May 30, 2023

Effect of Flaxseed as a Treatment for Adults With Type 2 Diabetes Mellitus in Mexico -CEI-04/2023-

Study Protocol and Informed Consent Form

UNDER THE LEADERSHIP OF: DR. SABINA LÓPEZ TOLEDO

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Effect of flaxseed consumption as a treatment for adults with type 2 Diabetes Mellitus in Oaxaca de Juarez, Oaxaca.

I. PRESENTATION OF THE PROTOCOL OR RESEARCH PROJECT

1. Summary of the study

Introduction: Type 2 Diabetes Mellitus represents one of the most important health emergencies of this century. It is estimated that by 2045 there will be 700 million people living with diabetes. Flaxseed is a food that is characterized by its nutritional properties, highlighting its content of alpha linoleic acid, flax lignans, digluc- secoisolariciresinol cosides. The latter have antioxidant, hypolipidemic and hypoglycemic effects, which makes it an excellent option as a functional treatment for type 2 diabetes.
Material and Method: Randomized clinical trial. The sample will be recruited by self-selection.

The control group will be given a nutritional education talk using the healthy eating plate and the group intervention you will be prescribed flaxseed supplementation (16 gr of flaxseed/day for three months) and also a talk of nutritional education using the healthy eating plate. A clinical history will be applied for the variables age, gender, occupation and marital status, duration of the disease, type of current diabetes treatment, control and comorbidities, weight, height and biochemical parameters glucose, glycosylated hemoglobin, total cholesterol, triglycerides, LDL cholesterol, and HDL cholesterol of each participant, at the beginning and at the end of the study.

Scientific/Practical Relevance: The use of flaxseed as a functional food for the treatment of type 2 diabetes is It has been used in different populations with success. However, in the state of Oaxaca its effectiveness has not been tested despite having this food available. If the results are positive, this food can be offered as a therapeutic alternative instead of or in combination with its pharmacological treatment, improving the results. This is important because the prevalence of this disease in the state is increasing.
Keywords: Type 2 Diabetes Mellitus, treatment, functional food, Flaxseed.

Expected start and completion dates of the study.

Start: October 2023

Study completion: March 2025

2. Objectives

General

- To assess the adjuvant effects of flaxseed consumption (16 g of flaxseed per day/3 months) on

Biochemical factors (glucose, glycosylated hemoglobin, total cholesterol, triglycerides, LDL cholesterol and cholesterol HDL) of adult patients (30 to 70 years) with type 2 diabetes mellitus, who attend the Nutrition outpatient clinic from the Regional Hospital of Oaxaca.

Specific Objectives

1. Describe the sociodemographic variables (age, sex, occupation, marital status) of adult patients (30 to 70 years) who suffer from type 2 diabetes, who attend the Nutrition outpatient clinic at the Regional Hospital from Oaxaca.

2. Describe the clinical characteristics (time of evolution of the disease, type of treatment, control and comor-bilities), of adult patients (30 to 70 years) who suffer from type 2 diabetes, who attend the outpatient clinic of Nutrition at the Regional Hospital of Oaxaca.

3. Assess the anthropometric variables (weight and height) of adult patients (30 to 70 years) who suffer from diabetestype 2, who attend the Nutrition outpatient clinic at the Regional Hospital in Oaxaca.

4. Evaluate the biochemical parameters (glucose, glycosylated hemoglobin, total cholesterol, triglycerides, LDL cholesterol and HDL cholesterol) of adult patients (30 to 70 years) suffering from type 2 diabetes, who attend the Nutrition outpatient clinic of the Regional Hospital of Oaxaca, prior to the consumption of flaxseed and threemonths after regular consumption of flaxseed.

5. Apply a nutritional intervention to two groups: Group A) Teaching the healthy eating plate and Group B) Teaching healthy eating dishes and indicating flaxseed consumption.

6. Evaluate the effect of flaxseed consumption on biochemical markers (glucose, glycosylated hemoglobin,

Total cholesterol, triglycerides, LDL cholesterol and HDL cholesterol of adult patients (30 to 70 years) suffering fromtype 2 diabetes, who attend the Nutrition outpatient clinic at the Regional Hospital in Oaxaca.

7. Analyze the most effective possible combinations (pharmacological + non-pharmacological) for the treatment ofAdult patients (30 to 70 years) who suffer from type 2 diabetes, who attend the Nutrition outpatient clinic at the Regional Hospital of Oaxaca.

4. Justification

Type 2 Diabetes Mellitus represents one of the most important health emergencies of this century. It is estimated that In 2019, there were already 463 million people with diabetes mellitus worldwide and this figure may increase to 578 million by 2030 and to 700 million by 2045. A state of hyperglycemia is associated with acute and chronic complications, in both cases affecting the cardiovascular system, mainly the blood vessels and consequently to the entire organism, but mainly to the eyes, kidneys, arteriovelocity systems. and peripheral nerves. Although it is known that insulin resistance is reversible and that diabetes mellitus type 2 is controllable with a change towards a healthy lifestyle, the population ignores these recommendations and continue with their unhealthy habits. Thus, the number of patients continues to grow exponentially, which leads to an increase in economic expenditure in terms of health. This is why non-pharmacological measures are sought that favor the reduction of glycemia in patients with Diabetes Mellitus where the consumption of functional foods is a good alternative for the treatment of this chronic disease (Tinajero et al., 2021; Wu et al., 2014). Flaxseed is a food characterized by its nutritional properties, highlighting its content of alpha linoleic acid, flax lignans, and secoisolariciresinol diglucosides. The latter have antioxidant, lipid-lowering and hypoglycemic effects, which makes it an excellent option as a dietary supplement for treatment of type 2 diabetes (Parikh et al., 2019).

Some studies have been conducted with flaxseed supplementation. In a randomized cross-sectional study conducted by Tharwat et al., in 2017, evaluated 90 patients with type 2 Diabetes Mellitus with a range of 5 to 7 years of diagnosis

that they received oral hypoglycemic agents (metformin 500 mg) 3 times a day, having an age range between 35 and 45 years old. They divided the population into 3 groups:
Group 1 selected 30 patients with a calculated diet to 1350kcal (in the form of 50% carbohydrates, 30% fat and 20% protein) without flaxseed supplementation.
Group 2 included 30 patients with the same diet, but adding linseed oil for 6 days a week in an amount of 13g/day. And in group 3, 30 patients were included in the same dietary regimen that group 1, adding flaxseed flour to their diet for 6 days a week, providing 32g of flaxseed per day. They concluded that in the 3 groups there was a reduction in blood glucose, however the decrease in glucose in Fasting reported by group 3 had better target figure achievements (Tharwat., 2017).
In a systemic review in 2018 Mohammadi et al, evaluated 25 randomized clinical trials, presenting a significant association between flaxseed supplementation and a reduction in blood glucose. It is worth mentioning that This relationship was more significant in the groups in trials that used ground flaxseed and reported an admin-Administration between 4 to 14 grams. (Mohammad., et al, 2018)
Hasaniani et al in 2019 conducted a randomized, controlled clinical trial with 57 patients with Diabetes Mellitus type 2. He divided his population into 2 groups. One group was prescribed 200g of natural yogurt in their diet and the other Another group was also prescribed 200g natural yogurt with 30g of flaxseed added for 8 weeks documented a significant reduction in hemoglobin A1c (p=0.001) compared to the control group (Ha-saniani, 2019). In another study, Nowrk concluded that regular consumption of flax seed improves the lipid profile by reducing triglycerides and total cholesterol and increasing HDL cholesterol (Nowak & Jeziorek.,2023)

5. Design of the research methodology.

Randomized clinical trial (case-control).

The sample will be recruited by self-selection.

The total number of recruited participants will be divided into two groups (A and B).

The control group will be given a talk nutritional education using the healthy eating plate

and the intervention group will be instructed on supplementation

with flaxseed (16 gr of flaxseed/day for three months) and also a nutritional education talk using the plate

of good eating.

Once they sign the legal informed consent for participation, a clinical history will be applied where

Sociodemographic variables such as age, sex, occupation and marital status will be

asked. Clinical characteristics such as time since the disease has been on the disease, type of current diabetes treatment, control and comorbidities will also be asked. These variables will be collected at the beginning of the research and only once during the study.

The nutritionist will take the participant's weight and height and record them at the beginning and end of the study.

Specialized nurses will take 5 milliliters of blood in the clinical laboratory area of the Regional Hospital

from the of Oaxaca and a clinical chemist professional will assess the biochemical parameters glucose, hemoglobin glycosylated, total cholesterol, triglycerides, LDL cholesterol and HDL cholesterol of each participant, at the beginning and at the end of the study (after three months of intervention, consuming 16 g of flaxseed/day).

The effect of flaxseed consumption on biochemical markers (glucose, hemoglobin) will subsequently be evaluated.

glycosylated, total cholesterol, triglycerides, LDL cholesterol and HDL cholesterol and the possible combinations will be analyzed (pharmacological + non-pharmacological) most effective for the treatment of type 2 diabetes.

6. Selection criteria and description of participants.

Selection criteria

Patients living with type 2 Diabetes Mellitus and who come with fasting blood glucose greater than 140 and hemoglobin glycosylated greater than 6.5%, who are beneficiaries who attend the Nutrition outpatient clinic of the

Hospital-Regional “Presidente Benito Juárez” diagnosed at most one year ago and who agree to participate in

the study, age between 45 and 65 years with regular attendance at the outpatient clinic, minimum of 3 consecutive months.

7. Methods of selection and inclusion of participants in the study.

Phase 1. Sample recruitment.

The convenience sample will be recruited by self-selection: patients who

attend the nutrition outpatient clinic tion that meet the inclusion criteria,

they will be invited to participate in the study. After giving them

all information, those who wish to participate will sign the legal informed consent for participation.

Phase 2. Case randomization procedure.

Patients who sign the informed consent will be assigned a group according to the following: in the case

If you have an even number in your file, you will be part of the control group (A), and

if you have an odd number, you will be part from intervention group B.

Group A.

They will be given verbal instructions to continue with the treatment established by the treating physician, and they will be provided with nutritional guidance with the help of the healthy eating plate.

Group B.

They will be given verbal instructions to continue with the treatment established by the treating physician, they will be given nutritional guidance with the help of the healthy eating plate and they will be provided with a pamphlet with the instructions.
written and photographed on how to consume flaxseed and its benefits.

Phase 3.

Administration of flaxseed

Researchers will purchase, package, and provide flaxseed powder to members of group B.

Flaxseed will be delivered in packages with 16 gr of ground flaxseed each,

which will be given to patients for their daily consumption (a tablespoon of 8

gr of flaxseed in the morning snack and 8 gr of flaxseed in the afternoon

snack)

(late). You will be provided with brochures with images explaining how to consume it and how the glass should look when finished. Various forms of consumption of the powder will also be provided to avoid getting bored with the taste and consistency.

from dust.

Phase 4.

Surveillance and monitoring.

Daily contact will be maintained with participants via WhatsApp in order to remind them to take flaxseed.

and also to find out if they have any adverse symptoms (abdominal distension, flatulence, gas, diarrhea, etc.), as well as to resolve doubts and ask if they should start taking some vitamins, minerals or medications.

Both groups will be given a 24-hour recall and a food frequency questionnaire. every 15 days. The food consumption of both groups will be analyzed according to its nutritional content (energy, macro and micronutrients) and each nutrient will be used as a nutritional variable that can influence the control of the biochemical markers.

Phase 5.

Data analysis.

Statistical analysis will be performed using the IBM SPSS Statistics program version 24, in which it will be performed descriptive statistics and for group comparisons different tests will be performed depending on the nature of the variables. The comparison between the values measured at the beginning and the values measured after 3 months in each group will be performed using the paired t test and will be

considered statistically significant when $p<0.05$.

Inclusion criteria:

ÿ Patients entitled to who attend the “Presidente” Regional Nutrition outpatient clinic Benito Juárez” diagnosed at most one year ago and who agree to participate in the study by signing theinformed consent.

ÿ Patients diagnosed with uncontrolled Diabetes Mellitus evidenced by biochemical markers, den-within a maximum of 1 month of validity, (fasting blood glucose greater than 140 and glycosylated hemoglobin greater than (6.5%).

ÿ Patients with regular attendance at the outpatient clinic for at least 3 consecutive months.

Exclusion criteria:

ÿ Patients diagnosed with chronic kidney disease undergoing renal function replacement therapy.

ÿ Patients who already consume enough fiber and omega 3, as evidenced by the application of a reminder of24 hours and a food frequency questionnaire.

ÿ Pregnant or breastfeeding women.

ÿ Patients in menopause.

ÿ Patients with glucose disorders secondary to autoimmune diabetes, thyroid diseasesor insulin-producing tumors.

ÿ Patients with a medical history of poor drug adherence.

ÿ Patients with adequate glycemic control evidenced by clinical laboratory tests for at least 2 months.ÿ Patients who cannot read or write.

ÿ Patients who do not have a means of contact for follow-up.

Elimination criteria:

ÿ Patients who do not agree to participate in the study. ÿ Data collection instrument with incomplete items.

ÿ People who voluntarily withdraw from the study at any time. ÿ If the patient has surgery during the study.

ÿ Patient who during the study begins to consume any type of supplement (vitamins, minerals, omega 3).

ÿ Patient who stops consuming flaxseed during the study.

8. Experience of the principal investigator and co-investigators in this type of research. (maximum)

The principal investigator has participated in different research projects in the area, both as a collaborator and as principal investigator:

-Collaborating researcher. Faculty of Nutrition. Universidad Veracruzana. **"Evaluation of waist circumference in fifth period students of proposal 3 and 4 as a risk factor for developing metabolic syndrome".** Faculty of Nutrition. Xalapa, Universidad Veracruzana, Mexico. 2010. SATISFACTORILY COMPLETED

-Collaborating researcher. Cooperation with the Coordination of the Master's Degree in Food and Nutritional Security.
"Influence of maternal nutrition on the programming of fetal adipose tissue development". Faculty of Nutrition. Universidad Veracruzana. 2011. SATISFACTORILY COMPLETED

- Collaborating Researcher. **"Influence of physical activity on biochemical and vascular factors determining endothelial dysfunction in postmenopausal women".** Sant Joan de Reus University Hospital, Tarragona, Spain, 2012. SATISFACTORY COMPLETED

-Collaborating researcher. INCOS Project (Community Health Intervention), **"Effect of a community intervention in school children, considering nutritional and cognitive status".** Ccorca District, Cusco, Peru.
NUTRISAM Research Group of the Rovira I Virgili University, Spain. 2013. Project Grant from the Rovira i Virgilli University, Spain. SATISFACTORILY COMPLETED

-Principal investigator. PESA-T Project (Health Assessment Project) **"Nutritional Transition State of the city of Cuzco, Peru".** NUTRISAM Research Group. Project Grant from the Rovira I Virgili University, Spain. March-September 2014. SATISFACTORILY COMPLETED

-Principal investigator of the project **"EMOTIONAL NUTRITIONAL STATUS IN FOOD SAFETY AND HEALTH**

THE OAXACAN POPULATION DURING CONFINEMENT DUE TO THE SARS-COV-2 VI-RUS", registered at the Nutrition Institute of the University of the Sierra Sur (UNSIS) with folio CEI-09A / 2020. In progress

-Principal investigator of the project **"NUTRITIONAL STATUS, FOOD CONSUMPTION AND INTAKE NUTRITIONAL IN CONFIRMED AND RECOVERED CASES BY SARS-Cov-2 IN THE STATE OF OAXACA, MEXICO",** registered at the Nutrition Institute of the University of the Sierra Sur (UNSIS) with the folio INUT/NC/2021/01/270821. In progress

-Co-technical manager of the Project **"Molecular epidemiology of drug use and co-morbidities in Mexican population, as well as its repercussions on the Mexican legal framework",** registered in the Institute of Nutrition from the University of the Sierra Sur. INUT/BMBCS/05/2020. In progress

9. Potential risks and benefits for participants and for society, as well as compensation for those involved participants.

According to the general health law on health research in its article 17, this is considered Low risk study because biochemical tests will be taken and this could cause the participant pain in the extraction area, and you may also experience some symptoms from taking flaxseed such asconstipation, diarrhea, or gastrointestinal upset.

The participant will not receive financial compensation, but the results of the study will be published and disseminated.results. Based on the results of the studies, participants may potentially receive the benefit of improved controlling your type 2 diabetes.

10. Management of potential risks for participants.

To minimize risks, researchers will be in daily contact with participants to warn them any damage to health and to know if any gastrointestinal reaction or even allergic reaction occurs, thisin order to be able to tell you what to do or even stop the study if necessary.

In case the discomfort persists, the responsibility of the research team will be guaranteed to provide immediate nutritional care to the participant (as established in articles 18 and 19 of the Regulations)of the General Health Law on Health Research).

The risk management process will be as follows:

1. Identify risk	The patient will be monitored in case of any health problems caused byflaxseed.
2. Analyze	The symptom will be analyzed.
3. Prioritize risk	It will be verified that your health is not compromised.
4. Control the risk	If the symptom is controllable, the treatment will continue and if it is not, the patient can withdraw.

of the study. If the patient presents any	stress problems due to the administration tion is withdrawn from the study.

11. Procedure by which consent to participate in the study will be obtained.

- Participants who meet the inclusion criteria will be recruited in the nutrition outpatient clinicfrom the Regional Hospital of Oaxaca.
- You will be provided with detailed information about the study and will be provided with written informed consent.legal participation document (ANNEX 1)
- You will be given time to proceed with the reading of the document and you will have time in case the participant hasdoubts or questions about the study.

12. Management of confidentiality of information.

Upon entering the study, each participant will be registered with a number by which they will be addressed throughout the study. All data will be treated anonymously.

13. Conflicts of interest.

There is no conflict of interest

14. Bibliography

Hasaniani N, Rahimlou M, Ramezani A, Mehdizadeh A and Alizadeh M. (2019) The Effect of Flaxseed Enriched Yogurt on the Glycemic Status and Cardiovascular Risk Factors in Patients with Type 2 Diabetes Mellitus: Randomized, Open-labeled, Controlled Study. Clinical Nutrition Research. 8(4):284- 295. https://doi.org/10.7762/cnr.2019.8.4.284

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ANNEX 1 LEGAL INFORMED CONSENT

Oaxaca de Juarez Oaxaca, to_____of _____.

INFORMED CONSENT

Dear patient:

A group of researchers attached to the Nutrition Institute of the University of the Sierra Sur, which is part of the SUNEO (State University System of Oaxaca) invites you to participate in the study **"Effect of consumption of flaxseed as a treatment for adults with type 2 diabetes mellitus in Oaxaca de Juárez, Oaxaca."**

We respectfully request that you read the following information carefully before agreeing to participate.

Researchers

Dr. Sabina López Toledo (Responsible)

Maria Cruz Pineda De La Cruz

General objective

To assess the adjuvant effects of flaxseed consumption (14 g of flaxseed) on biochemical markers cos (glucose, glycosylated hemoglobin, total cholesterol, triglycerides, LDL cholesterol and HDL cholesterol) of patients Adults (30 to 70 years) with type 2 diabetes mellitus, who attend the Nutrition outpatient clinic at the Re-Hospital regional of Oaxaca.

Specific objectives

1. Describe the sociodemographic variables (age, sex, occupation, marital status) of adult patients (30 to 70 years) who suffer from type 2 diabetes, who attend the Nutrition outpatient clinic at the Regional Hospital from Oaxaca.
2. Describe the clinical characteristics (time of evolution of the disease, type of treatment, control and comor-bilities), of adult patients (30 to 70 years) who suffer from type 2 diabetes, who attend the outpatient clinic of Nutrition at the Regional Hospital of Oaxaca.

3. Assess biochemical parameters (glucose, glycosylated hemoglobin, total cholesterol, triglycerides, cholesterol LDL and HDL cholesterol), of adult patients (30 to 70 years) who suffer from type 2 diabetes, who come to the consultation Nutrition external of the Regional Hospital of Oaxaca,

4. Apply a nutritional intervention to two groups: Group A) Teaching the healthy eating plate and Group B) Teaching healthy eating dishes and indicating flaxseed consumption.

5. Evaluate the effect of flaxseed consumption on biochemical markers (glucose, glycosylated hemoglobin, Total cholesterol, triglycerides, LDL cholesterol and HDL cholesterol of adult patients (30 to 70 years) suffering from type 2 diabetes, who attend the Nutrition outpatient clinic at the Regional Hospital in Oaxaca.

6. Analyze the most effective possible combinations (pharmacological + non-pharmacological) for the treatment of adult patients (30 to 70 years) suffering from type 2 diabetes, who attend the Nutrition outpatient clinic at the Regional Hospital in Oaxaca.

Justification

Type 2 Diabetes Mellitus represents one of the most important health emergencies of this century. It is estimated that In 2019, there were already 463 million people with diabetes mellitus worldwide and this figure may increase to 578 million by 2030 and to 700 million by 2045. A state of hyperglycemia is associated with acute and chronic complications, in both cases affecting the cardiovascular system, mainly the blood vessels and consequently to the entire organism, but mainly to the eyes, kidneys, arteriovelocity systems. and peripheral nerves. Although it is known that insulin resistance is reversible and that diabetes is mellitus type 2 is controllable with a change towards a healthy lifestyle, the population ignores these recommendations and continue with their unhealthy habits. Thus, the number of patients continues to grow expo- essentially, which leads to an increase in economic expenditure on health. This is why They are looking for non-pharmacological measures that favor the reduction of glycemia in patients with Diabetes

Mellitus where the consumption of functional foods is a good alternative for the treatment of this chronic disease.

Flaxseed is a food that is characterized by its nutritional properties, highlighting its content in acid alpha linoleic acid, flax lignans, secoisolariciresinol diglucosides. The latter have antioxidant, hypolipidemic effect. miante and hypoglycemic, which makes it an excellent option as a functional treatment for diabetes type 2.

Description of procedures

Patients who sign the informed consent will be assigned a group according to the following: in the case

If you have an even number in your file, you will be part of the control group (A), and if you have an odd number, you will be part from intervention group B.

Group A.

They will be given verbal instructions to continue with the treatment established by the treating physician, and they will be provided with nutritional guidance with the help of the healthy eating plate.

Group B.

They will be given verbal instructions to continue with the treatment established by the treating physician, they will be provided nutritional guidance with the help of the healthy eating plate and they will be provided with a pamphlet with the instructions written and photographed on how to consume flaxseed and its benefits.

Phase 3.

Administration of flaxseed

Researchers will purchase, package, and provide flaxseed powder to members of group B. The flaxseed will be delivered in packets containing 16 g of ground flaxseed each, which will be given to patients for daily consumption (one 8 g spoonful of flaxseed in the morning snack and one 8 g spoonful of flaxseed in the afternoon snack).

(late). You will be provided with brochures with images explaining how to consume it and how the glass should look when finished. Various forms of consumption of the powder will also be provided to avoid getting bored with the taste and consistency of the powder.

Phase 4.

Surveillance and monitoring.

Daily contact will be maintained with participants via WhatsApp in order to remind them to take flaxseed.

and also to find out if they have any adverse symptoms (abdominal distension, flatulence, gas, diarrhea, etc.), as well as to resolve doubts and ask if they should start taking some vitamins, minerals or medications.

Both groups will be given a 24-hour recall and a food frequency questionnaire. every 15 days. The food consumption of both groups will be analyzed according to its nutritional content (energy, macro and micronutrients) and each nutrient will be used as a nutritional variable that can influence the control of the biochemical markers.

Benefits

You will not receive financial compensation, but the results of the study will be published and the results will be disseminated. According to the results of studies, you may potentially receive the benefit of improving the control of your Diabetes.
type 2.

Risks

According to the general health law on health research in its article 17, this is considered

This is a low-risk study because biochemical tests will be taken and this could cause pain in the area, you may also experience some symptoms from taking flaxseed such as constipation, diarrhea or

gastrointestinal upset. To minimize risks, researchers will be in contact with you daily to tell you what to do or even stop the study if necessary.

Voluntary participation/dropout

Participation is completely voluntary, if for any reason you decide to leave the study, you may withdraw from research at any time you decide, without any repercussions of any kind.

Expenses generated by research

All expenses incurred will be covered by the researcher in charge.

Confidentiality and disclosure of results

Your privacy will be respected at all times; in all project processes you will be identified with a code based on a number and never by your name. The information you provide will be confidential. The results will be published/disclosed for the sole purpose of generating knowledge, always safeguarding your identification data.
certification.

Questions

If you have any questions, comments or concerns regarding the project, please contact the

Dr. Sabina López Toledo, project manager, at the email: sabina.ltoledo@gmail.com or at the phone number 5534142487
who will clarify it for you immediately.

Gratitude

If you agree to participate in the study, we will give you a copy of this document. The research team appreciates your valuable participation.

Consent

I have been informed about my participation in this research. Therefore I give my consent to those in charge.

of the project, so that they can ask the necessary questions, to which I will answer in a

concrete manner and with the truth in at all times.

Name and signature (or fingerprint) of **participant**	Name, signature (or fingerprint) and address of **witness** 1	Name, signature (or fingerprint) and address of **witness** 2