**Diabetes: improving blood sugar control through patients’ choice of evidence-based spices and foods with hypoglycaemic effect.**

**Generic Protocol Synopsis**

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**PROTOCOL SYNOPSIS:**

**CONTEXT**

-- With diabetes type II, patients often do not reach desired control of blood glucose, despite advices on life-style and medication.

-- In recent years, an array of clinical studies have shown the anti-diabetic effect of common spices and food products.

=> **Proposal**: patients with poorly controlled diabetes would be encouraged to eat or drink what they like within a list of validated (as hypoglycemic) food products with detailed information on recommended preparation mode and dosages. These products would be recommended alongside life-style / dietary advice and as well as usual anti-diabetic treatment, if applicable.

**Hypothesis:** this approach might be associated with a fair adherence to the intervention, thanks to its “user-friendly” aspect.

The selected food products for this study are plants that have been assessed as anti-diabetic for humans through at least one fair randomized comparative clinical trial, with a follow-up of several weeks or months. The selected food products are :

**Aloe vera, Astragalus, Bitter melon, Cinnamon, Fenugreek, Ginger, Black cumin, Psyllium fiber, Stinging Nettle.**

=> **RESEARCH QUESTION**: Does proposing to patients to use what they like within a list of validated products improve diabetes control?

**METHOD**

**Inclusion criteria** : Patients with diabetes type II since at least 3 months, with usual care (lifestyle advice + medication if applicable) but with uncontrolled glycaemia.

**Exclusion criteria :**

1. Severe and unstable complications of diabetes
2. If patient is under insulin, no rapid insulin
3. any health condition that requires urgent attention or may prevent conducting the study
4. Pregnancy

**STUDY DESIGN**

**Primary outcomes:**

- Percentage of patients in each group reaching a decrease of ≥ 0.5mmol/L in FPG;

- Percentage of patients reaching a decrease of ≥ 0.5 points of percentage from the baseline value in HbA1c; each of these reductions being deemed as clinically significant.

**Sample size**:

For each RCT, the total required sample at inclusion is 124 (62 in each group).

**Intervention:**

Abooklet with thelist ofcommon food products or common herbs, clinically validated, with instructions for use is presented to the diabetic patient. There will be a version for health professional (with scientific references) and a version for patients, adapted to the country’s available products and recipes.

**The patient will be encouraged to follow his/her preferences within the established list of foods and spices: he/she is expected to choose 2 plants from the list and to consume each of them everyday during the whole duration of the trial (3months).**

For each plant, several recipes are proposed. Recipes are designed so that the product is in the same state as in the reference clinical trial (e.g. a juice with limited heating), in order to maintain the hypoglycemic activity. Patients will receive information on doses, indicated in weight unit and their equivalent amount in tea spoons.

**Reference:**

Willcox ML, Elugbaju C, Al-Anbaki M, Lown M, Graz B. Effectiveness of Medicinal Plants for Glycaemic Control in Type 2 Diabetes: An Overview of Meta-Analyses of Clinical Trials. Front Pharmacol. 12:777561; 2021 Nov 26.

..and others..