



Screening and guided self-help intervention for anxiety and depression in patients with type 2 diabetes

A new role for diabetes nurses in primary care?

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Introduction

Major depressive disorder (depression) is highly prevalent in patients with type 2 diabetes (T2DM).¹ Estimates of the prevalence of anxiety disorder are also high.^{2,3} Both co-morbid anxiety and depression are associated with reduced well-being, functioning and quality of life, poor coping behaviour, decreased compliance and diabetes

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Summary

Strategies for timely recognition and adequate treatment of mental disorder in diabetes are urgently needed. The aims of this study are to develop and evaluate an intervention for anxiety disorder and major depressive disorder (depression) in patients with type 2 diabetes (T2DM) by diabetes nurses (DNs) in primary care that requires minimal effort of all caregivers involved.

In this pilot, an open clinical study with pre-post test, seven trained DNs screened their patients. Patients screen-positive for anxiety disorder or depression underwent a standardised interview (MINI) by a researcher for validation. Patients fulfilling DSM-IV-TR criteria for anxiety disorder or depression were offered a self-help intervention supported and monitored by the DN in one-to-one guidance. Follow-up assessment was at six months.

Of 311 eligible patients, 111 consented to screening. Fifty-five patients were screened positive; 26 screen-positives were confirmed. Of the latter, 16 started and 15 completed the guided self-help intervention. Anxiety symptoms dropped 3.2 points ($p=0.011$), depressive symptoms 5.7 points ($p=0.007$), and somatic symptom severity 2.9 points ($p=0.041$) on the Patient Health Questionnaire. Diabetes-related negative emotions (PAID-NL) dropped 3.8 points ($p=0.048$). General functioning (EuroQol) improved by 14 points ($p=0.007$), and emotional role-functioning (SF-36) showed 33.4 points improvement ($p=0.010$). To conclude, trained DNs succeeded in screening and guiding a self-help intervention; mental and somatic symptoms, general functioning, and quality of life improved significantly.

This pilot strongly indicates that DNs can perform screening and one-to-one guidance regarding a self-help intervention for anxiety disorder and depression, playing an important role in the early detection and follow up of co-morbid mental disorders complicating diabetes.

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Key words

diabetes mellitus type 2; anxiety disorder; depressive disorder; co-morbidity; self-help intervention; nursing; disease management

control, high HbA_{1c} levels and more diabetes complications.^{1–3} The importance of enabling diabetes patients through somatic and psychological well-being to improve self-management is well recognised.^{4,5} In order to improve treatment, timely and adequate intervention should closely follow early recognition of symptoms, addressing not only diabetes-related distress, but also anxiety disorder and depression.^{5,6}

In the Netherlands, as elsewhere in Europe, the rapidly growing prevalence of diabetes, along with the rising awareness of deficiencies (such as lack of care coordination, limited patient follow up over time, and inadequate support in self-management skills), calls for a transformation in diabetes care, and clear allocation of tasks and responsibilities of caregivers.^{7,8}

The role of the diabetes nurse (DN) is to provide education and



support to people with diabetes and to help patients to self-manage their diabetes.⁹ In the Netherlands, DNs can be, but are not necessarily, educated as a nurse practitioner or specialised as a nurse specialist. DNs can be affiliated with a general practice, home care services, a health care centre or hospital. Early detection of mental disorder, followed by appropriate intervention or referral, fits the professional profile of DNs and of all caregivers involved in diabetes care; as primary care managers of these patients, DNs are often the ones with the most frequent patient contact. When performed by the DN, these tasks would require minimal effort on the part of all of the caregivers involved and can be integrated into diabetes management, requiring little change in daily practice.

However, no specific tools for nurses are available and interventions focusing on co-morbid anxiety disorder and depression are not sufficiently integrated into diabetes care. Our research question concerned whether it is feasible for trained and equipped nurses to screen T2DM patients for co-morbid depression or anxiety disorder and support and monitor patients in following a self-help intervention, in collaboration with the general practitioner (GP).

The aims of this study are: (1) to develop an intervention targeting anxiety disorder and depression in patients with T2DM in primary care; and (2) to evaluate the effect of this intervention on mental health status, general functioning and quality of life.

Patients and methods

Enrolment and screening of patients. The study was carried out with seven DNs working with 73 GPs in seven general practice settings or home care services located throughout the Netherlands, recruited by

announcements in several nursing magazines and websites. Three DNs are additionally trained as a nurse practitioner, one as a nurse specialist. The DNs have on average 26 years (range=21) of experience as a registered nurse and six years (range=8) as a DN. Four DNs are directly affiliated with a general practice, and therefore know the patient's GP. Three DNs employed by home care services have no direct contact with the GP. DNs' main tasks concern: controlling patients' HbA_{1c}, cholesterol, blood pressure, feet and waistline; adjusting the amount of insulin; and providing advice on lifestyle (diet, exercise). The total number of DNs working in each setting differs from one to six. The caseload varies from 125–3000 patients per year per setting.

T2DM patients aged 18 years and older, listed with general practices and home care services, and receiving care from participating DNs, were asked for their written informed consent to participate in this study. Patients already receiving mental health care, or diagnosed with dementia or psychosis, were excluded. All patients who met the inclusion criteria and signed informed consent were screened for anxiety disorder and depression by their DN.

The screening procedure strictly followed written instructions. The interview of Koeter & van den Brink¹⁰ was used, an adaptation of the Goldberg screen¹¹ with comparable predictive values (positive predictive value 56.5%; negative predictive value 100%; sensitivity 100%; specificity 84.2%).¹² The altered algorithm improves time efficiency of the instrument while screening for both anxiety disorder and depression as defined by DSM-III. The screening needed about five minutes per patient.

A researcher interviewed patients with positive screening outcomes using a standardised telephone interview, the MINI International

Age mean yrs (SD), range	58.5 (9.86) 40.1–80.6
Gender , % female (n)	93.3 (14)
Native country other than Netherlands % (n)	20.0 (3)
Living situation % (n) Married/living together Living alone	53.3 (8) 46.7 (7)
Educational level % (n) Low Middle High	46.7 (7) 40.0 (6) 13.3 (2)
Time since onset of T2DM % (n) ≤ ≤1 year 1–5 years 5–10 years >10 years	6.7 (1) 40.0 (6) 33.3 (5) 20.0 (3)
Somatic co-morbidity, no. of other chronic somatic diseases % (n) 1 disease 2 diseases 3 diseases ≥4 diseases	20.0 (3) 13.3 (2) 40.0 (6) 26.7 (4)

Table 1. Sociodemographic and medical data of patients completing the self-help intervention (n=15)

Neuropsychiatric Interview (anxiety and depression sections), providing a classification for anxiety disorder or depression according to DSM-IV-TR criteria.¹³ Patients as thus classified were offered the self-help intervention and one-to-one guidance by the DN. Patients in need of more intensive treatment according to the MINI, and in the opinion of the GP, were considered non-eligible for this intervention.

Table 1 presents sociodemographic and medical data of those patients who received the guided self-help intervention.

Training programme for nurses.

Participating DNs followed a training programme developed for this



study, in four half-day sessions with six-week intervals. The trainers were a psychologist and a nurse (JM and GH). The learning goal of this training programme was to prepare the DNs for the screening and one-to-one guidance of their patients, and a follow-up procedure. The training comprised transferring knowledge and skills on diagnosis and treatment of anxiety and depressive disorder and co-occurrence with diabetes. Session one included: what are the symptoms of these disorders; how do these interact with diabetes and what are the consequences; how do you recognise these disorders; what type of treatments are available; and what can be the role of the diabetes nurse? Session 2 related to introducing and applying the screening instrument (including how to carry out the screening procedure strictly), and informing patients on screening results and follow-up intervention (using interviewing and feedback techniques); session 3 comprised introducing and applying the self-help intervention, and using coaching and motivational techniques for guiding patients one-to-one; and session 4 focused on adequate referral to the GP and a résumé of training. A follow-up meeting after two months provided a booster training session on supporting and monitoring patients.

Powerpoint presentations, a video recording of depressive elderly patients and role plays were used; printed material was supplied and explained verbally.

Guided self-help intervention. A work book was developed by adapting related bibliotherapy courses to the target group and using feedback of the participating nurses in this study.¹⁴ The work book gives patients insight into symptoms of anxiety and depression and dealing with diabetes as a chronic disease, and also trains

the patient in healthy lifestyles, relaxation techniques, thinking styles, assertiveness, social activities, and relapse prevention. Techniques from cognitive therapy, rational-emotive behavioural therapy, and social learning theory are used in a structured, stepwise approach, framing clear goals, and encouraging learning by practice with specific exercises.

One-to-one guidance by DNs. DNs guided patients one-to-one following a protocol, supporting and monitoring patients in following the self-help intervention (e.g. explaining how to use the self-help work book, discussing the material in the work book with the patient, and acting as a back-up if problems arose). To this end, patients had three to five sessions with the DN, which was an intensification of the normal frequencies of nurse visits (about once every two to three months) to a frequency of once every two to four weeks, during a period of at least six weeks and at most three months.

Additional tools were developed to equip DNs, including standardised referral letters to inform GPs about the patient, and psychoeducation material to hand out.

Follow-up procedure. Patients were referred to the GP by DNs if insufficient improvement of mental health status was achieved. All GPs agreed on treating patients according to current Dutch practice guidelines after referral by DNs.

A standardised procedure was initiated for patients with an increased suicide risk according to the MINI interview: one of the researchers informed the DN and GP by letter and telephone, and advised the GP to assess for suicide risk and mental disorder. If suicidal or in need of specific intervention, the patient was excluded from the

guided self-help intervention and the GP monitored the patient.

Assessment and main variables measured. In this 18-month pilot – an open clinical study – baseline measurement was conducted by the researchers with patients included for the guided self-help intervention and follow-up measurement with completers done at six months. Mental health status was measured by the Patient Health Questionnaire (PHQ).¹⁵ Diabetes-related negative emotions were assessed with the Problems Areas In Diabetes questionnaire (PAID-NL).¹⁶ Quality of life was measured by the SF-36,¹⁷ and general functioning by the EuroQol.¹⁸ Medical data were retrieved from the patient record, reported by the DNs.

For process evaluation, DNs were interviewed face-to-face and GPs by telephone in a semi-structured interview.

The study protocol received full ethical approval from the medical ethics committee, METIGG.

Analysis methods and statistics. Descriptive statistics for sociodemographic variables and medical data were used. The McNemar test was used to compare categorical outcome measures. The Wilcoxon signed rank test, a non-parametric variant of the paired *t*-test, was used for continuous variables. Spearman's rho was used to test for correlations of baseline scores of the physical component score on the SF-36 with baseline scores and difference scores on the PHQ and the PAID-NL.

Results

Screening results. Figure 1 shows the flow chart of patients. Screening resulted in 49.5% screen positives of whom 49.1% truly had an anxiety disorder (*n*=7), depression (*n*=6), or both (*n*=13), as validated by MINI interview.



Effects on mental health status. The results are presented in Table 2. The mean PHQ score for anxiety symptoms was reduced significantly, from moderate 10.4 to mild 7.2 ($p=0.011$) after intervention, as well as the mean score for depressive symptoms, from moderately severe 15.7 to moderate 10.0 ($p=0.007$). Most patients decreased one or more levels in depression severity (66.7%; $n=10$). For anxiety symptoms, no severity levels are available but 73.3% of patients improved in symptoms ($n=11$).

The mean PHQ score for somatic symptom severity, although remaining medium, reduced significantly from 14.8 to 11.9 ($p=0.041$). The percentage of patients whose somatic symptom severity decreased one or more levels was 40.0% ($n=6$).

In addition, diabetes-related emotional distress on the PAID-NL was reduced significantly after intervention, from 24.7 to 20.9 ($p=0.048$). The percentage of patients whose emotional distress decreased one or more levels was 40.0% ($n=6$).

Eleven patients (73.3%) showed improvement in at least one measure while remaining the same for all other measures of mental health status.

Effects on general functioning and quality of life. Functioning improved after intervention, as indicated by the EuroQol EQ-5D scores (Table 2), specifically in the areas of usual activities or related to anxiety or depression. Significantly improved functioning was shown by a raised score on the Visual Analogue Scale, from 44.7 to 58.7 ($p=0.007$), indicating a higher quality of life.

Health-related quality of life also improved significantly on the SF-36 role scales: from 8.3 to 48.3 for the physical role ($p=0.007$), and from 24.4 to 57.8 for the emotional role ($p=0.010$), as well as on the mental health scale ($p=0.003$).

The SF-36 mental component score also improved significantly

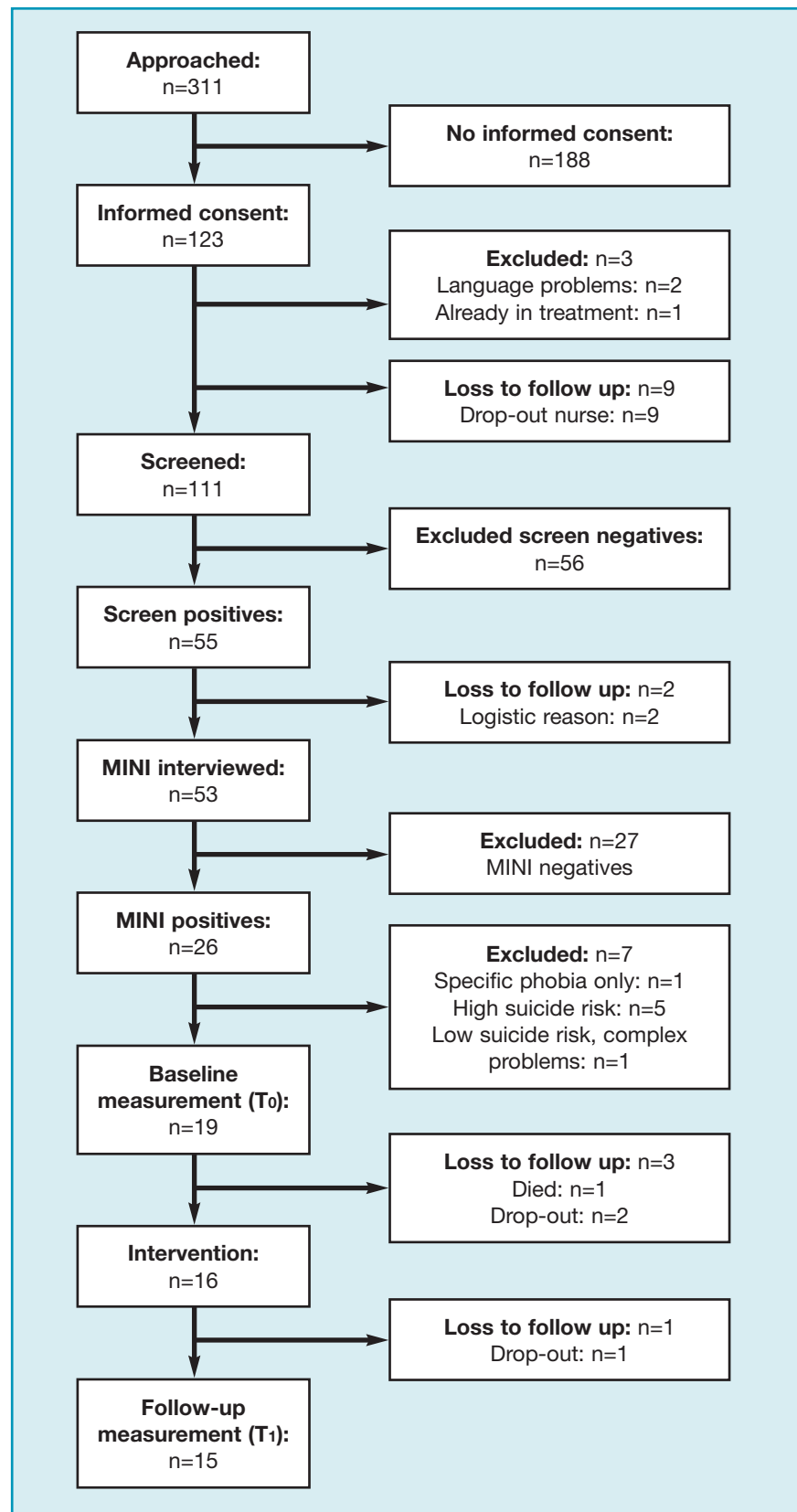


Figure 1. Patient flow chart



	Baseline			Follow-up			P-value
Health status: PHQ^a							
Depression (sum score)^b , mean (SD), range	15.7 (7.7), 5.0–26.0			10.0 (7.7), 0.0–19.0			0.007*
Depression severity level , % (n)							
None/minimal (0–4)	0.0 (0)			33.3 (5)			
Mild (5–9)	33.3 (5)			6.7 (1)			
Moderate (10–14)	13.3 (2)			13.3 (2)			
Moderately severe (15–19)	13.3 (2)			46.7 (7)			
Severe (20–27)	40.0 (6)			0.0 (0)			
Anxiety disorder (sum score)^{b,†} , mean (SD), range	10.4 (2.9), 6.0–14.0			7.2 (4.8), 0.0–14.0			0.011*
With panic disorder, % (n) ^c	26.7 (4)			6.7 (1)			0.250
Somatic symptom severity (sum score)^b , mean (SD), range	14.8 (5.8), 4.0–24.0			11.9 (5.8), 3.0–21.0			0.041*
Severity level , % (n)							
None/minimal (0–4)	6.7 (1)			6.7 (1)			
Low (5–9)	6.7 (1)			33.3 (5)			
Medium (10–14)	26.7 (4)			20.0 (3)			
High (15–30)	60.0 (9)			40.0 (6)			
Diabetes-related negative emotions: PAID-NL^d							
Diabetes-related distress^b , mean (SD), range	24.7 (21.1), 6.0–78.0			20.9 (24.3), 0.0–75.0			0.048*
Functioning: EuroQol EQ-5D							
Visual Analogue Scale^{b,e} , mean (SD), range	44.7 (21.7), 7–80			58.7 (18.3), 20.0–87.0			0.007*
Problem areas (none, some, extreme problems), % (n)	None	Some	Extreme	None	Some	Extreme	
Mobility	46.7 (7)	46.7 (7)	6.7 (1)	73.3 (11)	20.0 (3)	6.7 (1)	
Self-care	80.0 (12)	13.3 (2)	6.7 (1)	80.0 (12)	13.3 (2)	6.7 (1)	
Usual activities	13.3 (2)	66.7 (10)	20.0 (3)	33.3 (5)	46.7 (7)	20.0 (3)	
Pain/discomfort	13.3 (2)	46.7 (7)	40.0 (6)	53.3 (8)	13.3 (2)	33.3 (5)	
Anxiety/depression	6.7 (1)	73.3 (11)	20.0 (3)	66.7 (10)	33.3 (5)	0.0 (0)	
Quality of life: SF-36^e							
Roles^b , mean (SD), range							
Physical functioning	46.7 (26.6), 0.0–80.0			53.0 (29.9), 0.0–95.0			0.132
Role – physical	8.3 (20.4), 0.0–75.0			48.3 (47.7), 0.0–100.0			0.007*
Bodily pain	40.1 (24.6), 0.0–87.8			52.1 (29.9), 0.0–100.0			0.090
General health	43.0 (14.2), 20.0–80.0			44.7 (14.1), 20.0–65.0			0.342
Vitality	34.7 (15.5), 10.0–65.0			44.7 (26.8), 5.0–95.0			0.074
Social functioning	48.3 (30.9), 0.0–100.0			53.3 (35.5), 0.0–100.0			0.559
Role – emotional	24.4 (38.8), 0.0–100.0			57.8 (44.5), 0.0–100.0			0.010*
Mental health	41.9 (13.8), 16.0–64.0			61.3 (22.3), 20.0–100.0			0.003*
Relative health	41.7 (29.4), 0.0–100.0			51.7 (25.8), 0.0–100.0			0.218
Mental component score^b , mean (SD), range	31.8 (9.8), 17.9–52.7			41.0 (14.0), 20.8–61.4			0.020*
Physical component score^b , mean (SD), range	36.0 (9.4), 21.9–53.9			38.6 (11.7), 15.3–60.6			0.191
^a Higher score indicates more symptomatology. ^b Wilcoxon signed rank test. ^c McNemar test. ^d Higher score indicates more distress. ^e Higher score indicates higher quality of life. * $p < 0.05$. † $n = 14$.							

Table 2. Health status, diabetes-related emotional distress, functioning, and quality of life at baseline and at 6 months follow up (n=15)



($p=0.020$); the SF-36 physical component score (PCS) did not change significantly ($p=0.191$). We did not find any significant correlations between the baseline scores of the PCS with PHQ and PAID-NL baseline scores or difference scores.

Process evaluation. The mean level of self-perceived knowledge of participating DNs about anxiety and depression increased from 4 to 7 on a 10-point scale after training. Prior to training, most DNs lacked experience in coaching and motivational interviewing techniques; all DNs experienced problems in applying a pre-structured interview protocol. Therefore, more time than initially planned was used to instruct and practise the screening procedure.

Five DNs had patients eligible for the self-help intervention, one to six patients per DN; one patient dropped out. Patients visited the DN on average four times. Two patients were referred after completing the self-help intervention due to remaining symptoms. Overall, DNs considered the screening procedure and one-to-one guidance feasible and applicable.

GPs with DNs directly affiliated, or having more than one patient with guided self-help intervention, were the most positive about screening and follow up by the DN and about implementation of the intervention in their practice.

Discussion

This pilot strongly indicates that it is feasible for DNs to perform screening and follow up for anxiety disorder and depression by guiding a self-help intervention or adequate referral. DNs adhered to the guidance protocol, whereas patients complied with the guided self-help intervention, including nurse visits, or with referral advice. Screening and guided self-help intervention resulted in improved patient outcomes. Mental health status significantly improved,

as well as general functioning and quality of life, while diabetes-related negative emotions significantly reduced.

This pilot has several limitations. A limitation in the study design is that there was no control group. It is possible that purely the increased frequency of nurse contact was the active ingredient that achieved the positive effects shown. Evidently, a randomised controlled trial conducted in a larger population is needed in order to establish robust effects, accounting for spontaneous recovery or effects resulting purely by increased nurse contact.

Furthermore, the applied screening instrument did not show a good positive predictive value. Given that nurses can be trained in applying other screening instruments as well, there is a need for alternative screening instruments that can be used efficiently and with a better positive predictive value. For example, a validation study of the PHQ-9 as a screening instrument for co-morbid depression in patients visiting diabetes outpatient clinics found a cut-off point of a summed score of 12 on the PHQ-9, resulting in a sensitivity of 75.7% and a specificity of 80.0%.¹⁹

Moreover, in this study focusing on mental disorder instead of milder problems, we found not only a high prevalence of anxiety and depressive disorder, which is consistent with prior research, but also a relatively high number of patients with suicide risk or severe disorder, leaving fewer patients to include in the self-help intervention. Nevertheless, the effects in this small group of patients were strong enough to show significant improvement. Also, SF-36 scores were very low compared both to the Dutch general population and to patients in general practice diagnosed with T2DM.^{20,21} Whether the study group represents only more difficult cases – for example, the number of co-morbid chronic somatic illnesses is

high in our study group – or whether participating DNs are treating mainly more complex or severe cases, remains unknown. The severity of the physical status may affect mental health status; however, we did not find significant correlations between the SF-36 physical component score and mental health status.

This study demonstrates that introducing and embedding a screening procedure with follow-up intervention requires only small changes in diabetes primary care, and that expanding the role of DNs with these tasks requires relatively little training for diabetes nurses. In routine daily practice, screening could be fitted in with check-ups on a regular basis for those patients seen by DNs who are already aware of their individual circumstances and health-related problems. The standardised intervention developed in this study, addressing a disease management approach, could become part of regular diabetes training programmes. This study emphasises the key role that nurses can play in early detection and follow up of co-morbid mental disorders which complicate diabetes care, and in establishing improved patient outcomes. The positive findings of this pilot warrant further research into the efficacy of screening and self-help intervention guided by DNs.

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Declaration of interests

There are no conflicts of interest declared.

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