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Widening access to strategies for relatives (START) for dementia care

Submission date
27/01/2020

Recruitment status
No longer recruiting

Registration date
13/05/2020

Overall study status
Completed

Last Edited
17/01/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Family members providing care to a person with dementia are often distressed, anxious or depressed. The researchers developed the START (Strategies for RelaTives) intervention for family carers of relatives with dementia to promote helpful coping strategies for the difficulties of caring, and reduce these types of symptoms. The original START intervention was delivered within NHS service structures by psychology graduates. The main purpose of this study is to widen access to the START intervention by adapting it for delivery in the third sector and to Minority Ethnic (ME) groups, within existing structures of the Alzheimer's Society (AS) and the South Asian community in the first instance.

Who can participate?
Family carers of relatives with dementia, 18 years or over, providing care or support (or having done so in the past) to a relative with dementia and willing to provide informed consent to participate in the study

What does the study involve?
In Phase 1 (Month 1-18) the researchers will undertake focus groups and/or individual interviews, and consult with Alzheimer's Society stakeholders and
family carers of relatives with dementia from South Asian backgrounds (using translators as appropriate), to inform changes to the START intervention. The researchers will use the Consolidated Framework for Implementation Research Tool (CFIR) to assess baseline barriers and facilitators and the Knowledge-to-Action framework (KTA) as a guide for translating findings into practice. In Phase 2 (Month 12-30) the researchers will implement the modified intervention, within existing structures of the Alzheimer's Society and the South Asian community respectively. In Phase 3 (Month 20-33) an independent evaluation will assess the impact of the intervention incorporating qualitative and quantitative information, using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) implementation tool.

What are the possible benefits and risks of participating?
Benefits for participants are significant improvement in carer mental health and quality of life. The potential benefits for the organisation are expected in terms of improved access for family carers to START including for those in hard to reach groups, as well as a template for

implementation of the START intervention in the third sector and for other ME groups.
Risks: family carers may find the time commitment needed to participate in the research burdensome but they will only participate with fully informed consent. There is a risk of emotional distress among participants who take part in the interviews and/or intervention but in general the researchers have found that carers benefit from the research process.

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

When is the study starting and how long is it expected to run for?
March 2018 to December 2019

Who is funding the study?
Alzheimer's Society (UK)

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

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
234808

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 37850, IRAS 234808

Study information

Scientific Title
Foundation laying to widen access to START (Strategies for RelaTives)

Study objectives
Clinical and cost effectiveness of the intervention has already been established, and we expect outcomes in terms of affective symptoms and service use to be in line with trial results.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/03/2018, London - West London & GTAC Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8124; westlondon.rec@hra.nhs.uk), ref: 18/LO/0369

Study design
Interventional non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Treatment

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
This is a mixed methods study designed to assess implementation of a modified START intervention for family carers of relatives with dementia, within existing structures of the Alzheimer's Society and the South Asian community. The total study duration is 36 months from study set up through to write up. The study will be carried out in three phases, with some overlap between phases.

In Phase 1 (month 1-16), the researchers will interview Alzheimer's Society stakeholders (i.e. Dementia Advisers and Managers nominated by the Alzheimer's Society) and family carers from South Asian backgrounds about the START intervention using the Consolidated Framework for Implementation Research Tool (CFIR) to assess baseline barriers and facilitators, and scope voluntary sector and bilingual facilitators' training and support needs. Family carers of relatives with dementia from South Asian backgrounds will be identified and approached via the London Dementia Network, Camden and Islington NHS Foundation Trust Memory Services, and Bradford based community organisations with whom members of the research team have collaborated with in previous studies. The researchers will use a purposeful sampling technique widely used in qualitative research for the identification and selection of information rich cases for the most effective use of limited resources, and to achieve a depth of understanding. The researchers will sample participants to capture maximum variation in sociodemographic characteristics, and other variables including time in post at the Alzheimer's Society, relationship to relative with dementia (e.g. spouse or child) and living situation. The researchers will obtain a comprehensive understanding by continuing to sample until no new substantive information is acquired (theoretical saturation). Phase 1 participant groups will inform the adaptation of the START intervention and materials, and include (i) up to ten (n=10) Alzheimer's Society nominated Dementia Advisers, (ii) up to ten (n=10) Alzheimer's Society nominated managers and (iii) up to twenty (n=20) family carers of relatives with dementia from South Asian backgrounds. Participants will be interviewed following consent at a location convenient to them or at UCL. The Knowledge-to-Action framework (KTA) will be used as a guide for translating these findings into practice, i.e., designing the RE START THIRD SECTOR (TS), RE START SOUTH ASIAN (SA) interventions and materials. Work to explore and understand context using the CFIR and to ensure effective implementation through the KTA framework will involve iterative elements rather than a simple linear process. The researchers will follow up with Phase 1 interviewees to consult on changes and further refine interventions and materials.

In Phase 2 (month 12-30), the researchers will train and supervise three (n=3) Alzheimer's Society Dementia Advisers to deliver RE START TS to nine (n=9) Alzheimer's Society nominated family carers. The researchers will also train and supervise project researchers to deliver RE START SA to up to thirteen (n=13) family carers from South Asian backgrounds in English or in a South Asian Language. Alzheimer's Society Dementia Advisers and Carers, as well as family carers of relatives with dementia from South Asian backgrounds will be recruited as in Phase 1.

It is difficult to provide extensive detail regarding training, supervision and delivery procedures as these will be determined in large part by Phase 1 results. However, procedures are likely to be some variation of those followed in previous studies in which START has been delivered. The original START intervention is designed to be delivered in eight sessions over 8-14 weeks. The intervention is delivered where the carer prefers, usually at their home. The sessions cover (1) Introduction: Learning about dementia, carer stress and understanding behaviours of the person cared for; (2–6) Discussion of problems that the carer finds difficult, incorporating behavioural management
techniques; skills to take better care of themselves, including changing unhelpful thoughts, assertive communication, relaxation and planning pleasant activities; increasing communication; promoting acceptance; where to get emotional support and positive reframing; (7) Future needs of the patient, with psychoeducation about care and legal planning, specifically adapted to the UK; (8) Maintaining the skills learned over time. Carers are given homework tasks to complete between sessions, including identifying triggers and reactions to challenging behaviours, and identifying and challenging negative thoughts.

Training of Dementia Advisers and researchers to deliver the intervention will likely be delivered over two (2) days and contain a strong practical focus on how to deliver the intervention,

potential clinical dilemmas, empathic listening skills, effective use of supervision, safe working practice and when to ask for help. The researchers will train participants to adhere to the manual; they will be asked to demonstrate, by role-play, competence in delivering each session of the intervention. Following training, formal clinical supervision will begin. Our clinical psychologist, PR, will likely meet with Dementia Advisers and researchers separately for 1.5 hours of group supervision a fortnight. In addition to this group supervision, PR will be available for individual supervision. The supervision format will be tailored to reflect the specific needs of the research project. Supervision will perform a number of functions including case management, clinical skills development, monitoring the fidelity to the manualised intervention, ensuring safe practice with clients and staff support.

In Phase 3, Iain Lang (University of Exeter) will lead the evaluation using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) implementation framework to assess the impact of the intervention incorporating qualitative and quantitative information. To monitor fidelity to the manualised intervention, facilitators will record one session per family carer. Quantitative measures (see below) will be administered to carers prior to the intervention, immediately after the intervention and at one year. Follow up with Phase 2 participants will also include interviews about the intervention immediately after using the RE-AIM evaluation framework as a guide.

The researchers will use validated standardised quantitative measures to inform the evaluation (and see if the changes are those expected from the original study) administered to carers prior to the intervention, i.e., at Baseline (B), immediately after the intervention (T1) and at one year (T2). Quantitative measures will include:
1. The Hospital Anxiety and Depression Scale (HADS), a validated, reliable measure to measure mood in carers
2. The carer Health Status Questionnaire (HSQ), a 12 item health-related quality of life scale
3. The widely used Client Receipt Services Inventory (CSRI), to measure the service use consequences for the carer and the relative with dementia

Intervention Type
Other

Primary outcome measure
At baseline (B), immediately after the intervention (T1) and at one year (T2):
1. The Hospital Anxiety and Depression Scale (HADS), a validated, reliable measure to measure mood in carers
2. The carer Health Status Questionnaire (HSQ), a 12 item health-related quality of life scale
3. The widely used Client Receipt Services Inventory (CSRI), to measure the service use consequences for the carer and the relative with dementia

Secondary outcome measures
None

Overall study start date
01/11/2017

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Family carers of relatives with dementia
2. 18 years or over
3. Providing care or support (or having done so in the past) to a relative with dementia
4. Willing to provide informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 95; UK Sample Size: 95

Key exclusion criteria
None

Date of first enrolment
19/03/2018

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
Division of Psychiatry
149 Tottenham Court Road
London
United Kingdom
WC1 7TF

Study participating centre

Camden and Islington NHS Foundation Trust
4th Floor, East Wing
St Pancras Hospital
4 St Pancras Way
London
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Study participating centre
Alzheimer's Society
43 - 44 Crutched Friars
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Study participating centre
University of Bradford
The Centre for Applied Dementia Studies
Faculty of Health Studies
Richmond Road
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website

http://www.ucl.ac.uk/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
Alzheimer's Society

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

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

Intention to publish date
16/01/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1	17/12/2020	06/10/2022	No	No
Results article		02/06/2021	17/01/2023	Yes	No

Results article	09/01/2023	17/01/2023	Yes	No
HRA research summary		28/06/2023	No	No