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Feasibility study of an international framework to evaluate the impact of Open Dialogue

Submission date
17/02/2026

Recruitment status
No longer recruiting

Registration date
10/08/2026

Overall study status
Completed

Last Edited
10/08/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Open Dialogue (OD) is a mental health approach used to support people experiencing a mental health crisis. It involves the person in need of care together with their family members and social network and focuses on open communication and shared decision-making. OD was developed in northern Finland, where it showed very positive results in supporting recovery.
In recent years, mental health services in several countries have started using Open Dialogue in their everyday practice. However, scientific evidence on how OD works outside Finland and how it is delivered in different healthcare systems has remained limited. Since 2017, a large study called ODDESSI (https://www.isrctn.com/ISRCTN17977792) has been evaluating Open Dialogue in the United Kingdom.
The HOPEnDialogue study aimed to test whether it was feasible to run a shared research framework to evaluate Open Dialogue in different countries. The study collected data from mental health services in France, Germany, and Italy to explore whether outcomes could be measured consistently across countries and to support future international research on Open Dialogue.

Who can participate?
Adults aged between 18 and 65 who were experiencing a mental health crisis and were receiving care from one of the participating mental health services were eligible to take part in the study.

Family members or other caregivers of people who agreed to participate were also invited to take part by completing questionnaires about their experiences of providing care.

Some mental health professionals (such as nurses, psychologists, psychiatrists, and peer support workers) were involved in the study because their clinical practice was observed to check whether Open Dialogue principles were being applied.

What does the study involve?
All patients taking part in the study received Open Dialogue care as part of their usual mental health treatment. There was no comparison group and no change to the care they would normally have received.
Information such as age, background, and clinical history was collected at the start of the study

and again after 12 months. Mental health professionals regularly assessed the person's mental health using a standard clinical scale.
Patients were asked to complete questionnaires at the start of the study and after 3, 6, and 12 months. These questionnaires asked about quality of life, social relationships, recovery, satisfaction with care, and well-being. Caregivers were asked to complete questionnaires at the start of the study and after 6 and 12 months.
To understand whether Open Dialogue was being delivered in a consistent way, some network meetings were audio- or video-recorded for each clinical team at different points during the study. Experienced Open Dialogue practitioners reviewed these recordings.

What are the possible benefits and risks of participating?
Taking part in the study did not provide direct benefits to patients or caregivers. However, the study was expected to improve understanding of how Open Dialogue works in different countries and to benefit future service users and families. Mental health professionals could benefit from receiving feedback on their practice, which could support learning and professional development.

No clinical risks were expected from taking part in the study. Some people may have felt uncomfortable or upset when answering questionnaires or being recorded. Participation was voluntary, and participants could stop completing questionnaires or ask for recordings to be stopped at any time without affecting their care. The evaluation focused on team practice rather than on individual professionals.

Where is the study run from?
The study was coordinated by the Institute for Cognitive Sciences and Technologies of the National Research Council of Italy (ISTC-CNR). It involved five mental health pilot sites: three in France, one in Germany, and one in Italy.

When did the study take place?
May 2022 to July 2024.

Who funded the study?
The Open Excellence Foundation, USA.

Who was the main contact?
Dr Raffaella Pocobello, Researcher at the ISTC-CNR, raffaella.pocobello@istc.cnr.it

Contact information

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Study information

Scientific Title
HOPEnDialogue Feasibility Study

Study objectives
1. To assess the feasibility of conducting a multinational prospective cohort study using a shared evaluation framework to assess OD outcomes across different international settings.
2. To explore the feasibility of collecting and comparing standardized outcome data on service-user outcomes, including time to relapse, symptom severity, quality of life, social network size, and perceived social support.
3. To assess the feasibility of collecting data on caregivers, including burden of care and other psychosocial outcomes, within the proposed evaluation framework.

Ethics approval required

Ethics approval required

Ethics approval(s)
1. Approved 15/06/2022, Commissione per l'Etica e l'Integrità nella Ricerca del CNR (Commission for Ethics and Integrity in Research of the Italian National Research Council) (Via dei Taurini, 19, Rome, 00185, Italy; +39 06 4993/2999; cnr.ethics@cnr.it), ref: PARERE DI ETHICAL CLEARANCE – Commissione per l'Etica e l'Integrità nella Ricerca del CNR - 15/06/2022

2. Approved 08/09/2022, Comitato Etico dell'Area Vasta Emilia Nord (Ethics Committee of the North Emilia Region) (Via del Pozzo, 71, Modena, 41124, Italy; +39 059 422 3492; bristot.laura@aou.mo.it), ref: PROT AOU 0025379/22

3. Approved 17/03/2022, Comité d'éthique de l'université d'Aix-Marseille (Ethics Committee of the Aix-Marseille University) (Université d'Aix-Marseille - Jardin du Pharo - 58 boulevard Charles Livon, Marseille, 13284, France; +33 (0)4 91 39 65 00; audrey.janssens@univ-amu.fr), ref: 2022-03-10-006

4. Approved 15/12/2021, Ethikkommission der Medizinischen Hochschule Brandenburg Theodor Fontane (MHB) (Ethics Committee of the Brandenburg Medical School (MHB) Theodor Fontane) (Geschäftsstelle der Ethikkommission Medizinische Hochschule Brandenburg Theodor Fontane (MHB) Campus Rüdersdorf Haus 7, Etage 0, R. F.005 Seebad 82/83, Neuruppin, 15562, Germany; +49 (0) 33638 514433; ethikkommission@mhb-fontane.de), ref: E-01-20210209

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Severe and/or enduring mental illness

Interventions
This is a Exploratory feasibility design - Cohort study.
The study is an international naturalistic observational cohort study of consecutive patients with psychotic and other severe mental health difficulties receiving care through the Open Dialogue (OD) approach. Participants are recruited from mental health services providing OD. Clinical staff screen potential participants for eligibility and obtain informed consent. Once enrolled, demographic and clinical data, including psychiatric history and medication, are collected at baseline and again at 12 months.

After each network meeting, or at least every four weeks, two mental health professionals independently assess psychiatric symptom severity using the Global Assessment of Functioning (GAF) scale. GAF scores are used to identify "remission" and "relapse" events.

Participants also complete questionnaires on quality of life, social network size, perceived social support, and well-being at baseline, 3, 6, and 12 months. Caregivers complete questionnaires on burden of care and other psychosocial outcomes at baseline, 6, and 12 months.

The total duration of observation and follow-up for each participant is 12 months.

Intervention Type
Other

Primary outcome(s)
1. Global Assessment of Functioning (GAF) scale data completeness measured using proportion of required records with a valid GAF score recorded at end of study (12 months)

2. Retention rate measured using the percentage of participants who complete the 12-month follow-up questionnaires at end of study (12 months)

3. Attrition rate measured using the percentage of participants who did not complete the 12-month follow-up questionnaires at end of study (12 months)

Key secondary outcome(s)
1. Time to relapse measured using the number of days after first remission at end of study (12 months)

2. Change in Sociodemographic and Clinical Variables measured using the difference in the value of predefined patient sociodemographic and clinical variables at baseline and the 12-month assessment

3. Social Network Size measured using the 6-item Lubben Social Network Scale (LSNS-6) at baseline, 3, 6, and 12 months

4. Quality of life for patients measured using the 5-dimension 5-level EuroQol Questionnaire (EQ-5D-5L) at baseline, 3, 6, and 12 months

5. Personal recovery for patients measured using the Questionnaire about the Process of Recovery (QPR) at 3, 6, and 12 months

6. Client satisfaction for patients measured using the Client Satisfaction Questionnaire (CSQ-8) at 3 and 12 months

7. Mental well-being for patients and caregivers measured using the World Health Organisation-Five Well-Being Index (WHO-5) at baseline, 6, and 12 months

8. Evaluation of social systems for patients and caregivers measured using the Evaluation of Social Systems Scale (EVOS) at baseline, 6, and 12 months

9. Caregiver burden of care for caregivers measured using the Burden Assessment Scale (BAS) at baseline, 6, and 12 months

Completion date
31/07/2024

Eligibility

Key inclusion criteria

Patient
1. Experiencing psychotic or any other severe mental illness such as major depression, personality disorders, bipolar disorder, etc., requiring mental health support
OR
2. Evidence of a mental health crisis indicated by:
2.1. A rating of A-C on the UK Mental Health Triage Scale (Sands et al., 2016), which indicates either an emergency, very urgent or urgent response is needed based on a high risk of harm self or others and/or rapidly increasing symptoms of psychosis or severe mood disorder
2.2. An admission to an inpatient ward, or
2.3. Being accepted into the care of a mental health crisis service
AND
3. Between 18 and 65 years of age
AND
4. Sufficient abilities in the official language of the country where the pilot site is located

Carers
1. Being a family member or a caregiver of one of the patients enrolled in the study

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
76

Key exclusion criteria
1. A primary diagnosis of substance misuse
2. A diagnosis of dementia or an acquired cognitive impairment
3. A primary diagnosis of a learning disability
4. Current forensic involvement
5. Already received OD in the past
6. Participation in another research project that may impact the patient care in the HOPEnDialogue study
7. Risk of harm to the participant, study clinicians, or researchers

Date of first enrolment
11/05/2022

Date of final enrolment
31/07/2023

Locations

Countries of recruitment
France

Germany

Italy

Sponsor information

Organisation
Institute of Cognitive Sciences and Technologies

ROR
https://ror.org/05w9g2j85

Funder(s)

Funder type

Funder Name
Open Excellence Foundation

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available