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CareCoach Study: Testing the clinical and cost-effectiveness of an online support package (CareCoach) for family carers of people living with dementia

Submission date
18/11/2024

Recruitment status
No longer recruiting

Registration date
27/01/2025

Overall study status
Ongoing

Last Edited
22/04/2026

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
People who care for those living with dementia (carers or caregivers) need information and skills to manage daily care. This study aims to test the effects of an online support package called CareCoach. We want to see if CareCoach improves carers' ability to care, their mood, and quality of life. This study is part of the larger CareCoach Research Programme and follows a successful pilot study. We aim to recruit 404 family carers for this trial.

Who can participate?
Family carers of people living with dementia who are 18 years or older, living in the UK, and have access to a device with a camera and microphone connected to the internet.

What does the study involve?
Participants will be randomly assigned to either the CareCoach group or a control group that receives usual care. Those in the CareCoach group will use the online platform and receive support from a coach for 8 weeks. All participants will complete questionnaires online or by post at the start, 10 weeks, and 6 months into the study. Recruitment will be through various channels including social media, community groups, and charities. There will also be group discussions and interviews to explore experiences with CareCoach.

What are the possible benefits and risks of participating?
Participants may benefit from improved caregiving skills, mood, and quality of life. There are minimal risks, but some may find the questionnaires or discussions time-consuming or emotionally challenging.

Where is the study run from?
The study is run from the University of Exeter (UK).

When is the study starting and how long is it expected to run for?
December 2023 to January 2027.

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
carecoach@uea.ac.uk
Christopher.Fox@exeter.ac.uk
j.cross@uea.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Helen Morse

Contact details
Norwich Clinical Trials Unit
Norwich Medical School
University of East Anglia
Norwich
United Kingdom
NR4 7TJ
+44 1603 591120
carecoach@uea.ac.uk

Type(s)
Principal investigator

Contact name
Prof Christopher Fox

ORCID ID
https://orcid.org/0000-0001-9480-5704

Contact details
College of Medicine & Health
St Luke’s Campus
Heavitree Road
Exeter
United Kingdom
EX1 2HZ
+44 7411 746549
Christopher.Fox@exeter.ac.uk

Type(s)
Scientific

Contact name
Dr Jane Cross

ORCID ID
https://orcid.org/0000-0002-7003-1916

Contact details
School of Health Sciences
University of East Anglia
Norwich
United Kingdom
NR4 7TJ
+44 1603593315
j.cross@uea.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
338454

Central Portfolio Management System (CPMS)
61261

National Institute for Health and Care Research (NIHR)
201076

Protocol serial number
PGfAR

Study information

Scientific Title
CareCoach Study: Testing the clinical and cost-effectiveness of CareCoach for family carers of people living with dementia.

Study objectives
Testing the clinical and cost-effectiveness of using a blended care (e-health, one-to-one coaching) intervention (CareCoach) for family carers of people living with dementia compared to usual care.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/12/2024, North West - Greater Manchester East Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 207 104 8077; gmeast.rec@hra.nhs.uk), ref: 24/NW/0376

Study design

Multicentre mixed-methods two-armed parallel group (intervention vs control) randomized controlled trial with health economic evaluation and embedded qualitative sub-study (implementation and carer experience evaluation)

Primary study design
Interventional

Study type(s)
Efficacy, Quality of life

Health condition(s) or problem(s) studied
Family carers/caregivers of people living with dementia

Interventions
Randomisation to treatment arm will take place after consent and baseline data have been collected. The randomisation scheme will be computer-generated by the Clinical Trials Unit data manager. This will be an individually randomised trial. Randomisation will be stratified by recruiting site, age (<65 years vs ≥65 years), and relationship to the person living with dementia (e.g. spouse/partner versus all others). Randomisation will be blocked with random block lengths of either 2, 4 or 6.

Intervention Arm:
In addition to standard care, participants will be allocated a 'coach' (health, social care or dementia charity worker) and given a personal login to the CareCoach platform which is an online self-management programme where participants work through up to four learning modules. After an initial meeting with the coach (e.g., via video call), carers will use CareCoach for 8 weeks. They can consult with the coach throughout this period for guidance via the messaging function within the CareCoach platform. At the end of the 8-week course, the participant has a final review meeting with the coach.

Control (Usual Care):
Standard care provided by NHS and non-NHS organisations as per NICE guidance including advice from dementia services (e.g. memory clinics) and carer support (e.g. groups, leaflets from NHS Trust, Dementia UK, Alzheimer's Society, signpost to local authority carer forums, and carer counselling). Participants in the control group will be offered access to the CareCoach online resources for 6 months following the end of the study.

Intervention Type
Behavioural

Primary outcome(s)
Carer self-efficacy symptom management in the Caregiver Self-Efficacy Scale (CSES) at 6 months post-randomisation

Key secondary outcome(s))
Clinical outcomes (carers only):
1. Self-efficacy for symptom management is measured using CSES at 10 weeks post-randomisation
2. Self-efficacy for community support service use is measured using CSES at baseline, 10 weeks post-randomisation, and 6 months post-randomisation

3. Mastery is measured using the Pearlin Mastery Scale (PMS) at baseline, 10 weeks post-randomisation, and 6 months post-randomisation
4. Impact of dementia on carers is measured using SIDECAR-D at baseline, 10 weeks post-randomisation, and 6 months post-randomisation
5. Perceived stress is measured using the Perceived Stress Scale (PSS) at baseline, 10 weeks post-randomisation, and 6 months post-randomisation
6. Anxiety is measured using the Generalised Anxiety Disorder Scale (GAD-7) at baseline, 10 weeks post-randomisation, and 6 months post-randomisation
7. Depression is measured using the Patient Health Questionnaire (PHQ-9) at baseline, 10 weeks post-randomisation, and 6 months post-randomisation
8. Health-related quality of life is measured using EQ-5D-5L at baseline, 10 weeks post-randomisation, and 6 months post-randomisation

Cost-effectiveness outcomes:
9. Carer-rated proxy health-related quality of life of the person living with dementia is measured using EQ-5D-5L at baseline, 10 weeks post-randomisation, and 6 months post-randomisation
10. Service use is measured using the Modified Client Service Receipt Inventory (CSRI) at baseline and 6 months post-randomisation

Completion date
31/01/2027

Eligibility

Key inclusion criteria
1. Currently care/support (e.g., informally, unpaid*) for a person living with dementia (may be a partner, family member, in-law, close friend or neighbour)
2. The person living with dementia (all subtypes) has been diagnosed within the last 5 years
3. 18 years or over
4. Living in the UK
5. Access to a device with a camera and microphone which connects to the internet (e.g., laptop, tablet, smartphone)
6. Seeking to learn new skills and knowledge to cope well while caring for a person living with dementia
7. Able to engage in and understand the programme delivered in English (with the help of a family interpreter if required)
*Family carers claiming carer's allowance are not excluded

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit

100 years

Sex
All

Total final enrolment
404

Key exclusion criteria
1. Potential participants with insufficient cognitive abilities to engage with the online programme
2. Potential participants who report feeling overburdened
3. The person living with dementia currently resides in a care home
4. Taking part or recently taken part in a research study using a similar behaviour change or psychological intervention
5. Taken part in CareCoach (Work Package 3) feasibility study (ISRCTN12540555)
6. Is a paid, professional carer

Multiple members of the same family (e.g., individuals caring for the same person living with dementia) should not sign up for the trial to avoid potential contamination between groups

Date of first enrolment
31/01/2025

Date of final enrolment
21/04/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of East Anglia
Norwich Research Park
Earlham Road
Norwich
England
NR4 7TJ

Sponsor information

Organisation

University of Exeter

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

Individual participant data (IPD) sharing plan
A formal data-sharing plan for this trial is not yet available. Requests for access to trial data will be considered, and approved in writing where appropriate, after formal application to the Programme Management Group and/or Programme Steering Committee.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes