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Feedback of OutCome to Users and Staff

Submission date	Recruitment status	[ ] Prospectively registered
07/01/2003	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/01/2003	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/12/2017	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G108/390

Study information

Scientific Title
Feedback of OutCome to Users and Staff

Acronym
FOCUS

Study objectives
The FOCUS Study will test three hypotheses:
1. Baseline level of patient-rated unmet need will predict follow-up level of quality of life
2. The routine collection and feedback of outcome information for seven months will lead to 1.0 fewer patient-rated unmet needs, as measured using Camberwell Assessment of Need Short Appraisal Schedule - Patient version (CANSAS-P)
3. The routine collection and feedback of outcome information for seven months will lead to an increase of 0.25 points in quality of life, as measured using the Manchester Short Assessment (MANSA)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Mental heath problems

Interventions
The measures that will be used for routine collection and feedback are:
1. The Manchester Short Assessment of Quality of Life (MANSA) (Priebe et al, 1999, see Abstract on PMID: 10443245)
2. The Camberwell Assessment of Need Short Appraisal Schedule (CANSAS) (Slade et al, 1999, The Camberwell Assessment of Need, London: Gaskell)

3. The Helping Alliance Scale (HAS) (Priebe & Gruyters, 1993, see Abstract on PMID: 8245923)
4. The Threshold Assessment Grid (TAG) (Slade et al, 2000, see Abstract on PMID: 10784370)

The staff-completed measures will be TAG, HAS-S and CANSAS-S. According to guidance notes, each completion should take 6 - 11 minutes. The patient-completed measures will be MANSA, HAS-P and CANSAS-P, and completion should take 8 - 13 minutes. The intention is that comparison of the HAS assessments will focus staff and patient on the process of care, comparison of CANSAS assessments will increase collaboration and negotiation, and feedback of the MANSA and TAG assessments will lead to an increased focus on desirable outcomes.

The intervention comprises asking staff and patients each to complete an outcome assessment form every month for six months, with identical feedback provided to both people every three months.

Staff and patients will be asked to complete monthly assessments and will receive three monthly feedback. The intervention will last six months, and follow-up assessments will be made one month later.

Evaluation:
Follow-up is at seven months. The routinely collected data will also be used to investigate the effectiveness of the intervention, supplemented by extra data collected at baseline and follow-up. All measures completed as part of the intervention will be assessed at baseline and follow-up, including the objective questions from MANSA and the qualitative questions from HAS. In addition, the Brief Psychiatric Rating Scale (BPRS) (Overall & Gorham: Psychopharmacol Bull 1988, 24:97-99) will be used to assess symptomatology and the Health of the Nation Outcome Scale (HoNOS) (Wing et al, 1998, see Abstract on PMID: 9534825) will be used to assess social disability in more detail than the ROA measures. To identify changes in the content of care, an assessment of the care actually received will be needed. This will be assessed using the Client Service Receipt Inventory (CSRI) (Beecham & Knapp, 1992 [Costing psychiatric interventions. In Measuring mental health needs edited by Thornicroft G, Brewin C, Wing J. London: Gaskell, 1992: 163-183]), which assesses services received over the last 6 months. Since there is emerging evidence of Intelligence Quotient (IQ) as a predictor of response to different service models (Hassiotis et al, 2001, see Abstract on PMID: 11157431), intellectual functioning will be measured at baseline using the National Adult Reading Test (NART) Second Edition (Nelson, 1982 [In National Adult Reading Test {NART}: Test Manual. Windsor: NFER-Nelson]).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Patient-rated unmet need, as measured using CANSAS-P
2. Quality of life, as measured using MANSA

Secondary outcome measures
1. Mental health problem severity
2. Symptoms
3. Social disability

Overall study start date
01/05/2000

Completion date
30/06/2005

Eligibility

Key inclusion criteria
Patients will be included who meet all three of the following criteria:
1. Patient is on the caseload of an adult mental team in Croydon on 1 May 2001
2. Patient has been on the caseload for at least three months
3. Patient is aged between 18 and 65 inclusive

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
Does not comply with above inclusion criteria

Date of first enrolment
01/05/2000

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Sponsor information

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Sponsor type
Research council

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Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/01/2002		Yes	No
Results article	results	01/10/2006		Yes	No