

A Trial Platform of Enhanced care for Depression in Primary Care

Submission date

17/05/2004

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

14/07/2004

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

02/07/2009

Condition category

Mental and Behavioural Disorders

☐ 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

Protocol serial number

G0300677

Study information

Scientific Title

Study objectives

1. To design and refine a standardised ECD intervention protocol appropriate to the UK primary health care setting and acceptable to clinicians, practitioners and patients
2. To estimate contamination, clustering and effect size of the intervention within a pilot Phase II trial
3. To estimate trial recruitment rates through monitoring recruitment rates within the pilot Phase II trial
4. To examine the issue of treatment integrity and acceptability by monitoring the implementation of the ECD intervention protocol within a pilot Phase II trial and conducting qualitative stakeholder interviews

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Mental and Behavioural Disorders

Interventions

1. Enhanced care for depression
2. Usual care

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Clinical response (change from baseline Hamilton depression HAM-D score), 50% reduction in depressive symptoms

Key secondary outcome(s)

1. Quality of life (SF-12 & EQ-5D)
2. Health care utilisation (including GP visits, medication use, secondary care referrals)
3. Prescribing and adherence to medication measured against NICE guidelines (from individual patient records, filled prescriptions and patient self report)

Completion date

30/03/2006

Eligibility

Key inclusion criteria

Depression presenting in Primary Care

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Depression not as primary diagnosis; suicidal intent

Date of first enrolment

01/07/2004

Date of final enrolment

30/03/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Dept Health Sciences

York

United Kingdom

YO10 5DD

Sponsor information

Organisation

University of York (UK)

ROR

<https://ror.org/04m01e293>

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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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	01/07/2006		Yes	No
Results article	results	01/07/2009		Yes	No