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Can the behavioural symptoms of people severely affected by dementia be effectively and safely managed without use of regular psychotropic medication?

Submission date
02/08/2002

Registration date
02/08/2002

Last Edited
08/08/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.csm-oxford.org.uk/index.asp?o=1127

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
QRD/2002/01/01

Study information

Scientific Title

Acronym
FITS

Study objectives
Many people with dementia are prescribed antidepressants and minor or major tranquillizers. This may be appropriate treatment for psychiatric symptoms such as depression, hallucinations or delusions, but use of these drugs to control behavioural symptoms that may arise out of agitation for example is controversial. Major tranquillizers are highly effective in the treatment of hallucinations and delusions, but the little evidence that we have suggests that they have only modest efficacy in improving behavioural symptoms. In contrast to the lack of evidence that these drugs are helpful in the treatment of people with dementia, there are clear costs associated with their use. All of these drugs have side-effects to which people with dementia are particularly sensitive. Further, some researchers believe that use of these drugs may be associated with an accelerated decline in dementia.

The aim of this trial is to test the effectiveness and acceptability of alternatives to regular psychotropic prescription within those people with dementia who present the most serious behavioural problems and who would thus be most likely to receive drug treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics information required at time of registration.

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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

Interventions
Focused Intervention Training and Support (FITS) package delivered to Care staff within Continuing Care facilities versus a simple staff support group

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Determine whether this approach reduces the need for neuroleptics and other sedative medications
2. To measure the safety of this intervention
3. Determine whether this improves the quality of life of those people with dementia resident in such facilities
4. To examine whether a positive intervention on residents has a beneficial effect on staff

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2003

Completion date
01/02/2005

Eligibility

Key inclusion criteria
Being a continuing care facility providing care for people with severe dementia

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
340 (170 per arm)

Key exclusion criteria

Not applicable

Date of first enrolment
01/06/2003

Date of final enrolment
01/02/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Division of Psychological Medicine
London
United Kingdom
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Sponsor information

Organisation
Alzheimer's Society (UK)

Sponsor details
Gordon House
10 Greencoat Place
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SW1P 1PH
+44 (0)207 306 0606
enquiries@alzheimers.org.uk

Sponsor type
Charity

ROR
https://ror.org/0472gwq90

Funder(s)

Funder type
Charity

Funder Name
Alzheimer's Society, The Community Fund (RG 24052)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2006		Yes	No