ISRCTN16287377 https://doi.org/10.1186/ISRCTN16287377

Nutrition and Physical Activity Self Assessment for Child Care UK (NAP SACC UK)

Submission date
12/06/2014

Recruitment status
No longer recruiting

Registration date
10/04/2015

Overall study status
Completed

Last Edited
11/02/2021

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Nearly 10% of children aged 4 to 5 in England are obese and more than 13% are overweight. . In Wales over 11% of children aged 4-5 are obese and 15% are overweight. Obesity is more common in children from poorer backgrounds. However, we have little information about how to prevent young children becoming obese. It is recommended that pre-school children are physically active for at least 3 hours per day. Yet, only one third of 2 to 4 year olds are physically active for at least 60 minutes per day. Young children do not eat enough fruits and vegetables and most of their sugar intake is from soft drinks. It is important that care environments are healthy to reduce the risk of obesity. Over 3 million children attend some form of child care in England. In England and Wales free child care is available for children aged 3 to 4. This study will aim to test whether we can adapt and use a 6 month programme from the United States called "The Nutrition and Physical Activity Self Assessment for Child Care" (NAP SACC). We will make changes to use it in the UK and test whether we can work with child care providers to make the environments more healthy.

Who can participate?
Child care providers in North Somerset and Cardiff will be invited to take part in the study if they provide a main meal to children. The providers will include day nurseries, private nursery schools, maintained nurseries, Children's Centres with nurseries and pre-schools. Parents of children aged 2-4 in the child care providers will be asked if they would like their child to take part. Children can take part if they receive an average of at least 12 hours per week of child care and receive at least 1 main meal per week provided by the setting.

What does the study involve?
We will work with child care providers and parents before we start using NAP SACC to find out how we need to change to use it in the UK. We will invite child care providers and parents of children in these providers to take part. We will work with 12 providers. Six will be chosen at random to receive NAP SACC UK and six will be chosen at random not to receive NAP SACC UK. The six providers receiving NAP SACC UK will use the NAP SACC UK self assessment tool ('Review and Reflect') to assess their environment with respect to food, drink and physical activity. They will then work with trained staff (NAP SACC UK Partners) to action plan and set goals to make improvements in areas that have been identified as not meeting best practice.

This will be supported by workshops and ongoing support over six months. The other half of child care centres will not receive the programme but will take part in the measurements. At the beginning and end of the study we will take measurements from the children in all twelve child care providers. With the parent's agreement we will measure the child's height, weight, physical activity levels and diet. We will also collect information from parents about the child's quality of life. We will collect information about the costs of providing NAP SACC UK. We will be interested in whether it is possible to take the measurements. We will also be interested in comparing the group who have the NAP SACC UK intervention and those who did not. This will help us to see if there may be benefits from using NAP SACC UK. We will also be able to calculate how many child care providers and children we would need for a larger study. At the beginning and end of the study we will talk to child care staff, staff who work to support child care providers and parents about their views on the study.

What are the possible benefits and risks of participating?
The child care providers will gain from having an expert work alongside them to review and offer suggestions for improving the child care environment. The risks of taking part are very small and mainly involve the time taken to participate in the study, the assessments, communication with parents and measurements with children.

Where is the study run from?
The study is led by the University of Bristol with staff involved from the Universities of Cardiff, Glasgow and North Carolina at Chapel Hill.

When is the study starting and how long is it expected to run for?
September 2014 to April 2017

Who is funding the study?
The research costs are funded by the National Institute of Health Research. The costs for running the programme are funded by North Somerset Council and Public Health Wales.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PHR 12/153/39

Study information

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

Acronym
NAP SACC UK

Study objectives
1. Can the NAP SACC child care intervention from the US be adapted and developed for use in the UK?
2. Does the child care intervention have the potential to increase healthy eating, increase physical activity and decrease sedentary time among 2-4 year old children in child care provider settings?
3. Is it feasible to conduct a cluster RCT evaluation of NAP SACC in child care providers in the UK and how should such a trial be designed?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Phase 1: Intervention adaptation and development - Wales REC 3, 15/09/2014, ref: 14/WA/1134
2. Phase 2: Pilot RCT - Wales REC 3, 18/03/2015, ref: 15/WA/0043

Study design
Feasibility cluster randomised controlled trial with process evaluation and collection of costs to inform a future assessment of cost-effectiveness. The study is multi-centred with two centres.

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Physical activity, sedentary time and diet

Interventions
The Nutrition and Physical Activity Self Assessment for Child Care (NAP SACC) -http://www.napsacc.org/ - is an intervention delivered in child care centres with the aim of improving policies, practices and the nutrition and physical activity environment, through a process of self-assessment and targeted assistance. NAP SACC is a theory-based programme that employs components of social cognitive theory and socio-ecological framework. Goals of the programme are to improve:
1. The nutritional quality of food served
2. Amount and quality of physical activity
3. Staff-child interactions
4. Centre nutrition and physical activity policy

Intervention Type
Mixed

Primary outcome measure
For the purposes of the feasibility study, the primary outcomes are the acceptability of the intervention and the trial methods.

Secondary outcome measures
1. Environment and Policy Assessment and Observation (EPAO) Instrument score: The (EPAO) instrument was developed for NAP SACC14 and assesses child-care nutrition and physical activity environments, policies, and practices and was developed using the standards, recommendations, and research literature upon which the NAP SACC intervention itself was based. The EPAO consists of a 1-day observation and review of pertinent centre documents using 75-item responses, with the average of all subscale scores representing total nutrition and physical activity scores. The EPAO will be administered by a researcher who will receive a day of training and be blind to child care provider allocation. . The EPAO will be adapted for use in the UK prior to use.
2. Anthropometric measures of children (zBMI and proportion of overweight and obese, as determined by the UK1990 age and gender reference charts at 85% and 95% centiles, respectively; with further sensitivity analysis using the International Obesity Task Force thresholds). All anthropometric measurements will be completed with children in a private area with two DAB checked trained fieldworkers present and a member of nursery staff. Weight will be measured without shoes in light clothing to the nearest 0.1kg using a Seca digital scale. Height will be measured, to the nearest 0.1cm, without shoes using a portable Harpenden stadiometer. Fieldworkers will be trained to ensure correct position for height assessment.
3. Accelerometry measured activity (mean minutes of sedentary, light, moderate and vigorous

activity per day). We will use ActiGraph accelerometers which have been described as the most widely used and extensively validated accelerometer for assessment of physical activity among children. We have extensive experience (with over 8000 children) of collecting and processing Actigraph accelerometer data. Accelerometers have been widely used with pre-school aged children. Accelerometers will be worn for five days. Periods of 60-minutes with zero values will be interpreted as time that the monitor is not worn. A day will be considered valid if 8 hours of data are recorded. Mean minutes of sedentary, light, moderate and vigorous intensity physical activity will then be processed using the criteria proposed by van Cauwenberghe et al. Mean accelerometer counts per minute, which provides an indication of the overall volume of physical activity in which the children engage will also be calculated as this approach facilitates comparison with studies that may have applied a different cut-point.
4. Children's food and drink intake specifically fruit and vegetables, snacks and sugar sweetened drinks. Dietary assessment will be performed using the CADET (Child and Diet Evaluation Tool) diary as a 24 hour recall. CADET will be completed by trained fieldworkers for the hours the child is in nursery, and the children's parents (to reflect diet at home) by self-completion. Trained staff will contact non-responders by telephone to complete CADET.

All outcomes (primary and secondary) will be measured at baseline and after approximately 12 months.

Overall study start date
01/09/2014

Completion date
30/04/2017

Eligibility

Key inclusion criteria
Participants for Phase 1:
1. Child care provider managers and staff in day nurseries, private nursery schools, maintained nurseries, childrens centres with nurseries and pre-schools
2. Health Visitors in North Somerset
3. Healthy Preschool Programme staff in Cardiff and the Vale of Glamorgan
4. Early Years staff working at local authorities in North Somerset and Cardiff
5. Parents/carers with children aged 2-4 attending child care providers in North Somerset and Cardiff

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

Participant type(s)
Healthy volunteer

Age group
Child

Sex
Both

Target number of participants
12 child care providers and 168 children.

Total final enrolment
168

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

Date of first enrolment
01/05/2015

Date of final enrolment
31/10/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bristol
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Sponsor information

Organisation
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Sponsor type
University/education

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

Funder Name

North Somerset Council

Funder Name
Public Health Wales

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/04/2016		Yes	No
Results article	cross-sectional study results	14/11/2018		Yes	No
Other publications	process evaluation	03/07/2019	11/02/2021	Yes	No
Results article	results	01/07/2019	11/02/2021	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No