ISRCTN93873801 https://doi.org/10.1186/ISRCTN93873801

Effect of occupational therapy in elderly people living at home

Submission date	Recruitment status	[_] Prospectively registered
21/02/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/05/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/01/2019	Other	

Plain English summary of protocol

Background and study aims
For the past decade, there has been an increase in the elderly population and the number is expected to rise. Therefore the number of elderly citizens requiring help from the municipality services will rise and this could lead to an increased economic burden on the municipalities in Denmark.
Occupational therapy focuses on the individual needs and desires and the environment in which the person lives. Participation in meaningful daily activities seems to have a positive effect on occupational performance, satisfaction, and quality of life, but there is a need for further investigation.
The aim is to investigate the effect of a 11 weeks home-based occupational therapy rehabilitation program for elderly citizens, compared to the usual municipal practice of home-based rehabilitation, in terms of changes in activity performance, satisfaction with activity performance, motor and process skills (body movement related skills) and quality of life.

Who can participate?
Home dwelling citizens of a medium-sized Danish municipality are included. They are of either sex, in the age group 60+, and newly referred or re-evaluated for home care. Excluded are citizens with well-defined severe diagnoses, drug abuse or severe pain, citizens with a rehabilitation plan from a hospital and citizens who cannot speak Danish without an interpreter.

What does the study involve?
The elderly citizens will be randomly allocated to the intervention group and the control group. The intervention group receives an intensive home-based occupational therapy rehabilitation program. They will be practicing daily activities of own choice; for 1 hour twice a week for 11 weeks. The control group receives the usual home-based rehabilitation of the municipality. Reassessments at follow-up are performed at 3 and 6 months after the start of the intervention.

What are the possible benefits and risks of participating?
We believe that the intensive occupational therapy program will help the citizens to perform their daily activities better and improve their quality of life. No risks are involved.

Where is the study run from?
The study is organized by VIA University College in collaboration with the Municipality of Randers. The occupational therapists involved in the study are employed by the Municipality of Randers.

When is the study starting and how long is it expected to run for?
The study started in September 2012 and will run till December 2014.

Who is funding the study?
The municipality of Randers, Denmark, VIA University College, The TRYG-foundation and the Danish Association of Occupational Therapists.

Who is the main contact?
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Contact information

Type(s)
Scientific

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8200

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of a home-based occupational therapy rehabilitation program A randomized controlled trial

Study objectives

Elderly citizens randomised to receive occupational therapy will show improved self-reported occupational performance, improved satisfaction with own occupational performance, improved motor-and process skills and higher quality of life compared to elderly citizens randomised to receive treatment as usual offered by the municipality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study is reported to The Local Ethical Committee, The Danish Data Protection Agency and the ethical principles in The Helsinki Declaration are followed.

The Danish Data Agency has approved the study in December 2012 (Jnr 2012-52-0049) http://www.datatilsynet.dk/english/.
The Ethical board of The Central Denmark Region has found that, according to Danish Legislation, the study shall not be further approved (De videnskabsetiske Komitéer for Region Midtjylland, Skottenborg 26, DK-8800 Viborg, Phone: + 45 7841 0183, E-mail: komite@rm.dk).

Study design
Single blind randomized 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
Occupational therapy for elderly citizens

Interventions
1. Intervention: Occupational therapy
2. Control: Treatment as usual

Citizens randomised to the intervention group will receive 60 minutes training by an occupational therapist twice a week for the total of 11 weeks. Two assessments are used to assess occupational performance and goal-setting: The Occupational Performance and Assessment of Motor and Process Skills (AMPS) by Ann Fisher and The Canadian Occupational Performance Measure (COPM) by The Canadian Association of Occupational Therapy. The identified needs and goals of the citizen are used to plan the occupational therapy intervention.

Masked follow-up assessments at 3 and 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Changes in self-reported occupational performance (COPM score) are calculated for the intervention and control groups and tested by Wilcoxon Rang Sum Test in order to statistically test if any difference between the two groups occur. Measured at 0 (baseline), 3, and 6 months.

Secondary outcome measures
1. Changes in satisfaction with own occupational performance (COPM score) are calculated for the intervention and control groups and tested by the Wilcoxon Rang Sum Test in order to statistically test if any any differences between the two groups occur.
2. Changes in motor and process skills (AMPS score) are calculated for the intervention and control groups and tested by a Wicoxon Rang Sum Test in order to test if any statistically significant difference occur between the two groups.
3. Changes in Quality of life (SF-36) are calculated for the intervention and control groups and between groups differences will be tested by T-test if data are normally distributed, or by a Wilcoxon Rang Sum Test if they are not normally distributed.

Measured at 0 (baseline), 3, and 6 months.

Overall study start date
01/09/2012

Completion date
31/03/2014

Eligibility

Key inclusion criteria
1. Citizens from 60 years of age, either sex
2. Living at home or in sheltered housing
3. Admissioned to either personal help and/or practical help and meal delivery from the municipality

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants

100

Key exclusion criteria
1. Citizens living in assisted living facilities
2. Having a serious mental illness, dementia, mentally handicapped
3. Suffering from cancer or severe pain

Date of first enrolment
01/09/2012

Date of final enrolment
31/03/2014

Locations

Countries of recruitment
Denmark

Study participating centre
VIA University College
Aarhus N
Denmark
8200

Sponsor information

Organisation
VIA University College (Denmark)

Sponsor details
Faculty of Heath Sciences
Campus Aarhus N
Hedeager 2
Aarhus N
Denmark
8200

Sponsor type
University/education

Website
http://www.viauc.dk

ROR
https://ror.org/04ctbxy49

Funder(s)

Funder type
Charity

Funder Name
The municipality of Randers (Denmark)

Funder Name
The Danish Association of Occupational Therapists (Denmark)

Funder Name
TrygFoundation (Demark)

Funder Name
VIA University College (Denmark) project no. 40833

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?
Results article	results	01/07/2019	24/01/2019	Yes	No