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# Authentic participatory research with older adults for cognitive health

**Submission date**
24/01/2025

**Recruitment status**
Recruiting

**Registration date**
10/02/2025

**Overall study status**
Ongoing

**Last Edited**
10/02/2025

**Condition category**
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

**Plain English summary of protocol**
Background and study aims
Most people with dementia live in low- and middle-income countries, where there are fewer care resources. This study aims to prevent cognitive loss and improve care for older adults in Montreal and a rural area in Botswana. It focuses on increasing social engagement to help prevent dementia.

Who can participate?
Older women and men who are associated with a well-known long-term care organization in Montreal or who live in rural communities in south-eastern Botswana.

What does the study involve?
Participants will identify challenges in their living conditions and work together to find solutions. They will use visual and arts-based methods to express their needs. The study will compare these participants with others who receive usual care, measuring cognitive health and wellbeing.

What are the possible benefits and risks of participating?
Benefits may include improved cognitive health, better social engagement, and enhanced wellbeing. There are no significant risks mentioned, but as with any study, there may be unforeseen challenges.

Where is the study run from?
The study is run from Montreal, Canada, and rural communities in south-eastern Botswana.

When is the study starting and how long is it expected to run for?
The study starts in April 2024 and is expected to run until March 2028.

Who is funding the study?
The study is funded by the Canadian Institutes for Health Research.

Who is the main contact?
The main contact for the study is Professor Neil Andersson, who can be reached at neil.andersson@mcgill.ca.

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Prof Neil Andersson

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
Nil known

# Study information

### Scientific Title
Implications of participation mechanisms on executive function and dementia prevention

### Acronym
APROACH

### Study objectives
Co-management of shared concerns, active use of evidence and innovation, corresponding with hypothesized executive functions, revitalizes cognitive capacity and prevents Alzheimer's Disease

### Ethics approval required
Ethics approval required

### Ethics approval(s)

approved 18/09/2024, Institutional Review Board McGill Faculty of Medicine and Health Sciences (3655 Sir William Osler #633, Montreal, H3G 1Y6, Canada; +1 (514) 398-3124; researchethics@mcgill.ca), ref: A066-M27-24A (24-06-020)

## Study design
Multicenter intervention open-label cluster randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Prevention

## Health condition(s) or problem(s) studied
Alzheimer's Disease

## Interventions
Control (delayed intervention) Arm:
- Clinical exam (blood pressure, diabetes, sight, hearing)
- Cognitive test (Frontal Assessment Battery)
- Baseline questionnaire including individual priority issue and personal goal
- After 18 months, the intervention will begin in the control arm, and the baseline implemented in a new control (delayed intervention) arm

Intervention arm
- Clinical exam (blood pressure, diabetes, sight, hearing)
- Cognitive test (Frontal Assessment Battery)
- Baseline questionnaire including individual priority issue and personal goal
- Intervention protocol
• Group Assignments: 3-8 members sharing priority
• Collaborative Analysis in groups
• Participant-led actions/innovations
• Group socializing results (using visual and arts-based media)
• Self-evaluation - participants to rate their progress against their personal goals through interview after conclusion of the cycle or sharing of results, the 12th session or before (we expect 6 months per cycle)

Randomisation:
-Cluster randomisation using online random number generator.

## Intervention Type
Behavioural

## Primary outcome(s)
Executive function as measured by Frontal Assessment Battery and MOCA at baseline, 12 months, 24 months

## Key secondary outcome(s))
1. Self-assessed Integral brain health measured using the Integral Brain Health questionnaire at baseline and each year

2. Behavioural outcomes at baseline and annual follow up:
2.1. Berkman-Syme isolation index
2.2. Health self-assessment
2.3. Physical activity self-assessment
2.4. Autonomy self-assessment related to finances and medication administration
2.5. Health services use
3. Cognitive assessment: Participant changes in overall cognitive functioning will be measured using the MoCA64; we will use the five items of MOCA to validate the Frontal Assessment Battery (FAB) at baseline and each year

### Completion date
30/03/2028

## Eligibility

### Key inclusion criteria
1. Older than 65 years
2. Completed FAB-MOCA baseline (non-dementia)
3. Health exam addressing eyesight, hearing, blood pressure and diabetes management
4. Complete baseline questionnaire

### Participant type(s)
Resident

### Healthy volunteers allowed
No

### Age group
Senior

### Lower age limit
65 years

### Upper age limit
100 years

### Sex
All

### Key exclusion criteria
Cognitive disability including dementia

### Date of first enrolment
01/03/2025

### Date of final enrolment
01/03/2028

## Locations

### Countries of recruitment
Botswana

Canada

### Study participating centre
**CIET Trust**
POBox 1240
Gaborone
Botswana
-

### Study participating centre
**Centre for Research in Aging**
Lady Davis Institute for Medical Research - Jewish General Hospital
3755 Cote Ste-Catherine, H-461
Montreal
Canada
H3T 1E2

## Sponsor information

### Organisation
Canadian Institutes for Health Research

## Funder(s)

### Funder type
Government

### Funder Name
Canadian Institutes for Health Research

## Results and Publications

### Individual participant data (IPD) sharing plan
Data sharing will be determined by the conditions agreed in the informed consent. No individual or community identities will be shared.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |