The study of health assessment and risk evaluation: Obesity Prevention (SHARE-OP)

Submission date Recruitment status [] Prospectively registered 26/09/2005 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 26/09/2005 Completed [X] Results [] Individual participant data **Last Edited** Condition category 16/11/2009 Nutritional, Metabolic, Endocrine

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number NCT00334269

Secondary identifying numbers

MCT-64076

Study information

Scientific Title

Acronym

SHARE-OP

Study objectives

To develop an effective intervention strategy to prevent and reduce obesity among a high risk cohort of Aboriginal families.

Ethics approval required

Old ethics approval format

Ethics approval(s)

McMaster University Population Health Research Institute Research Ethics Board approved on the 23rd December 2003

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Obesity

Interventions

Intervention: Family based behavioural, dietary and physical activity lifestyles modification program of six months duration. Provision of goods: a water cooler, grocery and water.

Control: Families randomised to control:

- 1. Attend a 30-minute introductory session with our health counsellors
- 2. Are provided with written material, including Canadas Food Guide to Healthy Eating and Canadas Physical Activity Guide to Healthy Active Living, which outline suggestions for healthy living
- 3. After the baseline health assessment, control households receive their body mass index (BMI) and waist to hip measurements, and the Health Canadas Healthy Weight Chart. However, no

specific individualised program is offered as with intervention families.

- 4. The after-school physical activity program is also open to school-aged children from control households in order to minimize the sentiment that children in intervention households have received superior opportunities compared to control households
- 5. We also have a help phone line to answer any households (control or intervention) nutrition or activity questions during working hours.

Trial details received: 07 Sept 2005

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Change from baseline in daily energy intake (kcal per day), and the change in physical activity (minutes/week).

Secondary outcome measures

- 1. Blood pressure
- 2. BMI
- 3. HbA1c
- 4. Body fat
- 5. Changes (from baseline to end of study) in knowledge and attitudes toward healthy lifestyles

Overall study start date

01/10/2000

Completion date

30/09/2005

Eligibility

Key inclusion criteria

- 1. Households comprised of a male and female parent with at least one child living in the same household
- 2. Individuals between 5 and 65 years of age (including grandparents)

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

50

Key exclusion criteria

- 1. Households who are not willing to have the SHARE-OP health counselor visit their home on weekly basis
- 2. Have planned absence from the reservation for greater than 1 month during the intervention
- 3. If there is a planned break-up of the household in the next one year
- 4. Individual members with serious medical illness, which prevents them from making dietary and exercise changes
- 5. Terminal cancer
- 6. Suspected severe alcohol abuse
- 7. Have suffered a recent myocardial infarction (MI) or stroke in the past month

Date of first enrolment

01/10/2000

Date of final enrolment

30/09/2005

Locations

Countries of recruitment

Canada

Study participating centre Hamilton General Hospital Hamilton

Canada L8L 2X2

Sponsor information

Organisation

McMaster University (Canada)

Sponsor details

Office of the Associate Dean Research Faculty of Health Sciences 1200 Main St. W., Room HSC-3N8 Hamilton Canada L8N 3Z5 +1 905 525 9140 ext. 22465 hsresadm@mcmaster.ca

Sponsor type

University/education

Website

http://www.mcmaster.ca/

ROR

https://ror.org/02fa3aq29

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-64076)

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	06/10/2001		Yes	No