ISRCTN02507940 https://doi.org/10.1186/ISRCTN02507940

REFOCUS Randomised Controlled Trial (RCT)

Submission date	Recruitment status	[X] Prospectively registered
06/10/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/11/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/01/2016	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Approximately 1 in 100 people will experience mental health problems at some point in their lives. Psychotic disorders are a generalised term that describes a range of serious mental health problems, in which the sufferer loses touch with reality. The two main symptoms of psychotic disorders are delusions (unshakable beliefs in something that is not true) and hallucinations (seeing or hearing something that does not exist). These problems can be very upsetting for the sufferer and may cause them to become so anxious that they find it hard to cope with day-to-day life. Helping people suffering from these illnesses is one of the most important parts of mental health care. The REFOCUS programme is a specially designed training course which aims to help promote individual recovery from psychotic disorders. The aim of this study is to test the effectiveness of the programme in treating people with psychotic illnesses in the community.

Who can participate?
Adults suffering from a psychotic disorder and are being treated as an outpatient, and staff working in community mental health care teams in South London and Maudsley NHS Foundation Trust (SLaM) and2gether Partnership NHS Foundation Trust in Gloucestershire.

What does the study involve?
Mental health care teams are randomly allocated to one of two groups. Those in the first group take part in the 12 month REFOCUS program. The program is made up of training to help patients to take a more active role in their recovery and training to improve understanding about the best way to work with individual patients, such as setting personalised goals, focusing on a patient's strengths to support recovery. Those in the second group continue as usual for the 12 months of the study. At the start of the study and then again after 12 months, staff complete a number of questionnaires to test their knowledge and attitudes towards patients with a mental illness. Patients (service users) also complete a number of questionnaires at the same times in order to test how well they feel their recovery is going and to assess their mental wellbeing.

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

Where is the study run from?
The study takes place in two Mental Health Trusts: South London and Maudsley NHS Foundation

Trust (SLaM) and2gether Partnership NHS Foundation Trust in Gloucestershire.
When is the study starting and how long is it expected to run for?
April 2011 to August 2013

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

Who is the main contact?
Dr Mike Slade

Contact information

Type(s)
Scientific

Contact name
Dr Mike Slade

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10/H0807/4

Study information

Scientific Title
REFOCUS: a cluster randomised controlled trial of recovery interventions within community based mental health teams

Acronym
REFOCUS RCT

Study objectives

The personal recovery (Questionnaire about the Process of Recovery [QPR] scores) of service users receiving care from the recovery intervention teams will be significantly higher than the QPR scores of service users receiving care from the standard care teams.

Please note, as of 09/08/2011 the intervention for this trial has been reduced from 18 months to 12 months. Updates can be found under this date in the relevant fields below.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East London REC 3, 22/02/2011, ref: 11/LO/0083

Study design
Cluster multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised 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
Psychosis

Interventions
The intervention teams will receive personal recovery intervention. The intervention comprises an 12-month (updated 09/08/2011; 18-month at time of registration) team-level pro-recovery intervention in addition to standard care. The intervention involves two components:
1. Recovery-promoting relationships
2. Pro-recovery working practices

The control teams will receive treatment as usual.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Questionnaire about the Process of Recovery (QPR), measured at baseline and 12 months post-baseline (updated 09/08/2011; 18 months at time of registration)

Secondary outcome measures
Staff-rated measures (updated 09/08/2011; 18 months post-baseline measurements at time of registration):
1. Recovery Knowledge Inventory (RKI) - a 20-item staff-rated measure of staff knowledge and attitudes about recovery, measured at baseline and 12 months post-baseline
2. Mental Illness: Clinicians' Attitudes (MICA) Scale - a 16-item of attitudes towards mental illness, measured at baseline and 12 months post-baseline
3. Health of the Nation Outcome Scale (HoNOS) is a 12-item staff-rated measure of social disability, measured at baseline and 12 months post-baseline
4. Camberwell Assessment of Needs Short Appraisal Schedule (CANSAS-S) assesses social and health needs over 22 domains, staff rated, measured at baseline and 12 months post-baseline
5. Mental Health Confidence Scale (MHCS) is a 16 item measure of self-efficacy, optimism, advocacy, measured at baseline and 12 months post-baseline
6. Herth Hope Index (HHI) is a 12-item service user-rated measure of client levels of hope, measured at baseline and 12 months post-baseline
7. Manchester Short Assessment of Quality of Life (MANSA) a 16-item measure, measured at baseline and 12 months post-baseline
8. Goal Attainment Scale (GAS)/Preferred Personal Outcomes(PPO) - individualised approach to measuring recovery, measured at baseline and 12 months post-baseline
9. Client Satisfaction Questionnaire8 (CSQ8) is an 8 item measure of client satisfaction with mental health services, measured at baseline and 12 months post-baseline
10. Camberwell Assessment of Needs Short Appraisal Schedule (CANSAS-SU) assesses social and health needs over 22 domains, service user rated, measured at baseline and 12 months post-baseline
11. The Importance of services in recovery - TEAM (INSPIRE-worker) is new measure of recovery orientation of services, measured at baseline and 12 months post-baseline
12. National Adult Reading Test (NART) is measure of pre-morbid level of intellectual functioning, measured at baseline and 12 months post-baseline
13. Brief Psychiatric Rating Scale (BPRS) is an 18-item observer-rated measure of symptomatology which is completed with the service user, measured at baseline and 12 months post-baseline
14. Client Service Receipt Inventory (CSRI) is a tool for collecting cost-related information about people with mental health problems for use in mental health service evaluations, measured at baseline and 12 months post-baseline
15. ICECAP-A - A measure of adult capability
16. The Global Assessment of Functioning (GAF) is a 3-item staff rated measure of impairment in functioning

Overall study start date
18/04/2011

Completion date
31/08/2013

Eligibility

Key inclusion criteria

Service user criteria:
1. Aged 16 - 65 years, either sex
2. Primary clinical diagnosis of psychosis, e.g. schizophrenia, schizo-affective disorder, bipolar disorder
3. Expectation that service user will be in contact with team for 18 months
4. Not currently receiving in-patient care
5. Speaks and understands English
6. In opinion of clinician, is sufficiently well to participate

Team inclusion criteria:
1. Community-based mental health team with the SLaM Psychosis Clinical Academic Group (CAG) or any in2gether
2. Provide a care co-ordinating function

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
420

Key exclusion criteria
1. Currently receiving in-patient care
2. Does not speak and/or understand English

Date of first enrolment
18/04/2011

Date of final enrolment
31/08/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Psychiatry at King's College London
London

United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (KCL)

Sponsor details
SLaM/IoP R&D Office
Institute of Psychiatry at King's College London
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Sponsor type
University/education

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

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR) programme (ref: 10/H0807/4)

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date

30/06/2014

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?
Protocol article	protocol	23/11/2011		Yes	No
Results article	results	29/05/2014		Yes	No
Results article	results	01/06/2015		Yes	No