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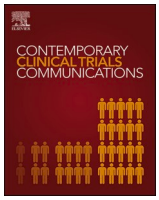

A multicomponent smoking cessation program for adults with Type 2 Diabetes Mellitus (*DiMe-SALUD2* project): A study protocol of a randomized controlled trial

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ABSTRACT

Background: Tobacco use represents a significant public health burden, being especially harmful for smokers with Type 2 Diabetes Mellitus (T2DM). Effective smoking cessation interventions are required for this vulnerable population. The goal is to describe a study protocol of a randomized controlled trial (RCT) aimed at analyzing the effectiveness and efficiency of a multicomponent smoking cessation intervention for T2DM smokers, including a training protocol on healthy lifestyle habits and self-management of T2DM (*DiMe-SALUD2* project).
Methods: This RCT will assign participants to: (1) Control Group (n = 30), including a brief psychoeducation advice about smoking cessation; (2) Cognitive-behavioral treatment (CBT) for smoking cessation (n = 30), based on a multicomponent program implemented in group-based sessions over an eight-week period; and (3) CBT plus *DiMeSALUD2* protocol (n = 30), which will develop an additional psychoeducational protocol specifically designed to improve healthy lifestyle habits. Participants will be assessed at baseline, post-treatment and several follow-ups (1-, 6- and 12-months). Primary outcomes will include smoking abstinence (24-h point prevalence abstinence at post-treatment and 7-day point prevalence at follow-ups) and smoking continuous abstinence. Secondary outcomes will include treatment retention, changes in smoking patterns and nicotine dependence, as well as the impact on T2DM clinical variables, mental health, and quality of life.
Discussion: The *DiMeSALUD2* program could assist T2DM smokers in quitting tobacco use and improving their overall quality of life. This project will help incorporating improvements in routine clinical practice with T2DM patients, offering a smoking cessation program adapted to their specific needs.
Trial registration: ClinicalTrials.gov. Identifier: NCT05885659. Date of registration: June 2nd, 2023.

1. Introduction

Tobacco use among people with Diabetes Mellitus (DM) is a significant public health burden [1–3]. Overall, 537 million adults live nowadays with DM, with this figure expected only to increase up to 643 million people by 2030 [4]. Type 2 DM (T2DM) is the most common form of DM, accounting for ~90–95 % of all diabetes [4–6] and is caused by a combination of insulin resistance and an inadequate insulin secretory response [5]; in other words, it is a progressive loss of β-cell insulin secretion [4,7]. The etiology of T2DM is commonly associated to bad health habits such as weight gain or obesity, lack of physical activity, unhealthy diet or ultimately, smoking behavior [4,5,8].

Globally, it is estimated that one in five individuals (21 %) with T2DM is a smoker [3]. Moreover, tobacco consumption has been linked to the etiology of T2DM [8], representing one of the most important modifiable risk factors for this disease [8,9]. In fact, smokers have a 30–40 % higher risk of developing T2DM when compared to non-smokers [10] since nicotine may impair the regulation of blood glucose levels and cause both insulin secretion impairment and insulin resistance [11].

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Smoking behavior has also a detrimental effect on T2DM patients' health as it increases the risk of mortality [1,2], coronary heart disease and stroke [12] as well as impaired glycemic control, due to the higher levels of glycated hemoglobin (HbA_{1c}) and the more severe hypoglycemia [13] of these patients. These negative consequences are aggravated by the fact that T2DM smokers metabolize nicotine faster, therefore increasing their cigarette consumption and, ultimately, their nicotine dependence levels [14].

In this context, it is not surprising that the American Diabetes Association [7,15] as well as the International Diabetes Federation [4,16] strongly recommend smoking cessation as a routine component for the treatment of diabetes, including T2DM. Smoking cessation in people with T2DM decreases the risk of death as well as both micro- and macrovascular events [1,2,9]. Overall, quitting represents a key factor to improve glycemic control and limiting health complications for T2DM patients [1,2]. However, T2DM smokers tend to minimize the risks of tobacco consumption [12,17] and to respond poorly to smoking cessation management [1,18]. Additionally, some mental health problems such as depression, anxiety or psychological distress occur in a higher proportion among diabetic patients than in the non-diabetic population, reinforcing tobacco consumption [19]. Addressing these problems would allow clinicians to detect diabetic smokers experiencing greater difficulties to quit as well as a higher probability of relapse in the long-term.

Despite the need to develop tailored smoking cessation treatments for T2DM smokers, studies providing robust evidence of effective interventions for this population are still scarce [2,20]. Previous programs have included brief [21–25] or intensive [26,27] counseling interventions, structured behavioral treatments [28,29] or specific education about DM [30–32]. Nonetheless, these interventions are often similar to those used in the general population [2,20], and the limited evidence on their efficacy prevents healthcare professionals from recommending them to T2DM patients [12]. Moreover, these studies often include a reduced number of participants and present a high risk of bias [20] while their heterogeneity limits comparisons on their effectiveness [12,20].

Overall, these shortcomings highlight the need to develop effective psychological treatments for smoking cessation to assist T2DM smokers in quitting. The goal is to describe the protocol of a randomized controlled (RCT) trial that aims to analyze the effectiveness and efficiency of a multicomponent smoking cessation intervention for T2DM smokers, including a training protocol on healthy lifestyle habits and self-management of T2DM called *DiMe-SALUD2* project.

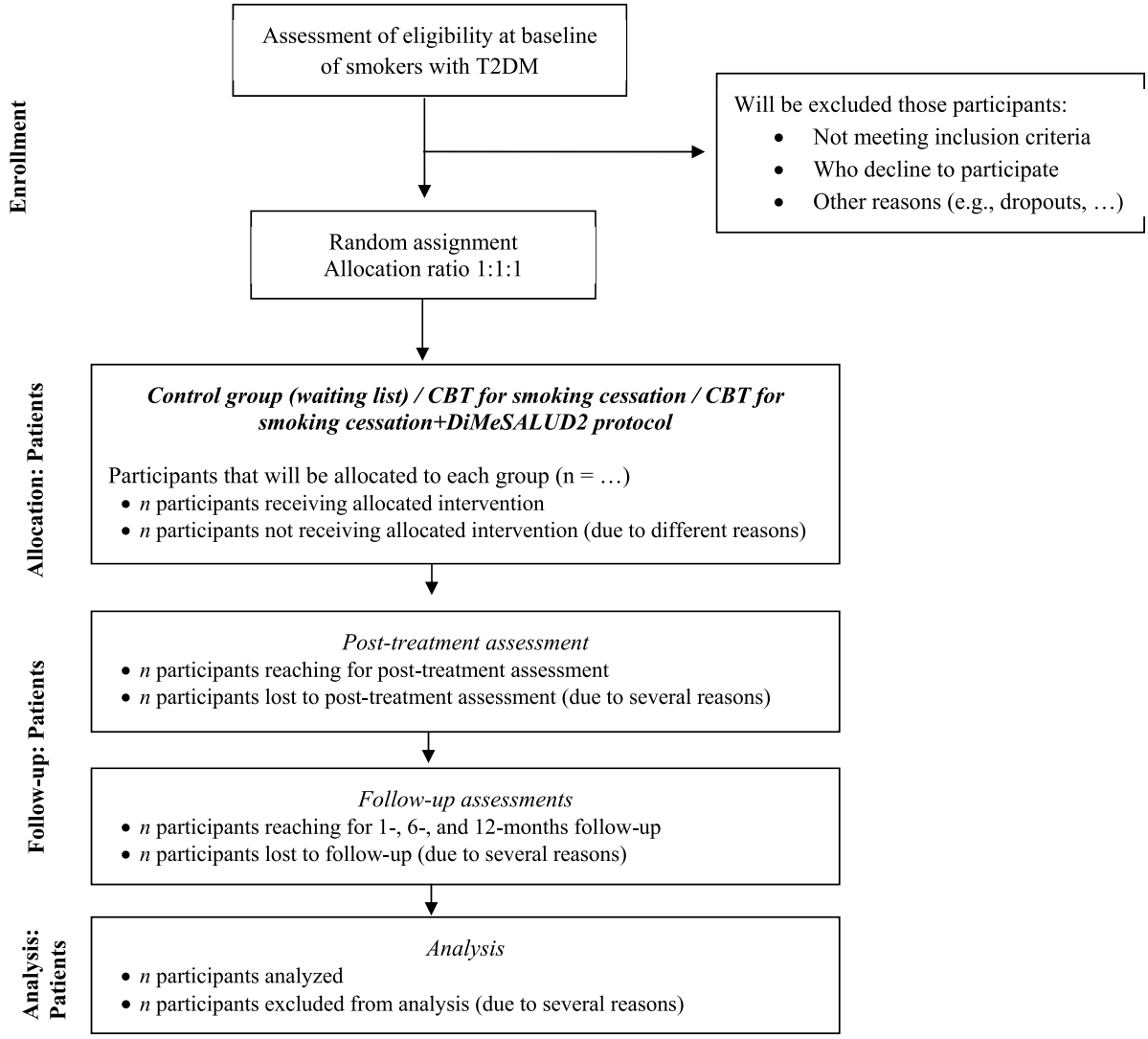

Fig. 1. Study design and participant flow diagram according to the modified CONSORT guidelines for individual randomized controlled trials of nonpharmacologic treatments (Boutron et al., 2017).

2. Methods and design

2.1. Study design, aims and hypotheses

This RCT will be developed as a single-blind, parallel three-arm group design (allocation ratio 1:1:1) and will be carried out at clinical settings associated to the researchers' institutions. Participants will be randomly assigned to: (1) Control Group (waiting list); (2) Experimental Group 1 - Cognitive-behavioral treatment (CBT) for smoking cessation; and (3) Experimental Group 2 - CBT for smoking cessation + *DiMeSALUD2* protocol. This research project will follow the *SPIRIT 2013 Statement* with the aim of describing the details of the proposed methods, ethical considerations, and dissemination policy [33]. Moreover, our project will adhere to the updated *CONSORT Statement for randomized trials of nonpharmacologic treatments* guidelines [34] (see Fig. 1).

The main goal of this study is to assess the effectiveness and efficiency of the *DiMeSALUD2* protocol added to a standard CBT for smoking cessation. The secondary goals are: (a) To evaluate the added efficacy of the psychoeducation protocol on healthy lifestyle habits and self-management of T2DM plus the multicomponent cognitive-behavioral program to quit smoking (CBT for smoking cessation + *DiMeSALUD2* protocol), compared to the standard application of this multicomponent CBT for smoking cessation and to the control group; (b) To analyze the impact of the CBT for smoking cessation + DiMeSALUD2 protocol on different clinical variables (e.g., variability of glycemic levels, healthy lifestyle habits, quality of life, etc.) and (c) To describe the efficiency or cost-effectiveness of the CBT for smoking cessation + *DiMeSALUD2* program. We hypothesize that participants assigned to CBT for smoking cessation + *DiMeSALUD2* protocol will achieve higher rates of quitting and that this condition will be more effective and efficient in comparison with the other groups. Moreover, these results are expected to be sustained not only in the short-term (1-month follow-up) but also in the medium-term (6-month) and long-term (12-month) follow-ups. It is also hypothesized that the CBT for smoking cessation + *DiMeSALUD2* protocol will positively impact on different clinical variables (e.g., reducing the variability of glycemic levels, or even improving healthy lifestyle habits and quality of life).

2.2. Participants

2.2.1. Eligibility criteria

The *inclusion criteria* of the participants will be: (a) Being 18 years or older; (b) having smoked 10 or more cigarettes per day within the last year; (c) meeting nicotine dependence criteria according to the *Diagnostic and Statistical Manual of Mental Disorders – 5^a Edition* [35]; (d) complying with baseline scores equal to or higher than 4 particles per million (ppm) of carbon monoxide (CO) levels in expired air and more than 80 ng/ml of cotinine levels in urine, and (e) having a diagnosis of T2DM and receiving routine medical treatment for this condition.

The *exclusion criteria* will be: (a) Meeting comorbidity with severe psychological or psychiatric disorders; (b) having a diagnosis of Diabetes Mellitus Type 1 (DMT1) or gestational diabetes mellitus; (c) meeting comorbid physical or neurological problems impairing communication; (d) meeting the criteria for any physical health condition whose medical treatment is incompatible or contraindicated for the development of the smoking cessation treatment (for example, comorbid physical problems such as neurological disorders which may impair communication); (e) receiving other psychological or pharmacological treatment for smoking cessation at the time of recruitment; (f) not being able to attend all treatment sessions and (g) not being fluent in Spanish.

2.2.2. Sample size and power analysis

To calculate the sample size, an alpha risk of 0.05 and a beta risk of 0.2 will be assumed in a bilateral contrast (statistical power of 80 %). The sample size will be estimated in unfavorable or unwanted conditions (considering the requirement of a greater number of patients due to experimental mortality processes), to detect statistically significant differences between the three experimental conditions. Using the statistical program G × Power 3.1 [36], it is estimated that a minimum of 17 participants per trial arm (51 across the three arms) would be needed to detect statistically significant differences between the groups. This estimate has been calculated assuming 30 % loss to follow-up [36]. It is expected that a small percentage of the sample will not complete the treatment or attend long-term follow-ups; therefore, the aim of including 90 participants in the study (i.e., 30 smokers in each experimental condition) will be pursued.

2.2.3. Recruitment and eligibility of participants

Firstly, recruitment will be carried out throughout the community, by disseminating the project using flyers and posters through different community settings, including healthcare centers (e.g., hospitals or outpatients' clinics), local associations, libraries, pharmacies, college campuses, etc. Moreover, we will disseminate this project through social networks and web applications (e.g., Twitter, Instagram, Facebook, electronic bulletin boards of different universities, etc.). Secondly, possible participants would contact the telephone number or email provided and the researcher would inform them about the project in progress. If smokers wish to participate, they will be assigned to an initial assessment. During the baseline evaluation, the patients will read the project information sheet and will sign the informed consent prior to their participation in the study. After that, a battery of questionnaires will be applied to verify that the participant meets the inclusion/exclusion criteria.

2.2.4. Randomization and blinding procedures

Patients meeting criteria will be randomly assigned to: (1) Control Group (waiting list, n = 30); (2) Experimental Group 1 - Cognitive-behavioral treatment (CBT) for smoking cessation (n = 30); (3) Experimental Group 2 - CBT for smoking cessation + *DiMeSALUD2* protocol (n = 30). A member of the research not directly involved in the trial (i.e., implementation of assessments and/or treatment sessions) will create a simple computer-generated randomization sequence using *Research Randomizer* software (version 4.0; http://www.randomizer.org) [37].

Our study will be single-blinded, since the psychologists in charge of the implementation of the interventions will necessarily be knowledgeable of the treatment applied (in trials where interventions of a psychological nature are assessed, it is usually not possible to mask the professionals implementing the intervention) [34]. Nonetheless, it should be noted that an independent outcomes assessor will conduct both the randomization procedures and data analyses. Furthermore, the following strategies will be carried out: 1) specialized training for psychologists on the treatments to be implemented; and 2) rotation of professionals through all treatment modalities.

2.2.5. Ethical considerations

This study has been approved by the Ethics Committee for Human Research of the University of Seville (reference no. 0722-N-22; date October 26, 2022), which includes a data and Safety Monitoring Board. The intervention will be conducted in accordance with the principles expressed in the Declaration of Helsinki. This protocol has been previously registered in https://clinicaltrials.gov/(identifier number NCT05885659; date of registration June 2nd, 2023).

2.2.6. Interventions

All interventions will be conducted by certified psychologists with masters' degree and PhD in health psychology. Table 1 summarizes the main components of the standard cognitive-behavioral multicomponent treatment and the *DiMe-SALUD2* protocol.

2.2.6.1. Cognitive-behavioral multicomponent treatment (CBT) for smoking cessation. CBT was designed based on previous studies [38–40]

Table 1
Summary of the main components of the standard cognitive-behavioral treatment (CBT) for smoking cessation and CBT + DiMeSALUD2 protocol, session by session.

Multicomponent program (Standard cognitive-behavioral treatment)			Multicomponent program (standard cognitive-behavioral treatment) plus DiMe-SALUD2 protocol		
Sessions	Components	Biochemical samples	Sessions	Components	Biochemical samples
Pre-treatment	Pre-treatment assessment (baseline)	CO/Cotinine Glycemic control monitoring	**Pre-treatment**	Pre-treatment assessment (baseline)	CO/Cotinine Glycemic control monitoring
1	Motivational Interviewing (MI) Tobacco psychoeducation Functional behavioral assessment of smoking behavior Behavioral contract Graphic representation of consumption Nicotine fading (30 % reduction)	CO/Cotinine Glycemic control monitoring	**1**	Motivational Interviewing (MI) Tobacco psychoeducation + **Specific tobacco and T2DM interaction psychoeducation** Functional behavioral assessment of smoking behavior **and impact on T2DM** Behavioral contract Graphic representation of consumption Nicotine fading (first 30 % reduction)	CO/Cotinine Glycemic control monitoring and **specific feedback on possible glycemic alterations**
1-A (control session)	–	CO/Cotinine Glycemic control monitoring	*1-A (control session)*	–	CO/Cotinine Glycemic control monitoring and **specific feedback on possible glycemic alterations**
2	Functional behavioral assessment of smoking behavior Choosing at least three situations where smoking will not occur Stimulus control guidelines General relaxation techniques Graphic representation of consumption Nicotine fading (60 % reduction)	CO/Cotinine Glycemic control monitoring	**2**	Functional behavioral assessment of smoking behavior **and impact on T2DM** Choosing at least three situations where smoking will not occur Stimulus control guidelines + **Specific tobacco and T2DM interaction psychoeducation** General relaxation techniques + **Specific psychoeducation on relaxation, T2DM and smoking interaction** Graphic representation of consumption Nicotine fading (60 % reduction)	CO/Cotinine Glycemic control monitoring and **specific feedback on possible glycemic alterations**
2-A (control session)	–	CO/Cotinine Glycemic control monitoring	*2-A (control session)*	–	CO/Cotinine Glycemic control monitoring and **specific feedback on possible glycemic alterations**
3	Choosing three new situations where smoking will not occur Stimulus control guidelines General physical exercise guidelines General weight control guidelines Graphic representation of consumption Nicotine fading (90 % reduction)	CO/Cotinine Glycemic control monitoring	**3**	Choosing three new situations where smoking will not occur Stimulus control guidelines **Specific physical exercise guidelines for T2DM patients who smoke + Weekly record sheet** **Specific weight control guidelines for T2DM who smoke + Psychoeducation about the interaction of withdrawal symptoms, anxiety, unhealthy increased eating, worsening of glycemic control and risk of relapse + Weekly record sheet** Graphic representation of consumption Nicotine fading (90 % reduction)	CO/Cotinine Glycemic control monitoring and **specific feedback on possible glycemic alterations**
3-A (control session)	–	CO/Cotinine Glycemic control monitoring	*3-A (control session)*	–	CO/Cotinine Glycemic control monitoring and **specific feedback on possible glycemic alterations**
4	Choosing three new situations where smoking will not occur Stimulus control guidelines General guidelines for anxiety and stress management Problem-solving training Graphic representation of consumption Nicotine fading to smoking abstinence	CO/Cotinine Glycemic control monitoring	**4**	Choosing three new situations where smoking will not occur Stimulus control guidelines **Specific guidelines for anxiety and stress management for T2DM patients who smoke + Psychoeducation about the interaction of anxiety and stress, with unhealthy increased eating and absence of physical exercise** **Specific problem-solving training for T2DM patients who smoke + Not using unhealthy food as a coping strategy** **Weekly physical exercise record sheet**	CO/Cotinine Glycemic control monitoring and **specific feedback on possible glycemic alterations**

(*continued on next page*)

Table 1 (*continued*)

Multicomponent program (Standard cognitive-behavioral treatment)			Multicomponent program (standard cognitive-behavioral treatment) plus DiMe-SALUD2 protocol		
Sessions	Components	Biochemical samples	Sessions	Components	Biochemical samples
				Weekly weight control record sheet Graphic representation of consumption Nicotine fading to smoking abstinence	
4-A (control session)	–	CO/Cotinine Glycemic control monitoring	*4-A (control session)*	–	CO/Cotinine Glycemic control monitoring and **specific feedback on possible glycemic alterations**
5	Analysis about the personal meaning and first sensations of quitting Review of previous guidelines in case of continued smoking Coping with withdrawal symptoms Relapse prevention strategies Graphic representation of consumption (if so) or days of abstinence	CO/Cotinine Glycemic control monitoring	**5**	Analysis about the personal meaning and first sensations of quitting Review of previous guidelines in case of continued smoking **Specific coping with withdrawal symptoms for T2DM patients + Psychoeducation on how to distinguish common withdrawal symptoms of hyper/hypoglycemia symptomatology** **Weekly physical exercise record sheet** **Weekly weight control record sheet** Relapse prevention strategies Graphic representation of consumption (if so) or days of abstinence	CO/Cotinine Glycemic control monitoring and **specific feedback on possible glycemic alterations**
5-A (control session)	–	CO/Cotinine Glycemic control monitoring	5-A (control session)	–	CO/Cotinine Glycemic control monitoring and **specific feedback on possible glycemic alterations**
6	Review of previous guidelines in case of continued smoking Review about how to cope with withdrawal symptoms Smoke-free living activities Relapse prevention strategies Graphic representation of consumption (if so) or days of abstinence	CO/Cotinine Glycemic control monitoring	6	Review of previous guidelines in case of continued smoking **Review about how to cope with withdrawal symptoms for T2DM patients + Psychoeducation on how to distinguish common withdrawal symptoms of hyper/hypoglycemia symptomatology** Smoke-free living activities **Weekly physical exercise record sheet** **Weekly weight control record sheet** Relapse prevention strategies Graphic representation of consumption (if so) or days of abstinence	CO/Cotinine Glycemic control monitoring and **specific feedback on possible glycemic alterations**
6-A (control session)	–	CO/Cotinine Glycemic control monitoring	6-A (control session)	–	CO/Cotinine Glycemic control monitoring and **specific feedback on possible glycemic alterations**
7	Review of previous guidelines in case of continued smoking Review of smoke-free living activities Strengthening relapse prevention strategies General long-term abstinence guidelines Graphic representation of consumption (if so) or days of abstinence	CO/Cotinine Glycemic control monitoring	7	Review of previous guidelines in case of continued smoking Review of smoke-free living activities **Weekly physical exercise record sheet** **Weekly weight control record sheet** Strengthening relapse prevention strategies + **Specific guidelines for T2DM patients** **Long-term abstinence guidelines adapted to T2DM patients** Graphic representation of consumption (if so) or days of abstinence	CO/Cotinine Glycemic control monitoring and **specific feedback on possible glycemic alterations**
7-A (control session)	–	CO/Cotinine Glycemic control monitoring	*7-A (control session)*	–	CO/Cotinine Glycemic control monitoring and **specific feedback on possible glycemic alterations**
8 (Post-treatment)	Therapeutic closure Post-treatment assessment	CO/Cotinine Glycemic control monitoring	**8 (Post-treatment)**	Therapeutic closure Post-treatment assessment	CO/Cotinine Glycemic control monitoring and **specific feedback on possible glycemic alterations**

where its efficacy for the treatment of adult smokers has been widely demonstrated. This cognitive-behavioral multicomponent program will be implemented in group-based sessions of four to six patients, carried out once a week over an eight-week period. CO and cotinine specimens will be collected in these group sessions as well as in control sessions, that will be scheduled midweek between sessions to monitor patients' weekly progress. These will be brief sessions (approximately 15 min) and will take place at the same location as the group sessions.

This CBT program [39] includes three different stages: (1) *Motivational interviewing to stop smoking*, aimed at increasing the motivation and commitment to quit, and (2) *smoking cessation*, focused on nicotine fading from the first to the fourth session. In particular, smokers are guided to gradually reduce a 30 % of their consumption of tobacco each week, following different strategies such as limiting the maximum number of cigarettes smoked per day, changing the brand of the preferred type of cigarettes and decreasing nicotine levels per cigarette; and (3) *maintenance of abstinence and relapse prevention strategies*, aimed at strengthening nicotine abstinence from the fifth session onwards and preventing relapses at long-term.

This modality of treatment also includes the following components [39,40], among others: Therapeutic contract, self-monitoring and graphical representation of tobacco consumption, psychoeducation about tobacco and specific characteristics of smoking behavior, stimulus control, strategies for coping with nicotine withdrawal symptoms, physiological feedback of consumption, social reinforcement when meeting nicotine reduction and abstinence goals, training in alternative behaviors to consumption and strategies for relapse prevention.

2.2.6.2. Training protocol on healthy lifestyle habits and self-management of T2DM (DiMe-SALUD2 protocol) added to usual care (CBT for smoking cessation). CBT plus DiMe-SALUD2 protocol will be developed as in the previous group, but with the addition of a psychoeducational protocol specifically designed to address the particular needs of T2DM smokers. The main components of this protocol will be focused on strengthening healthy lifestyle habits and will be structured around the following core elements: dietary control and healthy nutrition, physical exercise, and glycemic control through registration of both glycemic variability and nicotine fading or abstinence (see Table 1).

Overall, adding these components will allow to increase the natural reinforcement mechanisms of those healthy habits incompatible with smoking behavior. These activities will be developed in accordance with international [7,15,16,41,42], national [43] and regional guidelines [44–46], which include the most important clinical practices for carrying out diet, physical exercise and glycemic control among T2DM patients. If necessary, the therapist will adapt these guidelines according to their usual medical care.

2.2.6.3. Control group: waiting list. T2DM smokers in the control group will receive brief psychoeducation advice about smoking cessation as well as a general smoking cessation brochure/booklet. These participants will also participate in the scheduled assessments, but without receiving any of the intensive treatments previously described. Once the research project is completed, the patients in this control group will be offered to participate in the intervention program that demonstrates the highest long-term effectiveness and efficiency.

2.2.7. Data collection

Assessments will be carried out at baseline, post-treatment and at follow-ups (at 1-, 6- and 12-months after treatment completion (see Table 2). In our study, the 1-month follow-up was chosen based on previous studies [38–40] and given the special needs of the T2DM participants, who face greater barriers to maintain abstinence and greater risk of relapse in comparison to the general population. All patients will be evaluated according to this schedule. These assessment appointments will require approximately 60–90 min.

2.2.7.1. Brief personal and sociodemographic data sheet. This section will include the full name, contact information and sociodemographic data of participants: age, gender, nationality, residence, education, job, marital status and perceived socioeconomic level, using the MacArthur Scale of Subjective Social Status – Adult Version (MacArthur SSS Scale) [47].

2.2.7.2. Smoking-related characteristics. Information will be collected regarding the number of cigarettes per day, other possible ways of smoking behavior (pipe, e-cigarettes, hookah, etc.), age of smoking onset, years of regular smoking, number of quit attempts and, if applicable, the longest period without smoking and the reasons for relapse. Additionally, stages of change regarding tobacco use will be evaluated according to the Prochaska and DiClemente's transtheoretical model of change [48,49].

2.2.7.3. Clinical variables related to T2DM. This section will evaluate medical complications related to diabetes and cardiovascular diseases. Therapists will also assess T2DM onset and its clinical evolution. Patients will be provided with an information leaflet to deliver to their medical care service to inform them on their participation in this project.

Table 2
Data collection schedule for CBT, CBT-*DiMe-SALUD2* and control group.

Instruments	Variables	Baseline	Post-treatment	Follow-ups after treatment completion		
				1-month	6-months	12-months
Brief personal and sociodemographic data sheet	Sociodemographic	X				
Smoking pattern and state of change[a]	Tobacco use pattern and state of change	X	X	X	X	X
Clinical variables related to T2DM	T2DM	X				
Nicotine dependence						
SCID-5	Tobacco Use Disorder	X				
FTND[a]	Physical ND	X	X	X	X	X
B-WISDM[a]	Smoking dependence motives	X	X	X	X	X
Mental health						
STAI	Anxiety (State – Trait)	X	X	X	X	X
BDI-II	Depressive symptoms	X	X	X	X	X
Healthy lifestyle habits and quality of life						
ADDQoL	Diabetes quality of life	X	X	X	X	X
MEDAS	Diet	X	X	X	X	X
IPAQ-SF	Physical activity	X	X	X	X	X

ADDQoL = Audit of Diabetes Dependent Quality of Life; BDI-II: Beck's Depression Inventory-Second Edition; FTND = Fagerström Test for Nicotine Dependence; IPAQ-SF = International Physical Activity Questionnaire Short Form; MEDAS = Mediterranean Diet Adherence Screener; SCID-5 = Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition; STAI = State-Trait Anxiety Inventory.

[a] = Only for smokers at post-treatment and follow-up (1-, 6- and 12-months).

2.2.7.4. Nicotine dependence. The *Fagerström Test for Nicotine Dependence*, FTDN [50] will be used to evaluate nicotine dependence. This scale includes 6 items and provides five levels (very low, low, medium, high, and very high) of nicotine dependence severity. The Spanish adaptation was conducted by Becoña & Vázquez ($\alpha = .66$) [51].

To determine the presence of a Tobacco Use Disorder (TUD) according to the DSM-5 criteria [35], the *Structured Clinical Interview for the DSM-5* (SCID-5) [52] will be applied. The SCID-5 evaluates the presence of 11 criteria of nicotine dependence in the last year to establish TUD severity (absence, minimal, moderate and severe).

The brief version of the *Wisconsin Inventory of Smoking Dependence Motives*, B-WISDM [53] will measure the multidimensional nature of nicotine dependence. This scale contains 37 items and 11 different subscales classified into Primary and Secondary Dependence Motives. The Spanish adaptation conducted by López-Núñez et al. [54] showed high internal consistency ($\alpha = .95$; dimension α values ranging between 0.657 and 0.921).

2.2.7.5. Mental health. The *State-Trait Anxiety Inventory,* STAI [55] will assess anxiety symptoms across 40 items answered with a 4-point Likert-type response and divided into two subscales: State anxiety (20 items) and Trait anxiety (20 items). The Spanish adaptation [56] has demonstrated high internal consistency ($\alpha = .90$ for Trait anxiety and 0.94 for State anxiety) [57].

Depressive symptomatology will be assessed using the *Beck's Depression Inventory-Second Edition,* BDI-II [58]. This 21-item instrument assesses the severity of depression using a 4-point Likert-scale, allowing for the classification of patients in four different subgroups (normal to minimal, mild, moderate, and severe depression). The Spanish adaptation of Sanz et al. [59] has shown high internal consistency ($\alpha = .87$).

2.2.7.6. Healthy lifestyle habits and quality of life. Audit of Diabetes Dependent Quality of Life, ADDQoL [60]. This instrument measures quality of life (QoL) in diabetic patients ($\alpha = .85$). It contains 19 items aimed at measuring the impact of diabetes on different areas of life, and two additional overview items which analyze generic "present QoL" and specific "impact of diabetes on QoL". The ADDQoL will be used in this project with the consent from the author (Spanish version obtained via Health Psychology Research, UK; www.healthpsychologyresearch.com; License ref. CB1428).

Mediterranean Diet Adherence Screener (MEDAS) [61]. This questionnaire measures adherence to the Spanish Mediterranean diet thought 12 items regarding frequency of food consumption and 2 items about food habits (α not provided). We will use the modified version of 13 items recommended by the Andalusian Government and published by Maqueda et al. [62], who excludes item 8 related to wine consumption. The MEDAS includes dichotomous response options (0 = non-adherent or 1 = adherent to MD) and results equal to or greater than 8 points represent good adherence.

International Physical Activity Questionnaire Short Form (IPAQ-SF) [63]. This questionnaire consists of 7 multiple-choice items on the level of physical activity (high, moderate, low/inactive), evaluating the minutes of walking throughout the week and the number of weekly minutes devoted to moderate and to vigorous physical activity. Each activity is scored based on its METS (Metabolic Rate Units per minute per week). We will use this short version validated in Spanish by Rodríguez-Muñoz et al. [64] (α not provided) and recommended by the Andalusian Government [62,65].

2.3. Data analyses

We will examine the following primary outcomes: (1) smoking abstinence, including both the 24-h point prevalence abstinence (PPA) at post-treatment and 7-day PPA at different follow-ups, and (2) mean number of days of smoking continuous abstinence (defined as maintained smoking abstinence since the last time participants smoked, considering even a puff). On the other hand, the secondary outcomes will include: (1) treatment retention (number of sessions the participants have attended during the eight weeks of treatment); (2) stages of change and nicotine dependence characteristics of smokers who have not quit smoking or have relapsed; (3) changes occurring in clinical variables related to T2DM, especially the variability of glycemic levels (HbA_{1c}); (4) impact on mental health, and (5) changes in healthy lifestyle habits and quality of life.

The study groups will be controlled for identifying differences derived from the nature of the groups and the possible mediating role of such differences. In addition, sensitivity analyses will be carried out to analyze whether included participants are different from those excluded. Bivariate analyses will be conducted to provide basic descriptive statistics, including parametric and nonparametric analyses depending on the nature of the variables. Multivariate analyses of repeated measures are planned, considering both the primary and secondary variables previously described [66]. Besides calculating statistically significant differences, Minimum Clinically Important Difference (MCID) indexes will be considered for the main health outcomes when possible [66]."

Regarding the biochemical measures, self-reported abstinence will be confirmed by a negative result for the CO (less than 4 parts per million) and the urine cotinine tests (less than 80 ng/ml). It should be noted that both primary and secondary outcomes will be evaluated at the initial assessment (baseline), at post-treatment and at different follow-up assessments (1-, 6- and 12-months after treatment completion). Additionally, CO and urine cotinine tests will be conducted at all treatment sessions as well as at all follow-up assessments.

All analyses will be conducted using an intention-to-treat approach [67], with the aim of preserving the randomization of the participants. The SPSS statistical package (version 26.0; SPSS, Inc., Chicago, IL) and STATA-15 will be used for the analysis of the differential effectiveness and efficiency of the *DiMe-SALUD2* protocol.

3. Discussion

This protocol describes a study aimed at assessing the effectiveness and efficiency of a psychoeducation protocol on healthy lifestyle habits and self-management of T2DM plus CBT for smoking cessation among Spanish T2DM smokers (*DiMe-SALUD2* project). We hypothesize that the CBT + *DiMeSALUD2* group will achieve better results in terms of efficacy and efficiency at both short- and long-term follow-ups compared to CBT alone and the control group. Moreover, we assume that this intervention will have a positive impact on the physical and psychological health of participants due to the increased metabolic control and healthy lifestyle habits. Since current interventions do not usually address the characteristics and needs of T2DM smokers, these outcomes could help improving routine clinical care in the future.

The main strength of this intervention proposal is that the *DiMe-SALUD2* protocol includes different key components for smoking cessation that should be core aspects for T2DM smokers, such as glycemic control, healthy nutrition and physical exercise. These have been chosen as key elements in our treatment proposal as previous studies have indicated that smoking cessation may imply poorer metabolic control [13] and weight gain [68], characteristics that have not been considered so far in smoking cessation interventions conducted in this population. In particular, the effect of smoking on glycemic control in people with diabetes has shown contradictory results [1], since previous research has demonstrated that diabetic smokers usually present with poorer glycemic control [69] and smoking cessation does not increase HbA1c levels at long-term follow-ups [13]. However, other studies [70] have reported that quitting is related to increasing HbA1c levels (mostly during the first year after quitting). Consequently, it seems crucial to monitor glycemic variations in the participating of this study.

It is also important to promote healthy nutrition changes in the

dietary habits since smoking cessation may lead to an increased intake of high-calorie foods, resulting in bodyweight gain [71]. In this sense, evidence shows that weight gain can lead to poor diabetes control for T2DM smokers [68,72], with women being particularly at risk of gaining weight and, therefore, perceiving more barriers to stop smoking [73]. Moreover, some diabetic smokers report using tobacco as a weight control strategy and express concern about the potential impact of quitting on their DM management [74,75]. Providing information about what is considered a suitable physical exercise for T2DM smokers, as well as which specific exercises have an impact on improving glycemic levels could help managing both the participants' physical health and their smoking cessation efforts. For all these reasons, glycemic and weight control, healthy nutrition and physical exercise should be core components of smoking cessation treatments tailored to this specific population [72,76].

Our project will address these key targets for the treatment of TDM2 smokers by offering a structured psychoeducational program that complies with previous guidelines recommending longer behavioral and disease specific interventions to increase long-term abstinence among diabetic smokers [2]. In particular, Grech et al. [12] highlight that intensive smoking cessation programs may help succeeding in quitting by providing frequent smoking cessation support developed at least during three or four sessions that should last more than 20 min. Additionally, since the greatest glycemic variability related to smoking cessation can occur during the first year [72], we propose to carry out periodic follow-ups after the end of the program at 1-, 6-, and 12-months follow-ups.

Our protocol design is not exempt from limitations. Firstly, we will not be able to include participants meeting comorbidity with severe psychological or psychiatric disorders or even with certain medical health conditions, which could limit the representativeness of the sample. In addition, participants will continue to receive their usual medical treatment and may be exposed to additional medical advice for smoking cessation during the program, which could potentially confound the results of our RCT protocol. Furthermore, participants with different T2DM characteristics regarding their onset, clinical evolution, or diabetes-related medical complications will be included. Such heterogeneous T2DM features could have a significant impact on future smoking cessation' outcomes. Finally, despite the solid methodology used to elucidate the minimum number of participants required to detect significant differences between conditions, possible dropouts, as well as the limitation in the number of participants and the nature of the active intervention could lead to difficulties in detecting statistically significant differences between conditions.

4. Conclusions

Beyond the aforementioned shortcomings, we expect positive results on smoking cessation for those T2DM patients that will participate in our project. These results could, in turn, contribute to additional long-term positive health outcomes such as decreased rates of heart attacks and stroke [5,70], reduced cardiovascular complications and improvements on their lipid profile [13] and even mortality reduction [74], among others. We also aim to overcome limitations of previous research such as the application of general and non-specific interventions to T2DM smokers, the small samples' size or even the lack of methodological quality of some studies [2,12,20]. More importantly, we intend to expand on the limited scientific evidence that currently exists on the effects of smoking cessation programs tailored to T2DM smokers [12, 20]. We expect that this program will help T2DM smokers to quit as well as to improve their overall quality of life at both short- and long-term.

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CRediT authorship contribution statement

Carla López-Núñez: Writing – original draft, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization. **Sergio Fernández-Artamendi:** Writing – review & editing, Writing – original draft, Methodology, Conceptualization. **Desirée Ruiz-Aranda:** Writing – review & editing, Methodology, Conceptualization. **Davinia María Resurrección:** Writing – review & editing, Methodology. **Desirée Navas-Campaña:** Project administration, Methodology, Investigation, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare no conflicts of interest.

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