

Early Psychosocial Intervention: Through A Memory Clinic: A Randomised Controlled Trial

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/09/2013	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PCC1040C Moniz-Cook

Study information

Scientific Title

Study objectives

The aim of this study was to replicate a previous pilot (Moniz-Cook et al 1998) within a randomised controlled design. In the pilot study, families recruited to a Community Primary Care led Memory Clinic were taught early memory management crisis preventive strategies over six sessions following diagnosis, and then offered crisis preventive support. At 18 month follow-up the experimental group did better on patient, caregiver and services outcomes. Question: Can early psychosocial intervention offered to older people with dementia and their families, through a Community Memory Clinic, improve their quality of life?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Nervous system diseases: Dementia

Interventions

Following the memory clinic assessment, all families met with the team (psychiatrist or psychologist and a nurse) to discuss the diagnosis and receive advice on future management. Following this, they were randomised to the experimental condition, 'memory clinic' early psychosocial intervention group for support by a memory clinic nurse, or to the 'usual care group' - psychogeriatric community multidisciplinary team, for support by a community psychiatric nurse (CPN). The independent University of York Telephone Randomisation Service allocated patients to each group using the following stratification criteria: MMSE scores (i.e. above and below MMSE 22) and 'domestic situation' (i.e. living with or without a caregiver). The design was essentially pragmatic in order that it could be easily extrapolated to NHS practice.

Case audit of 'usual' practice for the control group was compared with what occurred in the experimental group, to explore 'what works for who?'

The memory clinic 'early intervention' multi-component programme was individualised to patient and family need and included:

1. Psycho-education and further discussion of the impact of diagnosis on day to day life with management advice, including a written individualised crisis preventive advice booklet.
2. A home-based crisis preventive memory management programme.
3. A behavioural depression-prevention programme.
4. Monitoring of physical health in families.
5. Review of psychotropic medication.
6. Arranging practical and social services if necessary.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Patient Measures: The Mini-Mental State Examination - Diagnostic Interview Schedule (MMSE - DIS) (Folstein et al., 1975). Rivermead Behavioural Memory Test (RMBT) Wilson et al., (1985); Cornell Scale (Depression in dementia), Alexopoulos et al., (1998) H.A.D - Anxiety & Depression, Zigmond, A.S., & Snaith, R.P. (1983); Memory Difficulties Locus of Control Adapted from 'Recovery Locus of Control', Partridge & Johnston (1989).

Caregiver Measures: Problem Behaviour checklist, Gilleard, C. (1984); Revised Memory and Behaviour Problem Checklist, Teri L. et al., (1992); H.A.D. - Anxiety & Depression, Zigmond, A.S., & Snaith, R.P. (1983). General Health Questionnaire - 28 (GHQ - 28), Goldberg, D. (1981). Short Sense of Competence Scale, Vernooij-Dassen et al., (1997).

Services Measures: Psychosocial Intervention Checklist 0 an independently rated questionnaire on observed use of psychosocial support; case note audit of number and types of nurse contacts and families and audit of medication prescriptions from GP's.

Secondary outcome measures

Not provided at time of registration

Overall study start date

31/05/1998

Completion date

31/10/2000

Eligibility

Key inclusion criteria

Patients over the age of 65 years who were diagnosed with an 'early dementia in a Memory Clinic'.

Participant type(s)

Patient

Age group

Senior

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

1. Patients below 65 years of age
2. Prescription of anti-dementia drugs, e.g. Aricept, Exelon
3. Longstanding Receipt of Social Service Care
4. Presence of premorbid enduring mental health problems/chronic mood problems, and thus, previous (or ongoing) contact with psychiatric services
5. Onset of dementia greater than 4 years and Mini-Mental State Examination (MMSE) score <14

Date of first enrolment

31/05/1998

Date of final enrolment

31/10/2000

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Department of Clinical Psychology (Older Adults)

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Sponsor information**Organisation**

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

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Sponsor type

Government

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Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

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