

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

Submission date 29/10/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/11/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 12/10/2016	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Few interventions have focused on child care for obesity prevention, despite the fact that in most developed countries the majority of children under five years of age spend time in these settings. Even fewer of these interventions have targeted very young children. The aim of this study is to evaluate the ability of an intervention to improve the nutrition and physical activity environments and practices in child care centers serving infants and toddlers.

Who can participate?

Child care centers located in the Boston area where at least 50% of children are racial minorities (non-white)

What does the study involve?

Participating child care centers are randomly allocated to either the intervention group or the control group. In the intervention group, center directors assess their child care environments, select areas for improvement, and make changes with the help of a trained interventionist. Interventionists also provide training for all child care providers in the intervention centers. The training focuses on infant and toddler nutrition, physical activity for infants and toddlers, and working with parents to help prevent obesity in young children. Center environments are assessed at the start of the study and at the six-month follow up. Control groups centers receive the intervention after the end of the study.

What are the possible benefits and risks of participating?

Benefits of participation in the study include improving the child care environment and preventing the development of obesity in young children. The main risk of participation was the potential for breach of confidentiality.

Where is the study run from?

The study took place in 32 child care centers in Boston, Massachusetts, and was conducted by researchers at Harvard Medical School and Harvard Pilgrim Health Care (USA)

When is the study starting and how long is it expected to run for?

March to December 2009

Who is funding the study?

1. National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (USA)
2. Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) (USA)

Who is the main contact?

Dr Sara Benjamin Neelon

Contact information

Type(s)

Scientific

Contact name

Dr Sara Benjamin Neelon

Contact details

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Durham
United States of America
27705

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Preventing obesity in infants and toddlers in child care

Acronym

Baby NAP SACC

Study objectives

Child care centers participating in the intervention would improve their practices and environments supporting nutrition and physical activity for young children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Institutional Review Board, Harvard Pilgrim Health Care, 07/03/2008 ref: HSC# 3.7.08
2. Institutional Review Board, Duke University Medical Center, 14/10/2009, ref: Pro00019220

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

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

Nutrition and physical activity to help prevent obesity

Interventions

The intervention allowed child care centers to assess their nutrition and physical activity environments, select areas for improvement, and make changes with the help of a trained interventionist.

Control centers received a delayed intervention.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

A researcher-administered assessment of each centers environment using the Environment and Policy Assessment and Observation instrument

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/03/2009

Completion date

31/12/2009

Eligibility

Key inclusion criteria

1. Child care centers located in the Boston area
2. The Massachusetts licensing office classified them as a child care center and not a family child care home
3. At least 50% of children were racial minorities (non-white)

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

32

Key exclusion criteria

Centers with an open or pending case of abuse or neglect on file with the state

Date of first enrolment

01/03/2009

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

United States of America

Study participating centre

Duke University

Durham

United States of America

27705

Sponsor information

Organisation

Eunice Kennedy Shriver National Institute of Child Health (NICHD) (USA)

Sponsor details

Bldg 31
Room 2A32, MSC 2425
31 Center Drive
Bethesda
United States of America
20892-2425

Sponsor type

Government

Website

<http://www.nichd.nih.gov/>

ROR

<https://ror.org/04byxyr05>

Funder(s)**Funder type**

Government

Funder Name

National Institutes of Health (USA) ref: F32DK80618

Alternative Name(s)

Institutos Nacionales de la Salud, US National Institutes of Health, NIH

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United States of America

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

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2014		Yes	No