## Prevention of Alzheimer's Dementia in High Risk Populations: A Randomized Controlled Trial of a Combination of Cognitive Remediation and Brain Stimulation

https://neurodegenerationresearch.eu/survey/prevention-of-alzheimer%c2%92s-dementia-in-high-risk-populations-a-randomized-controlled-trial-of-a-combination-of-cognitive-remediation-and-brain-stimulation-2/

Title of study

Prevention of Alzheimer's Dementia in High Risk Populations: A Randomized Controlled Trial of a Combination of Cognitive Remediation and Brain Stimulation

**Acronym for cohort** 

PACt-MD

Name of Principal Investigator - Title

Dr

Name of Principal Investigator - First name

**Benoit** 

Name of Principal Investigator - Last name

Mulsant

Address of institution -Institution

Centre for Addiction and Mental Health

Address of institution - Street address

1001 Queen Street West

**Address of institution - City** 

**Toronto** 

Address of institution - Postcode Country

Canada

Website

http://www.camh.ca/en/research/about\_research\_at\_CAMH/scientific\_staff\_profile/Pages/Benoit-Mulsant.aspx

## Contact email

benoit.mulsant@camh.ca

## **Funding source**

Chagnon Family and Brain Canada (with financial support of Health Canada)

Q1a. Please indicate below if your cohort includes or expects to include, incidence of the following conditions?

Alzheimer's disease and other dementias

Q2a. In a single sentence what is the stated aim of the study? (Maximum 30 words)

Assessing whether a combination of cognitive remediation and brain stimulation prevent Mild Cognitive Impairment and Alzheimer's Disease in 375 at-risk individuals.promising evidence of pro-cognitive effects.

Q2b. What distinguishes this case-control study from other studies?

The first randomized clinical trial to combine cognitive retraining and brain stimulation to prevent Alzheimer's.

Q3a. i) Number of publications that involve use of your cohort to date Q3a. ii) Please give up to three examples of studies to date (PI, Institution, Title of Study) Q3b. If data on research outputs are already available please paste the publication list/other data or provide a link to where these data are publicly available Q3c. If no research has been done as yet, please explain in a few sentences what information (i.e. research findings) you expect will be gained from the case-control study Q4a. Study criteria: what is the age range of participants at recruitment? Age in years From:

60

Q4a. Study criteria: what is the age range of participants at recruitment? To:

until death

Q4b. Study criteria: what are the inclusion criteria?

375 patients meeting DSM 5 diagnostic criteria for current MCI or Major Depressive Disorder (MDD), in remission (can have both); 50 healthy controls

Q4c. Study criteria: what are the exclusion criteria?

Dementia; inability to participate in assessments or intervention (e.g. blindness, not fluent in English).

Q5a. What is the size of the cohort (i.e. how many participants have enrolled)?

Q5b. What is the expected number of control participants?

200-500

Q6a. Please describe what measures are used to characterise participants

Neuropsychological battery; CDR; IQCODE; physical and functional status

Q6b. Are there additional measures for participants with the clinical disorder?

Biomarkers (DNA, head MRI/DTI/fMRI, PET amyloid, CSF)

Q6c. Are there defined primary and secondary endpoints (e.g. defined health parameters)?

Yes

## If YES please specify

Progression from normal cognitive status to MCI or progression from MCI to dementia

Q7. What is the study design?

Prospective cohort|Randomized Controlled Trial|Age|sex

Q8. Are your cases matched by

Co-morbidities|Cogntive function|Physical ability|Randomization

Q9a. Does your study includes a specialised subset of control participants?

Q9b. If your study includes a specialised subset of control participants please describe

50 healthy controls (no cognitive impairment; no depression)

Q10a. Is data collection for this study

Data collection ongoing

Q10b. If data collection is ongoing, are there plans to continue the cohort study beyond the current projected end date?

Yes - intend to apply for funding

Q11. Are data collected

Only through the study|Through links to medical records

Q12. Is there a system in place to enable re-contact with patients for future studies?

Yes (participants have given permission to be re-contacted via the PIs) Q13a. Please give information on data stored in a database (1) No % Available Q13a. Please give information on data stored in a database (2) Database is web-based % Available 100 Q13a. Please give information on data stored in a database (3) No % Available Q13a. Please give information on data stored in a database (4) No % Available Q13a. Please give information on data stored in a database (5) No % Available Please specify language used % Available Q13b. Please give information on how data is held as individual records Data is web-based % Available 100 Q14a. Are data available to other groups? Yes Q14b. If data is available to other groups what is the access policy/mechanisms for access? Access through collaboration with PI only|Access Committee mechanism|Resource has own

ethics approval so usually no need for separate external ethics approval

Q15. What data sharing policy is specified as a condition of use?

Q16a. Are tissues/samples/DNA available to other groups?
Yes
Q16b i) If yes, please describe below
Living donors: blood Living donors: DNA
Q16b. ii) In what form are tissues/samples/DNA supplied?
Secondary samples:(derivatives of primary samples) Secondary samples: plasma Secondary samples: DNA
Q16b iii) Is the access policy/mechanism for obtaining samples the same as that for obtaining data (Q14 above)?
Yes
Q17. Is information on biological characteristics available to other groups?
Yes, for all the cohort
Types: Case Control Studies
Member States: Canada
<b>Diseases:</b> Alzheimer's disease & other dementias
<b>Years:</b> 2016
Database Categories: N/A
Database Tags: N/A