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Patient-reported outcome measures for monitoring primary care patients with depression: PROMDEP randomised controlled trial

Submission date
01/10/2018

Recruitment status
No longer recruiting

Registration date
01/10/2018

Overall study status
Completed

Last Edited
03/04/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The researchers want to look at whether giving personal feedback to people being treated for depression might help them get better more quickly. One way of doing this is by using patient reported outcome measures (or 'PROMs') which involve patients filling out questionnaires to record their symptoms of depression and feeding back the questionnaire results to the health professionals looking after them, at follow-up appointments. Some benefit for patients from reduced depression has been shown to result from monitoring their progress with PROMs, at least in specialist psychological therapy and mental health settings. In a previous study in general practices in southern England between 2014 and 2016, lower levels of depression symptoms were found at 12 weeks follow-up among patients who used PROMs at follow-up assessment, suggesting that completing them may improve the outcome of depression treatment for patients. However, this approach has not yet been researched properly in UK general practices. General practice is the setting in which most people with depression are treated in the UK, so it's important to test whether PROMs can be helpful in that setting.

Who can participate?
Adult patients of participating general practices with new episodes of depression

What does the study involve?
Participating general practices are randomly allocated to either the intervention group or the control group. In the intervention practices the Patient Health Questionnaire (PHQ-9) is used as a patient-reported outcome measure for patients to use to be able to present their symptoms in a systematic way. The PHQ-9 is a symptom questionnaire that is acceptable to GPs and identified as useful by them. Engaging and instructive training materials are provided for GPs using PROMs, indicating specific actions to be taken following patient assessment informed by the PHQ-9 result. Written feedback on PHQ-9 results is also provided for patients, listing possible

treatment options for them to discuss with their GPs. In the control practices GPs refrain from using patient symptom questionnaires for the duration of the study, so that care informed by patient reported outcome measures can be compared against usual care.

What are the possible benefits and risks of participating?
The possible benefit to patients in the intervention group is improved assessment and treatment of their depression. There are no side effects from using questionnaires as patient-reported outcome measures.

Where is the study run from?
1. University of Southampton (lead centre) (UK)
2. University College London (UK)
3. University of Liverpool (UK)

When is the study starting and how long is it expected to run for?
November 2018 to Sepetember 2022

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (UK)

Who is the main contact?
Rachel Dewar-Haggart
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
250225

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 39486, IRAS 250225

Study information

Scientific Title
Patient-reported outcome measures for monitoring primary care patients with depression: PROMDEP randomised controlled trial

Acronym
PROMDEP

Study objectives
The study will look at whether giving personal feedback to people being treated for depression might help them get better more quickly. This will be done by using patient reported outcome measures ('PROMs') which involve patients completing questionnaires to record their symptoms of depression and feeding back these results to the practitioners looking after them.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland REC 5, 21/09/2018, ref: 18/WS/0144

Study design
Randomized; Both; Design type: Process of Care, Active Monitoring, Qualitative

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression

Interventions
Design: Parallel group cluster randomised trial with 1:1 allocation to intervention and control.

Intervention: Administration of PHQ-9 soon after diagnosis, and at follow-up 10-35 days later. GP reflective motivation and psychological capability will be targeted with guidance on assessment and treatment, informed by NICE guidelines. GPs will be trained in interpreting scores, along with asking open-ended questions and exploring the patient's life context, and asked to take them into account in their treatment decisions. Patients will be given written

feedback on their scores and suggested treatments to discuss with GPs. Control practice patients will not complete the PHQ-9. They will complete research outcome measures but not be given feedback on the results.

Sample size: Assuming baseline mean BDI-II 24.0; SD 10.0 (from feasibility RCT); follow-up mean of 14.0 at 12 weeks in intervention group, 17.0 in controls (difference 3.0 = effect size of 0.3 and MCID of 17.5% of control group score); mean 6 patients per practice; ICC 0.03; 5% significance; 90% power; needs 235 patients analysed per group. Cluster design effect 1.15; assuming 20% loss to follow-up gives 235x1.15x2/0.8 =676 total, from 113 practices across three centres.

Randomisation: by Clinical Trial Unit statistician with computerised sequence generation.

Blinding: of practitioners and patients is impossible given the nature of the intervention. Self-report outcome measures will prevent researcher rating bias.

Analysis: Differences at 12 and 26 weeks between intervention and controls in depression, social functioning and quality of life will be analysed using linear mixed models, adjusted for sociodemographics, baseline depression, anxiety, and clustering, including practice as a random effect. Patient satisfaction, quality of life (QALYs) and costs over 26 weeks will be compared between arms.

Qualitative process analysis: Interviews with 15-20 GP/NPs and 15-20 patients per arm to reflect on trial results and implementation issues, using Normalization Process Theory as a framework for the interview schedules and qualitative analyses. Practitioner/patient dyads to be interviewed as soon as possible after patient assessments at follow-up consultations, to explore recall of practitioner-patient discussion of scores and identify variations in the use of the PHQ-9.

(added 14/07/2022)
The sample size assumptions were monitored by the Independent Data Monitoring Committee. A check in April 2022 suggested that based on the original sample size assumptions but allowing for the correlation between baseline and follow up values for the primary outcome of 0.60, a sample size of 473 would be required. Therefore, the study team and IDMC were confident that the recruited sample size of 529 would be sufficient to meet the trial objectives, assuming the target follow up rate of 80% was achieved.

Intervention Type
Other

Primary outcome(s)
Symptoms of depression measured using the Beck Depression Inventory second edition BDI-II (36) at baseline and 12 weeks

Key secondary outcome(s))
1. Symptoms of depression measured on the Beck Depression Inventory second edition BDI-II at 26 weeks
2. Social functioning measured using the Work & Social Adjustment Scale at baseline, 12 weeks and 26 weeks
3. Quality of life measured using the EuroQol 5-item 5-level (EQ-5D) questionnaire at baseline, 12 weeks, and 26 weeks
4. Costs of consultations, drug treatments and referrals for depression over the six months trial period, measured using a patient questionnaire (modified Client Services Receipt Inventory)

combined with a medical notes review at 26 weeks
5. Patient satisfaction measured using a modified version of the Medical Informant Satisfaction Scale at 26 weeks

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1, Adult patients seen in participating general practices within the last two weeks and assigned Read computerised medical record codes by GPs or nurse practitioners (NPs) for new presentations with diagnoses or symptoms of depression
2. There will be no upper age limit, and no exclusion of patients with coexisting physical health problems

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
529

Key exclusion criteria
1. Patients will be excluded if they are already being treated for depression, or if they have comorbid dementia, psychosis, or substance misuse (as a main problem)
2. Patients will also be excluded if they have significant suicidal thoughts requiring possible urgent referral to specialist mental health care

Date of first enrolment
01/12/2018

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Southampton (lead centre)
Primary Care and Population Sciences
Faculty of Medicine
Aldermoor Health Centre
Southampton
United Kingdom
SO16 5ST

Study participating centre
University College London
Division of Psychiatry
Faculty of Brain Sciences
Gower St
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United Kingdom
WC1E 6BT

Study participating centre
University of Liverpool
Institute of Psychology Health and Society
Brownlow Hill
Liverpool
United Kingdom
L69 7ZX

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: 17/42/02

Results and Publications

Individual participant data (IPD) sharing plan
The anonymised quantitative datasets (but not the qualitative interview data) generated during the current study will be available upon request from Prof. Tony Kendrick (ark1@soton.ac.uk), from 31/10/2022, on request, depending on the types of analyses planned and submission of a peer-reviewed, funded, and ethically approved proposal.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2024	03/04/2024	Yes	No
Protocol article	protocol	29/05/2020	01/06/2020	Yes	No
Participant information sheet	version v1.2	07/09/2018	01/10/2018	No	Yes
Protocol file	version 1.8	10/06/2021	15/06/2021	No	No
Protocol file	version 1.9	04/11/2021	21/04/2022	No	No
Statistical Analysis Plan	version 1	06/07/2021	27/09/2022	No	No