A Randomized Controlled Trial to Compare the Cost-effectiveness of Group Versus Weblog-telecommunication Nutrition Education Program on Glycemic, Lipids, and Anthropometric Control of Patients with Type-2 Diabetes: Study Protocol

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Abstract

Background: Education is the most important principle in managing diseases, especially diabetes. On the other hand, economic burden of diabetes is another important issue. Thus, this study aimed to compare the cost-effectiveness of group vs. Weblog-Telecommunication (Web-Tel) nutrition education on glycemic, lipids, blood pressure, and anthropometric indices of type-2 diabetic patients.

Methods: This randomized controlled trial study will be conducted in health centers of Bushehr city. One-hundred five patients with type 2 diabetes will randomly be assigned to one of the three groups: group education, Web-Tel education, and the control. The study has two phases. The first phase (or pre-intervention phase) will last two weeks and the second phase (or intervention phase) 12 weeks. In group education, in addition to the usual cares, the participants will receive group seminars monthly (3 seminars in total), while the Web-Tel group will receive education via website monthly (3 sessions in total) besides the usual cares, and the control group will receive the usual cares. The outcomes include glycemic, lipids, blood pressure, and anthropometric indices. Also, the cost of each arm will be calculated.

Conclusion: The present study will compare the two methods of nutrition education to determine the more cost-effective nutrition education method for patients with diabetes which can help them in self-care and costs reduction.

Introduction

Uncontrolled diabetes mellitus (DM) could progress to micro/macro-vascular complications, reducing the quality of life, increasing the premature death, and imposing a substantial economic burden of absenteeism from work and health care on individuals and societies.[1-5]

In Iran, the total annual cost of diabetes is estimated $3.64 billion (including $1.71 billion direct and $1.93 billion indirect cost) in 2009 and is predicted to reach $9.0 billion by 2030 (including $ 4.2 billion in direct and $4.8 billion in indirect costs).[1] The direct costs of type-2 diabetes are estimated to be about 8.7% of the total health costs in Iran.[6, 7] Therefore, an effective and

sustainable approach to reduce the speed or prevent the complications of diabetes is a priority.[8]

Education is the basic principle in diabetes care.[9] Accordingly, one of the most important models of Diabetes Self-Management Education (DSME) for type-2 diabetes mellitus (T2DM) is "group education". This method enables the patients to increase their knowledge through discussion, finding the ability to solve the problems and improving their quality of life.[9-11] On the other hand, the Web-Tel nutrition education method involves the use of weblog and mobile phones, which is a new method for the educational purposes.[12]

There are several studies on the economic burden of DM in different parts of the world. However, few studies have been conducted on the cost-effectiveness of diabetes nutrition education. Accordingly, in the United States, a six-month randomized controlled trial examined the cost-effectiveness of nutrition education on 170 patients with diabetes without clinical symptoms. The results showed that the cost effectiveness was $ 4.20 in the intervention group and $ 5.32 in the control group.[13] Also, three studies were conducted in 2014, 2015 and 2018, which all showed that DSME has a better cost-effectiveness than usual cares in the quality of life.[14-16]

To the best of our knowledge, the effectiveness of nutrition education methods in diabetic patients, especially the Web-Tel nutrition education method, has not yet been studied in Iran. Also, there is no consensus on the most cost-effective approach of nutrition education. To answer the question of which educational method is the most cost-effective one in diabetic patients, we aim to compare the cost-effectiveness of the two nutrition education methods: the web-based vs. the group education on blood sugar, lipid profile, blood pressure, and anthropometric indices of patients with T2DM, through a parallel randomized controlled clinical trial study with allocation ratios of 1:1:1.

Aims

1) to use new nutrition education strategies to empower the patients with T2DM in self-care 2) to determine which educational method is more cost-effective for the patients with T2DM education 3) to change the teaching methods along with science progression and technology, in the health care system for the prevention/control of diabetes 4) to reduce the costs of treatment

Methods

This trial was registered in Thailand Clinical Trials Registry (TCTR). The TCTR identification number is TCTR20210331001. This protocol is written in accordance with 33-item SPIRIT checklist 2013.

Study Design, Population, and Recruitment

This is a parallel randomized controlled clinical trial. The study population consists of adult patients with T2DM who will be recruited from health centers of Bushehr city in Iran. In the present study, positive inclusion criteria include patients with uncontrolled T2DM (HbA1c≥7); diagnosis of the disease under 1 year; adults above 20 years old; reading and writing literacy; access and ability to use the Internet and mobile phones; and willingness to participate in the study. Negative inclusion criteria are persons with mental and emotional disorders or any disabilities; persons under treatment for AIDs, cancers, chronic heart, cerebrovascular, renal, and hepatic diseases; pregnant or lactating women; participation in professional group nutrition education of diabetic patients (except for usual cares) in the last year; and participation in other clinical studies in the past 6 months. The exclusion criteria include being diagnosed with any chronic diseases during the trial, being absent in more than one educational session, and lack of motivation to participate in the study at any time of the research.

Ethical Considerations

The current study was approved by the research ethics committee of Shiraz University of Medical Sciences [IR.SUMS.REC.1399.1162]. Before the study commencement, the main researcher explained all the possible advantages and disadvantage of it to the participants; then, they will be asked to sign a consent form. The results will be kept completely confidential and used only for research purposes. The identity of the participants will remain confidential within the framework of the law.

Sample Size Calculation

According to a previous study conducted by Kim et al. in 2006,[17] and with the power and confidence level of 99%, sample size was calculated as 26 participants in each group using the NCSS (PASS) 2007 software (NCSS, Kaysville, Utah, USA). After consideration of 35% attrition rate, a total of 105 participants was calculated (n=35 in each group). The formula used for the sample size calculation is as follows:

$$N = \frac{(Z1 - \frac{\alpha}{2} + Z1 - \beta)(\delta_1^2 + \delta_2^2)}{d^2}$$

In this formula: α=0.01, β=0.01, δ_1=0.81, δ_2=0.61, d=100z.

Recruitment and Random Allocation

Participants will be recruited from health centers of Bushehr province of Iran. After checking the volunteers' compatibility with the inclusion and exclusion criteria, eligible ones will receive a code. To control the prognostic factors, we will classify the

participants based on the age and disease severity (hemoglobinA1c); then, they will be randomly assigned to one of the three groups, using the block randomization method. For this purpose, random allocation software version 2.0 will be used by the main researcher.

Allocation Concealment and Blinding

To minimize prediction probability of the next intervention type or random allocation sequence by the person in charge of random allocation, a different researcher will perform it. Also, to prevent information bias, we will usedouble blind method (blinding of assessor and biostatistician).

Data Collection and Measurement Intervals

At the beginning of the study, demographic questionnaire (including sex, age, education, income, type of chronic diseases, drug use, and type of medication used) will be completed via face-to-face interview for each participant. The participants' physical activity will be assessed by IPAQ (International Physical Activity Questionnaire) at the beginning and end of the intervention. Anthropometric variables, glycemic indices, blood lipids, and blood pressure will be measured in months 0 and 3 of the study. Moreover, self-administered questionnaires including three-day food records (2 workdays and one weekend) in the months 0, 1, 2, and 3, as well as the diabetic nutritional knowledge questionnaire in the months 0 and 3, will be completed by the participants.

For measurements of biochemical factors and data analysis, we will use blind and researchers to prevent information bias. After data collection and entry by the main researcher, the accuracy of the entered information will be checked by another researcher to promote data quality.

Outcomes

In the current study, primary outcomes includeGlycosylated HemoglobinA1c (HbA1c) and cost-effectiveness analysis (by using HBA1c as the final mediating outcome), while secondary outcomes consist of glycemic indices (such as: Fasting Blood Sugar (FBS), fasting insulin, Homeostatic Model Assessment of Insulin Resistance (HOMA-IR), Quantitative Insulin sensitivity check Index (QUICKI)); anthropometric variables (such as waist circumference (WC) and body mass index (BMI)); blood Lipids (such as: Total Cholesterol (TC), High Density Lipoprotein cholesterol (HDL-C), Low Density Lipoprotein cholesterol (LDL-C), and triglycerides (TG)); blood pressure (Systolic Blood Pressure (SBP), and Diastolic Blood Pressure (DBP)); physical activity; dietary diversity Score (DDS); and nutrition knowledge assessment.

Measurements

Biochemical: Participants' blood samples will be collected early in the morning after at least 10 hours fasting, and they will be asked to stop taking glucose-lowering drugs for 8-10 hours before the test. Glycemic Indicators: *HbA1c* will be measured using a complete blood sample by high performance liquid chromatography (HPLC) (Bio-Rad Variant II, Sydney, Australia). *FBS* will be measured by hexokinase (Roche Modular Analyzer; Tokyo, Japan). Fasting insulin levels will be measured quantitatively by luminescence. *HOMA-IR* will be calculated by the following formula: [Fasting Insulin (Milli International Unit / Liter) * Fasting Blood Sugar (Mill Mol/L)]/22.5. *QUICKI* will be calculated by Formula: 1/ (Glucose concentration logarithm + insulin concentration logarithm). Blood fats: TC, HDL-C, LDL-C, and TG will be measured using the ELISA method.

Anthropometric measurements: *Weight* will be measured with the minimal clothing and no shoes using a digital scale (with an accuracy of 100 grams). *Height* will be measured barefoot by a tape meter (with an accuracy of 0.5 centimeter) in a standing position next to the wall, while the shoulders are in normal condition. *Body Mass Index (BMI)* will be calculated by dividing weight (in kilograms) by height squared (in square meters). *Waist circumference* will be measured on the middle distance between the last ribs and iliac bones, at the end of normal exhalation by using a non-elastic tape meter with an accuracy of 0.1 cm.

Blood Pressure: Blood pressure will be measured on the left arm with mercury sphygmomanometer while the patient is sitting at rest, 2 times, and the average of 2 times will be considered as the final blood pressure.

Physical Activity: Physical activity will be calculated using the IPAQ (International Physical Activity Questionnaire) in the form of metabolic equivalence hour-day (MET-h-d).

Dietary Diversity Score: Dietary records (two workdays and one weekend) will be analyzed using nutritionist IV software. Scoring of DDS will be based on the 12 food groups according to Food and Agriculture Organization (FAO) guidelines of the United Nations, including: "cereals; glandular and root plants (such as potatoes, beets, turnips, carrots, etc.); vegetables; fruits; meats; eggs; fish and other sea foods; cereals and nuts; milk and dairy products; oils and fats; sweets; spices, condiments, and beverages".[18] In this classification, the group of vegetables is a combination of 3 subgroups: vegetables rich in vitamin A, dark green leafy vegetables, and other vegetables; The fruits group is a combination of the two subgroups: fruits rich in vitamin A and other fruits; also, the group of meats is a combination

of the two subgroups: organ meat and boneless meat (meat and fat only). If a person has consumed half a unit of each group in two days, he/she is considered a consumer of that food group. The score of each group varies from 0 (no consumption) to 1 (consumer). Therefore, the total score is between 0 and 12. Higher scores indicate more food diversity.

Nutrition Knowledge: The Nutrition knowledge Questionnaire which will be used in this study is a researcher-made, self-administered questionnaire. This questionnaire consists of 30 multiple-choice questions including 24 three-choice questions as: 1) I agree, 2) I disagree, and 3) I don't know, and 6 four-choice questions. Only one choice is considered correct, and the rest are incorrect. The total score will be 100, and a higher score indicates higher nutrition knowledge of the participant. Face and content validity of this questionnaire have already been confirmed. The reliability of the questionnaire will be assessed by test-retest method and internal consistency will be evaluated by Cronbach's alpha method.

Statistical Methods

The collected data will be analyzed using SPSS software version 22 on an intention-to-treat (ITT) principle. Baseline values will be shown as mean±standard deviation (SD) for quantitative variables, and frequency (percentage) for qualitative variables. At first, the normality of the data will be assessed using Kolmogorov-Smirnov and Shapiro-Wilk tests. If data isnormally distributed, parametric test will be used. For within group comparisons paired-t-test, for between group comparisons one-way ANOVA (to compare two by two groups, follow-up tests such as Tukey or Scheffe), and for adjustment of the effects of potential confounders, Ancova will be applied. Repeated measure Anova will be used to analyze the differences between the three groups over time. If data has not normal distribution, nonparametric equivalence tests will be used. For within group comparisons Wilcoxon signed-rank test, and for between group comparisons Kruskal Wallis test will be applied. In all statistical tests, P-value less than 0.05 will be considered as significant.

Intervention

Stages of the study: The present study consists of 2 stages (2 phases).

Stage 1 (pre-intervention phase) for 2 weeks: In this phase, "nutritional knowledge", and "demographic" questionnaires will be completed. Food record completion will be explained to the participants. In addition, the participants in the Web-Tel group will be taught how to work on the Internet in the form of weblog, and WhatsApp. Also, to increase the accuracy of their intakes and records, all the participants will be given a home digital scale.

Stage 2 (intervention phase) for 3 months: In this phase, the participants will receive nutrition education. The educational content will be the same in both groups (Web-Tel and group method). Web-Tel Group will receive one lesson each month and be asked to send the completed food records via WhatsApp to the researcher every month. In the group education, nutrition education sessions will be held monthly (3 sessions in total and each session at last 2 hours). In this phase, the control group will receive only usual cares.

Types of Study GroupsWeb-Tel Nutrition Education: This model consists of 3 nutrition education lessons. For members of this group, open access to the weblog will be possible, and they can enter the weblog with their username and password, to be sure that the participants of the other two groups will not have access to this information. Three lessons will be available one after another at the beginning of each month, for 3 months. Each time the weblog will be updated with new lessons, some notifications will be sent via email, and the participants will be notified by the text messages within three days of updating if they do not log in. In addition, a WhatsApp group will be created for the web-based participants to allow potential questions to be sent to the researchers. To increase the participants' cooperation, the researchers will design some competitions on the weblog and some gifts will be given to the winners. In addition, each time the participants enter the weblog, they will be asked to record their dietary intakes and send it as a photo via WhatsApp.

Group Education: The sessions are held monthly for 3 months (3 seminars in total), and each educational session takes at least 2 hours (at least 6 hours in total). Educational content in the Web-Tel group and the group education are the same. It is a great opportunity for the participants to ask their questions, discuss their challenges with one another under the supervision of a nutritionist to find the best answer. To increase the participant's cooperation, we will design some competitions, and gifts will be specified to the right answers. The participants are required to record their diet and deliver it to the nutritionist the next session.

Control Group: The control group will receive just usual cares. Usual cares mean diabetes self-management education (DSME) which are provided by a team consisting of a general practitioner and a nutritionist. The educational sessions are held on a weekly basis by the team members. The participants in the control group will receive none of the text-messages related to the other two groups.

Educational Content: The Educational Content is summarized in Table 1.

Follow up the participants: For minimizing the participants' loss to follow up during the 3-month study period, all the participants will receive text

Table 1: Educational content of both group and Weblog-Telecommunication education

Class	Educational Contents	Tasks
First Session (for at least 2 hours)	Teaching the concept of healthy eating according to diabetic healthy eating guidelines Teaching portion sizes by using pictures and models Explaining about the impacts of energy and macronutrient intakes on weight, and glycemic control	To perform 3 days food record (for the next session)
Second Session (for at least 2 hours)	Review of the previous session content Teaching carbohydrate counting Explaining about glycemic index (GI) and glycemic load (GL) of foods Explaining about the advantages of dietary fibers, especially soluble fibers in the diet	To perform 3 days food record (for the next session) To apply carbohydrate counting in dietary intakes To consider GI/GL in dietary intakes
Third Session (for at least 2 hours)	Review on the previous session content Explaining about various types of dietary fats and their impacts on health Teaching how to read food label and apply it Teaching Traffic light on foods and how to apply it	To perform 3 days food record (for the next session) Pay attention to the food labels on foods Pay attention to the traffic light on foods

messages and a summary of their nutritional status and the results of their tests following each evaluation.

Cost-effectiveness

In this study, the cost-effectiveness will be determined from the health system perspective. In general, these costs are divided into two categories: 1) direct therapeutic costs including the cost of education, educational tools, and execution; and 2) direct non-therapeutic costs such as those of infrastructure materials.

Cost Effectiveness Ratio (CER) and Incremental Cost-effectiveness Ratio (ICER) Calculation and Interpretation

CER will be reported as proportion and calculated using the following formula: Cost $_{intervention}$/Effect $_{intervention}$ (in this study effects will be either HbA1c or FBS). The result will be interpreted as the cost of intervention, per unit reduction of HbA1c or FBS for three months compared to the usual care group, per person in each group. The results of cost-effectiveness studies are usually compared with another group. For this purpose, the Incremental Cost-Effectiveness Ratio (ICER) is used. ICER formula will be calculated as follows: (cost $_{intervention}$-cost $_{control}$)/(Effect $_{intervention}$-Effect $_{control}$). This ratio indicates how much extra cost we need to pay for one unit more reduction in effect.[19, 20] In general, as the intervention cost is lower and the effectiveness is higher than the control group it is more desirable, but in most of the interventions better effectiveness will be obtainable at a higher cost than the control group. In this situation, the interpretation of ICER number is based on a threshold level. Accordingly, WHO believes that if ICER is less than one per capita Gross Domestic Product (GDP), the cost effectiveness of the intervention is "good", and if ICER is less than one third of per capita GDP, the intervention cost effectiveness is "very good".[14, 21]

Sensitivity Analysis Test

After calculating ICER, to increase the accuracy of the work and due to the inherent uncertainty of the data, we will perform one-way sensitivity analysis. In fact, sensitivity analysis shows how much the results are sensitive to fluctuations and to what extent they are generalizable.

Discussion

Overview of Previous Works

Sun et al. (2017) conducted a systematic review and meta-analysis to assess the effectiveness and cost-effectiveness of the lifestyle interventions for diabetes prevention. The results showed that the lifestyle interventions are effective in reducing body weight, 2-hour BG, and HbA1c. Interventions delivered by dietitians, compared to other personnel who delivered them, resulted in greater weight reduction. Also, the technology-based interventions caused greater effectiveness in comparison with the in-person delivered interventions. The average cost of weight reduction per kilogram ranged from $53.87 (over 2 months) to $1,005.36 (over 12 months). According to a few available studies, the cost of dietitians-based interventions was lower than the non-dietitians-based interventions per participant.[22] Ali et al. (2012) conducted a meta-analysis on the effectiveness of twenty-eight US-trials on diabetes prevention programs and demonstrated that after a 12-month intervention, delivered by trained professionals, about 4 percent weight reduction was observed. With attending one additional lifestyle session, 0.26 point was added to weight loss percentage. They concluded that the costs of diabetes prevention programs can be decreased without sacrificing effectiveness by using nonclinical personnel.[23] Another systematic review assessed the cost, cost-effectiveness, and cost-benefit of combined diet and physical activity promotion programs to prevent T2DM among high-risk individuals. The

median program cost per participant was $653 (costs were based on 2013 US dollars).[24] Schellenberg et al. (2013) systematically reviewed the effectiveness of lifestyle interventions for minimizing DM progression in high-risk individuals or its progression to clinical outcomes (like cardiovascular disease and death) in T2DM patients. The results indicated that comprehensive lifestyle interventions including physical activity, dietary interventions, and at least one other component can be effective in reducing the incidence of T2DM in high-risk individuals, and it had a great impact on the body weight and BMI of high-risk individuals. On the other hand, in T2DM patients the benefits of comprehensive lifestyle interventions were less clear. There was no evidence of all-cause mortality reduction, and improvements were only observed for some secondary outcomes.[25] Similarly, another review in 2015 showed that combined diet and physical activity promotion programs were helpful in decreasing diabetes incidence and improving the body weight, FBG, and cardio-metabolic risk factors, in high-risk individuals for T2DM.[26]

Innovation

The International Diabetes Federation recommends at least 15 hours of educational classes including self-management and nutrition, per year for each diabetic patient. In the past, diabetes treatment was based on medication alone. However, the results were unsatisfactory in the long run, and a high percentage of patients developed chronic complications such as blindness, amputation, renal failure, dialysis and kidney transplantation, and heart attacks or strokes. With the increasing recognition of diabetes by physicians, and relying on team therapy, which also includes nutritional education, the role of the patients and their family in controlling the disease has become much more prominent. Today, in Iran and most countries around the world it has accepted that patients with diabetes need a variety of educational programs, including nutritional education.

The Iranian Diabetes Association (IDA) is the founder of diabetes education classes in Iran and has played a valuable role in diabetes control over the past two decades. One of the problems, reported by patients who attended the classes of the IDA is the lack of time or distance and traffic. For this reason, this study is an attempt to meet the needs of patients who are not able to participate in group classes of the IDA by organizing virtual classes (web-TEL education method). In addition to the problems of traffic and lack of time, due to the pandemic of COVID-19 disease and its high pathogenicity among the elderly and those with weak immune systems, the importance of this study becomes even more apparent to find which method is more cost-effective in this situation.

To the best of our knowledge, there is no other study which has compared the cost effectiveness of diabetes nutrition education using the two educational methods. On the other hand, there is no consensus on the most effective, cost-effective, and comprehensive model for educating the patients with T2DM. Therefore, the innovation of the present study is to investigate and compare the cost-effectiveness of the two different nutrition education methods, the web-based group vs. the group education, in patients with Type-2 diabetes mellitus.

Limitations

The method of calculating the costs in the present study may be different from other research in other parts of the world, which can be attributed to its constituent components. Also, in this study, some parts of type-2 diabetes costs cannot be examined due to the lack of registration or insufficient information recorded by the health care system.

Trial Status

The present study has not yet been started, and the participants will be recruited in September 2021.

Conclusion

Determining cost effective method for educating patients with T2DM can be helpful in controlling hyperglycemia, changing the teaching methods in the health care system, and decreasing diabetics' complications and expenses.

Funding

Author Contributions

S.F. helped in the protocol design, and coordination of the study materials; S.M.D.R. reviewed the literature, designed the protocol, and wrote the manuscript; D.G. cooperated in the protocol design, literature review, and is responsible for the data analysis and calculating cost-effectiveness; K.K. cooperated in the protocol design, and is responsible for the data analysis and calculating cost-effectiveness; G.P. helped in the protocol design, and coordination of the study materials. S.F., K.K. and D.G. revised the manuscript. S.F. had primary responsibility for the final content. All the authors read and approved the final manuscript.

Conflicts of interest*:* None declared.

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