ISRCTN19216873 https://doi.org/10.1186/ISRCTN19216873

Facilitating Early Diagnosis of Dementia (FED-D)

Submission date
03/05/2013

Recruitment status
No longer recruiting

Registration date
22/08/2013

Overall study status
Completed

Last Edited
16/03/2017

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In the UK, about 820,000 people have dementia (brain disorder). Nearly two-thirds of people never find out and for many that do, diagnosis takes a long time with the patient and family overcoming numerous obstacles. Although it is UK national policy in the Dementia Strategy that people are diagnosed early, and this has been accompanied by a nationwide information campaign, there has been little progress. Diagnostic barriers include people with memory problems being reluctant to see their general practitioner (GP), GPs not seeing there is a problem or referring for help, and patient and family concerns about stigma. We have designed a leaflet based on the CHOICE project which asked family carers what the problems were in making decisions for people with dementia and how they overcame them. The most common problem that carers struggled with was getting a diagnosis and help. The CHOICE leaflet for our study was developed from family carers of people with dementias answers. The aim of this study is to increase timely diagnosis of dementia. We intend to send a personal letter from the GP with the CHOICE leaflet explaining what to do to overcome barriers to getting help for memory problems to all people aged over 70 in the practice. We will find out whether this enables people with dementia to receive an earlier diagnosis.

Who can participate?
We are recruiting GP practices to the study. Our study will include all patients in the GP practices over the age of 70 years (unless already known to have dementia or living in a care home).

What does the study involve?
The GP practices will be randomly allocated to one of two groups. One group (intervention GP practices) will send the leaflet along with a letter from the GP to the patients and the other group provides usual care (control practices). The GP letter will go to every participant in the intervention group with an explanation about how memory problems which interfere with life become more common as people age. It will ask for people to consider the leaflet for themselves or members of their family. This will be sent to people who live alone as well as those living with others. We will test if this increases the number of people with undiagnosed dementia presenting with memory-related problems to their GP, the number of patients GPs refer appropriately to memory services, and if this referral is at an earlier stage. We will compare the brain function scores of those patients referred from the intervention GP practices to those

from the control practices. If our method is successful we want to know whether the cost is low. We will calculate the cost for every extra person diagnosed and whether there are many people who are referred to memory services with no dementia (which would increase the cost).

What are the possible benefits and risks of participating?
Our leaflet addresses how to overcome the common problems diagnosing people with dementia. Early diagnosis is useful because although there is no cure, many people with dementia and family carers feel relieved by knowing what the diagnosis is. The diagnosis leads to treatment and more support which reduces crises, can improve quality of life and delay care home admission. It also allows people to make choices about current and future care and other plans. It is also thought to save money for the state and for individual family carers.

Where is the study run from?
The study is run from University College London and the research will take place in UCL Partners partnership trusts where our team work clinically. This will include local GP surgeries and hospitals including mental health trusts within North London and surrounding counties.

When is study starting and how long is it expected to run for?
The study will start in mid-2013 and will run for 12 months. The GP practices will be enrolled in the study for a period of 12 months.

Who is funding the study?
The Alzheimers Society (UK)

Who is the main contact?
Prof. Gill Livingston
g.livingston@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Gill Livingston

ORCID ID
https://orcid.org/0000-0001-6741-5516

Contact details
Division of Psychiatry
University College London
6th Floor, Maple House
149 Tottenham Court Road
London
United Kingdom
W1T 7NF
-
g.livingston@ucl.ac.uk

Type(s)

Scientific

Contact name
Dr Juanita Hoe

ORCID ID
https://orcid.org/0000-0003-4647-8950

Contact details
Division of Psychiatry
University College London
6th Floor, Maple House
149 Tottenham Court Road
London
United Kingdom
W1T 7NF
-
j.hoe@ucl.ac.uk

Additional identifiers

Protocol serial number
177 (PG-2012-183)

Study information

Scientific Title
Facilitating Early Diagnosis of Dementia (FED-D): a pragmatic, multi-site, cluster randomised controlled trial

Acronym
FED-D

Study objectives
Does sending a leaflet on how to overcome barriers to accessing help for dementia to people aged over 70 registered in a general practice, with an accompanying personal letter from the GP, lead to people with dementia presenting earlier to specialist dementia services compared with usual care over 12 months and if so, is it at low cost? We will test the hypotheses that, over 12 months people receiving the intervention will present earlier (mean of 3 points higher on MMSE score) than those not receiving it and that the costs of the intervention are small.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Queen Square, 20/08/2013, ref: 13/LO/0996

Study design
Pragmatic multi-site cluster randomised controlled trial

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Dementia

Interventions
We intend to send a personal letter from the GP with the CHOICE leaflet explaining what to do to overcome barriers to getting help for memory problem to all people aged over 70 in the practice
Control: usual care

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The primary outcome is the cognitive score as measured by the Mini Mental State Examination (MMSE) of people referred to memory services in the intervention and control groups who receive a diagnosis of dementia. The minimum clinically important difference in MMSE score is three points and is the most widely used standard test of cognitive function. We will collate the baseline MMSE score from the new patients presenting to memory clinic (i.e. MMSE scores of new presentations) at 3, 6 and 12 months after sending the letters. We are not collecting follow-up MMSEs. There is a maximum score of 30, with scores of 0-10=severe, 11-20=moderate, and 21-24=mild dementia.

Added 05/01/2016:
As many memory services were using other cognitive measures than the MMSE, most commonly the 100 point Addenbrookes Cognitive Examination (ACE-R and ACE-III), it was agreed before we began the analysis to include patients without MMSE scores but with ACE scores. We used data on the latter to estimate the missing MMSE scores. We therefore converted the ACE scores so that ACE and MMSE were used as a single outcome score. The change to the primary outcome was agreed on 08/12/2014.

Key secondary outcome(s))
1. Number of people presenting with a possible diagnosis of dementia will be collected from GPs practices using MiQUEST (a Department of Health computer system allowing anonymised data extraction from GP practices). We will collect the number of people presenting to their GP who are and who are not referred on to memory services.
2. Numbers of patients referred to memory services from participating intervention and control practices
3. The number of memory services appointments offered and people attending for diagnostic assessment
4. The number of people referred who do not have dementia or mild cognitive impairment
5. Costs of implementing the intervention, including the costs associated with the CHOICE leaflet (printing, and distribution), GP visits to discuss possible diagnoses of dementia and use of

memory services and the cost of assessing those with and without dementia
6. We will systematically ask clinicians about any inappropriate presentations and patient distress and record these as adverse events

Completion date
31/10/2015

Eligibility

Key inclusion criteria
We are recruiting GP practices to the study and our study will include all patients in the GP practices over the age of 70 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
The intervention will not be given to registered patients within included GP practices over the age of 70 years who have a diagnosis of dementia, live in a care home or have been referred to specialist memory services

Date of first enrolment
27/09/2013

Date of final enrolment
11/12/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UCL Mental Health Sciences Unit
London
United Kingdom
W1W 7EJ

Study participating centre
Camden Memory Service
The Peckwater Centre
6 Peckwater Street
London
United Kingdom
NW5 2TX

Study participating centre
Waltham Forest Memory Service
Red Oak Lodge
17 Thorne Close
Langthorne Road
Leytonstone
London
United Kingdom
E11 4HU

Study participating centre
Havering Memory Service
119—121 Suttons House
Hornchurch
United Kingdom
RM12 6RU

Study participating centre
Redbridge Memory Service
Grovelands
Grove Road
Chadwell Heath
United Kingdom
RM6 4XH

Study participating centre
Barking & Dagenham Memory Service
Broad Street Health Centre
Morland Road
Dagenham
United Kingdom
RM10 9HU

Study participating centre
Tower Hamlets Diagnostic Memory Clinic
The Robinson Centre
Mile End Hospital
275 Bancroft Road
Mile End
London
United Kingdom
E1 4DG

Study participating centre
City & Hackney Diagnostic Memory Clinic
Unit 1
30 Felstead Street
Homerton
London
United Kingdom
E9 5LG

Study participating centre
Newham Diagnostic Memory Clinic
Newham First Avenue Resource Centre
103 First Avenue
Plaistow
London
United Kingdom
E13 8AP

Study participating centre
Barnet Older Peoples CMHT
Level 3, Springwell Centre
Barnet Hospital
Wellhouse Lane
Barnet
United Kingdom
EN5 3DJ

Study participating centre
Haringey Memory Service
Victoria Unit
St Ann’s Hospital

London
United Kingdom
N15 3TH

Study participating centre
EMDASS East
North Place Annex
82 Great North Road
Hatfield
United Kingdom
AL9 5BL

Study participating centre
EMDASS North West
Logandene
Ashley Close
Bennets End
Hemel Hempstead
United Kingdom
HP3 8BL

Study participating centre
EMDASS North
Glaxo Day Hospital
Lister Hospital
Stevenage
United Kingdom
SG1 4AB

Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type

Charity

Funder Name
Alzheimer's Society Project Grant: 177 (PG-2012-183) (UK)

Alternative Name(s)
alzheimerssoc

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/03/2017		Yes	No
HRA research summary			28/06/2023	No	No