ISRCTN34757603 https://doi.org/10.1186/ISRCTN34757603

The EPOS trial: effective patient-clinician communication in community mental health care

Submission date
19/12/2012

Recruitment status
No longer recruiting

Registration date
19/12/2012

Overall study status
Completed

Last Edited
10/02/2016

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Schizophrenia and related disorders are disabling for patients and generate high costs to the NHS and society. At present in Community Mental Health Teams (CMHTs), patients regularly meet with their key workers, but the communication between the patients and key workers is not guided by research evidence. DIALOG is a computer-mediated procedure that has been designed to structure the communication between key workers and patients in community mental health care. The aim is that this treatment approach can be used in routine care throughout the NHS, will be cost-effective and can benefit thousands of patients at the same time.We are carrying out a study of 180 patients with a diagnosis of Schizophrenia and related disorders to investigate whether structuring this communication using DIALOG will result in patient improvements in their own view of their quality of life, treatment satisfaction, well-being and other clinical outcomes. The findings should help to improve the well-being of service users and make routine outcome assessment easier in CMHTs in the NHS.

Who can participate?
The EPOS study aims to recruit 36 clinicians and 180 patients from Community Mental Health Teams in East London NHS Foundation Trust.

What does the study involve?
We are asking participating clinicians and their patients to try out one of two new approaches to treatment that includes the use of iPad computers for a period of 6 months. One approach involves patients completing a short satisfaction questionnaire called the DIALOG Scale after their routine meeting with the clinician. This scale involves rating 11 topics relevant to life and treatment (e.g. mental health, physical health, accommodation, medication). The other approach is called DIALOG+ and involves patients and clinicians using the DIALOG 2.0 software, on an iPad, together during their routine meeting. The procedure involves rating the same 11 topics as in the DIALOG Scale, and once rated the patient and clinician choose which areas they would like to address in the meeting. The chosen areas are discussed one by one, using the 4-step approach (a simple psychological approach). Following the discussion, the patient and clinician will decide together what actions can be taken to help with each of these areas. Half of the participating

clinicians and their patients will be using DIALOG+, and half will be using the DIALOG Scale. At the end of the study we will compare the outcomes of both treatment groups.

What are the possible benefits and risks of participating?
We expect that those patients taking part will directly benefit from both treatments. The structured communication of the DIALOG+ approach is expected to be beneficial as this was the case in a previous DIALOG study. Patients completing the DIALOG Scale may benefit as evidence suggests that assessing patient satisfaction may result in improvements. There is no research to suggest that this may be harmful. All patients stand to benefit from the understanding that their treatment is being monitored and reviewed and receiving £20 per clinical interview at baseline, and months 3, 6 and 12. There are no risks associated with participating in this study.

Where is the study run from?
Queen Mary, University of London in collaboration with East London NHS Foundation Trust (ELFT)

When is the study starting and how long is it expected to run for?
Recruitment began in October 2012. We expect to stop recruiting in March 2013. Once recruited, patients and clinicians will be using the new treatments for a period of 6 months, followed by a 6-month follow-up period. The study is expected to run until 2014.

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

Who is the main contact?
Lauren Kelley
l.e.kelley@qmul.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Eoin Golden

Contact details
Queen Mary University of London
Unit for Social and Community Psychiatry
Academic Unit
Glen Road
London
United Kingdom
E13 8SP
-
e.m.golden@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13516

Study information

Scientific Title
The EPOS trial: effective patient-clinician communication in community mental health care

Study objectives
Our research aims to find out if the effectiveness and cost-effectiveness of using a computer-mediated intervention to structure patient-clinician communication of patients with schizophrenia and related disorders.
The study hypothesis is that structuring this communication in routine meetings in community mental health care will lead to better clinical outcomes for patients with psychosis.

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetails.aspx?StudyID=13516

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London-Stanmore, 05/10/2012, ref: 12/LO/1145

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Schizophrenia

Interventions
DIALOG Scale:
The control group will include treatment as usual plus a defined intervention that also involves the use of an Apple iPad and an assessment of the patient's satisfaction. The patient will use the device to rate his/her satisfaction on the 11 domains of the DIALOG scale. The instruction will be to conduct such assessments after a meeting once per month for a period of 6 months and for clinicians and patients to not discuss the ratings. This will help to control for the effect of the implementation of an electronic device in routine care.

DIALOG+:
In the experimental group the DIALOG+ intervention will be used as defined in the DIALOG+ manual. DIALOG+ is based on the use of DIALOG 2.0 software, which will run on an Apple iPad. This software presents patients and clinicians with the same 11 domains as in the DIALOG Scale, with the option to select additional help for each. The instruction will be for patients and clinicians to complete the questions together. Once rated, the patient and clinician choose which areas they would like to address in the meeting. The chosen topics are discussed one by one, using the '4-step approach' (a simple psychological intervention informed by principles of Solution Focussed Therapy (SFT) and Cognitive Behavioural Therapy (CBT). Following the discussion, the patient and clinician will decide together what actions can be taken to help with each of these areas. The instruction will be to conduct this assessment during a routine meeting once per month for a period of 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Subjective quality of life measured on the Manchester Short Assessment of Quality of Life (MANSA)
Assessed at baseline, and at months 3, 6 and 12

Secondary outcome measures
1. Costs of formal and informal care, assessed on the Client Service Receipt Inventory (CSRI)
2. Mental well-being on the Warwick-Edinburgh Mental Well-Being Scale (WEMWBS)
3. Needs on the Camberwell Assessment of Need Short Appraisal Schedule, patient-rated version (CANSAS)
4. Objective Social Outcomes measured on the SIX scale, also assessed using the MANSA (sections 2a and 3)
5. Psychopathological Symptoms on the Brief Psychiatric Rating Scale (BPRS)
6. Recovery as measured on the severity parts of each of the 24 items of the CHOICE scale
7. Self-Efficacy on the General Self-Efficacy Scale
8. Social contacts in the last week measured in a structured interview
9. The Therapeutic Relationship measured on the Scale to Assess Therapeutic Relationships in Community Mental Health Care (STAR) patient and clinician versions
All secondary outcome measures will be assessed at baseline, and at months 3, 6 and 12

Overall study start date
05/10/2012

Completion date
01/07/2014

Eligibility

Key inclusion criteria
Patients:
1. Treatment in a community mental health care team in the NHS for at least one month
2. Clinical diagnosis of schizophrenia or a related disorder (F20-29)
3. Aged between 18 and 65 years
4. A mean score of less than 5 on the Short Assessment of Quality of Life (MANSA)
5. Capacity to give informed consent

Key workers:
1. Professional qualification as a clinician (nurse, social worker, psychologist, occupational therapist, doctor)
2. More than 6 months experience of working in community mental health care
3. Working as care coordinator

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 180

Key exclusion criteria
Patients:
1. Insufficient command of the English language for conducting meetings in English and filling in the assessment instruments of outcomes
2. A mean score of 5 or more on the MANSA
3. Learning difficulties

Key workers:
None

Date of first enrolment
05/10/2012

Date of final enrolment
01/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Queen Mary University of London
London
United Kingdom
E13 8SP

Sponsor information

Organisation
Queen Mary University of London (UK)

Sponsor details
Barts & London School of Medicine
Research & Development Office
QMI Building
5 Walden Street
London
England
United Kingdom
E1 2EF

Sponsor type
University/education

Website
http://www.qmul.ac.uk/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
NIHR - Programme Grants for Applied Research (UK), ref: RP-PG-0108-10023

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	26/06/2013		Yes	No
Results article	results	09/02/2016		Yes	No