ORİJİNAL ARAŞTIRMA ORIGINAL RESEARCH

Effects of the Telephone-Based Motivational Interviewing in Adults with Type 2 Diabetes: A Systematic Review of Randomized Controlled Trials

Tip 2 Diyabetli Erişkinlerde Telefona Dayalı Motivasyonel Görüşmenin Etkileri: Randomize Kontrollü Çalışmaların Sistematik Derlemesi

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ABSTRACT Objective: The aim of this systematic review is to evaluate the effect of the telephone-based MI intervention in adults with Type 2 diabetes with randomized controlled trials. **Material and Methods:** This research was created in line with the recommendations of the PRISMA systematic review guide. Literature was searched using Web of Science, ScienceDirect, EBSCO CINAHL Complete, PubMed, Cochrane Central Register of Controlled Trials as databases. Keywords consisted of "Diabetes mellitus" and "Motivational interview" and "telephone" and "randomized controlled trial" from 2010 to 2020. Inclusion criteria in the systematic review were determined according to the PICOS components. **Results:** The electronic search yielded 907 studies and 7 articles were included in the systematic review. Blood pressure control in 2 of 4 studies, body mass index (BMI) in one of two studies, weight loss in one of three studies, waist circumference loss in two of three studies, high density lipoprotein (HDL) in one of three studies, and low density lipoprotein (LDL) in one of four studies reached clinical targets. Two of three studies were healthy eating/diet, and one of two studies exercise/physical activity reached behavioral goals. There was no difference in clinical outcomes (HbA1c, total cholesterol, triglyceride, fasting plasma glucose, hip circumference loss), and self-care behaviors (diabetes self-efficacy, medication adherence, blood glucose monitoring, foot care). **Conclusion:** As a result of telephone-based MI interventions, some studies have found improvements in the clinical (blood pressure, BMI, weight loss, HDL, LDL) and behavioral outcomes (healthy eating/diet, exercise/physical activity) of patients with T2DM.

Keywords: Diabetes mellitus; Type 2; motivational interviewing; telephone; systematic review

ÖZET Amaç: Bu sistematik derlemenin amacı, Tip 2 diyabetli erişkinlerde telefona dayalı MG müdahalesinin etkisini, randomize kontrollü çalışmalarla değerlendirmektir. **Gereç ve Yöntemler:** Bu araştırma, PRISMA sistematik inceleme kılavuzunun önerileri doğrultusunda oluşturulmuştur. Literatür, "Web of Science", "ScienceDirect", "EBSCO CINAHL Complete", "PubMed", "Cochrane Central Register of Controlled Trials" veri tabanları kullanılarak taranmıştır. Anahtar kelimeler, 2010-2020 yıllarını kapsayacak şekilde "Diabetes mellitus" ve "Motivasyonel görüşme" ve "telefon" ve "randomize kontrollü çalışmalar"dır. Sistematik derlemeye dâhil edilme kriterleri PICOS bileşenlerine göre belirlenmiştir. **Bulgular:** Elektronik arama sonucunda ulaşılan 907 çalışmadan 7 makale sistematik derlemeye dâhil edilmiştir. Dört çalışmadan 2'sinde kan basıncı kontrolü, 2 çalışmadan 1'inde beden kitle indeksi (BKİ), 3 çalışmadan 1'inde kilo kaybı, 3 çalışmadan 2'sinde bel çevresinde azalma, 3 çalışmadan 1'inde yüksek yoğunluklu lipoprotein [high density lipoprotein (HDL)] ve 4 çalışmadan 1'inde düşük yoğunluklu lipoprotein [low density lipoprotein (LDL)] değerlerinde azalma klinik çıktıları bulunmuştur. Üç çalışmadan 2'si sağlıklı beslenme/diyet ve 2 çalışmadan 1'i egzersiz/fiziksel aktivite davranışsal çıktılarına ulaşmıştır. HbA1c, açlık plazma glukozu, kalça çevresinde azalma, toplam kolesterol, trigliserid gibi klinik sonuçlarda ve ilaç uyumu, diyabet öz-etkililik, kan şekeri izleme, ayak bakımı gibi öz bakım davranışlarında fark bulunmamıştır. **Sonuç:** Telefona dayalı MG müdahaleleri sonucunda bazı araştırmalarda, T2DM'li hastaların klinik (kan basıncı, BKİ, kilo kaybı, HDL, LDL) ve davranışsal (sağlıklı beslenme/diyet, egzersiz/fiziksel aktivite) sonuçlarında iyileşmeler saptanmıştır.

Anahtar Kelimeler: Diabetes mellitus; Tip 2; motivasyonel görüşme; telefon; sistematik derleme

Type 2 diabetes (T2D) accounts for about 90% of all diabetes in the world. There are an estimated 463 million adult diabetic patients aged 20-79 years worldwide.[1] Diabetes self-management is an important part of diabetes care. The American Diabetes Educators Association has defined seven self-care behaviors for diabetes self-management. These behaviors include healthy eating, physical activity, monitoring, medication, problem solving, risk reduction, and healthy coping.[2] With the self-management of increased diabetes, HbA1c levels decrease, quality of life increases, and the incidence of diabetes-related complications decreases.[3-5]

Recent studies have determined that the motivational interviewing (MI) has a positive effect on diabetes self-management.[6-9] The MI is an individual-centered communication skills technique that aims to increase the intrinsic motivation of the individual to manage his/her diabetes.[10] Miller and Rollnick describe the MI as a collaborative communication with an emphasis on the language of change.[11] The MI techniques can be used to reveal behavioral change to help patients recognize and analyze their ambivalent emotions (conflicting emotions).[12] Being motivated enables patients to feel ready for behavior change.[9-13] There should be no frightening, or irritating traditional attitudes about behavior change. Instead, counseling techniques that include empowering, educating, psycho-social understanding and changing behavior in a short time should be used.[10,11]

There are four processes of MI. These; "engaging", "focusing", "evoking" and "planning". In ensuring engage, health professionals initiate communication and involve them in the process by establishing a good relationship with the patient. In focus, it tries to set a goal for change. In diabetes care, the central goal is to achieve glycemic control. For this, it can be focused on disease management concerns that patients cannot adequately understand or share. In a patient who has participated and focused on the process, it is possible to reveal and realize his own motivation for health and change.[12] When the person seems willing enough to consider change, then it's time for the fourth process: planning. At this stage, the individual makes a plan for change.[10,11]

With the advancement of technology, attempts can now be made to improve a patient's clinical health status using electronic communication.[14] Evidence supports the effectiveness of tele-medicine interventions in improving patient outcomes.[14-17] While mobile phones are widely available, cost-effective, and reliable tools, they can be used to improve chronic disease management. Studies of the mobile phone-based interventions have had several successes in improving diabetes self-management.[14,16-18] Advantages of telephone-based interventions in diabetes can be listed as cost-effectiveness, increase in self-management and motivation, and prevent health inequalities by providing access to information for rural residents.[14,18]

Telephone-based interventions can empower people with diabetes and improve their self-care skills. Thus, individuals can increase diabetes self-management.[19] The MI can be continued by phone after a meeting with patients. It is stated that the success of the technique is not based on the educational background of the consultant. Effectiveness depends mostly on the quality of communication between the counselor and the patient and the counselor's competence in the MI technique.[20]

Although the positive effects of the face-to-face MI have been proven in individuals with T2D, the effect of the telephone-based MI is controversial. However, there is no systematic review discussing the effectiveness of the telephone-based MI in individuals with T2D. The aim of this systematic review is to investigate the effects of telephone-based MI intervention on adults with T2D.

■ MATERIAL AND METHODS

AIM

The aim of this systematic review is to investigate the effects of telephone-based MI intervention on adults with T2D with randomized controlled trials (RCTs).

Research questions are as follows:

■ How is the telephone-based MI intervention administered in adults with T2D?

■ Is the telephone-based MI intervention effective in improving clinical and behavioral outcomes of adults with T2D?

DESIGN

In this study, the effect of telephone-based MI intervention on clinical or behavioral outcomes in adults with T2D was investigated. This research has been prepared in accordance with the PRISMA systematic review guidelines.[21]

SEARCH STRATEGY AND REVIEW PROCESS

In this study, studies published in English and Turkish languages between 2010 and 2020 were examined to determine intervention studies involving the telephone-based MI intervention in adults with T2D. Web of Science, ScienceDirect, EBSCO CINAHL Complete, PubMed, Cochrane Central Register of Controlled Trials were used as databases. The following keywords were used: Diabetes mellitus AND Motivational interview AND telephone AND randomized controlled trial (Table S1). Studies accessed from databases were selected according to the inclusion and exclusion criteria with reference to Population, Intervention, Comparison, Outcome, Study Desing (PICOS) components.[21]

Inclusion Criteria are the Following (Table S2);

■ Population: Targeted participants will be adults over the age of 18 and with T2D.

■ Intervention: Telephone-based MI intervention.

■ Comparison: Using usual care or not using the MI.

■ Outcome: Evaluation of clinical or behavioral outcomes.

■ Study design: RCTs.

Exclusion Criteria are the Following;

■ Population: Patients with T1D and gestational diabetes.

■ Intervention: Telephone-based cognitive behavioral therapy.

■ Comparison: Comparison of the group in which telephone-based the cognitive behavioral therapy was applied.

■ Outcome: Evaluation of psychological state only.

■ Study design: Observational and qualitative research without RCT, systematic review and meta-analysis.

In this study, researchers were stored using Mendeley bibliographic software program (https://www.mendeley.com/search/).

REVIEW

The literature review process was initially performed by a researcher, after which each stage of the process (review) was independently evaluated by both authors. A study that met the inclusion criteria but had bias/rejection views by the researchers was consensually excluded. For the studies included in the review, study environment, characteristics of the study sample, intervention, evaluation of the intervention, clinical and behavioral outcomes were evaluated.

RESULTS

RETAINING STUDIES FOR REVIEW

Detailed literature screening and exclusion process are shown in the PRISMA flowchart in Figure 1. As a result of the literature review between 2010 and 2020, 907 studies were reached at the first step. In the second step, repeated studies were excluded. In the third step, articles not related to the purpose of our study were excluded according to the title and/or summary. In the fourth step, full text articles including the inclusion and exclusion criteria were reviewed. And in the last step, the seven articles were reviewed.[19,22-27]

The included studies were conducted in the United States, China, and Australia. Detailed information on the included studies (characteristics, sample, telephone-based MI, and results) is shown in Table 1.

METHODOLOGICAL QUALITY

All studies included in this review have been carefully analyzed methodologically. The quality of study was evaluated using the Cochrane method.[28] Two researchers rated each of the fields as high risk, low risk, or unclear or insufficient detail based on the methods and analysis reported in the studies (Table 2).

TELEPHONE-BASED MOTIVATIONAL INTERVIEWING INTERVENTION STRUCTURES

In all studies, the MI-based goal setting interventions were implemented to improve clinical and behavioral outcomes.

TABLE S1: Search strategy for databases.	
Web of Science	(Diabetes mellitus OR Type 2) AND (Motivational interview) AND (telephone) AND (randomized controlled trial OR RCT)
ScienceDirect	(Diabetes mellitus OR Type 2) AND (Motivational interview) AND (telephone) AND (randomized controlled trial OR RCT)
	Filtered research article
CINAHL	(Diabetes mellitus OR Type 2) AND (Motivational interview) AND (telephone) AND (randomized controlled trial OR RCT)
PubMed	(Diabetes mellitus OR Type 2) AND (Motivational interview) AND (telephone) AND (randomized controlled trial OR RCT)
	Filters: Clinical trial, randomized controlled trial
COCHRANE	(Diabetes mellitus OR Type 2) AND (Motivational interview) AND (telephone) AND (randomized controlled trial OR RCT)
	in all text-(word variations have been searched)

RCT: Randomized controlled trial.

The telephone-based MI intervention includes counseling and guidance on many different issues such as treatment adherence, weight management, healthy eating, exercise, monitoring, and problem solving.

Achieving a significant impact of the telephone-based MI intervention on clinical and behavioral goal, these studies have been conducted by various healthcare professionals. These healthcare professionals are nurses, physicians, pharmacists and dieticians. Most of the studies were conducted in primary health care facilities.[23-27] In addition, there were studies carried out by personnel working in hospitals, health insurance, laboratories, and community organizations.

TELEPHONE-BASED MOTIVATIONAL INTERVIEWING INTERVENTION ASSESSMENTS

Among the seven retained articles, five described the telephone-based MI methods. Techniques involving telephone-based MI interventions include asking open-ended questions, reflective listening and summarizing to reveal the ambivalence of individuals. Five studies report the telephone-based MI details, but two studies did not details.[23,26] It is important that the practitioners are qualified in terms of the quality of the MI intervention. In only two studies, researchers received training in MI techniques.[24,26]

Most studies did not provide information about the duration of each session of the telephone-based MI. Blackberry et al. stated that the length of each session is different.[25] In two studies, it was stated that the duration of the telephone-based MI was 30 minutes.[22,23] Interventions were applied to adults with T2D between 3 months and 20 months. Intervention frequency varies between once a week and every six weeks. In some

TABLE S2: Plan of systematic review according to PICOS.	
PICOS component	**Keywords**
Population	Diabetes mellitus AND Type 2
Intervention	Motivational intervention AND telephone
Comparison	Using usual care or not using the MI
Outcome	Evaluation of clinical or behavioural outcomes
Study design	RCTs

MI: Motivational interviewing; RCT: Randomized controlled trial; PICOS: Population, Intervention, Comparison, Outcome, Study Desing.

studies, the frequency of the intervention varies throughout the study.[25,27] For example, in the study of Eakin et al., 27 phone calls over 18 months were made at the following frequency: initially 4 meetings in the first week, bi-weekly meetings for the next 5 months, monthly meetings for the remaining 12 months.[27]

Although most of the studies included only the telephone-based MI, some also included diabetes education or face-to-face interviews.[17,19,22-26] In one study, participants received two face-to-face and two telephone coaching sessions per month during the first 3 months of the initiative. During the 12-month intervention, the frequency of the sessions decreased. In the last 6 months of the intervention, the participants were intervened face-to-face and by telephone once a month.[24]

In all studies, posttest measurements were carried out after the interventions were completed, and then follow-up was made.

CLINICAL OUTCOMES

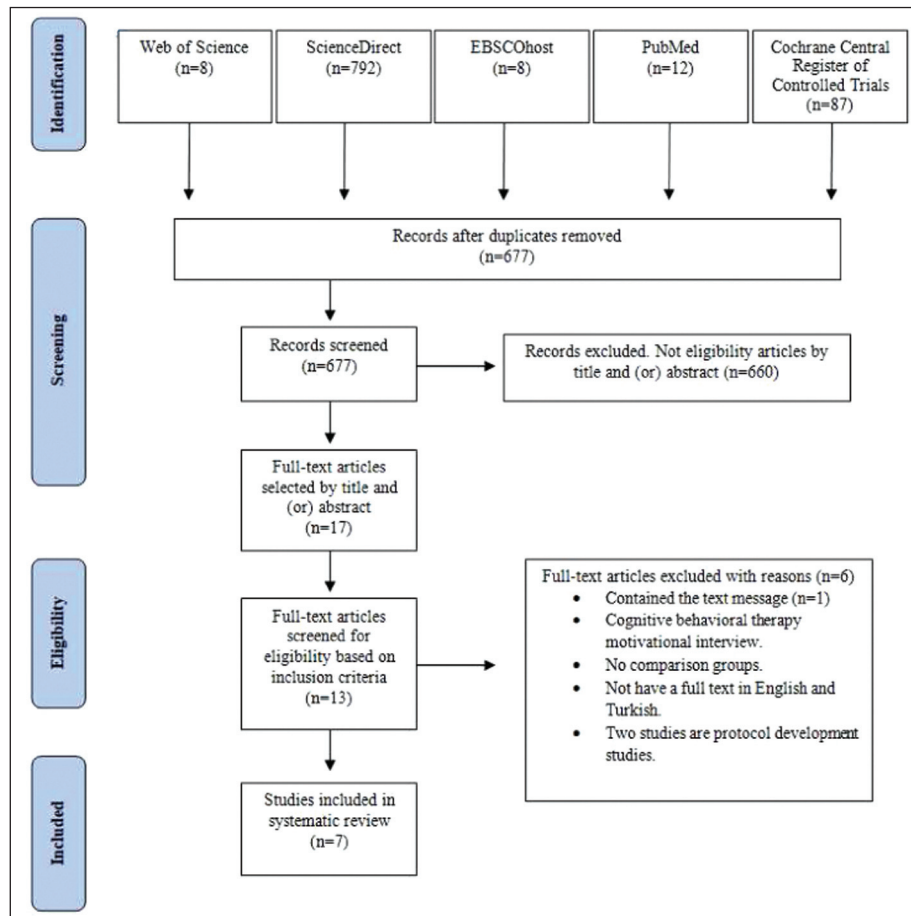The clinical outcomes of the seven studies are summarized in Table 3. The number of studies reaching

FIGURE 1: PRISMA flow diagram of study retention process for the systematic review.

clinical outcomes are as follows; glycemic control (n=6), blood pressure (n=4), waist circumference (n=3), body mass index (BMI) (n=2), weight loss (n=3), cholesterol (n=4), fasting plasma glucose (n=1) and waist circumference (n=1).

Significant systolic blood pressure control in the telephone-based MI group was reported by Browning et al. and Blackberry et al.[24,25] Significant BMI loss in the telephone-based MI group was reported by Blackberry et al.[25] Significant waist circumference loss in the telephone-based MI group were reported by Browning et al. and Eakin et al. but significant weight loss was reported by only Eakin et al.[24,27] While high density lipoprotein (HDL) value is significant in Blackberry's et al.'s study, low density lipoprotein (LDL) value is significant in Fischer's et al. study.[25,26] There was no significant difference between the two groups for other clinical outcomes such as fasting blood glucose, total cholesterol, triglycerides, and hip circumference.

BEHAVIORAL OUTCOMES

The behavioral outcomes regarding diabetes self-management among the intervention and the control group are summarized in Table 4. The number of studies reaching behavioral outcomes are as follows; healthy eating/diet (n=3), exercise/physical activity (n=2), blood glucose monitoring (n=1), foot care (n=1) and medication adherence (n=1). The behavioral changes examined in all studies were determined based on the self-reporting of the participants.

In one study, there was a significant difference between the intervention group and the control group regarding healthy eating/diet.[27] While Browning et al. demonstrating that there was no significant difference between the two groups about healthy eating, they

TABLE 1: Randomized controlled trials evaluating telephone-based motivational interviewing in Type 2 diabetes.

Source	Aim	Setting	Methods	Results
Lauffenburger et al., 2019 (USA)	-The aim of this study is to evaluate the effect of a phone-based and patient-centered intervention on HbA1c control in individuals with poorly controlled diabetes. -In this study, PEACH approach was applied.	-The study was conducted at an institution that provides health insurance in New Jersey. -Inclusion criteria in the study; use of 1 or more oral hypoglycemic agents in the last 12 months, poor diabetes control (HbA1c 8% and above), and being over 18 years of age. -Randomized in a 1:1 ratio to intervention (n=700) and normal care group (n=700).	**Intervention group:** -The intervention was conducted by **a clinical pharmacist** over the phone. In the study, a short interview and decision-making process was used in setting goals to increase the diabetes management of patients. The research includes **a 12-month** intervention. -The general structure of the telephone intervention is based on the **MI-based brief discussion principles.** Telephone counseling began with a review of patients' medications, followed by a conversation that revealed the reasons for poor diabetes control, using **open-ended questions** to determine patient preferences. Based on this, patients identified one of 3 goals to improve their diabetes control: 1) strengthening treatment, 2) enhancing compliance, or 3) lifestyle improvement. In addition, patients may determine that they are not ready to choose a goal as the fourth option. Each phone call lasted **30 minutes** on average. -Subsequent interventions are tailored to the goal chosen by each patient. For patients who are focused on improving **medication adherence** or **lifestyle changes,** a separate short interview process was used to help identify compliance barriers and suggest appropriate solutions to their disabilities. Solutions were offered to patients, including pill boxes, simple alarm reminders, mail order use, dietician support, counseling, or other exercise advice. -For patients who are not ready to set a goal, pharmacists have again called for a counseling. **Control group:** -No communication was established with the patients in the control group and they received usual care.	**Clinical and behavioral indicators** -**HbA1c** changes and **medication adherence** of the patients were evaluated at the end of a 12-month intervention.	-Phone-based and patient-centered intervention did not improve HbA1c in individuals with poorly controlled diabetes. -They found that the most common reasons why patients find their diabetes control inadequate are poor diet and exercise. -The fact that 25% of patients are not ready to change the way they manage their diabetes is an important factor that makes the intervention ineffective.

TABLE 1: Randomized controlled trials evaluating telephone-based motivational interviewing in Type 2 diabetes (*continued*).

Source	Aim	Setting	Methods	Clinical and behavioral indicators	Results
Swoboda et al., 2017 (USA)	-The purpose of this study is to evaluate the effect of telephone-based goal setting and decision-making support coaching intervention on nutrition and physical activity behaviors in adults with T2DM.	-The invitation of the participants to the research was provided by advertisements in online newsletters and brochures distributed to community organizations (e.g. libraries, medical facilities). Inclusion criteria in the study were being overweight or obese, age 40-75, being diagnosed with T2DM for at least 1 year, and having a CVD risk factor. -A phone call was made with interested people for research. As a result of this interview, a screening appointment was planned for the individuals who met the inclusion criteria in terms of eligibility for the study. Written informed consent was obtained from the individuals at the screening appointment, and clinical measurements were made and evaluated to verify their eligibility for the study. Participants were then randomly assigned to one of three groups. These groups are multiple target intervention, single target intervention (n=37) and control groups (n=17).	Intervention group: -An individual goal setting, and decision-making coaching session was applied by the dietician to encourage lifestyle change. Afterwards, a total of seven telephone coaching sessions were made to the intervention group every two weeks. -By using the MI technique, individual targets, and action plans regarding diet and/or physical activity were created. In the intervention, the participants were directed to create personalized goals compatible with their own preferences. Participants were instructed to set "SMART" (i.e. specific, measurable, achievable, realistic and timely) goals and a copy of their own set of goals and action plans was received by the dietician. -The study includes interviews that last every 2 weeks for 16 weeks. -Participants of the multi-target group set a diet and a physical activity goal in the first interview, then set many goals in both areas during each coaching interview. -Those in the single target group set a single goal for diet or physical activity-related behavior in the first session, according to individual preferences. Possible dietary changes included reducing intake of energy, total and/or saturated fat, added sugar or sodium, and increasing fruit, vegetable, or fiber intake. Physical activity changes include adding new types of physical activity or increasing the frequency, duration, or intensity of an activity. -During each coaching interview, the participant discussed their successes with the goals they set themselves and created new goals. If a goal was not achieved, it was discussed how the problem should be solved to minimize the barriers to achieving the goal, or an alternative goal was created by the decision coach. After each coaching session, the goals and action plans were sent to the participants by e-mail. Control group: The control group received the same number of calls as the intervention groups. No coaching or goal setting interventions were made with these participants.	-Data collection tools used to evaluate the study results were applied to the participants in the whole group at the beginning of the study and after the completion of the 16-week (4 months) intervention. -Data collection tools; •Socio-demographic question form •Healthy Eating Index 2010 Score •Diabetes Self-Efficacy •Diabetes Empowerment •Diabetes Distress •Patient Health Questionnaire-8	-While the scores of the Diabetes Self-Efficacy and Diabetes Empowerment scale of the post-intervention group increased significantly, there was a significant decrease in the diabetes anxiety scale score. -There was no difference in the control group. -However, there is no significant difference between the intervention and control groups (post-intervention).

TABLE 1: Randomized controlled trials evaluating telephone-based motivational interviewing in Type 2 diabetes *(continued)*.

Source	Aim	Setting	Methods	Clinical and behavioral indicators	Results
Egede et al., 2017 (USA)	-To evaluate the effectiveness of a combined telephone education and behavioral skills intervention to reduce HbA1c levels in individuals with T2DM.	-The study was conducted with individuals registered in two medical centers (departments; internal medicine, endocrine, family medicine, primary care) located in South Carolina. -Individuals included in the study must be older than 18 years of age, have poorly controlled T2D (HbA1c≥ 9% in the past 12 months), and have access to a telephone (fixed line or mobile phone) during the 12-week intervention period. -Participants were randomized into four study groups: (1) diabetes knowledge group (n=53), (2) skills education group (n=56), (3) combined knowledge and skills education group (n=53), and (4) control group (n=55) (usual care). -Randomization sequence is web-based and computer generated.	Intervention group: -All intervention sessions were held by the nurses over the phone. -Separate and combined interventions were based on the IMB skills model. According to the IMB model adapted to diabetes, knowledge about diabetes is a prerequisite for diabetes self-management, motivation determines adherence to self-management in diabetes, and behavioral skills are an important prerequisite for effective self-management of diabetes. -All participants received 12 telephone sessions. -Behavioral skills counseling was carried out by two graduate nurses who were trained in the content and execution of diabetes and general health education. -The nurses made weekly 30-minute phone calls to participants in all four study groups on this topic. -Participants randomized to the diabetes information group completed 12 diabetes education modules over a 12-week period. These educational materials have been developed based on guidelines for diabetes education. -Participants randomized to the skill group were given four behavioral skills education for 12 sessions over a 12-week period. These behaviors are: physical activity, diet, medication compliance, and self-monitoring of blood sugar. For the participants in this group, health educators trained in the MI conducted interviews to develop a patient-generated target behavior for 3 weeks. -Participants randomized to the combined diabetes knowledge and skills group received weekly diabetes knowledge, behavioral skills training, and individual empowerment support. In this group, training was discussed in the first 10 minutes of the interview, and then skill was addressed in the remaining 20 minutes. Control group: The control group received general health education, apart from diabetes education, for 12 weeks. General health education sessions included topics such as back pain, sleep problems, stroke and transient ischemic attacks, vitamins, fundamentals of health insurance, hepatitis, flu and pneumonia, colon cancer and migraine headaches.	-The study includes a 12-month follow-up period. During this follow-up period, HbA1c values of the patients were evaluated at 0, 3, 6 and 12 months.	-It was determined that there was no significant difference in HbA1c levels between the intervention groups at 12 months after the intervention (knowledge: 0.49, p=0.123; skill: 0.23, p=0.456; combined: 0.48, p=0.105). -A significant decrease in HbA1c values was observed over time for all intervention groups (-0.07, p<0.001). -However, the rate of decline in the intervention groups was not significantly different from those in the control group (knowledge: 0.06, p=0.052; skill: 0.02, p=0.448; combined: 0.05, p=0.062). -According to the study, the results obtained from the groups were similar.

TABLE 1: Randomized controlled trials evaluating telephone-based motivational interviewing in Type 2 diabetes (*continued*).

Source	Aim	Setting	Methods	Clinical and behavioral indicators	Results
Browning et al., 2016 (China)	-This study is to evaluate the clinical, psychosocial and self-care results of the coach-led MI intervention in individuals with T2DM compared to the usual care group (control).	-The study was conducted in 41 Public Health Centers located in Beijing. The distribution of these centers was determined by block randomization. -There were 372 participants in the intervention group and 296 participants in the control group. -Participants were randomly assigned on the computer by stratification according to gender to ensure balance between groups.	**Intervention group:** -A combination of telephone and face-to-face health coaching was applied to the intervention group, along with the usual care from the Public Health Centers. Health coaching was carried out by experienced clinicians (public health doctors, nurses and psychologists) working in Public Health Centers. Before starting the intervention, health coaches have completed a certified education program in coach-assisted chronic disease management. -This education provided learning about basic diseases, the MI and behavioral change, patient-centered communication, health psychology, epidemiology of basic diseases, the MI and behavioral change, program evaluation, clinical outcome measurement and the basic concepts in the Happy Life Club intervention protocol before the study. After this education, the participants attended an intensive 2-day MI workshop where the health coaches the MI basic techniques were applied. Reminder workshops were held throughout the intervention to improve the health coaches the MI skills. -The first step of every health coaching session was to determine the agenda of the session with the participant. After the participant identified a main topic for the discussion, the health coaches assessed the participant's behavior on the specified topic and used the MI skills to identify the stage of the participant's change process. Later, health coaches guided the conversation to strengthen participants' own motivation and commitment to change. -Health coaches have taken a guiding, collaborative role from their expert role and included the person in the process of making important and lasting changes in their life. -In the first 3 months, participants received two face-to-face and two telephone coaching sessions a month. The frequency of the sessions decreased during the 12-month intervention. In the last 6 months of the intervention, sessions were applied to the participants once a month, face-to-face and once a phone session. **Control group:** -The control group received the usual care from the Public Health Centers as stated in the Diabetes Prevention Guide. This guideline recommends that patients attend physician consultations every three months and have physical exams annually.	-The study was evaluated with clinical (HbA1c, blood pressure, weight, BMI, waist and hip circumference, fasting plasma glucose, total cholesterol, triglycerides, HDL- and LDL-), behavioral (self-care) and psychosocial outcomes. - Data collection tools; •Socio-demographic question form •Psychological Distress Scale • Quality of Life Scale •Diabetes Self-Care Activities Scale •Diabetes Self-Efficacy Scale -The evaluations of the participants in the intervention and control groups were made at 0., 6. and 12. months.	-At the end of the 12th month, the HbA1c value decreased significantly in both groups. However, there was no difference between the two groups. -At the end of the 12th month, systolic blood pressure, waist circumference in men and psychological distress decreased significantly compared to controls, while dietary compliance increased significantly. -Interestingly, triglyceride levels decreased significantly at 12 months in both groups. -While a significant increase was observed in the "Blood Sugar Monitoring" and "Foot Care" scores of the Diabetes Self-Care Scale sub-dimensions of the intervention group, a significant decrease was observed in the Diabetes Self-efficacy score in the control group.

TABLE 1: Randomized controlled trials evaluating telephone-based motivational interviewing in Type 2 diabetes *(continued)*.

Source	Aim	Setting	Methods	Clinical and behavioral indicators	Results
Eakin et al., 2014 (Australia)	-The aim of this study is to evaluate the effectiveness of behavioral weight loss and physical activity intervention given over the phone in patients with T2DM.	-Participants were selected from nine general primary health care centers in Queensland, Australia. -The population of the study consisted of individuals with a diagnosis of T2DM and registered phones between the ages of 20-75 with electronic patient records in health centers. -The patients included should have a BMI of 25.0 kg/m2, have not undergone bariatric surgery and should not be using weight loss medication. Patients who were contacted by phone and accepted to participate in the study were randomized into intervention (n=151) and control (n=151) groups.	**Intervention group:** Telephone based weight loss intervention -A complex approach, such as increasing physical activity, reducing energy intake, and behavioral therapy, was used in the completely telephone-based intervention. Participants are provided with a detailed workbook to support the initiation and maintenance of weight loss. 27 phone calls were made over the course of 18 months (initially 4 calls in the first week; two weekly calls for the next 5 months; monthly for the remaining 12 months). -The intervention was conducted using the MI approach based on Social Cognitive Theory. Behavior change strategies were applied in the structures of self-efficacy, social support, and outcome expectations in patients. Among these strategies; determining the benefits of weight loss, setting goals for gradual changes in physical activity and dieting, self-monitoring, problem solving, using accessible supports, and focusing on achievements with appropriate rewards. -Participants were encouraged to achieve moderate weight loss of 5-10% of their baseline body weight. A goal of moderate intensity aerobic activity of at least 210 minutes per week (30 minutes each day) consistent with the level of physical activity required to promote and sustain weight loss, combined with resistance exercise (two to three sessions per week) has been suggested. Participants were recommended a low-fat, high-fiber diet. Participants were provided with a pedometer and a set of digital weight scales. **Control group:** The control group received usual care. Within this care, a brief summary of their results and standard diabetes self-management education brochures were sent by post after each assessment of patients.	-The primary outcomes are weight, physical activity, and HbA1c level. -Secondary outcomes are dietary energy intake and dietary quality, waist circumference, fasting blood lipid levels and blood pressure. -Data were collected at baseline, 6 months, 18 months (end of intervention) and 24 months (follow-up) by a nurse through home visits and phone calls.	-At the end of the intervention, the telephone counseling group had significantly positive results for weight loss and physical activity compared t loss and physical activity compared to the usual care group. However, there is no difference in the HbA1c level. -In terms of secondary outcomes, significant intervention effects were observed for diet quality and waist circumference, while no difference was observed for energy intake, cholesterol, triglyceride levels and blood pressure. -When the changes within the groups were examined, the telephone counseling group showed positive improvements in all results except physical activity, HbA1c level and diet quality. -Although not statistically significant, there was a positive change in weight loss, diet quality and waist circumference in the intervention group.

TABLE 1: Randomized controlled trials evaluating telephone-based motivational interviewing in Type 2 diabetes *(continued)*.

Source	Aim	Setting	Methods	Clinical and behavioral indicators	Results
Blackberryet al., 2013 (Australia)	-The aim of this study is to evaluate the effectiveness of telephone coaching given by nurses in improving glycemic control in patients with T2D. -In this study, PEACH approach was applied. *The PEACH study is a nurse-led, 18-month, randomized controlled, practical implementation study among patients with T2D.	-In the study, 1:1 block randomization was applied. -The intervention group was n=30 and the control group was n=29. -All patients from local laboratories in the region included in the study who meet the inclusion criteria were listed in the electronic database. -Inclusion criteria; being diagnosed with T2DM, having an HbA1c level above 7.5% in the last 12 months, being over 18 years of age, and being able to communicate by phone. -Exclusion criteria are mental health disorder, cancer patient or non-signed consent.	-All patients in the intervention and control groups were assessed by the nurses through face-to-face interviews. -This assessment includes patients' smoking status, current exercise levels, diet frequency, physical measures (height, weight, waist and hip circumference), treatment of patients, diabetes-related complications, clinical examinations, final blood test results, diabetes self-efficacy, and diabetes support. -HbA1c and other blood values (LDL, HDL, triglyceride, kidney function) of the patients were studied in the laboratory. **Intervention group:** The nurses trained patients on lifestyle issues, medication compliance and dosage, and self-monitoring in disease management, through phone calls. This intervention includes the telephone coaching and educational intervention used in the PEACH study, which aims to motivate and empower patients. -The intervention period is 18 months. -The practitioner nurse gave a two-day training to the intervention group on the details of telephone coaching. The training includes especially decreasing the HbA1c level below 6.5% and lifestyle changes. In addition, total cholesterol, LDL, HDL and blood pressure are aimed to be within the appropriate range. -The nurses gave a total of five telephone coaching sessions at six-week intervals in the first six months, one telephone coaching session at each of the 8th and 10th months, one face-to-face coaching session in the 12th month and one telephone coaching session in the 15th month. A total of 9 sessions were provided. -Empowerment by constantly motivating the patients constitutes the basis of the next session in each coaching session. Adjusting drug doses and changes in drug types was an integral component of the coaching program. Since nurses were not authorized to prescribe to adjust drug doses, patients were asked to discuss action plans with their goal plan and arrange their treatment. -Since the coaching sessions are designed according to the patients, the length of each session is not fixed. The intervention group received their usual care throughout the study. **Control group:** The control group received usual diabetes care during the 18-month follow-up period.	-Posttest data were collected using the same questionnaires used in the initial evaluation. The nurse recorded basic data from patients' clinical files and made physical measurements. -At the end of 18 months, self-report questionnaires were sent to patients by mail. -The remaining data were collected by the research assistants using the telephone interview method. -Data collection tools; •Socio-demographic question form •Quality of Life Scale •Diabetes Self-Efficacy Scale •Depression Scale	-Mean HbA1c levels did not differ between the intervention and control groups. -There was no statistical difference between the intervention group in other biochemical measurements. -The intervention group reached a healthy BMI at a higher rate compared to the control group. -Improvements in systolic blood pressure and HDL cholesterol were found in the intervention group. None of the other clinical or psychosocial outcomes differed between the intervention and control groups. -It was determined that the 18-month telephone coaching intervention directed by the nurses had no effect on HbA1c, intensity of insulin therapy and other measurements. -Results that support the intervention and are not meaningful; systolic blood pressure and HDL cholesterol are the results.

continue...→

TABLE 1: Randomized controlled trials evaluating telephone-based motivational interviewing in Type 2 diabetes *(continued)*.

Source	Aim	Setting	Methods	Clinical and behavioral indicators	Results
Fisher et al., 2012 (Latin America)	The aim of this study is to determine the effect of telephone-based care given by nurses on lipid control of diabetic patients.	-This study was carried out at Westside Family Health Center of Denver Health, **a community health center** serving the poor Latin population. -As the inclusion criteria for the study, at least 2 visits in the last year were made an appointment to this family health service, speaking English or Spanish and being a T2D patient. Pregnant or nursing women, patients with renal impairment (creatinine >3.0 mg/dL), and patients with a comorbid disease were excluded from the study. -Intervention group: 217 control group: 381 people.	**Intervention group:** -The MI-based telephone support program for the intervention group, conducted by **nurses** in addition to usual care, lasted **20 months.** Usual care consists of diabetes care directed by primary health care professionals. -Most healthcare professionals recommend that they come for clinical examinations every 1 to 3 months for non-diabetic patients and every 6 months for those who do. -Nurses are **trained in MI techniques** and enhancing patient self-management. -The nurses have used algorithms that address glycemic and blood pressure control issues. **Control group:** The control group received **usual care.**	-Demographic and laboratory information of all patients have been accessed from electronic health records. -Comorbidities present in the patient were examined over the system. -HgA1c, LDL, HDL, blood pressure, number of hospital admissions (hospitalization, emergency) and hospital expenses of the patients before and after the intervention were examined.	-The percentage of the group in which the post-intervention LDL value was below 100 mg/dL increased in the intervention group, but decreased in the control group (p<0.01). -The interventions did not affect the HgA1c and blood pressure results in the intervention group. -Control group patients showed more hospitalizations than intervention patients and created a higher cost per patient. -During the study period, while the rate of inpatient treatment for the intervention group decreased, it increased for the control group.

PEACH: The Patient Engagement and Coaching for Health; MI: Motivational interviewing; T2D: Type 2 diabetes; T2DM: Type 2 diabetes mellitus; CVD: Cardiovascular disease; IMB: Information motivational behavior; BMI: Body mass index; HDL: High density lipoprotein; LDL: Low density lipoprotein.

found a difference between specific diets.[24] Significant exercise/physical activity in the telephone-based MI group was reported by Eakin et al. reported that they measured physical activity with an accelerometer.[27]

Only one study has examined medication adherence between the two groups. The study that assessed medication adherence reported no significant group differences.[22] In studies examining self-efficacy in diabetes, no significant difference was found between intervention and control groups.[19,24,25] Only one study examined monitoring and foot care outcomes, but no significant difference was found between the groups.[24]

In summary, significant differences have been reported between the phone-based MI group and the control group for healthy nutrition, exercise and specific diet.[24,27] No significant difference was reported between the telephone-based MI group and the control group for medication adherence, diabetes self-efficacy, blood glucose monitoring, and foot care.[19,22,24,25]

DISCUSSION

This systematic review considered seven RCTs examining the effect of telephone-based MI intervention on clinical and behavioral outcomes in adults with T2D. One of the most important metabolic outputs in diabetes management is HbA1c.[3-5] In six of the seven studies examined, the HbA1c value was examined, and no difference was found between the groups in all. Therefore, in the study of Browning et al., there was no difference between the intervention and the control group.[24] As a result of the studies, it can be said that the telephone-based MI intervention has no effect on HbA1c.

Positive result clinical outcome effects for the intervention group were observed in three of six studies that targeted anthropometric and clinical, two of four for systolic blood pressure, one of three for weight loss, two of three for waist circumference loss, one of three for HDL, and one of four studies for LDL. According to the results of three studies, it can be said that the telephone-based interventions have no effect on total cholesterol, triglycerides, and LDL.[24,25,27]

	TABLE 2: Risk-of-bias summary table for the randomized controlled trials.						
Source	**Random sequence generation (selection bias)**	**Allocation concealment (selection bias)**	**Blinding of participants and personnel (performance bias)**	**Blinding of outcome assessment (detection bias)**	**Incomplete outcome data (attrition bias)**	**Reporting bias**	**Other bias**
Lauffenburger et al., 2019	+	?	+	?	?	?	?
Swoboda et al., 2017	+	+	+	?	?	?	?
Egede et al., 2017	+	+	+	+	?	+	?
Browning et al., 2016	+	+	?	?	?	?	?
Eakin et al., 2014	+	+	+	?	?	?	?
Blackberry et al., 2013	+	+	?	?	?	+	?
Fischer et al., 2012	+	?	?	?	?	+	?

+: Low risk of bias in study design; -: High risk of bias in study design; ?: Unclear or insufficient detail.

	TABLE 3: Clinical outcomes based on tests of significance between the telephone-based motivational interviewing and control group.										
					Clinical outcome						
Source	**HbA1c**	**FPG**	**BP control**	**BMI loss**	**Weight loss**	**Waist circumference loss**	**Hip circumference loss**	**Total cholesterol**	**Triglyceride**	**HDL**	**LDL**
Lauffenburger et al., 2019	NS										
Swoboda et al., 2017											
Egede et al., 2017	NS[a]										
Browning et al., 2016	NS[a]	NS	Sig.[c]	NS	NS	Sig.[b]	NS	NS	NS	NS	NS
Eakin et al., 2014d	NS		NS		Sig.	Sig.		NS	NS	NS	NS
Blackberry et al., 2013	NS		Sig.[c]	Sig.	NS	NS		NS	NS	Sig.	NS
Fischer et al., 2012	NS		NS								Sig.

Sig: Significant at p<0.05; NS: Not significant at p>0.05; FPG: Fasting plasma glucose; BP: Blood pleasure; BMI: Body mass index; HDL: High density lipoprotein; LDL: Low density lipoprotein; [a]12 months; [b]Among men; [c]Systolic blood pressure; [d]18 months.

	TABLE 4: Behavioral outcomes based on tests of significance between the telephone-based motivational interviewing and control group.						
			Behavioral outcome				
Source	**Medication adherence**	**Healthy eating/diet**	**Diabetes self-efficacy**	**Specific diet**	**Exercise/Physical activity**	**Blood glucose monitoring**	**Foot care**
Lauffenburger et al., 2019	NS						
Swoboda et al., 2017		NS	NS				
Egede et al., 2017							
Browning et al., 2016		NS	NS	Sig.	NS	NS	NS
Eakin et al., 2014[a]		Sig.			Sig.		
Blackberry et al., 2013			NS				
Fischer et al., 2012							

Sig: Significant; NS: Not significant; [a]18 months.

Positive behavior change was observed in four studies: one of three for healthy eating/diet, and one of two studies for exercise/physical activity. No significant change in medication adherence, self-efficacy, monitoring, and foot care behavioral changes was observed in the studies in this review. As a result of the studies, it can be said that the telephone-based MI intervention has no effect on diabetes self-efficacy. In the studies reviewed, medication adherence, glucose monitoring and foot care behavior in terms of diabetes self-care was examined in only one study. For this reason, no difference in these outcomes cannot give a definite result in terms of effect.

When the results of the studies are examined in general, the clinical and behavioral outcomes are not at a good level. These results were thought to be related to the quality of the telephone-based MI. In only two studies, researchers received training in MI techniques.[24,26]

The components of diabetes self-management behaviors are healthy eating, physical activity, medication adherence, monitoring, foot care, smoking cessation, and alcohol reduction.[2] However, although the positive effect of the MI intervention on diabetes self-management is known, none of these components were examined in two studies.[23,26] We suggest that future studies should take all components of diabetes self-management behaviors to determine the impact of telephone-based MI intervention on individuals with T2D.

CONCLUSION

This systematic review provides literature evidence for the effectiveness of telephone-based MI in adults with T2D. Telephone-based MI interventions have been shown to have positive effects in individuals with T2D. This review resulted in an investigation of seven RCTs evaluating clinical and behavioral changes in individuals with T2D from the telephone-based MI intervention. Blood pressure control in two of four studies, BMI in one of two studies, weight loss in one of three studies, waist circumference loss in two of three studies, HDL in one of three studies, and LDL in one of four studies reached clinical targets. Two of three studies were healthy eating/diet, and one of two studies exercise/physical activity reached behavioral goals. There was no difference in clinical outcomes such as metabolic control, hip circumference loss, total cholesterol, triglyceride, and self-care behaviors such as diabetes self-efficacy, medication adherence, monitoring, and foot care.

Telephone-based MI interventions have shown similar clinical and behavioral effects, although they were administered at different duration and frequency. This technique, which is particularly effective in individuals who are resistant to change, is very suitable for individuals with T2D. We recommend that telephone-based MI interventions be administered by healthcare professionals with MI certification at an appropriate time and frequency for the individual.

REFERENCES

1. International Diabetes Federation. IDF Diabetes Atlas. 9th ed. India: International Diabetes Federation; 2019. Cited: 18 Aug 2020. Available from: [Link]

2. Beck J, Greenwood DA, Blanton L, Bollinger ST, Butcher MK, Condon JE, et al; 2017 Standards Revision Task Force. 2017 National Standards for Diabetes Self-Management Education and Support. Diabetes Educ. 2017; 43(5):449-64. Erratum in: Diabetes Educ. 2017;43(6):650. [Crossref] [PubMed]

3. Norris SL, Lau J, Smith SJ, Schmid CH, Engelgau MM. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. Diabetes Care. 2002;25(7):1159-71. [Crossref] [PubMed]

4. Cochran J, Conn VS. Meta-analysis of quality of life outcomes following diabetes self-management training. Diabetes Educ. 2008;34(5): 815-23. [Crossref] [PubMed] [PMC]

5. Powers MA, Bardsley J, Cypress M, Duker P, Funnell MM, Fischl AH, et al. Diabetes self-management education and support in type 2 diabetes: A joint position statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. J Acad Nutr Diet. 2015; 115(8):1323-34. [Crossref] [PubMed]

6. Berhe KK, Gebru HB, Kahsay HB. Effect of motivational interviewing intervention on HgbA1C and depression in people with type 2 diabetes mellitus (systematic review and meta-analysis). PLoS One. 2020;15(10): e0240839. [Crossref] [PubMed] [PMC]

7. Ekong G, Kavookjian J. Motivational interviewing and outcomes in adults with type 2 diabetes: A systematic review. Patient Educ Couns. 2016;99(6):944-52. [Crossref] [PubMed]

8. Song D, Xu TZ, Sun QH. Effect of motivational interviewing on self-management in patients with type 2 diabetes mellitus: A meta-analysis. Int J Nurs Sci. 2014;1(3):291-7. [Crossref]

9. Chen SM, Creedy D, Lin HS, Wollin J. Effects of motivational interviewing intervention on self-management, psychological and glycemic outcomes in type 2 diabetes: a randomized controlled trial. Int J Nurs Stud. 2012; 49(6): 637-44. [Crossref] [PubMed]

10. Miller WR, Rollnick S. Ten things that motivational interviewing is not. Behav Cogn Psychother. 2009;37(2):129-40. [Crossref] [PubMed]

11. Miller WR, Rollnick S. Motivational Interviewing: Helping People Change 3rd ed. New York: Guilford Press; 2012.

12. Fisher WA, Fisher JD, Harman J. The information-motivation-behavioral skills model: A general social psychological approach to understanding and promoting health behavior. In: Suls J, Wallston KA, eds. Social Psychological Foundations of Health and Illness. 1st ed. Blackwell Series in Health Psychology and Behavioral Medicine. Malden: Blackwell Publishing; 2003. p.82-106. [Crossref] [PubMed]

13. Winkley K, Upsher R, Stahl D, Pollard D, Kasera A, Brennan A, et al. Psychological interventions to improve self-management of type 1 and type 2 diabetes: a systematic review. Health Technol Assess. 2020;24(28):1-232. [Crossref] [PubMed] [PMC]

14. Lee JY, Chan CKY, Chua SS, Paraidathathu T, Lee KK, Tan CSS, et al. Using telemedicine to support care for people with type 2 diabetes mellitus: a qualitative analysis of patients' perspectives. BMJ Open. 2019;9(10):e026575. [Crossref] [PubMed] [PMC]

15. Shea S, Weinstock RS, Teresi JA, Palmas W, Starren J, Cimino JJ, et al; IDEATel Consortium. A randomized trial comparing telemedicine case management with usual care in older, ethnically diverse, medically underserved patients with diabetes mellitus: 5 year results of the IDEATel study. J Am Med Inform Assoc. 2009;16(4):446-56. [Crossref] [PubMed] [PMC]

16. Nundy S, Dick JJ, Solomon MC, Peek ME. Developing a behavioral model for mobile phone-based diabetes interventions. Patient Educ Couns. 2013;90(1):125-32. [Crossref] [PubMed] [PMC]

17. Krishna S, Boren SA, Balas EA. Healthcare via cell phones: a systematic review. Telemed J E Health. 2009;15(3):231-40. [Crossref] [PubMed]

18. Davis RM, Hitch AD, Salaam MM, Herman WH, Zimmer-Galler IE, Mayer-Davis EJ. TeleHealth improves diabetes self-management in an underserved community: diabetes TeleCare. Diabetes Care. 2010;33(8):1712-7. [Crossref] [PubMed] [PMC]

19. Swoboda CM, Miller CK, Wills CE. Impact of a goal setting and decision support telephone coaching intervention on diet, psychosocial, and decision outcomes among people with type 2 diabetes. Patient Educ Couns. 2017;100(7):1367-73. [Crossref] [PubMed]

20. Özdemir H, Taşcı S. Motivasyonel görüşme tekniği ve hemşirelikte kullanımı [Motivational interviewing technique and use of nursing]. ERÜ Journal of Health Science Faculty. 2013;1(1):41-7. [Link]

21. Moher D, Liberati A, Tetzlaff J, Altman DG; PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med. 2009;6(7): e1000097. [Crossref] [PubMed] [PMC]

22. Lauffenburger JC, Ghazinouri R, Jan S, Makanji S, Ferro CA, Lewey J, et al. Impact of a novel pharmacist-delivered behavioral intervention for patients with poorly-controlled diabetes: The ENhancing outcomes through Goal Assessment and Generating Engagement in Diabetes Mellitus (ENGAGE-DM) pragmatic randomized trial. PLoS One. 2019;14(4): e0214754. [Crossref] [PubMed] [PMC]

23. Egede LE, Williams JS, Voronca DC, Gebregziabher M, Lynch CP. Telephone-delivered behavioral skills intervention for African American adults with type 2 diabetes: a randomized controlled trial. J Gen Intern Med. 2017;32(7):775-82. [Crossref] [PubMed] [PMC]

24. Browning C, Chapman A, Yang H, Liu S, Zhang T, Enticott JC, et al. Management of type 2 diabetes in China: the Happy Life Club, a pragmatic cluster randomised controlled trial using health coaches. BMJ Open. 2016;6(3): e009319. [Crossref] [PubMed] [PMC]

25. Blackberry ID, Furler JS, Best JD, Chondros P, Vale M, Walker C, et al. Effectiveness of general practice based, practice nurse led telephone coaching on glycaemic control of type 2 diabetes: the Patient Engagement and Coaching for Health (PEACH) pragmatic cluster randomised controlled trial. BMJ. 2013; 347:f5272. [Crossref] [PubMed] [PMC]

26. Fischer HH, Eisert SL, Everhart RM, Durfee MJ, Moore SL, Soria S, et al. Nurse-run, telephone-based outreach to improve lipids in people with diabetes. Am J Manag Care. 2012;18(2):77-84. [PubMed]

27. Eakin EG, Winkler EA, Dunstan DW, Healy GN, Owen N, Marshall AM, et al. Living well with diabetes: 24-month outcomes from a randomized trial of telephone-delivered weight loss and physical activity intervention to improve glycemic control. Diabetes Care. 2014; 37(8):2177-85. [Crossref] [PubMed]

28. Higgins JP, Savović J, Page MJ, Elbers RG, Sterne JA. Chapter 8: Assessing risk of bias in a randomized trial. In: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, et al; eds. Cochrane Handbook for Systematic Reviews of Interventions version 6.1 (updated September 2020). 2nd ed. Cochrane: 2020. Available from: [Link]