

An intervention to improve psychiatrist-patient communication

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| Submission date 30/11/2009 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 15/01/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 29/07/2016 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

The benefit of psychiatric treatment is strongly influenced by the quality of the relationship between the psychiatrist and the patient. This can be an even stronger effect than the effect of medication or other treatments. The quality of psychiatrist-patient communication also influences adherence to treatment. However, communication often breaks down in consultations with psychotic patients because their unusual experiences (e.g., hallucinations, delusions) lie outside of ordinary human experience. Until recently, there was a lack of evidence about good communication with such patients. In previous studies we have shown that effective psychiatrist communication with psychotic patients depends on how well psychiatrists try to understand the patient's psychotic experiences. Moreover, we have shown that this leads to a better patient outcome (i.e., higher patient satisfaction), a better therapeutic relationship and treatment adherence, and fewer relapses. We will use our findings to develop a new intervention to train psychiatrists in communicating with patients who experience hallucinations and delusions. The training package will be developed with and delivered in collaboration with service users and psychiatrists. Psychiatrists will learn specific communicative strategies to help them reach a shared understanding with their patients about psychotic symptoms. We will test the training package to assess feasibility and determine how we could conduct a larger study using these methods. We will identify whether psychiatrists can improve their communication skills through training, whether they can use these skills appropriately in consultations with psychotic patients, and whether this improves patient clinical outcomes.

Who can participate?

Higher/advanced psychiatric trainees and patients aged 18 - 65 with schizophrenia or schizoaffective disorder.

What does the study involve?

Psychiatrists are randomly allocated to one of two groups. One group undergoes the training programme and the other does not. The training programme consists of four training sessions taking place one week apart and lasting 4 hours each. During the training period, at least one consultation with a participating patient per psychiatrist is recorded for training purposes. These consultations are viewed and psychiatrists receive and discuss feedback in the training sessions. There are also follow-up sessions four and eight weeks after the fourth training session. At the

end of the training the next consultation between each participating psychiatrist and patient is recorded and assessed.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Newham Centre for Mental Health, East London NHS Foundation Trust and North East London NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2010 to March 2013

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

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

Study information

Scientific Title

Developing and piloting a new intervention to improve psychiatrist-patient communication about psychosis: an exploratory cluster-randomised controlled trial

Study objectives

We wish to address the following research questions:

1. Can psychiatrists learn to use a particular communicative mechanism (repair) to communicate more effectively with patients with psychosis?
2. Can they apply this new way of communicating with their patients?
3. Does it have an effect on the following intermediate outcomes: psychiatrist confidence in communicating with psychotic patients, patient experience of the communication and patient centredness in the first consultation with each relevant patient after the 12 week training period
4. Does it have an effect on the following patient clinical outcomes: patient satisfaction with treatment, the therapeutic relationship, treatment adherence and relapse at 6 months follow-up

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Exploratory cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Schizophrenia/schizoaffective disorder

Interventions

Psychiatrists will be randomised to the intervention group (training programme) or control group (no training programme).

Training programme:

The proposed training programme is as follows. Training will be provided by the lead applicant, a psychiatrist and a service user in interactive groups with a maximum of 6 psychiatrists per group. Small groups are to facilitate some one-to-one work with each psychiatrist on their own recorded consultations. There will be 4 training sessions lasting 4 hours each. They will take place one week apart. During the training period, at least one consultation with a participating patient per psychiatrist will be recorded for training purposes. These consultation(s) will be viewed and psychiatrists will receive and discuss feedback in the training sessions. Four weeks after training session 4, there will be one follow-up refresher/supervision session, followed by a final refresher session eight weeks after training session 4. The proposed training schedule is:

1. Training session 1 at baseline
2. Training session 2 after one week
3. Training session 3 after two weeks
4. Training session 4 after three weeks
5. Refresher session after 8 weeks
6. Refresher session after 12 weeks

At the end of the training, the next consultation between each participating psychiatrist and patient will be recorded and communicative behaviours assessed.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Psychiatrists use of repair will be assessed using the Repair Protocol, which is a standardised and validated measure.

Secondary outcome measures

Intermediate outcomes:

1. Psychiatrist confidence in communicating with psychotic patients
2. Patient experience of the communication
3. Patient centredness

Measured in the first consultation with each relevant patient after the 12 week training period

Final outcomes:

4. Patient satisfaction with treatment
5. Therapeutic relationship
6. Treatment adherence and relapse

Measured at 6 months follow-up

Overall study start date

01/03/2010

Completion date

01/03/2013

Eligibility

Key inclusion criteria**Psychiatrists:**

Higher/advanced psychiatric trainees (ST4-6) working in outpatients or community mental health teams. Doctors in higher psychiatric training (ST4-6) already have basic knowledge and experience in psychiatry gained through core psychiatric training. During higher training they practice without direct supervision and aim to further develop specific competencies including communication skills. Hence, they are at the formative stage of their training, preparing to take up a consultant role in a few years time. We will focus on trainees in this pilot trial, because the effectiveness of an intervention on changing their communicative practice may be higher at this stage of their professional development.

Patients:

1. ICD-10 criteria for a diagnosis of schizophrenia or schizoaffective disorder
2. Currently attending outpatients or being cared for by community mental health teams
3. Capable of giving informed consent
4. Aged 18 - 65 years, both females and males

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

84 (72 patients and 12 psychiatrists)

Key exclusion criteria**Patients:**

1. Organic impairment
2. Require an interpreter

Date of first enrolment

01/09/2011

Date of final enrolment

01/10/2012

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre
Newham Centre for Mental Health
London
United Kingdom
E13 8SP

Study participating centre
East London NHS Foundation Trust
London
United Kingdom
E1 8DE

Study participating centre
North East London NHS Foundation Trust
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Sponsor information

Organisation
Queen Mary University of London (UK)

Sponsor details
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5 Walden Street
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Sponsor type
University/education

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

ROR
<https://ror.org/026zzn846>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0408-16279)

Results and Publications

Publication and dissemination plan

Manuscript in press

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/12/2016 | | Yes | No |