Online information resource pilot study: Background information

The pilot study aims to assess the acceptability of an online program of information (educational and skill-building) and support for carers of people with dementia, with onset before the age of 65. Participants' satisfaction with the program will be evaluated using the following criteria:
1 Participant retention and program use over time.
2 Intervention impact on participant knowledge, coping skills and psychosocial wellbeing.
3 Program-user satisfaction.
4 Health-economic analysis to provide preliminary estimates of cost-benefit ratio.
5 Delivery and implementation of the intervention, potentially to inform a larger-scale trial and future distribution.

Recruitment

A target of 20 participants will be recruited across three sites in England, France and Germany.

Inclusion criteria:

Primary informal carers, aged 18 years or over, of persons diagnosed with Alzheimer's disease (AD) or behavioural variant frontotemporal dementia (bv-FTD). Diagnosis should have been given no longer than 3 years ago and symptom onset should have been before the age of 65 with diagnosis before 68 years of age. The carer must have basic computer literacy, internet connection access via computer or smartphone and basic ability to use this technology.

Exclusion criteria:

Carers of patients with dementia caused by HIV, traumatic brain injury, Down's syndrome, Huntington's chorea, vascular or alcohol-related dementia are not included in this study.

Study Design

A randomized controlled trial design will be used. Participants will be assigned to one of two groups (A and B). Two consecutive participation phases are involved.

Phase 1 (6 weeks):

Group A receives the intervention, i.e. access to the online resource and technical support, if needed. Group B acts as waiting list control group (no access to online resource). Usual care is unaffected in both groups.

Phase 2 (6 weeks):

Group B receives the intervention. Group A has ongoing access to the resource without technical backup (i.e. to represent naturalistic conditions).

Online discussion forum:

During the 6 week intervention period, participants will have access to an online forum for comments, ideas and sharing questions. The forum will be moderated by to ensure no inappropriate material is posted.

Participant information session:

Each participant will have a one-to-one information session before having access to the program, delivered in person or by telephone. This will include baseline evaluation (questionnaire), randomisation and introduction to the online program. After collection of baseline information, participants will be informed of group allocation and provided with basic instructions on use of the program and forum.

Post phase 1 Evaluation (week 6):

Groups A and B will complete follow-up assessments by phone. Group A will complete the post-intervention evaluations. Group A will have additional access to the

Post phase 2 Evaluation (week 12):

Groups A and B will complete follow up assessments. Group B will complete the post-intervention evaluations.

Measures

Self-efficacy: The Revised Scale for Care-giving Self-Efficacy (RSCSE) (Steffen, McKibbin, Zeiss, Gallagher-Thompson, & Bandura, 2002) was selected as it is specific to the domain of care-giving. The RSCSE contains 19 items with a Likert response scale from 0 to 100. It covers three care-giving domains: obtaining respite, responding to disruptive behaviours and controlling upsetting thoughts about caregiving.

Perceived stress: The Perceived Stress Scale (Cohen et al, 1983) 10 item-version to assess stress management.

Health-related quality of life: EQ-5D-5L, a well-validated and widely used instrument capturing five dimensions (mobility, self care, usual activities, pain and anxiety and depression) which can be converted to a single index score for the analysis of quality adjusted life years. The thermometer section of the EQ5D5L will not be used, as this can vary on a day-to-day basis.

Carer burnout: Burden Scale for Family Caregivers (BSFC) – short version (10 items)

Patient symptoms: The Revised Memory and Behaviour Checklist (Teri et al., 1992) is a relevant measure for younger dementia patients and is one of few instruments covering both cognitive and behavioural symptoms of EOD and FTD.

User satisfaction: Technology Acceptance Model (TAM) 3 by Venkatesh & Bala (2008) will be used. Its core constructs are Perceived Usefulness (4 items), Perceived Ease of Use (4 items), and Behavioural Intention to Use (3 items). Due to restrictions in length, not all additional constructs of TAM 3 can be used. For the purpose of the intervention the following constructs are of particular relevance: Computer Self-efficacy (4 items) and Computer Anxiety (4 items).