picture of the CEW clinic models.

WP2.1: Examining the national context surrounding CEW clinics (months 1-6)

- *Design*: Concurrent mixed-methods approach comprising of semi-structured interviews with national policy leads and analysis of national policy documents.
- *Sampling*: Convenience and snowball sampling will recruit national policy leads (n~12 interviewees) who are / were involved in the design, commissioning, and monitoring of CEW clinics. We will ask Department of Health and Social Care (DHSC) / NHSE to support recruitment.
- *Methods*: Semi-structured online interviews will examine the history and context surrounding the CEW clinic policy development, including their intended purpose, and to explore expectations surrounding the CEW clinic content, delivery and workforce models, and anticipated outcomes. Interviews are expected

to last 45 minutes. We will also undertake an analysis of publicly available policy documents pertaining to the CEW clinic policy (2-5 documents anticipated). Insights gleaned from the policy analysis will be explored further in the stakeholder interviews. Data will bolster and inform stakeholder interviews, to provide insight surrounding the explicit expectations of CEW clinics.

- *Analysis*: An inductive thematic analysis [34] will be completed, drawing on data from interviews and documentary analyses, to identify themes related to the foci of this WP.

WP2.2: Mapping the local implementation and workforce of CEW clinics (months 4-22)

- *Design*: A detailed survey and documentary analysis will map workforce and delivery models for each CEW clinic. This standardised approach will enable comparison within and between CEW models and addresses RQ1.
- *Sampling*: All 21 original CEW clinics and 9 additional clinics from wave 2. In June 2025, we will send the STAR-LITE template to 9 more wave 3 sites, bringing the total sample to 39.
- *Data collection*: CEW providers will be asked to complete an adapted STAndardised Reporting of Lifestyle weight management InTerventions to aid Evaluation (STAR-LITE) template [35] at 6-12 and 18-24 months. The STAR-LITE template, developed by co-PI Ells and colleagues, draws upon the TiDieR checklist [36], NICE guidance [37], Standard Evaluation Framework [38], national mapping [13] and behaviour change taxonomies (CALORE) [31], BCT [31] and OxFAB [39], to enable reporting of behavioural weight management interventions. The STAR-LITE tool will examine intervention referral, delivery, staffing, components, and costs which will be used to support a primary analysis of key intervention features (including behaviour change content, underpinning theory and delivery, and intervention costs fed forward to WP4) across providers, and to compare against the national programme specification (see WP2.1). If response rates are low, or if a conversation is preferable to providers, a structured online interview will be used to complete the STAR-LITE template. The applications from the 39 sites (where available), submitted to NHSE / DHSC, will be subject to documentary analysis to determine the planned models of implementation. We will input data, where possible, into the STAR-LITE template to create this baseline picture.
- *Analysis*: All data will be descriptively analysed to determine the delivery models at baseline (via CEW applications), and at 6-12 and 18-24 months within our evaluation.

WP2.3: Understanding the realities of delivering a CEW clinic (Months 12-18)

- *Design: Semi-structured interviews with a sub-set of CEW clinics to understand the barriers and facilitators to designing and delivering a CEW clinics.*
- *Sampling: We will sample four to six CEW clinics using a maximum variation sampling approach, with the intention of understanding a broad range of CEW clinic designs, MDT make ups, and representing the different regions in England. We will use a one-to-one interviewing approach to provide clinical team members with the opportunity for in depth discussion. We anticipate speaking with ~5 members of the clinical team per site.*
- *Data collection: The semi-structured interviews will explore stakeholder perceptions setting up and delivering the service, the barriers and facilitators that they have encountered along the way, and do so from a holistic perspective (i.e. zooming out to see the bigger picture of the service and its integration with local and national systems). We will also build on the insights obtained from other work packages, and so, lines of inquiry may focus upon patient pathways, safeguarding procedures, and the use of GLP1 medications. Additional foci may be added to the topic guides as new emergent*
- *Analysis: Framework analysis will be used to determine patterns within and between CEW clinics*

WP2.4: Understanding service and workforce adaptations during CEW clinic implementation (months 18-24)

- *Design:* Semi-structured interviews and/or focus groups will gather detailed information to explain how and why CEW clinic delivery and workforce models have adapted over time. This will build on data obtained in WP2.2-2.3, addressing RQ 3 and fed forward into WP4.
- *Sampling:* Providers from all 21 CEW clinics (n=2-3 per CEW clinic).
- *Data collection:* Each CEW clinic will be invited to a final online interview / focus group to examine adaptations to the delivery or workforce models, guided by the findings from the STAR-LITE entries in WP2.2 (at 6&18 months). We will also examine whether services were adapted to meet the needs of different young people (e.g., those with a learning difficulty or mental health conditions).

- *Analysis:* Framework Analysis (FA) [41] will create a case-by-case description and narrative for each CEW clinic. Findings from the STAR-LITE analyses will be incorporated here to provide detail regarding delivery and workforce adaptations. A within, and between, case analysis will then be conducted.

WP3: Exploring the views and experiences of CYP and families attending CEW clinics (months 1-32) - *led by Swallow and Nield supported by Ioannou (SHU), Brown, Lamb, Homer, Ells, Coulman, Aswani and Sharman. To address objective C; RQs 4-6.*

- *Rationale*: The experiences of CYP & families attending CEW clinics are critical to success. Nationally, the CEW Clinics Framework has set high-level principles regarding what care delivery via the CEW clinics should entail. However, the delivery models of CEW clinics vary across the 30 sites and therefore evidence is needed on which service model and interventions are most likely to succeed for this cohort of CYP. We also know that CYP from these groups engage less well with health care services. It is therefore imperative that this evaluation comprehensively understands the experiences of CYP, and families sampled from diverse socio-demographic backgrounds to assess programme uptake, compliance, adherence, and success across the clinics, as well as any costs incurred by families referred to the clinics. This component of the evaluation is critical in ensuring the programme addresses the health inequalities prevalent across England [42], in particular the inequalities in obesity and prevalence relating to ethnic group and socio-economic status, and any barriers to access (e.g. costs) these groups may experience.
- *Overview of methods*: This WP will use a combination of complimentary methods: 1) longitudinal surveys, 2) interviews and questionnaires, and 3) focus groups with CYP and their families/carers. An Equality Impact Assessment has also informed our data collection, sampling and analysis plans.

WP3.1 CYP and family surveys (months 1-30)

- *Design:* A longitudinal patient survey (Timepoint [T]1, 0 months, T2,12 months) with the addition of 'mop up' surveys at a 12 month interval will be used to address RQ4. These short (≤15-30 minute) patient and family surveys will be age/developmentally appropriate, and co-developed, tested and refined with our PPIE group and NHSE to ensure usability and accessibility. The surveys will seek to understand what aspects of the service work or not, and outcomes and measures of success that are important to families and how these vary by socio-demographic factors, age and delivery model. The survey will also collect supplementary quantitative data (not currently collected by the CEW clinics, but required to support WP4 and WP5) to:
    1) Provide an overview of patient experiences and expectations.
    2) Help understand influencers of uptake, withdrawal, retention, and engagement with CEW clinics (including those related to costs paid for by families, fed forward to WP4), and how these may vary by socio-demographic factors and delivery model.
    3) Inform the sampling for WP3.2.
- *Sampling:* The survey will be shared with CYP aged 8-18 years and family/carers (age 2-18) referred to all 30 clinics (we anticipate at least n~500 distributed surveys but will seek advice from NHSE).
- *Recruitment and data collection:* We will provide posters (with QR codes) and short developmentally appropriate films about the survey for CEW clinics to display in waiting areas or use on their social media channels. CYP will also receive digital or hard copies of information leaflets and will consent to participation if 16 +years. Parent/carers will receive information leaflets and provide consent if CYP are <16 years or considered vulnerable; CYP 8-16 years will receive age and developmentally appropriate information leaflets and provide assent. The survey will be available via a secure GDPR compliant online survey i.e Qualtrics. CYP and their family/carer will be asked to provide contact details (phone or email address) if they wish to complete the follow up survey, would like more information and/or are interested in participating in the stage 2 interviews. Surveys will collect supplementary quantitative data including measures identified in the early rounds of the Delphi process [43] and not currently collected by the CEW minimum dataset (MDS), to establish whether families feel that measures should be added, altered or removed.

  We will ask each CEW clinic to provide the survey link and SMS number during the initial contact process (to capture baseline data). CEW staff will not be informed who has responded to the survey. The SMS number is for participants who would like to request that they complete the survey verbally or in another language, to enable participation irrespective of literacy, language or internet access (call

handlers with appropriate Good Clinical Practice training (see section 8) and Research Passports/LOAs will complete the online survey on behalf of the participant). Translators are costed so language is not a barrier to participation. At the end of the baseline survey, we will ask the completer if they are willing to be contacted again to participate in the follow up survey at 12 months. SMS and email reminders will be automated at the relevant follow up time points, and a prompt card given in clinic when SMS or email isn't available. £5 gift vouchers will be offered as a gesture of thanks for participation. We anticipate an initial survey response rate of around 10-20% based on the response rates within the Re:Mission study. At the end of the survey, we will ask participants if they agree to be contacted about taking part in the longitudinal interviews (WP3.2).

- *Analysis:* Descriptive statistics will be used to assess numerical and categorical data, and free text responses will be analysed using content analysis [44].

WP3.2 Longitudinal Interviews with CYP/families and questionnaires with parents (months 2-30)

- *Design:* Longitudinal semi-structured interviews with CYP (n=30) and parents/caregivers (n=30) 4-6 weeks after first appointment at the CEW clinic (Interview 1) and 10-12 months of clinic attendance (Interview 2). We will also interview ~10 families who did not take up the referral/continue to attend the clinic. Interviews will address RQ 3 and 4.
- *Sampling:* Purposive and theoretical sampling will be used in conjunction to achieve maximum variation [47] regarding age, developmental stage, sex, socio-demographic status and study site/delivery model. We will recruit n=30 CYP aged 2-18 years, and 30 parent/caregivers, recruited from those who expressed interest following the survey (WP3.1). Sampling is designed to explore multiple facets of a problem and investigate issues holistically [47]. We also aim to interview families n~10 who did not take up the referral or start the CEW programme to understand barriers to engagement. Recruitment will be via responders to the WP 3.1 questionnaires and through CEW clinicians providing information sheets and a short film about the study (co-produced with the PPIE group); CYP will receive appropriate information leaflets and will provide written or electronic consent (ages 16+) or assent (up to age 15). Parents/caregivers will receive information leaflets and consent forms for their participation; for under 16s parents will also consent for their child's participation.
- *Data collection:* Depending on individuals' preferences, we will conduct remote, individual or dyadic, semi-structured interviews with 8–18-year-olds, and parents of 2–7-year-olds or other CYP deemed unable to participate in interviews. CYP and their families can choose to be interviewed independently or together. Drawing on our prior experience of involving CYP in qualitative research, we will use developmentally appropriate and engaging approaches and methods to support involvement. Interviews will be undertaken using an interview guide informed by the realist approach, RQs, and co-production with key stakeholders and our PPIE group, and will provide insight into: patients'/parents' expectations and experience of the service, and where appropriate: the reason for (non-)enrolment, unexpected or unintended outcomes, and whether they perceived the service as being "tailored" to their needs, interaction with other services, cost to families of engaging with services, confidence in implementing clinic recommendations, greatest challenges and successes, impact of the service on the wider family and social networks, impacts of school attendance and attainment, and resultant lifestyle changes and achievements. To explore barriers and facilitators to engagement with the services, we will use principles of behavioural science i.e., COM-B (Capability, Opportunity, Motivation, Behaviour) model [31]. COM-B proposes that for a person or group to engage in and maintain any given behaviour, they must have the capability (knowledge and skill), opportunity (physical availability, social norms) and motivation (habits and beliefs) to do so [48, 49]. Once barriers and facilitators around families COM have been explored, it will enable us to identify the mechanisms of change and the behaviour change techniques that can address these issues and inform a targeted systematic approach to service development and delivery. Gift vouchers will be offered to thank them for participation, and translator costs are included for any participants who wish to undertake an interview in another language.
- *Analysis:* Interviews will be analysed using the FA (same approach as WP2). We have experience in FA in research involving CYP [50-52], findings will inform a content matrix detailing the elements that make up participants' accounts.

WP3.3 Deep dive focus groups (months 17-26)

- *Design:* We will build on WP2.3, 3.1 and 3.2 to extend insights into the service-user journeys and optimal models of care. Findings will inform development of typical user-journeys for CYP/families for case studies and workshops in WP5 and address *RQ5.*
- *Sampling:* Four focus groups will be conducted at each of the 4-6 deep dive sites (identified in WP2.4).
- *Data collection:* Focus groups will be conducted with two parent/carer groups, and two CYP groups either online or in person, age-appropriate techniques will be used for CYP focus groups and will include visual storytelling led by Nifty Fox creative who have previously and successfully collaborated with Homer, Ells and Lamb [53]. Visual storytelling uses images to evoke emotional and strategic narratives through 'live scribing' which deepens and democratises the relationship between researchers and service-users to improve the provision of services in a truly collaborative way [54].
- *Analysis:* Focus groups will be digitally recorded, transcribed and analysed. Based on the findings, we will develop typical user-journeys for CYP and inform the WP5 workshops using the service/clinic to illustrate different pathways they may follow depending on the severity of their obesity.

WP4: Quantitative data analysis and economic evaluation (months 1-32) - *led by Martin (WP lead), Matu, Zabula, Mattock, supported by Hamilton-Shield, Griffiths, Homer and Ells to address Objective D and RQs 5,7-8*

- *Rationale:* Quantitative analysis of the individual-level patient reported outcomes and clinical data across all CEW clinics will provide insights into:
    - the characteristics of CEW users at their first clinic appointment when compared to the underlying population who would be eligible for CEW (WP4.1)
    - (ii.) how clinical and quality-of-life outcomes evolve over time with clinic attendance, how this varies between individuals and CEW sites, and the implications for health inequalities when compared to a counterfactual scenario (WP4.2)
    - (iii.) the costs and benefits of CEW clinics which can inform decisions about the future commissioning of CEW clinics and their expansion nationwide (WP4.3).
- *Overview of methods:*
    - Data will come from three sources:
        - Clinical and demographic data collected in clinics by NHSE at baseline and at each clinic appointment. Our research team will provide input into discussions with NHSE about the items to be included in the data collection and the methods of data collection.
        - Patient reported outcomes.
            - PedsQL (used in CEW clinics since the beginning of the data collection period).
            - EQ-5D-Y-5L (data collection started in Autumn 2024). The EQ-5D-Y-5L is an effective tool for collecting health status data in children and young people because it is specifically designed to be age-appropriate, making it easier for younger populations or their parents and carers to understand and respond accurately. The tool captures key dimensions of health, such as mobility, self-care and mental wellbeing, through a simple, standardised format. This allows for reliable comparisons across different age groups and populations, providing valuable insights into the health and quality of life of children and adolescents. The 5L version which contains a five-level response scale enhances sensitivity in capturing subtle differences in health status.
        - Resources used in setting up and running CEW clinics. This will be provided by NHSE.
    - Data storage and access:
        - All clinical, demographic and patient-reported outcome data will be entered and stored in the externally managed Prescribing Services Limited ECLIPSE system, which uses an Amazon Web Services (AWS) cloud-based secure data facility that is protected by username and strong password along with multi factor authentication. Role based access ensures only authorised users can access data. All machines used to access CEW service evaluation data will be within a secure firewalled private cloud with all ports and IP addresses blocked except those essential for administration and functionality. All hard drives will be encrypted, and

machines kept up to date by AWS Workspaces. A Data Processing Agreement and Data Protection Impact Assessment signed by each Hospital Trust will enable the required authorisations to share and manage the anonymised patient data. AM, JM, TZ, RM and any other researcher who may in future be assigned to WP4 will have a current honorary contract with PSL in order to access the AWS Workspaces.

- The analyses will be conducted in three parts:
  - Analysis of baseline characteristics (WP4.1, led by JM): This will include service user demographics, clinical and the patient-reported quality-of-life outcomes.
  - Analysis of longitudinal (within-study) data (WP4.2, led by TZ): Changes in the clinical and patient-reported quality-of-life outcomes will be assessed between baseline and clinic discharge, including how these vary by individual characteristics (dependent on discussions with the wider team and data availability this could include child's age and gender, comorbidities, ethnicity, IMD and medications including GLP-1 agonists) and CEW site characteristics (e.g. delivery model). The primary outcome will be change in BMI-SDS between the first clinic appointment and clinic discharge. Secondary outcomes will include change in EQ-5D-Y-5L and PedsQL summary scores.
  - Analysis of longer-term cost-effectiveness (WP4.3, led by RM):

WP4.1 Analysis of baseline characteristics: Uptake, completion rates, coverage and service user demographics

- *Data collection and analysis:* individual level data will be used at national- and site-level to assess time trends in numbers of total and eligible referrals, uptake (i.e. proportion of eligible referrals who attended initial appointment) and completion rates (i.e. proportion attending who were discharged after completing the programme). Coverage will be assessed by comparing the characteristics of participants in the MDS data who were referred, who attended an initial appointment and who completed the programme with population level data from Office for National Statistics and National Child Measurement Programme data.

  Differences in uptake, completion rates, coverage and time between referral and completion will be reported by patient-level demographic characteristics which will be determined in consultation with our steering group (including appropriate measures of age, gender, weight, ethnicity, area-level deprivation, and school attendance) to identify where inequalities exist in the various stages of the CEW clinic patient pathway. Multilevel logistic regression models will be used to assess the patient- (recorded in the MDS) and site-level (captured in the mapping in WP2) characteristics which predict uptake and completion, when compared to participants who were referred but did not attend.

WP4.2: Analysis of longitudinal (within-study) data

- *Data collection and analysis:* Changes in clinical and quality-of-life outcomes between baseline (i.e. initial assessment) and final follow-up (i.e. discharge before or after successful completion of the CEW programme) will be reported descriptively and using multilevel generalised regression models, with different link functions dependent on the nature of the data and the dependent variable. All outcomes will be pre-specified in consultation with clinicians, NHSE and our steering group and will be dependent on the clinical relevance and the quality of data that is being collected. The primary outcome will be a weight-related outcome (e.g. likelihood of achieving BMI SDS reduction >0.25, change in BMI or weight after adjusting for height and baseline measurements) and secondary outcomes will include (but are not necessarily limited to) alternative obesity measures, other objectively measured clinical outcomes (related to hypertension, idiopathic intracranial hypertension, metabolic associated fatty liver disease, obstructive sleep apnoea, blood glucose, lipid profiles, mental health, liver function tests) and broader patient-reported quality-of-life measures (e.g. school attendance, emotional functioning, social functioning, school functioning). Dependent on the nature and extent of missing data in the covariates available, multiple imputation will be used in our base case analysis so that missing values are replaced with plausible substitutes. The regression models will sequentially adjust for observable confounding variables and include patient- and site-level interaction terms determined in consultation with NHSE which may be of policy relevance because of their expected relationship with intervention effectiveness and existing

health inequalities or can inform the design and delivery of CEW clinics in the future. The primary outcome will be compared to a counterfactual scenario which may draw on various sources including:

- MCS and/or HSE data
- PSL primary care data : ~4,000 children with BMI-SDS > 3.5 who did not attend CEW
- NCMP data collected in Y1 and Y6
- The assumption that the BMI-SDS line will provide an estimate of what would have happened to a child's BMI if no intervention had taken place
- The key challenge here is the BMI-SDS >3.5 means there is very little comparison data available.

WP4.3: Analysis of longer-term cost-effectiveness

- *Data collection and analysis:*
- (i.) Resource use and costs of delivering CEW:
- Resource use and cost data in relation to delivering the CEW intervention will be provided for each clinic by NHSE. This will be complemented by additional data collection as a fully integrated component of the semi-structured interviews (WP3.2), focus groups (WP3.3) and electronic questionnaire (STAR-LITE; WP2.2) which will include free text response questions to gather information about specific resources used and (where not adequately captured in national databases) their unit costs into the STAR-LITE survey. Where the data is sufficient, it will be used to assess the costs of CEW delivery using a bottom-up, micro-costing approach which follows best practice guidance [55]. This will include (but not limited to) costs of running the clinic such as details of specific specialists available and length and frequency of appointments with clinician. Resource use data provided by NSHE and captured in WP2 will be costed using external sources, e.g. national healthcare databases [56, 57] (e.g. PSSRU - Personal Social Services Research Unit data) and cost analyses of comparable interventions. Distinctions will be made between fixed sunk costs (e.g. setting up clinics), quasi-fixed costs (e.g. hospital space allocated to the clinic) and variable costs (e.g. staff time allocated to intervention delivery). Initial costs of delivering a new programme will be distinguished from costs of delivering a more established service at scale. The cost (£) and resource use per patient, and how this varies between different groups of patients, will be reported by site and different delivery models and clinic size, and adjusted for inflation to a common baseline year.
- (ii.) Patient out of pocket costs
- An exploratory analysis of patient out-of-pocket costs will be conducted to identify resource use and costs incurred by patients and their households who are enrolled on the programme, including any differences that may be attributed to different delivery models. Resource use questions will be designed (through consensus and discussion with NHSE) for inclusion in the patient questionnaires and interviews (WP3.1 and 3.2) and will capture travel to appointments (and other related costs), time off work or education, resources purchased to support children achieve their CEW goals at home, and lifestyle changes which include the individual and household-level changes related to physical activity or food purchases (examples only).

- **(iii.) Longer term cost-effectiveness analysis:** A distributional cost-effectiveness analysis will be conducted from the perspective of NHSE to assess inequalities in the distribution of costs and effects as well as efficiency in terms of aggregate costs and effects. To estimate the long-term gains from CEW clinics after the final data collection at discharge, a cost avoidance approach will be adopted whereby the costs to NHSE and the quality-of-life benefits to service users (QALYs) will be assessed using, a health economic Markov model that will be developed as part of the project. Inputs to the model will be dependent on data from the MDS at baseline and the final follow-up point, including patient-level weight, and other variables where a short-term change has been observed (in WP4.2) and that are deemed to be most relevant by clinicians and the steering group. Intention-to-treat analysis will be undertaken and a complete case analysis (excluding those who dropped out) will included in sensitivity analysis. Estimates of incremental cost per QALY will be provided comparing the intervention to a no intervention scenario in a cost-utility analysis. Outcomes in the no intervention scenario will be based on MDS data collected at baseline, prior to individuals being subjected to the intervention. Additionally, the model will be used to simulate, at the aggregate level, the potential total costs and QALYs that could arise from a national rollout of the clinics. Key assumptions inherent to the long-term economic modelling will be tested in sensitivity analysis, including the extent of weight regain after discharge from the clinic, when MDS data collection ends

WP5: Triangulation (months 1-32) – *led by Coulman and Griffiths, supported by Ioannou, Marwood, Homer, Ells, Nobles, Swallow, Neild, Martin and Matu to address objective E and RQ 9.*

- *Rationale:* A co-produced triangulation of each WP will be used to maximise the generation of new information and knowledge. Without robust consideration of the approach to triangulation the knowledge yield would be equivalent to undertaking each WP independently rather than achieving a "*a whole greater than the sum of the parts".* In this study, we use the term triangulation to describe the process of studying a problem using different methods to gain a more complete picture. Subsequently, our approach to data triangulation will inform the design, data collection and analysis stage of each WP independently as well as bringing the data together at the interpretation stage of the project. A co-produced convergence coding matrix will generate informed theories, aligned to the overarching realist informed framework, to understand which models of care work and don't work, for which population groups, in what context and why. These co-produced triangulated findings will inform the development of the National CEW Clinic Framework and future commissioning.

  WP5.1 Triangulation within WPs: We will work with the WP leads during the design, data collection and analysis stage of each WP to employ the method described as "*following a thread" [27]*. This begins with the initial analysis of each component to identify key themes and questions requiring further exploration, which are "*followed"* to the other components i.e., *the thread.* There are many examples of this; the survey from WP3.1 will inform the longitudinal interviews (WP3.2), and data from WP 2.1 will inform the cost analysis (WP4), and it is important that these decisions and processes are documented to inform the triangulation protocol. As WP2 & 3 collect multiple data on the same cases (note that cases may be individuals, groups, organisations (i.e., clinics) or geographic areas), this data should be studied together, focussing the attention on the case by using a *mixed methods matrix* [61]. These participatory workshops will take place aligned to key outputs from each workstream within the WP structure.

  WP 5.2 Between WPs: At the interpretation stage, we will produce a convergence coding matrix following the triangulation protocol framework [26]. The matrix will bring together the findings from the different methods (i.e., after they have been analysed separately). Through participatory workshops stakeholders, including the project team, commissioners, policy development, CEW clinic staff, CYP and families, will consider where findings from each method either: agree (converge), offer aligned information on the same issue (complementary), appear to contradict each other (discrepancy or dissonance) or there is silence. Explicitly looking for disagreements between findings from different methods is an important part of this process as it enables exploration of inter-method discrepancy, which may lead to a better collective understanding. A range of approaches have been used within health services to explore inter-method discrepancy [62]. This process moves away from thinking about the findings related to each method, to "meta-themes" that cut across the different methods and WPs. This shift in thinking will lead us away from reporting the findings from process mapping (WP2.3), survey (WP3.1) and interviews (WP3.2) sequentially to consider meta themes for example, convenience of care provided, aftercare and unexpected outcomes. The triangulation protocol describes this process as the third effort because it occurs after data analysis of the individual components, requires time and energy and must be planned into the study timetable. It is recommended that two researchers work together providing expertise from both qualitative (Coulman) and quantitative (Griffiths) approaches. These participatory workshops will take place alongside the workshops in WP5.1 to ensure triangulation within and between WPs is consistent throughout the whole evaluation.

5. DISSEMINATION, OUTPUTS AND ANTICIPATED IMPACT

Our PPIE work informed this approach to dissemination and outputs, and we will continue to work with NHSE and our PPIE team to further develop our outputs and dissemination plans to maximise reach and impact within and beyond clinical practice, policy and academic audiences. It is also critical our dissemination strategy effectively engages and communicates learning across both existing and eligible CYP and families engaging with CEW clinics. We are committed to the strapline – '*nothing about us without us'*, a value that is at the heart of our dissemination plans. We also draw on the research team members' experience of policy research and connections to the health care systems, to ensure our outputs can be quickly disseminated through existing communication channels, to ensure real time learning and action. Whilst our dissemination plans will be finalised following coproduction with our PPIE team, NHSE and key stakeholders, we anticipate this to include (anticipated deliver date / month):

- Evaluation plan (02/24); interim report (10/25) and final report autumn 26 – this will inform the CEW clinic framework, support the roll out of the programme, and inform Integrated Care Systems commissioning of services by 2025/2026.

- NIHR twelve monthly update reports and CRN CPMS recruitment reports.
- Short regular (biannual) update reports to all stakeholders including NHSE, the CEW clinics and PPIE team to ensure that emerging findings influence service delivery in real time.
- A plain English summary and short talking head film to accompany every report, that will be co-develop with our PPIE team and Nifty Fox Creative.
- Presentations at local, national and international seminars and conferences (co-presented by the research team and PPIE members)
- A study website (hosted by SHU) which will host all outputs and have a section to specifically designed for CYP and families taking part in the study.
- At least five open access peer reviewed journal publications
- An animated study overview / information film to be shared with CEW clinics and to encourage engagement of CYP and families in the study.
- A series of short talking head films to illustrate patient experience and evaluation learning – these will be patient focussed and shared on social media via our existing and appropriate stakeholder networks.
- The final study report, supported by summary infographics.
- An illustrated journal-style summary of the final report for patients and the public.
- A ~10 min film about the patient journey, and short 1-2 minute white board animation to overview study findings.
- End of year blogs provided by our PPIE team.
- Articles for The Conversation.

NB Dissemination plans will be finalised following consultation with NHSE and the CEW delivery board to ensure we maximise reach, impact, and use of the anticipated dissemination budget. All outputs will be available via the study website and will be disseminated via project co-investigators and steering group members, contributing Universities, NHS trusts, and associated organisations (European and UK Associations for the Study of Obesity, UK Coalition for People Living with Obesity, Office for Health Improvement and Disparities, European Association for People with a Lived Experience of Obesity, BiteBack2030), as well as community networks and forums. We will also use our personal social media channels, write articles and engage with local and national press where appropriate. All patient and public facing materials will be co-designed with our PPIE group. These outputs will support evidence-based commissioning, decision making, service development and patient choice.

6. Project / research timetable

Pre-funding we will arrange a meeting with NHSE to finalise the protocol, commence recruitment of PPIE members from Bristol and West Yorkshire, plan the residential PPIE training, and start to collect evidence for the documentary review. The project started on the 1st of February 2024. A comprehensive month by month summary of activity across the 3-year project, including key tasks and expected outputs from each WP, is shown in the project Gantt Chart in Appendix 1.

7. Project management

The project will be led by Homer and Ells (supported by Coulman, Griffiths and researchers: Matu, Ioannou and Marwood, with clinical support from Aswani, Wright, Hamilton-Shield) and run though the Advanced Wellbeing Research Centre (AWRC) at Sheffield Hallam University (contracting Higher Education Institute [HEI]) (PI Homer and CI's Neild, Swallow, Brown, Lamb) and the Obesity Institute at Leeds Beckett University (co-PI Ells and Matu, Nobles and Griffiths). The two HEIs have a track record of collaborative projects and applied policy related research and an established track record in highly applied obesity and inequality research and evaluation. The proposal brings together a highly experienced multidisciplinary team that extends to include established collaborative partnerships with HEIs: University of Leeds (Martin) and the University of Bristol (Coulman, Hamilton-Shield); voluntary sector – SHINE (Sharman, Fish, King, Bell) and clinical partners from Sheffield Childrens Hospital (Aswani, Wright). All of which are already working with Homer and/or Ells through other funded collaborative partnerships.

Given the size and complexity of this project, we have identified programme management as a specific work package (WP1) that will be led by Homer and Ells. WPs 2-5 have designated leads (Nobles, Neild, Swallow, Martin, Griffiths, Coulman respectively) selected for their experience in relation to the required methodological expertise, clinical practice, policy and career development (bringing together a selection of experienced and mid-career researchers). Clinical leadership will be provided by consultant paediatricians

Wright, Aswani, and Hamilton-Shield. The team will also be supported by a cross disciplinary steering group, chaired by the groups clinical lead, Dr Caroline Steele (lead and consultant paediatrician at the Leeds CEW clinic) along with experts bringing additional skills and knowledge in safeguarding, PPIE, public health, diabetes, commissioning, policy and psychology. We will also work with the NIHR to establish a formal oversight group and will report to the CEW Delivery Board as required.

Each WP has an experienced academic lead who will be responsible for the day-to-day activity within their WP and will remain in frequent contact with Homer and Ells, meeting formally with the WP1 team monthly via MS Teams. Each WP lead will manage the staff working to them for the tasks as outlined in Appendix 1. Coulman and Griffiths will report to Homer and Ells and will provide support for the qualitative and quantitative data collection and work together to triangulate findings into WP5. Lines of responsibility for, and location of, the newly recruited research staff will be as follows: Marwood - Matu (Leeds Beckett), Ioannou - Homer and Neild (Sheffield Hallam and University of sheffield), Researcher 3 – Martin (Leeds). The multi-site team will operate collectively through a dedicated MS Teams site, and a secure shared drive hosted by SHU. All Co-I's have extensive experience and track record of effective remote collaborative working together.

We have an ambitious plan for PPIE (under WP1), which will be led by CI Sharman, an experienced child weight management practitioner, clinician and counsellor. Coulman, a specialist dietician for weight management, experienced researcher (NIHR clinical fellowship) and PPIE specialist, will support Sharman by recruiting and co-ordinating the patient group (including training, coproduction activities and biannual formal meetings and regular communication through our closed online group) and ensuring the patient voice is reflected in every stage of the project.

8. Ethics

This protocol version is not currently ethically approved.

All required ethics and governance approvals will be sought prior to data collection. The team has considerable experience conducting studies involving NHS staff, CYP and families living with long term conditions, including recruiting and obtaining assent/consent using developmentally appropriate materials [24, 25]. Researchers appointed to recruit participants will complete the HRA Good Clinical Practice training https://www.nihr.ac.uk/health-and-care-professionals/learning-and-support/good-clinical-practice.htm and Informed Consent in Paediatric Research (nihr.ac.uk) and will follow the principles of consent/assent for CYP in England https://www.hra-decisiontools.org.uk/consent/principles-children-EngWalesNI.html. Where required, researchers will hold Research Passports (from the lead/sponsor NHS Trust) and letters of access from participating Trusts. Eligible participants will be told they are not obliged to participate but that if they do so, they are free to withdraw at any time without providing a reason. All data submitted online or on paper will be stored securely in accordance with the Data Protection Act 2018 and GDPR, accessible only to appropriate research team members for data management. Focus groups/interviews will be digitally recorded and later transcribed using a SHU-approved commercial transcription company. Transcripts will be anonymised, with any linking codes being stored separately and only available to the appointed researcher/s and the PI. No person-identifiable information will be used in reporting. Data from the NHSE MDS will be accessed by researchers (martin, Matu, Zabula and Mattocks) who will hold honorary contracts with PSLdata partner and be accessed on secure data platforms. A DSA owned by NHs E and signed by all trusts will allow the research team to access the MDS data t.

All ethics and governance work will be co-ordinated by Ells and Homer (as part of WP1), working in collaboration with respective WP leads and Matu. As this is a service evaluation we will require ethics approval from the lead University (SHU) and the academic sites of the WP leads. .We will also work with NHSE and the CEW delivery board to ensure we meet all governance requirements.

9. PROJECT / RESEARCH EXPERTISE

Full costings and grades for each member are presented in the financial summary information.

Dr Catherine Homer (20%FTE months1-32) is the joint PI, an Associate Professor in Public Health and Obesity at Sheffield Hallam University and co-leads the Healthy and Active 100 theme at the Advanced Wellbeing Research Centre. She has 20+ years' practice experience as a Public Health Specialist in an NHS Trust and Local Authority, where she led the obesity portfolio and commissioning of children's and adults weight management services. Catherine is a Fellow of the Royal Society of Public Health and Deputy Editor of the journal - Perspectives in Public Health. Catherine is Co-I / PI on research grants worth over £7.4m and has a credible publication record. Dr Homer has a specialist interest in the use of coproduction and person-centred approaches to research and service evaluation and co-led the development of the 'Public

Involvement in Research Group' (SHU) and is a member of the steering group for the Obesity Voices PPIE steering committee at Leeds Beckett University. Dr Homer's other interests include research capacity development in statutory and voluntary sectors. She is mid-career researcher with an increasing track record of high profile NIHR funded research delivery and will be supported and mentored as a joint PI by Professor Louisa Ells at Leeds Beckett University. Catherine and Louisa have worked together for several years and collaborate on a number of other NIHR funded research projects including the HSDR funded Re:Mission study and the NIHR CRN funded Yorkshire Obesity Research Alliance.

Professor Louisa Ells (5%FTE months1-32) Professor of Obesity, Leeds Beckett University and joint PI. Prof Ells is a registered public health nutritionist with over 20 years' experience working in obesity across policy, practice and academia. Louisa is co-director of the Obesity Institute at Leeds Beckett University working with Nobles, Matu, Evans and Griffiths. She is a Fellow of the Royal Society for Public Health and has been specialist academic advisor to Office of Health Improvement and Disparities (formally PHE) since 2013. Ells is a highly experienced project manager with a grant income ~£11 million (>£2million as PI), an extensive publication record and track record in coproduced, patient centred, multidisciplinary, cross-sector applied research and evaluation, and specialist interest in addressing inequalities. She has been PI of a number of high profile projects, including rigorous coproduced research delivered at pace across multiple sites for the World Health Organization (WHO) and PHE, and the NIHR/NHSE, all of which have directly informed international and national policy and practice. She has also been an expert advisor to NICE and sits on the NHSE CEW delivery board, so has vast experience of working with, and meeting the needs and expectations of policy and practice. She is also passionate about PPIE having established the UK's largest PPIE hub for obesity – Obesity Voices.

Dr Neil Wright (2%FTE months 1-32) is Clinical Lead for the Sheffield CEW service and has over 20 years clinical experience in delivering weight management services. He is a member of the NHSE Tier 3 Advisory Board developing and piloting different models of care for CYP and their families living with severe obesity. He has previously chaired the NHSE working group that developed the service specification, clinical standards and IFR commissioning for Tier 4 (Bariatric) services in young people < 18 years. He has expertise in service design, service delivery, clinical standards, clinical pathways and commissioning. Dr Wright has research experience of clinical trials managing paediatric obesity ranging from community lifestyle and exercise based interventions with an emphasis on psychological outcomes, through to clinical trials of intragastric balloons. These trials have utilised both quantitative and qualitative methodologies to assess the effectiveness and acceptability of the various interventions. He is familiar with assessing the clinical impact and psychological impact of services within both research and clinical settings and is currently supervising a PhD student focussing on social prescribing within CEW clinics with Homer. Dr Wright will be the clinical lead for WP2, using his expertise in supporting the connection and engagement with CEW clinics.

Dr Nivedita Aswani (2%FTE months1-32) has been a Consultant Paediatrician since 2012. She specialises in diabetes and weight management and works in the Sheffield CEW service. She sits on the NICE committee for guideline NG10182 - preventing, assessing and managing overweight and obesity in children and adults, and NG18 Diabetes (type 1 and type 2) in children and young people: diagnosis and management - medicines for type 2 diabetes (update). She is on the NPDA Methodology and Dataset working group at RCPCH, and NHSE North East and Yorkshire Clinical Lead Children and Young Adults Diabetes Programme focusing on four priority areas of Tackling unwanted variation in access and outcomes, improving outcomes for T2 diabetes, reducing health inequalities and improving transition. Dr Aswani is passionate about reducing stigma in children's obesity services, hearing the patient voice and improving access to culturally appropriate resources and has been the Clinical Lead for DigiBete Type 2 Project Oversight Group working with a CYP PPIE group developing resources to raise awareness of Type 2 diabetes. Dr Aswani will provide clinical expertise for WP3 through her knowledge and experience of the development of a Tier 3 obesity service, working with families, and also wider stakeholders.

Professor Julian Hamilton-Shield (2% FTE months1-32) leads research based in the NIHR Bristol Biomedical Research Centre with an emphasis on the clinical management of childhood obesity and diabetes and will provide clinical expertise to WP4. He has led an obesity service for children at Bristol Royal Hospital for Children for twenty years and the clinic model he developed, formed the initial basis of the CEW clinic model roll out in April 2022. He has led and supervised researchers and students who have described, key targets for weight loss to improve metabolic health during childhood, patient expectations and experience within childhood weight management services (twice) and equity of access to services across England. His current NIHR research is exploring how to improve care to young people with all forms of diabetes from under-served communities, developing a 3rd generation CBT intervention with adolescents to improve

intrinsic motivation to benefit outcomes in weight management, and methods to improve recruitment in to weight management interventions for children through parent sign-posting. He has expertise in the medical management of obesity and co-morbidities, patient and family engagement and the public health landscape of current childhood obesity provision. He currently sits on the NICE weight management for adults and children update committee.

Dr Karen Coulman (3%FTE months1-4, 30%FTE months5-32) is a NIHR-funded clinical academic dietitian experienced in leading NIHR-funded weight management mixed methods research. She is a current member of the NICE digital weight management technologies early value assessment committee and a steering committee member of the national tier 3 adult weight management database. Dr Coulman has extensive experience of multi-stakeholder qualitative research in weight management. Dr Coulman will co-lead WP 5 with Griffiths and will have an oversight role of all qualitative elements throughout the project including working closely with Nobles (WP2), Neild/Swallow (WP3) and Sharman (PPIE). Dr Coulman has collaborations with Ells, Homer, and Nobles having recently submitted an NIHR application to PHR.

Dr Claire Griffiths (20%FTE months1-32) is a Reader in Obesity and the Systems Approaches Theme lead at the Obesity Institute, Leeds Beckett University with Ells, Matu, Evans, and Nobles. She is interested in transdisciplinary approaches to understanding the complexity of obesity ensuring that the identification, implementation, and evaluation of effective responses to the prevention and treatment of obesity employ a set of approaches that work within this complexity. Although different methodological approaches pursue a process to create a systemic awareness of a problem situation, and their methods may (or may not) shed light on the same systemic elements, their merger is what provides the most comprehensive understanding. Dr Griffiths will lead WP5 with Coulman, together working with RA1 to develop a triangulation protocol that brings together the findings from the different WPs. The triangulated findings will inform the development of a realist informed framework to generate informed theories about which models of care work and don't work for which population groups, in what context and why. Dr Griffiths will also support Martin and Matu in WP4.

Dr James Nobles (20%FTE months1-24, 5%FTE months25-32) has a background in childhood obesity management, with particular reference to both service design and familial engagement in services. Based on this expertise, and his wider methodological expertise, Dr Nobles will lead on WP2 with support from Matu and RA1 to map CEW services in detail (via mixed methods) and understand participant journeys through CEW clinics (via participatory process mapping). Nobles is now based at the Obesity Institute at Leeds Beckett University having recently moved from the University of Bristol (working with Hamilton-Shield and Coulman), and completed his PhD in close collaboration with Sharman at SHINE.

Professor Veronica Swallow (5%FTE, months1-32) will lead WP3, providing mentoring support to WP3 co-lead Neild and provide advice to the wider project on healthcare research with and for children, young people, parents/carers and families. Professor Swallow brings long-standing experience of clinical leadership in the NHS and research leadership in Higher Education (HE) and currently leads a programme of qualitative and mixed-methods, multidisciplinary research at the HE/NHS interface that includes co-design, co-production and evaluation of self-management interventions in a wide range of long-term conditions. Veronica has an accrued grant income of around £6.5 million as both lead and co-applicant, and 70+publications in peer-reviewed journals.

Dr Adam Martin (20%FTE, months1-32) is Associate Professor in Health Economics at the University of Leeds, with methodological expertise in distributional cost-effectiveness analysis, applied econometrics, policy evaluation, and economic modelling. He currently leads a small team of researchers at the UoL conducting the economic evaluation of NHSE's low calorie diet programme (Remission, PI Ells) and of an intervention delivered in Children's Centres to help families be healthier and prevent children from becoming overweight (HENRY RCT). Other related projects include observational studies examining relationships between employment and obesity, and between travel to work and obesity. Dr Martin will lead WP4 in close collaboration with Matu and NHSE, with whom he has an established working relationship, and will manage a UoL-based WP4 research fellow (RA3).

Dr Jamie Matu (40%FTE, months1-32) is a Reader in Nutrition and Metabolic Health at Leeds Beckett University, and will support Nobles delivering WP2, and Martin delivering WP4. Dr Matu has a first-class honours degree in Sport and Exercise Science, an MSc in Sport and Exercise Physiology, and a PhD in appetite regulation. He holds an honorary contract with the OHID, where his work in obesity management has informed national policy and practice. Dr Matu is currently involved in the NIHR funded national evaluation of the NHS Low Calorie Diet with Homer, Ells, Martin and Evans and sits on the Leeds Beckett

University Ethics Committee and will support the ethics and governance processes. Jamie will also be the PI on the embedded SWAP study (mths 2-14) leading the work with Evans and Steele.

Dr Lucie Neild (15%FTE, months1-32) is a dietitian and nutritionist who is passionate about weight management, diabetes, and health inequalities research. She worked as a NHS specialist dietitian in complex weight management prior to joining the university and delivers obesity and weight management courses to MSc Nutrition students. Lucie will co-lead WP3 with Swallow and direct the work of Brown and Lamb and supervise and manage Ioannou. Lucie is a Senior Lecturer in Public Health at the University of Sheffield and previously worked within the AWRC working closely with Homer. Research is focussed primarily on qualitative work including systems evaluation and coproduction methodologies as well as implementation science. Lucie has worked with diverse groups of people and communities to address health inequalities and to understand the lived experience of individuals.

Mrs Kath Sharman (10%FTE months1-32) has 51 years' experience in health care. 31 years NHS as a registered nurse and senior nurse lecturer at the University of Sheffield (Bsc (Hons) in Nursing and Education) and qualifying as a BACP registered child and adolescent therapist in 1995 (MA in Counselling Studies and Counselling Supervision), leading to 20 years community experience working with children, young people and their families living with obesity. Kath is the founder of SHINE, a weight management programme embedded in a holistic approach and with sites nationally. The voice of young people has been paramount throughout, establishing the first Young People's Management Committee in 2003. This group of young people have always been proactive and were accompanied by Kath in 2019 to meet at government level with the Health Minister, Health Care Select Committee and key policy advisors to share their lived experience and to campaign for better care and treatment for young people living with severe obesity and complex needs. Kath has been a consultant for NHSE in the development of the CEW services, sharing 'real life' experiences and has responded to requests for reviews in the development and update of the NICE Obesity Guidelines. Kath supported the PPIE group during the CEW Delphi study and continues to support young people in their NHS Advisory role as an extension to this. Kath has a dedicated passion to ensure the voice of young people is heard. She will use these skills leading the recruitment, training, mentoring and retention of the PPIE team in this study. Kath will be supported by Coulman, Homer, Ells and our PPIE collaborators – Bell, Fish and King.

PPIE Collaborators: Mx Pluto King, Master Mason Fish, and Miss Grace Bell are existing patients of the SHINE weight management clinic in Sheffield. Miss Bell is a patient of the South Yorkshire CEW clinic. The group are aged between 11-17years, represent different demographics, and between them live with neurodiversity, obesity and other physical and psychological health conditions. They were involved with the Delphi study for the development of CEW clinic outcome measures and have spoken about their experiences of living with obesity at various events and featured on the BBC Panorama documentary on psychosocial aspects of obesity and stigma - Obesity: who cares if I'm bigger. Mx King is also a member of Bite Back 2030 Youth Involvement Board. Their parents / carers have provided their consent to being involved in the study, with two of the parents having agreed to be involved in the wider PPIE team as the family representative. The group will act as advocates for the PPIE element of the study in supporting the development of recruitment materials for the PPIE group and planning the PPIE training session with KS. The group will be joined by Master and Mrs Bolderson (Mother) who will also represent the South Yorkshire CEW clinic on the PPIE team. Master Bolderson lives with neurodiversity and with his Mother are passionate about sharing their experiences of services to support CYP and families who live with obesity. Our 3 PPI collaborators have worked with us to co-develop this proposal. Our intention was to include these 3 young people as co-applicants, however guidance from HSDR states they need to be included as collaborators. We anticipate their role within our PPIE team will remain the same as it would as co-applicants.

Dr Martin Lamb (10%FTE months7-30) is a Research Fellow based at the Centre for Behavioural Science and Applied Psychology at SHU. He has a background in Health Psychology and has extensive experience using behaviour change theory to promote positive health behaviours. Martin has worked with different populations within healthcare settings, as well as with underserved communities and children. He is a mixed-methods researcher with experience in conducting in-depth interviews/focus groups, large-scale surveys, co-design workshops, intervention design, and objective measures of activity. Martin is also the chair of the UK Society for Behavioural Medicine's Early Career Network. Dr Lamb will conduct interviews and focus groups delivery and analysis in WP3 with Brown and has worked with Homer and Brown on consultancy and charity funded qualitative projects.

Dr Chris Brown (10%FTE months7-30) is a Senior Lecturer in Psychology at SHU, and early career researcher, with expertise in health psychology, behavioural science, and evaluation methodologies. Chris

has experience using a range of qualitative research methods such as interviews, focus groups and ethnographic approaches. He has worked on externally funded projects, including designing and delivering training to support a Tier 2 weight management service in Bradford, and an evaluation of a Tier 3 Children's weight management service in Sheffield. Chris will work on WP3, helping to conduct qualitative research on families' experiences of CEW Services.

Summary: Our team draws on expertise from policy, medicine, academia and lived experience. CH (co-PI) is an experienced researcher leading NIHR funded research and has previously commissioned weight management services in the NHS and Local Authority. LE (co-PI) is a senior academic and NIHR lead researcher, with extensive experience of service evaluation and inequalities focused weight management research. The study team includes senior-, mid- and early- career academics from Sheffield Hallam, Leeds, Bristol and Leeds Beckett Universities and clinicians delivering CEW clinics in Bristol South and West Yorkshire. The team harnessing the expertise of Professors with a proven track record of health care and policy research to provide support and career development for aspiring researchers, with match funded PhD fellowships provided by Hallam and Beckett.

10. SUCCESS CRITERIA AND BARRIERS TO PROPOSED WORK

The key overall measures of success will be:

- The production of a rigorous evaluation of uptake, engagement, practitioner and patient experiences, and costs, and implementation, of the different delivery models, across the CEW sites.
- Data on practitioner and patient views on the different models of delivery across the different delivery sites, implementation issues, solutions and lessons learnt, that will inform a national roll out.

- Additional measures of success will also include:
  - Delivering a project underpinned and evaluated by informal and formal patient group feedback, and the dissemination and reach of public facing materials (measured through website, social media and other media engagement.[63]
  - The timely completion and dissemination of each project output (see ^ on Gantt chart), the publication of at least five peer reviewed publications (one for WP2-5), and reports in line with the requirements of NHSE namely:
    - Evaluation plan (02/24).
    - Interim report (010/25); and,
    - Final report (10/26).
- Risks and mitigation strategies for this project are provided in Table 1.

11. SWAP STUDY: An exploration of disordered eating in CEW clinics

11.1 SWAP Context and Existing Research: The NHS is commissioning clinics across the country to provide a treatment offer for CYP living with complications related to severe obesity. Due to the plethora of multiple long term conditions (MLTCs) that patients live with, clinics take a complex holistic approach to care.

Disordered eating is distinctly different to eating disorders, in that disordered eating refers to abnormal behaviours associated with eating disorders (e.g. restraint eating, emotional eating, binge eating) that do not warrant a psychiatric diagnosis [64]. A recent meta-analysis found that the overall global proportion of children and adolescents with disordered eating was 22%[63], suggesting that a substantial proportion of CYP attending CEW clinics may have disordered eating. Both our patient advisory group, and clinical co-applicants, suggest that disordered eating is a significant factor in the lives of those who attend CEW clinics. Disordered eating in adolescence has been shown to track into adulthood [65-67], and is associated with excess weight [68, 69], severe mental health problems [65, 70], and reduced quality of life [70-72]. Therefore, we propose this SWAP to explore disordered eating prevalence, what help is currently available in CEW clinics, whether participation at CEW clinics can help with disordered eating and investigate potential assessment tools for disordered eating.

11.2 Gap in Knowledge to be Addressed: The prevalence of disordered eating among CYP attending CEW clinics is currently unknown. The CEW clinic at Leeds Teaching Hospitals Trust (LTHT) has recently started collecting data on disordered eating behaviours and attitudes using the Eating Disorder examination

questionnaire (EDE-Q)[73]. Quantitative analysis of the available data will allow for the estimation of disordered eating prevalence in this CEW clinic, as well as whether disordered eating behaviours and attitudes change over time with attendance. We expect to analyse data at baseline, 6 months, and 1 year of clinic attendance.

It is also unknown what disordered eating assessments are being used, and support being offered, at the other 20 CEW clinics nationally. Therefore, we propose including questions in WP2 to gather insight around this. Finally, whilst the EDE-Q is a validated and well-established tool [74], it's acceptability in CEW clinics for both children and those administering the questionnaire is unknown.

The findings of this study will: 1) provide insight into the magnitude of the problem of disordered eating in this population, 2) establish what support is currently available nationally across CEW clinics, 3) show how disordered eating may change over time with attendance at CEW clinics, 4) provide recommendations on what measures should be used in further roll out of CEW clinics.

11.3 Aim: To analyse pre-existing quantitative data and collect new qualitative data to explore disordered eating prevalence, provision, changes over time, and available assessment tools in CEW clinics.

11.4 Research questions:

- What is the prevalence of disordered eating in children in CEW clinics, and is this influenced by key demographics?
- What help is currently offered in CEW clinics for disordered eating?
- Does disordered eating change over time with attendance at CEW clinics?
- Are the current assessment tools appropriate for the target population?

11.5 Methods: *Quantitative research:* Administration of the EDE-Q to CEW clinic patients has recently started at LTHT. New patients will complete the EDE-Q at baseline (first clinic appointment), 6 months, and 1 year (or completion if earlier). The EDE-Q will also be administered to existing clinic patients. We will seek patients' permission to link their data to the MDS via their unique referral ID, so the demographic and outcome data can be joined. We will conduct an evaluation of the data, to estimate disordered eating prevalence, and quantitatively assess whether disordered eating changes over time. If possible, we will investigate whether any patient characteristics influence the changes in disordered eating over time.

Qualitative research: Two questions will be added into the STAR-LITE template which will be completed by all 21 clinics (WP2). Additional questions will explore whether clinics assess disordered eating, and whether any help is offered for disordered eating. The STAR-LITE template will be completed in month 6 of the project, so ideally placed to coincide with this SWAP. Four semi-structured interviews will be undertaken with staff and another four with families, to explore their views on the EDE-Q, as well as what support is available to them for disordered eating.

PPIE: We will recruit five families, within which a child has attended CEW clinic, to provide PPIE support for this SWAP. The group will meet three times, once at study design phase, once at 6 months, and once towards the latter stages to provide support with dissemination of findings.

11.6 Impact The findings of this SWAP will feed directly into the measures and practices taken locally at LTHT, and nationally in other CEW clinics. We will share findings into the public domain as soon as they are available, as an interim output in coproduction with NHSE. The costs associated include clinical and research staff.

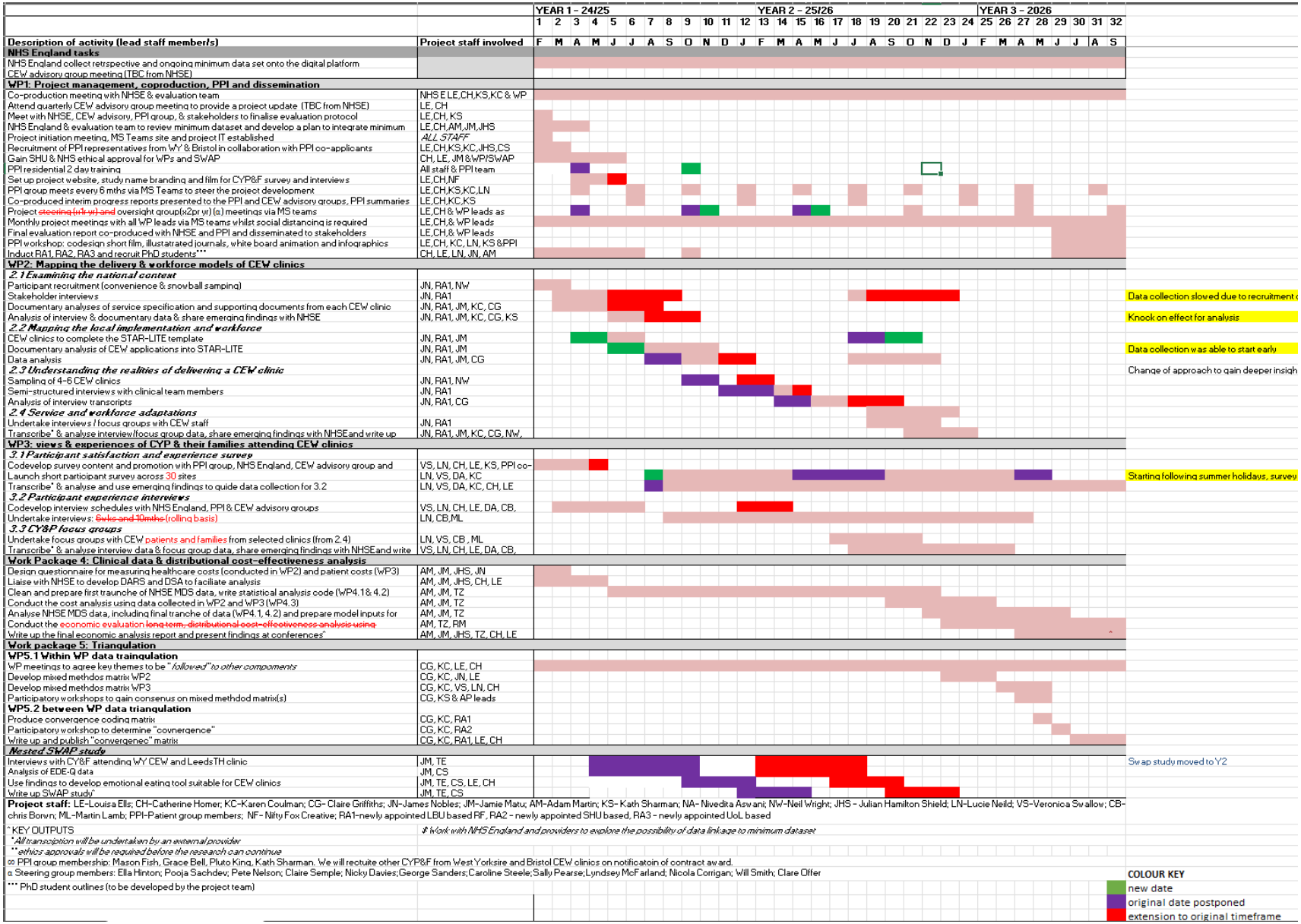
12. Funding Acknowledgement

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Table 1: ENHANCE - risks and mitigation assessment

Description of risk	***Mitigation assessment***
Delays in gaining ethics and governance approval	University ethical approvals will take no longer than two working weeks to process, and as we do not anticipate that the research will raise any material ethical issues, we are anticipating being triaged to the HRA proportionate review, which is processed within 21 calendar days. The team are also highly experienced in preparing ethical applications: Ells used to sit on the ethics committee at Teesside University, and Matu is on the ethics review panel at Leeds Beckett University (LBU). We have however allowed for five months to gain ethical clearance, to allow sufficient time should any unexpected delays occur.
Poor engagement from CEW delivery sites	Our four clinical co-applicants will support the engagement of CEW clinics with the research. Four of our co-applicants also sit on the CEW delivery board and as such have contact with all 21 CEW clinics which will support communication of the research and the opportunity to ask any direct questions to members of the research team. We will set up regular meetings with NHSE, weekly for the first few months and dropping to monthly as the project goes into delivery phase to update on project progress and request support from NHSE with CEW engagement as and when needed.
Staff absence	In the event of any unplanned staff absence, contingency cover can be provided by staff within the Health Research Institute at SHU and Obesity Institute at LBU, where several staff members possessing the required skills and expertise will be available to provide cover.
Poor uptake of the patient survey	Each family will be offered a £5 gift voucher as a thank you for their participation (following advice from our PPIE group). We will also produce flyers, a QR code, posters and short film for referral centres to publicise the survey and to feed any social media or messaging channels. We will also provide the opportunity for participants to complete the survey face to face in clinics, over the phone and in another language to ensure participation can occur irrespective of literacy, visual capability, internet access or language spoken. We will also maintain engagement through a comprehensive communication strategy that includes regular short films and lay updates led by CYP PPIE group on the study.
Difficulty in recruiting a representative sample of patients for interview	We have incorporated several mechanisms to facilitate the widest possible uptake. We will work with our PPIE co-applicants (who are from diverse backgrounds) to record some short films of them talking about the study importance and encourage involvement. We will work with our PPIE team and creative partners Nifty fox to design a participant information sheet that is easy to understand and engaging to CYP. We will offer CYP and families to be interviewed together or separately depending on their wishes. We will provide gift vouchers to incentivise participation in each interview.
Delayed access to NHS CEW data	We will work with NHSE pre-award to set out a timeline for access to data and keep in regular contact throughout the study to ensure the data is available in a timely manner to complete the work set out in WP4. We have successfully set up the data transfer systems between NHS England and LBU which will be used to transfer the data for this study.

APPENDIX 1 : PROJECT GANTT CHART



Project staff: LE-Louisa Ells; CH-Catherine Homer; KC-Karen Coulman; CG- Claire Griffiths; JN-James Nobles; JM-Jamie Matu; AM-Adam Martin; KS- Kath Sharman; NA- Nivedita Aswani; NW-Neil Wright; JHS - Julian Hamilton Shield; LN-Lucie Neild; VS-Veronica Swallow; CB-chris Bown; ML-Martin Lamb; PPI-Patient group members; NF- Nifty Fox Creative; RA1-newly appointed LBU based RF, RA2 - newly appointed SHU based, RA3 - newly appointed UoL based

^ KEY OUTPUTS

$ Work with NHS England and providers to explore the possibility of data linkage to minimum dataset

* *All transcription will be undertaken by an external provider*

** *ethics approvals will be required before the research can continue*

∞ PPI group membership: Mason Fish, Grace Bell, Pluto King, Kath Sharman. We will rectuite other CYP&F from West Yorksire and Bristol CEW clinics on notificatoin of contract award.

g Steering group members: Ella Hinton; Pooja Sachdev; Pete Nelson; Claire Semple; Nicky Davies;George Sanders;Caroline Steele;Sally Pearse;Lyndsey McFarland; Nicola Corrigan; Will Smith; Clare Offer

*** PhD student outlines (to be developed by the project team)