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Development and evaluation of open dialogue for severe mental illness: a feasibility study

Submission date
15/09/2025

Recruitment status
No longer recruiting

Registration date
16/10/2025

Overall study status
Completed

Last Edited
13/11/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This trial forms part of a NIHR programme grant investigating the development and evaluation of Open Dialogue (OD) for severe mental illness. OD is being developed and adapted for delivery in five NHS trusts and is a service delivery model for individuals in mental health crisis, developed in Finland, which has a collaborative approach and explicitly targets social networks. Appropriate pharmaceutical, psychological or social interventions are involved in shared decision making with social networks and healthcare professionals. This is in contrast to current models of care, in which families are rarely directly involved. Studies to date are promising and report reductions in hospital bed usage and improved recovery rates, but there is currently no high-quality evidence to support a NHS-wide adoption of this model. This approach offers the possibility of a potentially effective alternative to the current model

This trial aims to assess the feasibility of conducting a full multicentre cluster randomised controlled trial of the OD model compared to usual NHS crisis and longer-term community care (treatment as usual [TaU]) over 9 months. Participants will be eligible for the study if they are a service user in crisis with a primary diagnosis of a mental health disorder. The feasibility study will involve 2 OD teams and 2 TaU teams in two sites (NHS trusts). If the feasibility trial is successful, a multicentre cluster randomised controlled trial (RCT) with 28 clusters will be conducted over 3 years. This is a type of study where groups of participants (rather than individuals) are randomly assigned to different treatments, and the research is carried out at multiple locations or centres to improve the generalisability of the results.

Who can participate?
A service user in crisis within 24-48 hours of referral or having been discharged from in-patient care following a crisis admission to the Crisis Resolution and Home Treatment Team (CRHTT) for home treatment.

The service user must be over the age of 18, have a diagnosis of a mental health disorder, and be able to give informed consent (or consent is provided by a personal or nominated consultee).

What does the study involve?
All eligible service users will first be contacted by a member of the clinical team to obtain their

agreement to be approached by a member of the research team. The screening process and recruitment process will be supported by the relevant clinical team in order to support decisions of capacity and risk. The researcher will then contact the potential participant to explain the research study and send an information sheet to them via post or email. Potential participants will be given time (48 hours) to consider the information before the researcher contacts them again to answer any questions.

Service users will already be receiving OD or Treatment as Usual (TaU) as part of their care, and their treatment will continue regardless of their participation in the study. Appropriate psychological and pharmacological treatments will be deployed in either treatment as necessary.

The participants randomised to the OD clusters will receive the OD intervention. The OD intervention focuses on the social network to improve outcomes for service users. Typically, in the first few network meetings, two OD staff members as well as the social network are present. The service user and their network decide the length and frequency of meetings as well as the focus of discussions. The OD staff members are present to facilitate the meetings amongst the social network.

TaU will be routine crisis care and follow-up community care, which typically involves care from a CRHTT with an average duration of contact from 2-6 weeks, and, where appropriate, ongoing care from community services including psychological interventions.

Baseline interviews will be conducted over the phone or in patients' homes. Follow-up assessments will occur in the three months post-recruitment. The researcher will contact the participant to arrange a convenient time and date to meet. Participants will complete a set of outcome measures.

What are the possible benefits and risks of participating?
The benefits for participants are that they will be involved in the development of a potentially effective alternative to the current model of care for mental health crises. Service users randomised to the OD intervention will benefit from the coordinated and continuous care that the OD model offers. Service users randomised to the TaU intervention will benefit from a clear referral pathway to crisis services.

No major risks are anticipated for participants. The research interviews may, in some cases, involve discussing sensitive topics. There is the potential for participants to get upset. Although we anticipate this is unlikely, a member of the ODDESSI study team will be present during the interview if the service user does become distressed. A senior member of the research team will be able to support them and direct them to further support services.

Where is the study run from?
The study will run across two UK NHS sites, North East London NHS Foundation Trust and Kent and Medway NHS and Social Care Partnership Trust.

When is the study starting and how long is it expected to run for?
June 2018 to June 2019

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

Who is the main contact?
Dr Sandeep Toot, sandeep.toot@nelft.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
233243

Central Portfolio Management System (CPMS)
36235

Study information

Scientific Title
Open Dialogue compared to usual care for adults experiencing a mental health crisis: a feasibility study for the ODDESSI trial

Acronym
ODDESSI

Study objectives
1. To assess whether it is possible and acceptable to conduct a full-scale cluster randomised trial comparing Open Dialogue (OD) to Treatment as Usual (TaU) across multiple locations. We will measure recruitment, consent, and retention rates at 3 months.
2. To assess the acceptability of primary and secondary outcome measures that will be used in the full scale trial, and to refine measures of cost-effectiveness of OD.
3. To set up the randomisation system in preparation for the main trial and to define and randomise clusters in two catchment areas.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/06/2018, London-Bromley Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, United Kingdom; +44 (0)207 104 8027; nrescommittee.london-bromley@nhs.net), ref: 18/LO/0868

Primary study design
Interventional

Study design
Feasibility clustered randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe mental illness

Interventions
Overview
The research team will undertake a feasibility trial to assess whether it is possible to conduct a full-scale trial comparing Open Dialogue (OD) to Treatment as Usual (TaU). They will undertake a cluster randomised controlled trial, comprising four clusters of two Open Dialogue (OD) teams and two Treatment as Usual (TaU) teams in two NHS sites. Each of the pilot sites will be staffed by a team of therapists trained in OD, and all staff have agreed at least in principle to participate in a rigorous RCT. Please note that these service users will already be receiving OD or TaU as part of their care, and their treatment will continue regardless of their participation in the study. This is approximately 10% of the total sample size to be recruited.

Randomisation
The study will take place in four clusters from two catchment areas. For this feasibility trial, two separate catchment areas, whose clusters have already been established and randomised in preparation for the future RCT, will each provide two clusters (one allocated OD, and another allocated to TaU) to the current study. Randomisation will be carried out by statisticians with support from King's Clinical Trials Unit (KCTU).

Recruitment & Screening
The aim is to recruit 15 service users from each of four teams (two OD teams and two TaU teams). The study team has drawn upon their shared clinical and research experience to create a clear recruitment protocol for researchers to utilise during recruitment. Referrals to either the OD or Tau participating teams will be screened by a member of the clinical team or clinical studies officer for eligibility against the inclusion and exclusion criteria. All eligible service users will first be contacted by a member of the clinical team to obtain their agreement to be approached by a member of the research team. The screening and recruitment processes will be supported by the relevant clinical team to inform decisions regarding capacity and risk. The researcher will then contact the potential participant to explain the research study and send an information sheet to them via post or email. Potential participants will be given time (48 hours) to consider the information before the researcher contacts them again to answer any questions.

Consent and baseline
If the service user is interested in taking part in the study, the researcher will agree on a time and date to obtain informed consent between two days and two weeks of presentation to

services. Participants will be recruited over 6 months by a member of the research team, and followed up for 3 months post-presentation to services. Baseline measures will be recorded in an interview after the researcher has obtained informed consent. For those who lack the capacity to consent, a personal consultee who has no professional interests or incentives in the research or treatment will be identified. If a personal consultee cannot be identified, a nominated consultee will be identified and approached from the panel of consultees.

Intervention
Please note that these service users will already be receiving OD or Tau as part of their care, and their treatment will continue regardless of their participation in the study. Appropriate psychological and pharmacological treatments will be deployed in either treatment as necessary.

OD
The participants randomised to the OD clusters will receive the OD intervention. The OD intervention focuses on the social network to improve outcomes for service users. Typically, in the first few network meetings, two OD staff members as well as the social network are present. The service user and their network decide the length and frequency of meetings as well as the focus of discussions. The OD staff members are present to facilitate the meetings amongst the social network.

TaU
TaU will be routine crisis care and follow-up community care, which typically involves care from a (CRHTT) with an average duration of contact from 2-6 weeks, and, where appropriate, ongoing care from community services including psychological interventions.

Follow-ups
Follow-up assessments will occur in the three months post-recruitment. The researcher will contact the participant to arrange a convenient time and date to meet. The participant will complete a set of outcome measures.

Measures
The following measures will be delivered by researchers to assess their acceptability by participants. These outcome measures will be delivered by researchers. Each will be delivered at either baseline or follow-up and will be delivered only once to reduce time burden.

The measures given at baseline include;
-BPRS (Brief Psychiatric Rating Scale)
-BAS (Burden of care on caregivers)
-EQ-5D-5L (health-rated quality of life)
-LSN (Lubben Social Network)
-SPA (Social Provisions Scale)
-demographics form

The measures given at follow-up include:
-QPR (Questionnaire about the Process of Recovery)
-CSQ-8 (Service user and carer satisfaction with care)
-CSRI (Client Service Receipt Inventory)
-the dyadic OPTION scale (experience of shared decision making)

The following outcome measures will be obtained from anonymised patient electronic medical records.

-Time to first relapse in days following recovery
-Hospitalisation rate defined as an inpatient admission post index admission, and re-referral to CRHTTs, will be obtained from anonymised patient electronic medical records.

Analysis
Recruitment, retention, and consent rates will be measured and assessed against the predetermined stop-go criteria to inform progression to the multicentre cluster RCT in work package 3 of the programme:
-60 participants recruited (10% of the sample size to be recruited to the full trial)
-retention of 80% of participants at 3-month follow-up
-primary outcome data collected from 85% of participants at 3-month follow-up
-expected consent rate of 66%
-demonstration that all sites can establish clusters and that all OD teams operate within the agreed protocol (including referral pathways, caseload capacity and team composition)
-demonstration that all OD teams across all sites achieve adequate adherence and fidelity

Intervention Type
Behavioural

Primary outcome(s)
To assess the feasibility and acceptability of conducting a randomised controlled trial of the OD intervention versus TaU, the study will collect the following data:
1. Recruitment to the trial, measured by observing the number of participants after recruitment
2. Consent rate, measured using the number of participants providing full consent after screening
3. Retention rates, measured using the number of participants who remained in the study at the end of the study period

Key secondary outcome(s)
Acceptability will be assessed through the successful completion of the following participant-level secondary outcome measures:
The following measures are recorded at baseline:
1. Socio-demographics measured using data collected on a form created specifically for the trial, which records: date of birth, gender, ethnicity, country of birth, education, employment, marital status, and housing
2. Symptom severity measured using the Brief Psychiatric Rating Scale (BPRS)
3. Social network quality measured using the Social Provisions Scale (SPS), and social network size measured using the Lubben Social Network Scale - 6 item (LSNS-6)
4. Burden of care on caregivers measured using the Burden Assessment Scale (BAS)
5. Health-related quality of life measured using the EQ-5D-5L
6. Hospitalisation rate, defined as an inpatient admission post-index admission, and re-referral to Crisis Resolution and Home Treatment Teams (CRHTT), measured using data collected from anonymised patient electronic medical records
The following outcome measures are recorded at 3-month follow-up:
8. Time to first relapse in days following recovery (primary outcome measure in the main trial), measured using anonymised case notes by the chief investigator, a psychiatrist and a senior clinician (to define point of recovery)
9. Service user and carer satisfaction with care, measured by the Client Satisfaction Questionnaire (CSQ-8)
10. Use of health, social care services and wider societal costs measured using an adapted version of the self-report Client Services Receipt Inventory (CSRI)

11. Service user and primary clinician experience of shared decision making during treatment, measured by patient and clinician self-report on the dyadic OPTION scale
12. Service user-defined recovery, measured by the Questionnaire about the Process of Recovery (QPR)

Completion date
01/06/2019

Eligibility

Key inclusion criteria
Clusters must:
1. Be in a catchment area with a clear referral pathway to the community mental health service
2. Have protocols in place to deliver either OD or TAU
3. Contain a set of 2 to 4 geographically coterminous GP practices where
3.1. The cluster has an average number of referrals per cluster between 65 and 75 patients per year to crisis services
3.2. Each practice has a list size of over 2000 registered persons
3.3. Each practice refers only within the catchment area of the community MH service
3.4. Each practice only serves residents within the cluster catchment area (i.e. does not include practices which, as one of its primary functions, have the provisions of a student health service)

Service users from a cluster are eligible to take part in the study if they are:
1. Meeting criteria of a service user in crisis (meeting ICD criteria (WHO, 1992) for a mental health disorder) within 24-48 hours of referral or having been discharged from in-patient care following a crisis admission to the Crisis Resolution and Home Treatment Team (CRHTT) for home treatment. There will be some variability in the operational definition of ‘crisis’ across Trusts and, therefore, participants presenting to services. However, this variation will increase the generalisability of trial findings.
2. 18 years and above
3. Able to provide informed consent, or have consent provided by a personal or nominated consultee

Participant type(s)
Service user

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
99 Years

Sex
All

Total final enrolment
59

Key exclusion criteria
1. Having a diagnosis of dementia or a learning disability
2. Having a primary diagnosis of substance misuse
3. Having an acquired cognitive impairment
4. Being unable to comprehend both written and verbal English
5. Being under the care of forensic services
6. Being considered too high risk through participation in the study; that is, participation in the study is judged by the service users' clinician to pose potential harm to themselves or the research/clinical team
7. Residing outside their GP catchment area
8. Having no fixed abode
9. Currently participating in another research trial, which could affect their participation in this trial

Date of first enrolment
30/07/2018

Date of final enrolment
18/02/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North East London NHS Foundation Trust
West Wing, CEME Centre, Marsh Way
Rainham
England
RM13 8GQ

Study participating centre
Kent and Medway NHS and Social Care Partnership Trust
Farm Villa
Hermitage Lane
Maidstone
England
ME16 9PH

Sponsor information

Organisation
North East London NHS Foundation Trust

ROR
https://ror.org/023e5m798

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The researchers will be following the actions outlined by NIHR in regard to sharing research data. The datasets generated and analysed, and the corresponding statistical code, will be available in anonymised form from the research team on reasonable request, subject to review, following the publication of trial results. Dr Sandeep Toot, sandeep.toot@nelft.nhs.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.3	28/06/2018	17/09/2025	No	Yes

Participant information sheet	version 1.3	28/06/2018	17/09/2025	No	Yes
Participant information sheet	version 1.3	28/06/2018	17/09/2025	No	Yes