The effectiveness of an emotion-focused educational programme in reducing diabetes distress in adults with type 2 diabetes mellitus at 12-month follow-up: a cluster randomized controlled trial

Boon-How Chew (ID), Rimke C. Vos, Aaron Fernandez, Sazlina Shariff Ghazali, Nurainul Hana Shamsuddin, Mastura Ismail and Guy E.H.M. Rutten

Abstract

Background: Diabetes distress (DD) is an increasingly important part of clinical medicine, diabetes self-management and research topic in people with diabetes mellitus. The present study evaluated the effectiveness of a value-based emotion-focused educational program in Malay adults with type 2 diabetes (VEMOFIT) at 12-month follow-up compared with a program with systematic attention to participants' emotions (attention-control).

Methods: VEMOFIT consisted of four biweekly group sessions and a booster session after 3 months; the attention-control program consisted of three sessions over the same period. Intention-to-treat analysis with multilevel mixed modelling was done to estimate the intervention effect.

Results: Participants ($n = 124$) randomized to VEMOFIT ($n = 53$) or attention-control ($n = 71$). Mean (SD) age 55.7 (9.7) years, median diabetes duration 7.0 (8.0) years and mean HbA1c level 9.7% (82 mmol/mol). The mean DD (DDS-17 scale) level decreased in both groups (from 3.4 to 3.3 *versus* 3.1–2.5, respectively), significantly more in the attention-control group [adjusted difference –0.6, 95% confidence interval (CI) –1.1, –0.2]. The VEMOFIT group had a significant improvement in self-efficacy (DMSES, range 0–200; adjusted difference 16.4, 99.4% CI 1.9, 30.9). Other outcomes did not differ.

Conclusions: Because the attention-control program resulted in a decreased DD 1 year later, its implementation on a larger scale seems justified.

Trial registration: NCT02730078; NMRR-15-1144-24803

Keywords: behavioural medicine, depression, diabetes distress, educational models, emotions, type 2 diabetes mellitus

Correspondence to:
Boon-How Chew
Department of Family Medicine, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, Serdang, Selangor, 43400, Malaysia
chewboonhow@upm. edu.my

Boon-How Chew
Department of Family Medicine, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, Serdang, Malaysia

Rimke C. Vos
Department of Public Health and Primary Care/ LUMC Campus The Hague, Leiden University Medical Center, The Netherlands

Aaron Fernandez
Department of Psychiatry, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, Serdang, Malaysia

Sazlina Shariff Ghazali
Nurainul Hana Shamsuddin
Department of Family Medicine, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia, Serdang, Malaysia

Mastura Ismail
Health Clinic Seremban 2, Negeri Sembilan, Malaysia

Guy E.H.M. Rutten
Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, The Netherlands

Background

Diabetes distress (DD) is an increasingly important part of clinical care, diabetes self-management and research in people with diabetes.[1,2] Hence, psychological interventions to decrease DD are important and have been shown to be effective and safe.[1,3–5] The effectiveness of the interventions on DD seems to depend on their nature and length,[3,5] and is inconsistent between studies in the Western and the Eastern part of the world.[6] Psychological interventions that included both emotional and cognitive components are more effective than standard diabetes care in improving DD[5]; the same applies to more frequent and longer duration psycho-education and to interventions among those with elevated baseline DD.[3,4] Similarly, longer and

more advanced psycho-education and cognition-focused psychological interventions may improve HbA1c [mean difference −0.68, 95% confidence interval (CI) −0.15 to −1.21].[5]

We explored the effectiveness of a theory-based, structured, value-based and emotion-focused educational program (VEMOFIT) in Malay adults with type 2 diabetes (T2D), compared with an attention control program of active listening to participants' emotional experiences, their social support and their opinion on health clinic services regarding diabetes. After 6 months of follow-up, both the VEMOFIT program and the attention-control program had reduced DD significantly, without a significant between-group difference.[7] We hypothesized that DD would further decrease in the VEMOFIT group after a longer follow-up period, assuming that the gained knowledge and emotional skills would have positive impact on a patient's resilience and empowerment.[8,9] Accordingly, here we evaluate the effectiveness of VEMOFIT after a follow-up of 12 months.

Methods

Study design
The design of the VEMOFIT trial, and its results 6 months after the intervention, have been published elsewhere.[7,10,11] The VEMOFIT trial was a cluster randomized controlled trial in 10 public health clinics in Malaysia, from April 2016 to February 2018 (Figure 1), that compared the effectiveness of the VEMOFIT program with an attention-based control intervention (attention-control) in reducing high DD (mean score ⩾3 on the 17-item Diabetes Distress Scale, DDS-17) among Malay adults T2D with either an HbA1c level ⩾8.0% (64 mmol/mol), blood pressure ⩾140/90 mmHg or an LDL level ⩾2.6 mmol/L.[7,10] The study was approved in the ten centres by the Medical Research Ethics Committee (MREC), Ministry of Health Malaysia with the reference number of (10)KKM/NIHSEC/P15-1159. Patients who agreed to participate provided written informed consent.

Interventions
The VEMOFIT program consisted of four biweekly group sessions exploring personal values and providing diabetes education (session 1), a training on recognizing (session 2) and managing emotions

(session 3) in the self and others, providing social support and setting short- and long-term goals (session 4), and a booster session 3 months after the last session of the main intervention, reviewing the patient's goals and rehearsing the content of the fourth session. Each participant was allowed to bring along one significant other as a coparticipant.[10] The attention-control program consisted of three open-discussion sessions on feelings about and coping with T2D (session 1), social support at home and satisfaction with treatment (session 2) and care received at the respective clinics (session 3) over the same period.[10] People were not accompanied, and the sessions were not structured according to any module. Nurse-coaches and doctors were trained to conduct both programs at their own health clinics, supported by respective intervention materials and presentation slides.[7,10]

Outcomes
Outcomes included DD (primary outcome) (DDS-17, mean score range 1–6, higher scores indicating higher DD),[12] and a set of other questionnaires, all validated Malay versions,[7] with regard to depressive symptoms (9-item Patient Health Questionnaire, PHQ-9, scale 0–27, higher scores indicating more depressive symptoms), illness perceptions (Malay Brief Illness Perception Questionnaire, MBIPQ, 9 items; scores range 0–80, higher scores indicating more threatening perceptions), health-related quality of life (the 25-item WHO Quality of Life-brief version, WHOQOL-BREF, scores from 25 to 100, higher scores indicating higher quality of life), diabetes self-efficacy (20-item Diabetes Management Self Efficacy Scale, DMSES, scores range 0–200, higher scores indicating higher self-efficacy), self-care activities (11-item Summary of Diabetes Self-Care Activities, SDSCA, scores range 0–7, higher scores indicating more self-care activity), positive affects (4-item subscale of the Center for Epidemiologic Studies Depression Scale, scores range 0–12, higher scores indicate more positive feelings) and disease control (HbA1c, blood pressure and LDL-Cholesterol).[10] Follow-up measurements for this study were done 12 months after the first interventional session.

Statistical analyses
A total sample size of 165 was estimated (83 per group) to detect a difference between the VEMOFIT and attention-control programs in
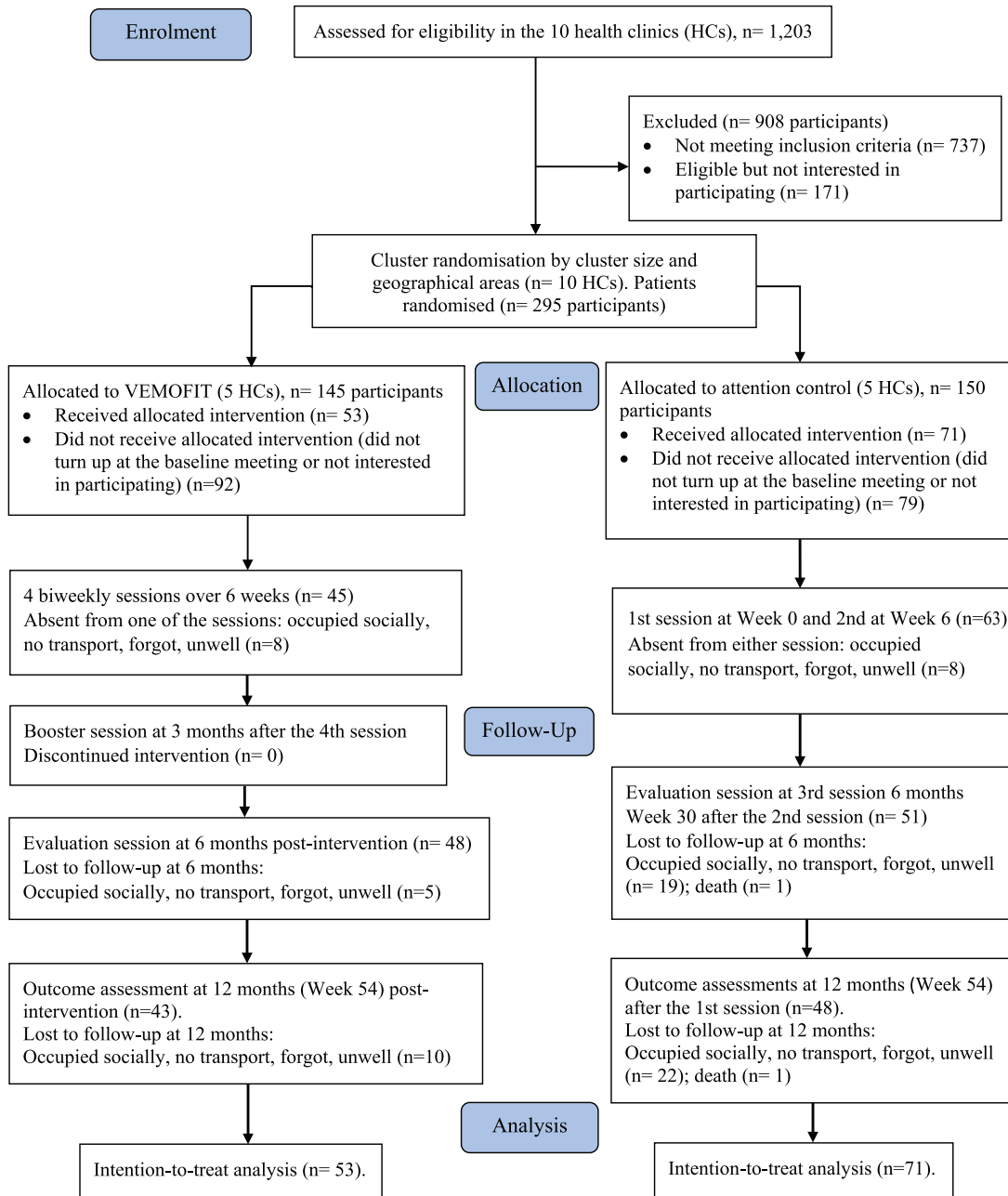
Figure 1. Flow of participants through trial.

DDS-17 mean (SD) score of 0.4 (SD 0.8) at 12 months with a power of 0.8 and type I error 0.05.[10] In addition to the 33 people lost to follow-up at 12-months, 5 additional missing data were noted with regard to PHQ-9, 3 to DMSES, 4 to SDSCA and 8 to LDL-Cholesterol. Ten multiple imputations were generated for the missing data before pooled estimates were reported with linear mixed models for all outcomes in continuous forms. The between-group differences were examined using a three-level mixed model; the random part of the model included a random intercept per centre and an unstructured matrix for the correlation of measurements over time within participants; and the fixed part of the model included the baseline measurement, time (categorical), treatment group, and a group*time interaction. A calculated 95% CI and two-sided α of 0.05 were used to test significance for the primary outcome; for the secondary outcomes a

two-sided α of 0.006 was used to account for the eight additional analyses. Intention-to-treat analyses were performed with PASW 25.0 (SPSS, Chicago, IL).

Results

Participants were randomized to either VEMOFIT ($n = 53$) or to the attention-control program ($n = 71$) (Figure 1); their mean (SD) age was 55.6 (10.8) *versus* 55.8 (8.8) years, they had a median diabetes duration of 7.0 (6.5) *versus* 8.0 (9.0) years, 21 (40%) *versus* 27 (38%) were men, 43 (81%) *versus* 55 (78%) had hypertension, 36 (68%) *versus* 59 (83%) dyslipidaemia, 48 (91%) *versus* 61 (96%) were prescribed oral hypoglycaemic agents, 38 (72%) *versus* 43 (61%) were prescribed insulin, 48 (91%) *versus* 58 (82%) were prescribed antihypertensive agents and 41 (77%) *versus* 60 (85%) were prescribed lipid-lowering agents[7]; the baseline mean HbA1c level was 9.9% (1.8) *versus* 9.5% (2.1) [84 (19) *versus* 81 (23) mmol/mol] (Table 1). At 12-month follow-up, the proportion of these pharmacological treatments between the two groups VEMOFIT *versus* attention-control were not significantly different: oral hypoglycaemic agents [46 (87%) *versus* 50 (71%), $\chi^2 = 4.94$, $p = 0.085$], insulin [44 (83%) *versus* 52 (73%), $\chi^2 = 1.66$, $p = 0.278$], antihypertensive agents [45 (85%) *versus* 51 (72%), $\chi^2 = 2.97$, $p = 0.128$] and lipid-lowering agents [45 (85)% *versus* 56 (79%), $\chi^2 = 1.69$, $p = 0.429$].

The mean DDS-17 level decreased in both groups (from 3.4 to 3.3 and from 3.1 to 2.5, respectively) with a significantly higher reduction in the attention-control group (adjusted difference −0.6, 95% CI −1.1, −0.2). At 6-month, the mean DDS-17 of the participants in the VEMOFIT group decreased from 3.4 to 2.9 ($p < 0.001$) and those in the attention-control group from 3.1 to 2.7 ($p < 0.001$), with the adjusted difference between groups of –0.01 (95% CI –0.38, 0.35).[7] The VEMOFIT group had a significant improvement in self-efficacy (adjusted difference 16.4, 99.4% CI 1.9, 30.9). Table 1 shows that other outcomes did not differ between groups; positive effect sizes show the outcome scores were higher in the VEMOFIT group; and *vice versa* with the negative effect sizes.

Discussion

After 1 year, the theory-based VEMOFIT intervention resulted in a significantly less decrease of DD, despite a higher (better) diabetes self-efficacy, compared with the nonstructured attention-control program. After going through the VEMOFIT program during five sessions over a span of about 5 months and up to 7 months of assimilation and habituation of the learned knowledge and skills and with a higher level of self-efficacy, participants' experienced DD did not improve more than in those who were provided the simpler attention-control program. This is contrary to our expectations but not totally surprising. Systematic reviews of psychological interventions for DD had reported similar but not significantly better effects of attention-control or enhanced control groups when compared with different interventional groups.[3–5] In that respect, the finding was contrary to our expectation. In fact, the favourable effect of the simpler psychological intervention of attention-control in this study may be the first to be observed. The finding was not totally surprising to us because a Taiwanese 12-month longitudinal study had shown that a discordant in self-management behaviours and empowerment (ability to think critically, knowledgeable about health problems, making own decisions and taking control of life) is significantly associated with an increase in DD.[8]

The theory underpinning VEMOFIT is that the participants who have come to terms with their own values/life-purpose would have a more profound understanding about themselves, a meaningful feeling about life and a stronger intention to realize their valued goals in life.[11] This should potentially lead to a realignment of cognition, emotion and behaviours that are consistent with healthful goals.[11] Besides, equipped with appropriate knowledge about T2D and healthy lifestyles and with sufficient motivation (emotional skills), an adjustment or change in personal goals would lead to successful coping with diabetes self-management.[11] Additionally, the participant's spouse or significant others would also increase the effectiveness of the intervention by serving as an informed companion providing continuous support to the participants at home. Indeed, these explanations fit the observed improvement in diabetes self-efficacy among the VEMOFIT participants. Intriguingly, their DD had increased back to baseline levels after 12 months after an initial decrease/ improvement 6 months before (DDS-17 mean scores from 3.4 at baseline to 2.9 after 6 months to 3.3 after 12 months) contrasting those in the attention-control group who maintained their improved DD at mild DD (2.7–2.5).[7] This disappointing longer-term result of the VEMOFIT

Table 1. Baseline and follow-up mean score (SD) on outcomes, unless otherwise specified (*n* = original number of complete cases).

Outcomes	VEMOFIT programme, n=53			Attention control programme, n=71			Adjusted intervention effect, β (95% CI), n=124	
	Baseline (week 0)	6-month post-intervention (week 30)	12-month post-intervention (week 54)	Baseline (week 0)	6-month after 2nd session (week 30)	12-month after 1st session (week 54)	12-month (week 54)	*p*
Diabetes distress (mean score range 1–6)	3.4 (0.6) [53]	2.9 (1.0) [37]	3.3 (0.8) [43]	3.1 (1.0) [69]	2.7 (0.9) [48]	2.5 (0.9) [48]	0.63 (0.17, 1.09)	0.008
							Adjusted intervention effect, β (99.4% CI)	*p*
Depressive symptoms (range 0–27)	4.3 (3.3) [50]	6.3 (4.2) [43]	6.0 (5.6) [42]	6.0 (4.8) [68]	6.0 (5.0) [49]	7.6 (6.5) [44]	−0.60 (−7.29, 6.09)	0.82
Illness perception on diabetes (range 0–80)	37.3 (10.2) [51]	36.4 (10.6) [47]	37.4 (7.6) [45]	34.1 (10.2) [67]	33.1 (9.1) [49]	33.2 (7.8) [46]	0.47 (−3.96, 4.91)	0.78
Quality of life (range 0–100)	55.3 (7.8) [49]	57.2 (6.7) [41]	57.0 (6.7) [46]	56.4 (5.6) [69]	56.0 (5.6) [51]	56.2 (6.8) [48]	2.69 (−1.35, 6.73)	0.08
Diabetes self-efficacy (range 0–200)	136.8 (42.2) [44]	148.1 (34.2) [42]	151.1 (15.7) [43]	145.9 (31.2) [63]	142.0 (28.8) [46]	144.9 (24.3) [45]	16.4 (1.9, 30.9)	0.003
Diabetes self-care activities (range 0–7)	3.7 (1.1) [47]	4.2 (1.1) [31]	4.2 (0.9) [43]	3.4 (1.1) [67]	3.8 (0.9) [45]	3.9 (1.1) [44]	0.32 (−0.33, 0.96)	0.20
Positive emotions (range 0–12)	9.7 (1.9) [49]	9.0 (2.7) [47]	9.1 (3.4) [45]	9.8 (1.8) [69]	8.6 (3.7) [49]	7.3 (3.3) [50]	1.24 (−1.59, 4.08)	0.25
HbA1c (%)	9.9 (1.8) [52]	9.4 (1.9) [48]	9.5 (2.2) [46]	9.5 (2.1) [71]	9.1 (2.2) [49]	8.8 (1.9) [50]	−0.11 (−1.35, 1.13)	0.82
HbA1c (mmol/mol)	84 [19]	79 [21]	81 [25]	81 [23]	76 [24]	73 [21]	−1.60 (−15.79, 12.59)	0.77
Systolic blood pressure (mmHg)	137 [16]	137 [16]	137 [11]	141 [21]	140 [22]	139 [16]	4.60 (−3.69, 12.89)	0.14
Diastolic blood pressure (mmHg)	82 [11]	80 [10]	78 [9]	82 [9]	81 [10]	80 [9]	1.10 (−3.94, 6.14)	0.57
LDL-Cholesterol (mmol/l)	2.9 (1.1) [53]	2.9 (0.9) [47]	2.6 (0.8) [41]	3.0 (1.0) [71]	2.7 (0.9) [45]	3.0 (1.0) [42]	−0.06 (−0.67, 0.55)	0.80

Intervention effect of the VEMOFIT compared with the Attention (time*group), analysed from 10 imputed datasets, adjusted for all baseline measurements, with the exception of the quality of life analysis with the exception of the quality of life analysis at 6-month post-intervention (week 30). Attention control, programme of an active listening to the participants' emotional experiences, social support and their opinion on the health clinic diabetes care services. VEMOFIT: value-based emotion-focused educational programme in Malay adults with type 2 diabetes.

intervention raises the question of why people who attended VEMOFIT lost their initial decrease of DD – and why those who attended the attention-control program did not. The educational levels were comparable between the two groups, which diminishes the likelihood that the cognitive component of VEMOFIT has a decisive impact in this respect. One-third to half of the significant others did not accompany the participants throughout all the VEMOFIT interventional sessions.[7] Comparing both groups, the suggested beneficial role of the participant's spouse or significant other in the VEMOFIT group, as described above, will not have been big. Besides, nurse-coaches expressed a lack of confidence in coaching the emotional skills and goal-setting sessions, citing that these skills were unfamiliar to their usual practice and not included in their previous nursing training (data from process evaluation not reported). This makes it less likely that their effectiveness was sustainable and the short-term effect might have been a result of just participating in group sessions, comparable with the attention-control program. In the latter, participants were involved in participant-led open discussions on any issues that were close to their heart and perceived to be important and relevant. They experienced active listening from the nurse-coaches and doctors who provided direct and short answers to queries. The unstructured content of the attention-control intervention seems to 'unwind' DD at least during a full year, not hindered by the 'burden' from newly learned disease and emotional knowledge, or by goals that demand to be achieved in the set time limits. Consequently, in the attention-control intervention, sufficient negative feelings associated with DD have been removed by the participants. Thus, we speculate that the unstructured content of the attention-control program was successful on the long-term, probably because it met personal needs and did not trigger distress.

The secondary outcomes of disease control regarding the HbA1c, systolic and diastolic blood pressure and LDL levels all showed similar improvement in both groups. The levels of HbA1c were >8.0% (64 mmol/mol) (the highest individualized HbA1c target)[13] despite treatment intensification with insulin in both groups. This observation might be due to low adherence to prescribed medication,[14,15] healthful lifestyles or self-care activities,[16] DD itself, physician-related and healthcare system-related barriers such as clinical inertia on the physician part and limited choices and availability of antidiabetic agents at public health clinics.[17,18]

One of the strengths of this study is the measurement of many outcomes at both 6 and 12 months follow-up. Limitations to be cautioned when interpreting the results of this study are similar to the earlier VEMOFIT at 6-month study.[7] Cultural appropriateness of the VEMOFIT psychological interventions might be insufficient, leading to lower than expected participation rates and not achieving the estimated sample size of $n = 83$ per group after an extended period in recruitment phase. The influence of chance on the results is possible because of the relatively small sample size in each group. However, it is likely to be small in view of the larger-than-estimated effect size and the favourable effect was observed in the attention-control group and opposite to our hypothesis. Selection bias might be due to participants who particularly interested in the programmes. The possible regression-to-the-mean of the DDS-17 score at 6-month follow-up has become more unlikely at this 12-month follow-up since there was an observed rebound of the score in the intervention group. Additional limitations at longer follow-up in this study might include differential effects of regional politico-socioeconomic occurrences and health clinic level or healthcare system and delivery changes due to small cluster size.

Conclusion

We think the findings support the statement that a relatively simple, unstructured intervention in which people with T2D may express their emotions, talk about social support and about the facilities of their outpatient clinic may be sufficient to ameliorate DD, also in the long run.

Conflict of interest statement

The authors declare that there is no conflict of interest.

Supplemental material

Participant-level datasets along with published reports from this trial is available by request to the corresponding author.

ORCID iD

Boon-How Chew https://orcid.org/0000-0002-8627-6248

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