

Motivational Interviewing and Self-care in Type 1 Diabetes:a randomized controlled clinical trial study protocol

Dacil Alvarado-Martel

Universidad de Las Palmas de Gran Canaria-IUIBS

Mauro Boronat

Complejo Hospitalario Universitario Insular Materno-Infantil de Gran Canaria

María del Pino Alberiche

Complejo Hospitalario Universitario Insular Materno-Infantil de Gran Canaria

María Andrea Algara

Universidad de Las Palmas de Gran Canaria IUIBS

Ana M Wägner (✉ ana.wagner@ulpgc.es)

Complejo Hospitalario Universitario Insular Materno-Infantil de Gran Canaria <https://orcid.org/0000-0002-7663-9308>

Study protocol

Keywords: Adherence, type 1 diabetes, diabetes self-care, motivation for self-care, self-efficacy, motivational interviewing

Posted Date: January 23rd, 2020

DOI: <https://doi.org/10.21203/rs.2.21658/v1>

License:  This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Abstract

Background

Type 1 diabetes is a chronic disease with complex therapeutic recommendations that require day-to-day lifestyle changes. People with type 1 diabetes need to be involved in their health care in order to achieve satisfactory control of the condition. Motivational Interviewing is a communication tool that has been shown to be effective in changing behaviors in people with addictions, obesity and type 2 diabetes.

Our objective is to evaluate the impact of a Motivational Interviewing intervention in patients with type 1 diabetes, through a randomized controlled clinical trial.

Methods

Sixty-six patients with type 1 diabetes and hemoglobin A1c \geq 8% have been included and randomly assigned (computer-generated sequence, sealed envelopes, ratio 1:1) either to the intervention group or to the control group. In the intervention group, appointments every four months with the endocrinologist include Motivational Interviewing; in the control group, the appointments proceed as usual. Patients will be followed for 16 months.

The primary outcome will be self-care behaviors, assessed according to a validated questionnaire, the Diabetes Self-Care Inventory-Revised Version. Secondary outcomes include: HbA1c, motivation for self-care, self-efficacy, health-related quality of life, satisfaction with professional-patient relationship, fulfillment of patients' own objectives and other sociodemographic and clinical variables related to disease control.

The practitioners will receive training in Motivational Interviewing in order to help them promote adherence to self-care, encourage patient motivation and improve the doctor-patient relationship. The Motivational Interviewing intervention will be evaluated through videorecordings of the sessions and the administration of a purpose-built questionnaire, the EVEM 2.0 scale, by two psychologists, blinded to the assigned treatment.

Discussion

There is evidence that MI can improve self-care in type 2 diabetes. In T1D, however, its application has focused on adolescents, but, at present, there are no published data on the effect of MI in adults with T1D. In this study, we aim to evaluate the effect of MI on self-care and HbA1c.

Background

People with type 1 diabetes (T1D) have to carry out a series of complex tasks every day in order to manage their disease and maintain good glycemic control (1). These tasks include glucose measurements, multiple insulin injections, carbohydrate counts in the diet and management of

hypoglycemia and hyperglycemia. In addition, patients must continuously make decisions regarding the adjustment of their insulin treatment and the everyday problems related to their illness (2–4). In a previous study which identified multiple factors related to self-care, the level of motivation reported by the patient was the strongest predictor of adherence to self-care, and was also recognized as one of the greatest obstacles to adherence to treatment (5). Currently, diabetes management is focused on person-centered care and empowerment, a philosophy that encourages patient involvement, awareness and participation in decisions concerning their health (6). One of the fundamental pillars for promoting empowerment of people in their self-care is therapeutic patient education (7,8). Therapeutic patient education provides patients with the knowledge, tools and skills needed to facilitate informed decision-making and self-management of the disease (8). However, therapeutic education alone does not guarantee the involvement of patients in the care of their health (8,9).

Since 2014, in its *Standards for Diabetes Self-Management Education and Support*, the American Diabetes Association recommends a set of evidence-based communication strategies which have been shown to facilitate behavioral changes and to complement therapeutic patient education. They include cognitive strategies, problem solving, enhanced self-efficacy, relapse prevention strategies and Motivational Interviewing (MI) (10,11). To quote the creators of MI: “Motivational Interviewing is a collaborative, goal-oriented method of communication with particular attention to the language of change. It is designed to strengthen an individual’s motivation for and movement toward a specific goal by eliciting and exploring the person’s own argument for change within an atmosphere of acceptance and compassion” (12).

MI emerged for the first time in Norway in 1982, and initially focused on addictions (13). Since then, its use has spread to other areas. It has been widely applied in the management of behavior-associated diseases (14) and more than three decades of research have established it as an effective approach for improving a series of health-related behaviors (14). Currently there is moderate, consistent and robust evidence that MI achieves behavioral changes and improves adherence to treatment in patients with alcohol abuse, unhealthy lifestyles (e.g., sedentarism, overeating) and obesity/overweight (16,17). Brief 15-minute MI interventions have also proven to be effective, though the probability of success increases with the number of encounters and with longer follow-up periods (14).

MI has been shown to be effective in improving glycemic control in people with type 2 diabetes (T2D) (15,17-20) and its superiority over cognitive behavioral therapy has also been demonstrated (21). MI has proved effective in reducing HbA1c in adolescents with T1D (22-24), and in a clinical trial it also improved quality of life (26,27). It is effective as a complement to therapeutic education (28) and to other treatments, or as an independent treatment (23). However, not all studies have reported improvement in glycemic control in T1D or T2D (29, 30). A recent systematic review, which included four randomized controlled trials, concluded that there is some evidence of benefit of MI in people with T1D, but that more research is needed to isolate the effect of MI alone on adherence to treatment and HbA1c (31).

Theoretical framework

MI is defined primarily by its spirit: that is, a style that nurtures the interpersonal relationship between the therapist and the patient. It explains how the process of change is formed by different stages and how people are more likely to abandon a habit at certain stages than at others. In addition, it considers that deciding to change, to commit oneself, and to take responsibility for a therapeutic process is key to achieving behavior changes. MI uses a style of collaborative communication focused on one or several objectives and pays special attention to the language of change. It is designed to strengthen personal motivation and commitment to a specific goal, eliciting and exploring the reasons that the person has for changing, in an atmosphere of acceptance and empathy. The approach is based on patient-centered counseling, cognitive therapy, systems theory and the social psychology of persuasion. It integrates clinical skills that promote motivation, combining managerial and non-managerial elements. In sum, it is a practical and specific contribution to daily life in which language is used to influence behavior by helping individuals express their own internal motivations, and guiding conversations in such a way that people persuade themselves to change in accordance with their own values and interests.

For maximum benefit to be derived from MI, the interviewer must have received adequate training, but must also believe in it in order to be able to influence the patient and initiate a process of change. MI involves eliciting from the patient what they already know and have, rather than giving them what they lack (for instance, knowledge, or medication) (32). This focus can improve patients' motivation, since they choose what they want to do or change, not what others want them to do or change. By developing MI skills, practitioners can help patients identify what matters to them and then use these motivations to bring about changes in their health behavior (32).

Assessing the effectiveness of MI in the context of diabetes may appear controversial, since adherence to self-care already obliges people with diabetes to carry out multiple tasks. In fact, previous studies have focused on assessing the impact of MI on glycemic control (14,15); to date, there are no clinical trials that study its impact on adherence to self-care behaviors in adults with T1D, or evaluate the standardized application of MI by practitioners.

Objective and hypothesis

The purpose of this randomized controlled clinical trial is to study the impact of the application of MI in routine follow-up visits of patients with T1D and poor metabolic control.

The hypothesis is that an intervention with MI can increase patients' self-care behaviors, reduce HbA1c, enhance their self-efficacy and health-related quality of life, and improve the doctor-patient relationship.

Methods

This study protocol was developed in accordance with the Recommendations for Interventional Trials 2013 Statement (SPIRIT 2013) and the Consolidated Standards of Reporting Trials statement (CONSORT 2010) when applicable (see checklist in supplementary file).

Study design and setting

This randomized, controlled, single-blind, parallel group clinical trial will be carried out at the Endocrinology and Nutrition service of the Insular University Hospital, Las Palmas de Gran Canaria, a reference center in its area for the care of people with T1D.

Participants and recruitment

A total of 66 people with T1D have been included in the study and will be followed over a period of 16 months. Patients who met the inclusion criteria were informed of the nature of the study and invited to participate. Subsequently, they were recruited by their endocrinologist at the outpatient clinics of the Endocrinology and Nutrition Service of the Insular University Hospital. The recruitment period lasted from March to August 2019.

Inclusion criteria

Diagnosis of T1D, age over 18, at least one year of disease duration, HbA1c \geq 8% and/or severe hypoglycemia in the previous six months.

Exclusion criteria

Pregnancy either in progress or scheduled in the following 12 months; any other circumstance that, in the opinion of the investigators, might interfere with the follow-up.

Patients who meet the inclusion criteria receive written information regarding the study and are invited to participate. They are also provided with more information by phone, when they are reminded that the trial will begin at the next scheduled follow-up appointment. At this first appointment, prior to the consultation, the participants sign the informed consent document and fill in a dossier that records all the clinical, sociodemographic and psychosocial variables. These variables are listed in the Measures section below.

Randomization and blinding

The participants are randomly assigned 1:1 to the intervention group or control group. A computer-generated randomization list is used to prepare the labels indicating the assignment of each patient, which is kept in sealed envelopes, numbered consecutively, and stored at the unit. At the time of inclusion of a patient in the study (appointment 1), the appropriate envelope is chosen and opened to show the endocrinologist the treatment assigned. The randomization is stratified by practitioner and the treatment assigned to the first participant each day is applied to all participants scheduled on that day, in order to facilitate the application of the MI and avoid contamination between treatment groups. To limit possible bias, patients are not informed of the assigned treatment. The informed consent document explains that the study will evaluate the effects of the doctor-patient communication, though without going into detail. The researcher who generated the randomization list and prepared the envelopes for the assignment of

the treatment group will not be involved in the treatment or evaluation of the participants; likewise, the researchers who will rate MI compliance and analyze the data will be blind to the treatment allocation.

Intervention

The intervention will consist in the application of MI by the endocrinologist at four follow-up visits, held at four-month intervals.

These visits proceed in the same way as standard appointments, with the addition of this new clinical approach. The visits last approximately 15-20 minutes, in accordance with routine hospital practices.

At each visit, the practitioner applies the four processes of MI (12):

- This first stage serves to establish a therapeutic relationship of trust and mutual respect, if this has not already been achieved.
- This stage is a continuous process of searching for and maintaining direction. The aim is to place the emphasis on the “focus”, i.e., the aspect that the person wants to change. It is not a static process; it may be that in other stages it is necessary to change course and renegotiate the objectives.
- This stage is aimed at eliciting “change talk” from the patient, so that he or she persuades him or herself to change. It begins with the expression of a desire, reason, or need. This stage promotes self-efficacy, one of the most powerful predictors of successful behavior. MI promotes change because it impacts on people’s self-efficacy.
- This stage is characterized by the presence of specific actions. There is less maintenance talk (regarding the behavior to be changed) and more change talk. The person begins to visualize the change and imagines the possible positive results. MI ends when the person commits to the plan.

Before the first appointment and four months after the fourth appointment, the participants complete the questionnaires. In each of the five visits the HbA1c value will be recorded.

A sample of 25 baseline appointments were videotaped in order to assess the application of MI, and serve as ongoing training for the practitioners. A similar procedure will be followed for appointment 4. The practitioners who apply MI have previously received training.

Professional training

MI is a set of skills designed to help patients overcome their ambivalence to change by evoking motivation and commitment. Professionals can gain expert experience in this method, for example, through an 8-step program (Motivational Interviewing Network of Trainers- MINT), which can be completed in 16 hours.

The three endocrinologists have received structured MI training through theoretical-practical workshops taught by a psychologist with previous training and experience in MI. The workshops, which included

didactic instruction and interactive exercises, were divided into two 3-4 hour sessions and two to four additional 60-90 minute encounters. The training started three months before recruitment, continued until the intervention began and addressed the contents established by MINT (table 1). Interactive exercises included interviews conducted with real playing (i.e., colleagues who proposed something they would like to change, in order to make the practice more realistic), as well as role playing (i.e., using cases that are built on the context of T1D). Furthermore, real-patient interviews were overseen by the psychologist, both directly and through visualization of video recordings, and feedback was provided. Finally, all researchers read the MI book “Motivational interviewing: helping people change” (16). In addition, as a reminder, they were given a magnet on which the main tasks associated with MI are printed, to be put up in a visible place in their unit.

To avoid skill erosion and further improve MI performance, regular coaching and feedback-based, post-training sessions were held at baseline and are repeated at 2-3 month intervals during the intervention trial, to adhere to evidence-based practices (33). Individual reading of the book “Motivational Interviewing in Diabetes: facilitating self-care” (34) will complement the post-training sessions.

Control group

Patients randomly assigned to the control group will receive their four follow-up visits with standard medical care. The visits will be held at the same intervals as in the intervention group, and will last a similar length of time. At each of the visits the HbA1c will be recorded, and before the first visit and four months after the fourth visit controls will complete the questionnaires in the same way as the intervention group.

Interventions: concomitant care

Participants will continue with their usual follow-up routine for diabetes care. They are not asked for anything additional

Patient and public involvement

The results of the study will be presented to the scientific community at scientific meetings and in a research article. The results will also be disseminated in the local press and on the web page of the research group. Patients will also be informed of the results at the diabetes unit, once the trial has finished.

Measures

The main variable of the study is adherence to self-care, measured through a validated questionnaire, the Diabetes Self-Care Inventory-Revised version (SCI-R). The secondary variables are: self-efficacy (EAG), health-related Quality of Life (ViDa1), satisfaction with the doctor-patient relationship, motivation for self-care, satisfaction with self-care, degree of fulfilment of a personal goal initially proposed by the

participant, and a series of sociodemographic and clinical variables listed below. The time intervals for the measurements are shown in table 2.

Adherence to self-care behaviors

The validated Spanish version of the SCI-R (35) will be used. This inventory consists of 15 items referring to self-care behaviors in the treatment of diabetes, which are scored on a Likert scale ranging from (1 = "never" to 5 = "always"). The scores are converted with a formula, and the responses range from 0-100; higher scores indicate higher levels of self-care.

Structured Self-administered Data Collection Sheet

This data sheet is designed specifically for the study and it covers the following sociodemographic and clinical variables: sex, age, level of education (unschooled, primary, secondary, and university studies), employment status, living arrangements, duration of disease, type of drug treatment, treatment with psychoactive drugs, carbohydrate count, level of training in diabetes, diabetes chronic complications and the limitation they represented for participants' daily lives, number of hypoglycemia episodes per week, number of daily capillary glucose readings, and previous history of acute complications (admissions for severe hyperglycemia or hypoglycemia). Medical variables are confirmed via the patients' medical history.

HbA1c

Glycated hemoglobin (HbA1c) (measured by HPLC or by point-of-care Alere Afinion AS100, standardized against DCCT/NGSP) is the standard measure for evaluating glycemic control over the last 2-3 months. The ADA recommendations suggest a general target level for HbA1c of less than 7% to reduce risk of diabetic complications (11).

Self-efficacy

The General Self-Efficacy Scale (36) is administered in its validated Spanish version (37). This scale measures respondents' expectations regarding their ability to cope adequately with a problematic situation. Responses are recorded on a Likert scale (1 = "not at all" to 5 = "totally") and the score range is 1–50. Higher scores indicate a higher perception of self-efficacy.

Health-related quality of life

Health-related quality of life is measured with the ViDa1 (38), which contains 34 items grouped in four dimensions: interference of diabetes in daily life, self-care, well-being, and worry about the disease. The response format is a Likert scale ranging from (1 = "strongly disagree" to 5 = "strongly agree"). A total score is obtained for each subscale, with a higher value indicating a higher level of the respective aspect.

Motivation for self-care

Motivation for self-care is measured on a Likert scale of 1-10, where 10 is the maximum score. This item is formulated specifically for this study.

Satisfaction with self-care

Satisfaction with Self-care is measured with a Likert scale of 1-10, where 10 is the maximum score. This item is formulated specifically for this study.

Doctor-patient relationship satisfaction

Satisfaction with the doctor-patient relationship is measured with a Likert scale of 1-10, where 10 is the maximum score. This item is formulated specifically for this study.

Personal goal

Patients set themselves a health-related goal which they aim to achieve through their participation in the trial. The degree of achievement is measured with a Likert scale (1-10).

Intervention Fidelity Assessment

To evaluate the application of MI by the practitioners, video recordings of 25 patients were be carried out at the first visit. At the fourth visit, all patient interviews will be recorded, and a random sample of 25 will be evaluated. A mobile phone with a tripod and an external memory card are used to make the video recordings. The recordings will be evaluated by two external observers using the Motivational Interviewing Rating Scale (MIAS/EVEM 2.0) (39). This scale has been previously validated for the application of MI in primary care; applied to several clinical sessions, it discriminates between the sessions in which the method has been used (and establishes to what degree) and the ones in which it has not been used. The raters will not know *a priori* to which group the patients in the recordings have been assigned.

Analysis

We estimated that each of the three clinical researchers involved the trial would be able to recruit around 20 patients in four months. With an expected sample size of 60 participants, we would be able to detect inter-group differences of 12.8 points on the SCI-R questionnaire and of 0.85% in HbA1c, with a power of 90% and a two-sided alpha of .05 [assuming an SD of 15 points in the SCI -R and 1% in HbA1c in line with previous studies (5)]. The equivalent detectable differences with a power of 0.8 would be 11 points and 0.74% respectively (calculated with

http://hedwig.mgh.harvard.edu/sample_size/js/js_parallel_quant.html).

Descriptive analyses will be performed (percentages, means (SD) and medians (interquartile range) and the treatment groups will be compared through chi-square, Student's t and Mann-Whitney U tests depending on the normality of the variables. A between-group ANCOVA will be applied to adjust the

estimators of the effect according to possible covariates and factors. A p value <0.05 will be considered significant. For the MIAS/EVEM 2.0 scale, the Intraclass Correlation Coefficient (ICC) will be used.

Discussion

This study protocol presents the design of a randomized controlled clinical trial aimed to evaluate the impact of an MI intervention on the self-care behaviors of people with T1D. We expect the MI-based intervention to improve the doctor-patient relationship and to increase the motivation for self-care, and with it, self-care behaviors. We also expect improvements in glycemic control and increases in self-efficacy and health-related quality of life.

There is evidence that MI can improve self-care in T2D (20,21). In T1D, to date, however, its application has focused on adolescents, in whom some studies have shown a statistically significant improvement in glycemic control (21-26, 31) but others have not (29). At present, there are no published data on the effect of MI in adults with T1D.

Increasing adherence to self-care is a challenge in a chronic disease such as T1D. An MI-based intervention to replace the traditional interview may improve glycemic control and thus prevent chronic complications in the future. In this study, we aim to evaluate the effect of MI on self-care and HbA1c.

We acknowledge that this study has some limitations. MI is a complex tool to learn; it takes time to manage it correctly, practitioners may not be experts in its use and learned skills tend to wear off. In order to reduce training erosion, regular coaching and feedback will be provided throughout the trial. On the other hand, the same practitioner will apply MI to some patients and the traditional interview to the others (control group), which carries a certain risk of contamination between the study groups. To monitor if MI is indeed applied in the intervention group and not in the control group, the sessions will be blindly evaluated at the first and last visits of the study. Finally, not all patients are comfortable with this method of interviewing, a situation that may hinder its application. Regarding outcomes, self-care, the primary outcome, comprises an array of behaviors, which might not accurately reflect the success of MI if change is focused on a single behavior, selected by the patient. The assessment of the achievement of self-defined goals should, at least partially, account for this drawback. Furthermore, some concepts will be examined on an exploratory basis using only a single-item and not a psychometrically tested measure, so these findings should be interpreted as descriptive and with caution.

Abbreviations

MI: motivational interviewing; MINT: Motivational Interviewing Network of Trainers; T1D: type 1 diabetes; T2D: type 2 diabetes

Declarations

Ethics and dissemination. The study has received ethical approval (CEIm-CHUIMI-2017/974). The participants give their consent for their appointments to be videorecorded. The study findings will be disseminated through peer-reviewed publications, at conferences, and via reports to key stakeholders.

Patient consent. For this study all participants sign an informed consent that has previously been approved by the Hospital Ethics Committee.

Confidentiality All study-related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with limited access. All reports, data collection, process, and administrative forms will be identified by a coded ID [identification] number only to maintain participant confidentiality. All records that contain names or other personal identifiers, such as locator forms and informed consent forms, will be stored separately from study records identified by code number. All local databases will be secured with password-protected access systems. Forms, lists, logbooks, appointment books, and any other listings that link participant ID numbers to other identifying information will be stored in a separate, locked file in an area with limited access or in secure, password-protected electronic files.

Model consent. The informed consent model used in this study is the one established by the local Ethics Committee.

Trial Sponsor: Dra. Ana M. Wágner. Address: Endocrinology and Nutrition Dept. Complejo Hospitalario Universitario Insular Materno-Infantil Gran Canaria. Av. Marítima s/n. 35016 Las Palmas de Gran Canaria, Spain. Tel: +34 928453431. FAX: +34 928442586.

Protocol amendments. Any modifications to the protocol which may impact on the conduct of the study, potential benefit of the patient or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendment will be agreed upon approved by the Ethics Committee of Las Palmas prior to implementation.

Data access

All investigators will have access to the trial data sets. Project data sets will be housed locally and will be password protected. Access to cleaned, anonymized data sets will be available to external investigators upon request. The present manuscript does not include data.

Data collection plan: retention. Participants may withdraw from the study for any reason at any time. In the informed consent model, a section is included for the participant to withdraw their participation if they deem it appropriate.

Competing interests. The authors have no conflicts of interest to declare with regard to this study.

Funding. This work is supported by the Menarini Group, as well as by a competitive, peer-reviewed grant funded by Fundación Mapfre Guanarteme, Spain. The funders have had no role in the design of the trial and will have no role in the collection, analysis or interpretation of the data, nor in the preparation or publication of the manuscripts related to this trial.

Trial registration number NCT03906786; Pre-results. Date of registration: April 8, 2019

Protocol version. Issue date: 30 Jul 2019

Contributors

D.A-M participated in the design of the study, provided MI training for practitioners, contacted the participants by phone, performed the interviews to complete the questionnaires and wrote the first draft of this article. M.B participated in the study design, received MI training, recruited patients, applied MI to the participants and contributed to the writing of this article. M. A.R received MI training, recruited patients and applied MI to the participants. M.A.A-G received MI training, and conducted interviews to complete the questionnaires. A.M.W participated in the design of the study, received MI training, recruited patients, applied the MI to the participants and contributed to the writing of this article.

Trial Sponsor: Dra. Ana M. Wágner. Address: Endocrinology and Nutrition Dept. Complejo Hospitalario Universitario Insular Materno-Infantil Gran Canaria. Av. Marítima s/n. 35016 Las Palmas de Gran Canaria, Spain. Tel: +34 928453431. FAX: +34 928442586.

References

1. American Association of Diabetes Educators. AADE7 Self-Care Behaviors. *Diabetes Educ* 2008;34: 445-9.
2. Anderson RM, Funnell MM. Patient empowerment: reflections on the challenge of fostering the adoption of a new paradigm. *Patient Educ Couns* 2005;57:153–7.
3. Borus JS, Laffel L. Adherence challenges in the management of type 1 diabetes in adolescents: prevention and intervention. *Curr Opin Pediatr* 2010;22:405–11.
4. Alvarado-Martel D, Velasco R, Sánchez-Hernández RM, Carrillo A, Nóvoa FJ, Wágner AM. Quality of life and type 1 diabetes: A study assessing patients' perceptions and self-management needs. *Patient Prefer Adherence* 2015;9:1315–23.
5. Alvarado-Martel D, Ruiz Fernández MA, Vigaray MC, Carrillo A, Boronat M, Montesdeoca AE, Wágner, A.M. Identification of psychological factors associated with adherence to self-care behaviors amongst patients with type 1 diabetes. *Journal of Diabetes Research* 2019; 627:6271591.
6. Funnell MM, Anderson RM. Patient Empowerment: A Look Back, A Look Ahead. *Diabetes Educ* 2003;29:454-64.
7. Mulcahy K, Maryniuk M, Peeples M, Peyrot M, Tomky D, Weaver T, et al. Diabetes Self-Management Education Core Outcomes Measures. *Diabetes Educ* 2003;29:768-83.

8. Golay A, Lagger G, Chambouleyron M, Carrard I, Lasserre-Moutet A. Therapeutic education of diabetic patients. *Diabetes Metab Res Rev* 2008;24(3):192–6.
9. DiMatteo MR. Variations in patients' adherence to medical recommendations: A quantitative review of 50 years of research. *Med Care* 2004;42:200-209.
10. Haas L, Maryniuk M, Beck J, Cox CE, Duker P, Edwards L, et al. National standards for diabetes self-management education and support. *Diabetes care* 2014;37 (Suppl 1):1630–7.
11. Beck J, Greenwood DA, Blanton L, Bollinger ST, Butcher MK, Condon JE, et al. National Standards for diabetes self-management education and support. *The diabetes EDUCATOR* 2018;44: 35-50.
12. Miller WR, Rollnick S. La entrevista motivacional. Ediciones Paidós. 2015.
13. Miller WR. Motivational Interviewing with Problem Drinkers. Behavioural and Cognitive Psychotherapy 1983;11:147–72.
14. Rubak S, Sandbæk A, Lauritzen T, Christensen B. Motivational interviewing: A systematic review and meta-analysis. *BJMP* 2005;55:305–12.
15. Lundahl B, Moleni T, Burke BL, Butters R, Tollefson D, Butler C, et al. Motivational interviewing in medical care settings: A systematic review and meta-analysis of randomized controlled trials. *Patient Educ Couns* 2013;93:157–68.
16. Miller WR. Applications of motivational interviewing. Motivational interviewing: Helping people change. 3rd ed. New York: Guilford Press. 2013.
17. Bóveda Fontán J, Péruña de Torres LÁ, Campiñez Navarro M, Bosch Fontcuberta JM, Barragán Brun N, Prados Castillejo JA. Current evidence on the motivational interview in the approach to health care problems in primary care. *Atencion primaria* 2013;45:486–95.
18. Martins RK, McNeil DW. Review of Motivational Interviewing in promoting health behaviors. *Clin. Psychol. Rev* 2009;29:283–93.
19. Hettema J, Steele J, Miller WR. Motivational Interviewing. *Annu Rev Clin Psychol* 2005;1:91–111.
20. Chen SM, Creedy D, Lin H-S, Wollin J. Effects of motivational interviewing intervention on self-management, psychological and glycemic outcomes in type 2 diabetes: A randomized controlled trial. *IJNS* 2012;49:637–44.
21. Hawkins SY. Improving glycemic control in older adults using a videophone motivational diabetes self-management intervention. *Res Theory Nurs Pract* 2010;24:217–32.
22. Pourisharif H, Babapour J, Zamani R, Besharat MA, Mehryar AH, Rajab A. The effectiveness of motivational interviewing in improving health outcomes in adults with type 2 diabetes. *Procedia Soc Behav Sci* 2010;5:1580–4.
23. Christie D, Channon S. The potential for motivational interviewing to improve outcomes in the management of diabetes and obesity in paediatric and adult populations: A clinical review. *Diabetes Obes Metab* 2014;16:381–7.
24. Viner RM, Christie D, Taylor V, Hey S. Motivational/solution-focused intervention improves HbA1c in adolescents with Type 1 diabetes: A pilot study. *Diabetic Medicine* 2003;20:739-42.

25. Ismail K, Maissi E, Thomas S, Chalder T, Schmidt U, Bartlett J, et al. A randomised controlled trial of cognitive behaviour therapy and motivational interviewing for people with type 1 diabetes mellitus with persistent sub-optimal glycaemic control: A diabetes and psychological therapies (ADaPT) study. *Health Technol Assess* 2010;14(22).
26. Channon SJ, Channon SJ, Huws-Thomas M, Huws-Thomas M, Rollnick S, Rollnick S, et al. A Multicenter Randomized Controlled Trial of Motivational Interviewing in Teenagers With Diabetes. *Diabetes Care* 2007;30:1390–5.
27. Gregory JW, Channon S. Motivational interviewing to improve blood-glucose control in childhood diabetes. *Paediatr Child Health* 2009;19:331–4.
28. Wang YCA, Stewart SM, Mackenzie M, Nakonezny PA, Edwards D, White PC. A randomized controlled trial comparing motivational interviewing in education to structured diabetes education in teens with type 1 diabetes. *Diabetes Care* 2010;33:1741–3.
29. Rosenbek Minet LK, Wagner L, Lønvig EM, Hjelmborg J, Henriksen JE. The effect of motivational interviewing on glycaemic control and perceived competence of diabetes self-management in patients with type 1 and type 2 diabetes mellitus after attending a group education programme: A randomised controlled trial. *Diabetologia* 2011;54:1620–9.
30. Jones A, Gladstone BP, Lübeck M, Lindekilde N, Upton D, Vach W. Motivational interventions in the management of HbA1c levels: A systematic review and meta-analysis. *Prim Care Diabetes* 2014;8:91–100.
31. Dehghan-Nayeri N, Ghaffari F, Sadeghi T, Mozaffari N. Effects of Motivational Interviewing and Adherence to Treatment Regimens Among Patients with Type 1 Diabetes a Systematic Review. *Diabetes Spectrum* 2019; 32: 112-117.
32. Rollnick S, Miller WR, Butler CC, Mark SA. Motivational Interviewing in Health Care: Helping Patients Change Behavior. *COPD* 2008, 5: 203
33. Schwalbe CS, Oh HY, Zweben A. Sustaining motivational interviewing: a meta-analysis of training studies. *Addiction* 2014;109: 1287-1294
34. Steinberg MP, Miller WR. Motivational Interviewing in Diabetes Care: Facilitating Self-Care. New York.Guildford Press. 2015.
35. Jansà M, Vidal M, Giménez M, Conget I, Galindo M, Roca D, et al. Psychometric analysis of the Spanish and Catalan versions of the Diabetes Self-Care Inventory-Revised version questionnaire. *Patient Prefer Adherence* 2013;7:997–1005.
36. Jerusalem, M., & Schwarzer R. Self-efficacy as a resource factor in stress appraisal processes. In: (Ed.) IRS, editor. Washington: DC: Hemisphere; 1992. p. 195–213.
37. Baessler, R., Schwarcer J. Evaluación de la autoeficacia: Adaptación española de la escala de Autoeficacia General. *Ansiedad y Estrés*. 1996;2:1–8.
38. Alvarado-Martel D, Ruiz Fernández MA, Vigaray MC, Carrillo A, Boronat M, Montesdeoca AE, et al. ViDa1: The development and validation of a new questionnaire for measuring health-related quality of life in patients with type 1 diabetes. *Front Psychol* 2017;8.

39. Campiñez Navarro M, Péruña de Torres LÁ, Bosch Fontcuberta JM, Barragán Brun N, Arbonies Ortiz JC, Novo Rodríguez JM, et al. Measuring the quality of motivational interviewing in primary health care encounters: The development and validation of the motivational interviewing assessment scale (MIAS). *Eur J Gen Pract* 2016;22:182–8.

Tables

Table 1. Contents of the theoretical-practical MI workshop

<i>Spirit of MI</i>	Openness to a new model of thinking and doing with respect to patients. Developing active curiosity to understanding the patient's perspectives, seeking to evoke the motivation for change in the patient him/herself. The spirit of the MI is based on four principles: collaboration, acceptance, evoking and compassion.
<i>Acquiring patient-centered counseling skills (OARS: open questions, affirmation, reflection, summary)</i>	Acquiring skills in the use of patient-centered communication. The key tools of MI are developed: empathy, open questions, affirmation, reflections for feedback, and summaries to take stock.
<i>Recognizing and reinforcing talk of change</i>	Developing the ability to recognize patients' talk of change when it appears naturally in the context of ambivalence. Paying attention to expressions indicating desire, possibility, motives or need, and which predict the commitment to change.
<i>Eliciting and strengthening talk of change</i>	Helping professionals to strengthen talk of change once it has been recognized. The aim is to evoke talk of change deliberately instead of waiting for it to occur naturally.
<i>Rolling with resistance</i>	Learning to avoid resistance and responding to it appropriately if it appears. Practitioners should adjust to resistance rather than oppose it, through strategies of simple and complex reflections.
<i>Developing a change plan</i>	Developing the skill to attempt the transition from change talk to the development of an action plan to achieve it. The usual process is to offer a progressive summary of the change talk provided by the patient (desire, ability, motives and need) and then pose an open question whose essence is "What are you going to do now?"

<i>Consolidating patients' commitment</i>	Once the plan is established, the crucial step is to maintain the patient's commitment. The skills in this stage are the same as the ones developed in the other stages, since the fundamental thing is to listen to and support the patient's language of commitment, understood as language that entails a decision once the action plan has been designed.
<i>Combining MI effectively with other tools</i>	MI is not the only tool in a professional's repertoire. Patients who are prepared for the change should not be interviewed with MI, as it might be frustrating. It is part of the professionals' task to recognize when to apply MI.

Table 2. Time points of measurements

Variable	Appointment	Appointment	Appointment	Appointment	Appointment
	1 baseline	2 4m	3 8m	4 12m	5 Post- intervention
Primary outcome measure					
Adherence to self-care (SCI-R)	X				X
Secondary outcome measures					
<i>HbA1c</i>	X	X	X	X	X
Self-efficacy (GSE)	X				X
Health-related quality of life (ViDa1)	X				X
Motivation for self-care	X				X
Satisfaction with self-care	X				X
Satisfaction with the doctor-patient relationship					X
Personal goal of diabetes care	X				X
Sociodemographic data	X				X
Clinical data	X				X