Evaluation of the Healthy Apple program to improve nutrition and physical activity practices and child weight change in child care centers in San Francisco

Submission date	Recruitment status	[] Pro
16/04/2015	No longer recruiting	[] Pro
Registration date	Overall study status	[] Sta
24/04/2015	Completed	[X] Re
Last Edited 17/05/2023	Condition category Nutritional, Metabolic, Endocrine	[X] Ind

ospectively registered

otocol

atistical analysis plan

esults

dividual participant data

Plain English summary of protocol

Background and study aims

In the USA, First Lady Michelle Obama started a nationwide child care initiative called 'Let's Move!' which aims to improve nutrition and physical activity practices in child care centres to promote healthy childhood weight. The Healthy Apple (HA) Program, developed by various organisations based in San Francisco, provides services specifically designed to support 'Let's Move!' and aims to tackle childhood obesity in children aged 0-5. The San Francisco Department of Public Health (SFDH) has an existing Child Care Health Program (CCHP) which promotes routine health screening of children and improvement of school health programmes. CCHP centres mainly help children from low income families. The aim of this study is to see whether child care centres using the HA programme alongside usual CCHP services could improve child care centre nutrition and physical activity practices better than centres using CCHP services alone. The study is also comparing changes in children's body mass index (BMI) during the course of a year in HA+CCHP centres and CCHP-alone centres.

Who can participate?

Children and staff of child care centres serviced by the SFDH CCHP.

What does the study involve?

Participating child care staff complete HA self-assessment questionnaires at the start and end of the trial. Staff receive help to implement positive changes to their centre's health programme, based on their own suggestions. Trained HA health workers visit centres and make note of their health and nutrition resources, such as play equipment and healthy food options. Staff are also interviewed about their centre's practices. Health workers also record the height and weight of each child to calculate their BMI.

What are the possible benefits and risks of participating?

Participating child care centres may show greater implementation of best practices for health and nutrition. Children who attend participating centres may show improved weight gain/loss as a result of better understanding of healthy eating choices and lifestyle. There are no risks associated with taking part in this study.

Where is the study run from? San Francisco Department of Public Health, Child Care Health Program (USA)

When is the study starting and how long is it expected to run for? September 2011 to June 2014

Who is funding the study? San Francisco Department of Public Health (USA)

Who is the main contact? Dr J Stookey jodi.stookey@sfdph.org

Contact information

Type(s) Scientific

Contact name Dr Jodi Stookey

ORCID ID http://orcid.org/0000-0001-9604-2392

Contact details

SFDPH MCAH 30 Van Ness, Ste 210 San Francisco United States of America 94102 +1 (0)415 575 5651 jodi.stookey@sfdph.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Healthy Apple Program pilot intervention for child care centers in San Francisco to improve their nutrition and physical activity practices and mean weight change for enrolled children ages 2 to 4 over 6 months

Acronym

HAP pilot

Study objectives

Child care centers that participate in the Healthy Apple (HA) program increase the number of nutrition and physical activity best practices and improve the mean weight change of enrolled children over 6 months relative to child care centers that do not participate in the HA program.

Ethics approval required

Old ethics approval format

Ethics approval(s)

UCSF Human Research Protection Program Committee on Human Research, 13/06/2015, IRB #: 15-16534, Reference #: 138098

Study design Cluster randomised controlled trial.

Primary study design Interventional

Secondary study design Cluster randomised trial

Study setting(s) School

SCHOOL

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Nutrition and physical activity practices of child care centers and weight change of children enrolled in child care centers.

Interventions

1. Intervention group receives usual San Francisco Dept of Health Child Care Health Program (SFDH CCHP) services plus additional invitation to:

- 1.1. Complete a Healthy Apple provider self-assessment
- 1.2. Set goals for improving nutrition and/or physical activity practices
- 1.3. Receive Healthy Apple technical assistance materials
- 1.4. Attend Healthy Apple nutrition and physical activity workshops
- 1.5. Receive a Healthy Apple award recognizing nutrition and/or physical activity best practices
- 2. Control group receives usual SFDH CCHP services, which include health worker assessment of

child care center nutrition and physical activity resources and BMI screening for all enrolled children.

Intervention Type Behavioural

Primary outcome measure Number of nutrition and physical activity best practices implemented

Secondary outcome measures Child care center mean 6 month change in BMI percentile

Overall study start date 01/09/2011

Completion date 31/12/2015

Eligibility

Key inclusion criteria

All children enrolled at the participating child care centers serviced by the SFDH CCHP are eligible to take part, and for services and follow-up.

Participant type(s) Other

Age group Child

Lower age limit 2 Years

Upper age limit 4 Years

Sex Both

Target number of participants 38 child care centers/~900 children ages 2-4

Key exclusion criteria

Child care centers not served by the SFDPH CCHP.

Date of first enrolment 01/09/2011

Date of final enrolment 30/06/2014

Locations

Countries of recruitment United States of America

Study participating centre San Francisco Department of Public Health, Child Care Health Program 30 Van Ness, Ste 260 San Francisco United States of America 94117

Sponsor information

Organisation San Francisco Department of Public Health (USA)

Sponsor details 30 Van Ness San Francisco United States of America 94102

Sponsor type Government

ROR https://ror.org/017ztfb41

Funder(s)

Funder type Government

Funder Name San Francisco Department of Public Health (USA)

Results and Publications

Publication and dissemination plan

We plan to publish the effect of Healthy Apple program participation on change in nutrition and physical activity best practices and 6-month change in BMI percentile. We expect to submit a manuscript for publication in Fall 2015.

Intention to publish date

01/01/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/12/2017	23/01/2019	Yes	No
<u>Dataset</u>		19/12/2017	17/05/2023	No	No