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Piloting, psychometric testing and feasibility studies of adapted DIALOG+ in people with mild to moderate learning disability

Submission date
27/06/2025

Recruitment status
Recruiting

Registration date
07/07/2025

Overall study status
Ongoing

Last Edited
04/11/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This research is part of the ICONIC programme, which aims to improve quality of life and behaviour that challenges in people with mild to moderate learning disability through person-centred solution focused communication. DIALOG+ is an evidence based, face-to-face intervention delivered by health professionals using a tablet, which structures routine care sessions to ensure that care planning is personalised, holistic and co-produced. DIALOG+ involves collaboratively completing a quality-of-life scale and then using those ratings to have a solution focused discussion in order to set actions and improve service user satisfaction. Studies have found that it can enhance the communication between service users and those who support them, and can improve quality of life in people with mental health problems, but it has not been used in people with learning disabilities. We want to make DIALOG+ accessible and suitable for people with learning disability and to use it to help individuals think about things in their life they want to improve (e.g. leisure activities, accommodation) by using resources available to them or their carers. Our aim is to test if it improves quality of life and behaviour.

Who can participate?
Piloting Study:
Service users will be eligible to take part if they are aged 18 or over, have mild or moderate learning disability based on service records / clinical notes, have a current history of behaviour that challenges (at least one incident of self-injurious behaviour, physical aggression or damage to property in the last 3 months), are living in any setting including the family home and supported living/ residential home, and can provide informed verbal or written consent. Clinicians will be eligible to take part if they are aged 18 or over, are currently working within a community learning disability service, intensive support team or in a local authority or social care organisation for people with learning disability, are from any profession (e.g. psychology, nursing, speech and language therapy, psychiatry, social work) at grade 4 and above with a minimum of six months experience working with people with learning disability, and consent to participate.

Care workers will be eligible to take part if they are aged 18 or over, have worked in the care home for at least three months, provide at least one day of support per week to service users, and consent to participate.

Psychometric Testing Study:
Service users will be eligible to take part if they are aged 18 or over, have mild or moderate learning disability based on service records / clinical notes, are under community learning disability services from participating NHS trusts, and can provide informed verbal or written consent.

Clinical Services Feasibility Study:
Service users will be eligible to take part if they are aged 18 or over, have mild or moderate learning disability based on service records / clinical notes, have a current history of behaviour that challenges (at least one incident of self-injurious behaviour, physical aggression or damage to property in the last 3 months), are living in any setting including the family home and supported living/ residential home, and can provide informed verbal or written consent.
Clinicians will be eligible to take part if they are aged 18 or over, are currently working within a community learning disability service, intensive support team or in a local authority or social care organisation for people with learning disability, are from any profession (e.g. psychology, nursing, speech and language therapy, psychiatry, social work) at grade 4 and above with a minimum of six months experience working with people with learning disability, consent to participate and haven't participated in other work packages.
Participant carers will be eligible to take part if they are aged 18 or over, are paid or unpaid (e.g. family carer); if a paid carer, they will need to have worked with the person for at least six months and should know the person well and support the person on a regular basis, and consent to participate.

Care Homes Feasibility Study:
Service users will be eligible to take part if they are aged 18 or over, have mild or moderate learning disability based on service records / clinical notes, have a current history of behaviour that challenges (at least one incident of self-injurious behaviour, physical aggression or damage to property in the last 3 months), are residing in supported living or residential care, and can provide informed verbal or written consent.
Care workers will be eligible to take part if they are aged 18 or over, have worked in the care home for at least three months, provide at least one day of support per week to service users, consent to participate and haven't participated in other work packages.
Care homes will be eligible to take part if they are supported living or residential placements for service users with learning disability in the participating areas and the service manager has agreed for the care home to take part.

What does the study involve?
Piloting Study:
In this study, we are interested in piloting an adapted version of the DIALOG scale and intervention (aDIALOG+) for people with learning disability.
Five clinicians and five care workers will receive training on how to deliver aDIALOG+ and a copy of the manual, and an electronic tablet. They will then be asked to administer the aDIALOG+ intervention using the app (at least once) to two service users (20 in total).
A clinical studies officer or a member of the research team will arrange a face-to-face or remote (via Teams or Zoom) meeting with 120 service users, where they will be asked to complete the aDIALOG scale, along with additional questionnaires. Alternatively, service users can be sent the consent form and questionnaires to complete via email or post. Following this service users will be asked to complete the aDIALOG scale again on another occasion (ideally 24 hours later but no

later than 1 week). This will be carried out face-to-face, online or via telephone, or alternatively service users can be sent the aDIALOG scale to complete again via email or post.
Following this we will invite clinicians, care workers and service users to take part in a focus group or interview to obtain feedback on what aspects of the intervention (including the DIALOG scale, app, training and manual) that worked well or did not work well, and suggestions for improvement. The focus groups/interviews will be audio-recorded and transcribed so that we can analyse the data and determine which aspects of the intervention that did not work well and require further modifications, which will inform changes to the intervention. We will also ask clinicians and care workers to complete a questionnaire for assessing intervention implementation processes from the perspective of professionals directly involved.

Psychometric Testing Study:
Research assistants will arrange a face-to-face or remote (via Teams or Zoom) meeting with service users, where they will be asked to complete the aDIALOG scale, along with additional questionnaires. Following this service users will be asked to complete the aDIALOG scale again on another occasion (ideally 24 hours later but no later than 1 week). This will be carried out face-to-face, online or via telephone.

Clinical Services Feasibility Study:
In this study, we will be assessing whether it is feasible for clinicians to deliver an adapted version of aDIALOG+ to service users with mild or moderate learning disability who have behaviours that challenge (such as aggression towards others or property and self-injurious behaviour). Our aim is to establish whether it is possible to recruit 8-12 clinicians, 30 service users and 30 participant carers into the study. We will also examine the number of sessions of aDIALOG+ that are delivered over 6 months, the quality of the sessions, and the experiences and views of clinicians and service users about the intervention, what worked well and what needs to be improved. We will also examine if there are any potential benefits of the intervention by looking at changes in outcome measures such as behaviour, community participation, quality of life and service use.

For service users that agree to take part and provide consent, their clinician will administer the aDIALOG+ intervention using the app during a face-to-face session at least once a month over 6 months. The service user's GP will also be informed of their participation. The intervention will take about 30 minutes but it might take less time or more time depending on the needs of the person. Participant carers may be asked to support the service user to their appointments with the clinician and may be asked to help with implementing some of the actions. Sessions will be audio-recorded (and video recorded using Microsoft Teams where possible). Service users will complete questionnaires at baseline and at 6 months, and clinicians and participant carers will also be asked to complete some questionnaires about themselves and the service user. After the 6-month period, some service users, clinicians and participant carers will be asked to share their views on the experience of using aDIALOG+ through participating in a focus group or interview, which will last about 30-45 minutes. We will obtain feedback on what aspects of the intervention (including the DIALOG scale, app, training and manual) worked well or did not work well, and suggestions for improvement. The interviews will be audio-recorded and transcribed so that we can analyse the data and determine which aspects of the intervention need further modifications, which will inform changes to the intervention.

Care Homes Feasibility Study:
In this study, we will be assessing whether it is feasible for care workers to deliver an adapted version of DIALOG+ (aDIALOG+) to service users with mild or moderate learning disability who have behaviours that challenge (such as aggression towards others or property and self-injurious behaviour). Our aim is to establish whether it is possible to recruit 10 care homes, 3-5 care

workers from each, and a total of 40-50 service users into the study. We will also examine the number of sessions of aDIALOG+ that are delivered over 6 months, the quality of the sessions, and the experiences and views of care workers and service users about the intervention, what worked well and what needs to be improved. We will also examine if there are any potential benefits of the intervention by looking at changes in outcome measures such as behaviour, community participation, quality of life and service use.

For service users that agree to take part and provide consent, their care workers will administer the aDIALOG+ intervention using the app during a face-to-face session. Delivery will involve a 'team approach', potentially involving more than one care worker. There will be flexibility in the number of aDIALOG+ sessions that are delivered, with an expectation that it is delivered at least once a month over 6 months. We recommend, if possible, that aDIALOG+ is used as part of routine meetings that care workers would usually have with the service user (e.g. at key worker meetings, to reduce burden on the care worker and the service user). The service user's GP will also be informed of their participation. The intervention will take about 30 minutes but it might take less time or more time depending on the needs of the person. Sessions will be audio-recorded (and video recorded using Microsoft Teams where possible). Service users will complete questionnaires at baseline and at 6 months, and care workers will also be asked to complete some questionnaires about themselves and the service user. After the 6-month period, some service users and care workers will be asked to share their views on the experience of using aDIALOG+ through participating in a focus group or interview, which will last about 30-45 minutes. We will obtain feedback on what aspects of the intervention (including the DIALOG scale, app, training and manual) worked well or did not work well, and suggestions for improvement. The interviews will be audio-recorded and transcribed so that we can analyse the data and determine which aspects of the intervention need further modifications, which will inform changes to the intervention.

What are the possible benefits and risks of participating?
For the piloting study, service users and care workers will receive a £20 shopping voucher for participating in the interview/focus group following the 6-week intervention period to thank them for their time, and service users will also receive a £20 voucher after taking part in the psychometric testing study. For the clinical services and care homes feasibility studies, service users, participant carers and care workers will receive a £20 shopping voucher for completing qualitative interviews, and service users will receive £20 after completing the baseline assessment and £20 prior to the 6-month follow-up assessments to thank them for their time. Participant carers and care workers will also receive £20 following completion of the baseline assessment and prior to the 6-month follow-up assessments. By sharing experience and views on the aDIALOG+ software, it will help us to improve it and adapt it for clinicians and care workers who use aDIALOG+ in the future. We know that using the original DIALOG+ intervention improved the quality of life of people with psychosis when they used it face to face and we are hoping we can replicate those benefits in service users with learning disability.

We believe that these studies are safe and do not expect participants to suffer any harm or injury because of taking part.

Where is the study run from?
The research is coordinated at the Unit for Social and Community Psychiatry, Queen Mary University of London. Dr Afia Ali has overall responsibility for the study and it is sponsored by East London NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
The piloting study is starting in November 2025 and is expected to run for 2 months. The

psychometric testing study in starting in July 2025 and is expected to run for 6 months. The clinical services and care homes feasibility studies are starting in December 2025 and are expected to run for 12 months.

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

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
349711

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 68145, NIHR205440

Study information

Scientific Title
Improving quality of life and behaviour that challenges in people with mild to moderate intellectual disability through person-centred solution focused communication (ICONIC)

Acronym
ICONIC

Study objectives
1. To pilot the adapted DIALOG quality of life scale and intervention (aDIALOG+) and obtain feedback on what aspects of the intervention (including the aDIALOG scale, supporting app, training and manual) worked well or did not work well and suggestions for improvement.
2. To test the psychometric properties of the aDIALOG scale to establish whether the aDIALOG scale is a useful quality of life measure in people with learning disability.
3. To conduct a feasibility study of aDIALOG+ delivered by clinicians from community learning disability services to assess recruitment and retention of service users and clinicians.
4. To conduct a feasibility study of aDIALOG+ delivered by care workers from care homes (supported living or residential care) for people with learning disability to assess recruitment and retention of care homes, care workers and service users.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 23/06/2025, South West - Cornwall & Plymouth Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8079; cornwallandplymouth.rec@hra.nhs.uk), ref: 25/SW/0055

Study design
Interventional non-randomized

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mild to moderate intellectual disability

Interventions
An adapted version of DIALOG+ (a brief, low-cost solution focused intervention that improves the therapeutic effectiveness of routine clinical meetings between patients and clinicians) for individuals with learning disability will be piloted for 4-6 weeks, tested for psychometric properties at 2 timepoints (within 24 hours-1 week), and delivered in clinical and care home feasibility studies for 6 months.

Intervention Type
Behavioural

Primary outcome(s)
WP1a Piloting:
1. Acceptability of / feedback on the intervention is measured using semi-structured interviews / focus groups with at 6 weeks.
2. Intervention implementation processes from the perspective of clinicians and care workers are assessed using the NoMAD questionnaire at 6 weeks.

WP1b Psychometric Testing:
1. Construct and concurrent validity of the aDIALOG scale are measured using the Mini-MANS LD and the WHOQOL Disabilities module and Clinical Outcome in Routine Evaluation- Learning Disability (CORE-LD), 14 item version (measure of psychological distress) at baseline.
2. Test re-test reliability of the aDIALOG scale is measured by completing the scale at baseline and again 24 hours to 1 week later.

Feasibility studies:
1. Changes in behaviour in service users is measured using the Aberrant Behaviour Checklist (ABC) – Irritability subscale at baseline and 6 months

Key secondary outcome(s))
Feasibility studies:
1. 2. Quality of life in service users is measured using the 13- item WHOQOL Disabilities module (WHOQOL-DIS) at baseline and 6 months
2. Community and Leisure participation in service users is measured using the Guernsey Community Participation and Leisure Assessment – Revised (GCPLA-R) at baseline and 6 months
3. Changes in psychological distress in service users is measured using the Learning Disability – Clinical Outcomes in Routine Evaluation, 14 item version (LD-CORE-14) at baseline and 6 months
4. Changes in the presence of psychiatric disorders in service users is measured using the Moss Psychiatric Assessment Schedule - Check (Moss-PAS Check) at baseline and 6 months
5. Changes in behaviour and functioning in service users as a result of the intervention is

measured using a modified version of the Clinical Global Impressions Scale – Improvement version (CGI-I) at 6 months
6. Paid and family carer distress in participant carers is measured using the Kessler Psychological Distress Scale - K6 at baseline and 6 months
7. Changes in health-related quality of life in service users is measured using the EuroQol Five Dimensions - Learning Disability modified version of the EQ-5D-3L at baseline and 6 months. A proxy version of the EQ-5D-5L will also be completed by participant carers at baseline and 6 months.
8. Health related quality of life in participant carers is measured using the EQ-5D-5L at baseline and 6 months.
9. Health and social care contacts and medication in service users is measured using a modified version of the Client Services Receipt Inventory (CSRI) at baseline and 6 months.
10. Treatment costs of delivering the intervention are measured using staff time, room bookings and other resource use in participating clinical services and care homes.
11. Intervention implementation processes from the perspective of clinicians and care workers are assessed using the NoMAD questionnaire at 6 months.
12. Recruitment is measured using screening logs of the number of clinicians, care workers and eligible service users who were approached agreed to take part throughout the study at 6 months.
13. Retention is measured using withdrawal forms completed to record clinicians, care workers and service users who drop out of the study and the reasons why, as well as the number of participants that complete the follow-up assessment at 6 months.
14. Intervention adherence is measured using session completion data from the aDIALOG+ app at 6 months.
15. Intervention fidelity is measured using audio/video recordings of sessions, action plans from the aDIALOG+ app and completed session fidelity checklists at 6 months.
16. Acceptability of the intervention is measured using semi-structured interviews / focus groups with at 6 months.

Completion date
26/02/2027

Eligibility

Key inclusion criteria
WP1a
1. Service Users Inclusion Criteria:
1. Aged 18 or over
2. Mild or moderate ID based on service records / clinical notes
3. Current history of behaviour that challenges (at least one incident of self-injurious behaviour, physical aggression or damage to property in the last 3 months)
4. Living in any setting including the family home and supported living/residential home
5. Can provide informed verbal or written consent
2. Clinicians Inclusion Criteria:
1. Aged 18 or over
2. Currently working within a community ID service, intensive support team or in a local authority or social care organisation for people with ID
3. From any profession (e.g. psychology, nursing, speech and language therapy, psychiatry, social work), grade 4 and above with a minimum of six months experience working with people with ID
4. Consent to participation
3. Care Workers Inclusion Criteria:

1. Aged 18 or over
2. Have worked in the care home for at least three months
3. Provide at least one day of support per week to service users
4. Consent to participation

WP1b
1. Service Users Inclusion Criteria:
1. Aged 18 or over
2. Mild or moderate ID based on service records / clinical notes
3. Under community ID services from the East London Foundation Trust - Updated 04/11/2025: from participating NHS trusts
4. Can provide informed verbal or written consent

WP2
1. Service Users Inclusion Criteria:
1. Aged 18 or over
2. Mild or moderate ID based on service records / clinical notes
3. Current history of behaviour that challenges (at least one incident of self-injurious behaviour, physical aggression or damage to property in the last 3 months)
4. Living in any setting including the family home and supported living/residential home
5. Can provide informed verbal or written consent
2. Clinicians Inclusion Criteria:
1. Aged 18 or over
2. Currently working within a community ID service, intensive support team or in a local authority or social care organisation for people with ID
3. From any profession (e.g. psychology, nursing, speech and language therapy, psychiatry, social work), grade 4 and above with a minimum of six months experience working with people with ID
4. Consent to participation
5. Have not participated in other work packages
3. Participant Carers Inclusion Criteria:
1. Aged 18 or over
2. Are paid or unpaid (e.g. family carer); if a paid carer, need to have worked with the person for at least six months and should know the person well and support the person on a regular basis
3. Consent to participation

WP3
1. Service Users Inclusion Criteria:
1. Aged 18 or over
2. Mild or moderate ID based on service records / clinical notes
3. Current history of behaviour that challenges (at least one incident of self-injurious behaviour, physical aggression or damage to property in the last 3 months)
4. Residing in supported living or residential care
5. Can provide informed verbal or written consent
2. Care Homes Inclusion Criteria:
1. Supported living or residential placements for service users with ID in the participating areas
2. Service manager has agreed for the care home to take part
3. Care Workers Inclusion Criteria:
1. Aged 18 or over
2. Have worked in the care home for at least three months
3. Provide at least one day of support per week to service users
4. Consent to participation
5. Have not participated in other work packages

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
WP1a
1. Service Users Exclusion Criteria:
1. Under 18 years of age
2. Severe ID based on service records / clinical notes
3. Likely to move out of borough within the next three months or at imminent risk of hospital admission
4. Unable to provide informed verbal or written consent
2. Clinicians Exclusion Criteria:
1. Under 18 years of age
2. Not currently working within a community ID service, intensive support team or in a local authority or social care organisation for people with ID
3. Below grade 4 and less than six months experience working with people with ID
4. Do not consent to participation
3. Care Workers Exclusion Criteria:
1. Under 18 years of age
2. Have worked in the care home for less than three months
3. Do not provide at least one day of support per week to service users
4. Do not consent to participation

WP1b
1. Service Users Exclusion Criteria:
1. Under 18 years of age
2. Severe ID based on service records / clinical notes
3. Not under community ID services from the East London Foundation Trust - Updated 04/11/2025: from participating NHS trusts
4. Unable to provide informed verbal or written consent

WP2
1. Service Users Exclusion Criteria:
1. Under 18 years of age
2. Severe ID based on service records / clinical notes
3. Already participating in WP3 or involved in another clinical trial
4. Likely to move out of borough within the next six months or at imminent risk of hospital admission

5. Unable to provide informed verbal or written consent
2. Clinicians Exclusion Criteria:
1. Under 18 years of age
2. Not currently working within a community ID service, intensive support team or in a local authority or social care organisation for people with ID
3. Below grade 4 and less than six months experience working with people with ID
4. Do not consent to participation
5. Have participated in other work packages
3. Participant Carers Exclusion Criteria:
1. Under 18 years of age
2. If a paid carer and have worked with the person for less than six months and/or do not know the person well and/or support the person on a regular basis
3. Do not consent to participation

WP3
1. Service Users Exclusion Criteria:
1. Under 18 years of age
2. Severe ID based on service records / clinical notes
3. Already participating in WP2 or involved in another clinical trial
4. Likely to move out of the care home within the next six months or are at imminent risk of hospital admission
5. Unable to provide informed verbal or written consent
2. Care Homes Exclusion Criteria:
1. Not supported living or residential placements for service users with ID and/or not in the participating areas
2. Service manager does not agree for the care home to take part
3. Care Workers Exclusion Criteria:
1. Under 18 years of age
2. Have worked in the care home for less than three months
3. Do not provide at least one day of support per week to service users
4. Do not consent to participation
5. Have participated in other work packages

Date of first enrolment
07/08/2025

Date of final enrolment
29/05/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
East London NHS Foundation Trust
Robert Dolan House

9 Alie Street
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Study participating centre
Cornwall Partnership NHS Foundation Trust
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Study participating centre
North London NHS Foundation Trust
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Sponsor information

Organisation
North East London NHS Foundation Trust

ROR
https://ror.org/023e5m798

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be 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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.0	30/05/2025	30/06/2025	No	No
Protocol file	version 3.0	14/10/2025	04/11/2025	No	No