ISRCTN86187625 https://doi.org/10.1186/ISRCTN86187625

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

Submission date	Recruitment status
26/09/2005	No longer recruiting
Registration date	**Overall study status**
26/09/2005	Completed
Last Edited	**Condition category**
16/11/2009	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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

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
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L8L 2X2

Sponsor information

Organisation
McMaster University (Canada)

Sponsor details
Office of the Associate Dean Research
Faculty of Health Sciences
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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