

Depression screening using patient-targeted feedback in general practices: study protocol of the German multicentre GET.FEEDBACK.GP randomised controlled trial

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ABSTRACT

Introduction Approximately one out of six patients in primary care suffers from depression, which often remains undetected. Evidence regarding the efficacy of depression screening in primary care, however, is inconsistent. A previous single-centre randomised controlled trial (RCT) in cardiac patients, the DEPSCREEN-INFO trial, provided the first evidence that written feedback to patients following a positive depression screening reduces depression severity and leads to more comprehensive patient engagement in mental healthcare. To amplify these effects, the feedback should be tailored according to patients' needs and preferences. The GET.FEEDBACK.GP RCT will test the efficacy of this patient-targeted feedback intervention in primary care.

Methods and analysis The multicentre three-arm GET.FEEDBACK.GP RCT aims to recruit a total of 1074 primary care patients from North, East and South Germany. Patients will be screened for depression using the Patient Health Questionnaire-9 (PHQ-9). In the case of a positive depression screening result (PHQ-9 score ≥ 10), the participant will be randomised into one of three groups to either receive (a) patient-targeted and general practitioner (GP)-targeted feedback regarding the depression screening results, (b) only GP-targeted feedback or (c) no feedback. Patients will be followed over a period of 12 months. The primary outcome is depression severity (PHQ-9) 6 months after screening. Secondary outcomes include patient engagement in mental healthcare, professional depression care and cost-effectiveness. According to a statistical analysis plan, the primary endpoint of all randomised patients will be analysed regarding the intention-to-treat principle.

Ethics and dissemination The Ethics Committee of the Hamburg Medical Association approved the study. A clinical trial company will ensure data safety, monitoring and supervision. The multicentre GET.FEEDBACK.GP RCT is the first trial in primary care that tests the efficacy of a patient-targeted feedback intervention as an adjunct

Strengths and limitations of this study

- GET.FEEDBACK.GP is an extension of the DEPSCREEN-INFO trial, which indicated that providing direct feedback to patients after depression screening reduces depression severity in cardiac patients.
- GET.FEEDBACK.GP is the first multicentre three-arm randomised controlled trial to test the efficacy of patient-targeted feedback as an adjunct to depression screening in primary care.
- The novel feedback intervention is open-source, developed for busy primary care settings and adapted to general practitioners' and patients' needs and preferences.
- As depression screening is feasible for primary care, no feasibility study for the feedback intervention was conducted.
- As GET.FEEDBACK.GP is not cluster-randomised, carry-over effects between patient groups cannot be definitely ruled out, and these effects could result in a conservative bias in favour of the null hypothesis.

to depression screening. Its results have the potential to influence future depression guidelines and will be disseminated in scientific as well as patient-friendly language.

Trial registration number NCT03988985.

INTRODUCTION

Major depression is one of the most disabling disorders worldwide and affects one out of ten individuals over their lifetime.^{1,2} However, major depression is under-recognised, diagnosed incorrectly and thus often remains untreated.^{3,4} In turn, undetected depression



increases the likelihood of a chronic course, treatment resistance, rising healthcare costs and, most importantly, increased disease burden.^{5–7} Standardised depression screening could be one solution for the early detection of increased depression severity.⁸ Its efficacy, however, is unclear, and international depression screening guidelines are inconsistent.^{9,10}

To date, interventional research has neglected to directly address patients within the depression screening process. However, involving patients as active partners in the screening process could support depression care and thus improve clinical outcomes.^{16,11} The DEPSCREEN-INFO randomised controlled trial (RCT) showed that patient-targeted feedback after depression screening can increase patient engagement and reduce depression severity.¹² Such patient-targeted feedback interventions provide a valuable framework for addressing the patient as an active partner in depression care.¹³ The rationale is that providing feedback (with respect to depression status and recommendations) will induce favourable behavioural changes (ie, active treatment seeking, increased involvement with depression, improved coping) and will lead to improved outcomes (ie, decreased depression severity).¹² The DEPSCREEN-INFO trial was conducted with cardiac patients. As major depression affects one out of six patients in primary care, feedback intervention could also have great potential for general practice.¹⁴ Therefore, the GET.FEEDBACK.GP multicentre RCT aims to test the efficacy of a patient-targeted feedback intervention as an adjunct to depression screening in primary care patients. Regarding the detection of depression, general practitioners (GPs) hold the key position in most healthcare systems: most cases are diagnosed in primary care and most antidepressants are prescribed by GPs.⁸ Despite the fact that evidence-based treatments are available, few patients receive guideline-based depression care, which could be due to low detection rates in primary care.^{14,15} Whereas research has focused on establishing effective treatments for depression, the process of a valid diagnosis and an effective referral process has been fairly neglected.⁸ Meta-analyses and systematic reviews also conclude that there appears to be insufficient evidence that depression screening alone improves clinical outcomes.^{11,16} The GET.FEEDBACK.GP multicentre RCT fills in this research gap by testing a novel patient-targeted feedback intervention that aims to increase patient participation and engagement in mental healthcare.

Trial objectives

The multicentre GET.FEEDBACK.GP RCT primarily aims to determine the efficacy of a widely available feedback intervention after depression screening to reduce depression severity. The primary hypothesis is that patient-targeted feedback leads to a greater reduction in depression severity 6 months after depression screening compared with GP-targeted feedback only or no feedback. The secondary hypotheses are that patient-targeted feedback is cost-effective and will increase patient

engagement in mental healthcare as well as professional depression care according to German guideline recommendations compared with GP-targeted feedback only or no feedback.

METHODS AND ANALYSIS

Design and procedures

The GET.FEEDBACK.GP trial is a multicentre, three-arm, observer-blinded, RCT that is conducted under real-world clinical conditions in primary care practices across North (Hamburg), East (Jena) and South (Heidelberg, Munich, Tübingen) Germany. All eligible patients will undergo a depression screening with the Patient Health Questionnaire-9 (PHQ-9). Thereafter, patients with suspected depressive disorder (PHQ-9 ≥ 10 points) will be randomised into one of the following three balanced study arms: (1) no feedback (screening only), (2) GP-targeted feedback only or (3) GP-targeted feedback and patient-targeted feedback. The GP-targeted feedback and patient-targeted feedback study arm is the intervention group. The GP-targeted feedback only study arm serves as the active control condition, and the no feedback study arm is the control condition. The study design reflects the fact that the GET.FEEDBACK.GP trial is an interventional feedback study and not a depression screening trial: the comparison between the GP-targeted and patient-targeted feedback study arm and the GP-targeted feedback study arm isolates the potential effect of patient-targeted feedback. The comparison between the GP-targeted feedback study arm and the no feedback study arm tests the potential effect of providing feedback to GPs. The design of this trial therefore separates the effect of feedback after depression screening from depression screening without feedback.

The GET.FEEDBACK.GP trial is expected to show the superiority of the GP-targeted feedback and patient-targeted feedback arm compared with the no feedback and GP-targeted feedback only arms regarding the primary endpoint. The primary hypothesis is that patient-targeted feedback combined with GP-targeted feedback leads to a lower depression severity 6 months after depression screening than both GP-targeted feedback only and no feedback at all. Based on the previous single-centre DEPSCREEN-INFO trial, we expect a small effect of the patient-targeted feedback and GP-targeted feedback intervention compared with both other study arms. To detect the underlying effect size through an F-test with a significance level of $\alpha=0.05$, a power of $1-\beta=0.8$ and group effects (standardised mean difference) of 0 and 0.25, a sample size of $n=233$ is needed in each group (balanced design). This adds up to a total sample size of $n=699$ (computations were conducted with PASS 2008).

Study sample and recruitment

At each of the five sites, general practices will be selected randomly from all available local GPs in the specific region of each site. General practices providing psychotherapy

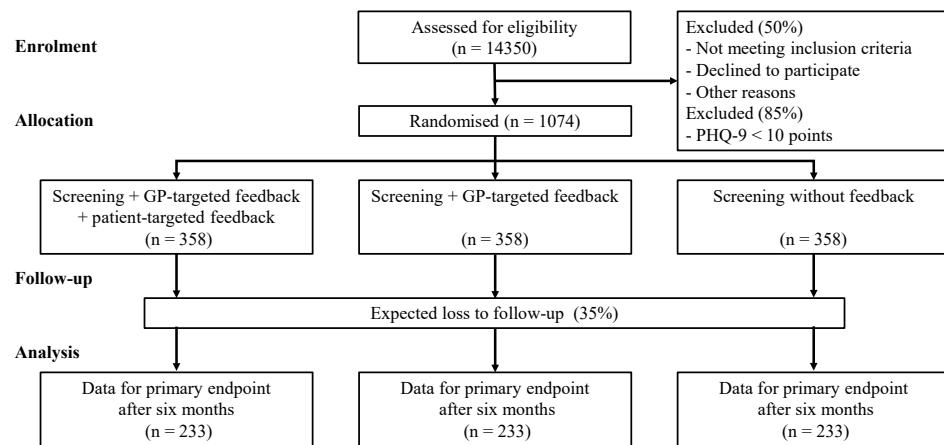


Figure 1 Flow chart of the multicentre GET.FEEDBACK.GP randomised controlled trial according to the Consolidated Standards of Reporting Trials statement. GP, general practitioner; PHQ-9, Patient HealthQuestionnaire-9.

will not be eligible for the trial. Practices will be invited to participate and recruit patients. The aim is to recruit 10 practices at each site. Patients presenting at general practices will be contacted by a study nurse to determine their eligibility. Patients will be invited to participate if they meet the following inclusion criteria: personal contact with the GP, 18 years old or older, proficient in German language and provide informed consent (translation of the consent form, see online supplemental file 1). Individuals who have been diagnosed with and/or treated for depressive disorder will be excluded, as will individuals presenting with acute suicidality (measured by the item ‘Having thoughts that you would be better off dead or of hurting yourself nearly every day’). Finally, patients will be included and randomised into the study if they score 10 points or greater on the PHQ-9.

According to primary care studies on depression, we estimate that 15% of patients in primary care suffer from increased depression severity. Furthermore, we assume that 50% of patients in the waiting room will either not be eligible or will decline participation. Regarding loss to follow-up, we expect 35% of patients to drop out 6 months after randomisation. To obtain a total sample size of 699 patients for the primary analysis, we estimate that we will have to contact 14 350 patients. The flow chart is depicted in figure 1. Since July 2019, recruitment has been ongoing.

Randomisation and blinding

A random sequence will be electronically created and not accessible by study nurses, GPs or any other study team member at any given point. The random sequence will be computed by an independent researcher of the Department of Biostatistics and Epidemiology who is not involved in the study. Allocation is concealed by giving a sealed envelope to every patient who consents to participate. The contents of each sealed envelope (feedback vs no feedback) will depend on the study arm. Similarly, all participating GPs will receive envelopes for patients who gave informed consent. All envelopes will be opaque and sealed. An identifying number based on the randomising

sequence will be printed on every envelope to ensure that envelopes contain the correct information. To further ensure the quality of the delivery, study nurses will be randomly advised to draw and check the content of envelopes.

Study nurses will hand out envelopes to all participating patients and GPs. Depending on the study arm, the envelopes either contain feedback (GP, patients), only a thank-you note (patient), or a note of participation (GP). This will allow study nurses and all participating GPs to be blinded to the inclusion of patients and the study arm. Patients will be stratified by depression severity (moderate: PHQ-9 $\geq 10\text{--}14$ points; severe: PHQ-9 ≥ 15 points). The study will not be cluster-randomised, as within every single GP’s office, each of the three conditions is realised, thus enabling an individual randomisation of patients. The GET.FEEDBACK.GP intervention may increase the general awareness of depression by the GP, but this would affect all three patient groups. A cluster-randomised trial would probably increase awareness specifically in the GP-targeted feedback arm, which may increase the risk of bias. The method of randomisation used for the GET.FEEDBACK.GP trial was previously used in the DEPSCREEN-INFO RCT, where carry-over effects between patient groups were not observed. Nevertheless, even if carry-over effects should occur, they would influence the study results in the sense of a conservative bias towards the null hypothesis. In this respect, significant study results would be a strong indication of the efficacy of the intervention.

Study arms

All eligible patients will fill in the PHQ-9 depression screening questionnaire. Patients who score 10 points or above will be randomised into one of the study arms described later. Independent of the study arm, all patients will receive an envelope containing a thank-you note.



No feedback

This study arm serves as a passive control condition. Neither patients nor GPs will receive the screening results via standardised feedback.

GP feedback

Patients in this study arm will not receive feedback regarding the screening result. The GP will receive a sealed envelope with standardised feedback. The feedback contains the screening result and a recommendation to conduct further diagnostics regarding depressive disorder. The development of the GP feedback is based on the feedback that was tested in the DEPSCREEN-INFO trial (see online supplemental file 2). In a qualitative study with GPs, we further developed the feedback to reflect the preferences of GPs. Additionally, we modified the feedback to fulfil the clinical needs of busy primary care settings (see online supplemental file 3).

GP and patient feedback

In this study arm, GPs will receive the same feedback as mentioned earlier for every case. Additionally, patients will receive patient-targeted feedback. The feedback will contain the screening result, guideline-based recommendations regarding depression care, further contact information for local mental healthcare and some brief general information about depression. Based on the feedback form from the DEPSCREEN-INFO trial (see online supplemental file 2), we further developed patient-targeted feedback. To foster patient participation, we conducted several focus groups with patients who were diagnosed with depressive disorder. Within three patient workshops, updated feedback was conceptualised, developed and re-evaluated. The aim was to develop patient-targeted feedback that addresses patients' needs

and preferences. Based on the results of this qualitative study, the patient-targeted feedback of GET.FEEBDACK. GP addresses content-related needs about feedback (eg, no distinction between severe and moderate symptoms), recommendations for action and patient-relevant information (see figure 2). The details of this qualitative study are described elsewhere.¹⁷

Measures

Baseline data will be collected in the GP practice by a study nurse, whereby the endpoints for the 1-month, 6-month and 12-month follow-ups will be collected via telephone interviews. The assessors (MD; BSc or MSc Psychology) will be trained before conducting interviews. Table 1 depicts the assessment points and the assessment instruments.

Sociodemographic data and depression risk factors

This assessment will include typical data such as age, gender and education, as well as factors that are related to depression care, such as rural/urban area living, living situation, migration background and health insurance status (private vs state). Furthermore, established risk factors for depression will be assessed (ie, somatic and psychological comorbidities, alcohol and nicotine abuse, pregnancy, etc).

Primary outcome

The PHQ-9 is among the most frequently used and best validated self-report depression questionnaires.^{18–20} It is one of the tools recommended for depression screening by the US Preventive Services Task Force and the German National Clinical Practice Guideline for Unipolar Depression.^{9 10} The PHQ-9 assesses the clinical symptoms of depressive disorder in the past 2 weeks

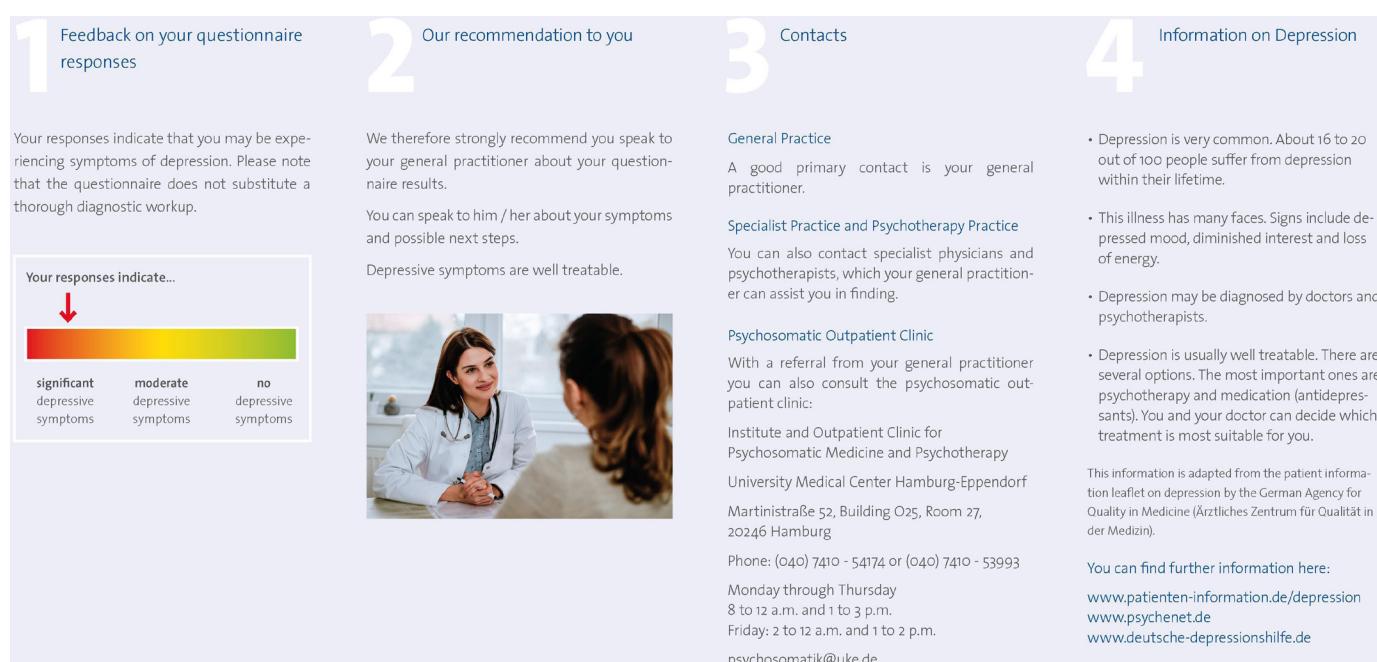


Figure 2 Patient-targeted feedback (the image was purchased from iStock).

Table 1 Assessment points and study endpoints

Instruments	Measurement			
	Baseline	1-month follow-up	6-month follow-up	12-month follow-up
Primary endpoint				
Depression severity (PHQ-9)	x	x	x*	x
Secondary endpoints				
Clinical scales (anxiety severity, GAD-7; somatic symptom severity, SSS-8; quality of life, EQ-5D)	x	x	x	x
Patient knowledge and behaviour with respect to guideline recommendations (eg, adherence, coping, search for information)			x	x
Healthcare use (eg, doctor consultations, medication) (CSSRI)			x	x
Structured diagnostic interview (MINI)		x	x	x
Patient activation (PAM-13D)			x	
Satisfaction and acceptance of screening and feedback (USE)			x	
Social Support (LSNS)			x	
Open questions (eg, positive and negative life events, coping response)				x
Demographic information	x			

*Primary endpoint.

CSSRI, Client Sociodemographic and Service Receipt Inventory; EQ-5D, EuroQol-5D; GAD-7, Generalised Anxiety Disorder-7; LSNS, Lubben Social Network Scale; MINI, Mini-International Neuropsychiatric Interview; PAM-13D, Patient Activation Measure-13; PHQ-9, Patient Health Questionnaire-9; SSS-8, Somatic Symptom Scale-8; USE, Usefulness scale for patient information material.

and directly implements the diagnostic criteria for major depressive disorder according to the Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV and DSM-5. The questionnaire has high sensitivity and specificity, is sensitive to change and is responsive to treatment.²⁰ On these grounds, the PHQ-9 was also used as a depression screening and outcome measure in the previous DEPSCREEN-INFO trial and was well accepted by patients and physicians.¹² Given that the DEPSCREEN-INFO trial indicated that a 1-month follow-up may be too short to reflect all effects of the feedback intervention, the primary outcome for this study is depression severity after 6 months.

Secondary outcomes

One of the secondary hypotheses is that GP feedback and patient-targeted feedback are cost-effective. To assess *healthcare use*, a modified version of the Client Sociodemographic and Service Receipt Inventory will be used.²¹ To calculate costs from the societal perspective, unit costs for the monetary valuation of resources will be applied. Cost-effectiveness from the societal perspective will be determined based on direct/indirect costs and quality-adjusted life-years (QALYs). To derive direct/indirect costs, healthcare utilisation and productivity loss during 6 months of follow-up will be assessed using specific German unit costs and gross wages, and intervention costs will be calculated

using accounting principles. QALYs will be calculated based on preference-based utilities derived from the EuroQol-5D (EQ-5D). The EQ-5D index will also be used to estimate *health-related quality of life*.²²

To assess the potential consequences of the feedback, *depression care* as recommended by the German National Clinical Practice Guideline for Unipolar Depression will be assessed via a structured interview that is based on the German National Clinical Practice Guideline for Unipolar Depression.¹⁰ This interview been successfully tested in the DEPSCREEN-INFO trial. The Mini-International Neuropsychiatric Interview, a short structured clinical interview, will be conducted to validate the *diagnosis of depression* according to DSM-5 criteria.^{23,24} The overlap of somatic, anxious and depressive syndromes is frequent and is associated with further impairments.²⁵ Therefore, the Somatic Symptom Scale-8 will be used to measure *somatic symptom severity*, and the well-validated Generalized Anxiety Disorder Scale (GAD-7) will be used to measure *anxiety severity*.^{26–28} Another secondary hypothesis is that the feedback will increase patient engagement. Therefore, the Patient Activation Measure-13D (PAM-13D) will be used to assess *patients' engagement in healthcare*.²⁹ With respect to potential dissemination, *satisfaction and acceptance* regarding patient feedback will be assessed using the Usefulness Scale for Patient Information Material.³⁰ *Social*



support will be assessed with the Lubben Social Network Scale.³¹ To offer explanations for the observed quantitative findings and to improve the validity of the conclusions regarding the utility of the feedback intervention, we will ask three open questions: "Within the last year, ... (1) Did you experience life events that positively influenced your mood? (2) Did you experience life events that negatively influenced your mood? (3) What has been particularly helpful to you in times when you have been feeling bad?"

Data management

Data management will be based on electronic and paper-pencil assessments in accordance with state-of-the-art data security approaches and German law. A full-service clinical research organisation (Clinical Trials Centre (CTC) NORTH, Hamburg, Germany) configured the electronic data capture system and database (secuTrial ; interActive Systems (iAS) GmbH, Berlin, Germany) that will be used in the study. CTC North provides user management for the study, including the administration of user rights such as who can view data, enter data and change data. CTC North supports the validation of the data by performing plausibility checks to find potential errors. Data safety is ensured through standardised entry guidelines and staff training as well as regular server updates and backups. In accordance with the ethics approval and the German Research Foundation guidelines for the handling of research data, deidentified data will be made publicly available. The times and conditions under which the data will be made available will also be in accordance with the 'Recommendations for Sharing Clinical Trial Data' of the Institute of Medicine. The full data package (ie, analysable data set, protocol, statistical analysis plan and statistical programming code) will be saved for at least 10 years. The data will be made available in a data repository. Data sharing will follow the FAIR Data Principles (Findable, Accessible, Interoperable and Reusable) and international naming conventions (eg, Systematized Nomenclature of Medicine) to maximise transparency and scientific reproducibility. The data management plan will (1) ensure long-term accessibility, (2) deliver a comprehensive, reliable view of data and (3) provide a future-proof solution for international healthcare interoperability. According to the WHO Statement on Public Disclosure of Clinical Trials, the main findings will be submitted for publication in a peer-reviewed journal with an open-access mechanism within 12 months of study completion and will be made publicly available in the clinical trial registry.

Analysis

The final analysis of the primary endpoint (depression severity after 6 months) will take place after the database has been reviewed for completeness and accuracy and is locked by the Steering Committee. No interim analysis is planned. The results will be reported according to the Consolidated Standards of Reporting Trials 2010 guidelines.³²

The two-tailed level of statistical significance is 5%. Because of the closed testing principle, the pairwise comparisons of the three groups do not have to be adjusted for multiplicity if the overall test yields a significant result. Accordingly, all applicable statistical tests will be two-sided and will be performed using a 5% significance level. Analyses of secondary outcomes will be performed without adjustment for multiplicity. All two-sided 95% CIs will be presented.

The primary outcome of all randomised patients will be analysed in accordance with the intention-to-treat principle. According to the memorandum of the German Research Foundation regarding good clinical practice, all study results will be documented and published. The primary outcome will be the change in depression severity (measured by the PHQ-9) between baseline and 6 months after screening. The primary outcome will be analysed via a mixed effects model including random effects for patients and GP practices nested in centres and fixed factors for group and depression severity. The baseline comparisons will be represented by statistical contrasts. The use of the closure test ensures a familywise significance level of 5% if the p value of the overall test is below 0.05. The mixed effects model is comparatively robust when handling missing data. In addition, an analysis using multiple imputations of missing data will be performed as a sensitivity analysis.

Patient and public involvement

A patient and public involvement research approach is applied for the development of patient-targeted feedback. Focus groups with patients with lived experiences of depression were conducted to refine the patient-targeted feedback from the DEPSCREEN-INFO trial.¹⁷ Patients will not be involved in the design of the trial. A participatory research team including patients formally suffering from depression will be invited to comment on the development and the results of the trial. There are no plans to disseminate the results of the research to study participants. However, we plan to communicate scientific results in lay language via press releases, social media and forums, which are popular among patients.

ETHICS AND DISSEMINATION

The trial will be conducted according to the Declaration of Helsinki. It was registered at ClinicalTrials.gov before inclusion of the first participant. Ethics approval was obtained from the Ethics Committee of the Hamburg Medical Association on 8 April 2019, approval number PV6031. Furthermore, the study follows international guidelines such as ICH-GCP as well as the guidelines and Steering Operating Procedures of the University Medical Centre Hamburg-Eppendorf.

The main risks and obstacles during the performance of the study are negative events for the patients. For that reason, suitable monitoring will be used. Monitoring and supervision will be controlled by a specialised company

(ie, CTC North, Hamburg, Germany). No major risks for serious adverse events caused by the application of the feedback intervention were identified in the DEPSCREEN-INFO trial.¹² Numerous studies have shown that depression screening does not cause suicidality or self-harm.^{33 34} It seems that questions about suicidality lower the risk of suicide.^{33 35} Nevertheless, we will treat acute suicidality as an adverse event. This adverse event will be monitored at every assessment point using item 9 of the PHQ-9 ('Having thoughts that you would be better off dead or of hurting yourself'). If this item is marked as 'nearly every day', the GPs will receive a standardised written note that the patient needs urgent clinical attention. In this case, the local GP is in charge of addressing suicidality. If suicidality is indicated during a follow-up interview, a mental health specialist will be called immediately and will talk to the patient. In case of acute suicidality, an ambulance will immediately be called, and the patient will be safely referred to a local psychiatric hospital. The Data Safety and Monitoring Board (DSMB) will be informed about every patient who reports acute suicidality. The trial will be stopped early if the DSMB sees any relation between participation or a certain trial condition and acute suicidality. The DSMB, principal investigator and coproject manager will discuss this option before deciding to stop the trial. The DSMB works independently and is not involved in the planning, conducting or analysis of the trial.

For the development and planning of the GET.FEEDBACK.GP trial, we included important healthcare providers and stakeholders such as GPs, patients, mental health specialists, health economists and biometrists. To optimise the feedback intervention, we also conducted qualitative studies with patients suffering from major depression and GPs. Addressing patients' needs and preferences, the trial tests the use of patient-targeted feedback that helps patients gain guideline-based information, apply self-management strategies and become active and informed partners in depression care. By incorporating the patient in the diagnostic process, we assume that healthcare resources will be used more efficiently. Based on the health economic analysis of the DEPSCREEN-INFO trial, we expect that this widely available feedback intervention is cost-effective.³⁶ Independent of our hypotheses, the trial will help to gain insights into the overuse, underuse and misuse of depression care resources in Germany. Moreover, the long-term follow-up period of 12 months may allow us to distinguish between effective and ineffective referral and treatment strategies in routine primary care. Next to publications in scientific journals our dissemination plan foresees to publish results in lay-language in media that is relevant to patients. Based on regular discussions with relevant stakeholders (patients, healthcare providers, health insurance representatives and health economists) we will derive further dissemination plans.

DISCUSSION

The multicentre GET.FEEDBACK.GP RCT aims to test a promising patient-targeted feedback intervention as an adjunct to depression screening in primary care patients. The trial is an extension of the previous DEPSCREEN-INFO RCT as GET.FEEDBACK.GP (1) targets a larger patient population affected by depression, (2) is conducted as a multicentre trial and (3) incorporates patients' needs and preferences in the design of the patient-targeted feedback intervention. Additionally, this intervention is brief, is minimally complex and has the potential to be implemented in clinical routine at low cost. We assume that the patient-targeted feedback intervention will have a significant but small effect on depression severity 6 months after screening. However, even a small effect at the individual patient level can lead to tremendous clinical significance at the population level (ie, all primary care patients). We therefore expect that the results of the multicentre GET.FEEDBACK.GP trial have the potential to influence future depression guidelines.

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Contributors SK, ML, ME, LEB, GM, AZ, KW, MH, HHK, JG, SJ, GR, AS, CA, JS, CN, SS, KB, MS and BL contributed substantially to the conception of the study. SK is one of the trial coordinators of the study and generated the first draft of this manuscript. SK, ML, ME, LEB, GM, AZ, KW, MH, HHK, JG, SJ, GR, AS, CA, JS, CN, SS, KB, MS and BL revised the draft critically for important intellectual content. KW and AZ are the trial statisticians and contributed to the analysis aspect of the protocol. SK, ML, ME, LEB, GM, AZ, KW, MH, HHK, JG, SJ, GR, AS, CA, JS, CN, SS, KB, MS and BL gave approval of the version published. SK, ML, ME, LEB, GM, AZ, KW, MH, HHK, JG, SJ, GR, AS, CA, JS, CN, SS, KB, MS and BL agree to be accountable for all



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