Scientific Title

Can embedding the MapMe intervention, a tool to improve parental acknowledgement and understanding of childhood overweight and obesity, in the National Child Measurement Programme lead to improved child weight outcomes at one year?

Short Title

The MapMe study

Protocol Version Number and Date

Version 0.2 7/3/2022

Research Reference Numbers

Project reference number (funders reference)	NIHR127745
Trial Registry Number and Date	
Sponsor/Co-Sponsor/Joint-Sponsors	Newcastle University will be the study sponsor Kay Howes Research Manager Faculty of Medical Sciences Ground Floor Medical School University of Newcastle Framlington Place Newcastle upon Tyne NE2 4HH Kay.Howes@Newcastle.ac.uk
ISRCTN Number/Clinical trials.gov Number	**TBC**
Sponsors Number:	NU-001299

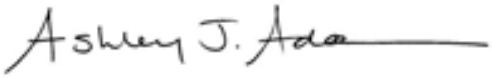
Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to adhere to the signed Newcastle University Sponsorship CI declaration.

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

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

Chief Investigator:

Signature: 

Date: 01/03/2020...

Name: (please print): Prof Ashley J. Adamson

Sponsor Statement

Support of Newcastle University as Sponsor is a prerequisite for ethical approval to be granted by Newcastle University Research Ethics Committee (REC). Therefore, ethical approval granted from Newcastle University REC will serve as confirmation of approval of the protocol by the Sponsor.

Key Study Contacts

Chief Investigator	Prof Ashley Adamson; Ashley.Adamson@ncl.ac.uk Tel: 0191 208 5276 Human Nutrition Research Centre, Population Health Sciences Institute, Newcastle University, Framlington Place, Newcastle upon Tyne. NE2 4HH
Trial Co-ordinator	Dr Angela Jones; Angela.Jones@ncl.ac.uk Tel: 0191 208 5276 Human Nutrition Research Centre, Population Health Sciences Institute, Newcastle University, Framlington Place, Newcastle upon Tyne. NE2 4HH
Sponsor	Newcastle University Kay Howes Research Manager Faculty of Medical Sciences Ground Floor Medical School University of Newcastle Framlington Place Newcastle upon Tyne NE2 4HH Kay.Howes@Newcastle.ac.uk
Funder(s)	This study is supported by funding from the National Institute for Health Research Public Health Research Programme NIHR127745. Donna White Research Manager (Monitoring) netspostawardsetup@nihr.ac.uk Support for this study is also provided 'in kind' from Public Health England. Loretta Sollars Office for Health Improvement and Disparities, Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU Loretta.sollars@dhsc.gov.uk
Key Protocol Contributors	**Co-Investigators:** Dr Angela Jones; Angela.Jones@ncl.ac.uk Tel: 0191 208 5276 Human Nutrition Research Centre, Population Health Sciences Institute, Newcastle University, Framlington Place, Newcastle upon Tyne. NE2 4HH Prof Vera Araujo-Soares; vera.araujo-soares@utwente.nl

	+31 (0)53 489 4857 Faculty of Behavioural, Management & Social Sciences (BMS), University of Twente, Hallenweg 5 I 7522 NH Enschede Dr Bronia Arnott; bronia.arnott@ncl.ac.uk Tel: 0191 208 3804 Population Health Sciences Institute, Newcastle University, Newcastle upon Tyne. NE2 4AX Dr Elizabeth Evans; elizabeth.evans@durham.ac.uk 0191 33 40365 Department of Psychology, University of Durham, Durham DH1 3LE Dr Yemi Oluboyede; yemi.oluboyede@ncl.ac.uk Tel: 0191 208 7349 Population Health Sciences Institute, Newcastle University, Newcastle upon Tyne. NE2 4AX Prof John Matthews; john.matthews@ncl.ac.uk Tel: 0191 208 7259 School of Mathematics, Statistics and Physics, Newcastle University, Newcastle upon Tyne. NE1 7RU Prof Louisa Ells; L.Ells@leedsbeckett.ac.uk Tel: 0113 812 0000 Prof of Obesity, Applied Obesity Research Centre, School of Clinical and Applied Sciences, Leeds Beckett. Prof Martin Tovée; martin.j.tovee@northumbria.ac.uk Tel: 0191 227 3356 Department of Psychology, Faculty of Health and Life Sciences, Northumbria University, Newcastle upon Tyne. NE1 8ST Loretta Sollars; Loretta.sollars@dhsc.gov.uk Tel: 0207 654 8186 Office for Health Improvement and Disparities, Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU Alison Gahagan;

	Alison.Gahagan@dhsc.gov.uk National Child Measurement Programme (NCMP), Office for Health Improvement and Disparities, Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU Tel: 07500835414/07717156593 Dr Laura Basterfield; laura.basterfield@ncl.ac.uk Tel: 0191 2085276 Human Nutrition Research Centre, Population Health Sciences Institute, Newcastle University, Framlington Place, Newcastle upon Tyne. NE2 4HH
Statistician	Co-investigator - Prof John Matthews; john.matthews@ncl.ac.uk Tel: 0191 208 7259 School of Mathematics, Statistics and Physics, Newcastle University, Newcastle upon Tyne. NE1 7RU
Committees	Trial Steering Committee: Chair. Prof Peymane Adab; p.adab@bham.ac.uk Tel: 0121 414 7878 College of Medical and Dental Sciences, Murray Learning Centre, University of Birmingham, Edgbaston, Birmingham. B15 2TT Helen Duncan; helen.duncan@dhsc.gov.uk 0113 85 57438 Programme Director, National Child and Maternal Health Intelligence Network, Health Improvement Directorate, Health Intelligence, OHID. Prof Simon Coulton, S.Coulton@Kent.ac.uk Tel: 01227 824535 Prof of Health Services Research, Centre for Health Services Studies, University of Kent, Canterbury, Kent, CT2 7NF Two Local Authority NCMP lead representatives Scott Lloyd, scott_lloyd@middlesbrough.gov.uk Tel: 01642 727 658

	Advanced Public Health Practitioner , Public Health South Tees [Associate Lead for Public Health Research, NIHR Clinical Research Network North East and North Cumbria], The Live Well Centre, Dundas House, Dundas Arcade, Middlesbrough, TS1 1HR Retired, to be replaced: Helen Robinson, helen.robinson@newcastle.gov.uk Tel: 44 (0)191 211 6302 Senior Specialist, Public Health, Newcastle City Council, Civic Centre, Newcastle upon Tyne, NE1 8QH <u>Two Parent Involvement Panel members</u> Paul Evans and Alina Andras Principal Investigator Prof Adamson and Co-Investigator Prof Matthews will also be members of the Trial Steering Committee. Parent Involvement Panel: Nine members.

List of Contents

List of Abbreviations

AcORD	Attributing the costs of health and social care Research & Development
BIS	Body Image Scales
BMI	Body Mass Index
CEACs	Cost Effectiveness Acceptability Curves
CHU	Child Health Utility
CI	Chief Investigator
CUA	Cost Utility Analyses
DMC	Data Monitoring Committee
DoB	Date of Birth
ECHO	Report of the Commission on Ending Childhood Obesity
GDPR	General Data Protection Regulations
GP	General Practitioner
HTA	Health Technology Assessment
IMD	Index of Multiple Deprivation
IP	Intellectual Property
LA	Local Authority
NCMP	National Child Measurement Programme
NHS	National Health Service
NIHR	National Institute for Health Research
OB	Obesity
OW	Overweight
PHE	Public Health England
PIP	Parent Involvement Panel
PPI	Patient and Public Involvement
QALY	Quality Adjusted Life Year
QoL	Quality of Life
RCT	Randomised Control Trial
RDS NE	Research Design Service North East
REC	Research Ethics Committee
ROI	Return on Investment
SoECAT	Schedule of Events Cost Attribution Template
TIDieR	Template for Intervention Description and Replication
TSC	Trial Steering Committee

WAItE	Weight Specific Adolescent Instrument for Economic Evaluation
WP	Work Package

Study Summary

Research Question: Can embedding the MapMe intervention in the National Child Measurement Programme (NCMP) lead to improved child weight outcomes?

Background: Childhood overweight and obesity (OW/OB) is a Public Health England (PHE) priority. Parents are key to managing children's weight, but tend to struggle to recognise OW/OB, and so do not take action. In England, the NCMP measures the weight status of 4-5 and 10-11 year-olds and reports results to parents via letter. Parents are often surprised by, and mistrust the result. More support is required to help parents understand and act upon the letter. The 'Map Me' intervention includes Body Image Scales (BIS) (images of underweight to very OW children of NCMP age, to help parents recognise child weight status), and information on healthy eating, physical activity, consequences of child OW and further support. MapMe was tested in ~300 OW/OB children who showed improved Body Mass Index (BMI) Z scores after 1 year. These findings now need to be confirmed in a larger study and, if confirmed, we need to establish how the intervention works, and if it cost effective.

Objectives:

1. Update MapMe
2. Assess the impact of enhanced NCMP letters including MapMe (delivered using 2 different approaches) on child BMI Z score at 1 year
3. Examine mechanisms of impact of MapMe
4. Examine the cost/benefit of MapMe
5. Assess the impact of MapMe enhanced NCMP letters on health inequalities and psychological outcomes
6. Explore the implementation and acceptability of the MapMe enhanced NCMP letters and potential for national adoption

Methods: Parents and key stakeholders will be consulted on how MapMe can be improved. The improved MapMe will then be examined by a Randomised Controlled Trial across 9 Local Authorities (LAs). Schools within each LA, will be randomised to 1 of 3 groups: 1) MapMe BIS and link to web-based MapMe added to the NCMP post-measurement letter; 2) as group 1, plus an additional 'booster' letter with the link to web-based MapMe sent 6 months later; 3) standard NCMP letters (control). Child BMI Z score changes will be assessed at 1 year. A sub-group will be recruited for a process evaluation examining: parents' perceptions of child weight status; changes in child food intake, activity, and parental help seeking. Child quality of life, use of NHS/LA services will inform an economic evaluation. Data on self-esteem, eating disorder risk, deprivation and ethnicity will be used to evaluate psychological impact and health inequalities. Views from NCMP teams and parents will explore experiences and implementation of MapMe.

Timelines for delivery: Total study duration is 36 months. MapMe update (months 1-6); Health-related and cost impacts of MapMe, and process and acceptability evaluations (months 7-29); Analysis and dissemination (months 30-36).

Anticipated impact: If found to be effective MapMe will be incorporated into routine NCMP delivery and hosted by NHS UK providing a minimal cost, national scale intervention capable of improving the weight status of children with OW/OB.

Dissemination: A PHE co-hosted workshop for NCMP commissioning and delivery teams; feedback to participating families, school nursing, NCMP teams, health practitioners, local and national policy makers (informed by the parent involvement panel); dissemination at conferences and in open-access academic journals.

Funding and Support in Kind

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
Newcastle University	Research Sponsorship
National Institute for Health Research	Provision of research related costs
Office for Health Improvement and Disparities	In kind contribution for Sollars and Gahagan research time

Role of Study Sponsor and Funder

Newcastle University, as the Sponsor, will assume overall responsibility for initiation and management of the study, and will control final decisions regarding all aspects of the study. The National Institute for Health Research, as the funder, will contribute financial support and facilitate dissemination of the results. Public Health England's 'in kind' contribution with provide lead on the delivery of the trial via the NCMP.

Roles and Responsibilities of Study Management Committees/Groups & Individuals

Study Management: Chief Investigator (CI) (AA) will have overall responsibility for the study. AJ, VAS, BA, EE, YO, JM, LE, MT, LB, LS, AG (Co-investigators) will form a core study management team, which will meet monthly to oversee all aspects of the study. All Co-investigators, together with the core research team, will form a Study Management Group which will meet approximately quarterly to guide the study. All meetings will be minuted with specified actions points, timelines and persons responsible identified.

Trial Steering Committee: A Trial Steering Group (TSC) will be convened. This will comprise, three external advisors (Prof Peymane Adab, University of Birmingham; Helen Duncan, Programme Director, National Child and Maternal Health Intelligence Network, OHID and a senior trialist (Prof Simon Coulton), two LA NCMP leads (Scott Lloyd and one other – to be determined) and two parent members to be drawn from the Parent Involvement Panel (PIP) and applicants Prof Adamson and Prof Matthews. Prof Adab will chair the TSC.

In the first instance the TSC will also act as the Data Monitoring Committee (DMC) and will ensure the research is completed rigorously and to time. A separate DMC will be established if recommended by the TSC. Terms of reference will be agreed. Meetings will be up to quarterly with the first meeting to be convened during Work Package (WP) 1 of the study and prior to the start of the trial and annually thereafter timed to coincide with critical study stages; these meetings will be held in Newcastle. Ad hoc meetings will be called at the request of either the Chair of the TSC or PI (AA) if need arises; these meetings will be by teleconference. TSC meetings will be minuted with specified action points, timelines and persons responsible identified.

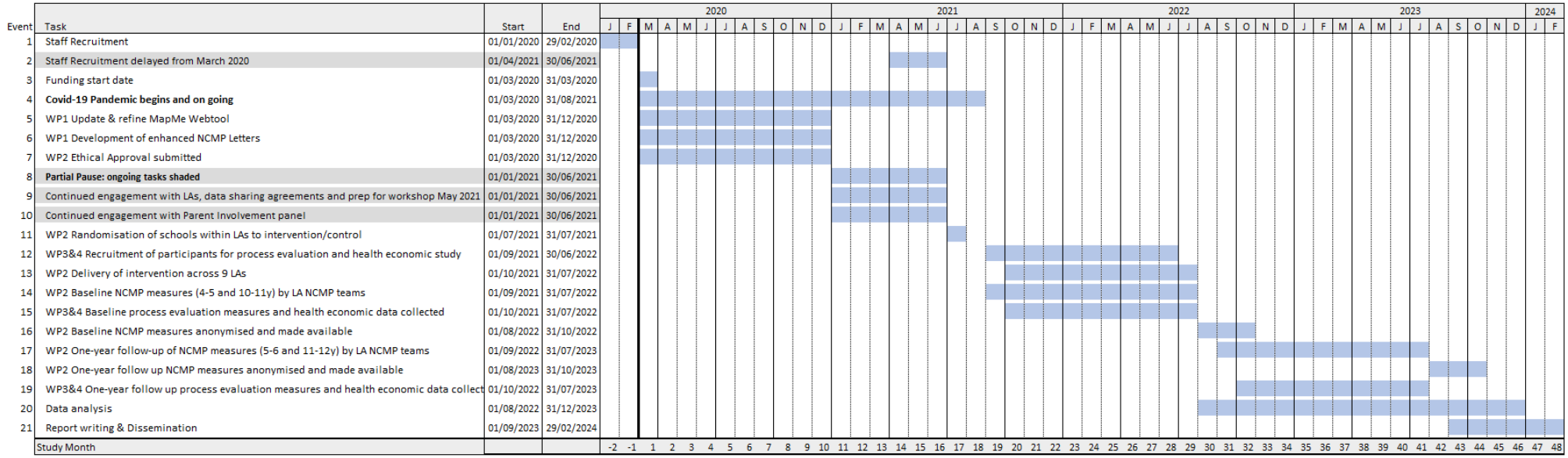
Public Involvement: A PIP will also be convened. The PIP will consist of parents of primary school aged children who will be involved throughout the research cycle, attending TSC/DMC meetings, providing input into the direction of the study, refining methods of data collection, and informing dissemination. All public involvement activities will be facilitated by a Patient and Public Involvement (PPI) co-ordinator and will be evaluated, in conjunction with members of the PIP, to understand what has worked well and what could have been improved and the impact of the activities on the study. All PIP members will receive training to enable them to be involved in the PPI activities.

Protocol contributors

The CI, with the wider support of the Co-investigators conceived and designed the study and drafted the original study protocol. PPI work has also contributed to the development of the protocol, as described in section 8. The study protocol has undergone multiple rounds of expert peer review as part of the funding process.

Key Words	Child*, Overweight*, Obesity* Public Health Intervention, National Child Measurement Programme, MapMe *MESH terms

Project Plan Project Reference Number NIHR127745

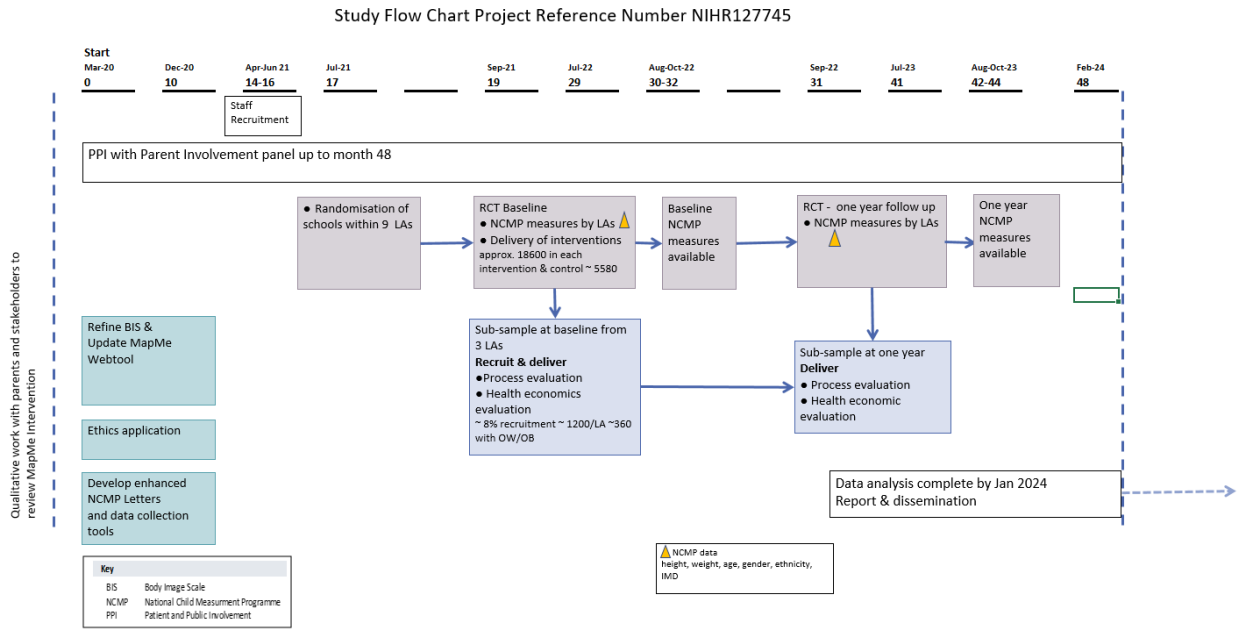


Event	Task	Start	End
1	Staff Recruitment	01/01/2020	29/02/2020
2	Staff Recruitment delayed from March 2020	01/04/2021	30/06/2021
3	Funding start date	01/03/2020	31/03/2020
4	**Covid-19 Pandemic begins and on going**	01/03/2020	31/08/2021
5	WP1 Update & refine MapMe Webtool	01/03/2020	31/12/2020
6	WP1 Development of enhanced NCMP Letters	01/03/2020	31/12/2020
7	WP2 Ethical Approval submitted	01/03/2020	31/12/2020
8	**Partial Pause: ongoing tasks shaded**	01/01/2021	30/06/2021
9	Continued engagement with LAs, data sharing agreements and prep for workshop May 2021	01/01/2021	30/06/2021
10	Continued engagement with Parent Involvement panel	01/01/2021	30/06/2021
11	WP2 Randomisation of schools within LAs to intervention/control	01/07/2021	31/07/2021
12	WP3&4 Recruitment of participants for process evaluation and health economic study	01/09/2021	30/06/2022
13	WP2 Delivery of intervention across 9 LAs	01/10/2021	31/07/2022
14	WP2 Baseline NCMP measures (4-5 and 10-11y) by LA NCMP teams	01/09/2021	31/07/2022
15	WP3&4 Baseline process evaluation measures and health economic data collected	01/10/2021	31/07/2022
16	WP2 Baseline NCMP measures anonymised and made available	01/08/2022	31/10/2022
17	WP2 One-year follow-up of NCMP measures (5-6 and 11-12y) by LA NCMP teams	01/09/2022	31/07/2023
18	WP2 One-year follow up NCMP measures anonymised and made available	01/08/2023	31/10/2023
19	WP3&4 One-year follow up process evaluation measures and health economic data collect	01/10/2022	31/07/2023
20	Data analysis	01/08/2022	31/12/2023
21	Report writing & Dissemination	01/09/2023	29/02/2024

The full study revised in the light of Covid-19 is 48mths duration. Work to update the MapMe intervention will be now be completed by month 10. The impact of the interventions on child weight outcomes, health related behaviours, parental perceptions of child weight status and health inequalities in childhood OW/OB at one year follow up will be known by month 45. The process and acceptability evaluations will be collected during months 19-40 and analysis completed by month 46. The health economic evaluation data will be collected during months 19-40 and analysis completed by month 46.

The full study duration is 48 months. Work to update the MapMe intervention was completed September 2021. The impact of the interventions on child weight outcomes, health related behaviours, parental perceptions of child weight status and health inequalities in childhood OW/OB at one year follow up will be known by month 44. The process and acceptability evaluations will be collected during months 20-41 and analysis completed by month 46. The health economic evaluation data will be collected during months 20-41 and analysis completed by month 46.

Study Flow Chart Project Reference Number NIHR127745



Study Protocol

Can embedding the MapMe intervention, a tool to improve parental acknowledgement and understanding of childhood overweight and obesity, in the National Child Measurement Programme lead to improved child weight outcomes at one year?

Short Title: The MapMe Study

1. Background and Scientific Rationale

Childhood obesity (OB) is both a national and international public health priority, with the prevalence of OB in the young increasing globally (1-4). Data from the National Child Measurement Programme (NCMP; a national mandated programme led by Public Health England (PHE), delivered by Local Authorities (LAs) and costing an estimated £20.6 million annually) shows that currently, 22% of children in England enter primary school at the age of 4-5 years with either overweight (OW) or OB with prevalence increasing to 34% in those children aged 10-11 years, in their final year of primary education (5). Furthermore, there is a strong relationship between deprivation and OB; its prevalence has been found to be over twice as high in the most deprived areas compared to the least deprived areas. In addition, an increase in the deprivation gap for OB has been observed between 2006/07, when annual monitoring of primary school aged children nationally began, and 2017/18 when the latest phase of monitoring was conducted, particularly for those children in the older age group (5).

The prevalence of childhood OW/OB and the evidence of widening inequalities is alarming as having OW/OB during childhood can adversely impact both short- and long-term physical and psychosocial outcomes since excess weight is known to track across the life course (1, 6, 7). There is also concerning evidence of disparities and lack of long term efficacy in current service provision (8-10) for tackling this important public health problem.

The Government are committed to addressing current trends in childhood OB and the recent chapter of the childhood OB plan has set the ambitious and long-term goal “to halve childhood OB and significantly reduce the gap in OB between children from the most and least deprived areas by 2030” (11). PHE are also ambitious with their goal “for people of this country to live as well as possible, for as long as possible” (12) but acknowledge that, based on current trends, this will not be realised due to the epidemic of largely preventable long-term diseases that the nation faces. The PHE strategy ‘From evidence to action’ puts prevention and early intervention at the heart of the nation’s health agenda, and accepts that there is a need to identify methods to reduce major risks such as OB (12). Therefore, successful early interventions for the prevention and management of childhood OW/OB that can be delivered at scale are urgently required. Research to address childhood OB is a priority for the public. This was confirmed from discussions with the Public Involvement Consumer Panel of the NIHR Research Design Service North East (NIHR RDS NE) whilst developing this proposal. This study, is aligned with PHE’s vision for interventions at scale and patient and public involvement (PPI) views for tackling OB in childhood, and will generate evidence of the impact of a novel intervention aiming to support families to maintain long term healthy weight in their children.

It is widely recognised that childhood OB is a complex issue with numerous drivers which makes addressing the problem particularly challenging (11). A recent report for the Commission of Ending Childhood Obesity (ECHO) acknowledged that no single intervention can halt the OB epidemic and a multidimensional approach is required (13). One area for action highlighted by this report is tackling the obesogenic environment and social norms; such norms influence the perception of healthy or desirable body weight, especially in the young, and in some instances add to the perpetuation of the obesogenic environment (13).

A wealth of data examining parents’ perceptions of child body weight exists and shows that parents typically do not correctly categorise their child with OW/OB (14-16). However, parents are critical in

tackling childhood OB since they play a key role in the shaping and maintenance of their child's health related behaviours, and in the case of children with OW/OB, seeking and accepting appropriate support for child weight management (15). Monitoring of child growth and identification of children with OW/OB is typically completed by health professionals using age- and sex-specific growth charts (17). Parents themselves, however, determine child weight status using visual assessments and comparisons with other children (who may be OW/OB) rather than relying on more objective measures (18-20). It has also been suggested that *without recognition* of childhood OW/OB, parents are *unlikely to take appropriate action* to change their child's dietary and/or physical activity behaviours, *or seek support* to address their child's weight status (21).

Few studies have directly examined how parental recognition of childhood OW can be improved, and crucially whether improved recognition leads to long term positive child weight outcomes (22-24). Those which have attempted to improve parental accuracy in perception of their child's weight status have tended to use educational interventions. In one such study, no impact on parental perceptions were observed and long term weight outcomes were not examined (24). In another, improved parental ability to identify childhood OB was observed but achieved via an intensive intervention unsuitable for implementation at a population level and child weight outcomes post intervention were not examined (22). Other work has also improved the percentage of parents accurately assessing their child's OW status but examination of impact on weight changes was limited due to the short term (3 months) follow up (23).

Directly informing parents of their child's weight status could be a possible solution to this issue and prompt parental action. The NCMP does this by annually measuring all 4-5 and 10-11 year-old children in state-maintained English schools (except children who are actively withdrawn from the measurement process by their parents), and providing parents with the results. A *pre-measurement letter* is sent to all parents informing them that their child will be measured and offering an opportunity to opt-out. Every year, more than one million children are measured, annual participation rates are consistently high (around 95%) with over 99% of eligible schools (approx. 17,000 schools) taking part (25). Feedback to parents is not mandatory but approximately 70% of all parents whose children are involved in the NCMP are routinely informed of their child's weight status by a *standard feedback letter*. However, parents often respond with shock and disbelief upon receipt of these letters (26) and our PPI activities have highlighted the stigma associated with OW/OB and the need for support for parents. As well as disbelief in the results in the letter a significant barrier to parental engagement with NCMP feedback is the misapprehension that weight management efforts reduce children's self-esteem and increase eating disorder risk (27). Contrary to this, a previous study showed children's self-esteem and levels of teasing or marginalisation to be unaffected by parental receipt of enhanced NCMP feedback (28) and research indicates that eating disorder symptoms in children with OB are reduced in evidence-based weight management programmes (29, 30). Indeed, untreated OB in childhood is itself associated with unhealthy weight control behaviours and eating pathology (31, 32), underscoring the importance of early, evidence-based, supportive interventions.

Further, the prevalence of childhood OW and OB at a population level has not fallen since the introduction of NCMP feedback letters (5) suggesting that simply informing parents that their child has OW/OB is not sufficient to prompt effective action. The use of alternative methods to discuss children's growth (33) and development with parents may therefore have the potential for success in tackling the issue. For this reason, there is a need to evaluate interventions promoting parental acknowledgment of their child's weight status, built around the evidence on how *parents* determine child weight status, and supporting parents to take action. In response to this need we have developed the 'MapMe' intervention. MapMe is a non-NHS public health intervention that includes Body Image Scales (BIS, visual images of child body shapes of different sizes) of known weight status for 4-5 and 10-11 year old children based on the same British growth reference clinical thresholds that are used by the NCMP to inform parents of their child's weight status (34). The BIS are designed to tap into the visual methods by which parents determine OW/OB in children, to help them understand what a child with OW/OB looks like and support them to prevent or address unhealthy weight gain in their child. MapMe

also provides information on the consequences of childhood OW and provides brief advice on healthy eating, physical activity and links to sources of further support to prompt parental action and promote positive family-based approaches focused on lifestyle rather than weight (27).

We have previously completed small scale testing of the MapMe intervention in paper-and web-based formats, and examined its impact on parental perceptions of childhood OW and longer term child weight outcomes (35). MapMe was associated with positive weight outcomes in children with OW/OB one year post intervention (n=338), difference in body mass index (BMI) Z score change between the intervention and control groups of -0.11 (95%CI -0.202 to -0.020 p=0.017) (36, 37), although it was *not* found to be associated with evident improvement in parental categorisation of child OW. This difference in BMI Z score change compares favourably to a recent review of treatment trials in 6-11 year olds (70 randomised control trials (RCT), BMI Z score change -0.06, p=0.001 (8)). These encouraging findings, though limited by small sample size, are contrary to the rationale that in order to improve child weight outcomes, parental perceptions of child OW/OB must be improved, and suggest that parents acted to achieve a healthy weight in their child without evident changes in their ability to correctly categorise their child's weight status. A possible explanation for this could be related to the widely used method for measuring parental identification of child weight status – that is by asking parents to 'label' their child's weight status. Previous work has suggested that parents may be reluctant to 'label' their child as OW/OB, possibly due to the stigma associated with these terms, but they may be aware of their child's body size since studies using images instead of 'labels' have found a higher percentage of OW children being identified as such (16, 38, 39). Parents of children with OW/OB provided with the MapMe intervention may have been aware of their child's body size, but unwilling to 'label' them as 'OW' but, via the MapMe intervention, were able to acknowledge their child's weight status and take remedial action. Observational evidence is also beginning to emerge to suggest that accurate parental perceptions of their child's OW status are not associated with better subsequent weight outcomes, and in some instances were linked to more negative outcomes (40-43). Our previous small scale testing of the MapMe intervention and these more recent findings support the suggestion above that there is a need for further work to examine how parental *acknowledgement* of child weight status and subsequent health related behaviour, rather than their reported *perception*, can be improved. Moreover, parental concerns about negative effects (27) of NCMP parental feedback on children's self-esteem and eating disorder symptoms (28) – combined with a limited amount of evidence which, on the contrary, suggests possible benefits in these areas mean that child-reported measures of psychological wellbeing should also be taken.

Our previous study was facilitated by access to participant NCMP measures at baseline but was not conducted within the NCMP and relied on parental opt-in consent for access to measures. The proposed research is embedded within the NCMP which operates on the basis of parental opt-out consent. The study will address the needs described above, evaluating the impact of including the MapMe intervention within the NCMP letters sent to parents on child weight outcomes at one year, with potential for longer term follow up, compared with the standard NCMP process. It will also determine the acceptability, cost effectiveness and wider impacts of the intervention including equity and inequalities in childhood OW/OB. This study will provide much needed new data on how parental *acknowledgement* (rather than *perception*) of their child's weight status and subsequent remedial action can be improved. As economic evaluations of child OB prevention and management interventions are currently limited to generic tools to inform cost-utility-analyses (44, 45), this will be the first study to assess weight-specific outcomes of importance based on the views of UK based young people, by way of the implementation of a novel tool, the Weight-Specific Adolescent Instrument for Economic Evaluation (WAItE) tool (46) (validated for self-completion by children from age 10 years). Moreover, the derivation of an algorithm to calculate weight-specific utilities will enable a comparative assessment between generic and weight-specific outcomes in the context of cost-utility analysis.

The novel approach proposed in this study could support both the prevention and management of childhood OB thus preventing poor physical and psychosocial health and reducing avoidable morbidity

and mortality in later life. This research could also improve the current NCMP, reduce the burden on weight management services, and decrease costs to the health service and wider society, by providing a practical, scalable intervention that is accessible to all, thus potentially reducing health inequalities. Finally, it could provide much needed data on the effects of enhanced NCMP feedback on psychological outcomes about which parents may be concerned i.e. children's self-esteem and eating disorder risk.

This proposal has been developed in collaboration with policy makers in childhood OB and NCMP delivery, and it has been designed to address the questions that they need to be answered for future planning and enhancement of the NCMP. Colleagues at OHID are co-investigators and the National Lead for the Life Course at OHID will join our Trial Steering Committee (TSC). PPI representatives have been involved in the development of the application, and both LA NCMP delivery teams and members of the public will be involved in the further refinement and evaluation of the intervention, and will be represented on our TSC.

2. Research Questions, Aims and Objectives

Key Research Question: Can embedding the MapMe intervention, a tool to improve parental acknowledgement and understanding of childhood OW and OB, in NCMP letters lead to improved child weight outcomes at one year and is it cost-effective?

Aims:

1: To review and update the MapMe intervention (WP1)

2: To assess the impact of enhanced NCMP letters including the MapMe intervention on child weight outcomes at one year (WP2)

3: To examine the context and potential mechanisms of action of the MapMe intervention including unanticipated pathways and consequences (WP3&4)

4: To explore intervention implementation and the acceptability of the enhanced NCMP letters and potential for adoption into usual practice (WP3&4)

5: To assess the impact of the enhanced NCMP letters on health inequalities and by ethnicity (WP2)

6: To assess the impact of the enhanced NCMP letters on child-reported psychological outcomes (WP4)

7: To examine the cost implications/benefits and cost-effectiveness of the enhanced NCMP letters and any additional cost implications/benefits and cost-effectiveness of reinforcement at 6months (WP5)

Objectives:

a: To use qualitative data (collected with support from Newcastle University and completed *prior* to this study) from parents and other key stakeholders on their views of the MapMe intervention and use it to inform intervention refinement, prepare the enhanced NCMP letters and methods for data collection (WP1);

b: To complete a 3 arm cluster randomised controlled effectiveness and implementation trial of an enhanced NCMP letter (intervention 1), enhanced NCMP letter plus a 6 month 'booster' reinforcement (intervention 2) vs the standard letter (control) to test the impact of inclusion of the MapMe intervention on BMI Z score change at one year (WP2);

c: To collect information on deprivation, ethnicity and geography to assess impact on inequalities (WP2).

d: To complete a process evaluation, linked to the intervention logic model (Appendix 1) and 'dark' logic model (Appendix 2), and developed with input from the NCMP team at PHE, LAs and PPI panel to explore key questions relating to the mechanisms of action, context, and implementation of the intervention and, to undertake this collecting both qualitative and quantitative measures from key stakeholders (WP3);

e: To complete a process evaluation, linked to the intervention logic model and 'dark' logic model, and developed with input from the NCMP team at PHE, LAs and PPI panel to explore key questions relating to the mechanism of impact by collecting both qualitative and quantitative measures from parents and children (WP4);

f: To collect data on the flow of participants including numbers recruited and numbers engaged in the intervention (with a focus on the web based tool for which we will have user data); numbers completing; numbers of participants at each time of measurement; reasons for drop out; social patterning in terms of engagement with the interventions; details on any unexpected outcomes or adverse events; participants satisfaction with the intervention; plans for the sustainability of the intervention (WP3&4);

g: As part of the process evaluation to collect data on parents' perceptions of child weight status, changes in help seeking activity, child food intake and physical activity (WP4&5)

h: To collect data on child-reported psychological outcomes (self-esteem and eating disorder risk) (WP4).

i: To collect data on child quality of life (QoL) and use of NHS/LA funded services, out of pocket expenses and estimate a weight specific algorithm for the WAItE, for the economic evaluation (WP5).

2.1 Questions to be answered during the project:

1: What is the impact of the enhanced NCMP letter including the MapMe intervention (delivered using two different approaches) on child weight outcomes at 1 year?

2: What is the impact of the enhanced NCMP letter including the MapMe intervention delivered using two different approaches) on health inequalities?

3: Is there any difference in the impact of the enhanced NCMP letters including the MapMe intervention (delivered using two different approaches) by ethnicity?

4: How successful was intervention implementation and what is the acceptability of the enhanced NCMP letters and potential for adoption into usual practice?

5: What are the contextual and implementation factors associated with the effectiveness of the MapMe intervention?

6: What are the unintended pathways and consequences, if any?

7: If effective, what are the mechanisms of impact of the MapMe intervention?

8: What is the participant's response to, and interactions with the enhanced NCMP letters?

9: What is the impact of the enhanced NCMP letters on child-reported psychological outcomes?

10: What are the cost implications and benefits and cost-effectiveness of the enhanced NCMP letters?

11: Do the benefits associated with child QoL outcomes differ when generic and weight-specific outcome measures are used to inform Quality Adjusted Life Year (QALY) calculations used in the cost-effectiveness analysis?

3. Research Plan and Methods

We will conduct a multicomponent and complex mixed-methods programme of work in four interconnected work packages addressing the research questions set out above.

3.1 Work Package 1: Refining the MapMe intervention and developing enhanced NCMP letters and data collection methods

(*Months 1-6*) Tovée, Araujo Soares, Arnott, Jones, Evans, Ells, Sollars and Gahagan

Objective to be achieved:

a: To use qualitative data (collected with support from Newcastle University and completed *prior* to this study) from parents and other key stakeholders on their views of the MapMe intervention and use it to inform intervention refinement, prepare the enhanced NCMP letters and methods for data collection.

During 2019, and before the start of the funding requested, we will build on our work to date and extend the process of understanding where the MapMe intervention can be optimised and refined. The current BIS and MapMe website was developed in 2014 in partnership with NHS Choices (now NHS.UK) and links to now out-of-date resources. Updated resources will be identified. Qualitative work with parents and other key stakeholders (PHE, NCMP local teams and those involved in the delivery of weight management services) will be completed and the results used in this WP to refine the intervention.

The aim of this WP will be to optimise the MapMe intervention and create the enhanced NCMP letters for the intervention to be embedded into the NCMP in 9 LAs and to develop methods for data collection. This will be achieved by application of new technology to improve the presentation of the BIS, and by collecting views on the improved BIS and on how the previous MapMe intervention should be refined and improved. These findings will be used to inform the final design of the BIS and the enhanced NCMP letters to be used in the two different approaches of delivery of the intervention, and further to inform the development and delivery of the evaluation including design of questionnaire and other data collection instruments.

3.1.1 Refining and Improving the BIS:

In the first 6 months of this study Co-Investigator Tovée will lead on updating and refining the BIS. The BIS is based on 3D scans of 388 children. In these scans, the children, boys and girls aged 4-5 and 10-11 years, differed in height and shape and so the raw scans were processed to bring all the corresponding body features into a register by age and sex. Bodies within specific BMI ranges were then averaged to create representative exemplars of each BMI category (34). In this process, some of the finer 3D detail of the bodies was lost. The software techniques used to carry out this feature registration and averaging have substantially improved, and we will reprocess the original raw scans to produce new higher-resolution and more accurate versions of the averaged bodies. Additionally, in the original creation of the MapMe BIS, these averaged bodies were imported into a 3D modelling programme and their size and shape duplicated using realistic 3D body models with simulated hair, skin and clothes. This duplication process can also lead to a loss of fine detail in the body's shape. However, we can now add the hair and skins directly onto the averaged bodies, and the improved quality of the hair and skin (which are now based on high-resolution photographs of real hair and skin) produces an extremely realistic final body.

In the current BIS, the images are presented both in front-view and in profile. We will simplify the BIS to one scale, presenting the images at the optimal angle of 45° (47), capturing visual cues to body weight from both the front-profile-view cues and representing a more ecologically valid, naturalistic view. The refined BIS will be subject to review by PPI representatives and refined further before being

provided to NHS Choices (now NHS.UK) who will embed them into the web-based MapMe intervention (Antbits working with NHS.UK).

3.1.2. Refining and Improving the web-based MapMe intervention:

As described above, the web-based MapMe intervention shows parents the BIS and asks parents to choose the image most resembling their child; they then enter a pathway designed to facilitate acknowledgment of their child's weight status and appropriate action. They receive information on the potential future weight status of their child (based on their current weight category) and information about health risks of child OW, tapping into parental concerns about future OW in their child (20) and raising awareness of potential health consequences (see logic model, Appendix 1). Information is also included to support parents to take action, to prevent, or address unhealthy weight gain in their child. The MapMe website was designed in 2014 with NHS Choices (now NHS.UK) with extensive input from health professionals with experience in childhood OB and parents. Given this tool was part of an intervention which has shown evidence of efficacy we do not propose to make fundamental changes but rather to update and refresh this website. Working again with NHS.UK the web-based MapMe intervention will be updated to link to up-to-date information and resources, and reviewed to ensure optimisation of motivational and volitional materials for goal setting, prompt practice, action planning and coping planning (48, 49) and compliance with the logic model. This will be completed with input from stakeholders and our PIP (48, 49).

The web-based intervention incorporating the BIS will also be made suitable for use on tablets and mobiles with enhanced analytics and reporting dashboard added to capture usage and user journeys on all platforms which will be used to measure intervention 'dose' as part of fidelity (WP3).

3.1.3 Creating the enhanced NCMP letters:

The enhanced NCMP letters to be used in each of the two new interventions to be tested will be co-produced with the NCMP team and parents. We will draw on PPI work which has been conducted in preparation for this proposal and seek further input from our PIP.

3.1.4 Preparation of the process evaluation and data collection materials:

Finally, in this WP, through conversations with stakeholders and our PIP, the process evaluation questions tailored to the logic model and instruments and methods of data collection will be finalised.

3.2 Work Package 2: A 3-arm cluster randomised controlled effectiveness and implementation trial of 2 enhanced NCMP letters vs the standard letter with follow up at one year

(Months 7- 32) Adamson, Ells, Matthews, Jones, Sollars and Gahagan

This trial will use the outputs from WP1 to test the effectiveness of the MapMe intervention embedded within the NCMP letter and will compare the change, over one year, in child BMI Z score in the control condition with each of two new approaches (interventions).

Objectives to be achieved:

b: To complete a 3-arm cluster randomised controlled effectiveness and implementation trial of 2 enhanced NCMP letters (intervention) vs the standard letter (control) to test the impact of inclusion of the MapMe intervention on BMI Z score change at one year;

c: To collect information on deprivation, ethnicity and geography to assess impact on inequalities.

Addressing questions:

1: What is the impact of the enhanced NCMP letters including the MapMe intervention (delivered using two different approaches) on child weight outcomes at one year?

2: What is the impact of the enhanced NCMP letters including the MapMe intervention (delivered using two different approaches) on health inequalities?

3: Is there any difference in the impact of the enhanced NCMP letters including the MapMe intervention (delivered using two different approaches) by ethnicity?

3.2.1 PICOST:

POPULATION: Parents of children aged 4-5 and 10-11 years, participating in the NCMP.

INTERVENTIONS: The MapMe intervention includes BIS of known weight status for 4-5 and 10-11 year old children based on the same British growth reference clinical thresholds that are used by the NCMP to inform parents of their child's weight status (34). The BIS are designed to tap into the visual methods by which parents determine OW in children, to help them understand what a child with OW/OB looks like. The web-based format of MapMe shows parents the BIS and asks them to choose the image most resembling their child. Parents then enter their child's height and weight (both provided in the NCMP letter), sex and date of birth (DOB); they are then shown the 3D image and weight status that matches that data, thus facilitating parental acknowledgment of weight status. Parents are also shown a 3D image of an adult in the same weight category as their child's current category and given information about health risks of childhood OW, tapping into parental concerns of future OW in their child (20) and raising awareness of potential health consequences. Information is included to support parents to prevent or address unhealthy weight gain in their child including brief advice on healthy eating, physical activity and signposts to sources of information and professional support, which include motivational and volitional materials for goal setting, practice, action and coping planning in family-based dietary and physical activity changes (48, 49), positive family approaches focused on lifestyle rather than weight (48, 49) and positive family discussions focused on lifestyle rather than weight (27).

*We will test **two trial interventions** of increasing complexity and with full consideration of TIDiER checklist (50)*

a) **Post-measurement intervention**: parents receive the standard NCMP pre-measurement letter, then the standard post-measurement NCMP letter ***and*** the paper-based MapMe BIS (age- and sex-specific computer-generated colour images of children of different, labelled weight statuses) (34). The images aim to re-calibrate parents' weight status decision boundaries, countering the effects of visual normalisation of childhood OW (51) and perceptual biases (52) in weight status decisions, ***and*** a link to the MapMe website.

b) **Post-measurement intervention with 6-month 'booster' reinforcement**: this is identical to (a) except parents receive a 'booster' letter 6 months after the initial intervention with a reminder of the link to the MapMe website, prompting parents to continue to monitor their child's weight status.

COMPARATOR: Standard pre- and post-measurement letters (Control Intervention).

Those families receiving the usual delivery of the NCMP, that is, standard NCMP pre- and post-measurement letters only, will serve as the control condition. These families will be informed in the usual way that their child will be measured during the current academic year and provided with the option to withdraw their child from the measurement process. Following measurement completion

parents will be informed of their child's measurements and their weight status, and will then be sign-posted to the standard care as appropriate to the child's weight status as offered within their LA.

In all conditions the standard pre-measurement letter will include additional information informing parents that their child is part of a study and will be measured again one year later and, for parents of 4-5 year-old children only, the request for access to their child's result from routine NCMP measurement 6 years later when their child is age 10-11 years. As part of General Data Protection Regulations (GDPR)/ data protection act the pre-measurement letter will clearly explain the intended uses of the data. The current specimen NCMP pre-measurement letter does this for the standard NCMP and will include additional information on uses of the data and data flow specific to the trial.

OUTCOMES: *Primary outcome*: Child BMI Z score change at one year follow up.

Secondary outcomes: Child BMI Z score change at one year follow up by Index of Multiple Deprivation (IMD), by ethnicity.

Further secondary outcomes will be addressed in WP3 (process evaluation including fidelity of delivery of the intervention), WP4 (mechanism of action) and in WP5 (health economic evaluation).

SETTING: State maintained English primary schools in 9 LAs.
TIMING: Baseline (before the intervention) and one year later when children are aged 5-6 and 11-12 years.

As the effects of the treatments may be different at different ages the groups will be analysed separately. This will be a cluster-randomised study with schools as clusters because it is not feasible to allocate children at a school to different treatments. The sample-size calculations reported below indicate that schools from nine LAs will be needed. With three interventions (two trial interventions and the standard (control) intervention) there are three pairs of interventions, and each pair will be randomly allocated to three of the LAs. This allows differences between LAs to be eliminated from estimates of the intervention effects. Allocating just one intervention to all schools in a LA would confound treatment differences with LA differences, while allocating more than two treatments to each LA would be administratively too onerous.

3.2.2 Recruitment and consent:

Parents will be recruited via the NCMP pre-measurement letter, which informs parents that their child will be measured and includes an opportunity to withdraw their child. PHE have confirmed that NCMP regulations and the general health improvement duty placed on LAs permit the trial to operate under these legislations as long as parents are given reasonable opportunity to withdraw their child from participation should they wish to. NCMP measurement procedures will take place as usual, with the appropriate letters being sent within each LA according to the requirements of the trial arms to which the LA is randomised. After one year local teams will re-measure the children's height and weight under the same conditions. Anonymised data (child height, weight (BMI), age, sex, ethnicity, individual and school level IMD) will be provided to the research team, with data linkage completed by pseudo-anonymization by Study ID.

3.2.3 Setting/context:

As above: the sample-size calculations given below indicate that schools from nine LAs will be needed. With three interventions (two trial interventions and one standard control intervention) there are three pairs of interventions, and each pair will be randomly allocated to three of the LAs. Ten socio-economically diverse LAs with a combined NCMP population of 60 000 have agreed to collaborate in this study giving approx. 18600 children in each of the three intervention arms. The LAs are: County Durham, South Tyneside, Isle of Wight, Middlesbrough with Redcar and Cleveland (South Tees), Newcastle upon Tyne, North Tyneside, Stoke-on-Trent, Sefton, Devon, Coventry.

Middlesbrough and Redcar & Cleveland have a combined public health team so will be classed as one LA (South Tees) in the design.

3.2.4 Study population:

Set within the context of the NCMP this study will involve all the families of 4-5 and 10-11 year olds living in the LAs whose children are participating in the NCMP measures (at least 95% of those eligible). The LAs vary in size of NCMP population, being between 2637 and 11177 in the current year, with approx. equal split between 4-5 and 10-11 years: County Durham 11177; Newcastle upon Tyne 6181; North Tyneside 4679; Isle of Wight 2637; South Tees 7227; Coventry 9137; Devon 2819; Sefton 6059; South Tyneside 3438; Stoke-on-Trent 6258. Over 900 primary schools will be involved in the study. All LAs include the full range of deciles of IMD with exception of Isle of Wight (1-9 only); where 1 is the most deprived. Ethnicity of total population varies from 1.5% (Redcar and Cleveland) to 36% (Coventry) with an average of 12%; ethnicity of NCMP in these areas is anticipated to broadly reflect total population.

3.2.5 Sampling:

The primary aim is to assess the impact of the interventions on children who are OW/OB at the start of the study. Therefore, the outcome for the primary analysis is the change in BMI Z-score over 12 months in children with a baseline BMI larger than the 91st centile, and it is this analysis which is used to determine the power of the study. The measured BMIs are transformed to Z-scores based on LMS curves derived from children measured (53). Given that the prevalence of OW/OB has increased since then the children who will be recruited to the study have a higher average BMI, so the Z-scores no longer have mean 0, although data collected in our preliminary study (37) indicated that they still had variance close to 1 and followed a Normal distribution. The same data suggested that the mean baseline Z-score would be 0.65 for the 4-5 year age group and 1.01 in the 10-11 year age group.

3.2.6 Simulation study:

The power of the proposed study was estimated by simulation as follows. Children in a school will be measured twice, at entry to the study and after 12 months, so if there are n children in a school there will be $2n$ measurements. There will be a strong correlation, R, between the n pairs of measurements made on the same child, and a smaller correlation, r, between the other $\frac{1}{2}n(n-1)$ pairs. The preliminary data suggested a value of R between 0.85 and 0.92. A likelihood analysis gave a 95% confidence interval for r as (0.03, 0.11). For many cluster-randomised trials r would have a value in the range 0.02-0.1, with larger r being associated with lower power, so it is reasonably conservative to assume r=0.1. The statistical programming language R was used to simulate the $2n$ values from a school, assuming a bivariate Normal distribution, with the above correlation structure and with unit variance for each observation. The baseline mean Z-score was taken to be 0.65 (that for the 4-5 year age group): the 12-month mean was determined by the assumed treatment effect. A model which closely approximated the LAs to be recruited assumed that Schools had one-form (30 children) or two-forms (60 children) per school year: values of n=24 or 48 were assumed to allow for absent or non-consenting pupils. The LAs provided data which allowed the number of one and two form entry schools to be determined.

For each school in the simulation the mean change in BMI Z-score was computed for children with baseline Z-scores exceeding 1.33. The means were then analysed using a linear model with fixed categorical effects for LA and for intervention and the P-value for the contrast between the effect of the standard intervention and each of the other two interventions was computed. A two-sided 5% Type I error rate was assumed, so the power was estimated by the proportion of the 5000 simulated P-values which were less than 0.05.

Size of Intervention Effect:

The mean change in Z-score for all children, irrespective of their baseline Z-score, is denoted by *F-B*, where *F*, *B* are the final and baseline Z-scores. The mean change among the children initially OW/OB is *F-B-f(B)*, where *f(B)* is a function of *B alone*, which allows for the selection effect. Therefore, the difference in mean change between interventions is the same whether all children or just OW/OB children are considered (because the baselines are the same and so *f(B)* cancels).

The study aims to have adequate power to detect a difference between interventions of 0.1 in the mean change in BMI Z-score. This change in BMI Z-score has been chosen to reflect a significant change in the context of 0.06 observed in the Cochrane review of interventions for the treatment of overweight or obese children (8) and the findings of our previous study which demonstrated a difference in change of 0.111 (CI -0.202 to -0.020, P=0.017).

Results and sensitivity:

The power estimation was performed assuming that the study seeks a difference of 0.1 between the standard intervention and either of the new interventions, in the mean change of BMI Z-score over 12 months. The correlation *R* was taken as 0.75, *r*=0.1 and the baseline mean BMI Z-score was 0.65: this gives a power of 0.85. The powers increase when the baseline mean increases to 1.01 (that of the 10-11 year olds), so the study will have adequate power in both age groups. The power increases as the correlation *R* increases: the value of *R*=0.75 was chosen to so that the calculation was conservative.

3.2.7 Methods for data collection:

To assess child BMI Z score change objective measures of child height and weight will be made within the NCMP at baseline. These measures are made by trained staff employed, or commissioned, by each LA and following the standard protocols of the NCMP. The NCMP IT system is managed by NHS Digital, consisting of an online browser-based system, plus an offline Excel spreadsheet-based tool for data entry. The system incorporates validation at the point of data entry and provides a secure environment according to NHS standards in which pupil identifiable records can be processed and stored. Data includes child's name, sex, DOB, home address and postcode, ethnicity (Asian or Asian British, black or black British, Mixed, Chinese or any other ethnic group) and NHS number. Follow up measures will be made at 12 months by the same teams following the same standard protocols. Data entry and validation will also follow standard protocols of NCMP as at baseline measure (25). NCMP measurements are collected in the school years between Sept to July (Months 7 to 17 and Months 19 to 29 for follow-up). The initial validation of the dataset is completed by NHS Digital in August (Month 18 and Month 28) and made available to LA's to download in September (Month 20 and Month 32). Study LAs will complete data matching/linking using the NCMP enhanced data sets as given in the analytical protocol in PHE publication to create unique identifier and remove data fields in order to share pseudo anonymised data with Newcastle for data analysis (as per data sharing agreement) (54).

3.2.8 Data & Statistical analysis:

The principal analysis will consider the change in individual Z-scores among children initially OW/OB. The analysis will fit a linear mixed effects model, assuming Normally distributed random effects. The clustering in schools will be allowed for by including a random school effect, and a fixed LA effect will be included to ensure differences between LAs are eliminated. A fixed treatment effect will be included and the contrasts between each of the two trial interventions and the standard intervention (control) will be estimated. The fit of the model will be assessed using standard model diagnostics. A sensitivity analysis will allow for the selection of OW/OB children by fitting a skew-normal model (55). A secondary analysis will apply the above model to data from all children, not just those initially OW/OB.

The study also provides the opportunity to assess whether the size of the intervention effect varies with measures of deprivation and so leads to any adverse or beneficial effect of the intervention on inequalities. To this end two further analyses will be conducted, in which the model will be extended to include a measure of deprivation (IMD derived from postcode within NCMP and provided in the anonymised data), and the interaction between this measure and the intervention effects. One of these analyses will include all children, while the other will only include those initially OW/OB. The possibility that the interventions will have different effects on those of different ethnicities will also be assessed, by using a model which includes a factor for ethnicity and its interaction with the interventions. It should be kept in mind that the power of the study is based on the main effect of the interventions and assessment of interactions will necessarily be exploratory.

It is quite possible that in this study missing data may be a source of noticeable bias. The effect of missing data will be assessed by repeating the above analyses using inverse probability weighting. This exercise will focus on those children with baseline but not follow-up BMIs. The weights will be estimated by fitting a logistic model to quantify the chance that a child is missing at follow-up given baseline data. The 'missingness' model will also be extended to include measures of deprivation.

3.3 Work Package 3 The process evaluation across whole intervention population

(*Months 7-29*) Araujo Soares, Arnott, Evans, Jones.

Objectives to be achieved:

d: To complete a process evaluation, linked to the intervention logic model and 'dark' logic model, and developed with input from the NCMP team at PHE, LAs and PPI panel to explore key questions relating to the context, and implementation of the intervention and, to undertake this collecting both qualitative and quantitative measures from key stakeholders;

f: To collect data on the flow of participants including numbers recruited and numbers engaged in the intervention (with a focus on the web based tool for which we will have user data); numbers completing; numbers of participants at each time of measurement; reasons for drop out; social patterning in terms of engagement with the interventions; details on any unexpected outcomes or adverse events; participants' satisfaction with the intervention; plans for the sustainability of the intervention.

Addressing questions:

4: How successful was intervention implementation and what is the acceptability of the enhanced NCMP letters and potential for adoption into usual practice?

5: What are the contextual and implementation factors associated with the effectiveness of the MapMe intervention?

6: What are the unintended pathways and consequences, if any?

3.3.1 Method:

Process evaluation methods will be finalised in WP1 but currently data is expected to be collected in the following ways:

Participant demographic characteristics will be collected to address questions relating to contextual factors which may impact on intervention engagement and effectiveness at the family and LAs level. IMD, age, gender will be collected at baseline.

Documentary analysis will be used to examine any adaptation made by participating LAs to determine the implementation of the intervention. Qualitative documentary analysis will be conducted on post-measurement letters following mail-out.

Data will be kept on the flow of participants through the study including reasons for opt-out, reasons for drop out, social patterning in terms of engagement with the intervention and details on any unexpected outcomes or adverse events (56).

Web-analytics will be collected routinely across the period of intervention implementation, including the number of unique visitors to the website and which pages are viewed and for how long. Analytics will be collected for all web-participants to explore intervention engagement.

Qualitative interviews will be conducted with key stakeholders in each LA to determine the weight management services offered to local families and to explore questions relating to the components of the intervention which were most challenging to integrate into current practice, any interaction with parents following receipt of the feedback letters and potential improvements. There will also be questions on plans for the sustainability of the intervention. Topic guides for these sessions will be developed with input from the PIP and representatives from all LAs involved in the study. Resource has been included to allow for up to 27 stakeholder interviews, that is up to three in each of 9 LAs.

3.3.2 Analysis:

Demographic data relating to participant characteristics will be examined in relation to the effectiveness results, implementation and mechanisms of action to determine how contextual factors may be influencing intervention effectiveness, delivery and impact.
Documents from LAs will be analysed using qualitative analysis and web analytics will be reported using descriptive statistics. Data from focus groups/interviews with LAs will be analysed qualitatively using thematic analysis.

Data will be kept on the flow of participants through the study.

3.4 Work Package 4 The process evaluation: an in-depth sub sample study

Araujo Soares, Arnott, Evans, Jones, Basterfield, Oluboyede

Objectives to be achieved:

e: To complete the process evaluation, linked to the intervention logic model and dark logic model, and developed with input from the NCMP team at PHE, LAs and PPI panel to explore key questions relating to the mechanism of impact by collecting both qualitative and quantitative measures from parents and children;

g: As part of the process evaluation to collect data on parents' perceptions of child weight status, changes in help seeking activity, child food intake and physical activity.

h: To collect data on child-reported psychological outcomes (self-esteem and eating disorder risk).

Addressing questions:

6: What are the unintended pathways and consequences, if any?
7: If effective, what are the mechanisms of impact of the MapMe intervention?
8: What is the participant's response to, and interactions with the enhanced NCMP letter?
9: What is the impact of the enhanced NCMP letters on child-reported psychological outcomes?

In addition to the process evaluation described in WP3 this WP will explore the mechanisms of impact of the intervention, which will include potential mechanisms of action (reported change in food intake or physical activity levels) and child-reported psychological outcomes will be examined in a sub-sample of participating families. This work will address our secondary outcomes of examining parental perceptions of child weight status, changes in child food intake and physical activity, child self-esteem, weight concerns and dietary restraint (please see dark logic model appended).

3.4.1 Sampling and recruitment for the mechanism of impact:

Families will be required to actively participate in data collection for this part of the process evaluation, therefore opt-in consent will be needed. A pragmatic approach will be taken whereby informed consent for this sub-study will be sought from all families who will be recruited to participate from at least three LAs. Efforts will be made to ensure the range of geographies, levels of deprivation and ethnicity are represented within the three LAs selected.

All families in these three LAs with children in the NCMP age groups at baseline (4-5 and 10-11 years) will be invited, via schools, to take part in this additional research prior to the provision of the NCMP letters. With an average of approx. 5000 eligible families in each LA (approx. 50% in each age group) and an estimated response of 8% (based on response achieved in our previous trial testing the MapMe intervention) we anticipate recruiting approx. 400 families from each of the three LAs (total 1200 families), of which, approx.120 in each LA will have a child who is OW or has OB (total of 360 children with approx. equal number each aged 4-5 and 10-11 years). These calculations assume that children of families agreeing to participate will be broadly representative of population therefore approx. 30% with OW or OB, however, based on our previous experience, it is probable that the proportion of families with OW or OB opting into this sub-study will be lower than in the general population, that is 15-20% which would reduce the number of children to 180-240. From the prevention perspective we are interested in understanding the mechanism of action of the intervention for all families not only those whose children have OW or OB at the time of the NCMP measure. The sample size is pragmatic to ensure we can explore mechanism of action in families with children in each category of adiposity making maximum use of LAs local to the study team to minimise study costs. All families agreeing to take part will be invited to participate in the full range of behavioural measures at baseline and at one year. The total sample size for the sub-sample study is 1200 which will be distributed equally across the three trial arms.

3.4.2 Outcome measures:

Views on weight status and psychological outcomes: An online questionnaire will be developed using Qualtrics to collect information from parents (and where appropriate children) at baseline, 6months and one year. This will include questions about their views on their child's weight status, their health related behaviours, health service utilisation and out of pocket expenses. Proxy (for 4-5 year age group) or self (for 10-11 year age group) completion of child QoL outcomes will be age dependent (Child Health Utility 9D (CHU-9D) and WAItE (46)). Further details on the health service utilisation questionnaire, out of pocket expenses, CHU-9D and WAItE are provided in WP5. As specified in the dark logic model, psychological outcomes will be assessed using the Lifespan Self-Esteem Scale (57), the Weight Concerns Scale (58); adapted by Davison et al, 2000 (59) and, for older children, the Dutch Eating Behaviour Questionnaire dietary restraint subscale, Child version (60).

Qualitative interviews with participating families will be conducted following collection of follow up measures at one year. A purposive sample of parents will be invited to participate in focus groups and/or interviews. This will include families from each of the three LAs and include parents of both boys and girls and from both age groups, from across the full range of IMD and ethnicity, parents of children from a range of baseline BMI Z-score (OW or OB and healthy body weight) including those that reveal change in BMI Z-score between measures. The sampling frame will be decided based on outcome data. Data collected will inform understanding on mechanism of action. We have included resource to include up to 80 parents; parents will be recruited until data saturation and information power is achieved (61, 62). Topic guides will be developed in collaboration with the PIP. These sessions will further explore the mechanisms of action of the intervention, collect information on engagement with the intervention, enquire on satisfaction with the intervention, and examine unintended pathways or consequences.

Dietary intake and physical activity: Child food intake will be assessed by 2x24 hour recalls, using Intake24, an online dietary recall system developed for use with families of young children and children from age 10 years developed at Newcastle University, www.intake24.co.uk (63, 64); this will be parent-completed for younger children and child completed for 10-11 year olds. Given the purpose of dietary assessment is to observe any change in parent feeding practices these assessments will not include school-days but rather food intake will be assessed to capture both weekend days on two different weekends at baseline and at one year at either end of the measurement of physical activity.

Child physical activity will be objectively measured for 7 days at baseline and at one-year using Actigraph GT3XP-BTLE accelerometers. Children will be provided with a £5 book token each time they return their accelerometer as a token of thanks and to aid retention.

3.4.3 Analysis:

Levels of each potential negative psychological outcome (child self-esteem, weight concerns and dietary restraint) will be compared between subsample participants in the three trial arms. We aim to ascertain whether children whose parents were allocated to receive the MapMe intervention report significantly more negative outcomes than those allocated to receive the control condition (i.e. standard NCMP feedback only).

Data from focus groups/interviews with participants will be analysed qualitatively using thematic analysis.

Data from Intake24 will be processed to create a healthy food index (fruit, vegetables, wholemeal bread, reduced fat milk and other indicator foods) and an unhealthy food index (high fat, salt and sugar foods including sugar sweetened beverages and other indicator foods (65)) and a four item diet quality score (66) for both time points.

Data from the accelerometers will be downloaded and stored securely until processed using a custom-built Excel macro. The macro will produce three main outputs for analysis: 1) overall amount of physical activity; 2) amount of moderate-to-vigorous intensity physical activity; 3) amount of time spent in sedentary behaviour. Levels of these variables at follow-up will be compared with baseline, to assess change over time. Adherence to national guidelines of amount of physical activity that children should be participating in (average 60mins/day) will also be assessed. Measurement over a week will allow assessment of adherence to updated national guidelines of an average of 60 mins/day in any given week.

3.5 Work Package 5: Health economic evaluation

(Months 7-29) Oluboyede (Senior health economist) and Senior Research Associate in Health Economics

Objectives to be achieved:

i: To collect data on child QoL and use of NHS/LA funded services, out of pocket expenses and estimate a weight specific algorithm for the WAItE, for the economic evaluation.

Addressing questions:

10: What are the cost implications and benefits and cost-effectiveness of the enhanced NCMP letters?

11: Do the benefits associated with child QoL outcomes differ when generic and weight-specific outcome measures are used to inform QALY calculations used in the cost-effectiveness analysis?

The economic evaluation will estimate the incremental cost per QALY and the net monetary benefits from the perspective of the NHS / LA funded services and families.

This WP directly addresses the limited cost-effectiveness evidence on public health initiatives to prevent OB in the younger population. It is not feasible to collect full health economics data on costs and outcomes for the full study sample of approx. 56000 therefore primary data will be collected from the sub sample study through questionnaire completion by 1200 children and their families (see WP4). An online questionnaire will be developed using Qualtrics to collect information from parents (and where appropriate children) at baseline, 6months and one year. The data from the sub sample study will be used to calculate total cost per child and total QALY scores over the 12 month follow up period. Once these have been calculated the total cost and QALY scores per child will be extrapolated to the full study sample (through application of multiple imputation methods) in order to derive the cost-effectives analysis for the full trial population providing evidence for MapMe as a public health intervention. The results derived from the health economics component of the trial will provide evidence for decision makers to make investment and/or disinvestment decisions around public health interventions regarding the provision of weight management services and across other public health schemes.

Economic data, as described below, will be collected in the sub-sample of the participants of the randomised controlled trial. The proposed analyses will conform to National Institute of Health and Care Excellence guidance (67, 68).

3.5.1 Costs:

For the sub-sample, data collection will focus on estimating the cost of the interventions (e.g. materials, staff) and use of health and social services (e.g. General Practitioner (GP) visits). Health care utilisation data will be collected using a health service utilisation questionnaire administered at six months and one-year post randomisation. Analyses will be carried out from the perspective of the NHS and personal and social services, but we will also take a wider perspective by including costs borne by families (e.g. time off work, out of pocket payments for health services). This data will be collected via a time and travel questionnaire, based upon one successfully used in a number of NIHR Heath Technology Assessment (HTA) funded trials e.g., completed at one-year post randomisation. All unit costs will be derived using routine data sources and study specific estimates. It is anticipated, based on the age of study participants, that the health utilisation and time and travel questionnaires will be proxy administered to parents and carers. From the sub-sample total costs for each participant will be estimated and multiple imputation methods used to impute cost data for the remaining trial participants (69).

3.5.2 Outcomes:

From the sub-sample outcome data will be collected that will be used to inform two cost-utility analyses (CUA) estimating the incremental cost per QALY gained. QALYs will be derived based on responses to the generic preference based tool - the CHU-9D (70, 71). Responses to the CHU-9D will be used to estimate QALYs using UK population preference weights and the area under the curve approach. QALYs derived via the CHU-9D will be the primary outcome measure for the economic evaluation and used in the base case analysis. However, QALYs, derived via the CHU-9D whilst appropriate, may not be sensitive to small but important changes in QoL in this population (72). Therefore, in addition to the CHU-9D we will also include the WAItE (73). Thus far, the WAItE demonstrates positive evidence of reliability and validity (73, 74). Currently it is not possible to use the WAItE to directly calculate QALYs as suitable utility scores are not available for the health states described by the WAItE. Directly assigning utility values to WAItE health states through a stand-alone valuation study is considered the gold standard method (75). As part of the current health economics study a valuation study will be performed that will generate WAItE utility scores suitable for the estimation of QALYs. This will enable direct comparisons between generic CHU-9D and the condition-specific WAItE utility scores in otherwise identical CUA. No existing study has been identified that has completed, or is planning to complete this, is known. The CHU-9D and WAItE will

be proxy completed in the younger children (aged 4-5 years) and self-completed in the older children (aged 10-11 years). Both questionnaires will be administered at baseline, six months and at one year post randomisation. For the CUA, data on total QALY scores will be estimated for each participant from the sub-sample using the CHU-9D and WAItE scores and will be derived from the sub-study participants and imputed for the full trial population (for use in a sensitivity analysis) using the multiple imputation statistical method (69).

3.5.3 Cost Utility Analysis:

Using data (including the imputed data) from the whole trial sample the results of the two CUA will be presented as point estimates of mean incremental costs and effects. The CUA will include deterministic (e.g. an analysis based on just the sub-study data, and an analysis looking at how results change when the perspective for costs change) and stochastic sensitivity analysis, presented as point estimates and cost-effectiveness acceptability curves (CEACs).

3.5.4 Return on investment:

Analyses based on standard Return on Investment (ROI), a method of priority-setting, will also be provided in addition to the CUA. Estimation of ROI will be informed by the data derived from the CUA.

4. Ethics / Regulatory Approvals and Reports:

Newcastle University will be the study sponsor. Ethical approval will be sought for all aspects of the work from Newcastle University Ethics Committee, and where appropriate LA ethics processes will also be followed. PHE/NCMP have confirmed the main study can operate under their ‘opt out’ system for measures at both time points on the condition that identifiable data is not shared and parents are provided with the opportunity to withdraw their child at each stage. A Schedule of Events Cost Attribution Template (SoECAT) with AcoRD approval through the North East and North Cumbria Clinical Research Network was uploaded with the proposal.

5. Assessment and management of risk:

The risk to participants in this study is very low. Potential negative outcomes, tracking and monitoring of these and approaches to ameliorating these outcomes are given in the Dark Logic Model in Appendix 2. There is a small possibility that the collecting of dietary data may be a sensitive issue for some participants. All participants (adults and children) have the right to withdraw from the study at any time. If during the collection of dietary or other data from children in a school setting a child becomes distressed the researcher will inform a member of staff at the school who can engage the child with the relevant welfare systems in place within the school. If a researcher becomes aware of a safeguarding issue in relation to a pupil, they will immediately inform the relevant member of staff within the participating school so that the school safeguarding procedures can be followed.

Discussing the topic of childhood overweight and obesity during focus groups/interviews could be distressing for some parents/stakeholders. Should this occur the researcher will explain to the participant that they are not trained to help them themselves but the study team can arrange help if they ask them to. The researcher will also explain that they can discuss any concerns they have with their GP.

6. Amendments:

Amendments to the study protocol will be submitted to the Sponsor, the Funder and the REC for review. Amendments will only be implemented when agreement from these parties has been gained. The amendment history will be tracked using version numbers and dates to identify the most recent protocol version.

7. Peer review:

The funding application, including the detailed study plan, has undergone independent, expert and proportionate peer review in line with NIHR research funding guidelines. Following submission of the funding application at stage 1 we received feedback from the Funding Board. Following submission of the funding application at stage 2 we received feedback from 5 independent peer reviewers and further feedback from the Board. The study team responded to the feedback in detail, incorporating changes where required. This was reviewed by the Board with further iteration before confirmation of funding.

8. Public Involvement:

An early version of this proposal was presented to the Public Involvement Consumer Panel of the NIHR RDS NE who confirmed this as a research priority. The consumer panel also commented on the Plain English Summary for the stage 2 application; their feedback helped to provide clarity to the summary and increased the ease of reading.
Feedback on a summary of the proposal was provided by a small group of parents of primary school aged children. The feedback from these individuals shaped our application, specifically how we engage with and retain participating families during the project, the methods to collect data during the study – for example whether questionnaires are made available online or in paper or both, and the creation of a PIP for the study.

The creation of the PIP has been further informed by both the NIHR RDS NE Consumer Panel and another small group of parents of school-aged children. The comments of these two groups informed the frequency with which the PIP would meet, the activities that they would be involved in, and the practicalities of being involved.

March 2022 update:
Public representatives recruited from across a broad range of relevant groups inform this study.

We engage with a group of Year 6 children via remote methods for feedback on study materials to ensure they can be understood and where relevant, completed by children of this age.

An ‘expert’ panel of stakeholders comprising academics, public health practitioners, Public Health England representatives and school nurses are consulted for the development of the study enhanced National Child Measurement Programme result letters and the body image scales.

To gain broader universal insights, we maintain an active parent involvement panel (PIP). The PIP are involved in a wide range of activities including providing feedback on aspects of the MapMe intervention, study outcome measures and contributing to written reports and blog posts about the project. Two members of the PIP are representatives on the Trial Steering Committee (TSC), bringing the parent voice to these meetings. We are cognizant of the potential burden that these activities could place on parents and work hard to ensure that involvement in the panel is not onerous, with careful spacing of requests. We provide members with regular study updates and let them know the impact their contribution is having on study progress with regular newsletters.

We adapted training materials and methods, which we had originally intended to deliver face to face, to ensure members can access the information in a variety of ways. This includes a hard copy of the study information/training pack, which is also available digitally, and includes information on reviewing documents and providing feedback and dissemination activities. We produced a series of short animated training videos and study information introduced by research team members which PIP members can watch in their own time and find out more about the study and about being a member of the parent panel.

All PPI activities are recorded and evaluated using the PiiAF model to identify/record PPI impact and the parent panel are encouraged to submit their own reflections to ensure robust and meaningful involvement. A publication of how PPI is shaping the development of MapMe2 has been written with parent panel involvement.

9. Protocol compliance:

Accidental protocol deviations will be documented and reported to the CI and Sponsor. Protocol non-compliance will be reported without delay by research staff to the CI, who will inform the Sponsor. The CI will ensure that the issue is investigated and appropriate actions taken. The REC will be notified of any serious breach of its approval conditions, security, confidentiality, or any other incident that could undermine public confidence in the research.

10. Participant confidentiality and data protection:

All study researchers will comply with the requirements of the Data Protection Act 2018 and General Data Protection Regulation (GDPR). All research staff involved in data collection will undergo/update Good Clinical Practice training and have enhanced Disclosure and Barring Service checks. Data protection measures will adhere to the relevant policies and procedures of Newcastle University. All study data collected on paper will be held securely, in a locked room or locked cabinet that is accessible only to the research team and relevant regulatory authorities. All study data in electronic form will be pseudoanonymised using ID numbers and held securely on encrypted machines protected by passwords. Audio files will be transcribed either internally by members of the research team or by a specialist external company subject to a Confidentiality Agreement to not disclose any information to third parties. Files will be transferred via a secure server with user identifiers and passwords. Transcripts will be marked with unique and anonymised identifiers. All data will be held securely in the custody of the CI for 10 years after publication of the main study results, in accordance with Newcastle University’s Research Data Management Policy.

11. Financial and other competing interests:

Prof. Louisa Ells is part funded by PHE/OHID as a specialist in obesity. Prof Ashley Adamson is part funded by NIHR as Director of the NIHR School for Public Health Research and is an NIHR Senior Investigator. No applicants declare any financial or competing interests.

12. Planned recruitment rate:

Detailed Figures Recruiting Centres – Local Authorities

Project Month	Month	Actual Cumulative Total	Initial Cumulative Target Total	Revised Cumulative Target Total
1	March-20		0	
2	April-20		0	
3	May-20		9	
4	June-20		9	
5	July-20		9	

Detailed Figures Recruiting Centres – Local Authorities –updated March 2022

Project Month	Month	Actual Cumulative Total	Initial Cumulative Target Total	Revised Cumulative Target Total
19	Sep-21	5	9	
22	Dec-21	8	9	
23	Jan-22	9	9	
25	Mar-22	10	9	9

The following tables have been updated following the disruption due to COVID19.

Detailed Figures Recruitment of participants/families - updated 28/3/2022

Project Month	Month	Actual Cumulative Total	Initial Cumulative Target Total	Revised Cumulative Target Total
18	August-21	0	0	0
19	September-21	0	0	0
20	October-21	0	5000	0
21	November-21	0	10000	0
22	December-21	0	15000	0
23	January-22	0	20000	0
24	February-22	0	25000	0
25	March-22	10573	30000	10000
26	April-22		35000	20000
27	May-22		40000	30000
28	June-22		50000	50000
29	July-22		55000	55000

Comments
These figures are estimated at present. Local Authority (LA) partners intended to measure children throughout the school year from Oct to July. This changed with teams being diverted to 12-15y Covid vaccines. NCMP measures became from Jan 2022. Most authorities are measuring now. All will have started measures by end April, figures have been updated. There is some delay between children being measured by LAs and the numbers being available to us. At this stage the extent of that delay is not known and may vary by LA.

Detailed Figures and Comments for Participants - Followed Up to Primary Endpoint

Project Month	Month	Actual Cumulative Total	Initial Cumulative Target Total	Revised Cumulative Target Total
31	September-22		0	
32	October-22		4500	
33	November-22		9000	
34	December-22		13500	
35	January-23		18000	
36	February-23		22500	
37	March-23		27000	9000
38	April-23		31500	18000
39	May-23		36000	36000
40	June-23		45000	45000
41	July-23		49500	49500

Comments
These figures are estimated at present. Local Authority (LA) partners intended to measure children throughout the school year from Oct 2021 to July 2022. This changed with teams being diverted to 12-15y Covid vaccines. NCMP measures became from Jan 2022. Most authorities are measuring now. This will impact on follow up measures due 12 months after the NCMP measures. There is some delay between children being measured by LAs and the numbers being available to us. At this stage the extent of that delay is not known and may vary by LA.

13. Indemnity:

Newcastle University, as the Sponsor, has in force a Public Liability Policy which provides cover for claims for "negligent harm". The activities of this study are included in the coverage. No provision has been made for indemnity in the event of a claim for non-negligent harm.

14. End of study and archiving:

Following the end of the study on 28th February 2024, data will be archived at Newcastle University for 10 years.

15. Access to the final dataset:

After publication of the main findings of the study, the CI will consider external requests to gain access to anonymised data. The dataset will be preserved and available for this purpose for 10 years following the end of the study. Those requesting data will be asked to provide a brief research proposal including the objectives, timelines, intellectual property rights, and expected outputs, and a Data Sharing Agreement between Newcastle University and the requestor will be drawn up. Requestors will be required to acknowledge the research team and funders as a minimum and consider co-authorship of any publications arising from the data. Permission for anonymised data to be shared for the purpose of future academic research will be sought from all participants via the informed consent form (opt-out for full study and opt-in for sub-study).

16. Dissemination, Outputs and Impact:

This research will determine if the inclusion of BIS and the MapMe intervention has a positive impact on child body weight after one year and therefore should be adopted as part of the standard delivery of the NCMP. The findings will be of value: to the public to support wider understanding of healthy child body weight; to parents and children increasing the value of the NCMP in supporting a healthy body weight in children; to Local Government responsible for commissioning the NCMP; at national level to inform design and delivery of the NCMP and potentially internationally as the intervention could be adapted for other populations.

Anticipated outputs: The full study report will be published in the NIHR Journals Library (https://www.journalslibrary.nihr.ac.uk/#/). This intervention has been developed in partnership with PHE and the NCMP team and is designed to answer research questions which have been co-produced with PHE and are directly relevant to the future delivery of the NCMP. The interventions will be tested as part of the NCMP across 9 LAs who have all agreed to collaborate in this research. If found to be effective the interventions, including the interactive web-based MapMe intervention, will be

made available to the NCMP team and LAs across England as a new public health intervention within the NCMP and therefore potentially available to parents of all children aged 4-5 and 10-11 years measured in the NCMP across England. The interactive web-based MapMe intervention will also be available to be incorporated into NHS.UK and therefore freely available across the UK and beyond.

Dissemination activities: Working with the national NCMP team we will host a workshop on the MapMe intervention for those commissioning and delivering the NCMP across England. A further workshop will be offered to the Local Government Association and Association of Directors of Public Health Annual Conference. Findings will be disseminated in academic journals; we anticipate at least four open access peer-reviewed journal articles including a trial protocol, papers detailing the impact of the intervention on weight outcomes at 1-year post intervention and the process evaluation to be published in journals such as International Journal of Obesity and including NIHR Public Health Research. Further our research will be shared at appropriate local, national and international conferences, such as PHE conferences, practice and science conferences, UK Congress on Obesity, European Congress on Obesity and International Society of Behaviour, Nutrition and Physical Activity.

Broader dissemination will be informed by the PIP, and will include creative and innovative methods to engage a wider audience, this was something that was highlighted in our PPI activities to date; for example, developing a brief animation of the study results which would fit in well with the visual nature of the BIS; brief report of the results for parents with top tips of changes found to be effective. Research findings, from the effectiveness study, the process evaluation, and the economic evaluation will be shared as appropriate with participating families, school nursing teams, NCMP teams, health practitioners and local and national policy makers facilitated by practice and policy team members through provision of a study website, news briefs and dissemination events. The team will utilise established connections with fuse, the Centre for Translational Research in Public Health ((http://www.fuse.ac.uk/) and established communication methods including short briefing papers (fuse Research Brief http://www.fuse.ac.uk/research/briefs/), updates on the fuse website, posts on the award-winning fuse blog and social media dissemination. This will be support by the fuse Communications Officer.

Anticipated impact: The outputs from this research has potential to make a positive impact on the weight status of children in England and thus contributing to the Government's target "to halve childhood OB and significantly reduce the gap in OB between children from the most and least deprived areas by 2030" (11). This research has been designed with PHE and NCMP colleagues to address their most pertinent and pressing questions with the aim of increasing the impact of the investment made in the NCMP in particular, how the feedback given to parents on their child's weight status can be enhanced and how parents can be better supported in helping their children maintain a healthy body weight.

Impact in the short to medium term will be improved *perception and /or acknowledgement* and awareness of healthy child body weight in local delivery teams and parents by virtue of access to the BIS. Medium term impact will be within the 9 LAs and parents of approx. 56000 children of which two-thirds (approx. 37000) will receive an intervention. In the longer term, after completion of this 3-year study, if found to be effective, the MapMe intervention will be considered to become part of the standard delivery of the NCMP and to be incorporated into NHS.UK and be widely available on other platforms. This intervention has the potential and power to detect a beneficial impact on change in BMI Z-score of -0.111 for children with OW or OB. This is comparable to the intervention effect of -0.06 observed in the Cochrane review of interventions for the treatment of OW or obese children (8) but the proposed interventions would be deliverable at minimal cost and at national scale.

If found to be effective the MapMe intervention will be made available to the NCMP team and LAs as a new public health intervention and available to parents of all children measured in Reception and Year 6 across England. The interactive web-based MapMe intervention has been developed with the NHS Choices (now NHS.UK) team who will also be involved in WP1 of this proposal updating the web-

based MapMe intervention so ensuring the design will facilitate easy transfer for MapMe to be incorporated into NHS.UK and therefore freely available across the UK and beyond. The initial part of this process will be with Antbits (costs provided by Antbits for the proposal) with liaison with NHS.UK through PHE.

For wide adoption by NCMP there will be some initial set up and administration and personnel costs likely to be borne by PHE. PHE have contributed to the design of this research and are committing time in kind to be actively involved in the research. There is likely to be some cost borne by LAs for implementation of the intervention (colour printing of the BIS); delivered at scale these costs will be small (up to £2/family) in the context of the current cost of delivery of NCMP which is approx. £20.6M.

Note on Intellectual Property (IP): All background IP is wholly owned by Newcastle University with no third party rights. Potential IP arising might be in the form of trademarks (e.g. MapMe), copyright (e.g. questionnaires, web-site) and know-how (e.g. the intervention). Newcastle University will lead exploitation of all foreground IP. The intervention will be in the public domain and be free to access and use. All arising foreground IP will be owned by Newcastle University who will lead on commercialisation and agree to share any future proceeds that might be generated.

16.1 Further research:

If any interventions are found to be effective further research could include further follow-up of the Reception children measured in the present study. The additional follow-up included in the outline proposal was removed following feedback from the Panel. However, from 2019 it will be possible to match NCMP measurements of an individual at ages 4-5 and 10-11. It will therefore be possible to obtain longitudinal information using routine measurements, which will greatly reduce the cost of this further research. To this end we will ask parents of 4-5 year old children in the present study for permission (opt-out) to use routine NCMP measurements on their child when aged 10-11 years. Routine methods for longitudinal analysis (76) will allow assessment of the sustainability of the initial intervention effects. Over this period, loss to follow-up should be anticipated and would require careful attention. Methods for missing data, such as inverse probability weighting, as well standard longitudinal analyses, would be needed.

16.2 Further development:

The current BIS used in the MapMe intervention are based on 3D body scans of children of largely White ethnic origin and UK90 body weight criteria. While these BIS were applied in our previous work without any concern expressed by parents of children of other ethnic origins we have maintained intention that ultimately we would develop ethnicity-specific BIS. Whincup, Hudda et al. (77).have published BMI adjustments based on equivalent body fatness levels for specific ethnic minority groups which offers some interesting potential for future collaborations Teesside University has a growing research portfolio examining the impact of OB in BME communities, which will help inform this future development. While this remains a future ambition the NCMP applies UK90 criteria to all children regardless of ethnicity to determine body weight status of children and to feedback to parents and therefore our current BIS and MapMe intervention are appropriate and aligned with current practice.

16.3 Adoption and Implementation:

If found to be effective there would be a small additional cost for delivery of the intervention which would be borne by the local NCMP commissioners. We have completed a SoECAT with AcoRD approval through the North East and North Cumbria Clinical Research Network. This cost ‘excess treatment costs’ will be supported by PHE for delivery of this research but if adopted by NCMP nationally costs would transfer to LA areas. This cost would depend on which of the interventions was found to be most effective, and most importantly cost effective, as delivery of each would vary. Based on costs for delivery of the intervention provided by the 9 LAs the total intervention cost will be in the

region of £97K, or an average of approx. £10 800 /LA which translates to approx. £2.60 per family receiving an intervention which compares favourably with previously published intervention costs/person ranging from £108-£858 for traditional weight management services (8). While the current financial restraints within LAs are well recognised, this additional cost should be seen within the context of adding value by enhancing the effectiveness of an existing mandated responsibility and the wider cost of £20.6M currently invested in the NCMP across England.

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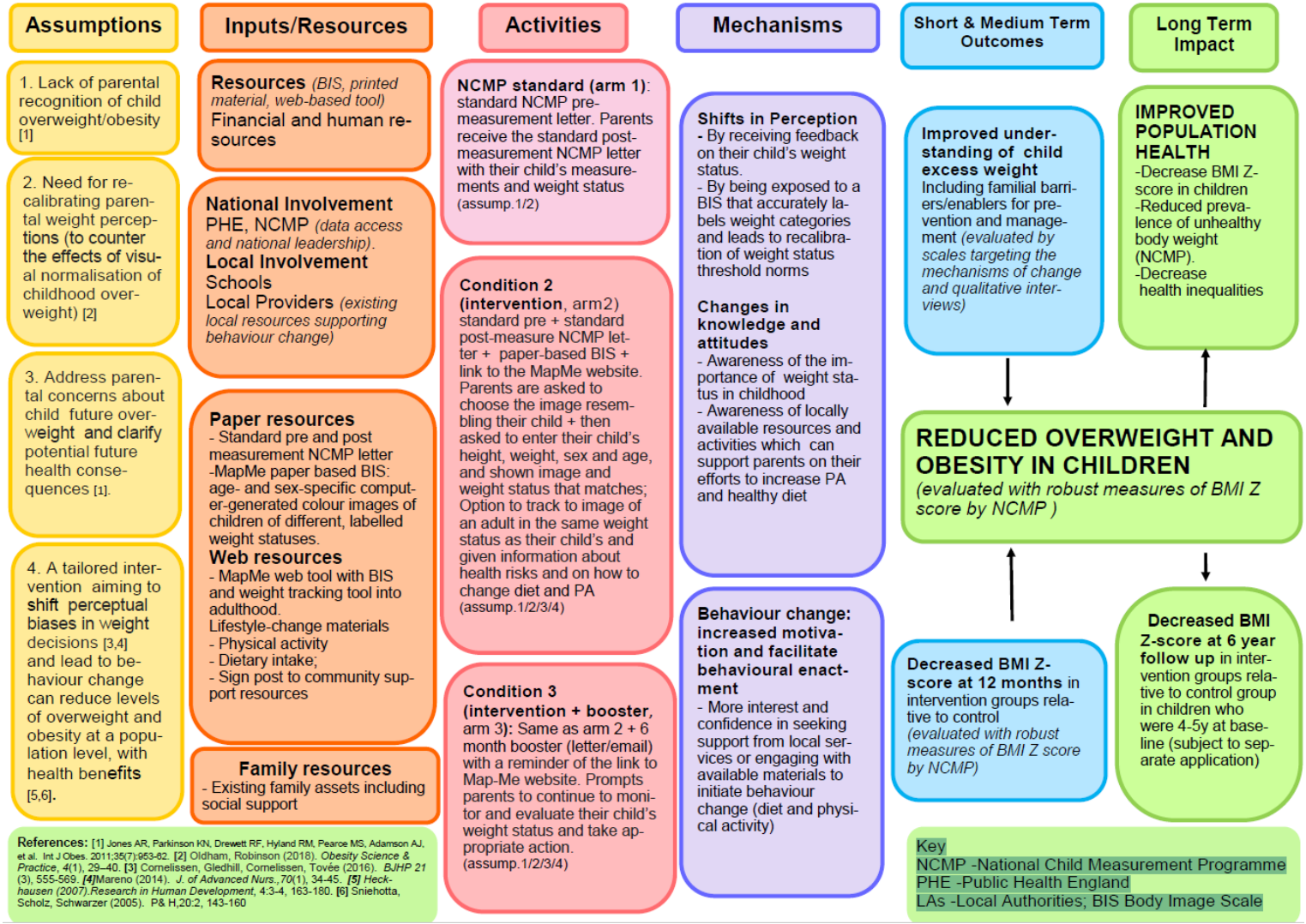
18. Appendices

Appendix 1: Logic Model



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Appendix 2: Dark Logic Model

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Key: * Sub-study data. NCMP -National Child Measurement Programme; BIS Body Image Scale