

Effect of individual reminiscence for older adults with mild to moderate dementia in nursing homes

Submission date 07/11/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 03/12/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/12/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Major neurocognitive disorder, commonly referred to as dementia, is a common condition in the aging population. People with dementia have difficulties with mental processes such as memory, language, reasoning and identifying people and objects, which become progressively worst over time. This can make it very difficult to deal with daily life and so many sufferers are eventually placed in nursing homes so that they can receive round-the-clock care. Reminiscing (thinking and talking about past experiences) is a popular activity in many nursing homes. It is generally considered to be enjoyable and helpful to patients, however more research is needed to find out if it actually has an effect on their condition. The SolCos model of reminiscence therapy is a type of talking therapy which involves talking about things from the past. By focussing on specific topics, patients are encouraged to talk about their life experiences using "memory prompts" such as photographs. Studies have shown that this type of therapy can help to improve mood, as well as mental abilities such as memory and attention. The aim of the initial study is to find out whether reminiscence therapy can help to improve the mood, behaviour and thinking ability (cognition) in older people with mild to moderate dementia compared to usual care. The aim of the following, larger study is to find out whether reminiscence therapy can help to improve the mood, behaviour and thinking ability (cognition) in older people with mild to moderate dementia compared to usual care and individual activities.

Who can participate?

Adults over the age of 60 who live in a nursing home and are suffering from dementia.

What does the study involve?

In the initial study, patients are randomly allocated to one of two groups. Those in the first group continue to receive normal care. Those in the second group have biweekly sessions of reminiscence therapy for eight weeks. Family and friends of the patient are asked to provide four "memory boxes" (containing photographs and items related to the patients' past) relating to the four topics (family, profession, holiday and games). A trained volunteer at the nursing home (facilitator) uses these objects to help to prompt the memory of the patient in these one-to-one sessions. At the start of the study and after 8 weeks, participants in both groups

complete a number of tests designed to find out if there has been any change to their mood, cognition and behaviour. Additionally, after each session, the facilitators complete questionnaires to give their views on how well they feel the sessions have gone and whether the participants were paying attention and taking part.

In follow up study, patients are randomly allocated to one of three groups. Those in the first group continue to receive normal care. Those in the second group take part in biweekly individual social activities (such as such as games, walking, music, knitting, handicrafts, massage, etc.) for eight weeks, which are not intended to have any expect (dummy activity group). Those in the third group have biweekly sessions of reminiscence therapy for eight weeks, which follows the same format as in the pilot study. After each session, the facilitators complete questionnaires to give their views on how well they feel the sessions have gone and whether the participants were paying attention and taking part. Of each group 10 residents will be observed through an observation technique performed by a special trained person (e.g. Dementia Care Mapping).

What are the possible benefits and risks of participating?

Participants who have the reminiscence therapy may benefit from an improvement to their mood, behaviour and thinking power. There are no notable risks of taking part in the study.

Where is the study run from?

1. Ten Kerselaere Living and Care House (Belgium)
2. Retirement home, Augustin (Belgium)
3. Retirement homes urando O.L.V. van 7 Weeën Ruiselede vzw (Belgium) (Follow up study only).

When is the study starting and how long is it expected to run for?

December 2014 to September 2016

Who is funding the study?

University of Antwerp (Belgium)

Who is the main contact?

Professor Peter Van Bogaert

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

SolCos based-model individual reminiscence for older adults with mild to moderate dementia in nursing homes: A randomized controlled intervention study

Study objectives

Cognition, well-being, depressive symptoms and behaviour of older people with mild to moderate dementia residing in nursing homes can be significantly positively influenced by specific developed individual structured reminiscence therapy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Initial study:

Antwerp University Hospital Ethics Committee, 15/11/2013, ref: B300201319055

Follow up study:

Antwerp University Hospital Ethics Committee, 19/10/2015, ref: B300201525962

Study design

Initial study:

Two-arm multi-centre randomized controlled study

Follow up study:

Three-arm multi-centre randomized controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Dementia

Interventions

Initial study:

Study participants are randomly allocated to one of two groups.

Control group: Participants continue to receive normal care only.

Intervention group: Participants take part standardized reminiscence therapy, based on the Solcos model (standardized individual reminiscence sessions around selected themes during a scheduled period guided by a facilitator). Two 45 minute sessions are arranged each week, delivered by trained nursing home volunteer as facilitator, for an 8 week period. Each week, one of four standardized topics will be explored (family, profession, holiday and games). The selected topics are based on our review of the literature, a previous pilot study and through involvement of nursing home residents and family caregivers during the project-planning phase. The purpose of the preliminary interview is to determine individual interests, establish access to artifacts such as photographs or other small items which family and friends will be asked to provide to supplement the contents of 4 personalized memory boxes, one for each theme. Each session is structured with an introduction and round off phase of 15 minutes and a reminiscence phase of 30 minutes. The sessions take place in the resident's bedroom or a small private lounge in the care facility. Both environments are familiar places to the participants and had homely décor.

Follow up study:

Study participants are randomly allocated to one of three groups.

Control group: Participants continue to receive normal care only.

Intervention group: Participants take part in standardized reminiscence therapy, using the three elements of the Solcos model, namely process, items and outcomes. The process component described the standard approach for the facilitator to use to interview participants with a raising awareness of their own characteristics and perspectives as well as the personalized context of the participants (e.g. family, home, community, and life role). The items component had two subcomponents: stimuli and responses. During structured sessions interviewee items evoke recollections used by the facilitator to focus and stimulate the reminiscence process. Intense verbalization and/or sensory stimulation can focus on family, home, community, or life role. As a result interviewee responses can be recorded (e.g. video, audio, or written documents). The outcome components focus on the participants as well the facilitator outcomes aiming to impact participants' behavior, cognition and well-being as well as to increase facilitators' supportive role and experience as a change agent in the reminiscence process. The reminiscence sessions will be strictly structured, commencing with an introduction interview to prepare the sessions (e.g. characteristics and particular life events and experiences of participants). The intervention will be administered over a period of 8 weeks, and comprised two 45 minutes sessions per week during 5 weeks and one 45 minutes session over 3 weeks, following the same protocol as in the pilot study.

Placebo group: Participants receive individual social activities (such as games, walking, music, knitting, handicrafts, massage, etc.) guided by a volunteer or staff with the same schedule as the intervention group (5 weeks two 45 minutes session and 3 weeks one 45 minutes session).

Intervention Type

Other

Primary outcome measure

Initial study:

1. Cognition is assessed using the Mini-Mental State Examination (MMSE) screening tool at baseline and 8 weeks
2. Frontal lobe function is assessed using the Frontal Assessment Battery (FAB) at baseline and 8 weeks
3. Behavioural disturbances are assessed using the Neuropsychiatric Inventory (NPI) at baseline and 8 weeks
4. Depression symptoms are assessed using the Cornell Scale for Depression in Dementia (CSDD) at baseline and 8 weeks

Follow up study:

1. Cognition assessed using the Mini-Mental Examination (MMSE) screening tool at baseline and 8 weeks
2. Behavioural disturbances are assessed using the Neuropsychiatric Inventory (NPI) at baseline and 8 weeks
3. Depression symptoms are assessed using the Cornell Scale for Depression in Dementia (CSDD) at baseline and 8 weeks
4. Quality of life assessed with the dedicated scale QUALIDEM at baseline and 8 weeks

Secondary outcome measures

Secondary outcomes for both the initial study and follow up study completed by facilitators in the intervention group:

1. Residents' attention and participation during the session measured using a 10-item survey after each session
2. Session conditions and facilitators' experiences measured using an 11-item survey after each session

Overall study start date

01/12/2014

Completion date

30/09/2016

Eligibility

Key inclusion criteria

1. Aged 60 years or over
2. Diagnosed with major neurocognitive disorder according to DSM-V criteria with a Mini-Mental State Examination <24 and >10
3. Considered by their physician or nurses to have mental capacity and sufficient verbal communication abilities to engage with the study
4. Living in a study nursing home

Participant type(s)

Other

Age group

Senior

Sex

Both

Target number of participants

The initial study will include 40 participants in each group (e.g. intervention and control group). The follow up study includes 40 participants in each group (e.g. intervention, control and placebo group).

Key exclusion criteria

1. Mini-Mental State Examination (MMSE) > 24 and < 10
2. Verbal communication issues which prevent engagement with the study

Date of first enrolment

15/12/2014

Date of final enrolment

15/01/2016

Locations**Countries of recruitment**

Belgium

Study participating centre

Ten Kerselaere Living and Care House (Ten Kerselaere Woon-en Zorghuis)

België

Boonmarkt 27

Heist-op-den-Berg

Belgium

B-2220

Study participating centre

Retirement home, Augustin (Bejaardentehuizen Augustin)

Cecilia Parkstraat 9

Alken

Belgium

B-3570

Study participating centre

Retirement homes Curando O.L.V. van 7 Weeën Ruiselede vzw
Pensionaatstraat 8a
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Sponsor information

Organisation

University of Antwerp

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/008x57b05>

Funder(s)

Funder type

University/education

Funder Name

University of Antwerp

Results and Publications

Publication and dissemination plan

Planned publication in an international peer reviewed journal.

Intention to publish date

01/04/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/11/2016	10/12/2020	Yes	No