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A population-level evaluation of a family-based community intervention for childhood overweight and obesity

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1. Project title

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2. Background

2.1 Existing research

The most recent data (2008) from the Health Survey of England (HSE) show that among children aged 2-15, 31% of boys and 29% of girls are overweight, of whom 17% of boys and 15% of girls are obese.[1] Levels of overweight and obesity have been rising steadily over the past decade. In 1995, comparable figures for the prevalence of overweight (including obesity) were 24% for boys and 26% for girls, and for obesity were 11% and 12%. The Foresight report "Tackling Obesities" predicted that, by 2025, around 15% of the population under 20 would be obese, and that this could rise to around 25% by 2050.[2] While these figures have now been revised downward, as the rise in prevalence appears to be levelling off[1], rates of childhood overweight remain high.

Childhood overweight arises because of a fundamental imbalance between energy intake and expenditure. This imbalance is linked to increased sedentary behaviour (particularly related to screen-based entertainment), low physical activity and patterns of diet such as consuming sweetened drinks. These common behaviours are potentially modifiable. However, the causes of childhood overweight need also to be considered at a societal level, with an obesogenic environment which operates at levels beyond families' control and as part of a dynamic and complex system.[2;3]

Compared to their peers with healthy weight, obese children have a higher risk of a range of adverse health and other outcomes. These include fatty liver disease, childhood onset type 2 diabetes mellitus, adverse cardiovascular risk profiles, impaired psychological health, low self-esteem and involvement in bullying.[2;4] Both the prevalence and adverse consequences of childhood overweight and obesity are underestimated by parents.[5] This may reflect general desensitisation to seeing excess body fatness, such that overweight amongst children is seen as normal, fatalism ("nothing can be done about it"), optimism ("they'll grow out of it") or denial of a stigmatising problem.[6] Childhood obesity is a risk factor for adult obesity, and so is associated with an increased risk of premature mortality and morbidity from a range of adult conditions.[2;4] In addition to its substantial health impact, obesity in childhood is also projected to have significant future cost implications for the NHS. Using a microsimulation model of obesity predictions based on current rates of obesity, it has been estimated that the NHS costs of managing obesity and its consequences in England will reach £9.7 billion by 2050[7], around 10% of current NHS expenditure. The burden of childhood obesity also falls outwith the NHS, including costs borne by parents and families, and lost productivity to society.[8] The societal costs of obesity are projected to be £49.9 billion in 2050.[7]

Childhood overweight is not distributed evenly across the population and varies by ethnicity, socio-economic circumstances (SEC), gender and age.[2] Studies in the last 20 years have found reasonably consistent evidence that children in disadvantaged circumstances are more likely to be overweight or obese than their more advantaged peers, but the association may depend on which measure of SEC is used and what it represents.[9] Furthermore, although trends in childhood obesity seem to be stabilising, socio-economic differentials in childhood obesity may be widening, at least in

England.[10] Plausible reasons include that families with better SEC have been more receptive to media and other policy interventions aimed at promoting healthy patterns of diet and physical activity[11], more likely to access services which support behaviour change, and less likely to be living in an obesogenic environment.[12]

Overweight in childhood also varies with ethnicity. In the 2004 HSE (which focused on the health of ethnic minorities)[13], the proportion of overweight (including obese) children aged 2-15 ranged from 22% of Chinese boys to 42% of Black African boys, and from 25% of Pakistani girls to 42% of Black Caribbean girls. Multivariable analysis using the National Child Measurement Programme (NCMP) shows that ethnicity is associated with overweight after taking account of material deprivation, with children from some South Asian groups at higher risk of overweight than the white majority.[14] The social and ethnic patterning of childhood overweight, coupled with the persistence of obesity into adult life, suggests that childhood obesity will result in persistence of at least some adult health inequalities, given the high burden of morbidity associated with adult obesity.[2]

Despite the scale of childhood overweight, and a large research endeavour, relatively few effective interventions for either prevention or treatment of childhood overweight have been described. Authoritative syntheses of evidence, both international[15;16] and applied to UK settings[2;8;17] for treatment of childhood overweight and obesity have noted that there is insufficient evidence to recommend one programme over another, although principles of effective interventions have been established. These include addressing both diet and physical activity, behaviour change, involvement of family and a positive emphasis on managing a healthy lifestyle for the whole family. Significant gaps in the evidence include information about effectiveness in vulnerable groups (e.g. by ethnicity or deprivation) and on cost-effectiveness.[8;15]

There is a general lack of information about what happens when public health interventions which are deemed to be effective under research conditions are delivered into practice, partly because outcome data are often not collected and/or collated during service delivery. Much of the existing literature on "scaling up" refers to middle or low income settings and focuses on costs and constraints.[18] There is also little consideration of how delivery at scale might impact on inequalities in health (for example, through differential access), although general theory on diffusion of innovation suggests that innovation is often associated with widening inequalities, at least initially.[12] Furthermore, some have argued that interventions should be regarded as events in systems, rather than as discrete entities, in recognition that the interaction of the intervention and context might be more significant than the intervention alone.[19]

These general problems in the evidence base for public health interventions are reflected in interventions to tackle obesity.[2;20] The systems map of the Foresight project demonstrates the complexity of the "obesity system". Despite the requirement for a public health approach to childhood overweight, most evidence to date comes from relatively small trials, often conducted in highly selected populations and controlled academic settings,[15] and so effectiveness in "real world" settings and in different groups of the population is largely unknown. At a population level, the effectiveness of an intervention may be sensitive to the complexities of the local context. The social environment in which individuals live influences behaviours by shaping norms, providing access to environmental opportunities to engage in particular behaviours and placing constraints on individual choices. Factors such as population density, access to green space and proximity to supermarkets may support or impede behaviour change.[2;21] Thus, evaluation also needs to take account of context.[22] Because of the lack of evidence, those who commission treatments for childhood overweight have been urged to include evaluation in their commissioning plans,[2;20;23] supporting more general calls to use practice to develop the evidence base.[24] A recent mapping review of schemes to promote healthy weight amongst obese and overweight children in England found that there were over 300 schemes running in England and that both the practice and form of evaluation were extremely variable.[25]

2.2 Risks and benefits

Risks of overweight and obesity to individuals are described above. Many of these risks are modifiable with loss of excess fat. Risks to society include the large economic burden which persisting or increasing levels of obesity will impose. Our study is aimed at improving the management of overweight children, the promotion of healthy lifestyles in families and tackling inequalities in healthy lifestyles. This should benefit families, particularly those living in disadvantage, and society at large.

The proposed study uses secondary analysis on already collected data (so poses no additional risks to individuals) and primary qualitative research (with families and commissioners of services). The risks to lay individuals of taking part in our qualitative work are the opportunity costs of their time and are otherwise no greater than the risks of conversations and discussions in daily life. The areas where we are inviting participants' views relate primarily to services. However, we are attuned to the issues of working with children, young people and families on potentially sensitive topics and will ensure our fieldwork takes account of these issues. For commissioners, the risks relate to opportunity costs in relation to the use of their time, but the time required will not be onerous.

Although there will be no direct benefits to lay participants from taking part in our study (other than a £10 "thank you" voucher), participants in well conducted qualitative studies may gain satisfaction from being heard, and from the opportunity to influence services.[26]

Risks to the study:
Data quality: part of this study uses data collected as part of the routine service delivery of MEND, a programme for overweight children, in many different locations around the country. As is common in service-level data, the quality will be variable and there will be missing data. We will employ a range of strategies to minimise the risk (see section 9).
Conflicts of interest, which may affect the perception of the study's rigour: two of the applicants (Sacher and Chadwick) work part of their time for MEND Central, which co-ordinates the delivery of MEND programmes (see section 7). The role of these applicants is described in section 15. Procedures for managing potential conflicts of interest are described in section 13.

2.3 Rationale for current study

The research evidence on which we act, or fail to act, is frequently imperfect. Even compelling research narratives such as that describing the Hawthorne effect, impose an academic interpretation on an "untidy reality".[27] Where a health or social problem is amenable to remedy, it is important not only to find out whether any solution is effective, but also to know how, under what conditions and in what contexts, a given solution may be made to work to maximum effect.

Our proposed study attempts to assess the outcomes associated with MEND, a family-based community intervention for childhood overweight and obesity, when implemented at scale in real world conditions, and particularly how it may be contributing to tackling inequalities in childhood overweight at a population level. MEND has been shown to be effective in a trial[28] (a further trial is in the field) and has been implemented rapidly at scale in several countries. We will gain information on who participates in MEND, whether they reflect those whom it is intended to benefit equitably, what outcomes are associated with participation and how these vary by person and place. Such issues cannot be addressed in randomised controlled trials (RCTs). We will also estimate the intervention costs borne by public services in delivering MEND.

This study cannot assess effectiveness per se, nor is this its intention, as this is properly done through an RCT. However, the effect size of a trial may be larger than that achievable in practice for a number of reasons. This study will demonstrate to what extent scaling up this intervention is linked to differences in outcomes associated with the intervention, either overall or for certain groups. Although local assessments of programmes are sometimes conducted (for example, at Primary Care Trust (PCT) level), these are too small to address our research questions on differential outcome.

In addition, our qualitative work will explore why MEND does or does not work for different families, what the barriers and facilitators to participation are, the types of costs to families resulting from participation in MEND, how the intervention couples with context, how resources are used and what activities are displaced.[19] It will also investigate commissioners' views on MEND and the issues linked to their commissioning decisions. We believe that our findings will throw light on issues of sustainability,[29] and, while our project draws on data only from the MEND programme, may have salience for other interventions designed to impact on childhood obesity.

In our outline application, we proposed a postal/online survey to obtain information on resources used by families participating in the MEND programme. Since we are not undertaking a formal incremental cost-effectiveness analysis of the MEND programme, we have decided to collect information on resources as part of the qualitative work instead. We consider this to be a more cost-effective use of research resources.

By combining quantitative and qualitative techniques, we aim to assess how MEND is contributing to tackling childhood overweight, how it works in different contexts, for whom and why. This can be used by those who commission and deliver MEND to improve their services and may have application more widely (to other weight management schemes or community interventions). Ongoing service evaluation and a focus on continuous improvement have been identified as core principles in tackling obesity.[2;30]

3. Research questions

1. What are the characteristics of children who take part in MEND, a family-based community intervention for childhood overweight and obesity, when implemented at scale and under service conditions?

2. How do the outcomes associated with participation in MEND vary by characteristics of children (gender, socio-economic circumstances and ethnicity), MEND centres (type of facility, funding source and programme group size) and areas where children live (in relation to area-level deprivation and the obesogenic environment)?

3. What is the cost of providing MEND per participant to the NHS and personal social services (PSS), how does this vary and how is it related to variation in

outcome?

4. What is the salience and acceptability of MEND for those who commission it, those who participate in full, those who participate but drop out and those who might benefit but do not take up the intervention?

5. What types of costs, if any, are borne by families (and by which members) when participating in MEND, and in sustaining a healthy lifestyle afterwards?

4. Research design

Research questions 1-3: Secondary analysis of service-level MEND data of participants and centres

- comparison with routinely collected data (to assess reach and equity)
- internal comparisons of primary and secondary outcomes by variables related to participant, centre and area (to assess variation in outcome)
- benchmarking of outcomes from service-level data against complete and concurrent trials (to see how long term follow-up relates to service-level measures)
- investigation of costs borne by the NHS and PSS in the delivery of MEND

Research questions 4-5: Qualitative component

Face to face individual and family-based group interviews with participants and potential participants of MEND (children and parents) in 3 locations (London, Bristol and the North East), plus telephone interviews with service commissioners. Pilot interviews will be carried out.

Interviews will begin with narrative questions, deriving from the literature, early findings of the quantitative work and previous qualitative studies. There will follow a series of semi-structured questions, including participants' understanding of:

- the opportunities and trade-offs of participation in a MEND programme
- costs and benefits within the family
- access to schemes
- positive or negative experiences of participation

Discussions with commissioners will include an exploration of the tension between programme fidelity and responsiveness to local context, circumstance and service users. Examples will be sought of modifications made to programmes and the perceived consequences of these.[31-33]

5. Study population

For the secondary data analysis: children aged 7-13 who are overweight or obese (above 91st centile on UK 1990 charts[34] – one of the criteria for participation in a MEND programme), and who were eligible to participate in MEND, which was/is locally available to them between January 2006 and October 2010. MEND operates in all English regions.

For the qualitative component: participants and potential participants (children and parents) in MEND, and commissioners of services for overweight children. The sampling of both will be purposive and built around our aims to explore barriers and levers to services in relation to ethnicity and deprivation.

It is a requirement of the MEND programme that the child be accompanied by a parent or carer. Our sample will therefore be based on family units, with the exception of non-participant children and young people who may prefer us not to contact family members, or parent-refusers who may prefer us not to contact their overweight child.

Recruitment of commissioners will also be designed to obtain a maximum variation sample. Again, we will sample to saturation, with the expectation that this will be reached by including around 30 individuals.

6. Socioeconomic inequalities

For the secondary data analysis, we are limited to the data that are collected by MEND as part of their routine service delivery. Indicators of participants' socio-economic circumstances will be tenure of housing, whether the main earner in the household is employed and whether the child lives in a lone parent or couple household. In addition, area-level secondary data on the social and physical environment will be collated. The home postcode of each child will be used to link the individual to a range of area data that might plausibly be associated with the generation of inequalities in outcomes through varying exposure to environmental risk factors. Such data will include area-level global measures of deprivation (Index of Multiple Deprivation IMD 2007: http://www.communities.gov.uk/communities/neighbourhoodrenewal/deprivation/deprivation07/) and child well-being (Local Index of Child Wellbeing 2009: http://www.communities.gov.uk/publications/communities/childwellbeing2009); Income Deprivation Affecting Children Index IDACI 2007: http://www.communities.gov.uk/communities/neighbourhoodrenewal/deprivation/deprivation07/), as well as plausible, routinely available 'obesogenic' environmental risk factors related to physical activity and diet such as access to green space (Generalised Land Use Database 2005: http://www.communities.gov.uk/publications/planningandbuilding/generalisedlanduse), sports facilities and reported crime (Local Index of Child Wellbeing 2009 Environment Sub-domains), and food retail mix (ratio of fast-food to grocery stores). Area-level data will be standardised to Lower Super Output Areas using GeoConvert (http://geoconvert.mimas.ac.uk/).

Thus, although we are limited to the variables collected in service delivery, we will be able to use multiple indicators of SEC, including a composite area-level measure, in accordance with recommendations.[35;36]

In the qualitative component, we will sample to include a range of socio-economic circumstances, family types and locations.

In our analysis for the quantitative and qualitative components, we will focus on how MEND might address inequalities in childhood overweight through assessing how participation in MEND and associated change in body mass index (and other outcomes), and barriers and levers to change, are influenced by individual and area characteristics linked to inequalities. This will include analyses which explore hypothesised causal pathways.

7. Planned intervention

MEND (**M**ind, **E**xercise, **N**utrition, **D**o It!) is a multi-component community intervention aimed to empower families of overweight and obese children to adopt and sustain healthy lifestyles. MEND can be characterized as a complex, multi-component, healthy lifestyle programme, which aims to catalyze the changes necessary for successful obesity management. It combines principles of nutritional and sports science with those from psychology, learning and social cognitive theories and the study of therapeutic processes. It addresses the three components necessary for individual-level behavioural change – education, skills training and motivational enhancement[37] - while recognising the need to engage multiple, interacting systems of influence within the family context.[38] It was developed on the basis of existing literature and expert guidance[8] and to be delivered in community settings. A traditional RCT demonstrated that MEND was effective at reducing waist circumference and body mass index at 6 and 12 months after the intervention.[28] MEND has been implemented rapidly and at scale over the last 4 years and is now one of the largest schemes available. It is listed as one of nine weight management providers in the Cross-Government Obesity Unit's framework (which aims to assist procurement).[39]

The primary aim of the MEND Programme is to teach families the principles of age-appropriate healthy living, safe weight management, and to help them establish health promoting behavioural habits and family routines. These healthy practices will lead the obese child to regular negative energy imbalance so as to gradually bring their weight into a healthy range for their height and age over the course of development. Principles of positive parenting are taught throughout the programme to help parents/carers constructively manage the contingencies that determine children's eating and activity habits, and encourage age-appropriate self-regulation of weight management behaviours. These include monitoring, reinforcement, modelling, goal-setting, stimulus control and relapse prevention.

Because of the importance of family involvement for behaviour change, the programme requires a parent or carer to attend all sessions. The programme runs twice a week after school in two-hour sessions over 10 weeks. Sessions include an hour's interactive workshop for children and parents, and an hour's exercise for the children whilst the parents engage in education sessions. Eligibility criteria are that children must be aged 7-13 years old, overweight or obese and be able to participate in the programme (e.g. not have a physical disability or co-morbidity that would preclude taking part in the physical activity sessions).

All programme staff are trained centrally and provided with resources to deliver a standardised, manualised intervention. MEND is conducted in schools and leisure centres mainly by non-obesity specialists. The intervention is free for families to attend and its implementation is funded by a variety of sources (including PCTs, Local Authorities (LAs), Sport England and commercial companies), with 60% provided by the Big Lottery Fund (BLF). BLF funding is accompanied by a commitment to supply evaluative information. This information includes activity, human resources and financial data, capacity development of programme staff, overall outcomes in the centres in receipt of BLF funding and attitudinal questionnaires on a small sub-sample of MEND participants. This has no substantive overlap with the work proposed in this application.

MEND describes itself as a social enterprise – an ethical business which aims to benefit society in general. In the UK, MEND has two operating arms, MEND Central, a limited company, and MEND Places, a not-for-profit company originally set up to provide a route for donations to subsidise places for families on the MEND programme. To date, all those commissioning MEND have chosen to place funding through MEND Central.

8. Proposed outcome measures

Primary outcome: change in body mass index (BMI)[34] after participation in MEND (i.e. over a 10- week period from first to penultimate appointment at MEND – outcomes are not measured at the final session). We will adjust analyses of BMI change for age, which will allow a crude adjustment for individual variability in pubertal stage (pubertal status is not collected by the MEND programme).
Secondary outcomes: change in body esteem[40] and self-esteem[41] (reflecting children's perceptions) and "Strengths and Difficulties" questionnaire (SDQ)[42] (reflecting parents' perceptions) over a 10-week period from first to penultimate appointment at MEND. These are all validated measures which are used widely in child health research and practice. However, the self-esteem measure has been adapted for use in the (younger) MEND age group.

Service-level information is also collected by MEND programmes on physical and sedentary activities (questionnaire adapted from Slemenda et al[43]) and diet behaviour and intake (questionnaire developed by MEND). We will assess variation in change of these variables as additional secondary outcomes, but interpret them cautiously, given the questionnaires are unvalidated. However, they may be useful to raise hypotheses for testing in future studies. We will also collect financial data from MEND Central and PCTs/LAs on intervention costs borne by the NHS and PSS in the delivery of MEND. These will include the costs of delivering the core MEND programme, local programme start-up costs, ongoing costs and typical venue costs (including exercise and discussion areas).

Justification for outcome measures: for the secondary data analysis, we are limited to using outcome measures which are collected as part of the routine service delivery of MEND programmes. We will use a range of outcomes, as none are optimal. Most children who participate in an intervention such as MEND might be expected to reduce BMI over a 10-week time period. However, we will be able to examine whether this happens equally across all groups of children or whether some groups lose more (or little). In addition, if some groups do not change their BMI over 10 weeks, a long term decrease in BMI is implausible. We can benchmark service-level 10-week data on BMI against similar data collected in the trial (where BMI loss was sustained over 6-12 months)[28]. The National Obesity Observatory (NOO) notes the usefulness of short term outcome data to assess progress within commissioning timetables.[20]

9. Assessment and follow-up

9.1 Assessment of outcome associated with participation in MEND

All measures are taken at the start and end of the programme (i.e. 10 weeks apart). Anthropometry is measured by programme staff. Height is measured using a standard stadiometer accurate to 1mm, and weight using electronic scales accurate to 0.1 kg following standardised procedures.[44] MEND issues sites with a list detailing suitable measurement equipment for obtaining these measurements. Parents complete questionnaires on strengths and difficulties, diet and physical activity. Children complete questionnaires on self-esteem and body esteem (see section 8).

9.2 Assessment of harms

We will use self-esteem as an indicator of possible harms, as it measures broad aspects of wellbeing and, unlike body esteem, is not targeted as part of the MEND programme.

Secondary data quality: all MEND leaders undergo a standardised training and are required to pass an assessment before being issued with a certificate to lead a MEND programme. Part of this training is dedicated to measurement processes, including the importance of accurate recording. Data entry systems alert programme staff to entered values that are likely to be errors (e.g. implausible values). Feedback on results is given to both MEND participants and local commissioners, which is a further incentive to record measurements accurately, as leaders are aware that inaccuracies may mislead and cause distress to participating families.

For data being used in the secondary data analysis, we will assess data quality and consider how to minimise risks associated with variable quality. We will carry out initial analyses to establish which measurable factors (related to individuals or MEND centres/programmes) are associated with missingness. As missingness may be associated with the outcomes of interest, we will consider using multiple imputation techniques to incorporate adjustments for "informative" missingness. We will construct datasets which attempt to optimise data availability for each research question.

Qualitative component:

Mapping work carried out for the Department of Health on large-scale and locally-based schemes to promote healthy weight among obese and overweight children in England,[25] while lacking the texture of the qualitative work we are proposing, suggests a number of areas which could provide barriers and/or levers to effective service provision including:

- *Practical factors* affecting implementation (extent of funding; transport accessibility and affordability; level of training and motivation of staff; involvement of other agencies).
- *Social factors* (general goodwill towards/feelings about scheme; degree and type of carer involvement; motivation of participants to attend).
- *Factors related to the programme features and socio-cultural context* (mode of referral; interpretation of programme in specific local contexts; follow-up/booster sessions).

These factors, and previous findings from qualitative work on childhood overweight and obesity and interventions to address these,[45;46] form the starting point for our qualitative work. We will use recalled experiences of children and their parents/carers before, during and one year following completion (or not) of the MEND programme to attempt to:

- understand the reasons for participation, non-participation and drop out
- provide case study examples of any ways in which MEND schemes have informed changes in the determinants of obesity, given that long term progress in the reduction of childhood obesity will depend crucially on wider changes
- ascertain the types of costs, if any, borne by families (and by which members). We will investigate with family members whether they perceive they are spending more or less money each week (and, if so, how much), on different categories of expenditure as a result of participating in MEND. Categories will include different types of food, drink, exercise and leisure activities. We will also consider other costs, including any changes made to the family budget or use of time as a result of parents or other care-givers attending each of the 20 sessions
- elucidate and understand the practical factors affecting implementation, with a focus on lessons for implementation of public health programmes more generally

(this work will largely involve commissioners but will also draw on the above)

10. Proposed sample size

Secondary data analysis: we expect approximately 14000 children across 300 centres in England to have completed a MEND programme between January 2006 and October 2010. We will use all the data that are already available, and so our sample size calculation is presented to show that we have sufficient power to detect meaningful changes, as there is no rationale for, nor resource implication from, selecting a smaller sample. To detect a difference of 0.3 kg/m^2 change in BMI score between two groups (e.g. children of lone versus couple parents) would require 260 children in each group, using a conservative estimate (0.025) of the intra-class correlation coefficient. Our analysis will use additional explanatory variables and levels, implying a larger sample size (though we cannot quantify this prior to access to the full data). As a result, we do not consider this study to be overpowered.

Qualitative component: the sample size for the qualitative component is based on our experience of the sample size needed to reach saturation (when additional data add little to ongoing analysis) on the key themes to be explored. The aims of the sampling strategy are to recruit a maximum variation sample (in terms of those variables likely to shape experiences and accounts, such as gender, age, ethnicity and area deprivation).

Using MEND records, we will recruit up to 30 families (around 100 individuals) - 10 families who have completed the programme, 10 who dropped out and, where feasible, 10 who were referred but did not take up the offer. Records are likely to be less good for non-attendees, such as young people who may have wanted to attend but could not as there was no family member to accompany them, or a parent unable to persuade their overweight child to attend. They are likely to be recruited through other means, including PCT contacts. The sample will be stratified in this way to maximise the potential for identifying and learning from barriers and levers and records used to cover a range of socio-economic backgrounds, family types and locations. They will be invited to participate in family-based focus group discussions including siblings and non-accompanying parents/carers as the index person (usually the accompanying parent) elects. Where there is no ‘’family group” (e.g. in the case of some non-participants), individuals will be interviewed. We will carry out a further 30 individual interviews by inviting individuals identified as good informants, on the basis of the group discussions, to an additional interview. Vouchers (£10) for a high street store will be offered as a “thank you” token to participants.

Recruitment of commissioners will also be designed to obtain a maximum variation sample. Again, we will sample to saturation, with the expectation that this will be reached by including around 30 individuals. They will be contacted for telephone interviews on their commissioning decisions. We will recruit using ‘’snowballing” techniques, starting with our two project partner PCTs, and drawing on the expertise of local and regional obesity leads and the National Obesity Observatory. Areas of high and low deprivation will be represented, as well as areas with differing ethnic profiles. Most of those interviewed will be health service commissioners, but we will also seek advice from the regional obesity co-ordinators on whether, in particular areas, the local authority or 3rd sector players (including scrutiny committees and those running programmes for looked after children) are likely to have particular insights into barriers, levers or resource allocation.

11. Statistical and qualitative analysis

Secondary data analysis

Data structure: service-level data are collected by MEND at local level and collated for storage at MEND Central. A MEND centre refers to the level at which a contract is placed between MEND and a funder (e.g. a PCT, LA or the BLF), for a specific location, defined by the first four characters of the post code. There are over 300 MEND centres which are running or have run MEND programmes over the period specified. Each centre will have run one or more 10-week programmes (range: 1 to 15) and each programme will have from 3-19 participants (median: 7).

The levels will therefore be:

- Individual: variables available include gender, age, ethnicity, housing tenure, parental unemployment, lone parent or couple household, distance from MEND centre
- Programme/centre – variables include funding source, type of facility, participant group size (staff size is constant), location
- Neighbourhood (based on area of child's residence): variables include global measures of area deprivation (Index of Multiple Deprivation IMD 2007: http://www.communities.gov.uk/communities/neighbourhoodrenewal/deprivation/deprivation07 /), as well as child-focused measures (Index of Deprivation Affecting Children IDACI 2007: http://www.communities.gov.uk/communities/neighbourhoodrenewal/deprivation/deprivation07 /). In addition, selected specific environmental risk factors for diet and physical activity will also be utilised. For physical activity, these include the Local Index of Child Wellbeing 2009 Environmental Sub-domain (access to sports and leisure facilities, levels of reported crime: http://www.communities.gov.uk/publications/communities/childwellbeing2009) and Generalised Land Use Database 2005 (access to green spaces, domestic gardens and water: http://communities.gov.uk/publications/planningandbuilding/generalisedlanduse). For diet, these include density and ratio measures of fast-food outlets to grocery stores (from telephone directories and online corporate websites). Data will be converted to a standard geography (Lower Super Output Area) using GeoConvert (http://geoconvert.mimas.ac.uk/).

NB: Although schools and family are potentially important levels in relation to childhood overweight, we do not have data on schools and the information on family is largely the same as that collected for participants. However, we will explore the influence of schools and families in our qualitative work.

We will first describe the participants in MEND, including comparing the characteristics of those who complete the programme with those who drop out. We will also assess whether characteristics of participants have changed over time (around 180 sites have been running for 2 years) and compare them to the participants in the original RCT.

To assess the reach of MEND, we will compare whether the characteristics of those who participate in MEND are what would be expected given the predicted characteristics of populations of overweight children, which we will estimate from synthetic populations constructed using routine and survey data. A similar approach has been used in evaluating the potential impact of stop smoking services on health inequalities.[47] First, we will construct an overweight population for England in the MEND target age range. We will estimate the demographic characteristics of the population of overweight children using characteristic-specific rates of childhood overweight from the HSE.[1] We will assess how the distribution of each demographic characteristic of interest (age, gender, ethnicity) differs between the synthesised overweight child population of England and the participants of MEND. We will repeat this approach using national-level data from the National Child Measurement Programme (NCMP) for gender, ethnicity and IDACI, and combinations of these (NCMP does not collect data on all ages of children in the MEND target age range and HSE does not collect the same socio-economic variables as MEND – hence the need to triangulate information from more than one data source). Using the NCMP, we will also carry out comparable analyses at regional level and, if data availability permits, at smaller areas. Our ability to do this will be facilitated by having two Public Health Observatories as project partners (the national Child and Maternal Health Observatory (ChiMat), hosted by Yorkshire and Humber Public Health Observatory, and the National Obesity Observatory (NOO), hosted by the South East Public Health Observatory).

To compare whether the outcome (primary outcome is BMI change) associated with participation in MEND varies, we will first describe the outcome seen in service-level data, using random effects modelling after adjusting for clustering within programmes. We will also assess whether or not the outcome has altered over time. We will benchmark this against the results seen in the original trial.

We will then use multi-level models to estimate outcome by individual characteristics (e.g. children of lone vs couple parents) and area of residence characteristics, recognising the potential importance of social and material context on individual responses to MEND[48]. In these models, the first level is the individual and the second level is the area of residence of the child (for variables, see above). We will study MEND centre/programme as a cross-classification where the data allow. We will test for pre-specified interactions: for example, we hypothesise that there will be a difference in BMI change between children of lone compared to couple parents, and this difference will be greater in areas of good access to green space (as the time constraints on lone parents may limit their capacity to exploit it).

Relevant models will be adjusted for BMI at baseline to adjust for regression to the mean. We will also investigate whether baseline self-esteem mediates the effect on outcomes and whether SDQ (as an indicator of parental perception of the psychological needs of their children) mediates programme completion. Siblings may attend MEND together, and we will investigate using within-family variation as an additional level in our models. Sensitivity analyses will be run to test assumptions associated with our models.

The financial data from MEND Central on intervention costs borne by the NHS and PSS in the delivery of MEND will be analysed to investigate the mean cost per participant. We will investigate how these costs vary by programme size, centre and area characteristics.

Analysis of qualitative data

Analysis of qualitative data will be initiated on the earliest interviews, using these to refine our conversations and questions. Interviews will be transcribed and analysis of data will use principles of the constant comparative method,[49;50] including detailed use of open coding on early data, development of conceptual coding schemes, double coding and an iterative approach. Our experience is that for policy and practice-orientated research, an approach which goes beyond thematic analysis is helpful for generating data that are both valid and useful.

12. Ethical arrangements

For the secondary data analysis, we will use data already collected and collated by MEND. Parents give informed written consent for their child to participate in the MEND programme. The consent form contains the following statement: “I also agree for my family’s data to be used anonymously for any purpose that MEND Central deems

appropriate.” We have applied for and received permission from UCL Research Ethics Committee (Application Number 2677/002, September 2010.) for the secondary data analysis.
The qualitative component includes a study of children, families and commissioners. For the study of children and their families requires primary data collection with participants in the MEND programme. We have applied for and received permission from UCL Research Ethics Committee (Application Number 2842/001, February 2011) for this component of the study. For the study of commissioners (most of whom work for the NHS), we approached the NHS National Research Ethics Committee (East London Research Ethics Committee 1). The committee deemed that this component of the study was a service evaluation and therefore did not require NRES permission. The study is also exempt from the need to seek ethics permission from UCL Ethics Committee. However, we will conduct this component with reference to the Economic and Social Research Council (ESRC) Research Ethics Framework.

13. Research governance

Anonymised data will be transferred from MEND Central to ICH MRC Centre of Epidemiology for Child Health’s secure data enclave and managed in accordance with ICH's established, regularly reviewed systems for confidential and secure data processing, management and archiving. All data management (for both quantitative and qualitative data) will be carried out within the MRC Centre's virtualised desktop environment, ensuring that data are contained within a highly secure data centre. Thin-client, remote access to the environment ensures that user access is tightly constrained and detailed audit trails of user interactions are maintained. Potentially disclosive variables such as postcode and date of birth will be transferred and stored in separate files, with a unique common identifier to allow re-linking. Qualitative data will be anonymised at reporting.

We propose a Study Steering Committee (SSC), to be chaired by an independent academic or commissioner. We propose that the composition of members (including the chair) will be two commissioners, two academics, two service users (parents) and the PI of this application. Co-investigators and project partners will be invited to be observers. The SSC will oversee the conduct of the study and will be asked particularly to ensure that processes to address potential conflicts of interest are adhered to. These include:

- Applicants from MEND will not take part in data analysis (quantitative or qualitative), though they will be involved in planning the analysis and in interpretation
- The results of the data analysis will be presented to the SSC prior to report or paper writing being commenced
- The reports of the results will be scrutinised by the SSC and checked against the presentation of the results made earlier.

To prevent potential reviewers being conflicted, we have not yet approached any individuals.

14. Project timetable and milestones

The project will run for two years. Ethics permission will be applied for before the project starts. The timetable/milestones are as follows:
Months 1-4: confirm ethics permission, collation and anonymisation of data at MEND, transfer data to ICH, start organisation of qualitative component
Months 5-7: obtain routine data on areas, assess missingness and other data quality issues on all data sets, link MEND data with area-level descriptors, construct optimal data sets for research questions, obtain customised prevalence rates from NCMP, assess and address remaining data needs, complete sample selection and administrative arrangements for qualitative component, start qualitative data

collection, first meeting of SSC
Months 7-20: carry out secondary data analysis, including multi-level modelling, qualitative data collection, transcription and analysis
Months 18-20: meeting of SSC (for presentation of results - see section 13), discussion with PEAR group (see section 16)
Months 20-24: preparation of papers, synthesis of results, final report, meeting of SSC (to agree final report), dissemination (including feedback to the PEAR group and participants in qualitative component).

15. Expertise

Our team has expertise in public health research, quantitative and qualitative methods, and health economics research. Catherine Law is an epidemiologist and public health physician with an interest in life course approaches to children's health, inequalities in health and the promotion of healthy behaviours and patterns of growth. She will be in overall charge of the project, will supervise the quantitative analysis, and will be guarantor of the data and manager of the funding. Helen Roberts is a sociologist working on inequalities in child health and knowledge translation. She will lead the qualitative component of the study. Stephen Morris is a health economist who has undertaken research for the National Audit Office on the cost of obesity to the NHS in England and has published papers on economic aspects of obesity. He will co-ordinate work on economic issues. Steven Cummins is a geographer with training in epidemiology and public health. He will bring expertise in the socioenvironmental determinants of health and the evaluation of community interventions to combat obesity. He will supervise the collation of environmental data. Tim Cole is a statistician with expertise in the assessment of childhood growth. He has been a collaborator on the MEND programme since its inception. He will provide statistical expertise. All members of the project team will take part in the planning, management and reporting of the project.

Project partners

MEND

Paul Sacher is a Senior Research Fellow at the UCL ICH, as well as part-time Chief Research and Development Officer at MEND Central. Paul Chadwick is a Consultant Clinical and Health Psychologist and Honorary Research Associate at Cancer Research UK Health Behaviour Research Centre, Department of Epidemiology and Public Health, UCL and Clinical Director at MEND Central. They will facilitate collation, anonymisation and transfer of data from MEND to UCL ICH but will not take part in the data analyses.

UCL ICH: we will work with Prof Harvey Goldstein (Honorary Professor, MRC Centre of Epidemiology for Child Health), an expert on multi-level modelling and techniques to address missing data. He will provide advice on the secondary data analysis. We will also work with Prof Atul Singhal (MRC Childhood Nutrition Research Centre), who is currently running an RCT of MEND in "field" conditions, with waiting list controls. He will provide data from this RCT, collected at 10 weeks, and 6 and 12 months, against which the 10-week service data, being analysed as part of the proposed study, will be benchmarked.

PCTs: we have developed this proposal in consultation with colleagues at two PCTs, Drs Ann-Marie Connolly and Helen Walters (one inner city and one that includes town, coastal and rural areas; both PCTs have areas with significant deprivation). We will work with them throughout the study to ensure the planning, conduct, analysis, reporting and dissemination reflect the needs of practitioners. Both partners have confirmed that this work will complement existing local process evaluations that some PCTs are conducting on their obesity projects.

Public Health Observatories: we will work with the NOO and ChiMat. They will advise on data availability and quality for non-standard presentations (e.g. tailored to the MEND age range or for different areas), provide customised overweight prevalence rates by gender, ethnicity and socioeconomic status (measured by IDACI) from the NCMP, and will facilitate local contacts, data access and transfer for other datasets, if necessary (see section 11).

The National Children's Bureau is also a partner (see section 16).

16. Members of the public

In July 2009, we met with the National Children's Bureau's young persons' group on public health (PEAR) to discuss this application. The PEAR project aims to enable young people to contribute to improving UK awareness of public health research and decisions being made about public health issues (www.ncb.org.uk/pear/). The young people in the group live in or near London or Leeds, are ethnically diverse and some (from the PI's observation) are overweight.

Following an introduction to the MEND programme, PEAR members worked in small groups on life scenarios of hypothetical MEND participants. These scenarios were designed to reflect possible barriers and levers to participation in MEND and ethnic and socio-economic diversity.

There was then feedback and discussion in a plenary session. PEAR members felt that MEND would be an attractive option for many overweight young people, but highlighted practical barriers, such as school work, to participation. They were also concerned that many parents, particularly those who were employed or had no partners, would find regular attendance at MEND challenging. We developed the outline proposal (particularly the research questions and project aims) based on this feedback and will plan our qualitative data collection with this in mind. We plan to report our findings back to the PEAR group and ask for their input to interpretation and dissemination.

17. Funding

NIHR Public Health Research Programme (awarded July 2010)

18. Changes since last version (23rd November 2010)

Update to section 12 (ethical arrangements)

Update to section 17 (Funding)

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