

# A demonstration area for type 2 diabetes prevention in Barranquilla and Juan Mina (Colombia)

## Baseline characteristics of the study participants

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### Abstract

Type 2 diabetes (T2D) imposes a heavy public health burden in both developed and developing countries. It is necessary to understand the effect of T2D in different settings and population groups. This report aimed to present baseline characteristics of study participants in the demonstration area for the “Type 2 Diabetes Prevention in Barranquilla and Juan Mina” (DEMOJUAN) project after randomization and to compare their fasting and 2-hour glucose levels according to lifestyle and T2D risk factor levels.

The DEMOJUAN project is a randomized controlled field trial. Study participants were recruited from study sites using population-wide screening using the Finnish Diabetes Risk Score (FINDRISC) questionnaire. All volunteers with FINDRISC of  $\geq 13$  points were invited to undergo an oral glucose tolerance test (OGTT). Participant inclusion criteria for the upcoming field trial were either FINDRISC of  $\geq 13$  points and 2-hour post-challenge glucose level of 7.0 to 11.0 mmol/L or FINDRISC of  $\geq 13$  points and fasting plasma glucose level of 6.1 to 6.9 mmol/L. Lifestyle habits and risk factors for T2D were assessed by trained interviewers using a validated questionnaire.

Among the 14,193 participants who completed the FINDRISC questionnaire, 35% ( $n = 4915$ ) had a FINDRISC score of  $\geq 13$  points and 47% ( $n = 2306$ ) agreed to undergo the OGTT. Approximately, 33% ( $n = 772$ ) of participants underwent the OGTT and met the entry criteria; these participants were randomized into 3 groups. There were no statistically significant differences found in anthropometric or lifestyle risk factors, distribution of the glucose metabolism categories, or other diabetes risk factors between the 3 groups ( $P > .05$ ). Women with a past history of hyperglycaemia had significantly higher fasting glucose levels than those without previous hyperglycaemia (103 vs 99 mg/dL;  $P < .05$ ).

Lifestyle habits and risk factors were evenly distributed among the 3 study groups. No differences were found in fasting or 2-hour glucose levels among different lifestyle or risk factor categories with the exception of body mass index, past history of hyperglycaemia, and age of  $\geq 64$  years in women.

Trial registration: NCT01296100 (2/12/2011; Clinical trials.gov).

**Abbreviations:** FPG = fasting plasma glucose, IFG = impaired fasting glucose, IGT = impaired glucose tolerance, OGTT = oral glucose tolerance test, T2D = type 2 diabetes.

**Keywords:** Colombia, nutrition, physical activity, primary healthcare

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## 1. Introduction

Type 2 diabetes (T2D) imposes a heavy public health burden in both developed and developing countries.<sup>[1]</sup> The growing prevalence of T2D with its high morbidity and mortality will impose a heavy burden on healthcare systems.<sup>[2]</sup> The predicted number of diagnosed T2D patients will increase in Latin America and a large number of asymptomatic cases of T2D will remain undiagnosed. This is problematic, as asymptomatic T2D is associated with 2-fold and impaired glucose tolerance (IGT) with 1.4-fold increased mortality.<sup>[3]</sup>

People with a positive family history of diabetes mellitus have a higher likelihood of developing T2D once exposed to a lifestyle that enhances obesity (unhealthy diet and physical inactivity).<sup>[4–6]</sup> The treatment of T2D is difficult and regardless of pharmacological treatment, blood glucose levels have been shown to increase over time.<sup>[7]</sup> Therefore, primary T2D prevention strategies may be more efficient than secondary prevention approaches. In addition, the most common T2D complications (e.g., cardiovascular diseases) may be postponed by preventing the development of T2D, highlighting the importance of early T2D prevention in the susceptible population.

There is a growing body of evidence suggesting that T2D can be prevented or at least delayed. Early studies in Finland and the USA revealed that nutritional and physical activity interventions can decrease the relative risk of T2D up to 58% in people with IGT.<sup>[8,9]</sup>

While these findings offer a compelling evidence base, it is necessary to understand how the prevention of T2D works in different settings and population groups. In addition, it is important to determine the extent to which each component (e.g., nutrition, physical activity, nutrition/physical activity) of lifestyle interventions works best in the prevention of T2D in Latin America, and especially in the Caribbean region. For instance, it has been clearly shown that each component (nutrition, physical activity) of lifestyle interventions either separately<sup>[10]</sup> or combined<sup>[8–13]</sup> has successfully decreased the risk of T2D in people with IGT. Thus far, such trials have not been conducted in the Caribbean region and it is unclear whether these lifestyle changes are effective in a hot, humid climate. This is particularly true for the physical activity component. The aim of this report is to present baseline characteristics of study participants in the demonstration area for the “Type 2 Diabetes Prevention in Barranquilla and Juan Mina” (DEMOJUAN) project after randomization to groups and to compare their fasting and 2-hour glucose levels according to lifestyle and T2D risk factor levels.

## 2. Methods

### 2.1. Design and sample size calculations

The study design of the DEMOJUAN project is a randomized controlled field trial. The main objective of the DEMOJUAN project is to investigate to what extent it is possible to reach normal glucose metabolism and optimal cardiovascular disease risk factor levels with early lifestyle interventions in people at high risk of T2D compared with those who receive standard therapy (usual care) only. Finally, this project will examine the effect of these interventions, for the first time, in people of low socio-economic levels living in a Caribbean environment. This study may provide important information and experiences for policy making and planning of primary prevention activities not only in the local healthcare system but in the entire Caribbean

region. The current report presents the results of the baseline assessment and participant recruitment process using a cross-sectional design.

The study was designed to have 90% power to detect a 20% unit difference in recovery from IGT (comparing 70% vs 50% recovery rates) between the treatment groups at a 5% significance level. Assuming a loss to follow-up of 30% at the end of the 24-month intervention, a total of 200 participants were needed in each treatment group (i.e., total sample size of 600 individuals). The drop-out rate of 30% was estimated according to the results and experiences of previous randomized controlled diabetes trials in translational research.<sup>[14,15]</sup> In addition, this sample size provides >90% power to detect a 6-mmHg difference in change in systolic blood pressure (standard deviation [SD]=14 mmHg) between the treatment groups with a 5% significance level.

### 2.2. Screening for study participants

Study participants were recruited from the study sites (Juan Mina and Barranquilla) by population-wide screening using the Finnish Diabetes Risk Score (FINDRISC).<sup>[14–16]</sup> The study sites have approximately 1,000,000 inhabitants. FINDRISC is based on easily attainable information using 8 parameters with categorized answers. The total risk score ranges from 0 to 26. FINDRISC was shown to predict the 10-year risk of drug-treated T2D with a sensitivity of 78% to 81% and a specificity of 76% to 77%.<sup>[14]</sup> Furthermore, it also detects reasonably prevalent asymptomatic T2D and other disorders of glucose metabolism.<sup>[17]</sup> FINDRISC has been validated in many populations with good results<sup>[18–23]</sup> and has been successfully applied in primary care in Barcelona, Spain.<sup>[21]</sup> It is recommended as a screening tool for T2D by the International Diabetes Federation and in the guidelines of the European Society for the Study of Diabetes and the European Society of Cardiology.<sup>[22,24]</sup> In the current study, all volunteers with a FINDRISC score of  $\geq 13$  were invited to undergo an oral glucose tolerance test (OGTT). Participant inclusion criteria for the upcoming field trial were either FINDRISC of  $\geq 13$  points and 2-hour post-challenge glucose level of 7.0 to 11.0 mmol/L or FINDRISC of  $\geq 13$  points and fasting plasma glucose level of 6.1 to 6.9 mmol/L.

If a study participant met the inclusion criteria and agreed to participate, he/she was randomized into 1 of 3 groups (A, B, or C). Sequences for the random allocation groups were generated by IBM SPSS Statistics for Windows (Version 19.0. Armonk, NY: IBM Corp.). This study followed the Good Clinical Practice guidelines and the guidelines of the Helsinki Declaration. All data have been collected using previously tested questionnaires and methods as much as possible. Besides blood samples, no invasive methods were used. The study protocol was approved by the Research Ethics Committee of the University Pontificia Javeriana, Bogota, Colombia. All participants gave their written informed consent prior to participation to the study.

## 3. Non-invasive measurements

Lifestyle habits and risk factors for T2D were assessed by an interview using a questionnaire consisting of information regarding sociodemographic factors, history of T2D, medical history, tobacco consumption, hypertension, and nutritional and physical activity habits. The instruments applied were designed based on FINDRISC, the STEPwise approach to surveillance and the International Physical Activity Questionnaire (IPAQ),<sup>[25–30]</sup> all of which have been previously successfully validated in large

international studies.<sup>[25–31]</sup> Physical activity measured with the questionnaire used herein (IPAQ) shows a high correlation with physical fitness, measured by maximal oxygen uptake.<sup>[32,33]</sup> Dietary habits were assessed via 16 questions (e.g., dietary pattern, quality and quantity of dietary fat, consumption of fruit and vegetables, grain, milk, and meat products, desserts, sweets, and alcoholic beverages). In addition, 6 questions were related to perceived need and intentions to make dietary changes. Scientific validation of the dietary questionnaire is ongoing in the National Institute for Health and Welfare in Helsinki, Finland.

Participant height and weight were measured without shoes and wearing light clothing. Body mass index (BMI) was calculated as weight (kg) divided by height squared ( $m^2$ ). Waist circumference (to the nearest cm) was measured at the approximate midpoint between the lower margin of the last palpable rib and the top of the iliac crest. Blood pressure (precision=2 mmHg) was recorded twice using a mercury sphygmomanometer while study participants were in a seated position.

#### 4. Biochemical measurements

All participants underwent an OGTT that was conducted according to the World Health Organization recommendations.<sup>[34]</sup> The test was conducted after fasting for 12 hours, and fasting and 2-hour blood samples were obtained after oral ingestion of a water solution with 75 g of anhydrous glucose. Glucose tolerance status was classified according to the criteria of the American Diabetes Association.<sup>[35]</sup> Participants with a fasting plasma glucose (FPG) level of  $\geq 126$  mg/dL or a 2-hour plasma

glucose (2hPG) level of  $\geq 200$  mg/dL were classified as having T2D. Those with 2hPG of  $\geq 140$  mg/dL but  $< 200$  mg/dL and FPG of  $< 100$  mg/dL were classified as having isolated IGT. Isolated impaired fasting glucose (IFG) was defined as FPG of  $\geq 100$  but  $< 126$  mg/dL and 2hPG of  $< 140$  mg/dL. Participants with 2hPG of  $\geq 140$  mg/dL but  $< 200$  mg/dL and FPG of  $\geq 100$  but  $< 126$  mg/dL were defined as having combined IGT and IFG. Finally, those with T2D, IGT, or IFG were classified as having impaired glucose regulation.

#### 5. Statistical analysis

Data were analyzed using IBM SPSS Statistics for Windows. Variables were checked for normality using Kolmogorov–Smirnov tests. The chi-squared test was used to test for differences in the distribution between categorized variables. The independent *t* test for normally distributed variables and the Mann–Whitney *U* test for non-normally distributed variables, respectively, were used to test for differences in continuous variables between men and women. Differences in continuous variables between  $\geq 3$  groups were assessed using analysis of variance. Results are expressed as percentages, means and standard errors or SDs. The threshold for statistical significance was set at  $P < .05$ .

#### 6. Results

Figure 1 presents the flow chart of participant recruitment of the DEMOJUAN project. In total, 14,193 participants completed the FINDRISC questionnaire during participant screening activities

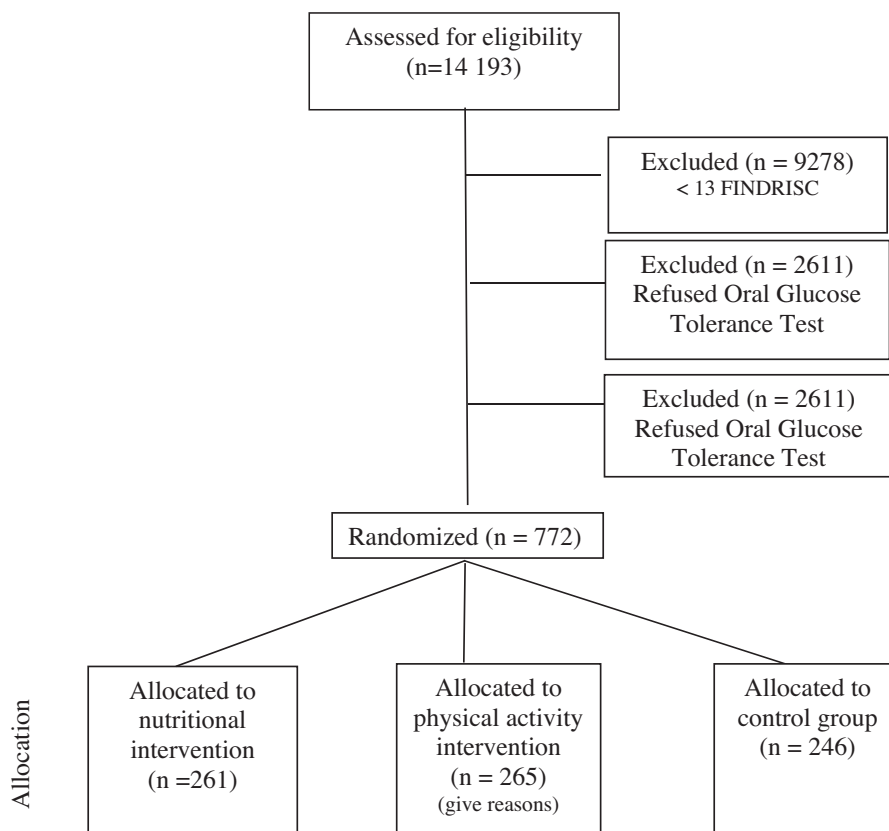


Figure 1. Flow chart of the participant recruitment for the DEMOJUAN project.

**Table 1****Baseline characteristics of the study participants.**

	Intervention groups			P value
	Control (n=246) Mean (SD)	Nutrition (n=261) Mean (SD)	Physical activity (n=265) Mean (SD)	
Age	54 (9)	53 (9)	52 (8)	.105
BMI	30.08 (5.06)	29.76 (5.49)	30.29 (5.41)	.511
Waist circumference	101.4 (10.9)	101.2 (10.9)	101.2 (11.6)	.982
FINDRISC	16 (0.2)	16 (0.2)	16 (0.2)	.663
	% (n)	% (n)		
>30 min physical activity/d	13 (31)	13 (35)	15 (40)	.703
Daily consumption of fruits and vegetables	23 (57)	20 (51)	23 (61)	.528
Anti-hypertension drug use	46 (114)	44 (115)	46 (121)	.868
Family history of diabetes	71 (175)	77 (200)	75 (198)	.648
Previous increased glucose in blood	28 (69)	30 (77)	35 (93)	.187

Baseline characteristics of the study participants recruited within the framework of the DEMOJUAN project in Barranquilla, Colombia. BMI=body mass index; FINDRISC=Finnish Diabetes Risk Score.

at the study sites. Among these, 35% (n=4915) had a FINDRISC of  $\geq 13$  points and 47% (n=2306) agreed to undergo the OGTT. Approximately, 33% (n=772) of participants underwent the OGTT and met the entry criteria; these participants were then randomized into 3 groups. The control group (A) comprised of 246 participants, the nutritional/physical activity intervention group (B) comprised of 261 participants, and the physical activity/nutrition group (C) comprised of 265 participants.

Participant characteristics at baseline are shown in Table 1. There was no statistically significant difference found in anthropometric, lifestyle, or other diabetes risk factors between the 3 groups ( $P > .05$  for all). The mean FINDRISC was 16 points, with no statistically significant differences between groups ( $P = .663$ ).

Table 2 shows the prevalence of glucose metabolism disorders between the 3 groups. No statistically significant difference in the distribution of glucose metabolism categories was observed between groups in the bivariate analysis ( $P = .069$ ).

Table 3 presents participants' mean fasting and 2-hour glucose levels according to lifestyle habits and risk factors of T2D. Women with a past history of hyperglycaemia had significantly higher fasting glucose levels compared with those without previous hyperglycaemia (mean=103 vs 99 mg/dL;  $P < .05$ ). In addition, women with a BMI of  $>30 \text{ kg/m}^2$  had higher fasting glucose levels compared with those with a normal BMI. Finally, women in the oldest age group ( $>64$  years) had significantly higher 2-hour glucose levels (mean=152 mg/dL) compared with younger age groups ( $P < .05$ ). No statistically significant

differences were found in men in regard to fasting or 2-hour glucose levels between different categories of lifestyle habits or risk factors of T2D.

## 7. Discussion

### 7.1. Screening and baseline characteristics of study participants

Up-to-date information regarding compliance with instructions to undergo an OGTT after a positive screening test is scant. Although Davies and Day<sup>[36]</sup> reported compliance of 93% following a positive screening test in Great Britain, in our project, only approximately half of high-risk individuals invited to an OGTT appeared at the laboratory.<sup>[37]</sup> Furthermore, in the European Diabetes Prevention Study (EDIPS), only 66% of participants invited to be screened using an OGTT appeared at the laboratory for blood extractions.<sup>[38]</sup> One possible reason for lower compliance may be related to time constraints, as the OGTT requires a visit to the laboratory in the morning and lasts at least 2 hours, which may be difficult to arrange for people working during the daytime. A possible explanation for the difference in the findings between our and the British study may be accessibility to a laboratory and the fact that access to/availability of public transportation surely differs between Barranquilla (Colombia) and Western Europe. Therefore, a future challenge will be to develop strategies to motivate individuals identified as being at a high risk of T2D to attend the laboratory test to confirm their diagnosis. Implementing simpler ways to test blood glucose levels, such as the recently

**Table 2****Categories of disturbances of glucose metabolism in participants in 2011 according to the intervention group.**

	Intervention group			P value
	Control group % (n)	Nutrition % (n)	Physical activity % (n)	
Normoglycemia	18 (22)	11 (15)	13 (17)	.069
Isolated IFG	32 (40)	28 (57)	23 (38)	
Isolated IGT	35 (44)	41 (38)	29 (30)	
IFG and IGT	15 (19)	20 (28)	35 (47)	
Type 2 diabetes	0 (0)	0 (0)	0 (0)	

Baseline characteristics of the study participants recruited within the framework of the DEMOJUAN project in Barranquilla, Colombia. IFG=impaired fasting glucose, IGT=impaired glucose tolerance.

**Table 3****Mean fasting and 2-hour glucose levels according to lifestyle habits and risk factors of type 2 diabetes in the study participants.**

	Men		Women		Total	
	Fasting glucose	2-h glucose	Fasting glucose	2-h glucose	Fasting glucose	2-h glucose
Age group						
<45 y	98 (3)	142 (6)	99 (1)	142 (2)	99 (1)	142 (2)
45–54 y	102 (2)	139 (4)	101 (1)	141 (2)	101 (1)	141 (2)
55–64 y	99 (2)	146 (4)	100 (1)	143 (2)	100 (1)	143 (2)
>64 y	96 (3)	142 (6)	100 (1)	152 (3) <sup>†</sup>	100 (1)	151 (3) <sup>†</sup>
BMI*						
<25 kg/m <sup>2</sup>	101 (3)	142 (7)	98 (1)	143 (3)	98 (1)	143 (3)
25–30 kg/m <sup>2</sup>	100 (2)	139 (4)	100 (1)	141 (2)	100 (1)	141 (1)
>30 kg/m <sup>2</sup>	98 (2)	146 (3)	101 (1) <sup>‡</sup>	145 (1)	101 (1)	145 (1)
Waist circumference						
<94 cm (men)/<90 cm (women)	107 (5)	129 (10)	96 (3)	154 (7)	101 (3)	144 (6)
≥94 cm (men)/≥90 cm (women)	98 (2)	142 (4)	98 (2)	147 (3)	98 (1)	145 (3)
	100 (1)	144 (3)	101 (1)	143 (1)	100 (1)	143 (1)
Physical activity						
<30 min physical activity/d	96 (3)	152 (8)	100 (1)	143 (3)	99 (1)	145 (3)
≥30 min physical activity/d	100 (1)	140 (2)	100 (1)	143 (1)	100 (1)	143 (1)
Past history of hyperglycemia						
No	99 (1)	143 (3)	99 (1)	142 (1)	99 (1)	142 (1)
Yes	101 (2)	141 (4)	103 (1) <sup>§</sup>	146 (2)	103 (1) <sup>§</sup>	145 (2)
Family history of diabetes mellitus						
No	97 (2)	141 (5)	101 (1)	145 (2)	100 (1)	144 (2)
Yes: grandparent, uncle, aunt, or cousin	97 (2)	143 (5)	100 (1)	141 (2)	99 (1)	141 (2)
Yes: biological father, mother, or sibling	102 (2)	142 (3)	100 (1)	144 (1)	101 (1)	143 (1)

\* Body mass index.

<sup>†</sup> P value <.05 compared with all other groups.<sup>‡</sup> P value <.05 compared with <25 kg/m<sup>2</sup> group.<sup>§</sup> P value <.05.

developed home-based OGTT test, may also offer solutions to improve treatment compliance.<sup>[39]</sup>

The baseline characteristics of our study sample in regard to fasting and 2-hour glucose levels were different compared with previous randomized clinical trials in individuals with glucose intolerance.<sup>[10,11,13,38,40–42]</sup> The 2-hour glucose levels reported in previous studies were approximately 160 mg/dL,<sup>[10,11,13,34,40–42]</sup> whereas the post-prandial glucose levels in our study participants were almost 15 mg/dL lower. Moreover, fasting glucose levels of participants at baseline in previous clinical trials were higher than those in our participants, with the exception of the Da Qing study population.<sup>[10]</sup> Further, whereas study participants of lifestyle intervention trials conducted in Asian populations<sup>[10,11,42]</sup> had a lower baseline waist circumference and BMI, those of our study participants were similar to those of the 2 European studies.<sup>[13,41]</sup> The participants of the US Diabetes Prevention Program and EDIPS-Newcastle<sup>[38,40]</sup> had a remarkably higher BMI and waist circumference at baseline than those observed in our study. In addition, whereas 7 out of 10 participants in our study had a positive family history of diabetes, only 1 out of 4 had family members with diabetes in a Japanese trial.<sup>[42]</sup> Finally, the Asian studies included participants with a lower mean age than did most other previous clinical lifestyle intervention trials.<sup>[10,11,42]</sup>

## 7.2. Description of upcoming lifestyle interventions

During the following 24 months, the control group (A) will receive standard treatment (usual care: lifestyle advice prescribed by his/her physician). The 2 intervention groups (B and C) will receive early, intensive lifestyle interventions. Group B will receive a 6-month nutritional intervention followed by a 6-month physical activity intervention and finally a 12-month combined

nutritional and physical activity intervention. Group B will also receive individual advice about how to achieve the intervention goals, which are as follows: reduction in weight of ≥5%; total fat intake of <30% of energy consumed; saturated fat intake of <10% of energy consumed, and fruit or vegetable intake of ≥500 g per day. Group C will begin with the 6-month physical activity intervention followed by the 6-month nutritional intervention. The physical activity intervention consists of individual visits with a physical activity specialist and monthly group seminars. Specifically, each participant will have 6 individual visits with a physical activity specialist (4 times during the first year and twice in the second year) in which they will receive an individual physical activity prescription. The goal of the physical activity intervention is to practice moderate-intensity exercise for ≥30 min/d. In addition, Group B and C participants will attend group seminars in groups of 10 participants. Group seminars will be held monthly during the first 12 months of the intervention and then every second month during the second year of the intervention. Group seminars will be led by a nutritionist and physical activity specialist.

Finally, in order to reduce the possibility of bias due to the visit schedule, both intervention groups will undergo their group sessions and individual visits in parallel. Another possible bias that will be more difficult to control for is the Hawthorne (i.e., observer) effect. As participants in the control group will be aware that they are at increased risk of T2D and that they are taking part in a T2D prevention study, they may change their lifestyles due to the fact that they are under supervision. However, the Hawthorn effect is reduced with longer intervention programme duration. Our intervention will last for 24 months and may thus be long enough to reduce the bias of the Hawthorne effect.



## 8. Conclusions

This baseline assessment of participants in the DEMOJUAN project revealed that it is possible to recruit individuals at risk of T2D for a field trial using a simple screening tool in a population of a country in economic transition such as Colombia. The randomization process revealed that lifestyle habits and risk factors were distributed evenly among the 3 study groups. No differences were found in fasting or 2-hour glucose levels among the various lifestyle or risk factor categories, with the exception of BMI, past history of hyperglycaemia and age >64 years in women.

As the participants in our study had lower fasting and 2-hour glucose levels at baseline compared with those of the previous trials mentioned above, the upcoming interventions will show to what extent normoglycaemia can be achieved, even in individuals with a more favorable glucose profile.

## 9. Authors' contributions

TA, NCB, and JT planned the study, analyzed the data and wrote the report. AA and CR reviewed the manuscript and assisted in statistical analysis and results interpretation.

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