

Research Article

Impact of Motivational Interviewing on Treatment Outcomes in Patients with Diabetes Type 2: A Randomized Controlled Trial

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Abstract

Background: Diabetes is a common chronic disease that is increasingly managed in primary care. Different systems have been proposed to manage diabetes care.

Aim: The purpose of this study was to determine the impact of motivational interviewing on treatment outcomes in patients with diabetes type 2.

Material and Methods: A sample of 200 patients with diabetes type 2 was randomly selected from Diabetes Registry of Heath Centre Bijeljina, Bosnia and Herzegovina. Participants were divided into two groups. Intervention group consisted of 100 participants, who were included in three months long program of motivational counselling. Control group consisted of 100 participants who obtained patient education as a part of their regular care in family practice. The measures used to portray patient's treatment outcomes included fasting blood glucose level, HbA1c, blood pressure, cholesterol, body mass index and smoking status.

Results: Although both groups experienced changes in treatment outcomes from baseline to follow up, statistically significant improvements in fasting blood glucose level ($\chi^2=6.607$; $p=0.037$), HbA1c levels ($\chi^2=4.023$; $p=0.045$), blood pressure ($\chi^2=4.063$; $p=0.044$) and serum cholesterol level ($\chi^2=6.728$; $p=0.035$) were found in the first group at follow-up compared to the second group. Statistically significant differences in body mass index and smoking status were not found between the groups.

Conclusion: The findings provided important evidence concerning the positive effect of motivational interviewing, which may be the most compelling reason to implement it more widely in routine primary diabetes care.

Keywords: Type 2 diabetes; Motivational interviewing; Treatment outcomes

Introduction

Low levels of physical activity, overweight, smoking and unhealthy diet are the risk factors for chronic diseases such as type 2 diabetes. The high prevalence of these risk factors has become an important public health problem [1-2]. In 2011, Whiting et al. estimated that there were 366 million people worldwide with diabetes and that by the year 2030; the global prevalence will lead to 50.7% increase [3]. Estimates are that diabetes mellitus is among 20 the most common problems in primary care setting and health care costs are 4.3 times higher for this group of patients than for people without diabetes [4]. Although uncontrolled diabetes is a major risk factor for cardiovascular and renal diseases, majority of patients with diabetes have poor glycaemic control. According to the studies, only 37% of patients have glycosylated haemoglobin (HbA1c) values at or below the recommended level [5]. Evidence-based studies indicate that good glycaemic control (HbA1c<7), blood pressure below 130/80 mmHg, and LDL cholesterol level lower than 100mg/dL decrease the incidence and progression of both microvascular and macrovascular complications of diabetes and is cost-effective [6, 7].

For children and adults struggling to manage their weight or keep diabetes under control the changes required can appear simple, for example; following a healthy diet, regular self-monitoring and exercise. However, primary care physicians often find that the change of patient's behaviour is the most demanding part of care for diabetes patients. Individuals are faced with conflicting motivations and pressures, the change feels too big, the reward too distant or maybe it was never their idea to change in the first place [1,8-10].

Motivational Interviewing (MI) is a patient-centred counselling approach that actively engages patients and draws on their underlying readiness and motivation to change behaviour [11]. It uses a guiding communication style which invites people to consider their own situation, find their own solutions to situations that they identify as problematic. Successful MI works through prompting a dialogue that reduces the patient's ambivalence toward change, so that current barriers to healthier behaviour could be minimized or removed [6, 12, 13]. MI specifically stresses the importance of understanding each patient's unique perspectives and priorities when developing a treatment plan, then uses reflective listening, therapeutic

communication and rapport-building skills to empower the patient (emotionally and psychologically) to make behaviour changes [13]. The rapidly growing evidence base for MI has been summarized in a meta-analysis of 72 clinical trials spanning a range of target health issues. In this meta-analysis, the average short-term between-group effect size of MI was 0.77, decreasing to 0.30 at follow ups to one year compared to the control group [6,14].

Therefore, the purpose of this study was to determine the impact of motivational interview on treatment outcomes in patients with diabetes type 2.

Material and Methods

Study sample

A randomized controlled trial with a sample of 200 type 2 diabetic patients was conducted in ten family medicine practices in Primary Health Care Centre Bijeljina, Bosnia and Herzegovina, during a period from January 2014 to April 2014. The sample size for the audit population of 1239 patients with diabetes included in local Diabetes Registry, with the confidence interval of 6.38% and confidence level of 95% was calculated to be 198. An especially established audit team randomly selected medical files of 20 patients with diabetes from the Diabetes Registry administered by each family medicine practice database. Patients were registered as patients with diabetes mellitus if they had two fasting blood glucose (FBG) levels above 7.8mmol/l or two random plasma glucose levels above 11.1mmol/l and/or were treated with insulin and/or oral hypoglycemic agents. Patients with an established cardiovascular and renal disease were excluded from the study.

The primary care nurse for each family practice sent information about the study to all included patients. Following consent to contact, the patients were seen by the researcher and given further information about the study. Informed consent was obtained from the patients before randomization.

Motivational Interviewing training and Intervention

Ten family physicians (FPs) and twenty primary care nurses from all ten family practices were asked to complete the training in motivational interviewing, none of them were previously educated or trained in MI, but all of them were trained in diabetes management. The MI training was conducted by three experienced MI trainers, who were all the members of the Motivational Interviewing Network of Trainers [15]. MI training focused on the exploration of patient ambivalence around behaviour change, self-motivational statements, problem solving barriers to change and exploring discrepancies between the patient's current self management behaviour and diabetes control by highlighting the benefits of change and costs of making no changes [16]. The theoretical part of the course curriculum was constituted of manual [17], together with "Motivational interviewing, preparing people to change Addictive behaviour" [12]. The nurses and physicians were coached in the key points of MI [12]. The training also included the use of specific skills, e.g. empowerment, ambivalence, the decisional balance schedule, stage of change and reflective listening, all of which are described in detail in the book MI [12]. The training consisted of three-day's session with two half-day follow ups.

All FPs and nurses also participated in the half-day course on

treatment of type 2 diabetes. During this training session, it was stressed that FPs should act as counsellors for the patients, allowing treatment decisions to be based on mutual understanding between the patient and the FPs.

Before the study was conducted, the patients were randomly allocated into two groups. The first or Intervention group (*I-group*) consisted of 100 patients who were included in three months long program of motivational interviewing. The second or control group (*C-group*) consisted of 100 participants who obtained patient education as a part of their regular care in family practice.

All patients, irrespective of participation in *I-group* or the *C-group*, were scheduled to see their FPs every three weeks over the period of three months. In the *I-group*, each encounter with FP took 30 minutes per patient. The MI intervention used the "menu of strategies" approach, eliciting patient views and then exploring discrepancies between beliefs and behaviour. The following aspects were used: awareness building, problem solving, making choices, goal setting and avoidance of confrontation. In the *C-group*, each encounter with FP took average 15 minutes per patient. The intervention was nondirective psychological support with the aim of providing regular diabetes care in family practice. The patients were counselled about healthy diet, physical activity, smoking cessation and other modalities of treatment by their family doctor

Measurements of treatment outcomes

The measures used to portray patients' treatment outcomes included fasting blood glucose level, HbA1c, serum cholesterol level, blood pressure value, body mass index and smoking status. According to ADA recommendations, FBG <7mmol/l, A1C <7%, BP <140/80mmHg (previously BP < 130/80mm Hg), total cholesterol level < 4.5mmol/l and BMI ≤25 kg/m² were defined as target values [18].

Data were collected at the enrollment in the study and after three months, during last visit in both groups.

All blood samples were analyzed by the Clinical biochemistry department of Health centre Bijeljina. HbA1c level was analyzed by high-pressure chromatography.

Both height and weight were measured without shoes. Weight was measured without accessories, i.e. wallet, keys. Based on height and weight body mass index - measure of body fat (BMI) was measured. Blood pressure was measured by the auscultatory method with use of a stethoscope and sphygmomanometer.

The study was conducted in accordance with the 1975 World Medical Association Declaration of Helsinki, as revised in 1983. In the analytical database, patient records and data were pseudonymised so individuals cannot be identified, while access to the database was controlled by the Committee for Science and Research of Faculty of Medicine in Foča, University of East Sarajevo.

Statistical analyses

Statistical analyses were carried out using SPSS 20 (SPSS Inc., Chicago, IL, USA). The P values of less than 0.05 were considered as statistically significant. The chi-square test was used to compare laboratory and clinical measurements before and after intervention

Table 1: Patient's socio-demographic characteristics.

Characteristics	I-group (N=100)	C-group (N=100)
Age		
Mean age, Y (SD)	52.2 (6.8)	53.4 (7.2)
Gender, %		
Male gender	52.84	54.38
Education, %		
Elementary school	6	8
Highs school	86	82
University	8	10
Employment, %		
Employed	80.2	84.6
Married, %	61	72
Place of living, %		
Village	17	22
Town	83	78

in *I-group* and *C-group* of patients. The results were shown as Figures and Tables.

Results

The study included 200 adult diabetic patients, selected in 10 family medicine practices and divided in two group's *I-group* (100) and *C-group* (100). Table 1 presents socio-demographic characteristics. Mean \pm SD age in study population was 52.8 \pm 10.2 years, and 54% of participants were male. Majority of patients in both groups are married and lives in town (Table 1).

Table 2 shows changes in the glycaemic control (FBG and HbA1c) and cholesterol levels in both groups of patients after the period of three months. The statistically significant difference in FBG level was found between baseline and follow up measurements in *I-group* of patients ($\chi^2=6.607$; $p=0.037$). At baseline 58% of patients had FBG >7mmol/l, however, that percentage decreased to 40% at follow-up. In *C-group* the follow up FBG levels also changed from baseline, but the change was not statistically significant. Statistically significant difference was also found between *I* and *C-group* at follow up ($\chi^2=7.765$; $p=0.000$).

Statistically significant differences between baseline and follow up measurements were found in *I-group* regarding to HbA1c values ($\chi^2=4.023$; $p=0.045$), while the difference between two measurements in *C-group* was not statistically significant. The difference in HbA1c level between two groups at follow up was statistically significant ($\chi^2=45.262$; $p=0.000$) (Table 2).

At baseline, 21% of patients in *I-group* had serum cholesterol <4.5mmol/L, but after MI was conducted this percentage increased to 32 % ($\chi^2=6.728$; $p=0.035$). The statistically significant difference within *C-group* was not observed in cholesterol level from baseline to follow up. The difference between the groups at follow up was statistically significant ($\chi^2=90.289$; $p=0.000$) (Table 2).

The statistically significant difference between the groups was not found regarding to BMI values. However, the difference in blood pressure level between two groups at follow up was statistically significant ($\chi^2=42.984$; $p=0.000$). The statistically significant difference in blood pressure level was found within *I-group* of participants ($\chi^2=4.063$; $p = 0.044$). At baseline 46% of participants had poorly controlled values of blood pressure (>140/80 mmHg), but at follow up 77 % reached blood pressure <140/80 mmHg. No statistically significant difference was found within *C-group* of patients (Table 3).

Figure 1 shows the prevalence of smoking in *I* and *C-group* of diabetic patients at baseline and follow up. The statistically significant differences were neither observed within the groups nor between the groups at follow up. Only two diabetic patients who declared as smokers at baseline quit smoking during three months period of MI (Figure 1).

Discussion

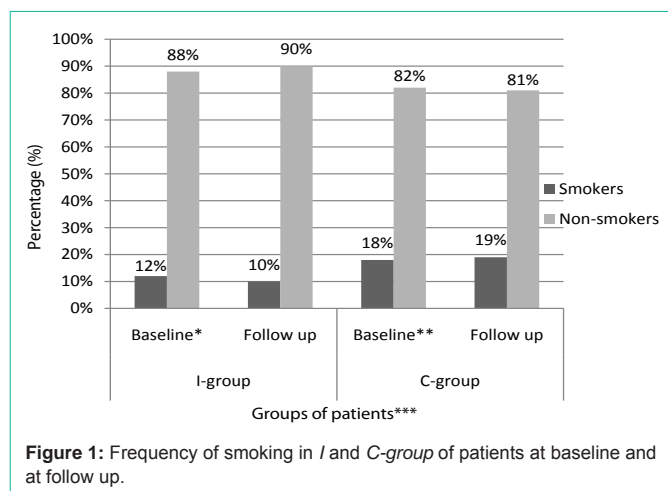
The results of this study show that MI can be an effective method of working with patients with diabetes, producing improvements in treatment outcomes. Our results support the findings from several other studies where MI in family practice has a positive effect on

Table 2: Comparisons of blood glucose level and HbA1c in two examined groups of patients at baseline and at follow up.

Glycemic control	Reference values and chi-square test	Patient's health outcome				χ^2	p**
		I-group (N=100) N (%)		C-croup (N=100) N (%)			
		Baseline	At follow up	Baseline	At follow up		
Glucose blood level (mmol/l) N (%)	<6	19 (19)	25 (25)	7 (7)	8 (8)	77.765	0.000
	6.1-6.9	23 (23)	35 (35)	21 (21)	24 (24)		
	>7	58 (58)	40 (40)	72 (72)	68 (68)		
	χ^2 / p^*	6.607 / 0.037		0.381 / 0.827			
HbA1c (%) N (%)	<7	35 (35)	49 (49)	34 (34)	37 (37)	45.262	0.000
	>7	65 (65)	51 (51)	66 (66)	63 (63)		
	χ^2 / p^*	4.023 / 0.045		0.197 / 0.384			
Cholesterol (mmol/l) N (%)	<4.5	21 (21)	32 (32)	25 (25)	22 (22)	90.289	0.000
	4.6-5.9	34 (34)	40 (40)	32 (32)	29 (29)		
	≥ 6	45 (45)	28 (28)	43 (43)	49 (49)		
	χ^2 / p^*	6.728 / 0.035		0.730 / 0.694			

*Within groups.

**Between groups (at follow up).



health variables and quality of life [19, 20]. In present study statistically significant improvements in FBG, HbA1c levels, blood pressure and serum cholesterol level were found in the *I-group* at follow-up compared to the *C-group*. In fact, a number of studies similar to ours did show statistically significant differences in glycaemic control between experimental and control subjects. Chen et al. [21] examined Taiwanese population, the follow up was at 3 months and MI did improve stage of change ($\chi^2=7.770$; $p<0.005$) and HbA1c levels ($t=4.250$; $p<0.001$) compared to the control group. Another study [22], where MI was done using videophone and follow up was 6 months, also showed a statistically significant decrease in HbA1c in experimental group of subjects ($p=0.043$), but not in control group ($p=0.086$).

Statistically significant differences in body mass index and smoking status were not found between the groups in our study. The lack of effect on BMI and smoking status in *I-group* may be result of the study's attempt to accomplish too much over too short period and it might indicate that the patients in the *I-group* did not change behaviour towards a higher degree of diabetes self-care towards to healthier diet and more physical activity, bearing in mind that the period of study was only three months [23]. MI had a significant effect on blood pressure from baseline to follow up in our present study, as well as in Sjoling et al [24], where 31 subjects, suffering from mild to moderate hypertension, significantly improved their leisure exercise

time from 60 minutes per week at baseline, to 300 minutes/week after 15 months of intervention. Furthermore, statistically significant improvements ($p<0.05$) were observed in systolic (mean difference -14.5 mmHg) and diastolic blood pressure (mean difference of -5.1 mmHg), heart rate, weight, BMI and reduction in serum cholesterol was observed upon intervention as compared to baseline [24].

In US study of 217 female overweight type 2 diabetes mellitus patients, a five sessions of MI interventions was delivered by mental health counsellors working within an 18-month behavioural weight loss program [25]. Patients exposed to MI showed statistically significant improvement in glycaemic control at six month follow up ($p=0.02$) compared to an attention control condition, such that HbA1c had dropped -0.8% for the MI treated group compared to -0.5% for the attention control condition. Mean HbA1c returned to baseline levels at the 12-month follow up time point and remained so at the end of the 18 month intervention. This study showed that MI was associated with significant short term benefit, confirming the clinical utility (and likely cost-effectiveness) of behavioural interventions that target poorly controlled diabetes patients. However, in the same study women in motivational interviewing lost significantly more weight at 6 months ($p=0.01$) and 18 months ($p=0.04$).

Unlike the present study as well as the study by Chen et al [21] and Sjoling et al [24] there are previous studies that were unable to establish an effect of MI on glycaemic, lipid and anthropometric outcomes. They have revealed that behavioural and educational interventions in diabetes have produced only modest short-term improvements in treatment outcomes [24, 25]. In a study involving Danish T1DM patients, no difference was found in HbA1c reduction at 12-month follow up between MI and usual care conditions when delivered by primary care providers, although both showed strong mean HbA1c reductions (-0.9%) [26].

This study provided insight into the effect of a behavioural and educational intervention. Previous studies using MI in family practice have demonstrated MI to be effective [19-21]. However, only a few studies have focused on how to implement MI in the daily clinical work in general practice in such way that it is ascertained that the method is used after study closure [27, 28]. They concluded that it was possible to implement the use of MI in family practice although barriers existed [27-29]. The results from two meta-analysis

Table 3: Comparisons of BMI and blood pressure in two examined groups of patients at baseline and at follow up.

Body mass index and cholesterol	Reference values and chi-square test	Patient's health outcome				χ^2	p^{**}
		I-group (N=100)		C-croup (N=100)			
		Baseline	At follow up	Baseline	At follow up		
Body mass index (kg/m ²) N (%)	<25	21 (21)	24 (24)	8 (8)	6 (6)	17.588	0.562
	26-29	47 (47)	51 (51)	55 (55)	53 (53)		
	≥30	32 (32)	25 (25)	37 (37)	41 (41)		
	χ^2 / p^*	1,223 / 0,543		0,528 / 0,768			
Blood pressure (mmHg) N (%)	<140/80	64 (64)	77 (77)	62 (62)	59 (59)	42.984	0.000
	>140/80	46 (46)	23 (23)	38 (38)	41 (41)		
	χ^2 / p^*	4.063/ 0.044		0.188 / 0.664			

*Within groups.

**Between groups (at follow up).

concluded that psychological therapies improve long-term glycaemic control and that MI had an effect on lifestyle factors such as food intake, smoking and alcohol consumption. These meta-analyses [30, 31] as well as the results from this study indicate a need for long-term evaluation of the effect of MI on the risk profile and a need for implementation of MI widely in routine primary diabetes care.

The study has, however, a few limitations. First, a major limitation of this study is that comparison with the C-group was done just after intervention, so whether these results can be sustained long term and whether this difference between the groups will disappear in future, has yet to be investigated. Secondly, the study did not analyze patient's knowledge of diabetes, knowledge and skills about the self-management and self-efficacy of diabetes. We did not measure psychological outcomes in diabetic patients and an impact of MI course on FPs professional behaviour. Finally, the study was conducted in only ten family medicine practices, which limits the generalizability of our findings.

Conclusion

MI was associated with improvements in glucose serum level, blood pressure value and serum cholesterol level. Short-term MI (≤ 3 months) also effectively decreased the HbA1c level, while statistically significant differences in body mass index and smoking status were not found between the two study groups. Further research is needed to establish the active underlying mechanisms which are driving change and to ascertain the longer-term benefits of MI to both patients and FPs. This would help to provide important evidence concerning the positive effect of motivational interview, which may be the most compelling reason to implement it more widely in routine primary diabetes care.

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