

Journeying through dementia; randomised controlled trial of clinical and cost effectiveness

<https://neurodegenerationresearch.eu/survey/journeying-through-dementia-randomised-controlled-trial-of-clinical-and-cost-effectiveness/>

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Country

United Kingdom

Title of project or programme

Journeying through dementia; randomised controlled trial of clinical and cost effectiveness

Source of funding information

NIHR

Total sum awarded (Euro)

€ 2,668,318

Start date of award

01/12/2015

Total duration of award in years

3.5

The project/programme is most relevant to:

Alzheimer's disease & other dementias

Keywords

Research Abstract

DESIGN: A randomised controlled trial of Journeying through Dementia, with an internal pilot trial with a defined stop/ go criteria. SETTING: Community venues for group delivery; participants' homes/ community for individual sessions. POPULATION: People with dementia

e.g. Alzheimer's disease, vascular dementia/ mixed Alzheimer's/ vascular dementia. People with dementia can also involve a family member or friend if they would like (participating supporters). However this is optional. **INCLUSION CRITERIA:** (i) in the early stages of dementia (MMSE score 18 and over); (ii) can make informed decisions; (iii) community living. **EXCLUSION CRITERIA** (i) in the moderate/late stages of dementia; (ii) lacks mental capacity; (iii) in residential/nursing care. **HEALTH TECHNOLOGIES BEING ASSESSED:** A manualised intervention which involves 12 group and 4 individual facilitated sessions to promote self-management and re-engagement with activities. **OUTCOME ASSESSMENT:** People with dementia will have outcomes measures taken at baseline and 8 months post randomisation. These include: Primary: DEMQOL- Measures self-reported health related quality of life in dementia. Secondary: improving skills in instrumental activities of daily living (IADLs), self-efficacy (General Self-Efficacy Scale), building relationships and sense of connectedness (Self-Management Ability Scale and Diner's Flourishing Scale), depressive symptomology (PHQ-9), anxiety symptoms (GAD-7), health related quality of life (EQ-5D-5L) and resource use (Health and Social Care Resource Use Questionnaire). In addition some measures will be repeated at 12 months post baseline: DEMQOL, EQ-5D-EL and Health and Social Care Resource Use Questionnaire. Participating supporters will be asked to complete at baseline and 8 months post randomisation the PHQ-9, Sense of Competency in Caregiving Questionnaire and the EQ-5D-5L. **SAMPLE SIZE:** Assuming a standard deviation of 11 points for DEMQOL and that a mean difference of 4 or more points is clinically and practically important. To have an 90% power of detecting this mean difference (a standardised effect size of 0.29) as statistically significant at the 5% (two-sided) level; allowing for clustering (average cluster size of 8 per group and an intra-cluster correlation of 0.03) and 20% loss to follow-up. We will recruit and randomise 243 participants per arm (N=486). **ANALYSIS:** Analyses will compare the two arms of the trial on an as allocated basis. The primary analyses will compare the mean DEMQOL scores of the participants with dementia at 8 months between the two arms using a marginal general linear model (GLM) with robust standard errors, to allow for clustering by group. Secondary outcomes between the intervention and control groups will be compared at 8 months and 12 months post randomisation. A cost-effectiveness analysis will be undertaken of the incremental cost per Quality Adjusted Life Years (QALYs) of the JtD intervention compared with treatment as usual. **ADDITIONAL SUB STUDIES:** Embedded qualitative and fidelity sub-studies will be conducted to explore the underlying mechanisms of the intervention. **TIMETABLE/ RECRUITMENT:** 42 month project. Recruitment will start in Month 10 and sites will recruit for 10 months. **EXPERTISE:** Clinical academics with dementia expertise, methodological experts, registered Trials Unit, PPI.

Lay Summary

Further information available at:

Types:

Investments > €500k

Member States:

United Kingdom

Diseases:

Alzheimer's disease & other dementias

Years:

2016

Database Categories:

N/A

Database Tags:

N/A