University of BRISTOL

A multicentre cluster randomised controlled trial to evaluate the effectiveness and cost-effectiveness of an environmental nutrition and physical activity intervention in nurseries (Nutrition and Physical Activity Self Assessment for Child Care - NAP SACC UK)

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STUDY SUMMARY

Title	A multicentre cluster randomised controlled trial to evaluate the effectiveness and cost-effectiveness of an environmental nutrition and physical activity intervention in nurseries (Nutrition and Physical Activity Self Assessment for Child Care - NAP SACC UK)
Short title	Nutrition and Physical Activity Self Assessment for Child Care - NAP SACC UK
Design	Parallel-group, multicentre, two-arm, cluster RCT, with process and economic evaluations
Participants	Children aged 2 years or over, who are not yet attending school, and are attending at least 12 hours of nursery per week. Nurseries which are not part of another local public health nutrition and/or physical activity intervention.
Planned Sample Size	Approximately 784 children from at least 56 nurseries (average of 14 children per nursery)
Intervention	NAP SACC UK is an intervention delivered in childcare settings with the aim of improving the nutrition and physical activity environment, through a process of self-assessment and targeted assistance The intervention is a five stage process: 1. Self-Assessment. 2. Workshop delivery: Specialised staff deliver workshops to all nursery staff on: i) Nutrition; ii) Physical Activity. 3. Goal setting and Action Planning: The NAP SACC UK Partner works with the nursery manager to develop an action plan, listing eight goals for improvement. 4. Tailored technical assistance: NAP SACC UK Partner continues regular contact with nursery to provide support and advice toward them meeting their goals. Evaluate, revise, repeat. The Review & Reflect self-assessment is repeated by the nursery manager after six months and reviewed with the NAP SACC UK Partner to see where improvements have been made or not, and to explore ways to overcome barriers; action plans are revised to set eight new goals for the next six months.
Intervention duration	12 months
Follow up	12 months after start of intervention
Control	Usual provision of childcare
Planned Trial Period *(re-started)*	01/02/2022 Start 31/10/2024 End

	Primary	Secondary
Objectives	To determine whether the NAP SACC UK intervention compared with usual practice at 12 months: a) increases mean accelerometer-measured total physical activity on nursery days compared with usual practice. b) reduces the energy (kcal) per eating occasion averaged across snack and lunch eating occasions that occur within nurseries, within Nationally recommended levels.	To determine whether the NAP SACC UK intervention compared with usual practice at 12 months: a) increases the mean moderate to vigorous physical activity (MVPA) time per nursery day b) reduces the mean sedentary time per nursery day c) increases the mean accelerometer-measured total physical activity on nursery days compared to non-nursery days by arm d) reduces the mean serving size of lunch and morning/afternoon snacks in nursery per day e) increases the balance of grams of core food to grams of non-core food consumed for lunch and morning/afternoon snacks in nursery per day (see section 2.1 above for description of core and non-core food) f) reduces child zBMI g) reduces the proportion of children who are overweight/obese h) increases the nutrition and physical activity quality of the nursery environment i) improves child quality of life j) is cost-effective k) is the intervention delivered with fidelity and in a way which is acceptable and sustainable
Outcome Measures	Measured at 12 months: a) mean total activity measured by accelerometer data b) total energy (kcal) per snack and lunch eating occasion averaged across all snack	Measured at 12 months: a) MVPA measured using ActiGraph accelerometers b) sedentary time using ActiGraph accelerometers per nursery day

	and lunch eating occasions that occur within nurseries.	c) the average serving size of lunch (kcal per occasion) using remote food photography d) the average serving size of snacks (kcal per occasion) using remote food photography e) the average size of lunch (kcal per occasion) consumed by children using remote food photography f) the average size of snacks (kcal per occasion) consumed by children using remote food photography g) the average percentage of total energy (kcal) in lunch from non-core food served consumed by children using remote food photography h) the average percentage of total energy (kcal) in snacks from non-core food served consumed by children using remote food photography i) child zBMI using height and weight j) proportion of children overweight/obese using zBMI scores k) child quality of life using parent reported PedsQL l) cost-effective using cost consequences analysis methodology (CCA) m) fidelity, acceptability and sustainability of the intervention by undertaking process evaluation using process evaluation observations, logs and interview data.

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Funder(s)	Financial and non-financial support given
NIHR Public Health Research Programme National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre University of Southampton Alpha House Enterprise Road Southampton, SO16 7NS Telephone: 023 8059 9697 Email: phr@nihr.ac.uk	Grant funding
Bristol Randomised Trials Collaboration (BRTC) Bristol Medical School, Population Health Sciences University of Bristol Canynge Hall 39 Whatley Road Bristol, BS8 2PS Telephone: 0117 928 7393 Email: enquiry-brtc@bristol.ac.uk	Methodological expertise
University of Bristol Research and Enterprise Development One Cathedral Square Bristol, BS1 5DD Tel: 0117 42 83065 Email: red-office@bristol.ac.uk	Sponsorship
NAP SACC UK intervention Sites	• NHS Ayrshire and Arran (includes 3 local authorities: North, South and East Ayrshire Councils) • Sandwell Metropolitan Borough Council • Swindon Borough Council • Somerset County Council

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LIST OF ABBREVIATIONS

AE	Adverse Event
BMI	Body Max Index
BRTC	Bristol Randomised Trials Collaboration
CCA	Cost effectiveness analysis
CI	Chief Investigator or Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CTU	Clinical Trials Unit
DMC	Data Monitoring Committee
DSA	Data Sharing Agreement
ED	Emergency Department
EEA	European Economic Area
EPAO	Environment and Policy Assessment and Observation
EYFS	Early Years Foundation Stage
GCP	Good Clinical Practice
GDPA	General Data Protection Regulation
ICH-GCP	International Conference on Harmonisation – Good Clinical Practice
IMD	Index of Multiple Deprivation
IOTF	International Obesity Task Force
ISBN	International Society of Behavioural Nutrition
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trials Number
IT	Information Technology
MVPA	Moderate to Vigorous Physical Activity
NDNS	National Diet and Nutrition Survey
NHS	National Health Service
NIHR	National Institute for Health Research
NIHR PHR	NIHR Public Health Research programme

NMES	Non-Milk Extrinsic Sugars
PA	Physical Activity
PedsQL	Pediatric Quality of Live Inventory
PIL	Participant Information Leaflet
PPI	Participant and Public Involvement- Lay Advisory Group
RCT	Randomised Control Trial
RDSF	Research Data Facility Storage
REC	Research Ethics Committee
RFPM	Remote Food Photography Method
SAE	Serious Adverse Event
SCT	Social Cognitive Theory
SD	Standard Deviation
SES	Socioeconomic Status
SLA	Service Level Agreement
SOP	Standard Operating Procedure
SQL	Structured Query Language
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
TV	Television
UH Bristol	University Hospitals Bristol NHS Foundation Trust
UK	United Kingdom
USA/US	United States of America/United States
UOB	University of Bristol
WHO-UK	World Health Organisation-United Kingdom Growth Charts
zBMI	BMI Z-score

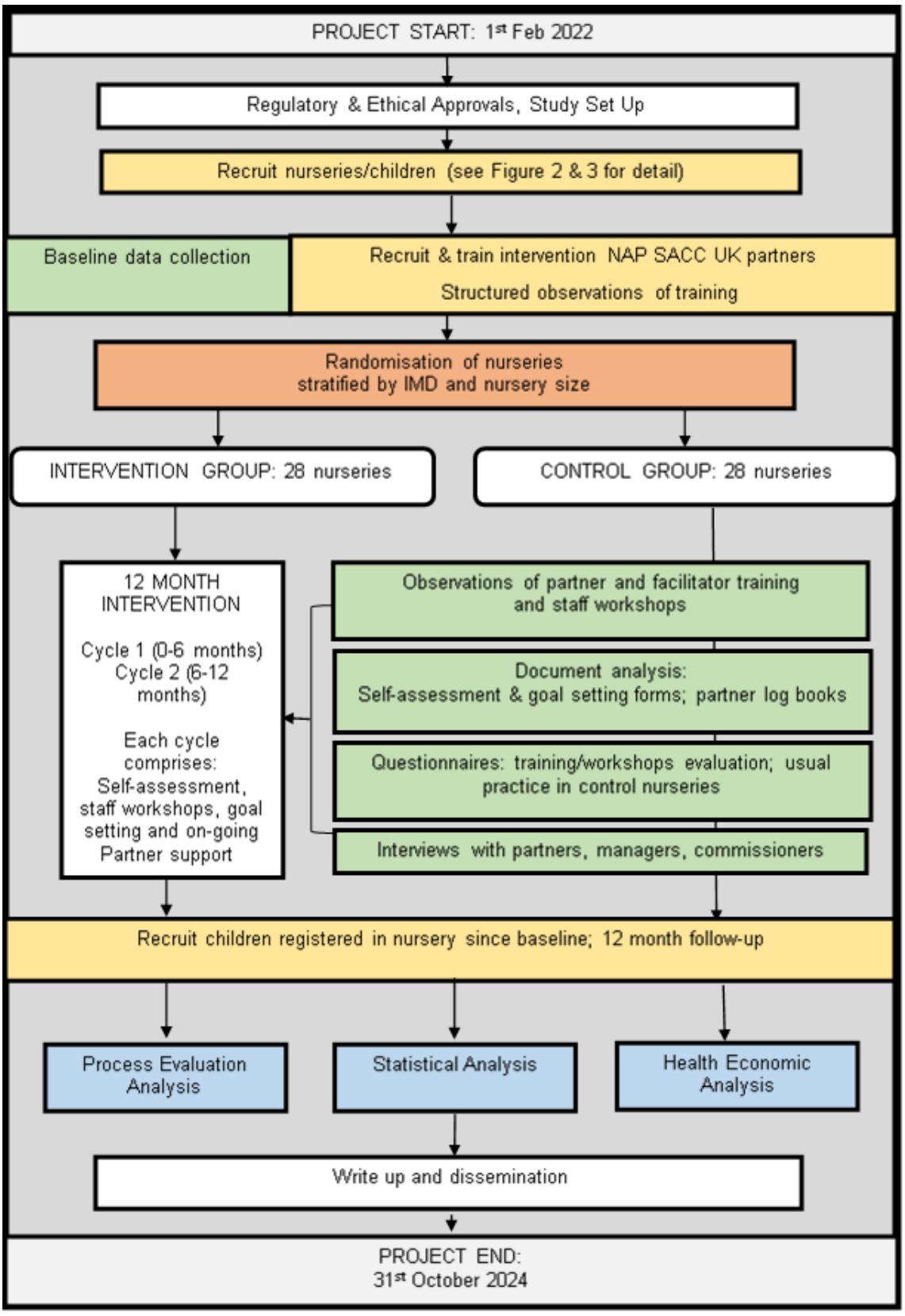


Figure 1 Overview Flow Chart

STUDY PROTOCOL

1 BACKGROUND

Obesity levels in children as they start primary school are high and showing no sign of decreasing: 10.5% in Scotland and 9.6% in England in 2016/17.[1,2] Obesity rates increase with deprivation; 12.7% in the most deprived areas are obese, compared to 5.8% in the least deprived decile.[1,2] It is predicted that by 2020 17% of children aged 2-11 in England will be overweight and a further 13% will be obese.[3] Therefore, it is a priority that interventions are developed, tested and implemented with pre-school aged children to reduce their risk of developing obesity and associated chronic diseases.

Among children, physical activity (PA) is associated with lower levels of cardio-metabolic risk factors, including blood lipids, blood pressure as well as improved psychological well-being.[4] Patterns of physical activity track moderately from childhood to adulthood.[5] The UK Chief Medical Officers recommendations are that children under five who are capable of walking should be physically active (i.e. moving) for at least three hours per day and sedentary time should be minimised.[6] There is currently no guidance about screen time viewing in the UK however the UK physical activity guidelines will be updated in 2019. In 2012, only 10% of two to four-year olds in England were classified as meeting guidelines[10] and three to four year olds in the UK are sedentary for an average of 10-11 hours per day.[7] A systematic review[8] of 96 studies found that physical activity interventions were consistently associated with improved motor and cognitive development, and psychosocial and cardiometabolic health. Further, moderate-to-vigorous-intensity, vigorous-intensity, and total physical activity were consistently favourably associated with multiple health indicators.[8] The amount of physical activity in which a young child engages is influenced by the activity obtained at pre-school[9] and particularly the time spent outside. For example, one study found children aged three to four years in the UK (in particular boys), spent more time in moderate-to-vigorous physical activity (MVPA) and were less sedentary in child care compared to time spent at home.[10] The lack of MVPA in pre-school settings may be influenced by space and equipment, policies (including scheduled times for free/outdoor play), and staff training in physical activity promotion.[11] A systematic review of interventions to increase physical activity in childcare settings concluded that regularly provided, structured physical activity programmes can increase the amount and intensity of physical activity undertaken.[9]

A diet that is high in fruits and vegetables and low in saturated fat has been associated with reduced risk of many forms of cancer, adult heart disease, and all-cause mortality. [12] Dietary patterns during childhood influence those in later life.[13] An obesogenic dietary pattern characterized by low intake of fruits, vegetables, high-fibre breakfast cereals (core foods) in tandem with a high intake of chocolate, confectionery, low-fibre bread, biscuits and cakes (non-core foods) is associated with a four-fold greater risk of excessive adiposity in mid-childhood.[14] The same obesogenic pattern exists in the early years suggesting improving the balance of core to non-core food in pre-schoolers could prevent obesity.[15] In the National Diet and Nutrition Survey (NDNS), non-core food makes up 44% of food intake among 1.5–3 year olds in care settings.[16]

In addition to diet quality and independent of eating frequency, meal size is a critical driver of weight gain. Every extra 10 kcal consumed per meal associated with 7% faster rate of weight gain from 2-5 years.[17] Children aged 1.5 to 10 in the UK do not eat sufficient amounts of fruit and vegetables; 32% of

boys and 18% of girls are reported as having eaten no fruit during a 4-day period.[18] The latest UK recommendation is that intake of free sugars should provide no more than 5% of total energy intake for adults and children aged over two years.[19] In 2012-14, the intake of non-milk extrinsic sugars (NMES; which approximates to free sugar intake) 12% of total daily energy intake for 1-3 year olds and 13% for 4-10 year olds.[20] Soft drinks contribute 10% to the intake of NMES in 1-3 year olds and 13% 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 14.6% for 1-3 year olds and 13.3% for 4-10 year olds. Pre-school aged children in low-income populations are more likely to consume table sugar and soft drinks than those in more affluent groups.[21]

1.1 Existing research

Three systematic reviews of obesity prevention, and improvement of physical activity and nutrition in young children have identified a clear need for more research in this area with robust study designs.[24,25,26] The 2011 Cochrane review of obesity prevention in children identified research gaps for effective interventions for children aged 0-5. [26] In addition, this review recommended studies should better report the impacts of interventions on the environment, setting and sustainability, as well as test interventions that are underpinned by theory-based frameworks such as the socio-ecological model. A review of the regulations, practices, policies and interventions for promoting healthy eating and physical activity and preventing obesity in children attending child care identified a lack of strong regulation of health behaviours such as physical activity and diet in child care settings.[24] A 2016 Cochrane Review of ten studies with strategies to improve healthy eating, physical activity and obesity prevention in child care services found "weak and inconsistent evidence of the effectiveness of such strategies in improving the implementation of policies and practices, child care service staff knowledge or attitudes, or child diet, physical activity or weight status. Further research in the field is required." [27]

There is ample opportunity within child care settings to improve nutritional quality and time engaged in physical activity. The Nutrition and Physical Activity Self Assessment for Child Care (NAP SACC) intervention[28] is delivered in child care settings 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 programme informed by components of social cognitive theory (SCT) which is within a socio-ecological framework. 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.[29] Goals of the NAP SACC programme are to improve: the nutritional quality of food served; amount and quality of physical activity; staff-child interactions; and nutrition and physical activity policies. NAP SACC nutrition areas of focus include: fruits and vegetables; fried food and high-fat meats; beverages; menus and variety; meals; 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.[28]

RCTs of NAP SACC in the USA have demonstrated: the feasibility and acceptability of the intervention; improvements in the environmental audit nutrition score (11% improvement from a

baseline EPAO score of 8.6) [30]; increases in nursery staff's knowledge of childhood obesity, healthy eating, personal health and working with families (all at p<0.05 level); decrease in children's zBMI (-0.14zBMI (95% CI −0.26,-0.02); p = 0.02) [31] (a measure of relative weight adjusted for child age and sex); an increase in accelerometer-measured physical activity by 17% (p<0.05) and a 46.2% increase in vigorous activity (p<0.05). [32] No studies have assessed cost-effectiveness. NAP SACC was updated in 2014 and the revised online version (Go NAP SACC) includes expanded best practices and is the version which NAP SACC UK is based on, excluding the materials for breastfeeding.

NAP SACC is one of the few interventions which works with child care providers to produce sustainable changes in the child care environment and promote improvements in children's activity levels and nutritional intake. NAP SACC is estimated to have been adopted in 30 States throughout the USA, which demonstrates that it is a model which, if shown to be effective, could be disseminated in the UK (personal communication, Dianne Ward). Compared to other more educational interventions, NAPSACC is relatively lower cost with potential for implementation in the real world and has a greater chance of sustained system effects.

Other than NAP SACC, 15 RCTs in child care settings (four in the UK) which aimed to improve nutrition and/or physical activity or sedentary time with 2-4 year olds have been published (see Table 1 in the NIHR Journal monograph of the feasibility study for the detail).[33] These studies focused on education, staff development, addressing child care policies or opportunities for increasing physical activity. Many, but not all, of the studies reported small changes in children's physical activity, sedentary time or nutrition in the short term. Only one intervention showed an effect on weight. There was a lack of long-term follow-up or demonstration of effect across a wide range of anthropometric and behavioural changes. Only four of the studies were in the UK and none of these targeted both diet and physical activity within child care settings. Internationally (Australia, Canada, Finland, Norway and the US) seven trials in early years' settings or with families of preschool children are currently being conducted with the aim of improving nutrition and or physical activity, which further demonstrates the importance of improving health for this age group and that this is a priority area for research and practice internationally. Please see detail in section 3.3 of the NIHR Journal monograph.[33]

2 RATIONALE

Child care settings provide opportunities to deliver interventions at the population level.[34] In England and Scotland 94% and 99% respectively of children aged three and four attend some form of Government-funded early years education.[35,36] In England 42.3% attend day care providers in settings which are not schools or childminders.[35] In England, Government-funded child care for three and four year olds increased from 15 to 30 hours/week in September 2017[37] (with certain conditions on parental employment); this has the potential to increase the amount of time children spend in child care settings. However, not all child care settings are health-promoting environments. Child care settings provide scalable opportunities to deliver interventions at the population level.[38] The 2017 Early Years Foundation Stage (EYFS) statutory framework sets standards to ensure children learn, develop and are kept healthy and safe.[38] The EYFS includes limited standards for physical activity and nutrition.[39]

Guidelines for food in early years settings were published in England in 2012[40] and updated guidelines were published in Scotland in 2018[41]; physical activity guidelines for young children in the UK were published in 2011 and will be updated in 2019.[10] Local Authorities in England and Wales are increasingly developing and implementing their own locally developed programmes to improve child health in early years' settings. We have reviewed Local Authority websites for the Core Cities in England and found all (except one) have some form of healthy early years programme. In Wales, the Healthy and Sustainable Pre School Scheme was started in 2011.[42] These programmes all include nutrition, and some have additional health topics. However, none of these programmes has been evaluated for effectiveness through an RCT. Therefore there is a need for obesity prevention interventions targeting the early years that are developed based upon theory and robustly evaluated.

2.1 Results of our NIHR PHR funded feasibility study

In partnership with stakeholders, we developed and tested NAP SACC UK, a nursery-based environmental intervention based upon the NAP SACC intervention developed in the US, to improve physical activity and nutrition quality in children aged 2-4.[43] Next, we conducted a feasibility cluster RCT (RCT) of NAP SACC UK with 166 2-4 year olds in England in 12 nurseries in North Somerset and Gloucestershire to assess the acceptability of the intervention and trial methods. An integrated process evaluation examined the feasibility and acceptability of the intervention and trial design. An assessment of intervention costs examined affordability and methods of economic data collection.

In order to determine if we progressed from the feasibility study to a large-scale trial, progression criteria were agreed by the Trial Management Group, an independent Trial Steering Committee and the NIHR PHR research funding board. The progression criteria are summarised in Table 1. Six criteria were achieved, but recruitment of nurseries (31.6%) and children (35.3%) were lower than the progression criteria of 40%, however, both were exceeded in one of the two study areas. In the full trial in order to enhance recruitment of both nurseries and children an online video explaining the trial (with endorsements from nursery managers and parents in the feasibility study) will be created and used and we will also increase the number of meetings with nursery managers and parents. No nurseries withdrew from the feasibility study. The intervention was delivered as planned in five of the six intervention nurseries with high levels of feasibility and acceptability, with the exception of the home component (which has not been included in this study).

Table 1 Progression criteria summary

Progression criteria	Results in NAP SACC UK feasibility study
Feasibility	
1a. At least 40% nurseries willing to participate	31.6% overall (42.9% in North Somerset; 25.0% in Gloucestershire)
1b. Synthesis of process evaluation elements regarding feasibility of intervention	Overall NAP SACC UK proved feasible to implement, with the majority of intervention elements delivered with good fidelity. Two exceptions: i) one recruited nursery did not to take part in intervention; ii) NAP SACC UK at Home (website) was not well-used
Acceptability: Intervention	
2a. Was the intervention acceptable to NAP SACC UK Partners?	NAP SACC UK was highly acceptable to Health Visitors, however, concerns were raised about their capacity. Alternative models of delivery were suggested including specialised Health Visitors dedicated to deliver NAP SACC UK, nursery nurses or health improvement staff.
2b. Was the intervention acceptable to the majority of nursery managers, staff and parents?	NAP SACC UK was highly acceptable to most nursery managers and staff. They particularly valued the workshops and contact with a named Health Visitor. Parents were often unaware of the specific changes made within the nurseries.
Acceptability: Trial Design	
3a. Expressions of interest from eligible nurseries	31.6% overall (42.9% in North Somerset; 25.0% in Gloucestershire)
3b. Acceptability of randomisation and data collection	Randomisation was acceptable to nursery staff, although some did not fully understand how they were allocated. Data collection measures (height/weight, accelerometery, observations, and questionnaires) were acceptable to staff and did not cause disruption. Parents were highly supportive of the research process.
3c. At least 40% parental opt-in consent rate	35.3% overall (43.5% in North Somerset; 30.8% in Gloucestershire)
3d. Maximum loss to follow-up of: i) 3 providers and ii) 40% children	i) Providers: no losses ii) Children: 14.2% (3 children withdrawn, 2 refused, 8 nursery movers, 11 children moved to school)
3e. Synthesis of parents' views of data collection	Overall parents reported data collection measures to be acceptable.

The nursery which did not deliver the intervention as intended was due to a lack of staff capacity (staff had recently received other out-of-hours training) and agreement to take part in the study was given by the deputy manager rather than the manager. Meetings with nursery staff to fully explain the trial requirements and use of a signed agreement from nursery managers will be used in a full trial. It was feasible to recruit and train Health Visitors to support nurseries, however Health Visitors reported they would not have capacity to deliver the intervention alongside their usual workload. This will be addressed in the full trial by giving Local Authorities choice of staff to deliver the intervention.

The trial methods and design were acceptable and feasible. The number of children lost-to-follow-up was 24 (14.2%): withdrawing consent (1.8%), child refusal to participate on the day (1.2%), children moving to primary school (6.5%) or moving nursery (4.7%). The response rate was 145 (85.8%) at follow-up.

Results of the (underpowered) complete-case multi-level linear regression of physical activity found that the adjusted mean difference (adjusted for baseline outcome, age, gender, average hours of attendance) for child total activity on nursery days was greater by 18.7 minutes/day (95% CI 3.8, 41.3) in intervention compared to control nurseries. In contrast on non-nursery days the mean difference was 2.4 minutes/day (95% CI -23.7, 28.4). When the analysis was also adjusted for IMD, nursery size, area the mean difference was 52.4 minutes/day (95% CI -4.5, 109.3) on nursery days and -3.1 minutes/day (-88.6, 82.3). Children did not meet the Chief Medical Officer's recommended 180-minute daily activity guideline by ~30 minutes on average. Evidence of promise was less clear for the anthropometry and dietary assessment, however the nursery managers reported improvements in several areas of feeding practice, such as staff role modelling eating with children and more appropriate portion sizes. The full trial will assess diet and capture portion sizes in more detail.

The feasibility RCT suggested NAP SACC UK has the potential to increase total activity on nursery days. to be made in this trial.

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1 Aim

The aim of the trial is to evaluate the effectiveness and cost-effectiveness of the NAP SACC UK intervention to increase physical activity, reduce sedentary time and improve the quality and quantity of nutritional intake, using a cluster RCT design with embedded process and economic evaluations.

3.2 Co-primary objectives

To determine whether the NAP SACC UK intervention at 12 months:

a) increases mean accelerometer-measured total physical activity on nursery days compared with usual practice.
b) reduces the energy (kcal) per eating occasion averaged across snack and lunch eating occasions that occur within nurseries compared with usual practice, within Nationally recommended levels.

3.3 Secondary objectives

To determine whether the NAP SACC UK intervention compared with usual practice at 12 months:

a) increases the mean moderate to vigorous physical activity time per nursery day
b) reduces the mean sedentary time per nursery day
c) increases the mean accelerometer-measured total physical activity on nursery days compared to non-nursery days by arm
d) reduces the mean serving size of lunch and morning/afternoon snacks in nursery per day
e) increases the balance of grams of core food to grams of non-core food consumed for lunch and morning/afternoon snacks in nursery per day

f) reduces child zBMI
g) reduces the proportion of children with overweight/obesity
h) increases the nutrition and physical activity quality of the nursery environment
i) improves child quality of life
j) is cost-effective
k) is delivered with fidelity and in a way which is acceptable and sustainable

3.4 Co-primary outcomes

The co-primary outcomes measured at 12 months are:

1) mean total activity measured by Actigraph accelerometer and/or

2) total energy (kcal) per snack and lunch eating occasion averaged across all snack and lunch eating occasions that occur within nurseries.

3.5 Secondary outcomes

Measured at 12 months:

a) MVPA measured using ActiGraph accelerometers
b) sedentary time using ActiGraph accelerometers
c) the average serving size of lunch (kcal per occasion) using remote food photography
d) the average serving size of snacks (kcal per occasion) using remote food photography
e) the average size of lunch (kcal per occasion) consumed by children using remote food photography
f) the average size of snacks (kcal per occasion) consumed by children using remote food photography
g) the average percentage of total energy (kcal) in lunch from non-core food served consumed by children using remote food photography
h) the average percentage of total energy (kcal) in snacks from non-core food served consumed by children using remote food photography
i) child zBMI using height and weight
j) proportion of children with overweight/obesity using zBMI scores using UK1990, WHO-UK and IOTF
k) child quality of life using parent reported PedsQL
l) cost-effectiveness using cost consequences analysis methodology (CCA)
m) fidelity, acceptability and sustainability of the intervention by undertaking process evaluation using observations, semi-structured interviews, questionnaires, document analysis and fieldnotes.

3.6 Measurement of outcomes

Outcomes will be assessed by several means, see section 7 for detail of these measures. The components and timing of follow-up measures are shown in Table 2.

3.7 Economic outcome measures

Intervention training costs (local government perspective): Study records will document all costs incurred during the two day Partner training to deliver the NAP SACC UK intervention (e.g. training preparation time, materials, distance travelled for trainers and attendees, training delivery time, number and type of attendees, number of trainers).

Intervention delivery costs (local government perspective): Each month during the intervention phase, NAP SACC UK Partners will complete an electronic log where they will record the contact time they had with each nursery provider. Contact time will relate to: delivering workshops, developing goals and action plans, providing 'review and reflect' consultations, and offering ongoing technical assistance. The electronic log will be stored in RedCap. The Partners will also be asked to record details on the type of nursery staff whom they have been in contact with and the mode of delivery (e.g. face-to-face, telephone or email). All partners will be requested to keep an up-to-date record of key details after each contact they have. The research team will send the Partners a monthly automated email with a RedCap link to their individual log, along with one follow up reminder if their monthly log is not completed.

Intervention participation costs (nursery perspective): At the 6-month point in the delivery of the intervention - all nursery managers for the intervention arm will be asked to complete a short health economic questionnaire. The questionnaire will be completed via videocall with a Research Site Manager or another member of the research team. In order, to prepare the nursery managers, they will be sent the questionnaire in advance via email. The questionnaire will ask nursery managers to report on whether any of the actions they undertook as part of the NAPSACC UK intervention, have had an impact on staff time and/or resulted in a financial cost to the nursery during the previous six-month period. Nursery managers will also be asked whether the workshops took place out-of-hours and if this incurred a financial cost to the nursery. At 12 months – a subsample (~50%) of nursery managers from the intervention group will be asked to complete the same health economic questionnaire. In addition, the subsample of nursery managers who are taking part in the process evaluation will also be invited to repeat the health economic questionnaire at the 12-month time point. In order to support the nursery managers to recall the nursery's resource use, Partners will inform the nursery managers about the questionnaire at the start of the intervention, and recommend they keep an eye on costs during the 12-month period. No formal receipts or invoices will be requested from the nursery managers, they will be asked to estimate these costs.

Intervention participant costs (parent perspective): At 12 months - time and out-of-pocket expense incurred by the parents during the 12-month intervention period will be captured retrospectively. This data will be captured immediately after the intervention through parental self-report questionnaires.

Lastly, our pilot study indicated insufficient value in collecting information from parents on their children's use of healthcare during the intervention to justify the burden. Healthcare use in this generally healthy population was infrequent and believed to be very unlikely to be causally related to the intervention.

4 TRIAL DESIGN

A multicentre, parallel-group, two-arm, cluster RCT with a repeat cross-sectional design to assess the effectiveness of NAP SACC UK, with embedded process and economic evaluations. We will be taking separate cross-sectional samples at each time point therefore some children will appear in more than one cross-section; this is because the intervention is a whole nursery environmental intervention and is expected to impact on all children not just on those present at baseline. In addition, we found in the feasibility study that there is considerable movement of individuals into or out of clusters due to four year olds moving to school and movement of children to other child care providers, so the baseline cohort may not remain representative of the cluster. Therefore this design minimises bias. This design has been used in the NIHR funded INCLUSIVE study.44 Clusters (nurseries) will be randomised to receive either the one-year NAP SACC UK intervention or continue with usual practice. The effectiveness and cost-effectiveness of NAP SACC UK will be assessed immediately after the end of the one-year intervention.

5 STUDY SETTING

This is a multi-centre trial recruiting participants from at least 56 nurseries in four sites with the research managed from three University "hubs" (Bristol, Birmingham and Glasgow).

The study population will be recruited from four Local Authority areas of England and Scotland (Somerset, Swindon, Sandwell and Ayrshire and Arran) to enable exploration of the generalisability of the findings across two countries. The study will take place within early years settings (referred to throughout as 'nurseries' although a range of settings will be eligible) which enrol children aged 2-years or over (who are not yet attending school) for at least 12 hours per week across the year (or 15 hours per week in term time) and the children consume at least one meal (provided by the nursery or from home) whilst attending the nursery (not only snacks).

6 ELIGIBILITY CRITERIA

6.1 Nursery Selection Criteria

6.1.1 Inclusion criteria

Day nurseries, private nursery schools, maintained nurseries (including nurseries within Children's Centres), nursery classes attached to primary schools and pre-schools where children consume at least lunch (provided by the nursery or family) in the four geographical areas outlined in this section

6.1.2 Exclusion criteria

Child care settings which are: childminders; crèches; playgroups; primary school reception classes, where schools operate an early admission policy to admit four year olds; solely outdoor nursery settings; solely Special Educational Needs and Disabilities (SEND) nursery settings; and au pairs.

Nurseries taking part in a research study or other initiative that would interfere with the NAP SACC UK study.

6.2 Subject population

6.2.1 Participant (staff, parents and children) inclusion criteria

Staff: Child care managers and staff in participating nurseries

Parents/carers: parents/carers in the participating nurseries with children aged 2 years or over at the time of assessment, who are not yet attending Reception (England) or Primary One (Scotland).

Children: children aged 2-years or over at the time of assessment, who are not yet attending Reception (England) or Primary One (Scotland), and who are attending the participating nurseries for a minimum of 12 hours per week across the year or 15 hours during term time and who consume at least lunch within the setting (provided by nursery or from home).

6.2.2 Participant (children) exclusion criteria

Children attending participating nurseries under 2 years old at the time of assessment, or who have started attending Reception (England) or Primary One (Scotland).

Children whose parents/carers refuse consent for measurements.

Children attending fewer than 12 hours per week across the year or 15 hours during term time.

Children who do not eat lunch at the nursery setting.

7 TRIAL PROCEDURES

7.1 Recruitment of nurseries

Figure 2 outlines the recruitment process for nurseries. Nurseries will be informed about the opportunity to take part in the study through Local Authority meetings with Early Years' managers/headteachers or Early Years' newsletters.

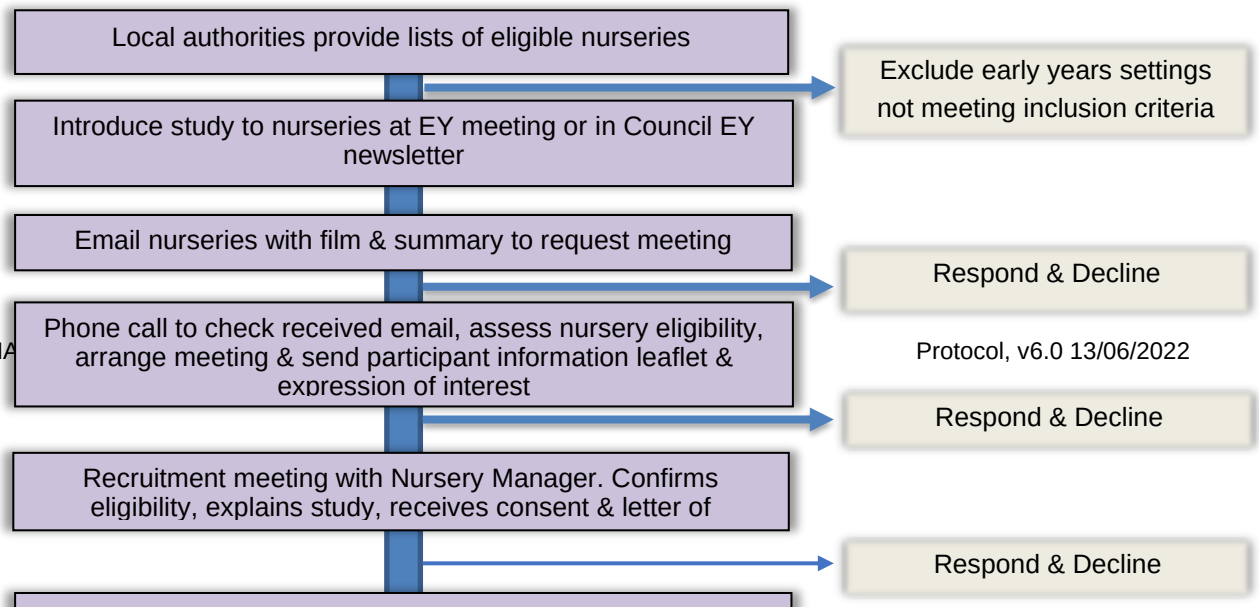


Figure 2 Nursery Flow Chart

The research team will send an email to nurseries with a link to an informative film about the study and a summary of the study. This email will be followed up by telephone with the nursery manager to undertake a screening check for eligibility and offer a meeting to discuss in more detail the opportunity to take part in the study. Before the meeting a participant information sheet, consent form and letter of agreement will be sent to the nursery by email and paper copies taken to the meeting.

All interested settings will then meet with a Research Site Manager, either via video call or in person, to discuss the study. This will be supported by a presentation. Nurseries will be emailed/sent a paper

copy of the participant information sheet in advance and asked to either complete the documentation online or return the consent form and signed letter of agreement in a stamped addressed envelope (SAE) if they would like to take part.

Within each of the four sites, Research Site Managers will calculate the IMD score for all nurseries in the site using the range of Index of Multiple Deprivation (IMD) (England and Scotland) and group nurseries into low, medium and high scores. Nurseries across the IMD range will first be invited and further invitations will be informed by the IMD of consented nurseries will the aim to achieve a balance of IMD scores across the site.

7.2 Recruitment of parents and children

Figure 3 outlines the recruitment process for children.

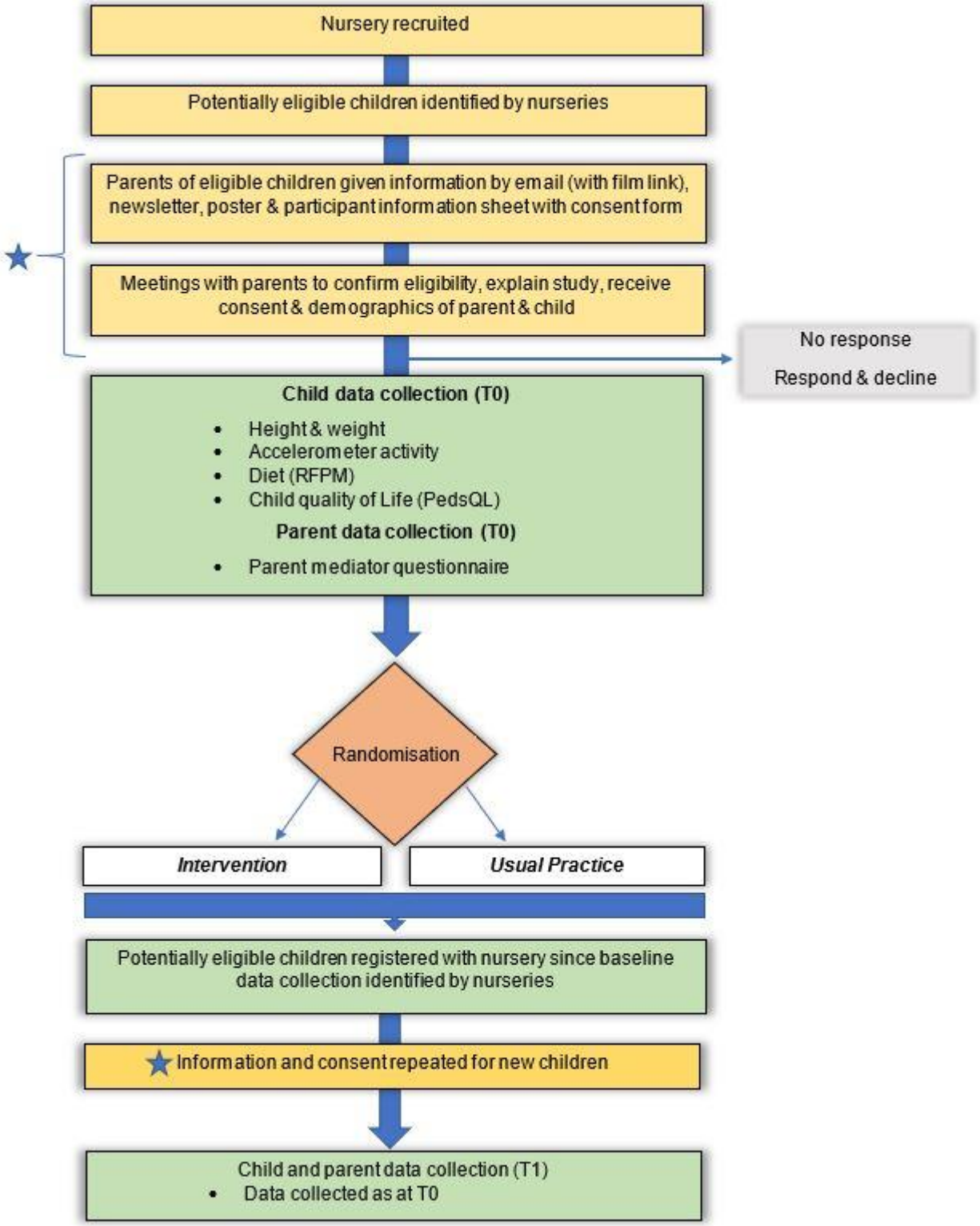


Figure 3 Parent and Child Flow Chart

In nurseries which have given consent to take part and have been selected to take part, all parents/carers of children aged 2-years or over who are not yet attending school, will be informed about the study as follows:

Nursery managers will be asked to assign an appropriate individual to act as a ‘study recruitment ambassador’ within the setting to support the recruitment process and be a key point of contact for parents. They will be given a brief description of the study to send to parents through their usual communication (e.g. email or newsletter) to inform parents about the study and a link to a parent version of the study information film.

The research team will provide posters, an information pack to give to each parent containing an invitation letter, an information sheet, a consent form and a reply envelope. Parents will also have the opportunity to read all documents online and provide e-consent via an email link.

The research team will be available by email or telephone to answer questions and, if appropriate, in person at a convenient time for the setting.

7.3 Randomisation

Parents will be asked to complete and return a child information sheet to enable eligibility of the child to be checked, and the consent form if they wish their child to take part.

Each nursery will be randomly allocated to the NAP SACC UK intervention or usual practice control group once all data have been collected from that nursery's children and parents at enrolment. Allocation will be conducted by an independent Bristol Trials Centre statistician, blind to the identity of nurseries. Within each hub separately, the allocation of nurseries will be conducted so as to minimise differences on an average IMD score (created for each nursery using the postcodes of the children recruited) and Local Authority. Each random allocation will attempt to balance the IMD score between the two groups. This minimisation procedure will be written in Stata statistical software, and the code included in the Statistical Analysis Plan.

7.4 Blinding

Two statisticians will support this trial. The senior statistician co-applicant will be blinded throughout the trial and will not have access to any identifying data. A study statistician will perform all disaggregated analyses according to a pre-specified statistical analysis plan and will attend TSC meetings as required. All interim reports e.g. on recruitment, data completeness, will be prepared by the study statistician. The remaining members of the study team will remain blinded to aggregate data only.

All baseline data will be collected prior to randomisation. The Trial Manager, Research Site Managers, Study Administrator and lead for the process evaluation (Dr Beki Langford) will not be blinded with regard to the follow-up data because of their need to correspond with intervention and control nurseries during the intervention period. The intention is for all other staff and co-applicants to be blinded. Some staff collecting follow-up data will be blinded (fieldworkers) and some will not (Research Site Managers). Nursery staff will not be blinded. Parents and children will not be blinded but the nurseries will not necessarily actively promote the involvement in the intervention or control arm to parents and children.

7.5 Data collection: Nurseries

Data will only be collected from nurseries where consent has been obtained from the nursery manager/owner and the nurseries are selected for the study. Measures at T0 will be prior to randomisation of settings in the two study arms. A second set of measurements (T1) will take place immediately after the 12-month intervention in both study arms, which will be between 12-16 months after T0 data were collected. See

Figure 2.

- *Demographics*: address; telephone number; email address; nursery manager's name; number of children aged 2 years or over meeting eligibility; food provision per meal/snack provided by nursery and/or child's family; number of employed childcare staff; opening hours.
- *Mediators:* Nursery staff (all nursery managers and all staff who work with children aged 2 years or over) knowledge (nutrition, physical activity and sedentary behaviours), self-efficacy and motivation will be assessed by the questionnaire created in the feasibility study.
- *Review and Reflect tool*: Nursery staff will complete the Review and Reflect tool at the beginning and end of the intervention. This will provide an indication of the staff's assessment of any changes in the nursery environment, policy and practice relating to nutrition, physical activity and sedentary behaviour. This tool is based upon the original and revised NAP SACC self-assessment tool.
- *Intervention delivery:* training sessions will be observed in a sample of intervention nurseries (see section 7.8.1for more detail); staff attending training sessions will be asked to complete a questionnaire.
- *Interviews with staff:* interviews will be undertaken in a sample of intervention and control nurseries (see section 7.8.1 for more detail).
- *Costs*: Staff time and financial costs incurred due to participating in the intervention will be captured via Partner monthly logs and short health economic questionnaires completed by the nursery managers at 6 and 12 months (see section 3.7 for more detail).

7.6 Data collection: Children

Data will only be collected for children where relevant consent has been obtained from the parent/carer. Measures will be completed at T0 for children prior to nursery randomisation. A second set of measurements will take place immediately after the 12-month intervention in both study arms, which will be between 12-16 months after T0 data were collected. See Figure 3.

- *Demographics*: date of birth, home postcode, gender, ethnicity, first language spoken at home, home postcode, usual start hour and end hour for each day of the week the child attend this nursery, number of days of week family provide food in nursery or child has nursery provided food
- *Accelerometry measured activity*: ActiGraph accelerometers (GT3X+) will be used for assessment of physical activity of children.[33] Accelerometers will be worn for five nursery days.[50]
- *Diet:* Estimates of total eating occasion size (from the sum of portion size served and grams/caloric intake of individual foods consumed) will be assessed using remote food photography method (RFPM)[49] from digital photographs of the food when served and left-overs for each eating occasion at lunch and morning/afternoon snacks in nurseries on one day per child

- *Anthropometric measures of children*: Weight will be measured without shoes in light clothing to the nearest 0.1kg using a calibrated medical grade digital scale. Height will be measured to the nearest 0.1cm without shoes using a portable stadiometer.
- *Quality of life:* Collection of data on short term quality of life measures will be assessed using the parent-reported PedsQL for 2-4 year olds. Parents with children attending Nursery who are 5 years old will also complete the parent-reported PedsQL for 2-4 year olds. This decision was informed through discussions with the developer of the PedsQL tool because older versions of the PedsQL have questions about school which would not be relevant for all 5 year-olds, particularly in Scotland. The PedsQL tool consists of 21 items where parents rate health related quality of life of their child in the past month on four domains (physical health, emotional function, social function and nursery function) and produce a summary score.

7.7 Data collection: Parents

Data will only be collected for parents where relevant consent has been obtained. Parent mediator questionnaires will be collected at T0, prior to randomisation, and immediately after the 12 month intervention at T1. See Figure *3*.

- *Demographics:* name, age in years, relationship to child, gender, ethnicity, home postcode, highest education level achieve, number of children in household, postal address.
- *Mediators:* Parental knowledge (nutrition, physical activity and sedentary behaviours), self-efficacy and motivation will be assessed by the questionnaire created in the feasibility study.
- *Costs:* Time and out-of-pocket costs incurred by the parents which is attributable to their child's participation in the intervention will be captured via questionnaires at T1.

7.8 Process evaluation

Two elements have been identified as critical to successful implementation: 1) the valued relationship formed between the nursery manager and Partner and 2) the motivation and "buy in" created among nursery staff at the workshop. Local Authorities (or the NHS Board in Scotland) have identified relevant health or health improvement staff to take on the roles of Partners to replicate what is likely to happen in any future implementation. However, each group of staff will be trained to the same specifications. The process evaluation will specifically seek to explore this variation to understand its impact on how the intervention was implemented and received. The process evaluation will explore the following components:

- Fidelity: did the intervention happen as planned in each area?
- Acceptability: was the intervention acceptable to nursery managers, Partners and Local Authority/NHS Board commissioners.
- Sustainability: exploration of the appropriateness of differing models of Partner provision; if [and how] NAP SACC UK becomes embedded into nursery and Partner processes.
- Context: the way in which context affected the fidelity, acceptability and sustainability of the intervention and how it interacted with the hypothesized mechanisms of the intervention.

The process evaluation will also explore the ways in which COVID-19 may have altered the practices within settings and children's activities and any potential interactions this may have with the intervention.

The process evaluation will use a combination of methods (observations, semi-structured interviews, questionnaires, document analysis and fieldnotes) to collect detailed information to contextualise the results of the trial and inform any potential roll-out plans should the intervention prove effective.

7.8.1 Process evaluation methods

Document Analysis: Review & Reflect (self-assessment) and goal-setting forms will be collected from intervention nurseries, entered into a database and cross-referenced with interview data (from Partners and Managers) to assess changes made. To assess the fidelity of the on-going Partner support, Partners will log each contact with their allocated nurseries, documenting the type of interaction (email/phone/meeting) and time spent.

Observations: These will be used to assess the fidelity and acceptability of the training sessions for Partners (n=2). Because our previous process evaluation suggested nursery workshops were critical for engaging staff, we will also observe approximately 20 staff workshops in intervention nurseries. We will observe nurseries in each study area, aiming to include variation in workshop topic (physical activity, nutrition or 'top up' training), nursery size (small or large) and level of deprivation (high, medium or low). Observations will be semi-structured, with standardised data (e.g. on topics covered) to be collected for each observation, while also allowing for qualitative observations to provide more detailed contextual information (e.g. group dynamics).

Questionnaires: At the end of each training session/workshop, participants will be asked to complete a brief evaluation to provide quantitative assessments of acceptability. To assess 'usual practice' and contamination, managers at control nurseries will be sent a short questionnaire at the end of the intervention to assess their usual practice, what (if any) work they had done on physical activity and nutrition in the previous year.

Semi-structured interviews: In-depth semi-structured interviews will be conducted with NAP SACC UK Partners and approximately 15 Intervention nursery managers (sampling to include variation in study area, nursery size and deprivation level). Interviews will focus on: the changes made within the nursery and relevant facilitators/barriers; the relationship between Partner/Manager; the sustainability of the intervention; and any relevant contextual issues including any other work they had undertaken on related health topics during the intervention year. A random sample of four control managers (one per area) will be interviewed to gain greater insight into usual practice. Local commissioners in different study areas will be interviewed to explore views on the sustainability of NAP SACC UK (if found to be effective) and how it might fit with local priorities. All interviews will be digitally recorded (with permission) on an encryptable device and transcribed verbatim.

Fieldnotes: Research Site Managers will be asked to record any relevant issues relating to implementation and/or nursery context in fieldnotes, recorded in a central database. These will be discussed with the process evaluation lead to inform Partner/manager interview schedules and data analysis.

Table 2 Schedule of data collection

	Screening eligibility check	Consent	Baseline data (T0)	Intervention/ Usual Care	Screening eligibility check for new children registered with nursery	Consent for new children registered with nursery	Follow-up data (T1)
Nursery							
Demographics	•						
Consent		•					
Number of eligible children		•					
Staff mediator questionnaire			•				•
Observation of training[1]				•			
Staff questionnaires after workshops[1]				•			
Review and reflect tool[1]				•			
Goal-setting forms[1]				•			
Nursery staff time and NAP SACC partners time and costs[1]				•			*
Staff interviews							•
Child							
Demographics	•				•		
Consent		•				•	
Height			•				•
Weight			•				•
Accelerometer activity			•				•
Diet (RFPM)			•				•
Child Quality of Life (PedsQL)			•				•
Parent							
Demographics	•				•	•	
Consent		•			•	•	
Parent mediator questionnaire			•				•
Data linkage consent to school height and weight			•				•

[1] Intervention nurseries only; *The time taken to complete each intervention component (e.g. workshops, ‘review and reflect’ consultations and ongoing technical assistance) will be electronically logged by the Partner immediately after each activity for the full 12-month intervention period.

7.8.2 Intervention

The TiDIER reporting guidance is used as a framework for presenting the detail of how the intervention will be delivered and the theory used (see Table 3). The Logic Model is shown in Figure 4. Local Authorities have chosen the most appropriate locally employed staff to deliver the intervention, to enable us to test the effectiveness of the intervention as it might be delivered outside a trial.

Table 3 TiDIER

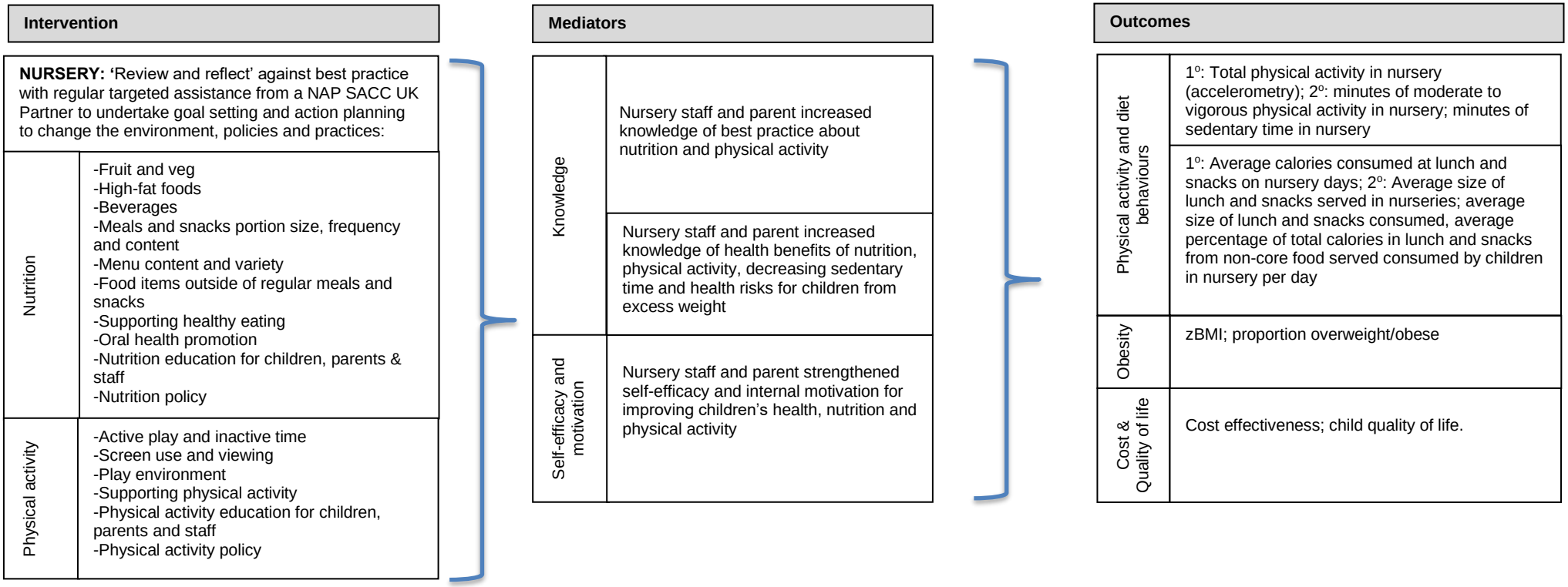
Item	Description
Name	Nutrition and Physical Activity Self-Assessment for Child Care UK (NAP SACC UK)
Why	NAP SACC UK is an intervention delivered in child care settings with the aim of improving the nutrition and physical activity environment, through a process of self-assessment and targeted assistance. NAP SACC UK is a theory-based program that employs components of social cognitive theory (SCT) and the socio-ecological framework. The objectives of the programme are to improve the nutritional quality, variety and quantity of food served, amount and quality of physical activity, staff-child interactions and staff behaviours around nutrition and physical activity and child care provider policies.
What: materials	The NAP SACC UK intervention is based around a self-assessment tool completed by nursery managers with advice and support from a NAP SACC UK "Partner". This document, called the 'Review & Reflect', is an 80-item multiple choice questionnaire, completed by the nursery manager, covering areas in nutrition, physical activity and play, outdoor play and learning, and screen time. Following completion of the Review & Reflect, the nursery manager along with the NAP SACC UK Partner agree on eight goals; three nutrition, three physical activity and a further two of the nursery's choice.
What: procedures	The NAP SACC UK intervention is a five stage process: 1. Self-Assessment. 2. Workshop delivery: Specialised staff deliver workshops to all nursery staff on: i) Nutrition; ii) Physical Activity. 3. Goal setting and Action Planning: The NAP SACC UK Partner works with the nursery manager to develop an action plan, listing eight goals for improvement. 4. Tailored technical assistance: NAP SACC UK Partner continues regular contact with nursery to provide support and advice toward them meeting their goals. 5. Evaluate, revise, repeat. The Review & Reflect self-assessment is repeated by the nursery manager after six months and reviewed with the NAP SACC UK Partner to see where improvements have been made or not, and to explore ways to overcome barriers; action plans are revised to set eight new goals for the next six months.

Who provided	NAP SACC UK Partners and Local Authority staff who deliver the nursery workshops will be chosen locally from a range of health or health improvement staff with appropriate skills. All staff will be provided with one day of training led by specialists in nutrition and physical activity who provided the training in the feasibility study.
How	The main part of the intervention will be delivered face to face; this includes Partners going through the Review & Reflect, action planning and attending or delivering the workshops (depending on whether the Partners are also the staff delivering the workshops). Other parts of the intervention, such as on-going support and advice from the NAP SACC UK Partner can be provided over the phone, by email or face to face. All parts of the intervention will be delivered to participating nurseries individually. Some parts may be delivered on a one-to-one basis (e.g. nursery manager and NAP SACC UK Partner setting goals), while other parts such as the workshops will be delivered to a group of staff from one nursery. Partners will have four days contact with each nursery over the 12 months.
Where	The NAP SACC UK intervention is delivered in the nursery itself. The NAP SACC UK Partner offers visits to the nursery and the workshops take place at the nursery.
When and how much	The NAP SACC UK intervention takes place over 12 months. The length of the workshops are a total of six hours, followed by a two hour workshop after 6 months. The nurseries receive ongoing regular support over the 12 months.
Tailoring	The technical assistance offered by the NAP SACC UK Partner will depend on the goals.
Modificat-ions	In the feasibility study the intervention was five months; in the full trial it will be 12 months. NAP SACC was designed in the US to be for a year and this longer period enables a mid-intervention review of progress against goals and further goals to be sets. In the feasibility study the Partners were Health Visitors; in the full trial Local Authorities will chose appropriate health staff.

7.8.3 Comparator

The comparison nurseries will continue with usual practice which may or may not involve early years' quality improvement initiatives, physical activity or nutrition programmes. The details of any other relevant interventions, policies or initiatives will be examined as part of the process evaluation.

Household and nursery environment characteristics
Socio-demographic factors for the child and family: area-level deprivation (IMD Score using home postcode); gender; ethnicity
Nursery environment factors self-reported by nursery: nursery policy to promote healthy eating and physical activity and reduce sedentary behaviours; external initiatives to promote healthy eating and physical activity and/or reduce sedentary behaviour
Nursery factors reported on national website: Ofsted performance factors



Guidance and policy context
Eat Better Start Better; Setting the Table; Change4Life; Food and Health Guidelines for early years and child care settings; Start Active, Stay Active: a report on physical activity for health from the four home countries' Chief Medical Officers

Figure 4 Logic Model: NAP SACC UK

7.8.4 Trial follow-up

Prior to follow-up, new children who have joined the nursery since the initial consent period, and who are aged 2-years or over and are not yet attending school, will be recruited to the study if parental consent is provided. The follow-up data collection (T1) will include children originally with parental consent and who still attend the nursery and new children with consent.

7.9 Withdrawal criteria

It is not possible for parents to withdraw their child from the allocated trial treatment as the intervention is delivered at the cluster level (of nursery). Should a parent wish to withdraw their child from measurements after giving consent, they will be able to do so. Any data collected up to the point of withdrawal will be retained for analysis unless the parent specifically requests otherwise.

7.9.1 Post trial

After the intervention, the support from the NAP SACC UK Partners will cease and any continued work on the goals and changes will be the decision of the local nursery manager.

8 SAFETY

Serious and other adverse events will be recorded and reported in accordance with the Good Clinical Practice (GCP) guidelines and the Sponsor's Research Related Adverse Event Reporting Policy.

8.1 Study (S)AE Definitions

Table 4 Study definitions

Term	Definition
Adverse Event (AE)	Any untoward incident or medical occurrence in a trial participant.
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: ● results in death ● is life-threatening ● requires inpatient hospitalisation or prolongation of existing hospitalisation ● results in persistent or significant disability/incapacity Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

8.2 Recording and reporting of (S)AEs

There are no expected (S)AEs. Any treatment received by a participant that was planned prior to the start of the study will not be considered a (S)AE. All (S)AEs will be reported to the REC using approved standard (S)AE reporting forms.

Participants will be monitored for (S)AEs from the time of consent until the end of their participation in the study, i.e. after final data collection with the participant is completed.

Nursery managers and those delivering the intervention will be asked to contact the study team within 5 working days if any untoward incident or adverse event 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 Chief 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.

8.3 COVID-19 related health and safety

Government guidance, University procedures and local hub policies will be regularly reviewed to ensure that risks are appropriately mitigated for both study participants and staff. The Trial Manager will be responsible for reviewing, and making available to the study team, updated guidance from the Government and University. The Research Site Managers will be responsible for obtaining local site policies from each recruited early years setting.

Research staff will be required to be familiar with University; Departmental and, where appropriate, Early Years setting SOP's and other documents relating to safe working during the COVID alert and prior to site visits. All the requirements in force for social distancing, hand hygiene and other University recommendations should be strictly observed.

A study risk assessment will support the identification of potential risks and mitigation approaches.

General safety approaches to be adhered to (and included in training) by fieldworker staff during data collection periods:

Before data collection:

- Completion and submission of Local Authority risk assessment forms prior to nursery visits in that area, for the following purposes:

    - Risk related to study data collection
    - Risk related to intervention delivery.
- Obtain COVID-19 nursery specific policies prior to a visit
- No research staff will attend a nursery if they experience COVID-19 symptoms (high temperature, new continuous cough or loss of sense of taste/smell) or have received/living with someone who has received a positive COVID-19 test (within previous 10 days)
- Nursery managers will be requested to notify researchers of any confirmed COVID-19 cases among children or staff that have occurred 10 days before a nursery visit
- Twice weekly lateral flow tests
- Staff working directly with study participants will be strongly encouraged to be fully vaccinated against COVID-19.
- Provide option for remote meetings where possible and e-consent procedures

During data collection:

- Temperature checks by research staff prior to any nursery visits. If any staff have a temperature of 37.8C or greater, on the morning of a visit, they will not attend a nursery
- Regular hand washing with soap and water or cleaned with alcohol-based hand rub.
- Wear gloves and masks (unless requested otherwise by the setting), including when handling food items.
- Carry out data collection either outside or in a well-ventilated space

After data collection:

- On return, accelerometer belts will be quarantined for 72 hours and sprayed with antibacterial disinfectant spray before being handled by research staff
- Following a nursery visit, any research staff who receive a positive test result (confirmed by PCR) within 7 days will be reported back to the nursery manager. Similarly, nursery managers will be requested to notify researchers of any COVID-19 cases among children or staff at the setting who have mixed closely with research staff within 7 days of a visit.

9 STATISTICS AND DATA ANALYSIS

9.1 Sample size calculation

Whilst observation and intervention studies support the premise that more total and MPVA activity is positive for child health,[45] there is scant evidence to inform the amount of activity per day in relation to health outcomes. Thus, we have designed the trial to detect an increase in total physical activity between study arms which would provide a benefit at a population level. In our feasibility study, 121 children provided valid accelerometer data at baseline for days they were at nursery. The mean total activity per day was 146 minutes, with a standard deviation of 43, and 40% of children met the recommendation of at least 180 minutes of activity per day. Increasing the mean total activity per day

by 17 minutes would increase the percentage of children meeting the 180 minute guideline to 47%. In our feasibility study, the 22 intervention group children providing valid accelerometer data for nursery days at both baseline and follow-up showed an increase in total activity per day from 152 minutes to 172 minutes, so an increase of 17 minutes is achievable.

In the absence of a good estimate of the variation in mean total activity per day between nurseries, we allowed for variation up to a magnitude corresponding to an intra-cluster correlation of 0.087. This is the degree of variation in moderate to vigorous physical activity between schools, allowed for in the sample size calculation for a trial of a school-based dance intervention. [46] Using the Stata clsampsi command,[47] assuming nine children will provide valid primary outcome data at each nursery, then 27 nurseries in each of the intervention and control groups will provide 90% power at the 5% significance level to detect a 17 minute difference (0.4 standard deviations) in total daily physical activity. Our aim is to recruit an average of 14 children per nursery, so allowing for up to 35% failing to provide valid accelerometer data on nursery days. Furthermore, our aim is to recruit a total of 56 nurseries (784 children), so allowing for up to two nurseries withdrawing from the study.

The magnitude of change in the primary nutrition measure that is of public health importance is similarly uncertain. As our measure of nutrition is on a continuous scale, then a trial of 56 nurseries will also be able to detect a 0.4 standard deviation difference on that measure, under the same assumptions. From our feasibility data, this is about 45kcal which equates to approximately half a banana or half a cup of milk.

In the feasibility study 62 nurseries in North Somerset (population of 208,154) met the inclusion criteria, therefore we are confident that we will be able to recruit 14 from each of the four geographical areas.

9.2 Statistical analysis plan

A detailed statistical, health economic and qualitative analysis plan will be written and made publicly available prior to analysis. The reporting of findings will be in accordance with the CONSORT guidelines, including the extension for cluster RCTs. Analysis will be performed in Stata statistical software.

9.3 Summary of baseline data

Descriptive statistics will be used to summarise characteristics of nurseries and participants and compare baseline characteristics between groups. Means and standard deviations will be used for continuous and count outcomes or medians and interquartile range if required for skewed data. Categorical variables will be summarised using frequencies and proportions.

9.4 Primary outcome analysis

The primary analyses will be of the observed data, without imputation of missing measurements, but otherwise will follow the intention to treat principle. P-values and confidence intervals (CI) will be presented for estimates of the intervention effect on primary and secondary outcomes; both will be two-sided.

The evidence for an overall intervention effect on the primary outcomes (activity and nutrition) will be estimated using a multivariate multilevel linear regression model, which will include the following nursery level covariates, intervention group, IMD as used to stratify the allocation, geographical area. The intervention effects will be presented as differences in mean total activity and total energy

consumed with their 95% confidence intervals, and a multivariate p-value testing the null hypothesis that the two intervention effects are zero. If there is evidence against this null hypothesis, the individual p-values for the two outcome measures will also be presented, this conditional approach keeping the type I error rate to 5%. More detail will be provided in the Statistical Analysis Plan.

9.5 Secondary outcome analysis

The primary analysis approach will be adapted to estimate the intervention effect on each of the secondary outcomes, utilizing univariate multilevel linear regression (continuous outcome measures) or univariate multilevel logistic regress (binary outcome measures).

9.6 Subgroup & sensitivity analyses

We will examine whether the intervention effect varies by sub-groups of participants. These sub-groups will be pre-specified in the statistical analysis plan and may include parental employment status, geographical area, child's gender and time spent in nursery.

Sensitivity analyses will repeat the primary analysis with (i) additional covariates where one or more measures was found to be unbalanced at baseline; and (ii) missing data imputed under different assumptions about the mechanisms leading to those data being missing.

9.7 Process Evaluation analysis

Information collected from document analysis, questionnaires and structured elements of the training sessions/workshops observations will be entered into the REDCAP data management system or an Excel file. Interview transcripts, qualitative observations and fieldnotes will be uploaded into NVivo 12 to aid data management and analysis. For the process evaluation a coding framework will be developed using thematic analysis. An initial coding framework will be developed by two staff including both deductive codes derived from research questions and inductive codes emerging from the data from four transcripts. This framework will be independently applied to two to four further transcripts depending on the consistency of coding; any discrepancies in coding will be discussed and appropriate revisions made. We will triangulate between different process evaluation data sources (observations, questionnaires, documentary data and interviews) to identify confirmatory or contradictory results. For example, we will compare data from the observations of training workshops with the staff evaluation forms and comments from manager and/or Partner interviews to understand how the workshops were received and their importance within the intervention as a whole. Analysis of the process evaluation data will be led by Dr Beki Langford (co-applicant), with assistance from a research assistant and input from the Research Site Managers who will be collecting the observational data.

9.8 Health Economic analysis

The primary economic analysis will consist of a within-trial cost consequences analysis (CCA) from the perspective of the local government, nursery and parents. Detail on the resource use that will be captured for each perspective are reported in section 3.7. Detail on the main economic outcome measure (PedsQL) is reported in section 7.6. Results from the within-trial CCA will allow the costs and consequences to be presented clearly in a disaggregated format rather than summarised into a single index. If there is an important difference in physical activity and/or diet at T1, a secondary analysis

considering the potential longer term costs and outcomes of the intervention will be considered. This would include a review of the economic evidence on the medium and long term costs and consequences of changes in physical activity and diet in young children.

10 DATA HANDLING

10.1 Source data and documents

When a participant consents to enter the trial, they will have a unique participant identification number allocated. Personal data entered directly onto the password protected database and maintained on a SQL Server database system within the University of Bristol which will only be accessible to members of the research team. Any data stored on laptops will be encrypted. Any information that is analysed or transferred outside the EEA will be anonymised. Participants/parents will be asked to consent to their name, email address and phone number being stored on the secure database with the central research team.

Data obtained by paper will also be entered onto the password protected database. Information capable of identifying individuals and the nature of treatment received will be held in the database with passwords restricted to trial staff. Information capable of identifying participants will not be removed from University of Bristol or research centres or made available in any form to those outside the trial, for the exception of regulatory authorities.

Consent forms and letters with personal identifiable data will be stored separately in a locked filing cabinet. Participant details will be anonymised in any publications that result from the trial.

Source data for this trial will consist of paper copies of the consent form, participant completed questionnaires as well as the paper case report forms designed specifically for the study.

10.2 Data collection

Outcomes will be assessed at T0, after consent and prior to randomisation, and again after 12 months in both the intervention and control nurseries. Outcome measures will be collected within the nursery setting by a member of the NAPSACC UK research team.

We are using standardised outcome instruments. The components and timing of follow-up measures are shown in Table 2.

10.3 Case Report Forms (CRFs)

Demographic data from nurseries, parents and children will be completed on paper and entered into the secure trial database. Nursery, parent and child data will use participant trial number and will be returned by the study centres by post or via electronic means to the central research team. Any paper copies will be stored in a secure locked cabinet in a locked room.

10.4 Data handling and record keeping

Data will be collected and retained in accordance with the Caldicott Principles, UK Data Protection Act 2018 and General Data Protection Regulation (GDPR).

For this trial, research data will be kept for at least 5 years. Personal data (e.g. name and address, or any data from which a participant might be identified) will not be kept for longer than is required for the purpose for which it has been acquired. Documents will be reviewed by the CI before being destroyed.

10.5 Access to data

For monitoring purposes, the CI will allow monitors from the sponsor (or delegate), persons responsible for the audit, representatives of the REC and other regulatory authorities to have direct access to source data/documents.

The Trial Manager (in collaboration with the Chief Investigator) will manage access rights to the data set. Prospective new users must demonstrate compliance with legal, data protection and ethical guidelines before any data are released. We anticipate that anonymised trial data will be shared with other researchers to enable meta-analyses (see section 15.9).

10.6 Archiving

This trial will be sponsored by the University of Bristol (UoB) who are also the data custodian. All research data will be retained in a secure location during the conduct of the trial and for 5 years after the end of the trial, when all paper records will be destroyed by confidential means. An archiving plan will be developed for all trial materials in accordance with the University of Bristol archiving policy.

11 TRIAL MANAGEMENT

The trial is supported by the Bristol Randomised Trials Collaboration (BRTC). The BRTC is a UK Clinical Research Collaboration registered Clinical Trials Unit which, as part of the Bristol Trials Centre, is in receipt of National Institute for Health Research CTU support funding. The trial will conform to the BRTC standard operating procedures. The central research team will prepare all the trial documentation and data collection forms, specify the randomisation scheme, develop and maintain the study database, check data quality as the trial progresses, monitor recruitment and carry out trial analyses in collaboration with the investigators

11.1 Day-to-day management

The Study Office will be based in Population Health Sciences at the University of Bristol and will provide day to day support for the research sites. The Trial Manager will take responsibility for the day to day supervision of study activities and will coordinate the trial directly with the Research Site Managers. The Senior IT manager will oversee all IT aspects of the study, while the BRTC Senior Trials Manager will provide mentoring and guidance to the Trial Manager and advice to the team on generic coordination issues.

11.2 Trial Management Group (TMG)

The TMG will oversee the trial and be the key decision-making group, provide oversight of the management and conduct of the trial. They will meet on a regular basis with a core working group of the research team having frequent progress meetings over conference calls involving the hubs to facilitate continuous feedback and early troubleshooting of local site issues that arise. The TMG will report to the TSC.

11.3 Trial Steering Committee (TSC)

An independent Trial Steering Committee (TSC) will be established. The TSC will provide overall supervision of the trial and make recommendations to the TMG. The meeting minutes will be sent to the funder and sponsor. The TSC will comprise those listed in Table 5. In addition, Prof Metcalfe (Lead Statistician) and Ruth Kipping (CI) will attend the TSC to represent the TMG. As the trial is low risk, it is unlikely that a DMC will be required for this trial, however, this will be discussed with the TSC at

their first meeting and a DMC will be set up if deemed necessary, otherwise the TSC will be asked to take on this role. Membership, responsibilities and reporting mechanisms of the TSC will be formalised in a TSC charter. The TSC will meet at least annually.

Table 5 Trial Steering Committee Members

University	Name	Expertise
Newcastle	Prof Ashley Adamson (Chair)	Trials, public health, nutrition
Exeter	Dr Mark Kelson	Statistician
Edge Hill	Prof Stuart Fairclough	Physical activity
Warwick	Prof Stavros Petrou	Health economist
-	Ms Justine Britton	Nursery manager
Bristol	Dr Ruth Kipping	Chief Investigator
Bristol (Observer)	Anna Brooke	Sponsor; observer
Bristol (Attending not member)	Prof Pete Blair	Trial Statistician/Trials Unit

11.4 Data Management Committee (DMC)

Given the low risk nature of the study, and the fact that there are no interim data collections scheduled, we will ask the TSC to act as DMC.

11.5 Local Advisory Group (LAG)

A Local Advisory Group (LAG) will be formed of representatives from our collaborators (contributing by teleconference) with representatives from Early Years advisors in the Councils, 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 report to the Trial Management Group. The group will meet three times during the study and will be chaired by one of the co-applicants and managed by the Trial Manager.

12 MONITORING, AUDIT & INSPECTION

The study will be monitored and audited in accordance with the Sponsor's policy, which is consistent with the UK Policy Framework for Health and Social Care Research. All study related documents will be made available on request for monitoring by the REC or BRTC. Quality assurance checks are carried out on 10% of approved REC studies.

The sponsor usually delegates some of the monitoring to the central research team. The following checks would be typical:

- That written informed consent has been properly documented
- That data collected are consistent with adherence to the study protocol
- That CRFs are only being completed by authorised persons
- That SAE recording and reporting procedures are being followed correctly
- That no key data are missing
- That data is valid
- Review of recruitment rates, withdrawals and losses to follow up.

The TSC will be kept informed of any significant findings.

12.1 Protocol compliance

There will be no prospective, planned deviations or waivers to the protocol. Accidental protocol deviations can happen at any time, but they must be adequately documented on the relevant forms and reported to the CI and Sponsor immediately. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

12.2 Notification of Serious Breaches to GCP and/or the protocol

A “serious breach” is a breach which is likely to effect to a significant degree:

a) the safety or physical or mental integrity of the subjects of the trial; or
b) the scientific value of the trial

The sponsor must be notified immediately of any case where the above definition applies during the trial conduct phase. They will assess the seriousness of any breach as per the appropriate SOP.

13 ETHICAL AND REGULATORY CONSIDERATIONS

13.1 Governance and legislation

This trial will be conducted in accordance with:

- Good Clinical Practice (GCP) guidelines
- UK Policy Framework for Health and Social Care Research
- Data Protection Act 2018
- General Data Protection Regulation

This research trial will be run in accordance with GCP. GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting studies that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that originated in the Declaration of Helsinki and that the clinical trial data are credible.

13.2 Research Ethics Committee (REC) review and reports

Ethics review of the protocol for the trial and other trial related participant facing documents (e.g. PIL and consent form) will be carried out by a University Research Ethics Committee (REC). Any amendments to these documents, after a favourable opinion from the REC has been given, will be submitted to the REC for approval prior to implementation.

All correspondence with the REC will be retained in the Trial Master File (TMF)/Investigator Site File (ISF). All (S)AEs will be reported to the REC during the study period (as detailed in section 8) The CI will notify the REC of the end of the trial and if the trial is ended prematurely (including the reasons for the premature termination). Within one year after the end of the trial, the CI will submit a final report with the results, including any publications/abstracts, to the REC.

GCP training will be carried out by certain staff members depending on their delegated responsibilities within the trial, the level of training required will be determined according to the NIHR Delegation and Training Decision Aid. Informed consent to participate in the trial will be sought and obtained according to GCP guidelines.

13.3 Amendments

Study document amendments will be submitted to the REC for approval. A 'notification of amendment' form, along with all amended documents (with highlighted changes) will be completed by the CI and submitted to the Research Governance and Ethics Officer, who will facilitate a review with the REC chair. If the amendment is deemed to be substantial by the REC chair, the amendment will be additionally reviewed by the committee

13.4 Peer review

The proposal for this trial has been peer-reviewed through the NIHR PHR peer-review process, which includes independent expert and lay reviewers.

13.5 Regulatory compliance

The trial will comply with the necessary regulations and will gain sponsor and REC approval. The trial will not commence until a Favourable REC opinion has been provided.

13.6 Poor quality data, notification of serious breaches to GCP and/or the protocol

13.6.1 Poor quality data

The quality of the trial data will be monitored throughout the trial and data completeness will be reported to the TSC, and any cause for concern over data quality will be highlighted and an action plan put in place.

13.6.2 Notification of serious breaches to GCP and/or the protocol

Some breaches which occur during a research study may not necessarily require immediate reporting to the Sponsor. These will be recorded locally and reviewed by the Trial Managers.

Serious breaches are classed as those which are likely to effect to a significant degree:

- The safety or physical or mental integrity of the subjects of the trial;
- The scientific value of the trial

The research team will ensure the sponsor is notified promptly about breaches that are suspected to be serious.

13.7 Financial and other competing interests

The research team and all PIs must disclose any ownership interests that may be related to products, services, or interventions considered for use in the trial or that may be significantly affected by the trial. Competing interests will be reported in all publications and in the final report.

13.8 Indemnity

The necessary trial insurance is provided by the Sponsor. The PIL provides a statement regarding indemnity for negligent and non-negligent harm.

13.9 Access to the final trial dataset

Anonymous research data will be stored securely and kept for future analysis. Members of the TMG will develop a data sharing policy consistent with UoB policy. Data will be kept anonymous on research data facility storage (RDSF). Requests for access to data must be via a written confidentiality

and data sharing agreements (DSA) available from the RDSF website which will be confirmed by the CI (or appointed nominee).

The DSA should cover limitations of use, transfer to 3rd parties, data storage and acknowledgements. The person applying for use of the data will be scrutinised for appropriate eligibility by members of the research team.

14 DISSEMINATION POLICY

An engagement plan will be produced with collaborators and the Lay Advisory Group. Participants will be informed of the findings through local meetings and briefing summaries. We will disseminate findings to public health, early years and local authority colleagues and the wider scientific community via meetings, articles in practice newsletters, scientific articles and conferences. If the intervention proves effective, we will work with stakeholders to develop a scalability plan.

The results of the study will be published in the academic press and all participants will be offered a lay summary of the main findings of the study. It is anticipated that the protocol will be submitted to a journal, with a view to subsequent publication of the main research output paper. The trial will also be presented at national and international conferences such as International Society of Behavioural Nutrition and Physical Activity, ISBM, European Conference of Public Health. This will in turn be used by the national and international community to inform practice and research.

The findings of the trial will be disseminated nationally to Public Health England, Public Health Wales, and Public Health Scotland, as these are the specialist body with the responsibility for guiding clinical practice, policy matters, research priorities, governance and training in matters related to public health of early years. These organisations are well placed to implement the findings by informing policy and by dissemination of evidence-based practice to its members.

On completion of the trial a final report will be prepared for the Funder (NIHR PHR) and once approved made publicly available on their website.

Study progress and results will be disseminated through the existing communication channels of the Centre for Public Health at the University of Bristol, which has an active twitter account. A NAP SACC UK Twitter account will be set up to keep interested parents, managers and policy makers up-to-date with trial progress.

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