Pilot and Feasibility Studies

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Implementation of the Cognitive Daisy (COG-D) for improving care planning and delivery for residents with dementia in care homes: results of a feasibility randomised controlled trial

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Abstract

Background Many residents in care homes for older adults live with dementia. Understanding the unique profiles of cognitive impairments for each resident is important for person-centred care, yet information about specific cognitive problems is limited, and knowledge varies. This study explored the feasibility of implementing the Cognitive Daisy (COG-D) intervention, which provide a visual summary in the shape of a 15-petal flower derived from the scores on a neuropsychological assessment battery, in care homes for older adults.

Methods A parallel-group feasibility cluster randomised controlled trial (cRCT) was conducted over 24 months. Eight care homes were randomised in a 1:1 ratio to either usual care plus the Cognitive Daisy intervention (COG-D) or usual care (control). Care staff were trained on how to use Cognitive Daisies and/or on how to conduct the COG-D assessments with residents. Cognitive Daisies were displayed in residents' rooms and included in care plans. COG-D assessments were repeated after 6 months. The primary objective was to explore areas of uncertainty for a future large-scale trial including recruitment rates and intervention implementation and adherence. Secondary objectives were to explore signals of effects in candidate outcome measures for residents and staff, obtained at baseline and 6- and 9-month post-randomisation. A process evaluation explored barriers and facilitators to intervention implementation through care-plan audits (to explore recommendations in response to COG-D assessments), interviews and focus groups with staff, residents and relatives.

Results Resident recruitment ($n=115$) and staff recruitment ($n=99$) in 8 care homes exceeded targets (100 and 50, respectively, in 8–10 care homes). Staff training was perceived positively with high completion rates (77.1% and 83.3% for basic and advanced training, respectively). Completion rates were also high for COG-D assessments (75.5% for assessment 1, and 72.5% of these residents completed assessment 2), and COG-D scores remained stable across the two assessment points. No clear signals of effects were found for candidate outcome measures. Number of recommendations in care plans varied across care homes, and interviews/focus groups highlighted several barriers to staff's use of the Cognitive Daisies in daily practice.

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Conclusion Findings indicate trial delivery was feasible. However, the COG-D requires modification if it is to be feasibly implemented in care home settings.

Trial registration This trial was registered on (date) (ISRCTN15208844).

Keywords Dementia, Cognitive impairments, Cognitive daisy intervention, Care homes, Feasibility

Key messages regarding feasibility

- *Existing uncertainties regarding the feasibility*

  ➢ Care home recruitment and recruitment/retention of residents for investigating effectiveness of COG-D intervention in care homes for older adults

  ➢ Acceptability of, and adherence to, COG-D intervention in a care homes setting
- *Key feasibility findings*
  ➢ Recruitment/retention targets were achievable for care homes and residents.
  ➢ COG-D assessments were acceptable for residents.
  ➢ Staff engagement with COG-D was high during the initial training phase but declined afterwards.
- *Implications for design of main study*
  ➢ The protocol for recruitment was suitable for a large-scale trial.
  ➢ More research is needed to adapt the COG-D materials for digitisation and to explore in which specific care home context COG-D would be most impactful.

Introduction

As the older population is growing worldwide [1, 2], the associated increase of dementia poses a challenge to those living with the condition, their relatives and friends and the social care workforce. Approximately, 280,000 people over the age of 65 years are currently living in care homes in the UK [3], at least 70% of those residents are estimated to live with dementia and 78% experience distress behaviours [4] (e.g. agitation, disinhibition and aggression), causing suffering for residents living with dementia, increased burden for care staff [5, 6] and present significant financial costs to the National Health Service (NHS) and social care [7]. Underlying causes of distress behaviour are heterogenous and are associated with decline in cognitive functions [8], such as cognitive inhibition, memory, attention and perception [9, 10]. The cognitive problems experienced by people living with dementia vary as a function of dementia subtype, premorbid cognitive status and disease progression [11–13] and tend to fluctuate [14]. The importance of understanding the unique combination of cognitive impairments for each individual living with dementia is recognised in models for best practice of person-centred care and is considered essential knowledge for social care staff [15], yet it is an area not often included in dementia training of care staff in care homes [16, 17]. Moreover, information about a resident's cognitive impairments may not be available in care plans or may be limited to a general statement about a diagnosis of dementia [18]. Specific cognitive problems could therefore remain undetected or misunderstood by care staff [19], which could result in unmet needs and greater dependence in activities of daily living. Literature about care staff's knowledge about specific cognitive problems of individual residents with dementia is sparse, which highlights the need for more cognition-focused interventions to support care staff .

The Cognitive Daisy (COG-D) provides a visual representation of a person's cognitive profile in five cognitive domains (visuospatial perception, comprehension, communication, memory and attention) in a 2D flower with 15 petals (Fig. 1). The colour for each petal is derived from the score on 1 of 15 cognitive tasks included in the COG-D assessment battery. Coloured petals indicate cognitive problems that are likely to affect daily living, whereas white petals indicate that problems in this assessed area are less likely. COG-D assesses whether a person can perform a specific task (as opposed to "how well") and is therefore not a diagnostic tool [20]. The cut-off scores for coloured petals are based on normative data obtained from older adults living independently in the community who had no diagnosed cognitive impairments [20, 21]. The COG-D intervention includes staff training (focussed on how to use the daisies or how to conduct the COG-D assessments) and the "petal-by-petal" guide (listing suggestions for care approaches for each cognitive function assessed). The aim of the intervention is to support care home staff to identify resident needs arising from specific cognitive problems and how to adjust in-the-moment care decisions in response to these needs. In alignment with our LOGIC model [21], this is assumed to reduce distress behaviours of residents with dementia and to improve quality of life. A pilot study, focused on exploring perceived usefulness of the COG-D intervention in six care homes, showed that the

Fig. 1 The Cognitive Daisy

introduction of COG-D increased staff ratings of their own understanding of residents' cognitive problems, and that staff perceived the Cognitive Daisies as highly useful for delivery of person-centred care [20].

Given this promise, the present feasibility study aimed to address areas of uncertainty about study design and recruitment for a future large-scale trial evaluating the effectiveness and cost-effectiveness of the COG-D intervention for care home residents. Feasibility was investigated with regard to uncertainty about the following: (1) recruitment and retention of care homes, residents and care staff in both intervention and control conditions, (2) adherence to the COG-D intervention protocol, (3) acceptability and data completion rates of the candidate outcome measures, (4) estimates of effect sizes of proposed outcome measures to establish primary endpoint and sample size for the future CRT and (5) ability to collect health economic data required to undertake a cost-effectiveness analysis in the definitive trial. Additional secondary objectives focused on exploring any signals

of efficacy of COG-D on a range of outcome measures for residents and staff and on exploring implementation and pathways of impact of the COG-D in care homes in a process evaluation.

Methods

We conducted a feasibility cRCT, implementing the COG-D intervention for a 6-month period in eight residential care homes for older adults. The study protocol was delivered in line with the published protocol [21], with subsequent changes outlined in this " Methods" section. The care home recruitment period was from May 2022 to February 2023, and the trial stop date was in August 2024. Care homes were recruited and randomised to either usual care plus the Cognitive Daisy intervention (COG-D) or usual care (control), stratified by size (large > 40 beds vs small < 40). The protocol specified stratification by nursing vs residential homes, but as most of the approached homes were a combination of both, this was not used as a stratification factor in the final randomisation schedule. Care homes were initially informed about the study via the East Midlands Clinical Research Network. Care homes who expressed their interest via email were contacted for a follow-up conversation to discuss the details of involvement before they signed up to the trial. Randomisation of care homes took place after collection of baseline measures. A web-based randomisation system built in the REDCap Cloud electronic data capture system (EDC) was provided by the Hull Health Trials Unit (HHTU). Randomisation by minimisation was undertaken at care home level in 1:1 ratio and stratified by site size (large > 40 beds—small < 40 beds). Each care home was randomised centrally and dynamically after collection of baseline data was completed. A mixed-methods model for data collection was used. The key feasibility outcomes were recruitment and retention rates. Candidate outcome measures for a future RCT for both residents and staff were obtained at baseline and at 6- and 9-month post-randomisation. The first COG-D assessments of residents were completed after randomisation. To investigate whether cognitive change could be captured in a care home setting with COG-D, assessments were repeated 6 m after the first assessment. A process evaluation assessed intervention implementation and barriers and facilitators to this through care plan reviews and with interviews/focus groups.

Care home and participant recruitment

The sample size for this study, 70 care home residents (35 per arm), was based on recommended sample sizes for feasibility studies [22]. The target for resident recruitment was 100 to accommodate a 30% loss to follow-up. Only care homes with a minimum of 20 beds were considered eligible to ensure that the recruitment target could be achieved with 8–10 care homes (recruitment of ~ 40–60% of residents per care homes was expected). Feasibility of recruiting staff was an area of uncertainty. We aimed to recruit 50 members of staff for the COG-D intervention.

Inclusion criteria for care homes were a minimum of 20 beds and specialism in dementia care. Care homes were excluded if a CQC enforcement notice was in place, if the home was involved in another complex intervention or if they already used COG-D. Inclusion criteria for residents were consent (either personal consent or via personal or nominated consultees). For COG-D assessments, additional inclusion criteria were the ability to communicate without an interpreter and adequate vision/hearing. The exclusion criterion for residents was end-of-life care. Inclusion criteria for care staff were permanent employment, contracted via agency or bank, consent and sufficient proficiency in English to contribute to data collection. Staff were excluded if they acted as nominated consultees for residents participating in the study.

Care homes were informed about the study by the East Midlands Clinical Research Network. Expressions of interest from eligible care homes were followed up by meetings with care home managers and senior care staff to discuss details of trial participation and resource requirements (e.g. care staff roles in the intervention homes, care staff time).

Following formal care home recruitment to the trial, anonymous screening of residents was conducted with the lead senior staff and/or manager. Residents who received end-of-life care or who were not well enough to be approached about the study were excluded. The protocol for resident recruitment followed the guidelines of the Mental Capacity Act [23]. Mental capacity was assessed by researchers for eligible residents before obtaining either individual informed consent or advice from a personal consultee (relative or friend of the resident) where the resident lacked capacity to give informed consent. Staff were informed about the study by researchers in person and via leaflets and posters in the staff/nurse's offices. Staff consent was initially obtained for participation in the trial. Additional consent was obtained for the anonymous staff questionnaires. Information leaflets explaining the ongoing study for nonparticipating residents and relatives/friends/visitors were placed at different locations in the care home. For interviews at the end of the trial (process evaluation), separate informed consent was obtained from residents, staff and relatives/friends.

Intervention details

The COG-D intervention commenced after care home randomisation and involved two phases. Phase 1 consisted of staff training and the first COG-D assessment of residents. Phase 2 consisted of the daily use of the Daisies (6 months) and the second COG-D assessment of residents (6 m after the first COG-D assessment).

Phase 1

Staff training There were two levels of training — basic and advanced. The basic training focused on how to read the Daisies and on how to use them in daily practice. This training was aimed at all care staff in the care home. The session started with a discussion of examples in daily care where more specific information about a resident's cognitive profile could be helpful for reducing uncertainty about care decisions. This was followed by an introduction to the different cognitive domains and how they are visualised in the Cognitive Daisy. Interactive practice exercises were included to facilitate learning of the link between colour, petal and cognitive domain and cue cards illustrating these links were handed out. The petal-by-petal guide was introduced and discussed with reference to specific example Cognitive Daisies. Whilst the training could either be completed face-to-face or online, all care homes opted for face-to-face sessions. The advanced training (which could only be completed after finishing the basic training) focused on the COG-D assessment and was aimed at senior staff who would be involved in these assessments. Senior staff was introduced to the COG-D assessment protocol, the individual cognitive tests and the COG-D assessment scripts (a verbatim script for the COG-D assessment to ensure consistency across assessments). This was accompanied by an instructional video where one full assessment was completed by actors and included practice with the tests. Several examples of how the Daisy could inform recommendations in residents' care plans with reference to the petal-by-petal guide were discussed at the end of the session. Indicators of retention of materials were anticipated to be provided in the huddles and in care plan reviews but were not formally assessed at the end of the trial.

The first COG-D assessments with residents were conducted by researchers and were attended by a member of staff. The COG-D ability assessment [20, 21] consists of 15 tests, variants of which are routinely used for assessment of dementia and other neurological disorders. The test materials are presented in a colourful booklet (A6) to enable assessment in a comfortable environment, and colour photos of objects and a large font are used to accommodate reduced vision. Before administering the 15 cognitive tasks, the ability to produce meaningful speech is assessed. For people with speech production problems, a non-verbal version of the assessment (COG-D speech production problems (SP)) is included in the COG-D materials, where alternative methods for responding are used (e.g. pointing, writing or other gestures). For residents who have speech production problems, the centre of the Cognitive Daisy is coloured orange. See supplementary materials for more details about the individual tests.

Tests were introduced as "puzzles" to avoid performance anxiety. Assessments were conducted in the residents' rooms or in another quiet location in the care home. The Cognitive Daisies were created digitally by the researchers after the assessment. A coloured petal indicates that the score for a test is below the cut-off score. If the test cannot be completed, the petal is grey. The Daisies were placed in the care plans and in the residents' rooms at a location where they were considered to be most useful. COG-D assessment scores have high internal consistency and concordance with the 6-item cognitive impairment task [24] in normative data collected from healthy older adults [20].

Phase 2

Researchers visited each intervention care home regularly to provide opportunities for staff to ask questions about the Cognitive Daisies. Scheduled support was provided in the form of huddles with care staff [25]. The aim of the huddles was for researchers to ask care staff questions about their use of the Cognitive Daisies (fidelity/adherence), to answer any queries or to discuss specific cases. After inclusion of the Cognitive Daisies in care plans, senior staff were invited to a care plan review meeting to discuss whether any changes in the care plan would be required based on the resident's COG-D assessment. Newsletters about the trial were circulated in each intervention care home, and staff was informed about the posts on the COG-D website about the trial. Six months after the first COG-D assessment (within a 2-week window), researchers completed the second COG-D assessment with the residents. Senior care staff who attended the advanced training were invited to lead the assessment and to score the assessment independently from the researcher (fidelity/adherence). On completion of the second assessment, care home managers and staff were advised that the Cognitive Daisies would still be useful for approximately 6 months after the second COG-D assessment. Phase 2 of the intervention was finished for a care home when all COG-D reassessments and care plan reviews were completed.

Data collection

The key aim of this study was to address different areas of uncertainty about conducting a future large-scale trial. A mixed-methods approach was used, collecting quantitative and qualitative data to explore the feasibility and acceptability of the implementation of the COG-D intervention in care homes.

Key feasibility outcome measures were related to recruitment and retention of care homes, residents and care staff. Acceptability, fidelity and adherence were evaluated with completion rates for staff training, COG-D assessments, and revisions to care plans. Demographic data for residents was collected from resident care plans, and data for staff was collected in brief questionnaire at the start of the staff training. Candidate outcome measures for residents were obtained by proxy in interviews with staff, whereas outcome measures for staff were collected in an anonymous questionnaire. The key candidate outcome measures for this study were the Cohen-Mansfield Agitation Inventory (CMAI) [26, 27] and the Quality of Life in late-stage Dementia Scale (QUALID) [28]. The CMAI lists 29 agitated behaviours (verbal or behaviourally, e.g. aimless wandering, screaming) and requires ratings of frequency in the previous 2 weeks (1 = never, 7 = several times per hour), with a high score indicating high agitation. The QUALID requires ratings (1–5) of 11 behaviours reflecting indicators of quality of life (e.g. smiling, crying), with scores ranging from 11 to 55; low scores indicate higher levels of quality of life. See Table 1 for the schedule of events.

Table 1 Schedule of events table

Schedule of Events	BL	1 - 8 m PR	6 m PR	9 m PR	Post-trial
Data collection of candidate outcome measures					
Resident Questionnaire (By Proxy)					
CMAI [26, 27]	X		X	X	
QUALID [28]	X		X	X	
BADLS [29]	X		X	X	
EQ- 5D- 5L [30]	X		X	X	
FAST [31]	X		X	X	
Staff Questionnaire					
SCIDS [32]	X		X	X	
CBI [33]	X		X	X	
INTERVENTION					
• *COG-D staff training:*		X			
• *COG-D assessment:*		X			
• *Huddles:*		X			
• *Care plan Review:*		X			
• *COG-D re-assessment:*		X			
Interviews and Focus Group					X

BL Baseline, *PR* Post-randomisation. For full details of measures, see [21]. *CMAI* Cohen-Mansfield Agitation Inventory, *QUALID* Quality of Life in late-stage Dementia Scale, *BADLS* Bristol Activities of Daily Living Scale, *EQ- 5D- 5L* EuroQol – 5D health status questionnaire, *FAST* Functional Assessment Staging of Alzheimer's disease, *SCIDS* Sense of Competence in Dementia Care Scale, *CBI* Copenhagen Burn-out Inventory

Data analysis Analysis and reporting were conducted adhering to CONSORT 2010 guidelines extension for feasibility trials [34]. A CONSORT flow diagram was used to display data completeness and resident throughput from eligibility screening, invitation, study acceptance and final follow-up visit. Feasibility figures on recruitment and retention, COG-D completion and adherence to COG-D implementation protocol were reported and checked against the pre-defined progression criteria. A table showing baseline demographic information for residents was presented. Proposed outcome measures (resident and staff) were summarised with average completion rates at baseline, 6-month and 9-month follow-up. To detect the signal of efficacy, linear mixed models with care home as a cluster (random effects), adjusted for the intervention group and the baseline score of the candidate outcome measure, were employed to calculate the effect sizes of candidate outcome measures (CMAI and QUALID), along with their corresponding intraclass correlation coefficients (ICCs). Adverse events in intervention and control group were summarised. All statistical analyses were performed using SPSS version 28 and R language version 4.2.

Process evaluation Mechanisms of impact, context and the implementation of COG-D in care homes (following guidelines for content of process evaluations [35] were explored through semi-structured interviews and focus groups after the 9 m follow-up data collection period. Interviews were held with residents who completed the COG-D assessments, and focus groups or interviews were conducted with care home managers, senior staff who completed the advanced training, care staff who completed the basic training and relatives of residents who completed the COG-D. Questions explored experiences of the COG-D implementation, perceptions of efficacy and barriers or facilitators to implementation and suggestions for revisions. Data were analysed using template variant of thematic [36] analysis using initial deductive codes related to phases of implementation (e.g. training, use of Cognitive Daisies in daily practice), impacts, barriers and facilitators to implementation. We further explored implementation, dose, reach and fidelity through audits of the COG-D assessments, care plan

Table 2 Key progression criteria

Key progression criteria	
Percentage recruited residents [a]	Green > 60%, Amber 40 - 60%, Red < 40%
Percentage of recruited residents for completion of COG-D and COG-D re-assessment	*First COG-D assessment: Green > 60%, Amber 40 - 60%, Red < 39; Re-assessment: 70% of residents who completed the first COG-D assessment*
Percentage of recruited staff completing Basic Training	*Green > 60%, Amber: 40 - 60%, Red < 40%*
Percentage of recruited senior staff completing Advanced Training	*Green > 75%, amber 60 - 74%, Red < 60%*

Green areas indicate "greenlit" progression criteria. [a]Target recruitment for residents was achieved without the use of nominated consultees

revisions made after assessments and the number of staff trained at basic or advanced level.

Withdrawals All participants were informed about their right to withdraw from the study at any point without giving a reason and without it affecting their care/employment. Withdrawal could be at an individual participant or care home level and from participation in delivery of the COG-D intervention (where relevant) and/or data collection. Staff could decide to continue using the COG-D in their day-to-day practice if they preferred to be withdrawn from intervention delivery and data collection.

Blinding The aim was to blind the researcher responsible for 6 and 9 m data collection for care home allocation (to control or intervention arm) to minimise potential biases in proxy interviews with staff. In practice, this was not feasible as it would require removal of any cues to the intervention by care home staff before each interview (leaflets, displayed daisies) and avoiding any references to the allocation in resident interviews. Blinding was therefore abandoned before the 6 m data collection period.

Data management Hull Health Trials Unit (HHTU) provided the study randomisation system and database built within REDcap cloud and box file storage system which are both within scope of the HHTU NHS Data Security and Protection Toolkit (Organization Code EE133824-HHTU). Healthcare records of residents were only accessed with consent from the participant (or their consultee). The resident's name was held to link the resident with their health and social care records. Staff questionnaire responses were entered directly into the REDcap database via an online link provided by HHTU, with no directly identifiable personal data of staff recorded or stored.

Results

Feasibility outcomes

Feasibility outcomes were analysed against pre-defined progression criteria to assess the feasibility of conducting a full trial. The progression criteria for feasibility were evaluated using a traffic light system, where green (go) indicates criteria have been met — proceed, amber (amend) — some changes required (solutions for remediation for the future large-scale trials are needed) and red (stop) — trial is not feasible. See Table 2. for the progression criteria and Fig. 2 for the flow chart including recruitment numbers.

Care home recruitment

ENRICH contacted eligible care homes (55) registered with ENRICH for expressions of interest at the start of the study. Sixteen care homes responded (29.1%). Eight care homes (50%) were recruited (three nursing homes, five residential homes). Four homes were classified as small (< 40 beds) and four as large (> 40 beds). Four homes were randomised into the intervention group and four into the control group.

Resident recruitment

Out of 256 eligible residents, 115 were recruited (44.9%: control group 62 residents, intervention group 53 residents) via personal consent or via personal consultees. To avoid excessive over-recruitment, recruitment was stopped without the need for consent via nominated consultees (Table 3). Attrition rate at 6 m was 27% and

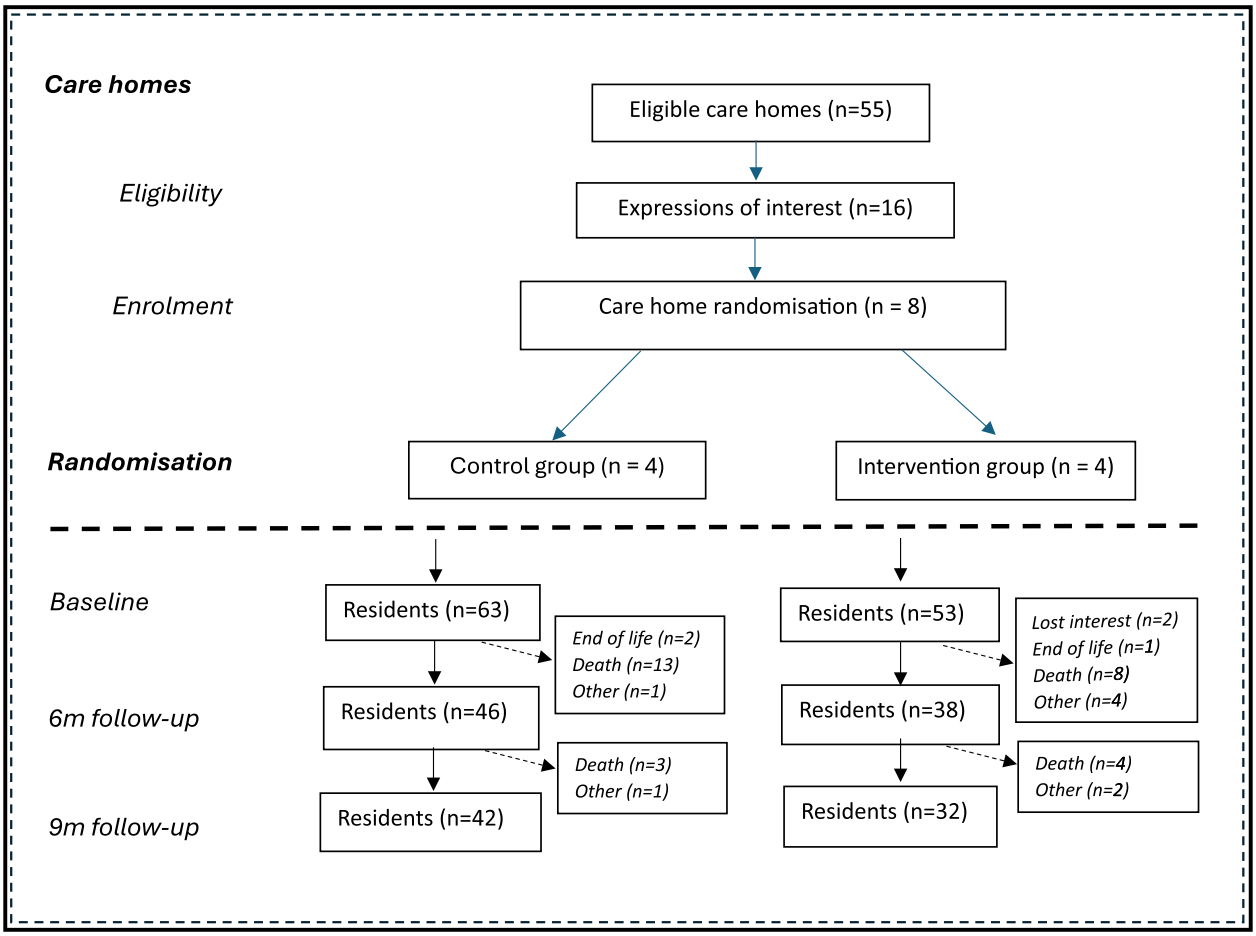

Fig. 2 Care home and resident flow diagram

at 9 m 35%. Intervention and control groups were balanced for age, ethnicity, dementia diagnosis and residence stay. More female residents were included in both groups, although the balance was more even in the control group. As the protocol for resident recruitment had to be changed to avoid over-recruitment (excluded the use of nominated consultees), an evaluation with reference to the traffic system was not appropriate for this feasibility criterion.

Staff recruitment

Ninety-nine staff were recruited (control group 51, intervention group 48). In the intervention group, 114 staff were available and approached (approach to consent rate 42.1%).

COG-D assessment completion

Completion rate for the first assessment was 75.5%. Twenty-seven residents completed the COG-D

Table 3 Demographic information for residents

	C-arm **(n= *62*)**	***I-arm*** **(n= *53*)**	***All*** **(n= *115*)**
Age – Mean (SD)	*N*= 58	*N*= 51	*N*= 109
Age in years	84.1 (7.9)	89.0 (5.8)	86.4 (7.4)
Gender – *n* (%)			
Male	28 (45.2%)	10 (18.9%)	38 (33.0%)
Female	34 (54.8%)	42 (79.2%)	76 (66.1%)
Missing	0 (0%)	1 (1.9%)	1 (0.9%)
Ethnicity – *n* (%)			
White British	59 (95.2%)	51 (98.0%)	110 (95.7%)
Missing	3 (4.8%)	2 (2.0%)	5 (4.3%)
Dementia diagnosis – *n* (%)			
Yes	40 (64.5%)	27 (59.9%)	67 (58.3%)
No	18 (29.0%)	24 (45.3%)	42 (36.5%)
Missing	4 (6.5%)	2 (3.8%)	6 (5.2%)
Residence stay – *n* (%)	*N*= 58	*N*= 51	*N*= 109
Mean (in years)	7.1 (4.2)	5.5 (4.3)	6.4 (4.3)

C-arm Control group residents, *I-arm* Intervention group residents

Table 4 Resident candidate outcome data

			C-arm			*I-arm*	
		BL	***6 m***	***9 m***	***BL***	***6 m***	***9 m***
CMAI	*n*	*54*	*45*	*42*	*52*	*38*	*32*
	Mean (SD)	43.3 (17.8)	40.3 (11.2)	38.4 (14.6)	37.4 (11.1)	36.4 (10.3)	35 (8.9)
QUALID	*n*	*55*	*46*	*42*	*52*	*38*	*32*
	Mean (SD)	20.5 (6.4)	21.6 (6.7)	21 (5.7)	18.4 (6.6)	20.2 (7.2)	20.5 (8.2)
BADLS	*n*	*55*	*46*	*42*	*52*	*38*	*32*
	Mean (SD)	29.8 (13.8)	34.4 (13.4)	36.1 (12.5)	17 (11)	20.8 (14.5)	26.2 (13.2)
FAST n (%)	*n*	*55*	*45*	*42*	*52*	*38*	*32*
	No dementia	14 (22.5)	12 (26.7)	6 (14.3)	22 (42.3)	9 (23.7)	9 (28.1)
	Early/mild dementia	10 (18.2)	5 (11.1)	6 (14.3)	10 (19.2)	10 (26.3)	3 (9.4)
	Moderate dementia	27 (49/1)	20 (44.4)	19 (45.2)	13 (34.2)	13 (34.2)	16 (50)
	Severe dementia	4 (7.3)	8 (17.8)	11 (26.2)	6 (15.8)	6 (15.8)	4 (12.5)
EQ- 5D- 5L	*n*	*55*	*46*	*42*	*52*	*38*	*32*
Mean (SD)	*Utility score*	0.40 (0.35)	0.31 (0.34)	0.29 (0.34)	0.45 (0.36)	0.32 (0.37)	0.28 (0.37)
	EQ-VAS score	64 (18.3)	52 (21.7)	58.8 (15.5)	65.4 (16.1)	55.3 (17.5)	60.3 (18.9)
Average completion rate	%	89%	74%	67%	98%	71%	60%

C-arm Control group residents, *I-arm* Intervention group residents, *BL Baseline*, *6 m* 6-month post-randomisation, *9 m* 9-month post-randomisation, *Mean (SD)* mean total score (standard deviation), *CMAI* Cohen-Mansfield Agitation Inventory, *QUALID* Quality of Life in late-stage Dementia Scale, *BADLS* Bristol Activities of Daily Living Scale, *EQ- 5D- 5L* EuroQol- 5D health status questionnaire, *EQ-VAS* EuroQol Visual Analogue Scale, *FAST* Functional Assessment Staging of Alzheimer's disease

reassessment, whilst another two attempted reassessment (72.5%). Both figures are green traffic light.

Staff training completion

Completion rate was 77.1% for the basic training and 83.3% for the advanced training, indicating green traffic light. See supplementary materials for demographic data.

Candidate outcomes

Tables 4 and 5 show resident and staff candidate outcome data. For residents, BADLS scores were notably lower in intervention homes.

To explore the feasibility of tracking anonymous questionnaires across the three time-points, staff created a code with the first two letters of the answers to three questions repeated at each time-point. Of 63 codes at baseline, only 14 staff (22.2%) created the same code at 6-month follow-up and only 4 staff (6.3%) at 9-month follow-up. This method of tracking responses was therefore not feasible. Data in Table 5 are averages of staff questionnaires completed at the three time-points.

Effect sizes and intraclass correlation coefficients (ICCs)

For proposed primary outcomes, i.e. CMAI and QUALID, scores with error bars (mean score ± SD) at baseline, 6-month and 9-month follow-ups were represented in Fig. 3a and b. Linear mixed models were employed to calculate the adjusted mean difference,

Table 5 Staff candidate outcome data

			C-arm			*I-arm*	
		BL	***6 m***	***9 m***	***BL***	***6 m***	***9 m***
SCIDS	*n*	*34*	*31*	*20*	*29*	*32*	*17*
	Mean (SD)	55.7 (8.3)	58.1 (7.1)	58.4 (6.4)	52.7 (5.7)	57.9 (6.3)	56.3 (6.7)
CBI Mean (SD)	*n*	*33*	*32*	*20*	*29*	*31*	*17*
	Personal burnout	46.2 (17.9)	41.0 (18.0)	42.3 (19.7)	51.3 (20.9)	43.8 (19.9)	49.3 (17.3)
	Work-related burnout	44.6 (15.4)	42.3 (14.1)	37.9 (15.8)	48.0 (17.9)	39.8 (19.1)	41.8 (18.3)
	Client-related burnout	22.5 (16.8)	21.1 (19.2)	12.3 (11.7)	22.6 (21.6)	17.7 (20.0)	17.7 (18.4)

C-arm Control group residents, *I-arm* Intervention group residents, *BL* Baseline, *6 m* 6-month post-randomisation, *9 m* 9-month post-randomisation, *Mean (SD)* Mean total score (standard deviation). See text for details about questionnaires. *SCIDS* Sense of Competence in Dementia Care Scale. *CBI* Copenhagen Burnout Inventory

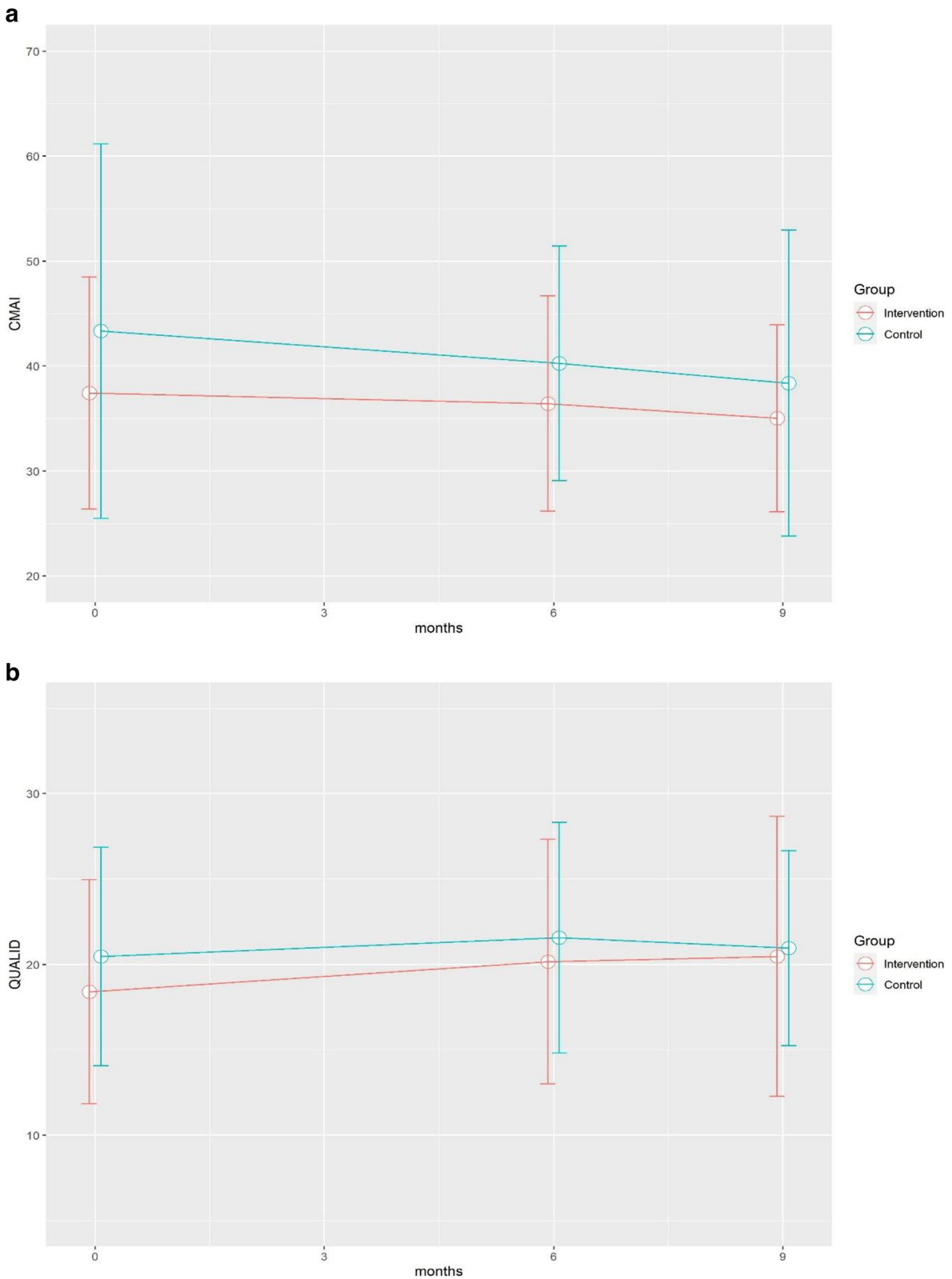

Fig. 3 **a** CMAI score with error bars (mean score ± SD) at baseline, 6-month, and 9-month follow-up. **b** QUALID score with error bars (mean score ± SD) at baseline, 6-month, and 9-month follow-up

together with its ICC. For CMAI, the adjusted mean difference is −2.36 (95% *CI*: −7.21, 2.51) at 6-month follow-up, indicating a reduction of 2.36 in CMAI total score I-arm compared to C-arm (effect size is 0.16). The corresponding ICC was 0.04. However, at 9-month follow-up, CMAI increased with 0.09 (95% *CI*: −3.81, 3.78). The ICC was 0.03. For QUALID, the adjusted mean difference is −0.73 (− 3.82, 2.42) at 6-month follow-up, indicating a reduction of 0.73 in QUALID total score in the intervention group compared to control group (effect size is 0.11). However, at 9-month follow-up, QUALID score increased with 0.17 (95% *CI*: −2.61, 2.87) in the intervention groups compared to the control group. The ICCs were 0.07 and 0.01.

Adverse events (AEs)

Adverse and serious adverse events were recorded and reported in accordance with the HHTU SOP for adverse event reporting for non-CTIMPs and were in accordance with ICH GCP and the Research Governance Framework 2005. All AEs and serious AEs were closely monitored until resolved or until it was established that the intervention was not the cause. Relatedness for AEs, SAEs and deaths was evaluated by the care home managers and the PI.

AEs were observed for 31 residents in the control group (mean (SD) = 1.9 (1.4)) and for 32 residents in the intervention group (2.8 (3.0)). The imbalance in AEs was primarily due to one resident in the intervention group who experienced 18 AEs. After removing this outlier, the mean AEs per resident in the intervention group decreased to 2.3 (1.1).

Serious AEs were observed in 23 residents in the Control group (1.3 (0.6) per resident) and 19 in the Intervention group (1.2 (0.5)). Thirty-eight residents (19 in each arm) were withdrawn. There were 27 deaths (none related to the intervention), 3 residents transitioned to end-of-life care, 2 residents moved out of the care home and preferred not to continue with the study, and 2 residents lost interest.

Process evaluation

Care plan reviews

Daisies were displayed in bedrooms and included in care plans for all recruited intervention arm residents. Care plan meetings were organised in all four intervention homes. Twenty-two (42%) residents who completed COG-D assessments had their care plans reviewed (3 (30%), 2 (17%), 15 (83%), and 2 (15%) in CH 1–4, respectively). Of these reviewed care plans, care plan changes were suggested for 2 (28%), 0%, 13 (87%) and 1 (10%) resident in CH 1–4, respectively. Senior staff were not willing to make any changes to the care plans of residents in one intervention home as they felt that these recommendations could potentially be confusing for staff who were not involved in the COG-D trial. Recommended changes were most frequently made for sustained attention, resisting distraction and memory problems and were all formulated with reference to the petal-by-petal guide (e.g. "choose quiet environment for explaining new information or asking important questions", "break down information into small steps", "ask to repeat important information back", "keep objects in the same place", "try activities that do not rely too heavily on memory or concentration").

Huddles

These were difficult to organise. To facilitate opportunities for huddles, researchers stayed in the care home for prolonged periods of time twice per week. The huddles were discontinued after repeated cancellations and rejections. In total, 9 huddles were attended by staff (1 (11%), 3 (33%), 4 (44%), and 1 (11%) in CH 1–4, respectively); mean group size of the huddles was 2.6 (min–max = 1–5). Change of approach in response to viewing a resident's Cognitive Daisy was mentioned four times, references to fluctuation were mentioned three times and reassessment of specific cognitive tasks was requested once.

COG-D assessments

COG-D assessment scores and percentage of coloured and grey petals were relatively stable across assessments 1 and 2, suggesting minimal cognitive decline for the 29/40 residents who were able to complete the second assessment. COG-D scores correlated moderately with FAST scores for most tests (Table 6). According to FAST scores, on average, 63.3%, 29% and 13% of residents who completed COG-D were categorised as living with mild, moderate or severe dementia, respectively, suggesting that the COG-D assessment was suitable for residents at different stages of the disease. Calculation of concordance rates between researcher and staff scores at reassessment was not feasible; staff regularly asked for confirmation of their scoring during the assessment, which violated the independence criterion.

Qualitative analysis

Themes for areas of interest are summarised below.

Training Overall, the basic training was enjoyed by participants and felt to be easy to understand. Face-to-face delivery was preferred. Remembering what the Cognitive Daisy petals meant after training was a challenge. Participants felt all staff needed access to training:

> *I think that's been our biggest thing, hasn't it? There was very small minority of us that started the training. But not many carers are there and they're the*

Table 6 Correlations between baseline FAST score and COG-D score (Assessment 1)

COG-D test	Coefficient	*CI–LL (95%)*	*CI–UL (95%)*
Spatial awareness	– 0.51	*– 0.24*	*– 0.70*
Face recognition	– 0.64	*– 0.43*	*– 0.79*
Object recognition	– 0.34	*– 0.04*	*0.58*
Concept formation	– 0.56	*– 0.31*	*0.74*
Comprehension	– 0.49	*– 0.22*	*0.68*
Reading	– 0.31	*– 0.009*	*0.55*
Object naming	– 0.56	*– 0.31*	*0.74*
Writing	– 0.44	*– 0.17*	*0.65*
Gesturing	– 0.53	*– 0.27*	*0.71*
Delayed memory	– 0.32	*0.01*	*0.56*
Recognition memory	– 0.57	*0.33*	*0.74*
Short-term memory	– 0.42	*0.13*	*0.64*
Sustained attention	– 0.64	*0.42*	*0.79*
Visual search	– 0.56	*0.32*	*0.74*
Resisting distraction	– 0.44	*0.16*	*0.65*

N = 38

ones that would actually be using it. (B1S-FG – care staff).

Assessment using the COG-D The few staff who had conducted assessments with residents commented that although daunting at first, they were easy to complete for both staff and residents.

I think it's a bit daunting when you first start doing it, but that's just because … it's something new that you have to learn to do. But once I've done a few of them, I felt a lot more comfortable, confident in it and it, it became quite easy. (C1S-I – care staff).

Staff were aware that residents' cognitive abilities could fluctuate, and whilst some were concerned that this might mean abilities were under or overestimated, others saw this as potentially informative:

And for us, that would also be something that would benefit us in writing a care plan because we could say, well, actually, on a good day in this particular resident is able to independently manage this, this and that when they're not having such a good day, then they will need assistance with this, this and that. And it will make a difference because that will actually then be a complex care plan (B1S-FG – care staff).

Use of and implementation of COG-D Whilst those conducting Cognitive Daisy assessments found the process interesting and insightful, use of daisies in everyday care practice was limited. Time to conduct the assessments and use daisies in practice was the biggest challenge and most commonly cited reason. Some staff expressed the daisies did not add to what they already knew about residents, and others felt fluctuating resident abilities could not be adequately reflected by the Cognitive Daisy profile.

Let's be honest, I'm not sure I needed it because I know them inside out. (A2S-I – care staff).

Other reasons included lack of access to the daisies due to their displayed in bedrooms and the transition to e-record systems which meant the paper-based care records in which daisies were held became obsolete. Where staff said the Cognitive Daisy had been implemented, this had largely been done or led by researchers, supported by a few staff. Leadership for the COG-D was identified as a key factor for improved future implementation. Managers felt that ongoing external leadership was essential and would be needed for wider roll-out:

That, yeah. Yeah, like you, we've got a dementia lead across the board for [county]. You know what I mean? … to look at taking that role on and being part of it? …. I mean, you've gotta have somebody that's able to put it out everywhere. (M1 FG – care home manager).

Impact on residents Not all residents interviewed recalled what the Cognitive Daisy was for, but some recalled completing the assessment. Whilst some enjoyed the assessment activities, one person reportedly found them childish. Staff expressed that many residents would struggle to understand the purpose of the Cognitive Daisy:

Aside from [resident], a lot of our residents wouldn't really understand. So whilst I've explained what we're doing and what it's for, I haven't really gone into detail because it isn't something that they would, it would go over their head. (C1S-I – care staff).

Impact on families Like residents, families interviewed were unclear on what the Cognitive Daisy was for and had not engaged in discussions about them with staff. However, families welcomed the chance to have more information about their relative but recognised that busy staff would struggle to find time to share information:

Good idea if it's implemented properly (C1 F-FG –

relatives).

Staff members felt that the Cognitive Daisy might help families to understand their relative's behaviour, with one staff member providing an example of where the Cognitive Daisy assessment identifying facial recognition difficulties helped a family member make sense of her mum not recognising her anymore.

Benefits to staff Staff who felt that they knew their residents well were less likely to engage with the Cognitive Daisy, as there was a sense they were not needed. For this reason, several staff members proposed daisies might be more useful for understanding the needs of new residents or for new staff members to get to know residents.

> *Whereas if you've got a new resident, you find out a lot straight away and also new members staff if they were to be trained upon Cognitive Daisy they could then when they were going in their rooms think 'Ohh yeah, this lady struggles with this, or this gentleman you know has got really poor eyesight' you know. (A3S-I – care staff).*

Activity coordinators were another group staff felt could benefit from the learning gained about a person's abilities:

> *Think it's helped them [activity coordinator] as well to gear the activities, tailor them more to you, know what they can and can't do now it's, it's given that insight (M1 FG – care home manager).*

Several staff who engaged with the assessment process described the benefits to them of being surprised by abilities of residents that they thought they knew well and having their assumptions challenged. They indicated that being involved in the assessment process was more beneficial to learning about the resident than simply looking at their completed Cognitive Daisy:

> *She did a lot better than I expected. So sometimes I think our own expectations are detrimental to them. (B1S-I – care staff).*

The focus on strengths and abilities as well as areas of support was welcomed in the context of caring for residents with a progressive and life-limiting illness. Having assumptions about resident's abilities challenged whilst enlightening was not always interpreted positively, for example one manager now felt that residents were capable of doing more and were lazy:

> *The whole project, really the whole, you know, what they actually can do and I think I think some of them, I found out that they're quite lazy. You know, they just don't wanna do it, but they actually can. (M1-FG – care home manager).*

Reflections on research Some participants expressed initial trepidation about getting involved in research. Key to success was a flexible approach from the researchers, recognising staff workloads and the engagement of care home managers. Setting clear expectations about involvement and providing regular updates for staff were important. The research added to the workload of staff who already felt "bombarded", and whilst some staff enjoyed the chance to engage with research others were too busy:

> *And then, I mean no disrespect, but I know I'm busy, and out there (care home) they are struggling as well (A1S-FG – care staff).*

Discussion

The primary objective of this feasibility study was to investigate whether the study protocol would be suitable for a future large-scale trial investigating the effectiveness of the Cognitive Daisy intervention on the delivery of person-centred care in care homes. The target for resident recruitment was exceeded without the use of nominated consultees, and evaluation of resident recruitment rate against the progression criteria is therefore not appropriate. Recruitment of staff was higher than anticipated (almost double than the target number), and the completion rate for the COG-D training was within the green light margins of the progression criteria.

Whilst feedback on content and delivery of the staff training indicates initial positive perceptions of the COG-D intervention by staff who engaged, the high pressure of care work, perceived lack of clarity about what new knowledge the daisies offered and limited numbers of staff who took part were key reasons for the limited uptake observed. Staff willingness to dedicate time and effort to interventions and their perceived effectiveness are known barriers to sustaining interventions in care homes [37, 38]. In addition, successful interventions in care homes are those that help staff to get to know, connect with and understand residents better [39]. We saw evidence of this in positive views of the daisies expressed by activity co-ordinators and views shared by staff that they would be beneficial for new staff or getting to know new residents. Those conducting COG-D assessments also expressed learning novel insights about residents. However, poor uptake of daisies by many staff may be explained by our finding that the picture of the Cognitive Daisy alone was not felt to offer new insights to what staff already knew about residents. This was an unexpected

finding given this perception was neither mentioned by staff participating in our developmental work in different organisations nor by care home staff involved in our previous pilot study [20]. One possible explanation may be related to the fact that the majority of the care homes were from one large UK care home trust, with likely effective life history and care planning processes and a good training offer that help staff to know residents well. Nonetheless, more research may be needed to explore whether optimal usefulness and impact of the COG-D intervention in care homes may be limited to specific situations or context (e.g. for new staff, at intake of new residents or for staff with more general roles such as activity leaders).

Care home manager involvement and leadership are recognised as highly influential to the success of intervention implementation [38, 40]. Despite efforts to engagement managers in this trial, lack of manager involvement and leadership remained a challenge in 3 out of 4 intervention homes. Staff prioritising the time to engage with the Daisies proved to be challenging without direction and support from managers or deferred internal leaders.

Implementation challenges were exacerbated by other external factors including the national switch to digital care plans in some care homes during the period of the trial, which drew on care home resources and involved additional staff training. It also changed the way in which care homes and staff engaged with care planning and paper-based resources such as the daisies were felt to not be useable. Adapting and digitising the COG-D toolkit to accommodate inclusion in digital care plans could ensure easy and immediate access to resident Daisies and the petal-by-petal guide.

Analysis of key candidate outcome measures suggest small differences from baseline in the predicted direction for CMAI and QUALID at 6 m post-randomisation (with small effect sizes), which disappear at 9 m post-randomisation. This trend may be indicative of the initial engagement of staff with the intervention, followed by reduced interest in Phase 2. High completion rates of by proxy data collection of resident measures suggest that this approach was acceptable. A few proxy raters were uncertain about how to answer several items of the BADLS (measuring independence in daily living), particularly those items referring to situations or contexts that were not applicable in their care home (e.g. the ability to cook). Proxy raters may choose different strategies to answer these questions (e.g. give the lowest rating or guess the rating if the situation would be applicable). This may introduce systematic variation in responses between raters. Therefore, a different, care home-specific outcome measure for independence in daily living may need to be considered in future care home studies.

Acceptability of the COG-D assessments for residents was reflected in high completion rates of the first assessment and a lack of concerns raised about the assessment experience for residents by staff or residents. Proposed care plan changes frequently referred to petal-by-petal suggestions for problems with sustained attention, resisting distraction and memory, commonly associated with advanced age and dementia [8, 9]. Comments and recommended changes made by staff who completed the care plan reviews indicate a general increased awareness of the relationship between environment (e.g. noisy or busy), attention, distraction, comprehension and retention. A few specific instances of object or face recognition problems revealed by the COG-D assessments were explored further in real-life situations by staff and instigated discussions about approaches to accommodate these specific impairments. Despite the barriers raised for the use of Daisies in the current feasibility study, these observations suggest novel insights among interested and engaged care staff, which aligns with our LOGIC model for the potential pathway to impact of the COG-D toolkit for enhancing person-centred care of care home residents with dementia [21].

The FAST scores showed that residents classified as living with mild, moderate and severe dementia were able to complete the COG-D assessments, suggesting that the COG-D assessment can be suitable and acceptable for people at more advanced stages of dementia. It is noteworthy that loss to follow-up for COG-D reassessments was largely due to death or transitions to end-of-life care of participants (50%), and it is uncertain if physical decline was accompanied by cognitive decline for these residents. More research may be needed to explore whether COG-D is not sensitive enough to monitor cognitive decline in care home residents or if cognitive decline tends to co-occur with rapid declining physical health in this context, thereby prohibiting further assessments.

To conclude, this feasibility study showed that whilst the study protocol may be suitable for a future large-scale trial, more research is needed to adapt the COG-D toolkit for digitisation and to delineate the situations and contexts where the potential impact of COG-D on the wellbeing of people living with dementia might be optimal in care homes. Moreover, whilst our focus in the present study was on care homes, COG-D might be useful in several other social care contexts, for instance in community care or acute hospital care where familiarity with patients or clients is often lower. Future work

could explore the usefulness and acceptability of the COG-D for use in such health and care settings.

Supplementary Information

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Additional file 1. Demographic data of staff in intervention care homes who completed the COG-D training

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Authors' contributions
CH analysed data for key progression criteria, PP analysed quantitative process evaluation data, and CS and EW conducted the qualitative analyses. All authors read and approved the final manuscript.

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Data availability
The datasets during and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
The study was given ethical approval by Wales Research Ethics Committee 1 Cardiff (22/WA/0034), IRAS ID: 305462, date 21 February 2022. REC approval was obtained to contact personal consultees by email and to use DocuSign for signatures (approved 26 June 2022), protocol version 5.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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