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NAP SACC (UK): Nutrition and physical activity self-assessment for childcare

Submission date
24/10/2019

Recruitment status
No longer recruiting

Registration date
31/10/2019

Overall study status
Ongoing

Last Edited
18/10/2024

Condition category
Other

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English Summary
Background and study aims
In the UK, most children under 5 years do not get enough physical activity for health and many also have a poor diet. As a result, more than one in five children are overweight or obese by the time they start primary school. Many children attend nurseries for childcare, but not all nurseries provide healthy environments. Local Authorities in the UK are increasingly developing and employing their own locally developed programmes to improve child health in early years' settings, however, none of these have been evaluated to see whether they are effective through a randomised controlled trial. This study will test whether an American programme called NAP SACC (Nutrition and Physical Activity Self Assessment for Childcare) can improve children's health by making nurseries in the UK a place where children can be physically active and eat healthy food. In a pilot study of NAP SACC UK, we found that nursery staff, parents and health staff liked the programme and the methods we used. This new, larger study will now test whether NAP SACC UK improves children's physical activity, food intake and obesity levels. We will also test whether it is a good use of money

Who can participate?
Nurseries which are not part of another local public health nutrition and/or physical activity programme. Children aged 2-years or above at the time of assessment, who are not yet attending Reception (England) or Primary One (Scotland), who are attending the participating nurseries for a minimum of 12 hours per week across the year or 15 hours during term time, and consume at least one meal at nursery, either provided by the nursery or family

What does the study involve?
We will conduct a nursery based, cluster randomised controlled trial of an environmental nutrition and physical activity programme for child care providers. The study is based on the feasibility trial in which we adapted and tested the feasibility and acceptability of the American programme (NAP SACC - Nutrition And Physical Activity Self Assessment for Child Care) for its suitability for delivery in UK nurseries. The study will be conducted in 56 nurseries across four areas of the UK (Somerset, Swindon, Sandwell and Ayrshire and Arran), 28 of which will receive the programme (the NAP SACC UK programme), which consists of expert support to nurseries in improving their physical activity and nutrition environment. The other 28 nurseries will act as 'comparison nurseries' and will not receive the NAP SACC UK programme. Nurseries will be

allocated to programme or comparison groups at random. Data will be collected from nurseries and eligible children at two time points: before nurseries are randomly allocated to programme or comparison groups, and 12 months after the first data collection point. We will measure each child's height and weight; ask them to wear an activity monitor; and take photographs of everything they are served and eat at nursery snack and mealtimes to estimate how much food they eat. We will see if children in the NAP SACC UK group have better physical activity levels, nutrition and obesity levels than children who did not receive the programme. If we see a positive difference we will apply for funding to take some or all of these measurements again later to see if the changes last. To check how the programme is run, we will observe staff workshops and interview nursery managers and NAP SACC UK Partners to understand how the programme was delivered, any problems there were and in what ways it has been helpful. We will also work out how much the NAP SACC UK programme costs and weigh this against any benefits to decide if it provides value for money

What are the possible benefits and risks of participating?
The benefits of participation for nurseries is an increase in the health-promoting environment through staff training and supported practical changes to policy, practice and the environment. The benefits to participation for the children at the nursery are potential increase in physical activity and healthy eating whilst in the nursery environment. The benefits to public health staff include an increase in knowledge of nutrition and physical activity in early years' settings and new relationships with early years' staff. The potential risks to participants are minimal and mainly involve the time taken to participate in the study, the assessments, communication with parents and measures with children

Where is the study run from?
The study is led from University of Bristol (UK) with staff involved from the Universities of Cardiff, Glasgow, Birmingham, North Carolina (USA), Pennington Biomedical Research Centre (USA) and Bristol Randomised Trials Collaboration (BRTC)

When is the study starting and how long is it expected to run for?
July 2019 to April 2025

Who is funding the study?
National Institute for Health Research (Public Health Research Programme) (UK)

Who is the main contact?
Dr Ruth Kipping
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Study website
https://napsaccuk.blogs.bristol.ac.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR PHR 12/75/51

Study information

Scientific 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)

Acronym
NAP SACC UK

Study hypothesis
Total physical activity will increase and the mean calories consumed across all eating occasions at nursery will be reduced among eligible children in the intervention arm at time 1 compared to eligible children in the control arm. We also hypothesise that there will be secondary effects on MVPA, sedentary time, serving size, balance of core vs non-core food consumed, zBMI, proportion of overweight/obesity and quality of life.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/10/2019, Faculty of Health Sciences Research Ethics Committee, University of Bristol (University of Bristol Faculty of Health Sciences, First Floor South, Senate House, Tyndall

Avenue, Bristol, BS8 1TH, United Kingdom; +44 (0)117 9289089; liam.mckervey@bristol.ac.uk), ref: 93764

Study design
Multicentre parallel-group two-arm cluster randomized controlled trial with a repeat cross-sectional design

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Information sheets will be made available via the project webpage

Condition
Physical activity, sedentary time and diet

Interventions
Randomisation
Within each study area, nurseries will be randomly allocated to the intervention or control group once all data has been collected from child and parents at T0 from participating nurseries. Cluster (nursery) allocation will be to two arms: NAP SACC UK or usual practice. Allocation will be conducted by an independent Bristol Randomised Trials Collaboration statistician, blind to the identity of nurseries. Within each of the four study areas, nurseries will be stratified (high /medium/low) based upon an average IMD created for each nursery using the postcodes of the children recruited to the study to ensure balance across arms on socioeconomic disadvantage.

Trial arm: NAP SACC UK programme
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.

The programme 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

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.

Trial arm: Usual practice
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.

Follow-up:
Follow-up data (T1) will be collected immediately after the 12-month intervention in both study arms, which will be between 12-16 months after T0 data were collected.
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 Reception or Primary 1, 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

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 18/02/2022:
Measured at T0: baseline and T1: immediately after the 12-month intervention, which will be between 12-16 months after T0:
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

Previous primary outcome measures:
1. Mean total activity measured by Actigraph accelerometer
and/or
2. Mean energy (kcal) per eating occasion averaged across all eating occasions at 12 months measured by remote food photography

Secondary outcome measures
Current secondary outcome measures as of 18/02/2022:
Measured at T0: baseline and T1: immediately after the 12-month intervention, which will be between 12-16 months after T0:
1. Moderate-to-vigorous physical activity measured using ActiGraph accelerometers
2. Sedentary time measured using ActiGraph accelerometers

3. The average serving size of lunch (kcal per occasion) measured using remote food photography
4. The average serving size of snacks (kcal per occasion) measured using remote food photography
5. The average size of lunch (kcal per occasion) consumed by children measured using remote food photography
6. The average size of snacks (kcal per occasion) consumed by children measured using remote food photography
7. The average percentage of total energy (kcal) in lunch from non-core food served consumed by children measured using remote food photography
8. The average percentage of total energy (kcal) in snacks from non-core food served consumed by children measured using remote food photography
9. Child BMI-for-age z-score (zBMI) calculated using height and weight
10. Proportion of children with overweight/obesity determined by zBMI scores using UK 1990, WHO-UK and International Obesity Task Force (IOTF) criteria
11. Child quality of life measured using parent-reported PedsQL
12. Cost-effectiveness measured using cost consequences analysis methodology (CCA)
13. Fidelity, acceptability and sustainability of the intervention assessed by undertaking process evaluation using observations, semi-structured interviews, questionnaires, document analysis and fieldnotes

Previous secondary outcome measures:
1. Accelerometer assessed mean daily moderate to vigorous physical activity
2. Accelerometer assessed mean daily sedentary time
3. Average size (calories) of food served, using remote food photography, across all eating occasions in nursery per day
4. Balance of core food to non-core food consumed using remote food photography
5. zBMI determined by weight and height
6. Proportion of children who are overweight/obese, determined by zBMI scores using UK1990, WHO-UK and IOTF
7. Quality of nutrition and physical activity in the nursery environment measured by the Environment and Policy Assessment and Observation (EPAO) UK Instrument score
8. Child quality of life using parent-reported PedsQL
9. Cost-effectiveness using cost consequences analysis methodology (CCA)
10. Fidelity, acceptability and sustainability of the intervention by undertaking process evaluation using observations, semi-structured interviews, questionnaires, document analysis and fieldnotes

Overall study start date
01/07/2019

Overall study end date
30/04/2025

Eligibility

Participant inclusion criteria
1. Setting: 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 one meal per day (provided by the nursery or family) in the four geographical areas outlined in this section

2. Staff: Child care managers and staff in participating nurseries
3. 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)
4. 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 one meal (provided by nursery or from home)

Participant type(s)
Other

Age group
Child

Lower age limit
2 Years

Sex
Both

Target number of participants
784

Total final enrolment
570

Participant exclusion criteria
1. Settings: 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. Children:
2.1. Attending participating nurseries under 2 years old at the time of assessment, or who have started attending Reception (England) or Primary One (Scotland).
2.2. Whose parents/carers refuse consent for measurements
2.3. Attending fewer than 12 hours per week across the year or 15 hours during term time
2.4. Attending participating nurseries under 2 years old at the time of assessment, or who have started attending Reception (England) or Primary One (Scotland)

Recruitment start date
01/03/2022

Recruitment end date
30/03/2024

Locations

Countries of recruitment

England

Scotland

United Kingdom

Study participating centre
Centre for Public Health
Bristol Medical School
University of Bristol
Canynge Hall
39 Whatley Road
Bristol
United Kingdom
BS8 2PS

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Study participating centre
University of Glasgow
University Avenue
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G12 8QQ

Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We plan to publish up to four study papers. 1) a study protocol paper; 2) main trial (cost and cost effectiveness) paper; 3) process evaluation paper; and 4) health economics evaluation paper.

The protocol (not peer-reviewed) is available at: https://www.journalslibrary.nihr.ac.uk/programmes/phr/NIHR127551

Intention to publish date
14/05/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.
In line with the NIHR research contract, anonymised data from this study will be made available to other researchers. This will be done using the University of Bristol's Research Data Repository

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol (preprint)		02/03/2023	14/03/2023	No	No
Protocol article		02/08/2023	03/08/2023	Yes	No
Statistical Analysis Plan	version 1.0	10/05/2024	18/10/2024	No	No