





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

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}

To cite: Zabihi S, Duffy L, Kelleher D, *et al.* 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. *BMJ Open* 2022;**12**:e066166. doi:10.1136/bmjopen-2022-066166

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-066166>).

Received 28 June 2022
Accepted 08 December 2022



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For numbered affiliations see end of article.

Correspondence to

Sedigheh Zabihi;
sedigheh.zabihi.18@ucl.ac.uk

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 (1) its acceptability among homecare workers and employing agencies, and (2) 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, multisite 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 video call 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. 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.

Trial registration number ISRCTN15757555.

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

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 the 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

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

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 the 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 co-production 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

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 Checklist¹³ and family carers of included clients who are in at least monthly contact.

Eligibility criteria

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

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 National Health Service, memory services (clients), GP (General Practitioner) 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 6 months, contemporaneously with the delivery of the NIDUS-Professional intervention.

NIDUS-Professional intervention

NIDUS-Professional training comprises six structured manualised 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 six to eight 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 six sessions are awarded a certificate of completion.

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 six to eight 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 the 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

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 four out of six sessions).
- ▶ Proportion of homecare workers completing the proposed primary outcome for a future trial at 6-month follow-up (work related strain inventory).¹⁵
- ▶ Proportion of homecare agency clients with dementia for whom the proposed main outcome (Dementia



Quality of Life (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 6 months (see data collection section below and online supplemental 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 (ie, 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

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 prespecified progression criteria (table 2).

Recruitment

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

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

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 block 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

To achieve allocation concealment, the randomisation list will be held with limited access at the PRIMENT

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 adaptations	Consider not proceeding
Proportion of homecare workers adhering to intervention (attending at least four out of six 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%

DEMqOL, Dementia Quality of Life.

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

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

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 the intervention status of each agency.

Procedure for unblinding if needed

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

Data will be collected at baseline and at 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 online supplemental material for full details of measures and [table 1](#) 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 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

All assessments and study visits will be conducted over video call 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

The proportion of eligible homecare staff, clients and family carers approached who agree to take part in the study will be reported with 95% CIs 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% CIs.

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 four out of six 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 analytical 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

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

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

Any serious adverse events (SAEs) which are classed as related and unexpected will be reported to the sponsor. All SAEs will be recorded on the online database hosted by Sealed Envelope on a 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 CI 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

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 consultees 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 home-care agency was randomised in December 2021.

Author affiliations

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

Twitter Sedigheh Zabihi @NIDUS_study

Contributors 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 patient and public involvement work. JAB 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.

Funding This work is part of the NIDUS (New Interventions for Independence 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.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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ORCID iDs

Sedigheh Zabihi <http://orcid.org/0000-0002-2770-0862>
 Daniel Kelleher <http://orcid.org/0000-0003-2659-1606>
 Kathryn Lord <http://orcid.org/0000-0001-6681-2624>
 Kate Walters <http://orcid.org/0000-0003-2173-2430>
 Iain Lang <http://orcid.org/0000-0002-8473-2350>
 Claudia Cooper <http://orcid.org/0000-0002-2777-7616>

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