CareCoach Programme: WP3 Feasibility study

Statistical Analysis Plan (SAP)

Version 1.0

11/05/2024

Authors and approvers	Title	Signature	Date
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SAP REVISION HISTORY

Document Name	Version No.	Reason for Revision	Effective Date
CareCoach Feasibility study WP3 SAP	1.0	Addition of "Completion rate of outcome variables" to 8.2.1 Updated reference in Table 1. Appendix added.	11/05/2024

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 Investigator and Trial Manager both of whom should approve the plan.

Contents

1.0 Administrative Information

Sponsor	: University of Exeter
Sponsor Reference	: 2021-22-60
Host	: Norfolk & Suffolk NHS Foundation Trust - NSFT
Funder Reference	: PGfAR R208076
Trial Registration	: ISRCTN12540555
NIHR	: PGfAR NIHR201076
IRAS	: 316710
Chief Investigator	: Professor Chris Fox & Dr Jane Cross
Trial Statistician	: Professor Lee Shepstone
UKCRC Trials Unit	: Norwich CTU
Latest Protocol	: V2.4 01/11/2023

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
GAS	The Goal Attainment Scaling
IRAS	Integrated Research Application System
ITT	Intention-to-Treat
NCTU	Norwich Clinical Trials Unit
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute of Health Research
NPI-Q	Neuropsychiatric Inventory
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

3.0 Introduction

Currently 55 million people live with dementia worldwide, 944,000 in the United Kingdom (UK). Most people living with dementia are cared for at home by family or other unpaid, untrained carers with little additional support. Family carers are the main source of support and care for people with dementia and it is estimated that 700,000 people in the UK care for someone with dementia. From a societal perspective, family carers provide around £13.9 billion per year of care which would otherwise be paid by the government. Carers may need to make necessary changes to their employment (i.e., reduction in hours) to care for their family member or friend with dementia. Financial stress can be challenging to cope with, as can balancing the demands of work, family and caring.

How the carer and person with dementia acknowledge or resist physical and emotional stressors can have a significant impact on how they adapt to the dementia diagnosis. Extensive evidence shows such stressors lead to significant health problems for carers, including depression, anxiety and poorer physical health including hypertension, arthritis, and heart disease, ultimately leading to increased healthcare usage for the carer. Interventions which help carers achieve a more positive experience of caregiving can be beneficial to their well-being, however evidence-based support programmes for dementia carers are rarely systematically implemented. Family members of people newly diagnosed with dementia tend not to use services early, either because they do not feel the need, do not see themselves as 'carers' or struggle with acceptance due to stigma . This can leave carers unprepared and without support when caring becomes more difficult or crises develop. Furthermore, early-stage carer support can be experienced adversely by the carer if it is not tailored to their personal situation or the stage of the disease. For example, negative and stigmatising information about dementia can be difficult for carers to identify with and hamper their acceptance. Alternatively, a purposively developed, evidence-based intervention for those supporting a person living with dementia early after diagnosis may prevent high levels of burden and psychosocial problems later and reduce or delay use of health and social care services. Moreover, it may obviate or delay the need for the person with dementia to move to a care home.

Research with carers reports some positive benefits of their caring, for example, offering a closer relationship, satisfaction with caregiving, or opportunities to assist others. Interventions that help carers achieve a more positive experience of caregiving benefit their well-being. Self-efficacy, optimism and self-esteem are associated with a better capacity for 'living well' for carers. Therefore, learning to positively manage life with dementia, instead of the dementia itself, may facilitate carers' adjustment and adaptation. Most available interventions for carers are face-to-face but with the projected increase in people with dementia, and associated costs, there is a need to develop novel, cost-effective interventions which can be accessed flexibly by carers without requiring them to leave their relatives at home or make alternative care arrangements.

Internet use amongst people 75 years and older has nearly doubled since 2013, with 87% of 65–74-year-olds and 59% of those aged over 75 being internet users in 2020. This has increased since the onset of the COVID-19 pandemic; 45% and 41% of those aged 52-64 and 60-74, respectively, reported using the internet more. Solutions which include online interventions show promise supporting dementia carers and provide resources at a time and place convenient to carers. Reducing the complexity of

interventions, supporting access with support from health professionals, and highlighting the benefits of such interventions may assist bridging the digital divide of internet literacy and access to the internet. The National Institute for Health and Care Excellence (NICE) has highlighted the need for research on dementia carer self-management and prophylactic strategies to prevent depression. However, whilst the internet can provide support, and foster new relationships and networks, it is not enough for human interaction, and a blended method may improve intervention outcomes.

Recently a blended, self-management programme, 'Partner in Balance' (PiB), developed in the Netherlands, in partnership with carers and professionals, demonstrated significant benefits. PiB aimed to increase self-efficacy by encouraging carers to actively manage their lives and identify solutions for their specific needs. PiB comprised of a face-to-face session between the carer and a personal coach who was an experienced dementia care professional. This facilitated the carer to set goals and choose from a list of modules to build preparedness, resilience, and good caring habits. A pilot study tested feasibility and established preliminary effects on self-efficacy and goal attainment in carers of people with early dementia. Moreover, findings from an efficacy randomised controlled trial included significant improvements in self-efficacy, mastery and quality of life for carers, potentially generalisable across countries and health care systems.

This intervention required adaption for the UK cultural context. PiB has been developed for UK use using Experience Based Co-Design (EBCD) with carers, dementia staff and core stakeholders. Changes to PiB have now been implemented following feedback from EBCD participants, notably increasing inclusivity of language. The current study protocol aims to test the feasibility of a small-scale study of the UK adapted PiB intervention, called 'CareCoach', prior to running a larger randomised controlled trial in the future to definitively test the clinical and cost effectiveness of CareCoach.

The CareCoach Programme aims to adapt PiB for the UK cultural context to produce the CareCoach package and:

- Test if it is feasible to implement in the UK;
- Test the effect on outcomes for carers of people with dementia;
- Develop pathways for widespread implementation.

This analysis plan is specifically for work package 3 (WP3) of the wider CareCoach Programme, testing the feasibility of conducting a randomised controlled trial of the CareCoach package for carers and dementia care staff in the UK.

3.1 Trial Objectives

This trial aims to investigate the feasibility of a randomised controlled trial using the CareCoach intervention in a UK setting. The study will assess participant identification, recruitment strategies, and operational procedures to inform the design and deliverability of a definitive trial within the CareCoach research programme. The objectives of the study are:

1. To assess the ability to identify and recruit potential participants - informal carers.

2. To test the procedures for data collection and completion rate of trial outcome and economic data at 6-month follow-up.

3. Assess the deliverability of the CareCoach intervention by exploring the fidelity of coaches delivering the intervention and engagement amongst carer participants.

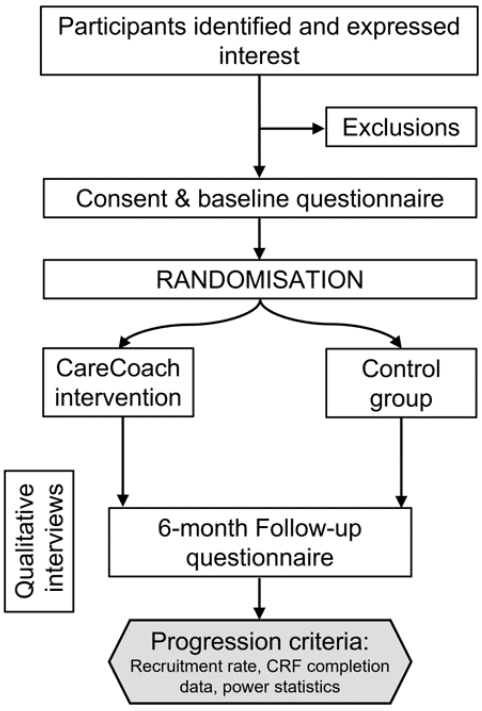
This feasibility study will incorporate elements of longitudinal process and implementation evaluations to identify and understand the barriers, facilitators, and consequences of CareCoach being implemented for carers, professionals, and healthcare systems.

4.0 Study Methods

4.1 Trial Design

This feasibility study uses a parallel, multicentre, individually randomised controlled trial with embedded qualitative components. Participants are unpaid carers (e.g., spouses, relatives, friends) of people with dementia. Participants will complete measures at two time points: baseline and at 6-months post-randomisation. Participants are randomised to receive the CareCoach intervention for 8-weeks or usual care.

Figure 1: Study overview:



4.2 Allocation and concealment mechanism

Participants are randomised following consent and baseline data collection. The randomisation scheme is computer generated using REDCap, at the Norwich Clinical Trials Unit. Given the small sample size, block lengths of two and four are used. Participants are individually randomised (1:1 ratio) to the intervention arm (n = 21) or usual care (n = 21), stratified by site. 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. As data collection is via self-administered questionnaires, researchers will not be blinded to group allocation. There is no attempt to provide a 'sham' intervention as control.

4.4 Sample Size

This feasibility study it is not powered to detect a difference in clinical outcome between the two groups, thus no power calculation has been performed. For practical reasons and keeping with typical sample sizes of this form of trial, a total sample size of 42 participants, across seven sites, was set.

4.5 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.

4.6 Timing of outcome assessments

Assessments are made at baseline prior to randomisation and post intervention, six months after randomisation.

5.0 Trial Population

Potential participants are unpaid, informal carers of people with dementia.

5.1 Recruitment

Multiple recruitment strategies are used including identification of participants at NHS sites, community organisations or local groups, through dissemination (e.g., posters, flyers, newsletters, mailing lists) via organisations supporting the study (e.g., TIDE, Dementia UK, Alzheimer's Society, Meri Yaadain),

dementia research databases (e.g., Join Dementia Research), and via social media advertising (e.g., Facebook, X, Instagram, study website).

At NHS sites, staff identify potentially eligible participants by screening their dementia patient lists and approaching eligible carers of those patients. Staff then invite eligible participants to provide consent for the research team to contact and invite them to the study.

Self-referred participants (e.g., via social media) are directed to a link to the secure database where they answer eligibility questions. If eligible, participants provide their contact information directly into the study database. Recruitment is not restricted to geographical regions covered by NHS sites.

5.2 Eligibility

Eligibility to the study is based upon the following entry criteria. Participants are 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;
- Spoken understanding of the English language (with the help of a family translator if required);
- Currently caring for a person with dementia (all subtypes, diagnosed within the last 5 years);
- Has a first-degree relationship (spouse/partner, sibling, son or daughter) with the person with dementia, OR must have a close personal relationship with the person with dementia (e.g., in-law family member, close friend or neighbour);
- Has capacity to give informed consent to participate;
- Has access to the internet (via a home computer/laptop, iPad/tablet or mobile phone with internet capability).

5.2.2 Exclusion criteria:

- Insufficient cognitive abilities to engage with the online programme;
- The person with dementia they care for resides in a care home.

6.0 Statistical Populations

6.1 Treatment Adherence

No definition of treatment adherence is provided, and no definition is required to define any analysis population. Assessing adherence is a potential result of the study.

6.2 Protocol deviations

All major deviations from protocol will be recorded and should be reported as part of the study output. These may inform the design of a future trial.

6.3 Analysis populations

All participants randomised to the study will represent the study population for analyses related to efficacy outcomes and follow-up, excluding any participants who withdraw and do not provide or agree to use of relevant data. An Intention-to-Treat (ITT) approach will be used when making group comparisons as an estimate of intervention effect.

7.0 Baseline participant characteristics

The characteristics of all participants at baseline will be compared between treatment group. No formal hypothesis testing will be carried out.

The following characteristics will be summarised using descriptive statistics:

- Demographic details.
    - Age (years)
    - Gender
    - Educational qualification
    - Ethnicity
    - Employment status
    - Socioeconomic status
    - Marital status
- Generalised Anxiety Disorder Assessment (GAD-7)-Total GAD7 score
- NPI-Q - Total score
- NPI-Q - Distress ratings
- NPI-Q - symptom Severity
- PMS raw score
- Patient Health Questionnaire (PHQ-9)
- SIDECAR-D Raw score
- Perceived Stress Scale (PSS 14 items)
- The Centre for Epidemiological Studies Depression Scale (CES-D) scoring
- Caregiver Self-Efficacy Scale (CSES)-Total score

- Caregiver Self-Efficacy Scale (CSES)-Self-efficacy for community support service use
- Caregiver Self-Efficacy Scale (CSES)-Self-efficacy for symptom management

7.1 Withdrawal information

Where possible, the time and reason for withdrawal from the study will be ascertained and reported. Reasons may be grouped and frequencies reported by intervention group.

8.0 Analysis

8.1 Framework and 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.

8.2 Outcomes

The study objectives are to assess the:

- ability to identify carers of people with dementia who are willing to consent to the study and be randomised across all sites.
- retention of participants to provide outcome data at 6 months.
- fidelity of coaches to deliver the experimental CareCoach intervention and participant's engagement.
- follow-up rates and viability of carer outcome measures at 6 months follow-up for a future definitive trial.

8.2.1 Feasibility Outcomes

Feasibility outcomes will be collected to enable an estimation of key parameters to inform a future trial, and to provide preliminary information about the impact of the intervention. These are:

- Numbers of potentially eligible participants.
- Number of participants subsequently recruited into the study.
- Attrition rate and reason for withdrawals.
- Completion rate of outcome variables.

8.2.2 Efficacy Outcomes

The following outcome efficacy variables, all related to the carer of the person with dementia, are collected at 6-months follow-up.

- The Caregiver Self-Efficacy Scale (CSES)
- The Pearlin Mastery Scale (PMS)
- The Perceived Stress Scale (PSS-14)
- The Centre for Epidemiological Studies Depression Scale (CES-D)
- Generalised Anxiety Disorder Scale (GAD-7)

- Scale measuring the Impact of DEmentia on CARers (SIDECAR-D)
- EuroQol Health related quality of life (EQ-5D-5L)
- Patient Health Questionnaire (PHQ-9)
- The Goal Attainment Scaling (GAS, intervention only, collected during final intervention session)

Carer proxy rating of the person with Dementia:
- Neuropsychiatric Inventory (NPI-Q)
- EuroQol Health related quality of life (Proxy EQ-5D-5L)

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

Table 1 : Outcome measure scoring

Outcome variable	*Version number (if applicable)*	*Calculation required*	*Reference*
CSES		CSES symptom management (Q1-5). Total score across 5 questions (ranges between 5 to 50). CSES community support (Q6-9). Total score across 4 statements (ranges between 4 to 40).	Fortinsky, Kercher & Burant (2002)
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 so that higher scores represent greater mastery, i.e., strongly agree=1, agree=2, disagree=3, strongly disagree=4.	Pearlin & Schooler (1978)
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	Cohen, Kamarck & Mermelstein (1983)
CES-D		Sum all 20 item weights for total score (ranges between 0 to 60). If more than 4 items are missing, do not score the scale. Items 4, 8, 12, and 16 scored as: rarely of none of the time = 3, some or a little of the time = 2, Occasionally or a moderate amount of the time = 1, all of the time = 0. All other items are scored as: rarely of none of the time =	Radloff (1977)

<table>
<tr><td></td><td></td><td>0, some or a little of the time = 1, Occasionally or a moderate amount of the time = 2, all of the time = 3.</td><td></td></tr>
<tr><td>GAD-7</td><td></td><td>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.</td><td>Spitzer, Kroenke, Williams & Lowe (2006)</td></tr>
<tr><td>SIDECAR-D</td><td></td><td>Sum scores for each statement for total score (ranges between 0 to 18). Statements are scored 1 for each ‘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></td><td>Horton et al. (2020)</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).</td><td>The EuroQol Group (1990)</td></tr>
</table>

<table>
<tr><td></td><td></td><td>2. EQ visual analogue scale. Report number entered by participant on scale of 0-100. 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).</td><td></td></tr>
<tr><td>PHQ-9</td><td></td><td>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.</td><td>Kroenke, Spitzer and Williams (2001)</td></tr>
<tr><td>GAS</td><td></td><td>1. Weight the goal on importance and difficulty on a scale of 0 to 3 (where 0 = not at all important/difficult, 1 = a little important/difficult, 2 = moderately important/difficult, 3 = very important/difficult).
2. Score current/baseline performance. Rates as ‘some function’ = -1, unless participant is as bad as they could be so scored as ‘none, as bad as can be’ = -2.
3. Scoring achievement of goal at follow-up. State ‘yes’ or ‘no’ as to whether the goal was achieved. Also score level of achievement from six options:
<table>
<tr><td></td><td></td><td colspan="2">Baseline score:</td></tr>
<tr><td>Achieved?</td><td></td><td>-1</td><td>-2</td></tr>
<tr><td rowspan="3">Yes</td><td>Much better</td><td>+2</td><td>+2</td></tr>
<tr><td>A little better</td><td>+1</td><td>+1</td></tr>
<tr><td>As expected</td><td>0</td><td>0</td></tr>
<tr><td rowspan="3">No</td><td>Partially achieved</td><td>-1</td><td>-1</td></tr>
<tr><td>Same as baseline</td><td>-1</td><td>-2</td></tr>
<tr><td>Worse</td><td>-2</td><td></td></tr>
</table>
These scores are entered into a standardised calculation spreadsheet created by Turner-Stokes (https://www.kcl.ac.uk/nmpc/assets/rehab/tools-gas-calculation-sheet.xls) which produces a baseline GAS score, achieved GAS T-score and change in GAS score. The baseline versus achieved GAS T-score is reported. A T score of over 50 indicates effective goal achievement.</td><td>Kiresuk & Sherman (1968); Jennings, Ramirez, Hays, Wenger & Reuben (2018); Turner-Stokes (2009)</td></tr>
</table>

		Formulas used in the calculation spreadsheet are available here: Goal Attainment Scaling in Rehabilitation (kcl.ac.uk)	
NPI-Q		Sum of individual domain scores to report total NPI-Q distress score and NPI-Q distress score. A response of 'No' to presence of each symptom scores 0. Severity is scored between 1 to 3 and range from mild = 1, moderate = 2, and severe = 3. Total severity scores range between 0-36. Distress is scored between 0 to 5: not distressing at all = 0, minimal = 1, mild = 2, moderate = 3, severe = 4, and extreme or very severe = 5. Total distress scores range between 0 to 60.	Kaufer, Ketchel, Smith, MacMillan, Shelley, Lopez & DeKosky (2000)
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 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.	The EuroQol Group (1990)

8.3 Analysis Methods

The primary analyses will be related to the trial 'feasibility' information, particularly with respect to participant 'flow' through the study (presented using the CONSORT flowchart; see Appendix) and availability of outcome data. These analyses are to inform and assist the design of the future full-scale trial, i.e. work-package 4 of the research programme. Numbers of eligible participants, recruitment and attrition rates will be calculated. Rates will be estimated based on data collected and 95% CIs determined for these. The rate of incomplete information either due to drop-out from the interventions or non-completion of the outcome measures will be based on the number of participants randomised. The statistical analyses will also estimate, with 95% CIs, the parameters required for a formal power calculation, particularly the standard deviation of potential outcome measures.

The distribution of each measure will be inspected to assess the possibility of 'ceiling' or 'flooring' effects, which could potentially make an outcome inappropriate for a full-scale trial.

Initial efficacy estimates will also be produced for each efficacy outcome. A general linear model, with appropriate link and error distribution will be used including randomization group and baseline outcome value where available.

8.4 Missing Data and Invalid data

Whilst missing and invalid data will be tabulated (i.e. to provide an estimate of complete data) there will be no attempt at imputing missing data or otherwise incorporating these data into any efficacy analyses.

8.5 Additional analyses

No additional subgroup or sensitivity analyses are planned.

8.6 Software

Statistical analyses will be carried out using SAS version 9.4.

9.0 References

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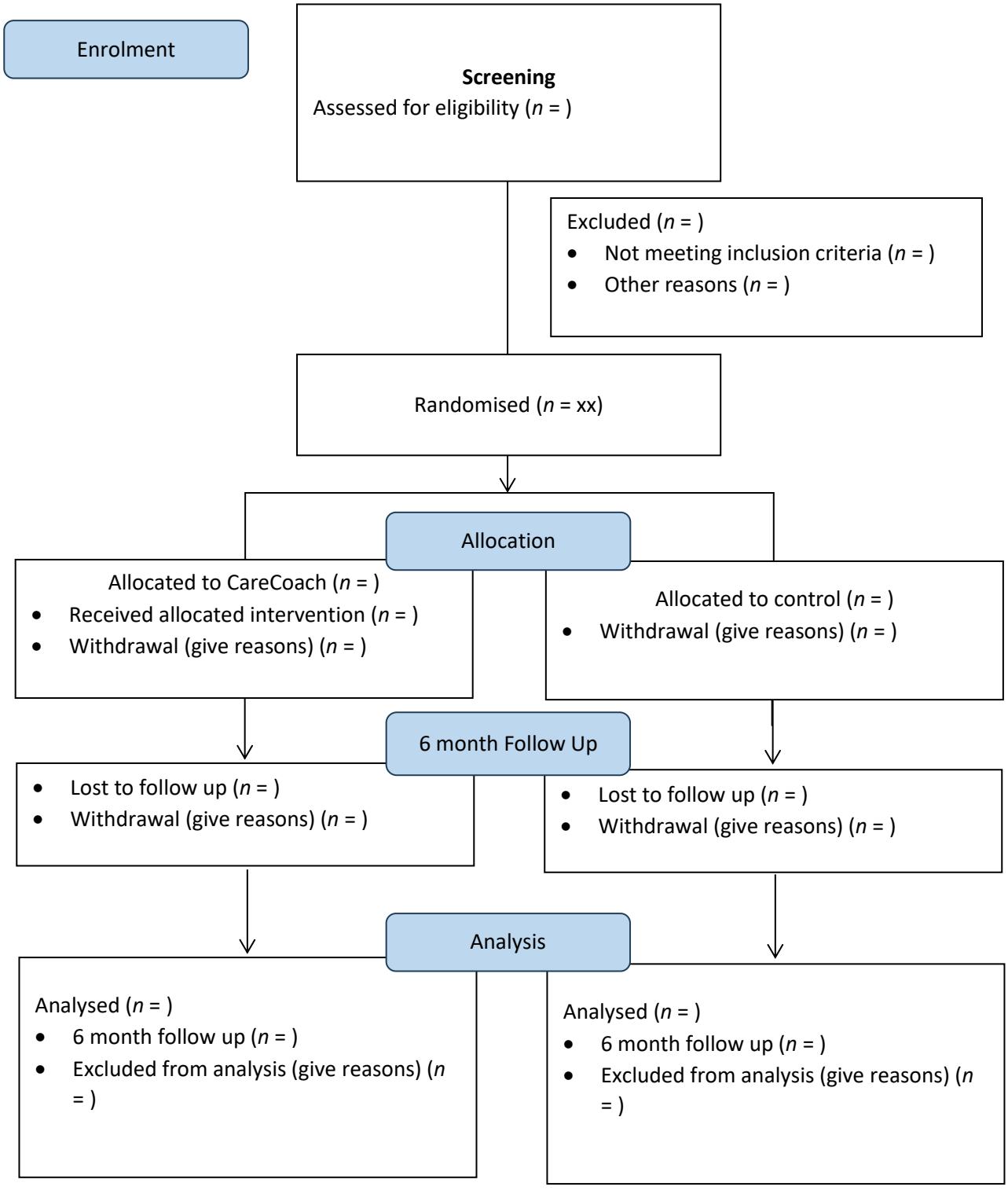
11. Appendix


Enrolment
Screening
Assessed for eligibility (n =)
Excluded (n =)
Not meeting inclusion criteria (n =)
Other reasons (n =)
Randomised (n = xx)
Allocation
Allocated to CareCoach (n =)
Received allocated intervention (n =)
Withdrawal (give reasons) (n =)
Allocated to control (n =)
Withdrawal (give reasons) (n =)
6 month Follow Up
Lost to follow up (n =)
Withdrawal (give reasons) (n =)
Lost to follow up (n =)
Withdrawal (give reasons) (n =)
Analysis
Analysed (n =)
6 month follow up (n =)
Excluded from analysis (give reasons) (n =)
Analysed (n =)
6 month follow up (n =)
Excluded from analysis (give reasons) (n =)