Nutrition and Physical Activity Self-Assessment for Child Care

(NAP SACC UK Trial)

Statistical Analysis Plan

ISRCTN: 33134697

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Table of Contents

LIST OF ABBREVIATIONS

AE	Adverse Event
BMI	Body Mass Index
BTC	Bristol Trials Centre
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
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
NAP SACC UK	Nutrition and Physical Activity Self-Assessment for Child Care United Kingdom
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
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
SOP	Standard Operating Procedure
SQL	Structured Query Language
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
UK	United Kingdom
UK90	UK1990 growth charts
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

1 INTRODUCTION & PURPOSE

The statistical analysis plan (SAP) for the NAP SACC UK trial has been written in accordance with BTC standard operating procedures, the CONSORT statement, and International Conference on Harmonisation (ICH) Statistical Principles for Clinical Trials E9, by Liping Wen, NAP SACC UK study statistician, Research Associate in Medical Statistics, Bristol Trials Centre, Bristol Medical School, University of Bristol, under the supervision of Pete Blair, Professor of Epidemiology and Statistics, and covers all final statistical analyses to be performed, outlined in the study protocol within the study master file.

This document details the rules proposed and the presentation that will be followed, as closely as possible, when analysing and reporting the main results from the Nutrition and Physical Activity Self-Assessment for Child Care United Kingdom (NAP SACC UK) Trial.

The purpose of the plan is to:

a) Ensure that the analysis is appropriate for the aims of the trial, reflects good statistical practice, and that interpretation of *a priori* and *post hoc* analyses respectively is appropriate

b) Explain in detail how the data will be handled and analysed to enable others to perform the actual analysis in the event of sickness or other absence

Additional exploratory or auxiliary analyses of data not specified in the protocol are permitted (and will be described as exploratory) but fall outside the scope of this analysis plan (although such analyses would be expected to follow Good Statistical Practice).

The analysis strategy will be made available if required for journal editors or referees when the main papers are submitted for publication. Additional analyses suggested by reviewers or editors will, if considered appropriate, be performed in accordance with the Analysis Plan, but if published the source of such a *post-hoc* analysis will be declared.

Amendments to the statistical analysis plan will be described and justified in the final report of the trial.

2 SYNOPSIS OF STUDY DESIGN AND PROCEDURES

2.1 Objectives and outcome measures/endpoints

2.1.1 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 for children attending nurseries, using a cluster RCT design with embedded process and economic evaluations.

2.1.2 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 (consumed (kcal)) per eating occasion averaged across snack and lunch eating occasions that occur within nurseries compared with usual practice, within Nationally recommended levels.

2.1.3 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 difference in mean accelerometer-measured total physical activity on nursery days compared to non-nursery days
d) reduces the mean serving size of lunch and morning/afternoon snacks as a single outcome in nursery per day
e) increases the balance of kcal of core food to kcal of non-core food consumed for lunch and morning/afternoon snacks in nursery per day
f) reduces child Body Mass Index z-score (zBMI)
g) reduces the proportion of children with overweight/obesity

2.1.4 Co-primary outcomes

The co-primary outcomes measured at 12 months are:

1) mean total activity measured by Actigraph accelerometer (per nursery day)

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

2.1.5 Secondary outcomes

Measured at 12 months:

a) MVPA measured using ActiGraph accelerometers (per nursery day)
b) Sedentary time using ActiGraph accelerometers (per nursery day)
c) The difference in mean total physical activity measured by Actigraph accelerometer between nursery and non-nursery days
d) the average serving size of lunch (kcal per occasion) using remote food photography
e) the average serving size of snacks (kcal per occasion) using remote food photography
f) the average size of lunch (kcal per occasion) consumed by children using remote food photography
g) the average size of snacks (kcal per occasion) consumed by children using remote food photography
h) the average percentage of total energy (kcal) in lunch from non-core food served consumed by children using remote food photography
i) the average percentage of total energy (kcal) in snacks from non-core food served consumed by children using remote food photography
j) child zBMI using height, weight, age and gender, according to references of UK90
k) proportion of children with overweight/obesity using zBMI scores using UK90

Accelerometry data: Valid accelerometer data will be at least 2 days of data worn for at least 6 h per 24 h, informed by the methodology used by Pate et al. [1]. Given the variability of opening times and child attendance between nurseries, the minimum number of hours in order to be categorised as a 'nursery day' will be explored and a suitable cut-off used. Periods of 60-min with zero values will be interpreted as time that the monitor is not worn. A day will be considered valid if ≥ 6 h of data are recorded on a day when the child attended nursery. Children with ≥ 2 nursery days of accelerometer data will be included in the analyses. Mean minutes of sedentary time (using two thresholds of 0–25 and 0–199 counts per 15 s using the criteria proposed by Evenson and Puyau [2, 3]) will be used and mean minutes of light, moderate to vigorous intensity physical activity will be processed (thresholds of 200–799; and > = 800 counts per 15 s) [4]. 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. The accelerometer data will be checked for outliers. Informed by previous studies with children we will exclude implausibly high values, such as might occur when a participant uses a trampoline, using a cap of 11,714 counts per minute (cpm) [5].

Diet data: Total eating occasion size (kcal per occasion) will be computed from the sum of energy in each portion food or drink consumed for each snack (morning or afternoon) or lunch consumed in nursery. The average total size of eating occasions consumed within nursery for each child will then be derived (primary outcome). Specific foods will also be classified as core or non-core and the total intake (kcal) of core and non-core foods will be separately summed in each eating occasion consumed at nursery and expressed as a percentage of total energy consumed in an eating occasion for each child [6]. To represent the balance of healthy to less-healthy food intake consumed, the average percentage (i.e kcal of core or non-core food divided by the total kcal consumed) in lunch and morning/afternoon snacks by each child will be calculated.

Anthropometric measures of children: zBMI and proportion of overweight and obese, as determined by the UK90 age and gender reference charts at 85% and 95% centiles, respectively, with further sensitivity analysis using the World Health Organization Growth Reference thresholds to facilitate international comparisons

2.2 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 [7].Clusters (nurseries) will be randomised to receive either the NAP SACC UK intervention or continue with usual practice.

2.3 Eligibility criteria

2.3.1 Nursery Selection Criteria

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 four geographical areas of England and Scotland: Somerset, Swindon, Sandwell and Ayrshire and Arran.

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.

2.3.2 Subject population

Participant (staff, parents/ carers 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).

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 or child refuses assent.

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.

2.4 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 1).

Table 1. 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 101item 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 or an online recording.
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 where they are delivered in person, followed by an online refresher workshop after 6 months; recorded workshops (without group interaction) will be available where individual

	staff need flexibility to engage with the workshops. 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.
Modifications	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.

2.5 Randomisation

Each nursery will be randomly allocated using a 1:1 ratio to either the NAP SACC UK intervention or usual practice control group once all data have been collected from that nursery's children, parents and nursery staff at enrolment. Allocation will be conducted by an independent Bristol Trials Centre statistician within the co-ordinating study hub at the University of Bristol, blind to the identity of nurseries. Within each hub separately (University of Bristol, Birmingham and Glasgow), 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) at each site. Each random allocation will attempt to balance the IMD score between the two groups per site. This minimisation procedure will be written in Stata statistical software, and the code provided in section 5 Appendix.

2.6. Sample size calculation

Whilst observation and intervention studies support the premise that more total and MPVA activity is positive for child health [8], 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 realistic.

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 [9]. The coefficient of variation of cluster size is 0.3 to account for slightly variable cluster size, i.e., different numbers of children in nurseries. Using the Stata clustersampsi command [10], 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, we aim to recruit a total of 56 nurseries (784 children), allowing for up to two nurseries withdrawing from the study.

Whether 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.

2.7 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 be presented with aggregate data only.

All baseline data will be collected prior to randomisation. Research staff and the following co-investigators (Dr Beki Langford, Prof Sharon Simpon and Prof Miranda Pallan) will not be blinded to allocation because of their need to correspond with intervention and control nurseries and the research team during the intervention period. The trail statistician will also be unblinded to liaise with the study team and all study data (the trial statistical lead will be blinded). The intention is for all other co-applicants to be blinded. Nursery staff will not be blinded. Parents and children will not be blinded but the nurseries will not actively promote their involvement in the intervention or control arm to parents and children.

3 DESCRIPTION OF PARTICIPANT CHARACTERISTICS

3.1 Disposition

The flow of clusters and participants through the trial will be summarised in a CONSORT diagram that will include the eligibility, reasons for exclusion, numbers randomised to the two treatment groups, losses to follow up and the numbers analysed.

3.2 Summary of baseline data

Descriptive statistics of demographic and anthropometric, diet and activity measures will be used to describe the population and to examine balance between the arms at baseline. Baseline data will be presented by arm, for both individual- and cluster-level characteristics. Continuous data will be summarised using a measure of central tendency and variation as appropriate given the nature of data distribution (e.g., mean and standard deviation for Normally distributed data, median and interquartile range for Skewed distributions). Categorical data will be summarised in terms of frequencies and percentages.

4. ANALYSIS OF EFFECTIVENESS

4.1 Primary 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 an overall intervention effect on the primary outcomes (activity and nutrition) will be estimated using a multilevel linear regression model, both of which will include the following nursery level covariates: intervention group; IMD for English postcodes (updated 2019) and SIMD for Scottish postcodes (updated 2022) used as a minimisation variable (an average IMD score created for each nursery using the postcodes of the recruited children within the setting); geographical area; and will include a random effect for nursery to account for clustering. For physical activity, the primary analysis will be a 2-level model (child and nursery), including an additional covariate, the mean baseline measurement of mean total activity for each nursery. For nutrition, the primary analysis model will be a 3-level model (eating occasion, child, nursery), including an additional covariate, the mean kcal of each eating occasion at baseline for each nursery; this model will possibly use log transformation for the kcal per eating occasion given the potential skewness of the outcome, as well as the systematically different size of lunch and snack. For physical activity There needs to be evidence of an effect on BOTH physical activity AND kcal consumption for NAPSACC-UK in its present form to be adopted - this is in fact a more stringent test (the overall false positive / type 1 error rate will not exceed and is likely to be below the 5% level) and NO allowance for

multiple testing is required. Only if we would take evidence of an effect on EITHER physical activity OR/AND kcal consumed would we inflate the overall false positive / type 1 error rate above the intended 5% level.

The primary analysis model for nutrition will be a 3-level model:

$$\log(y_{ijk)} = \beta_0 + \beta_1 allocation_k + \beta_2 imd_k + \beta_3 site_k + \beta_4 x_{ik} + u_k + v_{jk} + \varepsilon_{ijk}$$

for nursery (*k*), child (*j*) and eating occasion (*i*) , in which *allocation* is the treatment group, *imd* (IMD rank created for each nursery using the postcodes of the recruited children) and *site* (the geographical area) are the minimisation variables, x_{ik} is the mean baseline kcal of each eating occasion *i* at a nursery *k*, and u_k and v_{jk} are random effects accounted for the clustering. Also, log transformation of the response variable will be used given the positively skewed outcome at baseline and to avoid problems with reducing the kcal from two very different sized meals, snack and lunch.

The primary analysis model for physical activity will be a 2-level model,

$$y_{jk} = \beta_0 + \beta_1 allocation_k + \beta_2 imd_k + \beta_3 site_k + \beta_4 x_{jk} + u_k + \varepsilon_{jk}$$

for nursery *(k*) and child (*j*), in which *allocation* is the treatment group, *imd* (IMD rank created for each nursery using the postcodes of the recruited children) and *site* (the geographical area) are the minimisation variables, x_{ik} is the average baseline measurement of the outcome of each child *j* at a nursery *k*, and u_k is the random effects accounted for the clustering.

NAPSACC-UK aims to improve diet and increase physical activity in children at nurseries, and evidence of an impact on both primary outcome measures is required to support the adoption of the programme in its current form into routine practice. In this situation, the two co-primary outcomes do not increase the probability of a false-positive conclusion, and no adjustment of the significance level is required. Evidence of an impact of NAPSACC-UK on one co-primary outcome but not the other will be discussed, as this may indicate that revising the programme may be worthwhile before further evaluation.

4.2 Secondary analyses

4.2.1 Secondary outcome analysis

The primary analysis approach will be adapted to estimate the intervention effect on each of the secondary outcomes, utilizing multilevel linear regression (continuous outcome measures) or multilevel logistic regression (binary outcome measures), including a random effect for nursery to account for clustering.

4.2.2 Sensitivity analysis

The impact of missing data. Sensitivity analyses will repeat the primary analysis to investigate the impact of missing data, with the approach taken depending on the assumptions about missingness deemed appropriate. The data will be explored before this decision is made, taking account of: the amount of missingness; differences between arms;

variables associated with/ predictive of missingness; and where available, reasons for missingness.

The impact of compliance. A Complier Average Causal Effect (CACE) analysis will be conducted to investigate the efficacy of the intervention, based on intervention compliance for comparison to the ITT analysis estimate of the effect of the offer of the intervention.

Compliance will be assessed as a binary measure of compliant or not compliant based on all the following:

- One self-assessment (called Review & Reflect) completed
- Engagement from at least one member of nursery staff in one of the workshops either in-person or online
- One goal setting form completed

Higher levels of compliance will also be assessed.

The impact of additional covariates. The primary analysis will be repeated with additional covariates where one or more measures was found to be unbalanced at baseline.

The impact of outliers. Graphical checks will be done on outcomes to identify potential outliers and these data points will be investigated. If inspection reveals outliers are genuine data points, then the primary analysis will be repeated excluding the outliers.

Growth reference charts. For the secondary analysis we are using the UK90 age and gender reference charts but will also conduct a sensitivity analysis using the WHO growth reference for children aged 2-5 years.

Intercurrent events. Any events that impact on the trial (such as a nursery not delivering the intervention) will be explored.[11]

4.2.3 Subgroup analysis

A limited number of pre-specified exploratory subgroup analyses will be performed. As the trial was not powered to detect effectiveness in subgroups, these analyses were treated as exploratory and interpreted with caution. Potential treatment effect moderators will be investigated at the area (e.g. four Health or Local Authority areas), cluster (number of children in nursery) and individual-levels (e.g., deprivation, gender, age and time child spends at nursery per week). Potential moderators will be investigated by introducing moderator-by-treatment interactions into the primary analysis model (separately).

5 FINAL REPORT TABLES AND FIGURES

5.1 Baseline characteristics for nurseries and children

Table 1. Baseline characteristics

Baseline demographic and clinical characteristics for NAPSACC UK Nursery settings and child participants		
	Control group	**Intervention group**
Nursery	**N=**	**N=**
Consented children	**N=**	**N=**

* Data are medians (IQR)/Mean (SD) or numbers (%).

5.2 Primary analysis and sensitivity analyses

Table 2. Comparison on co-primary outcome (activity) between two arms

	Control group				Intervention group				Adjusted mean difference* for n=	95% CI	p-value
	Baseline		12 months		Baseline		12 months				
Analyses	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)			
Primary analysis:											
Activity[1]											
Sensitivity analyses:											
Additional covariates											
CACE											
Imputation											

Excluding outliers											

[1]Mean total activity that occurs within nurseries.

*Adjusted for allocation, IMD and geographical area.

Table 3. Comparison on co-primary outcome (nutrition) between two arms

	Control group				Intervention group				Adjusted mean difference** for n=	95% CI	p-value
	Baseline		12 months		Baseline		12 months				
Analyses	n	Mean (SD)*	n	Mean (SD)*	n	Mean (SD)*	n	Mean (SD)*			
Primary analysis:											
Nutrition[1]											
Sensitivity analyses:											
Imputation											
CACE											
Additional covariates											
Excluding outliers											

[1]Total energy (kcal) consumed per snack and lunch eating occasion averaged across all snack and lunch eating occasions that occur within nurseries.

*Median (IQR) might be used if the data is skewed.

**Adjusted for allocation, IMD, geographical area and mean kcal of each eating occasion at baseline for each nursery.

5.3 Secondary outcome analysis

Table 4. Baseline and 12-month follow-up measures for the secondary outcomes

Secondary outcome variables	Control group				Intervention group				Adjusted mean difference for n=	95% CI	p-value
	Baseline		12 months		Baseline		12 months				
	n	Mean (SD)*	n	Mean (SD)*	n	Mean (SD)*	n	Mean (SD)*			
MVPA											
Sedentary time											
Average serving size of lunch											
Average serving size of snacks											
Average size of lunch consumed											
Average size of snacks consumed											
Percentage non-core food (lunch)[1]											
Percentage non-core food (snacks)[2]											
zBMI (UK 1990)											
zBMI (WHO)											
Overweight/Obesity proportion											

[1]The average percentage of total energy (kcal) in lunch from non-core food served consumed by children using remote food photography

[2]The average percentage of total energy (kcal) in snacks from non-core food served consumed by children using remote food photography
*Median (IQR) might be used if the data is skewed.

5.4 Subgroup analysis

Interaction test

Table 5. The moderator-by-treatment interaction test results

	Activity				Nutrition			
moderator	n	Adjusted mean difference	95% CI	p-value	n	Adjusted mean difference	95% CI	p-value
Moderator 1								
…								

* This adjusted mean difference is according to the interaction term based on the primary analysis model.

Exploratory results

Table 6. Exploratory results for different moderators that are deemed to have different effect between two arms due to different categories of moderators (for **activity**)

Moderator* and its category	Control group				Intervention group				Adjusted mean difference for n=	95% CI	p-value
	Baseline		12 months		Baseline		12 months				
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)			
Moderator 1											
Category 1											
Category 2											
Moderator 2											
Category 1											
Category 2											
Category 3											
…											

* The moderators here are based on Table 5.

Table 7. Exploratory results for different moderators that are deemed to have different effect between two arms due to different categories of moderators (for **nutrition**)

Moderator* and its category	Control group				Intervention group				Adjusted mean difference for n=	95% CI	p-value
	Baseline		12 months		Baseline		12 months				
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)			
Moderator 1											
Category 1											
Category 2											
Moderator 2											
Category 1											
Category 2											
Category 3											
…											

* The moderators here are based on Table 5.

5 Appendix

Randomisation coding:

NAPSACC_rand.do

```
capture log close
set more off
clear
version 13
global path "C:\Users\epcrm\OneDrive - University of Bristol\H_DRIVE\chrism\BRTC\NAPSACC UK"
```

```
input nursery_id hub index IMD
1001 1 1 25763
1005 1 2 14996
1011 1 3 14227
3002 2 1 7197
end


label define hubname 1 "Bristol" 2 "Birmingham" 3 "Scotland"
label values hub hubname

gen rand=.
label define randfmt 0 "Comparison" 1 "Intervention"
label values rand randfmt

replace IMD=int(IMD/1000)

** Bristol hub **
global hub 1
qui summ IMD if hub==1
global count=r(N)
set seed 9287326
local rand1 = (uniform()>.5)
replace rand=`rand1' if hub==1 & index==1
replace rand=(1-`rand1') if hub==1 & index==2

do "$path\NAPSACC_rand_sr.do"

** Birmingham hub **
global hub 2
qui summ IMD if hub==2
global count=r(N)
set seed 201098
```

```
local rand1 = (uniform()>.5)
replace rand=`rand1' if hub==2 & index==1
replace rand=(1-`rand1') if hub==2 & index==2

do "$path\NAPSACC_rand_sr.do"

** Scotland hub **
global hub 3
qui summ IMD if hub==3
global count=r(N)
set seed 315677
local rand1 = (uniform()>.5)
replace rand=`rand1' if hub==3 & index==1
replace rand=(1-`rand1') if hub==3 & index==2

do "$path\NAPSACC_rand_sr.do"

tab rand, summ(IMD)
list nursery_id rand, noobs sepby(hub)
```

NAPSACC_rand_sr.do

```
forvalues i=3/$count {
        qui{
                replace rand=0 if index==`i' & hub==$hub

                summ IMD if rand==0 & hub==$hub
                local IMD00=r(mean)
                local n00=r(N)
                summ IMD if rand==1 & hub==$hub
                local IMD01=r(mean)
```

```
local n01=r(N)

replace rand=1 if index==`i' & hub==$hub

summ IMD if rand==0 & hub==$hub
local IMD10=r(mean)
local n10=r(N)
summ IMD if rand==1 & hub==$hub
local IMD11=r(mean)
local n11=r(N)

local tilt1=(abs(`IMD00'-`IMD01')-abs(`IMD10'-`IMD11'))
if abs(`tilt1')<=5{
        local tilt1=0
        }
local tilt2=(abs(`n00'-`n01')-abs(`n10'-`n11'))
if abs(`tilt2')<=1{
        local tilt2=0
        }

local tilt=(`tilt1'>0)-(`tilt1'<0)+(`tilt2'>0)-(`tilt2'<0)
display "Tilt 1 " `tilt1' " 2 " `tilt2' " sum " `tilt'

if `tilt'<0{
        local rand=0.80
        }
if `tilt'==0{
        local rand=0.50
        }
if `tilt'>0{
        local rand=0.20
        }
```

```
        local rrr=uniform()
        replace rand=(`rrr'>`rand') if hub==$hub & index==`i'

        }
        display `rand'
        display `rrr'
        tab rand if hub==$hub, summ(IMD)
}
```

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