

## Abstract

# The VEGANScreener Project: The Protocol for the Clinical Observational Study <sup>†</sup>

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**Abstract:** Background and Objectives: Consumption of plant-based diets, including vegan diets, requires attention towards diet quality and the early detection and prevention of nutritional deficiencies. The VEGANScreener project aims to develop and validate a standardized brief web- and app-based screening tool to assess and monitor diet quality among vegans in Europe. To this end, a clinical study will be performed to evaluate the VEGANScreener against a reference diet assessment method and nutritional biomarkers. Materials and Methods: An observational cross-sectional study will comprise six hundred participants across four European sites (Germany, Spain, Belgium, Czech Republic): 400 self-reported vegans ( $\geq 2$  years on vegan diet) and 200 self-reported omnivore controls; without diseases affecting the metabolism and intestinal integrity; aged 18 to 65 years (1:1 ratio 18–35 and 36–65); males and females (1:1 ratio). Subjects will be enrolled after an online eligibility check. Informed consent will be obtained, and the subjects enrolled will be given a unique ID (pseudonymized). The initial clinical visit consists of structured medical history-taking, blood pressure, heart rate and anthropometric measurements, blood, spot urine and saliva sampling, distributing the VEGANScreener access, diet record instructions, and general survey access. A follow-up collection visit will be scheduled 14–21 days apart: 24 h urine and 4-day diet records will be collected, and subjects' participation will be terminated. VEGANScreener will be administered twice to limit the within-person errors. Results: Field work is ongoing, and we expect to have results by the time of the conference. Discussion: The VEGANScreener tool will be validated for the target population. The primary objective is to assess the construct validity and criterion validity of the VEGANScreener through associations of the score with nutrient intakes from a 4-day diet record and associations with biomarkers of dietary intake. Standard statistical models will be implemented for cross-sectional comparisons of geographical groups. Secondary outcomes will include analyses of dietary data and metabolomics. Vegan subgroups will be identified with dimensionality reduction methods and univariable statistical tests. Major nutrient sources and variations across groups will be assessed. Exploratory metabolomic analysis (blood, urine, saliva) to identify novel concentration biomarkers of dietary intake and nutritional adequacy will be performed using multivariable analysis.



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**Institutional Review Board Statement:** The study will be conducted in accordance with GCP and the declaration of Helsinki. The study protocol was approved by the following institutional review boards: KVVH ethical board (EK-VP03/0/2022), UNAV (2022.120), IFPE (AZ 37/23), UGent (ONZ-2023-0169), Cantonal Ethic Committee Zurich (2023-01112).

**Informed Consent Statement:** Informed consent will be obtained from all subjects involved in the study.

**Data Availability Statement:** Data sharing is not applicable to this abstract.

**Conflicts of Interest:** The authors declare no conflict of interest.

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