

Debt counselling for depression in primary care

Submission date 17/04/2014	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered
Registration date 17/04/2014	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 02/06/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Depression and associated anxiety are common among patients seen in general practices. Many such patients also have debt and prolonged absence from work. There is increasing evidence of a relationship between indebtedness, depression and risk of self-harm and suicide. It is suggested that anti-depressants and talking therapies are cost-effective in the treatment of depression in general practices. Whilst indebtedness and poverty are common in society, particularly in areas of deprivation and high unemployment, the economic recession has worsened these problems. Whilst debt advice services are widely available, there is no robust evidence of their impact on mental health outcomes or their cost-effectiveness. There is a long history of welfare advice provided in primary care, particularly in areas of greatest economic need. However, debt advice is different from general welfare advice, and in the model we propose testing (that provided by the Citizens Advice Bureau - CAB) different from many of the commercially available offers of debt consolidation. Instead it focuses on assessing the level and urgency of debts and arrears and triaging to specific detailed advice on debt, or money management. We propose to test the impact of a shared assessment and management plan between GPs and CAB staff, linked to sessions of individual debt advice.

Who can participate?

Patients with depression (with and without additional anxiety) who also are worried about debt

What does the study involve?

People wishing to participate in the study are first screened to see if they are eligible to take part. If they are, they complete an initial assessment visit with a researcher in the participant's own home or at a venue of their choosing. After this, the participant is randomly allocated to either receive debt advice from the Citizens Advice Bureau (CAB) and a shared comprehensive assessment between a general practitioner (GP) and the CAB advisor, or to receive treatment as usual and a debt advice leaflet. Participants take part in two further assessment visits with a researcher one at 3 months after allocation and one at 12 months. A number of participants are also invited to take part in two interviews with a second researcher to explore the participants' experience of debt, its impact on their life and their experience of the intervention. A number of staff (GPs and CAB advisors) also take part in interviews 6-12 months after the start of their participation. The purpose of these interviews is to look at the intervention in more detail from the professionals' point of view.

What are the possible benefits and risks of participating?

It is hoped that the debt advice will aid recovery from depression. The likely main risk is that people may become distressed when talking about their current difficulties. Researchers will follow protocol guidance in such circumstances.

Where is the study run from?

The study will recruit from sites in England and Wales and will be managed from three centres: Liverpool University (lead University), Plymouth University and Swansea University. Participants will be recruited from general practices in Liverpool, Plymouth and Bridgend.

When is the study starting and how long is it expected to run for?

June 2014 to May 2016

Who is funding the study?

Health Technology Assessment Programme (UK)

Who is the main contact?

Dr Adele Ring

adeler@liverpool.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr Adele Ring

Contact details

Division of Public Health

Whelan Building

Quadrangle

Brownlow Hill

Liverpool

United Kingdom

L69 3GB

-

adeler@liverpool.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

16531; HTA 11/148/01

Study information

Scientific Title

Debt Counselling for Depression Randomised controlled trial

Acronym

DeCoDeR

Study objectives

To what extent does debt advice from Citizens Advice Bureau counsellors for patients with debt and depression, accessed through general practices, make a difference to patients' recovery from depression.

Ethics approval required

Old ethics approval format

Ethics approval(s)

14/NW/0230

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Topic: Mental Health, Primary Care; Subtopic: Depression, Not Assigned; Disease: Depression, All Diseases

Interventions

Patients are randomised to two groups:

1. GP treatment as usual (TAU) supplemented by a debt management advice leaflet (control)
2. GP treatment as usual supplemented by debt advice leaflet and primary care based CAB debt advice, including a shared GP/CAB Advisor comprehensive assessment (intervention)

Follow Up Length: 12 month(s)

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Depression, measured using the BDI-II score; Timepoint(s): baseline, 4 and 12 months

Secondary outcome measures

1. Explanatory measures; Timepoint(s): baseline and 4 months
2. Health and social care utilisation and employment factors; Timepoint(s): baseline, 4 and 12 months
3. Health-related QoL; Timepoint(s): baseline, 4 and 12 months
4. Life events; Timepoint(s): baseline and 4 months
5. Psychological wellbeing; Timepoint(s): baseline, 4 and 12 months
6. Service satisfaction; Timepoint(s): 4 months
7. Substance misuse; Timepoint(s): baseline, 4 and 12 months

Overall study start date

30/06/2014

Completion date

16/05/2016

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. Aged 18 or above
2. Scoring 14 or above on the BDI
3. Self-identifying as having worries about debt

Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 470; UK Sample Size: 470; Description: 390 if individual randomisation; 470 if cluster randomised

Key exclusion criteria

1. Housebound and/or unable to get to CAB advice sessions
2. Actively suicidal or psychotic and/or severely depressed and unresponsive to treatment
3. Unlikely to comply with the intervention or follow-up e.g. experiencing severe problems with addiction to alcohol or illicit drugs
4. Unable or unwilling to give written informed consent to participate in study
5. Currently participating in another research study including follow-up data collection phase
6. Has received CAB debt advice in the past 12 months

Date of first enrolment

30/06/2014

Date of final enrolment

16/05/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Liverpool

Liverpool

United Kingdom

L69 3GB

Sponsor information

Organisation

University of Liverpool (UK)

Sponsor details

Head of Division of Primary Care

Whelan Building

Quadrangle

Brownlow Hill

Liverpool

England

United Kingdom

L69 3BX

Sponsor type

University/education

ROR

<https://ror.org/04xs57h96>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

The report will be published in the Health Technology Assessment Journal.

Intention to publish date

09/06/2017

Individual participant data (IPD) sharing plan

Electronic records will be stored in a Structured Query Language (SQL) Server database, stored on a restricted access, secure server maintained by Plymouth University. The website will be encrypted using Secure Sockets Layer. Direct access to the trial data will be restricted to members of the research team and the CTU, with access granted to others on request. Access to the database will be overseen by

the CTU data manager and trial manager. Those interested in accessing the data should contact the corresponding author Dr Adele Ring (adeler@liverpool.ac.uk).

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No