



Efficacy of a Web-Based Intervention With Mobile Phone Support in Treating Depressive Symptoms in Adults With Type 1 and Type 2 Diabetes: A Randomized Controlled Trial

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OBJECTIVE

Depression is common in diabetes and linked to adverse health outcomes. This study evaluated the efficacy of a guided web-based intervention in reducing depression in adults with type 1 and type 2 diabetes.

RESEARCH DESIGN AND METHODS

A total of 260 participants with diabetes and elevated depressive symptoms (Center for Epidemiologic Studies Depression Scale [CES-D ≥ 23]) were randomly assigned to the GET.ON Mood Enhancer Diabetes (a guided self-help intervention, $n = 130$) or a brief online unguided psychoeducation program for depression ($n = 130$). The primary outcome was depressive symptoms severity (CES-D). The secondary outcomes included diabetes-specific emotional distress (Problem Areas in Diabetes [PAID] scale) and participant satisfaction (adaption CSQ-8). Data were collected at baseline and 2 months after randomization. To identify differences in outcome between the groups, we used analyses of covariance with the baseline CES-D score as covariate on both intent-to-treat (ITT) and per-protocol (PP) basis.

RESULTS

Compared with the control group, the intervention group showed significantly less depressive symptom severity at posttreatment based on ITT ($d = 0.89$) and PP analyses ($d = 1.00$). The intervention participants displayed a significantly larger reduction in diabetes-specific emotional distress ($d = 0.58$, ITT). The intervention appeared to be acceptable to the participants; 95% ($n = 121$) would recommend the training to a friend with diabetes in need of psychological help.

CONCLUSIONS

A guided, web-based intervention to reduce depression in adults with type 1 and type 2 diabetes is effective in reducing both depressive symptoms and diabetes-specific emotional distress.

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Individuals diagnosed with diabetes have a higher risk of developing symptoms of depression (odds ratio 1.38 [95% CI 1.15–1.66]) than the general population (1), resulting in worse glycaemic control compared with individuals with diabetes without a mood disorder (2). A meta-analysis showed a significant association between depression and nonadherence in diabetes (3).

There have only been a few randomized controlled trials (RCTs) on treating comorbid depression in diabetes with psychological or pharmacological interventions. A recent Cochrane review on psychological and pharmacological treatments in randomized trials showed that such an intervention can be an effective approach in reducing depressive symptoms (4). Eight studies reported depression effects for psychological interventions (range of standardized mean differences = 1.47–0.14), although between-study heterogeneity was substantial and the results were not pooled across studies (3). Most of the interventions examined so far were mostly face-to-face sessions, which may not be an appropriate approach for all individuals with diabetes and depression (5). In addition, barriers at the health care system level, such as limited availability of evidence-based treatment approaches, lead to depression in patients with diabetes to remain untreated (6).

In web-based interventions, participants log in whenever they prefer, thereby reducing the need for time-constrained appointments. Moreover, participants do not have face-to-face contacts, which may help them avoid the stigma often associated with requiring treatment for depression. Thus, Internet-based interventions may reach out to depressed individuals who have gone untreated for many years despite their need for help (7).

A recent meta-analysis of studies across various populations provided evidence for the efficacy of web-based interventions in reducing depressive symptoms ($d = 0.56$). The most effective interventions were those that included some support from a health care professional ($d = 0.78$) (8). Evidence from RCTs demonstrated that web-based interventions could also be effective for individuals with severe depression (9).

Web-based interventions have been shown to be effective for participants

with chronic somatic conditions (primarily chronic pain, migraine, and tinnitus) in improving disease-specific outcomes and psychological outcomes (10). A systematic review and meta-analysis of computer-based interventions to improve self-management in adults with type 2 diabetes found a small beneficial effect on blood glucose control but no improvements concerning depression or quality of life (11). However, so far, only one web-based intervention has been specifically developed and tested for individuals with diabetes and comorbid depression with the primary aim to reduce depressive symptoms (12). van Bastelaar et al. (12) demonstrated that a web-based guided intervention developed for individuals with diabetes was effective in reducing depressive symptoms (ranging from $d = 0.29$ intent to treat [ITT] to $d = 0.70$ per protocol [PP]) and diabetes-specific emotional distress when compared with a wait-list control group (CG) at 1 month follow-up. There was no difference in glycaemic control between the two groups at 2 months after completion of treatment (12). Importantly, the intervention was effective for participants with a more severe or less severe clinical profile (13). In line with other minimally guided web-based self-help interventions (14), van Bastelaar et al. (12) found a relatively high attrition rate (58%) in the intervention group (IG). Based on these results, studying how participant adherence to web-based interventions can be enhanced by using features such as videos, audio, interactive elements, and mobile phone support is important to address.

Because of the limited evidence on web-based depression treatments for individuals with diabetes and depression to date, there is a need for further research. Hence, we developed a new intervention GET.ON Mood Enhancer Diabetes (GET.ON M.E.D.), which is a minimally guided web-based self-help intervention for adults with type 1 and type 2 diabetes and comorbid depressive symptoms. Taking into account that treatment adherence is a common problem in web-based interventions (14), we used adherence-facilitating features, which included a mobile phone support system that offered daily text messages and phone calls as part of the intervention. This article reports on

the results of an RCT comparing the efficacy of GET.ON M.E.D. with an online psychoeducation control intervention in individuals with diabetes and depressive symptoms. We hypothesized that the intervention would be more effective compared with the control condition in reducing depressive symptoms as well as diabetes-related distress.

RESEARCH DESIGN AND METHODS

Design

Participants ($n = 260$) were randomly assigned to either the IG (access to the guided GET.ON M.E.D. intervention) or the active CG (access to unguided online psychoeducation). Outcome variables were assessed at baseline (T1) and at 8 weeks after randomization (post-treatment; T2) (Fig. 1). A detailed description of the study is provided elsewhere (15). The study was approved by the Psychology Ethics Committee of the Philipps-University of Marburg, Germany (German Clinical Trial Register DRKS00004748).

Setting and Subjects

Participants were recruited by means of a comprehensive online and offline advertisement strategy. Through collaboration with a large-scale German health insurance company, individuals diagnosed with diabetes were informed of the study. Additionally, advertisements were placed in German journals for individuals with diabetes and on social networks such as Facebook.

German-speaking adults with type 1 and type 2 diabetes and comorbid depressive symptoms were recruited between March 2013 and January 2014. Knowing that web-based interventions are effective for individuals with severe and less severe mental health problems (9,13), we decided to include participants with both moderate and high depressive symptoms (Center for Epidemiologic Studies Depression Scale [CES-D] ≥ 23 ; 23 is the cutoff score for clinically relevant symptoms of depression in the German version of the CES-D [16]). To measure actual and past presence and severity of depressive symptoms, we included a telephone-administered Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I, section A) (17). Exclusion criteria were suicide risk, current psychotherapeutic treatment, or presence on a waiting list for such treatment. All of the participants

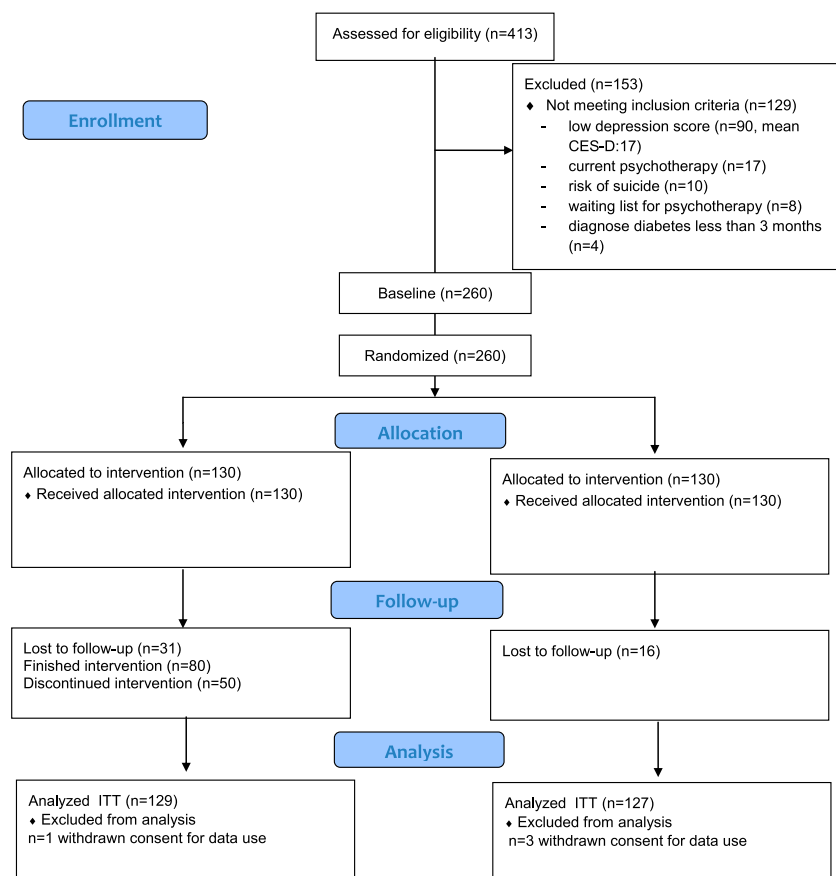


Figure 1—CONSORT 2010 flow diagram.

had full access to treatment as usual in their routine diabetes and mental health care. To control for potential confounding effects, we asked for subject usage of other mental health care services during the trial at posttreatment.

Randomization

Eligible participants were invited to complete the baseline measurement, sign their informed consent, and participate in the SCID-I. In addition to the SCID-I, we included a suicide protocol to identify and exclude individuals who reported current suicidal ideations. For randomization, an automated web-based program was used (<http://randomisation.eu>).

Interventions

Intervention Group

The GET.ON M.E.D. intervention consisted of six consecutive sessions, with the opportunity of two additional sessions addressing weight management and improving healthy sleeping. They were advised to complete one session per week; each session lasted ~45 min.

One month after the end of the intervention, participants were offered an optional booster session.

The intervention GET.ON M.E.D. was based on two core evidence-based elements: systematic behavioral activation (18) and problem solving (19). Diabetes-specific themes were an essential part of each session, covering the link between diabetes and depression, worrying about diabetes problems, diabetes and sexuality, physical activity, and communication with general practitioners. Coaches (graduate students or psychologists) gave personalized feedback by e-mail within 48 h of each session. Each coach was supervised by an experienced clinical psychologist.

To address poor adherence, known to be a problem in web-based interventions (12,14), we integrated a text message coach and phone calls. The participants had the opportunity to receive daily standardized text messages, with the aim of supporting participants to reach intervention goals and to implement behavioral change strategies. If a

participant showed no activity within 7 days, the coach sent an e-mail and offered assistance. If there was no contact within 1 week, the participant received a phone call. Participants were asked about current obstacles and encouraged to proceed with the intervention.

CG

The CG received access to an online psychoeducational program, based on the German S3-Guideline/National Disease Management Guideline for Unipolar Depression (20). There is evidence that psychoeducation is helpful in reducing depressive symptoms (21).

Outcome Measures

Primary Outcome

The primary outcome was depressive symptom severity as measured by the German version of the CES-D. The CES-D assesses the frequency of depressive symptoms during the preceding week. Items are scored on a 4-point Likert scale ranging from “not at all” (0) to “nearly every day” (4). A total score ranging between 0 and 60 can be calculated (22). A score of 23 or higher is indicative of clinically relevant depressive symptoms in German populations (16). The scale has been shown to display good to very good internal consistency ($\alpha = 0.87$ – 0.92 in various German samples) (16). Cronbach α in this study was $\alpha = 0.91$.

Secondary Outcomes

Hospital Anxiety and Depression Scale. We used the depression subscale from the Hospital Anxiety and Depression Scale (HADS) as an additional measure on depressive affect, suited for use in somatic patients. The higher the score, the more the participant suffers from depressive symptoms. Values less than 7 indicate the absence of depressive symptoms (23). The internal consistency of the HADS subscale for Depression (HADS-D) varied from $\alpha = 0.67$ to 0.90 (24). In this study, Cronbach α was $\alpha = 0.86$.

Problem Areas in Diabetes. The Problem Areas in Diabetes (PAID) scale five-item short form was used to assess participants' current emotional distress related to living with diabetes (25). A total score higher than 7 denotes elevated diabetes-related emotional distress (26). Reliability and validity of the scale have shown to be good ($\alpha = 0.83$). In this study, Cronbach α was $\alpha = 0.88$.

Acceptance and Action Diabetes Questionnaire. As an indicator of coping with diabetes, we used the German version of the Acceptance and Action Diabetes Questionnaire (AADQ). The total values vary between 11 and 77. A higher value represents better diabetes acceptance. The scale displays good internal consistency ($\alpha = 0.86$) (27). In this study, Cronbach α was $\alpha = 0.77$.

Diabetes Self-Management Questionnaire. Diabetes self-management was assessed using the Diabetes Self-Management Questionnaire (DSMQ). The DSMQ is a 16-item self-report questionnaire that measures self-care activities associated with glycemic control. A total score of 6 or higher indicates possible diabetes self-management problems. Cronbach α is good ($\alpha = 0.84$) (28). In this study, Cronbach α was $\alpha = 0.77$.

User Satisfaction. We assessed participant satisfaction using an adapted, eight-item version of the German Client Satisfaction Questionnaire (CSQ-8) (29,30).

Statistical Analysis

Based on previous studies (8,12), this trial was powered to detect a mean difference of $d = 0.35$ in the primary outcome between the groups at post-measurement, with an α of 0.05 and a power of 80% in a two-tailed test. Based on the power calculation, we needed to include 260 participants. The analyses were performed according to the recommendations of the Consolidated Standards of Reporting Trials (CONSORT) statement (31). Efficacy of GET.ON M.E.D. was analyzed on an ITT basis. To examine the efficacy of the intervention for those who adhered to the full treatment (session one to six), additional PP analyses were conducted.

Missing Data

All of the participants completed the baseline assessment. Missing data at posttreatment were imputed using a Markov chain Monte Carlo multivariate imputation algorithm (missing data module in SPSS 20) with 10 estimations per missing value. According to the recommendations of Schafer and Graham (32), this technique can generate precise estimates and is more likely to result in a precise estimation of the true intervention effect compared with other approaches such as the more conservative last observation carried forward method.

Differences in Depressive Symptom Severity and Secondary Outcomes

To evaluate the difference between the two groups at posttreatment, we performed ANCOVA with the baseline CES-D score as covariate. Cohen d was calculated as a measure of effect size; as a rule of thumb, $d = 0.8$ or more was classified as a large effect, $d = 0.5$ – 0.8 was classified as a moderate effect, and $d = 0.2$ – 0.5 was classified as a small effect (33).

Treatment Response

To assess the improvements in depressive symptoms (primary outcome) on an individual level, we calculated the reliable change index of Jacobson and Truax (34). Means and SDs were derived from normative data (16). According to the CES-D German manual, participants with a reliable positive change (reliable change index >1.96 ; greater than -8.99 points on the CES-D) were classified as “responders,” and those who displayed a reliable negative change (greater than $+8.99$ points on the CES-D) were classified as “deteriorated.”

Clinical Significant Change

We determined the number of participants who had scores <23 on the CES-D (16) in both groups and who were also categorized as responders. We assumed that participants who fulfilled both of these criteria achieved a promising improvement. Finally, we assessed the numbers needed to be treated (NNT) (35).

RESULTS

Recruitment

Over a period of 11 months, 911 individuals registered on our study website. Almost 50% ($n = 413$) replied via e-mail to our first contact and confirmed their interest. Of these 413 individuals, 284 met the inclusion criteria. Individuals who did not complete the baseline measurement or did not sign the informed consent were excluded ($n = 24$; 8%) (Fig. 1).

Baseline Characteristics

The demographic and clinical characteristics of the participants at baseline are shown in Table 1. Over half of the participants ($n = 142$; 55%) were diagnosed with type 2 diabetes. A mean PAID score of 10 indicates high levels of diabetes-specific emotional distress. Mean HbA_{1c} was 7.41% (SD 1.4), which corresponds to 151 mmol/mol (SD 36.9). The participants had relatively good diabetes

acceptance and reported no noticeable problems with diabetes self-management. Three-quarters of the participants were Caucasian ($n = 190$; 74%). The majority were middle-aged (mean age 51 years, range 18–79), female (63%), overweight (mean BMI of 30), and well educated (45% had at least a college qualification). At baseline, the mean CES-D score was 32, which indicates a moderate to severely depressed target group (15). Based on the SCID-I interview, the most common diagnosis (34%) was partial remission of depression (DSM-IV 296.25), 30% of the participants had recurrent major depression (DSM-IV 296.32), and 24% exhibited current major depression (DSM-IV 296.22). Moreover, 56% ($n = 143$) had previous experience with psychotherapy, and 44% ($n = 114$) were seeking psychological help for the first time.

Study Dropout

The number of enrolled participants who dropped out of the study was relatively low (47 [18%] at postmeasurement), which left data from 213 (82%) subjects. A significantly higher dropout rate was observed in the IG ($n = 31$; 24%) than in the CG ($n = 16$; 12%) ($\chi^2 = 5.58$; $df = 1$; $P < 0.05$). Three participants in the CG and one in the IG requested deletion of their data. Therefore, we present data for 256 participants. We conducted a series of sensitivity analyses, imputing a range of possible values for the participants who requested data deletion. None of the sensitivity analyses changed the interpretation of the results.

Intervention Completers

Overall, 80 (62%) out of the 129 participants completed all six sessions. Six participants (5%) never started the intervention, and seven (5%) completed only one session. The vast majority ($n = 96$; 74%) finished sessions one through four, in which the two core elements of the training (behavioral activation and problem solving) were addressed. Moreover, 75 (58%) participants chose the additional session “healthy sleeping,” and 67 (52%) participants chose the “weight management” session. One month post-treatment, 69 (53%) participants completed the booster session.

Effect of Treatments on Depressive Symptom Severity

Table 2 shows the results (means and SDs) for the primary and secondary

Table 1—Characteristics of the study sample at baseline

Characteristics	All participants (n = 256)	Intervention group (n = 129)	CG (n = 127)
Sociodemographic characteristics			
Age, mean (SD)	51 (12)	50 (12)	51 (12)
Female sex, n (%)	162 (63)	82 (64)	80 (63)
Ethnicity white, n (%)	190 (74)	96 (74)	94 (74)
Married or in a relationship, n (%)	160 (63)	85 (66)	75 (59)
Educational level			
No qualification, n (%)	0 (0)	0 (0)	0 (0)
High school, n (%)	142 (55)	78 (60)	64 (50)
College qualification or more, n (%)	114 (45)	51 (40)	63 (50)
Employed, n (%)	148 (58)	72 (56)	76 (60)
Lifestyle-related factors			
BMI, mean (SD)	30 (7)	30 (7)	30 (7)
Smoking, n (%)	60 (23)	31 (24)	29 (23)
Weekly time on the Internet			
Less than 1 h, n (%)	27 (11)	12 (9)	15 (12)
1–3 h, n (%)	75 (29)	41 (32)	35 (28)
More than 3 h, n (%)	154 (60)	77 (60)	77 (61)
Diabetes-related characteristics			
Type 2 diabetes, n (%)	142 (55)	64 (50)	78 (61)
Insulin-treated type 2 diabetes, n (%)	54 (21)	28 (22)	26 (20)
Diabetes complications, n (%)	64 (25)	34 (26)	30 (24)
Duration of diabetes, 3–12 months, n (%)	18 (7)	10 (8)	8 (6)
Duration of diabetes, 1–10 years, n (%)	119 (46)	57 (44)	62 (49)
Duration of diabetes, >10 years, n (%)	119 (46)	62 (48)	57 (45)
PAID score ¹ , mean (SD)	10 (4)	10 (4)	10 (5)
AADQ score ² , mean (SD)	37 (10)	37 (10)	37 (10)
DSMQ score ³ , mean (SD)	4.73 (0.65)	4.78 (0.65)	4.68 (0.65)
HbA _{1c} , % (mmol/mol)	7.41 (152)	7.45 (152)	7.36 (151)
SCID-I			
Current major depression, n (%)	61 (24)	35 (27)	26 (20)
Partial remission of depression, n (%)	87 (34)	42 (33)	45 (35)
Recurrent major depression, n (%)	78 (30)	38 (29)	40 (31)
No diagnosis, n (%)	30 (12)	14 (11)	16 (13)
Depression			
CES-D score ⁴ , mean (SD)	32 (7)	32 (7)	32 (8)
HADS-D score ⁵ , mean (SD)	12 (3)	12 (3)	12 (3)
Experience with psychotherapy, n (%)	143 (56)	71 (55)	72 (57)
Experience with depression psychotherapy, n (%)	102 (40)	49 (38)	53 (42)

¹A total score of ≥ 8 indicates possible diabetes-related emotional distress. ²The total values vary between 11 and 77. A higher value represents a higher diabetes acceptance. ³A total score of ≥ 6.0 indicates possible diabetes self-management problems. ⁴Values ≥ 23 characterized depressive symptoms. ⁵Values ≥ 11 characterized depressive symptoms, values ≤ 7 are unremarkable.

outcome measures at baseline and at posttreatment.

Table 3 highlights the results of the ANCOVAs for all of the outcome measures. The GET.ON M.E.D. group reported significantly lower depressive symptoms at posttreatment compared with the CG ($F = 78.34$; $P < 0.001$). Based on a Cohen d of $d = 0.89$ (95% CI 0.64–1.15), this is a large effect size. Moreover, individuals with major depressive disorder benefit more ($F = 50.29$; $P < 0.001$; $d = 1.06$) from the web-based intervention than patients without major depressive disorder at baseline ($F = 27.23$; $P < 0.001$; $d = 0.74$).

Concerning the PP subsample (IG 80; CG 127), the intervention effect was $d = 1.00$ (95% CI 0.70–1.29; $P < 0.001$). The

number of sessions attended was not significantly correlated with a reduction in depressive symptoms from baseline to postassessment ($r = -0.085$; $P = 0.33$).

Treatment Response

Significantly more participants in the IG were classified as treatment responders relative to the CG (IG: $n = 83$, 65%; CG: $n = 24$, 19%) ($\chi^2 = 54.33$; $df = 1$; $P > 0.001$). This corresponds to an NNT of 2.2 (95% CI 1.78–2.88). Eight (6%) participants from the CG and one (0.7%) participant from the IG had a reliable deterioration in change scores from baseline to posttreatment.

Clinical Significant Change

Significantly more participants in the IG ($n = 63$; 50%) were below the critical

value of 23 on the CES-D were also categorized as responders compared with the CG ($n = 11$; 9%) ($\chi^2 = 50.26$; $df = 1$; $P > 0.001$). This corresponds to an NNT of 2.5 (95% CI 2.0–3.30).

Secondary Outcomes

Table 3 displays the differences in effects on the secondary outcomes. The result of the depression subscale of the HADS-D indicates a large effect of $d = 0.82$ (ITT) for reduced depressive symptoms in the IG compared with the CG. The GET.ON M.E.D. intervention was effective in decreasing diabetes-specific emotional distress (PAID), achieving a medium standardized effect size of $d = 0.58$ (ITT). A small effect was achieved

Table 2—Means and SDs of outcome variables at baseline and posttreatment (ITT sample)

Outcome	T1				T2			
	GET.ON M.E.D.		CG		GET.ON M.E.D.		CG	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
CES-D	32.17	6.95	31.53	7.51	21.08	8.84	28.90	8.65
HADS-D	11.99	3.23	11.69	3.08	8.12	3.92	11.26	3.72
PAID	10.24	4.27	10.57	4.52	8.35	3.94	10.87	4.67
AADQ	36.93	8.96	36.56	10.27	34.13	8.45	36.11	9.86
DSMQ	4.78	0.65	4.68	0.65	4.76	0.55	4.72	0.62

concerning diabetes acceptance as measured with the AADQ ($d = 0.22$) for the CG. No significant between-group differences were observed for diabetes self-management (DSMQ).

Use of Other Mental Health Care Services

Eleven (9%) participants from the IG and 15 (12%) participants from the CG had appointments with a psychotherapist. Moreover, eight individuals of the CG and four individuals of the IG reported in an open-ended question that they had taken antidepressants.

User Satisfaction

The intervention was well accepted, and user satisfaction with the intervention was high (mean 27.35 [SD 4.29]) as measured using the adaptation of the CSQ-8. The majority of subjects ($n = 121$; 95%) would recommend the training to a friend in need of psychological help.

Usage of Text Messages and Reminders

Less than half of the participants ($n = 61$; 47%) used the text message support. Furthermore, 112 (88%) participants received at least one reminder e-mail from their coach. Overall, 47 (37%) individuals were called at least once and were

asked if there were any problems with the intervention. The primary reasons for discontinuation were sickness, time constraints, or technical problems. Of the 47 participants called, 15 (32%) continued with the intervention.

Reasons for Participation

The primary reason mentioned for study participation ($n = 175$, 37%) was the desire to try an alternative treatment method for depression after having had previous experience with psychotherapy. Other reasons were that traditional psychotherapy was not possible (e.g., there was no therapist available or concerns about therapy) (20%) or that participants did not want to start face-to-face psychotherapy (19%).

CONCLUSIONS

The current study confirmed the efficacy of a web-based intervention (GET.ON M.E.D.) aimed to reduce depressive symptoms in diabetes patients. The intervention was significantly more effective in reducing depressive symptoms compared with the active CG ($d = 0.89$). Significantly more participants in the IG were classified as treatment responders and had a clinical significant change compared with the CG. Moreover, we

found medium (diabetes-related distress) and large (depression assessed with the HADS-D) effects on the secondary outcomes. No significant effects were found for diabetes self-management after 2 months, possibly explained by the fact that mean DSMQ scores were below the problematic threshold and most individuals were in relatively good glycaemic control at baseline. In addition, another study tracking individuals with diabetes and depression failed to detect a relationship between depression amelioration and improved diabetes self-management (36). Surprisingly, the intervention had a negative effect on diabetes acceptance.

The participants in this study reported clinically relevant depressive symptoms (mean CES-D score 32) with 54% diagnosed with a current or recurrent major depression disorder. Approximately 45% of the participants were first-time seekers of professional psychological help, confirming a web-based intervention can reach individuals with diabetes and comorbid depression who previously did not seek or declined mental health services. Moreover, nearly 40% of the participants declared to lack access to psychological services or did not want to participate in face-to-face psychotherapy. These findings support the added value of our web-based interventions in addition to traditional treatments for individuals with diabetes and comorbid depressive symptoms.

The findings of this study for the short-term effect on depression compare favorably to the few other trials on psychological and pharmacological interventions for comorbid depression and diabetes (4). Moreover, short-term effect on diabetes-related distress is higher in comparison with the Cochrane review's results, where no significant effect on the PAID was shown (4). The current study also found higher effect sizes for the reduction of depression compared with web-based depression interventions in general (8). Additionally, the effect sizes of this study were also higher ($d = 0.89$ compared with $d = 0.29$ ITT; $d = 1.00$ compared with $d = 0.70$ PP) compared with the only prior web-based depression intervention study for individuals with diabetes and depression (12). There are several possible explanations for the relatively strong effect in our study compared with van

Table 3—Results of the ANCOVAs for primary and secondary outcomes (ITT sample)

Measure	Between-groups effect T2 ^a		
	Cohen d (95% CI)	ANCOVA ^b	
		F ^c	P
CES-D	0.89 (0.64–1.15)	78.34	<0.001
HADS-D	0.82 (0.57–1.08)	79.16	<0.001
PAID	0.58 (0.33–0.83)	37.37	<0.001
AADQ	0.22 (0.03–0.46)	9.03	0.003
DSMQ	0.07 (0.18–0.31)	0.09	0.058

^aMissing data imputed by multiple imputation. ^bControlling for pretreatment scores (T1).

^cDegrees of freedom not provided due to multiple imputation.

Bastelaar et al. (12). First, in both samples, approximately half of the participants (54 and 57%, respectively) had a major depression disorder at baseline, but mean depression scores (CES-D) did differ between the two studies (CES-D 28 vs. 32). This is probably a consequence of the fact that van Bastelaar et al. (12) included individuals with a CES-D of 16 and higher, whereas we used a cutoff of 23 (16). There was thus more room for improvement in our study. Second, treatment adherence was substantially higher in our study (64 vs. 42% completing the whole intervention), and adherence has been shown to be associated with treatment outcome in web-based interventions for depression (37). Third, incorporating mobile phone support may have added to the efficacy. However, future studies should evaluate the individual additional impact of mobile phone support in an RCT. Moreover, the short-term effect on diabetes-related distress is higher in comparison with the Cochrane review, where no significant effect on the PAID could be shown (4).

This study has a number of limitations. In this study, participants were overall well educated and primarily female. This may limit the generalizability of our results. Second, we did not measure glycemic control at posttreatment. Taking into account that the posttreatment occurred 8 weeks after randomization, we assumed that the period of time was too short to reliably measure changes in HbA_{1c} values. Interestingly, glycemic control in the depressed and distressed patient group was not a substantial problem at baseline. However, given the significant effect on the PAID that we found in this study, further improvements in glycemic control could be expected (38,39). Third, due to technical limitations of the platform, it was not possible to assess whether the participants of the CG actually read the information. Fourth, the evaluated intervention is a multicomponent intervention with a number of hypothesized mechanisms (e.g., behavioral activation, problem solving, and acceptance of diabetes). However, the current study did not assess potential mechanisms of change at multiple occasions prior to the primary end point, which would be needed in order to establish causal mechanisms, and thus, the mechanism for the observed effects of

the intervention remain unclear. Finally, we report only short-term effects and cannot draw conclusions concerning the long-term effects of the GET.ON M.E.D. intervention.

In summary, the intervention has been shown to be effective in treating comorbid depressive symptoms and diabetes-related distress in individuals with type 1 or type 2 diabetes. Given the increasing number of individuals with diabetes (40), it will be worthwhile to integrate and further disseminate effective web-based depression treatments in routine diabetes care. Research on the long-term effects and cost-effectiveness of such web-based diabetes interventions is warranted.

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