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Depression screening with patient-targeted feedback in cardiology: DEPSCREEN-INFO randomised clinical trial

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Background
International guidelines advocate depression screening in patients with coronary heart disease (CHD) and other chronic illnesses, but evidence is lacking.

Aims
To test the differential efficacy of written patient-targeted feedback *v.* no written patient feedback after depression screening.

Method
Patients with CHD or hypertension from three cardiology settings were randomised and screened for depression (ClinicalTrials.gov Identifier: NCT01879111). Compared with the control group, where only cardiologists received written feedback, in the intervention group both cardiologists and patients received written feedback regarding depression status. Depression severity was measured 1 month (primary outcome) and 6 months after screening.

Results
The control group ($n = 220$) and the patient-feedback group ($n = 155$) did not differ in depression severity 1 month after screening. Six months after screening, the patient-feedback group showed significantly greater improvements in depression severity and was twice as likely to seek information about depression compared with the control group.

Conclusions
Patient-targeted feedback in addition to screening has a significant but small effect on depression severity after 6 months and may encourage patients to take an active role in the self-management of depression.

Declaration of interest
None.

The 2010 Global Burden of Disease Study names coronary heart disease (CHD) as the condition with the most years of life lost and major depressive disorder as ranked second in terms of years lived with disability.[1] In 2008, the American Heart Association (AHA) Science Advisory recommended routine depression screening for all patients with CHD,[2] which sparked heated debate. In 2009, the National Institute for Health and Care Excellence (NICE) clinical guideline 91 suggested systematic case identification for depression in patients with chronic illnesses.[3] In primary care, the guidelines in different countries are very heterogeneous, ranging from recommending not to screen at all to screening all patients for depression.[4–6] Finally, in 2016, the US Preventive Services Task Force (USPSTF) recommended screening for depression in the general adult population, including pregnant and postpartum women.[7] Advocates of routine depression screening argue that depression is an independent major risk factor for adverse cardiovascular outcomes and poor quality of life, that routine screening can be conducted at low cost and that effective treatment for depression is readily available.[2,8] However, critics of the AHA Science Advisory assert that routine depression screening in patients with CHD is not supported empirically.[9,10] Thus, randomised controlled trials (RCTs) that evaluate the potential clinical efficacy of depression screening have been named a research priority.[10,11] Furthermore, if screening of patients with CHD is recommended, the optimal strategy must be found.

Although studies suggest that greater patient participation in depression care has the potential to improve clinical outcome[12,13] the role of the patient within the depression screening process has not yet been studied. Therefore, we argue that clinical trials should not only focus on clinical symptom improvement, but should also investigate the impact of active patient participation within the screening process and investigate what governs the relationship between depression screening and clinical outcome. Our underlying rationale was that direct feedback encourages greater patient participation and engagement in mental health. We designed the DEPSCREEN-INFO (Increasing the Efficiency of Depression-Screening Using Patient-Targeted Feedback) trial to investigate the efficacy of two depression screening approaches (ClinicalTrials.gov Identifier: NCT01879111). The study aimed to reflect the situation in most cardiology settings, where mental health professionals are not typically readily available and where the time for cardiologists to counsel their patients with depression is limited.

Specifically, we compared the efficacy of depression screening alone *v.* depression screening plus individual patient-targeted feedback. A 'no screening' condition was not included because evidence suggests that it is very unlikely that depression screening alone will result in better clinical outcomes.[10,14,15] We hypothesised that depression screening plus individual patient-targeted feedback should be more effective in reducing depression severity than depression screening alone. Secondary outcomes included anxiety severity, somatic symptom burden and quality of life. The manner in which patients handled their depression screening result, whether physicians discussed depression, whether treatment was initiated, whether additional healthcare was utilised and the acceptance of screening were also investigated.

Method

Study design and patients

DEPSCREEN-INFO is a randomised controlled observer-masked parallel group efficacy trial of depression screening in cardiology

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settings. A consecutive sample of patients was recruited from three centres in Hamburg, Germany, i.e. a large cardiology out-patient centre, the hospital cardiology out-patient clinic and an in-patient ward of the University Heart Centre. As figures in the first three months indicated that a CHD-only patient recruitment goal was not feasible, patients with arterial hypertension were also eligible to participate. Thus, eligible patients were aged 18 years or older, had clinical diagnoses of either CHD or arterial hypertension, had sufficient German literacy skills to complete the questionnaires, and provided written informed consent. Exclusion criteria were having an acute life-threatening condition, severe somatic or psychiatric disorders with immediate necessity of intervention, active suicidality and severe cognitive or visual impairment, as assessed by clinical judgement. The study was approved by the ethics committee of the Medical Association, Hamburg, Germany (PV 3805).

Randomisation and masking

Patients were randomly assigned to either depression screening or to depression screening plus patient-targeted feedback. Randomisation was conducted by a coin toss prior to screening in a 1:1 ratio. Randomisation was done prior to screening because we aimed to reflect real-world practice. Importantly, the provision of patients' screening status was part of the intervention so could not be provided before randomisation. Patients were informed that they were randomly allocated to a group that would receive written feedback of their screening result or a group that would not. Patients were also informed that the treating physician would receive their depression screening results irrespective of their study group allocation. The design of the study, therefore, precluded patient masking. In contrast, physicians, investigators and outcome raters were masked with respect to group assignment. All data from the two follow-up measurements were collected independently by masked outcome raters. Thus, disclosure of the participant's experimental condition to the physicians at baseline was unlikely to affect later outcomes.

Outcome measures

We took measurements at three time points: at screening (baseline), after 1 and 6 months. The primary outcome was change in depression severity from baseline to 1 month. A 1-month outcome assessment was considered appropriate to assess patients' cognitions, behaviours and healthcare use since depression screening without 'co-intervening' by asking too early. The 6-month outcome assessment was used to assess medium-term outcomes. At baseline, demographic characteristics and pre-existing conditions were assessed using a questionnaire with structured self-report items. Trained raters conducted a structured telephone interview after 1 and 6 months. The questionnaire and interviews included the following:

The 9-item Patient Health Questionnaire (PHQ-9)[16–18] was used to screen for depression and measure depression symptom severity at baseline and follow-ups. The AHA Science Advisory recommended the use of 'at a minimum' the 2-item Patient Health Questionnaire (PHQ-2)[19] to identify patients who are currently depressed and to use all nine PHQ-9 items if the answer is 'yes' to either or both of the PHQ-2 questions.[2] However, previous research suggests that this two-step approach is no better than either instrument alone,[20] and that PHQ-2 and PHQ-9 predict death and admissions to hospital in patients with heart failure similarly.[21] Given that a one-step depression screening approach using the PHQ-9 alone might be more efficient than the two-step approach,[22] we used the PHQ-9 alone with the recommended cut-off score of $\geqslant 10$.[2] For potential future interest, we compared the screening results obtained using the PHQ-9 with those using the PHQ-2. The PHQ-9 has demonstrated criterion validity and sensitivity to change in multiple studies and languages.[16–18] PHQ-9 sum scores range from 0 to 27, with scores of $\geqslant 0$, $\geqslant 5$, $\geqslant 10$ and $\geqslant 15$ representing minimal, mild, moderate and severe depression symptom levels, respectively.

Secondary patient-reported outcome scales included the well-validated Generalized Anxiety Disorder Scale (GAD-7)[16,23,24] that was used to measure anxiety severity and the Patient Health Questionnaire-15 (PHQ-15)[16,25] to measure somatic symptom severity. The EQ-5D index of the UK was used to measure health-related quality of life (HRQOL).[26] Cardiac diagnosis, history of myocardial infarction, and prior admission to hospital because of cardiac disease were requested from the treating physician or extracted from patients' records. Severity of cardiac illness was measured by structured self-report measures reflecting the New York Heart Association (NYHA) Functional Classification system as well as the Canadian Cardiovascular Society (CCS) Angina Grading Scale.[27]

The patient telephone follow-up interview at 1 month also included structured questions regarding the acceptance of the depression screening procedure,[28] prior diagnosis and treatment of depression, patients' information-seeking tendencies about depression, patients' illness perceptions, as well as the cardiologists' handling of the screening result in the consultation.

At 6 months, healthcare use was assessed in the structured telephone interview using a modified version of the Client Socio-demographic and Service Receipt Inventory (CSSRI).[29] Finally, we reviewed all available records of patients who screened positive to assess the percentage of individuals with probable depression already known to the physician before screening.

Intervention

Control group – depression screening alone

Patient recruitment took place during the waiting time for patients' out-patient appointment or on the in-patient wards. Depression screening was conducted according to the current AHA guidelines.[2,22] If patients screened positive (PHQ-9 score $\geqslant 10$), the treating physicians received the screening result in written form before their consultation with the patient. The written physician feedback indicated the severity of depression for either moderately (PHQ-9 score: 10–14) or severely elevated PHQ-9 depression scores (PHQ-9 score: 15–27) using a schematised traffic light and brief description of the depression severity and the corresponding guideline-based treatment[6] (online Fig. DS1). No physician feedback was given if patients screened negative. All treating cardiologists were encouraged to act in accordance with current guidelines, i.e. to inform patients of their depression screening result. Nevertheless, in order to reflect routine clinical practice, the physicians decided themselves whether or not to address depression during their consultation with the patient.

Intervention group – depression screening plus patient-targeted feedback

All procedures for the intervention group, including the written physician feedback form for the cardiologist, were the same as those for the control group. In addition, all patients (regardless of their screening result) in the intervention group received individualised feedback, which included:

(a) a patient feedback form corresponding to one of the four PHQ-9 depression severity levels. The four feedback forms each included a schematic traffic light indicating the severity level of depression as well as a brief explanation regarding the clinical relevance of the scores. In addition, the feedback

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forms included an icon array, designed according to evidence-based recommendations,[30] that depicted the patients' depression severity score in relation to the general population (online Fig. DS1).

(b) if a patient screened positive, a two-page written patient information sheet[31] regarding guideline-based depression diagnosis and treatment;[6]

(c) if a patient screened positive, the contact information of the local university psychosomatic out-patient clinic.

Statistical analyses

We calculated the required sample size for the primary outcome i.e. the standardised mean difference in the PHQ-9 depression score between the intervention group and the control group 1 month after screening.[32] We specified a two-tailed significance level of 5%, a power of 80% and an effect size of Cohen's $d = 0.30$. This procedure led to a required sample size of 176 patients with positive depression screens per study group. Quantitative outcomes were compared between the intervention group and the control group at the 1 month (primary outcome) and the 6 month (secondary outcome) follow-ups using a linear mixed model (LMM).[32] While adjusting for baseline values, the LMM included the following fixed factors: study group (intervention group *v.* control group), assessment time point (1 month follow-up *v.* 6 month follow-up), study setting (cardiology out-patient centre *v.* hospital cardiology out-patient clinic *v.* cardiology in-patient ward) and cardiac diagnosis (CHD *v.* arterial hypertension). We presented means and standard errors as descriptive statistics and adjusted mean differences based on the LMM. In an additional analysis, we included an interaction term of group and diagnosis to test whether the intervention effect was modified by the cardiac diagnosis. Effects sizes were calculated using Cohen's *d* formula and the LMM's residuals. Group differences in the binary outcomes were analysed by χ^2-tests. If cells included 20 or fewer individuals, we applied Fisher's exact test. Odds ratios were calculated as effect measures. Intention-to-treat (ITT) analyses, which included all patients with baseline depression scores, were conducted for all quantitative outcomes. Direct maximum likelihood estimation (as opposed to multiple imputation) was applied to handle missing follow-up data. Complete case analyses were used to test all quantitative outcomes as sensitivity analyses and for all binary outcomes. Two-tailed *P*-values < 0.05 were considered significant. We used SPSS 21 for statistical analyses.

Results

Participants

Between 1 October 2011 and 30 October 2013, we screened 4151 patients for eligibility; 1976 patients met the inclusion criteria and underwent randomisation. Of those, 375 patients (19%) screened positive and were analysed in ITT analyses of quantitative outcomes (Fig. 1). The overall participation rates were 69% at the 1-month and 65% at the 6-month follow-up. Approximately two-thirds of patients had CHD, and one-third had a history of myocardial infarction. The study groups were well balanced with respect to the baseline variables demonstrated in Table 1. In a subsample of 285 patients (76% of the total sample) with available medical

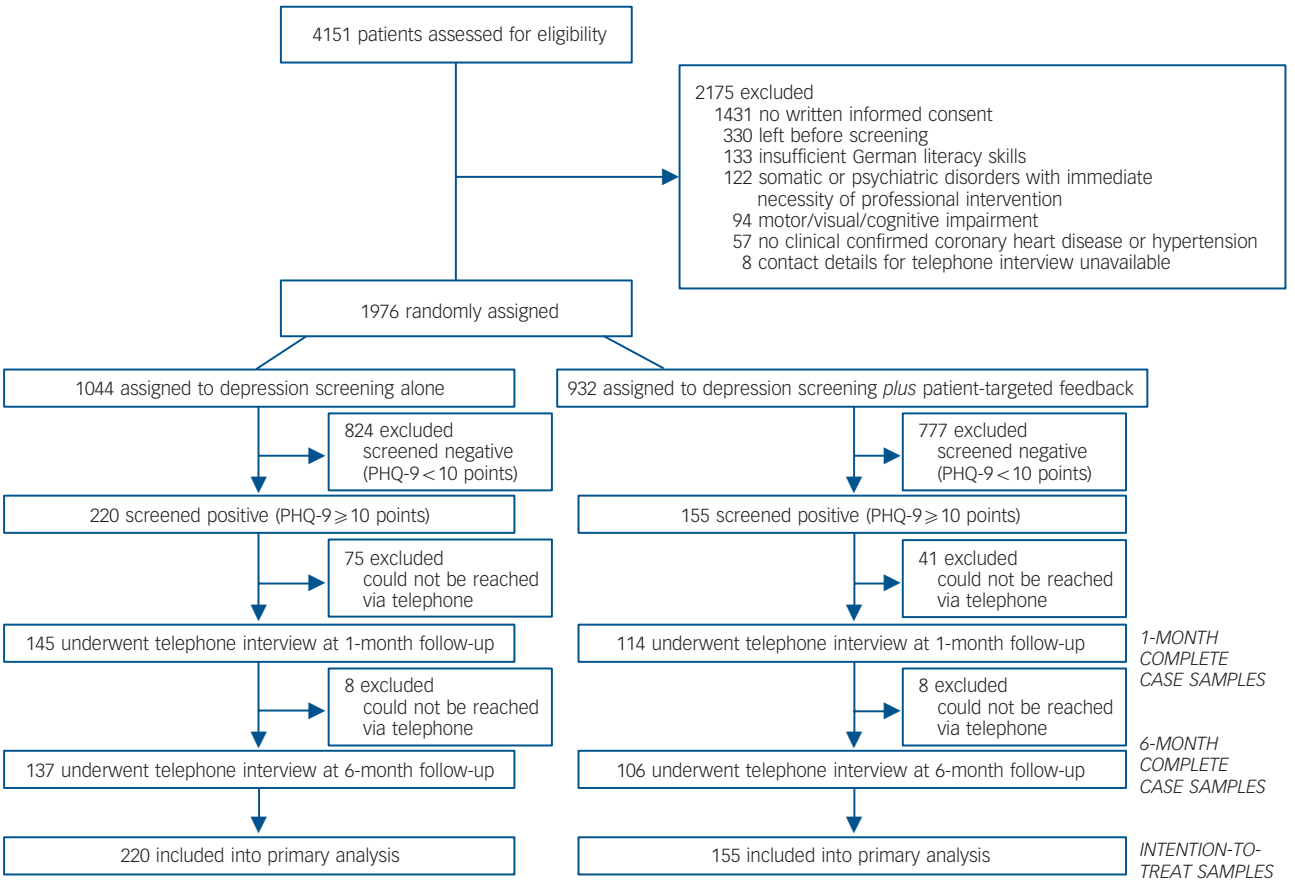

Fig. 1 Flow of patients through the DEPSCREEN-INFO (Increasing the Efficiency of Depression-Screening Using Patient-Targeted Feedback) trial.

Control group: left arm; intervention group: right arm. PHQ-9, 9-item Patient Health Questionnaire.

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Table 1 Sample characteristics[a]

	Control group ($n = 220$)	Intervention group ($n = 155$)
Demographics		
Age, years: mean (s.d.)	63.8 (11.9)	62.0 (11.6)
Women, *n* (%)	88 (40.0)	72 (46.5)
⩾10 years of formal education, *n* (%)	106 (48.2)	78 (50.3)
Living alone, *n* (%)	72 (36.6)	62 (41.9)
Study centre, *n* (%)		
University hospital out-patient clinic	57 (25.9)	46 (29.7)
University hospital in-patient ward	65 (29.5)	42 (27.1)
Cardiology out-patient centre	98 (44.5)	67 (43.2)
Cardiac diagnosis, *n* (%)		
Coronary heart disease	139 (63.2)	101 (65.2)
Arterial hypertension without CHD	81 (36.8)	54 (34.8)
NYHA functional classification, *n* (%)		
Class I	44 (20.7)	36 (23.7)
Class II	53 (24.9)	42 (27.6)
Class III	80 (37.6)	44 (28.9)
Class IV	36 (16.9)	30 (19.7)
CCS angina grading scale, *n* (%)		
Class I	91 (42.3)	49 (32.7)
Class II	45 (20.9)	28 (18.7)
Class III	33 (15.3)	35 (23.3)
Class IV	46 (21.4)	38 (25.3)
History of myocardial infarction, *n* (%)	75 (34.7)	52 (34.2)
Prior admission to hospital because of cardiac disease, *n* (%)	138 (64.5)	109 (70.8)

NYHA, New York Heart Association; CCS, Canadian Cardiovascular Society.
a. Percentages may be calculated using different denominators because of missing values. Sample characteristics do not differ when using a 5% level of significance.

charts, we also found no significant baseline differences in the use of antidepressants, benzodiazepines, antipsychotics, analgesics and psychotherapy. According to the charts from the patients who screened positive, 45 (15.8%) cases of depression were already known to the physicians. The screening results of the PHQ-2 (symptoms present 'more than half the days' in either or both PHQ-2 questions) and PHQ-9 (cut-off score ⩾10) were both negative in 1429 patients (72.3%), both positive in 267 individuals (13.5%), and divergent in 108 patients (5.5%, PHQ-2 negative, PHQ-9 positive) and in 172 patients (8.7%; PHQ-2 positive, PHQ-9 negative).

Quantitative endpoints

Depression severity improved in both patient groups over the three measurement points (see online Fig. DS2). Although there was no significant difference in baseline-adjusted depression severity between the groups 1 month after screening, depression severity after 6 months was significantly lower in the intervention group than in the control group (Table 2). Similarly, there was a significant secondary outcome group difference regarding baseline-adjusted somatic symptom severity favouring the intervention group compared with the control group 6 months but not 1 month after screening. No significant group differences in anxiety severity and HRQOL were noted. Complete cases analyses confirmed the direction of the ITT results. Neither setting nor cardiac diagnosis had a significant influence on the depression change scores.

Binary endpoints

At the 1-month outcome assessment, patients in the intervention group reported that they were significantly more frequently worried about depression directly after screening (44% *v.* 27%)

Table 2 Intention-to-treat analyses of quantitative outcomes ($n = 220$ control group; $n = 155$ intervention group)[a]

Outcome	Baseline		1-month follow-up					6-month follow-up				
	Control, mean (s.e.)[b]	Intervention, mean (s.e.)[b]	Control, mean (s.e.)[b]	Intervention, mean (s.e.)[b]	Adjusted difference, mean (s.e.)[c]	*P*	Effect size	Control, mean (s.e.)[b]	Intervention, mean (s.e.)[b]	Adjusted difference, mean (s.e.)[c]	*P*	Effect size
Primary												
Depression severity (PHQ-9)	13.48 (0.23)	13.77 (0.26)	10.41 (0.48)	11.02 (0.59)	−0.32 (0.64)	0.62	−0.06	10.00 (0.46)	9.04 (0.55)	1.39 (0.66)	0.04	0.27
Secondary												
Anxiety severity (GAD-7)	8.95 (0.35)	9.88 (0.39)	7.09 (0.45)	7.35 (0.50)	−0.13 (0.57)	0.82	−0.03	6.38 (0.42)	5.62 (0.50)	0.90 (0.62)	0.14	0.21
Somatic symptom burden (PHQ-15)	13.18 (0.30)	14.77 (0.38)	11.59 (0.41)	11.46 (0.50)	0.67 (0.60)	0.27	0.14	9.77 (0.44)	9.01 (0.54)	1.52 (0.61)	0.01	0.33
Quality of life (EQ-5D)	0.62 (0.02)	0.66 (0.02)	0.65 (0.03)	0.68 (0.03)	−0.005 (0.03)	0.89	−0.02	0.69 (0.02)	0.71 (0.03)	0.003 (0.03)	0.92	0.01

PHQ-9, Patient Health Questionnaire-9; PHQ-15, Patient Health Questionnaire-15; GAD-7, Generalized Anxiety Disorder Scale-7; EQ-5D, EuroQol Group measure of health outcome, index of the UK.
a. The linear mixed model included the following fixed factors: study group (intervention group *v.* control group), assessment time points (baseline *v.* 1-month follow-up *v.* 6-month follow-up), study setting (cardiology out-patient centre *v.* hospital cardiology out-patient clinic *v.* in-patient ward) and cardiac diagnosis (CHD *v.* arterial hypertension). Each analysis was adjusted for the respective baseline values of depression, anxiety, somatic symptom burden and quality of life.
b. Descriptive means and standard errors in parenthesis without adjustment.
c. Adjusted differences and standard errors in parenthesis estimated by the linear mixed model.

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as well as at any time during the month after screening (50% *v.* 34%; Table 3). In addition, the intervention group independently sought information regarding depression approximately twice as frequently as controls (24% *v.* 13%). According to patients' records, physicians infrequently addressed positive depression screening results in both groups (18% and 10%). Very few patients were referred to mental health specialists (2% and 0%), and suicidality was addressed in both groups in only 2% of participants. The acceptance of depression screening in both groups was high, and the vast majority of patients thought that screening for depression helps physicians better understand their patients.

Six months after screening there were no significant differences between the two patient groups with respect to cardiologist, psychotherapist, mental health services and hospital visits (Table 3). Pharmacotherapy was most frequently recommended by psychiatrists and there were no significant differences between the study groups in the consumption of antidepressants, antipsychotics, anxiolytics, hypnotics, beta-blockers, calcium channel blockers, angiotensin converting enzyme inhibitors, angiotensin antagonists and statins 6 months after screening (data not shown in Table 3). However, 83% of the patients from the intervention group had visited their general practitioner (GP) within the past 6 months compared with 93% of the control group ($P = 0.03$); 24% of patients of the intervention group and 15% of the control group ($P = 0.11$) contacted their GP about depression (not shown).

Discussion

The DEPSCREEN-INFO trial is the first RCT to compare the clinical efficacy of two depression screening approaches. Here we show that individual patient-targeted feedback in addition to depression screening did not improve depression 1 month after screening (primary study outcome), but significantly improved depression severity 6 months after screening (secondary study outcome). The intervention group also showed a greater improvement in somatic symptom severity 6 months after screening compared with the control group. In line with this finding is the result that individuals in the screen-positive intervention group visited their GP significantly less frequently than those in the screen-positive control group. Direct diagnostic feedback and information on depression might have enabled those in the intervention group to attribute somatic symptoms to depression rather than a somatic disease, thus resulting in fewer GP visits. Both groups improved in terms of symptom severity over the whole study period. This effect is known from intervention and control conditions in psychotherapy studies of depression[33] and probably reflects the natural decline in symptoms over time.

Binary outcomes indicate that the intervention group were more concerned and more active in their approach to depression compared with the control group, for example by information seeking. In contrast, the role of the cardiologists within the screening process appears limited in both groups: regardless of intervention group allocation, only a small minority of cardiologists talked about depression with their patients who had screened positive, referred them to mental health specialists or addressed suicidality. These results indicate that physicians in routine care do not act according to depression guidelines when they are informed about positive depression screening results, which raises an ethical dilemma. Like in other medical disciplines, feedback should be given to patients after screening, because only informed patients can react appropriately to a known indication of their health status. As a potential consequence of patients not being informed by their physicians, no differences in specific mental health treatment were found between the two study groups

Table 3 Complete case analyses of binary outcomes[a]

	Control group	Intervention group	*P*	Odds ratio (95% CI)
One-month outcome, n	145	114		
Patient's cognitions and behaviours, *n* (%)				
Worries/thoughts about depression directly after completing the questionnaire	39 (27.1)	48 (44.0)	0.005	2.12 (1.25–3.59)
Worries/thoughts about depression in the past month	49 (34.0)	54 (49.5)	0.01	1.90 (1.14–3.17)
Currently thinks that he/she suffers from depression	43 (29.9)	43 (39.4)	0.11	1.53 (0.91–2.59)
Independently collected information about depression	18 (12.5)	26 (23.9)	0.02	2.19 (1.13–4.25)
Made contact with general practitioner to find out more about depression	14 (9.7)	19 (17.4)	0.09	1.96 (0.94–4.11)
Cardiologists' treatment of patients' depression, *n* (%)				
Talked about depression	14 (9.7)	20 (18.3)	0.06	2.09 (1.00–4.35)
Referred patient to mental health professional	0 (0)	2 (1.8)	0.19	–[b]
Addressed suicidality	3 (2.1)	2 (1.8)	1.00	0.85 (0.14–5.15)
Evaluation of depression screening, *n* (%)				
Remembered undergoing screening	124 (85.5)	89 (78.1)	0.15	0.63 (0.34–1.19)
Liked/not bothered by screening	123 (99.2)	88 (98.9)	0.81	0.72 (0.04–11.59)
Thinks screening helps the physician to better understand his/her patient	107 (86.3)	71 (79.8)	0.21	0.63 (0.30–1.30)
Six-months outcome, n	137	106		
Visits in diverse healthcare settings, *n* (%)				
Visited cardiologist	61 (45.2)	48 (45.7)	0.94	1.02 (0.61–1.71)
Visited general practitioner	126 (92.6)	88 (83.3)	0.03	0.41 (0.18–0.94)
Visited general hospital	47 (38.8)	31 (33.7)	0.44	0.80 (0.45–1.41)
Visited psychiatric day-clinic	2 (1.7)	2 (2.2)	1.00	1.42 (0.18–9.57)
Visited in psychiatric hospital	2 (1.7)	3 (3.3)	0.65	2.01 (0.33–12.26)
Specific mental health treatment, *n* (%)				
Contacted psychotherapist	16 (13.2)	12 (13.0)	1.00	0.97 (0.44–2.20)
On a waiting list for psychotherapy	2 (2.0)	3 (3.8)	0.66	1.97 (0.32–12.11)
In treatment with a mental health professional (psychiatrist, psychosomatic specialist, psychotherapist)	26 (19.0)	19 (17.9)	0.87	0.93 (0.48–1.79)
Received the offer of psychotropic medication	28 (23.1)	30 (32.6)	0.12	1.61 (0.88–2.95)
Took the offered psychotropic medication	18 (64.3)	21 (70.0)	0.78	1.30 (0.43–3.89)

a. For *n* (%) denominators may vary because of missing values. χ^2 tests used if cells had at least 20 individuals, otherwise Fisher exact tests were used.
b. Not available.

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6 months after screening. The better clinical outcome in the intervention group compared with the control group cannot, therefore, be explained by differences in mental healthcare utilisation.

At this point, we can only speculate how being more concerned and seeking more information might have led to greater improvements in depression severity without professional treatment: first, the fact that patients are informed about their depression status is the precondition for an active coping-response to this disorder. In contrast to the patients who were not systematically informed of their depression status, the patient group who received patient-targeted feedback had the opportunity to mobilise coping-responses that are known to improve outcomes, such as communicating with others, venting of emotions and cognitions, optimism, extraversion and conscientiousness.[34] We also suspect that the less frequent visits to the GPs in the intervention group is related to the informed patients' understanding that their somatic symptoms might be related to depression, and not to a cardiac problem. Second, given that changes in social support and depression are closely interrelated,[35] it is possible that the informed patients' depression improved because they were able to obtain social support by actively involving their families, friends and others in their care. Finally, the informed patients might have utilised other forms of treatment, such as bibliotherapy or self-help groups. All these options are potentially powerful forms of depression self-management. Given that potential modes of actions were not the focus of our study, we suggest that future studies should directly investigate the process of how exactly informing patients of their screening result translates into improved depression outcomes. These studies might consider results from a recent cognitive–behavioural intervention trial in patients with heart failure and depression, which indicated that cognitive–behavioural therapy improved depression but had no influence on heart failure self-care behaviour.[36] Altogether, targeted feedback about patients' depression status has the potential to promote patients' active role in an informed self-management of depression, which may have contributed to the improved depression outcomes.

Given that the patient-targeted feedback intervention was minimally time-consuming, we expected small effect sizes (effect size 0.30) for our primary study outcome and planned our sample size accordingly. Of note, the observed adjusted between-group effect size for the change in depression at 6 months (effect size 0.27) is within the range of effect sizes of much more intensive interventions for depression in patients with CHD and other chronic illnesses (range, effect size 0.25–0.61).[35,37–40] Despite the fact that the group difference at 6 months was statistically significant, one might question whether the adjusted difference of 1.4 PHQ-9 scores is also clinically significant. In a previous study, we estimated the minimally clinical important difference (MCID) for individual change on the PHQ-9 scale to be between 2.6 and 4.8.[18] Nevertheless, a one-point improvement of the total PHQ-9 score corresponds to a one-point improvement in one of the PHQ-9 items. For example, this means that the patients' response to the PHQ-9 item 'feeling down, depressed, or hopeless' moves from 'being bothered on more than half the days' to 'being bothered on several days' during the past 2 weeks. We believe that this one-point difference might represent a meaningful difference to the patient. Moreover, the reduction in somatic symptom severity and the promotion of active information seeking indicate that the minimally invasive feedback intervention had multi-dimensional affects that warrant its application once a patient has been screened for depression.

In accordance with previous studies[28,41] our results suggest that the majority of patients have positive attitudes regarding depression screening. We assume that depression screening gives patients confidence that the treating physicians are making systematic efforts to assess and manage their mental health problems.[41] The study results do not suggest that either screening approach caused harm (for example by over-referral or treatment). In fact, depression screening revealed new information in most cases; depression diagnoses were only documented in 15.8% of patient who screened positive before screening. The comparison of individuals who screened positive using the PHQ-9 alone *v.* using the PHQ-2 alone indicates that 5.5% of people were screened positive by the PHQ-9 but negative by the PHQ-2. These patients would have been missed if the two-step screening approach was used. In contrast, none of these people were missed by our one-step screening approach using the PHQ-9 only. Thus, for screening purposes, for which high sensitivity is required, we recommend employing the more sensitive one-step screening approach with the PHQ-9.

Limitations

Despite the strengths of DEPSCREEN-INFO, including its randomised controlled design, large sample size, the reflection of real-world cardiology settings and the inclusion of patients' perspective, the following limitations need to be acknowledged. First, the response rates of 69% at the 1-month assessment and 65% at the 6-month follow-up may challenge the generalisability of results. However, to avoid sampling bias, we primarily performed ITT analyses including all 375 patients who were randomised to one of the study groups for quantitative analysis. Second, because previous study results have suggested that depression screening alone does not result in better clinical outcomes compared with no screening,[10,14,15] a group of patients who were not screened was not included in our trial. Given that less than 10% of physicians from the control group talked about depression with patients who screened positive, it appears very unlikely that depression screening without patient feedback improved depression severity. Nevertheless, we acknowledge that the value of screening alone cannot be determined in our study. Third, we relied on self-report measures of depression and other outcomes. Nevertheless, the PHQ-9 reliably predicts risk of adverse cardiovascular outcomes[21] and has been shown to have reasonable accuracy in cardiology and in primary care.[9] Fourth, we cannot exclude the possibility that our randomisation strategy via coin toss resulted in imbalances in group assignment. Finally, 15.8% of patients who screened positive already had a diagnosis of major depression according to their medical records and may, therefore, have undergone depression screening unnecessarily. However, given that depression severity varies over time, and that there is no suggestion that depression screening causes harm, we had decided to apply the same screening approach to all patients, regardless of their depression status *a priori*.

Implications

The results from our study should be generalisable to similar cardiology settings. Given that there is no evidence of differential depression screening outcomes in specialist and primary care settings,[10] we believe that our study results might also be applicable to primary and secondary care. However, independent replication studies are needed to assess the generalisability of our study results to other settings and more directly investigate the underlying mechanisms of patient-targeted feedback.

Many treatment guidelines recommend depression screening in cardiology and other healthcare settings.[2,4,6,7] Results from the DEPSCREEN-INFO trial indicate that, if depression screening

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is recommended at all, patient-targeted feedback including screening results should be part of the screening process. Although the modes of action remain poorly understood to date, it seems that such feedback has the potential to engage the patient as an active information seeker and to improve depression and other clinical outcomes. Feedback can be implemented at low cost either alone or in addition to staff-assisted depression management programmes. If patient-targeted screening informs and encourages patients to be active participants in the healthcare system and to make well-informed decisions, then such an approach is certainly worthwhile.

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