Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

Funded by NIHR | National Institute for Health and Care Research

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

Statistical Analysis Plan (SAP)

Version 1.0

13/11/2026

Authors and approvers	Title	Signature	Date
Prof Jane Cross	Chief Investigator	Signed by: Jane Cross C309D4668CC94B8...	16 November 2026
Prof Chris Fox	Chief Investigator	Signed by: 9E84F9F9D9D644A...	16 November 2026
Prof Allan Clark	Lead statistician	Signed by: Allan Clark AC8ACE6AEBA34CA...	19 November 2026
Dr Ramesh Vishwakarma	Statistician	Signed by: Ramesh Vishwakarma 3ACB7E28D7494E2...	16 November 2026
Dr Helen Morse	Trial Manager	DocuSigned by: 3A34FBACF1FA4FD...	16 November 2026

SAP REVISION HISTORY

Document Name	Version No.	Reason for Revision	Effective Date
SAP	1.0		

This statistical analysis plan relates specifically to Work Package 4 of the wider CareCoach Programme, which will evaluate the full-scale randomised controlled trial of the CareCoach intervention for carers of people living with dementia in the UK.

PURPOSE: The Statistical Analysis Plan (SAP) is consistent with the guidance provided by Gamble et al., *Guidelines for the Content of Statistical Analysis Plans in Clinical Trials*, JAMA;2017:318;2337-2343. It provides details of the analyses to be carried out for this study prior to any analyses being performed.

RESPONSIBILITY: The Trial Statistician is responsible for the writing and maintenance of the SAP but may delegate responsibilities to other, appropriate, team members. The plan should be written in collaboration with the Chief Investigators and Trial Manager all of whom should approve the plan.

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

Contents

1.0 Administrative Information 4
2.0 Abbreviations 5
3.0 Introduction 6
3.1 Background and rationale 6
3.2 Objectives 6
4.0 Study Methods 6
4.1 Trial Design 6
4.2 Allocation and concealment mechanism 8
4.3 Blinding 8
4.4 Sample Size 8
4.5 Internal pilot 8
4.6 Interim analyses and stopping guidance 9
4.7 Timing of outcome assessments 9
4.8 Timing of analyses 10
5.0 Statistical Principles 10
5.1 Levels of statistical significance 10
5.2 Treatment Adherence 10
5.3 Protocol deviations 11
5.4 Analysis populations 12
5.0 Trial Population 12
5.1 Screening data 12
5.2 Eligibility 12
5.2.1 Inclusion Criteria: 12
5.2.2 Exclusion criteria: 13
5.3 Recruitment and participant flow 13
5.4 Withdrawal information 13
5.5 Baseline participant characteristics 13
6. Analysis 14
6.1 Outcome definitions 14
6.2 Analysis Methods 19
6.2.1 Primary outcome model 19
6.2.1 Additional analysis 20

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

6.3 Missing Data....21
6.4 Deviations from planned analysis....21
6.5 Safety data....21
6.6 Software....22
7. Description of Tables and Figures....22
8. References....22
Appendix A....23
Appendix B....24

List of Figures

Figure 1:Study overview:....7
Figure A1: Consort Diagram....23

List of Tables

Table 1: Timing of outcome assessments....9
Table 2: Outcome measure scoring....15
Table B1: Deprivation Index Source....24

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

1.0 Administrative Information

Sponsor	University of Exeter
Sponsor Reference	23-24-36
Host	Norfolk & Suffolk NHS Foundation Trust - NSFT
UEA Reference	R208076
Trial Registration	ISRCTN15462720
NIHR/Funder reference	PGfAR NIHR201076
IRAS	338454
Chief Investigator	Professor Jane Cross Professor Chris Fox
Lead Statistician	Professor Allan Clark
Trial Statistician	Dr Ramesh Vishwakarma
UKCRC Trials Unit	Norwich CTU
Latest Protocol	V6.0 20/05/2026

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

2.0 Abbreviations

CI	Confidence Intervals
COVID-19	Coronavirus disease
CSES	The Caregiver Self-Efficacy Scale
CSRI	Adapted Modified Client Service Receipt Inventory
DMC	Data Monitoring Committee
EBCD	Experience Based Co-Design
EQ-5D-5L	EuroQol Health related quality of life
GAD-7	Generalised Anxiety Disorder Scale
IRAS	Integrated Research Application System
ITT	Intention-to-Treat
IQR	Interquartile Range
NCTU	Norwich Clinical Trials Unit
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute of Health Research
PHQ-9	Patient Health Questionnaire
PiB	Partner in Balance
PMS	The Pearlin Mastery Scale
PSS	The Perceived Stress Scale
SAP	Statistical Analysis Plan
SAS	Statistical Data Analysis Software
SIDECAR-D	Scale measuring the Impact of DEmentia on CARers
TIDE	Together In Dementia Everyday
UKCRC	UK Clinical Research Collaboration

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

3.0 Introduction

3.1 Background and rationale

People who care for those living with dementia (carers or caregivers) need information and skills to manage daily care. CareCoach is a co-designed self-management support package comprising of online learning resources and support from a trained coach over 8-weeks. This study aims to evaluate 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. A comprehensive introduction is provided in section 4.1 of the protocol.

3.2 Objectives

The overall trial objectives are provided in section 4.2 of the protocol; however this SAP covers the following:

- To evaluate the clinical effectiveness of CareCoach, compared with usual care, on carers' self-efficacy for symptom management, measured using the Symptom Management subscale of the Caregiver Self-Efficacy Scale (Fortinsky et al., 2002), at 6 months post-randomisation (primary outcome).
- To evaluate the clinical effectiveness of CareCoach, compared with usual care, on carers' self-efficacy for symptom management at 10 weeks post-randomisation.
- To evaluate the clinical effectiveness of CareCoach, compared with usual care, on carers' self-efficacy for community support, psychological well-being (anxiety, depression, and stress), mastery, and quality of life at 10 weeks and 6 months post-randomisation.

The health economic analysis is described separately in the Health Economic Analysis Plan (HEAP).

4.0 Study Methods

4.1 Trial Design

Multicentre, mixed-methods, two-armed parallel group RCT (intervention vs control) with health economic evaluation and embedded qualitative sub-study (implementation and carer experience evaluation). Participants are unpaid carers (e.g., spouses, relatives, friends) of people with dementia. Participants complete measures at three time points: baseline, 10 weeks and 6-months post-randomisation (see Figure 1). Participants were randomised to receive the CareCoach intervention for 8-weeks, plus usual care (intervention group) or usual care alone (control group).

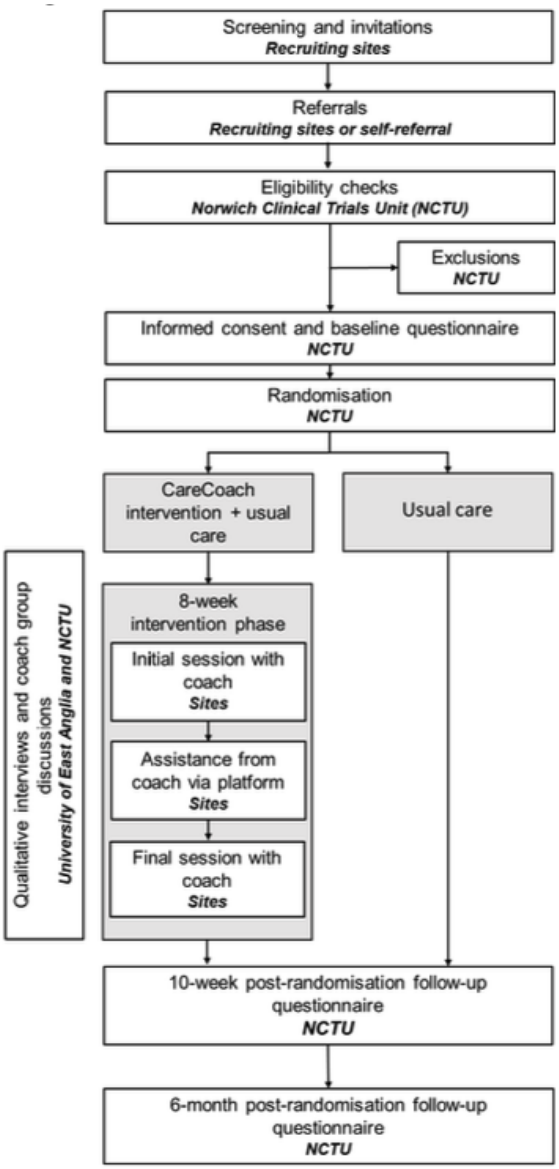
Intervention: CareCoach is a co-designed self-management package which combines online learning modules with coach support over 8-weeks. In addition to usual care, participants are allocated a 'coach' (health, social care or dementia charity worker) and given a personal login to the CareCoach platform. After an initial meeting with the coach (e.g., via video call), carers use CareCoach for 8-weeks. Carers consult with the coach throughout this period for guidance via

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

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.

Figure 1:Study overview:



Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

4.2 Allocation and concealment mechanism

Participants are randomised by the unblinded trial manager or trial assistant by telephone following consent and baseline data collection. The randomisation scheme is computer generated using REDCap, at the Norwich Clinical Trials Unit so will not be known prior to randomisation. Random block lengths of two, four and six are used. Participants are individually randomised (1:1 ratio) to the intervention arm or usual care, stratified by recruiting site, carer age (<65 v ≥65) and relationship to the person living with dementia (e.g. spouse/partner versus all others). Participants randomised to the intervention group are notified of their allocated coach who will then contact the participant and organise the initial session and provide login details for CareCoach.

4.3 Blinding

Due to the behavioural nature of the intervention, it is not possible to blind participants to group allocation. Delegated individuals at NCTU (e.g., a trial assistant) collecting follow-up data are blinded to group allocation. Permissions on the database are set so as to blind the person conducting follow-ups. There is no attempt to provide a 'sham' intervention as control.

4.4 Sample Size

The CareCoach target sample size is 404 participants (202 per group), based upon the symptom management sub-scale within the CSES (Fortinsky et al., 2002). Assuming a maximum 15% drop-out (11.9% was observed in the feasibility study), this sample size would provide 79% statistical power for an effect size of 0.3 standard deviations (a mean difference of 2.92 units); 90% statistical power for an effect size of 0.35 (a mean difference of 3.41); and 95% statistical power for an effect size of 0.4 (a mean difference of 3.90). From the feasibility study, an effect size of 0.30 was observed with an upper 95% confidence limit of 0.82 standard deviations.

4.5 Internal pilot

An internal pilot ran from study start (recruitment opens) until the point at which 20% of the target sample (n= 81) was expected to be enrolled (month 4). Data from this internal pilot phase was intended to be used to compare observed with expected recruitment, re-estimate drop-out rates and provide an estimate of data completion rates. Progression to the remaining study was dependent upon these data and stopping guidelines, which would be agreed with the trial oversight committees prior to commencement of the trial. The decision to continue was to be on advice from the DMC and rested with PSC.

The target was met (and exceeded); by month 4 (end of July 2025) 92 participants were enrolled in the study.

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

4.6 Interim analyses and stopping guidance

No formal interim analyses or stopping rules based upon efficacy were planned. A Data Monitoring Committee (DMC) made up an independent chair, clinician, and statistician review accumulating data on a 6 month basis.
The trial protocol stated that stopping/progression criteria would be defined prior to trial opening. These criteria were not formally established before recruitment began. However, the internal pilot recruitment target was achieved, and therefore progression criteria were not required to inform continuation of the study. This approach was discussed and agreed by the trial management team, and the Data Monitoring Committee (DMC) was informed of this decision.

4.7 Timing of outcome assessments

The table below presents the schedule of enrolment, interventions, and assessments.

Table 1: Timing of outcome assessments

	Enrolment	Baseline	Randomisation	Post-randomisation		
TIMEPOINT	t_{-1}	t_0	t_1	*8-week intervention phase*	*10 weeks (t_2)*	*6-months (t_3)*
ENROLMENT:						
Eligibility checks	X	X			X	X
Expression of interest	X					
Informed consent	X					
Allocation			X			
INTERVENTIONS:						
CareCoach Intervention				X		
Usual care/control group						
ASSESSMENTS:						
Demographic information		X				

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

CSES, PMS, SIDECAR-D, PSS, GAD-7, PHQ-9, EQ-5D-5L (+ proxy version), perseverance time		X			X	X
Modified CSRI		X				X
Implementation evaluation (e.g., coach interviews, group discussions, observations, carer interviews)		←	—	—	—	→

4.8 Timing of analyses

The analysis will be done once the database is locked and the SAP approved once all of the outcome data has been collected.

5.0 Statistical Principles

5.1 Levels of statistical significance

Statistical analyses will use a classical frequentist approach. Statistical significance will be set at the conventional two-sided 5% level. Confidence intervals will be of corresponding 95% size.

5.2 Treatment Adherence

The amount and type of contacts over the 8-week intervention was at the discretion of the carer, but at a minimum, carers must attend the initial and final session with the coach to have completed the intervention. Assessing adherence is a potential result of the study and will be assessed using the fidelity checklists completed by coaches delivering the trial intervention. The following data will be reported:

Intervention delivery

- Number and percentage of participants allocated to intervention who:
  - completed an initial coaching session
  - completed a final coaching session
  - completed both initial and final sessions
  - received no coaching sessions
- Time from randomisation to initial session:

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

- mean (SD), median (IQR), range

Session characteristics

Initial session

- Duration (mean [SD], median [IQR], range)
- Method of delivery:
  - video call, telephone, face-to-face
- Device used:
  - smartphone, tablet, laptop/computer

Final session

- Duration (mean [SD], median [IQR], range)
- Method of delivery
- Device used

Online assistance contacts

- Number of contacts
  - mean (SD), median (IQR), range
- Duration of contacts:
  - mean (SD), median (IQR), range

Intervention receipt / engagement

- Number and percentage selecting each module during the initial session
- Mean number of modules selected

5.3 Protocol deviations

All major deviations from protocol are recorded on REDCap.

Thirteen participants completed their 10-week follow-up questionnaire before completion of the intervention (NCR: 2025_NCR_067). In most cases, this occurred because the planned date of the final intervention session changed after scheduling of the follow-up questionnaire, and the updated session date was not entered into REDCap before the questionnaire was automatically issued. This deviation affected a small number of participants and does not affect the study primary endpoint. Consequently, no changes to the planned statistical analyses are required, and all affected participants remain included in the intention-to-treat analysis population.

Other NCRs affecting analysis will be flagged for the statisticians to consider before analysis (e.g. post-randomisation exclusions).

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

5.4 Analysis populations

All participants randomised to the study will represent the study population for analyses related to efficacy outcomes and follow-up. In the case of withdrawals, data already collected will be kept and included in analyses according to the intention to-treat principle for all participants who stop follow up early. An Intention-to-Treat (ITT) approach will be used when making group comparisons as an estimate of intervention effect.

5.0 Trial Population

5.1 Screening data

Recruitment sites were required to record anonymised screening data on a digital standardised screening log provided by NCTU. The screening log included a request for demographic data (if known) including sex, age, ethnicity, and relationship to person living with dementia. Screening data (i.e. eligibility checks) is also recorded on the database and required for every participant before joining the study.

Site screening logs were maintained for recruitment monitoring purposes. Owing to variation in recruitment methods across sites and the inclusion of individuals who were invited but not formally assessed for eligibility, screening log data will not be used to determine the number of individuals screened for the trial but will be reported. Such as, number of individuals approached (e.g. sent an invite), number of individuals declining, number ineligible, and reasons for ineligibility.

Formal screening and eligibility summaries will be based on data recorded within the REDCap trial database. The following data recorded on REDCap will be reported:

- Number assessed for eligibility (i.e. completed the screening questionnaire)
- Number eligible
- Number declining participation
- Number ineligible
- Reasons for ineligibility
- Number consented
- Number randomised
- Recruitment pathway (recruitment site, social media, etc.)

5.2 Eligibility

Participants were eligible for enrolment into the trial if they fulfil all the inclusion criteria and none of the exclusion criteria.

5.2.1 Inclusion Criteria:

- ≥ 18 years old;
- 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).

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

- The person living with dementia (all subtypes) has been diagnosed within the last 5 years.
- Living in the UK.
- Access to a device with a camera and microphone which connects to the internet (e.g., laptop, tablet, smartphone).
- Seeking to learn new skills and knowledge to cope well while caring for a person living with dementia.
- Able to engage in and understand the programme delivered in English (with the help of family interpreter if required).

*Individuals claiming carer's allowance were not excluded.

5.2.2 Exclusion criteria:

- Potential participants with insufficient cognitive abilities to engage with the online programme.
- Potential participants who report feeling overburdened.
- The person living with dementia currently resides in a care home.
- Taking part or recently taken part in research study using a similar behaviour change or psychological intervention.
- Taken part in CareCoach WP3 feasibility study.
- 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.

5.3 Recruitment and participant flow

Participant flow will be presented in the CONSORT flow diagram (Appendix A). A table and graph will present predicted versus actual recruitment for each month over the recruitment period.

5.4 Withdrawal information

The number and percentage of withdrawal and loss to follow-up, including reasons, will be grouped and reported by group at each time-point.

5.5 Baseline participant characteristics

The characteristics of all randomised participants at baseline will be compared between treatment group. No formal hypothesis testing will be carried out. Characteristics of randomised and non-randomised screened individuals will be summarised descriptively to assess the representativeness of the recruited sample. No formal statistical testing will be undertaken.

The following characteristics will be summarised using descriptive statistics:

- Demographic details.
    - Age (years)

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

    - Sex
    - Relationship to the person living with dementia
    - Educational qualification
    - Ethnicity
    - Employment status
    - Index of Multiple Deprivation score (using the participant's postcode; see Appendix B)
    - Type of dementia of the person they care for
    - Marital status
    - Number of children living with carer
    - Living with person with dementia
    - Number of carers involved in care
- Caregiver Self-Efficacy Scale (CSES)-Total score
    - CSES community support service use score
    - CSES symptom management score
- Pearlin Mastery Scale (PMS) total score
- SIDECAR-D total score
- Generalised Anxiety Disorder Assessment (GAD-7) total score and severity category
- Patient Health Questionnaire (PHQ-9) total score and severity category
- Perceived Stress Scale (PSS 14 items) total score
- Perseverance time category of response

6. Analysis

6.1 Outcome definitions

The following outcome efficacy variables are collected at 6-months follow-up.

- The Caregiver Self-Efficacy Scale (CSES)
- The Pearlin Mastery Scale (PMS)
- Scale measuring the Impact of DEmentia on CARers (SIDECAR-D)
- The Perceived Stress Scale (PSS-14)
- Generalised Anxiety Disorder Scale (GAD-7)
- Patient Health Questionnaire (PHQ-9)
- EuroQol Health related quality of life (EQ-5D-5L)
- Perseverance time

Carer proxy rating of the person with dementia:
• EuroQol Health related quality of life (Proxy EQ-5D-5L)

The scoring for each outcome measure is summarised in Table 1.

Table 2: Outcome measure scoring

Outcome variable	***Version number (if applicable)***	***Description of calculation required***	***Reference***	***Who has responsibility for calculation***
CSES		CSES symptom management (Q1, Q2, Q3, Q4, & Q6). Total score across 5 questions (ranges between 5 to 50). CSES community support (Q5, Q7, Q8 & Q9). Total score across 4 statements (ranges between 4 to 40). A higher total score indicates greater self-efficacy.	Fortinsky, Kercher & Burant (2002)	Score calculated by database. Trial Manager and Statistician provided calculation to database management team.
PMS		Sum scores for each statement for total score (ranges between 7 to 49). Scoring for items 4 and 6: strongly agree=4, agree=3, disagree=2, strongly disagree=1. Scoring for items 1, 2, 3, 5, 7 are reversed i.e., strongly agree=1, agree=2, disagree=3, strongly disagree=4. A higher total score indicates greater self-efficacy/mastery.	Pearlin & Schooler (1978)	Score calculated by database. Trial Manager and Statistician provided calculation to database management team.
PSS-14		Sum scores for each statement for total score (ranges between 0 to 56). Response scoring: 0=never; 1=almost never; 2=sometimes; 3=fairly often; 4=very often. Items 4, 5, 6, 7, 9, 10, and 13 are scored in reverse direction, i.e., 4=never; 3=almost never; 2=sometimes; 1=fairly often; 0=very often A higher total score indicates greater perceived stress.	Cohen, Kamarck & Mermelstein (1983)	Score calculated by database. Trial Manager and Statistician provided calculation to database management team.
GAD-7		Sum scores for each statement for total score (ranges between 0 to 21). Each item scored: not sure at all = 0, several days = 1. Over half the days = 2, nearly every day = 3. Higher score indicating greater severity of anxiety.	Spitzer, Kroenke, Williams & Lowe (2006)	Score calculated by database. Trial Manager and Statistician provided calculation to database management team.
SIDECAR-D		Sum scores for each statement for total score (ranges between 0 to 18). Statements are scored 1 for each	Horton et al. (2020)	Score calculated by database.

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

<table>
<tr>
<td></td>
<td></td>
<td>'Agree' response and 0 for each 'Disagree' response.

In the case of COMPLETE data, a 0-100 linear score transformation is available for each of the SIDECAR scales, as below. *Please note that this transformation is only valid when ALL items within a scale have responses.

<table>
<tr><th colspan="2">SIDECAR D</th></tr>
<tr><th>Raw Score</th><th>0-100 Score</th></tr>
<tr><td>0</td><td>0</td></tr>
<tr><td>1</td><td>11</td></tr>
<tr><td>2</td><td>19</td></tr>
<tr><td>3</td><td>25</td></tr>
<tr><td>4</td><td>30</td></tr>
<tr><td>5</td><td>34</td></tr>
<tr><td>6</td><td>38</td></tr>
<tr><td>7</td><td>42</td></tr>
<tr><td>8</td><td>46</td></tr>
<tr><td>9</td><td>49</td></tr>
<tr><td>10</td><td>53</td></tr>
<tr><td>11</td><td>56</td></tr>
<tr><td>12</td><td>60</td></tr>
<tr><td>13</td><td>64</td></tr>
<tr><td>14</td><td>68</td></tr>
<tr><td>15</td><td>73</td></tr>
<tr><td>16</td><td>79</td></tr>
<tr><td>17</td><td>88</td></tr>
<tr><td>18</td><td>100</td></tr>
</table>
A higher total score indicates a poorer quality of life.</td>
<td></td>
<td>Trial Manager and Statistician provided calculation to database management team.</td>
</tr>
<tr>
<td>EQ-5D-5L</td>
<td>Paper: V1.2

REDCap: v2.0</td>
<td>1. EQ-5D descriptive system. Sum scores for each statement for total score (ranges between 5 to 25). Each statement is scored according to levels of perceived problems, coded as: I have no problems = 1; I have slight problems = 2, I have moderate problems = 3, I have severe problems = 4, I am unable to = 5.

Can report frequency of each level reported (e.g., X% reported Level 1), or dichotomise the levels into 'problems' (i.e. level 1) and 'problems' (i.e., levels 2 to 5) and reporting frequency of reported problems (source: https://www.unmc.edu/centric/_documents/EQ-5D-5L.pdf).

2. EQ visual analogue scale. Report number entered by</td>
<td>The EuroQol Group (1990)</td>
<td>Score calculated by database. Scoring provided by authors and applied to REDCap.</td>
</tr>
</table>

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

		participant on scale of 0-100 (0 worst & 100 best health). Present both a measure of the central tendency and a measure of dispersion (mean and SD, or if skewed, median and 25th, 75th percentiles; source: https://www.unmc.edu/centric/_documents/EQ-5D-5L.pdf).		
PHQ-9		Sum responses for each statement for total score. Each statement is scored 0 to 3: not at all = 0, several days = 1, more than half the days = 2, nearly every day = 3. Total scores range from 0 to 27. Depression severity cut points: total scores = 5 (mild), 10 (moderate), 15 (moderately severe), and 20 (severe depression).	Kroenke, Spitzer and Williams (2001)	Score calculated by database. Trial Manager and Statistician provided calculation to database management team.
Perseverance time		Perseverance time is a single-item question to the informal caregiver "If the informal care situation stays as it is now, how long will you be able to cope with the care?" with ordinal answer categories: less than one week; more than one week, but less than one month; more than one month, but less than six months; more than six months, but less than one year; more than one year, but less than two years; more than two years. No total score is calculated. The outcome score is equal to the response category selected by the informal carer, ranging from 1 to 6, where 1 indicates the shortest expected ability to cope and 6 indicates the longest expected ability to cope. Perseverance time in months is determined by taking the middle of the category in the first five answer categories (for example 3.5 months for the category 'more than one month, but less than 6 months') and was arbitrarily set at 30 months in the (open-ended) sixth category 'more than two years'. Higher scores indicate a more favourable outcome	Kraijo et all (2013)	No calculation required; single-item ordinal outcome.
EQ-5D-5L proxy	*Paper: V1.5* *REDCap: v1.0*	1. EQ-5D descriptive system. Each statement (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) is scored	The EuroQol Group (1990)	Score calculated by database. Scoring provided by authors

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

		according to levels of perceived problems, coded as: No problems = 1; Slight problems = 2, Moderate problems = 3, Severe problems = 4, Unable to = 5. There should be only ONE response for each dimension. *2.* Includes a scale where the carer rates the person living with dementia's health on a scale from 0 (worst) to 100 (best health).		and applied to REDCap.

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

6.2 Analysis Methods

All analyses will be conducted according to the intention-to-treat principle. Participants will be analysed according to their randomised treatment allocation, irrespective of adherence to or receipt of the allocated intervention. For each outcome, the analysis population will include all randomised participants with the relevant outcome data available at the specified follow-up time point.

6.2.1 Primary outcome model

The primary analysis will use a linear mixed-effects model with the 6-month (CSES) score as the dependent variable. The model will include independent variables treatment arm (intervention/control), baseline CSES symptom management score (continuous), carer age group (<65 years versus ≥65 years), and relationship to the person living with dementia (spouse/partner versus all others) as fixed effects and recruiting site as a random intercept. The control group will be the reference category.

The model will be estimated using the maximum likelihood method. The contribution of the random effect for recruiting site will be assessed using a likelihood ratio test comparing the mixed-effects model with the corresponding fixed-effects model without the random site effect. If the random effect does not make a statistically significant contribution to improvement in model fit it will be omitted, unless, the mixed-effects model fails to converge or produces unstable variance estimates as then sites contributing less than 5% of the total study recruitment may be combined with other sites, provided that the grouping is clinically justified. The model will then be refitted using the grouped site as random factor.

Parameter estimates will be presented with 95% confidence intervals and corresponding p-values. Statistical significance will be set at the 5% level using two-sided tests.

The assumptions of the model will be assessed using appropriate diagnostic checks. The distribution of residuals will be assessed visually using residual plots and normal quantile-quantile plots, and with reference to relevant summary statistics, such as the skewness statistic. Homogeneity of residual variance will be assessed using plots of residuals against fitted values and by treatment group. If residuals from the model show substantial departure from normality, appropriate transformations of the outcome data will be considered, for example a logarithmic transformation in the case of a positively skewed distribution. If transformation does not adequately address these departures, a non-parametric bootstrap approach will be considered to obtain confidence intervals for the estimated treatment effect. Results from any transformed or bootstrap analysis will be considered alongside the original-scale analysis to facilitate clinical interpretation.

The analyses of secondary continuous outcomes will follow an analogous approach. The secondary outcomes to be analysed using this framework at 10 weeks and 6-months include the CSES community support service use, PMS, PSS-14, GAD-7, SIDECAR-D, and PHQ-9. For each outcome, an appropriate linear mixed-effects model will be fitted with the follow-up outcome score as the dependent variable. The model will include treatment arm, the corresponding baseline

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

outcome score where available, carer age group, and relationship to the person living with dementia as fixed effects and recruiting site as a random intercept. If the random site effect does not contribute significantly to model fit, or if the model fails to converge, the model may be reduced to a standard multiple linear regression model.

For each secondary continuous outcome, the parameter estimates will be presented with 95% confidence intervals and corresponding p-values.

EQ-5D-5L responses will also be summarised descriptively by dimension and severity level using frequencies and percentages. The detailed analysis of this outcome will be included in Health Economics analysis plan (HEAP).

Perseverance time outcome will be analysed as an ordered categorical outcome. The response will be scored from 1 to 6, with higher scores indicating longer expected ability to continue caregiving. No total score will be calculated because perseverance time is a single-item measure. The main analysis will use an ordinal logistic regression model with treatment arm, baseline perseverance time where available, carer age group, relationship to the person living with dementia, and recruiting site included in the model. Where feasible, recruiting site will be included as a random effect. If the mixed-effects model fails to converge or produces unstable variance estimates, sites contributing less than 5% of the total study recruitment may be combined with other sites, provided that the grouping is clinically justified. The model will then be refitted using the grouped site as random factor.

The treatment effect for perseverance time will be reported as a common odds ratio with a 95% confidence interval and p-value. The proportional odds assumption will be assessed using the Brant test. A statistically significant Brant test ($p<0.05$) will be considered evidence of a potential violation of the proportional odds assumption.

If this assumption is not considered reasonable, Van Elteren test or binary logistic regression may be used as an alternative approach. Any dichotomisation threshold will be decided by blinded team.

Sensitivity analyses will be conducted to assess the robustness of the primary and key secondary outcome findings.

6.2.1 Additional analysis

Change in caring status (defined as no longer caring for a person with dementia and/or the person with dementia moving into a care home) will be summarised descriptively by treatment group at each follow-up time point. A sensitivity analysis of the primary outcome will be conducted excluding participants who report a change in caring status by the 6-month follow-up.

No exploratory analyses investigating predictors of outcome (e.g. participant characteristics, intervention engagement, or other factors associated with outcomes) are planned as part of this statistical analysis plan. Any such analyses may be undertaken separately as secondary analyses under a separate analysis plan.

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

Should any other additional statistical analyses be required during the final analysis, appropriate methods will be used, and any changes, including the rationale for use, will be documented in the clinical study report and/or manuscript.

6.3 Missing Data

All efforts to avoid missing data will be made. For both the primary and secondary outcomes the extent and possible patterns of missing data will be checked. The relationship between baseline variables and missing primary outcome data will be examined.

If the proportion of missing primary outcome data is between 5% and 50%, a sensitivity analysis using multiple imputation under the Missing At Random (MAR) assumption will be performed to assess the robustness of the primary analysis findings. The imputation model will include treatment arm, baseline CSES symptom management score, baseline score of all applicable secondary endpoints, carer age group (<65 years versus ≥65 years), and relationship to the person living with dementia (spouse/partner versus all others). Additional baseline characteristics associated with the outcome or missingness will also be considered. Where available, outcome measurements from other follow-up time points will be included in the imputation model to improve the estimation of missing values.

The imputed datasets will be analysed using the prespecified primary analysis model, and treatment effect estimates will be combined using Rubin's rules. The results will be compared with those from the primary analysis to assess the robustness of the findings.

The secondary endpoints may be imputed in similar fashion.

Where repeated outcome measurements are available, a linear mixed model for repeated measurements may also be used as a supplementary analysis, incorporating all available observations across assessment time points. Missing data for secondary outcomes will be described, and the need for additional sensitivity analyses will be considered according to the extent and patterns of missingness.

6.4 Deviations from planned analysis

Should any additional statistical analyses be required during the final analysis, appropriate methods will be used, and any changes, including the rationale for use, will be documented in the clinical study report and/or manuscript.

6.5 Safety data

Only descriptive analysis of the SAE and non-SAE incidents will be reported. Reports of SAEs will include the date reported, data of onset, description, date of resolution, related to trial intervention, and randomisation group. Non-SAE incidents will be reported descriptively, such as the time-point reported (e.g. baseline, 10-week, 6-months post-randomisation) and incident type (e.g. severe mood scores).

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

6.6 Software

The majority of analysis will be performed using SAS® Software version 9.4, but other software may be used as required.

7. Description of Tables and Figures

All raw data will be presented to the original number of decimal places. The mean and standard deviation will be presented with to 2 decimal places or 3 significant figures depending upon the nature of the data. Percentages will be presented into 1 decimal place. All categories of variables will be presented even if there is no data. Blank cells, were data are not expected, will be filled by "-" in reporting of results.

Precision of p-values will be 3 decimal places, i.e. p-values less than 0.001 will be presented as <0.001 and if equal to 1 then ≥ 0.999.

8. References

Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav*. 1983;24(4):385-96.

Fortinsky RH, Kercher K, Burant CJ. Measurement and correlates of family caregiver self-efficacy for managing dementia. *Aging Ment Health*. 2002;6(2):153-60.

Horton MC, Oyebode J, Clare L, Megson M, Shearsmith L, Brayne C, et al. Measuring quality of life in carers of people with dementia: development and psychometric evaluation of Scales measuring the Impact of DEmentia on CARers (SIDECAR). *Gerontologist*. 2021;61(3):e1-e11.

Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity measure. *J Gen Intern Med*. 2001;16(9):606-13.

Pearlin LI, Schooler C. The structure of coping. *J Health Soc Behav*. 1978;19(1):2-21.

Spitzer RL, Kroenke K, Williams JBW, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. *Arch Intern Med*. 2006;166(10):1092-7.

The EuroQol Group. EuroQol: a new facility for the measurement of health-related quality of life. *Health Policy*. 1990;16(3):199-208.

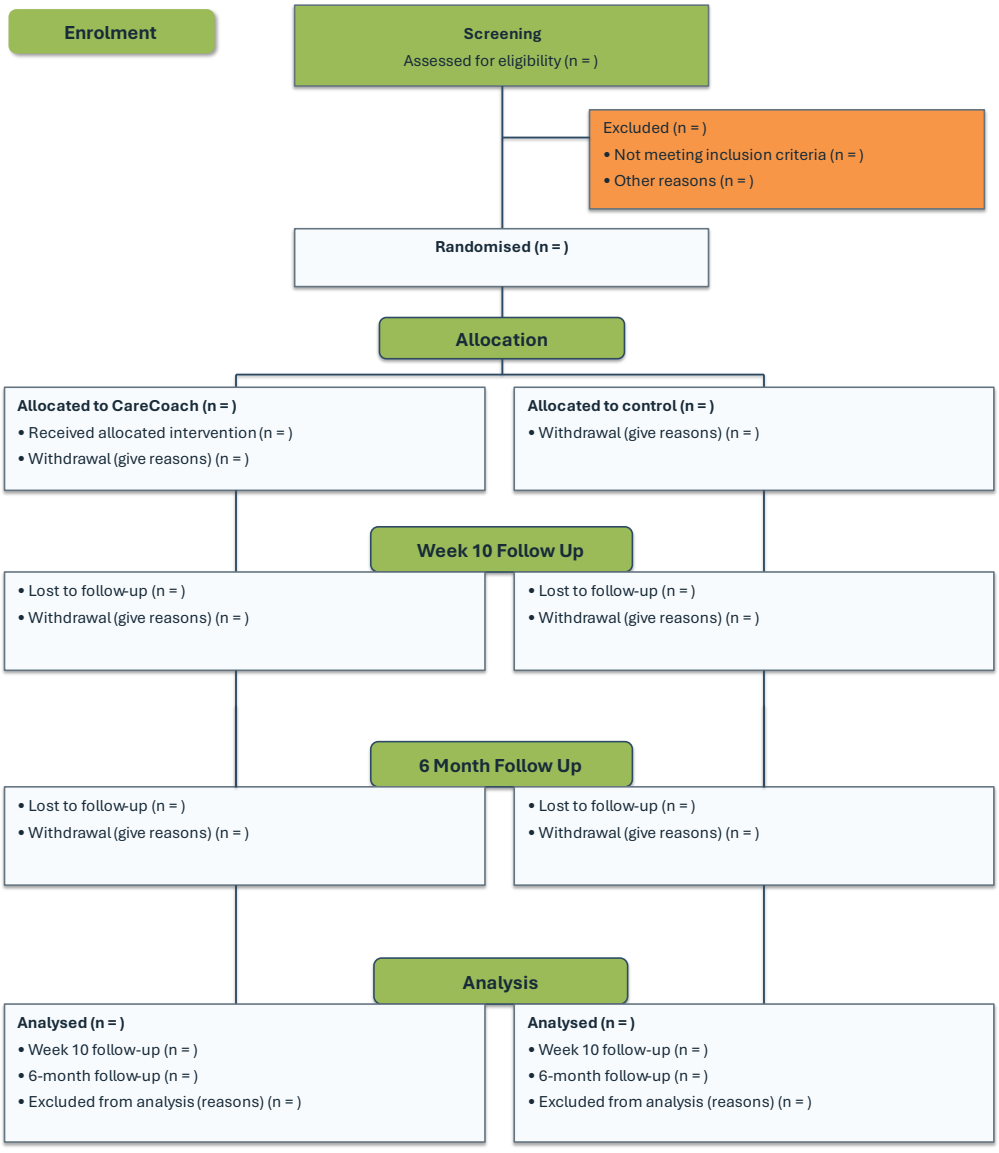
Kraijo H, Brouwer W, de Leeuw R, Schrijvers G, van Exel J. The perseverance time of informal carers of dementia patients: validation of a new measure to initiate transition of care at home to nursing home care. J Alzheimers Dis. 2014;40(3):631-42. doi: 10.3233/JAD-132420. PMID: 24496076.

Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

9. Appendices

Appendix A

Figure A1: Consort Diagram



Docusign Envelope ID: C46CD9E7-2086-8D05-8075-AEFAFACDB317

Appendix B

Sources used to extract Index of Multiple Deprivation for all carers who provided a valid Expression of Interest (i.e. which included a full, UK postcode).

Table B1 : Deprivation Index Source

Nation	Deprivation Index Source	Deprivation measure	Deprivation ranking/scale
England	https://deprivation.communities.gov.uk/	IMD	1 (most deprived) to 10 (least deprived)
Wales	https://datamap.gov.wales/maps/welsh-index-of-multiple-deprivation-wimd-2025/view#/	WIMD	1 (most deprived) to 5 (least deprived)
Scotland	https://simd.scot/#/simd2020/BTTTFTT/9/-4.0000/55.9000/	SIMD	1 (0-10% most deprived) to 10 (50% least deprived)
Northern Ireland	https://deprivation.nisra.gov.uk/	NIMDM	Rank 1 (Most deprived) to 890 (Lest deprived)