ICONIC
Improving quality of life for people with learning disabilities

NHS
East London
NHS Foundation Trust

Queen Mary
University of London

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

ICONIC Piloting, Psychometric Testing and Feasibility Protocol (WP1, WP2 and WP3)

This protocol has regard for the HRA guidance and order of content.

FULL/LONG TITLE OF THE STUDY

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

SHORT STUDY TITLE / ACRONYM

ICONIC Piloting, Psychometric Testing and Feasibility Protocol (WP1, WP2 and WP3)

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:		
Signature: ……		Date: ……..
Name (please print): ……		
Position: ……..		
Chief Investigator:		
Signature: ……		Date: ……
Name (please print): ……		
Statistician:		
Signature: ……		Date: ……
Name (please print): ……		

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Committees	The study committees include: • Patient and Public Involvement Advisory Group • Programme Steering Committee

STUDY SUMMARY

Study Title	Improving quality of life and behaviour that challenges in people with mild to moderate intellectual disability through person-centred solution focused communication
Short Title	ICONIC Piloting, Psychometric Testing and Feasibility Protocol (WP1, WP2 and WP3)
Study Design	Mixed methods study consisting of: Qualitative focus groups/interviews, Exploratory validation study (cross-sectional design), Single arm, uncontrolled, feasibility study assessing outcome measures over a 6-month period
Study Participants	*Service users* with mild or moderate intellectual disability (ID) based on service records / clinical notes; aged 18 or above; have a history of behaviour that challenges (at least one incident of self-injurious behaviour, physical or verbal aggression, anger / frustration outbursts, or damage to property) and are currently receiving or waiting for treatment OR have a diagnosis of a mental health condition and are currently receiving or waiting for treatment; living in any setting OR residing in supported living or residential care; capacity to provide informed verbal or written consent. *Clinicians* who are currently working within a community ID service, intensive support team or in a local authority or social care organisation for people with ID; aged 18 or above; from any profession (e.g. psychology, nursing, speech and language therapy, psychiatry, social work), with a minimum of six months experience working

	with people with ID; provide consent to participation. *Participant carers* who are a paid or unpaid (e.g. family carer); or if they are a paid carer, they 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; aged 18 or above; provide consent to participation. *Care homes* that are supported living or residential placements for service users with ID in the participating areas; the service manager has agreed for the care home to take part. *Care workers* who have worked in the care home for at least three months; aged 18 or above; provide at least one day of support per week to service users; provide consent to participation. For psychometric testing comparison study: *Service users* treated as outpatients by a community psychiatric team in East London NHS Foundation Trust or currently an inpatient in East London NHS Foundation Trust; at least 3 months of continuous care in the current service; having a primary diagnosis of a mental health issue; aged between 18 and 65 years; capacity to provide informed verbal or written consent.
Planned Size of Sample (if applicable)	– Work package 1a: 5 clinicians, 5 care workers and 20 service users. – Work package 1b: 120 service users with learning disability and 200 service users with a mental health diagnosis (without a learning disability). – Work package 2: 8-12 clinicians, 30 service users, and 30 participant carers (if available). – Work package 3: 10 care homes and their care workers (around 2 care workers in each care home, approx 20 carers). 3-5 service users in each care home (approximately 30 service users).
Follow up duration (if applicable)	– Work package 1a: 2-4 weeks – Work package 1b: 24 hours-1 week – Work package 2: 6 months – Work package 3: 6 months
Planned Study Duration	24 months (August 2025 – July 2027)

Principle Research Question / Aim(s)	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, 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 ID, and to compare it to the original DIALOG scale in people with a primary mental health diagnosis. 3) To conduct a single arm, uncontrolled, feasibility study of aDIALOG+ delivered by professionals from community ID services to assess recruitment and retention of service users and clinicians. 4) To conduct a single arm, uncontrolled, feasibility study of aDIALOG+ delivered by care workers from care homes (supported living or residential care) for people with ID to assess recruitment and retention of care homes, care workers and service users.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIAL SUPPORT GIVEN**
National Institute for Health Research (NIHR)	NIHR Programme Grants for Applied Research Award
East London NHS Foundation Trust (supported by Noclor)	Study sponsorship
East London NHS Foundation Trust Cornwall Partnership NHS Foundation Trust	Permissions to conduct study on Trust premises with Trust employees and service users
Ten residential or supported living care homes (to be determined)	Permissions to conduct study on premises with employees and service users
Queen Mary University of London	Substantive employer of Chief Investigator and Programme Manager

ROLE OF STUDY SPONSOR AND FUNDER

East London NHS Foundation Trust is the study sponsor. Noclor Research Support Service is the sponsor representative acting on behalf of East London NHS Foundation Trust to assume overall responsibility for the initiation and management of the study. The National Institute of Health Research (Programme Grants for Applied Research Award) has provided funding for the study.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

Study Steering Groups

- Patient and Public Involvement Advisory Group

  There will be a PPI advisory panel of individuals with intellectual disability (ID) who will meet regularly throughout the programme (every three months) to provide advice on all aspects of the study. The groups will be facilitated by the PPI lead and PPIE co-applicant. PPI members will be recruited from existing service user groups within the East London Foundation Trust, and through local community intellectual disability teams. Our aim is to include a diverse group of individuals in terms of age, gender, ethnicity and severity of intellectual disability (mild or moderate). For WP1, we will also establish a 'adaptation team' and co-production group, which will include clinicians and carers, as well as service users and they will provide input into the adaptation of DIALOG+.

- Programme Steering Committee

  A Programme Steering Committee (PSC) will be convened to oversee the entire programme. An independent chair will be appointed and the PSC will comprise three other independent members (e.g. statistician, methodologist, clinician with expertise in ID) and PPI representative. The members will meet at least once a year but may meet more often depending on the progress of the programme.

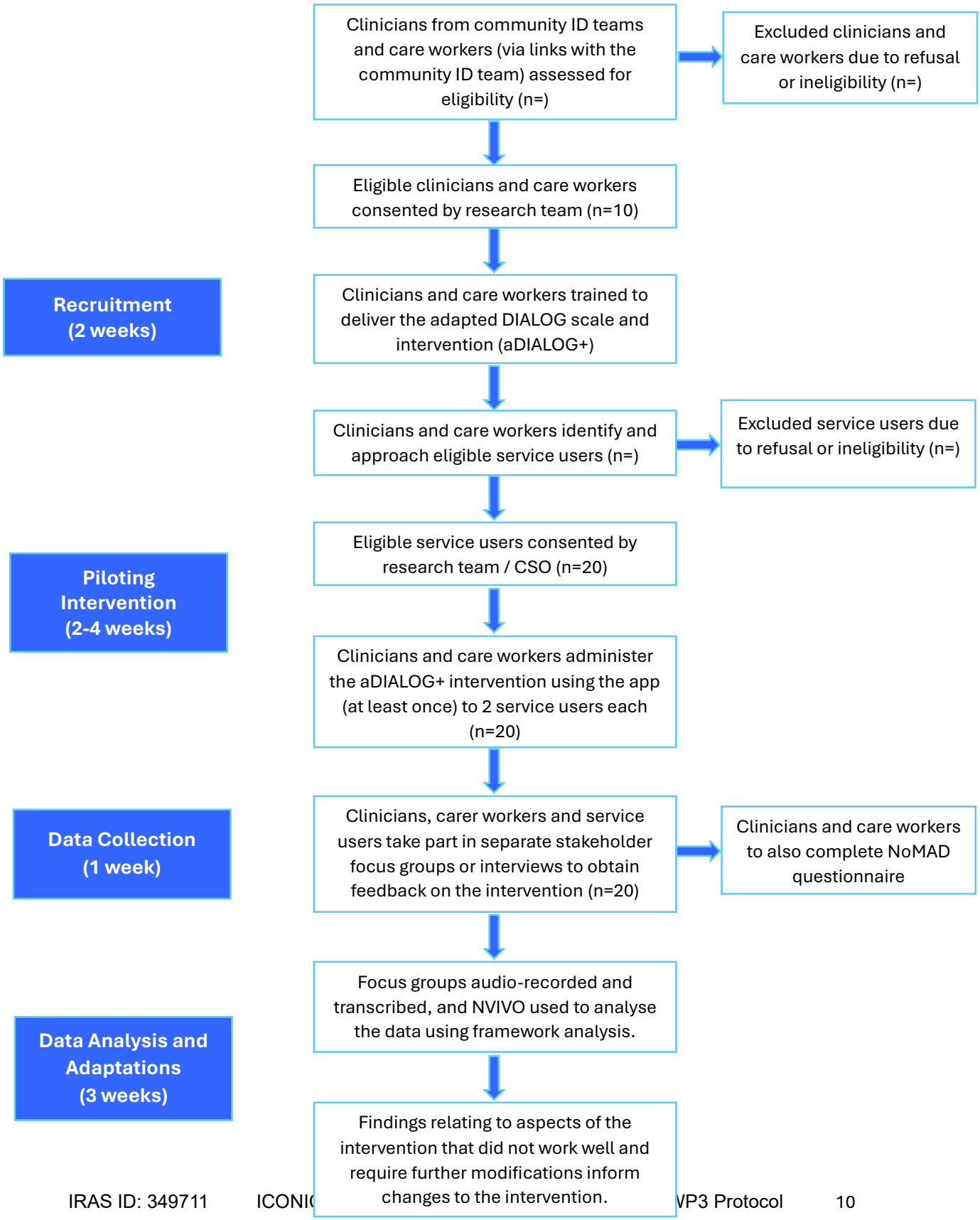
PROTOCOL CONTRIBUTORS

The protocol contributors are:
● Dr Afia Ali, Chief Investigator
● Laura Miller, Programme Manager
● Professor Victoria Bird, Co-Investigator
●Dr Clare Robinson, Co-Investigator

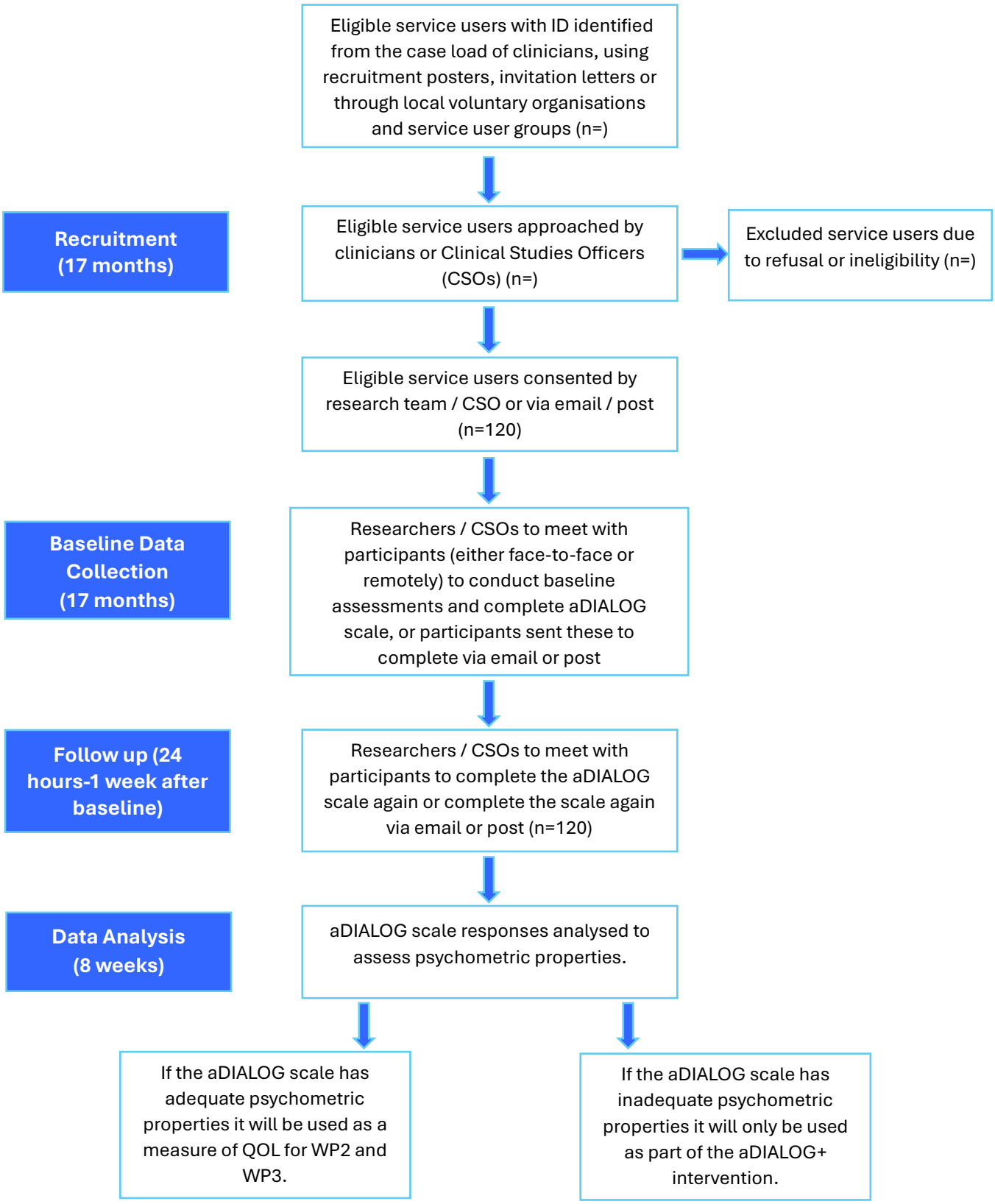
Some aspects of protocol design such as participant-facing documents have been developed with consultation from the programme PPI advisory group. This group has lived experience of ID and their involvement has allowed us to ensure that our service-user facing documents are accessible.

KEY WORDS:	Intellectual disability, digital mental health intervention, challenging behaviour, feasibility study

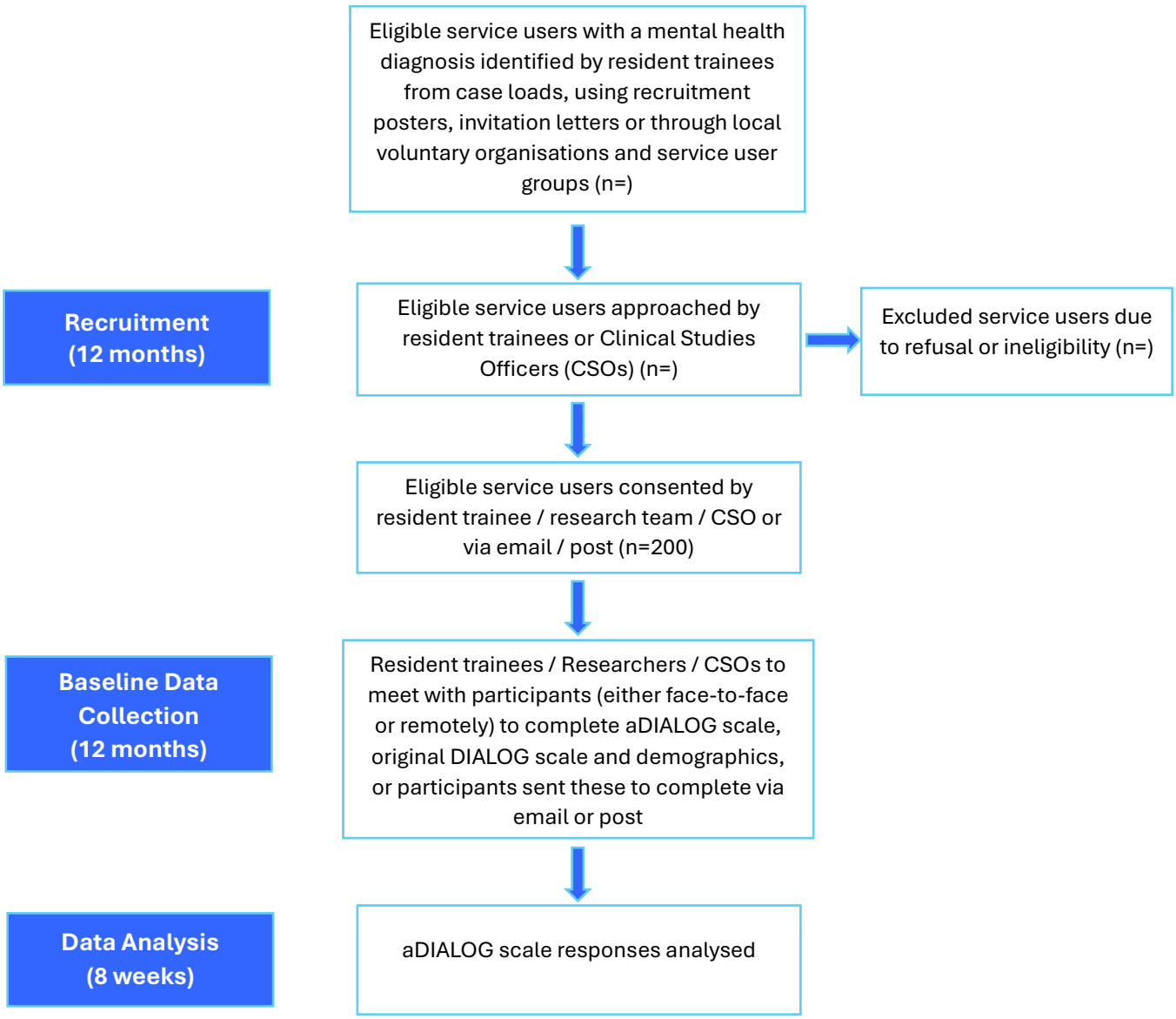
STUDY FLOW CHART- WP1a PILOTING ADAPTED DIALOG+



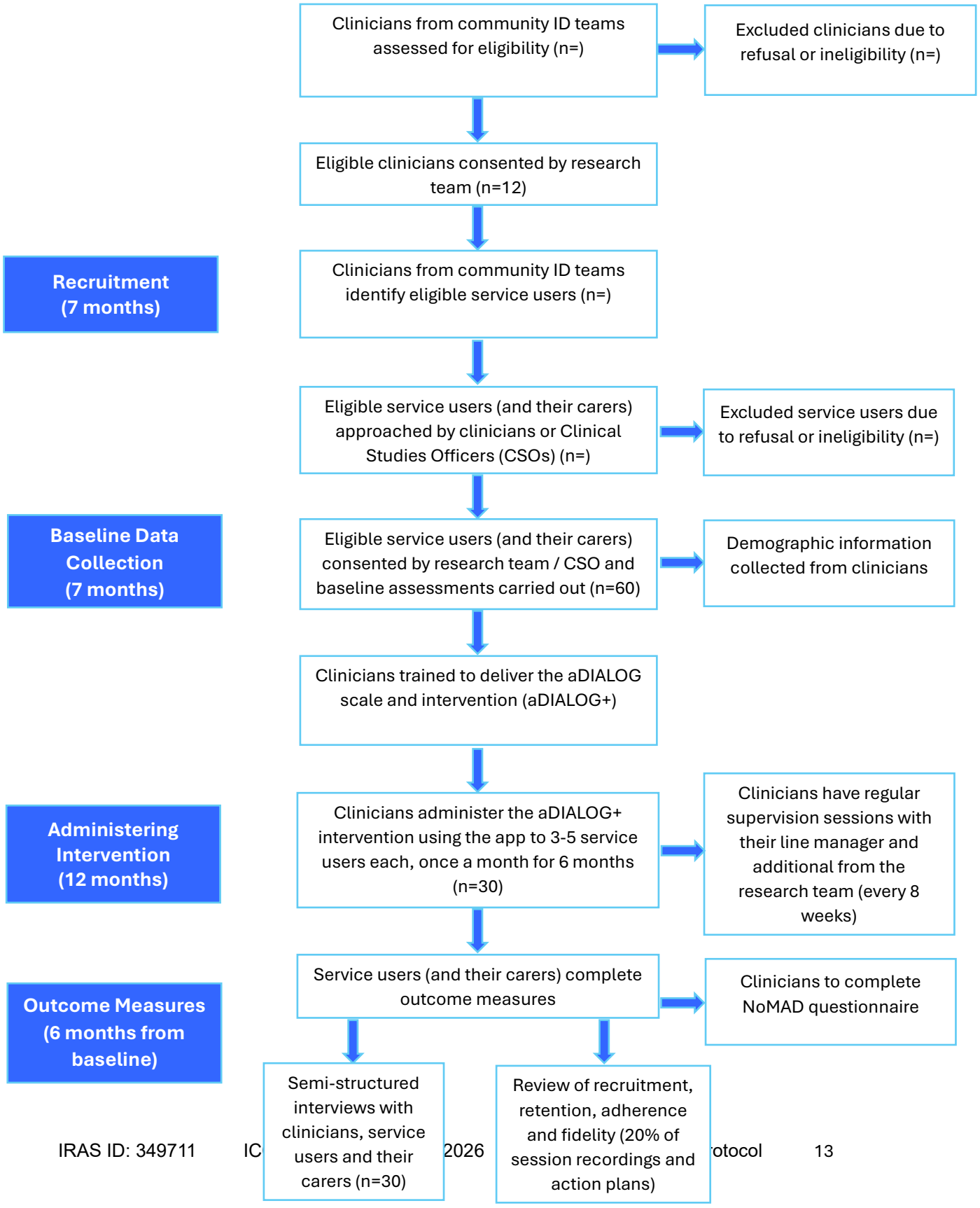
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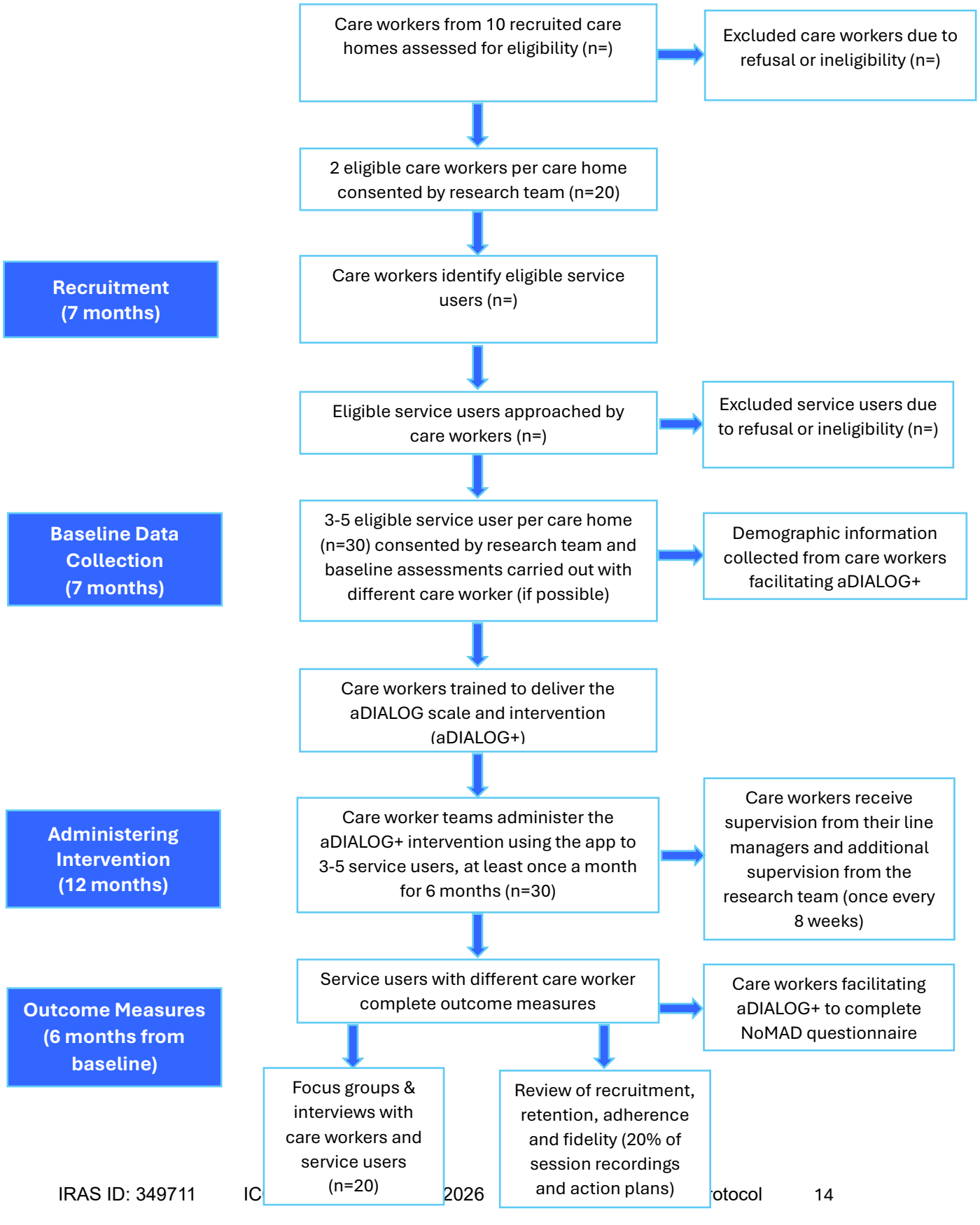
STUDY FLOW CHART- WP1b COMPARISON TESTING OF aDIALOG SCALE



STUDY FLOW CHART- WP2 FEASIBILITY STUDY OF DELIVERING aDIALOG+ IN CLINICAL SERVICES



STUDY FLOW CHART- WP3 FEASIBILITY STUDY OF DELIVERING aDIALOG+ IN CARE HOMES



STUDY PROTOCOL

ICONIC Piloting, Psychometric Testing and Feasibility Protocol (WP1, WP2 and WP3)

1 BACKGROUND

What is the problem being addressed?

Learning or intellectual disability (ID) affects 2% of the population and is characterised by limited cognitive ability and impaired adaptive functioning, arising before the age of 18 (1). People with ID experience social inequalities such as unemployment, have limited social networks and are less likely to be involved in community groups or leisure activities (2), which may impact their quality of life. They also have higher rates of physical and mental health comorbidities but experience inequities in accessing health services compared to the general population (3-5).

Behaviour that challenges (e.g. aggression/self-injury) occur in 18% of people with ID living in the community (6) and over 50% in inpatient settings (7). Reducing behaviour that challenges is important because of its detrimental impact as individuals are exposed to restrictive practices and abuse, inappropriate psychotropic medication, exclusion from day services, accommodation breakdown (8-10) and admission to psychiatric hospitals (11). The causes of behaviour that challenges in people with ID include physical and mental health conditions, and social factors contributing to a poor quality of life (QoL) such as inadequate support, leisure activities, relationships and housing (12). There is evidence that QoL may act as a mediator in the relationship between ID and behaviour that challenges (13) and psychiatric symptoms are strongly associated with behavioural problems (14-15). One plausible mechanism is that poor QoL leads to boredom and frustration, contributing to anxiety or low mood, and finally irritability and aggression. Therefore, addressing and improving QoL is a key target for interventions aiming to reduce challenging behaviour.

Current interventions for behaviour that challenges

Positive Behavioural Support (PBS) and anger management are recommended by NICE for managing behaviour that challenges (16). A Cochrane systematic review (17) found evidence from two large RCTs of moderate certainty that anger management and PBS reduced aggressive behaviour post intervention, compared to usual care or a waitlist control group, but effects were not maintained at 10 and 12 months respectively (18-19) and they did not reduce service use costs or improve QoL, suggesting that the lack of long-term benefits could be attributed to failure to improve QoL. Psychosocial interventions that promote QoL in people with challenging behaviour, and the effectiveness of models of person-centred support are both NICE research priorities (20). The current dearth of evidence supports the importance of identifying and evaluating person-centred interventions that could reduce behaviours that challenge by improving QoL, resulting in long-term sustained benefits and reduced NHS and social care costs.

Adapting existing evidence-based interventions from other populations (DIALOG+)

The adaptation of existing evidence-based interventions to a new context, in this case, people with ID, may be more efficient than developing a new intervention (21). One candidate person-centred intervention with established effectiveness in improving QoL of patients with mental illness is DIALOG+. This is a brief, low-cost solution focussed intervention that improves the therapeutic effectiveness of routine clinical meetings between patients and clinicians by using existing staffing and resources, and requires little training (22-23). These qualities of DIALOG+ makes it particularly appealing for adaptation in the

context of people with ID. The intervention delivery is supported by a free app and a Progressive Web Application (PWA), enabling its use on electronic devices. The patient rates their satisfaction with eight life domains on the DIALOG QoL scale (mental health, physical health, job situation, accommodation, leisure activities, relationship with partner/family, friendships, personal safety) and three treatment aspects (medication, practical help, meetings with professionals) on a scale from 1 (totally dissatisfied) to 7 (totally satisfied), followed by a question on whether additional help is required with that domain. The ratings are summarised and the patient and clinician agree which domains to discuss further, followed by a four-step solution focussed approach to identify the individual's existing resources that can be mobilised to address the concerns: 1. Understanding the individual's concerns and previous effective coping strategies; 2. Looking Forward (what is the best-case scenario and smallest step forward?); 3. Exploring Options (what resources are available to the individual, clinician or others in the person's network?); and 4. Agreeing on Actions (e.g. homework and referrals), which are reviewed at the next meeting. The DIALOG scale has good psychometric properties (24) and is a mandatory outcome scale recommended for use in the NHS, which has aided the implementation of DIALOG+ in several NHS trusts where it is currently used in routine care planning (25). The app supporting the DIALOG+ intervention will automatically store usage data (such as number of log ins, clicks and time spent on the software, etc), domain ratings and goals set, but does not collect any identifiable information about the patients it is used with.

Why DIALOG+ needs to be adapted for people with ID

DIALOG+ has not been used or evaluated in people with ID. Feedback from service users with ID and clinicians who we have engaged with, have been positive about the potential for DIALOG+ to facilitate improved communication between clinicians and service users. One service user commented "it's important that professionals ask the right questions about what is important to me". DIALOG+ could empower individuals with ID to engage in meaningful conversations, promoting a greater sense of control and agency, potentially leading to improved QoL and fewer behaviours that challenge. However, they emphasised that the existing intervention is not accessible for this population (e.g. language/ response format of the DIALOG scale/ supporting app is too complex and the QoL domains are not all relevant. Evidence from the literature suggests that quality of life domains such as autonomy and rights are important for people with ID but the existing DIALOG scale does not include these domains (26-27).

2 RATIONALE

Our aim is to develop and evaluate an adapted version of the DIALOG scale and intervention (aDIALOG+) for people with ID that could be used in clinical and social care settings. Validating the aDIALOG scale will address the lack of a reliable, valid and sensitive measure of QoL in this population (27). The use of an intervention which is supported by an app is also novel and although apps are increasingly used by people with ID (28), evidence for their effectiveness in improving mental health outcomes or QoL is lacking. People with ID may experience several barriers in accessing digital mental health interventions, which include cognitive and linguistic limitations, physical disability, sight and hearing impairment, inadequate support from carers, lack of appropriate training and economic and attitudinal barriers (29). This programme will bridge the current gaps in the evidence highlighted by NICE (16, 20). The intervention will be aimed at people with mild and moderate ID as they will be able to directly engage in conversations about their QoL and it is crucial that their perspectives dictate any action plans that are developed and initiated. However, carers will have an important role in helping to implement the action plan.

Why this research is important and potential impact

Individuals with ID displaying aggressive behaviour are a significant burden on health and social care services and have increased contact with services (30). As well as reducing human suffering and distress for individuals, there could be significant cost savings if admissions are avoided and this is an urgent priority for the NHS (31). There are costs incurred from family carer distress and burden, contributing to individuals moving from family homes into residential placements; and staff burnout and poor staff retention in care homes leading to residential placements breaking down. Interventions such as PBS are time and resource intensive, difficult to access due to long waiting lists and are poorly implemented (32). Consequently, psychotropic medications are often prescribed inappropriately rather than addressing the problem but cause significant side effects (33). Rationalising their use is a national priority (31, 34).

Adapted DIALOG+ could improve the culture and delivery of care in clinical services and care homes, by providing staff with key skills that enhance person centred care during routine interactions. This could increase staff competence and resilience and improve sustainability of residential placements, leading to reduced placement breakdowns. Empowering individuals with ID to make changes that improve their QoL could reduce behavioural problems, thus reducing exposure to psychotropic medications, hospital admissions and NHS and social care costs.

This research may contribute to future clinical guidelines (e.g. NICE guidelines on challenging behaviour) and NHS and social care policies. As DIALOG+ is already being implemented in several NHS trusts, aDIALOG+ could be integrated into community ID services with relative ease.

3 REVIEW OF EXISTING EVIDENCE

An updated Cochrane systematic review (17) found evidence that behavioural and cognitive behavioural interventions reduced aggressive behaviour in people with ID post intervention but there was no evidence that benefits were sustained at follow-up, and no evidence that these interventions improved QoL or were cost effective. We postulate that sustained benefits in reducing behaviour that challenges may be achieved through interventions that improve QoL, but currently there is dearth of psychosocial interventions that address this gap in people with ID. We are therefore proposing to adapt DIALOG+ for people with ID.

In a cluster RCT of DIALOG+ delivered by clinicians in East London, compared to an active control arm (completion of DIALOG scale using app only), comprising 49 clinicians and 179 participants with psychosis, at three, six and 12 months post randomisation, participants receiving DIALOG+ had better quality of life (measured using the Manchester Short Assessment of Quality of Life (MANSA), fewer unmet needs, lower symptom levels, and better social outcomes compared to the control arm (22). This was despite variable implementation of DIALOG+ (mean number of sessions was 1.8 at three months). An economic evaluation demonstrated cost savings of over £1000 per participant per year with fewer in-patient days. There was a 74.2% probability of the intervention improving outcomes and saving costs and a 26.5% probability of DIALOG+ being effective at a higher cost (22).

The process evaluation, based on qualitative interviews with clinicians and participants, revealed that there were four themes related to the mechanism of action of DIALOG+: the provision of a comprehensive structure to meetings; opportunities for self-reflection; therapeutic self-expression and empowerment. The treatment effect was largest for accommodation and mental health (35).

DIALOG+ has been piloted and found to be acceptable in forensic in-patient mental health units and patients with chronic depression in the UK (36, 37). It is also being evaluated in low- and middle-income countries (23, 38). One cluster RCT in Bosnia and Herzegovina of 72 participants with anxiety or depression and 15 clinicians randomised to the intervention arm or a control arm, found improvements in quality of life (MANSA) after 12 months in participants receiving DIALOG+, with an effect size of 0.6 (Cohen's d). Symptoms of anxiety and depression were lower at six and 12 months (23).

Since 2017, East London NHS Foundation Trust (ELFT) has adopted DIALOG+ as part of routine care for all patients with mental illness. Using records from 5646 patients, changes in the scores on the DIALOG scale were examined (25) and there was an increase in satisfaction for all the items across time (mean increase was 0.47). The largest increase was in mental health (0.94). This suggests that DIALOG+ may produce sustained improvements in QoL over time, and has the potential to benefit individuals with ID.

4 RESEARCH QUESTION / AIM(S)

Aim: To develop and test the feasibility and acceptability of an adapted version of the DIALOG scale and intervention (aDIALOG+) for people with ID in clinical and social care settings.

4.1 Objectives

The principle objectives of these phases of the programme are:

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 ID, and compare it with the original DIALOG scale in people with mental health issues.

3) To conduct a single arm, uncontrolled, feasibility study of aDIALOG+ delivered by clinicians from community ID services to assess recruitment and retention of service users and clinicians.

4) To conduct a single arm, uncontrolled, feasibility study of aDIALOG+ delivered by care workers from care homes (supported living or residential care) for people with ID to assess recruitment and retention of care homes, care workers and service users.

The secondary objectives of these phases of the programme are:

1) To examine intervention adherence (number of sessions attended)

2) To examine intervention fidelity (whether intervention is delivered as intended)

3) To examine completion and changes in clinical outcome measures (behaviour that challenges, quality of life; community participation, psychological distress, psychiatric disorders, health related quality of life).

4) To explore acceptability of the intervention amongst service users, clinicians and care workers.

5) To examine the feasibility of collecting data on costs and service use.

6) To establish the minimal clinically important difference (MCID) for the Aberrant Behaviour Checklist – Irritability scale (primary outcome)

5 STUDY DESIGN AND METHODS OF DATA COLLECTION AND DATA ANALYSIS

Intervention

The current DIALOG+ intervention is a person-centred intervention delivered/supported by a free app and a Progressive Web Application (PWA), enabling its use on electronic devices. It aims to improve the therapeutic effectiveness of routine clinical meetings between patients and clinicians by asking the patient to rate their satisfaction with eight life domains on the DIALOG QoL scale:

1) Mental health
2) Physical health
3) Job situation
4) Accommodation
5) Leisure activities
6) Relationship with partner/family
7) Friendships
8) Personal safety

and three treatment aspects:

1) Medication
2) Practical help
3) Meetings with professionals

The scale has a seven-point response format from 1 (totally dissatisfied) to 7 (totally satisfied). After the patient rates each domain, they are asked whether additional help is required with that domain. The ratings are summarised and the patient and clinician agree which domains to discuss further, followed by a four-step solution focussed approach to identify the individual's existing resources that can be mobilised to address the concerns:

1) Understanding the individual's concerns and previous effective coping strategies

2) Looking Forward (what is the best-case scenario and smallest step forward?)

3) Exploring Options (what resources are available to the individual, clinician or others in the person's network?)

4) Agreeing on Actions (e.g. homework and referrals), which are reviewed at the next meeting.

The app supporting the DIALOG+ intervention will automatically store usage data (such as number of log ins, clicks and time spent on the software, etc), domain ratings and goals set, but does not collect any identifiable information about the patients it is used with.

Co-production work to develop an adapted version of DIALOG+

Prior to the study, we will hold five workshops with service users, clinicians and care workers in order to develop an adapted version of the DIALOG+ (aDIALOG)+ that will be accessible and suitable for use in people with ID. This may involve changes to the response format and wording of the DIALOG+ QoL scale and four step solution focused approach, as well as updating the Progressive Web Application to make it more accessible and engaging for people with ID. We will modify the training manual and training resources.

Study Design

1. Work package 1a: Piloting adapted DIALOG+

The adapted DIALOG scale and intervention (aDIALOG+) will be piloted with five clinicians (any background e.g. nurse, occupational therapist, psychiatrist, social worker) from community ID teams and five care workers. Clinicians will be eligible if they are aged 18 or over, are currently working within a community ID service, intensive support team or in a local authority or social care organisation for people with ID, are from any profession (e.g. psychology, nursing, speech and language therapy, psychiatry, social work) with a minimum of six months experience working with people with ID, and consent to participate. Care workers will be eligible 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. Clinicians and care workers will receive training on how to deliver aDIALOG+ and will receive a copy of the manual, and an electronic tablet to enable them to access the app. The tablet will be insured and it will be the research team's responsibility to provide replacements. Clinicians and care workers will be asked to administer the aDIALOG+ intervention using the app (at least once) to two service users each (20 service users in total).

For clinical services, eligible service users with ID will be identified from the case load of the participating clinician through the review of medical records. They will then be approached by the participating clinician or Clinical Studies Officer (CSO) to take part in the study and an information sheet will be provided. If service users are interested, the CSO or a member of the research team will contact the person to discuss the study, assess their eligibility, and obtain consent either in a face-to-face meeting or remotely on Teams or Zoom. For care homes, eligible service users with ID will be identified from service records / clinical notes by care workers, and the research team will ask staff to approach eligible service users to take part in the study. If they are interested, their details will be passed to the CSO or the research team, who will contact the potential participant, provide an information sheet, and assess their eligibility, and obtain consent either in a face-to-face meeting or remotely on Teams or Zoom. Service users will be eligible if they are aged 18 or over, have mild or moderate ID based on service records / clinical notes, have a current history of behaviour that challenges (at least one incident of self-injurious behaviour, physical or verbal aggression, anger / frustration outbursts, 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. We will ask clinicians and care workers to identify and approach all the service users on their caseload or within the care home, who are potentially eligible to take part, to take part in the study until they reach the recruitment target. This should reduce the likelihood of clinicians and care workers only approaching certain individuals to take part.

After 2-4 weeks we will invite the five clinicians, five care workers and at least ten service users to take part in separate stakeholder focus groups or interviews to obtain feedback on what aspects of the intervention (including the aDIALOG scale, app, training and manual) that worked well or did not work well and suggestions for improvement. Topic guides for the focus groups/interviews will be developed with input from the adaptation group (group of clinicians, carers and service users overseeing the work). We will also ask clinicians and care workers to complete the NoMAD questionnaire (39) for assessing implementation processes.

2. Work package 1b: Testing the psychometric properties of the aDIALOG quality of life scale

The psychometric properties of the aDIALOG scale (validity and reliability) will be tested in an exploratory validation study (cross-sectional study design), where the scale will be administered to 120 service users. Service users will be eligible if they are aged 18 or over, have mild or moderate ID based on service records / clinical notes, are known to community ID services from participating NHS trusts or to voluntary groups for people with ID, and can provide informed verbal or written consent.

Eligible service users with ID will be identified from the case load of clinicians through the review of medical records, using recruitment posters, invitation letters or through local voluntary organisations and service user groups. They will then be approached by the CSO to take part in the study and an information sheet will be provided. If service users are interested in taking part, the CSO or a member of the research team will contact the person to discuss the study, assess eligibility, obtain consent and conduct assessments, either in a face-to-face meeting or remotely on Teams or Zoom. Alternatively, service users can be sent the consent form and questionnaires to complete via email or post.

We will collect basic socio-demographic data and we will ask participants to complete the aDIALOG scale, along with additional measures. In order to assess test re-test reliability, we will ask participants 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.

The aDIALOG scale will also be compared with the original DIALOG scale in 200 service users with mental health issues (who do not have ID). Service users will be eligible if they are aged between 18 and 65 years, are being treated as outpatients by a community psychiatric team or currently an inpatient in a participating NHS trust, have a primary diagnosis of a mental health issue, and can provide informed verbal or written consent. At least 20% of the patients recruited will be from an outpatient setting.

Eligible service users with any mental health diagnosis will be identified from the case load of clinicians through the review of medical records, using recruitment posters, invitation letters or through local voluntary organisations and service user groups. They will then be approached by the CSO to take part in the study and an information sheet will be provided. If service users are interested in taking part, the CSO or a member of the research team will contact the person to discuss the study, assess eligibility, obtain consent and conduct assessments, either in a face-to-face meeting or remotely on Teams or Zoom. Alternatively, service users can be sent the consent form and questionnaires to complete via email or post. We will ask participants to complete the aDIALOG scale, along with the original DIALOG scale, and some demographic questions (e.g. gender, age, ethnicity, primary mental health diagnosis, how they receive their care and the number of years of treatment).

3.Work package 2: A feasibility study of delivering aDIALOG+ in clinical services

We will conduct a single arm, uncontrolled, feasibility study of aDIALOG+ delivered by clinicians from community ID services to assess recruitment and retention of service users and clinicians. We will recruit 8-12 clinicians, who will be eligible if they are aged 18 or over, are currently working within a community ID service, intensive support team or in a local authority or social care organisation for people with ID, are from any profession (e.g. psychology, nursing, speech and language therapy, psychiatry, social work) with a minimum of six months experience working with people with ID, and consent to participate.

Clinicians will administer aDIALOG+ to 3-5 service users with ID on their caseload (30 service users in total), and they will be identified through the review of medical records. Service users and their carers will then be approached by the participating clinician or CSO to take part in the study and an information sheet will be provided. Service users will be eligible if they are aged 18 or over, have mild or moderate ID based on service records / clinical notes, have a history of behaviour that challenges (at least one incident of self-injurious behaviour, physical or verbal aggression, anger / frustration outbursts, or damage to property) and are currently receiving or waiting for treatment OR have a diagnosis of a mental health condition and are currently receiving or waiting for treatment, are living in any setting including the family home and supported living/ residential home, and can provide informed verbal or written consent. Participant carers will be eligible 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. If service users are interested in taking part, the CSO or a member of the research team will contact the person and their carer to discuss the study, will assess eligibility, obtain consent and conduct a baseline assessment either in a face-to-face meeting or remotely on Teams or Zoom. We will ask clinicians to identify and approach all the service users on their caseload, who are potentially eligible to take part, to take part in the study until they reach the recruitment target. This should reduce the likelihood of clinicians only approaching certain individuals to take part.

Clinicians will deliver aDIALOG+ using the app on a tablet (provided by the research team), once a month for six months to each of the 3-5 service users on their caseload. The tablet will be insured and it will be the research team's responsibility to provide replacements. Clinicians will receive full training (half a day) after service users have been recruited, which will include the manual and will have access to online resources (including videos). Clinical supervision will be provided by their line manager as usual (at least once a month) and they will also have access to additional supervision relating to the delivery of the intervention from the research team (every 8 weeks). Assessments will be conducted at baseline and post intervention (6 months), either in a face-to-face meeting or remotely on Teams, Zoom, via email or post. Semi-structured interviews will be held with 6-10 clinicians, 10 service users and 10 participant carers (if available) supporting service users. Questions will be framed using the Theoretical Domains Framework, which examines issues related to implementation. Clinicians will be asked about their perspectives on the quality of training and supervision received, views about the ease of using the app and technical challenges and practical and organisational issues (e.g. time, resources) in implementing aDIALOG+. Service users and participant carers will be asked about their views on the accessibility and ease of using the app, perceived benefits and unintended consequences of aDIALOG+, and aspects that did or did not work well and suggestions for improvements/changes. We will also ask clinicians to complete the NoMAD questionnaire (39) for assessing implementation processes.

4. Work package 3: A feasibility study of aDIALOG+ in care homes

We will conduct a single arm, uncontrolled study of aDIALOG+ delivered by care workers from care homes (supported living or residential care) for people with ID. The main aim of this study is to explore the recruitment and retention of care homes, care workers and service users, the acceptability, adherence and fidelity of aDIALOG+ delivered by care workers and completion of outcome measures. We will recruit ten care homes and their paid staff (approximately two staff in each participating care home, which are to be determined). Care homes will be identified from Care Quality Commission websites and local authority

and national registers. We will also consult with Regional Research Delivery Networks to identify care homes that are interested in research.

We will approach the service managers at the care home and seek permission for staff to take part. Care homes will be eligible if they are supported living or residential placements for service users with ID in the participating areas and the service manager has agreed for the care home to take part. Care workers will be eligible 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. Participating care workers in each of the participating care homes will receive training on how to use aDIALOG+ and will deliver the intervention using the app on a tablet (provided by the research team) to eligible service users residing in the care home. The tablet will be insured and it will be the research team's responsibility to provide replacements. Service users will be identified from service records / clinical notes by care workers, and the research team will ask staff to approach eligible service users to take part in the study. If they are interested, their details will be passed to the CSO or a member of the research team, who will contact the potential participant, provide an information sheet, assess their eligibility, and obtain consent either in a face-to-face meeting or remotely on Teams or Zoom. Service users will be eligible if they are aged 18 or over, have mild or moderate ID based on service records / clinical notes, have a history of behaviour that challenges (at least one incident of self-injurious behaviour, physical or verbal aggression, anger / frustration outbursts, or damage to property) and are currently receiving or waiting for treatment OR have a diagnosis of a mental health condition and are currently receiving or waiting for treatment, are residing in supported living or residential care, and can provide informed verbal or written consent. We will ask care workers to identify and approach all the service users within the care home, who are potentially eligible to take part, to take part in the study until they reach the recruitment target. This should reduce the likelihood of care workers only approaching certain individuals to take part.

Participating care workers in each of the participating care homes will receive training on how to use aDIALOG+ after service users have been recruited and will deliver the intervention using the app on a tablet (provided by the research team) to eligible service users residing in the care home. The tablet will be insured and it will be the research team's responsibility to provide replacements. More than one care worker can deliver the intervention to a service user, but for consistency it is advised that the same care worker sees the service user throughout where possible. 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 six months. Care workers will receive supervision from their line managers and additional supervision from the research team once every 8 weeks. Line managers will also be invited to the training session offered to the care workers, and an additional training session can be provided regarding expectations related to their role. Additionally, the research team can offer supervision sessions for line managers once every 8 weeks, and care workers and line managers will also be able to contact the research team in between supervision sessions if they need additional support, with the option to arrange ad hoc meetings. Assessments will be conducted at baseline and post intervention (6 months), either in a face-to-face meeting or remotely on Teams, Zoom, via email or post. Acceptability will be assessed by carrying out focus groups at five care homes (at least 10 care workers) and interviews with 10 service users. We will also ask care workers to complete the NoMAD questionnaire (39) for assessing implementation processes.

Data Collection

1. Work package 1a: Piloting adapted DIALOG+

If service users are interested in taking part, the CSO or a member of the research team will contact the person to discuss the study, assess their eligibility, and obtain consent either in a face-to-face meeting or remotely on Teams or Zoom. After 2-4 weeks will invite the five clinicians, five care workers and at least ten service users to take part in separate stakeholder focus groups or interviews to obtain feedback on what aspects of the intervention (including the aDIALOG 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. We will also ask clinicians and care workers to complete the NoMAD questionnaire (39) for assessing implementation processes from the perspective of professionals directly involved in the work of implementing complex interventions in healthcare.

Table 1: ICONIC WP1a Piloting screening and data collection schedule

	Completed by	*Pre-consent*	*Consent*	*2-4 weeks*	*Ongoing or during intervention*
Clinicians and care workers screened for eligibility	RT / CSO	x			
Clinician and care workers consent form	C / CW / RT / CSO		x		
Service users screened for eligibility	C / CW	x			
Service users consent form	SU / RT / CSO		x		
aDIALOG+ app data	SU / C / CW				x
Participant withdrawal CRF	RT / CSO / SU / C / CW				x
Focus group / interview audio recordings and transcripts	SU / C / CW / RT / TC			x	
NoMAD questionnaires	C / CW / RT			x	

2. Work package 1b: testing the psychometric properties of the aDIALOG quality of life scale

If service users are interested in taking part, the CSO or a member of the research team will contact the person to discuss the study, assess eligibility, obtain consent and conduct assessments, either in a face-to-face meeting or remotely on Teams or Zoom. Alternatively, service users can be sent the consent form and questionnaires to complete via email or post. We will collect basic socio-demographic data (gender, age, ethnicity, severity of ID,

neurodevelopmental conditions, day activities, living arrangements, co-morbid psychiatric and physical illnesses) and we will ask service users to complete the aDIALOG scale and the following measures (in order to assess construct and concurrent validity):

i. Mini-MANS LD and the WHOQOL Disabilities module (measures of quality of life in people with ID) (40, 41).

ii. Clinical Outcome in Routine Evaluation- Learning Disability (CORE-LD), 14 item version (measure of psychological distress) (42).

In order to assess test re-test reliability, we will ask service users 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.

Table 2: ICONIC WP1b Psychometric testing screening and data collection schedule

	Completed by	*Pre-consent*	*Consent*	*Baseline*	*Follow up (24 hours to 1 week)*	*Ongoing or during intervention*
Service users screened for eligibility	C	x				
Service users consent form	SU / RT / CSO		x			
Service user questionnaire	RT / CSO / SU			x		
aDIALOG item scores	RT / CSO / SU			x	x	
Participant withdrawal CRF	RT / CSO / SU					x

Work package 1b: comparison testing of the aDIALOG quality of life scale

If service users are interested in taking part, the resident trainee, CSO or a member of the research team will contact the person to discuss the study, assess eligibility, obtain consent and conduct assessments, either in a face-to-face meeting or remotely on Teams or Zoom. Alternatively, service users can be sent the consent form and questionnaires to complete via email or post. We will ask service users to complete the aDIALOG scale and the original DIALOG scale (in order to assess construct and concurrent validity), along with some demographic questions (e.g. gender, age, ethnicity, primary mental health diagnosis, how they receive their care and the number of years of treatment).

Table 3: ICONIC WP1b Psychometric testing comparison screening and data collection schedule

	Completed by	*Pre-consent*	*Consent*	*Baseline*	*Ongoing or during intervention*
Service users screened for eligibility	RTR	x			
Service users consent form	SU / RTR / RT / CSO		x		
Questionnaire scores	RTR / RT / CSO / SU			x	
aDIALOG and original DIALOG scale scores	RTR / RT / CSO / SU			x	
Participant withdrawal CRF	RTR / RT / CSO / SU				x

3. Work package 2: A feasibility study of delivering aDIALOG+ in clinical services

If service users are interested in taking part, the CSO or a member of the research team will contact the person and their carer to discuss the study, will assess eligibility, obtain consent and conduct a baseline assessment, either in a face-to-face meeting or remotely on Teams or Zoom. The baseline assessment will include completion of a socio-demographic and clinical data collection form (gender, age, ethnicity, severity of ID, neurodevelopmental conditions, day activities, living arrangements, co-morbid psychiatric and physical illnesses, prescribed medication (e.g. psychotropic medication), and psycho-social interventions that they are have received or are receiving (e.g. positive behavioural support). Demographic information will also be collected from clinicians participating in the study (gender, age, ethnicity, profession, number of years in the service and years' experience working with people with ID) and participant carers (gender, age, ethnicity and education level) if available. The aDIALOG+ app will capture data on the number of times aDIALOG+ was administered, changes in the aDIALOG scale scores over the duration of the intervention and goals set, but does not collect any identifiable information about the patients it is used with. Data on the number of sessions attended will be used to assess adherence to the intervention; we will analyse the mean changes in the scores for each domain on the aDIALOG scale.

Feasibility outcomes

1. Recruitment:

We will record the number of clinicians and eligible service users who were approached and agreed to take part.

2. Retention:

We will record the number of clinicians and service users who dropped out of the study and reasons, and the number of participants that complete the follow-up assessment.

3. Adherence:

We will examine data on how many sessions were delivered and reasons for sessions being missed.

4. Fidelity:

All the sessions will be audiotaped (and videotaped using Microsoft Teams if possible) and 20% of the recordings for each clinician will be selected randomly and rated using a fidelity checklist to identify the extent to which the intervention was delivered as intended. We will also review 20% of the action plans. The fidelity checklist will be adapted from the checklist developed for the DIALOG+ trial in people with psychosis.

5. Acceptability:

Semi-structured interviews/focus groups will be held with 6-10 clinicians, 10 service users and 10 participant carers supporting service users (if available). We will use purposive sampling to identify service users who received at least half the sessions (3 or more), and those who received less than half the sessions (0-2 sessions) and we will interview clinicians from different backgrounds, and paid and family participant carers, in order to obtain a range of perspectives. Clinicians will be asked about their perspectives on the quality of training and supervision received, views about the ease of using the app and technical challenges and practical and organisational issues (e.g. time, resources) in implementing aDIALOG+. Topic guides for the service users will be developed with input from the PPI advisory group. The questions will include views about the accessibility and ease of using the app, perceived benefits and unintended consequences of aDIALOG+, and aspects that did or did not work well and suggestions for improvements/changes. The interviews will be held after the collection of outcome data and will be conducted by a research assistant not involved in the collection of outcome data. The interviews will be audiotaped and transcribed verbatim using an approved transcription company or internally using transcription software. We will also ask clinicians to complete the NoMAD questionnaire (39) for assessing implementation processes from the perspective of professionals directly involved in the work of implementing complex interventions in healthcare.

6. Completion of outcome measures:

Assessments will be conducted at baseline and post intervention (6 months) by the research assistants or CSOs and will take place face-to-face or conducted remotely (telephone or videoconference depending on preference). Outcomes will be assessed in both service users and participant carers (if available). We will examine the proportion of participants who complete the following outcomes:

Outcomes in service users

i. Behaviour that challenges

Changes in behaviour will be measured using the Aberrant Behaviour Checklist (ABC)-Irritability subscale (43). This is one of the five domains of the Aberrant Behaviour Checklist-Community (ABC-Community) and comprises 15 items rated on a 4-point Likert scale

(0=never a problem; 3=severe problem). This will be completed by participant carers if available.

ii. Quality of life

Changes in quality of life will be measured using the 13- item WHOQOL Disabilities module (WHOQOL-DIS) (40) which will be completed with service users and has been validated in people with people with ID.

iii. Community participation

Community and Leisure participation will be measured using the Guernsey Community Participation and Leisure Assessment – Revised (GCPLA-R), a 23 item scale developed for use in people with ID (44). This will completed by participant carers if available.

iv. Psychological distress

Changes in psychological distress will be measured using the Learning Disability – Clinical Outcomes in Routine Evaluation, 14 item version (LD-CORE-14) (42), which will be completed with service users.

v. Psychiatric disorders

We will assess changes in the presence of psychiatric disorders using the Moss Psychiatric Assessment Schedule - Check (Moss-PAS Check) (45), which provides scores relating to anxiety, depression, elevated mood and hyperactivity, obsessive compulsive disorder, psychosis and possible organic disorder in people with ID. This will be completed by participant carers if available.

vi. Global improvement

We will assess whether there are changes in behaviour and functioning as a result of the intervention (at 6 months) using a modified version of the Clinical Global Impressions Scale (CGI) (46). The CGI global improvement measure (CGI-I) will be rated by the clinician (or care worker) delivering aDIALOG+, the service user and also the participant carer (if possible). The scale is rated from 1 (very much improved) to 7 (very much worse).

Outcomes in participant carers (if available)

i. Psychological distress

Paid and family carer distress will be measured with the Kessler Psychological Distress Scale - K6 (47).

Health economics

The feasibility of collecting health economic data: The ease of completing the following measures and response rates will be assessed:

i. Health Related Quality of Life for service users

Changes in health-related quality of life in participants with ID will be assessed using the EuroQol Five Dimensions - Learning Disability version, a recently developed, modified version of the EQ-5D-3L (48, 49), which will be completed with service users. A proxy version of the EQ-5D-5L (50) will also be completed by participant carers if available.

ii. Health Related Quality of Life for participant carers

Health related quality of life for paid/family carers will be measured using the EQ-5D-5L (50).

iii. Service use

Information about health and social care contacts and medication in the preceding six months will be collected using a modified version of the Client Services Receipt Inventory (CSRI) (51). The CSRI has been used in previous economic evaluations in people with ID and will be adapted for use in this study (52). The number and duration of contacts with primary care, professionals within community ID services (e.g. psychiatrists, nurses, social workers), secondary care (outpatient, Accident and Emergency visits and hospital admissions), day services, medication, paid and unpaid carer input and contacts with criminal justice system, will be collected. All measures will be administered with participant carers if available, but we will also explore the feasibility of collecting information using electronic patient records.

iv. Treatment costs

We will collect information on the costs of delivering the intervention within clinical services and care homes (e.g. staff time, room bookings, other resources use).

Table 4: ICONIC WP2 Feasibility screening and data collection schedule

	Completed by	*Pre-consent*	*Consent*	*Baseline*	*6-month follow-up*	*Ongoing or during intervention*
Clinicians screened for eligibility	RT / CSO	x				
Clinicians consent form	C / RT / CSO		x			
Clinicians socio-demographic form	C / RT / CSO			x		
Service users and participant carers screened for eligibility	C	x				
Service users and participant carers consent form	SU / PC / RT / CSO		x			
Service users socio-demographic	RT / CSO / SU / PC			x		

and baseline questionnaire						
Participant carers socio-demographic and baseline questionnaire	PC / RT / CSO			x		
Clinician training costs data	CL / CSO / RT					x
aDIALOG+ app data	SU / C / PC					x
Video/audio recordings of sessions and checklists	SU / C / PC					x
Participant withdrawal CRF	RT / CSO / C / PC / SU					x
SAE CRF	RT / CSO / C / PC / SU					x
Service user 6-month follow up questionnaire	RT / SU / PC / C				x	
Participant carer 6-month follow up questionnaire	PC / RT				x	
Focus group / interview audio recordings and transcripts	SU / C / PC / RT / TC				x	
NoMAD questionnaires	C / RT				x	
Treatment costs data	C / RT				x	

4. Work package 3: A feasibility study of aDIALOG+ in care homes

Care workers will identify eligible service users and approach them about possibly taking part. If service users are interested, their details will be passed to the CSO or a member of the research team, who will contact the potential participant, provide an information sheet, and assess their eligibility and capacity to consent. This will be followed by the baseline assessment, which will include demographic and clinical data as described above for service users. This will be collected either in a face-to-face meeting or remotely on Teams or Zoom. For care workers, we will collect demographic data on gender, age, ethnicity, level of education, how many years they have worked in the care home and how many years' experience they have working with people with ID. We will collect information about the care home from service managers (e.g. number of service users and staff employed). Service users will complete the outcome measures (at baseline and 6 months) described above. Informant outcome measures will be completed by a care worker other than those facilitating aDIALOG+ if possible.

We will record the number of care homes, care workers and eligible service users who were approached and agreed to take part. We will also record the number of care workers and service users who dropped out of the study and reasons, and the number of participants that complete the follow-up assessment. We will assess the number of sessions of aDIALOG+ completed by each service user and we will review 20% of the action plans, which will be rated for quality using a fidelity checklist. All the sessions will be audiotaped where possible (and videotaped using Microsoft Teams if possible) and 20% of the recordings for each care worker will be selected randomly and rated using a fidelity checklist to identify the extent to which the intervention was delivered as intended. Acceptability will be assessed by carrying out focus groups at five care homes (at least ten care workers) and interviews with 10 service users. We will purposively select service users based on the number of sessions completed (as above) and a range of care homes will be selected based on the type of care home (supported living/ residential) and size (number of service users). Interviews/ focus groups will be audio-taped and transcribed. We will also ask care workers to complete the NoMAD questionnaire (39) for assessing implementation processes from the perspective of professionals directly involved in the work of implementing complex interventions in healthcare.

Table 5: ICONIC WP3 Feasibility screening and data collection schedule

	Completed by	*Pre-consent*	*Consent*	*Baseline*	*6-month follow-up*	*Ongoing or during intervention*
Care homes and workers screened for eligibility	RT / CSO	x				
Care workers consent form	CW / RT / CSO		x			
Care workers socio-	CW / RT / CSO			x		

demographic form						
Service users screened for eligibility	CW	x				
Service users consent form	SU / RT / CSO		x			
Service users socio-demographic and baseline questionnaire	RT / CSO / SU / CW			x		
Care worker training costs data						x
aDIALOG+ app data	SU / CW					x
Video/audio recordings of sessions and checklists	SU / CW					x
Participant withdrawal CRF	RT / CSO / CW / SU					x
SAE CRF	RT / CSO/ CW / SU					x
Service user 6-month follow up questionnaire	RT / SU / CW				x	
Focus group / interview audio recordings and transcripts	SU / CW / RT / TC				x	
NoMAD questionnaires	CW / RT				x	
Treatment costs data	CW / RT				x	

For work package 1a, service users and care workers will receive a £20 shopping voucher for participating in the interview/focus group following the 2-4 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 in work package 1b. For the psychometric comparison study service users will receive a £10 voucher for taking part.

For work packages 2 and 3, 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.

Data Storage and Analysis

Data collected by CRFs will be collected on paper or directly inputted into the applicable database or safe haven by either CSOs, research assistants or the research team. Paper CRFs will be stored in a locked cabinet on NHS or care home premises.

Development of study databases will be the responsibility of the PCTU, hosted within the PCTU Data Safe Haven. Access to study data will be restricted to the research team based within NHS and Queen Mary University of London.

The app supporting the aDIALOG+ intervention will automatically store usage data (such as number of log ins, clicks and time spent on the software, etc), domain ratings and goals set, but does not collect any identifiable information about the patients it is used with. Such usage data is created and stored automatically by the software on the specific encrypted tablet being used. Data from here will be safely transferred to Queen Mary University of London at the end of the study to allow for proper analysis. Data on the number of sessions attended will be used to assess adherence to the intervention, and we will analyse the mean changes in the scores for each domain on the aDIALOG scale.

Screening / recruitment data and some treatment costs will be stored in a data safe haven after being sent to the research team, as will the audio and video recordings of sessions by participating professionals (after being securely transferred to the research team in batches), which will be deleted once the fidelity assessments have been completed. For the qualitative component, audio-files will be transcribed by an approved transcription company or internally using transcription software, and stored in a data safe haven for analysis by the research team. The original files will be destroyed following transcription and completion of data analysis.

The data generated by the study will be analysed by the Pragmatic Clinical Trials Unit (PCTU), who will be providing methodological, statistical and health economic input, as well as developing the study databases, data management and statistical analysis plans, and ensuring that quality assurance and standard operating procedures are followed. For the qualitative component, audio-files will be transcribed by an approved transcription company, or internally using transcription software, and stored in a data safe haven to be analysed by the research team.

Statistical analysis (work package 1b- testing the psychometric properties of the aDIALOG quality of life scale): We will examine the distribution, variability and mean/median scores for each of the items. In order to assess concurrent and convergent validity, we will examine spearman's correlation between the items relating to subjective quality of life on the

aDIALOG scale and the other measures. We will assess test re-test reliability by calculating the intra class correlation coefficient (ICC). Items that show poor distribution, variability and poor test re-test reliability may be removed from the scale. We will measure the internal consistency of the items relating to subjective quality of life and the treatment aspects separately using Cronbach's alpha.

Statistical analysis (work package 1b- comparison testing of the aDIALOG quality of life scale with the original version):

We will compare the original 11 item DIALOG scale (7-point Likert scale) with the adapted 13 item scale (3-point scale) by examining descriptive statistics (mean, standard deviation) for the sum of the items and for each individual item on both scales.

We will compare the distribution of scores on the 7 item and 3 item scales to examine if there is even distribution of scores by plotting a merged distribution plot. For example, we would expect a score of 1-2 on the 7 item scale to correspond to a score of 0 (unhappy) on the 3 item scale; a score of 3-5 to correspond to a score of 1 (in the middle) and a score of 6-7 on the 7 item scale to correspond to a score of 2 (happy) on the 3 item scale. If there is noticeable overlap in scores, this will suggest an uneven distribution of scores.

We will examine the internal consistency of the scales by calculating Cronbach's alpha. We will use the following cut-off points: excellent ≥ 0.90; good ≥ 0.80; acceptable ≥ 0.70.

We will conduct confirmatory factor analyses with a robust mean and variance adjusted weighted least squares (WLSMV) estimator to explore the latent structure of each measure. We will use the root mean square error of approximation (RMSEA), the comparative fit index (CFI), and the Tucker-Lewis Index (TLI). RMSEA values up to 0.05 will indicate a good fit, and values up to 0.08 will indicate adequate fit. CFI and TLI values >0.90 will indicate adequate, and those >0.95 will indicate good model fit.

Statistical analysis (WP 2 and WP 3): The feasibility outcomes will be the main focus of analysis and descriptive statistics, with associated measures of precision appropriately accounting for clustering, will be used to assess recruitment and retention, adherence, response rates in completing the outcome measures, demographic and clinical data, and cost data. We will explore changes in the scores of the outcome measures using paired t-tests or non-parametric tests where appropriate. The primary outcome measure of changes in behaviour will be measured using the Aberrant Behaviour Checklist (ABC)- irritability subscale (43). For secondary outcomes we will measure changes in quality of life (WHOQOL Disabilities module) (40), community participation (Guernsey Community Participation and Leisure Assessment – Revised) (44), psychological distress (Clinical Outcomes in Routine Evaluation, 14 item version) (42), psychiatric disorders (Moss Psychiatric Assessment Schedule - Check) (45), global improvement (Clinical Global Impression Scale) (46), health related quality of life (modified version of the EQ-5D-3L for people with ID) (48, 49) and service use (the Client Services Receipt Inventory) (51). The frequencies of adverse and serious adverse events will also be reported.

In order to determine the minimal clinically important difference (MCID) for our primary outcome measure (ABC-I), we will compare changes in the ABC-I before and after aDIALOG+ and this will be linked to improvements in service users', care workers' or clinicians' ratings on the Clinical Global Impression Scale (global improvement measure). A change indicating that the patient is at least a "minimally improved" will be used as the cut-off score to indicate improvement. We will conduct sensitivity analyses to test different assumptions.

Qualitative data will be analysed using framework analysis to identify themes relating to the barriers and facilitators in implementing aDIALOG+ in clinical and care home settings and aspects of the intervention that need to be refined such as training, supervision and number and frequency of sessions. The focus groups/interviews will be audio-recorded and transcribed. We will use NVIVO to analyse the data using framework analysis to identify relevant themes relating to 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 the NoMAD questionnaire (39) for assessing implementation processes from the perspective of professionals directly involved in the work of implementing complex interventions in healthcare.

Statistical analysis will be carried out on pseudo-anonymised data, and therefore personal identifiable data will not be published. For qualitative interviews, we will remove all identifiable information from interview transcripts prior to analysis. Participants will be identified using a study ID in publications and we will take care not to present a combination of personal information together that could identify the person (e.g. age, gender, ethnicity).

Data Archiving

Consent forms containing identifiable personal data will need to be retained for a minimum of 10 years, though will be archived separately to the study data collected. Data collated centrally will be archived by the East London NHS Foundation Trust, which is the host NHS trust sponsoring the study; participating sites will be responsible for archiving the study data that they hold based on their local policy.

6 STUDY SETTING

This study will be coordinated by East London NHS Foundation Trust. Recruitment and data collection will take place in additional NHS England Trusts and care homes identified from Care Quality Commission websites and local authority and national registers, who have the capability and capacity to take part. In addition, we will recruit participants from voluntary organisations and service user groups for people with ID as long as individuals are known to participating ID services or to voluntary groups for people with ID. aDIALOG+ sessions will take place face-to-face, and sessions with the research team will take place either face-to-face or remotely.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion and Exclusion Criteria

WP1a

Service Users Inclusion Criteria

- Aged 18 or over
- Mild or moderate ID based on service records / clinical notes
- Current history of behaviour that challenges (at least one incident of self-injurious behaviour, physical or verbal aggression, anger / frustration outbursts, or damage to property in the last 3 months)
- Living in any setting including the family home and supported living/ residential home
- Can provide informed verbal or written consent

Service Users Exclusion Criteria

- Under 18 years of age
- Severe ID based on service records / clinical notes
- Likely to move out of borough within the next three months or at imminent risk of hospital admission
- Unable to provide informed verbal or written consent

Clinicians Inclusion Criteria

- Aged 18 or over
- Currently working within a community ID service, intensive support team or in a local authority or social care organisation for people with ID
- From any profession (e.g. psychology, nursing, speech and language therapy, psychiatry, social work), with a minimum of six months experience working with people with ID
- Consent to participation

Clinicians Exclusion Criteria

- Under 18 years of age
- Not currently working within a community ID service, intensive support team or in a local authority or social care organisation for people with ID
- Less than six months experience working with people with ID
- Do not consent to participation

Care Workers Inclusion Criteria

- 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 participation

Care Workers Exclusion Criteria

- Under 18 years of age
- Have worked in the care home for less than three months
- Do not provide at least one day of support per week to service users
- Do not consent to participation

WP1b (testing the psychometric properties of the aDIALOG quality of life scale)

Service Users Inclusion Criteria

- Aged 18 or over
- Mild or moderate ID based on service records / clinical notes
- Known to community ID services from participating NHS trusts or to voluntary groups for people with ID
- Can provide informed verbal or written consent

Service Users Exclusion Criteria

- Under 18 years of age
- Severe ID based on service records / clinical notes
- Not known to community ID services from participating NHS trusts or to voluntary groups for people with ID
- Unable to provide informed verbal or written consent

WP1b (comparison testing of the aDIALOG quality of life scale with the original version)

Service Users Inclusion Criteria

- Aged between 18 and 65 years
- Under the care of a community psychiatric team or currently an inpatient in a psychiatric hospital in East London NHS Foundation Trust
- Have a primary diagnosis of a mental health issue
- Can provide informed verbal or written consent

Service Users Exclusion Criteria

- Under 18 years of age and over 66 years of age
- Do not have a primary mental health diagnosis (e.g. substance misuse disorder)
- Unable to provide informed verbal or written consent

WP2

Service Users Inclusion Criteria

- Aged 18 or over
- Mild or moderate ID based on service records / clinical notes
- History of behaviour that challenges (at least one incident of self-injurious behaviour, physical or verbal aggression, anger / frustration outbursts, or damage to property) and are currently receiving or waiting for treatment OR have a diagnosis of a mental health condition and are currently receiving or waiting for treatment
- Living in any setting including the family home and supported living/ residential home
- Can provide informed verbal or written consent

Service Users Exclusion Criteria

- Under 18 years of age
- Severe ID based on service records / clinical notes
- Already participating in WP3 involved in another clinical trial
- Likely to move out of borough within the next six months or at imminent risk of hospital admission
- Unable to provide informed verbal or written consent

Clinicians Inclusion Criteria

- Aged 18 or over
- Currently working within a community ID service, intensive support team or in a local authority or social care organisation for people with ID
- From any profession (e.g. psychology, nursing, speech and language therapy, psychiatry, social work), with a minimum of six months experience working with people with ID
- Consent to participation

Clinicians Exclusion Criteria

- Under 18 years of age
- Not currently working within a community ID service, intensive support team or in a local authority or social care organisation for people with ID
- Less than six months experience working with people with ID
- Do not consent to participation

Participant Carers Inclusion Criteria

- Aged 18 or over

- 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
- Consent to participation

Participant Carers Exclusion Criteria

- Under 18 years of age
- 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
- Do not consent to participation

WP3

Service Users Inclusion Criteria

- Aged 18 or over
- Mild or moderate ID based on service records / clinical notes
- History of behaviour that challenges (at least one incident of self-injurious behaviour, physical or verbal aggression, anger / frustration outbursts, or damage to property) and are currently receiving or waiting for treatment OR have a diagnosis of a mental health condition and are currently receiving or waiting for treatment
- Residing in supported living or residential care
- Can provide informed verbal or written consent

Service Users Exclusion Criteria

- Under 18 years of age
- Severe ID based on service records / clinical notes
- Already participating in WP2 or involved in another clinical trial
- Likely to move out of the care home within the next six months or are at imminent risk of hospital admission
- Unable to provide informed verbal or written consent

Care Homes Inclusion Criteria

- Supported living or residential placements for service users with ID in the participating areas
- Service manager has agreed for the care home to take part

Care Homes Exclusion Criteria

- Not supported living or residential placements for service users with ID and/or in the participating areas
- Service manager does not agree for the care home to take part

Care Workers Inclusion Criteria

- 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 participation

Care Workers Exclusion Criteria

- Under 18 years of age
- Have worked in the care home for less than three months
- Do not provide at least one day of support per week to service users

- Do not consent to participation

7.2 Sampling

7.2.1 Size of Sample

- Work package 1a: 5 clinicians, 5 care workers and 20 service users.
- Work package 1b: 120 service users with ID and 200 service users with a mental health diagnosis (without ID).
- Work package 2: 8-12 clinicians, 30 service users, and 30 participant carers.
- Work package 3: 10 care homes and their care workers (around 2 care workers in each care home, approx. 20 care workers). 3-5 service users in each care home (approximately 30 service users).

Total number of participants: clinicians - 17; care workers- 25; service users- 400; participant carers- 30.

For the psychometric testing of the aDIALOG scale we will administer the measure in 120 participants. Historically the proposed approaches for justifying sample size requirements for exploratory factor analysis (EFA) have been based on rules of thumb regarding: a minimum number of participants; a ratio of participants to total number of scale items; or the ratio of items to the number of expected factors. However, determining sample size is more complex than these rules allow and researchers are encouraged to use more evidence based recommendations (53). We have used the simulation study of Mundfrom et al. (54) to determine a minimum sample size of 75 as sufficient assuming the number of variables (n=10 for the subjective quality of life items on the aDIALOG scale) to number of factors expected (n=2) ratio of 5, a coefficient of congruence of at least 0.92, and a communality of between 0.2 and 0.4. However, we may remove item if the responses are low and so we will aim for a sample size of 120.

For the comparison testing of the aDIALOG scale we will aim to recruit 200 participants; a minimum of 120 participants will be considered acceptable given that there are fewer items on the original DIALOG scale ((54)– see justification for the psychometric testing study in people with intellectual disability).

For the feasibility study there is no formal sample size calculation but the sample size would need to be sufficient in order to estimate our main parameters of interest (recruitment and retention rates) and the precision of these estimates, allowing for the clustered nature of the data (Assuming an ICC of 0.04). If we anticipate a recruitment and retention rate of 75%, 12 clinicians, and 30 service users, would allow us to estimate 95% Confidence Intervals for recruitment and retention rates with a half width of 18%.

7.2.2 Sampling Technique

This study will utilise opportunistic sampling techniques to engage eligible clinicians, care workers and service users in the research.

All clinician participants will be recruited from community services within participating NHS trusts, and all care worker participants will be recruited from care homes identified from Care Quality Commission websites and local authority and national registers. Once eligible clinicians and care workers have consented to the study, they will screen and identify service users who meet the inclusion criteria. Clinicians and care workers will ask the service users for consent to give their contact details to a CSO or member of the research team. If consent

is given, service users will be approached about the study by the CSO or member of the research team.

7.3 Recruitment

7.3.1 Sample Identification

For Clinicians and Care Workers:

Work package 1a: Piloting DIALOG+

The adapted DIALOG scale and intervention (aDIALOG+) will be piloted with 5 clinicians (any background e.g. nurse, occupational therapist, psychiatrist, social worker) from community ID teams and 5 care workers who will be recruited (via links with the community ID teams).

Work package 2: A feasibility study of delivering aDIALOG+ in clinical services

Clinicians will be recruited from community ID services in participating NHS Trusts.

Work package 3: A feasibility study of aDIALOG+ in care homes

We will recruit ten care homes and their care workers (approximately two staff in each participating care home, which are to be determined). Care homes will be identified from Care Quality Commission websites and local authority and national registers. We will also consult with Regional Research Delivery Networks to identify care homes that are interested in research. We will approach the service managers at the care home and seek permission for staff to take part.

For Service Users:

For the clinical services, eligible service users with ID (or eligible service users with a mental health diagnosis in the psychometric testing comparison study) will be identified from the case load of clinicians through the review of medical records, and using recruitment posters, invitation letters or through local voluntary organisations and service user groups for the psychometric testing studies. They will then be approached by the participating clinician or CSO to take part in the study and an information sheet will be provided. For the care home, eligible service users with ID will be identified from service records / clinical notes by care workers, and the research team will ask staff to approach eligible service users to take part in the study. If they are interested, their details will be passed to the CSO or a member of the research team, who will contact the potential participant, provide an information sheet, and assess their eligibility and capacity to consent. Service users will receive £20 gift vouchers for each follow up/interview to reimburse them for their time.

7.3.2 Consent

For Clinicians and Care Workers:

Clinicians from community ID services in participating NHS trusts will be approached by a member of the research team or CSOs from Local Clinical Research Networks and invited to take part in the study. They will receive an information sheet and will need to provide consent to take part.

We will approach the service managers at selected care homes (to be determined) and seek permission for staff to take part. We will provide care workers with an information sheet and they will need to provide consent to take part in the study.

For Service Users:

If the potential participant is interested in taking part, the CSO or member of the research team will contact the person (and their carer if applicable) to discuss the study. Accessible (easy read) information sheets will be provided to service users with ID, and if they are unable to read, the information sheet will be read out to them, with support from their carer. The CSO/member of the research team will explain the study, including any potential advantages and disadvantages of taking part. They will assess capacity according to Mental Capacity Act guidelines, including whether the individual has understood the information and potential risks and benefits of taking part and that there would be no negative consequences if they chose not to take part; whether they can retain the information; weigh up the information; and communicate their decision to take part. Service users will be given sufficient time so that they can take in the information and speak with their carer, as well as again with the clinician / care worker if they need to.

If service users agree to take part, they will be asked to provide written consent using an accessible consent form, or if they cannot write or are consenting remotely, they can give verbal consent, which will be audio-recorded. A hard copy of the consent form should also be completed on their behalf by the CSO/member of the research team who is taking consent, which will also specify that they have given consent verbally. For feasibility participants who do not have English as their first language, we will assess whether we can use interpreters to support the consent process and within each aDIALOG+ session with a clinician/care worker. As the number of non-English speakers taking part is likely to be small, we will not translate the information sheet into different language but can consider specific requests for translation. Research staff will receive training on how to conduct capacity assessments in people with ID, as well as awareness of unconscious bias and cultural competence. If service users consent to take part in the study the research team will inform their GP of their participation via letter.

If service users initially have capacity, but lose their capacity during the study, we will withdraw the person from the study but data collected previously will be retained. We will not include any participants who lack capacity to consent. However, a service user having a Deprivation of Liberty Safeguard (DoLS) assessment does not necessarily exclude them from taking part, as they may still have the capacity to decide to participate in the research. The research team will have regular contact with participating clinicians and care workers, and they will make them aware if any information becomes available during the course of the research that may be relevant to continued participation which participants need to receive. Additionally, if a service user moves out of the borough or is unexpectedly hospitalised during the study the data collected previously will be retained but the service user will be withdrawn, unless they are only hospitalised briefly (e.g. for a few weeks) and may still be able to participate.

8 END OF STUDY

The end of the research study will occur on the date that the last 6-month follow-up questionnaire and qualitative focus group/interview have been completed, which will mark the end of the data collection activity.

9 ETHICAL AND REGULATORY CONSIDERATIONS

9.1 Assessment and Management of Risk

We do not anticipate any unintended consequences/ adverse events. Safety concerns will be discussed with the study steering committee and the ethics committee will be informed if necessary. This may lead to termination of the study or the study may be paused until the issue is investigated. As this is a feasibility study, there will not be a data monitoring committee.

It will be explained to all participants that participation is voluntary, that they can withdraw at any time without providing an explanation, and that their care will not be affected if they do not participate in the study. Baseline and follow-up assessments will be conducted face-to-face where possible but we will accommodate remote assessments if needed. Assessments may be carried out in clinic settings or in service user's homes based on their preference. We have kept the number of measures to a reasonable number in order to reduce burden on service users and carers, and where possible we have used short versions of measures. We will provide £20 gift vouchers to service users and carers to thank them for their time for completing qualitative interviews and after the baseline assessment and prior to the follow-up assessments.

To maintain participant and researcher safety, we will ensure that risk assessments are conducted prior to meeting the service user, especially if they are going to be seen in their home. This will involve reviewing existing risk assessments, and if one is not available, researchers will seek information from the referrer. If there is a potential risk of physical aggression to researchers, each case will be discussed with their line manager / supervisor and arrangements will be made to ensure risks can be mitigated (e.g. carrying a personal alarm, ensuring service user is seen with their carers). Lone working policies will be followed for home visits.

If service users become distressed during their aDIALOG+ sessions or during end of study interviews, sessions will be stopped or service users will be offered a break and given the option of continuing or rescheduling the session. We will discuss concerns with the service user's clinical team.

If there are safeguarding issues (e.g. participants disclose abuse or there is a risk of harm to themselves or others), we will follow the service's safeguarding policy (e.g. to raise safeguarding alert). In this situation, we will seek permission from the individual to raise a safeguarding alert but if they do not provide permission, we will explain that confidentiality will need to be broken as there is a professional obligation to report such issues. Research assistants will discuss these issues with the local PI and study CI and all incidents will be recorded.

<u>Safety Reporting</u>

Adverse Events (AE)

For work packages 2 and 3 adverse events will be monitored and recorded. Adverse events (AEs) are any clinical change, disease or disorder experienced by the participant during their participation in the trial, whether or not considered related to the use of treatments being studied in the trial. Any adverse events that occur will be recorded in an Adverse Event Log, designed for this study, and the service user's clinical records, if appropriate. The service user will be followed up by the research team to ensure the event is resolved.

Serious Adverse Events (SAE)

A SAE is defined as an untoward occurrence that:

a) Results in death

b) Is life-threatening

c) Requires hospitalisation or prolongation of existing hospitalisation

d) Results in persistent or significant disability or incapacity

e) Consists of a congenital anomaly or birth defect or

f) Is otherwise considered medically significant by the investigator.

An SAE occurring to a research participant should be reported to the Sponsor and REC wherein the

local PI deems the event:

● Related- that is, resulted from administration of any of the research procedures and

● Unexpected- that is, the type of event is not listed in the protocol as an expected occurrence.

Hospitalisation will not be reported if it is for routine treatment, treatment which was elective or preplanned, hospitalisation for general care where there was no deterioration in condition, or treatment on an emergency outpatient basis for an event not fulfilling any of the definitions of serious as given above, and not resulting in hospital admission.

SAEs that are related and unexpected will be reported to sponsor within 24 hours and to the main REC within 15 days of learning of the event.

All SAE's will be logged via a SAE Case Report Form that will be completed by a local researcher and signed and dated by the local Principal Investigator.

Urgent Safety Measures

In the case of urgent safety measures being required, the CI will inform the sponsor and the REC of the event immediately via telephone. The CI will then inform the REC and the Sponsor in writing within 3 days.

Annual Safety Reporting

If required by the REC, the CI will send the Annual Progress Report to the main REC using the HRA template and to the sponsor.

Overview of the Safety Reporting Responsibilities

The CI will ensure that safety monitoring and reporting is conducted in accordance with the sponsor's requirements.

Central Monitoring

For work packages 2 and 3 the programme manager will carry out central monitoring of recruitment rates and every 3-4 months review required documentation for sites (e.g. delegation logs) and data completion.

Audits

The Sponsor or delegate retains the right to audit any study, study sites, or central facility. Any part of the study may be audited by the regulatory bodies, and funders, where applicable. The TMF will be audited once at minimum by PCTU.

9.2 Research Ethics Committee (REC) and Other Regulatory Review and Reports

The CI (Ali) will ensure that the study is carried out in accordance with the ethical principles in the UK Policy Framework for Health and Social Care Research.

As this study involves NHS service users and is being conducted in England, before the study starts it will require approval from the Health Research Authority (HRA) and a favourable opinion from the REC for the study protocol, informed consent forms and other relevant documents, e.g. information sheets, topic guides etc.

Any substantial amendments requiring review by the REC will not be implemented until a favourable opinion has been granted and approved by the relevant NHS R&D departments and HRA. The CI will ensure that an annual progress report is submitted to the REC within 30 days of the anniversary date on which the favourable opinion was granted. The annual report will be submitted each year until the study is declared ended.

The CI will notify the REC, HRA and study sponsor of the end of the study, and will immediately notify the REC, HRA and study sponsor should the study end prematurely. This will include notification of the reasons for premature termination**.**

Regulatory Review and Compliance

The Chief Investigator will ensure that appropriate approvals from participating organisations are in place. Specific arrangements to gain approval from participating organisations will comply with the Health Research Authority's Assessment Criteria and Standards Document. Once informed, organisations will be given 35 days to object to the approvals based on their resources. For example, the institution may object if it does not have eligible staff members for participation. Then the study may commence without institutional confirmation if not forthcoming.

Amendments

If the sponsor wishes to make a substantial amendment to the IRAS/HRA application or the supporting documents, the sponsor must submit a valid notice of amendment to the IRAS for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of the submission to the REC. The amendment history will be tracked via version and date control of protocols, with changes to the protocol highlighted in Appendix 2.

9.3 Peer Review

The funding for the study came from a competitive NIHR programme grant, which had a two-stage application process, and the scientific quality of the study was reviewed thoroughly by the funding panel as well as external scientific peer reviewers, who have provided comments and feedback which we have addressed.

Before submission, this protocol will be reviewed by the Chief Investigator (Dr Afia Ali) and the study sponsor (Noclor).

9.4 Patient and Public Involvement

We will follow the NIHR guidelines on public involvement and maximising inclusion. We will establish a service user advisory group with individuals with mild/ moderate ID from diverse backgrounds where possible, recruited using different strategies (e.g. existing links with ID services, charities, existing PPI groups, social groups, community day centres for ethnic minority groups) and we will assess whether we can use interpreters if needed. Our PPI lead will recruit service users to the advisory group and co-facilitate the groups with our PPIE co-applicant. As a speech and language therapist, our PPI lead has relevant skills in promoting inclusive communication with people with ID who may struggle to communicate verbally. Clinicians and carers will be involved in the co-production and adaptation groups in workstream 1. The groups will meet every three months (and more often during the initial stages).

Groups will run as hybrid meetings to enable accessibility for individuals less able to travel or living outside of London. Group members will be paid for their time, based on ELFT's reward and recognition policy, taking into consideration impact on benefits. Payment will cover preparation and attendance at meetings and transport costs. We will agree the terms of reference and responsibilities of the group. Carers will be paid for their time and travel expenses. We will follow guidelines on maximising PPI input and impact; We will record and measure PPI impact through feedback and interviews with advisory group members and the research team. The advisory group will:

i. provide advice about study procedures (e.g. recruitment strategies)

ii. be involved in the co-production group and adaptation group

iii. co-produce information sheets, consent forms, recruitment posters, invitation letters and films; review topic guides

v. review themes arising from qualitative data

vi. support dissemination activities (producing accessible summaries of research, films, blogs, presenting at the dissemination seminar)

vii. help produce training videos to train clinicians in using aDIALOG+ and attend training workshops

9.5 Protocol Compliance

Protocol compliance will be ensured by the Chief Investigator. All cases of non-compliance or breach will be documented, with all major breaches reported to the Sponsor immediately.

9.6 Data Protection and Patient Confidentiality

All investigators and study staff will comply with the requirements of the Data Protection Act 2018 and the General Data Protection Regulation (GDPR) with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles throughout the study.

Personal Information

Participants will be allocated a personal identification (ID) number and data will be pseudo-anonymised; all participant-related information will be stored separately from any identifiable study data. The research team will have access to personal data (e.g. names and contact details of participants) only if the participant has given permission for this information to be

shared, and after the person has consented to take part in the study. We will only hold information that is necessary to enable us to contact the participant to arrange assessments, and some personal data will need to be collected as part of data collection (e.g. age, gender, ethnicity) but this will be pseudo-anonymised. The app supporting the aDIALOG+ intervention does not collect any identifiable information about the patients it is used with.

Pseudonymised Data

Access to the electronic files and datasets for analysis will be restricted to the research team, and will be stored on password-protected databases / data safe havens. However, in the event of safety concerns, confidentiality will be broken and the relevant, services and/or authorities informed. For the qualitative component, audio-files will be transcribed by an approved transcription company, or internally using transcription software, and stored in a data safe haven for analysis by the research team. The original files will be destroyed following transcription and completion of data analysis.

9.7 Indemnity

The study will have indemnity through a standard NHS insurance scheme. The NHS indemnity scheme will cover the potential legal liability of the sponsor arising from the design, conduct and management of the study.

NHS indemnity does not offer no-fault compensation (i.e. for non-negligent harm), and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm. They are permitted to consider an ex-gratia payment in the case of a claim.

Additionally, the feasibility study in care homes is covered by The Clinical Negligence Scheme for Trusts (CNST), which provides cover for NHS staff conducting research, whether that activity is taking place within NHS premises, patients' homes, care homes, hospices or other spaces in which NHS researchers undertake NHS research.]

9.8 Access to the Final Study Dataset

Only members of the research team will have access to the full dataset. Requests from external researchers to use the dataset for secondary analysis, may be made to the Chief Investigator.

10 DISSEMINATION POLICY

10.1 Dissemination Policy

East London NHS will own the data arising from this study.

The funders (NIHR) will be contacted at least 30 days prior to any publication arising from the project. Within publications, the funding body will be acknowledged using the standard text as set out within the research contract. A dissemination plan will be developed within the first 6 months of the study, with contributions from the sponsor and the PPI advisory group. The full study report will be produced when these grant-funded work packages are completed in July 2027.

We will work closely with our PPI advisory group to summarise the study findings into formats that are accessible for people with ID and their carers and will include co-produced newsletters, blogs, and film clips. A leaflet summarising the study findings will be made available to all the participating services and a copy will be sent to participants once the

study results have been analysed and written up. We will also use social media such as X and Facebook to publicise the study findings.

10.2 Authorship Eligibility Guidelines and Any Intended Use of Professional Writers

Authorship will be granted to co-applicants and researchers who worked on the project, dependent on their contributions.

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12. APPENDICES

12.1 Appendix 1 – Required documentation

There will be an official invite to all sites which will contain the Local Document Pack, this will include all pertinent documents including the Organisation Information Document (OID), which will be completed collaboratively with the sites.

12.2 Appendix 2 – WP1a and b Schedule of Procedures

Procedures	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
	Aug 25	Sep 25	Oct 25	Nov 25	Dec 25	Jan 26	Feb 26	Mar 26	Apr 26	May 26	Jun 26	Jul 26	Aug 26	Sep 26	Oct 26	Nov 26	Dec 26	Jan 27	Feb 27	Mar 27	Apr 27
Recruitment of clinicians and care workers					x	x	x	x													
Clinician and care worker training in aDIALOG+					x	x	x	x													
Recruitment of service users						x	x	x	x												
Delivery of aDIALOG+ intervention						x	x	x	x												
Stakeholder focus groups/ interviews									x												
Data analysis and adaptations									x												
Recruitment of service users	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Baseline data collection	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Follow up	x	x	x	x	x	x	x	x	x	x	x	x	x								
Data analysis																		x	x	x	x

12.3 Appendix 2 – WP2 Schedule of Procedures

Procedures	8 Apr 26	9 May 26	10 Jun 26	11 Jul 26	12 Aug 26	13 Sep 26	14 Oct 26	15 Nov 26	16 Dec 26	17 Jan 27	18 Feb 27	19 Mar 27	20 Apr 27	21 May 27	22 Jun 27	23 Jul 27
Recruitment of clinicians	x	x	x	x	x	x	x	x								
Clinician training in aDIALOG+	x	x	x	x	x	x	x	x								
Recruitment of service users		x	x	x	x	x	x	x								
Baseline data collection		x	x	x	x	x	x	x								
Delivery of aDIALOG+ intervention		x	x	x	x	x	x	x	x	x	x	x	x	x		
Follow up								x	x	x	x	x	x	x	x	
Stakeholder interviews								x	x	x	x	x	x	x	x	
Data cleaning and analysis														x	x	x

12.4 Appendix 3 – WP3 Schedule of Procedures

Procedures	8 Apr 26	9 May 26	10 Jun 26	11 Jul 26	12 Aug 26	13 Sep 26	14 Oct 26	15 Nov 26	16 Dec 26	17 Jan 27	18 Feb 27	19 Mar 27	20 Apr 27	21 May 27	22 Jun 27	23 Jul 27
Recruitment of clinicians	x	x	x	x	x	x	x	x								
Clinician training in aDIALOG+	x	x	x	x	x	x	x	x								
Recruitment of service users		x	x	x	x	x	x	x								
Baseline data collection		x	x	x	x	x	x	x								
Delivery of aDIALOG+ intervention		x	x	x	x	x	x	x	x	x	x	x	x	x		
Follow up								x	x	x	x	x	x	x	x	
Stakeholder interviews								x	x	x	x	x	x	x	x	
Data cleaning and analysis														x	x	x

12.5 Appendix 4 – Amendment History

Amendment no.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	2.0	03/09/2025	Laura Miller	• Update of planned sample size in work package 2 to 30 participant carers. • Update of planned study duration to 20 months (July 2025 – February 2027) and study timelines. • Update to allow sites outside of ELFT to participate in WP1b. • Clarification of consent procedures, the role of CSOs and that members of the research team will be carrying out study procedures, not just research assistants. • Update that paper CRFs will be stored on NHS / care home premises. • Update of study data storage and entry processes. • Clarification that the Behaviour Problems Inventory will not be used in work packages 1a, 1b, 2 and 3. • Clarification that we will be recruiting from three NHS trusts for work package 2 rather than five, with one being East London.
2	3.0	14/10/2025	Laura Miller	• Clarification that participating care homes are to be determined • Correction of study timescales and recruitment numbers on flow charts • Addition of option in work package 1b for service users to be sent the consent form and questionnaires to complete via email or post • Clarification the participating NHS trusts are to be determined
3	4.0	25/02/2026	Laura Miller	• Update of WP1a Piloting follow-up period to 2-4 weeks. • Update of study participants and sample size to include 200 service users with mental health diagnosis (without ID) for psychometric comparison study. • Update of planned study duration to 21 months (August 2025 – April 2027) and study timelines. • Update of Principle Research Question / Aim(s) to include comparison of the aDIALOG scale to the original DIALOG scale in people with mental health diagnosis. • Clarification that clinicians don't need to be new for WP1b referrals.

				• Update of WP1b recruitment and data collection timeframe to 10 months, and analysis timeframe to 8 weeks. • Update of Study Design to include comparing the aDIALOG scale with the original DIALOG scale in 200 service users with mental health issues. • Update of study design to include identification of service users using recruitment posters and through local voluntary organisations and service user groups for WP1b studies. • Update of study design to include focus groups as well as semi-structured interviews for WP2. • Update of Data Collection to include original DIALOG scale and aDIALOG scale for WP1b comparison testing. • Update of Data Analysis to include comparison of the aDIALOG scale to the original DIALOG scale. • Addition of inclusion and exclusion criteria for comparison testing of the aDIALOG quality of life scale. • Update of sampling to provide rationale for psychometric testing sample sizes. • Clarification that service users and their carers will be contacted if applicable.
4	5.0	02/04/2026	Laura Miller	• Update of planned study duration to 22 months (August 2025 – May 2027) and study timelines. • Clarification that history of behaviour that challenges can include physical or verbal aggression or temper tantrums / outbursts.
5	6.0	29/05/2026	Laura Miller	• Correction of typos. • Update of key study contacts addresses. • Update of inclusion criteria to clarify that history of behaviour that challenges can include anger / frustration outbursts, that clinicians, care workers can have participated in the previous work packages and that for WP1b psychometric testing service users can be known to teams rather than needing to be under them or to voluntary groups for people with ID. • Update of study flow so that aDIALOG+ training takes place after service user recruitment and baseline measures.

				• Clarification that participant carers will be involved where available and that care workers who are not facilitating aDIALOG+ will be asked to help complete service user outcomes. • Update of number of members for PPI advisory group. • Update of recruitment timeframes for WP1b psychometric testing to 13 months (July 2025-August 2026) and WP1b comparison testing to 12 months (May 2026-April 2027). • Update of study design to include identification of service users using invitation letters for WP1b studies. • Clarification that we will consult with Regional Research Delivery Networks to identify care homes that are interested in research, as the ENRICH network is no longer running. • Clarification of the areas of PPIE involvement to reflect how the advisory group are currently helping the study.
6	7.0	07/08/2026	Laura Miller	• Update of WP1a and WP2 inclusion criteria to remove requirement of clinicians to be grade 4 and above. • Update of WP1b comparison testing to include recruitment by resident trainees and patients who are currently being treated in a psychiatric hospital and are within East London NHS Foundation Trust. • Update of recruitment timeframes for WP1b psychometric testing to 17 months (July 2025-December 2026), for WP2 feasibility to 5 months (May 2026-September 2026) and for WP3 feasibility to 5 months (July 2025-September 2026). • Clarification that consent and data collection for WP1a, 2 and 3 can be done remotely. • Clarification that transcription will be done either through a transcription company or internally using transcription software. • Clarification re consenting that service users will be given sufficient time rather than a few days to take in information.
7	8.0	03/09/2026	Laura Miller	• Reduction of the number of care workers in WP3 to 20 so that this is more in line with the number of clinicians in WP2. • Reduction of the number of service users in WP3 to 30 so that this is line with the number of service users in WP2.

				• Update of recruitment and baseline data collection timeframes for WP2 feasibility to 6 months (May 2026-October 2026) and for WP3 feasibility to 7 months (July 2025-November 2026). • Clarification that having a Deprivation of Liberty Safeguard (DoLS) assessment does not necessarily exclude service users from taking part.
8	9.0	15/10/2026	Laura Miller	• Update of WP2 and WP3 feasibility service user inclusion criteria to include individuals who have a history of behaviour that challenges and are currently receiving or waiting for treatment OR have a diagnosis of a mental health condition and are currently receiving or waiting for treatment • Update of overall study duration to 24 months (August 2025-July 2027) • Clarification that for WP3 approximately 2 staff per home will be recruited • Clarification that in WP3 more than one care worker can deliver the intervention to a service user, but for consistency it is advised that the same care worker sees the service user throughout where possible- hence the reduction in the total number of care workers taking part • Update of recruitment and baseline data collection timeframes for WP2 feasibility to 7 months (May 2026-November 2026) • Update of aDIALOG+ facilitation timeframe for WP2 feasibility to 12 months (May 2026-May 2027) • Update of follow-up data collection timeframe for WP2 and WP3 feasibility to finish in June 2027 • Update of data analysis timeframe for WP2 and WP3 feasibility to finish in July 2027