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Intervention adaptation for hallucinations in the context of dementia

Submission date
02/09/2024

Recruitment status
No longer recruiting

Registration date
10/09/2024

Overall study status
Completed

Last Edited
14/04/2026

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Hallucinations are a common experience for people living with dementia (PLWD), often leading to significant distress. While anti-psychotic medications have been used to manage these experiences, they have not focused on reducing the associated distress, and there are currently no non-pharmacological interventions available to support PLWD and their family carers. The Coping Strategy Enhancement (CSE) intervention, effective across various populations, has yet to be applied to the dementia population. The study aims to develop an adapted version of the CSE intervention tailored for addressing hallucinations in PLWD and to evaluate its feasibility through a single-arm trial in real-world settings. It seeks to assess the initial effectiveness of the adapted intervention in reducing distress caused by hallucinations in PLWD and their caregivers. Additionally, the study will gather and analyse qualitative data on participant experiences to refine future research and interventions. Ensuring the safe delivery of the adapted CSE intervention within community settings is also a key objective.

Who can participate?
Participants will be PLWD aged 60 to 90 years old, carers of PLWD aged 18 years old and over and clinicians who work with PLWD

What does the study involve?
The study will involve focus groups with PLWD, their carers, and clinicians to help develop adaptations of the psychological intervention for coping with hallucinatory experiences. The study will be conducted across two sites in Sussex and the North of England. Participants will receive four therapy sessions with a clinical psychologist, followed by a final assessment and exit interviews.

What are the possible benefits and risks of participating?
Benefits include meeting with people in focus groups that have similar life experiences. Trial participants will receive a therapy that has the potential to reduce distress from hallucinations. Also, monetary compensation will be given to focus group participants (carers and PLWD dyads only, in both phases 1+4), which will be set at £20 per session, per individual; this compensation will be awarded in the form of a Mark's and Spencer's voucher, provided by Brighton and Sussex Medical School, Centre for Dementia Studies. Travel compensation will also be provided, with a

cap of up to £25 per person per session. Fuel costs will be calculated at 45p per mile. A travel expenses form will be required to be filled out, and funds will be paid directly into the participants' bank accounts. The researcher will provide the travel expenses forms on the day of the focus groups. Trial participants will be reimbursed for their time in pre and post-intervention meetings to collect baseline data and deliver exit interviews, at £20 per individual, per meeting. There will be no monetary reimbursement for participation in the four intervention sessions, as it is deemed that there is a benefit in receiving the therapeutic intervention. Travel compensation will also be provided, with a cap of up to £25 per person, per meeting. Fuel costs will be calculated at 45p per mile.

There may be risks associated with the topics of conversation in the focus groups as well as the intervention that relates to hallucinatory experiences, which may be difficult to discuss at times. This will be mitigated by reminding participants that they can take a break or withdraw at any point in the study. The chief investigator, educational supervisor and psychologists are very experienced in supporting people that are experiencing any distress, so are qualified to manage these situations.

Where is the study run from?
Sussex Partnership Foundation Trust

When is the study starting and how long is it expected to run for?
October 2023 to March 2026

Who is funding the study?
National Institute for Health and Care Research (NIHR), Applied Research Collaboration (ARC) for Kent, Surrey and Sussex (KSS)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Integrated Research Application System (IRAS)
336425

Central Portfolio Management System (CPMS)
60832

Study information

Scientific Title
OASIS (optimising an intervention for sensory hallucinations): a novel adaptation of the coping strategy enhancement intervention, for hallucinatory experiences in the context of dementia

Acronym
OASIS

Study objectives
The Coping Strategy Enhancement (CSE) intervention is yet to be utilised and evaluated in the dementia population. Hallucinatory experiences are common among PLWD, who often present with multi-modal experiences; the previous literature has shown that the CSE can be effective for multi-modal hallucinations, which is particularly applicable to the dementia population. In addition, the risk of side effects from anti-psychotic medication warrants the development of more non-pharmacological interventions. Therefore, this study will focus on the adaptation and application of the CSE intervention to the dementia population, with the inclusion of caregivers. For this study, caregivers will be exclusively family carers, as their extensive knowledge of the PLWD will facilitate an active role in delivering the intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/08/2024, Yorkshire & The Humber- Leeds West REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048053; leedswest.rec@hra.nhs.uk), ref: 24/YH/0126

Primary study design

Interventional

Study design
Non-randomized single-arm feasibility/pilot study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dementia

Interventions
Methodology Justification:
This research study will follow the guidelines from the Medical Research Council (MRC) framework for the development of complex interventions; the process will be iterative. This study design has been chosen, as it was a priority of the researcher to ensure that experts by experience were key in the development and evaluation of the adapted CSE. A small single-arm feasibility is justified by the fact that this is the first study of its kind, and feasibility is required to be tested before moving to larger sample sizes.

Design:
Phase 1- Co-Adapt focus groups
• This first phase will inform the adaptations made to the CSE intervention, through consultation with dyads of family carers and PLWD dyads, or individual PLWD or family carers and clinicians that work with PLWD.
• Two separate focus groups will be facilitated. For each group, there will be 2-3 sessions.
• The 2 groups will be:
1. Family Carer and PLWD dyads or individuals.
2. Clinicians.
- Sample sizes- maximum for 6-8 participants per group. This will allow collective conversation to be easily held and ensure that voices are heard in the group, whilst allowing for diversity of experience.

Phase 2- Single-Arm Feasibility Trial
• The adapted version of the CSE will then be tested in a single-arm feasibility trial with 12-18 dyads of PLWD and carer. (total N=24-36).
• Participants will complete a baseline assessment before the delivery of the four sessions of the intervention with a clinical psychologist.
• This will be a multi-site trial, with an additional site outside of the SPFT, in CNTW.

Phase 3 – Data collection and analysis
• A final assessment meeting will take place.
• Quantitative will be collected from participants who complete the CSE intervention.
• Qualitative data will be collected through exit interviews with all participants, including the psychologists who delivered the intervention. These will take place virtually or face-to-face in participant homes or an NHS site.
• Qualitative data will be analysed using the framework method.

Phase 4 – Co-Evaluate
• Further consultation with focus groups from Phase 1 about additional adaptation in the light of learning from Phases 2 and 3.

• Co-evaluation of the adapted CSE intervention.
• Discussion of lessons learnt.
• Suggestions for a revised intervention for future research.

Setting: This project will take place within the Centre for Dementia Studies, based at the Brighton and Sussex Medical School. It is being funded by the National Institute for Health and Care Research (NIHR), and Applied Research Collaboration (ARC) for Kent, Surrey and Sussex (KSS). The KSS ARC currently has a theme of "Living well with dementia" to become a leading region for dementia health care research and to further translate this into helping PLWD live and age well; this project has been designed to support this current theme. This study will be sponsored by and delivered within SPFT, with a second site (CNTW) recruiting participants within Phases 2 and 3. A scoping review was completed and funded by Research England, before the creation of this project, to explore the current issues surrounding accessing support for hallucinations in the context of dementia. Results found that there was a need for the development of specialised dementia support in hallucinations.

Procedure:
Phase 1- Co-Adapt.
Two focus groups will be recruited for this phase of the study: Family carers and PLWD dyads and clinicians who work with PLWD. For the sake of clarity, those who engage in Phases 1+4 of the research will be referred to as focus group participants. Those who engage in the trial (phase 2+3) will be referred to as trial participants. For the recruitment of family carers and PLWD for phase 1, contact will be made to support groups for carers of PLWD, the DCG for SPFT, and third-sector organisations; this will include Age UK and Alzheimer's Society. With regards to the recruitment of clinicians for the phase 1 focus groups, the opportunity to participate will be advertised within the Dementia Services of SPFT. Sussex Partnership NHS Foundation Trust has the Everyone Counts scheme in place for consent to contact about research opportunities. The Everyone Counts scheme is viewed as being a task in the public interest and as such has been approved by the SPFT Trust Board after consultation with the Information Governance Lead. Members of the Research & Development Department will contact potential eligible participants, to discuss the study and invite them to take part. The report of potential participants is only accessible to a limited number of authorised individuals in the research department.

Those who express interest in participating in the focus groups, phases 1+4, will be sent the participant information sheet (PIS) for the study and can contact the researcher. If interested the participant will meet with the researcher where consent will be given, and eligibility will be confirmed. If consent will need to be taken over the phone, the researcher will follow the protocol for taking remote consent. A copy of the remote consent forms will be sent via secure postal service to the participants. To ensure accessibility to the study, those that require easy-read versions of the participant documents, will be able to request these, before meeting with the researcher. Easy-read versions will include the use of inclusive graphics, simplified language and larger text.

Following this stage, if consent is given, focus group participants will be invited to join the appropriate focus group meeting. For both focus groups, there will be 2-3 focus group meetings held, each lasting up to a maximum of 2 hours; this will allow for processing and reflection between sessions. The location and method of holding these meetings will be determined by the ease of accessibility of travel for focus group participants and the physical geographical distribution of them; the meetings will either take place face-to-face or virtually via a Microsoft Teams or Zoom call. Depending on the preferences of the focus group participants, the first session may take place in person and then following this, the groups could be held virtually; an

initial face-to-face meeting will aid in focus group participants feeling more comfortable in the group and foster familiarity with each other and the researcher.

Before the focus group meetings, the focus group participants will be sent, electronically, the intervention protocol of the CSE. The meetings will be structured as such 1) to review the existing intervention protocol of the CSE intervention and the associated materials, 2) to offer suggestions for adaptation to the intervention protocol to be appropriate for PLWD and their carers 3) to discuss the potential relevant outcome measures that could be used in the adapted intervention protocol.

As the dyads (PLWD + family carer) and clinicians have different roles and associated statuses in the healthcare system, the focus groups will be kept separate to enable less censored communication between focus group participants. Similarities in the experiences of group members may also generate some positive group effects of empathy which will be less hindered if the groups are kept separate.

A member from each of the groups will be appointed as a representative and will meet with the lead researcher after the adaptations have been made to do a 'final check' of adapted intervention before the single-arm feasibility trial; this will help to ensure that ideas and comments have not been misinterpreted. This representative will be chosen based on whoever volunteers first.

Monetary compensation will be given to focus group participants (carers and PLWD dyads only), which will be set at £20 per session, per individual; this compensation will be awarded in the form of a Marks and Spencer's voucher, provided by Brighton and Sussex Medical School, Centre for Dementia Studies. Travel compensation will also be provided, with a cap of up to £25 per person, per session. Fuel costs will be calculated at 45p per mile. A travel expenses form will be required to be filled out, and funds will be paid directly into focus group participants' bank accounts. The researcher will provide the travel expenses forms on the day of the focus groups. For clarity, the adapted intervention will hereon be referred to as the C-DEM-CSE (Carer-Dementia Coping Strategy Enhancement).

Phase 2- Single-arm Feasibility Trial
The C-DEM-CSE will then be tested in a single-arm feasibility trial with 12-18 dyads of PLWD and carer. (total N=24- 36).
Trial participants for this phase of the study will be recruited from a variety of Dementia Care Services and Memory Assessment Clinics in SPFT and CNTW. In SPFT, the referral pathway will be as follows: (1) Referral from the most relevant healthcare professional to the Dementia Research Unit, Crowborough. (2) contact will then be passed to the researcher whereby all further liaison will happen.

The referral pathway for the CNTW site will have two routes. Route (1) Direct referral from the most relevant healthcare professional to the research team, DeNDRoN (Dementias and Neurodegeneration Research Network, CNTW). Route (2) The research case register will be scanned for potential participants and the research team will then contact the individual and their most relevant healthcare professional and participation in the trial will be discussed. A formal referral will then be sought.

The aim for the sample size recruitment will be a total of 12-18 dyads of PLWD and carer (total N=24-36) across both SPFT and CNTW. This will be exclusively limited to informal family carers

due to the level of engagement and familiarity with the PLWD that is required for the intervention (see inclusion and exclusion criteria for further detail). Recruitment will be advertised through the usual communication channels as used in Phase 1.

Once recruitment is complete, trial participants (both PLWD and carer) will be issued with a participant information sheet. All participants will be offered to access the easy-to-read versions of PIS and consent forms before meeting with the researcher. Easy-read versions will include the use of inclusive graphics, simplified language and larger text.

Following this, a meeting will be arranged with a researcher where eligibility will be confirmed. This will be achieved by checking against set criteria and delivering Addenbrooke's Cognitive Examination III (ACE), which is a test widely used in memory assessment clinics and studies. It is a comprehensive test which covers 5 individual domains: attention, memory, verbal fluency, language and visuospatial abilities. The researcher in SPFT and research assistants in CNTW will be trained to deliver the ACE effectively by staff within SPFT memory clinic services. The ACE III provides an overall score out of 100, with higher scores indicating higher cognitive function. Any PLWD that scores below 36 or above 81 will not be eligible for participation, as this is outside the range of mild-moderate dementia.

Informed dyadic consent will be taken on separate forms, requiring individual signatures from each person (PLWD and family carer) to ensure that the autonomy of decision-making is upheld and respected. The form will state that in the event of one individual from the dyad losing capacity during the study, or wishing to withdraw, then the whole dyad will be withdrawn; any data previously collected will be retained. If consent will need to be taken over the phone, the researcher will follow the protocol for taking remote consent. A copy of the remote consent forms will be sent via postal service to the participants.

Baseline demographic measures will be collected from those who choose to participate. At this stage, the outcome measures will also be administered which will create a pre-intervention data set.

The trial participants will then complete the C-DEM-CSE, as informed by phase 1. The intervention will be delivered by therapists who have been trained in the delivery of CSE. Please see the intervention protocol for the current non-adapted version of the CSE intervention.

The therapists that will deliver the intervention in SPFT will be Prof Mark Hayward and Dr Kirstie Chandler. They both have significant experience working in a variety of mental healthcare settings and patient groups. Prof Mark Hayward is the Director of Research at SPFT and is the lead for the Sussex Voices Clinic; Dr Kirstie Chandler has a wealth of experience in psychosis research including delirium in dementia and currently works in Specialist Older Adult Mental Health Services (SOAMHS), SPFT. Both of their backgrounds and experiences will suit the nature of the research study. Each therapist will deliver the intervention to approximately 3 of the dyads.

There will also be a therapist based in CNTW, Dr Katharina Reichelt, at the CNTW trust, who will deliver the intervention to 6 of the dyads. This therapist will be trained by the chief investigator in the delivery of the C-DEM-CSE and will have regular contact with the research team based in Sussex; the 3 therapists will meet regularly for clinical supervision, facilitated by the chief investigator, Dr Mark Hayward.

Phase 3
- Data collection and analysis

Upon completion of the intervention, trial participants will be asked to meet for a final assessment where post-intervention outcome measures will be administered so that pre and post-intervention data can be compared and analysed. An exit interview for both the PLWD and the carer will be conducted to gain feedback from the intervention; where appropriate, the interviews will be delivered to the PLWD and the carer separately as it is important that the participants feel that they can express and explore their experiences of the intervention candidly. An exit interview will also be conducted with the therapists who delivered the C-DEM-CSE, to understand their experiences of delivering it to this population. These meetings will take place either face-to-face or virtually depending on the preferences, location and availability of the participants, the researcher (SPFT) and the research assistants (CNTW).

Trial participants will be reimbursed for their time in pre- and post-intervention meetings to collect baseline data and deliver exit interviews, at £20 per individual, per meeting. There will be no monetary reimbursement for participation in the four intervention sessions. Travel compensation will also be provided, with a cap of up to £25 per person, per meeting. Fuel costs will be calculated at 45p per mile.

All data analysis will be completed by the student researcher. See the analysis plans in the data management section.

Phase 4- Co-Evaluate
As outlined in Phase 1, the two focus groups will be invited to reconvene, to discuss and evaluate the C-DEM-CSE. As before, the groups will meet separately and then representatives will come together for a final meeting to collectively discuss learnings from phases 2 and 3. Monetary compensation will be provided to focus group participants for this meeting, at the same rates as in Phase 1.

Planned Data Analysis
Qualitative- Phase 1- Co-Adapt
During Phase 1, focus group participants from the focus groups will partake in facilitated discussions and negotiations regarding ideas for adaptations to the CSE intervention. As a group, they will identify key features that they believe should be included or adapted in the intervention. Following this, the use of concept mapping will allow the participants and researcher to group themes that could then translate into proposed adaptations. Each of the two focus groups will produce these maps. The representatives from these two groups will then have a final meeting with the researcher where it will be decided which adaptations go forward into the final design of the C-DEM-CSE.

Quantitative- Phase 2- Single-arm feasibility trial
Calculating recruitment and retention rates will help to inform the primary feasibility outcomes regarding recruitment, retention, completion/ exposure and acceptability. Quantitative measurements collected pre- and post-intervention will be used to indicate average levels of change with associated 95% Confidence Intervals, but no hypothesis testing will be carried out. This information will be for indicative purposes only. Levels of data completeness will be summarised. Descriptive statistical analyses will be conducted to map the demographical picture of the PLWD and their carers; this data will be explored by mapping it against other demographical reports of PLWD who experience hallucinations.

As this is a single-arm feasibility study, an exploratory stance will be adopted to ensure that results and effects are not limited by existing theories or biases.

Qualitative – Phase 3- Data collection and analysis
Following the exit interviews, anonymised verbatim transcripts will be analysed using the Framework Method which is commonly employed in the evaluation of studies of complex interventions in health research. According to the MRC recommendations, this method of analysis aims to generate a specifically nuanced understanding of the personal experiences of engaging with the C-DEM-CSE intervention, what worked well for the participants and what could be improved upon for further adaptation; through this data, we aim to gain a deeper context around the research questions surrounding reducing distress around hallucinatory experiences and improving quality of life. To maintain careful attention to the idiographic nature of participants' reflections, leading to an in-depth inductive analysis, we will follow the seven steps of the Framework Method: (1) verbatim transcription, (2) familiarisation, (3) coding, (4) developing an analytical framework, (5) applying the analytical framework to the data, (6) charting data into the framework matrix, and (7) interpreting the data. Within steps four and five, we will tailor and enrich this method by employing a six-stage analytical framework of Foucauldian-informed narrative analysis of principles for analysis (step four) and actions for analysis (step five).

Intervention Type
Mixed

Primary outcome(s)
1. Recruitment Effectiveness: Demographic representativeness of recruited participants measured using an analysis of recruitment strategies and eligibility criteria after the recruitment phase
2. Participant Retention: Retention rate and reasons for attrition measured using an evaluation of retention strategies and analysis of attrition trends throughout the intervention period, with a final assessment at study completion
3. Intervention Completion and Exposure: The number of sessions attended by participants measured by monitoring attendance and engagement levels through session logs and exit interviews continuously throughout phases 2+3, with final analysis post-intervention
4. Intervention Acceptability: Participant feedback on acceptability measured using qualitative data through semi-structured exit interviews at the end of phases 2+3
5. Safety Monitoring: Incidence of adverse events and serious adverse events measured by auditing and monitoring adverse events with causality assessment continuously throughout the study, with final review at study completion

Key secondary outcome(s)
The research on the clinical outcome measures to be used in the single-arm feasibility trial has not been finalised, as the decisions will also depend on the conversations and discussions with focus group participants (family carers, PLWD and clinicians) in phase 1. The following suggested secondary outcome measures will be assessed at baseline and post-intervention:

1. Adaptation for Hallucinatory Experiences: The severity and frequency of hallucinatory experiences across all five senses measured using the Adapted Hamilton Program for Voices Questionnaire (HPSVQ).
2. Family Carer Quality of Life: The quality of life of family carers measured using the C-DEMQOL questionnaire
3. The Person with Dementia's Quality of Life: The quality of life of the person with dementia measured using the DEM-QOL questionnaire
4. Carer Burden: Level of burden experienced by the carer measured using the Zarit Carer

Burden Interview
5. Depression Symptom Severity: The severity of depression symptoms measured using the PHQ-9 self-report measure
6. Anxiety Symptom Severity: Severity of anxiety symptoms measured using the GAD-7 measure

Completion date
31/03/2026

Eligibility

Key inclusion criteria
Focus Group Participants - Phases 1+ 4 (Co-Adapt and Co-evaluate)

Family carers:
1. Lived experience of caring for a PLWD
2. Able to communicate in English
3. Age 18+ years old

PLWD:
1. Lived experience of dementia
2. Able to communicate in English

Clinicians:
1. Lived experience for working in an NHS clinical environment with PLWD
2. Able to communicate in English

Trial Participants - Phases 2+3 (Single-Arm feasibility trial and data collection and analysis)

PLWD:
1. Have received a clinical diagnosis of dementia
2. A score between 36 and 81 on the ACE III test
3. Have reported hallucinatory experiences
4. Have a family carer that can also participate in the intervention
5. Deemed to have capacity
6. Age 60-90 years old
7. Able to communicate in English

Family carers
1. To be a family carer of someone who has had a clinical diagnosis of dementia
2. A minimum of 10 hours contact time per week with the PLWD (excluding time for meetings with lead researcher and the therapy sessions)
3. For their relative to also be able to participate in the intervention
4. To be able to participate in the intervention and engage with the materials outside of the clinical contact sessions
5. Able to communicate in English
6. Age 18+ years old

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

Total final enrolment
20

Key exclusion criteria
Focus Group Participants- Phases 1+ 4 (Co-Adapt and Co-evaluate)

Family carer:
1. No lived experience of caring for a PLWD
2. Not able to communicate in English
3. Under age 18 years old

PLWD:
1. No lived experience of dementia
2. Not able to communicate in English

Clinicians:
1. No lived experience of working in an NHS clinical environment with PLWD
2. Not proficient in English

Trial Participants - Phases 2+3 (Single-arm feasibility trial and data collection and analysis)

PLWD:
1. No clinical dementia diagnosis
2. A score lower than 36 or higher than 81 on the ACE III test
3. No reports of hallucinatory experiences
4. Does not have a family carer that can participate in the intervention
5. Not deemed to have capacity
6. < 60 or 90< years old
7. Not able to communicate in English

Family carer:
1. Not a family carer of someone who has had an official diagnosis of dementia
2. To have a less than 10 hours contact time per week with the PLWD (excluding time for meetings with lead researcher and the therapy sessions)
3. If their relative is not able to participate in the intervention
4. Not proficient in in English
5. Under age 18 years old

Date of first enrolment
02/09/2024

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Centre for Dementia Studies
Brighton and Sussex Medical School, University of Sussex
Brighton
England
BN1 9PX

Study participating centre
St Nicholas Hospital
Jubilee Road
Gosforth
Newcastle upon Tyne
England
NE3 3XT

Sponsor information

Organisation
Sussex Partnership NHS Foundation Trust

ROR
https://ror.org/05fmrjg27

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository at the Sussex Partnership Foundation Trust. The datasets will be stored in the data repository during the study, and the direct research team will only be able to access this data. Following the closure of the study, the data will be kept for up to 10 years, which is in line with Sussex Partnership Foundation Trust, data storage guidelines. Consent will be sought from participants verbally and on paper. From the point that consent is given, participants will be anonymised and allocated an ID code which will be used thereon. For the dissemination of qualitative work, participant pseudonyms may be used to aid the flow of reading.

IPD sharing plan summary
Stored in non-publicly available repository