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Review Paper

The effectiveness of theory- and model-based lifestyle interventions on HbA1c among patients with type 2 diabetes: a systematic review and meta-analysis

P. Doshmangir ^{a,b}, L. Jahangiry ^{b,c,*}, M.A. Farhangi ^d, L. Doshmangir ^e, L. Faraji ^c

^a Tabriz Heath Services Management Research Center, Iranian Center of Excellence in Health Management, Tabriz University of Medical Sciences, Tabriz, Iran

^b Health Education and Health Promotion Department, Faculty of Health, Tabriz University of Medical Sciences, Tabriz, Iran

^c Research Center for Evidence Based Medicine, Tabriz University of Medical Sciences, Tabriz, Iran

^d Nutrition Research Center, Department of Nutrition in Community, Tabriz University of Medical Sciences, Tabriz, Iran

^e Tabriz Heath Services Management Research Center, Iranian Center of Excellence in Health Management, School of Management and Medical Informatics, Tabriz University of Medical Sciences, Tabriz, Iran

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ABSTRACT

Objectives: The prevalence of type 2 diabetes is rising rapidly around the world. A number of systematic reviews have provided evidence for the effectiveness of lifestyle interventions on diabetic patients. The effectiveness of theory- and model-based education-lifestyle interventions for diabetic patients are unclear. The systematic review and meta-analysis aimed to evaluate and quantify the impact of theory-based lifestyle interventions on type 2 diabetes.

Study design: A literature search of authentic electronic resources including PubMed, Scopus, and Cochrane collaboration was performed to identify published papers between January 2002 and July 2016.

Methods: The PICOs (participants, intervention, comparison, and outcomes) elements were used for the selection of studies to meet the inclusion and exclusion criteria. Mean differences and standard deviations of hemoglobin A1c (HbA1c [mmol/mol]) level in baseline and follow-up measures of studies in intervention and control groups were considered for data synthesis. A random-effects model was used for estimating pooled effect sizes. To investigate the source of heterogeneity, predefined subgroup analyses were performed using trial duration, baseline HbA1c (mmol/mol) level, and the age of participants. Metaregression was performed to examine the contribution of trial duration, baseline HbA1c

^{*} Corresponding author. Health Education and Health Promotion Department, Faculty of Health, Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran

E-mail addresses: pdoshmangir@yahoo.com (P. Doshmangir), Jahangiry@razi.tums.ac.ir (L. Jahangiry), abbasalizad_m@yahoo.com (M.A. Farhangi), leiladoshmangir@yahoo.com (L. Doshmangir), Farajileila@yahoo.com (L. Faraji). https://doi.org/10.1016/j.puhe.2017.11.022

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(mmol/mol) level, the age of participants, and mean differences of HbA1c (mmol/mol) level. The significant level was considered P < 0.05.

Results: Eighteen studies with 2384 participants met the inclusion criteria. The pooled main outcomes by random-effects model showed significant improvements in HbA1c (mmol/mol) -5.35% (95% confidence interval = -6.3, -4.40; P < 0.001) with the evidence of heterogeneity across studies.

Conclusion: The findings of this meta-analysis suggest that theory- and model-based lifestyle interventions have positive effects on HbA1c (mmol/mol) indices in patients with type 2 diabetes. Health education theories have been applied as a useful tool for lifestyle change among people with type 2 diabetes.

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Introduction

Diabetes is a common metabolic disease with adverse impact on the lives of patients that reduces life expectancy by up to one-third of adults.¹ The prevalence of type 2 diabetes is rising rapidly around the world. The World Health Organization estimates that diabetes is the 7 leading cause of death, and by the year 2030 there will be 366 million adults with diabetes in 2030.²

To prevent acute and long-term complications of diabetes, educational lifestyle interventions are considered as a fundamental aspect of care among diabetic patients. Diabetic patients' education is an ongoing process of receiving information from clinician-educators to develop knowledge, skills and ability for continuing self-care, and management of the diseases.³ Education plays an important role in the process of care and treatment to improve clinical outcomes, health status, and quality of life for diabetic patients.⁴ A number of systematic reviews have provided evidence for the effectiveness of educational lifestyle interventions on diabetic patients.^{5–7} Choi et al.⁵ 2016 has focused on the effect of different diabetes education approaches on glycemic control for Chinese patients. They reported that diabetes education in any format generates glycemic improvement for Chinese patients and in studies using information reinforcement strategies, the glycemic control was further enhanced. Different education and psychological interventions have been aimed at the management of type 2 diabetes. A systematic review has explored effectiveness of self-management educational studies on diabetic adults, findings show that self-management educations significantly decrease hemoglobin A1c (HbA1c) levels.⁷ In a similar study, Zhao et al.8 synthesized the effects of self-management educational interventions on patients with type 2 diabetes. The results indicated that patients who underwent diabetes self-management educations significantly improved HbA1c, self-efficacy, and knowledge levels.

Although both theories and models explain behavior and suggest ways to achieve behavior change, there are some differences between theories and models. A theory is a set of broad and interrelated concepts that help to describe events generally. Models help the understanding of a specific problem in a particular population and context. They are often used to explain empirical findings and informed by more than one theory.⁹ Theories and models both include concepts and constructs that help to explain individual behavior. To increase the effectiveness of intervention programs, theories and models can provide a systematic framework for designing, implementation, and evaluation of the program.¹⁰ Despite this fact that implementing theory- and model-based lifestyle interventions is an essential method to change behavior and modify the consequences of the diabetes,¹¹ the effectiveness of theory- and model-based education-lifestyle interventions for diabetic patients are unclear. This systematic review and meta-analysis aimed to identify, evaluate, and quantify the impact of theory- and model-based lifestyle interventions on type 2 diabetes.

Methods

A systematic review with meta-analysis was performed using a prespecified protocol with reviewing the evidence to show the effectiveness of theory- and model-based diabetes lifestyle interventions for patients with type 2 diabetes. The statement of Preferred Reporting Items for Systematic Reviews and Meta-Analyses has been used for reporting this study.¹²

Search strategy and study selection

A literature search of authentic electronic resources including PubMed, Scopus, and Cochrane collaboration was performed to identify published papers between January 2002 and July 2016. Publications with the combination of following search words in the titles and abstracts or keywords of the original studies were included: education, model, theory, framework, intervention, lifestyle, type 2 diabetes, and diabetes mellitus. Also, the manual search of the references and the bibliographies of the original studies were supplemented for both English and Persian articles. The PICOs (participants, intervention, comparison, and outcomes) elements were used for selection of studies to meet the inclusion and exclusion criteria. Each letter represents a component: the patient population (P), the interventions or exposure (I), the comparator group (C), the outcome (O), and the study design chosen (S).¹³ Duplicate articles were removed from retrieved studies before screening articles by title and abstract to identify studies that met the following inclusion criteria: a) published articles in English and Persian language, b)

describes an education intervention based on models or theories for diabetic patients, c) publications identified reporting HbA1c in absolute values with at least 10-week follow-up duration. Articles with insufficient detail in the title and abstract to make a clear decision were included for further review. The earliest publication was selected for studies that have the same methodological descriptions and results. Full-text versions of all included publications were retrieved.

Data extraction and quality assessment

The quality control of the articles was performed independently by two authors (PD and LD) and any disagreement solved by discussion or help of a third author (LJ). Articles that met the inclusion criteria were independently hand selected by two authors using a structured extraction forms including the study design, intervention duration, setting, country of origin, mean age, baseline and after intervention level of HbA1c, and number of participants in control and intervention groups.

Jadad scale that assigns scores for reported randomization (two items for randomization and the sequence randomization), blinding (two items for double blind and the method of double blind), and withdrawals (one item) was used for evaluating the quality of studies (one point is added for a 'yes' answer to each items). Total quality scores can range between 0 (lowest score) and 5 (highest).¹⁴

Data synthesis and statistical analysis

Mean differences and standard deviation (SD) of HbA1c level in baseline and follow-up measure of studies in intervention and control groups were considered. The studies that used more than one follow-up measure were considered as more than one study, and if a confidence interval was reported in place of median, it was converted to SD for analyses. Those studies that reported HbA1c in percent units were changed to mmol/mol according to the International Federation of Clinical Chemistry unit.¹⁵ Existence of heterogeneity was tested by Cochran's Q-test at P < 0.05 level of significance. The I^2 test was also used to calculate the percentage of heterogeneity.¹⁶ A random-effects model was used for estimating pooled effect sizes. To investigate the source of heterogeneity, pre-defined subgroup analyses were performed using trial duration, baseline HbA1c (mmol/mol) level, and the age of participants. Meta-regression was performed to examine the contribution of trial duration, baseline HbA1c (mmol/mol) level, the age of participants, and mean differences of HbA1c (mmol/mol) level. Publication bias was analyzed by funnel plot analysis



Fig. 1 – Flowchart of study selection for inclusion in the systematic review. HbA1c, hemoglobin A1c.

and Egger's regression asymmetry test.¹⁷ All of the analyses performed using STATA version 12.0 (Stata Corporation, College Station, TX, USA) and P < 0.05 were considered significant.

Results

Search results and study selection

The flowchart of the selection process in the meta-analysis is shown in Fig. 1. Of 1618 studies, 97 duplicate articles were removed. In all, 1521 articles were included for the title and abstract screening. Of these, 1435 articles were excluded because they did not meet the inclusion criteria and 86 were chosen for assessing full-text eligibility, and in this step, 38 were excluded because they did not report HbA1c (mmol/mol) value at baseline or after the intervention, 48 studies included for quantitative synthesis, finally 14 articles (13 English and one Persian)¹⁸⁻³¹ were included for meta-analysis (18 data extraction) which were all controlled trials.

Study characteristics

The theories and models of reviewed studies were described in Table 1. The summary descriptions of the included studies are presented in Table 2. Publication year of these studies were 2002–2015. Sample size of participants varied from 24 to 300 with a total sample size of 1151 and 1233 in intervention and control groups respectively. All trials involved parallel designs; three were reported blinding but all of them did not mention the blinding method of the studies. Study duration was from 10 to 96 weeks (Table 3). Six trials used the health belief model (HBM) for intervention,^{19,20,24,29,31,40} two used social cognitive theory and learning theory,^{22,32} two used

Table 1 – Description of the theories and models that referred to the reviewed publications.				
Theory name	Description			
TOE	Empowerment is a process of transition from a state of powerlessness to a state of relative control over one's life, destiny, and environment. ²³			
LT	Learning theories are conceptual frameworks describing how information is absorbed, processed, and retained during learning ³²			
SCT	Social cognitive theory postulates that behavior is influenced by the constant interaction among the environment, the personal characteristics of an individual (e.g., knowledge, skills, health beliefs) ²²			
HBM	It predicts that the likelihood of action is increased if the perceived threat of the disease is high and if the benefits of behavior are thought to outweigh the barriers ¹⁹			
TTM	Transtheoretical model which includes strategies to assist individuals in making transitions across the various stages of change (SOC) ²⁷			
PRECEDE	An acronym for predisposing, reinforcing and enabling causes in educational diagnosis			
-PROCEED	and evaluation. Used for planning safety programs and consists of four process phases			
model	(from assessing quality of life to identifying enabling factors) ^{21,28}			
BASNEF model	An acronym for beliefs, attitude, subjective norms, enabling factors ¹⁸			
IMB model	One who is well informed and motivated to act is thought to develop the skills necessary to enact the behavior at focus, and thus reap the health benefits of doing ^{25,26}			

Abbreviations: HBM, health belief model; TTM, transtheoretical model; PRECEDE–PROCEED: predisposing, reinforcing, and enabling constructs in educational/environmental diagnosis and evaluation; TOE, theory of empowerment; IMB, information motivation behavior; LT, learning theory; SCT, social cognitive theory.

Table 2 — The summary of studies.								
Number	Source	Country	Intervention (n=)	Control (n=)	Mean age, (yr)		Quality score	
					Intervention	Control		
1	Afshari ¹⁸	Iran	82	82	56	57	3	
2	Baghianimoghadam ¹⁹	Iran	40	40	49	49	3	
3	Kashfi ²⁰	Iran	50	50	44	45	3	
4	Kim ²¹	Korea	120	130	59	58	2	
5	Miller ²²	USA	45	47	72	73	3	
6	Mohamed ²³	Qatar	215	215	52	55	3	
7	Najimi ²⁴	Iran	48	48	67	67	3	
8	Orsama ²⁵	Finland	24	24	62	61	3	
9	Osborn ²⁶	USA	48	43	57	58	3	
10	Partapsingh ²⁷	Trinidad	58	61	20–69	20–69	3	
11	Salinero-Fortet ²⁸	Spain	300	300	67	67	4	
12	Shamsi ³¹	Iran	44	44	44	45	2	
13	Sharifirad ³⁰	Iran	50	50	67	67	3	
14	Zareban ²⁹	Iran	69	69	NR	NR	3	
NR, not reported.								

beliefs, attitudes, subjective norms, and enabling factors (BASNEF model),^{18,30} PRECEDE–PROCEED,^{21,28} transtheoretical model,²⁷ theory of empowerment,²³ and two used information motivation behavior model.^{25,26} Quality assessment results are presented in Table 2. No studies scored positive on all quality criteria. The majority of studies lacked a concise description on the sequence generation in randomization, allocation concealment.

Meta-analysis

Of the 18 trials included in this meta-analysis, 16 trials showed a significant reduction in the HbA1c (mmol/mol) level after theory-based diabetes intervention. The forest plot with weighted mean differences in post-trial HbA1c (mmol/mol) between intervention and control groups and their confidence interval (CIs) are shown in Fig. 2. As there was significant heterogeneity between studies (test for heterogeneity: P < 0.001 and $I^2 = 97.8\%$), we used a random-effects model to estimate the pooled mean difference (MD) in the HbA1c (mmol/mol) level. Using the random-effects model, the pooled

effect size of theory- and model-based education interventions on HbA1c (mmol/mol) level versus control was calculated at -5.35% (95%CI = -6.3, -4.40; P < 0.001).

Subgroup analyses

The results of subgroup analysis are shown in Table 4. The analyses showed that HbA1c (mmol/mol) level decreased more significantly after theory- and model-based interventions in participants older than 50 years (-5.4 [95% CI = -5.6, -5.3]) compared with participants aged 50 years and less (-2.6 [95%CI = -5.1, -0.88]). There was a greater reduction after interventions in participants with baseline of HbA1c greater than 53 mmol/mol (-5.6 [95%CI = -6.7, -4.6]) compared with participants with baseline of HbA1c stream that participants with baseline of HbA1c stream that -4.5 [95%CI = -5.8, -5.2]). The results showed that each of the pre-specified factors significantly affected the pooled effect size and analyses of between group heterogeneity showed the significant source of heterogeneity between studies (P < 0.05). Also, when educational periods were categorized into ≤ 12 weeks and >12

Table 3 – Characteristics of the interventions.						
Source	Model or theory	Duration (weeks)	Intervention duration	Educational strategy	Types of intervention	
Afshari ¹⁸	BASNEF	24	Six sessions	Role playing; group discussion	Patient education	
Baghianimoghadam ¹⁹	HBM	12	Two sessions	Group discussion; interaction	Walking	
Kashfi ²⁰	HBM	12	Three sessions (each 60 min	Not stated	Exercises and jogging	
Kim ²¹	PRECEDE- PROCEED	48	12 h (weekly 2-h sessions over the course of 6 weeks)	Feedback; role play; and group discussions	Exercise	
Miller ²²	SCT, IMB	10	Six 2-h group sessions	Goal setting; self- monitoring	Nutrition education	
Mohamed ²³	HBM, TOE	48	Four educational sessions	Goal setting; counseling techniques.	Food habits and health beliefs, exercise benefits	
Najimi ²⁴	BASNEF		Four Educational sessions in 70 min	Not explained	Nutritional education	
Orsama ²⁵	IMB	40	A mobile telephone- based remote patient	Feedback and counseling; self-management information, motivation	Diabetes education, behavioral skills learning	
Osborn ²⁶	IMB	40		Tailored education; self- management planning strategies	Physical activity, meal planning strategies	
Partapsingh ²⁷	TTM	48	One session with return visits in 16 weeks.	Consultation	Diet, exercise, and medications	
Salinero-Fortet ²⁸	PRECEDE-PROCEED	96	Four visits average time 40 min per session	Self-monitoring usual care and individual counseling	Physical exercise, diet healthy behavior	
Shamsi ³¹	HBM	12	Six 60 min sessions	Group discussion; role playing	Walking	
Sharifirad ³⁰	НВМ	24	30–45 min sessions	Pamphlets and face-to-face lectures, question and answer	Nutritional education	
Zareban ²⁹	HBM	24		Lectures; playing films; question and answer and CD and pamphlets	Proper diet, walking, regular drug intake	

Abbreviations: HBM, health belief model; TTM, transtheoretical model; PRECEDE–PROCEED, predisposing, reinforcing, and enabling constructs in educational/environmental diagnosis and evaluation; TOE, theory of empowerment; IMB, information motivation behavior; BASNEF, beliefs, attitude, subjective norms, enabling factors; SCT, social cognitive theory.



Fig. 2 – Pooled effect size of lifestyle intervention on HbA1c (mmol/mol). HbA1c, hemoglobin A1c; CI, confidence interval; WMD, weighted mean difference.

Table 4 – Subgroup analyses of lifestyle intervention on HbA1c (mmol/mol).								
Variables	Number of data	Mean differences [95%CI]	I ² (%)	P-value for heterogeneity	Significance ^a	Meta-regression ^b		
Total mean age								
\leq 50 years	3	-2.6 [-5.1 to -0.88]	86.4	<0.001	0.04	Reference		
>50 years	13	-5.4 [-5.6 to -5.3]	94	<0.007	<0.001	0.004		
Trial duration								
\leq 12 weeks	10	-4.9 [-5.2 to -4.8]	81	<0.001	0.001	Reference		
>12 weeks	9	-7.4 [-7.8 to -7.0]	89	<0.001	<0.001	0.104		
Baseline HbA1c								
≤53 mmol/mol	3	-4.5 [-5.8 to -5.2]	85.4	<0.001	<0.001	Reference		
>53 mmol/mol	15	-5.6 [-6.7 to -4.6]	93.9	<0.001	<0.001	0.003		
Study quality								
\leq 2 score	7	-5.0 [-5.2 to -4.8]	88.6	<0.001	0.002	Reference		
>2 score	12	-6.8 [-7.1 to -6.4]	91.4	<0.001	<0.001	0.227		
Country								
Iran	6	-5.2 [-6.7 to -3.7]	64.9	<0.006	<0.001	0.79		
Others	12	-5.4 [-5.5 to -5.2]	96	<0.001	<0.001	Reference		
HhA1c hemoglobin A1c: CI confidence interval								

HbA1c, hemoglobin A1c; CI, confidence interval.

^a P-values for significance of mean difference in HbA1c between intervention and control groups.

^b P-values for difference in HbA1c change across strata.

weeks, although it was significant in both categories, in the studies with >12 week the effect was greater (-6.8 [95% CI = -7.1, -6.4]).

Publication bias

The Egger's and Begg's tests showed publication bias (P = 0.001; Fig. 4).

Fig. 3 shows the differences in HbA1c (mmol/mol) reduction according to using of theory and model in interventions. BASNEF model shows greater significant reduction in HbA1c level (mmol/mol) (-6.5 [95%CI = -9.4, -3.6]). In comparison with using of HBM and PRECED–PROCEED model, the lifestyle intervention programs with using of HBM model were significantly more effective (-5.8 [95%CI -9.3, -2.4], P = 0.006) than studies using of PRECED-PRODEED model (-5.2 [95%CI -6.0, -4.3], P < 0.001.

Discussion

In this meta-analysis of the effect of theory- and model-based lifestyle interventions on improving HbA1c (mmol/mol) level including 18 trials with 2396 participants between 2002 and 2016, we found that theory- and model-based lifestyle



Fig. 3 – Pooled effect size of lifestyle intervention on HbA1c based on theories. HbA1c, hemoglobin A1c; CI, confidence interval; WMD, weighted mean difference.



Fig. 4 – Funnel plot Standard error; SMD: Standardized mean differences.

interventions can reduce HbA1c (mmol/mol) level around -5.35 (95% CI = -6.3, -4.40; P < 0.001). Some of the heterogeneities between studies were accounted for by variation in the baseline levels of HbA1c (mmol/mol). Our results are consistent with the previous meta-analysis that estimated the overall weighted mean difference in HbA1c of -1.19%.⁵ The meta-analysis on theory- and model-based self-management education for patients with type 2 diabetes reported lower pooled effect size (-0.38% [95% CI -0.51, -0.26]) than our study and what has been previously reported.⁸

Lifestyle modification is the first-line treatment for the management of type 2 diabetes through focusing on improving dietary quality, physical activity, and medical intervention for glycemic control and other modifiable cardiovascular risk factors.³³ In fact, developing theory- and model-based lifestyle interventions provide conditions that patients can be managed and altered for the diabetic status by making certain lifestyle changes. It means applying the theories and behavior change techniques such as specific goal setting, relapse prevention, and self-monitoring related to diabetes care contribute the most to the effectiveness of the diabetes education programs.³⁴ These specific behavioral techniques can help to specify key determinants of the target behaviors and also provide a supportive bonding that facilitates patients to arrive at the desired health outcomes, apply them in their daily life, and particularly adhere to medical regimens.9,35

Stratton et al.³⁶ indicated that each 1% reduction in updated mean HbA1c was associated with a 37% decrease in risk for microvascular complications and a 21% decrease in the risk of any end point or death related to diabetes. Diabetic patients in the theory- and model-based lifestyle intervention programs obtained more information and better self-care behavior.

HBM and PRECEDE–PROCEED models were the most frequent theoretical frameworks (n = 5) with the significant effects that have been used in educational intervention for type 2 diabetic patients. Since, planning and evaluation are the key elements for developing health educational programs, adequate and appropriate application of theories and models is essential

for more effective behavior changes. In their recent review, Hansen et al.³⁷ have demonstrated that theories or models were used inappropriately and did not adequately address how lifestyle can be changed in such interventional programs. Understanding concepts and constructs for each theory and model are a useful way to apply them with full recognition. In our view, studies claiming a theoretical basis should pay much more attention to good reporting and high quality description of the models underlying health education interventions.

Another finding from the stratified analyses was that the interventions with >12 weeks have a significantly greater effect than interventions \leq 12 weeks. One supposition for these results derived from the perception that diabetic patients in long term are better supported by theory constructs and behavior changes techniques like self-monitoring and feedback, as has been already suggested by a previous study.^{38,39}

There were some limitations for this study. Although we classified educational strategies, owing to multiple strategies implied in the interventions, we were not able to determine which strategy was more effective.

However the results should be interpreted with caution. In particular, in three studies, the design of studies was quasiexperimental, then these studies were of low quality and we cannot state with absolute certainty that lifestyle interventions effectively reduce HbA1c.

Conclusion

The findings of this systematic review and meta-analysis implied that theory- and model-based lifestyle interventions have positive effects on HbA1c (mmol/mol) indices in patients with type 2 diabetes. Overall, in addition to change in constructs of models and theories, applying models and theories in educational interventions has been reported to be influential. Health models and theories have been applied as a useful tool for changing the lifestyle among people with type 2 diabetes.

Author statements

Ethical approval

The ethics committee of Tabriz University of Medical Sciences, Vice Chancellor for Research approved the study.

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Competing interests

None declared.

Authors' contribution

PD designed the research data. LJ analyzed and interpreted the research data and wrote the final manuscript draft. MAF, LD, and LF collected and extracted the data.

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