

# A Trial Platform of Enhanced care for Depression in Primary Care

<b>Submission date</b> 17/05/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 14/07/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/07/2009	<b>Condition category</b> 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**  
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, 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?
<a href="#">Results article</a>	results	01/07/2006		Yes	No
<a href="#">Results article</a>	results	01/07/2009		Yes	No