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Support at home interventions to enhance life in dementia: Home Treatment Programme

Submission date	Recruitment status	[ ] Prospectively registered
24/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/03/2018	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ucl.ac.uk/mental-health-sciences/Current%20research/SHIELD.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Phase II, cluster-randomised controlled trial of home-based interventions delivered using the Home Treatment Programme Advisory protocol for people with dementia

Acronym
SHIELD HTP

Study objectives
Those people with dementia supported at home and receiving interventions delivered using the HTP Advisory protocol will have significantly better quality of life than those receiving treatment as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Phase II multicentre pragmatic single blind cluster randomised controlled exploratory trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not yet available in web format. please use contact details to request a patient information sheet

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

Interventions
Intervention group
The Home Treatment Package will function as an advisory protocol/care pathway that offers guidance on appropriate interventions for home treatment and will consist of a structured approach to need assessment and include a combined risk assessment and care-planning tool.

The HTP advisory protocol will be based on the evidence collected through the Cochrane and systematic review undertaken as part of Home Treatment Programme work package 1, along with the scoping exercise of existing home treatment teams and expert and service user consultation processes undertaken as part of Home Treatment Programme work package 2. The home treatment interventions will target the needs identified for the person with dementia and their family caregiver and will include a range of approaches, such as intensive support from a mental health keyworker for observation and monitoring of the home situation, provision of increased homecare support services, access to community based services, physical screening and medical treatment, availability of aids and adaptations including the use of assistive technology, respite services, carer education, skills training, counselling and family centred therapy. The HTP advisory protocol will be compiled into a manual and training provided to the mental health keyworkers who will be providing the interventions.

Control group
Participants randomised to the control groups will receive treatment as usual (TAU). Treatment as usual implies the person with dementia and the family caregiver will receive an acceptable standard of care as currently provided within existing Home Treatment Team (HTT) and Community Mental Health Team (CMHT) teams. Treatment as usual will therefore reflect currently accepted practice and participants will continue to receive treatment as usual from statutory and voluntary services within their locality.

The duration of the intervention is 12 months

Intervention Type
Other

Phase
Phase II

Primary outcome measure
1. Quality of life (QoL) for people with dementia
2. Number of admissions to hospital (both psychiatric and medical)
3. Number of inpatient days
4. Time until care home placement
5. Met and unmet needs for the person with dementia

Outcomes (primary and secondary) will be measured using the following tools
1. Camberwell Assessment of Needs for the Elderly (CANE) (Included in HTP Advisory Protocol)
2. Clinical Dementia Rating (CDR)
3. Mini Mental State Examination (MMSE)
4. Quality of Life - Alzheimer's Disease (QoL-AD)
5. EQ-5D - Patients with Dementia (PWD)
6. EQ-5D - Family carer
7. Cornell depression scale in dementia
8. Rating for Anxiety in Dementia (RAID)
9. Neuro Psychiatric Inventory (NPI)
10. Alzheimer's Disease Cooperative Study - Activities of Daily Living (ADCS-ADL)
11. Hospital Anxiety Depression Scale (HADS)
12. General Health Questionnaire (GHQ-12)
13. Practitioner Assessment of Network Typology (PANT) (Grant & Wenger, 1993)
14. Client Service Receipt Inventory (CSRI)

All outcomes will be assessed at baseline, 3, 6 and 12 months.

Secondary outcome measures
1. Mood
2. Behaviour
3. Activities of daily living
4. Service use and support networks of the person with dementia

All outcomes will be assessed at baseline, 3, 6 and 12 months.

Overall study start date
01/04/2010

Completion date
01/09/2013

Eligibility

Key inclusion criteria
1. Clinical centres
1.1. Have a minimum of 2 clinical areas that can be recruited to the Home Treatment Trial
1.2. Be staffed by appropriately qualified and trained mental health staff such as registered mental health nurses, occupational therapists, social workers and psychologists.
1.3. Provide mental health assessment and treatment to people with dementia
1.4. Have access to psychiatric inpatient beds
1.5. Be currently open to new referrals for people with dementia requiring mental health assessment and treatment
1.6. Be willing to provide the HTP Advisory Protocol as part of the exploratory trial (minimum involvement - 80% of staff members)

2. Participants
2.1. Meet the Diagnostic and Statistical Manual of Mental Disorders 4th edition (DSMIV) criteria for dementia (American Psychiatric Association [APA], 1994) including Alzheimers disease, vascular dementia, Lewy Body type dementia, atypical and mixed dementia
2.2. A Mini Mental State Examination (MMSE) score <24 that indicates the presence of cognitive impairment (Folstein et al, 1975)
2.3. Have a family caregiver / informant (e.g. family member, neighbour, care home staff member) willing to participate in the study
2.4. Have a family caregiver / informant (e.g. family member, neighbour, care home staff member) who provides care for a minimum of 4 hours per week
2.5. Have a mental health keyworker willing to participate in the study
2.6. Have an appropriately qualified mental health keyworker involved in their care i.e. mental health nurse, occupational therapist, psychologist, social worker
2.7. Both the person with dementia and their caregiver live within the geographical areas covered by the research
2.8. The person with dementia and their caregiver will be English-speaking
2.9. Have the potential to benefit from HTP Advisory Protocol interventions - implementation of the HTP Advisory Protocol should not be detrimental to the person with dementias wellbeing, such as by delaying hospital admission for those requiring immediate access to inpatient care
2.10. Male or female, age >65 years
2.11. In addition all participants will meet one of the following criteria:

2.11.1. Are at serious risk of requiring hospital admission within the next month
2.11.2. Meet criteria for admission to an inpatient psychiatric unit

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Clinical centres
1.1. Mental Health settings that do not routinely care for people with dementia
1.2. Non NHS settings, such as voluntary sector services
1.3. Unable to nominate a suitably qualified and experienced senior staff to provide a clinical lead to support the mental health keyworkers
1.4. Unable to nominate a suitably qualified and experienced senior staff to provide a research lead to support the mental health keyworkers

2. Participants
2.1. Have a diagnosis of a learning disability
2.2. Are experiencing acute mental health distress that warrants detention under the mental health act
2.3. Are refusing to accept Home Treatment interventions
2.4. The person with dementia or their family caregiver is already taking part in an existing research study involving psychosocial interventions

Date of first enrolment
01/04/2010

Date of final enrolment
01/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

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Sponsor information

Organisation
North East London NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/023e5m798

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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