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Evaluating the suitability and effectiveness of the Open Dialogue model within an NHS Trust

Submission date 22/10/2018	**Recruitment status** No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 04/01/2019	**Overall study status** Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 31/10/2022	**Condition category** Mental and Behavioural Disorders	☐ Individual participant data

Plain English summary of protocol
Background and study aims
The Kent and Medway NHS Trust have begun a new mental health service which aims to use the support of family and friends to help people recover. This service allows people to talk about their experiences in a way that previous services have not allowed for and this may be reflected in patient satisfaction being higher than it is for other services. The study will also examine if carers are happy with this service.

Who can participate?
People aged 18 to 65 receiving treatment from the KMPT Open Dialogue service for a mental health problem

What does this study involve?
People being treated by the Open Dialogue service are asked if they would like to take part and if they agree they are given questionnaires to fill in at the beginning, after 3 months and at 6 months.

What are the possible benefits and risks of participating?
The findings of this study will be used to decide whether the Open Dialogue model is suitable for using in an NHS Mental Health Trust. There is no direct benefit to participants but taking part in the study gives participants an opportunity to give feedback on what they think about their mental health treatment. This will be useful for improving mental health services in the future. The main disadvantage of taking part is that it takes up some time to fill in the questionnaires, between 30-60 minutes. Participants are asked to fill these in three times, at the start of the study, after 3 months and after 6 months. It is also possible that answering questions regarding mental health issues would be upsetting for some participants.

Where is this study run from?
Open Dialogue service, St Martin’s Hospital, Canterbury, Kent (UK)

When is the study starting and how long is it expected to run for?
July 2016 to February 2019

Who is funding the study?
The Health Foundation (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
31831

Study information

Scientific Title
Evaluating Peer Supported Open Dialogue (POD) in NHS mental health services: accessing patient social networks to optimise outcomes ("Evaluating POD")

Study objectives
This study is designed to test the hypothesis that the Open Dialogue model will reduce symptoms of mental illness over a six month period and patients will report higher levels of satisfaction with the service compared to standard mental health care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London – Camden and Kings Cross Research Ethics Committee, 19/09/2016, ref: 16/LO/1606

Study design
Non-randomised; Both; Design type: Treatment, Diagnosis, Psychological & Behavioural, Management of Care, Active Monitoring, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Mental Health, Primary sub-specialty: Study not assigned to a MH Clinical Studies Group; Health Category: Mental health; Disease/Condition: Unspecified mental disorder

Interventions
The study will employ a mixed methods design which involves the quantitative analysis of longitudinal survey data and the qualitative analysis of data from focus groups with the aim to encompass both the service user and clinician perspectives effectively.

Participants: Any eligible service users who are referred to receive the POD model of treatment.

It is proposed that each POD team (Medway and Canterbury) will accept 3-4 referrals a week until they reach a number of 25 consenting service users each, giving a total number of 50 participants with at least one consenting family member per participant.

It is during a service users initial network meeting, which should be within 24 hours of their first contact that written information about POD and the research will be given at this point. POD clinicians will enquire whether those receiving the service would like to discuss potential involvement in the research at the second network meeting, in a dialogical manner, as long as it has been agreed by the clinical team leader that the person has the capacity for consent. If the answer is Yes, the Research Assistant will arrange to meet with the participants, to discuss the project and obtain informed consent. They will be informed of their right to confidentiality, withdrawal and that their treatment will not be affected regardless of whether they decline to take part. Non-consenting participants will still receive the POD intervention as normal but data will not be gathered.

Family members and social networks will also be asked for their informed consent to take part in the research as they will be asked to complete a self-report on their well-being, this is required from at least 1 family member.

Intervention: The practice of Open Dialogue has two fundamental features (Olson, Seikkula & Ziedonis, 2014):

1. The engagement of families and social networks at the point of contact:
In order to incorporate these features into the treatment being offered at KMPT, a POD practitioner from that team will contact the service user or carer to ask if the POD team can meet with the service user at a location which is comfortable for them and will further be asked to invite other members of the family or social network to be present at the meeting. A case-specific, multidisciplinary team of POD trained clinicians will be set up and the initial network

meeting will be held within 24 hours of first contact with the POD team. The team will consist of at least two members of staff which may include a nurse, social worker, peer support worker, care coordinator, psychologist or psychiatrist.

2. A "Dialogic Practice" based on the Twelve Key Elements of Fidelity (Olson et al., 2014):
During the network meetings, the POD clinicians will to adhere to the Open Dialogue Fidelity Criteria in order to maintain consistency; the POD team will assess this by completing the 10 point Key Elements of fidelity to dialogic practice in Open Dialogue (Olsen et al, 2014) at the end of every network meeting.

The same clinicians will attend regular meetings with the service user, family members and important social networks in order to promote co-production and create new understanding of the mental distress which opens up new opportunities for change and recovery. Fundamental to Open Dialogue is the principal of 'flexibility and mobility' which means the duration and frequency of network meetings are not fixed and are decided within the meetings using a case by case, needs-based approach.

The primary outcome of this study will be the hospital admission rate which will be measured by assessing the number of any hospital admissions and the length of any in-patient stay in the 12 months prior to contact with POD service and number of admissions during the timeline of the project. Secondary outcomes will be measured at baseline (within 2 weeks of first contact with POD), 3 months post baseline and 6 months post baseline. These include self report measures to determine service user well-being, impact on daily routine and experience. Family members and social networks will be asked to complete a self report measure on carer well-being. Both service users and members of the social network will be asked to complete a single question regarding whether they would recommend the POD Service to friends and family.

At the 6-7 month mark, focus groups involving POD clinicians and Trust personnel will be held. Those who express an interest in partaking in the focus groups will also be asked if they would like to participate in the research and would thus require informed consent in order to record their data for qualitative analysis.

Once all the data has been gathered, service users who still require the service will continue to receive POD as normal.

Intervention Type
Other

Primary outcome(s)
Hospital admission rate measured by assessing the number of any hospital admissions and the length of any in-patient stay in the 12 months prior to contact with POD service and number of admissions during the timeline of the project.

Key secondary outcome(s))
Measured at baseline (within 2 weeks of first contact with POD), 3 months post baseline and 6 months post baseline:
1. Hospital bed-days are measured through data collected from medical progress notes
2. Symptom severity is measured through Health of the Nation Outcome Scales (HoNOS) at baseline and 180 days (or discharge if earlier)
3. Mental wellbeing is measured using the Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS) at baseline, 90 days and 180 days

4. Impairment to work and social activities is measured using the Work and Social Adjustment Scale (WSAS) at baseline, 90 days and 180 days
5. Satisfaction with mental health services is measured using the NHS/CQC Community Mental Health Survey (CMHS) at baseline, 90 days and 180 days
6. Perceived support for carers is measured using the 17-item ‘support’ subscale from the Carer Wellbeing and Support Scale (CWS) at baseline, 90 days and 180 days
7. Perceived usefulness (SRS) of the Open Dialogue network meetings is measured using the Session Rating Scale (SRS) at the end of each network meeting

Completion date
28/02/2019

Eligibility

Key inclusion criteria
1. Aged between 18-65
2. Experiencing a new episode of care
3. Meets criteria for secondary care mental health services as defined by the Single Point of Access.
4. Are at the point of an urgent mental health crisis and would be considered suitable for the Crisis Resolution Home Treatment team

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Anyone who does not meet the age criteria
2. Does not meet criteria for secondary care mental health services as defined by the Single Point of Access

Date of first enrolment
01/02/2017

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Open Dialogue Service
Eastern and Coastal Area Office
St Martin’s Hospital
Littlebourne Road
Canterbury
United Kingdom
CT1 1AZ

Sponsor information

Organisation
Canterbury Christ Church University

ROR
https://ror.org/0489ggv38

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation

Results and Publications

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?
Results article		22/02/2022	31/10/2022	Yes	No
HRA research summary			26/07/2023	No	No