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## CLINICAL TRIAL

# 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

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## Abstract

**Introduction:** In the first randomised controlled trial of a dementia training and support intervention in UK homecare agencies, we aimed to assess: acceptability of our co-designed, manualised training, delivered by non-clinical facilitators; outcome completion feasibility; and costs for a future trial.

**Methods:** This cluster-randomised (2:1) single-blind, feasibility trial involved English homecare agencies. Intervention arm agency staff were offered group videocall sessions: 6 over 3 months, then monthly for 3 months (NIDUS-professional). Family carers (henceforth carers) and clients with dementia (dyads) were offered six to eight complementary, individual intervention sessions (NIDUS-Family). We collected potential trial measures as secondary outcomes remotely at baseline and 6 months: HCW (homecare worker) Work-related Strain Inventory (WRSI), Sense of Competence (SoC); proxy-rated Quality of Life (QOL), Disability Assessment for Dementia scale (DAD), Neuropsychiatric Inventory (NPI) and Homecare Satisfaction (HCS).

**Results:** From December 2021 to September 2022, we met agency (4 intervention, 2 control) and HCWs ( $n=62$ ) recruitment targets and recruited 16 carers and 16/60 planned clients. We met a priori progression criteria for adherence ( $\geq 4/6$  sessions: 29/44 [65.9%, 95% confidence interval (CI): 50.1, 79.5]), HCW or carer proxy-outcome completion (15/16 [93.8% [69.8, 99.8]]) and proceeding with adaptation for HCWs outcome completion (46/63 [73.0% [CI: 60.3, 83.4]]). Delivery of NIDUS-Professional costs was £6,423 (£137 per eligible client). WRSI scores decreased and SoC increased at follow-up, with no significant between-group differences. For intervention arm proxy-rated outcomes, carer-rated QOL increased, HCW-rated was unchanged; carer and HCW-rated NPI decreased; DAD decreased (greater disability) and HCS was unchanged.

**Conclusion:** A pragmatic trial is warranted; we will consider using aggregated, agency-level client outcomes, including neuropsychiatric symptoms.

**Keywords:** dementia, homecare, training, feasibility randomised controlled trial (RCT), carers, older people

## Key Points

- This is the first randomised controlled trial of a dementia training and support intervention in UK homecare agencies.
- We met a priori progression criteria for adherence ( $\geq 4/6$  sessions) to the intervention (65.9%).
- We also met a priori criteria for proxy-outcome completion (93.4%).
- We met a priori criteria for proceeding with adaptations for home care worker outcome completion (73%).
- We recruited to target for home care agencies and home care workers, but not clients and their family carers.

## Introduction

Around 900,000 people living in the UK have dementia. Homecare (in-home, domestic and personal care provided by professional, paid care workers) is pivotal to client and family carer (henceforth carer) wellbeing, yet inconsistent and variable in quality [1]. Homecare Workers (HCWs) are underpaid, undervalued and expected to provide skilled care with little or no training [1–3].

The non-mandatory English Care Certificate describes standards HCW are expected to attain or work towards in their first 3 months of employment [4]. However, evidence to guide its implementation is scarce [5]. NIDUS-professional development was intended to support plans to increase social care workforce capacity and skills in England [6], building on the Care Certificate [4, 7]. To our knowledge, only two previous randomised controlled trials (RCTs) have tested interventions to improve dementia homecare quality, neither in the UK. Both evaluated 6 h of HCW training; a Norwegian trial measured outcomes in clients only and did not meet recruitment targets [8]. An Australian RCT (yet to report) aimed to collect outcomes in HCW and clients [9].

Homecare for people living with dementia should be personalised, enabling, inclusive and collaborative [10, 11]. We initially developed NIDUS-Family, a goal-setting and manualised intervention that was more effective than goal-setting alone on the primary outcome of Goal Attainment Scaling [12], an individualised global outcome, over 1 year in a RCT [13]. We also co-designed and piloted NIDUS-Professional as an evidence-based support and training programme for homecare staff, to reduce HCW strain and improve client quality of life [14]. We intended these interventions to be synergistic.

Our primary objective was to determine feasibility and acceptability of delivering NIDUS-Professional to eligible staff. We assessed whether we met a priori criteria for progression to a full trial: intervention adherence of HCW and follow-up measures completion by HCW and client/family dyads. Secondary objectives were to establish the feasibility of collecting health economic data and to estimate intervention costs.

## Methods

### Study design

Camden & King's Cross Research Ethics Committee (20/LO/0567) approved the study in May 2020. It is a

single-blind, multi-site, cluster-randomised (2:1) controlled feasibility trial of NIDUS-Professional intervention for HCW, with delivery of the NIDUS-Family intervention to eligible agency clients and carers. Its protocol is published [15].

### Study settings and population

We recruited and randomised English homecare agencies between December 2021 and September 2022. We advertised at managers' forums and contacted homecare agencies and franchises directly. We recruited agencies for diversity of region, urban/suburban/rural locations and independent agencies/franchises. Within each agency, we aimed to recruit the manager and all eligible HCW, clients and carers. Interested managers were asked to approach all eligible staff. Criteria for agency eligibility were identifying  $\geq 5$  eligible staff members and willingness to support training attendance. Client inclusion criteria were: (a) documented dementia diagnosis of any severity; or (b) scoring positive for probable dementia (a score of 5 or 6) on the Noticeable Problems Checklist rated by staff [16]. We excluded clients receiving palliative care support and considered to be in the last 6 months of life. For each client, we sought to include a carer in at least monthly face-to-face, email or telephone contact with them. We included all HCWs providing hands-on care to clients with dementia, and the manager, provided they intended to remain at the agency for at least 6 months. We excluded carers without capacity to consent.

### Interventions

All participants with dementia received routine health or social care. In intervention arm agencies, participating HCWs received NIDUS-Professional; clients with dementia and carers were offered dyadic or carer support sessions (NIDUS-Family). Both interventions were facilitated by researchers who were psychology or social science graduates, selected for family, volunteer or professional dementia care experience and communication skills, but without formal clinical training. To facilitate intervention linking, the same facilitators delivered NIDUS-Professional to an agency (in pairs) and NIDUS-Family to dyads or carers (one facilitator per dyad). The facilitators received 1 h of group supervision fortnightly from a clinical psychologist (SB).

**NIDUS-Professional** [14, 15] comprises six manualised, 1–1.5 h sessions delivered over 3 months online by two facilitators to groups of 6–8 HCWs, followed by three monthly groups to support them in applying their learning in practice.

Sessions, which were provided in a manual to participants, covered specific topics:

Session	Main elements of session
1	Introduction and your vital role: importance of peer support and HCW wellbeing
2	Building positive relationships and managing reluctance to engage
3	Supporting people to stay active and involved in meaningful activities
4	Supporting each other and working as a team with carers, other HCWs and professionals
5	Quality care: managing behaviours that challenge and other care challenges
6	Putting it all together (developing individual and agency action plans)

HCWs who missed sessions were invited to 1:1 catch-up sessions. Those attending six main sessions received a certificate. The monthly groups were more informal and less structured; facilitators followed a topic guide, discussing with HCWs how they used learning in practice. Intervention arm agency managers were invited to three individual sessions with the programme manager (L.D.) and clinical psychologist (S.B.), covering topics likely to influence agency adoption of NIDUS-Professional recommendations, including: manager capability and confidence, buy-in from relevant agency staff and senior managers (where the agency was not independent); and receptiveness to culture change. Managers did not attend HCW NIDUS-professional groups.

**NIDUS-Family** is delivered to the carer alone or to carer and care recipient dyads. Dyads set personalised and measurable goals, then select modules to help them achieve them. It comprises six to eight sessions over 6 months [13, 17]. NIDUS-Professional facilitators encouraged HCW to discuss clients' NIDUS-Family goals in NIDUS-Professional sessions.

### Procedures

All trial procedures were remote, by telephone or video-call due to pandemic restrictions. Trained researchers obtained written or verbally recorded informed consent from HCWs, clients living with dementia and carers. If clients were judged not to have capacity, we identified an appropriate consultee as per the Mental Capacity Act 2005. Agencies or the HCWs were reimbursed, depending on whether activities were on their own or work time (participants £20 per hour; agencies for their usual hourly rate). Potential interviewees were offered a £20 voucher to thank them for completing assessments.

### Outcomes

Primary outcomes were:

- Successful recruitment of HCWs and client:carer dyads
- Proportion of HCWs adhering to the intervention (attending at least 4/6 sessions)

- Proportion of HCWs completing Work-Related Strain Inventory (WRSI) [18].
- Proportion of homecare agency clients with dementia for whom Dementia Quality of Life proxy (DEMQOL-Proxy) was completed at follow-up by HCW or carer [19].

At baseline, we collected sociodemographic details of all participants and information from HCWs about their training and role (Tables 1–3). Researchers blind to allocation group collected outcomes intended for a full trial at baseline and 6 months, selected to assess different levels of training impact [20]: HCWs' sense of competence and decreased work-related strain; and changes at the organisational level, including client outcomes and satisfaction with services.

HCW completed:

- **Work-Related Strain Inventory (WRSI)** [18];
- **The Sense of Competence in Dementia Care Staff:** about how able staff feel to deliver person-centred care [21].

Proxy measure for clients with dementia was completed by carers and HCW working most closely with them:

- **DEMQOL-Proxy** is a valid and reliable measure of quality of life in the last week [19];
- **Disability Assessment for Dementia scale (DAD)** measures the proportion of basic and instrumental activities of daily living performed without prompting or assistance in the last 2 weeks [22];
- **The brief Neuropsychiatric Inventory Scale (NPI-Q)** [23];

Carers proxy-completed:

- **An adapted version of the Client Services Receipt Inventory**, recording health and social care resource utilisation [24];
- **Home Care satisfaction measure** [25];

Clients with dementia were invited to complete: the self-reported Dementia Quality of Life (DEMQOL) [19] and Home Care Satisfaction Measure. Details of measures are in the protocol [15].

### Randomisation and concealment of allocation

Allocation used a computer-generated randomisation list created and held by PRIMENT Clinical Trials Unit, based on random blocks sizes (to prevent allocations being predictable), aiming for an allocation ratio of approximately 2:1 (intervention: control). Only the trial manager and intervention facilitators knew agencies' allocation.

### Analysis

We aimed to recruit 60–90 homecare staff (40–60 in the intervention arm), 60 clients, including 30 carer: client dyads through 6–9 English homecare agencies. Numbers were calculated as adequate to estimate feasibility parameters with sufficient precision to inform continuation to a larger trial based on pre-specified progression criteria. These were:

**Table 1.** Characteristics of participating home care workers

Variable	Intervention ( <i>N</i> = 44)		Control ( <i>N</i> = 19)		Total ( <i>N</i> = 63)	
	Mean (SD) or <i>n/N</i>	Median (LQ, UQ) or %	Mean (SD) or <i>n/N</i>	Median (LQ, UQ) or %	Mean (SD) or <i>n/N</i>	Median (LQ, UQ) or %
Age	48.8 (13.0)	50.8 (38.8, 56.6)	44.1 (11.0)	48.1 (33.4, 53.0)	47.4 (12.5)	50.0 (36.6, 55.6)
Missing	0		1		1	
Gender						
Male	0/44	0.0	3/19	15.8	3/63	4.8
Female	44/44	100.0	16/19	84.2	60/63	95.2
Ethnicity						
British	39/44	88.6	15/19	79.0	54/63	85.7
Other	5/44	11.4	4/19	21.0	9/63	24.3
First language						
English	39/44	88.6	17/19	89.5	56/63	89.0
Other	5/44	11.4	2/19	10.5	7/63	11.0
Education						
Postgraduate	3/44	6.8	2/19	10.5	3/63	4.8
Undergraduate	5/44	11.4	0/19	0.0	7/63	11.1
HNC/HND	2/44	4.6	1/19	5.3	3/63	4.8
Vocational	23/44	52.3	10/19	52.6	33/63	52.4
GCSE/O level/A level	6/44	13.6	4/19	21.1	10/63	15.9
No formal qualification	1/44	2.3	0/19	0.0	1/63	1.6
Other	4/44	9.1	2/19	10.5	6/63	9.5
Dementia Training						
Yes	38/44	86.4	16/19	84.2	54/63	85.7
No	6/44	13.6	3/19	15.8	9/63	14.3
Days of training						
1 day or less	22/37	59.5	11/13	73.3	33/52	63.5
2–3 days	4/37	10.8	1/13	6.7	5/52	9.6
4 or more	11/37	29.7	3/13	20.0	14/52	26.9
Missing	1		1		2	
Employment						
Home carer	36/44	81.8	15/19	79.0	51/63	81.0
Home care manager	1/44	2.3	1/19	5.3	2/63	3.2
Other	7/44	15.9	3/19	15.8	10/63	15.9
Working hours						
Full-time	21/44	47.7	13/19	68.4	34/63	54.0
Part-time	19/44	43.2	6/19	31.6	25/63	39.7
Other	4/44	9.1	0/19	0.0	4/63	6.4
Time worked in current agency						
Less than 6 months	2/44	4.6	1/19	5.3	3/63	4.8
6 months to 1 year	6/44	13.6	4/19	21.1	10/63	15.9
1–3 years	14/44	31.8	7/19	36.8	21/63	33.3
3–5 years	9/44	20.5	5/19	26.3	14/63	22.3
5–10 years	9/44	20.5	2/19	10.5	11/63	17.5
10+ years	4/44	9.1	0/19	0.0	4/63	6.4
Time worked in home care overall						
Less than 6 months	2/44	4.6	1/19	5.3	3/63	4.8
6 months to 1 year	3/44	6.8	3/19	15.8	6/63	9.5
1–3 years	9/44	20.5	5/19	26.3	14/63	22.2
3–5 years	5/44	11.4	4/19	21.1	9/63	14.3
5–10 years	10/44	22.7	3/19	15.8	13/63	20.6
10+ years	14/44	31.8	3/19	15.8	17/63	27.0
Unable to specify	1/44	2.3	0/19	0.0	1/63	1.6

SD, standard deviation; LQ, lower quartile; UQ, upper quartile

- Proportion of HCWs attending at least 4/6 intervention sessions (proceed without adaptations: >65%; with adaptations: 51–65%; consider not proceeding: ≤50%);
- Proportion of HCWs completing WRSI at follow-up: (proceed without adaptations: >75%; with adaptations: 51–75%; consider not proceeding: ≤50%)
- Proportion of clients with DEMQOL-Proxy completed at follow-up (proceed without adaptations: >75%; with adaptations: 51–75%; consider not proceeding: ≤50%)

We reported the proportion of eligible HCWs, clients and carers approached agreeing to take part with 95% confidence

**Table 2.** Characteristics of participating people living with dementia

Variable	Intervention ( <i>N</i> = 13)		Control ( <i>N</i> = 3)		Total ( <i>N</i> = 16)	
	Mean (SD) or <i>n/N</i>	Median (LQ, UQ) or %	Mean (SD) or <i>n/N</i>	Median (LQ, UQ) or %	Mean (SD) or <i>n/N</i>	Median (LQ, UQ) or %
Age	88.8 (8.4)	92.4 (85.7, 93.3)	88.6 (1.9)	88.9 (86.5, 90.4)	88.8 (7.6)	91.4 (86.1, 93.2)
Gender						
Male	5/13	38.5	1/3	33.3	6/16	37.5
Female	8/13	61.5	2/3	66.7	10/16	62.5
Marital status						
Single	1/13	7.7	0/3	0.0	1/16	6.3
Widowed	8/13	61.5	3/3	100.0	11/16	68.8
Married/Civil partnership	3/13	23.1	0/3	0.0	3/16	18.8
Divorced	1/13	7.7	0/3	0.0	1/16	6.3
Ethnicity						
British	13/13	100.0	3/3	100.0	16/16	100.0
First language						
English	13/13	100.0	3/3	100.0	16/16	100.0
Education						
Postgraduate	2/13	15.4	0/3	0.0	2/16	12.5
Undergraduate	2/13	15.4	1/3	33.3	3/16	18.8
HNC/HND	1/13	7.7	0/3	0.0	1/16	6.3
Vocational	1/13	7.7	0/3	0.0	1/16	6.3
GCSE/O level/A level	0/13	0.0	1/3	33.3	1/16	6.3
No formal qualification	1/13	7.7	0/3	0.0	1/16	6.3
Other	6/13	46.2	1/3	33.3	7/16	43.8
Accommodation						
Rented	3/13	23.1	0/3	0.0	3/16	18.8
Owner-occupied	9/13	69.2	3/3	100.0	12/16	75.0
Other	1/13	7.7	0/3	0.0	1/16	6.3
Living situation						
Alone	8/13	61.5	2/3	66.7	10/16	62.5
With partner/spouse	2/13	15.4	0/3	0.0	2/16	12.5
Other	3/13	23.1	1/3	33.3	4/16	25.0
Dementia diagnosis						
Alzheimer's disease	6/13	46.2	0/3	0.0	6/16	37.5
Vascular dementia	3/13	23.1	0/3	0.0	3/16	18.8
Unable to specify	1/13	7.7	1/3	33.3	2/16	12.5
Other	3/13	23.1	2/3	66.7	5/16	31.3
Current agency years	2.8 (2.0)	2.0 (1, 4)	3.3 (3.2)	2.0 (1, 7)	2.9 (2.2)	2.0 (1, 4.5)
Overall agency years	3.7 (2.6)	4.0 (2, 5)	3.3 (3.2)	2.0 (1, 7)	3.6 (2.6)	3.0 (2, 5)

SD, standard deviation; LQ, lower quartile; UQ, upper quartile

**Table 3.** Mean and median values for HCW secondary outcomes, missing values imputed<sup>a</sup>

Measure	Time	Intervention ( <i>n</i> = 44)		Control ( <i>N</i> = 19)	
		Mean (SD)	Median (LQ, UQ)	Mean (SD)	Median (LQ, UQ)
<i>Analysis:</i>					
<i>WRSI</i>	Baseline	28.2 (5.9)	28.0 (24, 33)	27.0 (3.9)	27.0 (23, 29)
	Missing	1		0	
	6 months	28.9 (6.4)	27.0 (24, 35)	27.1 (7.0)	25.0 (21.5, 32.5)
<i>Sense of competency</i>	Baseline	53.9 (6.7)	53.0 (50, 58)	56.4 (5.7)	57.0 (52, 59)
	Missing	0		0	
	6 months	55.0 (6.1)	54.5 (50, 60)	58.0 (6.0)	58.5 (53.5, 62)
	Missing	14		3	

<sup>a</sup>Mean imputation—summaries are for scores calculated following mean imputation of missing questionnaire items in cases where less than 10% of items were unavailable: for Sense of Competency, there were no values to impute; LQ, lower quartile; UQ, upper quartile

intervals (CIs), reasons for refusal and summarised demographic characteristics and scores. The three progression parameters (above) were estimated with 95% CIs. For scores

measured at 6 months, we report the differences between randomised groups with 95% CIs estimated from regression models that account for the baseline score and clustering by

agency. For cases where missing items prevented scoring of a questionnaire, and less than 10% of items were missing, we imputed the missing responses using individual mean imputation. Data for these scores are summarised; and data before such imputation are shown in Supplementary Tables.

### Health economic analysis

As costs of NIDUS-Family are being evaluated separately [13, 26], we only measured NIDUS-Professional costs. Training costs were calculated based on agency manager and HCW attendance, assuming hourly reimbursement of £20; and salary rates for non-clinical facilitators, supervising clinical psychologist and trial manager for manager consultation sessions. Our estimate of the cost per client was based on the potential number of clients who could have benefited (all eligible clients). Two scenarios analysed were (a) all HCW participated in the main sessions, (b) one HCW participated in each main sessions per site and others completed it in catch-up sessions. Costs were from a health and social care perspective and calculated with unit costs from the Personal Social Services Research Unit [27], NHS references costs (2021/2022) and for medication the British National Formulary (2023). Utility tariffs were calculated using Dementia Quality of Life (DEMQOL-Proxy-U) proxy responses.

## Results

### Recruitment

Figure 1 describes recruitment and follow-up. Six out of 31 (19.4%; 95% CI 7.5–37.5) agencies, located in North-West, North-East, Midlands, East Anglia, South coast and South-East England, initially expressing interest were randomised. Five were franchises and one independent; all had overall Care Quality Commission ratings of ‘good’ (on a four-point scale: poor, fair, good, excellent). Others declined ( $n = 14$ ), citing lack of time or resources, or were uncontactable after expressing interest; 11 agencies were unable to recruit  $\geq 5$  eligible staff members. Within participating agencies, we randomised 63/179 (35.2% [28.2, 42.7]) eligible HCWs and 16/55 (29.1% [17.6, 42.9]) eligible dyads. Participation rates varied across sites, as discussed in our accompanying process evaluation paper [28].

We met our recruitment targets for agencies and HCWs, but for only 53% (16/30) of our target for client: carer dyads. We fell short of the 30 targeted clients without carers as agencies were unwilling to approach them. Clients with dementia who took part gave consent (or their consultees signed a declaration) to agree to proxy measures, but no clients completed self-administered measures. Tables 1 and 2 and Table S1 (Supplementary Material) show participants’ sociodemographic characteristics. Of 11/16 clients for whom the Clinical Dementia Rating was completed, two (18.5%) were rated as having questionable, three (27.3%) mild, five (45.5%) moderate and one (9.1%) severe dementia at baseline. Two

serious adverse events (unrelated to the intervention) were recorded, one in each arm. Reasons for 17 HCWs not being followed up at 6 months were: 4 withdrew as they left the agency, 2 declined and 11 were lost to follow-up.

### Primary outcomes (progression parameters)

#### Intervention adherence

The proportion of HCWs adhering to NIDUS-Professional intervention (attending at least 4/6 sessions) was 29/44 (65.9% [50.1, 79.5]). This met a priori criteria for proceeding to full trial without adaptation.

Amongst dyads eligible for NIDUS-Family, 7/13 (54%) received any intervention: four received six to eight sessions, two four sessions and one a single session.

#### Outcome completion

Fifteen out of sixteen (93.8% [69.8, 99.8]) of clients had DEMQOL-Proxy completed by a HCW or carer at follow-up in complete case and 16/16 (100% [79.4, 100]) in analyses following mean imputation of missing questionnaire items in cases where <10% items were incomplete. This met a priori criteria for proceeding to full trial without adaptation.

We also considered whether proxy ratings by each group of raters individually met progression criteria; 13/16 (81.3% [54.4, 96.0]) of clients had HCW completed DEMQOL-Proxy in complete case and 14/16 (87.5% [61.7, 98.4]) in imputation analyses. 10/16 clients (62.5% [35.4, 84.8]) had carer-completed DEMQOL-Proxy. These met criteria for progressing without and with adaptations respectively.

Forty-three out of 63 (68.3% [55.3, 79.4]) HCWs completed the WRSI at follow-up in complete case analysis and 46/63 (73.0% [60.3, 83.4]) in analysis with imputation. This met a priori criteria to proceed with adaptations. The Sense of Competence in Dementia questionnaire was completed by 46/63 (73.0%) of HCW.

### Secondary outcomes

We report these by group with imputed values (Tables 3 and 4), and complete case in Supplementary Material (Tables S2 and S3). Median WRSI scores decreased slightly, and mean and median Sense of Competence scores increased in both groups; adjusted differences in means between groups (intervention-control) at follow-up were 0.941 [95% CI: -2.380, 4.262] and -0.457 [-4.696, 1.782], respectively;  $n = 46$ , intra cluster correlation co-efficient <0.001).

Because there were only three control arm carers, we did not statistically compare groups for carer assessed outcomes. In the intervention arm, proxy-rated outcomes showed the following changes: DEMQOL-proxy rated by carers increased, while it remained unchanged when rated by HCWs; both carer and HCW-rated NPI-Q scores decreased; DAD scores decreased (greater disability) and Home Care Satisfaction scores were unchanged at follow-up.



**Table 4.** Mean and median values for proxy-rated client secondary outcomes, missing values imputed<sup>a</sup>

	Home Care Worker proxy completion				Family carer proxy completion				
	Intervention (n = 13)		Control (N = 3)		Intervention (n = 13)		Control (N = 3)		
	Mean (SD)	Median (LQ, UQ)	Mean (SD)	Median (LQ, UQ)	Mean (SD)	Median (LQ, UQ)	Mean (SD)	Median (LQ, UQ)	
<i>Disability Assessment for Dementia Scale</i>									
Baseline	42.2 (26.1)	33.3 (21.9, 64.1)	12.5 (.)	12.5 (12.5, 12.5)	39.6 (20.6)	31.8 (27.5, 55)	32.5 (35.3)	27.5 (0, 70)	
Missing	2	2	2	2	0	0	0	0	
6 months	32.9 (24.1)	30.8 (10, 57.1)	64.7 (38.5)	64.7 (37.5, 91.9)	20.1 (21.2)	15.0 (5.7, 36.8)	30.8 (39.2)	17.5 (0, 75)	
<i>DEMQL-Proxy</i>									
Baseline	102.7 (8.9)	101.0 (98, 107)	100.0 (.)	100.0 (100, 100)	88.8 (15.0)	82.0 (79, 104)	90.3 (9.5)	90.0 (81, 100)	
Missing	2	2	2	2	6	0	0	0	
6 months	98.7 (13.9)	101.5 (96, 106)	101.0 (5.7)	101.0 (97, 105)	87.3 (13.2)	89.0 (79, 100)	99.0 (7.0)	99.0 (92, 106)	
<i>NPI questionnaire</i>									
Baseline	22.5 (24.0)	15 (0, 36)	108 (.)	108 (108, 108)	174.9 (200.7)	120 (104, 180)	166 (168.1)	121 (25, 352)	
Missing	2	2	2	2	0	0	0	0	
6 months	13.0 (21.0)	3.5 (0, 19.5)	4 (5.7)	4 (0, 8)	142.2 (235.0)	40 (15, 165)	50.0 (62.4)	30 (0, 120)	
<i>HCS—home carer service</i>									
Baseline					59.2 (7.4)	58.5 (54, 65)	60.5 (3.6)	58.5 (58, 65)	
Missing	1	1	1	1	1	1	1	1	
6 months					58.9 (6.8)	58.5 (54, 66)	61.5 (5.5)	60.0 (57, 68)	
<i>HCS—care management</i>									
Baseline					62.8 (9.5)	64.6 (55, 72)	64.1 (7.3)	61.5 (59, 72)	
Missing					1	1	0	0	
6 months					61.3 (8.4)	63.1 (55, 68)	62.6 (4.4)	60.0 (60, 68)	
<i>HCS meal service</i>									
Baseline					12.0 (24.3)	0 (0, 9.1)	9.1 (15.7)	0 (0, 27)	
Missing					1	1	0	0	
6 months					9.4 (24.7)	0 (0, 0)	0 (0)	0 (0, 0)	
Missing					6	6	0	0	

<sup>a</sup> Mean imputation—summaries are for scores calculated following mean imputation of missing questionnaire items in cases where less than 10% of items were unavailable; LQ = lower quartile, UQ = upper quartile

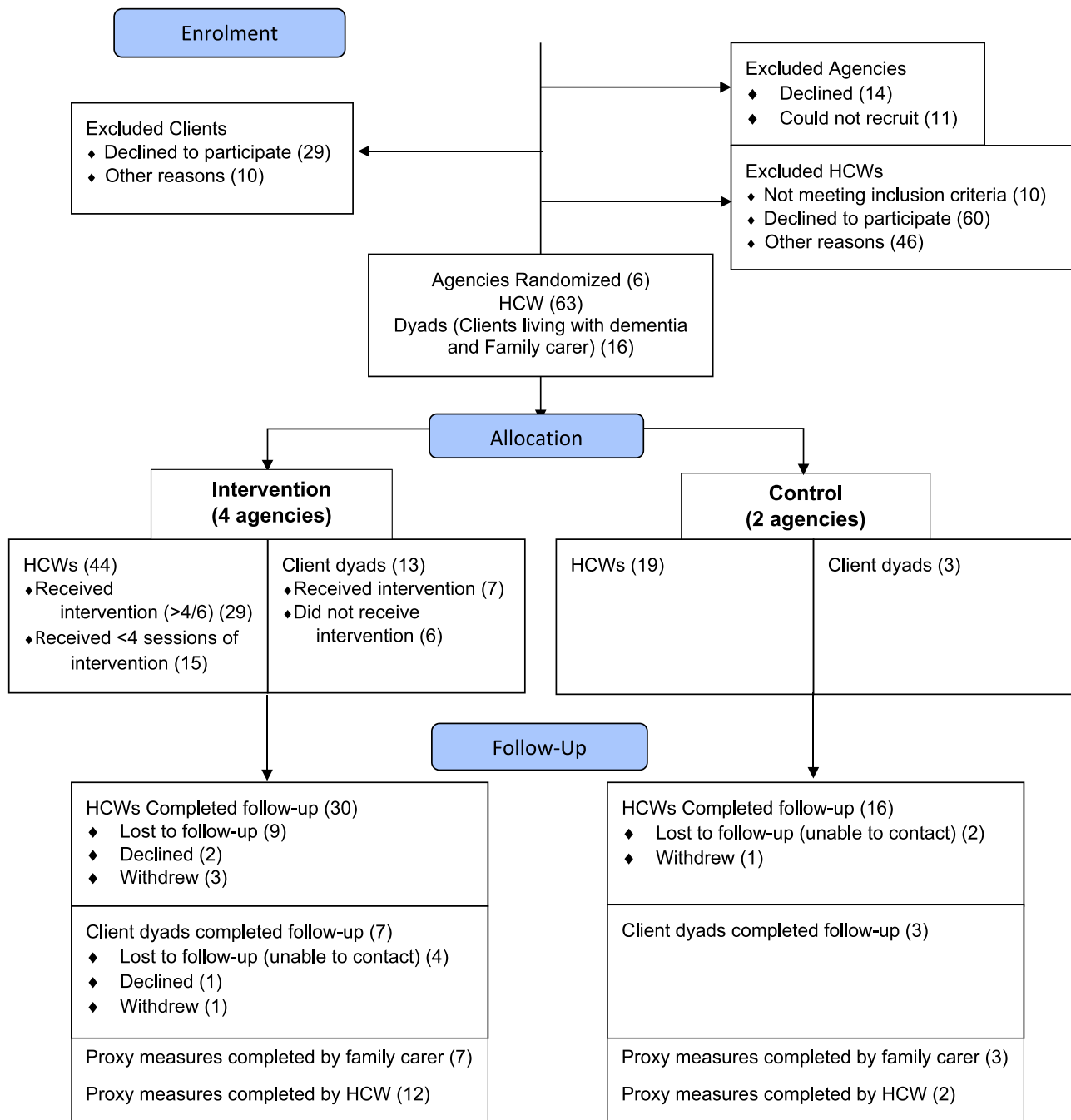


Figure 1. CONSORT diagram

### Health economic analyses

The total cost for delivering the NIDUS intervention training was calculated as £6,423 (£137 per eligible client [ $n = 55$ ]); scenario analyses indicated a range from £5,560 to £6,605. Full details of intervention, health and social care costs by group and DEMQOL-Proxy-U scores are in Tables S4–S6 (Supplementary Material).

### Discussion

This is the first RCT of a dementia training and support intervention in UK homecare agencies. Findings suggest

that NIDUS-Professional is potentially feasible and acceptable to deliver in a challenging research environment (Homecare agencies during the Covid-19 pandemic). A priori progression criteria (without adaptations) were met for intervention adherence and HCW proxy-rater follow-up, and for proceeding with adaptations for HCW outcomes and carer proxy-outcome completion. We met recruitment targets for agencies and HCWs but not for carers or clients, primarily due to agency reluctance to approach clients with dementia to invite them to take part in research, without the engagement of a regular carer.

Our findings could support either WRSI or the Sense of Competence measure as a future trial primary outcome; both have been included in a recent Australian trial [9], for which results are awaited. HCW proxy-rated quality of life was higher than those of carers at baseline, reflecting previous observational study findings [29], and a ceiling effect may have contributed to lack of change in HCW ratings in the trial. HCW and carer neuropsychiatric symptoms ratings were more aligned. HCWs usually visit for short periods to provide personal care, when neuropsychiatric symptoms often manifest, so may have been better able to rate these symptoms compared to quality of life.

Potential adaptations in a full trial may include HCW completing outcomes at 3 (after the main intervention) and 6 months, to mitigate staff turnover, which reduced completion rates. All processes were remote in the pandemic, and engaging in-person may improve retention. Due to the challenges in recruiting agency clients and carers, we will consider collecting client outcomes aggregated at the agency level, using brief HCW or client measures that participating agencies use or agree to adopt routinely, as in previous trials [30]. Shorter measures such as the EQ-5D may be sufficient for calculating Quality-adjusted life years (QALYs) and have better completion rates, and without the additional burden or consent processes, more clients may complete this [31]. HCW proxy-rated neuropsychiatric symptoms may be an appropriate client-related outcome for a future trial.

We will consider paying HCW research champions' time to collect outcomes and co-facilitate the intervention to increase agency buy-in. Aggregated outcomes would enable us to test how the intervention might have improved care for all clients. Face-to-face collection of data from clients or carers with assurance of anonymity would increase completion; we have collected outcomes anonymously in previous cluster RCTs [32]. Most costs reported were for emergency care and care provision. In a future trial, we will focus on collecting emergency care data, and estimating carer input, particularly for clients who require 24-h care.

To our knowledge, this is the first RCT of a whole-homecare agency training and support intervention [8, 9]. A third of eligible HCWs in participating agencies participated—probably a more representative study population than for evaluations of opt-in programmes likely to engage only more committed and engaged staff. Similar training models have proven effective in care homes [33]. As only four carers received an adequate dose of NIDUS-Family, it is likely that any intervention effects were related to NIDUS-Professional. A future trial involving HCW training only may be more pragmatic, especially as the effectiveness of NIDUS-Family is now demonstrated [13], and opportunities to link the interventions were, in practice, limited. Only a fifth of the agencies we initially engaged took part, and one randomised agency had low engagement; as we discuss in our process evaluation, we will explore how to be more inclusive of agency management in a full trial intervention [28].

Training reduces care worker turnover and improves care quality [34]. England policy makers plan to increase social

care workforce capacity and skills [6], and introduce a knowledge and skills framework, building on the Care Certificate [4, 7]. NIDUS-Professional may, if effectiveness is demonstrated, provide a credible option for homecare agencies to deliver training and support. We will use our findings to plan a full-scale trial.

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