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START (STrAtegies for RelaTives) study

Submission date
18/05/2009

Recruitment status
No longer recruiting

Registration date
20/05/2009

Overall study status
Completed

Last Edited
25/08/2017

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
Family carers of people with dementia are a group at high risk of mental health problems like depression and anxiety. As they provide most of the care received by people with dementia in this country, and the number of people with dementia is projected to increase substantially, there is an urgent need within society to develop ways to decrease their distress. The UK government has recognised that family dementia carers need dedicated psychological therapies, and that this should be a key component of high quality dementia care, but in practice resources are not available. The only studies that have demonstrated efficacy of a manual based psychological therapy in this group were carried out in the
USA and the therapy was conducted by clinical psychologists. Clinical psychologists are a highly trained and finite resource within the NHS. Researchers in the USA have developed a talking therapy programme to help family or friends of people with memory problems. This has been adapted this for Britain (for example; seeing people individually rather than in groups). The aim of this study is to test whether this programme is effective in friends and relatives of people with memory problems in the UK.

Who can participate?
Family carers who provide emotional or practical support at least weekly and identify themselves as the primary carer of someone with dementia not living in 24 hour care and who are carers of patients referred in the last year.

What does the study involve?
An interviewer conducts an initial interview. This takes about an hour. They ask participants about their relative/friend's memory and behavioural symptoms, difficulties they may have with their daily routine, their and their relative's/friend's health, services that provide assistance to their friend/relative, and the rewards and difficulties of caring including how they have coped with these difficulties over recent times. A researcher (the same person if possible) visits again 4, 8, 12 and 24 months after the initial interview. At these visits, they ask some of the same questions again to see whether things have changed. Participants are randomly allocated to one of two groups after the first interview. The first group do not receive any extra visits apart from the researcher coming back to see how they are getting on. In the second group a psychological therapist conducts eight talking therapy sessions. The first visit is shortly after the first interview, and the meetings are weekly for eight sessions. The meetings are scheduled for a time and place that is convenient, and most people prefer this to be at their home. Each lasts

about an hour. The psychological therapist is someone who has received training to deliver this programme. Participants are encouraged to discuss recent problems that have arisen while helping the person with memory problems and what to do. Participants are also given brief exercises to do between sessions, for example, making a note of incidents which cause stress. With consent some of the sessions are tape recorded for later analysis, to ensure that the therapy is being delivered correctly. The study does not involve the person with memory problems, and no specific additional care is offered. Participants are followed up every six months from 2 years until the person with dementia goes into a care home or dies, or for 6 years.

What are the possible benefits and risks of participating?
It cannot be promised that the study will help the participants. It will provide evidence regarding whether the programme is helpful for family and friends of people with memory problems. If it is, then knowing this could help improve the support offered to family and friends of people with memory problems. It is not anticipated that there will be any disadvantages to taking part except for the inconvenience of making time for the interviews and the talking therapy sessions, but it is possible that some topics discussed concerning the stresses of caring may be upsetting.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
August 2009 to December 2018

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 08/14/06

Study information

Scientific Title
START (STrAtegies for RelaTives) study: a pragmatic randomised controlled trial to determine the effectiveness of a manual based coping strategy programme in promoting the mental health of carers of people with dementia

Acronym
START

Study objectives
That eight sessions of manual based coping strategy therapy, delivered over 8-14 weeks by supervised graduate mental health workers is clinically (in terms of anxiety and depressive symptoms) and cost-effectiveness for family carers, compared to usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East London and the City Research Ethics Committee 1, 11/08/2009, ref: 09/H0703/84
Approval for substantial amendment on 11/09/2011

Study design
Randomised multi-centre single-blind 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Family carer of patient with dementia

Interventions
An interviewer conducts an initial interview. This takes about an hour. They ask participants about their relative/friend's memory and behavioural symptoms, difficulties they may have with their daily routine, their and their relative's/friend's health, services that provide assistance to their friend/relative, and the rewards and difficulties of caring including how they have coped with these difficulties over recent times. A researcher (the same person if possible) visits again 4, 8, 12 and 24 months after the initial interview. At these visits, they ask some of the same questions again to see whether things have changed. Participants are randomly allocated to one of two groups after the first interview. The first group do not receive any extra visits apart from the researcher coming back to see how they are getting on. In the second group a psychological therapist conducts eight talking therapy sessions. The first visit is shortly after the first interview, and the meetings are weekly for eight sessions. The meetings are scheduled for a time and place that is convenient, and most people prefer this to be at their home. Each lasts about an hour. The psychological therapist is someone who has received training to deliver this programme. Participants are encouraged to discuss recent problems that have arisen while helping the person with memory problems and what to do. Participants are also given brief exercises to do between sessions, for example, making a note of incidents which cause stress. With consent some of the sessions are tape recorded for later analysis, to ensure that the therapy is being delivered correctly. The study does not involve the person with memory problems, and no specific additional care is offered.

Added 24/08/2017:
Participants are followed up every six months from 2 years until the person with dementia goes into a care home or dies, or for 6 years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 10/05/2013:
1. Carer HADS Total
2. Cost-effectiveness: Cost of care for each group will be measured using the Client Service Receipt Inventory (CSRI). The EQ5D is a generic measure to generate QALYs (quality of life adjusted health years); societal weights will be applied.

At 2 years:
1. Carer HADS Total
2. Cost-effectiveness: Cost of care for each group will be measured using the Client Service Receipt Inventory (CSRI). The EQ5D is a generic measure to generate QALYs (quality of life adjusted health years); societal weights will be applied.

At 7 years:
Time to entry to 24 care

Previous primary outcome measures until 10/05/2013:
1. Carer HADS depression and anxiety scores
2. Cost-effectiveness: Cost of care for each group will be measured using the Client Service Receipt Inventory (CSRI). The EQ5D is a generic measure to generate QALYs (quality of life adjusted health years); societal weights will be applied.

Secondary outcome measures
Current secondary outcome measures as of 10/05/2013:
At 8 months:
1 Depression and anxiety caseness and scores on the HADS
2. Carer (HSQ mental health) and care recipient (QoL-AD) quality of life
3. Modified Conflict Tactics Scale

At 2 years:
1 Time to entry of the person with dementia to 24-hr care
2 Depression and anxiety caseness and scores on the HADS
3 Carer (HSQ mental health) and care recipient (QoL-AD) quality of life
4. Modified Conflict Tactics Scale

Previous secondary outcome measures until 10/05/2013:
1. Time to entry of the person with dementia to 24-hr care
2. Depression and anxiety caseness on the HADS
3. Carer (HSQ) and care recipient (QoL-AD) quality of life
4. Modified Conflict Tactics Scale

Overall study start date
01/08/2009

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Family carers who provide emotional or practical support at least weekly and identify themselves as the primary carer of someone with dementia not living in 24 hour care referred in the last year
2. Participants must be over 18 years of age and can be of either sex

Participant type(s)
Carer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
258

Key exclusion criteria
1. Carers who are unable to give informed consent to the trial, for example because they have dementia themselves
2. Carers who are currently taking part in a randomised clinical trial in their capacity as a family carer
3. Carers who live more than 1.5 hours from the researchers' base

Date of first enrolment
01/08/2009

Date of final enrolment
01/06/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
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Sponsor information

Organisation
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Sponsor type
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Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	clinical effectiveness results	25/10/2013		Yes	No
Results article	cost effectiveness results	25/10/2013		Yes	No
Other publications	participants' views	04/06/2014		Yes	No
Other publications	HTA report	01/10/2014		Yes	No
Results article	coping strategies results	01/10/2014		Yes	No
Results article	main results	01/12/2014		Yes	No
Results article	reducing abuse results	01/06/2016		Yes	No
Results article	dissemination results	21/08/2017		Yes	No
HRA research summary			28/06/2023	No	No