

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

<b>Submission date</b> 26/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/11/2009	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Sonia Savitri Anand

**Contact details**  
Hamilton General Hospital  
McMaster Clinic, Rm. 522  
237 Barton Street East  
Hamilton  
Canada  
L8L 2X2  
+1 905 527 4322 ext. 44557  
anands@mcmaster.ca

## 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

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **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?
<a href="#">Results article</a>	results	06/10/2001		Yes	No