**Cognitive Behavioural Therapy for Persons with Dementia.**

**A randomized controlled Trial**

**Protocol, English Version**

**1. Introduction**

Dementia is a severe and chronic disease characterised by progressive decline in memory. In addition, other cognitive domains are commonly impaired in dementia, such as attention, abstract thinking, planning, language, orientation and problem solving (DSM-IV-R; American Psychiatric Association, 2000). Occurring in up to two thirds of all patients, symptoms of depression are both in ICD-10 and in DSM-5 listed among the core symptoms of the dementia syndrome (Enache, Winblad & Aarsland, 2011). Furthermore, loss of emotional control and changed social behaviour (such as apathy) is common in dementia. Additionally, empirical studies demonstrate that also caregivers have increased risk of developing depression and other psychiatric and somatic health problems (Hooker et al., 2002; Rosness, Ulstein & Engedal, 2009; Ulstein et al., 2007).

To improve the quality of life for people with dementia and their carers a randomized controlled trial will be conducted with the strategic aims of the partners:

* Oslo University Hospital, Department of Geriatric Medicine. Ingun Ulstein, MD, PhD.
* Oslo University Hospital, Department of Old Age Psychiatry. Johanne Tonga, psychologist, PhD student.
* Research network in old age psychiatry in the former health south in Norway. Ingun Ulstein, MD, PhD, Director for research at Vestfold Psychiatric Health Trust

**2. Background**

In the last decades pharmacological treatments have been conducted to help people with dementia, but unfortunately with limiting results (Birks, 2006; Cummings, 2000; Moniz-Cook et al., 2011). Thus, there are demands for nonpharmacological treatment options that aim at helping coping with intellectual decline and depressive symptoms, as well as maintaining daily function.

There have been different psychosocial interventions that have demonstrated to have some effect for people with dementia and their caregivers. Studies have demonstrated that structured counselling, psychoeducation and support to the caregivers can reduce depression both for the patient and the caregiver (Bedard et al., 1997; Brodaty et al., 1997, Mittelman et al., 1996; 2006; Strain et al., 2003). This is consistent with a meta-analysis that reported a medium effect size in terms of significantly reducing depressive symptoms in residents of long-term-care (Cody & Drysdale, 2013; Oregeta et al., 2015). When examining specific interventions, cognitive behavioral therapy, with a focus on behavioral activity scheduling, significantly reduces depression both in people with dementia living at home (Teri, Logsdon, Uomoto, & McCurry, 1997; Teri, McKenzie, & LaFazia, 2005) and in a nursing home (Hyer, Yeager, Hilton, & Sacks, 2009). Another specific intervention is reminiscence therapy, which involves reflection of past activities, events and experiences, usually with prompts such as photographs and music (Woods et al., 2012). Reminiscence therapy has shown to be effective in improving cognitive function and mood for people with dementia (Cotelli, Manenti, & Zanetti, 2012; Woods et al., 2018). These findings are also supported by a meta-analysis of randomized controlled trials demonstrating that reminiscence therapy had a small effect size on cognitive functions and a moderate effect size on depressive symptoms (Huang et al., 2015). Contrary, two other studies have failed to demonstrate positive findings on reminiscence therapy (Wang, 2007; Woods et al., 2012). Also, cognitive rehabilitation, focusing on intact memory skills and learning compensatory strategies for managing memory problems, have shown a positive effect on mood and memory performance in people with mild cognitive impairment (Kurz, Pohl, Ramsenthaler, & Sorg, 2009).

However, recent meta-analysis has demonstrated that interventions on dementia have most effect if they are multi-component interventions, if the carer is involved, longer treatment duration (more than nine sessions) and specialised training in the therapist (Pinquart & Sörensen, 2006; Parker et al., 2008). Unfortunately, few interventions are conducted based on these requirements. However, a German study, called the Kordial study, combined these different interventions into one treatment intervention (Kurz et al., 2012). Particularly, the Kordial study was conducted as a randomized controlled trial of 201 patients with mild dementia and their carers (control condition, *n* = 100; intervention condition, *n* = 101). The results of the study demonstrated improvements favouring the intervention group on quality of life and treatment satisfaction compared to the control group. Furthermore, the study found a significant antidepressant effect in female participants. However, this was not found in male participants. Nevertheless, the study is promising.

Based on these promising results, and the requirement for more treatment options for people with dementia, a Norwegian research team, have decided to conduct this treatment intervention in Norway. From the beginning of January 2012, a pilot-project on three patients has been conducted as well as translating and adapting the manual from German to Norwegian.

**3. Methods**

**Study design**

The study presented is an intervention study, specifically randomized controlled trial, allocating patients with mild Alzheimer’s disease and their primary carer to treatment as usual on their allocated hospitals (control-group, *n* = 100) or to a cognitive behavioural intervention (*n* = 100).

**Eligibility criteria**

Inclusion criteria for the patients are:

* Participants had to fulfill the criteria for mild cognitive impairment (MCI) due to Alzheimer’s disease according to the Winblad criteria for MCI (Winblad et al., 2004), or the criteria for Alzheimer’s disease or mixed Alzheimer’s disease according to ICD-10 or NINCDS-ADRDA (Dubois et al., 2007).
* Being in the early stage of MCI or dementia, as indicated by a Mini Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975) score of 20 or above, and had to have received a diagnosis of MCI due to Alzheimer’s disease or the diagnosis of dementia within the past 12 months before study participation.
* Participants should be living at home.
* A caregiver who is willing to participate in the interventions, as this is part of the treatment programme. A caregiver is here defined as the main person responsible for the informal care for the patient and who has regular weekly contact with the patient.

Exclusion criteria for the patients are:

* Severe somatic or psychiatric comorbid diagnoses, including alcohol and substance abuse, that would impair their cooperation in the intervention programme
* Dementia with Lewy bodies and frontotemporal dementia, as the intervention is considered to be too cognitively challenging for these patients
* Poor command of Norwegian
* Ongoing psychotherapy
* Living outside home, e.g., nursing home

There are no preset age criteria for the study presented. Thus, including both young-onset dementia and late-onset dementia. Also, both male and female participants will be included. In addition, medication at stable doses (e.g., antidepressant, cholinesterase inhibitors) will be accepted for inclusion.

The patients will be included from the following hospitals:

* Department of Geriatric Medicine, Institute of Clinical Medicine, Oslo University Hospital, Ullevål, Norway
* Department of Old Age Psychiatry, Oslo University Hospital, Grønland, Norway,
* Department of Old Age Psychiatry, Akershus University Hospital, Skytta, Norway,
* Department of Old Age Psychiatry, Innlandet Hospital Trust, Sanderud, Norway

Department of Old Age Psychiatry, Vestfold Hospital Trust, Granli, Norway.

**Participants**

A total of 200 participants, who fulfil the inclusion criteria, will be recruited from three different hospitals in Norway. The recruitment is expected to start April 2013. Participants will receive written information about the study, and two weeks later asked over the phone if they want to participate. Randomisation to the two different intervention groups will be performed by computer-generated randomisation.

The flow of participants through the study is demonstrated in Figure 1.

Figur 1. Participant flow

**4. Study Description**

**The intervention**

The intervention is based on a standardized manual, and consists of 12 standardised weekly one-hour sessions, which are organized into thematic modules (see figure 2). In Module one an introduction to the programme is completed, where the main focus of the intervention is explained and the patients’ problems and treatment goals are identified. Module two focuses on pleasant activities to improve mood and depressive symptoms. The main topic of Module three is the use of external memory aids to help the patients to maintain their independence in their daily life. Module four emphasises the importance of establishing behavioural routines to reduce demands on memory. Thus, memory-related problems are identified and ways of coping with these problems in daily routines are explored. Module five stimulates patients to actively engage in reminiscence and memories to improve mood and well-being. Module six consists of a review of the programme and individual treatment goals.

The content of each session is specified by a treatment manual, which additionally consists of worksheets, suggestions for homework in between sessions and letters to the caregivers (the German manual: Werheid & Thöne-Otto, 2010; the Norwegian manual: Ulstein, Gordner & Tonga, not published).

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| --- | --- | --- |
| **Module 1** | **Introduction** | |
|  | 1st session | Introduction to the program |
|  | 2nd session | Individual problems and treatment goals with the carer |
| **Module 2** | **Pleasant Activities** | |
|  | 3rd session | Identify pleasant activities and activity planning |
|  | 4th session | How to complete pleasant activities |
| **Module 3** | **Memory Aids** | |
|  | 5th session | Introduction to memory aids (e.g., calendar) |
|  | 6th session | How to complete memory aids with the carer |
| **Module 4** | **Daily Routines** | |
|  | 7th session | Establishing daily routines to reduce demands on memory |
|  | 8th session | How to establish memory routines with the carer |
| **Module 5** | **Reminiscence** | |
|  | 9th session | Biographical material to aid good memories |
|  | 10th session | Biographical material with the carer |
| **Module 6** | **Closing module** | |
|  | 11th session | Review of the program and the treatment goals |
|  | 12th session | Closing module with the carer |

Figure 2. An overview of the intervention.

Every other session is conducted with the patient alone, and every other session is conducted with both the patients and his/her carer to improve the carers coping and the transfer of the patient’s newly learned strategies into everyday life. Additionally, the caregivers receive written information describing the background and content of each module (standardised letters to the caregivers).

The treatment will be conducted by experienced health staff (nurses, psychologist, doctors) with formal training in Cognitive Behavioural Therapy, and formal training in Alzheimer’s Disease. Furthermore, the health staff will be familiarised with the manual before study inception, participate in two-day training and will regularly be supervised.

**Control condition**

The control condition will receive treatment-as-usual. This varies and includes doctor or nurse follow-up, counselling, day care center etc.

**5. Outcomes**

**Primary Outcome**

The primary outcomes for the patients:

1. Depression, measured by the Montegomery and Åsberg Depression Rating Scale (MADRS) (Åsberg et al., 1978)

**Secondary Outcomes**

The study presented also included secondary outcomes, both for the patient and caregiver.

The following are for the patients:

- Quality of life, measured by the Quality of Life in Alzheimer’s Disease (QOL-AD) (Logdson et al., 1999).

- Self Efficacy, measured by Generalized Self-Efficacy Scale (Sherer et al., 1982)

- The Neuropsychiatric Inventory Questionnaire (NPI-Q) (Cummings et al., 1997)

Secondary outcomes for the carers:

- Overall burden, measured by The Relative Stress Scale (RSS) (Greene, Smith, Gardiner & Timbury, 1982).

- Quality of life, measured by the Quality of Life in Alzheimer’s Disease (QOL-AD) (Logdson et al., 1999).

- Self Efficacy, measured by Generalized Self-Efficacy Scale (Sherer et al., 1982).

**6. Ethics**

The study have been accepted by the Regional Committee for Ethics in Medical Research in South-Eastern Norway and the Data Inspectorate. The participants, both patients and caregivers, will receive written and oral information and asked to give a written consent to participate. Only participants with capacity to consent will be included.

**7. Statistics**

Statistical analysis will be completed by the statistical programme SPSS. Significant differences between patients in the treatment condition and control condition before and after the treatment, on the relevant parameters (depression, quality of life and self-efficacy), will be completed by Linear Mixed Models. Furthermore, to test if the carers have had effect by the treatment or the control condition, t-test or Mann-Whitney test will be completed on the relevant parameters (depression, quality of life and self-efficacy).

All the participants included those who drop-out, who have been assessed and included in the study, will be included in intention-to-treat-analysis. Additionally, last-observation-carried forward method and observed cases method will be employed.

Linear mixed model analyses will be applied in order to adjust for possible clustering differences between the different hospitals that are conducting the treatment.

SSPS Sample Power is conducted to conduct poweranalysis. Taking into consideration that the study presented consists of 100 patients in each group, the statistical power is calculated to be high, which reduce the risk of Type 2 error (Field, 2009).

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