Hybridized Three Steps (HITS) Intervention to Prevent Diabetes in Venezuela: HITS Diabetes With Prevention, An EVESCAM Lifestyle Intervention Study
Study Protocol

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Hybr**i**dized **T**hree **S**teps (HITS) Intervention to Prevent Diabetes in Venezuela. HITS Diabetes with Prevention, An EVESCAM lifestyle intervention study.

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Introduction

In Venezuela, mortality for cardiovascular disease (CVD) was responsible for 30.5% of all deaths, increasing by 8.3% since 2007 to 2017[1,2]. The prevalence of cardiometabolic risk factors in the country is also increasing. We led two cross-sectional surveys in Venezuela, the VEMSOLS[3-7], evaluating 1320 adults between 2006 to 2010, and the EVESCAM, a national representative sample of 3420 adults, from 2014 to 2017[8-12], and

the change of cardiometabolic risk factors prevalence was hypertension from 30.0% to 34.1%, metabolic syndrome from 35.7% to 42.2%, diabetes from 8.0% to 12.3%, and prediabetes from 14.4% to 34.9%. Prediabetes increased 242% in a decade, from 2.4 to 7 million of adults, representing that around 1.7 million of adults could advance to type 2 diabetes (T2D) in the next 3 to 5 years (For glossary of terms see Supplements).

The American Diabetes Association recommends implementing the Diabetes Prevention Program (DPP) in subjects with prediabetes[13]. This program aims weight reduction increasing physical activity and healthy eating. In controlled settings, DPP has consistently proved to reduce T2D incidence by 58%, with long term benefits[13]. However, to translate this effectiveness to primary care settings is a major challenge. In Latin America, two studies on T2D prevention were done at the same time, funded by an International Diabetes Federation (IDF) initiative[14], with contradictory results. In Venezuela, Florez et al.[15] implemented a Randomized Controlled Trial (RCT) using the US-DPP version, with a multidisciplinary team, on 140 adults with prediabetes and overweight, to receive standard care vs. lifestyle intervention (LSI), during two-years. LSI group lost more than 10% of basal weight compared with 2.3% in the standard care group ($p< 0.001$), none developed T2D compared with 6% of the crude cumulative incidence of T2D in the standard care group ($p<0.05$)[15], and lipid profile and cardiovascular health score also improved[15]. Contrarily, in Colombia, Barengo et al[16] implemented the Finnish Diabetes Prevention Study (DPS) in primary health care centers, provided by specialist in physical activity and nutritionist, on 772 adults with prediabetes, randomly assigned to LSI vs. standard care, during two-years, with no effect on metabolic components, reversion to normoglycemia and T2D incidence were similar between groups[16]. A meta-analysis of 36 pragmatic clinical trials of diabetes prevention programs in primary care settings showed a reduction in T2D incidence by 26%[17], less than half than the original studies (58%)[18,19]. In these studies LSI only showed a pooled mean weight loss 1.57 kg higher than standard care[17], demonstrating the large difficulties to reduce weight of participants at community levels.

This team is leading in Venezuela a transculturalization process incorporating multiple validated components to significantly improve the effectiveness of preventive medicine initiatives for T2D in Venezuela, and by extension, positively impact T2D incidence, prevalence, quality of life, and health care costs[20-22] (Figure 1).

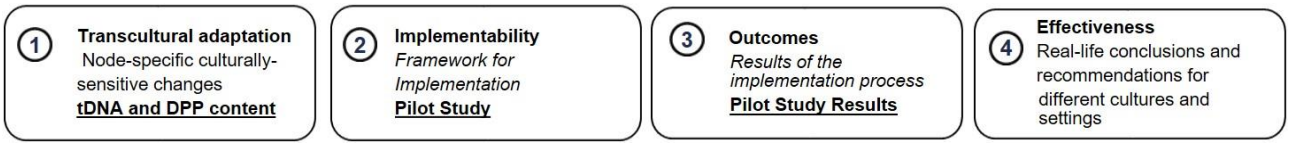

Figure 1: Transculturalization process implemented in Venezuela. From the transcultural adaptation to the evaluation of the effectiveness of evidence-based recommendations. This project represents the step 4.

This process is based on the transcultural Diabetes Nutrition Algorithm (tDNA)[23] adapted to Venezuela[24], which includes a stepwise an approach to detect subjects at risk using locally validated tool (LA-FIDNRISC)[25], and a protocolized intervention to provide medical nutrition therapy that includes structured low-calorie meal plan, diabetes-specific meal replacements, as well as, start or increase physical activities, get enough sleep, and tobacco cessation. (Figure 2 – Supplement). Our work also includes cultural adaption of the DPP content to the Venezuelan population (e.g. change the names of foods, units of measure, incorporate local healthy foods, warning for unhealthy traditions) and the implementation of two pilot studies (More details below).

To prevent T2D effectively, LSI programs need to induce weight loss. In the DPP, weight reduction was the main predictor of a lower incidence of T2D, each kilogram lost was related with 16% lower incidence[26]. Total diet replacement (TDR) with low-energy liquid-diet or solid diet (825–853 kcal/day) is an effective strategy to reduce weight[27]. In the PREVIEW study, 2224 participants with prediabetes and obesity received a low energy

diet during 8-week and presented a mean weight loss of 10.7 ± 0.4 kg[28], and 83.5% achieved the target of ≥8% weight reduction, the three-years expected incidence of T2D was only 4%, independent on the intervention used post-weight-loss[29]. However, effectiveness of intervention including initial rapid weight loss is ignored in primary care levels in Venezuela. In order to improve the effectiveness of T2D prevention programs are proposed the following objectives:

- To compare the weight loss achieved of two LSI programs in a community health center of Venezuela: **a)** A hybrid LSI including rapid weight loss with total diet replacement (TDR), then medical nutrition therapy (MNT), and the DPP, VS **b)** only the DPP.
- To evaluate the change of cardiometabolic risk factors between groups.
- To evaluate the implementation process.

Our hypothesis is: after six months of intervention, subjects receiving a hybridized LSI (TDR+MNT+DPP) will double the weight loss of those that only receive DPP (This is based on the pilot study – see below). If this outcome is achieved, it will have an enormous impact in the way that the DPP should be provided in the primary health care systems in developing countries, increasing the effectiveness of weight reduction, and in consequence, improving cardiovascular health.

Approach

Design: A pragmatic mix trial was designed with two groups a) subjects receiving a hybridized LSI (TDR-MNT-DPP) and b) only DPP.

Population: In Venezuela, there are many community health care centers (CHCs) attended by general physicians. Many of these are "communal houses", with different activities like dancing, aerobics, yoga, karate, etc. The CHC selected is in Mérida city, at the Andes region, with around 508.988 inhabitants, in 2018. The population is organized in "Communal Councils", representing a location or small sector, two or more create the "Commonwealth", representing neighborhoods or sectors. The CHC selected is in a commonwealth, mid-class urban area, easily accessible for the inhabitants. Community leaders are highly motivated to promote this kind of activities in their neighborhood.

Inclusion Criteria: Adults with 20 years or older, no personal history of T2D, BMI ≥ 25 kg/m^2, and high risk for T2D (see below) will be included.

Exclusion criteria: Self-report of the following conditions:

- Chronic ischemic heart disease: acute myocardial infarction, stable angina, unstable angina.
- Stroke.
- Use of anticoagulants
- Severe renal failure
- Heart failure.
- Cannot do moderate-intensity physical activity
- Cannot attend most sessions
- Pregnancy or plans of having during the next sixth months
- Cancer or chemotherapy.
- Use of medications that affect weight (e.g. levothyroxine, pregabalin, orlistat)

During the physical examination by the general practitioner:

- Peripheral obstructive arteriopathy.
- Osteoarthritis of knees, ankles or hips.
- Body mass index (BMI) ≥ 40 kg/m^2

- Systolic blood pressure ≥ 180 mmHg or diastolic blood pressure ≥ 110 mmHg.

At the end of the pilot study, emigration was the most important cause if dropout. Subjects with plans of migration in the following months during the study will be excluded. To avoid contamination risk, if a family member is selected, only one member per family will be included.

Sampling: Community members will be invited to a medical screening at the CHC. Those with high risk will be identified using the Latin America Finish Diabetes Risk Score (LA-FINRISC). The LA-FINDRISC is a non-invasive tool that includes age, body mass index (BMI), waist circumference, physical activity, daily consumption of fruits and vegetables, history of hyperglycemia, history of antihypertensive drug treatment, and family history of diabetes, assigning a score ranging from 0 to 26 points. In Venezuelan adults, 9 points are the best score (sensitivity 71.4% + specificity 65.4%) to detect subjects with impaired glucose tolerance[25]. Those with an LA-FINDRISC ≥ 10 points and having the inclusion criteria will be invited to laboratory test and medical evaluation and those with laboratory criteria will be invited to participate.

Sample Size: The formula to compare two mean was used. Based on preliminary results of our pilot study, the aim was to detect a two-fold reduction of weight loss in the intensive group (mean = 5.0 kg, standard deviation = 4.9) compared with only DPP (mean = 2.4 kg, standard deviation = 1.9). Using a Beta error of 0.2 and an Alpha error of 0.01, the sample size required for each group is 50, and assuming a 20% of loss to follow up (based on the pilot study), and a 30% additional to ensure representativeness of the sample and power, the sample size will be incremented to **78** participants in each group, total sample size of 156 participants.

Randomization: Eligible participants will be randomly assigned to hybridized LSI or standard care with 1:1 allocation.

Implementation:

Diabetes Prevention Program: The DPP Group Lifestyle Balance (GLB) core curriculum content modified from the original DPP is available online, in both English and Spanish. Despite the intent of facilitating T2D care for the U.S. Hispanic population, the advantage of the Spanish language version, and the robust and general recommendations in which the DPP GLB program is based, this effort was not a true transculturalization process. Important differences among various ethnocultural co-populations and environments were not addressed. For example, in Venezuela, there are unique culinary customs: units of measure during food preparation, types of whole foods in their natural form, and recipes with foods that are not easily available. In addition, recommendations of physical activities must be feasible for a certain population based on religious customs, social norms, the built environment, climate and terrain, and socioeconomic constraints; even, there are food patterns and behaviors regionally different in the same country[23].

The tDNA process was implemented in the following steps to undertake the transcultural adaptation of the DPP content: 1) *Identification target population:* adult's population in Venezuela. 2) *Identification of the topic or research/clinical question:* One out three adults in Venezuela has prediabetes. Evidence-based solutions are required to reduce diabetes burden in Venezuela. 3) *Team of experts in the source (DPP) and target population (Venezuelan culture):* A group of Venezuelan experts composed by four diabetologists, one primary care physician, and two community members trained and certificate by this team to provide T2D prevention programs implemented the adaptive content of the DPP GLB program. 4) *Identification and resolution of cultural nodes using a framework*: The DPP content was organized with the Ecological Validity Model (EVM)[30]. Using an interactive process each discrepancy between the content and cultural or local costumes were identified and modified in base to the EVM framework (e.g. recipes were adapted to the current socio-economic moment of the country). Finally, T2D prevention curriculum content was culturally adapted to Venezuelan adults avoiding any incongruence with the original version. Healthy options, goal settings, and problem-solving were consistent attributes of the culturally adapted program. Details of this transcultural adaptation will be published soon. This content was used in the pilot study.

Low-Energy Liquid-Diet (LELD): LELD, structured food reintroduction, and then a weight-loss maintenance program have demonstrated being a feasible and acceptable strategy to lose and maintain weight during 12 months[27]. A "home-made" milk- and fruit-juice-based diet (811 kcal/day, 64 g protein, 132 g carbohydrate, 6 g fat) will be recommended. Recipes and preparation techniques were transculturally adapted to the population using local available low-cost foods in Venezuela. A pilot study assessing acceptability, appropriateness, and feasibility of this LELD strategy in 14 Venezuelan adults with obesity is ongoing.

Implementation Process – The Pilot Studies

A major concern was the feasibility to implement an LSI program in the current environment of Venezuela. A pilot study implementing the DPP-tDNA was done in 26 adults in the CHC. Preliminary results are summarized in Table 1. Results are presented using the implementation process framework[31].

Table 1: Implementation Process[31] of the DPP-tDNA Pilot Study*

	n	%
Feasibility		
Screening	67	100.0
Invited to Evaluation (Meet the inclusion criteria)	47	70.1
Assisted to the Evaluation (% of those invited)	36	76.6
Started the Program	**26**	**72.2**
Assisted to only 1 session	4	**15.4**
Drop out (total)	7	26.9
Completed 3 months of intervention (10 sessions)	19	73.1
Fidelity		
Attendance to all the sessions	5	19.2
Attended ≥ 50% sessions	18	94.7
Average of Attendance	6.6	72.1
Acceptability (Likert scale from 1 to 5 points)	4.6	92.0
Appropriateness (Likert scale from 1 to 5 points)	4.6	92.0
Effectiveness	**n**	**% Goal†**
Mean of weight loss (Kilograms)	**2.45**	**88.2**
Subjects that reached the weight goal of the third month	6	31.6

*The pilot study is currently ongoing; these are the results of three months of intervention (50%) with 10 sessions provided. †Goal= to lose 7% of basal weight at the six months, corresponding to 3.5% in the third month.

More details of the implementation process results are in the Supplements (Table 2). Reasons of dropout were: emigration 3 (42.9%), family problems 2 (28.6%), financial problems 1 (14.3%), did not answer 1 (14.3%). Although this pilot study was implemented in the context of a complex humanitarian emergency in Venezuela, with a severe failure of basic services including extensive and repetitive blackouts, scare of gas and gasoline, and the highest inflation rate in the world[32], without a budget to provide proper tools to the participants and implementers, the intervention is feasible with a 26.9% of dropout, which is expected in community base scenarios, and with high average of attendance (72.1% - Fidelity). Participants considered the intervention acceptable and appropriate. The mean of weight loss was 2.45 kg in three months and 31.6% had reached the third-month goal.

A second concern was to assess the acceptance of a LELD intervention in Venezuelans. A pilot study to assess its implementation was undertaken in adults with increased weight. A nutritionist provided weekly group sessions recommending "Home-Made" LEDL replacing usual foods during a month, reintroduction diet for 1 week, and then four weekly educative sessions of maintenance weight program. 14 participants assisted to the

first session and nine started the program. In four weeks of intervention, the average weight reduction was 3.23 kg. Using a Likert scale, participants implementing the program (n=9) reported: frequency of secondary symptoms (dizziness, gastrointestinal disorders, headache, hunger, etc.) 0.8/3 points (never = 0 and very frequent = 3); severity of secondary symptoms: 0.5/3 points (mild = 0 and severe = 3); acceptability (satisfaction): 4.9/5 (totally disagree = 1 and totally agree = 5); appropriateness = 5/5 (totally disagree = 1 and totally agree = 5). In summary, the participants reported the intervention acceptable, appropriate, effective, and with a low frequency and intensity of secondary symptoms.

Effectiveness – Intervention. The Flowchart is presented in Supplements (Figure 3).

Duration: 6 months. The DPP has two phases, weight reduction to reach 7% of weight loss during the first sixth months, and weight maintenance during the next six months. This project aims to evaluate a new strategy to improve the effectiveness of weight reduction in the initial semester.

All participants will be attended by a physician and will receive current guideline recommendations to improve their cardiometabolic health. Healthy lifestyle recommendations including healthy diet, increase physical activity until reach 150 minutes weeks, and weight reduction will be recommended. These encounters will be repeated at the third and sixth months.

Standard Care: a trained peer-led (Coach) will provide a group-based DPP-GLB program in 16-sessions along 6-months. DPP has two primary goals: achieving at least 7% weight loss and engaging in 150 minutes per week of moderate physical activity. Participants will be introduced to self-monitoring of weight and management of the amount and frequency of food consumption, with an emphasis on the reduction of calories coming from fats.

Lifestyle intervention group: Participants in the hybridized LSI group will receive:

a) The nutritionist will provide a total diet replacement (TDR) with Low-Energy Liquid-Diet (LELD - 811 kcal/day, 64 g protein, 132 g carbohydrate, 6 g fat) and the food reintroduction for two months (Phase 1).
b) The nutritionist will provide Medical Nutritional Therapy (MNT) using the tDNA Toolkit adapted for Venezuela (Phase 2a).
c) The coach will provide a group-based DPP-GLB version in weekly encounters during 4-months (Phase 2b) (Similar than standard care)

This hybridized LSI has similar goals than the standard care group: achieving at least 7% weight loss and engaging in 150 minutes per week of moderate physical activity.

In phase 1, nutritionist in group sessions will recommend to participants to lose at least 7% of their weight using LELD for two months. LELD was related in the pilot study with a mean of weekly average weight loss of 0.8 kg. Participants will return after a week, and then bi-weekly encounters until complete food reintroduction. A "Home-Made" LEDL will replace usual foods, vitamin supplements will be recommended to participants during this phase. If during the year of intervention, the participant relapse (weight regain > 2 kg), TDR to replace one or two main-meal per day for 4 weeks will be recommended.

In phase 2 nutritionist will recommend weight maintenance or weight reduction strategies. In phase 2a nutritionist individually will recommend to participants medical nutrition therapy and healthy lifestyle recommendations using the Venezuelan's tDNA-Toolkit. Phases 2a and 2b will begin simultaneously. In phase 2b, the coach will provide group-based DPP-GLB program in 16-sessions along 4-months. Total intervention time planned include phases 1 and 2 is six months.

Training Peers: Coach can deliver educative programs in an acceptable way to their peers[33] and with similar effectiveness than health professionals[34,35]. The coach was already selected and trained using a face-to-face

approach during three-days, improving their knowledge on goal setting, action plans, problem-solving, and communications skills. During the intervention process, peers will be supervised and supported.

Side Effects and Weight Regain with Rapid Weight Loss: Beliefs that more intensive interventions and rapid weight loss lead to greater weight regain are not supported by evidence from controlled trials[27]. In a feasibility study in primary care, 97 participants (mean BMI of 48 kg/m^2) were recommended to receive TDR with LELD during 12 weeks, then food reintroduction and weight maintenance plan[36]. 64% completed the LELD stage with a mean of weight loss of 16.9 ± 6.0 kg. At 12 months, 75% (68/91) assisted to the evaluation and the mean weight loss was 12.4 ± 11.4 kg. In the qualitative analysis some experience transient constipation and dizziness[36]. In the DiRECT study (Remission of T2D study) was used the LELD during three months, at the year of one year intervention, nine serious adverse events were reported by seven (4%) of 157 participants in the intervention group and two were reported by two (1%) participants in the control group, these included gastrointestinal disorders, dizziness, and abdominal pain[37]. Those in the intervention group lost 14.5 kg during the TDR phase and then regained 1.0 kg during the food reintroduction phase and 1.9 kg during the maintenance phase[37].

Variables Evaluated: The list of variables is summarized in Supplements (Table 3).

Data analysis plan:

Aims comparing effectiveness: I will be done using an intention-to-treat analysis. To evaluate the distribution of values at baseline and after follow-up, Student t-test will be used to compare weight at baseline and at the end of the intervention, as well as, other continues variables (blood pressure, lipid profile, blood glucose, physical activity level, etc.). Chi-square test will be applied to assess the different proportion of subjects that reached their weight goal. To assess the implementation process will be applied the Implementation Outcomes Framework, this was partially reported in this project (Table 1), additionally, it will be evaluated the cost of the intervention. Implementation outcomes will be presented as proportions, means, and qualitative comments.

Research team and their role:

Two Lown Scholars, PI, and mentor designed the study, are going to supervise the implementation, do the analysis, and write the paper. An investigator from Icahn School of Medicine at Mount Sinai, New York, NY, USA, four co-investigators from the EVESCAM Research team, collaborated with the design and will collaborate with supervision of implementation, data analysis, and critical review. Implementers will coordinate intervention. The organizational structure includes: (a) Collaborative coordinating institution: Venezuelan Society of Internal Medicine (SVMI), Caracas, Venezuela; (b) Cardiometabolic Unit, Barquisimeto, Venezuela, where it is located laboratory (c) Field center: the Community health care center (d) Investigators (e) International consultants; (f) Local coordinators (n=2); (g) Nutritionist and research assistant (n=2); (h) Certified Coach (n=1). The budget will be administrated by the Foundation for Clinical, Public Health, and Epidemiological Research of Venezuela (FISPEVEN). See support letters

Timeline:

Months	1 - 3	4 - 9	10 – 12
Screening and Medical Evaluation	X		
Intervention		X	
Data analysis and draft writing			X

Challenges and Alternative Response

According to the observed in the pilot studies, there are two major challenges: a) *high dropout and lower fidelity*: a 20% of dropout is expected, however, implementers will be trained to be in continuous contact with the participants and maintain them highly motivated. Workshops of cooking and group physical activities are two

examples of activities that increased motivation and attendance rates. B) *Not compliance with the TDR*: In the pilot study, TDR showed being an effective way to lose weight, however, some participants didn't accept the TDR, others changed the components frequently, and some only replaced one or two main plates, to avoid these threats, well-designed recipes with lower cost available foods showed increase compliance, additionally, in the first session it will include a workshop of how to prepare different milkshakes, and how to improve its taste, and increase volume without increasing calories to avoid hunger, a large list of different milkshakes will be provided.

Ethics:

This project will be registered in ClinicalTrials.gov. This study protocol was designed in compliance with the Helsinki declaration. The protocol and informed consent forms used in this project will be reviewed and approved by an ethics committee in Venezuela before its implementation. A researcher will read all the informed consent to the participant and will explain the benefits and risk of participation in the study answering all his/her questions, this includes: rationally of the study, identification of subjects at risk, random assignation, responsibilities, duration, potential health benefits, data management (with special emphasis in their confidentiality), and wiliness to participate, including that his/her participation it can last as long as the participant want (for more detail see Informed Consent). Then, if the participant decides to participate will sign the informed consent. This will take place in the primary health care center where the intervention will be done, after the campaign of screening of risk factors in the community.

Management of Secondary Effects:

All the participants will be attended by a specialist in Internal Medicine three times throughout the study. A general practitioner will attend with the nutritionist to all the sessions of the implementation of the liquid diet, this represents that this will be under weekly medical surveillance during the most sensitive part of the process. Then, this physician will attend at least one per month to each session of the participants. If the patient presents an acute medical problem will be able to call the general physician of the team to receive medical attention, and this will be provided in the community health care center of the community, in case of more specialized advice, the general practitioner can request help to the specialist of internal medicine to attend the patient. If it is observed a secondary effect consequence to the intervention the nutritionist or the coach will modify the intervention according to the recommendations provided by the doctors to avoid related complications. All this medical attention potentially related to the participation of the study will be provided for free to the participants.

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Supplements

Glossary

BMI – Body Mass Index

CHC – Community Health Center

CVD – Cardiovascular Disease

DALY – Disability-Adjusted Life Year

DPP – Diabetes Prevention Program

EVESCAM – Venezuelan Study of Cardio-Metabolic Health

EVM – Ecological Validity Model

FISPEVEN - Foundation for Public Health and Epidemiology Research in Venezuela

GLB – Group Lifestyle Balance

IDF – International Diabetes Federation

LA-FINRISC – Latin America Finish Diabetes Risk Score

LELD – Low-Energy Liquid-Diet

LSI – Lifestyle Intervention

MNT – Medical Nutrition Therapy

RCT – Randomized Controlled Trial

T2D – Type 2 Diabetes

tDNA - transcultural Diabetes Nutrition Algorithm

TDR – Total Diet Replacement

PREVIEW – PREVention of diabetes through lifestyle Intervention and population studies in Europe and around the World

VEMSOLS – Venezuelan Study of Obesity, Metabolic Syndrome, and Lifestyle.

Table 2: Weight Change in Each Session and Evaluation of the Implementation Process of the Pilot Study

Sessions	1	2	3	4	5	6	7	8	9	10	Encounters	Assistance	Goal (7%)	Weight Change	% to the goal
Participant 1	64,2	63,2	63,6		62,4					59	5	50	4,5	5,2	115,7
Participant 2	75	74,1	73,3	72,4	72,7	71,3	71,7	71	70,9	69,6	10	100	5,3	5,4	102,9
Participant 3	87,1	86,5	85,1	85,4	83,9	83,6	83	81,9	81,6	81	10	100	6,1	6,1	100,0
Participant 4							75,7	75,5	73,9	70,9	4	100,0	5,3	4,8	90,6
Participant 5	80,8	79,8	79,5	77,9	78,4	78,3	77,6	77,3	77,1	77,3	10	100	5,7	3,5	61,9
Participant 6	81	82,7	80,1	81,4	78,6		78,3	77,8			7	70,0	5,7	3,2	56,4
Participant 7	77,2	77,8	76,9		77,1	76,2			76	74,8	7	70	5,4	2,4	44,4
Participant 8	87,6	87	85,5	87,6	86	86	85,2		85,7	85	9	90,0	6,1	2,6	42,4
Participant 9	96	97,2	95,3	95,3	93,2						5	50,0	6,7	2,8	41,7
Participant 10	82,4	81,8	81,8	81,8	80,4	80					6	60,0	5,8	2,4	41,6
Participant 11							91,8	92	90,1	89,3	4	100,0	6,4	2,5	38,9
Participant 12	70,4	69,6		69,6	69,7		68,5	68,5			6	60,0	4,9	1,9	38,6
Participant 13	84,7	84,5		81,2	81,4	82	82,7				6	60,0	5,9	2	33,7
Participant 14	79,8	80,1	78,7	79,6	80,2				78,8	78,8	6	60,0	5,6	1	17,9
Participant 15			73,3	73,6	72,7		73,6	72,1	74,1	72,6	7	70,0	5,1	0,7	13,6
Participant 16	94	93,6	93,4	93,5							5	50,0	6,6	0,5	7,6
Participant 17	57,8	58	56,6	58,3	58,9				57,8	57,8	6	60,0	4,0	0	0,0
Participant 18	67,4	66,5	66,6		67,6						4	40,0	4,7	-0,2	-4,2
Participant 19	78,6	78,7	78,1	78,6	78,2	78,8		78,7	78,9		8	80,0	5,5	-0,3	-5,5
										Averages	6,6	**72,1**	**5,54**	**2,45**	**44,1**
										Goal at the third month (3.5%)			2,77	2,45	**88,3**

Table 3: Variables to evaluate

Variables Months	Baseline	1	2	3	4	5	6
Height	x						
Weight	x	x	x	x	x	x	x
Waist circumference	x			x			x
Body fat percent	x			x			x
Blood pressure	x			x			x
Physical activity IPAQ	x			x			x
24 hours food count	x			x			x
EQ-5D	x			x			x
DS14 (Type D personality)	x			x			x
Acceptance questionnaire				x			x
Appropriateness questionnaire				x			x
Qualitative interviews				x			x
Sociodemographic data of humanitarian emergency	x						
Secondary effects questionnaire	x			x			x
Blood samples	x			x*			x

*Only fasting blood glucose

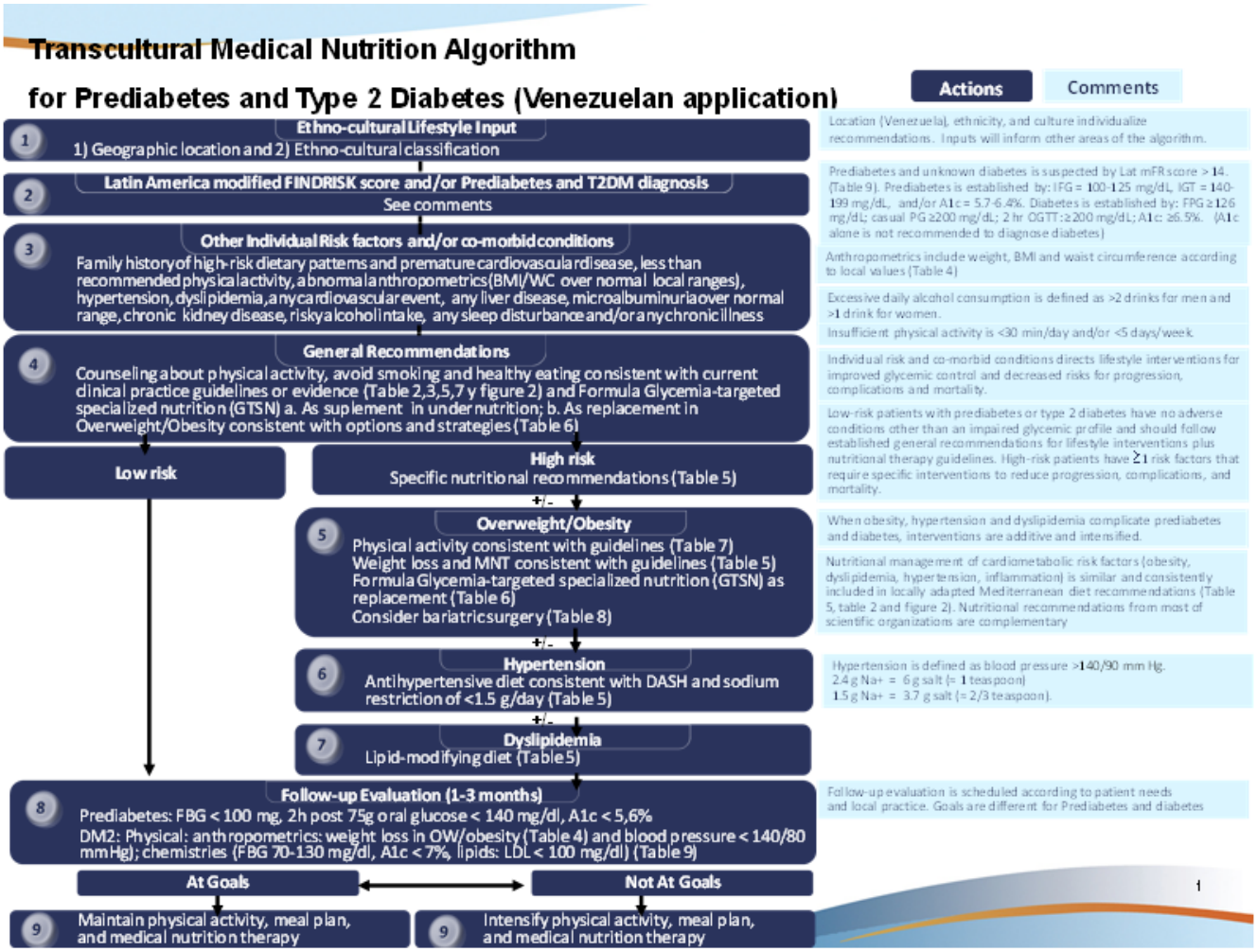

Figure 2: Transcultural Medical Nutrition Algorithm for Venezuela.

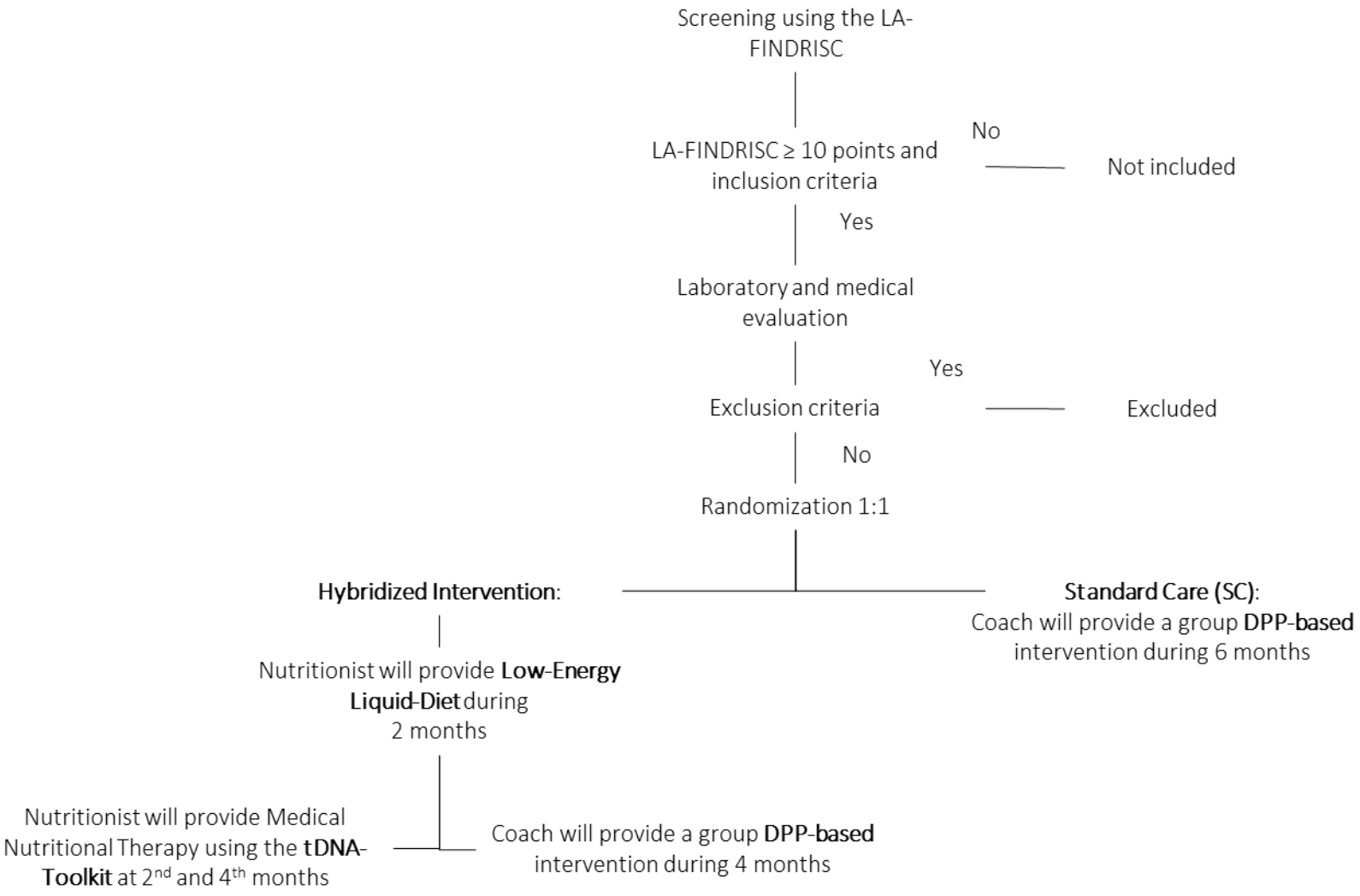

Figure 3: Flowchart of the screening and intervention