Chapter 3 - Does Low Well-being Modify the Effects of PRISMA (Dutch DESMOND), a Structured Self-management-education Program for People with Type 2 Diabetes?

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Abstract

Aims
Diabetes self-management education improves behavioral and clinical outcomes in type 2 diabetes patients, however little is known about the modifying effects of well-being. This is relevant given high prevalence of depression and distress among diabetes patients. We aimed to test whether low well-being modifies the effects of the PRISMA self-management education program (Dutch DESMOND).

Methods
297 primary care type 2 diabetes patients participated in the PRISMA observational study with a pre-post measurement design. Patients were grouped in low (n=63) and normal well-being (n=234). Low well-being was defined as either low mood (WHO-5<50) and/or high diabetes-distress (PAID-5>8). Outcome measures were: diabetes self-efficacy (CIDS), illness perception (IPQ) and diabetes self-care activities (SDSCA).

Results
Improvements were found in illness perception (b=1.586, p<.001), general diet (b=1.508, p=.001), foot care (b=.678, p=.037), weekly average diet (b=1.140, p=.001), creating action plan (b=.405, p=.007). Well-being interaction effects were found for general diet (p=.009), weekly average diet (p=.022), and creating an action plan (p=.002).

Conclusions
PRISMA self-management education seems as effective for people with normal well-being as for people with low well-being. Further research should examine whether addressing mood and diabetes-distress as part of self-management education could reduce attrition and maintain or improve well-being among participants.

Keywords
Well-being; self-management; education; type 2 diabetes mellitus

Introduction

Type 2 Diabetes Mellitus (T2DM) is a highly prevalent and burdensome chronic condition, where the patient has a central role in the treatment.[73] Patients have to perform a multitude of self-care tasks on a daily basis in order to control their blood glucose and associated metabolic risk factors such as weight, blood pressure, lipids and smoking.[41] Diabetes self-management education (DSME) is therefore regarded a key component of diabetes care, aimed not only to enhance the patients' medical understanding, but also improve their intrinsic motivation, self-efficacy, illness perception, behavioral skills and behavior.[41,74,75] Interventions targeting diabetes self-management behavior have shown to improve behavioral and, to a lesser extent, clinical outcomes among its participants.[27,32] Structured DSME programs are therefore considered a meaningful addition to standard diabetes care. Most DSME programs are group-based and composed of different modules, e.g. medical information on diabetes and (modifiable) risk factors, treatment options, the role of weight management and physical activity, diary keeping (self-monitoring), goal setting and action planning.[26,27,32] One example of an evidence-based DSME program is the Dutch Proactive Interdisciplinary Self-Management Training (PRISMA), based on the 'Diabetes Education and Self-Management for Ongoing and Newly Diagnosed' (DESMOND), developed and tested in the United Kingdom.[30] DESMOND is theoretically well founded, and proven (cost)effective for newly diagnosed T2DM patients at least up to 12 months.[28,29]

Existing DSME programs may offer some guidance for stress management, but commonly do not specifically address depressive symptoms and emotional distress. Yet epidemiological studies have shown depression and diabetes distress to be prevalent among people with diabetes.[53,76,77] Moreover, depression in diabetes is associated with less adherence to recommended self-care behaviors, an increased risk of developing diabetes-related complications, and distress has effects on glycaemia control.[48,51,78] Some studies have reported beneficial effects of DSME programs on mental health outcomes[79], which could be due to behavioral activation that is known to help improve people's mood and stress levels.[80] However, little is known about the moderating effects of well-being, defined here as the influence of low mood and/or elevated diabetes-related distress, on DSME program efficacy in terms of self-efficacy, illness perception and diabetes self-care. One could speculate that DSME is less effective in participants with low well-being. Not only because of their initial poorer lifestyle in terms of diet and physical inactivity, but also due to symptoms inherent to depressed mood and high distress such as difficulty concentrating, low level of energy and lack of motivation.[81,82] The question whether the level of well-being operates as effect modifier in DSME is clinically relevant. First, if DSME in diabetes patients with low well-being is less effective or even counter indicated, then screening for stress or depressive symptoms should be integral part of patient selection. If on the other hand, well-being does not modify program outcomes negatively, DSME could (perhaps with the exclusion of severely depressed) be regarded 'safe' and productive in the context of promoting self-care and behavior change in diabetes patients, without the need of pre-screening for stress or depressive symptoms. Second, if depression and/or distress negatively modify DSME effects, it may be indicated to address depression and distress even more explicitly for this sub-group in DSME and thereby enhance their mental health status, adherence and subsequent clinical outcomes.

We aimed to test the modifying effects of low well-being of diabetes patients participating in a structured DSME program (PRISMA), using data from an observational study in primary diabetes care in the Netherlands.

Methods

Settings and participants

Between 2012 and 2013 T2DM patients were referred to the DSME program 'PRISMA' by primary health care practitioners from 7 primary care groups throughout the Netherlands (serving approximately 59.000 T2DM Patients), as part of usual care. Patients were eligible for the PRISMA program if they had a diagnosis of T2DM, regardless of duration of the disease, and were able to speak and read Dutch. If the local practitioner deemed a person not capable of functioning in a group, they were excluded from the course and received DSME on an individual basis. Of all the referred patients from these 7 primary care practices, 53.4% participated in the study.

DSME Intervention

The PRISMA-course is the Dutch adapted version of the DESMOND program (Diabetes Education for Self-Management in Ongoing and Newly Diagnosed Diabetes) developed in the UK for primary diabetes care. DESMOND/PRISMA was developed from a patient empowerment philosophy and is grounded in social-cognitive theory.[30] PRISMA was adapted in the Netherlands to enhance dietary behaviors, self-efficacy, and in lesser extend physical activity, for newly diagnosed as well as existing patients with T2DM who are treated in primary care.[31] The PRISMA program consists of two interactive group meetings ('workshops') of in total 7 hours, with 8-10 participants. The course is delivered by 2 trained diabetes educators (e.g. dietician and nurse practitioner). During the course, the following topics are covered: T2DM, insulin and tablets, hyper-hypoglycemia, checking blood glucose, diet, the influences of physical activity, diabetes complications and risks, medical outcomes measures, action planning and goal setting. Additionally participants are stimulated to continue discussing their goals and actions with their health care provider after completing the program.

Design

The study had a pre-post measurement design. Before the start of the PRISMA course participants were invited to fill in a questionnaire, either online or on paper (T0). Three months after completion of the course, participants were asked again to fill in the questionnaire (T1). All patients provided written informed consent. The study protocol was approved by the medical ethical committee of the VU University Medical Center (certified by the Central Committee on Research involving Human Subjects in the Netherlands).

Measurements

At baseline participants filled in a questionnaire covering socio-demographics (gender, date of birth, marital status, highest level of education, employment status, country of origin), and self-reported clinical characteristics (year of diabetes diagnosis, treatment regimen, diabetes complications and comorbidities (e.g. asthma, chronic heart disease, stroke, rheumatoid arthritis), most recent glycemic control (HbA1c), most recent blood pressure and cholesterol values), and outcome measures (mood, diabetes-related distress, diabetes self-efficacy, Illness perception, and diabetes self-

care). At 3-month follow-up, participants received a questionnaire containing only the outcome measures.

Outcomes measures

Mood was measured with the World Health Organization Wellbeing Index 5 items questionnaire (WHO-5) on a 5 point Likert scale (α = .90). The total sum score ranges from 0-100, where higher scores indicate better mood. The questionnaire measures emotional well-being, but has clinical use as screener for clinically relevant low mood, using scores < 50 as cut-off.[56,57,83]

Diabetes-related distress was measured with the Problem Areas in Diabetes 5 items questionnaire (PAID-5) on a 5 point Likert scale (α = .88) with total sum score ranging from 0-20, with higher scores indicating more distress, where elevated distress is defined by scores > 8.[58]

Diabetes self-efficacy was measured with the Confidence in Diabetes Self-Care questionnaire (CIDS) on a 5 point Likert scale (α = .83) with total sum score ranging from 7-35 (higher scores indicate more confidence in diabetes self-care).[84]

Illness perception was measured with three dimensions (coherence - understanding of the illness, personal control - perceived control of the illness, and consequences - understanding of the illness) of the Illness Perception Questionnaire (IPQ) on a 5 point Likert scale (α = .61) with total sum score ranging from 0-12 (higher scores indicate a more accurate illness perception).[85] Diabetes self-care activities were measured by 11 dimensions (general diet, specific diet, fruit intake, carbohydrate intake, fat intake, 30 minutes of exercise per day, specific workouts, blood-glucose control, medication adherence, foot care, and shoes check-up) of the Summary of Diabetes Self-Care Activities questionnaire (SDSCA) measured on a 8 point scale (α = .56) generating mean scores ranging from 0-7 (scores indicate days per week on a specific subscale).[59,60] Because of the Cronbach's α of the sum scores, the subscales will be analyzed individually. All measures have demonstrated satisfactory psychometric properties.

Statistical analyses

Data are presented as mean, standard deviations, percentages (if applicable) regression coefficients (B), and p-values. To distinguish between levels of low well-being and normal well-being, we used a score lower than 50 on the WHO-5 and/or a score higher than 8 on the PAID-5, as used in clinical practice.[18] Generalized Estimated Equations (GEE) analyses, with a two-way interaction term (well-being group x time), was used to examine group by time effects (indicating effect modifying) from baseline to 3-months follow-up. Analyses were corrected for correlating variables (age, gender, comorbidities, education, and diabetes duration) and baseline outcome values. Single missing variables within an outcome were treated by mean substitution. Cases were omitted if they had multiple missing variables within an outcome. Checks of normality indicated that the distributions of 'general diet, 'medication adherence' and 'blood glucose control' were skewed (skewness: -1.106, -2.735, and 1.962 respectively). However the maximum likelihood estimation procedure of GEE analysis is fairly robust against skewness.[86] Results are based on intention-to-treat analyses. All statistical analyses were performed using SPSS 20 (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.).

Results

At baseline, a total of 297 participants were included. Baseline socio-demographical information and self-reported clinical characteristics are presented in Table 1. About half of the participants were female (48.5%). Mean age was 67.3 (*SD* = 9.88) with a minimum age of 39 and maximum age of 90. Most participants were Dutch Caucasian (96.9%). As can be read from baseline measurements in Table 1, 63 (21.2%) of the 297 participants reported low well-being at baseline. Participants with low well-being were more likely to be female, treated with insulin, and reporting more comorbidities compared to participants with normal well-being. Moreover, Table 1 shows that participants with low well-being reported lower diabetes self-efficacy and worse diabetes self-care regarding general diet and exercise behavior.

At 3 months follow-up, a total of 235 participants filled in the questionnaire, resulting in an attrition of 20.8%. There were no significant differences at baseline regarding socio-demographics, clinical characteristics, or outcome measures between completers and non-completers. Of the 234 people that reported a normal well-being at baseline, 23 (9.8%) had low well-being at follow-up and 41 (17.5%) did not fill in the questionnaire. Of the 63 people with low well-being at baseline, 24 (38.1%) again reported low well-being at follow-up, 18 (28.5%) people improved and 21 (33.3%) did not fill in the questionnaire.

After 3 months, significant changes over time were found for the total sample for: illness perception $B = 1.586$, $p < 0.001$, general diet $B = 1.508$, $p = 0.001$, and foot care $B = .678$, $p = 0.037$ (Table 2). Per item analysis showed significant changes over time for 'average diet of the past 7 days' $B = .816$, $p = 0.029$, 'weekly average diet' $B = 1.140$, $p = 0.001$, checking shoes $B = .759$, $p = 0.021$, and 'creating an action plan' $B = 0.405$, $p = 0.007$ (Table 3). No other changes over time were found.

Interaction effects (well-being group x time) were found for General diet $B = -1.292$, $p = 0.009$ and for the specific items 'weekly average diet' $B = -.830$, $p = 0.022$, and 'creating an action plan' (a sub-item of the self-efficacy questionnaire) $B = -.490$, $p = 0.002$. Table 4 shows indications that both groups improved on all 3 items, and that the low well-being group seemed to improve more than the normal well-being group. No other interaction effects were found, indicating the absence of additional modifying effects by well-being.

Discussion

Our results show that T2DM patients treated in primary care, with low mood and/or high diabetes distress, and who remain in the program, seem to benefit from the PRISMA program as much as T2DM patients with 'normal' well-being. Three months after the course, both the low and normal well-being group show indications of improvements in illness perceptions, dietary behaviors, foot care, and action planning. Although it is known that people with low well-being generally have poorer self-care[78], in this study the low well-being group seemed to improve towards levels of the normal well-being group for dietary behavior and action planning. It could be that the behavioral components of the DSME program are helpful in this respect, particularly in augmenting the patients' feelings of control.[87] The further absence of modifying effects of well-being could suggest that no distinction or pre-selection based on well-being (mood or distress) is required in people with type 2 diabetes who wish to participate in the PRISMA DSME course. However, we should acknowledge the fact that 33% of the low well-being group was lost at follow-up. Attrition rates are known to be particularly prevalent among people with poor well-being and deserve special attention in DSME programs.[78]

Of the people with low well-being at baseline, 28.5% reported having improved well-being at follow-up; of the people with normal well-being at baseline, 9.8% reported low well-being at 3 months follow-up. These data are in line with previous reports on depression prevalence and incidence in type 2 diabetes patients in primary care.[77] Whether the observed changes in well-being are related to the PRISMA DSME program is difficult to establish in an uncontrolled study, and should be investigated further. Adverse effects of DSME on well-being have not been reported in literature. In contrast, DSME could improve well-being through 'empowerment' and increased self-confidence and feelings of control.[87] Integrating cognitive behavioral therapy, coping skills training, and an exercise component into the PRISMA DSME program could potentially reduce attrition, and improve program efficacy with regard to mental health, especially in more psychologically vulnerable patient groups.[88,89]

Although the percentage of participants with low well-being in our study is in line with prevalence data in the literature, we should keep in mind that diabetes patients with low well-being may be less inclined to join a DSME program and may therefore under represented. Future research should further investigate uptake and efficacy of DSME programs in those with low well-being.

Strengths and limitations

Participants were included from different regions in the Netherlands without a pre-selection bias and the study was carried out in routine primary diabetes care, adding to the external validity of the study.

This study had a pre-post measurement design and therefore the true effectiveness of the PRISMA course could not be established. However, the main purpose of the study was to uncover effect modification, which does not require a control group.

The used sample of participants consisted of mainly Caucasian Dutch people, and lacked ethnic minorities. Modifying effects of low well-being on DSME programs within ethnic minorities are therefore unknown and warrant future research. A 3-month follow-up would most likely be too short to see changes in clinical parameters but the observed changes in illness perception, self-efficacy and self-care behaviors could be positive predictors of health changes in the long term.

No direct measure of depressive symptom was available in this study. We chose the WHO-5 for measuring low mood mainly because of the nature of the study (patients are participating in an educational program, not focused on depression case finding). In a separate study we did confirm the depression screening properties of the WHO-5 against the PHQ-9.[57] However, future research should verify the extent to which WHO-5 scores match diagnostic criteria for depression.

Conclusion

The current DSME program PRISMA does not seem to need additional pre-screening on well-being to ensure self-care improvements for people with low well-being. The PRISMA DSME program, which mainly focuses on diabetes self-care, seems as effective for people with normal well-being as well as for people with a sub-optimal well-being. Nonetheless, attention to depressive mood and diabetes distress within DSME courses could be beneficial for reducing attrition and maintaining or improving well-being among the participants, which warrants further research.

Table 1
Baseline Socio-Demographical Characteristics and Outcome Measures

	Total Sample (n=297)		Normal well-being (n=234)		Low Well-being (n=63)		p-value
	M or n	% or SD	M or n	% or SD	M or n	% or SD	
Gender							.061
Female	144	48.5%	104	44.4%	37	58.7%	
Male	153	51.5%	125	53.4%	26	41.2%	
Ethnicity[1]							.404
Caucasian	284	96.9%	219	93.5%	60	95.2%	
Non-Caucasian Dutch	9	3.0%	6	2.5%	3	4.8%	
Age (years)[2]	67.3	±9.88					.399
<40	2	.7%	1	0.4%	1	1.6%	
40-49	16	5.4%	11	4.8%	5	7.9%	
50-59	37	12.5%	25	10.9%	12	19.0%	
60-69	105	35.4%	81	35.4%	21	33.3%	
70-79	93	31.3%	74	32.3%	17	27.0%	
80>	29	9.8%	24	10.5%	5	7.9%	
With partner[3]	240	81.4%	186	79.4%	49	77.7%	.456
Education[4]							.696
School level qualifications	173	58.2%	132	56.4%	40	63.5%	
Professional or vocational	66	22.2%	53	22.6%	13	20.6%	
Bachelor's degree or higher	40	13.5%	32	13.6%	7	11.1%	
Employed[5]	60	20.2%	48	20.5%	12	19.0%	.096
Diabetes							
Diabetes duration in years	8.42	±6.88	8.45	±6.86	8.63	±7.17	.859
Treatment							.023*
Tablets	231	77.2%	176	75.2%	52	82.5%	
Insulin	48	16.2%	31	13.2%	16	25.3%	
Complications							
Retinopathy	18	6.1%	13	5.5%	5	7.9%	.509
Nephropathy	9	3.0%	8	3.4%	1	1.5%	.438
Foot complication	31	10.4%	20	85.4%	11	17.4%	.046*
Cardiovascular	27	9.1%	19	8.1%	8	12.6%	.286
Neuropathy	7	2.4%	5	2.1%	2	3.2%	.649
Medical outcome measures							
HbA1c[6]	53 (7.00)	±13.4 (±1.22)	52 (6.98)	13.8 (1.26)	54 (7.12)	11.4 (1.04)	.570
Systolic blood pressure[7]	134.4	±14.2	134.2	±14.5	135.6	±13.1	.573
Diastolic blood pressure[7]	79.4	±11.0	79.2	±11.1	81.0	±10.5	.377
Cholesterol[8]	4.5	±1.1	4.5	±1.2	4.7	±1.0	.481
No. additional chronic comorbidities							.002*
0	60	20.2%	47	20.0%	10	15.8%	
1	94	31.6%	79	33.7%	15	23.8%	
2	81	27.3%	64	27.3%	16	25.3%	
> 3	62	20.8%	39	16.6%	22	34.9%	

Table 1 (continued)
Baseline Socio-Demographical Characteristics and Outcome Measures

	Total Sample (n=297)		Normal well-being (n=234)		Low Well-being (n=63)		p-value
	M or n	% or SD	M or n	% or SD	M or n	% or SD	
Mood[9]	71.4	18.6	78.0	12.0	46.9	17.7	
Score<50	40	13.7%					
Diabetes distress[10]	3.96	3.57	2.86	2.48	7.97	4.06	
Score> 8	39	13.2%					
Illness perception[10]	7.60	2.06	7.73	2.04	7.21	2.04	.071
Diabetes self-efficacy[11]	31.27	3.45	31.72	3.15	29.53	3.93	<.001*
Diabetes self-care							
General diet	4.86	2.00	4.99	1.92	4.36	2.25	.031*
Specific diet	5.23	1.08	5.44	1.03	5.31	1.20	.385
Exercise	4.05	2.03	4.27	1.98	3.21	2.03	<.001*
Medication adherence	6.31	2.08	6.28	2.12	6.44	1.93	.721
Foot care	1.76	2.08	1.68	2.10	2.02	2.00	.246
Self-monitoring Blood glucose	1.10	2.07	1.04	2.04	1.36	2.22	.291

Note. * Indicates statistical significance; *M* mean; *SD* standard deviation; *WHO-5* World Health Organization Wellbeing Index 5 items questionnaire; *HbA1c* Blood glucose levels; [1]n = 4 missing data; [2]n = 15 missing data; [3]n = 7 missing data; [4]n = 18 missing data; [5]n = 3 missing data; [6]n = 130 missing data; [7]n = 69 missing data; [8]n = 158 missing data; [9]n = 4 missing data; [10]n = 1 missing data; [11]n = 66 missing data.

Table 2
Total Sample Baseline and Follow-up Measurements of the Outcome measures

	Baseline (n=297)		3- Months Follow-up (n=235)		Time		Interaction well-being group x time
	M	SD	M	SD	B	p	p
Illness perception	7.60	2.06	8.76	2.00	1.586	<.001*	.235
Diabetes self-efficacy	31.27	3.45	31.54	2.79	.931	.071	.068
Diabetes self-care							
General diet	4.86	2.00	5.23	1.55	1.508	.001*	.009*
Specific diet	5.23	1.08	5.56	0.99	.394	.096	.325
Exercise	4.05	2.03	4.32	1.91	.358	.314	.653
Medication adherence	6.31	2.08	6.19	2.21	.554	.255	.332
Foot care	1.76	2.08	2.24	2.13	.678	.037*	.775
Self-monitoring Blood glucose	1.10	2.07	1.12	2.17	-.171	.641	.699

Note. * Indicates statistical significance; *M* mean; *SD* standard deviation; *B* regression coefficient.

Table 3
Total Sample Baseline and 3 Month Follow-up Measurements per Item

	Baseline (n=297)		3- Months Follow-up (n=235)		Time		Interaction Time x group
	M	SD	M	SD	B	p	p
SDSCA							
Average diet of the past 7 days	4.75	2.13	5.14	1.62	.816	.029*	.242
Weekly average diet	4.95	1.98	5.34	1.55	1.140	.001*	.022*
Fruit intake	5.37	1.84	5.56	1.63	.291	.150	.377
Carbohydrate intake	5.78	1.67	5.92	1.45	-.206	.578	.287
Fat intake	5.08	1.49	5.18	1.38	.208	.428	.593
30 minutes of exercise per day	4.82	2.18	5.03	1.97	.395	.284	.683
Specific workouts	3.31	2.36	3.57	2.41	.351	.349	.822
Self-monitoring Blood glucose	1.10	2.07	1.12	2.17	-.171	.641	.699
Medication adherence	6.31	2.08	6.19	2.21	.554	.255	.332
Foot care	2.72	2.92	3.35	2.84	.641	.159	.740
Checking Shoes	0.72	1.81	1.15	2.10	.759	.021*	.455
IPQ							
Coherence	2.43	.957	3.06	.776	.873	<.001*	.075
Personal control	2.77	.879	3.07	.840	.489	.002*	.243
Consequences	2.41	.919	2.63	1.024	.220	.166	.818
CIDS							
reconsider diet	4.35	.76	4.40	.657	.087	.349	.893
adhere to medication	4.90	.36	4.90	.376	-.002	.956	.605
consult HCP	4.77	.53	4.79	.537	.094	.532	.473
create action plan	4.34	.73	4.38	.712	.405	.007*	.002*
Execute action plan	4.32	.71	4.30	.735	.128	.330	.139
maintain self-care behavior	4.19	.79	4.21	.787	-.006	.960	.992
asking for social support	4.37	.90	4.39	.740	-.115	.428	.632

*Note.** Indicates statistical significance; *M* mean; *SD* standard deviation; *B* regression coefficient; *SDSCA* Summary of Diabetes Self Care Activities; *IPQ* Illness Perception Questionnaire; *CIDS* Confidence In Diabetes Self-care. *HCP* Health Care Practitioner.

Table 4
Post hoc analyses of items with significant time x group interactions

	Normal well-being				Low Well-being			
	T0		T1		T0		T1	
	M	SD	M	SD	M	SD	M	SD
General diet	4.99	1.93	5.22	1.57	4.36	2.25	5.23	1.53
Item: average weekly diet	5.09	1.88	5.31	1.58	4.42	2.26	5.37	1.48
Item: create an action plan	4.46	.66	4.40	.73	3.90	.85	4.28	.66

Note. *T0* baseline measurement; *T1* three month follow-up measurement; *M* mean; *SD* standard deviation.