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Patient-reported outcome measures (PROMs) in the assessment and follow-up monitoring of patients with depression in primary care

Submission date
21/08/2014

Recruitment status
No longer recruiting

Registration date
21/08/2014

Overall study status
Completed

Last Edited
03/04/2017

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
This study looks at whether giving personal feedback to people being treated for depression can help them get better more quickly. This is done through the use of patient-reported outcome measures (PROMs) which involve patients assessing their own symptoms, daily functioning, and quality of life and feeding back to the professionals involved in their care. This approach has not been researched in UK general practice yet. We want to find out whether patients, general practitioners, and practice nurses are willing to take part in such a study. It will test out whether PROMs, including questionnaires for symptoms of depression, daily functioning, quality of life, and problems particular to the individual patient, are acceptable to patients and to their general practitioners and practice nurses. If using PROMs is beneficial then their use is likely to be very cost-effective, and the benefits at a population level would be considerable given how common, disabling and long-lasting depression can be.

Who can participate?
Patients undergoing treatment for depression in each of eight participating general practices.

What does the study involve?
For patients:
Patients would be asked to see a researcher on three occasions over six months while they are having treatment for depression. Their treatment will be given by their doctor and/or nurse as usual, but they would be asked to fill out questionnaires and answer questions about their symptoms of depression, daily activities, quality of life, and any particular problems which they think may have caused their depression. Half the patients taking part will be chosen at random to be given the results of some of the questionnaires they complete (the PROMs), as will the doctors and nurses involved in their care. The other half of the patients taking part will not be asked to complete the PROMs for their doctor or nurse, but will still be asked to complete questionnaires and answer questions about their symptoms, activities, problems and quality of life, but these will be for the purpose of assessing differences between them and the patients completing the PROMs, and will be kept by the research team. In both patient groups all treatments within the patients general practices will be given by the doctors and nurses as usual

but in one group the results of the results of the PROMS may be taken into account when deciding whether to continue or change treatments. It is possible that patients may be asked to take part in a one-off half-hour interview about their experience in taking part in the study and using the PROMS.

For professionals:
Healthcare professionals would use PROMs with either all of their patients with depression, or with half of them, or with none of them (depending on their group allocation). Professionals will treat patients with depression as usual, but will be asked to encourage those patients randomly allocated to use PROMs to complete the measures within the first 10 days of diagnosis, and again 10 to 35 days later. Healthcare professionals will be encouraged to take the results of the PROMs into account in their management of the patient, as appropriate, using clinical judgement. It is possible that health professionals would also be asked to participate in a one-off half-hour interview about their experience in taking part in the study and in using the PROMs with some or all of their patients, if they are allocated at random to use them.

What are the possible benefits and risks of participating?
For patients:
It is not known whether a patients treatment may be improved through more adjustments, if they are in the group chosen at random to have the results of the PROMs fed back to them and their doctor or nurse. The effect will only be known after a larger study to test out this approach. The main disadvantage is that patients would need to give their time to being interviewed on three occasions over a six-month period with a study researcher, each interview taking around an hour to an hour and a half. Patients would be asked questions about their education, employment, past history of depression, symptoms of depression and anxiety, quality of life, personal life problems, work and home life, some of which patients might find sensitive or difficult to answer. However, patients would not be put under any pressure to answer questions they do not want to answer.
For professionals:
If professionals are in the group chosen to have some or all patients complete the PROMs then it is possible that the treatment of those patients may be improved due to making more adjustments to their treatment, but this cannot be guaranteed. The main disadvantage is that professionals would need to spend around 10 minutes longer in the consultations they have with participating patients if they are randomly allocated to filling out PROMs, but the cost of the extra time spent would be reimbursed.

Where is the study run from?
University of Southampton (UK)

When is the study starting and how long is it expected to run for?
October 2014 to November 2015

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17281

Study information

Scientific Title
Patient-reported outcome measures (PROMs) in the assessment and follow-up monitoring of patients with depression in primary care: a feasibility study

Acronym
PROMDEP

Study objectives
Is systematic assessment and follow-up monitoring of patients treated for depression using PROMs effective in terms of improved patient outcomes, and is it cost-effective?

The hypothesis is that more systematic assessment of patients using PROMs at diagnosis and follow-up will result in significantly better outcomes for patients, and be cost-effective at the level usually adopted for recommendation by NICE for use in the NHS.

The objectives of the feasibility study are to determine key elements of the best design for the main study, including whether to randomise individual patients to intervention or control arms within practices, or to allocate whole practices to intervention or control arms in a cluster randomisation design. We will select four practices at random to try out individual patient randomisation, and four to be cluster randomised.

Ethics approval required

Old ethics approval format

Ethics approval(s)
14/SC/1067; First MREC approval date 04/07/2014

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
See additional files

Health condition(s) or problem(s) studied
Topic: Mental Health, Primary Care; Subtopic: Depression, Mental Health, Primary care; Disease: Depression, All Diseases

Interventions
Eight practices will be randomised: four cluster-randomised practices and four practices with individually randomised patients. Two practices within the cluster-randomised arm will be intervention practices, and two will be control practices. The four cluster-randomised practices will recruit a total of 24 patients. The other four practices will individually randomise 24 patients.

All patients will be assessed at baseline, and have two follow-ups at 12 weeks and 26 weeks. Severity of symptoms, demographic details, self-reported duration of symptoms and anxiety symptoms will be collected at baseline. Depressive symptoms, social functioning and health-related quality of life will be measured in all patients at baseline, and at the 12-week and 26-week follow up. In addition, use of services, sickness absence, and patient satisfaction will be assessed at the 26-week follow-up.

Intervention: Three PROMs will be assessed:
PHQ-9; PSYCHLOPS; Distress Thermometer

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Primary outcomes as of 15/12/2016:
1. Depressive symptoms are measured using the Beck Depression Inventory (BDI)-II at baseline, 12 weeks, and 26 weeks
2. Health-related quality of life is measured using the EuroQoL five-dimension scale (EQ-5D-DL) at baseline, 12 weeks, and 26 weeks
3. Social functioning is measured using the Work and Social Adjustment Scale (WSAS) at baseline, 12 weeks, and 26 weeks

Original primary outcome:
Beck Depression Inventory (BDI)-II; Timepoint(s): 12 weeks and 26 weeks

Secondary outcome measures
Secondary outcomes as of 15/12/2016:
1. Anxiety symptoms are measured using the GAD-7 screening questionnaire at baseline
2. Participant characteristic data is assessed using a bespoke demographic questionnaire at baseline
3. Previous history and treatment received by participant is assessed using a bespoke duration and past history of depression questionnaire at baseline
4. Details of use of health services by participant is assessed using a bespoke Client Services Receipt Inventory (CSRI) questionnaire at 26 weeks
5. Absence from work by participant is assessed using a bespoke Sickness Absence Questionnaire at 26 weeks
6. Satisfaction with GP consultations for depression is assessed using the Medical Informant Satisfaction Scale (MISS) at 26 weeks

Original secondary outcome:
1. EQ-5D; Timepoint(s): 12 weeks and 26 weeks
2. Short Form (SF)-12; Timepoint(s): 12 weeks and 26 weeks
3. Work and Social Adjustment Scale (WSAS); Timepoint(s): 12 weeks and 26 weeks

Overall study start date
01/09/2014

Completion date
14/10/2016

Eligibility

Key inclusion criteria
Adults who are diagnosed with depression by their GPs

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

Planned Sample Size: 48; UK Sample Size: 48; Description: 24 in monitoring arm and 24 receiving usual care.

Key exclusion criteria
1. Patients with comorbid dementia, psychosis, or significant substance misuse, of a level that makes depression a secondary rather than primary diagnosis
2. Patients who are seriously suicidal and need urgent referral to secondary care

Date of first enrolment
01/10/2014

Date of final enrolment
28/02/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Primary Medical Group
Southampton
United Kingdom
SO16 5ST

Sponsor information

Organisation
University of Southampton (UK)

Sponsor details
Southampton Primary Care Academic Unit
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Sponsor type
University/education

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0613-31004

Results and Publications

Publication and dissemination plan
Planned publication in BMJ Open.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		13/12/2016	15/12/2016	No	No
Participant information sheet	version V1	27/10/2015	15/12/2016	No	Yes
Results article	results	30/03/2017		Yes	No
HRA research summary			28/06/2023	No	No