PROTOCOL

Health promotion and quality of life in dementia – User experiences from an educative intervention in early stage dementia

Protocol: Version 4
10/05/2017

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STUDY SUMMARY

TITLE
Learning and Coping With Dementia - User Experiences From an Educative Intervention in Early Stage Dementia

DESIGN
A quasi-experimental study with multiple methods

AIMS
The overall aim is to investigate how home dwelling people with early-stage dementia cope with their disease, explored through their participation in a 12-week health promotion course

TARGET POPULATION
Home dwelling persons with early-stage dementia

SAMPLE SIZE
100 people over the age of 65

STUDY START
March 3, 2014

STUDY COMPLETION
December 31, 2021 [Anticipated]

ETHICAL APPROVAL
2013/2266
Regional Committees for Medical and Health Research Ethics, Norway

Introduction

There are more than 35 million people living with dementia around the world and these numbers are expected to nearly double every 20 years (Prince et al., 2013). Dementia is the leading chronic condition among older adults. In Norway there are few services available for older adults in early or moderate stages of dementia, and there are few evaluated treatment protocols. The Norwegian government´s national Dementia plan 2020: a more dementia friendly society (2015) emphasizes the need for educational programmes for people with dementia and meeting places for people with dementia for mutual support and the exchange of experiences. There is a growing emphasis on providing information and support for people diagnosed with dementia. Information and support provided after a diagnosis of dementia may lead to health behavior changes that prevent excess disability or premature loss of function and institutionalization (Bossen, Specht, McKenzie, 2009; Buettner & Fitzsimmons, 2009).

Dementia is a brain organic syndrome, usually chronic and progressive and defined as cognitive impairment of sufficient severity to impair daily functioning, deterioration in emotional control, and social behaviour (Engedal & Haugen, 2008). The most common forms of dementia are Alzheimer's disease and vascular dementia (Engedal & Haugen, 2008). There is currently no treatment that can cure the disease, medications can temporarily slow the worsening of symptoms. However, people with dementia are still able to learn new things and benefits from challenging their brain, which can help preserving cognitive skills (Martin et al., 2015; Laakkonen et al., 2016).

Much of the literature on early stage dementia is focused on the caregiver's perspective, while little is known about the perspective of the person with dementia such as the process of learning to live with the chronic condition (Testad et al., 2016). In a review by Quinn et al. (2016), 15 studies focused on group-based psychosocial interventions developed for people with dementia and people with mild cognitive impairment were included. The studies were published between 1995 and 2013, and several had methodological limitations, such as few participants and lack of robust design. 12 of the studies included interventions for people with dementia, while 3 were for people with mild cognitive impairment. Out of the 12 studies there were only 3 who had a psychoeducative perspective and 2 who used a self-management program. The remaining 7 studies covered support groups and did not have a structured educative programme (Quinn et al., 2016). There is a clear need for more research in this area and knowledge on whether a structured educative intervention can help people with early-stage dementia better cope with their disease. Increased knowledge about learning and coping with early-stage dementia will be useful in delivering future services.

The overall aim of this study is to investigate how home dwelling people with early-stage dementia cope with their disease, explored through their participation in a 12-week health promotion course, through 3 sub-studies; 1) The users' experience in gaining information about dementia and meeting others in the same situation, 2) observation of the group interactions and support processes, and 3) investigate the effect of the 12-week health promotion course for people with early stage dementia on their cognitive function, psychosocial function and health behavior.

Methods and design

The design of the study is quasi-experimental with multiple methods:

a) assessment of cognitive function, psychosocial function and health behaviour is collected at baseline (prior to attending the 12-week course) and follow-up interviews are arranged shortly after the 12-week course. For each participant a caregiver also has to take part for proxy interviews.
b) the users' experience of attending the 12-week health promotion course will be collected through qualitative individual interviews with the participants and their caregiver after attending the course.
c) over the duration of the course a moderate participant observation will be carried out to explore changes over the 12-week course, in-session behaviour, social interaction and to capture motivational and empowering aspects of the course.

The inclusion criteria were as follows:
- 65 years of age or older
- Home dwelling
- A diagnosis of early or moderate stage dementia
- Capable of reading and writing
- Hearing and vision which are sufficiently good to work in a group setting
- Proficient in the language in which the course is provided

Exclusion criteria:
- A diagnosis of alcohol abuse
- A limited life expectancy due to any terminal disease or other serious illness
- Chemotherapy or radiation treatment ongoing at enrolment
- Head injuries
- Epilepsy
- Parkinson's disease
- A history of psychiatric illness
- A history of a diagnosis of subnormal intelligence
- Prior participation in health promotion or cognitive training programs.

Recruitment
Posters advertising the project will be distributed in doctor's offices and local newspapers inviting persons with dementia, family members and/or health care professionals to contact the researchers if they were or knew anyone interested in taking part in the study. Participants will also be recruited from memory clinics. To ensure participants voluntarily attending the study, health care professionals will only hand over eligible participants contact information and a research nurse will contacted the participant to go through the inclusion criteria and invite them to the study.

Description of the intervention
An innovative college course for individuals with a newly diagnosed dementia called Health Promotion for the Mind, Body, and Spirit has been designed to provide information on the disease process and on healthy behaviours to prevent problems that are common later in the disease (Fitzsimmons & Buettner, 2009).

The 12-week course includes nutrition, cognitive fitness, stress reduction, communication, information about the course of the disease, and coping strategies (Fitzsimmons & Buettner, 2009). Based on this a Norwegian version of the Health Promotion for the Mind, Body, and Spirit called "Dementia school" (Demensskolen) has been developed by this research group and tested in a small group of participants.

Structure of the course:
To provide consistency and familiarity, the lead instructors of the course will teach the modules, and be present during all classes. The teachers will be retired nurses with great experience in education and guidance of people in need for health services. The course will be offered in nice surroundings once a week from 10:00 AM to 12:00 noon, for 12 weeks. During the first class session participants are provided with name tags and a booklet with the course material. This booklet is a critical component of the educational method for the participants. The booklet contains 12 dividers for the 12 modules that the instructor taught during the course. The caregiver is not present at the course, however the participants are encouraged to share the booklet provided at the course with the caregiver between session. Teaching methods include lecture, question and answer periods, and interactive hands-on learning.

Measures

Demographics:
Standard demographic information will be collected, including age, gender, marital status, education, ethnicity, number of hospitalization and nursing home placement.

Cognitive function:
The Clinical Dementia Rating (CDR) scale (Morris, 1993).The CDR is a validated scale used to quantify the severity of symptoms of dementia. Using a structured-interview, six domains are assessed in terms of person's cognitive and functional performance. These include memory, orientation, judgment & problem solving, community affairs, home & hobbies, and personal care. CDR ratings are 0 for healthy people, 0.5 for questionable dementia and 1, 2 and 3 for mild, moderate and severe dementia. Scores in each of these are combined to obtain a composite score ranging from 0 (none) through 3 (severe).

The Mini Mental State Examination (MMSE) (Folstein, Folstein, & McHuch, 1975).The MMSE is a widely used method for assessing cognitive mental status. As a clinical tool, it has been used to detect impairment, follow the course of an illness, and monitor response to treatment. The MMSE represents a brief, standardized method by which to grade cognitive mental status. It assesses orientation, attention, immediate and short-term recall, language, and the ability to follow simple verbal and written commands. Additionally, it provides a total score that places the individual on a scale of cognitive function.

Mental health status:
The Neuro Psychiatric Inventory (NPI) (Cummings, et al., 1994) is a validated structured interview assessment with the informant (care staff), that assesses behavioural disturbances in patients with dementia. This 12-item version consists of 10 behavioural and two neurovegetative areas. It provides both a total score as well as scores for a number of sub-scales (e.g., delusions, hallucinations, agitation/aggression, depression/dysphoria, anxiety, disinhibition, elation/euphoria, apathy/indifference, irritability/lability, aberrant motor activity, sleep, and appetite/eating disorders). The frequency, severity and caregiver distress for each domain are measured. The total possible maximum score is 144. A higher score reflects increased frequency and severity of the disturbances. This specific version is developed for use in nursing homes (NPI-NH), with adapted questions in the standardized interview and the caregiver distress assessment is adapted to occupational disruptiveness.

Cornell Scale for Depression in Dementia (CSDD) (Alexopoulos et al., 1988). The CSDD is an assessment of signs and symptoms of major depression in patients with dementia. The CSDD uses a comprehensive interviewing approach that derives information via semi-structured interviews with the participant and the care staff. In this study, relatives will be asked instead of care staff. Many of the items during the patient interview can be filled after direct observation of the patient. The final ratings of the CSDD items represent the rater's clinical impression rather than the responses of the informant or the patient. Each item is rated for severity on a scale of 0-2 (0=absent, 1=mild or intermittent,2=severe). The item scores are added. Scores above 10 indicate a probable major depression. Scores above 18 indicate a definite major depression. Scores below 6 as a rule are associated with absence of significant depressive symptoms.

Health and functional status:
The levels of personal an instrumental functioning was measured by Lawton and Brody's Physical Self-Maintenance Scale (P-ADL) and Instrumental Activities of Daily Living Scale (I-ADL) (Lawton et al, 1988). The P-ADL sum-score is based on six items (range 0-30) and the I-ADL is based on eight items (range 0-31), with higher scores indicating a lower function.

Relative Stress Scale:
The Relative Stress Scale (RSS), developed by Greene (Greene et al., 1982) assesses the caregiver burden for people caring for individuals with dementia. The RSS has 15 different questions, each scored 0–4 (0=never/not at all, 1=rarely/a little, =sometimes/moderately, 3=frequently/quite a lot, 4=always/considerably perceived burden), with a total score range of 0–60. Higher scores reflect a higher reported caregiver burden (Ulstein et al.,2007).

Administration of assessment tools:
The diagnostic instruments, psychosocial functioning tests and health behaviour questionnaire will be administered at baseline and 3 months.

Individual interviews:
To identify promoting and hindering factors of the intervention qualitative data will be collected through semi-structured individual interviews with both participants and their caregiver (proxy). 5-8 groups consisting of up to 6 participants will be chosen for qualitative interviews after the 12-week course. The caregivers role is to contributed with additional information as they were the ones observing the person on a daily basis during the 12-weeks. There will be used an interview guide with open-ended questions. The questions were designed to encourage the participants and their caregiver to express their experiences after participating at the 12-week course. The interviews will be recorded by handwritten notes which later will be transcribed into reflective, reconstructed field notes.

Observational study:
To study the educational situations, we observe 2-5 groups consisting of up to 6 participants over the duration of the course (12-weeks). Data will be collected through moderate participant observations (Dewalt & DeWalt, 2011). combined with individual interviews. Participants and their caregiver will interviewed prior to attending the 12-week course, over the duration of the course a moderate participant observation will be carried out, and shortly after the 12-week course individual semi-structured interviews will be arranged with both the

participant and their caregiver. The caregivers role is to contributed with additional information and support as they were the ones observing the person on a daily basis during the 12-weeks.

After each session, the observer discusses the day's session with the course leaders to clarify and validate the observers understanding of the interaction between group participants, the peer discussion/ peer support and the participant's progress. The observations will be recorded through handwritten field notes and transcribed immediately after each session.

The observational protocol consist of pre-selected topics, including (1) communication, (2) participant engagement, (3) social interaction within the group, (4) peer support (5) change in perception of living with dementia and (6) educational outcome.

Relevance and significance

Dementia is a major challenge to society, and the societal burden will increase markedly due to future demographic changes (Alzheimer Europe, 2014; Vossius et al., 2015). Despite these large numbers, there is a huge amount we still don´t know about the condition. There is a growing emphasis on providing information and support for people diagnosed with dementia. Information and support provided after a diagnosis of dementia may lead to health behavior changes that prevent excess disability or premature loss of function and institutionalization (Bossen, Specht, McKenzie, 2009; Buettner & Fitzsimmons, 2009). Therefore, given the high and growing prevalence of dementia and the tremendous costs of dementia care (Vossius et al., 2015), efforts to improve quality of life in early and moderate stages for community dwelling persons with dementia and thereby potentially set the stage for a possible improved course of the disease, and possible prevention of nursing home placement is of tremendous importance to persons with dementia, their caregivers and the society.

Patient and Public Involvement

Service users and carers will play an integral role throughout this program of research to ensure the work is based on the principles of Patient and Public Involvement (PPI). Active involvement of service users can lead to research of greater quality and relevance owing to the unique perspective that users can bring to a research project (Brett et al., 2014). Individuals will be identified according to their experiences, with a focus on ensuring a broad representative PPI approach. These individuals will be involved throughout each stage of the study, as participants of the trials expert group. A group of users will be invited to contribute to data analysis and interpretation through workshops with a research team. This will ensure that the outcomes and deliverables are accessible and relevant to the people with dementia, their caregivers and the health care sector in general. A dedicated dissemination plan will be developed in conjunction with users to promote the findings. A close collaboration with users will ensure that the lay perspective is covered in presentation of the results. This can increase the perceived relevance and acceptance of findings and might lead to optimization of implementation of research findings.

Data analysis

Statistical analyses will be performed using the IBM SPSS statistical package, version 24 for Windows®. Baseline characteristics will be explored using descriptive statistics. Differences between follow-up and baseline will be tested with Wilcoxon Signed Rank test (paired) and t-test (paired) for to assess the effectiveness of the intervention.

The qualitative data from both individual interviews and observations will be explored using content analysis.

Ethical aspects
The study received formal approval from the Committee for Medical and Health Research Ethics of Norway (REC no. 2013/2266). All participants will receive written information about the study before taking part. At the day of the screening all participants will provide written consent after the study procedures has been explained in detail to the participant and their caregiver.

Sponsor
Helse Stavanger HF will act as the sponsor for this study.

Funding
Norwegian Extra Foundation for Health and Rehabilitation through Nasjonalforeningen for folkehelsen are funding this study.

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