

Advance planning for health care and research among older adults

Submission date 10/08/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/08/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/12/2020	Condition category Other	<input type="checkbox"/> 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

Secondary identifying numbers
MCT-94830

Study information

Scientific Title

Advance planning for health care and research among older adults: a single centre, single-blind randomised controlled trial

Study objectives

By comparison with a non-exposed control group, does a multimodal professionally-led advance planning intervention stimulating discussion between an older adult and a self-selected proxy about end-of-life care and research participation, and including an educational component on advance directives (ADs) improve the accuracy of substitute decision-making and increase the frequency of written ADs for health care and research?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local medical ethics committee (comité d'éthique de la recherche sur le vieillissement du Centre de santé et de services sociaux - Institut universitaire de gériatrie de Sherbrooke [CSSS-IUGS]) approved on the 7th July 2009 (ref: 2009-12)

Study design

Single centre single-blind stratified randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Advance directives for health care and research

Interventions

Experimental group:

One- to two-hour meetings once monthly over three months. First and third meetings will be with trained social workers, at the home of the older adult or proxy. Second meeting will be a group information session on ADs at the research centre, conducted by three co-investigators with expertise in health law, decisional incapacity and end-of-life care. At the first home visit, there will be discussion of vignettes highlighting importance of communicating one's wishes about future medical care and research participation. At third and last meeting, understanding of the information delivered at second meeting will be checked.

Control group:

One- to two-hour group educational seminars held once a month over three months, about preventive health practices.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Prediction accuracy of substitute decision-making. Concordance assessments will be measured at 3 months and 12 months after the end of the intervention, using the same procedure as at baseline.

Secondary outcome measures

Rates of written ADs. Three months and 12 months post-intervention, participants will be asked whether they have indicated their healthcare and/or research preferences in writing.

Overall study start date

01/10/2009

Completion date

01/02/2011

Eligibility

Key inclusion criteria

1. Community-dwelling French-speaking individuals
2. Aged 70 years and over, either sex
3. Living in the Sherbrooke area in the province of Quebec
4. No cognitive deficits
5. Agree to designate a potential French-speaking proxy living in the same area

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

240 dyads

Total final enrolment

470

Key exclusion criteria

1. Mental disorders (International Classification of Diseases, 9th Edition [ICD-9], section 5)
2. Some diseases of the nervous system and sense organs (ICD-9, section 6)
3. Deafness
4. Blindness
5. Alcoholism

Date of first enrolment

01/10/2009

Date of final enrolment

01/02/2011

Locations**Countries of recruitment**

Canada

Study participating centre

Research Centre on Aging

Sherbrooke

Canada

J1H 4C4

Sponsor information**Organisation**

Research Centre on Aging (Canada)

Sponsor details

Sherbrooke University Institute of Geriatrics

1036 South Belvedere Street

Sherbrooke QC

Canada

J1H 4C4

Sponsor type

Research organisation

Website

<http://www.csss-iugs.ca/cdrv>

ROR

<https://ror.org/05jsjqy14>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-94830)

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?
Protocol article	protocol	05/01/2012	29/12/2020	Yes	No
Results article	results	01/07/2017	29/12/2020	Yes	No
Results article	results	01/07/2018	29/12/2020	Yes	No