BMJ Open

FEASIBILITY AND ACCEPTABILITY OF NIDUS-PROFESSIONAL, A TRAINING AND SUPPORT INTERVENTION FOR HOMECARE WORKERS CARING FOR CLIENTS LIVING WITH DEMENTIA: A CLUSTER- RANDOMISED FEASIBILITY TRIAL PROTOCOL

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-066166
Article Type:	Protocol
Date Submitted by the Author:	28-Jun-2022
Keywords:	Dementia < NEUROLOGY, Old age psychiatry < PSYCHIATRY, Clinical trials < THERAPEUTICS

Complete List of Authors:
Zabihi, Sedigheh; University College London, Division of Psychiatry
Duffy, Larisa ; University College London, Division of Psychiatry
Kelleher, Daniel; University of Bradford, Centre for Applied Dementia Studies
Lord, Kathryn; University of Bradford, Centre for Applied Dementia Studies
Dar, Ayesha; University College London, Division of Psychiatry
Koutsoubelis, Freya; University College London, Division of Psychiatry
Banks, Sara; University College London, Division of Psychiatry
Rapaport, Penny; University College London, Division of Psychiatry
Mason, Clare; University of Bradford, Centre for Applied Dementia Studies
Vickerstaff, Victoria; University College London, Research Department of Primary Care and Population Health
Barber, Julie; University College London, Department of Statistical Science
Manthorpe, Jill; King's College London, NIHR Policy Research Unit in Health and Social Care Workforce
Walters, Kate; University College London, Research Department of Primary Care and Population Health
Lang, Iain; University of Exeter Medical School, NIHR Applied Research Collaboration South West Peninsula (PenARC)
Rockwood, Kenneth; Dalhousie University, Division of Geriatric Medicine
Duggan, Sandra; Alzheimer's Society Research Network
Kales, Helen; University of California Davis, Department of Psychiatry and Behavioural Sciences
Cooper, Claudia; Queen Mary University of London; East London NHS Foundation Trust

FEASIBILITY AND ACCEPTABILITY OF NIDUS-PROFESSIONAL, A TRAINING AND SUPPORT INTERVENTION FOR HOMECARE WORKERS CARING FOR CLIENTS LIVING WITH DEMENTIA: A CLUSTER-RANDOMISED FEASIBILITY TRIAL PROTOCOL

Authors

Sedigheh Zabihi[1], Larisa Duffy[1], Daniel Kelleher[2], Kathryn Lord[2], Ayesha Dar[1], Freya Koutsoubelis[1], Sara Banks[1], Penny Rapaport[1], Clare Mason[2], Victoria Vickerstaff[3], Julie A Barber[4], Jill Manthorpe[5], Kate Walters[3], Iain Lang[6], Kenneth Rockwood[7], Sandra Duggan[8], Helen Kales[9], Claudia Cooper[1,10,11]

Author Affiliations

1. Division of Psychiatry, University College London, London, UK
2. Centre for Applied Dementia Studies, University of Bradford, Bradford, UK
3. Research Department of Primary Care and Population Health, University College London, London, UK
4. Department of Statistical Science, University College London, London, UK
5. NIHR Policy Research Unit in Health and Social Care Workforce, King's College London, London, UK
6. NIHR Applied Research Collaboration South West Peninsula (PenARC), University of Exeter Medical School, Exeter, UK
7. Division of Geriatric Medicine, Dalhousie University, Halifax, Canada
8. Alzheimer's Society Research Network, London, UK
9. Department of Psychiatry and Behavioural Sciences, UC Davis Health, University of California, California, USA
10. Centre for Psychiatry and Mental Health, Wolfson Institute of Population Health, Queen Mary University of London, London, UK
11. East London NHS Foundation Trust

Corresponding Author

Sedigheh Zabihi, Division of Psychiatry, 6th Floor Maple House, 149 Tottenham Court Road, University College London, London W1T 7NF, UK. Email: sedigheh.zabihi.18@ucl.ac.uk

Word count : 3993

ABSTRACT

Introduction

Most people living with dementia want to remain living in their own homes, and are supported to do so by family carers and homecare workers. There are concerns that homecare is often unable to meet the needs of this client group, with limited evidence regarding effective interventions to improve it for people living with dementia. We have developed a training and support programme for homecare workers (NIDUS-Professional) to be delivered alongside support sessions for people living with dementia and their family carers (NIDUS-Family). We aim to assess (i) its acceptability among homecare workers and employing agencies, and (ii) the feasibility of homecare workers, people living with dementia and their family carers completing the outcomes of intervention in a future randomised controlled trial.

Methods and analysis

This is a cluster-randomised (2:1) single-blind, multi-site feasibility trial. We aim to recruit 60-90 homecare workers, 30-60 clients living with dementia and their family carers through 6-9 English homecare agencies. In the intervention arm, homecare staff will be offered six group sessions on videocall over three months, followed by monthly group sessions over the subsequent three-month period. Outcome measures will be collected at baseline and at six months.

Ethics and Dissemination

The study received ethical approval on 7 January 2020 from the Camden & King's Cross Research Ethics Committee (REC). Study reference: 19/LO/1667.

Findings will be disseminated through a peer reviewed journal, conference presentation and blog to research and clinical audiences; we will attend forums to present findings to participating homecare agencies and their clients.

Keywords: dementia, homecare, training, feasibility RCT

STRENGTHS AND LIMITATIONS OF THIS STUDY

- To our knowledge, this will be the first study to explore the feasibility of evaluating a training and support intervention for homecare workers through measures completed by homecare agency staff and managers, people living with dementia and their family carers.
- It is the first randomised trial to evaluate a remote group delivery format for homecare worker training and support, which has the potential to improve access to training and support for home care workers

INTRODUCTION

Background and rationale (6a)

About 885,000 people in the UK live with dementia; this number is expected to rise to one million by 2024.[1] Most people living with dementia prefer to stay at home[2, 3] and more than 60% of them are able to do so.[4] In addition to people with dementia's preference to stay at home, the often-negative outcomes of moving to a care home,[5, 6] highlight the importance of improving quality of care at home.

Evidence on effectiveness of interventions to improve the quality of homecare for older people, including those living with dementia, is scarce.[7] We define homecare as domestic and personal care provided by professional, paid care workers to people living in their own homes. The NIDUS programme (New Interventions for Independence in Dementia Study) aims to improve independence and quality of life of people living with dementia. Our theoretical model posits that good quality care at home requires a focus on needs and goals of people living with dementia and their family carers, reducing disability from behavioural and functional impairments, and support for self-management, alongside joined-up care across health and social care providers.[8]

We initially developed the NIDUS-Family intervention, which focuses on the individual needs of people with dementia; and is delivered to family carers and their relatives living with dementia.[9, 10] Given the importance of joined-up care, we co-designed NIDUS-Professional as an evidence-based support and training programme for homecare agency staff, to be delivered alongside the NIDUS-Family intervention.[11] Our aspiration is that our interventions with homecare staff and with their clients and family carers would be synergistic, through training and supporting staff to work with their clients to reach personalised goals. After a successful pilot of the intervention,[12] we describe here the protocol for our randomised feasibility study to test the feasibility and acceptability of this training and support programme among homecare staff, people living with dementia and their family carers.

Objectives (7)

The primary objective of the trial is to determine the feasibility and acceptability of delivering a homecare training and support intervention (NIDUS-Professional) together with delivery of NIDUS-Family intervention to eligible homecare agency clients and family carers. We will assess whether the NIDUS-Professional intervention is acceptable and feasible to deliver in practice and confirm if *a priori* criteria for progression to a full trial are met. These criteria include adherence of homecare staff to the NIDUS-Professional intervention and completion of follow-up measures by homecare workers and clients.

Secondary objectives include piloting recruitment and assessment processes for the planned full trial of the linked interventions and assessing fidelity of intervention delivery.

METHODS AND ANALYSIS

Trial design (8)

The trial is a single-blind, multi-site, cluster-randomised (2:1) controlled feasibility trial of the NIDUS-Professional intervention with homecare staff, with delivery of the NIDUS-Family intervention to eligible agency clients and family carers.

Patient and Public Involvement

Patient and Public Involvement (PPI) of NIDUS programme is led by the Alzheimer's Society. Two people living with dementia, four family carers, several homecare workers and two homecare managers have been involved in the co-production of the NIDUS-professional intervention. This study protocol has been discussed with PPI representatives in our NIDUS-professional coproduction group (November 2019), including two family carers of people living with dementia, recruited via the Alzheimer's society Research Volunteer Network.

Our PPI community of interest group supporting the study, will assist with understanding the data and dissemination. We aim to invite people (including people living with dementia, family carers, homecare workers, homecare managers) to join our network to keep informed and contribute ideas.

Study settings and population (9)

We are recruiting 6-9 homecare agencies from across England. Within each agency, we plan to recruit all eligible homecare staff and homecare agency clients living with a diagnosis of dementia or screening positive for probable dementia on the Noticeable Problems Checklist[13] and family carers of included clients who are in at least monthly contact.

Eligibility criteria (10)

Eligible agencies will have ≥5 staff members who are able to attend training.

From participating agencies, people living with dementia/ family carer dyads and homecare staff who meet the following inclusion criteria will be recruited:

People living with dementia receiving care from eligible homecare workers:

- Clients with a documented diagnosis of dementia of any severity who are living in their own homes: alone or with others and with/without a family carer willing to participate in the study.
- Clients who screen positive for probable dementia (a score of 5 or 6) on the Noticeable Problems Checklist.

Family Carer:

- 18 years or older.
- Have at least monthly face-to-face, email or telephone contact with the person living with dementia.

Homecare staff:

- Employee of participating homecare agencies providing direct care to dementia clients.
- 18 years or older.
- Able to understand spoken English.

Exclusion criteria

- People living with dementia who are receiving palliative care support and considered to be in the last 6 months of their life.
- People living with dementia who, because they are temporary clients or have given notice, are not expected to be clients of the agency in 6 months' time.
- Homecare staff who do not plan to remain working in the agency for 6 months or more.

- Family carers or homecare workers who lack capacity to consent.

Interventions (11)

Homecare workers and people living with dementia receiving care from an agency in the control arm of the trial will continue to receive usual care from NHS, memory services (clients), GP surgeries, and any other health or social care services.

All participating homecare staff working in agencies randomised to the intervention arm will receive the NIDUS-Professional intervention. Their participating clients living with dementia and their family carers will be offered individual support sessions (NIDUS-Family) over six months, contemporaneously with the delivery of the NIDUS-Professional intervention.

NIDUS-Professional intervention

NIDUS-Professional training comprises six structured manualized group intervention sessions delivered over three months, followed by three monthly catch-up groups to support homecare workers and explore the extent to which they are applying what they have learnt in practice. The intervention was developed in collaboration with people living with dementia, family carers, homecare workers and managers, health professionals, and researchers using their personal experiences and drawing on evidence of best practice in training and support for homecare workers for people living with dementia. Full details of NIDUS-Professional content, the process of co-design and results from an initial pilot study are reported elsewhere.[11, 12] The intervention is delivered online by two facilitators to groups of 6-8 homecare workers. Sessions are held every two weeks for 12 weeks; each last around 1-1.5 hours and cover specific topics (Table 1). Homecare workers who cannot attend a session receive a catch-up session with one of the facilitators. Participants who attend all 6 sessions are awarded a certificate of completion.

Table 1. Sessions' Content

Session	Topic
1	Introduction and your vital role: the importance of peer support and homecare staff wellbeing
2	Opening doors: building positive relationships and managing reluctance to engage with support
3	Doing with, not for: supporting people to stay active and involved in meaningful activities
4	Being a team: Supporting each other and working as a team with family carers and other homecare workers and professionals
5	Quality care: managing behaviours that challenge and other care challenges
6	Putting it all together (developing individual and agency action plans)

Managers of homecare agencies who have been randomised to the intervention arm receive three one-to-one sessions with the programme manager and team clinical psychologist (at the beginning, middle and end of the delivery period). These sessions cover topics likely to influence agency adoption of NIDUS-Professional recommendations,[14] including:

1. Capability and confidence of the homecare manager and autonomy to make decisions
2. Evidence of buy-in from relevant agency staff and senior managers (where the agency is not independent)

3. Engagement from leaders who express a shared vision to improve services / quality of care
4. Evidence of a culture of wanting change or seeing change as something to be welcomed
5. Receptiveness of manager and senior staff within the agency to engage and lead the change

NIDUS-Family intervention

NIDUS-Family is a manualised intervention currently being evaluated in a randomised trial.[9] It is delivered to either the family carer alone or the family carer and person living with dementia together; dyads select personal goals and modules to help them achieve their goals. The intervention consists of 6-8 sessions, once every 2-3 weeks over six months. Participating dyads (people living with dementia and their family carers) will discuss with facilitators how homecare workers can support them to work towards the goals they set. NIDUS-Professional facilitators will encourage homecare workers to bring their client's NIDUS-Family goals to group sessions, and to discuss progress or results of strategies suggested by the group in subsequent sessions. Facilitators will also encourage the group to reflect on how learning from NIDUS-Family goals and plans is brought to the group and how it can inform how homecare workers deliver care to people living with dementia without a family carer.

The NIDUS researchers are psychology or social science graduates who are selected for family, volunteer or professional dementia care experience and excellent communication skills, but do not have formal clinical training. To facilitate linking of the two interventions, the same facilitators who deliver NIDUS-professional to an agency (in pairs) also deliver NIDUS-family to clients (in individual sessions) from that agency. They receive supervision from a clinical psychologist.

Outcomes (12)

Primary outcomes of the feasibility trial are:

- Successful recruitment of homecare workers and clients to the trial
- Proportion of homecare workers adhering to the intervention (attending at least 4/6 sessions)
- Proportion of homecare workers completing the proposed primary outcome for a future trial at 6-six month follow-up (work related strain inventory)[15]
- Proportion of homecare agency clients with dementia for whom the proposed main outcome (DEMQol or DEMQOL-proxy)[16] is completed at 6-month follow-up.

All outcomes intended for the full trial will be collected at baseline and after six months (see data collection section below and supplementary material for the full list of outcomes).

Process evaluation: All intervention participants will be asked to complete an intervention acceptability questionnaire, and around 12 homecare workers, all homecare managers, and 12 family carers/people living with dementia dyads will also be invited to take part in qualitative interviews. These will be at three months and six months after randomisation. At three months (i.e., after the final session of the intervention is delivered) homecare workers are invited to join a focus group or attend an individual interview if they prefer. Managers are also invited to participate in an interview at this stage. We will also invite all the NIDUS facilitators to provide structured feedback on the intervention. We will undertake individual, qualitative interviews with family carers and people living with dementia at six months (after NIDUS-Family intervention delivery is complete) to explore their experiences of the intervention, with a specific focus on how their homecare worker has supported them during the intervention. We will ask homecare workers whether and how the intervention has impacted client and

family carer wellbeing and homecare workers' wellbeing and practice. The feedback will then be used to develop a final version of the intervention manual for a future pragmatic trial.

After the monthly catch-up sessions scheduled between three and six months have been completed, homecare workers, managers, and facilitators will be contacted either by email or phone, to answer some brief follow-up questions about how they have experienced the catch-up sessions.

Sample size (14)

We aim to recruit 60-90 homecare staff (40-60 in the intervention arm) and at least 60 clients and 30 family carers through 6-9 English homecare agencies. With these numbers we will be able to estimate parameters with sufficient precision to help inform continuation to a larger trial based on our pre-specified progression criteria (Table 2).

Table 2: A priori criteria for progression to a full randomised trial: These criteria are intended as guidance, and would not be implemented in isolation, but considered within the wider context of the study and fidelity work

Progression parameter	Proceed without adaption	Proceed with adaptions	Consider not proceeding
Proportion of homecare workers adhering to intervention (attending at least 4/6 sessions)	>65%	51-65%	≤50%
Proportion of homecare workers completing work related strain inventory at 6-month follow-up	>75%	51-75%	≤50%
Proportion of homecare agency clients with dementia with DEMQol or DEMQOL-proxy completed at 6-month follow-up.	>75%	51-75%	≤50%

Recruitment (15)

We advertised the opportunity to take part in this trial by speaking at clinical forums for homecare agency managers, and through direct contact with independent homecare agencies and franchises. We made contact with homecare agency managers, asking them to approach all their eligible homecare staff inviting them to take part.

We will ask homecare agencies to identify and approach all eligible clients living with dementia and their family carers. Researchers will then contact eligible clients and carers who are interested and an appointment will be arranged to explain the study, obtain informed consent and carry out the baseline assessment.

All study appointments will be conducted remotely either on the telephone or by videocall.

Consent (26a)

Trained researchers will take informed consent from homecare workers, people living with dementia and their family carer. Researchers will obtain verbally-recorded or written informed consent from each participant. If the person living with dementia does not have capacity to consent, the family member/carer will be asked to complete a personal consultee declaration form as set out in the Mental

Capacity Act 2005. If no personal consultee can be identified, the opinion of a nominated consultee will be sought.

Allocation

Sequence generation (16a)

Allocation of agencies to NIDUS-Professional and control groups will be carried out based on a computer-generated randomisation list created and held by the PRIMENT Clinical Trials Unit (CTU). The list will be constructed based on random blocks sizes (to prevent allocations being predictable), aiming to achieve an allocation ratio of approximately 2:1 (such that for every two agencies randomised to the intervention, one agency will be allocated to the control).

Allocation concealment mechanism (16b)

To achieve allocation concealment, the randomisation list will be held with limited access at the PRIMENT CTU. Once an eligible agency has been identified, the trial manager will request the next allocation from the responsible CTU member. From that point only the trial manager and the researchers delivering the intervention will be aware of the agencies' allocation status.

Implementation (16c)

Once an eligible agency is identified, researchers will recruit participants and collect baseline data. As soon as this data collection for the agency is completed, the trial manager will request allocation from the responsible person at the PRIMENT CTU.

Blinding (17a)

Researchers who have not been involved in recruitment or intervention delivery, will collect follow-up measures and will be blinded to group allocations. Success of the blinding process will be examined by asking assessors to guess intervention status of each agency.

Procedure for unblinding if needed (17b)

Independent researchers conducting the follow-up assessments will remain blinded to randomisation status throughout the study unless a participant accidentally discloses this. We do not foresee any circumstances where unblinding the researchers conducting follow-up assessments will be necessary.

Data collection (18a)

Data will be collected at baseline and six month follow-up for all participants. At baseline we will collect sociodemographic details of all participants. In addition, we will collect information from homecare staff about their training, employment role, hours worked per week, duration of time working in homecare and for current agency; client with dementia and their family carers will be asked about their relationship, frequency of contact with each other and the duration of time they have received homecare. All researchers will be trained to use data collection tools. Full trial outcomes will be measured using validated questionnaires (see Supplementary material for full details of measures and table 2 for schedule of assessments).

All homecare workers will be asked to complete:

- Work-related Strain Inventory[15]
- Sense of Competence in Dementia Care Staff[17]

Clients with dementia will be asked to complete:

- The Dementia Quality of Life (DEMQoL)[16]
- Home Care Satisfaction Measure (home health aide scale)[18]

Proxy measure for clients with dementia will be completed by their family carers and the homecare worker who works most closely with the client:

- The Dementia Quality of Life (DEMQoL) proxy[16]
- Disability Assessment for Dementia scale[19]
- The brief Neuropsychiatric Inventory Scale (NPI-Q)[20]

Family carers will be asked to proxy-complete:

- Adapted version of the Client Services Receipt Inventory (CSRI)[21]
- Homecare satisfaction measure (home health aide scale)[18]

In addition, we will collect data in the intervention arm to enable us to report intervention attendance. We will audio-record intervention sessions, and two researchers will independently rate sessions against a checklist to estimate fidelity to the manual.

Plans to promote participant retention and complete follow-up (18b)

All assessments and study visits will be conducted over videocall or telephone (where participants are unable or unwilling to use videocall). Agencies and homecare staff will be reimbursed for their time (£20 per hour). People living with dementia/ family carer dyads will be offered a £20 voucher per dyad to thank them for their time after each assessment appointment (baseline, six month and qualitative interview).

Statistical methods (20a)

The proportion of eligible homecare staff, clients, and family carers approached who agree to take part in the study will be reported with 95% confidence intervals and reasons for refusal summarised. We will summarise the demographic characteristics and scores measured at baseline and six months, using appropriate summary statistics, and including the proportion with missing data for each measure. For all scores measured at six months, differences between the randomised groups will be calculated with 95% confidence intervals.

We will estimate progression parameters to inform continuation to the larger trial, specifically recruitment rates (per month), the proportion of homecare workers adhering to the intervention (attending at least 4/6 sessions); proportion of clients for whom six month DEMQOL or DEMQOL-proxy-rated outcomes are completed, and proportion of homecare staff completing the six month Work Related Strain Inventory.

For qualitative data analysis, we will use NVivo software and take a thematic analytic approach to analysing transcripts of NIDUS-Professional intervention sessions, facilitator process notes, and semi-

structured interview findings.[22] Our findings will be used to adapt the NIDUS-Professional intervention and the supervision and training programme for researchers delivering it before a future full pragmatic trial of the NIDUS-Professional intervention, if required.

To analyse fidelity of NIDUS-Professional delivery, checklists will be applied independently to transcribed audio recordings of the training sessions by two researchers. A mean fidelity score will be produced by dividing the number of items on the checklist identified as being delivered in the training sessions, by the number of items on the checklist that should have been delivered per training session, per researcher and across all training sessions. We will adopt thresholds used in other intervention fidelity work:[23, 24] where 81–100% constitutes high fidelity, 51-80 is moderate fidelity and 50% or lower constitutes low fidelity.

ETHICS AND DISSEMINATION

Research Ethics approval (24)

The study received ethical approval on 7 January 2020 from the Camden & King's Cross Research Ethics Committee (REC). Study reference: 19/LO/1667 (with a subsequent amendment (approved 07.04.20 by sponsor) to conduct research processes, including consent and intervention sessions remotely). All participants are required to give written or verbal informed consent to take part in the trial. For people living with dementia who lack capacity to take part, a written consultee declaration form will need to be signed by their family member or a nominated consultee (who at the request of the ethics committee may not be a staff member of the homecare agency) for them to participate.

Confidentiality (27)

Personal data needed to re-contact participants for follow up assessments and intervention sessions will be held securely on password protected excel spreadsheets on password-protected computers by the research team. Storage of data will be consistent with ethical procedures, as evidenced by REC approval.

Harms (22)

Any serious adverse events which are classed as related and unexpected will be reported to the sponsor. All serious adverse events will be recorded on the online database hosted by Sealed Envelope on a serious adverse event (SAE) form. The Chief Investigator (CI) or designated researcher will complete the SAE form and the form will be preferably emailed to the sponsor within 24 hours of becoming aware of the event by the trial manager. The Chief or Principal Investigator will respond to any SAE queries raised by the sponsor as soon as possible.

Where the event is unexpected and thought to be related to the procedure it will be reported by the CI to the Health Research Authority within 15 days.

Dissemination policy (31)

We will disseminate our findings in a peer reviewed journal and present findings in appropriate fora for health and social care professionals. Participants who have indicated they are interested in the results will be sent a lay summary of the findings. The data used and analysed during the study will be available from the corresponding author upon study completion on reasonable request.

DISCUSSION

This protocol describes a cluster-randomised feasibility trial of a training and support programme aiming to improve quality of life and care at home for people living with dementia. To the best of our knowledge, NIDUS-Professional is the first training intervention to be designed by people living with dementia and their family carers, homecare staff and their managers, and health professionals.[8] Our study will examine whether a manualised structured intervention is feasible and acceptable to be delivered to homecare agencies in a full trial.

Homecare workers have a crucial role in supporting people living with dementia to remain in their homes for longer.[25] However, few receive dementia-specific training.[26] Although evidence shows efficacy of psychosocial interventions in improving quality of life and care for people with dementia living in care homes,[27, 28] evidence on interventions aimed at people with dementia living at home remains limited.[7] NIDUS-Professional will address this gap. Our aim is to increase knowledge around the feasibility of delivering such training interventions to homecare staff with a linked support programme for people living with dementia and their family carers. We will conduct a process evaluation and will collect data on fidelity which will be useful for the subsequent full trial.

One of the challenges we expect is adherence to intervention among homecare staff. Homecare workers have tight and busy schedules often with limited autonomy and the demands of their role may lead to low adherence. In the light of Covid-19, the NIDUS-Family stream of the programme shifted to remote delivery and assessment which provided an opportunity to consider benefits and disadvantages of remote delivery of NIDUS-Professional. Offering telephone or videocalls instead of in-person visits can improve the rate of adherence as it offers more flexibility. Furthermore, it will allow for more inclusive recruitment without the additional cost of travel. Another challenge will be the high turnover of homecare staff: even prior to Covid-19 this was estimated at 38% annually among social care staff.[29] We also plan to recruit people living with dementia who do not have capacity to consent, through consent of a personal or nominated consultee. The challenge we foresee would be to recruit people living with dementia who do not have a family carer to act as a personal consultee, as per ethical stipulations, homecare workers cannot act as nominated consultee for clients without capacity. In our pilot trial,[12] while adherence to NIDUS-professional was promising, we did not manage to recruit any clients living with dementia or family carers. We refined our processes in response to this, initiating discussions with agencies about client recruitment earlier. However, this experience did highlight the challenges of recruiting clients of homecare agencies living with dementia to take part in a trial, many of whom were living alone and were very isolated, apart from being supported by the homecare agency, whose staff by requirements of our ethics consent were not permitted to act as nominated consultees. An important purpose of this randomised feasibility trial will be to determine whether and how many homecare clients with dementia it is feasible to recruit using this trial design, to inform a future larger pragmatic trial.

Trial Status

Protocol version: No 5., 19 November 2020. First homecare agency was randomised in December 2021.

ACKNOWLEDGEMENTS

Funding

This work is part of the NIDUS (New Interventions in Dementia Study), which is hosted within the Alzheimer's Society Centre of Excellence for Independence at home (Centre of Excellence grant 330).

IL's time on this independent research project is in part supported by the National Institute for Health and Care Research (NIHR) Applied Research Collaboration South West Peninsula. The views expressed in this publication are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

Declaration of Interest

The authors declare no conflict of interest.

Authors Contribution

CC is the chief investigator of the study and secured the funding for the study. LD is managing the recruitment and study procedures. KL provided input into study and intervention design. JB and VV designed the statistical aspects. SZ wrote the first draft of the manuscript. All authors contributed intellectual content to the paper and reviewed the final version prior to submission.

REFERENCES

1 Wittenberg R, Hu B, Barraza-Araiza L, et al. Projections of older people with dementia and costs of dementia care in the United Kingdom, 2019–2040. *London: London School of Economics* 2019.

2 van der Roest HG, Meiland FJM, Maroccini R, et al. Subjective needs of people with dementia: a review of the literature. *Int Psychogeriatr* 2007;19(3):559-92. doi: 10.1017/S1041610206004716 [published Online First: 2007/01/04]

3 Lord K, Livingston G, Robertson S, et al. How people with dementia and their families decide about moving to a care home and support their needs: development of a decision aid, a qualitative study. *BMC Geriatr* 2016;16(1):68. doi: 10.1186/s12877-016-0242-1

4 Prince M, Knapp M, Guerchet M, et al. Dementia UK: Update(Second edition): King's College London, 2014.

5 Brodaty H, Draper B, Saab D, et al. Psychosis, depression and behavioural disturbances in Sydney nursing home residents: prevalence and predictors. *Int J Geriatr Psychiatry* 2001;16(5):504-12. doi: https://doi.org/10.1002/gps.382

6 Gaugler JE, Mittelman MS, Hepburn K, et al. Clinically significant changes in burden and depression among dementia caregivers following nursing home admission. *BMC Med* 2010;8(1):85. doi: 10.1186/1741-7015-8-85

7 Cooper C, Cenko B, Dow B, et al. A systematic review evaluating the impact of paid home carer training, supervision, and other interventions on the health and well-being of older home care clients. *Int Psychogeriatr* 2017;29(4):595-604. doi: 10.1017/S1041610216002386 [published Online First: 2017/01/16]

8 Lord K, Beresford-Dent J, Rapaport P, et al. Developing the New Interventions for independence in Dementia Study (NIDUS) theoretical model for supporting people to live well with dementia at home for longer: a systematic review of theoretical models and Randomised Controlled Trial evidence. *Soc Psychiatry Psychiatr Epidemiol* 2020;55(1):1-14. doi: 10.1007/s00127-019-01784-w

9 Burton A, Rapaport P, Palomo M, et al. Clinical and cost-effectiveness of a New psychosocial intervention to support Independence in Dementia (NIDUS-family) for family carers and people living

with dementia in their own homes: a randomised controlled trial. *Trials* 2021;22(1):865. doi: 10.1186/s13063-021-05851-z

10 Rapaport P, Burton A, Palomo M, et al. A mixed-methods feasibility study of a goal-focused manualised intervention to support people with dementia to stay living independently at home with support from family carers: NIDUS (New Interventions for Independence in Dementia Study) Family. *Aging & Ment Health* 2021;25(8):1463-74.

11 Lord K, Kelleher D, Ogden M, et al. Co-designing complex interventions with people living with dementia and their supporters. *Dementia* 2022;21(2):426-41. doi: 10.1177/14713012211042466

12 Kelleher D, Lord K, Duffy L, et al. Time to reflect is a rare and valued opportunity; a pilot of the NIDUS-professional dementia training intervention for homecare workers during the Covid-19 pandemic. *Health Soc Care Community* 2022; 00: 1-12. doi: https://doi.org/10.1111/hsc.13737

13 Levin E. Noticeable problems checklist. *London: National Institute for Social Work* 1989

14 Goodman C, Sharpe R, Russell C, et al. Care home readiness: a rapid review and consensus workshops on how organisational context affects care home engagement with health care innovation. UK: NHS England 2017.

15 Revicki DA, May HJ, Whitley TW. Reliability and validity of the Work-Related Strain Inventory among health professionals. *Behav Med* 1991;17(3):111-20.

16 Banerjee S, Smith S, Lamping D, et al. DEMQOL-Evaluation of a new system for measuring quality of life in people with dementia: validity, reliability and use in regular practice. *Neurobiol Aging* 2004;25:S321-S21.

17 Schepers AK, Orrell M, Shanahan N, et al. Sense of competence in dementia care staff (SCIDS) scale: development, reliability, and validity. *Int psychogeriatr* 2012;24(7):1153-62.

18 Geron SM, Smith K, Tennstedt S, et al. The home care satisfaction measure: A client-centered approach to assessing the satisfaction of frail older adults with home care services. *J Gerontol B Psychol Sci Soc Sci* 2000;55(5):S259-S70.

19 Feldman H, Sauter A, Donald A, et al. The disability assessment for dementia scale: a 12-month study of functional ability in mild to moderate severity Alzheimer disease. *Alzheimer Dis Assoc Disord* 2001;15(2):89-95.

20 Kaufer DI, Cummings JL, Ketchel P, et al. Validation of the NPI-Q, a brief clinical form of the Neuropsychiatric Inventory. *J Neuropsychiatry Clin Neurosci* 2000;12(2):233-39.

21 Beecham J, Knapp M. Costing psychiatric interventions. In: Thornicraft G, Brewin C, Wing J, eds. Measuring mental health needs. Gaskell: Royal College of Psychiatrists 1992:200-24.

22 Braun V, Clarke V. Reflecting on reflexive thematic analysis. *Qual Res Sport Exerc Health* 2019;11(4):589-97.

23 Noell GH, Gresham FM, Gansle KA. Does treatment integrity matter? A preliminary investigation of instructional implementation and mathematics performance. *J Behav Educ* 2002;11(1):51-67.

24 Holcombe A, Wolery M, Snyder E. Effects of two levels of procedural fidelity with constant time delay on children's learning. *J Behav Educ* 1994;4(1):49-73.

25 Carter, D. Fix Dementia Care: Homecare Report. London: Alzheimer's Society, 2016.

26 Polacsek M, Goh A, Malta S, et al. 'I know they are not trained in dementia': addressing the need for specialist dementia training for home care workers. *Health Soc Care Community* 2020;28(2):475-84.

27 Lawrence V, Fossey J, Ballard C, et al. Improving quality of life for people with dementia in care homes: making psychosocial interventions work. *Br J Psychiatry* 2012;201(5):344-51. doi: 10.1192/bjp.bp.111.101402 [published Online First: 2018/01/02]

28 Lawrence V, Fossey J, Ballard C, et al. Helping staff to implement psychosocial interventions in care homes: augmenting existing practices and meeting needs for support. *Int J Geriatr Psychiatry* 2016;31(3):284-93. doi: https://doi.org/10.1002/gps.4322

29 Skills for Care. The state of the adult social care sector and workforce in England, 2021. Leeds: Skills for Care, 2021.

Full trial outcomes:

All homecare workers will complete:

- **Work-related Strain Inventory** comprises 18 items, each scored on a 4-point response scale, ranging from Does not apply to me (1) to Does apply to me (4). Total scale scores range from 18 to 72. The WRSI can be completed in 5 minutes[15]
- **Sense of Competence in Dementia Care Staff** asks staff 17 questions to find out about how able they feel to deliver person-centred care. It asks, for example, how well they feel they can *understand the feelings of a person with dementia or engage a person with dementia in a conversation*[17]

People living with dementia will be asked to complete:

- **The Dementia Quality of Life** (DEMQoL)[16]
- **Home Care Satisfaction Measure** provides an overall homecare satisfaction score and subscale scores for five common services on a 0-100 scale (home health aide scale)[18]

Proxy measure for people living with dementia will be completed by their family carers and the homecare worker who works most closely with the client:

- **The Dementia Quality of Life (DEMQoL) proxy** is a valid and reliable measure of quality of life in people living with dementia in the last week. It is a 31-item interviewer-administered questionnaire[16]
- **Disability Assessment for Dementia scale** is a standard measure of functional independence (basic and instrumental activities of daily living).[19]
- **The brief Neuropsychiatric Inventory Scale (NPI-Q)** is a 12 domain survey assessing neuropsychiatric symptomatology. The NPI-Q provides symptom Severity and Distress ratings for each symptom reported, and total Severity and Distress scores reflecting the sum of individual domain scores.[20]

Family carers will be asked to proxy-complete:

- **Adapted version of the Client Services Receipt Inventory (CSRI)** health and social care resource utilisation including homecare, hospitalisations, respite and all-cause time to transition from home to an institution.[21]
- **Home care satisfaction measure** (home health aide scale)

Table 2. Schedule of Assessments

	Screening and baseline (Pre-treatment assessment)	**Intervention phase**					**Follow up**	**Optional qualitative interview**
Visit No:	1	2	3	4	5	6	7	8
Window of flexibility for timing of visits:		+/- 2 weeks	+/- 2 weeks	+/- 2 weeks	+/- 2 weeks	+/- 2 weeks	+/- 4 weeks	+/- 2 weeks
Informed Consent	x							
Eligibility confirmation	x							
Baseline assessment (Self report questionnaires)	x							
Randomisation	x							
Training intervention		x	x	x	x	x		
6 month follow up assessment (self-report questionnaires)							x	
Optional qualitative interview								x
Adverse Events review	X	X	X	X	X	X	X	
Concomitant Medication review (if applicable)	X	X	X	X	X	X	X	

BMJ Open

FEASIBILITY AND ACCEPTABILITY OF NIDUS-PROFESSIONAL, A TRAINING AND SUPPORT INTERVENTION FOR HOMECARE WORKERS CARING FOR CLIENTS LIVING WITH DEMENTIA: A CLUSTER- RANDOMISED FEASIBILITY TRIAL PROTOCOL

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2022-066166.R1
Article Type:	Protocol
Date Submitted by the Author:	29-Nov-2022
Complete List of Authors:	Zabihi, Sedigheh; University College London, Division of Psychiatry Duffy, Larisa ; University College London, Division of Psychiatry Kelleher, Daniel; University of Bradford, Centre for Applied Dementia Studies Lord, Kathryn; University of Bradford, Centre for Applied Dementia Studies Dar, Ayesha; University College London, Division of Psychiatry Koutsoubelis, Freya; University College London, Division of Psychiatry Banks, Sara; University College London, Division of Psychiatry Rapaport, Penny; University College London, Division of Psychiatry Mason, Clare; University of Bradford, Centre for Applied Dementia Studies Vickerstaff, Victoria; University College London, Research Department of Primary Care and Population Health Barber, Julie; University College London, Department of Statistical Science Manthorpe, Jill; King's College London, NIHR Policy Research Unit in Health and Social Care Workforce Walters, Kate; University College London, Research Department of Primary Care and Population Health Lang, Iain; University of Exeter Medical School, NIHR Applied Research Collaboration South West Peninsula (PenARC) Rockwood, Kenneth; Dalhousie University, Division of Geriatric Medicine Duggan, Sandra; Alzheimer's Society Research Network Kales, Helen; University of California Davis, Department of Psychiatry and Behavioural Sciences Cooper, Claudia; Queen Mary University of London; East London NHS Foundation Trust
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Mental health
Keywords:	Dementia < NEUROLOGY, Old age psychiatry < PSYCHIATRY, Clinical trials < THERAPEUTICS

FEASIBILITY AND ACCEPTABILITY OF NIDUS-PROFESSIONAL, A TRAINING AND SUPPORT INTERVENTION FOR HOMECARE WORKERS CARING FOR CLIENTS LIVING WITH DEMENTIA: A CLUSTER-RANDOMISED FEASIBILITY TRIAL PROTOCOL

Authors

Sedigheh Zabihi[1], Larisa Duffy[1], Daniel Kelleher[2], Kathryn Lord[2], Ayesha Dar[1], Freya Koutsoubelis[1], Sara Banks[1], Penny Rapaport[1], Clare Mason[2], Victoria Vickerstaff[3], Julie A Barber[4], Jill Manthorpe[5], Kate Walters[3], Iain Lang[6], Kenneth Rockwood[7], Sandra Duggan[8], Helen Kales[9], Claudia Cooper[1,10,11]

Author Affiliations

1. Division of Psychiatry, University College London, London, UK
2. Centre for Applied Dementia Studies, University of Bradford, Bradford, UK
3. Research Department of Primary Care and Population Health, University College London, London, UK
4. Department of Statistical Science, University College London, London, UK
5. NIHR Policy Research Unit in Health and Social Care Workforce, King's College London, London, UK
6. NIHR Applied Research Collaboration South West Peninsula (PenARC), University of Exeter Medical School, Exeter, UK
7. Division of Geriatric Medicine, Dalhousie University, Halifax, Canada
8. Alzheimer's Society Research Network, London, UK
9. Department of Psychiatry and Behavioural Sciences, UC Davis Health, University of California, California, USA
10. Centre for Psychiatry and Mental Health, Wolfson Institute of Population Health, Queen Mary University of London, London, UK
11. East London NHS Foundation Trust

Corresponding Author

Sedigheh Zabihi, Division of Psychiatry, 6th Floor Maple House, 149 Tottenham Court Road, University College London, London W1T 7NF, UK. Email: sedigheh.zabihi.18@ucl.ac.uk

Word count : 4056

ABSTRACT

Introduction

Most people living with dementia want to remain living in their own homes, and are supported to do so by family carers and homecare workers. There are concerns that homecare is often unable to meet the needs of this client group, with limited evidence regarding effective interventions to improve it for people living with dementia. We have developed a training and support programme for homecare workers (NIDUS-Professional) to be delivered alongside support sessions for people living with dementia and their family carers (NIDUS-Family). We aim to assess (i) its acceptability among homecare workers and employing agencies, and (ii) the feasibility of homecare workers, people living with dementia and their family carers completing the outcomes of intervention in a future randomised controlled trial.

Methods and analysis

This is a cluster-randomised (2:1) single-blind, multi-site feasibility trial. We aim to recruit 60-90 homecare workers, 30-60 clients living with dementia and their family carers through 6-9 English homecare agencies. In the intervention arm, homecare staff will be offered six group sessions on videocall over three months, followed by monthly group sessions over the subsequent three-month period. Outcome measures will be collected at baseline and at six months.

Ethics and Dissemination

The study received ethical approval on 7 January 2020 from the Camden & King's Cross Research Ethics Committee (REC). Study reference: 19/LO/1667.

Findings will be disseminated through a peer reviewed journal, conference presentation and blog to research and clinical audiences; we will attend forums to present findings to participating homecare agencies and their clients.

Keywords: dementia, homecare, training, feasibility RCT

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This trial evaluates the acceptability and feasibility of evaluating a six-session remote group training and support programme for homecare workers over three months, followed by monthly sessions to support implementation of new strategies.
- We aim to recruit 60-90 homecare workers, 30-60 clients living with dementia and their family carers.
- The main outcomes are intervention acceptability among homecare workers and employing agencies, and the feasibility of homecare workers, people living with dementia and their family carers completing outcomes.

INTRODUCTION

Background and rationale (6a)

About 885,000 people in the UK live with dementia; this number is expected to rise to one million by 2024.[1] Most people living with dementia prefer to stay at home[2, 3] and more than 60% of them are able to do so.[4] In addition to people with dementia's preference to stay at home, the often-negative outcomes of moving to a care home,[5, 6] highlight the importance of improving quality of care at home.

Evidence on effectiveness of interventions to improve the quality of homecare for older people, including those living with dementia, is scarce.[7] We define homecare as domestic and personal care provided by professional, paid care workers to people living in their own homes. The NIDUS programme (New Interventions for Independence in Dementia Study) aims to improve independence and quality of life of people living with dementia. Our theoretical model posits that good quality care at home requires a focus on needs and goals of people living with dementia and their family carers, reducing disability from behavioural and functional impairments, and support for self-management, alongside joined-up care across health and social care providers.[8]

We initially developed the NIDUS-Family intervention, which focuses on the individual needs of people with dementia; and is delivered to family carers and their relatives living with dementia.[9, 10] Given the importance of joined-up care, we co-designed NIDUS-Professional as an evidence-based support and training programme for homecare agency staff, to be delivered alongside the NIDUS-Family intervention.[11] Our aspiration is that our interventions with homecare staff and with their clients and family carers would be synergistic, through training and supporting staff to work with their clients to reach personalised goals. After a successful pilot of the intervention,[12] we describe here the protocol for our randomised feasibility study to test the feasibility and acceptability of this training and support programme among homecare staff, people living with dementia and their family carers.

Objectives (7)

The primary objective of the trial is to determine the feasibility and acceptability of delivering a homecare training and support intervention (NIDUS-Professional) together with delivery of NIDUS-Family intervention to eligible homecare agency clients and family carers. We will assess whether the NIDUS-Professional intervention is acceptable and feasible to deliver in practice and confirm if *a priori* criteria for progression to a full trial are met. These criteria include adherence of homecare staff to the NIDUS-Professional intervention and completion of follow-up measures by homecare workers and clients.

Secondary objectives include piloting recruitment and assessment processes for the planned full trial of the linked interventions and assessing fidelity of intervention delivery.

METHODS AND ANALYSIS

Trial design (8)

The trial is a single-blind, multi-site, cluster-randomised (2:1) controlled feasibility trial of the NIDUS-Professional intervention with homecare staff, with delivery of the NIDUS-Family intervention to eligible agency clients and family carers.

Patient and Public Involvement

Patient and Public Involvement (PPI) of NIDUS programme is led by the Alzheimer's Society. Two people living with dementia, four family carers, several homecare workers and two homecare managers have been involved in the co-production of the NIDUS-professional intervention. This study protocol has been discussed with PPI representatives in our NIDUS-professional coproduction group (November 2019), including two family carers of people living with dementia, recruited via the Alzheimer's society Research Volunteer Network.

Our PPI community of interest group supporting the study, will assist with understanding the data and dissemination. We aim to invite people (including people living with dementia, family carers, homecare workers, homecare managers) to join our network to keep informed and contribute ideas.

Study settings and population (9)

We are recruiting 6-9 homecare agencies from across England. Within each agency, we plan to recruit all eligible homecare staff and homecare agency clients living with a diagnosis of dementia or screening positive for probable dementia on the Noticeable Problems Checklist[13] and family carers of included clients who are in at least monthly contact.

Eligibility criteria (10)

Eligible agencies will have ≥5 staff members who are able to attend training.

From participating agencies, people living with dementia/ family carer dyads and homecare staff who meet the following inclusion criteria will be recruited:

People living with dementia receiving care from eligible homecare workers:

- Clients with a documented diagnosis of dementia of any severity who are living in their own homes: alone or with others and with/without a family carer willing to participate in the study.
- Clients who screen positive for probable dementia (a score of 5 or 6) on the Noticeable Problems Checklist.

Family Carer:

- 18 years or older.
- Have at least monthly face-to-face, email or telephone contact with the person living with dementia.

Homecare staff:

- Employee of participating homecare agencies providing direct care to dementia clients.
- 18 years or older.
- Able to understand spoken English.

Exclusion criteria

- People living with dementia who are receiving palliative care support and considered to be in the last 6 months of their life.
- People living with dementia who, because they are temporary clients or have given notice, are not expected to be clients of the agency in 6 months' time.
- Homecare staff who do not plan to remain working in the agency for 6 months or more.

- Family carers or homecare workers who lack capacity to consent.

Interventions (11)

Homecare workers and people living with dementia receiving care from an agency in the control arm of the trial will continue to receive usual care from NHS, memory services (clients), GP surgeries, and any other health or social care services. Participants in the control arm will not receive the intervention and will only be contacted to collect outcome measures at follow-up.

All participating homecare staff working in agencies randomised to the intervention arm will receive the NIDUS-Professional intervention. Their participating clients living with dementia and their family carers will be offered individual support sessions (NIDUS-Family) over six months, contemporaneously with the delivery of the NIDUS-Professional intervention.

NIDUS-Professional intervention

NIDUS-Professional training comprises six structured manualized group intervention sessions delivered over three months, followed by three monthly catch-up groups to support homecare workers and explore the extent to which they are applying what they have learnt in practice. The intervention was developed in collaboration with people living with dementia, family carers, homecare workers and managers, health professionals, and researchers using their personal experiences and drawing on evidence of best practice in training and support for homecare workers for people living with dementia. Full details of NIDUS-Professional content, the process of co-design and results from an initial pilot study are reported elsewhere.[11, 12] The intervention is delivered online by two facilitators to groups of 6-8 homecare workers. Sessions are held every two weeks for 12 weeks; each last around 1-1.5 hours and cover specific topics (Table 1). Homecare workers who cannot attend a session receive a catch-up session with one of the facilitators. Participants who attend all 6 sessions are awarded a certificate of completion.

Table 1. Sessions' Content

Session	Topic
1	Introduction and your vital role: the importance of peer support and homecare staff wellbeing
2	Opening doors: building positive relationships and managing reluctance to engage with support
3	Doing with, not for: supporting people to stay active and involved in meaningful activities
4	Being a team: Supporting each other and working as a team with family carers and other homecare workers and professionals
5	Quality care: managing behaviours that challenge and other care challenges
6	Putting it all together (developing individual and agency action plans)

Managers of homecare agencies who have been randomised to the intervention arm receive three one-to-one sessions with the programme manager and team clinical psychologist (at the beginning, middle and end of the delivery period). These sessions cover topics likely to influence agency adoption of NIDUS-Professional recommendations,[14] including:

1. Capability and confidence of the homecare manager and autonomy to make decisions

2. Evidence of buy-in from relevant agency staff and senior managers (where the agency is not independent)
3. Engagement from leaders who express a shared vision to improve services / quality of care
4. Evidence of a culture of wanting change or seeing change as something to be welcomed
5. Receptiveness of manager and senior staff within the agency to engage and lead the change

NIDUS-Family intervention

NIDUS-Family is a manualised intervention currently being evaluated in a randomised trial.[9] It is delivered to either the family carer alone or the family carer and person living with dementia together; dyads select personal goals and modules to help them achieve their goals. The intervention consists of 6-8 sessions, once every 2-3 weeks over six months. Participating dyads (people living with dementia and their family carers) will discuss with facilitators how homecare workers can support them to work towards the goals they set. NIDUS-Professional facilitators will encourage homecare workers to bring their client's NIDUS-Family goals to group sessions, and to discuss progress or results of strategies suggested by the group in subsequent sessions. Facilitators will also encourage the group to reflect on how learning from NIDUS-Family goals and plans is brought to the group and how it can inform how homecare workers deliver care to people living with dementia without a family carer.

The NIDUS researchers are psychology or social science graduates who are selected for family, volunteer or professional dementia care experience and excellent communication skills, but do not have formal clinical training. To facilitate linking of the two interventions, the same facilitators who deliver NIDUS-professional to an agency (in pairs) also deliver NIDUS-family to clients (in individual sessions) from that agency. They receive supervision from a clinical psychologist.

Outcomes (12)
Primary outcomes of the feasibility trial are:

- Successful recruitment of homecare workers and clients to the trial
- Proportion of homecare workers adhering to the intervention (attending at least 4/6 sessions)
- Proportion of homecare workers completing the proposed primary outcome for a future trial at 6-six month follow-up (work related strain inventory)[15]
- Proportion of homecare agency clients with dementia for whom the proposed main outcome (DEMQol or DEMQOL-proxy)[16] is completed at 6-month follow-up.

All outcomes intended for the full trial will be collected at baseline and after six months (see data collection section below and supplementary material for the full list of outcomes).

Process evaluation: All intervention participants will be asked to complete an intervention acceptability questionnaire, and around 12 homecare workers, all homecare managers, and 12 family carers/people living with dementia dyads will also be invited to take part in qualitative interviews. These will be at three months and six months after randomisation. At three months (i.e., after the final session of the intervention is delivered) homecare workers are invited to join a focus group or attend an individual interview if they prefer. Managers are also invited to participate in an interview at this stage. We will also invite all the NIDUS facilitators to provide structured feedback on the intervention. We will undertake individual, qualitative interviews with family carers and people living with dementia at six months (after NIDUS-Family intervention delivery is complete) to explore their experiences of the

intervention, with a specific focus on how their homecare worker has supported them during the intervention. We will ask homecare workers whether and how the intervention has impacted client and family carer wellbeing and homecare workers' wellbeing and practice. The feedback will then be used to develop a final version of the intervention manual for a future pragmatic trial.

After the monthly catch-up sessions scheduled between three and six months have been completed, homecare workers, managers, and facilitators will be contacted either by email or phone, to answer some brief follow-up questions about how they have experienced the catch-up sessions.

Sample size (14)

We aim to recruit 60-90 homecare staff (40-60 in the intervention arm) and at least 60 clients and 30 family carers through 6-9 English homecare agencies. With these numbers we will be able to estimate parameters with sufficient precision to help inform continuation to a larger trial based on our pre-specified progression criteria (Table 2).

Table 2: A priori criteria for progression to a full randomised trial: These criteria are intended as guidance, and would not be implemented in isolation, but considered within the wider context of the study and fidelity work

Progression parameter	**Proceed without adaption**	**Proceed with adaptions**	**Consider not proceeding**
Proportion of homecare workers adhering to intervention (attending at least 4/6 sessions)	>65%	51-65%	≤50%
Proportion of homecare workers completing work related strain inventory at 6-month follow-up	>75%	51-75%	≤50%
Proportion of homecare agency clients with dementia with DEMQol or DEMQOL-proxy completed at 6-month follow-up.	>75%	51-75%	≤50%

Recruitment (15)

We advertised the opportunity to take part in this trial by speaking at clinical forums for homecare agency managers, and through direct contact with independent homecare agencies and franchises. We made contact with homecare agency managers, asking them to approach all their eligible homecare staff inviting them to take part.

We will ask homecare agencies to identify and approach all eligible clients living with dementia and their family carers. Researchers will then contact eligible clients and carers who are interested and an appointment will be arranged to explain the study, obtain informed consent and carry out the baseline assessment.

All study appointments will be conducted remotely either on the telephone or by videocall.

Consent (26a)

Trained researchers will take informed consent from homecare workers, people living with dementia and their family carer. Researchers will obtain verbally-recorded or written informed consent from each

participant. If the person living with dementia does not have capacity to consent, the family member/carer will be asked to complete a personal consultee declaration form as set out in the Mental Capacity Act 2005. If no personal consultee can be identified, the opinion of a nominated consultee will be sought.

Allocation

Sequence generation (16a)

Allocation of agencies to NIDUS-Professional and control groups will be carried out based on a computer-generated randomisation list created and held by the PRIMENT Clinical Trials Unit (CTU). The list will be constructed based on random blocks sizes (to prevent allocations being predictable), aiming to achieve an allocation ratio of approximately 2:1 (such that for every two agencies randomised to the intervention, one agency will be allocated to the control).

Allocation concealment mechanism (16b)

To achieve allocation concealment, the randomisation list will be held with limited access at the PRIMENT CTU. Once an eligible agency has been identified, the trial manager will request the next allocation from the responsible CTU member. From that point only the trial manager and the researchers delivering the intervention will be aware of the agencies' allocation status.

Implementation (16c)

Once an eligible agency is identified, researchers will recruit participants and collect baseline data. As soon as this data collection for the agency is completed, the trial manager will request allocation from the responsible person at the PRIMENT CTU.

Blinding (17a)

Researchers who have not been involved in recruitment or intervention delivery, will collect follow-up measures and will be blinded to group allocations. Success of the blinding process will be examined by asking assessors to guess intervention status of each agency.

Procedure for unblinding if needed (17b)

Independent researchers conducting the follow-up assessments will remain blinded to randomisation status throughout the study unless a participant accidentally discloses this. We do not foresee any circumstances where unblinding the researchers conducting follow-up assessments will be necessary.

Data collection (18a)

Data will be collected at baseline and six month follow-up for all participants. At baseline we will collect sociodemographic details of all participants. In addition, we will collect information from homecare staff about their training, employment role, hours worked per week, duration of time working in homecare and for current agency; client with dementia and their family carers will be asked about their relationship, frequency of contact with each other and the duration of time they have received homecare. All researchers will be trained to use data collection tools. Full trial outcomes will be measured using validated questionnaires (see Supplementary material for full details of measures and table 2 for schedule of assessments).

All homecare workers will be asked to complete:

- Work-related Strain Inventory[15]
- Sense of Competence in Dementia Care Staff[17]

Clients with dementia will be asked to complete:

- The Dementia Quality of Life (DEMQoL)[16]
- Home Care Satisfaction Measure (home health aide scale)[18]

Proxy measure for clients with dementia will be completed by their family carers and the homecare worker who works most closely with the client:

- The Dementia Quality of Life (DEMQoL) proxy[16]
- Disability Assessment for Dementia scale[19]
- The brief Neuropsychiatric Inventory Scale (NPI-Q)[20]

Family carers will be asked to proxy-complete:

- Adapted version of the Client Services Receipt Inventory (CSRI)[21] (including information about service use and medication)
- Homecare satisfaction measure (home health aide scale)[18]

In addition, we will collect data in the intervention arm to enable us to report intervention attendance. We will audio-record intervention sessions, and two researchers will independently rate sessions against a checklist to estimate fidelity to the manual.

Plans to promote participant retention and complete follow-up (18b)

All assessments and study visits will be conducted over videocall or telephone (where participants are unable or unwilling to use videocall). Agencies and homecare staff will be reimbursed for their time (£20 per hour). People living with dementia/ family carer dyads will be offered a £20 voucher per dyad to thank them for their time after each assessment appointment (baseline, six month and qualitative interview).

Statistical methods (20a)

The proportion of eligible homecare staff, clients, and family carers approached who agree to take part in the study will be reported with 95% confidence intervals and reasons for refusal summarised. We will summarise the demographic characteristics and scores measured at baseline and six months, using appropriate summary statistics, and including the proportion with missing data for each measure. For all scores measured at six months, differences between the randomised groups will be calculated with 95% confidence intervals.

We will estimate progression parameters to inform continuation to the larger trial, specifically recruitment rates (per month), the proportion of homecare workers adhering to the intervention (attending at least 4/6 sessions); proportion of clients for whom six month DEMQOL or DEMQOL-proxy-rated outcomes are completed, and proportion of homecare staff completing the six month Work Related Strain Inventory.

For qualitative data analysis, we will use NVivo software and take a thematic analytic approach to analysing transcripts of NIDUS-Professional intervention sessions, facilitator process notes, and semi-structured interview findings.[22] Our findings will be used to adapt the NIDUS-Professional intervention and the supervision and training programme for researchers delivering it before a future full pragmatic trial of the NIDUS-Professional intervention, if required.

To analyse fidelity of NIDUS-Professional delivery, checklists will be applied independently to transcribed audio recordings of the training sessions by two researchers. A mean fidelity score will be produced by dividing the number of items on the checklist identified as being delivered in the training sessions, by the number of items on the checklist that should have been delivered per training session, per researcher and across all training sessions. We will adopt thresholds used in other intervention fidelity work:[23, 24] where 81–100% constitutes high fidelity, 51-80 is moderate fidelity and 50% or lower constitutes low fidelity.

ETHICS AND DISSEMINATION

Research Ethics approval (24)
The study received ethical approval on 7 January 2020 from the Camden & King's Cross Research Ethics Committee (REC). Study reference: 19/LO/1667 (with a subsequent amendment (approved 07.04.20 by sponsor) to conduct research processes, including consent and intervention sessions remotely). All participants are required to give written or verbal informed consent to take part in the trial. For people living with dementia who lack capacity to take part, a written consultee declaration form will need to be signed by their family member or a nominated consultee (who at the request of the ethics committee may not be a staff member of the homecare agency) for them to participate.

Confidentiality (27)
Personal data needed to re-contact participants for follow up assessments and intervention sessions will be held securely on password protected excel spreadsheets on password-protected computers by the research team. Storage of data will be consistent with ethical procedures, as evidenced by REC approval.

Harms (22)
Any serious adverse events which are classed as related and unexpected will be reported to the sponsor. All serious adverse events will be recorded on the online database hosted by Sealed Envelope on a serious adverse event (SAE) form. The Chief Investigator (CI) or designated researcher will complete the SAE form and the form will be preferably emailed to the sponsor within 24 hours of becoming aware of the event by the trial manager. The Chief or Principal Investigator will respond to any SAE queries raised by the sponsor as soon as possible.

Where the event is unexpected and thought to be related to the procedure it will be reported by the CI to the Health Research Authority within 15 days.

Dissemination policy (31)
We will disseminate our findings in a peer reviewed journal and present findings in appropriate fora for health and social care professionals. Participants who have indicated they are interested in the results will be sent a lay summary of the findings. The data used and analysed during the study will be available from the corresponding author upon study completion on reasonable request.

DISCUSSION

This protocol describes a cluster-randomised feasibility trial of a training and support programme aiming to improve quality of life and care at home for people living with dementia. To the best of our knowledge, NIDUS-Professional is the first training intervention to be designed by people living with dementia and their family carers, homecare staff and their managers, and health professionals.[8] Our study will examine whether a manualised structured intervention is feasible and acceptable to be delivered to homecare agencies in a full trial.

Homecare workers have a crucial role in supporting people living with dementia to remain in their homes for longer.[25] However, few receive dementia-specific training.[26] Although evidence shows efficacy of psychosocial interventions in improving quality of life and care for people with dementia living in care homes,[27, 28] evidence on interventions aimed at people with dementia living at home remains limited.[7] NIDUS-Professional will address this gap. Our aim is to increase knowledge around the feasibility of delivering such training interventions to homecare staff with a linked support programme for people living with dementia and their family carers. We will conduct a process evaluation and will collect data on fidelity which will be useful for the subsequent full trial.

One of the challenges we expect is adherence to intervention among homecare staff. Homecare workers have tight and busy schedules often with limited autonomy and the demands of their role may lead to low adherence. In the light of Covid-19, the NIDUS-Family stream of the programme shifted to remote delivery and assessment which provided an opportunity to consider benefits and disadvantages of remote delivery of NIDUS-Professional. Offering telephone or videocalls instead of in-person visits can improve the rate of adherence as it offers more flexibility. Furthermore, it will allow for more inclusive recruitment without the additional cost of travel. Another challenge will be the high turnover of homecare staff: even prior to Covid-19 this was estimated at 38% annually among social care staff.[29] We also plan to recruit people living with dementia who do not have capacity to consent, through consent of a personal or nominated consultee. The challenge we foresee would be to recruit people living with dementia who do not have a family carer to act as a personal consultee, as per ethical stipulations, homecare workers cannot act as nominated consultee for clients without capacity. In our pilot trial,[12] while adherence to NIDUS-professional was promising, we did not manage to recruit any clients living with dementia or family carers. We refined our processes in response to this, initiating discussions with agencies about client recruitment earlier. However, this experience did highlight the challenges of recruiting clients of homecare agencies living with dementia to take part in a trial, many of whom were living alone and were very isolated, apart from being supported by the homecare agency, whose staff by requirements of our ethics consent were not permitted to act as nominated consultees. An important purpose of this randomised feasibility trial will be to determine whether and how many homecare clients with dementia it is feasible to recruit using this trial design, to inform a future larger pragmatic trial.

Trial Status

Protocol version: No 5., 19 November 2020. First homecare agency was randomised in December 2021.

ACKNOWLEDGEMENTS

Funding

This work is part of the NIDUS (New Interventions in Dementia Study), which is hosted within the Alzheimer's Society Centre of Excellence for Independence at home (Centre of Excellence grant 330).

IL's time on this independent research project is in part supported by the National Institute for Health and Care Research (NIHR) Applied Research Collaboration South West Peninsula. The views expressed in this publication are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.

Declaration of Interest

The authors declare no conflict of interest.

Authors Contribution

CC is the chief investigator of the study and secured the funding for the study. LD is managing the recruitment and study procedures. SZ, AD, FK, and DK are involved in conducting recruitment and collecting data. KL, SB, and PR provided input into study and intervention design. CM, JM, KW, IL, KR and HK provided input into study and trial design. SD contributed to PPI work. JB and VV designed the statistical aspects. SZ wrote the first draft of the manuscript. All authors contributed intellectual content to the paper and reviewed the final version prior to submission.

REFERENCES

1 Wittenberg R, Hu B, Barraza-Araiza L, et al. Projections of older people with dementia and costs of dementia care in the United Kingdom, 2019–2040. *London: London School of Economics* 2019.

2 van der Roest HG, Meiland FJM, Maroccini R, et al. Subjective needs of people with dementia: a review of the literature. *Int Psychogeriatr* 2007;19(3):559-92. doi: 10.1017/S1041610206004716 [published Online First: 2007/01/04]

3 Lord K, Livingston G, Robertson S, et al. How people with dementia and their families decide about moving to a care home and support their needs: development of a decision aid, a qualitative study. *BMC Geriatr* 2016;16(1):68. doi: 10.1186/s12877-016-0242-1

4 Prince M, Knapp M, Guerchet M, et al. Dementia UK: Update(Second edition): King's College London, 2014.

5 Brodaty H, Draper B, Saab D, et al. Psychosis, depression and behavioural disturbances in Sydney nursing home residents: prevalence and predictors. *Int J Geriatr Psychiatry* 2001;16(5):504-12. doi: https://doi.org/10.1002/gps.382

6 Gaugler JE, Mittelman MS, Hepburn K, et al. Clinically significant changes in burden and depression among dementia caregivers following nursing home admission. *BMC Med* 2010;8(1):85. doi: 10.1186/1741-7015-8-85

7 Cooper C, Cenko B, Dow B, et al. A systematic review evaluating the impact of paid home carer training, supervision, and other interventions on the health and well-being of older home care clients. *Int Psychogeriatr* 2017;29(4):595-604. doi: 10.1017/S1041610216002386 [published Online First: 2017/01/16]

8 Lord K, Beresford-Dent J, Rapaport P, et al. Developing the New Interventions for independence in Dementia Study (NIDUS) theoretical model for supporting people to live well with dementia at home for longer: a systematic review of theoretical models and Randomised Controlled Trial evidence. *Soc Psychiatry Psychiatr Epidemiol* 2020;55(1):1-14. doi: 10.1007/s00127-019-01784-w

9 Burton A, Rapaport P, Palomo M, et al. Clinical and cost-effectiveness of a New psychosocial intervention to support Independence in Dementia (NIDUS-family) for family carers and people living with dementia in their own homes: a randomised controlled trial. *Trials* 2021;22(1):865. doi: 10.1186/s13063-021-05851-z

10 Rapaport P, Burton A, Palomo M, et al. A mixed-methods feasibility study of a goal-focused manualised intervention to support people with dementia to stay living independently at home with support from family carers: NIDUS (New Interventions for Independence in Dementia Study) Family. *Aging & Ment Health* 2021;25(8):1463-74.

11 Lord K, Kelleher D, Ogden M, et al. Co-designing complex interventions with people living with dementia and their supporters. *Dementia* 2022;21(2):426-41. doi: 10.1177/14713012211042466

12 Kelleher D, Lord K, Duffy L, et al. Time to reflect is a rare and valued opportunity; a pilot of the NIDUS-professional dementia training intervention for homecare workers during the Covid-19 pandemic. *Health Soc Care Community* 2022; 00: 1-12. doi: https://doi.org/10.1111/hsc.13737

13 Levin E. Noticeable problems checklist. *London: National Institute for Social Work* 1989

14 Goodman C, Sharpe R, Russell C, et al. Care home readiness: a rapid review and consensus workshops on how organisational context affects care home engagement with health care innovation. UK: NHS England 2017.

15 Revicki DA, May HJ, Whitley TW. Reliability and validity of the Work-Related Strain Inventory among health professionals. *Behav Med* 1991;17(3):111-20.

16 Smith SC, Lamping DL, Banerjee S, et al. Measurement of health-related quality of life for people with dementia: development of a new instrument (DEMQOL) and an evaluation of current methodology. *Health Technol Assess (Winchester, England)*. 2005;9(10):1-iv. doi: 10.3310/hta9100

17 Schepers AK, Orrell M, Shanahan N, et al. Sense of competence in dementia care staff (SCIDS) scale: development, reliability, and validity. *Int psychogeriatr* 2012;24(7):1153-62.

18 Geron SM, Smith K, Tennstedt S, et al. The home care satisfaction measure: A client-centered approach to assessing the satisfaction of frail older adults with home care services. *J Gerontol B Psychol Sci Soc Sci* 2000;55(5):S259-S70.

19 Feldman H, Sauter A, Donald A, et al. The disability assessment for dementia scale: a 12-month study of functional ability in mild to moderate severity Alzheimer disease. *Alzheimer Dis Assoc Disord* 2001;15(2):89-95.

20 Kaufer DI, Cummings JL, Ketchel P, et al. Validation of the NPI-Q, a brief clinical form of the Neuropsychiatric Inventory. *J Neuropsychiatry Clin Neurosci* 2000;12(2):233-39.

21 Beecham J, Knapp M. Costing psychiatric interventions. In: Thornicraft G, Brewin C, Wing J, eds. Measuring mental health needs. Gaskell: Royal College of Psychiatrists 1992:200-24.

22 Braun V, Clarke V. Reflecting on reflexive thematic analysis. *Qual Res Sport Exerc Health* 2019;11(4):589-97.

23 Noell GH, Gresham FM, Gansle KA. Does treatment integrity matter? A preliminary investigation of instructional implementation and mathematics performance. *J Behav Educ* 2002;11(1):51-67.

24 Holcombe A, Wolery M, Snyder E. Effects of two levels of procedural fidelity with constant time delay on children's learning. *J Behav Educ* 1994;4(1):49-73.

25 Carter, D. Fix Dementia Care: Homecare Report. London: Alzheimer's Society, 2016.

26 Polacsek M, Goh A, Malta S, et al. 'I know they are not trained in dementia': addressing the need for specialist dementia training for home care workers. *Health Soc Care Community* 2020;28(2):475-84.

27 Lawrence V, Fossey J, Ballard C, et al. Improving quality of life for people with dementia in care homes: making psychosocial interventions work. *Br J Psychiatry* 2012;201(5):344-51. doi: 10.1192/bjp.bp.111.101402 [published Online First: 2018/01/02]

28 Lawrence V, Fossey J, Ballard C, et al. Helping staff to implement psychosocial interventions in care homes: augmenting existing practices and meeting needs for support. *Int J Geriatr Psychiatry* 2016;31(3):284-93. doi: https://doi.org/10.1002/gps.4322

29 Skills for Care. The state of the adult social care sector and workforce in England, 2021. Leeds: Skills for Care, 2021.

Full trial outcomes:

All homecare workers will complete:

- **Work-related Strain Inventory** comprises 18 items, each scored on a 4-point response scale, ranging from Does not apply to me (1) to Does apply to me (4). Total scale scores range from 18 to 72. The WRSI can be completed in 5 minutes, has satisfactory internal (0.85 to 0.9) and test-retest reliability (0.63) and convergent validity.[15]
- **Sense of Competence in Dementia Care Staff** asks staff 17 questions to find out about how able they feel to deliver person-centred care. It asks, for example, how well they feel they can *understand the feelings of a person with dementia or engage a person with dementia in a conversation.* This scale has been shown to have good internal consistency (Cronbach's alpha=0.91) and test-retest reliability (0.74).[17]

People living with dementia will be asked to complete:

- **The Dementia Quality of Life** (DEMQoL) is a 28-item questionnaire measuring quality of life in people living with dementia. DEMQoL has been shown to have good internal consistency (Cronbach's alpha=0.87), test-retest reliability (0.84) and moderate convergent validity [16]
- **Home Care Satisfaction Measure** provides an overall homecare satisfaction score and subscale scores for five common services on a 0-100 scale (home health aide scale). This scale has high internal consistency, test-retest validity (ranging between 0.68 and 0.88) and substantial concurrent validity.[18]

Proxy measure for people living with dementia will be completed by their family carers and the homecare worker who works most closely with the client:

- **The Dementia Quality of Life (DEMQoL) proxy** is a valid and reliable measure of quality of life in people living with dementia in the last week which is completed with carers. It is a 31-item interviewer-administered questionnaire with good internal consistency (Cronbach's alpha=0.87), test-retest reliability (0.75) and moderate convergent validity [16]
- **Disability Assessment for Dementia scale (DAD)** is a standard measure of functional independence (basic and instrumental activities of daily living). Content validity of DAD has been established as well as internal consistency (Cronbach's alpha>0.8) and excellent inter-rater (r=0.95) and test-retest reliability (r=0.96).[19]
- **The brief Neuropsychiatric Inventory Scale (NPI-Q)** is a 12 domain survey assessing neuropsychiatric symptomatology. The NPI-Q provides symptom Severity and Distress ratings for each symptom reported, and total Severity and Distress scores reflecting the sum of individual domain scores. This scale has shown test-retest reliability (r>0.8) and adequate convergent validity.[20]

Family carers will be asked to proxy-complete:

- **Adapted version of the Client Services Receipt Inventory (CSRI)** records health and social care resource utilisation including homecare, hospitalisations, respite and all-cause time to transition from home to an institution.[21]
- **Home care satisfaction measure** (home health aide scale)[18]

CONSORT Flow Diagram

(http://www.consort-statement.org/)

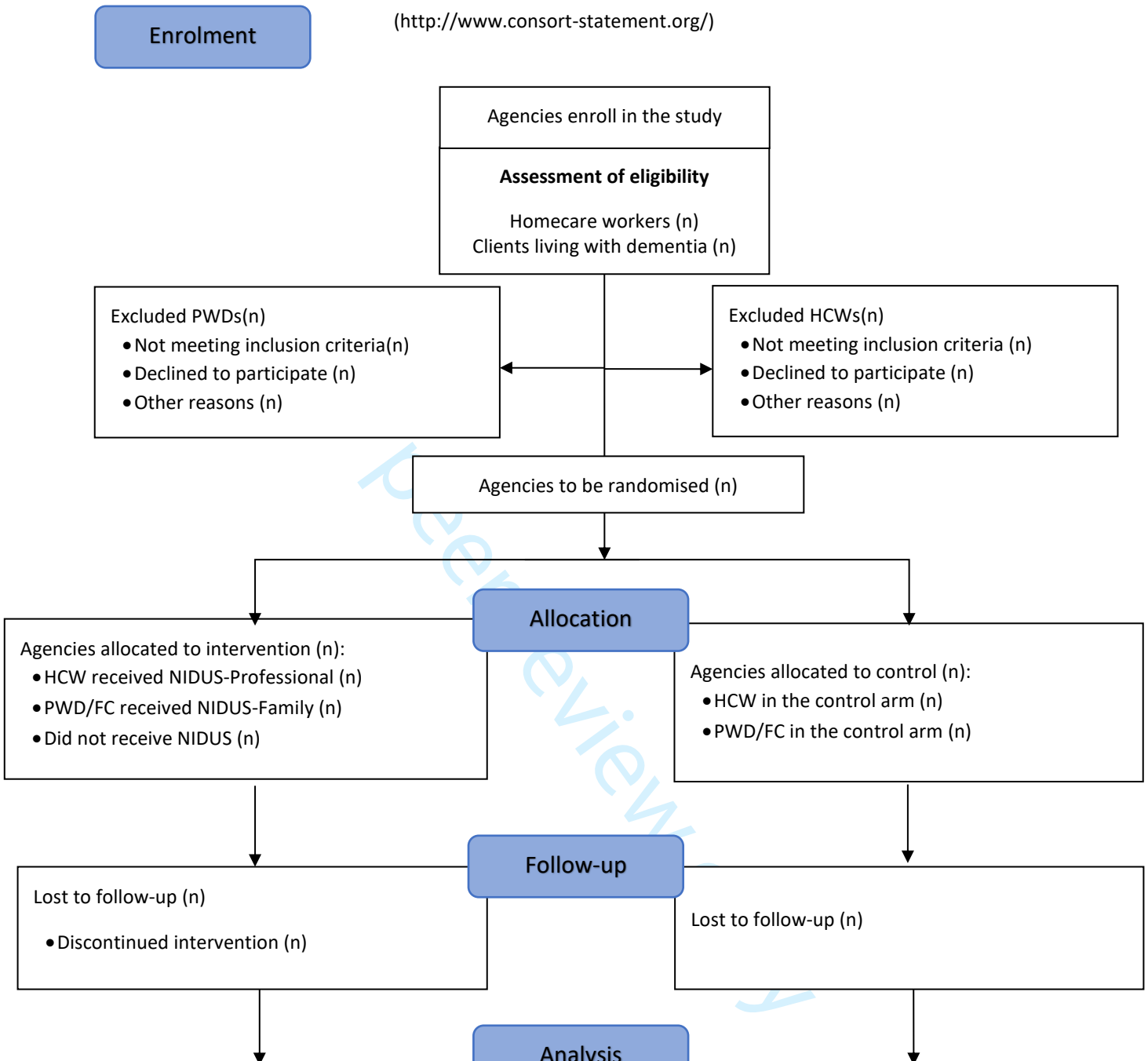

Table 1. Schedule of Assessments

	Screening and baseline (Pre-treatment assessment)	**Intervention phase**					**Follow up**	**Optional qualitative interview**
Visit No:	1	2	3	4	5	6	7	8
Window of flexibility for timing of visits:		+/- 2 weeks	+/- 2 weeks	+/- 2 weeks	+/- 2 weeks	+/- 2 weeks	+/- 4 weeks	+/- 2 weeks
Informed Consent	x							
Eligibility confirmation	x							
Baseline assessment (Self report questionnaires)	x							
Randomisation	x							
Training intervention		x	x	x	x	x		
6 month follow up assessment (self-report questionnaires)							x	
Optional qualitative interview								x
Adverse Events review	X	X	X	X	X	X	X	
Concomitant Medication review (if applicable)	X	X	X	X	X	X	X	

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	ItemNo	Description	No. Page
Administrative information			
Title (1)	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	ISRCTN15757555
	2b	All items from the World Health Organization Trial Registration Data Set	
Protocol version	3	Date and version identifier	11
Funding	4	This work is part of the NIDUS (New Interventions in Dementia Study), which is hosted within the Alzheimer's Society Centre of Excellence for Independence at home (Centre of Excellence grant 330).	11-12
Author details	5a	Names, affiliations, and roles of protocol contributors	1
	5b	Name and contact information for the trial sponsor	Joint Research Office, UCL Gower Street, London WC1E 6BT Email: uclh.randd@nhs.net

	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	Neither the study sponsor (UCL Joint Research Office), nor the funder (Alzheimer's Society) have been involved in study design; collection, management, analysis, and interpretation of data; writing of the report; or the decision to submit the report for publication. They do not have ultimate authority over any of these activities.
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	Not included
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3
	6b	Explanation for choice of comparators	Not included
Objectives	7	Specific objectives or hypotheses	3
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	3

Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	4
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	4
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	5-6
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Not included
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	Not included
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	Not included
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	6
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Supplementary material
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	7
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			

Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	8
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	8
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	8
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	8-9
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	9

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	Not included
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	9-10
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	Not included
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	Not included
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Not included
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Not included
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	10
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	Not included
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	10

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Not included
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	7
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Not applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	12
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	Not included
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	Not included
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	10
	31b	Authorship eligibility guidelines and any intended use of professional writers	Not included
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Not included

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Not included
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

(A page number column has been added to this checklist to link to the appropriate section of submitted manuscript.)