**CASE REPORT FORM -- Patient in the “Control Group”**

**Improving blood sugar control through patients’ choice of evidence-based spices and foods with hypoglycaemic effect – A series of randomized controlled trials.**

**ENROLMENT VISIT (WEEK -2)**

1. **ELIGIBILITY CRITERIA:** For the following questions please make a tick in the correct answer

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| * 1. **Inclusion criteria: *(If yes include)*** |  |  |  |  |
| * + 1. **Do you have type 2 diabetes mellitus for** ≥ **3 months AND uncontrolled blood sugar despite** ≥ **3 months of usual care treatment (Lifestyle + standard medication if applicable)?** * Fasting Plasma Glucose (FPG) mmol/L or mg/dL: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_   ***(Include if*** FPG ≥ 7.0 mmol/L (126 mg/dL)   * HbA1c (%), if available: \_\_\_\_\_\_\_ Date of measurement: \_\_\_\_\_\_\_\_\_   ***(Include if*** HbA1c > 6.5% and ≤ 11.5%, and even if today FBG is normal (OR criteria)) |  | YES |  | NO |
| ***If you are under standard medication:*** |  |  |  |  |
| * + 1. **Have you followed the same treatment and a stable dosage for at least the last 3 months?** |  | YES |  | NO |
| * + 1. **Can the treatment stay the same for the next 3 months?** |  | YES |  | NO |
| * + 1. **If you are taking insulin, do you ONLY use long-acting insulin?** |  | YES |  | NO |
| * + 1. **If you are taking any analogue GLP-1, has the dosage been stable for** ≥ **1 year?** |  | YES |  | NO |
| * 1. **Exclusion criteria:** ***(If yes exclude)*** |  |  |  |  |
| * + 1. **Do you have any severe and unstable complications of diabetes: end-organ damage such as nephropathy, retinopathy, neuropathy, etc.?** |  | YES |  | NO |
| * + 1. **Do you have any health conditions that require urgent attention?** |  | YES |  | NO |
| * + 1. **Do you have any cognitive or sensory impairment that may prevent conducting the interview?** |  | YES |  | NO |
| * + 1. **If the patient is a woman, are you pregnant and/or breastfeeding?** |  | YES |  | NO |

After explaining the study entirely, identifying a potential patient for enrolment, and clarifying any doubts, if the patient is interested in participating, do not forget to sign the informed consent form and randomly assign her/him to the study group.

**After randomisation:** the patient is allocated in the **control group**: \_\_\_\_\_\_\_ or the **intervention group**: \_\_\_\_\_\_\_\_\_

**Next appointment, for the second visit in 2 weeks for the beginning of the study, that is, date: \_ \_ /\_ \_ / \_ \_ \_ \_**

**Initials of the person filling out the form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of the person in charge: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Please, fill the survey up to here for the first visit***

**START OF THE TRIAL (WEEK 0)**

**ID Number: \_ \_ \_ \_ (*Patient number: Starts with 001)***

**Date:** **\_ \_ / \_ \_ / \_ \_ \_ \_ Country: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Name of the center: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. **PERSONAL DATA**

**Patient name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Phone number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

* 1. **Age: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**
  2. **Gender:** M / F
  3. **Formal education:** Primary school / Secondary school / University/ None

1. **PERSONAL HISTORY-RISK FACTORS:**
   1. **Since how long have you been diagnosed with diabetes? \_\_\_\_\_\_\_\_\_\_\_ (years)**
   2. **Do you take any conventional treatment to control your diabetes?** Yes / No
      1. ***If yes,* which one(s)** (ex. Metformin, sulfonylurea, Dipeptidyl peptidase-4 (DPP-4) inhibitor “Gliptins”, Thiazolidinedione, Insulin).
   3. **Do you have high blood pressure?** Yes / No
   4. **Do you have heart disease?** Yes / No
   5. **Do you have any other health problem?** Yes / No
      1. *If yes*, please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Other risk factors- lifestyle and physical activity:**

|  |  |  |
| --- | --- | --- |
| **History of** | **Yes** | **No** |
| * 1. **Smoking (daily)** |  |  |
| * 1. **Alcohol (daily)** |  |  |
| * 1. **Doing vigorous activity at work?** e.g., heavy lifting, digging or construction work |  |  |
| * 1. **Doing intense physical activity in leisure time, at least 30 mins for 2 times per week?** (e.g., running, or strenuous sports, weightlifting, etc..) |  |  |
| * 1. **Doing moderate-intensity physical activities in leisure time,** **at least 30 mins for 2 times per week** (e.g., walking or swimming, etc.) |  |  |

* 1. **In general, how do you find your health during the past 4 weeks?**

**1)**Very good, **2)** Good, **3)** Neither poor nor good, **4)** Poor, **5)** Very poor

* 1. **If the patient is a woman:**
     1. **Are you newly pregnant?**  Yes / No (*If* ***yes***🡪***Exclude the patient from the study)***

1. **USE OF COMPLEMENTARY / ALTERNATIVE MEDICINE**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Yes** | **No** | **4.1.1 If yes, please specify which one(s):** | |
| * 1. **Do you take any traditional medicine for the management of diabetes?** |  |  |  | |
| * 1. **Do you frequently consume any food products or common spices\* listed below?**   *\*Aloe vera, Astragalus, Bitter melon, Black cumin, Cinnamon, Fenugreek, Ginger, Nettle or Psyllium fiber.* |  |  | **Product** | **Quantity -Frequency- Form** |
| **4.2.1**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **4.2.1.a Dose:** (e.g., How many mg, spoons, or teaspoons) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **4.2.1.b How many times per day?**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **4.2.1.c What form?** Gel/Root/Powder/Seed/Oil |
| **4.2.2**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **5.2.2.a Dose:** (e.g., How many mg, spoons, or teaspoons) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **5.2.2.b How many times per day?**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **5.2.2.c What form?** Gel/Root/Powder/Seed/Oil |

1. **ANTHROPOMETRIC AND CLINICAL PARAMETERS**

|  |  |
| --- | --- |
| * 1. **Weight** (Kg): \_\_\_\_\_\_\_\_\_\_\_ | * 1. **Height** (cm): \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| * 1. **Waist circumference** (cm): \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | * 1. **Blood pressure** (mmHg): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Blood glucose measurements**

* 1. **Fasting Plasma Glucose (FPG) mmol/L or mg/dL: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
  2. **Glycated haemoglobin (HbA1C) %** (If available)**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
  3. **Is the patient really “fasting” (no food since > 8 hours, and if not possible, 4 hours)?** Yes / No
  4. **Did you take anti-diabetic pill today or injections** (if applicable)**?** Yes / No

|  |  |
| --- | --- |
| **Lipid profile (if available,** and if measured anyway as routine care**)** | |
| **Measurements** | **Values** |
| * 1. **Cholesterol** |  |
| * 1. **Non-high-density lipoprotein (HDL) cholesterol** |  |
| * 1. **Low density lipoprotein cholesterol** |  |
| * 1. **Very low-density lipoprotein cholesterol** |  |
| * 1. **HDL cholesterol** |  |
| * 1. **Triglycerides** |  |

**Next appointment, for the third visit in 2 weeks, for the first follow-up, that is, date: \_ \_ /\_ \_ / \_ \_ \_ \_**

**Initials of the person filling out the form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of the person in charge: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Please, fill the survey up to here for the second visit***

**FIRST FOLLOW UP (WEEK 2)**

**Check ID number: \_\_ \_ \_ \_ \_ \_ Date:** **\_ \_ / \_ \_ / \_ \_ \_ \_**

1. **REGARDING LIFESTYLE**
   1. **In General, how do you find your health during last 2 weeks?**

**1)** Very good, **2)** Good, **3)** Neither poor nor good, **4)** Poor, **5)** Very poor

* 1. **Do you have any extra announcements to report that have happened in the last week?** (e.g., pregnancy, changes in emotional state or others? Yes / No
     1. *If yes***,** please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  2. **If the patient is a woman, are you newly pregnant?**  Yes / No *(If* ***yes*** *🡪* ***Exclude the patient from the study)***

1. **THERAPEUTIC MANAGEMENT AND USUAL CARE:**
   1. **Did you continue during last week with your current conventional diabetes treatment?** Yes / No
      1. If no, **specify the reason and the patient should be withdrawn from the study** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
      2. If no**, which treatment(s) was/ were change or stopped? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
   2. **Did you have any new symptoms or adverse event since last visit?** Yes / No
      1. If yes, please specify from the following:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Symptoms** | | | **How would you describe this?** | | |
| **Symptoms** | **Yes** | **No** | **Slight** | **Moderate** | **Severe** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

\*The shaded boxes: discuss with Doctor if preferable to exclude patient from the study



1. **ANTHROPOMETRIC AND CLINICAL PARAMETERS**

* 1. **Blood pressure** (mmHg): \_\_\_\_\_\_\_\_\_\_\_
  2. **Fasting Plasma Glucose (FPG)** (mg/dL or mmol/ L) : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  3. **Is the patient really “fasting”?** (No food since > 8 hours, and if not possible, 4 hours)Yes / No
  4. **Did you take anti-diabetic pill today or injections (if applicable)?** Yes / No
  5. **Is the target FPG reached?** Yes / No

**Please explain how to continue the new lifestyle for the next 10 weeks.**

**Tell the patient that he/she can fill in the glucose and blood pressure measurements on the home follow-up chart and that he/she should present it on the day of the final visit.**

**Clarify any doubts and motivate the patient.**

**Next appointment, for the last visit in 10 weeks, for the end follow-up, that is, date: \_ \_ /\_ \_ / \_ \_ \_ \_**

**Initials of the person filling out the form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of the person in charge: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Please, fill the survey up to here for the third visit***

**LAST FOLLOW UP (WEEK 12)**

**Check ID number: \_\_ \_ \_ \_ \_ \_ Date:** **\_ \_ / \_ \_ / \_ \_ \_ \_**

1. **REGARDING LIFESTYLE AND PHYSICAL ACTIVITY**
   1. **In general, how do you find your health during last 10 weeks?**

**1)** Very good, **2)** Good, **3)** Neither poor nor good, **4)** Poor, **5)** Very poor¨

* 1. **Since the beginning of this study 3 months ago, did you have any change in the lifestyle and physical activity such as diet, vigorous activity, sport, moderate-intensity activities, and any other(s) physical activity?** Yes / No
     1. *If yes***,** **what was it?** (Tick the correct answers, can be several):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **1.** Better diet | **2.** More vigorous activity at work | **3.** More sport | **4.** More moderate-intensity activities | **5.**Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **6.** Worse diet | **7.** Less vigorous activity at work | **8.** Less sport | **9.** Less moderate-intensity activities | **10.**Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

* 1. **Do you have any extra announcements to report that have happened?**
  2. **in the last 10 weeks?** (e.g., pregnancy, changes in emotional state or others? Yes / No
     1. *If yes***,** please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  3. **If the patient is a woman, are you newly pregnant?**  Yes / No

1. **THERAPEUTIC MANAGEMENT AND USUAL CARE:**
   1. **Did you continue during the last 10weeks with your current conventional diabetes treatment?** Yes / No
      1. If no, **specify the reason** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
      2. **Which treatment(s) was/ were change or stopped? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
      3. **Why was/ were the treatment(s) change or stopped? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
   2. **Did you have any new symptoms or adverse event?** Yes / No
      1. If yes, please specify from the following:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Symptoms** | | | **How would you describe this?** | | |
| **Symptoms** | **Yes** | **No** | **Slight** | **Moderate** | **Severe** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |



\*The shaded boxes exclude patient from the study

1. **ANTHROPOMETRIC AND CLINICAL PARAMETERS**

|  |  |
| --- | --- |
| * 1. **Weight** (Kg): \_\_\_\_\_\_\_\_\_\_\_ | * 1. **Height** (cm): \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| * 1. **Waist circumference** (cm): \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | * 1. **Blood pressure** (mmHg): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Lab measurements**

* 1. **Blood pressure** (mmHg): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  2. **Fasting Plasma Glucose (FPG)** mmol/L or mg/dL : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  3. **Is the patient really “fasting” (no food since > 8 hours, and if not possible, 4 hours)?** Yes / No
  4. **Glycated haemoglobin (HbA1C) %** (If available) : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  5. **Did you take anti-diabetic pill today or injections (if applicable)?** Yes / No

|  |  |
| --- | --- |
| **Lipid profile (if available,** and if measured anyway as routine care**)** | |
| **Measurements** | **Values** |
| * 1. **Cholesterol** |  |
| * 1. **Non-high-density lipoprotein (HDL) cholesterol** |  |
| * 1. **Low density lipoprotein cholesterol** |  |
| * 1. **Very low-density lipoprotein cholesterol** |  |
| * 1. **HDL cholesterol** |  |
| * 1. **Triglycerides** |  |

1. **QUESTIONS TO THE PATIENT (There are no good or bad answers – we do not judge, just need the facts)**
   1. **In General, how do you find your health in the past 12 weeks?**

**1)**Very good, **2)** Good, **3)** Neither poor nor good, **4)** Poor, **5)** Very poor

* 1. **How satisfied are you with your participation in this study?**

**1)**Very satisfied, **2)** Satisfied, **3)** Neither satisfied nor dissatisfied, **4)** Dissatisfied, **5)** Very dissatisfied

* + 1. If **4)** Dissatisfied or **5)** Very dissatisfied, please explain why: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  1. **How useful did you find the information material provided?**

**1)**Very good, **2)** Good, **3)** Neither poor nor good, **4)** Poor, **5)** Very poor

* 1. **What is your overall perception of the suggested recipes?**

**1)**Very good, **2)** Good, **3)** Neither poor nor good, **4)** Poor, **5)** Very poor

* 1. **Did you plan to continue with the acquired habits and the new lifestyle to control diabetes?** Yes / No

***Important:*** *Please remind the patient again that all information collected is anonymous.*

**Initials of the person filling out the form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of the person in charge: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Please, fill the survey up to here for the last visit***

**THANK YOU!**