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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
[_] 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

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
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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?
	Study website				

Study website	11/11/2025	11/11/2025	No	Yes