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Exploring the feasibility of implementing the Cognitive Daisy (COG-D) assessment in care homes to support individualised care

Submission date
08/09/2022

Recruitment status
No longer recruiting

Registration date
28/09/2022

Overall study status
Completed

Last Edited
12/05/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and aims
Changes in the brain are common as we age and are often caused by conditions like dementia. These changes mean that people struggle with things like remembering, paying attention, finding words and making decisions – these mental processes are known as cognitive abilities. Appreciating how these cognitive changes affect each person and how care staff can best support them forms an important part of good care. For example, knowing that someone struggles with making decisions can help you to support making choices at mealtimes. Knowledge about these cognitive changes varies among care-home staff and may not always be taken into account when planning and providing care. The Cognitive Daisy (COG-D) is a package we developed to help staff to assess and plan care around each individual's cognitive abilities. It includes:
1. Staff training on cognition and on how to use COG-D,
2. A cognition assessment (looking at senses, understanding, communication, remembering and attention),
3. A 'Cognitive Daisy' that visually summarises cognitive strengths and difficulties using coloured petals, personalised in each resident's care plan (see www.cognitivedaisy.co.uk),
4. A 'Petal-By-Petal' Guide of possible ways to support different cognitive difficulties for use in care planning.
In our COG-D development work, care-home staff found it useful to learn more about their residents' needs and care-home residents were happy to complete the assessments. We now need to understand how COG-D benefits individual residents (e.g., for their quality of life). We also need
more data on how the COG-D package is best carried out in a care home setting, including what helps and hinders its use. Before we can do a large study, we need to check that our research approach will work and gather information to help us design a future trial. To do this we will carry out what is called a feasibility randomised controlled trial.

Who can participate?
We will recruit 100 residents and ~50 care staff in up to 10 care homes

What does the study involve?
Half of the homes will be chosen at random to continue with usual care and half to use the COG-D package, which will be led by a researcher and supported by staff. We will collect data on residents and staff before and after we introduce COG-D to look for any changes. We will record COG-D use and interview staff, relatives and residents in the COG-D care homes about their experiences and any challenges of using it.

What are the possible benefits and risks of participating?
There are no direct benefits to residents of taking part. We do not anticipate that this study will cause any harm or distress to the participants.

Where is the study run from?
The University of Lincoln (UK)

When is the study starting and how long is it expected to run for?
January 2021 to March 2024

Who is funding the study?
The National Institute of Health and Care Research (NIHR) (UK)

Who is the main contact?
Associate Professor Petra M. J. Pollux (Chief Investigator) (UK)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
305462

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52529, IRAS 305462

Study information

Scientific Title
The Cognitive Daisy (COG-D) in care homes to support person-centred care: A feasibility cluster randomised trial

Study objectives
The overall aim is to conduct a future large-scale cluster randomised trial (CRT) to assess the effectiveness and cost-effectiveness of the Cognitive Daisy (COG-D) intervention in care homes. The current study aims to investigate the feasibility of this future planned trial.

Feasibility will be investigated with regard to the following areas of uncertainty:
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 candidate outcome measures
4. Estimates of effect sizes of proposed outcome measures to establish primary endpoint and sample size for the future CRT
5. Ability to collect health economic data required to undertake a cost-effectiveness analysis in the definitive trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/02/2022, Health and Care Research Wales (Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)29 2023 0457; healthandcareresearch@wales.nhs.uk), ref: 22/WA/0034

Study design
Randomized qualitative process-of-care study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Organic, including symptomatic, mental disorders

Interventions
RESEARCH PLAN AND METHODS
Please note:
The research team will recruit one PDRA for 20 months (0.8) and 2 RA's for 12 months (0.6% to complete intervention activities in the care homes: staff training and COG-D assessments). Recruitment of care homes is staggered to manage the workload of the researchers.

DESIGN: A cluster-randomised controlled feasibility trial randomising 8-10 care homes to receive i) usual care plus COG-D intervention (COG-D) or ii) usual care (Control). Data will be collected at baseline and then 6- and 9-months post-randomisation.
Setting: Residential and nursing care homes in Lincolnshire and East Riding and Humberside.
Target population: Care homes, residents, their relatives and care home staff.
Trial set-up: Contracting, preparation of study documentation and ethics application including PPI input, identification of care homes. Pre-intervention meetings will be organised with care home managers to discuss the details of the implementation protocol, the impact of participation on staff and residents and on IT availability and the agreement of care homes to take part.
Recruitment: Researchers will be present in each care home for 2 weeks to recruit participants and to obtain the baseline candidate outcome measures. Residents, nominated informants /consultees and staff will be provided with the PIS and consent forms and will have the opportunity to ask any questions. Cluster RCT feasibility study: The care homes will be randomised (after recruitment of residents/staff and the collection of candidate outcome measures at baseline) to intervention or Usual Care. Care homes in the intervention arm will then commence the training period and the COG-D intervention activities.
Eligibility, Recruitment and consent: In line with recommended sample sizes for feasibility studies, the aim is to recruit 70 care home residents (35 per group). To accommodate a 30% loss at follow-up, 100 residents will be recruited. Eight to ten care homes (an average of 10-13 residents per care home) will be recruited from local care home networks and organisations with whom the trial team have an existing relationship and who are not currently using but have expressed an interest in COG-D. Selected care homes will vary in terms of type (residential /nursing) and will not have been involved in the COG-D pilot study. We also aim to recruit in a total of 50 care staff across these 10 care homes.

CONTROL HOMES
Usual Care (UC), defined as normal care delivered within the setting, will continue in both arms. No restrictions will be imposed on current practices or on homes undertaking additional development or training as part of usual care, with the exception of control arm homes being required not to implement COG-D during their trial involvement period. To be able to investigate signals of impact, candidate outcome measures for staff and residents will be collected in all care homes.

INTERVENTION HOMES
PHASE 1: (1) Staff training and (2) COG-D assessments (2 months per CH)
1. Staff training:
A) Basic Staff Training: ~45 mins:
Aimed at all care staff who will use the Cognitive Daisy in daily care.
Mode of delivery: The basic training can be completed either individually (online), in groups of staff from single or multiple care homes using video-conferencing, or in single care home groups face-to-face (preferences will be discussed with the care home). If face-to-face, then the training will take place in the care home. To facilitate inclusive access to the online training, verbal presentations can be selected on each page.
Content: The training introduces the Cognitive Daisy, and describes the five cognitive domains represented in the coloured petals and the different functions associated with each petal. The use of Daisies in practice is discussed with reference to several examples of Daisies that vary in terms of cognitive profile. To illustrate the immediate impact of the Daisies, a description of several common care scenarios is presented, without a hypothetical resident's Daisy before the training and including their Daisy at the end. Staff will be provided with a cue card depicting the Daisy with associated functions for each petal and a certificate upon training completion.
B) Advanced Staff Training (~ 3 hours)
Aimed at recruiting senior staff who will be involved in the COG-D assessment of residents.
Mode of delivery: Face-to-face or in groups using videoconferencing. The training is taught by the researchers. Each attendee will be provided with a training pack including all training and COG-D assessment materials. Training will take place in the care home.
Content: PART 1 is a recap of the Basic Training. PART 2 introduces standardised screening tests for dementia and contextualises the COG-D assessments in relation to these (i.e. the focus of the COG-D being on managing and support of care and NOT on screening for dementia, diagnosis or measurement of dementia severity). Staff are then introduced to the COG-D assessment process and the individual assessment items. They practice completing the assessment in small groups and practice creating Daisies using stickers and the COG-D app. PART 3 introduces the Petal-By-Petal guide and how it can be used with the Cognitive Daisies to create a specific list of problems and recommendations for inclusion in a resident's care plan. Other issues addressed are re-assessment time periods, the potential impact of the testing environment, integration of information from the Daisies with care observations, life history information and resident and family carer experiences/wishes for care-planning and decisions. The interest of senior staff to be trained as a trainer will be recorded to evaluate the suitability of a cascade learning model in the future large-scale RCT. Senior care staff will be provided with the COG-D cue card and a certificate for completion of the training.
2. COG-D assessments of residents (completed in the resident's care home)
Completed by the researchers and shadowed by senior staff. The assessment tool COG-DAA constitutes 16 tasks, variants of which are routinely used for the assessment of dementia and other neurological disorders. A detailed assessment script is used with verbatim instructions to ensure consistency.
A version of non-verbal responses is included to accommodate people with impoverished speech. Assessments can be conducted using the COG-D application or an assessment booklet (A6 size). Both methods allow assessment in a comfortable environment and the order of the tests allows for breaks without affecting performance. Word lists for the different tests were carefully balanced in terms of age of acquisition, word length, word frequency, semantic category and concreteness.
The COG-D app produces 1) A Daisy without labels (which can be printed, laminated and displayed), 2) COG-D display sheets (for the care plan) which include the Daisy (with labels) and suggestions for care recommendations from the Petal-By-Petal Guide (generated automatically by the application for coloured petals).

PHASE 2: IMPLEMENTATION OF COG-D IN DAILY CARE PRACTICE (6 months per CH) AND COG-D REASSESSMENTS (2 months per CH).
The laminated Daisies are placed in locations where they are most useful (e.g. in residents' rooms) and Daisy display sheets are included in the care plans. All care staff are provided with the Petal-By-Petal Guide and a Daisy cue card. Larger posters of the Cognitive Daisy (not resident-specific versions) will be displayed in dining areas and in communal spaces where scheduled activities take place.
Staff support during Phase 2:
Support for care staff who completed the Basic Training:
1. Weekly guided 'huddles' at the hand-over
2. Fortnightly virtual COG-D drop-in sessions
3. Monthly Newsletters
Support for senior care staff who completed the Advanced Training:
4. COG-D assessment and reassessment sessions: Staff who complete the Advanced Training will be invited to attend residents' COG-D assessments
5. Care-plan meetings with the researcher (two meetings) to discuss how each resident's Cognitive Daisy could be informing shorter and longer-term care decisions.
6. Monthly Virtual COG-D Assessor drop-in sessions: This is to provide an opportunity to ask the researcher any questions
7. Newsletter
COG-D re-assessment of residents: Six months after the first COG-D assessment, identified residents will be re-assessed on COG-D by researchers and senior staff. Senior staff will be encouraged to lead the assessments and both assessors will score performance independently for concordance rates.

PROCESS EVALUATION:
After completion of the intervention phase and collection of candidate outcome measures post-intervention in both arms, context, implementation and mechanisms of impact will be explored using semi-structured interviews/focus groups with 1) residents who completed the COG-D, 2) care home managers, 3) senior staff who completed the advanced training 4) care-staff who completed the basic training 5) relatives of residents who completed the COG-D. Staff in control homes will be recruited to explore experiences as control arm participants to inform the future large-scale RCT. Interviews and/or focus groups with staff will take place in the care home. Interviews with relatives/friends will also take place in the care home if possible or at the University of Lincoln (travel costs will be compensated). The focus groups will be led by an experienced and trained facilitator who has not been involved in the COG-D feasibility trial.

STAKEHOLDER AND PUBLIC AND PATIENT INVOLVEMENT
The COG-D PPI team Lincoln has provided feedback (since 2016) on the different uses and potential benefits of COG-D for care home residents, staff and relatives, and for people with dementia living in the community. Members of the COG-D stakeholder committee have provided feedback on the assessment protocol (e.g. care home staff suggested the use of a user-friendly booklet) and have been instrumental in the conceptualisation (Prof Moniz-Cook) and development of the Petal-By-Petal Guide (occupational therapists of the Lincolnshire Partnership NHS Foundation Trust helped to the develop the list of problems and solutions for each 'petal'). The Alzheimer's Society (Lincoln Branch) has provided feedback on the COG-D assessor's training, highlighting the strength that the assessment could be broken up into several sessions. Eight health care professionals of the Derbyshire Mental Health NHS Foundation Trust attended the COG-D assessors training in Sept 2020 and integrated the COG-D toolkit and the assessment training in their Cognitive Re-enablement training program for mental health support workers on hospital wards and in the community. After their trial with COG-D, feedback was obtained on the suitability of the COG-D assessor's training to prepare

attendees to train other HC professionals on COG-D in their Cognitive Re-enablement training program.
The COG-D implementation protocol for the proposed study has been reviewed by care-home managers and senior staff of Lincolnshire care homes (varying in size between ~30 and 70 beds) in online interviews (Sept-Dec 2020). Different domains of feasibility and acceptability were explored with questions around care staff burden, delivery of staff training and COG-D assessments (e.g. suitability of online training), contextual barriers or facilitators to intervention, adherence and monitoring, willingness to be randomised (100%) and percentage of residents who would be suitable for the COG-D assessments.
Co-I Mrs Mountain (who is an experienced PPI panel member) has been involved with, and a promotor of, COG-D from 2016 and has discussed COG-D in several CLAHR meetings. She has been involved at every stage of the project application to the funder and has reviewed all documents (including PIS, Consent, questionnaires, and recruitment materials) for this HRA/REC approval process.

Intervention Type
Other

Primary outcome measure
Effect signals of the COG-D intervention for residents will be investigated with the following (proxy) measures:
1. Quality of Life (QUALID)
2. Agitation (CMAI)
3. Independence on activities in daily living (BADLS)
4. Health Cost/resource usage (ED-5D-5L and medical records).

For care staff, signals of effects will be explored for:
1. Sense of Competence in dementia care (SCIDS)
2. Burnout (CBI)
3. Understanding of COG-D and cognition (COG-D Q)

All measures will be collected at baseline, and at 6 and 9 months post-randomisation.

Pathways to the impact of the COG-D in care homes will be investigated in a process evaluation, exploring context and mechanisms of impact in interviews/focus groups with residents, staff, and family/relatives. Interviews will take place after the last collection of candidate outcome measures.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
21/01/2021

Completion date
31/03/2024

Eligibility

Key inclusion criteria

Care homes:
1. Residential or nursing home
2. Provides care to people with dementia
3. Has a minimum of 20 beds to facilitate recruitment of a sufficient number of residents in each care home

Residents:
1. Consent to take part (personal or via consultation)

Additional inclusion criteria for residents taking part in the COG-D assessment:
1. Can communicate well enough in English to not require an interpreter
2. Vision/hearing (with correction) adequate to participate in COG-D assessment
3. Deemed well enough by staff/researcher to complete the assessment by a member of staff or the assessor

Care home staff:
1. Permanent, contracted, agency or bank member of staff at the time of data collection
2. Provide consent
3. Have sufficient proficiency in English to contribute to the data collection required for the research

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 101; UK Sample Size: 100

Key exclusion criteria
Care homes:
1) Have already used COG-D
2) Subject to Care Quality Commission enforcement notices Local Authority quality concerns

Residents:
1. Receiving end-of-life care.

Care home staff:
1. Acting as a consultee for any residents participating in the trial

Date of first enrolment
01/04/2022

Date of final enrolment
29/02/2024

Locations

Countries of recruitment
United Kingdom

Study participating centre
-
United Kingdom
-

Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/03yeq9x20

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research Central Commissioning Facility (CCF); Grant Codes: NIHR202962

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals; investigators aim to submit the study protocol (planned submission in October 2022) and the findings regarding feasibility and signals of efficacy (planned submission in 2024/2025)
2. Internal report
3. Conference presentation at a dementia-themed conference
4. Publication on a website
5. Other publication
6. Submission to regulatory authorities
7. Access to raw data and the right to publish freely is provided to all investigators in the study or by the Independent Steering Committee on behalf of all investigators

Intention to publish date
30/03/2025

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		03/03/2023	06/03/2023	Yes	No
HRA research summary			26/07/2023	No	No
Results article		10/05/2025	12/05/2025	Yes	No