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Early Detection and Intervention Evaluation for individuals at high risk of psychosis 2

Submission date	**Recruitment status**
03/03/2008	No longer recruiting
Registration date	**Overall study status**
29/08/2008	Completed
Last Edited	**Condition category**
29/05/2012	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.psych-sci.manchester.ac.uk/edie2/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MRC ref: G0500264

Study information

Scientific Title
Early detection and psychological intervention for individuals at high risk of psychosis 2

Acronym
EDIE-2

Study objectives
The main hypothesis is that cognitive therapy (CT) will reduce or delay transition to psychosis in people who are at high risk of developing psychosis.

More details can be found at:
http://www.mrc.ac.uk/ResearchPortfolio/Grant/Record.htm?GrantRef=G0500264&CaseId=5270

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Eastern Multicentre Research Ethics Committee approved the study on 3rd October 2005 (ref: 05/MRE05/6)

Study design
Single-blind multicentre 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
Patient information can be found at: http://www.psych-sci.manchester.ac.uk/edie2/referral/leaflets/

Health condition(s) or problem(s) studied
Psychosis

Interventions
Cognitive therapy plus monitoring (Intervention group) vs monitoring alone (Control group).

Intervention group:
CT will be based on a specific cognitive model (French & Morrison, 2004). Cognitive therapy

allows an individualised approach within clear boundaries, and incorporates a process of assessment and formulation, which is manualised. The specific interventions are dependent on the individual formulation, but the range of permissible interventions is described in our published manual. Fidelity to the treatment protocol will be ensured by regular supervision of the therapists and assessed by rating tape recordings of sessions using a revised version of the Cognitive Therapy Scale (Dobson, Shaw, & Vallis, 1985). This is a widely-accepted approach to the standardisation of CT, which we have adopted in previous large-scale trials. Participants will receive up to 25 weekly one-hour sessions plus up to four booster sessions.

Control group:
The control condition is treatment as usual plus monitoring, which represents an enhancement over routine care since psychotic symptoms will be detected earlier than in usual practice and appropriate treatment referrals made (the reduction of duration of untreated psychosis is a national target for the NHS, and our control condition will achieve this). Monitoring will identify untreated psychosis and any risks to self or others that require immediate action. In addition, the monitoring group will also receive two standardised components of care: ensuring that the patient has a General Practitioner and encouraging regular contact with them (since several of our pilot study patients did not have a GP at intake); and development of a crisis card providing contact details for appropriate local sources of help in a psychiatric emergency. Monitoring will not include liaison with a clinical team, should one be involved, except where risk issues necessitate this. The use of enhanced standard care as a control has the advantages of (i) controlling at least in part for non-specific contact and (ii) ensuring that all trial participants derive some benefit from the trial (this expected benefit was included in the power calculations), therefore ensuring that it conforms to the highest ethical standards.

All participants will be monitored by a monthly assessment for the first six months and then every three months for up to two years total.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Comprehensive Assessment of At Risk Mental States (CAARMS) at baseline, every month from Months 1 to 6, then every three months from Month 9 to 24.

Secondary outcome measures
1. Structured Clinical Interview for DSM-IV at baseline, at transition to psychosis if it occurs (which may be any month), and at the end of participation in study
2. Beck Depression Inventory-FS at baseline, every months from Months 1 to 6, and then every three months from Month 9 to 24
3. Social Interaction and Anxiety Scale at baseline, every month from Months 1 to 6, then every three months from Month 9 to 24
4. EQ-5D at baseline, every months from Months 1 to 6, then every three months from Month 9 to 24
5. Manchester Short Assessment of Quality of Life at baseline, Months 6, 12, 18 and 24
6. Personal Beliefs about Illness Questionnaire at baseline, Months 6, 12, 18 and 24
7. Drug Check at baseline, Months 6, 12, 18 and 24
8. Beliefs About Paranoia Scale at Months 1 and 6

9. Persecution and Deservedness Scale at Months 1 and 6
10. Brief Core Schema Scales at Months 1 and 6
11. Metacognitions Questionnaire (short form) at Months 1 and 6
12. Interpretations of Voices Inventory at Months 1 and 6
13. California Psychotherapy Alliance Scales at Months 1 and 6

We are also recording prescriptions of psychiatric medications, including anti-psychotic medications. Timepoints of assessment: Baseline, every months from Months 1 to 6, then every three months from Month 9 to 24

Overall study start date
01/11/2006

Completion date
31/12/2009

Eligibility

Key inclusion criteria
Trial entry criteria will be assessed using the Comprehensive Assessment of At-Risk Mental States (CAARMS). Patents must satisfy one of the following to be eligible for inclusion into this study:
1. Brief limited intermittent psychotic symptoms (BLIPS) defined as a score of 6 on any positive item, with symptoms lasting less than one week and resolving without antipsychotic medication
2. Attenuated symptoms (AS), defined as the presence of positive symptoms that score 3-5 and have begun in the last year and which occur at least once per week in the last month
3. State-plus-trait group (SPT), operationally defined by the presence of an at-risk mental state (recent deterioration in function of 30 points or more on the Global Assessment of Functioning) plus either a family history indicated by a first degree relative with a history of any psychotic disorder or a diagnosis of schizotypal personality disorder in the participant

In addition, the patient must fulfil both of the following:
4. Age 14-35
5. Seeking help for symptoms (the latter criterion is necessary to ensure that the provision of treatment to the participants is ethical)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
320

Key exclusion criteria

1. Current or previous receipt of antipsychotic medication for more than two days
2. Moderate to severe learning disability
3. Organic impairment
4. Non-English speaking (since this would prevent the use of standardised assessment instruments)

Date of first enrolment
01/11/2006

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Psychological Sciences
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Sponsor type
University/education

Website

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

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (G0500264) (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

Funder Name
Department of Health (UK)

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	05/04/2012	Yes	No