

An Interventional Study Of Health-Related Behavior Concerning The Systematic Physical Exercise In Diabetes Mellitus Patients With The Application Of The Transtheoretical Model And Motivational Interviewing.

Thanasa Georgia, RN

Phd Candidate, General Hospital Of Athens "G. Gennimatas"

Kaba Evridiki

Professor, Nursing Faculty, West Attica University

Vlachou Eugenia

Professor, Nursing Faculty, West Attica University

Tsampoula Iliana

RN, General University Hospital "Atticon"

George Intas

RN, General Hospital Of Nikaia

Kelesi Martha

Professor Nursing Faculty, West Attica University

Abstract

Purpose and Objectives: Present study utilizing Transtheoretical Model (TTM) and Motivational Interviewing (MI) in the form of Motivational Enhancement Therapy (MET) targets to support people living with diabetes in modifying their behavior concerning physical activity and therefore improve diabetes management and care. Objectives of the study include the evaluation of behavior improvement regarding physical exercise as well as the effectiveness of the TTM and MI in patients with diabetes. Additional objective of the study is the evaluation of clinical DM regulation as it's manifested in patient BMI, blood pressure, cholesterol and glycemc control.

Method:

An interventional controlled randomized study was carried out with 80DM patients from outpatient DM clinic of main hospital setting in Athens, Greece. Population was randomly divided into two groups (study/intervention group and control group). Randomization was acquired by placing each participant to one to one basis to the two study groups. The study/intervention group followed four 40-minute MI interviews/sessions and three 10-minute phone calls in between the interview sessions. The control group followed a 10-minute-long interview of instructional consultation nature regarding the importance of systematic physical activity and exercise to the effective management of DM.

Participants voluntarily joined and had free access to their data throughout the duration of the program. All participants signed informed consent and had free option of stopping or leaving at any time they choose to do so.

Results:

Participants from both the study and control group demonstrated no significant difference regarding the BMI, glycemc control and physical activity before intervention. After the intervention, the participants from the study group showed significant increase in physical activity, and the number of calories consumed in activity. They had significantly less time spend in sedentary activities and showed significant decrease of HbAc1 levels compared to control group participants who showed no significant changes in the above aspects.

Conclusion: The study/ intervention group seems to have managed to adapt effectively to behavior change and achieved elevated clinical benefits compared to participants of the control group. The intervention utilizing TTM and MI in the form of MET seem to have offered significant support to DM patients regarding DM management.

Keywords: *Transtheoretical Model, Motivational Interviewing, Diabetes Mellitus, Physical Activity, Chronic care patient support, Behavior Change Program*

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I. Introduction

The 10th edition of the Diabetes Atlas of the International Diabetes Federation in its recommendations for DM management states that health promotion programs can reduce the incidence and consequences of DM. Furthermore it is recommending the implementation of education/instructional and lifestyle change programs which aim at physical activity and healthy eating behaviors - as key modifying factors for the optimal management of the DM and the prevention of its complications^{1,2,8}.

The TTM is the theoretical model of behavior change that has been the basis for the development of effective interventions to promote health-related behavior change. The model has been applied to a wide range of health-compromising behaviors, targeting lifestyle changes^{8,9}. Within the context of this model, the interest is focused on the decision-making process by the individual that can lead to the progress of the individual in between the stages of change that the model describes, towards achieving behavior change^{9 10}.

The concept behind the stages of change as described in the applied model has been incorporated into the development of motivational interviewing. The relationship between the two theories is thoroughly described by the authors of the MI as a complementary relationship¹¹. In addition the TTM provides a framework for understanding the process of change while MI provides the tools and the facilitating processes to achieve change¹².

The application of MI to people who attend health promotion programs has been discussed and researched in great length^{13,14,15}. Its use focuses on the greatest part of research on managing patients' ambivalence, finding and using patients' motivations in order to empower them to modify lifestyles and choose health-beneficial behaviors. In addition, its use has been suggested as particularly effective in the management of patients with chronic diseases such as DM^{15,16,17}.

Present study by utilizing TTM and MI in the form of Motivational Enhancement Therapy (MET) targets to support people living with diabetes in modifying their behavior concerning physical activity and therefore improve diabetes management and care. Main objectives of the study include the evaluation of behavior improvement regarding physical exercise as well as the effectiveness of the TTM and MI in patients with diabetes. Additional objective of the study is the evaluation of clinical DM regulation as it's manifested in patient BMI, blood pressure, cholesterol and glycemetic control.

II. Material And Methods

This interventional randomized controlled study was carried out to patients living with DM at the diabetes outpatient clinic of the General Hospital of Athens "G. Gennimatas" and aimed in assessing the modification of health behavior concerning systematic physical activity and with the application of the TTM and the MI offering MET.

The present study has been conducted on a doctoral thesis basis approved by the West Attica University General Assembly on 20th July 2020nd approved by the scientific council of the General Hospital of Athens, G. Gennimatas that has reviewed the study protocol in terms of ethics, patient needs and study holistic approach.

The Hospital Scientific Council approval was issued on 7th September 2020 before the study onset. There is no conflict-of-interest present in the study from any researcher taking part in it. The study was conducted from February 2021 to December 2023 and included the preparatory stage (population and sample selection), the intervention stage (patient sessions and data collection), and the evaluation stage (delivery and analysis of findings).

Sample size: 80 patients with DM participated in the study

Subjects and Methodology A sample selection method was not followed as the study addressed all the patients monitored in the DM outpatient clinic. Leaflets and posters promoting the intervention and informing about its goals and details were posted in outpatient hospital setting.

Population was randomly divided into two groups (study/intervention group and control group). Randomization was acquired by placing each participant to one to one basis to the two study groups.

The study/intervention group followed four 40-minute MI interviews/sessions and three 10-minute phone calls in between the interview sessions. The control group followed a 10-minute-long interview of

instructional consultation nature regarding the importance of systematic physical activity and exercise to the effective management of DM.

Participants voluntarily joined and had free access to their data throughout the duration of the program. All participants signed informed consent and had free option of stopping or leaving at any time they choose to do so.

The exclusion criteria applied were related to: diagnosed mental illness or depression, systematic engagement in physical activity for the optimal regulation of DM, parallel participation in another supportive program, obvious mental deprivation or inability to participate due to physical obstacles.

The study tools used to carry out the intervention are:

1. A population assessment questionnaire consisting of 5 sections:

- 1st section : Demographic data of participants
- 2nd section: IPAC questionnaire - physical activity questionnaire short-answered 7 item versions. It has been translated into the Greek language and has been validated for Greek population 22, as well as DM population¹⁸. A license for the use of the tool has been requested and received.
- 3rd section: somatometric measurements and laboratory tests conducted on a hospital outpatient routine basis
- 4th section: targeted data of individual history record supporting the knowledge of the researcher for health habits of the participants
- 5th section: open questions for participants to freely express any opinions, objections and experiences related to their health management and intervention participation.

The assessment questionnaire was completed by the entire population under study.

2. Preliminary interview of the intervention/study population

A preparatory interview lasting 30 minutes was conducted initially for the whole population under study. During the preparatory interview the study questionnaire was completed by the participants and the informed consent was signed. Participants were informed thoroughly about the safeguarding of any information shared throughout the interview and the rigid principles of the researcher ensuring their safety and anonymity in all stages of the intervention. Population sample was derived after the preliminary interview on one-to-one basis for each group (intervention and control group).

3. Semi-structured interviews of the intervention /study group.

The intervention /study group followed four 40-minute interviews/sessions and three 10-minute phone calls sessions in between interview sessions following the methodology of MET¹⁹. The meeting times of the interview/sessions were arranged in agreement with the participant and followed a 15-day timeline during which phone call sessions took place a week after each interview session. During the interview sessions behavior change was addressed and discussed and the pros and cons of a change were also addressed and elicited. An individualized agreed-on change plan was drawn up for each participated with smart goals set towards change of behavior. The specific change plan was designed and based on the suggested intervention tools of motivational interviewing^{20,21}. The change plan was used as an element of positive reinforcement and reward as well as a means to evaluate participants' progress in the behavior change modification process. The principles and techniques of motivational interviewing were applied with the aim to support the individual's motivation to pursue behavioral change through the resolution of ambivalence, the elicitation method and strengthening of self-efficacy, and the management of the individual's resistance to change with empathetic dialectics²². An important key factor in the process was the involvement of the participants in the change process with their personal choice and responsibility and without exerting any pressure or engaging in any manipulative process for change throughout the interviews. The telephone sessions conducted aimed at supporting, as well as, evaluating participant progress and motivate further for behavior change and a physical activity engagement plan.

4. Semi-structured interview of the control group

A 10-minute-long interview that followed an instructional and advisory approach style without following any other specific methodological scheme was offered to the control group. During the interview, the participants were informed about the importance of systematic physical activity and exercise for the effective management of DM. The participants were encouraged to comply with the instructions provided concerning the effective management of their disease as well as the prevention of potential complications as previously advised by their doctor.

Study objectives and variables

The main objective of the present study was to improve health behavior related to physical activity and therefore support the improvement of the participants' DM management plan by applying the TTM and the MI. Additionally, it was also expected to support significant changes in the ways of supporting, motivating and managing DM patients regarding the adoption of beneficial health behaviors through an organized systematic behavior intervention.

Specifically concerning the patients of the intervention/study group they were expected to:

A) Improve their score on the physical activity rating scale after the end of the intervention by improving the assessed physical activity behavior by one level.

B) Demonstrate significant improvement in their health status regarding glycemic control and clinical parameters compared to the participants of the control group.

Concerning methodology used

C) Demonstrate significant superiority of MI in the form of MET compared to the instructional /consultation short term support of DM patients of the study concerning behavior change and physical activity adaptation to daily life. (intervention/study group versus control group support)

Statistical analysis

Statistical analysis of the study data was conducted with the IBM SPSS for Windows (version 26) statistical software. The statistical analysis included, descriptive statistics calculated for all qualitative/ categorical variables as well as means and standard deviations were calculated for quantitative/non-categorical variables (mean±standard deviation), such as age, body mass index, blood cholesterol and HbAc1 levels. Moreover, the variables were checked with Kolmogorov-Smirnov test to see if they follow a normal distribution or not and the comparison of two quantitative variables that followed a normal distribution was performed with a t-test, while those that did not follow a normal distribution were performed with the Man Whitney test. Accordingly, the comparison of two or more variables that followed a normal distribution was done with one way ANOVA analysis and if they did not follow a normal distribution, they were compared with Kruskal Wallis. The comparison of the qualitative/categorical variables among themselves was done with a χ^2 test. The level of significance (P-value) was set at 0.05. Lastly the analysis included Binary regression logistic, where various factors were correlated with the dependent variable: Intervention versus control group. Univariate logarithmic regression was first performed and then multivariate, where all those variables found to have P<0.1 were included. The Backward Conditional method was followed and variables that had P<0.05 in the model were considered.

III. Results

A total of 80 participants with diabetes mellitus participated in the present study, of which 40 (50%) participants joined the intervention group and 40 (50%) the control group. Overall, 48 (60%) were male and 32 (40%) female (figure 1). The mean age of the sample was 66±10.6 years. Only 2 (2.6%) participants reported participating in a diabetes support program in the past. Also, 10 (13.2%) participants had made an effort to change their lifestyle concerning physical activity.

Before the intervention there was no significant statistical difference between the control group and the intervention group in terms of their physical activity, which increases the reliability of the results.

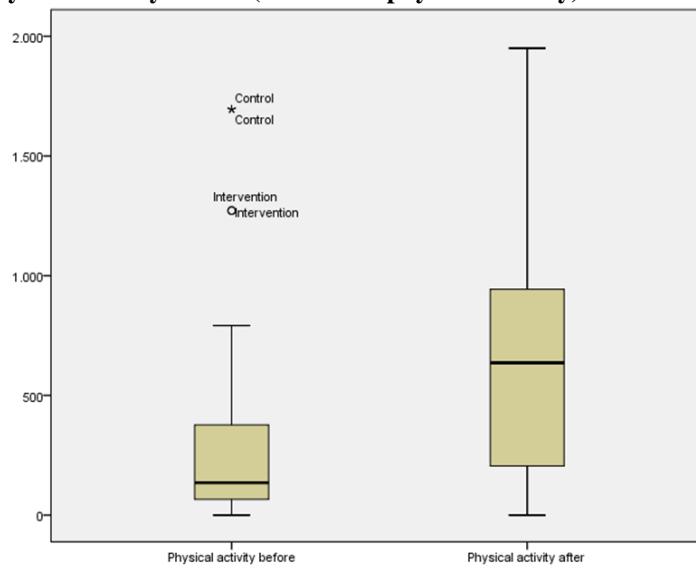
After the intervention, participants in the intervention group compared to those in the control group, walked significantly more (655.1±360.1 vs. 309.4±241.5 minutes, p<0.05), had significantly more total physical activity (867.1±438.5 vs. 423.4±392.5 min, p<0.05), consumed significantly more calories while walking (958.2±561.1 vs. 423.9±332.6, Kcal, p<0.05), consumed significantly more total calories while walking (1264.8±638.2 vs. 605.8±655.7 Kcal, p<0.05) and had significantly less time spent in sedentary activities (384±157.4 vs. 545±158.5 minutes, p<0.05). (Table 1, Graph 1)

Table no1. Physical activity results between two groups before and after intervention

	Control Group	Intervention Group	p-value
Before Intervention			
Walking in minutes	207,9±235,8	146,9±189,6	0,373
Moderate Physical Activity in minutes	121±287,9	73±131,9	0,502
Total Moderate Activity in minutes	328,9±413,8	219,9±281,3	0,336
Calories during walking, Kcal	286,5±321,3	245,8±349,4	0,704
Calories during moderate physical activity, Kcal	188,1±486,5	107,4±216,9	0,502
Total calories during walking, Kcal	474,6±675,2	353,3±514,7	0,527
No activity time, min	555±171,8	504±155,1	0,330
Moderate Physical Activity	25%	5%	0,077

After intervention			
Walking in minutes	309,4±241,5	655,1±360,1	0,001
Moderate Physical Activity in minutes	114±292,1	212,2±242,1	0,255
Total Moderate Activity in minutes	423,4±392,5	867,1±438,5	0,002
Calories during walking, Kcal	423,9±332,6	958,2±561,1	0,001
Calories during moderate physical activity, Kcal	181,8±497,4	306,7±328,7	0,355
Total calories during walking, Kcal	605,8±655,7	1264,8±638,2	0,003
No activity time, min	545±158,5	384±157,4	0,003
Moderate Physical Activity	30%	75%	0,004

Graph no1: Physical activity results (minutes of physical activity) between two study groups

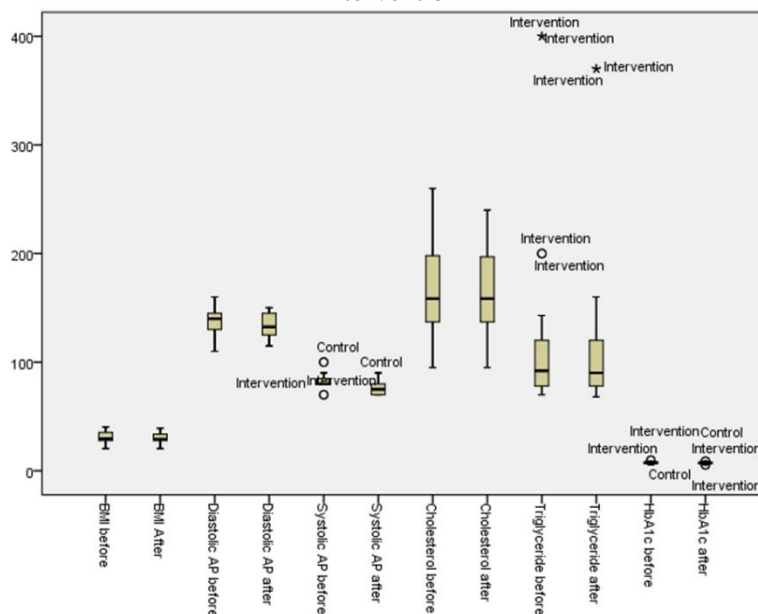


Also, participants in the intervention group compared to those in the control group performed moderate physical exercise at a significantly higher rate (75% vs. 30%, $p < 0.05$).

Before the intervention there was no significant statistical difference between the control group and the intervention group regarding their body mass index and laboratory tests.

After the intervention, participants in the intervention group compared to those in the control group had a significantly greater reduction in HbA1c levels (-0.18 ± 0.2 vs. -0.4 ± 0.2 , $p < 0.05$) although there were no significant reductions in BMI, blood pressure and blood cholesterol. (Graph 2)

Graph no 2: Changes in somatometric and clinical results between two groups before and after intervention



Multiple logarithim regression conducted in order to identify factors that potentially were affected by the intervention program revealed that study/intervention group individuals were 1,004 times more likely to walk more after the intervention and were 1,003 times more likely to engage in total physical activity after the intervention. Moreover, the study/ intervention group was 1,003 times more likely to consume more calories while walking after the intervention and 1,002 times more likely to consume more total calories while walking after the intervention. (Table 2)

Table no 2: Mutliple logarithim regression analysis between two study groups (dependent variable: intervention group versus control group)

	B	p-value	OR	95% OR
Walking after intervention	-0,004	0,004	0,996	0,994-0,999
Total physical activity after intervention	-0,003	0,007	0,997	0,995-0,999
Calories consumed during activity after intervention	-0,003	0,004	0,997	0,996-0,999
Total calories consumed after intervention	-0,002	0,008	0,998	0,997-1,000
Behavior change	-2,733	0,032	0,065	0,005-0,790

IV. Discussion

The present study findings seem to advocate further on the need of well structured, health promotion theory-based and behavior change targeting programs in order to support individuals with DM manage their disease by adopting health behavior changes in their daily routine. Study results concerning participants of the study/control group compared to the participants in control group concerning adaptation to daily exercise and glycemic control suggest that behavior modification programs could significantly motivate towards behavior change.

Implementation of structured behavior programs could potentially prove more supportive for people living with diabetes in adapting systematic physical activity in their daily life when compared to the standard instructional/advisory sessions. Behavior change regarding physical activity adaptation to daily routine could therefore prove to be potential for both glycemic and DM management in those patients.

Study findings align with current literature that suggests that TTM and MI can be very efficient in empowering individuals with DM to manage their disease and control diabetes with its complications by adopting physical activity and behavior change in general. Relevant studies have indicated that MI is a promising intervention approach to encourage positive health behavior change in medical settings²³.

Specifically, MI seems to enhance adherence to diet and exercise modification programs, and overall diabetes management. Another study using MI to DM teenagers showed that MI can be an effective method when working with teenagers with diabetes demonstrating long-term improvement in glycemic control, psychological well-being and quality of life²⁴.

Furthermore, study that used TTM and MI in DM adults also showed an increased self-efficacy level of participants with type 2 diabetes mellitus, which helped them improve their metabolic control and health behavior stage over a 6-month period²⁵.

Burke et al have found MI to be more effective than no treatment, and in many cases, more effective than other active treatments²⁶ while Salimi C, Momtazi S, Zenuzian S after reviewing the effectiveness of MI in the DM management have concluded that the majority of studies have emphasized the effectiveness of MI in types 1 and 2 diabetes on adults, children, and adolescents. Therefore, this therapeutic method can be used for managing and controlling blood sugar levels in DM patients²⁷.

A large-scale study by Wei-Yuan Yao, Meng-Ge Han, Giuseppe De Vito et al has showed that physical activity levels can be improved by exercise-focused intervention in Chinese T2DM patients and that the beneficial effect of physical activity on HbA1c level is dependent on baseline levels of PA and HbA1c²⁸. The study also concluded that the interventions should be directed to the physically inactive patients to improve their physical activity level to a functional threshold and benefit further.

A systematic review on the implementation of MI in patients with DM reports that MI can be effective in changing the behavior of patients with DM and supporting them to achieve goals related to their disease management. In addition, MI is reported as a technique that may improve quality of life and clinical outcomes in patients with type 2 DM, through empowerment, decision support, problem solving, and improvement of self-care behaviors³⁹.

The results of the review seem to be supported respectively in a study concerning the implementation and evaluation of MI by nurses in people with prediabetes. The study emphasizes that the implementation of MI by nurses would give hope in addressing the diabetes "pandemic"³⁰.

Limitations of the current study could be the number of the intervention participants, as a larger scale intervention could lead to more concrete findings regarding the importance of relevant interventions in DM management and glycemic control and thus to potential generalizations of the findings. In addition, the study

took place right after Covid pandemic a fact that could have affected participants need of going out to exercise and have long walks, baring in mind that during pandemic people were home restrained for a long period of time.

In future research of TTM and MI health behavior change intervention it could be interesting to evaluate further, whether certain personality traits of participants could boost behavior change.

V. Conclusion

We share increased hope that the DM management and DM patients' autonomy and disease management could be significantly supported with the use of targeted behavior change interventions using TTM and MI theory as well as other health related behavior change theories.

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