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A pilot trial to assess the effect of a structured communication approach on quality of life in secure mental health settings

Submission date
22/06/2012

Recruitment status
No longer recruiting

Registration date
22/06/2012

Overall study status
Completed

Last Edited
03/10/2016

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
The main focus of the study is to examine the effect of the computer-mediated structured communication approach named DIALOG in secure mental health in-patient units, and utilise the principles of Solution Focused Therapy to aid this approach. Although the benefits of the structured communication approach have been shown in community mental health services, no previous work has been done in secure mental health settings. The structured communication approach places service users views of their care at the heart of the discussions with clinicians. It is proposed that this focus on peoples individual concerns will lead to an improvement in their care and quality of life. The aim of this study is to evaluate structured monthly discussions between the patient and his/her key worker using the structured communication approach. It is designed to increase the quality of life of service users in secure settings.

Who can participate?
We will be recruiting 60 keyworkers and 96 users of in-patient services at six medium secure mental health units in Southern England and London. Each service user whose key worker is participating in the study will be eligible to participate as long as they have a history of least 3 months of current in-patient treatment in a medium secure mental health unit.

What does the study involve?
The participants will be randomly allocated to either an intervention group or control group. Those participants allocated to the control group will continue to receive their standard care and treatment while those allocated to the intervention group will be asked to attend a one-hour meeting with their key worker as an addition to the standard care. This will be once a month for a period of six months. They will be asked to complete a simple checklist at the start of each meeting which rates their satisfaction in eight areas. They will then be asked whether they would like any further help in each area with all answers recorded and entered onto an iPad. This allows the results to be placed on a screen display which the service user and their key worker can view. They can also view previous ratings. The sessions focus on areas users want to discuss. Solution Focused Therapy is used to complement the structured communication approach. It is a talking therapy which focuses on the future and looks at what will be different

when things are better.
Formal assessments will take place at three time points: prior to the intervention, at 6 months and at 12 months. The following data will be collected from the service user participants: quality of life, satisfaction with services, recovery, amount of disturbed behaviour, relationship with staff, and views about the ward atmosphere. We will also collect data from the key workers at the three time points in relation to their levels of work stress.

What are the possible benefits and risks of participating?
It is proposed that the structured communication approach will help develop a more collaborative approach to care and that this will benefit service users, clinicians and services. Service users will be offered access to a new treatment that has been shown to be beneficial in other mental health settings. Key workers will be given training and support in the use of the structured communication approach and solution focused therapy approaches. Previous studies that have used the structured communication approach have not found any adverse effects. Participants will be monitored by their key workers for any indicators of distress.

Where is the study run from?
The study has been developed by Canterbury Christ Church University in collaboration with the host organisation, Kent and Medway NHS and Social Care Partnership Trust.

When is study starting and how long is it expected to run for?
The study started in January 2012 and will run for 3 years.

Who is funding the study?
The study has been funded by the NIHR: Research for Patient Benefit Fund.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11423

Study information

Scientific Title
A pilot randomised trial to assess the effect of a structured Communication approach on QUality Of Life in secure mental health settings

Acronym
ComQUOL

Study objectives
A pilot study is proposed to evaluate a structured six-month approach designed to increase the quality of life of service users in secure settings. The value of a pilot trial lies in providing a thorough evaluation of the acceptance and feasibility of the proposed approach which combines DIALOG with principles of Solution Focused Therapy (SFT). This is necessary before large-scale prospective randomised trials can be conducted in an efficient and cost-effective manner The specific objectives of the study are to:
1. Establish the feasibility of the trial design as the basis for determining the viability of a large full-scale trial (the estimated treatment effect, randomisation procedures, outcome measures, estimates of recruitment for a main trial and follow up of participants).
2. Determine the variability of the outcomes of interest (quality of life, levels of satisfaction, disturbance, ward climate, and engagement with services)
3. Estimate the costs of the intervention.
4. To refine the intervention following the outcome of the study based upon the experiences of the clinicians and service users.

It is proposed to undertake a 36 month pilot trial. The study will also estimate the effect of the intervention on a range of outcomes giving an indication of its effect. The intervention group will use a structured communication approach. This will be based on DIALOG and use elements of SFT. Assessments will take place prior to the intervention (baseline), at 6 months (post intervention) and at 12 months (follow-up).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London Surrey Borders, 11/LO/0104; First MREC approval date 15/07/2011

Study design
Randomised; Interventional; Design type: Treatment

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Personality disorder, Psychosis; Disease: Personality disorders, Psychosis

Interventions
The DIALOG approach involves monthly meetings between the service user and key worker for a period of six months. The intervention consists of two elements: a computer-mediated approach in conjunction with non-directive counselling which has been found to be an effective practical method of developing users involvement in their treatment. DIALOG will be used by key workers, in addition to continuing with standard treatment with their participating service users, to enable individualised therapeutic discussions. The service users complete a simple checklist during the meeting with their key worker, recording the degree of satisfaction with a range of life and treatment domains. Each domain is rated on a scale of 1-7 (from couldnt be worse to couldnt be better), and followed by a question on whether the patient wanted any additional or different help in the given domain. If the patient answers yes, the type of the requested additional or different support is recorded. The eight domains will be presented in a fixed order and an explicit response will be required for each item before proceeding to the next item. Participants answers to all questions will be entered directly onto a laptop, it will allow service users and key worker to view screen displays detailing a range of information concerning the service users ratings. The current rating of a domain can be compared with the rating one months previously. The domain can also be viewed in the context of all the other domains in a summary graph comparing previous and current ratings for all eight domains. The procedure is designed to alter interactions so that the service users views on their situation and needs for care are the central point of treatment discussions and the service users view on what kind of help would improve their current situation is explicit. Service users and key workers will discuss current and previous ratings, reasons for change and what kind of additional or different support might be helpful.

The counselling approach offered during these meetings will be the Solution Focused Approach. It is a structured conversational approach that promotes the movement towards positive change in individuals, families and other systems. It is based on Solution Focused Brief Therapy (SFBT). The approach is characterised by a focus on the future, more specifically, exploring what will be different when things are better. The conversation may focus on what someone will be doing differently, what might be different in the environment, or on how they may be being treated differently.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quality of life assessed by Manchester Short Assessment of Quality of Life (MANSA)

Secondary outcome measures
1. Key Worker Stress measured by Maslach Burnout Inventory; Timepoint(s): Time Point 1 - baseline assessment of service users
2. Recovery measured by The Process of Recovery Questionnaire; Timepoint(s): Time Point 1 - baseline assessment of service users
3. Service User Satisfaction; Timepoint(s): Time Point 1 - baseline assessment of service users
4. Social Climate of Ward; Timepoint(s): Time Point 1 - baseline assessment of service users
5. Therapeutic Relationships; Timepoint(s): Time Point 1 - baseline assessment of service users

Outcomes will be completed at three time points:

Time Point 1 - baseline assessment of service users; for the intervention group this will be prior to their first structured communication session while for the control group this will be at the same time;
Time Point 2 within the two weeks following the intervention; the last DIALOG approach meeting (after six months);
Time Point 3 six months post intervention (twelve months after time point one)

The remaining secondary outcome measure disturbance will be completed at 15 time points. (Any disturbed behaviour involving the service users will be taken from the ward untoward incident forms on a monthly basis from three months prior to the assessment till the six-month post intervention follow up).

Overall study start date
01/06/2012

Completion date
31/03/2013

Eligibility

Key inclusion criteria
The inclusion criterion for the clinicians will be that they are designated primary key workers for in-patients within the participating wards. Each service user whose key worker is participating in the study will be eligible to participate as long as the following inclusion criteria are met
1. They have a history of least 3 months of current in-patient treatment in the service and are capable of giving informed consent. Informed consent from both key workers and service users will be obtained before inclusion into the study.
2. Target Gender: Male & Female; Upper Age Limit 75 years ; Lower Age Limit 18 years

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 96; UK Sample Size: 96; Description: Participants will be recruited from six medium secure inpatient services with 48 in the intervention group and 48 in the control group.

Key exclusion criteria
1. The key workers or service users do not wish to participate in the study
2. Service users are required to have been in-patients in the unit for more than three months and able to give informed consent.

Date of first enrolment
01/06/2012

Date of final enrolment
31/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Trevor Gibbens Unit
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Sponsor information

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Sponsor type
University/education

ROR
https://ror.org/0489ggv38

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0609-19107

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	16/08/2013		Yes	No
Results article	results	29/09/2016		Yes	No