ISRCTN37956201 https://doi.org/10.1186/ISRCTN37956201

SHIELD Carer Supporter Programme for family carers of people with dementia

Submission date	Recruitment status	[ ] Prospectively registered
15/06/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/08/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/08/2016	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Martin Orrell

Contact details
Department of Mental Health Sciences (Bloomsbury Campus)
University College London
67-73 Riding House Street
1st Floor, Charles Bell House
London
United Kingdom
W1W 7EJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RP-PG-0606-1083

Study information

Scientific Title
SHIELD Carer Supporter Programme: a peer support intervention for newer family carers of people with dementia

Acronym
SHIELD CSP

Study objectives
SHIELD Carer Supporter Programme (CSP) alone or in combination with reminiscence group work will be more effective in improving quality of life, effect, and self-efficacy of family carers than treatment as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Outer North East London Research Ethics Committee (REC), 11/06/2009, ref: 09/H0701/54

Study design
Multicentre single-blind randomised controlled 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 available in web format, please use the contact details below to request a patient information sheet

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

Interventions
Three intervention conditions and one control condition are evaluated. These are:
1. SHIELD Carer Supporter Programme (CSP)
2. Remembering Yesterday, Caring Today (RYCT) group reminiscence work
3. Combined SHIELD CSP/RYCT
4. Treatment as Usual (TAU)

SHIELD CSP:
The aim of the SHIELD CSP intervention is to improve a sense of self-efficacy/competence in the early stage carer through encouragement and positive reinforcement of carer skills development and carer network building activities. The Carer Supporters will be recruited through the voluntary sector by the Carer Supporter Manager based at Age Concern Havering, and will be supported by local Carer Supporter Coordinators based in voluntary organisations at each research site. Once recruited and trained, Carer Supporters will be matched with newer family carers through the voluntary sector. The SHIELD CSP intervention will involve weekly contact between a research participant and a more experienced carer (Carer Supporter) over a 3-month period. In this time, Carer Supporters may meet with the carers alone or jointly with the carer and relative with dementia. They may also attend support groups, educational meeting sor social gatherings with the matched newer carer. The Carer Supporter will not meet with the PwD in the absence of the carer. Ongoing contact between the Carer Supporter and early stage carer will be encouraged with a target of a fortnightly meeting, supported and monitored for a further 7 months.

RYCT:
The aim of the RYCT intervention is to improve the relationship and communication between the carer and PwD. This is achieved through the carer and PwD attending a weekly Remembering Yesterday Caring Today (RYCT) Reminiscence group over a 3-month period. The RYCT uses memory triggers (photographs, recordings, artefacts, etc.) to promote personal and shared memories. Groups of approximately 12 pairs are facilitated by a worker with experience in reminiscence work and running active or arts groups, and are supported by a team of paid staff and volunteers drawn from health, social services and the voluntary sector. After the initial 3 months of the RYCT intervention, participants are encouraged to take part in 'reunion' meetings at monthly intervals.

Combined SHIELD CSP/RYCT:
The aim of the SHIELD CSP/RYCT intervention is to combine the essential elements of the SHIELD CSP and RYCT interventions, and to extend the benefits of RYCT through bringing knowledge of the care dyad to the group, and taking knowledge of reminiscence into the carer's home. As such, it will involve both attendance at the RYCT group intervention and contact with a more experienced carer (Carer Supporter). The newer carer will have weekly contact with the Carer Supporter for at least 1 month prior to attending a 12-week RYCT group. During the RYCT group programme, Carer Supporters will be encouraged to attend as a part of the reminiscence team in place of other health, social care or voluntary sector personnel. After the RYCT group programme is complete, carers will be in contact with the Carer Supporters on a fortnightly basis, including attendance at the monthly RYCT 'reunions'.

NB. All participants, including those in the intervention groups, will continue to receive treatment as usual from statutory and voluntary services in their locality.

Treatment as Usual:
Participants randomised to the control group will continue to receive treatment as usual.

Baseline assessments will be carried out pre-randomisation. After this, two follow up assessments will be carried out at 5 months and 12 months after baseline. It is anticipated that participants will be involved in the intervention for a total of 12 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Quality of life
2. Self-efficacy

Measured at baseline pre-randomisation, then at 2 follow ups: + 5 months from randomisation and +12 months randomisation.

Secondary outcome measures
1. Relationship quality
2. Anxiety and depression
3. Social Support
4. Hospitalisation/institutionalisation

Measured at baseline pre-randomisation, then at 2 follow ups: + 5 months from randomisation and +12 months randomisation.

Overall study start date
01/07/2009

Completion date
30/09/2012

Eligibility

Key inclusion criteria
1. English-speaking family caregivers aged 18 years or over, either sex
2. Identified by themselves as a carer for person with a primary progressive cognitive impairment /dementia as defined by Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria for dementia including Alzheimer's, vascular dementia, dementia of Lewy Body type, and mixed dementias
3. Both the family carers and the person with dementia live within the areas covered by the research

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300 family carer/person with dementia dyads

Key exclusion criteria
1. Carers of people who are living in Residential, Nursing or long-stay hospital accommodation on a permanent basis
2. Carers of people with: congenital cognitive impairments (e.g. Down's syndrome); acquired non-progressive brain injury; cognitive impairments in the context of longstanding psychiatric illness e.g. schizophrenia
3. 'Carers' with significant congenital or acquired cognitive impairment, or where cognitive deficits are suspected in the carer
4. Family members with whom the suspected diagnosis of dementia has not been disclosed /discussed
5. Seriously ill carers, e.g. those receiving hospice or hospital treatment for terminal illness
6. Carers unable to take part in an intervention of 10 months duration
7. Carer unwilling for their person they care for to be approached
8. Non-family, paid carers
9. Either party already taking part in a psychosocial research study

Date of first enrolment
01/07/2009

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
London
United Kingdom
W1W 7EJ

Sponsor information

Organisation
North East London NHS Foundation Trust (UK)

Sponsor details
Research and Development department
Maggie Lilley Suite
Goodmayes Hospital
Barley Lane

Ilford
England
United Kingdom
IG3 8XJ

Sponsor type
Hospital/treatment centre

Website
http://www.nelmht.nhs.uk/

ROR
https://ror.org/023e5m798

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR) (ref: RP-PG-0606-1083)

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?
Protocol article	protocol	15/09/2011		Yes	No
Results article	results	01/11/2016		Yes	No