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Advance planning for health care and research among older adults

Submission date 10/08/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/08/2009	**Overall study status** Completed	
Last Edited 29/12/2020	**Condition category** Other	

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
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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