Protocol

Scientific title: NAP SACC UK: A feasibility cluster randomised controlled trial in child care settings to increase physical activity and healthy eating in 2-4 year olds

Lay title: NAP SACC UK

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Logo:

1. Background

1.1. Existing research

Among adults regular physical activity is associated with reduced risk of heart disease, stroke, type 2 diabetes and all cause mortality. Among children physical activity is associated with lower levels of cardio-metabolic risk factors including lipids, blood pressure and improved psychological well-being. Physical activity patterns track moderately from childhood to adulthood indicating that physical activity is associated with both short and longer-term health among children. The English Chief Medical Officer's recommendations are that children under 5 who are capable of walking should be physically active for at least 3 hours per day and sedentary time should be minimised.[1] In 2008, a third of 2 to 4 year olds met the previous guideline of a minimum of 60 minutes of at least moderate intensity physical activity each day.[2]

A diet high in fruits and vegetables and low in saturated fat has been associated with reduced risk of adult heart disease, many forms of cancer and all cause mortality. Dietary patterns are established during childhood. Children aged 1.5 to 10 years do not eat sufficient fruit and vegetables; 32% of boys and 18% of girls are reported as having eaten no fruit during a 4-day period.[3] Intake of non-milk extrinsic sugars (NMES) is close to the daily reference value of 11% of total daily energy intake for 1-3 year olds and exceeds this value for 4-18 year olds (15%). Soft drinks contribute 14% to the intake of NMES in 1-3 year olds and 19% to the intake of NMES in 4-10 year olds. Saturated fat intake is also higher than the recommended 11% of total daily energy intake, at 15% for 1-3 year olds and 13.6% for 4-10 year olds. Within low-income populations, pre-school aged children, are more likely to consume table sugar and soft drinks compared to more affluent groups.[4]

There is an urgent need to find new ways to increase physical activity and healthy eating among pre-school aged children to reduce their risk of developing obesity and chronic diseases. Child care settings provide scalable opportunities to deliver interventions at the population level.[5] The Early Years Foundation Stage statutory framework requires nurseries to maintain a high staff to child ratio (1:4 for 2 year olds; 1:13 for 3-5 year olds).[6] This provides nursery staff with contact during mealtimes to apply the techniques of taste exposure, encouragement, praise, and modeling of healthy eating. Obesity rates in children have increased since the 1990s and now 9.4% of children aged 4 to 5 in England are obese with a further 13.2% overweight.[7] Obesity rates increase with deprivation; 12.2% of 4 to 5 year olds in the most deprived areas are obese, compared to 6.3% in the least deprived quintile. It is predicted that 17% of children aged 2-11 in England will be overweight in 2020 and a further 13% will be obese.[8]

A common misperception is that young children are very active. Assessment of physical activity in 3-5 year old children at pre-school has shown that they are physically inactive during most of their time in preschool, with only 3% of time engaged in moderate to vigorous physical activity (MVPA). MVPA is closely associated with cardio-respiratory fitness and body mass index (BMI) in adolescence, therefore it is of concern that such a small proportion of time in preschool is spent in MVPA. Further, around 80% of time is spent in sedentary activities.[9] The particular pre-school that a child attends is a strong predictor of physical activity levels and being outdoors is one of the most powerful correlates of physical activity in children.9 The lack of MVPA in pre-school settings may be influenced by constraints of space, lack of equipment, lack of scheduled times for free play and outdoor play. A systematic review of interventions to increase physical activity in child care settings found regularly provided, structured physical activity programmes can increase the amount and intensity of physical activity.[10]

Three systematic reviews of obesity prevention, physical activity and nutrition in young children have all identified the lack of studies in young children and the need for more research with robust study designs.[11,12,13] The Cochrane review of obesity prevention in children identified research gaps for effective interventions for children aged 0-5 years.[13] In addition, the review recommended that studies need to better report the impacts on the environment, setting and sustainability and recommended that studies testing interventions are guided by theories such as the socio-ecological model. Larson et al reviewed the regulations, practices, policies and interventions for promoting healthy eating and physical activity and for preventing obesity in children attending child care.[11] The review identified a lack of strong regulation in child care settings in relation to health behaviours such as physical activity and diet.

Yet, within child care settings there is ample opportunity to improve nutritional quality, time engaged in physical activity, and caregivers' promotion of health behaviours. There have been a limited number of childcare interventions and only two interventions have successfully demonstrated an effect on weight.[11]

The research is timely because the 2012 Early Years Foundation Stage (EYFS) statutory framework sets the standards to ensure that children learn, develop and are kept healthy and safe. The EYFS includes standards for physical activity and healthy diet. The School Food Trust has published a guide for implementing food and drink guidelines. In addition, revised physical activity guidelines for young children in England were published in 2011. However, no programme is available to support child care settings in England to assess, plan and implement changes for nutrition and physical activity. A programme has recently been established in Wales, the "Welsh Healthy and Sustainable Preschool Scheme", to work with all early years providers.

A small number of randomised controlled trials in child care settings which aim to improve nutrition and/or physical activity or sedentary time with 2-4 year olds have been published or are underway (see Table 1). Interventions in kindergartens, homes or other settings; with younger or older children; or obesity management are not included. The studies in Table 1 focused on education, staff development, addressing child care policies or opportunities for increasing physical activity. Many of the studies reported small changes in children's physical activity, sedentary time or nutrition in the short term. There was a lack of long-term follow-up or demonstration of effect across a wide range of anthropometric and behavioural changes. Only three of the studies were in the UK.

Table 1 indicates that a limited number of environmental interventions in child care settings exist, and none target both the diet and physical activity aspects of child care environments. The Nutrition and Physical Activity Self Assessment for Child Care (NAP SACC) intervention was developed to fill this research and practice gap. NAP SACC was developed in the USA aimed at improving nutrition and physical activity environment, policies and practices in child care centres through self-assessment and targeted technical assistance. It addresses nutrition, physical activity and sedentary behaviours by giving providers choice of where they focus change. In light of the evidence above we propose to adapt NAP SACC for the UK, building upon the findings from systematic reviews of obesity prevention, physical activity and nutrition in young children.

1.2. Risks and benefits

There are major potential public health benefits for children and wider society if the intervention is found to be feasible, and later effective to improve child care environments and reduce risks of obesity. If NAP SACC is found to be cost-effective in a subsequent full-scale trial, the intervention will be readily implementable as an intervention for adoption and long term maintenance across the UK.

Child care settings participating in the evaluation will implement the intervention and provide access to children and parents to collect data. There will be a limited degree of disruption to the child care provider and the children's participation in activities during data collection. To minimise the burden on child care staff and minimise attrition, as well as complying with child protection policies, two members of the research team will attend each data collection. We will also work with child care providers to identify appropriate methods and times of data collection to minimise disruption. A potential risk is that some children or parents might find aspects of the study upsetting if they are particularly sensitive to issues of food or weight. The Principal Investigator will work with child care providers to ensure a system is in place to enable appropriate support to be provided in such circumstances. Any potential for harmful effects due to the intervention itself will be explored via the collection and analysis of qualitative data to explore any unintended consequences.

1.3 NAP SACC: intervention, previous studies and planned UK intervention

NAP SACC intervention: The Nutrition and Physical Activity Self Assessment for Child Care (NAP SACC) - http://www.napsacc.org/ - is an intervention delivered in child care centres with the aim of improving policies, practices and the nutrition and physical activity environment, through a process of self-assessment and targeted assistance. NAP SACC is a theory-based program that employs

Table 1 Published and ongoing cluster RCTs in child care settings to improve nutrition and/or physical activity with 2-4 year olds

Name of study/author	Type of intervention	Setting *Country* (age range)	Results for intervention group compared to control group
Active Play[14]	Family focused intervention to decrease sedentary time and increase physical activity for 10 weeks	Surestart Centres; *England;* (3-4.9 years)	1.5% and 4.3% less sedentary time during week and weekend days, respectively and 4.5% and 13.1% more physical activity during week and weekend days
Alhassan[15]	An increase of 60 minutes per day in time spent outdoors for 2 days.	Head start centres; *USA;* (3-5 years)	No difference in total daily physical activity.
Binkley[16]	Children assigned to gross motor or fine motor group for a year.	Nursery; *USA;* (3-5 years)	Time spent in vigorous activity was higher in the gross motor group at 18 months but not 24 months.
Brocodile the Crocodile[17]	7 educational sessions encouraged to reduce TV	Nursery; *USA;* (2.6-5.5 years)	-4.7 h/wk television/ video viewing (95% confidence interval, -8.4 to -1.0 h/wk; P =.02).
CHERRY[18]	An exploratory trial, focused on family centred nutrition	Children's Centres; *England;* (1.5-5 years)	Positive, but non-significant changes in fruit and vegetables, decreasing sugary drinks and snacks.
Healthy Caregivers /Children	Curricula for teachers/parents, menu modifications and policies for nutrition, physical activity and screen time.	Children's Centres; *USA;* (2-5 years)	Study still underway
Hip-Hop to Health[19]	Healthy eating and physical activity lessons for 14 weeks	Preschools; *USA* (3-5 years)	More moderate-to-vigorous physical activity (difference between adjusted group means = 7.46 min/day, P = 0.02) and less total screen time (−27.8 min/day, P = 0.05). No differences in BMI, BMI *Z* score, or dietary intake.
Move and Learn[20]	Integration of physical activity into preschool half day over 8 weeks	Preschools; *USA;* (3-5 years)	In 2 of the 8 weeks the levels of physical activity were higher.
Munch and Move[21]	Professional development to promote healthy eating and physical activity among children	Preschools; *Australia;* (mean age 4.4 years)	Fundamental movement skills (FMS) improved (P < 0.001) and the number of FMS sessions increased by 1.5/week (P = 0.05). Sweetened drinks reduced by 0.13 servings (46 ml) (P = 0.05).
Pre-school nutritional intervention[22]	Sessions by nutritionists with some parent involvement. Activities covered different foods, preparing food and eating behaviour.	Pre-schools; *German;* (3-6 years)	Fruit and vegetable intakes increased by 0.23 and 0.15 portions per day (*P* < 0·001 and *P* < 0·05, respectively) respectively. No changes in water or sugary drinks consumed.
Reilly[23]	Nursery and home elements with enhanced physical activity programme and materials for home	Nursery; *Scotland;* (mean age 4.2)	No differences in BMI, physical activity or sedentary behavior.
Tigerkids[24]	Modules on physical activity, fruit and vegetables and water	Pre-schools; *Germany*; (3-5 years*)*	Higher consumption of fruits and at 6 months, which was sustained at 18months.
Toy box[25]	Preschool-based, family-involved intervention to influence obesity-related behaviours in 4-6 year olds	Preschools; *6 European countries;* (4-6 years)	Study still underway

components of social cognitive theory (SCT) and socio-ecological framework.[26] Social cognitive theory identifies the inter- relationship between the environment, people and behaviour. The socio-ecological health promotion framework identifies multiple, interdependent elements at policy, community, organisational, interpersonal and intrapersonal levels.[27] Goals of the programme are to improve the nutritional quality of food served, amount and quality of physical activity, staff-child interactions, and centre nutrition and physical activity policy. NAP SACC nutrition areas of focus include: fruits and vegetables; fried food and high-fat meats; beverages; menus and variety; meals and snacks; food items outside of regular meals and snacks; supporting healthy eating; nutrition education for children, parents and staff; and nutrition policy. NAP SACC physical activity areas of focus include: active play and inactive time; TV use and TV viewing; play environment; supporting physical activity; physical activity education for children, parents, and staff; and physical activity policy.[29] The NAP SACC approach, which uses data, evidence backed action planning, choice, support, engagement and ownership, tailoring, and sustained change have been used in other public health interventions (e.g. the 'Social and Emotional Education and Development' RCT and the Gatehouse Project).[28] The steps include:

Steps of the NAP SACC intervention	*Theory/ framework*	
1. Self-Assessment: The child care manager, together with key centre staff complete the NAP SACC self assessment tool. This tool assesses the centre on 15 key areas in nutrition and physical activity with response options ranging from minimal to best practice.	*Social Cognitive Theory: Environment; People; Behaviour*	*Socio-economic framework: Policy; Community; Organisational; Interpersonal; Intrapersonal*
2. Action Planning: Based on self-assessment answers, facilities choose 3 to 4 areas for improvement and map out an action plan for making these improvements with guidance and support from the NAP SACC Consultant		
3. Workshop Delivery: The NAP SACC Consultant delivers 4 workshops to the facility. These workshops include: 1) Childhood Overweight, 2) Nutrition for Children, 3) Physical Activity for Children, and 4) Personal Health and Wellness for Staff		
4. Targeted technical assistance: NAP SACC Consultants maintain regular contact with the facility to provide support and guidance in making their improvements.		
5. Evaluate, Revise, and Repeat: The NAP SACC self assessment instrument is completed a second time to see where improvement have or haven't been made. At this time Action Plans are revised to include new goals and objectives and technical assistance continues.		

Previous NAP SACC studies: A pilot study and full scale RCT of NAP SACC in the USA have been published.[26,29] The pilot determined the feasibility, acceptability, and reported impact of the NAP SACC environmental intervention in 8 child care settings and found intervention centres rated themselves higher at follow-up than at baseline, and relative to comparison centres, reported a variety of environmental nutrition and physical activity improvements confirmed by research staff. Qualitative research found all the child care provider directors reported that the self-assessment instrument was either fairly or very easy to use and took an average of 26 minutes to complete.[26]

In the full-scale RCT of NAP SACC 30 child-care health consultants serving child-care centres in North Carolina were recruited and randomly assigned into intervention or delayed-intervention control groups.[29] These staff implemented the NAP SACC intervention in up to three child-care centres (n=84) from their existing caseload. 41/56 intervention centres completed most or all of the intervention. After adjusting for consultant (random effect) and baseline environmental audit score, the intervention centres showed an 11% improvement from baseline to follow-up, while no change was observed in the control centres (p=0.06). A key weakness of this trial was the low level of fidelity of implementation. In a per-protocol analysis, using centres that implemented the intervention, the pre–post difference between intervention and control centres (p=0.01) was observed for the total nutrition score. No difference was observed between intervention and control groups for the physical activity component of the environmental audit score. However, in both analyses a positive change was noted for the intervention group compared to a negative change in the control group. A second trial which assessed physical activity levels found an increase in accelerometer measured light to moderate intensity physical activity.[30]

NAP SACC UK: A feasibility cluster randomised controlled trial in child care settings to increase physical activity and healthy eating in 2-4 year olds

Planned NAP SACC UK intervention: NAP SACC will be adapted for use in the UK through the formative work of this study with a particular emphasis on increasing parental involvement and tailoring the intervention for the UK context. The intervention will be delivered in child care providers. The intervention will be delivered in North Somerset by Health Visitors, employed by North Somerset Community Partnership, and in Gloucestershire by Health Visitors employed by Gloucestershire Care Services NHS Trust. The intervention will be funded by Public Health in North Somerset Counciland by Gloucestershire County Council.

NHS components: Public Health Wales provides an expert public health resource as part of the NHS in Wales. Public health in North Somerset ceased to be part of the NHS from April 2013 and is provided by the Council. The Health Visitors in North Somerset are not employed by the NHS (they are employed by a social enterprise: North Somerset Community Partnership). Welsh Healthy and Sustainable Preschool Scheme staff are employed by Public Health Wales. Health Visitors in Gloucestershire are employed by the NHS, by Gloucestershire Care Services NHS Trust.

1.4 Rationale for current study:
The 2012 NHS Public Health Outcomes Framework for England includes three areas relevant to this study: excess weight in 4-5 year olds and older children, measures of physical activity, inactivity and diet. In 2011, 87% of 3 to 4 year olds attended formal child care in England; with 44% attending some form of nursery care.[31] Nurseries are a particularly important provider of childcare in more deprived areas. Fifteen hours a week of free early education are provided to all 3 and 4 year olds in England and Wales; 98% of 4 year olds and 70% of 3 year olds receive their entitled provision.[31] In 2013 this free entitlement will be extended to 2 year olds in some deprived areas. Therefore, it is important that child care environments are healthy to promote healthy behaviours and reduce the risk of obesity.

NAP SACC is one of the few interventions which works with child care providers to produce sustainable changes in the childcare environment and to promote improvements in children's activity levels and nutritional intake. NAP SACC has been widely adopted in States throughout the US, which demonstrates that it is a model which if shown to be effective could easily be disseminated in the UK. NAP SACC has not been assessed for feasibility or acceptability of use in the UK or with direct measures of nutrition or BMI. In addition, some issues of fidelity to the intervention were encountered in the US trial, which will be addressed through this feasibility study. Therefore this study will generate new knowledge, which in turn will inform an assessment of the benefit of undertaking a full scale trial of effectiveness and cost-effectiveness. The intervention, if successful, has the potential to be provided cheaply and widely through a range of staff and child care providers. The research has the potential to increase children's health through increased physical activity and healthy eating and drinking.

2. Research objectives:
Primary objective
To assess whether pre-specified criteria relating to the feasibility and acceptability of the intervention and trial design are met sufficiently for progression to a full scale RCT.
Secondary objectives

- To explore the experiences of nursery staff, the intervention delivery team and parents, in terms of acceptability, barriers, facilitators, fidelity to the intervention, data collection methods, participant burden, and feasibility of long term follow-up, with the aim of informing refinement of the intervention and study design prior to a potential full scale RCT.
- To pilot primary and secondary outcome measures and economic evaluation methods, and determine the practicality of data linkage for BMI through the Child Measurement Programme in England and Wales, in advance of a potential full scale RCT.
- To calculate the sample size required for a full scale RCT and to estimate likely recruitment, attendance, adherence and retention rates.

3. Research design:
The research design includes adapting the NAP SACC materials for use in the UK including adapting the NAP SACC home component to involve parents; piloting a cluster randomised controlled trial; piloting the intervention in 12 nurseries with an embedded process evaluation. This proposed project has 2-phases (see

attached flow diagram): (phase 1) Intervention adaptation and development; (phase 2) pilot cluster RCT and process evaluation. See the logic model in Appendix A.

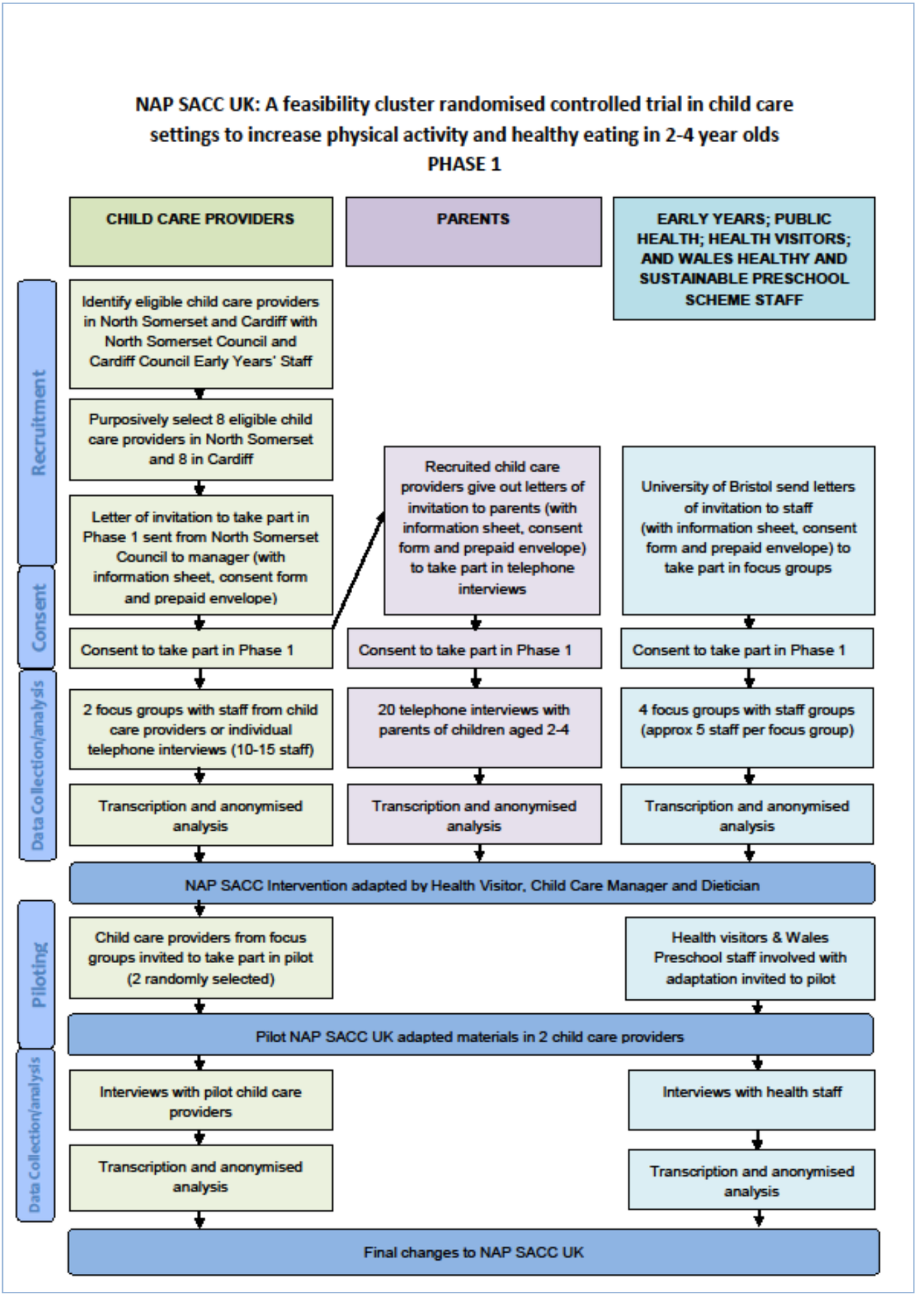
Phase 1 Intervention adaptation and development (6 months):
We will adapt NAP SACC to the UK setting; we anticipate the changes will include changes to wording, use of examples, tailoring self-assessment and standards to comply with UK guidelines and policy on physical activity, nutrition and the Early Years Framework and developing the NAP SACC home component to involve parents (see Appendix B). The adaptations will be made by reviewing each component of the intervention with a Health Visitor, Dietician and Child Care Provider Manager, informed by 6 focus groups with stakeholders: child care provider staff; Health Visitors from North Somerset and Wales Healthy and Sustainable Preschool Scheme staff; and Local Authority staff. Separate focus groups will take place in North Somerset and Cardiff to reduce travel time and thereby facilitate participation. Focus groups or telephone interviews will be conducted with child care staff depending on availability. In addition telephone interviews will be conducted with parents. During Phase 1 we will work with the US founder of NAP SACC (DW) to adapt the intervention and conduct pilot sessions in which we will ask for feedback on the revised materials from child care provider staff and NAP SACC Consultants. The intervention will be further refined before being used in Phase 2. See flow diagram. This refinement will be informed by inviting parents in North Somerset who took part in the Phase 1 interviews to take part in a focus group where the NAP SACC at Home intervention (developed through Phase 1) will be discussed further. Parents in Cardiff who took part in the Phase 1 interviews will not be invited to the focus group because of the subsequent removal of Wales from the study.

Data collection procedures
A purposive sample of 8 child care providers in North Somerset and 8 child care providers in Cardiff will be sent a letter inviting the child care provider staff to take part in focus groups or telephone interview to inform the development of the NAP SACC trial. A letter, project information sheet, reply envelope and form indicating if they wish to participate in a focus group or telephone interview will be sent. Centres will be purposively sampled based on local staff (Council or health staff)'s local knowledge of providers who are likely to be interested in taking part in the study and from a range of settings.

Health Visitors in North Somerset, Healthy Preschool Programme staff in Cardiff and Early Years' staff working at Local Authorities in North Somerset and Cardiff will be sent the same information inviting them to take part in separate focus groups. Six focus groups will be held with each group of staff aiming to determine: which aspects of NAP SACC need to be adapted to incorporate UK guidance, recommendations and terminology; the potential to integrate information for parents and additional training for child care staff to deliver structured active play; how to promote the intervention to child care providers, factors that might influence low participation, adherence to the programme and study; and strategies to ensure participation.

The recruited child care settings will be asked to send letters to parents/carers with children aged 2-4 (excluding children where it is known that the child will be leaving the child care provider during the academic year September 2015-August 2016). The letters will invite them to take part in telephone interviews to discuss the intervention and trial. We will conduct interviews with parents/carers with sufficient numbers until we reach saturation, which we anticipate being approximately 20, to identify ways in which we can adapt the NAP SACC intervention to involve parents in the programme and identify ways of maximising participation. If sufficient numbers of parents/carers are not recruited, we will randomly select other child care settings to ask them to contact parents/carers on our behalf.

Phase 2 Pilot cluster RCT (18 months):
The adapted NAP SACC UK intervention will be a 6 month programme delivered in child care providers in two English and one Welsh Local Authorities.


NAP SACC UK: A feasibility cluster randomised controlled trial in child care settings to increase physical activity and healthy eating in 2-4 year olds
PHASE 1
CHILD CARE PROVIDERS
PARENTS
EARLY YEARS; PUBLIC HEALTH; HEALTH VISITORS; AND WALES HEALTHY AND SUSTAINABLE PRESCHOOL SCHEME STAFF
Recruitment
Identify eligible child care providers in North Somerset and Cardiff with North Somerset Council and Cardiff Council Early Years' Staff
Purposively select 8 eligible child care providers in North Somerset and 8 in Cardiff
Consent
Letter of invitation to take part in Phase 1 sent from North Somerset Council to manager (with information sheet, consent form and prepaid envelope)
Recruited child care providers give out letters of invitation to parents (with information sheet, consent form and prepaid envelope) to take part in telephone interviews
University of Bristol send letters of invitation to staff (with information sheet, consent form and prepaid envelope) to take part in focus groups
Consent to take part in Phase 1
Consent to take part in Phase 1
Consent to take part in Phase 1
Data Collection/analysis
2 focus groups with staff from child care providers or individual telephone interviews (10-15 staff)
20 telephone interviews with parents of children aged 2-4
4 focus groups with staff groups (approx 5 staff per focus group)
Transcription and anonymised analysis
Transcription and anonymised analysis
Transcription and anonymised analysis
NAP SACC Intervention adapted by Health Visitor, Child Care Manager and Dietician
Piloting
Child care providers from focus groups invited to take part in pilot (2 randomly selected)
Health visitors & Wales Preschool staff involved with adaptation invited to pilot
Pilot NAP SACC UK adapted materials in 2 child care providers
Data Collection/analysis
Interviews with pilot child care providers
Interviews with health staff
Transcription and anonymised analysis
Transcription and anonymised analysis
Final changes to NAP SACC UK

Setting: Eligible settings will be local child care providers (day nurseries, private nursery schools, maintained nursery schools, Children's Centres with nurseries and pre-schools) which provide lunch (or another main meal) in North Somerset and Gloucestershire, with a minimum of 20 children aged 2-4 who attend the child care providers for at least 12 hours per week over 50 weeks of the year or 15 hours per week in term time. In North Somerset there are 62 child care providers meeting our inclusion criterion; a similar number is expected for Gloucestershire. Twelve child care providers (6 in each area) will participate in the trial, of which 6 will be randomised to the control group and 6 to the intervention. The child care providers in the control group will continue with their usual planned activities and policies. There will be no placebo intervention for the control group.

Recruitment of child care providers: The NAP SACC study will be discussed with child care provider managers at meetings convened by the Local Authorities and advertised in their Early Years' newsletters. Child care providers will also be sent a letter, project information sheet, reply envelope and form indicating if they wish to participate and reason for their response. If necessary, non-responders will be followed up with a reminder and then a phone call. All interested child care providers will be contacted by telephone to discuss the study; following which, if the provider is still interested they will be visited to discuss the intervention and study in more detail. Twelve child care providers willing to take part in the study who sign a contract of agreement will be randomly allocated to the intervention or control group.

Allocation: The child care providers will be the unit of allocation to 2 arms: NAP SACC or no intervention (usual practice). Allocation will be conducted by an independent statistician at the Bristol Randomised Trials Collaboration, blind to the identity of the child care providers. Stratified randomisation will be used to ensure that the childcare providers receiving the intervention and the controls are closely balanced for a) deprivation (using English or Welsh indices of Multiple Deprivation for the Local Super Output Area where the provider is located), b) size (small or large depending on number of children attending), and c) location (North Somerset and Gloucestershire).

Data collection procedures:

1) Environmental audit: the environmental audit will be undertaken by a trained researcher (who will be blind to allocation arm) during a day of observation in the child care provider.

2) Child measurements: All parents/carers will be informed by letter in advance of data collection that a study will be taking place in the nursery. They will be invited to attend a parents' meeting at the child care setting with the research staff to find out more about the study. Parents/carers will be sent a letter, project information sheet, reply envelope and form indicating if they wish to give consent for their child to take part in the data collection. All child outcomes will be assessed at baseline (prior to starting the intervention) and 1 year later. The Research Study Manager will undertake assessments with a fieldworker who will work together at all times. The staff will be trained and will have completed enhanced Disclosure and Barring Checks as required for those working with children. The indicative primary and secondary outcomes for the trial will be measured in addition to demographic information and potential effect modifiers. At baseline and follow-up parents will be asked to complete a questionnaire including demographics and a 24 hour recall food diary on behalf of their child/children; non-returns will be contacted by telephone by a field worker. The 24 hour food recall for food and drink consumed in the childcare centre will be administered by field workers with the child care staff. At the baseline and follow-up data collections, the child's weight and height will be measured by two trained researchers in the child care setting and the children will be fitted with ActiGraph accelerometers to calculate physical activity and sedentary behaviours. Child care staff and parents will be given simple instructions and advice about the child wearing the accelerometer.

3) Process evaluation: The process evaluation will be called Phase 3 of the study. The study design will use the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, Maintenance), which recognises that, alongside assessment of effectiveness, considerations of reach, adoption, implementation and maintenance are also important in determining whether the desired impacts in the 'real world' will be achieved.[32] The RE-AIM framework and the five levels of the socio-ecological framework will be considered throughout the process evaluation (see Table 2 below). Data collection and analysis will be undertaken by a qualitative Research Assistant using the following methods:

- the initial and final NAP SACC UK self-assessment completed by a child care provider staff member
- observations of at least one meeting between the NAP SACC Consultants and each of the child care providers
- child care manager and NAP SACC Consultant completed logs of NAP SACC meetings including goals, support given and progress made; and for the managers, changes made and reflections on these changes
- semi-structured interviews with child care managers in all the providers, a sample of staff, the four NAP SACC Consultants and sufficient numbers of parents until saturation is reached.

The home component will be evaluated with respect to use of the website, goal setting, text messages, emails and Facebook using reports from the website.

Parental and nursery staff knowledge (nutrition, oral health, physical activity and sedentary behaviours), self-efficacy and motivation will be assessed using questions created for this study

Table 2 Process evaluation and RE-AIM framework

	Participants in process evaluation		
RE-AIM framework	**Child care providers**	**NAP SACC Consultants**	**Parents of children**
Reach	Recruitment and retention of providers	Recruitment and retention of NAP SACC Consultants	Recruitment and retention of parents/children
Efficacy	This will not be assessed in the feasibility study, but would be assessed in a full-scale trial; the feasibility of collecting the secondary outcomes will be assessed which will inform the design of a full-scale trial		
Adoption	Acceptability of the intervention and trial methodology		
Implementation	Adherence and delivery of the intervention		
Maintenance	This will not be assessed in the feasibility study, but would be assessed in a full-scale trial		

The context is an important part of the process evaluation. The Research Study Manager will collect information at baseline (T0) and follow-up (T1) from the child care managers in intervention and control settings using a structured questionnaire during a face to face meeting. The questionnaire will include: the child care provider's involvement in training, improvements or projects to promote healthy eating, physical activity or sedentary time (including the Wales Healthy and Sustainable Preschool Scheme); physical activity provision (number of scheduled active play or structure physical activity sessions per week per age group); sedentary sessions per week per age group; child care physical activity and nutrition policies; and (at T1) costs incurred for their participation in the intervention. The process evaluation will investigate the usual activities and policies in the control group and whether contamination occurs between the intervention and control groups. If contamination occurs steps will be taken to explore the reasons for this and to address this.

4) Cost: To inform the assessment of costs to the public sector, child care providers and parents, intervention related resource use in the form of time and expenses will be collected through the child care audits from child care providers and from a log provided to the NAP SACC Consultants. The Trial Manager will also record the costs of providing training, materials and information. The parental questionnaires at baseline and follow up will include questions about expenses incurred for their child participating in physical activities, any additional expenses resulting from changes in dietary patterns and changes at home and the parent-reported PedsQL for 2-4 year olds.

Proposed duration of intervention and follow-up periods:
The intervention will take place over 6 months. The baseline data collection will take place prior to the intervention at T0. Follow-up assessment will take place 12 months after the baseline at (T1). The follow-up period will assess the feasibility of following older children moving to primary schools, consent rates and the practicality of data linkage to BMI as part of the Child Measurement Programmes in England and Wales in the first year of primary school at age 4-5.

Methods to protect against other sources of bias:
The procedures we would intend to employ in a main trial are outlined below. During the pilot study the purpose will be to ensure they are feasible and acceptable.
Confounding: The threat of confounding due to baseline differences between groups will be reduced by random allocation stratified on location, deprivation and size. The main analysis will be conducted blind to treatment allocation and adjusted for hypothesized baseline confounders. At baseline, data will be collected on socio-demographic characteristics and other potential confounders. Should the small numbers involved in this pilot study result in randomisation not being sufficient to equally distribute all known confounders, these data can be incorporated into multivariable analysis.
Selection Bias: Allocation concealment will be ensured by the use of central concealed randomisation by the Bristol Randomisation Trials Collaboration to allocate eligible and consented child care settings to either the intervention or the control arm. Since the random allocation is concealed from study staff, it will not be possible to influence allocation and therefore selection bias will be minimised.
Attrition bias: Following the protocols used in previous trials undertaken by the Development and Evaluation of Complex Interventions for Public Health Improvement Centre (DECIPHer), we will carry out, where necessary, multiple absentee sessions in order to minimise attrition.
Detection bias: Researchers undertaking the assessment of the outcomes will not have any involvement in the delivery of the intervention. The participation of the Research Study Manager in data collection will make it impossible to blind the allocation of the setting. The staff who analyse the outcome data will be blinded to allocation.
Measurement bias: Bias will be minimised by using validated measuring instruments (questionnaires and equipment) and cut-points for BMI and MVPA; also by using standard operational procedures and ensuring field workers are trained to high standards.

Progression criteria: The primary aim of the feasibility trial will be to assess the feasibility and acceptability of delivering the NAP SACC UK intervention and trial methods prior to a potentially larger, definitive trial. The predefined progression criteria for phase 2 of this study are the following:

Criterion 1: Feasibility
- Was it feasible to implement the NAP SACC intervention in child care providers? This will be assessed according to a) at least 40% of contacted eligible child care providers expressing a willingness in principle to take part in the feasibility trial in response to an invitation to take part; and b) a synthesis from the different aspects of the process evaluation (observation, interviews and analysis of meeting logs between NAP SACC Consultants and child care providers).

Criterion 2: Acceptability of intervention
- Was the intervention acceptable to NAP SACC Consultants? This will be assessed via interviews with Consultants and analysis of meeting logs between NAP SACC Consultants and child care providers.
- Was the intervention acceptable to the majority of child care managers, staff and parents? This will be assessed via interviews with managers, staff and parents.

Criterion 3: Acceptability of the trial design
- Were the trial design and methods acceptable? This will be assessed according to: a) expressions of interest from eligible child care settings; b) interviews with child care providers about randomisation and data collection; c) at least a 40% parental opt-in consent rate for measurements with eligible 2-4 year old children; d) a maximum loss to follow-up of 3 providers (or no more than 2 in any arm) or 40% of children; e) a synthesis of interviews with parents about data collection.

Stopping rules
We do not propose to have formal stopping rules because the pilot trial is not treating patients with a disease which may cause serious harm and the study is not designed to indicate whether the intervention is efficacious. However, the exploratory nature of this trial means that it may be appropriate to alter or stop the trial during the course of the trial if unforeseen results are obtained. Were such a circumstance to arise it would be discussed with co-applicants and with the Trial Steering Committee.

4. Study population:

Phase 1:

Inclusion criteria: the study sample will be recruited from the North Somerset Local Authority area in England and the Cardiff Local Authority area in Wales.

Participants for Phase 1:

- Child care provider managers and staff in day nurseries, private nursery schools, maintained nurseries, Children's Centres with nurseries and pre-schools
- Health Visitors in North Somerset
- Healthy Preschool Programme staff in Cardiff
- Early Years' staff working at Local Authorities in North Somerset and Cardiff
- Parents/carers with children aged 2-4 attending child care providers in North Somerset and Cardiff

Phase 2:

Inclusion criteria: the study sample will be recruited from the North Somerset and Gloucestershire Local Authority areas in England.

Participants for Phase 2:

- Child care provider managers and staff recruited to the trial
- NAP SACC Partners (Health Visitors in North Somerset and Gloucestershire)
- Parents/carers in the recruited providers with children aged 2-4 attending the providers recruited to the trial
- Children aged 2-4 attending child care in the recruited providers attending for an average of 12 hours per week across the year (15 hours per week term time only), being provided with at least 1 main meal by the childcare setting.

Exclusion criteria:

- Child care settings in North Somerset and Gloucestershire which are: Childminders; Crèches; playgroups; primary school reception classes, where schools operate an early admission policy to admit four year olds; Au pairs.; child care providers previously or currently participating in the Wales Healthy and Sustainable Preschool Scheme; child care providers defined as 'Flying Start' centres.
- Children aged <2 and >4 in providers which are recruited
- Children where the parents know the child will be leaving the child care provider during the academic year September 2015-August 2016
- Children whose parents/carers refuse consent for measurements

5. Socioeconomic position and inequalities:

At recruitment child care settings will be assessed for area deprivation using the English and Welsh Indices of Deprivation for Local Super Output Area of the child care provider. At baseline parental socio-economic status will be assessed using the highest of either parent's occupation. Inequalities will be addressed through the research design by selecting child care settings across the range of deprivation. Child care providers will be stratified for high/low deprivation (by ranking the providers by IMD score and dividing into two groups) to ensure that the numbers of participants receiving the intervention are closely balanced within each stratum. Within the recruited sample we will also assess attrition rates according to parental socio-economic status with a view to developing strategies to reduce such differences. In preparation for a main trial we will have an initial look at whether SES appears to modify the effect of the intervention.

6. Explanation of the methods proposed

In the NAP SACC pilot in the US the acceptance rate by child care centre was 43%. A total of 16 of the original 19 centres completed all aspects of the project (16% attrition rate).[26] The RCT of the NAP SACC intervention in the USA provides some indication of compliance and loss- to-follow up of NAP SACC consultants and participation of child care providers. 84 child-care centres were recruited into the study. During the intervention period, two centres closed and were excluded from the study. One of thirty NAP SACC consultants failed to participate in training, resulting in non-implementation in three centres; two additional

NAP SACC consultants were unable to implement the intervention in their respective three centres, and an additional six centres chose not to follow through with implementation. Therefore, 56 of the original 84 (66.7%) centres complied with the intervention and 41 completed most or all of the intervention. This study assessed outcomes at the child care centre level. We will be working with a smaller number of NAP SACC Consultants and any problems with attending training or being unable to implement the intervention from the perspective of the NAP SACC Consultant will be addressed during the study in consultation with the collaborating partners. The reason for any problems and changes required to address problems of participation will be documented as part of the process evaluation. The experience of the NAP SACC trial in the US highlights the importance of piloting and assessing fidelity as proposed in this study.

Two RCTs in England recruited parents and children from Children's Centres to health promoting interventions; these studies provide some indication of compliance and loss to follow up. Recruitment rates for centres were 59%[18] and 62%.[14] Therefore anticipating a centre recruitment rate of least 50% this would equate to 30 providers in North Somerset and a higher number in Gloucestershire. In one of the RCTs, 42% of parents and children were recruited. Therefore assuming a 40% recruitment rate in child care providers with an average of 35 children per provider who are eligible, we would anticipate 168 children and parents will be recruited across 12 providers. It is possible that the recruitment rate will be higher in our study because of differences between Children's Centres and providers such as nurseries.

We anticipate that there will be some loss to follow-up from period T0 to T1 because some children will be moving from child care providers to primary schools. This potential loss to follow up will be minimised by following up individual children for measurements at home or at their primary care school. The feasibility study will be assessing the feasibility and acceptability of longer term follow-up. In addition, we will explore the likely consent rates from parents in a full trial for data linkage to measures of BMI through the Child Measurement Programmes in England and Wales at age 4-5.

7. Proposed outcome measures:

Primary outcomes: for the purposes of the feasibility study, the primary outcomes are the acceptability of the intervention and the trial methods as outlined in section 2 above.

Secondary outcomes: the secondary outcomes will be measured at baseline (T0) prior to the intervention and 12 months after the baseline (T1). The assessment of the secondary outcomes will inform the choice of primary outcomes for a full-scale trial and particularly whether the outcomes require data collection from parents/children, or if the outcomes could be the environmental audit and zBMI using data linkage from the Child Measurement Programmes. The outcomes will include:

1. *Environment and Policy Assessment and Observation (EPAO) Instrument score*: The (EPAO) instrument was developed for NAP SACC[26] and assesses child-care nutrition and physical activity environments, policies, and practices and was developed using the standards, recommendations, and research literature upon which the NAP SACC intervention itself was based. The EPAO consists of a 1-day observation and review of pertinent centre documents using 75-item responses, with the average of all subscale scores representing total nutrition and physical activity scores. The EPAO will be administered by a researcher who will receive a day of training and be blind to child care provider allocation.

2. *Anthropometric measures of* children (zBMI and proportion of overweight and obese, as determined by the UK1990 age and gender reference charts at 85% and 95% centiles, respectively; with further sensitivity analysis using the International Obesity Task Force thresholds). All anthropometric measurements will be completed with children in a private room with two DAB checked trained fieldworkers present and a member of nursery staff. Weight will be measured without shoes in light clothing to the nearest 0.1kg using a Seca digital scale. Height will be measured, to the nearest 0.1cm, without shoes using a portable Harpenden stadiometer. Fieldworkers will be trained to ensure correct position for height assessment.

3. *Accelerometry measured activity* (mean minutes of sedentary, light, moderate and vigorous activity per day). We will use ActiGraph accelerometers which have been described as 'the most widely used and extensively validated accelerometer for assessment of physical activity among children'.[33] We have extensive experience (with over 8000 children) of collecting and processing Actigraph accelerometer data. Accelerometers have been widely used with pre-school aged children. Accelerometers will be worn for five days (given out on a Wednesday and will be collected the following Tuesday). Periods of 60-minutes with zero values will be interpreted as time that the monitor is not worn. A day will be considered valid if 8 hours of data are recorded. Mean minutes of sedentary, light, moderate and vigorous intensity physical activity will then be processed using the criteria proposed by Evenson and Puyau (thresholds of 0-25; 0-199; 200-799; and >=800 counts per 15 seconds).[33,34] Mean accelerometer counts per minute, which provides an indication of the overall volume of physical activity in which the children engage will also be calculated as this approach facilitates comparison with studies that may have applied a different cut-point.

4. *Children's food and drink intake specifically fruit and vegetables, snacks and sugar sweetened drinks.* Dietary assessment will be performed using the CADET (Child and Diet Evaluation Tool) diary as a 24 hour recall.[35] CADET will be completed by research staff (to record diet at pre-school day care settings) and by the children's parents (to reflect diet at home) be self-completion. Trained staff will contact non-responders by telephone to complete CADET. In four nurseries the CADET will be piloted for completion by parents to record all the food the children eat and drink over the weekend; for two of these nurseries parents will be asked to complete and return a paper version of CADET and in two nurseries parents will be phoned to complete it over the telephone.

5. *Sedentary time:* sedentary time will be assessed by asking parents to record all screen time and quiet play time the day the CADET tool was completed and the previous Saturday.

6. *Mediators:* parental and nursery staff knowledge (nutrition, oral health, physical activity and sedentary behaviours), self-efficacy and motivation will be assessed using tools created for this study. The reliability and validity of the tools will be explored in a separate study to inform whether they need further refinement for use in a fullscale trial.

7. *Costs:* Nursery staff time and costs of partaking in the intervention and NAP SACC UK Partners' time and costs will be recorded on logs. Parent direct personal costs of the child's participation in physical activity, changes in dietary patterns and health will be recorded over the previous month in a questionnaire.

8. Assessment and follow up

8.1. Assessment of efficacy/effectiveness and cost-effectiveness:

The primary outcomes will be assessed throughout the intervention and following the intervention using a range of methods for the process evaluation. The secondary outcomes will be measured at baseline (T0), and at follow-up assessment 12 months after the baseline at (T1). The 12 month follow-up is timed to coincide with the time when the older children will move from child care providers to reception year at school. Therefore, this will allow the feasibility of follow-up for older children in homes or primary schools to be assessed, with a view to assessing the feasibility of longer-term follow-up in a full scale trial.

This feasibility study is not designed to assess efficacy, effectiveness or cost-effectiveness, but is primarily designed to assess feasibility and acceptability. The methods of assessing the process evaluation measures are outlined above in section 4.

To enable an economic evaluation to be conducted as part of a future definitive trial we will measure in detail key cost components for the public sector, child care providers and parents. We will estimate child care providers and NAP SACC consultant's time and expenses through the cost audit and consultant and trial manager's logs. These will include a fixed set up cost and a variable cost of ongoing support to providers.

We will also pilot questions in the parental questionnaire assessing the direct personal costs of the child's participation in physical activity and any changes in dietary patterns and changes at home.

Collection of data on short term quality of life measures will be assessed using the parent-reported PedsQL for 2-4 year olds at T0 and T1. The PedsQL consists of 21 items which rate health related quality of life on four domains (physical health, emotional function, social function and nursery function) and produce a summary score. Work is currently in progress to develop a preference-based index for PedsQL and would be available for a subsequent definitive trial.

8.2. Assessment of harms:

The emphasis of the intervention is on changing the environment to promote healthy levels of physical activity and healthy diet. It does not include calorie counting or an emphasis on weight or ideal body size or shape. All anthropometric assessments will be undertaken with individual children in privacy, with a member of staff present to enable the child to feel comfortable and only with their parents' consent. We will collect information during the qualitative assessment with parents and staff of any evidence of negative behaviours or consequences. Child care providers will have contact details for the trial manager and if they have any concerns or parents report concerns to them they will be able to contact the study team.

8.3 Safety and Adverse Event Reporting

Reporting procedures

Nursery managers and those delivering the intervention (Health visitors and Welsh Healthy and Sustainable Preschool Scheme staff) will be asked to contact the study team within 5 working days if any untoward incident or adverse event (AE) occurs to a member of staff or child, as a direct result of taking part in NAP SACC, or due to changes that have occurred in the nursery environment due to participation in NAP SACC. In these cases, study specific adverse event/incident report forms will be used to record information on the event.

All adverse event/incident report forms will be discussed with the Principal Investigator to assess seriousness and to confirm causality. All AEs deemed to be 'serious' (SAE) will be reported to the Sponsor within 24 hours. Where the SAE is suspected to be related to the intervention and unexpected (NB. there are no expected events for this intervention), i.e. a suspected unrelated serious adverse reaction (SUSAR), the Chair of the TSC and the REC will be notified within 15 days of the study team receiving the initial report.

Safety reporting definitions:

Untoward Incident

An untoward incident is something unintended or unplanned, that could have or did lead to harm.

Adverse Events

Adverse Events (AE): Any untoward medical occurrence in a trial participant to whom the intervention has been delivered, including occurrences which are not necessarily caused by or related to that intervention.

Serious Adverse Events

Serious Adverse Events (SAEs) are any adverse event that:

- Results in death
- Is life-threatening
- Results in persistent or significant disability/incapacity
- Requires hospitalisation or prolongs a current hospitalisation
- Results in a congenital anomaly or birth defect

Expected AEs/SAEs

There are no expected AEs/SAEs for this intervention. Any treatment received by a participant that was planned prior to the start of the study will not be considered an AE/SAE.

Adverse Reaction /Serious Adverse Reaction/Suspected Unexpected Serious Adverse Reaction

Adverse Reactions (ARs) and Serious Adverse Reactions (SARs) are AEs/SAEs that are thought to be related to the intervention. NAP SACC is an environmental intervention, therefore it is unlikely that any AEs/SAEs will be directly related to its administration. SAEs that are both unexpected and related to the intervention, are classed as SUSARs (suspected unexpected serious adverse reaction).

9. Proposed sample size:

The primary outcomes for this feasibility study include the recruitment of centres (indicating the acceptability of the intervention to child care providers), rate of consent to data collection (indicating the acceptability of the study procedures to parents), and the proportion of children for whom full outcome data are obtained (indicating the feasibility of study procedures).

RCTs in England have reported recruitment rates of 59% and 62% for Children's Centres.[18,14] In North Somerset there are 62 child care providers meeting our inclusion criterion of having a minimum of 20 children aged 2-4 attending for a minimum of 12 hours per week; a similar number is expected for the study area in Gloucestershire. We will approach child care providers in a random order, until 12 have agreed to participate. This will allow a true centre recruitment rate of 50% (12 of 24 approached) to be estimated with 95% confidence interval in the region of 29% to 71% recruitment; sufficiently precise for planning the main study.

With regards to securing consent from parents for data collection, one RCT[14] recruited 42% of parents and children. The eligible child care providers in North Somerset have an average of 35 children (range 20 to 86), so 12 providers will equate to around 420 children. Approaching this many parents will allow a true 40% consent rate (168 of 420 approached) to be estimated with 95% confidence interval in the region of 35% to 45% consent.

The resulting estimates of centre recruitment rate, consent rate, and retention, will indicate the number of child care providers that will need to be approached for the main trial to achieve its sample size target. The primary outcome for the main trial is anticipated to be zBMI. The smallest effect size that would lead to a change in practice will be determined by discussion with the Trial Steering Committee and public health members of the advisory group.The sample size target for the main trial will be informed by a systematic review of intra-cluster correlation coefficients in similar studies with a similar outcome measure, the mean number of children (and standard deviation) per child care provider observed in this feasibility study, and expert consensus on the smallest effect of the intervention that it will be important to detect. In addition the feasibility study will provide an estimate of the standard deviation for the primary outcome measure, and an estimate of the intra-cluster correlation (albeit an imprecise one) at the level of child care provider and NAP SACC Consultant, which can be compared to the estimates from the systematic review.

10. Analysis:

Statistical analysis: The statistical analyses for this feasibility study will be primarily descriptive, providing realistic estimates of eligibility, recruitment, intervention delivery and retention rates in the study population, with 95% confidence intervals calculated to incorporate between-provider variation where appropriate. Summary statistics will also be presented for the outcome measures, as these will also inform the sample size and recruitment plan for the main trial. Differences will be explored for each of these measures by study location (North Somerset/ Gloucestershire) and deprivation (high vs. low). Stata statistical software will be used for all analyses.

Economic analyses: We do not plan a definitive economic evaluation alongside this feasibility trial. Our aim is to pilot measures of resource use for child care providers, NAP SACC consultants and parents, estimate more precisely the cost of the intervention in order to inform the viability and design of a full trial and economic evaluation. Costs and outcomes will be presented in a cost-consequence table. We will delineate the resource use (e.g. hours), unit costs (e.g. cost per hour) and calculate mean public sector, provider and parental costs in the intervention and control groups. We will estimate incremental costs and 95% confidence intervals for descriptive purposes.

Qualitative analyses: We will aim for a maximum variation sample of interviewees to achieve a broad perspective on the salient issues. Emergent issues from earlier interviews and focus groups will be explored in subsequent interviews and the number of interview undertaken will be determined by data saturation (no

new issues or themes emerging from within/across participants). All interviews and focus groups will be audio-taped and transcribed verbatim. All of the transcripts will be read and re-read in order to gain an overall understanding of participants' views and experiences. Data will then be coded in NVivo software, and analysed thematically, allowing comparisons to be made within and across the interviews.

11. Ethical arrangements and governance:

We will apply for ethical approval from the NHS Wales REC 3 for Phase 1, 2 and 3 separately. Parents/carers of children from the recruited child care providers will be asked for written consent for their children to take part in data collection. Parents/carers, child care providers and staff and NAP SACC Consultants taking part in qualitative data collection will be asked to give written consent.

Data will be entered and transcribed by the research staff using a secure data management system at the University of Bristol. Completed questionnaires will be transported to the University of Bristol by the Study Manager or the recruited field workers. Data from questionnaires will be stored in anonymised form, using participant identification numbers. Participant identification numbers and corresponding participant names will be held in separate files. Both files will be stored in secure password protected folders. Individuals' names will be replaced with pseudonyms in interview/focus group transcripts. A list of participant names, pseudonyms and their unique identification number will be held in a separate location. Digital recordings of interviews/focus groups will be stored securely, and will be held separately from transcripts and information on participant identities. In reporting the results of the process evaluation, care will be taken to use quotations which do not reveal the identity of respondents and anonymised data will be used wherever possible. The main circumstances under which the researchers would break confidentiality are where participants were are at risk of serious harm. All participants will be informed that if they disclose information about neglect or abuse that we will pass this information on to an appropriate source. Each child care provider participating in the study will be asked to identify a named individual who can provide support to any child who becomes upset or distressed.

Any member of the research team visiting a child care provider, or having any contact with parents, will be required to have a full Disclosure and Barring Service check. All work will be carried out in accordance with guidelines laid down by the Economic and Social Research Council (ESRC) [49], the Data Protection Act 1998, and the latest Directive on Good Clinical Practice (2005/28/EC).

Research Governance: The Principal Investigator will have overall responsibility for the conduct of the study. Day-to-day management will be coordinated by the Trial Manager who will be closely monitored and supported by the Principal Investigator. We will instigate 3 groups to provide governance and guidance. We will form a **Trial Management Group (TMG)** which will be chaired monthly by the Principal Investigator and include the co-investigators and the Trial Manager. In addition the Principal Investigator will meet with the Trial Manager every 2 weeks to address day to day issues. We will form a **Local Advisory Group (LAG)** of representatives from our collaborators with representatives from Early Years advisors in the Councils, Health Visitors and the Welsh Healthy Preschool Programme, child care managers, child care staff and parents. The LAG will advise on the delivery of the intervention and provide guidance on any provider, parent or child related issues that might arise during the course of the intervention. The LAG will meet twice during the intervention year and immediately before the follow-up assessment. An independent **Trial Steering Committee (TSC)** will be established. The TSC will be Chaired by Professor Russell Viner, Professor of Adolescent Health at University College London's (UCL) Institute of Child Health and Clinical Director for Paediatric & Adolescent Division at UCL Hospitals London NHS Foundation Trust. In addition, the TSC will have two other independent members (statistician, trial expert) and senior members of the study team. We will in addition ask an academic in nutritional epidemiology to be a member of the TSC. The TSC will meet annually. The project will use standardised research protocols and adherence will be monitored by the TMG and TSC.

Sponsorship: University of Bristol has agreed to act as the sponsor for this study and we will seek ethical approval from the Faculty of Medicine and Dentistry (University of Bristol) ethics committee. The study is adopted by the UKCRC DECIPHer (Development and Evaluation of Complex Interventions for Public Health

Improvement) Centre, which is based jointly at the School of Social and Community Medicine, University of Bristol and Cardiff University and in addition the study is affiliated to the Bristol Randomised Trials Collaboration (BRTC) a UKCRC/NCRI-accredited trials unit based in the School of Social and Community Medicine. We will register the trial with the International Standard Randomised Controlled Trial Number Register (http://www.controlled-trials.com/isrctn/).

12. Project timetable and milestones:

The Principal Investigator will be on maternity leave until April 2014, therefore preparatory work for the study will start in April 2014. The study will start in September 2014, to allow the timing of data collection at T1 to coincide with older children moving from child care to reception year in schools.

Sep '14-Jan 2015	Phase 1 ethics application; phase I focus groups & interviews; transcription & analysis
Feb-April 2015	Adapt intervention; pilot test elements of intervention; recruit and train Trainers; Phase 2 ethics application
May-July 2015	Phase II recruit settings and parents/children; randomise settings; prepare materials
Aug-Oct 2015	Baseline data collection & data entry (T0)
Nov-Jan 2016	Implement intervention; process evaluation observation
Feb-April 2016	Implement intervention; process evaluation observation
May-July 2016	Process evaluation interviews; process evaluation transcription & coding
Aug-Oct 2016	Process evaluation transcription & coding; follow-up data collection & data entry (T1)
Nov-Jan 2017	Data analysis
Feb-April 2017	Data analysis; paper writing and dissemination

13. Expertise:

The study is a collaboration between Bristol and Cardiff Universities (including the Bristol Randomised Trials Collaboration), North Somerset Council, Gloucestershire County Council and Public Health Wales, under the umbrella of the Centre for the Development and Evaluation of Complex Interventions for Public Health Improvement (DECIPHer) - a UKCRC Public Health Research Centre of Excellence.

Dr Ruth Kipping is the PI and Research Fellow in Public Health and Epidemiology at the University of Bristol and Consultant in Public Health at North Somerset Council. She has expertise in the public health relevance of the proposed research through her work in the NHS; and expertise in developing a feasibility and pilot RCT to increase healthy eating, physical activity and sedentary behaviours.

Professor Rona Campbell is Professor of Public Health Research at the University of Bristol and co-Director of DECIPHer. She has expertise in leading complex interventions with children and taking a feasibility and pilot RCT to full-scale trial including national dissemination of a public health intervention; expertise in process evaluation and qualitative methods.

Professor Laurence Moore is Director of the MRC/CSO Social & Public Health Sciences Unit at the University of Glasgow. He has expertise in undertaking trials of complex interventions in child public health, study design and statistical methods.

Professor Dianne Ward is Professor of Nutrition at The University of North Carolina at Chapel Hill, USA. She has developed the NAP SACC intervention and extensive dissemination within the USA; she has expertise in interventions to improve physical activity and nutrition in young children.

Professor Russell Jago is Professor of Paediatric Physical Activity and Public Health at the University of Bristol. He has expertise in measuring physical activity, sedentary behaviours and nutrition in children and parents and undertaking feasibility and full-scale RCTs with children.

Professor Will Hollingworth is Professor of Health Economics at the University of Bristol. He has expertise in economic evaluation of public health interventions.

Dr Angeliki Papadaki is Lecturer in Public Health Nutrition at the University of Bristol. She has expertise in measuring changes in food intake and nutritional content in children.

Dr Chris Metcalfe is Reader of Medical Statistics at the University of Bristol and Co-director of the Bristol Randomised Trials Collaboration. He has expertise and experience of supporting the design, conduct, and analysis of community-based cluster randomised trials.

Dr James White is Research Associate in Social Epidemiology at Cardiff University and DECIPHer. He has experience in the aetiology and prevention of child obesity and evaluation of public health interventions.

Sian Wells is a trial manager at the University of Bristol and will be the trial manager for this study. She has experience in managing a full-scale RCT to increase healthy eating, physical activity and sedentary behaviours in children (Active for Life Year 5). She has expertise in managing trial staff, large study budgets, conducting research with children and data collection.

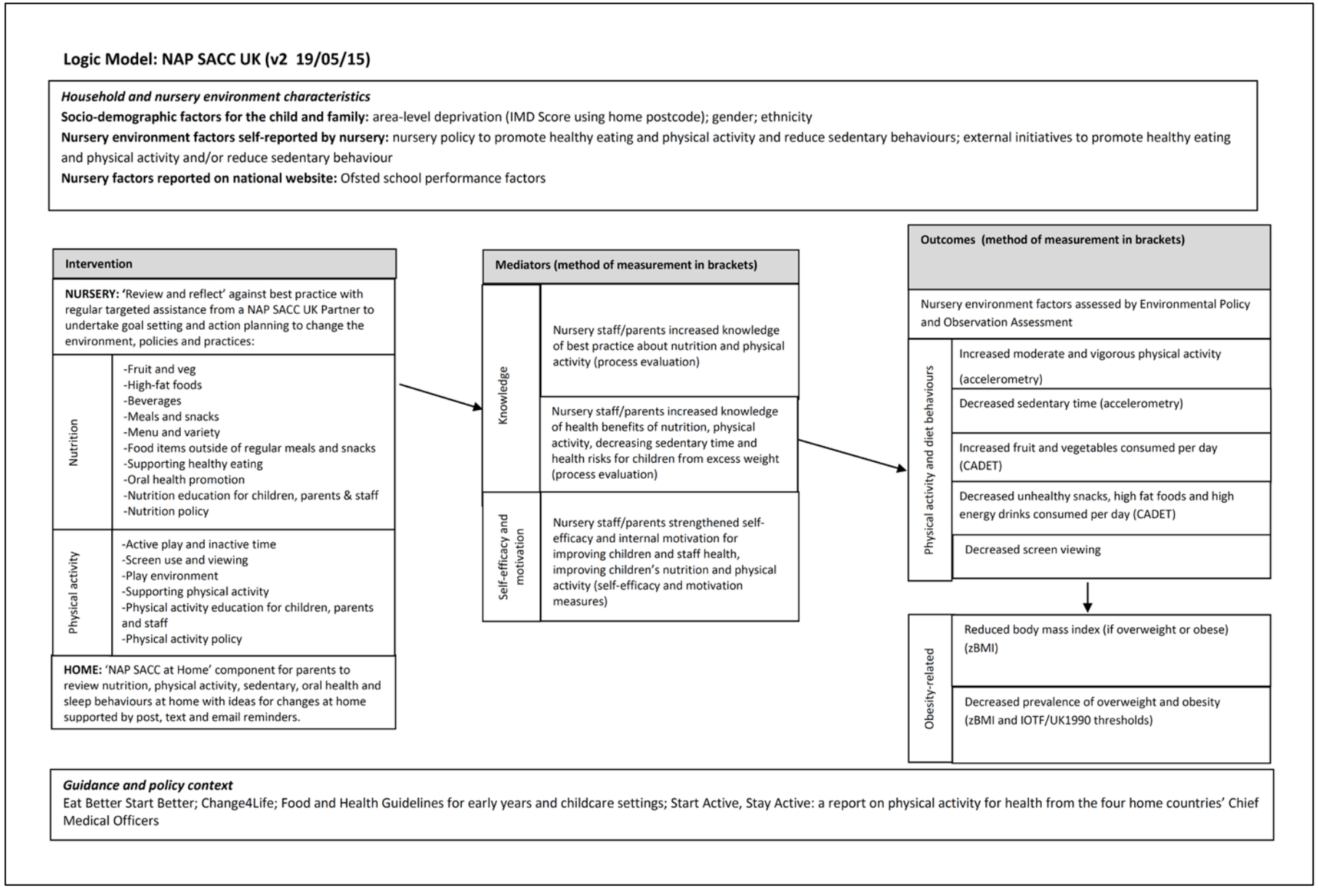
Alex Nicholson will cover Sian Well's maternity leave as Trial Coordinator. She has experience in managing a full-scale RCT in schools to promote hand washing and conducting research with young children and data collection.

14. Partner Collaboration

The following partners have confirmed their involvement in the study and will be members of either the Trial Management Group or Local Advisory Group:

- North Somerset Council: NHS North Somerset Acting Director of Public Health (Natalie Field), Dr Jon Roberts (Public Health Consultant) and the Lead Early Years Advisor (Ruth Glover) will be collaborators. North Somerset Council has confirmed they will pay the intervention costs.
- North Somerset Community Partnership: The Assistant Lead for Children and Young People (Janine Newbury), who manages the Health Visitors in North Somerset who will be the NAP SACC Partners.
- Gloucestershire County Council: Interim Director of Public Health (Sarah Scott), Lead Early Years Commissioner (Ruth Lewis) will be collaborators. Gloucestershire have confirmed they will pay the intervention costs.
- Gloucestershire Care Services NHS Trust: The Health Visitor lead (Jane Hayhurst).
- Bristol Randomised Trials Collaboration: the Co-director of BRTC is a co-applicant and will provide research design advice and expertise throughout the study. The Research Governance Manager and Database Manager will provide advice in the areas of database design and research governance.
- Development and Evaluation of Complex Interventions for Public Health Improvement (DECIPHer): four of the co-applicants on this study are DECIPHer Executive members or staff. DECIPHer will provide support and expertise in the design and conduct of complex public health interventions.

Appendix A: Logic Model



Appendix B: NAP SACC at Home (developed during Phase 1)

Steps in the NAP SACC UK at Home
1. **Sign up:** parents are invited to sign up to take part in NAP SACC at Home. This involves logging onto the NAP SACC UK at Home website and registering an email address and mobile phone number for correspondence and preferred methods of communication; or returning the information on paper to the NAP SACC UK office.
2. **Select areas for change and support**: parents are asked to indicate online or on paper areas of child health they would like support. These include: eating, drinking, teeth, sleeping, indoor play, outdoor play, TV and screen behaviours.
3. **Tailoring support:** Parents are asked to complete a questionnaire about their family habits at home with respect to the areas covered by the home component to allow tailoring of support.
4. **Goal setting and action planning:** parents will be asked to set goals for change and plan actions to meet the goals.
5. **Tailored suggestions:** parents will receive fortnightly tips and suggestions, using motivational methods to prompt behaviour changes in the areas where support has been requested. These will be sent via Facebook, text and emails or by post for those not online.
6. **Review:** parents will encouraged to review their goals and actions, to consider what has worked and what could be approached differently; to set new goals and actions and consider other areas for change.

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