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

A Trial Platform of Enhanced care for Depression in Primary Care

Submission date
17/05/2004

Recruitment status
No longer recruiting

Registration date
14/07/2004

Overall study status
Completed

Last Edited
02/07/2009

Condition category
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

Contact name
Prof David Richards

Contact details
Dept Health Sciences
Seebohm Rowntree Building
University of York
University Road
Heslington
York
United Kingdom
YO10 5DD

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

Study design
Randomised controlled trial

Primary study design
Interventional

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, 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