

Feasibility of a Soccer-based Adaptation of the Diabetes Prevention Program

Soccer DPP

Scientific Protocol

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Background and Rationale

Football (soccer) has proven successful as a health intervention globally, owing in large part to its extreme popularity with over 500 million active participants worldwide.(1) The Federation Internationale de Football Association (FIFA) developed the initiative “Football for Health” to help reduce NCDs starting in Africa (2) and later in adolescents in Mexico as “FIFA 11 for Health.”(1, 3) Additionally in 2010, FIFA marketed the evidence-based phrase “Playing football for 45 minutes twice a week – best prevention of NCDs.”(4) Soccer has also been leveraged to deliver lifestyle intervention programming in several European countries. (5, 6)

Recreational soccer (RS) is effective in reducing cardio-metabolic risk in both children and adults of all shapes and backgrounds, which stems from its varied movement patterns and highly functional training throughout a single session. (7) Generally, **RS participants achieve more than 100 high-intensity runs** and specific intense actions such as dribbles, shots, tackles, turns and jumps over a typical 1-hour training session, with **average heart rates being around 80% of maximal heart rate, irrespective of age, fitness status and previous experience of football training.** These high intensity intervals result in broad-ranging physiological effects such as reduced insulin resistance, chronic inflammation and arterial stiffness and have positive effects on T2DM and cardiovascular disease (CVD) risk factors.(8, 9) Evidence indicates that high intensity interval training (HIIT) modalities such as RS are not only highly efficacious but also safe and engaging interventions for cardio-metabolic risk reduction.(10-12) In addition, RS also builds social capital and is associated with positive motivational factors.(4)

In a two-arm, pragmatic, randomized controlled trial (n=747 men aged 35–65 years with a BMI of $\geq 28 \text{ kg/m}^2$) soccer program, an **average 4.36% weight-loss effect** (95% CI 3.64% to 5.08%) was reported in favor of the intervention.(13) Highly significant improvements on waist, percentage body fat, systolic and diastolic blood pressure, self-reported PA, diet and indicators of well-being and physical aspects of quality of life were also observed. At an estimated cost £862 per additional participant maintaining a 5% weight reduction at 12 months and £13,847 per additional QALY, compared with no active intervention, there was an **89% probability for the program to be cost-effective** at the prevailing £30,000/QALY threshold in the UK health care system.(13)

Adherence to PA in sedentary individuals is an ongoing challenge with barriers including lack of intrinsic motivation, time and resources.(14) Rate of perceived exertion plays a key role for PA sustainability in untrained individuals (15) and is lower when activity intensity is self-selected. (16) There is no difference between RS sessions of 3v3, 5v5 or 7v7 when the pitch is adapted for number of players. (17). **Despite the high heart rates, small-sided RS had the lowest perceived exertion rate** (4 out of 10) when compared to other forms of HIIT such as interval running. (17) This may **explain the high adherence rates (> 90%) for participants in RS interventions** and high enjoyment reports while also maintaining interest in playing RS even after the intervention period was over.(18) RS could be a key intervention to engage the Hispanic male community in Atlanta in health promoting PA.

Men, in general, are harder to engage in traditional disease prevention programs using traditional diet and PA interventions (19), Several studies have translated the DPP to be culturally-specific to the Hispanic community in various settings but predominantly in females.(20, 21) **Hispanic men are significantly understudied** and we are not aware of DPP translational programs tailored to Hispanic male populations. These community-based approaches had retention rates ranging between 63-93% after the core sessions at 6 months. These approaches worked well in females, but there was **little discussion on what drove the lack of recruitment in males.** Furthermore, previous DPP translation trials typically lack reporting of PA results, one of the pillars of the program, specifically objectively-measured PA.(22)

Using technology in an intervention setting can be a simple, efficient, motivational substitute to the traditional DPP format. An abbreviated mobile application version of the DPP was employed effectively in a multiethnic population in San Francisco. This study provided an iOS mobile app in combination with an in-person five month DPP. (23) This group of mostly middle-aged (mean 55 years) females had a retention rate of 93% at five months with a mean 7% weight loss. (23) A 13-week diabetes prevention program was implemented in Northern Mexico, in which 63% of the 184 participants completed the intervention. This mostly female cohort improved their fasting glucose by 7.5 ng/dL after a 3-month follow up. (24) In summary, the DPP can be adapted to a Hispanic community and abbreviated to coincide with a RS intervention.

Our objective is to harness the popularity of RS in local Atlanta Hispanic males and determine the feasibility of a RS implementation in combination with online education and facilitated lifestyle coaching to decrease T2DM

risk. Translating the DPP with a simple online tool and alongside a free opportunity to play a venerated sport in a supportive atmosphere may prove to be exactly what is needed for adherence in Hispanic males.

Protocol Synopsis

Study Design: A longitudinal pre-post pilot intervention study evaluating feasibility of implementation of a soccer-based Diabetes Prevention Program and preliminary changes in physical activity and diet-related measures.

Planned Sample Size: 40 subjects

Subject population: Hispanic overweight males age 35 to 55 years with a CDC pre-diabetes risk score ≥ 9 and not currently engaged in soccer or other regular physical activity.

Specific Aims

We will test the following central hypothesis: **A soccer-based adaptation to the DPP can be feasibly implemented in a population of middle-age Latino men at high risk for T2DM.**

Aim 1: 1a: To adapt the current National Diabetes Prevention Program (NDPP) curriculum to a novel, translational soccer-based DPP programming and delivered by trained coaches as facilitators.

1b: To conduct formative research addressing barriers and acceptability for implementation of this soccer-based DPP adaptation among Latino adults via questionnaires and key informant interviews.

Aim 2: 2a: To assess implementation feasibility of this novel soccer-based DPP adaptation by conducting a single-arm, pre-post pilot study among Latino males ($n=40$; 35-55 years) residing in the Atlanta metro area.

2b: To explore preliminary signals for improvements in objectively-measured PA, dietary behaviors, physical fitness and body composition outcomes with our soccer-based DPP adaptation.

Overweight (BMI between 25 and 60 kg/m²) participants at high risk for T2DM (CDC pre-diabetes screening tool score >9)(25) will be recruited through soccer interest groups, local leagues and Hispanic health organizations. After a baseline assessment visit, participants will attend soccer practice twice/week for 12-weeks while completing NDPP core curriculum modules with facilitated discussion by trained coaches during each soccer practice. Participants will then be invited to join an established small-sided soccer league in their community (12-weeks) offering one game/week and also complete the NDPP maintenance modules and PA/diet self-tracking via mobile health technologies. After the core (12-weeks) and maintenance intervention periods (24-weeks) baseline measurements will be repeated. We will also conduct a 1-year follow up assessment after 6 months of minimal contact. Data on the feasibility of this DPP soccer-based adaptation will inform future randomized, controlled trials testing the effectiveness of this translation model to reduce T2DM risk while extrapolating to other sports-based adaptation and age, gender and racial sub-populations.

Research Design:

Organizational structure of study team: This study was investigator initiated and proposed to the Georgia Center for Diabetes Translation Research at Emory University as part of an internal pilot grant. The funder's expectation was for the investigator to conduct feasibility or pilot research to support a larger grant. Funder will provide a speedtype for all expenses related to the study.

Setting: Aim 1 will be conducted in the field at Latino community health fairs put on by Ventanillas de Salud. The majority of Aim 2 will be conducted on rented soccer fields, no permission is needed to conduct the study, but field owners are aware of the study be conducted. All data will be collected on paper and transferred to a RedCap database at Emory University Rollins School of Public Health.

Aim 1a. During the first phase of this pilot study, we will adapt the CDC's NDPP to an electronic online curriculum dissemination, accelerated to conform to our planned 24-week soccer intervention while maintaining the separation between core and maintenance modules.

Experienced soccer coaches will be identified and hired from the local area to deliver the RS program. These coaches will be trained in two key aspects of the program: 1) leading small-sided RS training designed to safely

engage pre-diabetic participants in HIIT conditioning; 2) facilitate the lifestyle coaching in the NDPP curriculum by devoting time during each soccer training session to reviewing the NDPP material, fostering discussion and using the groups' social dynamics to promote sustained lifestyle behavior change and increase self-efficacy. These coaches will be the primary facilitator of the study, conducting both soccer specific activities and online education discussion. The study staff will conduct consent and all measurements and assessments.

Aim 1b. Secondly, we will conduct a brief survey among middle-aged adult Latino community members to determine potential barriers to participation in the soccer-adapted NDPP program and usability of mobile health technologies. These interviews will inform scheduling and recruitment for Aim 2. We will focus recruitment in Clayton (13%), Cobb (12.8%), and Gwinnett (20.5%) counties which have the highest percentages of Hispanic residents.

Aim 2. We will conduct a pilot feasibility study in 40 males recruited from the local Atlanta community.

Inclusion criteria

- 1) Hispanic/Latino men aged 35-55 years
- 2) BMI ≥ 25 kg/m²
- 3) CDC pre-diabetes risk score ≥ 9 (25)
- 4) Not currently engaged in soccer practice or league or other PA or lifestyle intervention program
- 5) Ability to read in English or Spanish and provide informed consent

Exclusion criteria

- 1) T2DM diagnosis or medication
- 2) BMI ≥ 41
- 3) Resting blood pressure $\geq 165/100$ at screening
- 4) Any mobility issues or contraindications for HIIT PA program (26)

Recruitment: Participants will be recruited from the mentioned local Atlanta area organizations using online a study recruitment flier in both print and electronic format. Interested participants will be provided an online survey to ascertain eligibility (CDC pre-diabetes screening, demographic questions and PA habits) and those meeting inclusion criteria will be invited to an informative session at one of participating soccer field for informed consent and confirmatory baseline assessments including BMI, blood pressure, HbA1c and exercise pre-participation risk screening. Siemens DCA Vantage HbA1c point-of-care devices will be used for screening of diabetes. (27) A cut off point of 6.5% will be used as a putative definition of diabetes and these individuals will be referred to a local clinic for confirmatory testing and appropriate management. (28) Both systolic and diastolic blood pressure will be measured while sitting using a calibrated electronic blood pressure sphygmomanometer prior to any activity and after five minutes of rest. Participants meeting inclusion and exclusion criteria will be invited to participate in the study.

Study Assessments. Prior to testing, subjects will be asked to refrain from physical activity for 48 hours prior to test day, refrain from alcohol 24 hour prior to testing, and refrain from caffeinated drinks, smoking and other stimulants one hour prior to testing. Assessments will be conducted at baseline during the first soccer practice and after the 12-week initial soccer conditioning phase. Assessments will also be repeated at 24-weeks and 1 year from study initiation at the final monthly meeting after the soccer league (maintenance phase of the program) has been completed. Blood pressure, HbA1c, height and weight, waist circumference, aerobic and musculoskeletal fitness assessments will be performed. In addition, questionnaires will be used for self-reported physical and mental health, quality of life, PA and diet self-efficacy, program satisfaction and injuries. Dietary recalls will be conducted at baseline, 12, 24 weeks, and 1 year and by trained staff and analyzed using Nutrition Database System for Research.(29) Participants will participate in online education modules located on the CDC website during an initial 12 week conditioning phase where they will participate in soccer drills and other fitness routines (two 1-hour sessions per week). At the 12 week mark participants will transition onto a soccer league team for the following 12 weeks where they will continue to complete online modules and meet with the soccer coach monthly to discuss. There will be a 1-year follow up to be conducted 6 months from the final soccer session to complete all measurements again. During the soccer sessions/games participants will

be fitted with a wearable soccer-specific device to measure how much they move and their heart rate. All of these measurements will be done on the soccer field. In addition, they will also be asked to wear a Garmin fitness tracker for the duration of the study to measure steps and moderate and vigorous activity. The online education will be a version of the Diabetes Prevention Program and can be completed on a phone or computer with internet access. We will send reminders by text message to do the online education and the soccer coach will talk to the soccer team during soccer practice about what they've learned and answer any questions they may have about the education material.

Informed Consent Process:

Adult consent forms in both English and Spanish will be prepared for this study. The consent form will describe the purpose of the study, the procedures and risks. Participant will be presented with the consent form by the PI of the project, who is a native Spanish speaker and has conducted many research studies in the Hispanic community in the US as well as Latin America, in person and given time to read and ask questions. A signed consent form will be obtained from the participant. A copy of the consent form will be given to the participant and this process will be documented.

Risks:

There is minimal risk in this study. Potential risks are related to 1) Finger sticks 2) Physical injury related to sport and 3) Confidentiality. 1) A single-use finger stick device will be used during assessments along with alcohol to clean the site prior to stick to reduce chances of infection. 2) Exercise can cause muscle soreness, weakness and in some cases muscle strains, ligament sprains and rarely bone fractures can occur. In very rare cases exercise can induce chest pain or a heart attack or other medical emergency. The training program led by the soccer coach is designed to minimize risk of injuries or events by slowly progressing on the practice of soccer using soccer and exercise drills appropriate for your age and level of fitness. Soccer sessions will be led by trained professionals who are able to offer suggestions to limit and prevent these adverse events. They are trained to recognize medical emergencies, will have basic equipment available, and seek emergency care if needed. 3) There is a risk of loss of confidentiality. Efforts will be made to keep all personal information confidential. All data will be stored in locked offices and password-protected computers. Personal identity will be protected in any publication.

Benefits: There are no direct benefits of this study beyond opportunity to exercise and information about healthy behaviors.

Compensation:

Participants will receive free entry into soccer leagues in their local area for the maintenance portion of the study. (A ~\$100 value) Subjects that complete the study will be allowed to keep the Garmin fitness tracker.

Data Analytics and Statistical Plan:

Data and statistics will be managed by the PI and the study team using RedCap. Any paper forms will be kept in a locked cabinet in a locked office. Demographics and characteristics of the overall cohort will be tabulated using means and standard deviations or counts and percentages, as appropriate. Prior to analysis, continuous measures will be tested for normality. Non-normally distributed variables will be transformed prior to analysis or non-parametric approaches will be utilized. Linear regression will be used to control for anthropometrics and other factors that may influence improvement and will contain no more than five predictors at a time, given our sample size of 40. Standardized mean differences and effect sizes with associated 95% CI will be calculated for outcomes of interest.

Training of study team:

As stated above all staff and soccer coaches will receive adequate training of all study procedures. All study staff and collaborators will take CITI training upon hire.

Confidentiality: Screens will be used on the soccer fields for consent and study measurements. All participants will receive a study ID and this will be used on all paper and electronic forms. We will destroy all identifiers and any audio from key interviews after the study is complete.

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Protection of Human Subjects

Risk to the Subjects

Human Subjects Involvement and Characteristics. We will recruit 40 subjects for this study who are overweight or obesity class 1. Subjects will be required to meet the following inclusion criteria: 1) Hispanic/Latino men aged 35-55 years; 2) BMI ≥ 27 kg/m²; 3) CDC pre-diabetes risk score ≥ 9 ; 4) not currently engaged in soccer practice or other PA or lifestyle intervention program; 5) ability to read in English or Spanish and provide informed consent; Exclusion criteria are participants with 1) T2DM diagnosis or medication; 2) BMI ≥ 33 ; 3) resting blood pressure $\geq 165/100$ at screening 4) any mobility issues or contraindications for HIIT PA program. Subjects will be recruited from local Atlanta area Latino health centers. Each subject will receive a free intervention performed by trained soccer coaches in a small group format. Enrollment fees for league play will be covered by the study. Retention of these subjects will be aided by text messages given through the app technology used to track physical activity. Research Material Collected: These will include medical history (previous diagnoses), demographic information, anthropometrics, blood pressure, HbA1c, physical activity assessments and tracking of physical activity via a fitness tracker throughout the study.

Potential Risks:

There is some mild discomfort with the finger stick required by the HbA1c point-of-care device. Standard sterile techniques will be used; thus, infection is unlikely. There is small-to-moderate risk of injury with the most common being muscle strains and joint sprains while playing soccer and during conditioning. However, we will implement an evidence-based approach proven to reduce in up to 40% the risk of common soccer injuries and protocols to screen for exercise-related adverse events. Soccer coaches will be certified in cardio-pulmonary resuscitation and soccer field protocols for emergency situations reviewed and improved as needed, including availability of AED's. There is a small risk of loss of confidentiality. We will follow all procedures required by Emory University to protect participants. Efforts will be made to ensure that all personal information remains confidential. All data will be stored in locked offices and password-protected computers. The study app we will be using is HIPAA compliant and approved by Emory IT services. Personal identity will be protected in any publication.

Adequacy of Protection Against Risks

Recruitment and Informed Consent: Aim 2 will require prospective recruitment of 70 (expect 30 screen fails for an enrollment of 40) subjects. Recruitment will be through Latino health centers. Permission to perform this study will be sought from the Emory University IRB. At the time of screening, the trained study staff will discuss the study with the subject and give them all the information listed above in language understandable at the level of the subject and all information needed to make an informed choice about participation. Informed consents will be obtained prior to initiating any study procedure.

Protection Against Risk: Risk will be minimized to the subjects by continuous monitoring and water breaks when needed. Risk to confidentiality will be reduced by using non-identifying participant numbers and removing all identifiers as early as feasible. Only study personnel will have access to identifying data. Coaches will be on a first name basis with subjects but not have access to non-relevant data.

Potential Benefits of the Proposed Research to the Participants and Others

The proposed research has substantial potential benefits for these men. The positive engagement of Hispanic men in a successful diabetes prevention program will allow for expansion into other communities as well as with children and adolescents and women, ultimately resulting in improved quality of life in the Hispanic community. Each man in the study will undergo assessments not typically clinically available.

Any new diagnosis of diabetes or potential hypertension that occurs during the research studies will be shared with the subject and they will be referred to their doctor or health clinic.