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Is Open Dialogue more clinically effective and cost-effective than standard care for people who present to services in mental health crisis?

Submission date
08/07/2019

Recruitment status
No longer recruiting

Registration date
20/12/2019

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This trial tests the clinical- and cost-effectiveness of a treatment for severe mental illness, Open Dialogue (OD), in comparison to usual treatment. OD is a collaborative approach to the care of people who experience a mental health crisis and require ongoing treatment and support. Its main focus is on people's social networks, using shared decision-making to provide suitable medication-based, psychological or social interventions. Until now, studies looking at the effectiveness of OD have shown promising results, reporting reductions in hospital-bed usage and improved recovery rates, but there is currently no high-quality evidence to support the delivery of this treatment across the NHS. If found to be more effective than usual treatment, this approach could be used in the NHS to care for people in mental health crisis.

Who can participate?
People over the age of 18 who are registered with a GP surgery involved in the trial, and who are referred to secondary mental health services or psychiatric inpatient care after experiencing a mental health crisis. Several other criteria would prevent a patient from taking part, such as whether the person had previously received OD treatment, or were under the care of forensic services.

What does the study involve?
Participants who meet the criteria are asked to join the study if they receive treatment from a secondary mental health service involved in the trial. Before being considered for the trial, a person will be randomly allocated to one of two groups, depending on which GP practice they are registered with. People in the first group will receive Open Dialogue, and those in the second group will receive usual treatment. The treatment that a person receives does not depend on their participation in the study, and their care will not change if they decline to take part. Interviews lasting around 45 minutes will take place with all participants at the beginning of the study, measuring factors such as social network quality and size. Further interviews will then take place 3, 6, 12 and 24 months after the person experiences the crisis. Participant medical notes are also viewed at 24 months to find out about any relapses that have taken place in that time.

What are the possible benefits and risks of participating?
It is hoped that participants will find it interesting to take part in research and talk with a researcher. No major risks are anticipated for people taking part in this study. There is a chance that topics discussed may cause upset or distress. If this happens the researcher will stop the interview and only continue if/when the participant feels ready. In this case, the researcher will also to provide information about support services.

Where is the study run from?
The study is being run from University College London and involves 5 mental health trusts across the UK

When is the study starting and how long is it expected to run for?
June 2019 to October 2022

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

Who is the main contact?
Katherine Clarke
Katherine.clarke@ucl.ac.uk

Study website
https://www.ucl.ac.uk/pals/research/cehp/oddessi

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
CPMS: 41662; RP-PG-0615-20021

Study information

Scientific Title
Open Dialogue: Development and Evaluation of a Social Network Intervention for Severe Mental Illness (ODDESSI)

Acronym
ODDESSI

Study objectives
This application concerns the final phase of a National Institute for Health Research (NIHR) programme grant investigating the development and evaluation of Open Dialogue (OD) for severe mental illness (ODDESSI, RP-PG-0615-20021). OD is a collaborative approach to the care and management of people who present in mental health crises and require continuing treatment and support. Its primary focus is on people's social networks, in particular families, as well providing appropriate pharmaceutical, psychological or social interventions. It is in contrast to current models of care, in which families are rarely directly involved. International 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 an NHS-wide adoption of this model. This approach offers the possibility of a potentially clinically and cost-effective alternative to current models of care. The programme grant consists of five Work Packages (WP) over a five-year period. We have already had HRA approval and undertaken the development phase (WP1) and the feasibility phase of the trial (WP2) (REC Reference: 18/LO/0868, IRAS Project ID: 233243). This application focuses on WPs 3, 4, and 5.

The current study aims to test the clinical and cost effectiveness of OD compared to treatment as usual. This will involve a multi-centre cluster randomised trial (WP 3) comparing OD with TAU in 5 mental health Trusts in England. In parallel with the trial, WP4 will examine a series of organisational and service related factors associated with the delivery and implementation of OD to inform the future implementation of OD, if OD is shown to be effective. As part of this the views and experience of people who have been received Open Dialogue will also be assessed (WP5).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/04/2019, Wales REC 5 (Dinorwig Room, Neuadd Reichel Building, Bangor University, Ffriddoedd Road, Bangor, LL57 2TR; Tel: +44 (0)2920785741, +44 (0)7970 422139, +44 (0)2920785739; Email: WalesREC5@wales.nhs.uk), REC ref: 19/WA/0096

Study design
Randomised; Both; Design type: Treatment, Prevention, Process of Care, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Management of Care, Rehabilitation, Active Monitoring, Health Economic

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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

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

Interventions
This research is a cluster randomised trial of Open Dialogue (OD) compared to Treatment as Usual (TAU) for people who experience a mental health crisis (WP3). In the OD component of the trial a multi-disciplinary OD team will provide continuity of care, centred on network meetings with participants and their carers, throughout any periods of care for the trial. In the TaU component of the trial different multi-disciplinary teams (crisis teams, community recovery teams, out-patients services) will provide care, during any periods of care for the trial. Clusters will be constructed from a small number (2 to 4) of General Practice Surgeries which are located closely with each other. The researchers have established 28 clusters (14 OD, 14TaU) and will seek to recruit 23 participants from each cluster, giving a total of 644 participants.

Mental health crises are different for everyone, but can be described in general as a problem with mental health that is so acute and severe that the person should be seen by a healthcare professional within 24 hours, and closely monitored. The researchers will recruit people from participating clusters who present to NHS services during a mental health crisis: this could be people who have been referred to a ‘crisis team’ or other assessment services by their GP, who have attended A&E or who have been admitted to inpatient psychiatric unit. Participants who meet trial criteria for a crisis and for whom consent to participate in the study is obtained, will complete an initial 30-45 minute interview. The duration of the study is 24 months. There will be further interviews of a similar length 3 months, 6 months, 12 months and 24 months (5 interviews in total). The interviews be undertaken by a Research Assistant using standardised questionnaires on topics such as the size of the person’s social network, their experience of the process of recovery and their satisfaction with services. The primary outcome (time to relapse after first recovery) will be obtained participants medical records.

In parallel with the trial, the researchers will explore the delivery of care for both participants and their carers and staff in both OD and TaU (WP4). In total 140 participants and their carers will complete questionnaires on their experience of shared decision making and 140 family members their experience of care burden. A selected sub-sample of participants and their carers (up to 40) will also be interviewed in more detail about their experience of care. The researchers will also describe the care and treatment that participants in the study received (from electronic medical records). For services and staff they assess how all OD teams deliver interventions using

data from team records and medical records and an OD adherence measure (developed in WP1). For all TAU teams they will also assess the delivery of interventions using data using data from team records and medical records and an adherence measure (developed in WP1). For both OD and TAU teams they will assess the overall organisation and delivery of services using a fidelity measure developed in WP1. They will also assess staff experience of training in and the organisation and delivery OD (from interviews, focus groups and written reports from staff totalling about 50 staff across all participating sites).

The researchers will assess participants and family and carer experience of receiving OD in WP5. This will be based a selection of trial participants (20 participants and families/carers who were not interviewed as part of WP4) selected on the basis of how much they have benefited from OD and who will be asked to complete an additional interview (maximum one hour in length) about their experiences.

Intervention Type
Other

Primary outcome measure
Time to first relapse following recovery (measured in days) assessed using an established method (Bebbington at al., 2006) via data extracted from medical records at 24 months

Secondary outcome measures
1. Time to initial recovery (measured in days from the date of crisis referral to the date there is a 'change of status' to recovery), assessed using the same method as the primary outcome (Bebbington et al., 2006) at 24 months
2. Days spent in recovery (measured as the total number of days between the point of the crisis referral and 24 months following crisis referral, where a person's status was labelled as in 'recovery') using the same method as the primary outcome (Bebbington et al., 2006).
3. Days in hospital (measured as the total number of days between the point of the crisis referral and 24 months following crisis referral, where a person is an inpatient in a psychiatric hospital)
4. Self-rated recovery score measured using the Questionnaire on the Process of Recovery (QPR) (Law et al., 2004), at 3, 6, 12 and 24 months after index crisis referral
5. Service user satisfaction with care measured using the Client Satisfaction Questionnaire (CSQ-8) (Attkinsson & Greenfield, 1999) at 3, 6 and 24 months after index crisis referral
6. Cost-effectiveness of OD (compared to TAU) calculated by measuring service use costs, assessed using the Client Services Receipt Inventory (CSRI) (Beecham & Knapp) at 3, 12 and 24 months after index crisis referral. It will also measure societal costs, including hospitalisation or re-referral to crisis care, assessed at an individual participant level for the 24-month follow up period. It will also measure health-related quality of life, using the EQ-5D-5L at first assessment, and 3, 6, 12 and 24 months after index crisis referral.
7. Social network quality and size measured using the Social Provisions Scale (SPS) (Cutrona & Russell, 1987) and the Lubben Social Network Scale (LSNS-6) (Lubben et al., 2006) at first assessment, and 3, 6, 12 and 24 months after index crisis referral

Overall study start date
01/11/2017

Completion date
01/04/2023

Eligibility

Key inclusion criteria
Service users are eligible to participate in the study if they:
1. Are experiencing, or have recently experienced a mental health crisis, indicated by an A-C rating on the UK Mental Health Triage Scale or are admitted to an inpatient ward or taken on to a crisis service caseload
2. Are registered with one of the GP practices in a trial cluster
3. Are 18 years and above
4. Have sufficient English language abilities to participate in the research

A purposive sample of 20% of trial participants will be invited to nominate a carer to complete some additional outcome measures, but this process is separate and does not impact eligibility for, or participation in the trial. Similarly, a purposive sample of participants (estimated to be 10% of the trial sample) and staff will be approached to complete an interview, focus group, or provide written information. Sections A17-2 to A21 and A27 to A35 of this IRAS form relate just to all trial participants, and the other sections relate to trial participants, as well as the carers of the subsample of trial participants and the staff.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 644; UK Sample Size: 644

Key exclusion criteria
Current exclusion criteria as of 12/01/2022:

Service users are not eligible if:
1. They have a diagnosis of dementia or a learning disability
2. They have a primary diagnosis of substance misuse
3. They have an acquired cognitive impairment
4. They are under the care of forensic services
5. They have no fixed abode
6. They are participating in another research trial which may impact on their care or treatment in the ODDESSI programme
7. Their participation in the study is judged to pose a risk of harm to themselves, study clinicians, or researchers
8. They have received Open Dialogue prior to the study

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Previous exclusion criteria:

Service users are not eligible if they:
1. Have a diagnosis of dementia or a learning disability
2. Have a primary diagnosis of substance misuse
3. Have an acquired cognitive impairment
4. Are under the care of forensic services
5. Have no fixed abode
6. Are participating in another research trial which may impact on their care or treatment in the ODDESSI programme
7. They will also be excluded if their participation in the study is judged to pose a risk of harm to themselves, study clinicians, or researchers

Date of first enrolment
03/06/2019

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
United Kingdom
RM13 8GQ

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

Study participating centre
Barnet, Enfield and Haringey Mental Health NHS Trust
Trust Headquarters Block B2
St Ann's Hospital

St Ann's Road
London
United Kingdom
N15 3TH

Study participating centre
Camden and Islington NHS Foundation Trust
St. Pancras Hospital
4 St. Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre
Devon Partnership NHS Trust
Wonford House Hospital
Dryden Road
Exeter
United Kingdom
EX2 5AF

Sponsor information

Organisation
North East London NHS Foundation Trust

Sponsor details
c/o Fiona Horton
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0615-20021

Results and Publications

Publication and dissemination plan
1. The researchers will be submitting a study protocol paper for publication shortly.
2. Peer-reviewed scientific journals
3. Internal report
4. Conference presentation
5. Publication on website
6. Submission to regulatory authorities

Intention to publish date
01/08/2023

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		24/12/2021	30/12/2021	Yes	No
HRA research summary			20/09/2023	No	No