

An evaluation of Motivational (MI) plus Cognitive Therapy (CBT) for Schizophrenia and Substance Misuse

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| Submission date 29/08/2003 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 01/09/2003 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 03/08/2009 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G0200471

Study information

Scientific Title

Acronym

Motivational Interventions for Drug and Alcohol Use in Schizophrenia (MIDAS)

Study objectives

The aim of the study is to evaluate the benefits of the adjunct of a psychological treatment over standard available care for patients with schizophrenia and a co-morbid drug or alcohol problem.

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)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Mental and behavioural disorder

Interventions

The experimental treatment (MI plus CBT) will consist of motivational interviewing to increase motivation to reduce substance use; CBT for help with both substance use reduction and symptom management; and relapse prevention strategies. Patients randomised to receive MI plus CBT will be offered up to 26 sessions over 12 months with treatment being located at home or clinic according to the patient's choice. The MI plus CBT treatment will be in addition to standard psychiatric care. The control group will receive standard psychiatric care alone.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Either readmission to hospital for reason related to psychosis or death from any cause/not admitted to hospital in the 12 month post-treatment period.

Secondary outcome measures

Added as of 6 February 2007: Measures of symptomatology, relapses, substance misuse and health economic analyses.

Overall study start date

03/10/2004

Completion date

02/05/2009

Eligibility**Key inclusion criteria**

1. Diagnostic and Statistical Manual of Mental Disorders, Fourth edition (DSM IV) diagnostic criteria for schizophrenia, schizophreniform or schizoaffective disorder
2. Recorded contact and treatment from mental health services at the point of recruitment
3. Prescribed anti-psychotic medication
4. Alcohol use exceeding 28 units for males, 21 units for females on at least half the weeks in the previous 3 months
5. DSM IV diagnosis of drug and/or alcohol dependence or abuse
6. No significant history of organic factors implicated in the aetiology of psychotic symptoms
7. English speaking
8. Informed patient consent
9. Having a fixed abode

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

400

Key exclusion criteria

See inclusion criteria

Date of first enrolment

03/10/2004

Date of final enrolment

02/05/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Academic Division of Clinical Psychology

Manchester

United Kingdom

M23 9LT

Sponsor information

Organisation

University of Manchester (UK)

Sponsor details

Oxford Road

Manchester

England

United Kingdom

M13 9PL

+44 (0)161 306 6000

Sponsor type

University/education

Website

<http://www.manchester.ac.uk/>

ROR

<https://ror.org/027m9bs27>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 01/10/2009 | | Yes | No |