ISRCTN06248443 https://doi.org/10.1186/ISRCTN06248443

Obesity Prevention Tailored for Health II

Submission date
16/01/2014

Recruitment status
No longer recruiting

Registration date
30/01/2014

Overall study status
Completed

Last Edited
04/08/2015

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
This study was designed to test a program to modify diet and physical activity among families. We hoped to learn whether a family-based nutrition and physical activity education program could improve diet and increase physical activity in children and their parents. Previous research suggests that diet, physical activity and obesity may be related to cancer risk and other serious health conditions. The main aims of the program were to reduce the rate of increase of Body Mass Index, improve eating habits and increase physical activity among the participating children.

Who can participate?
To participate, at least one parent of the family enrolled must have been a member of the Kaiser Permanente Southern California Medical Program. Eligible families were identified and randomly selected from the health plan's electronic membership files. Families were eligible to participate if they had a 10-12-year-old child living in the home, the child was free of major illness (i.e., cancer, heart disease, diabetes), the child was not receiving clinical treatment for obesity, and the target child and at least one parent were English speakers.

What does the study involve?
Families were randomly allocated to receive either the OPT for Health program or the usual educational programs available through Kaiser Permanente Southern California regarding diet, physical activity and obesity. Families allocated to the OPT for Health program received one in-person meeting with a health coach, four newsletters for the parent, four newsletters for the child, five telephone calls to the parent, and two collaborative family activities. All program activities were designed to encourage and/or produce diet and physical activity change. Parents and children completed assessments at in-person meetings with study staff at the start of the study and at the 6-month follow-up.

What are the possible benefits and risks of participating?
Loss of privacy and confidentiality, as well as embarrassment that could occur in the event of disclosure of personal information about study participants.

Where is the study run from?
This study was conducted by Kaiser Permanente Southern California and Claremont Graduate University. All study activities were conducted in Los Angeles County, California.

When is the study starting and how long is it expected to run for?
Recruitment for the study began in June 2010 and ended in January 2012.

Who is funding the study?
Funding for the project was provided by the National Institutes of Health, National Cancer Institute and the National Institute of Diabetes and Digestive and Kidney Diseases, USA.

Who is the main contact?
Dr Kim Reynolds

Contact information

Type(s)
Scientific

Contact name
Dr Kim Reynolds

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Additional identifiers

Protocol serial number
5R01CA120945

Study information

Scientific Title
Obesity Prevention Tailored for Health II: a randomized study

Acronym
OPT

Study objectives
Primary Hypothesis
Hypothesis 1: At 12-month follow-up, children in the OPT for Health II intervention condition will exhibit a 0.45 greater difference in body mass index (BMI) change score than children in the control condition.

Secondary Hypotheses
Hypothesis 2: At 12-month follow-up, children in the OPT for Health II intervention condition will report consuming 0.50 more servings per day of fruit and vegetables than children in the control condition.
Hypothesis 3: At 12-month follow-up, children in the OPT for Health II intervention condition will

engage in 10 more minutes of moderate physical activity per day than children in the control condition.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Claremont Graduate University Institutional Review Board, 06/01/2014, ref.: Proposal #1064
2. Kaiser Permanente Southern California Institutional Review Board, 25/01/2013, ref.: Proposal #4916

Primary study design
Interventional

Study design
Randomized study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
The prevention of obesity

Interventions
A randomized study was conducted among 400 families from Kaiser Permanente Southern California. Families were randomized to receive either behavioral intervention or usual care control.

This project developed and evaluated a program to modify diet and physical activity and reduce risk for obesity in children aged 10 to 12 years recruited through a managed care setting. The development of the intervention was completed using established theories in health behavior (e. g., Social Cognitive Theory, Self-Determination Theory), research on the predictors of diet and physical activity in children, and knowledge gleaned from the prior tailored print intervention studies conducted to modify weight and diet in children and adults. Families in the control condition received usual care in the Kaiser Permanente Southern California system which included notification and access to classes on diet, physical activity and weight control. The OPT for Health intervention included one Motivational Interviewing session for families (parent and child) conducted by a health coach, four tailored and culturally targeted newsletters (two for diet, two for physical activity) for parents and four tailored newsletters for children, two family activities (one for diet, one for physical activity) for both parents and children with instructions included as part of the tailored newsletters, and five Motivational Interviewing telephone counseling calls (two focused on diet, two focused on physical activity, and one summary call) for parents. Tailoring occurred on selected variables in both the parent and child newsletters (e.g., perceived self-efficacy, availability of selected foods and physical activity equipment). Parents self-identifying as Hispanic also received messaging targeted to Hispanics in selected portions of the parent newsletter.

Nature of the control condition
The objective of this research effort was to develop a successful intervention that would produce greater improvements in BMI, physical activity and dietary behavior than the usual intervention strategies employed by Kaiser Permanente Southern California and similar

managed care organizations. At Kaiser Permanente Southern California usual care is composed of provider advice during health care visits and access to prevention services including classes on diet, weight management and physical activity. Participating families in the control condition retained access to these services and were sent materials reminding them of their availability. In addition, control parents and participating children were sent two generic newsletters between pre-test and post-test, one focusing on diet and a second focusing on physical activity.

Intervention duration: 4 months
The follow-up assessment occurred as close to 6 months post-baseline as possible.

Intervention Type
Behavioural

Primary outcome(s)
Height and weight were measured to obtain the data necessary to calculate BMI. The Tanita BWB-800-S digital scale was used to obtain weight in kilograms for each participant. The process was repeated three times and a mean weight was calculated. A calibrated stadiometer, portable professional PE-AIM-101, was used to obtain the height in centimeters of each subject. This procedure will be repeated two additional times. The height to the nearest tenth of a centimeter (0.1 cm) was recorded each time.

Measured at baseline and again 6 months post-baseline.

Key secondary outcome(s)
1. Diet was assessed in children using 24-hour dietary recall assessments. Two 24-hour dietary recall assessments were completed by the target child at each measurement period. Diet was assessed in adults using a food frequency questionnaire. Parents completed the Diet History Questionnaire, a 124-item FFQ, developed and maintained by the National Institutes of Health.
2. Physical activity was assessed in children using accelerometry providing a direct measure of light, moderate and vigorous physical activity completed by the children while the monitors were worn. We utilized MTI Actigraph 7164 activity monitors. Physical activity was measured in adults using the Community Healthy Activities Model Program for Seniors (CHAMPS) self-report instrument.
3. A household availability scale asked parents whether selected foods (e.g., fruit and vegetables) and physical activity equipment were in the home. The attitude questionnaire for adults included questions about confidence to make changes in diet and physical activity and the amount of support parents feel they received from family and friends to make these changes. The attitude questionnaire for children asked how confident children feel about making changes in diet and physical activity.

Measured at baseline and again 6 months post-baseline.

Completion date
30/01/2012

Eligibility

Key inclusion criteria
In this study, families from all sociodemographic groups in the Kaiser Permanente Southern California Medical Care Program were eligible to participate if they
1. Had a 10-12-year-old child living in the home

2. The child was free of major illness (i.e., cancer, heart disease, diabetes)
3. The child was not currently receiving clinical treatment for obesity
4. The target child and at least one parent were English speakers

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/06/2010

Date of final enrolment
30/01/2012

Locations

Countries of recruitment
United States of America

Study participating centre
Claremont Graduate University
Claremont, CA
United States of America
91773

Sponsor information

Organisation
National Cancer Institute (USA)

ROR
https://ror.org/040gcmg81

Funder(s)

Funder type
Research organisation

Funder Name
National Cancer Institute (USA)

Alternative Name(s)
National Cancer Institute at the National Institutes of Health, Instituto Nacional del Cáncer, Instituto Nacional del Cáncer de los Institutos Nacionales de la Salud, NCI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Funder Name
National Institute of Diabetes and Digestive and Kidney Diseases (USA)

Alternative Name(s)
NIH National Institute of Diabetes and Digestive and Kidney Diseases, NIH/National Institute of Diabetes, Digestive & Kidney Diseases, Experimental Biology and Medicine Institute, National Institute of Arthritis and Metabolic Diseases; National Institute of Arthritis, Metabolism, and Digestive Diseases, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, NIDDK, NIAMDD

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Funder Name
National Institutes of Health (USA)

Alternative Name(s)

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/11/2014		Yes	No