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CareCoach Feasibility trial – part of the CareCoach programme: adapting and testing an intervention for carers of people with dementia

Submission date
12/08/2022

Recruitment status
No longer recruiting

Registration date
18/11/2022

Overall study status
Completed

Last Edited
21/11/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Family and informal carers are the main source of support and care for people with dementia. Such carers need to have information and skills to manage and support the day-to-day care they give to the person with dementia. Attention to the carer's own wellbeing can have positive benefits to the carer and the person with dementia. We have taken a promising online intervention developed in the Netherlands, called 'Partner in Balance' (PiB), and adapted this to the UK setting to produce the 'CareCoach intervention' package. This is a package of online resources and tips to help carers with the support of a coach to help guide and support carers. The aim of this study is to run a small study of the CareCoach intervention to see if a larger randomised controlled trial is feasible. The main objectives are to test the procedures to identify and recruit carers of people with dementia, test the procedures for collecting outcome data and to see how well we can deliver the CareCoach intervention.

Who can participate?
Participants will be adults (18 years or over) who are currently caring for a person with dementia (all subtypes, diagnosed within the last 5 years). They may be a family member or close friend of the person with dementia. They need to have a spoken understanding of English (with the help of family translators if required). As this is an online intervention, they must have access to internet via a computer, laptop, tablet, iPad or mobile phone with internet capability. If the person with dementia currently lives in a care home, then this intervention would not be suitable for them.
We aim to recruit 42 carers from 7 sites across England and Wales.

What does the study involve?
We will compare the CareCoach intervention with current care as usual (control group). After consenting to the study, approximately half the Carer participants will be randomly assigned to the CareCoach intervention or and the other half will continue usual care. Those in the CareCoach intervention group will be given a personal login and have access to the CareCoach online resources and a coach for 8 weeks who will encourage the participant to work through several of the CareCoach modules. After 8 weeks, CareCoach participants may continue to have

access to the online resources but not the coach. At 6 months, we will ask all participants a series of questions about their health, wellbeing, use of health resources and the person with dementia's health and wellbeing.
A small number of participants will be asked to take part in an interview study to find out their views and experiences of being part of this study.

What are the possible benefits and risks of participating
The possible benefits of taking part are that some participants may enjoy taking part in research and may find some benefit of the intervention or talking about their situation. The risks are that it may take up some of their time and could raise sensitive issues or anxieties around the person with dementia that they care for.

Where is the study run from?
The study is run from the Norwich Clinical Trials Unit, based at the University of East Anglia, UK. The University of Exeter is sponsoring the whole programme of research.

When is the study starting and how long is it expected to run for?
August 2021 to December 2024

Who is funding the study?
The study is funded as part of the programme grant from the National Institute for Health and Care Research, UK. (PGfAR NIHR201076)

Who is the main contact?
1. Dr Helen Morse, carecoach@uea.ac.uk
2. Prof. Chris Fox, christopher.fox@exeter.ac.uk

Study website
https://carecoachtimes.org/

Contact information

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
316710

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS316710

Study information

Scientific Title
CareCoachWP3 - A feasibility trial to assess the design and deliverability of a multi-centre randomised controlled trial of the CareCoach package, part of the CareCoach programme: adapting and testing an intervention for carers of people with dementia

Acronym
CareCoachWP3

Study objectives
It is feasible to run a full scale randomised controlled trial to test the effectiveness of the CareCoach intervention package?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/11/2022, North West Greater Manchester East Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 2071048199; gmeast.rec@hra.nhs.uk), ref: 22/NW/0293

Study design
Mixed methods multicentre randomized controlled trial feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

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
The well-being of carers of people with dementia

Interventions
Participants will be randomised by a computer generated randomisation scheme on an individual participant level (1:1) stratified by site. They will be allocated to the CareCoach intervention group or control arm.
CareCoach intervention – This group will be given access to an online self-management CareCoach programme comprising an 8 week course of up to 9 modules with 1-to-1 support from a coach. The coach will arrange at least two meetings with them (at the start and end of the 8 week course) and may be available for additional brief meetings or on the message

function of the programme at other times. After 8 weeks, the participants will continue to have access to the online materials, but not to the coach.
The usual care/control group – This will be care as usual as per NICE guidance. This may include carer support groups or information leaflets provided by the Trust or other organisations.
Both groups will be asked to complete follow up questionnaires (paper or online) at 6 months post randomisation.

Intervention Type
Behavioural

Primary outcome measure
1. The recruitment rate will be recorded as the number of eligible participants who consented to participate in the study over the 6 month recruitment period.
2. The attrition rate will be recorded as the number of eligible participants who consented to participate in the study but had not completed the final 6 month follow-up measures.

Secondary outcome measures
Measured at baseline and 6 months:
1. The Caregiver Self-Efficacy Scale (CSES)
2. The Pearlin Mastery Scale (PMS)
3. The Perceived Stress Scale (PSS)
4. The Centre for Epidemiological Studies Depression scale (CES-D)
5. The Generalised Anxiety Disorder 7-item scale (GAD-7)
6. Scale measuring the Impact of DEmentia on CARers (SIDECAR-D)
7. Modified Client Service Receipt Inventory (CSRI)
8. EuroQol Health Related Quality of Life (EQ-5D-5L)
9. Patient Health Questionnaire (PHQ-9).
10. The Goal Attainment Scaling (GAS, intervention only)
Carer proxy rating of the person with Dementia:
11. Neuropsychiatric Inventory (NPI-Q)
12. Proxy EuroQol Health Related Quality of Life (EQ-5D-5L)
13. A small subset of participants will be interviewed and qualitative data will assess whether the intervention is perceived as acceptable to participants.

Overall study start date
01/08/2021

Completion date
31/05/2024

Eligibility

Key inclusion criteria
1. Aged 18 years old or above
2. Spoken understanding of the English language (with the help of family translators if required)
3. Currently caring for a person with dementia (all subtypes, diagnosed within the last 5 years)
4. Has a first-degree relationship (spouse/partner, sibling, son or daughter) with a person with dementia; OR must have a close personal relationship with a person with dementia (e.g. in-law family member, close friend or neighbour)

5. Has capacity to give informed consent to participate;
6. Has access to the internet (via a home computer/laptop, iPad/tablet or mobile phone with internet capability)

Participant type(s)
Carer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
42

Total final enrolment
42

Key exclusion criteria
1. Potential participants with insufficient cognitive abilities to engage in the online programme
2. Overburdened, as determined by study staff.
3. If the person with dementia they care for currently resides in a care home

Date of first enrolment
19/06/2023

Date of final enrolment
19/10/2023

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Norfolk and Suffolk NHS Foundation Trust
Hellesdon Hospital
Drayton High Road
Norwich
United Kingdom
NR6 5BE

Study participating centre
North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
United Kingdom
RM13 8GQ

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter
United Kingdom
EX2 5AF

Study participating centre
Solent NHS Trust
Solent NHS Trust Headquarters
Highpoint Venue
Bursledon Road
Southampton
United Kingdom
SO19 8BR

Study participating centre
Nottinghamshire Healthcare NHS Foundation Trust
Highbury Hospital
Nottingham
United Kingdom
NG6 9DR

Study participating centre
Bradford District Care Trust
Lynfield Mount Hospital
Heights Lane
Bradford
United Kingdom
BD9 6DP

Study participating centre
RICE - The Research Institute for the Care of Older People
The RICE Centre
Royal United Hospital
Combe Park
Bath
United Kingdom
BA1 3NG

Sponsor information

Organisation
University of Exeter

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Sponsor type
University/education

Website
http://www.exeter.ac.uk/

ROR
https://ror.org/03yghzc09

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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
Given that this is a feasibility study, the results of this trial will inform the study processes and outcome measures of a definitive RCT (CareCoachWP4). The results of the wider programme will be disseminated regardless of the direction of effect. We will inform professionals through academic and professional journals, conferences, events, and social media. Participants taking part in the study may be sent a newsletter and can be kept informed about the study by accessing our study website and social media.

Intention to publish date
30/12/2027

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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?
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 1.0	11/05/2024	15/05/2024	No	No
Results article		22/05/2024	23/05/2024	Yes	No
Statistical Analysis Plan	version 2.0	07/11/2024	21/11/2024	No	No