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Development and evaluation of a questionnaire for the assessment of depression in general practice

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Complete membership of the POKAL-Study Group can be found in the Acknowledgments

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Diagnostics, primary care, heuristics, general practitioner, depression

ABSTRACT

Objectives: To develop a new questionnaire for the diagnostic assessment of depression adapted to the primary care setting by combining psychiatric criteria and heuristics of general practitioners. Psychometric evaluation of the new questionnaire and first validity evidence.

Design: The questionnaire was developed using cognitive interviews with think-aloud technique. The factorial validity was then examined in a cross-sectional study.

Setting: Primary care. Five general practices in Bavaria, Germany.

Participants: 15 general practitioners (GPs), four psychiatrists/psychotherapists and 13 patients participated in the cognitive expert interviews. A primary care sample of N=277 consecutive patients participated in the cross-sectional study.

Methods: After consultation with experts and literature research, the questionnaire contained a self-rating part for patients and an external part for GPs. Items were then iteratively optimised using cognitive interviews. Factorial validity was examined. To estimate the internal consistency, Cronbach's α was calculated. Validity was assessed by correlating the new questionnaire and the PHQ-9.

Results: The preliminary version of the two-part "Questionnaire for the Assessment of DEpression SYmptoms in Primary Care" (DESY-PC) comprised 52 items for patients (DESY-PAT-1/2) and 21 items for GPs (DESY-GP). The analysis of the DESY-PAT-1 revealed a one-factor solution ("environmental factors") with Cronbach's α of 0.55. The items of the DESY-PAT-2 were assigned to three factors, "depressive cognitions", "suicidality", and "symptoms of fatigue", with Cronbach's α of 0.86, 0.79 and 0.85, respectively. Factorial analysis revealed two factors for the DESY-GP: "depression symptoms" and "medical history/external factors". Cronbach's α was 0.90 and 0.59, respectively. After factorial analysis, the DESY-PAT was reduced to 28 items, and the DESY-GP was reduced to 15 items. Correlations of the DESY-PC with the PHQ-9 were high and significant, indicating convergent validity.

Conclusions: The new questionnaire represents an innovative extension of depression questionnaires and could be particularly suitable for general practices.

ARTICLE SUMMARY

Strengths and limitations of this study

- The participation of 32 experts in the construction of the questionnaire ensured that GP-specific heuristics and patient-related characteristics of the primary care setting were incorporated into the new questionnaire.
- Unlike other validated depression questionnaires, the new questionnaire includes not only psychiatric criteria for depression, but also contextual factors relevant to general practice that may improve the diagnosis of depression.
- It was not tested whether the DESY-PC identifies depression more accurately than commonly used depression questionnaires, as we did not apply a SCID interview to confirm or rule out a depression diagnosis.

INTRODUCTION

Depression is one of the most prevalent mental disorders [1-3]. Various studies have reported a lifetime prevalence of depressive disorders ranging from 12% to 19% [2, 4-6]. Depression has a major impact on the lives of those who are affected, on their family members, and on their immediate environment. Therefore, it represents a considerable health problem for our society [7, 8]. Between 2005 and 2015, depression rose from the fourth to the third leading cause of disability [9]. Moreover, the World Health Organization (WHO) predicts that depression will be the largest burden of disease worldwide by 2030 [10]. Hence, it is particularly important to improve the diagnosis and care of patients with depression and to optimise treatment processes [11]. It is crucial to identify and treat people with depression in the early stages of their illness to prevent chronicity [12]. Besides, proactive management of subthreshold depression can also protect affected individuals from developing major depression [13].

The general practitioner (GP) is usually the first healthcare provider that patients consult [14-16]. In most cases, GPs are also the gatekeepers for further diagnostics and treatment of patients with depression [17, 18]. However, identifying depression in primary care can be challenging when only somatic symptoms are reported, and patients do not explicitly mention their depressed mood [19]. In addition to this challenge, the diagnosis of depression in primary care is further complicated by multimorbidity. Somatic complaints often overlap and mask symptoms of depression, so it can be difficult to distinguish between somatic disorders and depression [20, 21]. In any case, the initial diagnosis is essential for subsequent treatment [18, 22]. Thus, it is crucial that GPs follow a guideline-oriented diagnostic process and treatment, as the majority of patients with depression are only seen in general practice [22, 23].

Standardised screening questionnaires could be one approach to improve the diagnosis of depression in primary care. However, expert panels like the Canadian Task Force on Preventive Health Care do not recommend routine screening for depression in general practice [24]. Similarly, guidelines such as the UK National Institute for Health and Care Excellence guideline (NICE) or the German National Health Care Guideline for Depression (NVL) do not explicitly call for routine screening. Nevertheless, both recommend it if risk factors for depression are present and the GP suspects depression [25, 26]. Although the Patient Health Questionnaire-9 (PHQ-9) has good sensitivity and specificity, previous studies have shown that screening for depression in primary care can result in a high rate of false-positives [27-32], leading to the misclassification of healthy patients as depressed. In addition, screening for depression has not been shown to improve mental health [33]. An alternative to screening in primary care could be the use of diagnostic tools as an aid to diagnosis if the clinician already suspects depression.

Furthermore, it was shown that standard diagnostic systems (e.g. International Statistical Classification of Diseases and Related Health Problems 10, ICD-10) do not work adequately in the GP context [12, 34, 35]. GPs use their heuristics and rely on factors other than ICD-10/11 or DSM-V (Diagnostic and Statistical Manual of Mental Disorders V) criteria [23, 36, 37]. The GP's intuition, the consideration of biopsychosocial factors, and their impression during the watchful waiting process, especially when depression is suspected, could represent such heuristics [35, 38]. While several studies have highlighted the impact of heuristics on medical decision-making [20, 39], current questionnaires for depression do not incorporate the GP perspective so far [35, 38]. Considering GP heuristics and their perspective alongside the inclusion of psychiatric criteria could improve diagnostic decision-making and might be superior for diagnosing depression in the primary care setting [40]. To our knowledge, no such questionnaire is adapted to the primary care setting and considers GP heuristics, thought processes, and criteria for measuring depression. Therefore, a questionnaire that measures both psychiatric criteria or typical symptoms of depression and GP heuristics should be introduced in general practice. The planned questionnaire is, therefore, not intended as a classic screener but primarily as a diagnostic aid in general practice for patients who are considered to be at increased risk of depression.

In this article, we describe: 1) The development of a new questionnaire for the assessment of depression adapted to the GP setting, which considers GP heuristics and psychiatric criteria. 2) The psychometric evaluation of the new questionnaire and a first validity evidence in a primary care sample of N=277 patients.

METHODS

Development of the preliminary questionnaire

The first draft of the questionnaire was based on practical considerations, an initial literature review and discussions with three experienced GPs. It was further developed by conceptual considerations of questionnaire construction and the consideration of commonly used screening questionnaires for depression, which were found to be relevant in a thorough literature review [30, 41-45].

In the next step, the questionnaire design and content were iteratively optimised through cognitive expert interviews with general practitioners, psychiatrists/psychotherapists and patients. During the cognitive interviews, participants had to complete the new questionnaire by thinking out loud. We used this technique to detect inconsistencies, missing information/items, or information about items that were difficult to understand. The cognitive think-aloud technique is optimal for capturing thought processes [44]. The idea was to consider psychiatric criteria and aspects essential to the GPs and their

patients. The interviews were audiotaped and continuously analysed by the authors (CT, AS, MB), who discussed the plausibility of the suggestions and then iteratively incorporated them into the questionnaire before showing the revised version to the next interview partner. This process was conducted from April to October 2021 until construct saturation occurred, and no further far-reaching suggestions for improvement were made. GP interview partners were recruited through the Bavarian practice-based research network (BayFoNet); patients were recruited through GP referral and recruitment on a psychiatric ward. Psychiatrists/psychotherapists were motivated to participate in an interview by direct invitation. The Medical Ethics Committee of the Technical University Munich/University Hospital Klinikum rechts der Isar (169/21 S-EB) approved the development of the preliminary questionnaire, and the 32 interview partners gave written informed consent.

The development process resulted in a two-part questionnaire: a self-rating questionnaire for general practice patients and an external rating questionnaire for GPs. As a next step, a cross-sectional study was conducted, and the factorial structure of the new two-part questionnaire was examined to identify its factorial and psychometric properties.

Study design, procedure and participants during the evaluation of the questionnaire

The cross-sectional study was performed between March and July 2022 in five general practices in Bavaria, Germany. This study part was also approved by the Medical Ethics Committee of the Technical University Munich/University Hospital Klinikum rechts der Isar (63/22 S-KK) and was registered with the German Clinical Trials Registry (DRKS-ID: DRKS00028950). Inclusion criteria were an age of at least 18 years, sufficient knowledge of the German language and a signed consent form. Patients were consecutively approached on certain days at regular intervals in the general practitioner's waiting room. After giving informed consent, they were asked to complete a self-report questionnaire consisting of our newly developed questionnaire and the PHQ-9. After the consultation with the patient, the GP had to fill in the external rating part of the newly developed questionnaire.

Instruments

Preliminary Questionnaire for the Assessment of DEpression SYmptoms in Primary Care (DESY-PC):

Our newly developed questionnaire DESY-PC contains a self-rating part for patients and an external rating part for GPs. As part of the following analysis of the factorial structure, the number of items in both questionnaire parts was reduced (see Supplementary Material for the preliminary version of the DESY-PC). The questionnaire was originally written in German. To present an English version as part of this article, we translated the questionnaire back and forth between German and English using an online machine translation service (DeepL Translator, DeepL.com). The English version was then reviewed with a native speaker.

Preliminary self-rating part for patients (DESY-PAT): This part contains 13 items with general questions about the patient's environment (DESY-PAT-1), followed by 29 questions about depression-specific symptoms (DESY-PAT-2). All items are presented in a closed-answer format (yes/no). This preliminary part is depicted in the online supplement (Supplementary material S1).

Preliminary external rating part for GPs (DESY-GP): This part examines the presence of depression in the patient from the general practitioner's point of view. The questionnaire part comprises 21 items, which are presented in a closed-answer format (yes/no). This preliminary part is depicted in the online supplement (Supplementary material S2).

Patient Health Questionnaire 9 (PHQ-9):

The validated questionnaire PHQ-9 is used to detect patients at high risk for depression [47]. The PHQ-9 is a module of the Patient Health Questionnaire (PHQ-D). It includes nine items and can be used to determine the severity of depression. A cut-off score of ≥10 is used to indicate a high risk of depression [48]. In this study, the PHQ-9 is used as a comparative questionnaire for the convergent validity of the newly developed DESY-PC.

Further recorded data:

Demographic data was examined with respect to age, gender, origin, sociodemographic background and reason for encounter. Additionally, the permanent diagnoses noted in the GP's computer system, the current reason for the encounter noted by the GP and the medication were recorded.

Data analysis

Descriptive statistics of quantitative or qualitative data are mean (M), standard deviation (SD) and range, or absolute and relative frequencies.

We conducted an explorative factor analysis to assess the factorial validity of the questionnaire scales, DESY-GP, DESY-PAT-1, and DESY-PAT-2. We used the maximum likelihood method of the R package "psych" with polychoric correlations and continuity correction [49]. We applied an oblimin rotation because the occurring factors were assumed to be correlated. The criterion for factor extraction was based on the results of the parallel analysis (polychoric correlations with ML-estimation and 5000 iterations). Additionally, we used the Minimum Average Partial Test (MAP-Test) and a series of Maximum-Likelihood model tests (ML-test) to determine the number of factors. This method was also used for factor extraction since overfactoring is less severe than underfactoring [50]. Afterwards, confirmatory factor analysis using the R package "lavaan" [51] with mean and variance-adjusted weighted least squares (WLSMV) was applied to detect violations of local fit. The model fit was

assessed with TLI (Tucker-Lewis-Index) and RMSEA (Root-Mean-Square-Error of Approximation). For the item analysis and the associated item selection, the item statistics (mean, standard deviation, skewness) and the intercorrelations of the items were determined.

To estimate the internal consistency, we calculated Cronbach's coefficient α (Cronbach's α) for each scale of the DESY-PC as a minimum estimate of reliability. The PHQ-9 was used for convergent validation, which was estimated by correlating the DESY-PC and the PHQ-9. The associations between the scales of DESY-GP, DESY-PAT-1, DESY-PAT-2 and PHQ-9 were assessed with Pearson correlation coefficients and respective correction for attenuation. We used SPSS 26.0 (IBM Corp., Armonk, NY, USA) and R Version 4.1.0 (The R Foundation for Statistical Computing, Vienna, Austria) for statistical analyses. Hypothesis testing was performed at exploratory 5% significance levels.

Patient and public involvement

During the development of the questionnaire, we consulted a patient representative from the POKAL (Predictors and Outcomes in primary depression care) study group advisory board (DFG-GRK 2621), who advised us on the presentation and wording of the questionnaire and its application. Their approval was obtained before the questionnaire was used in the cross-sectional study. In addition, we sought advice from 13 primary care and psychiatric patients during the iterative development of the questionnaire.

RESULTS

Development of the DESY-PC

The first draft of the DESY-PC contained a distinct questionnaire part for GPs (DESY-GP) and consisted of 10 items with a closed-answer format (yes/no). After the revision of three experienced GPs, two items were added to the questionnaire, the wording of the present items was slightly modified, and the structure was adjusted. The following systematic literature review resulted in additional changes: the order of the items was changed to guide the GP through the questions in a reasonable sequence, and items about family history of mental illness and medication replaced items regarding obesity and sleep. Besides, after careful conceptual considerations, the DESY-PC was extended by a separate self-rating questionnaire part for primary care patients (DESY-PAT). This questionnaire part was based on common depression questionnaires and contained 34 items with a closed answer format (yes/no).

The questionnaire construction process was followed by the iterative optimisation of the two-part questionnaire during 32 cognitive interviews with 15 general practitioners, four psychiatrists/psychotherapists and 13 patients. The cognitive thinking aloud procedure revealed that

some items and questions were formulated too vague or that other questions were still missing. As a result, the number of items of the DESY-GP increased from 12 to 21. The DESY-PAT was split into two sections and contained 13 items about the patient's environment and 29 items regarding depression-specific symptoms, respectively. Various recommendations were made to change the wording and to improve the comprehensibility. The corresponding adjustments were made to finalise the development process. During this iterative development process, construct saturation was reached after interviewing 32 experts when no additional comments came up. The preliminary version of the two-part DESY-PC comprised 21 items for GPs (DESY-GP) and 13 plus 39 items for patients (DESY-PAT-1/2) with a closed answer format (yes/no) after the iterative construction process.

Results of the cross-sectional study

Sample characteristics:

From March to July 2022, 458 primary care patients were consecutively contacted in the waiting rooms of five general practices with twelve general practitioners in Bavaria. 286 patients agreed to participate in the study, and 277 signed the consent form and completed the questionnaire that was handed out to them (see Figure 1). The mean age of the participants was 53.7 years (SD=18.2 years), and 55.2% were female. 15.2% patients showed PHQ-9 sum scores ≥10. For further sociodemographic descriptions, see Table 1.

Figure 1. Flow chart of participants

GP (general practitioner).

Table 1. Characteristics of patients (N=277).

Variable (missing values)	Absolute frequency (percentage) or mean±SD (range)
Age in years (13)	53.7±18.2, (min.=18.1, max.= 94.3)
Sex (1)	
Female	153 (55.2)
Diverse	8 (3.9)
Size of residence (27)	
<10,000 inhabitants	93 (33.6)
10,000-100,000 inhabitants	115 (41.5)
>100,000 inhabitants	42 (15.2)
Marital status (2)	
Married or in relationship	191 (69.0)
Divorced/widowed/single/other	79 (28.5)
Multiple answers	5 (1.8)
German nationality (27)	234 (84.5)
With children (7)	193 (69.7)
Highest level of general education completed (1)	
No secondary general school-leaving certificate	3 (1.1)
Secondary general/intermediate school-leaving certificate/ other/multiple answers	172 (62.1)
High school diploma	101 (36.5)
Vocational qualification (4)	
No vocational training	5 (1.8)
Vocational qualification/other/multiple answers	198 (71.6)
Higher education degree	70 (25.3)
Currently employed (9)	165 (59.6)
Diagnosis of depression detected in the past (5)	64 (23.1)
Present chronic disease(s) (0)	218 (78.7)
PHQ-9 ≥10 (4)	42 (15.2)

PHQ-9=Patient Health Questionnaire-9; SD=standard deviation; min.=minimum, max.=maximum.

DESY-PC: Factorial validity and assessing scale internal consistency:

DESY-PAT: The analysis of the DESY-PAT-1 (Table 2) included n=240 (of N=277) usable cases (cases with missing values were removed). Although the parallel analysis suggested one factor, the MAP-Test indicated a three-factor solution, and the ML-tests indicated eight factors. Thus, we conducted an exploratory factor analysis with eight factors since overfactoring is a less severe problem than underfactoring [50]. We decided to select from each factor the item with the highest loading to build a content valid short scale. The DESY-PAT-1 now comprised eight essential items that were assigned to one factor, which measures "environmental factors". The loadings, communality, mean, standard deviation, factor loadings and skewness are presented in Table 2. We tested the model with a WLSMV confirmatory factor analysis. A RMSEA of 0.05 (90% Confidence Interval, CI: 0.00-0.08) and TLI of 0.96 were found. For the DESY-PAT-1 scale, Cronbach's α was 0.55 ("environmental factors").

Table 2. ML-factor analysis with loadings of the DESY-PAT-1 and ML-factor analysis based on polychoric correlations with rotated loadings of the DESY-PAT-2, descriptive values.

DESY-PAT-1	Factor	h^2	M	SD	r_{it}	V
Items	1 (environmental factors)*					
5 Do you currently have any financial difficulties?	0.86	0.74	0.10	0.29	0.42	2.65
7 Have you had depressive phases before?	0.56	0.31	0.38	0.49	0.41	0.51
4 Do you currently experience difficulties at work?	0.55	0.30	0.19	0.39	0.26	1.59
2 Do you currently have any family and/or partnership strains?	0.54	0.30	0.29	0.46	0.28	0.91
3 Do you currently have difficulties with friends and acquaintances?	0.51	0.26	0.15	0.36	0.23	1.90
8 Are you taking medication in connection with a mental illness (psychopharmacological drugs)?	0.46	0.21	0.09	0.28	0.21	2.90
1 Do you suffer from frequently occurring pain?	0.39	0.15	0.36	0.48	0.13	0.59
6 Are you burdened by raising children?	0.35	0.12	0.10	0.29	0.22	2.73

DESY-PAT-2	Factors							
Items	1 (depressive cognition)	2 (suicidality)	3 (somatoms fatigue)	h^2	M	SD	r_{it}	V
4 In the last 2 weeks, have you had more problems concentrating than usual?	**0.80**	-0.07	0.14	0.74	0.35	0.48	0.60	0.64
5 In the last 2 weeks, have you been ruminating more than usual?	**0.78**	-0.05	0.14	0.73	0.36	0.48	0.66	0.57
17 In the last 2 weeks, have you been more irritable than usual?	**0.72**	0.00	0.07	0.60	0.23	0.42	0.52	1.30
7 In the last 2 weeks, have you felt guilty?	**0.71**	0.17	-0.16	0.52	0.21	0.40	0.46	1.45
6 In the last 2 weeks, have you found making decisions more challenging than usual?	**0.64**	0.06	0.16	0.63	0.17	0.38	0.57	1.72
1 In the last 2 weeks, have you felt down and/or sad often?	**0.58**	0.21	0.23	0.78	0.35	0.48	0.63	0.62
2 In the last 2 weeks, have you had significantly less pleasure in things you usually like to do?	**0.55**	0.39	0.10	0.82	0.24	0.43	0.69	1.22
16 In the last 2 weeks, have you felt like you were failing?	**0.51**	0.42	0.04	0.73	0.23	0.42	0.59	1.87
18 In the last 2 weeks, have you been concerned about things or situations that usually do not bother you?	**0.51**	0.01	0.23	0.48	0.24	0.43	0.49	1.22
19 In the last 2 weeks, have you felt like life is not worth living?	-0.21	**1.00**	0.19	0.96	0.05	0.22	0.68	3.99
20 In the last 2 weeks, have you thought you would rather be dead?	0.07	**0.90**	-0.07	0.83	0.04	0.20	0.57	4.65
14 In the last 2 weeks, have you felt like everything is hopeless?	0.25	**0.84**	-0.07	0.92	0.10	0.31	0.72	2.56
15 In the last 2 weeks, have you felt like everything is meaningless?	0.25	**0.82**	-0.01	0.89	0.09	0.28	0.71	2.88
8 In the last 2 weeks, have you felt lonely?	0.10	**0.40**	0.34	0.50	0.21	0.41	0.37	1.42
11 In the last 2 weeks, have you felt tired and/or exhausted more often than usual?	0.07	-0.15	**0.95**	0.88	0.48	0.50	0.64	0.10
12 In the last 2 weeks, have you felt listless and without energy?	0.00	0.16	**0.88**	0.91	0.34	0.47	0.74	0.68
13 In the last 2 weeks, has everything been more stressful for you than usual?	0.12	0.00	**0.75**	0.69	0.35	0.48	0.67	0.62
10 In the last 2 weeks, did you find everyday activities (e.g. getting up, eating, going to work) more difficult than usual?	0.08	0.17	**0.72**	0.74	0.30	0.46	0.67	0.88
3 In the last 2 weeks, have you had less interest in your activities than usual?	0.43	0.11	**0.47**	0.77	0.26	0.44	0.61	1.10
9 In the last 2 weeks, have you reduced your social contacts?	0.22	0.17	**0.38**	0.43	0.21	0.40	0.47	1.45

DESY-PAT-1 (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients 1); DESY-PAT-2 (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients 2); h^2=communality score, M=mean, SD=standard deviation, r_{it}= discriminatory power, V=skewness, highest loadings are printed bold; *factor was tested independently.

The analysis of the DESY-PAT-2 (Table 2) included n=248 (of N=277) usable cases. Before we started the analysis, item 28 ("In the last 2 weeks, have you tried to compensate for unpleasant feelings by using other addictive substances (e.g., cannabis, ecstasy, cocaine, pills)?") of the DESY-PAT-2 was removed because there was too little variance in the response behaviour of the patients (too many "no" answers). Since the parallel analysis revealed only one factor, and the model tests were significant for each solution, we decided to use the MAP-Test to achieve a higher resolution of factors. The MAP-Test revealed a three-factor solution. We removed eight items to reduce redundancy and to obtain a short scale that was as content-valid as possible. The exclusion of the items was discussed with a team of experts and finally approved. Therefore, the final DESY-PAT-2 comprised 20 items that were assigned to three factors: Factor one measures "depressive cognitions", using nine items; factor two measures "suicidality", using five items; and factor three measures "symptoms of fatigue", using six items. The loadings, communality, mean, standard deviation, factor loadings and skewness are presented in Table 2. We tested the model with a WLSMV confirmatory factor analysis. A RMSEA of 0.05 (90% CI: 0.03-0.06) and TLI of 0.92 were found in the confirmatory factor analysis. For the DESY-PAT-2 scales, Cronbach's α was 0.86 ("depressive cognition"), 0.79 ("suicidality") and 0.85 ("symptoms of fatigue"). Additionally, we analysed the intercorrelations between the three DESY-PAT-2 scales, which ranged from 0.40 to 0.63. "Depressive cognition" and "suicidality" had the highest correlation (r=0.63), followed by "depressive cognition" and "symptoms of fatigue" (r=0.51). The lowest correlation was found between "suicidality" and "symptoms of fatigue" (r=0.40).

DESY-GP: For the factor analysis of the DESY-GP (Table 3), we used the data of n=263 (of N=277) completed GP assessments. Before we started the analysis, item 20 ("For women: is a hormonal contraceptive being utilised?") of the DESY-GP was removed only for the analysis because this item produced, as expected, too many missing values. The item was also unable to capture any necessary additional information in terms of content and was, therefore, finally removed from the questionnaire. Although the parallel analysis suggested one factor, the MAP-Test indicated a two-factor solution, and a series of ML tests indicated eight factors. Thus, we conducted an exploratory factor analysis with eight factors. For factor one, we selected six items out of seven representing "depression symptoms". One item (Item 6, "Is there evidence of increased fatigue and/or exhaustion?") was removed since there was a low loading on the main factor and similar high loadings on two other factors. The remaining factors consisted of only one or two items. We took the items with the highest loadings from these factors to build a content-valid factor, "medical history/external factors", consisting of seven items. One item remained a universal item; even if this item did not load high enough on any factor, its requested content is considered necessary for the questionnaire ("Have there ever been

depressive phases?"). The loadings, communality, mean, standard deviation, factor loadings and skewness are presented in Table 3.

We tested both measurement models separately with a WLSMV confirmatory factor analysis. A RMSEA of 0.04 (90% CI: 0.00-0.08) and TLI of 1.02 could be found in the confirmatory factor analysis for "depressive cognitions". For the factor "medical history/external factors", a RMSEA of 0.04 (90% CI: 0.00-0.08) and a TLI of 0.98 could be found. For the DESY-GP scales, Cronbach's α was 0.59 and 0.90 concerning "medical history/external factors" and "depression symptoms", respectively.

316 Table 3. ML-factor analysis with loadings of the DESY-GP, descriptive values.

DESY-GP	Factor					
Items	1 (depression symptoms)	h^2	M	SD	r_{it}	V
8 Is there evidence of joylessness and/or loss of interest?	0.98	0.95	.15	.36	.77	1.97
9 Is there evidence of dejection, melancholy and/or hopelessness?	0.96	0.93	.21	.41	.79	1.45
1 Does this patient make a depressive impression on me?	0.93	0.87	.22	.41	.78	1.37
6 Is there evidence of social withdrawal?	0.91	0.83	.15	.36	.70	1.93
11 Is there evidence of impaired concentration?	0.88	0.78	.18	.39	.70	1.63
7 Is there evidence of worrying about the future?	0.88	0.77	.22	.42	.69	1.34
3 Is there evidence of reduced resilience in daily life?	0.86	0.74	.35	.48	.63	0.61
	2 (medical history/external factors)					
10 Is there evidence of sleep disorders?	0.85	0.73	.21	.41	.47	1.45
5 Is there evidence of family problems?	0.80	0.63	.23	.42	.47	1.26
4 Is there evidence of work-related problems?	0.56	0.31	.14	.35	.27	2.01
2 Do the current reason for the consultation and the symptoms form a coherent picture? (inverted)	0.55	0.29	.11	.31	.30	2.54
15 Does anything else regarding depression seem unusual to me?	0.52	0.27	.12	.32	.28	2.30
13 Are there any close relatives with mental illness?	0.45	0.20	.13	.34	.24	2.20
14 Are there any relevant physical illnesses?	0.30	0.09	.43	.49	.19	0.28
Universal item: 12 Have there ever been depressive phases?	-	-	.35	.48	-	1.97

317 DESY-GP (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, external rating part for general practitioners); h^2=communality score, M=mean, SD=standard deviation, r_{it}=
318 discriminatory power, V=skewness, factors were tested independently.

Convergent validity:

The correlations of the DESY-PC and its subscales with the PHQ-9 all reach statistical significance. The correlation of the PHQ-9 with the DESY-PAT-1 and the DESY-PAT-2 is r=0.57 and r=0.81, respectively. In contrast to these high correlations, the DESY-GP only shows a moderate correlation of r=0.45 with the PHQ-9. Detailed correlations between DESY-PC and PHQ-9 can be found in Figure 2. The distribution of observations is displayed by histograms and density plots on the diagonal. The lower triangle shows dot plots with a linear regression fit. The upper triangle shows Pearson correlation coefficients and a respective correction for attenuation.

Figure 2. Correlations of DESY-PC and PHQ-9

PHQ-9 (Patient Health Questionnaire 9), DESY-PAT (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients), DESY-PAT-1 (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients 1), DESY-PAT-2 (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients 2), DESY-GP (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, external rating part for general practitioners), DESY-PC (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care); (*** p<0.001). The values in brackets are the values corrected for attenuation. The numbers were set to one if they exceeded this value.

DISCUSSION

The newly developed two-part questionnaire (DESY-PC) showed different factors for the self-rating part for patients (DESY-PAT) and for the external rating part for GPs (DESY-GP). The DESY-PAT consisted of two parts. The DESY-PAT-1 presented a one-factor structure measuring "environmental factors" for depression. During the development process of the questionnaire, the corresponding items in the DESY-PAT-1 were strongly influenced by the patients' understanding of depression and by what they thought could play an essential role in the development of a depressive disorder. Therefore, the items of the DESY-PAT-1 go beyond validated depression questionnaires, like the PHQ-9, which primarily ask about commonly used psychiatric symptoms of depression, such as cognitive, emotional, physiological and behavioural symptoms [47]. Although impairments in social, family and occupational functioning are also mentioned in the standard diagnostic criteria for depression [52], they have not yet been included in validated depression questionnaires [45]. The newly developed items in the DESY-PAT-1 focus on such environmental and contextual factors that can promote the onset of depression [53] and might play an essential role in diagnostic decision-making in general practice [35]. Environmental and contextual factors for depression can be very diverse and, when combined into a single factor, can lead to the relatively low internal consistency of 0.55 that we observed. The applicability of the DESY-PAT-1 requires further research to validate the findings and to demonstrate the diagnostic usefulness.

The DESY-PAT-2 showed a three-factor structure with one factor measuring "depressive cognitions", another factor representing "suicidality", and a third factor capturing "symptoms of fatigue". The factor "depressive cognitions" measures clinically relevant cognitive symptoms of depression, which are similarly captured, e.g. by the PHQ-9 [47]. The distinct factor "suicidality" captures the proximity to death. This concept appears to be essential in the context of depression and should not be neglected during the process of diagnostic decision-making [53]. The concept of fatigue and lack of energy, captured by the third factor, is particularly striking and represents a crucial aspect during diagnostic decision-making of depression [53]. Many depressive primary care patients show reduced energy or fatigue symptoms, so this factor can be considered specific to the primary care setting [54]. The internal consistency of these three factors varied from 0.86 for "depressive cognition", 0.79 for "suicidality", to 0.85 for "symptoms of fatigue". The results show that this part of the questionnaire measures three relevant aspects of depression in the primary care setting with sufficient precision to use the questionnaire for psychometric single-case diagnostic.

The items of the external rating part for GPs (DESY-GP) could be assigned to two independent factors, "depression symptoms" and "medical history/external factors". Besides, one universal item ("Have there ever been depressive phases?") was created. The internal consistency of the DESY-GP factors ranged from high, 0.90 for "depression symptoms", to low, 0.59 for "medical history/external factors". The first factor captures the symptoms of depression that GPs consider by comparing their impression of the patient in the current consultation with their experience of previous encounters with the same patient. In doing so, GPs take into account their in-depth knowledge of the patient, given by their shared medical history and familiarity, which ensures effective decision-making when considering standard psychiatric criteria for depression [54]. However, the symptom count of standard diagnostic criteria should not be the only means for diagnosing depression in general practice. In addition, aetiological and contextual considerations are crucial for diagnostic decision-making [35]. Therefore, the DESY-GP also focuses on external factors of depression by the factor "medical history/external factors", for which we found a relatively low internal consistency (Cronbach's α=0.59). One possible explanation for the low consistency is the rather broad range of external risk factors for depression [53], which may be difficult to capture in a single consistent factor. Nevertheless, the factor "medical history/external factors" remains important for the DESY-GP as it reflects GP-specific heuristics [35, 38].

Furthermore, our findings implicate a high convergent validity of the DESY-PC, as its correlation with the validated depression questionnaire PHQ-9 is significant. However, the DESY-GP is less associated with the PHQ-9 than the DESY-PAT (r=.45 compared to r=.81). This indicates as well that the DESY-GP possibly measures a different aspect of depression, which is essential for the general practice context.

The DESY-PAT, on the other hand, correlates highly with the PHQ-9 (r=.81), reflecting the similarity of the content of the two questionnaires. The DESY-PAT-1 shows a lower correlation with the PHQ-9 than the DESY-PAT-2 (r=.57 compared to r=.81). This difference in correlation with the PHQ-9 reflects the fact that the DESY-PAT-1 captures environmental and contextual factors for depression that are not captured by the PHQ-9, but which can be a useful addition for effective diagnostic decision-making in general practice. Nevertheless, the diagnostic accuracy of all scales needs to be clarified in a diagnostic study in general practices using standardised clinical interviews as a reference standard.

As the DESY-PC is adapted to the primary care setting, it could be used as an improved diagnostic aid for general practice patients who are considered to be at increased risk of depression. It could represent an interesting alternative to the screening approach of common depression questionnaires.

Strengths and limitations

A strength of the study is that the questionnaire was developed with the help of numerous experts from general practices, psychiatric clinics and patients so that a broad view of the illness of depression is represented. As a resulting innovation, the new DESY-PC questionnaire includes both external and self-report measures. Previous studies have shown that self-assessment is subject to bias and that the inclusion of a clinician's assessment can improve the accuracy of the diagnosis [56]. Additionally, the closed forced response format (yes/no) of the DESY-PC represents an advantage as it could avoid problems arising from using a middle response category [57].

However, there are several limitations. In the present study, it was not tested whether the DESY-PC identifies depression more accurately than commonly used depression questionnaires. We used the PHQ-9 as the only validated depression screening instrument for comparison. Therefore, in further investigations on the diagnostic accuracy of the new questionnaire, its performance should be compared to an already validated questionnaire regarding one confirmed depression diagnosis. A reference standard like the SCID interview (Structured Clinical Interview for DSM Disorders) should be applied to confirm or rule out a diagnosis. In this way, the sensitivity and specificity of the new two-part questionnaire can be tested and compared with other commonly used depression questionnaires.

A further limitation of our findings might be that we developed our questionnaire with motivated GPs and patients who regularly participate in scientific studies and research projects. These GPs and patients could be more reflective and prone to critical thinking than the average GP and their patients. It remains unclear to what extent this fact influenced the internal consistency of the questionnaire. Additionally, as participation during the validation phase was voluntary, there might have been a selection bias towards more motivated patients. This circumstance may have artificially altered the ratio of depressed to non-depressed patients, as one of these patient groups may be more likely to

refuse to participate in the study than the other. Furthermore, patient self-rating questionnaires have the general limitation that patients tend to answer questions influenced by social desirability. However, we accounted for this limitation by implementing an external rating questionnaire for GPs in the DESY-PC.

On a practical level, it remains to be seen how the new questionnaire can be used in primary care and elsewhere. It needs to be clarified whether the questionnaire is to be used only for those suspected of having a depressive disorder or for all primary care patients. Besides, most questionnaires, like the PHQ-9, have a specific cut-off value that indicates a depression diagnosis. For the new questionnaire, no such cut-off exists so far. Future research needs to investigate how a sum score is formed, whether it is weighted and whether all items are equally included in the sum score.

Finally, applying confirmatory and exploratory factor analyses using the same sample is problematic. Thus, the found factor structure must be cross-validated in future studies with a different sample.

CONCLUSION

The new DESY-PC questionnaire combines psychiatric criteria, the patient's perspective and GP heuristics. The questionnaire extends the standard criteria for depressive symptoms and provides additional insight for diagnostic decision-making in general practice. During the development process of the questionnaire, the thought processes and heuristics of GPs, as well as the perspective of their patients, were carefully considered, tailoring the questionnaire for the general practice setting. Factor analysis revealed an easy-to-interpret two-factor (DESY-GP) and four-factor (DESY-PAT) structure of the questionnaire. Overall, the new DESY-PC questionnaire considers both standard diagnostic criteria and diagnostic approaches from general practice, representing an innovative extension of existing diagnostic tools for primary care patients.

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COMPETING INTERESTS

None declared.

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DATA SHARING STATEMENT

The pseudomised dataset is available from the corresponding author on reasonable request.

AUTHOR CONTRIBUTORS

AS had the study idea. CT prepared the study protocol, took over data collection, wrote the first draft of the manuscript and was involved in data analysis. MB and AH performed statistical analysis and were involved in manuscript preparation. VS and JG were involved in reviewing the manuscript. AS was substantially involved in study design and manuscript preparation.

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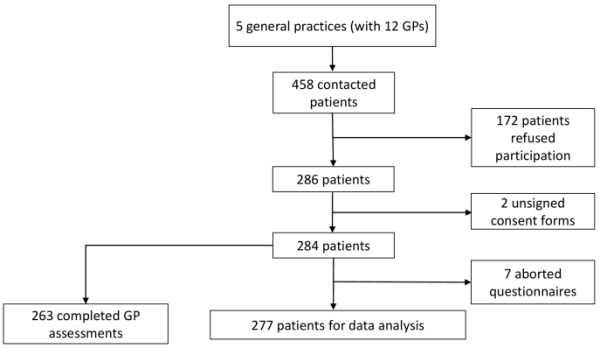

Figure 1. Flow chart of participants / GP (general practitioner).

338x190mm (300 x 300 DPI)

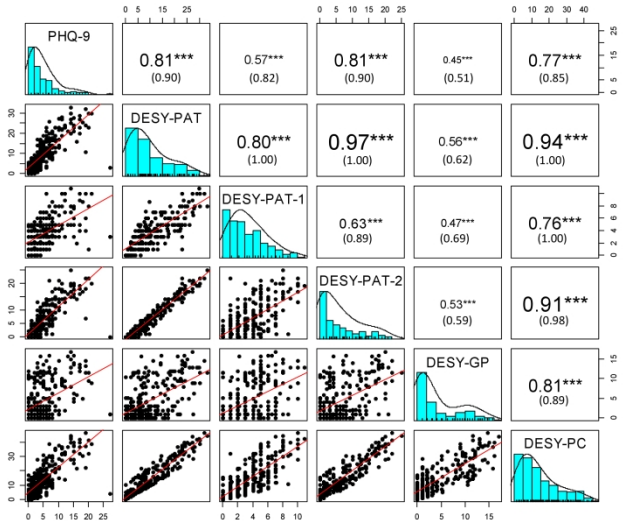

Figure 2. Correlations of the DESY-PC and PHQ-9 / PHQ-9 (Patient Health Questionnaire 9), DESY-PAT (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients), DESY-PAT-1 (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients 1), DESY-PAT-2 (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients 2), DESY-GP (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, external rating part for general practitioners), DESY-PC (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care); (*** p<0.001). The values in brackets are the values corrected for attenuation. The numbers were set to one if they exceeded this value.

338x190mm (300 x 300 DPI)

Supplementary material

Preliminary Questionnaire for the Assessment of Depression Symptoms in Primary Care (DESY-PC)

S1. Preliminary DESY-GP after iterative construction

TECHNISCHE UNIVERSITÄT MÜNCHEN
Klinikum rechts der Isar, Institut für
Allgemeinmedizin und Versorgungsforschung
Ärztlicher Direktor: Univ. Prof. Dr. Antonius Schneider

Development of a questionnaire for depression diagnosis in general practices

Documentation for general practitioner

☐☐☐
Patient number

Dear colleague,

We ask you to fill out this questionnaire for depression diagnostics after the consultation with your patient. The following questions are designed to help you assess whether or not the patient you are examining suffers from depression. Try to evaluate the following questions by considering your **impression from the last consultation** and also your **general knowledge of the patient**. If no answer alternative seems correct, choose the one that is most likely to be accurate.

		Yes	No
1.	Does this patient make a depressive impression on me?	☐	☐
2.	Does this patient make an irritated impression on me?	☐	☐
3.	Do the current reason for the consultation and the symptoms form a coherent picture?	☐	☐
4.	Is there a more substantial pain experience than according to the medical findings (e.g. increased complaining)?	☐	☐
5.	Is there evidence of reduced resilience in daily life?	☐	☐
6.	Is there evidence of increased fatigue and/or exhaustion?	☐	☐
7.	Are there any abnormalities in claiming attestations or certificates of incapacity for work?	☐	☐
8.	Is there evidence of work-related problems?	☐	☐
9.	Is there evidence of family problems?	☐	☐
10.	Is there evidence of social withdrawal?	☐	☐
11.	Is there evidence of worrying about the future?	☐	☐
12.	Is there evidence of joylessness and/or loss of interest?	☐	☐
13.	Is there evidence of dejection, melancholy and/or hopelessness?	☐	☐
14.	Is there evidence of sleep disorders?	☐	☐
15.	Is there evidence of impaired concentration?	☐	☐
16.	Have there ever been depressive phases?	☐	☐
17.	Are there any close relatives with mental illness?	☐	☐
18.	Is there evidence of an addiction problem (C2, nicotine, cannabis, medication, other drugs, media or gambling addiction)?	☐	☐
19.	Are there any relevant physical illnesses?	☐	☐
20.	For women: Is a hormonal contraceptive being utilized?	☐	☐
21.	Does anything else regarding depression seem unusual to me?	☐	☐

S2. Preliminary DESY-PAT after iterative construction

TECHNISCHE UNIVERSITÄT MÜNCHEN
Klinikum rechts der Isar, Institut für
Allgemeinmedizin und Versorgungsforschung
Ärztlicher Direktor: Univ. Prof. Dr. Antonius Schneider

Development of a questionnaire for the diagnostics of depression in general practices

Documentation for patient

☐☐☐
Patient number

We are interested in **factors that are often associated with depression**. Please answer each question as well as you can. If no answer alternative seems suitable for you, choose the one that corresponds most to your situation.

	Yes	No
1. Do you have any physical illnesses from which you particularly suffer?	☐	☐
2. Do you suffer from frequently occurring pain?	☐	☐
3. Do you currently have any family strains?	☐	☐
4. Do you currently have difficulties with friends and acquaintances?	☐	☐
5. Do you currently experience difficulties in your relationship?	☐	☐
6. Do you currently experience difficulties at work?	☐	☐
7. Do you currently have any financial difficulties?	☐	☐
8. Are you burdened by raising children?	☐	☐
9. Have you had depressive phases before?	☐	☐
10. Were there any events in your life that were particularly distressing for you?	☐	☐
11. Have you been or are you receiving treatment for a mental illness?	☐	☐
12. Are you taking medication in connection with a mental illness (psychopharmacological drugs)?	☐	☐
13. Are there any mental illnesses in your immediate family?	☐	☐

In the following, we are interested in how you have been feeling lately. The following questions are about **the past 2 weeks**. Please answer each question as well as you can. If no answer alternative seems suitable for you, choose the one that corresponds most to your situation.

	Yes	No
1. In the last 2 weeks, have you felt down and/or sad often?	☐	☐
2. In the last 2 weeks, have you had significantly less pleasure in things you usually like to do?	☐	☐
3. In the last 2 weeks, have you had less interest in your activities than usual?	☐	☐
4. In the last 2 weeks, have you had more problems concentrating than usual?	☐	☐
5. In the last 2 weeks, have you been ruminating more than usual?	☐	☐
6. In the last 2 weeks, have you found making decisions more challenging than usual?	☐	☐
7. In the last 2 weeks, have you felt guilty?	☐	☐
8. In the last 2 weeks, have you felt lonely?	☐	☐
9. In the last 2 weeks, have you reduced your social contacts?	☐	☐
10. In the last 2 weeks, did you find everyday activities (e.g. getting up, eating, going to work) more difficult than usual?	☐	☐

	Yes	No
11. In the last 2 weeks, have you been sleeping worse than usual (e.g., disturbed falling asleep and/or sleeping through the night, early morning awakenings, or increased sleep)?	☐	☐
12. In the last 2 weeks, have you felt tired and/or exhausted more often than usual?	☐	☐
13. In the last 2 weeks, have you felt listless and without energy?	☐	☐
14. In the last 2 weeks, has everything been more stressful for you than usual?	☐	☐
15. In the last 2 weeks, have you felt like everything is hopeless?	☐	☐
16. In the last 2 weeks, have you felt like everything is meaningless?	☐	☐
17. In the last 2 weeks, have you felt like you were failing?	☐	☐
18. In the last 2 weeks, have you been more irritable than usual?	☐	☐
19. In the last 2 weeks, have you been concerned about things or situations that usually do not bother you?	☐	☐
20. In the last 2 weeks, have you thought your speech and/or movements have been slower than usual?	☐	☐
21. In the last 2 weeks, have you been "fidgety" and/or restless and had a stronger urge to move than usual?	☐	☐
22. In the last 2 weeks, have you noticed any changes in appetite (e.g. less or more appetite than usual)?	☐	☐
23. In the last 2 weeks, have you had less desire for sex than usual?	☐	☐
24. In the last 2 weeks, have you felt like life is not worth living?	☐	☐
25. In the last 2 weeks, have you thought you would rather be dead?	☐	☐
26. In the last 2 weeks, have you tried to compensate for unpleasant feelings by smoking more?	☐	☐
27. In the last 2 weeks, have you tried to compensate for unpleasant feelings by drinking more alcohol?	☐	☐
28. In the last 2 weeks, have you tried to compensate for unpleasant feelings by using other addictive substances (e.g., cannabis, ecstasy, cocaine, pills)?	☐	☐
29. In the last 2 weeks, have you tried to compensate for unpleasant feelings by consuming media (cell phone, television, internet)?	☐	☐

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	#3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	#3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	#5-6
Objectives	3	State specific objectives, including any prespecified hypotheses	#6
Methods			
Study design	4	Present key elements of study design early in the paper	#6-7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	#6-7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	#7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	#7-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	#8
Bias	9	Describe any efforts to address potential sources of bias	#7
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	#8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	#8-9
		(*b*) Describe any methods used to examine subgroups and interactions	
		(*c*) Explain how missing data were addressed	#11, #13
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	#9-10
		(b) Give reasons for non-participation at each stage	#10
		(c) Consider use of a flow diagram	#10
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	#11
		(b) Indicate number of participants with missing data for each variable of interest	#11
Outcome data	15*	Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	#11-15
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	#16
Discussion			
Key results	18	Summarise key results with reference to study objectives	#16-18
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	#18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	#18, #19
Generalisability	21	Discuss the generalisability (external validity) of the study results	#18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	#20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Development and psychometric evaluation of a questionnaire for the assessment of depression in primary care: A cross-sectional study

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Development and psychometric evaluation of a questionnaire for the assessment of depression in primary care: A cross-sectional study

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Diagnostics, primary care, heuristics, general practitioner, depression

ABSTRACT

Objectives: To develop a new questionnaire for the diagnostic assessment of depression adapted to the primary care setting by combining psychiatric criteria and heuristics of general practitioners. Psychometric evaluation of the new questionnaire and first validity evidence.

Design: The questionnaire was developed using cognitive interviews with think-aloud technique. Factorial validity was then examined in a cross-sectional study.

Setting: Primary care. Five general practices in Bavaria, Germany.

Participants: 15 general practitioners (GPs), four psychiatrists/psychotherapists and 13 patients participated in cognitive expert interviews. A primary care sample of N=277 consecutive patients participated in the cross-sectional study.

Methods: After consultation with experts and literature research, the questionnaire contained a self-rating part for patients and an external part for GPs. Items were then iteratively optimised using cognitive interviews. Factorial validity was examined. To estimate internal consistency, Cronbach's α was calculated. Validity was assessed by correlating the new questionnaire and the PHQ-9.

Results: The preliminary version of the two-part "Questionnaire for the Assessment of DEpression SYmptoms in Primary Care" (DESY-PC) comprised 52 items for patients (DESY-PAT-1: questions about patient's environment; DESY-PAT-2: questions about depression-specific symptoms) and 21 items for GPs (DESY-GP). The analysis of the DESY-PAT-1 revealed a one-factor solution ("environmental factors") with Cronbach's α of 0.55. The items of the DESY-PAT-2 were assigned to three factors, "depressive cognitions", "suicidality", and "symptoms of fatigue", with Cronbach's α of 0.86, 0.79 and 0.85, respectively. Factorial analysis revealed two factors for the DESY-GP: "depression symptoms" and "medical history/external factors". Cronbach's α was 0.90 and 0.59, respectively. After factorial analysis, the DESY-PAT was reduced to 28 items, and the DESY-GP was reduced to 15 items. Correlations of the DESY-PC with the PHQ-9 were high and significant, indicating convergent validity.

Conclusions: The new questionnaire represents an innovative extension of depression questionnaires and could be particularly suitable for general practices.

ARTICLE SUMMARY

Strengths and limitations of this study

- The participation of 32 experts in the construction of the questionnaire ensured that GP-specific heuristics and patient-related characteristics of the primary care setting were incorporated into the new questionnaire.
- Unlike other validated depression questionnaires, the new questionnaire includes not only psychiatric criteria for depression, but also contextual factors relevant to general practice that may improve the diagnosis of depression.
- It was not tested whether the DESY-PC identifies depression more accurately than commonly used depression questionnaires, as we did not apply a SCID interview to confirm or rule out a depression diagnosis.

INTRODUCTION

The general practitioner (GP) is usually the first healthcare provider that patients consult [1-3]. In most cases, GPs are also the gatekeepers for further diagnostics and treatment of patients with depression [4, 5]. However, identifying depression in primary care can be challenging when only somatic symptoms are reported, and patients do not explicitly mention their depressed mood [6]. In addition to this challenge, the diagnosis of depression in primary care is further complicated by multimorbidity. Somatic complaints often overlap and mask symptoms of depression, so it can be difficult to distinguish between somatic disorders and depression [7, 8]. In any case, the initial diagnosis is essential for subsequent treatment [5, 9]. Thus, it is crucial that GPs follow a guideline-oriented diagnostic process and treatment, as the majority of patients with depression are only seen in general practice [9, 10].

In this context, it is important to note that depression is one of the most prevalent mental disorders [11-13]. Various studies have reported a lifetime prevalence of depressive disorders ranging from 12% to 19% [12, 14-16]. Depression has a major impact on the lives of those who are affected, on their family members, and on their immediate environment. Therefore, it represents a considerable health problem for our society [17, 18]. Between 2005 and 2015, depression rose from the fourth to the third leading cause of disability [19]. Moreover, the World Health Organization (WHO) predicts that depression will be the largest burden of disease worldwide by 2030 [20]. Hence, it is particularly important to improve the diagnosis and care of patients with depression and to optimise treatment processes [21]. It is crucial to identify and treat people with depression in the early stages of their illness to prevent chronicity [22]. Besides, proactive management of subthreshold depression can also protect affected individuals from developing major depression [23].

Standardised screening questionnaires could be one approach to improve the diagnosis of depression in primary care. However, expert panels like the Canadian Task Force on Preventive Health Care do not recommend routine screening for depression in general practice [24]. Similarly, guidelines such as the UK National Institute for Health and Care Excellence guideline (NICE) or the German National Health Care Guideline for Depression (NVL) do not explicitly call for routine screening. Nevertheless, both recommend it if risk factors for depression are present and the GP suspects depression [25, 26]. Although the Patient Health Questionnaire-9 (PHQ-9) has good sensitivity and specificity, previous studies have shown that screening for depression in primary care can result in a high rate of false-positives [27-32], leading to the misclassification of healthy patients as depressed. In addition, screening for depression has not been shown to improve mental health [33]. An alternative to screening in primary care could be the use of diagnostic tools as an aid to diagnosis if the clinician already suspects depression.

Furthermore, it was shown that standard diagnostic systems (e.g. International Statistical Classification of Diseases and Related Health Problems 10, ICD-10) do not work adequately in the GP context [22, 34, 35]. GPs use their heuristics and rely on factors other than ICD-10/11 or DSM-V (Diagnostic and Statistical Manual of Mental Disorders V) criteria [10, 36, 37]. The GP's intuition, the consideration of biopsychosocial factors, and their impression during the watchful waiting process, especially when depression is suspected, could represent such heuristics [35, 38]. While several studies have highlighted the impact of heuristics on medical decision-making [7, 39], current questionnaires for depression do not incorporate the GP perspective so far [35, 38]. Considering GP heuristics and their perspective alongside the inclusion of psychiatric criteria could improve diagnostic decision-making and might be superior for diagnosing depression in the primary care setting [40]. To our knowledge, no such questionnaire is adapted to the primary care setting and considers GP heuristics, thought processes, and criteria for measuring depression. Therefore, a questionnaire that measures both psychiatric criteria or typical symptoms of depression and GP heuristics should be introduced in general practice. The planned questionnaire is, therefore, not intended as a classic screener but primarily as a diagnostic aid in general practice for patients who are considered to be at increased risk of depression.

In this article, we describe: 1) The development of a new questionnaire for the assessment of depression adapted to the GP setting, which considers GP heuristics and psychiatric criteria. 2) The psychometric evaluation of the new questionnaire and a first validity evidence in a primary care sample of N=277 patients.

METHODS

Development of the preliminary questionnaire

The first draft of the questionnaire was based on practical considerations, the clinical experience of the research team, and the consideration of the main depression criteria from ICD-10. An initial literature review and discussions with three experienced GPs helped to refine the wording and number of items used. The first draft of the questionnaire was further developed by conceptual considerations of questionnaire construction and the consideration of commonly used screening questionnaires for depression, which were found to be relevant in a thorough literature review [30, 41-45].

In the next step, the questionnaire design and content were iteratively optimised through cognitive expert interviews with general practitioners, psychiatrists/psychotherapists and patients. During the cognitive interviews, participants had to complete the new questionnaire by thinking out loud. We used this technique to detect inconsistencies, missing information/items, or information about items

that were difficult to understand. The cognitive think-aloud technique is optimal for capturing thought processes [46]. The idea was to consider psychiatric criteria and aspects essential to the GPs and their patients. The interviews were audiotaped and continuously analysed by the authors (CT, AS, MB), who discussed the plausibility of the suggestions and then iteratively incorporated them into the questionnaire before showing the revised version to the next interview partner. This process was conducted from April to October 2021 until construct saturation occurred, and no further far-reaching suggestions for improvement were made. GP interview partners were recruited through the Bavarian practice-based research network (BayFoNet); patients were recruited through GP referral and recruitment on a psychiatric ward. Psychiatrists/psychotherapists were motivated to participate in an interview by direct invitation. The Medical Ethics Committee of the Technical University Munich/University Hospital Klinikum rechts der Isar (169/21 S-EB) approved the development of the preliminary questionnaire, and the 32 interview partners gave written informed consent.

The development process resulted in a two-part questionnaire: a self-rating questionnaire for general practice patients and an external rating questionnaire for GPs. As a next step, a cross-sectional study was conducted, and the factorial structure of the new two-part questionnaire was examined to identify its factorial and psychometric properties.

Study design, procedure and participants during the evaluation of the questionnaire

The cross-sectional study was performed between March and July 2022 in five general practices in Bavaria, Germany. This study part was also approved by the Medical Ethics Committee of the Technical University Munich/University Hospital Klinikum rechts der Isar (63/22 S-KK) and was registered with the German Clinical Trials Registry (DRKS-ID: DRKS00028950). Inclusion criteria were an age of at least 18 years, sufficient knowledge of the German language and a signed consent form. All patients were approached consecutively (i.e. without pre-selection) on certain days at regular intervals in the general practitioner's waiting room, regardless of their reason for the encounter with the GP. As the new questionnaire was to be tested first, patients with and without depression had to fill it out in order to examine how well the questionnaire discriminated between these patients. After giving informed consent, they were asked to complete a self-report questionnaire consisting of our newly developed questionnaire and the PHQ-9. After the consultation with the patient, the GP had to fill in the external rating part of the newly developed questionnaire.

Instruments

Preliminary Questionnaire for the Assessment of DEpression SYmptoms in Primary Care (DESY-PC):

Our newly developed questionnaire DESY-PC contains a self-rating part for patients and an external rating part for GPs. As part of the following analysis of the factorial structure, the number of items in

both questionnaire parts was reduced (see Supplementary Material for the preliminary version of the DESY-PC). The questionnaire was originally written in German. To present an English version as part of this article, we translated the questionnaire back and forth between German and English using an online machine translation service (DeepL Translator, DeepL.com). The English version was then reviewed with a native speaker who is fluent in German.

Preliminary self-rating part for patients (DESY-PAT): This part contains 13 items with general questions about the patient's environment (DESY-PAT-1), followed by 29 questions about depression-specific symptoms (DESY-PAT-2). All items are presented in a closed-answer format (yes/no). This preliminary part is depicted in the online supplement (Supplementary material S1).

Preliminary external rating part for GPs (DESY-GP): This part examines the presence of depression in the patient from the general practitioner's point of view. The questionnaire part comprises 21 items, which are presented in a closed-answer format (yes/no). This preliminary part is depicted in the online supplement (Supplementary material S2).

Patient Health Questionnaire 9 (PHQ-9):

The validated questionnaire PHQ-9 is used to detect patients at high risk for depression [47]. The PHQ-9 is a module of the Patient Health Questionnaire (PHQ-D). It includes nine items and can be used to determine the severity of depression. A cut-off score of ≥10 is used to indicate a high risk of depression [48]. In this study, the PHQ-9 is used as a comparative questionnaire for the convergent validity of the newly developed DESY-PC.

Further recorded data:

Demographic data was examined with respect to age, gender, origin, sociodemographic background and reason for encounter. Additionally, the permanent diagnoses noted in the GP's computer system, the current reason for the encounter noted by the GP and the medication were recorded.

Data analysis

Descriptive statistics of quantitative or qualitative data are mean (M), standard deviation (SD) and range, or absolute and relative frequencies.

We conducted an explorative factor analysis to assess the factorial validity of the questionnaire scales, DESY-GP, DESY-PAT-1, and DESY-PAT-2. We used the maximum likelihood method of the R package "psych" with polychoric correlations and continuity correction [49]. We applied an oblimin rotation because the occurring factors were assumed to be correlated. The criterion for factor extraction was based on the results of the parallel analysis (polychoric correlations with ML-estimation and 5000

iterations). Additionally, we used the Minimum Average Partial Test (MAP-Test) and a series of Maximum-Likelihood model tests (ML-test) to determine the number of factors. This method was also used for factor extraction since overfactoring is less severe than underfactoring [50]. Afterwards, confirmatory factor analysis using the R package "lavaan" [51] with mean and variance-adjusted weighted least squares (WLSMV) was applied to detect violations of local fit. The model fit was assessed with TLI (Tucker-Lewis-Index) and RMSEA (Root-Mean-Square-Error of Approximation). For the item analysis and the associated item selection, the item statistics (mean, standard deviation, skewness) and the intercorrelations of the items were determined.

To estimate the internal consistency, we calculated Cronbach's coefficient α (Cronbach's α) for each scale of the DESY-PC as a minimum estimate of reliability. The PHQ-9 was used for convergent validation, which was estimated by correlating the DESY-PC and the PHQ-9. The associations between the scales of DESY-GP, DESY-PAT-1, DESY-PAT-2 and PHQ-9 were assessed with Pearson correlation coefficients and respective correction for attenuation. Items within a factor were 0/1 dummy-coded and summed, and corresponding sum scores were used to calculate Pearson correlation coefficients. We used SPSS 26.0 (IBM Corp., Armonk, NY, USA) and R Version 4.1.0 (The R Foundation for Statistical Computing, Vienna, Austria) for statistical analyses. Hypothesis testing was performed at exploratory 5% significance levels.

Patient and public involvement

During the development of the questionnaire, we consulted a patient representative from the POKAL (Predictors and Outcomes in primary depression care) study group advisory board (DFG-GRK 2621), who advised us on the presentation and wording of the questionnaire and its application. Their approval was obtained before the questionnaire was used in the cross-sectional study. In addition, we sought advice from 13 primary care and psychiatric patients during the iterative development of the questionnaire.

RESULTS

Development of the DESY-PC

The first draft of the DESY-PC contained a distinct questionnaire part for GPs (DESY-GP) and consisted of 10 items with a closed-answer format (yes/no). After the revision of three experienced GPs, two items were added to the questionnaire, the wording of the present items was slightly modified, and the structure was adjusted. The following systematic literature review resulted in additional changes: the order of the items was changed to guide the GP through the questions in a reasonable sequence,

and items about family history of mental illness and medication replaced items regarding obesity and sleep. Besides, after careful conceptual considerations, the DESY-PC was extended by a separate self-rating questionnaire part for primary care patients (DESY-PAT). This questionnaire part was based on common depression questionnaires and contained 34 items with a closed answer format (yes/no).

The questionnaire construction process was followed by the iterative optimisation of the two-part questionnaire during 32 cognitive interviews with 15 general practitioners, four psychiatrists/psychotherapists and 13 patients. The cognitive thinking aloud procedure revealed that some items and questions were formulated too vague or that other questions were still missing. As a result, the number of items of the DESY-GP increased from 12 to 21. The DESY-PAT was split into two sections and contained 13 items about the patient's environment and 29 items regarding depression-specific symptoms, respectively. Various recommendations were made to change the wording and to improve the comprehensibility. The corresponding adjustments were made to finalise the development process. During this iterative development process, construct saturation was reached after interviewing 32 experts when no additional comments came up. The preliminary version of the two-part DESY-PC comprised 21 items for GPs (DESY-GP) and 13 plus 39 items for patients (DESY-PAT-1/2) with a closed answer format (yes/no) after the iterative construction process.

Results of the cross-sectional study

Sample characteristics:

From March to July 2022, 458 primary care patients were consecutively contacted in the waiting rooms of five general practices with twelve general practitioners in Bavaria. 286 patients agreed to participate in the study, and 277 signed the consent form and completed the questionnaire that was handed out to them (see Figure 1). The mean age of the participants was 53.7 years (SD=18.2 years), and 55.2% were female. 15.2% patients showed PHQ-9 sum scores ≥10. For further sociodemographic descriptions, see Table 1.

Figure 1. Flow chart of participants

GP (general practitioner).

Table 1. Characteristics of patients (N=277).

Variable (missing values)	Absolute frequency (percentage) or mean±SD (range)
Age in years (13)	53.7±18.2, (min.=18.1, max.= 94.3)
Sex (1)	
Female	153 (55.2)
Diverse	8 (3.9)
Size of residence (27)	
<10,000 inhabitants	93 (33.6)
10,000-100,000 inhabitants	115 (41.5)
>100,000 inhabitants	42 (15.2)
Marital status (2)	
Married or in relationship	191 (69.0)
Divorced/widowed/single/other	79 (28.5)
Multiple answers	5 (1.8)
German nationality (27)	234 (84.5)
With children (7)	193 (69.7)
Highest level of general education completed (1)	
No secondary general school-leaving certificate	3 (1.1)
Secondary general/intermediate school-leaving certificate/ other/multiple answers	172 (62.1)
High school diploma	101 (36.5)
Vocational qualification (4)	
No vocational training	5 (1.8)
Vocational qualification/other/multiple answers	198 (71.6)
Higher education degree	70 (25.3)
Currently employed (9)	165 (59.6)
Diagnosis of depression detected in the past (5)	64 (23.1)
Present chronic disease(s) (0)	218 (78.7)
PHQ-9 ≥10 (4)	42 (15.2)

PHQ-9=Patient Health Questionnaire-9; SD=standard deviation; min.=minimum, max.=maximum.

DESY-PC: Factorial validity and assessing scale internal consistency:

DESY-PAT: The analysis of the DESY-PAT-1 (Table 2) included n=240 (of N=277) usable cases (cases with missing values were removed). Although the parallel analysis suggested one factor, the MAP-Test indicated a three-factor solution, and the ML-tests indicated eight factors. Thus, we conducted an exploratory factor analysis with eight factors since overfactoring is a less severe problem than underfactoring [50]. We decided to select from each factor the item with the highest loading to build a content valid short scale. The DESY-PAT-1 now comprised eight essential items that were assigned to one factor, which measures "environmental factors". The loadings, communality, mean, standard deviation, factor loadings and skewness are presented in Table 2. We tested the model with a WLSMV confirmatory factor analysis. A RMSEA of 0.05 (90% Confidence Interval, CI: 0.00-0.08) and TLI of 0.81 were found. For the DESY-PAT-1 scale, Cronbach's α was 0.55 ("environmental factors").

Table 2. ML-factor analysis with loadings of the DESY-PAT-1 and ML-factor analysis based on polychoric correlations with rotated loadings of the DESY-PAT-2, descriptive values.

DESY-PAT-1	Factor	h^2	M	SD	r_{it}	V
Items	1 (environmental factors)*					
5 Do you currently have any financial difficulties?	0.86	0.74	0.10	0.29	0.42	2.65
7 Have you had depressive phases before?	0.56	0.31	0.38	0.49	0.41	0.51
4 Do you currently experience difficulties at work?	0.55	0.30	0.19	0.39	0.26	1.59
2 Do you currently have any family problems and/or difficulties in your romantic relationship?	0.54	0.30	0.29	0.46	0.28	0.91
3 Do you currently have difficulties with friends and acquaintances?	0.51	0.26	0.15	0.36	0.23	1.90
8 Are you taking medication to treat any mental illnesses (psychopharmacological drugs)?	0.46	0.21	0.09	0.28	0.21	2.90
1 Do you suffer from frequently occurring pain?	0.39	0.15	0.36	0.48	0.13	0.59
6 Are you burdened by raising children?	0.35	0.12	0.10	0.29	0.22	2.73

DESY-PAT-2	Factors							
Items	1 (depressive cognition)	2 (suicidality)	3 (Symptoms of fatigue)	h^2	M	SD	r_{it}	V
4 In the last 2 weeks, have you had more problems concentrating than usual?	**0.80**	-0.07	0.14	0.74	0.35	0.48	0.60	0.64
5 In the last 2 weeks, have you been ruminating more than usual?	**0.78**	-0.05	0.14	0.73	0.36	0.48	0.66	0.57
17 In the last 2 weeks, have you been more irritable than usual?	**0.72**	0.00	0.07	0.60	0.23	0.42	0.52	1.30
7 In the last 2 weeks, have you felt guilty?	**0.71**	0.17	-0.16	0.52	0.21	0.40	0.46	1.45
6 In the last 2 weeks, have you found decision-making more challenging than usual?	**0.64**	0.06	0.16	0.63	0.17	0.38	0.57	1.72
1 In the last 2 weeks, have you felt down and/or sad often?	**0.58**	0.21	0.23	0.78	0.35	0.48	0.63	0.62
2 In the last 2 weeks, have you had significantly less pleasure in things you usually like to do?	**0.55**	0.39	0.10	0.82	0.24	0.43	0.69	1.22
16 In the last 2 weeks, have you felt like you were failing?	**0.51**	0.42	0.04	0.73	0.23	0.42	0.59	1.87
18 In the last 2 weeks, have you been concerned about things or situations that usually do not bother you?	**0.51**	0.01	0.23	0.48	0.24	0.43	0.49	1.22
19 In the last 2 weeks, have you felt like life is not worth living?	-0.21	**1.00**	0.19	0.96	0.05	0.22	0.68	3.99
20 In the last 2 weeks, have you thought you would rather be dead?	0.07	**0.90**	-0.07	0.83	0.04	0.20	0.57	4.65
14 In the last 2 weeks, have you felt like everything is hopeless?	0.25	**0.84**	-0.07	0.92	0.10	0.31	0.72	2.56
15 In the last 2 weeks, have you felt like everything is meaningless?	0.25	**0.82**	-0.01	0.89	0.09	0.28	0.71	2.88
8 In the last 2 weeks, have you felt lonely?	0.10	**0.40**	0.34	0.50	0.21	0.41	0.37	1.42
11 In the last 2 weeks, have you felt tired and/or exhausted more often than usual?	0.07	-0.15	**0.95**	0.88	0.48	0.50	0.64	0.10
12 In the last 2 weeks, have you felt listless and without energy?	0.00	0.16	**0.88**	0.91	0.34	0.47	0.74	0.68
13 In the last 2 weeks, has everything been more stressful for you than usual?	0.12	0.00	**0.75**	0.69	0.35	0.48	0.67	0.62
10 In the last 2 weeks, did you find everyday activities (e.g. getting up, eating, going to work) more difficult to perform than usual?	0.08	0.17	**0.72**	0.74	0.30	0.46	0.67	0.88
3 In the last 2 weeks, have you had less interest in your activities than usual?	0.43	0.11	**0.47**	0.77	0.26	0.44	0.61	1.10
9 In the last 2 weeks, have you found yourself reducing your social encounters?	0.22	0.17	**0.38**	0.43	0.21	0.40	0.47	1.45

DESY-PAT-1 (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients 1); DESY-PAT-2 (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients 2); h^2=communality score, M=mean, SD=standard deviation, r_{it}= discriminatory power, V=skewness, highest loadings are printed bold; *factor was tested independently.

The analysis of the DESY-PAT-2 (Table 2) included n=248 (of N=277) usable cases. Before we started the analysis, item 28 ("In the last 2 weeks, have you tried to compensate for unpleasant feelings by using other addictive substances (e.g., cannabis, ecstasy, cocaine, pills)?") of the DESY-PAT-2 was removed because there was too little variance in the response behaviour of the patients (too many "no" answers). Since the parallel analysis revealed only one factor, and the model tests were significant for each solution, we decided to use the MAP-Test to achieve a higher resolution of factors. The MAP-Test revealed a three-factor solution. We removed eight items to reduce redundancy and to obtain a short scale that was as content-valid as possible. The exclusion of the items was discussed with a team of experts and finally approved. Therefore, the final DESY-PAT-2 comprised 20 items that were assigned to three factors: Factor one measures "depressive cognitions", using nine items; factor two measures "suicidality", using five items; and factor three measures "symptoms of fatigue", using six items. The loadings, communality, mean, standard deviation, factor loadings and skewness are presented in Table 2. We tested the model with a WLSMV confirmatory factor analysis. A RMSEA of 0.05 (90% CI: 0.03-0.06) and TLI of 0.92 were found in the confirmatory factor analysis. For the DESY-PAT-2 scales, Cronbach's α was 0.86 ("depressive cognition"), 0.79 ("suicidality") and 0.85 ("symptoms of fatigue"). Additionally, we analysed the intercorrelations between the three DESY-PAT-2 scales, which ranged from 0.40 to 0.63. "Depressive cognition" and "suicidality" had the highest correlation (r=0.63), followed by "depressive cognition" and "symptoms of fatigue" (r=0.51). The lowest correlation was found between "suicidality" and "symptoms of fatigue" (r=0.40).

DESY-GP: For the factor analysis of the DESY-GP (Table 3), we used the data of n=263 (of N=277) completed GP assessments. Before we started the analysis, item 20 ("For women: is a hormonal contraceptive being utilised?") of the DESY-GP was removed only for the analysis because this item produced, as expected, too many missing values. The item was also unable to capture any necessary additional information in terms of content and was, therefore, finally removed from the questionnaire. Although the parallel analysis suggested one factor, the MAP-Test indicated a two-factor solution, and a series of ML tests indicated eight factors. Thus, we conducted an exploratory factor analysis with eight factors. For factor one, we selected six items out of seven representing "depression symptoms". One item (Item 6, "Is there evidence of increased fatigue and/or exhaustion?") was removed since there was a low loading on the main factor and similar high loadings on two other factors. The remaining factors consisted of only one or two items. We took the items with the highest loadings from these factors to build a content-valid factor, "medical history/external factors", consisting of seven items. One item remained a universal item; even if this item did not load high enough on any factor, its requested content is considered necessary for the questionnaire ("Have there ever been

depressive phases?"). The loadings, communality, mean, standard deviation, factor loadings and skewness are presented in Table 3.

We tested both measurement models separately with a WLSMV confirmatory factor analysis. A RMSEA of 0.04 (90% CI: 0.00-0.08) and TLI of 0.98 could be found in the confirmatory factor analysis for "depressive cognitions". For the factor "medical history/external factors", a RMSEA of 0.04 (90% CI: 0.00-0.08) and a TLI of 0.89 could be found. For the DESY-GP scales, Cronbach's α was 0.59 and 0.90 concerning "medical history/external factors" and "depression symptoms", respectively.

319 Table 3. ML-factor analysis with loadings of the DESY-GP, descriptive values.

DESY-GP	Factor					
Items	1 (depression symptoms)	h^2	M	SD	r_{it}	V
8 Does this patient show signs of joylessness and/or loss of interest?	0.98	0.95	.15	.36	.77	1.97
9 Does this patient show signs of dejection, melancholy and/or hopelessness?	0.96	0.93	.21	.41	.79	1.45
1 Do I have the impression that this patient is depressed?	0.93	0.87	.22	.41	.78	1.37
6 Has this patient shown signs of social withdrawal?	0.91	0.83	.15	.36	.70	1.93
11 Does this patient show signs of impaired concentration?	0.88	0.78	.18	.39	.70	1.63
7 Has this patient shown signs of worrying about the future?	0.88	0.77	.22	.42	.69	1.34
3 Does this patient show signs of reduced resilience in their daily life?	0.86	0.74	.35	.48	.63	0.61
	2 (medical history/external factors)					
10 Does this patient show signs of sleep disorders?	0.85	0.73	.21	.41	.47	1.45
5 Has this patient mentioned family problems?	0.80	0.63	.23	.42	.47	1.26
4 Has this patient mentioned work-related problems?	0.56	0.31	.14	.35	.27	2.01
2 Do I agree that the patient's reason for the encounter sufficiently explains the symptoms presented? (inverted)	0.55	0.29	.11	.31	.30	2.54
15 Do I notice anything else unusual regarding depression?	0.52	0.27	.12	.32	.28	2.30
13 Does this patient have any close relatives with mental illness?	0.45	0.20	.13	.34	.24	2.20
14 Does this patient have any relevant physical illnesses?	0.30	0.09	.43	.49	.19	0.28
Universal item: 12 Does this patient have a history of depressive phases?	-	-	.35	.48	-	1.97

320 DESY-GP (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, external rating part for general practitioners); h^2=communality score, M=mean, SD=standard deviation, r_{it}=
321 discriminatory power, V=skewness, factors were tested independently.

Convergent validity:

The correlations of the DESY-PC and its subscales with the PHQ-9 all reach statistical significance. The correlation of the PHQ-9 with the DESY-PAT-1 and the DESY-PAT-2 is r=0.57 and r=0.81, respectively. In contrast to these high correlations, the DESY-GP only shows a moderate correlation of r=0.45 with the PHQ-9. Detailed correlations between DESY-PC and PHQ-9 can be found in Figure 2. The distribution of observations is displayed by histograms and density plots on the diagonal. The lower triangle shows dot plots with a linear regression fit. The upper triangle shows Pearson correlation coefficients and a respective correction for attenuation.

Figure 2. Correlations of DESY-PC and PHQ-9

PHQ-9 (Patient Health Questionnaire 9), DESY-PAT (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients), DESY-PAT-1 (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients 1), DESY-PAT-2 (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients 2), DESY-GP (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, external rating part for general practitioners), DESY-PC (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care); (*** p<0.001). The values in brackets are the values corrected for attenuation. The numbers were set to one if they exceeded this value.

DISCUSSION

The newly developed two-part questionnaire (DESY-PC) showed different factors for the self-rating part for patients (DESY-PAT) and for the external rating part for GPs (DESY-GP). The DESY-PAT consisted of two parts. The DESY-PAT-1 presented a one-factor structure measuring "environmental factors" for depression. During the development process of the questionnaire, the corresponding items in the DESY-PAT-1 were strongly influenced by the patients' understanding of depression and by what they thought could play an essential role in the development of a depressive disorder. Therefore, the items of the DESY-PAT-1 go beyond validated depression questionnaires, like the PHQ-9, which primarily ask about commonly used psychiatric symptoms of depression, such as cognitive, emotional, physiological and behavioural symptoms [47]. Although impairments in social, family and occupational functioning are also mentioned in the standard diagnostic criteria for depression [52], they have not yet been included in validated depression questionnaires [45]. The newly developed items in the DESY-PAT-1 focus on such environmental and contextual factors that can promote the onset of depression [53] and might play an essential role in diagnostic decision-making in general practice [35]. Environmental and contextual factors for depression can be very diverse and, when combined into a single factor, can lead to the relatively low internal consistency of 0.55 that we observed. The applicability of the DESY-PAT-1 requires further research to validate the findings and to demonstrate the diagnostic usefulness.

The DESY-PAT-2 showed a three-factor structure with one factor measuring "depressive cognitions", another factor representing "suicidality", and a third factor capturing "symptoms of fatigue". The factor "depressive cognitions" measures clinically relevant cognitive symptoms of depression, which are similarly captured, e.g. by the PHQ-9 [47]. The distinct factor "suicidality" captures the proximity to death. This concept appears to be essential in the context of depression and should not be neglected during the process of diagnostic decision-making [53]. The concept of fatigue and lack of energy, captured by the third factor, is particularly striking and represents a crucial aspect during diagnostic decision-making of depression [53]. Many depressive primary care patients show reduced energy or fatigue symptoms, so this factor can be considered specific to the primary care setting [54]. The internal consistency of these three factors varied from 0.86 for "depressive cognition", 0.79 for "suicidality", to 0.85 for "symptoms of fatigue". The results show that this part of the questionnaire measures three relevant aspects of depression in the primary care setting with sufficient precision to use the questionnaire for psychometric single-case diagnostic.

The items of the external rating part for GPs (DESY-GP) could be assigned to two independent factors, "depression symptoms" and "medical history/external factors". Besides, one universal item ("Have there ever been depressive phases?") was created. The internal consistency of the DESY-GP factors ranged from high, 0.90 for "depression symptoms", to low, 0.59 for "medical history/external factors". The first factor captures the symptoms of depression that GPs consider by comparing their impression of the patient in the current consultation with their experience of previous encounters with the same patient. In doing so, GPs take into account their in-depth knowledge of the patient, given by their shared medical history and familiarity, which ensures effective decision-making when considering standard psychiatric criteria for depression [54, 55]. However, the symptom count of standard diagnostic criteria should not be the only means for diagnosing depression in general practice. In addition, aetiological and contextual considerations are crucial for diagnostic decision-making [35]. Therefore, the DESY-GP also focuses on external factors of depression by the factor "medical history/external factors", for which we found a relatively low internal consistency (Cronbach's α=0.59). One possible explanation for the low consistency is the rather broad range of external risk factors for depression [53], which may be difficult to capture in a single consistent factor. Nevertheless, the factor "medical history/external factors" remains important for the DESY-GP as it reflects GP-specific heuristics [35, 38].

Furthermore, our findings implicate a high convergent validity of the DESY-PC, as its correlation with the validated depression questionnaire PHQ-9 is significant. However, the DESY-GP is less associated with the PHQ-9 than the DESY-PAT (r=.45 compared to r=.81). This indicates as well that the DESY-GP possibly measures a different aspect of depression, which is essential for the general practice context.

The DESY-PAT, on the other hand, correlates highly with the PHQ-9 (r=.81), reflecting the similarity of the content of the two questionnaires. The DESY-PAT-1 shows a lower correlation with the PHQ-9 than the DESY-PAT-2 (r=.57 compared to r=.81). This difference in correlation with the PHQ-9 reflects the fact that the DESY-PAT-1 captures environmental and contextual factors for depression that are not captured by the PHQ-9, but which can be a useful addition for effective diagnostic decision-making in general practice. There are already many validated depression questionnaires, such as the PHQ-9 or the Hospital Anxiety and Depression Scale [41]. Therefore, a detailed investigation of the diagnostic accuracy of the DESY-PC and all its parts should be carried out using standardised clinical interviews as a reference standard to justify its use as a new symptom-based questionnaire that is adapted to the primary care setting and takes into account the patient's perspectives. If no additional diagnostic use of all parts can be demonstrated, the DESY-PAT-1 and the DESY-GP could be used in addition to already established depression questionnaires to collect contextual information. The high correlation of the DESY-PAT-2 with the PHQ-9 could be an indication of similarity between the two questionnaires and thus partially deprive the DESY-PC of its justification. However, a follow-up study investigates whether the new questionnaire improves the accuracy of diagnostic decision-making in primary care and captures additional information (German Clinical Trials Registry ID: DRKS00031581). A positive finding could be an indicator of the superiority of the DESY-PAT-2 over other validated symptom-based depression questionnaires.

As the DESY-PC is adapted to the primary care setting, it could be used as an improved diagnostic aid for general practice patients who are considered to be at increased risk of depression. It could represent an interesting alternative to the screening approach of common depression questionnaires.

Strengths and limitations

A strength of the study is that the questionnaire was developed with the help of numerous experts from general practices, psychiatric clinics and patients so that a broad view of the illness of depression is represented. As a resulting innovation, the new DESY-PC questionnaire includes both external and self-report measures. Previous studies have shown that self-assessment is subject to bias and that the inclusion of a clinician's assessment can improve the accuracy of the diagnosis [56]. In this light, the diagnostic and classification system embedded in WONCA's (World Organization of Family Doctors) International Classification for Primary Care (ICPC-3) follows a very similar approach which emerges from the experience of primary care consultations and explicitly includes both GP and patient perspectives [57]. In contrast to previous editions (ICPC-1 and ICPC-2), there is a shift from a strictly medical or disease-based approach to care to a more person-centred approach. The new questionnaire similarly covers the perspectives of both GPs and patients. This approach is in line with the ICPC-3

recommendation that better diagnostic decision-making in primary care is achieved by including both perspectives [57].

Additionally, the closed forced response format (yes/no) of the DESY-PC represents an advantage as it could avoid problems arising from using a middle response category [58].

However, there are several limitations. In the present study, it was not tested whether the DESY-PC identifies depression more accurately than commonly used depression questionnaires. We used the PHQ-9 as the only validated depression screening instrument for comparison. Therefore, in further investigations on the diagnostic accuracy of the new questionnaire, its performance should be compared to an already validated questionnaire regarding one confirmed depression diagnosis. A reference standard like the SCID interview (Structured Clinical Interview for DSM Disorders) should be applied to confirm or rule out a diagnosis. In this way, the sensitivity and specificity of the new two-part questionnaire can be tested and compared with other commonly used depression questionnaires.

A further limitation of our findings might be that we developed our questionnaire with motivated GPs and patients who regularly participate in scientific studies and research projects. These GPs and patients could be more reflective and prone to critical thinking than the average GP and their patients. It remains unclear to what extent this fact influenced the internal consistency of the questionnaire. Additionally, as participation during the validation phase was voluntary, there might have been a selection bias towards more motivated patients. This circumstance may have artificially altered the ratio of depressed to non-depressed patients, as one of these patient groups may be more likely to refuse to participate in the study than the other. Furthermore, patient self-rating questionnaires have the general limitation that patients tend to answer questions influenced by social desirability. However, we accounted for this limitation by implementing an external rating questionnaire for GPs in the DESY-PC.

On a practical level, it remains to be seen how the new questionnaire can be used in primary care and elsewhere. It needs to be clarified whether the questionnaire is to be used only for those suspected of having a depressive disorder or for all primary care patients. Besides, most questionnaires, like the PHQ-9, have a specific cut-off value that indicates a depression diagnosis. For the new questionnaire, no such cut-off exists so far. Future research needs to investigate how a sum score is formed, whether it is weighted and whether all items are equally included in the sum score.

Finally, applying confirmatory and exploratory factor analyses using the same sample is problematic. Thus, the found factor structure must be cross-validated in future studies with a different sample.

CONCLUSION

The new DESY-PC questionnaire combines psychiatric criteria, the patient's perspective and GP heuristics. The questionnaire extends the standard criteria for depressive symptoms and provides additional insight for diagnostic decision-making in general practice. During the development process of the questionnaire, the thought processes and heuristics of GPs, as well as the perspective of their patients, were carefully considered, tailoring the questionnaire for the general practice setting. Factor analysis revealed an easy-to-interpret two-factor (DESY-GP) and four-factor (DESY-PAT) structure of the questionnaire. Overall, the new DESY-PC questionnaire considers both standard diagnostic criteria and diagnostic approaches from general practice, representing an innovative extension of existing diagnostic tools for primary care patients.

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COMPETING INTERESTS

None declared.

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DATA SHARING STATEMENT

The pseudonymised dataset is available from the corresponding author on reasonable request.

AUTHOR CONTRIBUTORS

AS had the study idea. CT prepared the study protocol, took over data collection, wrote the first draft of the manuscript and was involved in data analysis. MB and AH performed statistical analysis and were involved in manuscript preparation. KL, VS and JG were involved in reviewing the manuscript. AS was substantially involved in study design and manuscript preparation. CT is the author acting as guarantor and is responsible for the conduct of the study and the decision to publish.

ETHICS APPROVAL STATEMENT

The Medical Ethics Committee of the Technical University Munich/University Hospital Klinikum rechts der Isar approved our study (169/21 S-EB, 63/22 S-KK).

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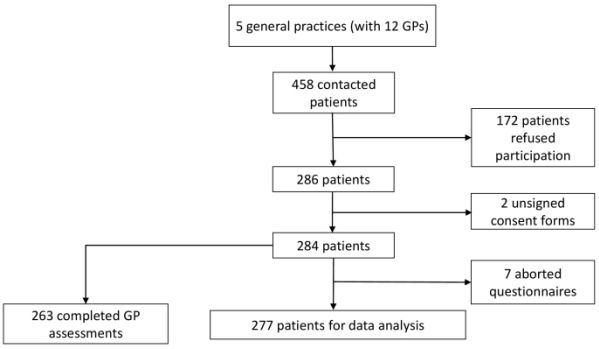

Figure 1. Flow chart of participants / GP (general practitioner).

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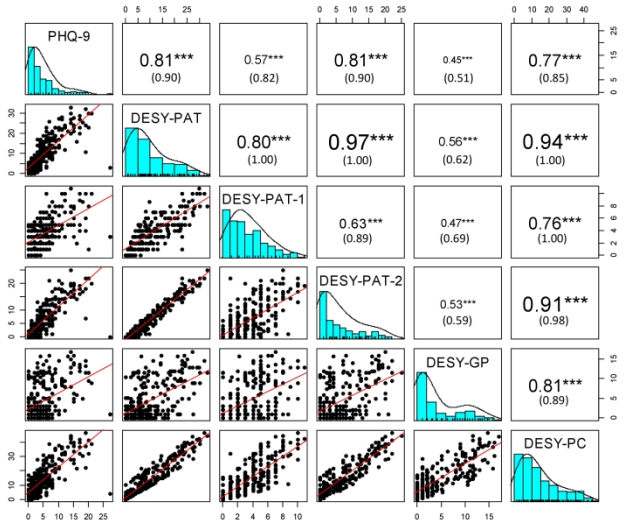

Figure 2. Correlations of the DESY-PC and PHQ-9 / PHQ-9 (Patient Health Questionnaire 9), DESY-PAT (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients), DESY-PAT-1 (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients 1), DESY-PAT-2 (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, self-rating part for patients 2), DESY-GP (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care, external rating part for general practitioners), DESY-PC (Questionnaire for the Assessment of DEpression SYmptoms in Primary Care); (*** p<0.001). The values in brackets are the values corrected for attenuation. The numbers were set to one if they exceeded this value.

338x190mm (300 x 300 DPI)

Supplementary material

Preliminary Questionnaire for the Assessment of Depression Symptoms in Primary Care (DESY-PC)

S1. Preliminary DESY-GP after iterative construction

TECHNISCHE UNIVERSITÄT MÜNCHEN
Klinikum rechts der Isar, Institut für
Allgemeinmedizin und Versorgungsforschung
Ärztlicher Direktor: Univ. Prof. Dr. Antonius Schneider

Development of a questionnaire for depression diagnosis in general practices

Documentation for general practitioner

☐☐☐
Patient number

Dear colleague,

We would like to ask you to complete this questionnaire for depression diagnostics after the consultation with your patient. The following questions are intended to help you assess if the patient you are examining suffers from depression. Try to answer the following questions by using your **impression from the last consultation** and also your **general knowledge of the patient**. If none of the options seems correct, choose the one that is most likely to be accurate.

		Yes	No
1.	Do I have the impression that this patient is depressed?	☐	☐
2.	Do I have the impression that this patient is irritated?	☐	☐
3.	Do I agree that the patient's reason for the encounter sufficiently explains the symptoms presented?	☐	☐
4.	Does this patient show a more substantial pain experience than that defined by medical findings (e.g. increased complaints)?	☐	☐
5.	Does this patient show signs of reduced resilience in their daily life?	☐	☐
6.	Does this patient show signs of increased fatigue and/or exhaustion?	☐	☐
7.	Has this patient claimed an abnormal number of attestations or work incapacity certificates?	☐	☐
8.	Has this patient mentioned work-related problems?	☐	☐
9.	Has this patient mentioned family problems?	☐	☐
10.	Has this patient shown signs of social withdrawal?	☐	☐
11.	Has this patient shown signs of worrying about the future?	☐	☐
12.	Does this patient show signs of joylessness and/or loss of interest?	☐	☐
13.	Does this patient show signs of dejection, melancholy and/or hopelessness?	☐	☐
14.	Does this patient show signs of sleep disorders?	☐	☐
15.	Does this patient show signs of impaired concentration?	☐	☐
16.	Does this patient have a history of depressive phases?	☐	☐
17.	Does this patient have any close relatives with mental illness?	☐	☐
18.	Does this patient show signs of an addiction problem (C2, nicotine, cannabis, medication, other drugs, media or gambling addiction)?	☐	☐
19.	Does this patient have any relevant physical illnesses?	☐	☐
20.	For women: Does this patient use hormonal contraceptives?	☐	☐
21.	Do I notice anything else unusual regarding depression?	☐	☐

S2. Preliminary DESY-PAT after iterative construction

TECHNISCHE UNIVERSITÄT MÜNCHEN
Klinikum rechts der Isar, Institut für
Allgemeinmedizin und Versorgungsforschung
Ärztlicher Direktor: Univ. Prof. Dr. Antonius Schneider

Development of a questionnaire for the diagnostics of depression in general practices

Documentation for patient

☐☐☐
Patient number

We are interested in **factors that are often associated with depression**. Please answer each question as well as you can. If none of the options seem suitable to you, choose the one that corresponds the most to your situation.

	Yes	No
1. Do you have any physical illnesses from which you particularly suffer?	☐	☐
2. Do you suffer from frequently occurring pain?	☐	☐
3. Do you currently have any family problems?	☐	☐
4. Do you currently have difficulties with friends and acquaintances?	☐	☐
5. Do you currently experience difficulties in your romantic relationship?	☐	☐
6. Do you currently experience difficulties at work?	☐	☐
7. Do you currently have any financial difficulties?	☐	☐
8. Are you burdened by raising children?	☐	☐
9. Have you had depressive phases before?	☐	☐
10. Were there any events in your life that were particularly distressing for you?	☐	☐
11. Have you been or are you receiving treatment for a mental illness?	☐	☐
12. Are you taking medication to treat any mental illnesses (psychopharmacological drugs)?	☐	☐
13. Does anyone in your immediate family have a mental illness?	☐	☐

In the following, we are interested in how you have been feeling lately. The following questions are about **the past 2 weeks**. Please answer each question as well as you can. If none of the options seems suitable to you, choose the one that corresponds most to your situation.

	Yes	No
1. In the last 2 weeks, have you felt down and/or sad often?	☐	☐
2. In the last 2 weeks, have you had significantly less pleasure in things you usually like to do?	☐	☐
3. In the last 2 weeks, have you had less interest in your activities than usual?	☐	☐
4. In the last 2 weeks, have you had more problems concentrating than usual?	☐	☐
5. In the last 2 weeks, have you been ruminating more than usual?	☐	☐
6. In the last 2 weeks, have you found decision-making more challenging than usual?	☐	☐
7. In the last 2 weeks, have you felt guilty?	☐	☐
8. In the last 2 weeks, have you felt lonely?	☐	☐
9. In the last 2 weeks, have you found yourself reducing your social encounters?	☐	☐
10. In the last 2 weeks, did you find everyday activities (e.g. getting up, eating, going to work) more difficult to perform than usual?	☐	☐

	Yes	No
11. In the last 2 weeks, have you been sleeping worse than usual (e.g., trouble falling asleep, trouble staying asleep, early morning awakenings, and/or increased amount of sleep)?	☐	☐
12. In the last 2 weeks, have you felt tired and/or exhausted more often than usual?	☐	☐
13. In the last 2 weeks, have you felt listless and without energy?	☐	☐
14. In the last 2 weeks, has everything been more stressful for you than usual?	☐	☐
15. In the last 2 weeks, have you felt like everything is hopeless?	☐	☐
16. In the last 2 weeks, have you felt like everything is meaningless?	☐	☐
17. In the last 2 weeks, have you felt like you were failing?	☐	☐
18. In the last 2 weeks, have you been more irritable than usual?	☐	☐
19. In the last 2 weeks, have you been concerned about things or situations that usually do not bother you?	☐	☐
20. In the last 2 weeks, have you thought your speech and/or movements have been slower than usual?	☐	☐
21. In the last 2 weeks, have you been "fidgety" and/or restless and had a stronger urge to move than usual?	☐	☐
22. In the last 2 weeks, have you noticed any changes in appetite (e.g. less or more appetite than usual)?	☐	☐
23. In the last 2 weeks, have you had less desire for sex than usual?	☐	☐
24. In the last 2 weeks, have you felt like life is not worth living?	☐	☐
25. In the last 2 weeks, have you thought you would rather be dead?	☐	☐
26. In the last 2 weeks, have you tried to compensate for unpleasant feelings by smoking more?	☐	☐
27. In the last 2 weeks, have you tried to compensate for unpleasant feelings by drinking more alcohol?	☐	☐
28. In the last 2 weeks, have you tried to compensate for unpleasant feelings by using other addictive substances (e.g., cannabis, ecstasy, cocaine, pills)?	☐	☐
29. In the last 2 weeks, have you tried to compensate for unpleasant feelings by consuming media (cell phone, television, internet)?	☐	☐

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	#3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	#3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	#5-6
Objectives	3	State specific objectives, including any prespecified hypotheses	#6
Methods			
Study design	4	Present key elements of study design early in the paper	#6-7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	#6-7
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	#7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	#7-8
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	#8
Bias	9	Describe any efforts to address potential sources of bias	#7
Study size	10	Explain how the study size was arrived at	#7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	#8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	#8-9
		(*b*) Describe any methods used to examine subgroups and interactions	Not Applicable
		(*c*) Explain how missing data were addressed	#11, #13
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	Not Applicable
		(*e*) Describe any sensitivity analyses	Not Applicable
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	#9-10
		(b) Give reasons for non-participation at each stage	#10
		(c) Consider use of a flow diagram	#10
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	#11
		(b) Indicate number of participants with missing data for each variable of interest	#11
Outcome data	15*	Report numbers of outcome events or summary measures	Not Applicable
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	#11-15
		(*b*) Report category boundaries when continuous variables were categorized	Not Applicable
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not Applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	#16
Discussion			
Key results	18	Summarise key results with reference to study objectives	#16-18
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	#18
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	#18, #19
Generalisability	21	Discuss the generalisability (external validity) of the study results	#18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	#20

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.