ISRCTN63222059 https://doi.org/10.1186/ISRCTN63222059

A Trial Platform of Enhanced care for Depression in Primary Care

Submission date	Recruitment status
17/05/2004	No longer recruiting
Registration date	**Overall study status**
14/07/2004	Completed
Last Edited	**Condition category**
02/07/2009	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

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Not Specified

Participant information sheet

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

Secondary outcome measures
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)

Overall study start date
01/07/2004

Completion date
30/03/2006

Eligibility

Key inclusion criteria
Depression presenting in Primary Care

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
144

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
England

United Kingdom

Study participating centre
Dept Health Sciences
York
United Kingdom
YO10 5DD

Sponsor information

Organisation
University of York (UK)

Sponsor details
Prof Trevor Sheldon
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Sponsor type
University/education

Website
http://www.york.ac.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, 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	01/07/2006		Yes	No
Results article	results	01/07/2009		Yes	No