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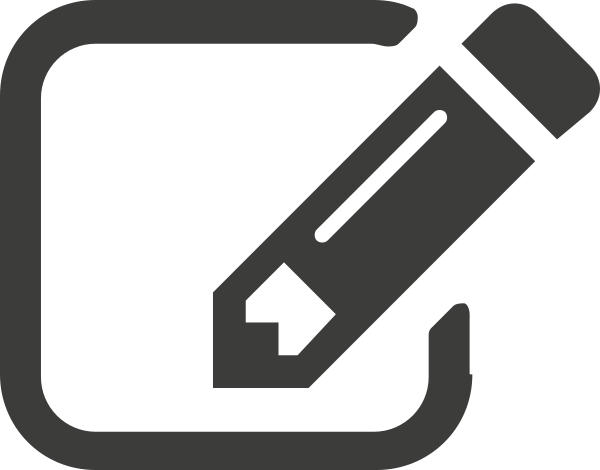
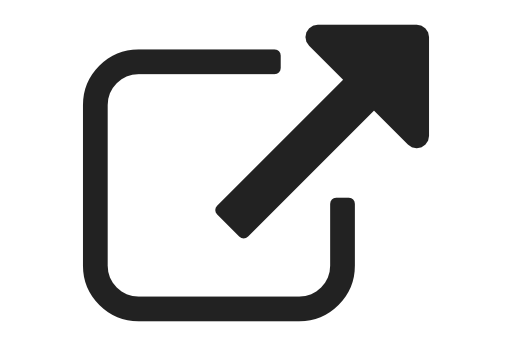
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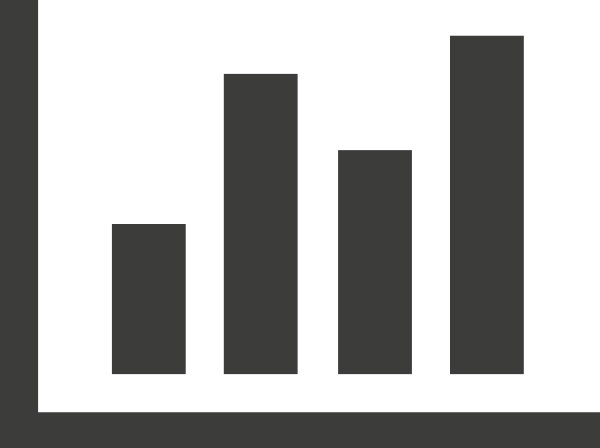
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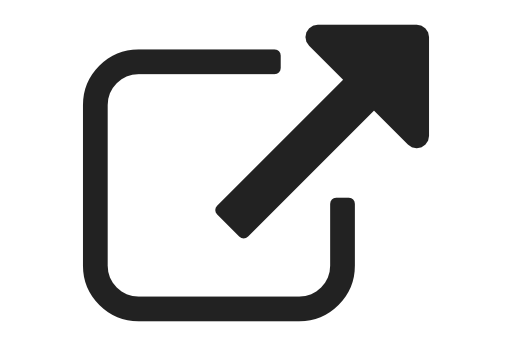
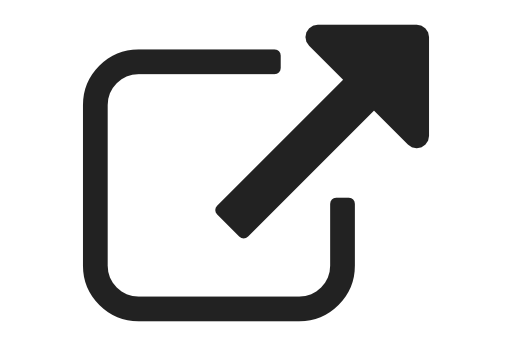
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A randomized controlled trial on the effect of behavioral strategies for adherence to oral antidiabetic drugs: study protocol

Danilo D. Trevisan[a](#_bookmark0)\*, Thaís M. São-João[a](#_bookmark0), Marilia E. Cornélio[a](#_bookmark0), Fernanda F. Jannuzzi[b](#_bookmark0),

Roberta C. M. Rodrigues[a](#_bookmark0) and Maria Helena M. Lima[a](#_bookmark0)

*aSchool of Nursing, University of Campinas, Campinas, Brazil; bTechnical School of Campinas, University of Campinas, Campinas, Brazil*

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*Background:* Non-adherence to oral antidiabetics drugs (OADs) has been a common problem and may contribute to poor glycemic control.

*Aim:* To describe an experimental study protocol that aims at implementing and evaluating the effect of the “action planning and coping planning” interventions on medication adherence to OADs in patients with type 2 diabetes mellitus (T2DM) in follow-up at primary care services.

*Design:* A randomized controlled trial. *Methods:* Two groups (intervention and control) will be followed over a period of 105 days. The intervention group will receive a combination of the “action planning” and “coping planning” intervention strategies. There will be in-person meetings and phone calls to reinforce the intervention. The control group will receive the usual care from the health unit.

*Conclusions:* It is hoped that this study will help health professionals to improve their approach with patients who have T2DM in relation to medication adherence.

Keywords: medication adherence; type 2 diabetes mellitus; hypoglycemics; planning techniques; nursing; intervention studies

Introduction

In chronic diseases, such as type 2 diabetes mellitus (T2DM), non-adherence to the medication may result in worsened outcomes for medical treatments, greater rates of hospitalization, and increased costs (Rwegerera, [2014](#_bookmark8)). Studies have shown that non-adherence to oral antidiabetics drugs (OADs) has been a common problem and may contribute to poor glycemic control and to higher chances of complications of the disease (Claydon-Platt, Manias, & Dunning, [2014](#_bookmark7); Schernthaner, [2010](#_bookmark8)). In order to help T2DM patients initiate and sustain lifestyle modiﬁcations, healthcare providers are encouraged to be empathetic and supportive and an understanding of the coping strategies planned will ensure that effective coping strategies are utilized (Li, Drury, & Taylor, [2013](#_bookmark8)). To our knowledge, few studies have used theoretical references to study the behav- ior of medication adherence in patients with T2DM (Guénette et al., [2015](#_bookmark7), [2016](#_bookmark7); Jannuzzi, Rodri- gues, Cornélio, São-João, & Gallani, [2014](#_bookmark8)).

\*Corresponding author. Email: [ddtrevisan@gmail.com](mailto:ddtrevisan@gmail.com)

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One of the most commonly used theoretical frameworks to study health behaviors is the Theory of Planned Behavior (TPB) (Armitage & Conner, [2001](#_bookmark7)). According to this theory, inten- tion is the immediate and main determinant of the behavior and is determined by three major com- ponents: (1) attitude, which is the degree to which performing the behavior is positively or negatively evaluated; (2) subjective norm, which accounts for the perceived social pressure to engage or not in a certain behavior; and (3) perceived behavioral control, which refers to one’s perceptions of his/her ability in performing a behavior (Ajzen, [1985](#_bookmark7), [1991](#_bookmark7)). The TPB was used by Jannuzzi et al. ([2014](#_bookmark8)) to identify the psychosocial factors for adhering to OADs in patients with T2DM in Brazil.

A theoretical model has been proposed to aid the translation of a positive intention into actual behavior, known as implementation intentions. This model is composed of two strategies: action planning and coping planning (Gollwitzer, [1999](#_bookmark7)). Action planning aims at raising awareness in the individual as to the possible future situations in which the behavior can be achieved and the possible responses to these situations, making explicit when, where, and how the individual will perform the behavior (Gollwitzer, [1999](#_bookmark7)). Coping planning focuses on risky situations or barriers that may impede, interfere with, or complicate the achievement of the target behavior (Gollwitzer, [1999](#_bookmark7)).

Therefore, the main objective of this paper is to describe an experimental study protocol aimed at implementing and evaluating the effect of “action planning and coping planning” interventions on medication adherence to oral antidiabetics in patients with T2DM at primary care services.

Methods

This study was structured in accordance with the recommendations from the SPIRIT 2013 State- ment (Chan et al., [2013](#_bookmark7)).

*Trial design*

A two-arm single-blind randomized controlled trial will be carried out involving parallel groups (intervention and control) over a period of 15 weeks (105 days). Participants will be allocated in each of the groups through a random sequence list generated by the website [randomization.com](http://randomization.com/) ([Figure 1](#_bookmark2)).



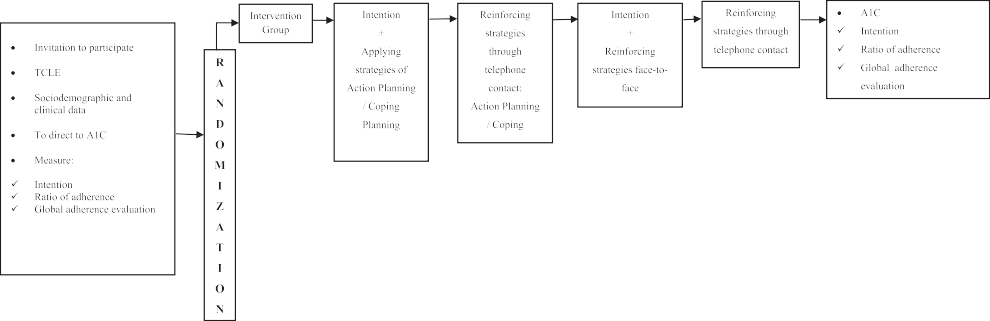


Figure 1. Data collection protocol.

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*Study settings*

Participants will be recruited from two primary healthcare units of a city in the interior of the state of São Paulo, Brazil. These services belong to the Uniﬁed Health System from the country and provide assistance focused on promoting and restoring health as well as preventing diseases.

*Eligibility criteria*

It will be included patients who (1) have a diagnosis of T2DM; (2) have been continuously using OADs for at least six months (Ciechanowski, Katon, & Russo, [2000](#_bookmark7); Sclar et al., [1999](#_bookmark8));

1. possess the ability to read and write in Brazilian Portuguese; (4) are able to communicate verb- ally; (5) aged 18 years or older; and (6) who have an average score indicating positive behavioral intention (equal to or greater than 4). But before the start of the selection, all participants will take part in the evaluation of short Portable Mental Status Questionnaire, a tool able to evaluate several aspects of intellectual functioning, including short-term memory, long-term memory, orientation to surroundings, information about current events, and the capacity to perform serial mathemat- ical tasks; to be brief; easy score and test usable for both community and institutional populations (Pfeiffer, [1975](#_bookmark8)). Exclusion criteria will include (1) patients in whom the administration of the medications is handled by a caregiver; (2) patients who use insulin to treat T2DM; or (3) patients who use more than one health service for T2DM follow-ups.

*Intervention*

*Intervention group*

Individuals from intervention group (IG) will elaborate, with the researcher assistance, the action plans (action planning) and plans to face obstacles with strategies to overcome them (coping plan- ning) in order to increase adherence to the medication therapy of the OADs. Both the action plans and the coping plans will be registered manually in the spreadsheet by the researcher and archived individually for future reference during the follow-up.

*Action planning* is related to the responses to the situational cues and the desired objective by means of speciﬁcation. Thus, the patient will be asked to complete a form, where up to three action plans will be described concerning when, where, and how he intends to take the OADs in the next two months. Note that the authors developed this instrument using studies on the for- mation of “implementation intention” in the adoption of health-related behaviors, in addition to previously used instruments in a similar format (Lourenço et al., [2014](#_bookmark8); O’Carroll, Chambers, Dennis, Sudlow, & Johnston, [2013](#_bookmark8); Sniehotta, Scholz, & Schwarzer, [2006](#_bookmark8)). The participants will be encouraged to commit to taking OADs according to the medical prescription. The follow- ing questions will be asked:

* 1. When, where, and how do you plan on taking the medications for treating the diabetes? (2) Let’s write your plans together on the table I will show you. Remember that the more accurate and realistic you are in preparing your plans and the more you make these plans on your own, the higher the chances are that you will be able to implement them.

*Coping planning* is based on the assumption that the necessary responses to self-regulatory coping are already available to the subject, falling back on the prior experience. Thus, the individual is encouraged to anticipate the barriers that hinder the achievement of the desired behavior and then formulate strategies to overcome them. The following questions will be asked:

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(1) How could you overcome these obstacles or barriers? (2) Let’s write down together ﬁrst the obstacles and then your plans for overcoming them on the table I will show you. Remember that the more accurate and realistic you are in designing your plans, the better the chances that you will be able to implement them.

In order to reinforce the plans, a telephone call will be made in 15-day intervals between Times 1 and 3 (30th day) and between Times 3 and 5 (75th day). During the call, participants will be asked:

(1) “Have you taken the medications to treat diabetes? If not, why not?” (2) “Are you having trouble taking the medications to treat the diabetes? If so, what is the trouble?” and (3) “Let’s go over what you had planned in order to be able to take the diabetes medications.” After the third question, the nurse will read the contents of the sheet to remind the participant of his plans. The intervention will be delivery in four in-person meetings (one at the baseline (T0), one 15 days later after T0, one 60 days after T0, and one at the end of the follow-up) and two reinforcements over the phone (one in 30 days and one in 75 days after the baseline, respectively).

*Control group*

Participants assigned to the control group (CG) will receive routine healthcare during their regular appointments, as well as the usual information about the prescribed medication.

*Criteria for discontinuing or modifying allocated interventions for a given trial participant*

Participants will be discontinued for not attending scheduled meetings, ending participation in the study during the intervention and/or in the data collection phase, or begin the use of insulin during the study. Nevertheless, participants will be discontinued if they start clinical follow-up in a differ- ent outpatient setting.

*Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence*

A day before the scheduled appointment, a phone call reminding the patient to attend the health facility for follow-up of the study protocol will be held.

*Relevant concomitant care and interventions that are permitted or prohibited during the trial*

The CG will receive only the usual orientations of the healthcare unit and shall not come into contact with the intervention. However, after completion of the protocol, this group will receive an explanatory material with directions to improve adherence to the OADs. CG and IG will be instructed to keep clinical follow-up exclusively at the health facility where the study will take place. In addition, individuals should remain registered in that health unit during all follow-up over 105 days. Both groups will also be instructed not to participate in other programs or inter- ventions aimed at measuring or improving adherence to any drugs used by them during the follow-up period.

*Outcomes*

Outcome measures will be obtained from IG and CG at *baseline* and at the105th day of follow-up. The primary outcome measures will be the behavioral measure of adherence, the ratio of adher- ence, and the global adherence evaluation (Jannuzzi et al., [2014](#_bookmark8); Lourenço et al., [2014](#_bookmark8)). The

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glycated hemoglobin (A1c) level and the strength of intention will be evaluated as secondary outcomes.

*Primary outcomes*

*Behavioral measure of adherence to OADs*. This will be evaluated through an instrument created and used in a prior survey, which is composed of a single question: “In the last two months, I took the medications to treat the diabetes exactly as prescribed by my doctor.” The responses are orga- nized on a four-point Likert scale. The frequency is distributed as follows: 1 = rarely or never; 2 = some days of the week; 3 = most days of the week; 4 = every day or practically every day of the week (Jannuzzi et al., [2014](#_bookmark8)).

*Ratio of adherence*. This will be evaluated by means of an instrument used in prior surveys (Hansen et al., [2009](#_bookmark8); Jannuzzi et al., [2014](#_bookmark8); Lourenço et al., [2014](#_bookmark8)), which will be composed of: description of the name, dosage, and method of use of the medications prescribed on the day before the interview, as well as in the preceding week and month. Each participant will state the number of doses skipped the day before, the week before, and the month before based only on their memory. Adherence to OADs will be calculated based on the doses skipped, as stated by the patient, according to the following calculation: *(doses prescribed* – *doses missed) × 100/doses prescribed*. If the patients use more than one OAD, the ﬁnal ratio of adherence will be calculated by the average of the percentages of adherence to each medication. The ratio will be classiﬁed as follows: adequate dose (when this is equal to or greater than 80% of the prescribed dosage) or insufﬁcient dose (when the dose used is less than 80% of the prescribed dosage) (Hutchins, Zhang, Fleurence, Krishnarajah, & Graham, [2011](#_bookmark8); Kalyango, Owino, & Nambuya, [2008](#_bookmark8); Khan et al., [2012](#_bookmark8)).

*Global adherence evaluation*. This item considers the manner in which the medications are taken, the frequency, and the precautions necessary for their administration. The following are con- sidered temporal markers: before breakfast, breakfast, lunch, dinner, and bedtime. The global adherence evaluation will be assessed in four groups: Group I: Doses and precautions according to the medical prescription; Group II: Adequate doses and inadequate precautions; Group III: Inadequate doses and adequate precautions; Group IV: Inadequate doses and precautions. The patients classiﬁed in Group I will be deemed “adherent”, and those classiﬁed in Groups II, III, or IV will be considered “non-adherent”.

*Glycated hemoglobin*. Blood samples will be obtained from the patients included in this study at the beginning and end of the data collection (T0 and T5) in order to measure A1c. The blood will be collected by means of an intravenous puncture in one of the veins of the patients’ arms by a trained professional licensed for this purpose, without causing harm and at no risk to the partici- pant except potential pain and bruising. A1c is a measure that reﬂects the average glucose in the plasma within a three-month timeframe and can be examined at any time of the day without the participant having to fast. The A1c level will be based on that of the National Glycohemoglobin Standardization Program and standardized by the reference test from the Diabetes Control and Complications Trial (American Diabetes Association – ADA, [2016](#_bookmark7)).

*Secondary outcome*

*Measure of intention*. The intention will be measured by means of six items, using a ﬁve-point Likert scale. For the ﬁnal calculation of intention, the arithmetic average of the scores measured

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in the six items will be obtained. The higher the score, the more positive the intention to take the medications to treat diabetes in the next two months. The patient with a score of 4 or higher will be considered as having positive intentions. The measurement of intention will be held at all meet- ings of the IG. According to the intention implementation strategy, it is necessary that the patient keep the average positive intention (≥4) throughout the patient treatment.

*Participant timeline*

To carry out the protocol, a time schedule of enrollment with the participants will be held as described.

*Sample size*

The methodology used for estimating the sample size was the chi-square test. The parameters necessary for the calculation were obtained from a prior study (Lourenço et al., [2014](#_bookmark8)) that assumed a power of 80% and a signiﬁcance level of 1.25%. This signiﬁcance level was deter- mined after applying Bonferroni’s criterion, since in total four tests will be performed involving these variables (between groups at each of the times and between times for each group). The ﬁnal sample will include, at minimum, 44 individuals per group.

*Recruitment*

Through a list of registered patients in health units, the medical records of each of the eligible participants will be accessed. Participants who accept to participate in the study will be scheduled a baseline appointment in the health unit. On the appointed day, the interviewer will personally invite the participant and the research consent form will be signed in two copies by both.

*Randomization and allocation concealment*

The individuals will be randomized into two groups employing the block randomization method through randomly selected block sizes. A member of the research team who will not be in contact with the participants prepared a list of random sequence generated by the website [randomization.](http://randomization.com/) [com](http://randomization.com/) with 100 participants in numeric sequence concealed from the investigators. Next, each of these numbers was sealed individually in opaque envelopes. Thus, in the ﬁrst interview (*base- line*), and only after the interview is ﬁnished, the investigator will open an envelope and allocate the participant to one of the groups. A number exceeding the sample calculation was prepared due to possible losses during the data collection.

*Implementation*

The study’s principal researcher will conduct the draw with the envelope and will allocate the par- ticipant in the IG or CG. Intervention strategies will be implemented by the lead investigator until T4.

*Blinding*

This is a two-arm single-blind study, that is, only the lead investigator will know which of the participants were allocated to which groups. The health team and other researchers of the study will not know to which group the participant was allocated. In addition, recruited patients will not know in which of the groups they will be allocated. It will only be informed to the

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participants that the study consists of two groups and through a sortition; they will be allocated to one group. Afterwards, the following schedule will be agreed according to the participation allo- cation. In T5, a different interviewer who did not come into contact with participants during follow-up will hold the last stage of the study.

*Data collection methods*

The data will be collected by administering instruments and developing “action planning” and “coping planning” strategies. At baseline, the subject will be invited to participate in the program, and the objectives and procedures of the study will be explained. After agreeing to par- ticipate in the study, the participants will sign two copies of forms providing their written consent. Then, sociodemographic and clinical data will be collected, and the strength of their intention will be measured. If the average intention score is greater than or equal to four, the subject will answer the remaining instruments proposed – that is, the behavioral evaluation of the ratio instrument as well as the global adherence evaluation – and then will be randomized. If the average intention score is less than 4, the subject will be excluded from the study and the sociodemographic and clinical data will be analyzed separately.

At *baseline*, the patients included in the CG will receive the usual guidance regarding manage- ment of the disease. At T1 (15 days after the baseline), the patients included in the IG will be invited to go to the health service to receive the action planning intervention to develop strategies and address obstacles. At T2 (30 days after the baseline), the intervention for patients included in the IG will be reinforced through telephone contact.

At T3 (60 days after the baseline), patients from the IG will be invited to go to the health service to receive reinforcement of the action planning intervention and at T4 (75 days after the baseline), the patients included in the IG will receive another reinforcement of the intervention by telephone contact. Finally, at T5 (105 days after the baseline), all patients included in the IG and in the CG will be invited to go to the health service for ﬁnal follow-up and re-administration of the assessment instruments. In this phase, the collection will not be performed by the researcher who monitored the participant to avoid bias in the results.

In order to assure external and internal validity and reliability, satisfactory evidence and methods will be taken into consideration throughout the process of the study: when applying the instruments, when handling the data and performing the collection, and when developing the intervention (DeVon et al., [2007](#_bookmark7)).

The data will be collected during the same period of time for IG and CG. During the data col- lection period, all completed forms will be carefully examined at the location to ensure there are no missing responses. If any item is missing, we will check with the participants to determine if the missing items were deliberately ignored. They will be asked to complete the missing infor- mation if the items were omitted by mistake.

To ensure adherence to the treatment protocol, we will prepare a spreadsheet that will be com- pleted, together with the participant, including action plans, barriers identiﬁed, and coping plans that will be used during the intervention sessions.

*Data management*

The gathered data will be transferred to a spreadsheet from Microsoft Excel 2010® Windows 8, using double entry. In this spreadsheet, for categorical variables encodings will be created with a number corresponding to each of them. Quantitative variables will be inserted as collected, with the corresponding own number. To avoid erroneous double entry or different values of the created codes, the application will be held from preset values for categorical variables in order to avoid

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this type of error. The spreadsheet with the data will be protected by a password that only lead investigator shall have access.

*Data analysis*

The data collected will be entered in an electronic spreadsheet (Excel 2010 software program) and transferred to the SAS (Statistical Analysis System) program, version 9.4 for the following analyses:

* Internal consistency as measured by estimating Cronbach’s alpha coefﬁcient for the ques- tionnaire on global adherence. A Cronbach’s alpha higher than 0.70 will be considered as satisfactory internal consistence;
* Comparison tests of either the Mann–Whitney test or the unpaired Student’s *t*-test will be

applied to compare the measurements of intention and adherence (quantitative variable) in relation to the sociodemographic and clinical categorical variables;

* Association tests of either the chi-square or Fisher’s exact test will be applied to compare

the measurements of intention and adherence (qualitative variable) in relation to the socio- demographic and clinical categorical variables;

* The Spearman or Pearson correlation coefﬁcient will be used to determine the existence of a

correlation between the measurement of intention and adherence;

* Mixed-effect linear regression will be used to verify the relationship between the outcome and independent variables.
* A level of signiﬁcance equal to 5% will be adopted.

*Data monitoring*

For this study, there was no formation of a monitoring committee, since we understand it can bring minimal risk to participants, as described in the item below. In addition, there is the possi- bility of early termination of the protocol due to these minimal predicted risks.

*Harms*

For this study, small risks and discomforts to patients are foreseen. Blood samples for assessment of A1c at the beginning and at the end of the study protocol will be performed by trained and qualiﬁed professionals for this purpose, in order to expose the participant to a small risk related to the intravenous punction. It is noteworthy that in any steps there will be no loss in patient care (in examination achievements, consultations, hospitalizations) in the health unit.

*Auditing*

In this study, audit procedures will not be performed. To carry out the protocol, all the suitability criteria will be maintained and we highlight that shall not exist the presence of a sponsor.

*Ethics and dissemination*

The protocol of the present study was approved by the local Committee for Ethics in Research (Documents n. 1.278.099, n. 1.408.883 and n. 1.528.738) and is registered at International Clini- cal Trials Registry Platform (ICTRP, RBR-439f77). This study will be conducted in accordance

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with the principles of the Declaration of Helsinki and in accordance with the Medical Research Involving Human Subjects Act. The patient’s personal information will be gathered through an instrument of sample characterization. To identify each participant, will be used only the initials of their names. Research forms shall be kept by the lead investigator for ﬁve years and after that they shall be incinerated. The ﬁnal results will be disseminated to the scientiﬁc community in the form of a scientiﬁc paper. For the health team of the participating units, the data will be presented in the form of charts and graphs, through a personal presentation conducted by the lead investi- gator during a previous appointed meeting.

Discussion

To our knowledge, this will be the ﬁrst randomized controlled clinical trial to analyze the effect of an intervention on adherence to OADs in patients with T2DM in follow-up in primary care. Two intervention strategies, action planning and coping planning, will be developed in the IG, and these will be compared with the usual measures taken in the CG. The self-reported adherence measures as well as the A1c evaluation at the end of the follow-up will be used as outcomes in this study.

Practical strategies designed to manage DM are urgently needed, in addition to programs to improve medication adherence in adults with T2DM (ADA, [2016](#_bookmark7); Bartholomew, Parcel, Kok, Gottlieb, & Fernandez, [2010](#_bookmark7); Guénette et al., [2016](#_bookmark7); Raebel, Schmittdiel, Karter, Konieczny, & Steiner, [2013](#_bookmark8); Vermeire et al., [2005](#_bookmark8)).

Currently, intervention studies have focussed on lifestyle behaviors, as physical activity, weight loss and diet. However, few of the studies have shown a relationship between adhering to OADs and behavior models. This points to the imperious need of developing researches which establish strategies for the identiﬁcation of facilitating and hindering factors in adhering to OADs, based on theoretical frameworks. Besides, the implementation of a theory-based intervention is one of the ﬁrst steps to aid patients with problems in adhering to OADs to prevent negative outcomes (ADA, [2016](#_bookmark7); Bartholomew et al., [2010](#_bookmark7); Guénette et al., [2016](#_bookmark7)).

This study has a few methodological limitations. Firstly, it is based on self-reported measures for taking OADs, which have been associated with biases such as memory and social desirability. However, the advantage of using this measure is that it allows for differen- tiation between medication non-adherence for intentional reasons (such as not taking the medi- cation when away from home) and non-intentional reasons (such as forgetfulness or incorrectly interpreting the medical prescription), in addition to allowing for comparison of past and current behavior.

Impact statement

The implementation intention strategy was chosen for the study development. This technique con- sists of individual activities designed to develop action planning and to shield striving for goals from anticipated obstacles. The individual develops at least three plans of how, where, and with whom to implement the planned behavior. Then, the individual is asked to anticipate three likely obstacles that may hinder the achievement of such a goal and establish a plan to overcome these obstacles. It is a simple, brief, and adequate technique, with good results for different behaviors. This paper clearly presents the design of a nurse-led behavior intervention, which allows others to reproduce this program with different populations, when adequate. A systematically planned implementation intervention enables better allocation of resources and the optimization of results, improving the care provided to patients with chronic diseases, such as T2DM, improving the chances of attaining positive outcomes.

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Conclusions

This study will help health professionals improve their approach to patients with T2DM in regard to medication adherence. This theory-based intervention is inexpensive, easy to carry out, and may be implemented at various levels of health complexity, strengthening the change in adher- ence behavior. Furthermore, this intervention can be expanded to outpatient care and other primary care units. This paper presents a study protocol that aims at evaluating the effect of the combination of the “action planning” and “coping planning” strategies for adherence to OADs in patients with T2DM in follow-up at primary care services. Additional research can be conducted to further test the effectiveness of the program using randomized clinical trials with larger samples in various healthcare units.

Acknowledgements

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