

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00334269

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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)

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

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