**Study protocol**

# Evaluation of the Nutri-plus module

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Contents

## 1 Introduction

The Nutri+ module is part of the TNO 360-degree diagnostics tool (Harakeh et al., submitted). The aim of this tool is to generate a holistic perspective on an individual's health; that is, in addition to biomedical health, it also maps an individual's behavior, mental health, and socio-economic environment. This tool can be used for decision support and shared decision-making in, for example, primary care (Kalache et al., 2019). Furthermore, based on this more holistic diagnostic approach, more personalized advice or better-tailored interventions can be offered to individuals.

However, the dietary questionnaire that is currently part of the 360-degree diagnostics tool is still fairly limited; it assesses consumption in only four food groups. In contrast, the Health Council distinguishes 15 product groups (Gezondheidsraad, 2015). As a result, the current 360-degree diagnostics tool provides an insufficient picture of an individual's dietary intake. In order to better assess dietary behavior within the 360-degree diagnostics and to provide more appropriate advice, the dietary questionnaire was further developed last year into the so-called "Nutri+ module."

The new questionnaire consists of 38 questions on an individual's dietary intake across 17 product groups. The questionnaire and cutoff values are based on the Guidelines for Healthy Diet (Kromhout et al., 2016), where applicable further refined using the recommendations of the Netherlands Nutrition Centre. After completing the questionnaire, a profile wheel (see Figure 1) is displayed, providing insight into compliance with the guidelines for 17 product groups. In this profile wheel, a "traffic light" color is used for each product group to indicate whether an individual roughly meets the guidelines (green), consumes more than 50% of the recommended amount (orange), or consumes less than 50% of the recommended amount (red). For (sub)product groups for which no guideline exists, a grey color is shown (for example, for potatoes).

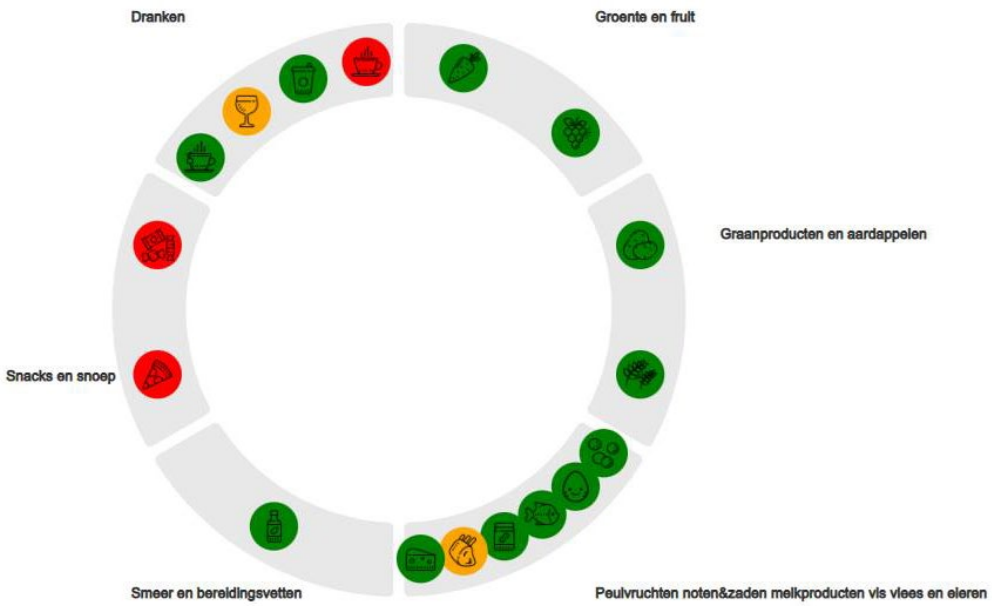


*Figure 1. Example of a "Profile wheel" for an individual after filling out the Nutri-plus module.*

The product groups defined by the Health Council were further refined to provide participants with more detailed insight into areas of their dietary pattern that could be improved. In addition, unhealthy choices are included in the Nutri+ module, even though they are not part of the Guidelines for Healthy Diet (Gezondheidsraad, 2015). By assessing and displaying these in the profile wheel, individuals can also gain insight into the extent of their unhealthy choices.

With the Nutri+ module, we aim to offer a dietary intake assessment as an integral part of the 360-degree tool, enabling individuals to gain insight into their own dietary patterns and areas for improvement. These outcomes can be used to provide personalized dietary advice or interventions tailored to the individual.

Before the Nutri+ module can be used for personalized dietary assessment and advice, it must be evaluated to determine whether it provides an accurate picture of an individual's dietary intake. To this end, the outcomes of the Nutri+ module, consisting of a red–orange–green categorization, can be compared with those of an already validated method for dietary intake assessment. In the literature, (weighed) dietary recall methods are commonly used to validate dietary questionnaires (Cade, 2002), as these methods are less sensitive to underreporting than food frequency questionnaires (Prentice, 2011).

In a 24-hour recall method, individuals are asked to provide detailed information about all foods and beverages consumed in the previous 24 hours (Meijboom, 2017). To obtain a reliable estimate of habitual dietary intake, the 24-hour recall must be repeated on multiple days in order to correct for day-to-day variation. Wageningen University & Research has developed and validated a Dutch online 24-hour dietary recall method that can be completed entirely online by participants, known as "Compl-Eat" (Meijboom, 2017). This significantly reduces the costs and burden for both researchers and participants.

This study will consist of two phases. The first phase will involve a pre-test to assess the usability, comprehensibility, and completeness of the developed Nutri+ module among end users and experts. The insights generated will be used to further improve the Nutri+ module and the profile wheel visualization. After completion of the first phase, the second phase will commence, in which the Nutri+ module will be compared with a reference method in an evaluation study. The selected reference method for this evaluation study is a 24-hour recall using Compl-Eat.

## 2 Goal

**Goal of the Nutri+ module:** To assess, at the individual level, the extent to which a person complies with the dietary guidelines and where there is room for improvement. These insights are used to provide personalized dietary advice and to monitor an individual's dietary intake.

**Phase 1: Pre-test**

**Objectives**

- To gain insight into the user experiences of the target group with completing the questionnaire and with regard to the visualization of the profile wheel.
- To collect feedback from experts on the Nutri+ module (including completeness, question formulation, example products, etc.).
- To use the collected user insights and expert feedback to further improve the Nutri+ module and the profile wheel visualization before starting the second phase of the study (the evaluation study).

**Phase 2: Evaluation study**

**Main objective:** To evaluate whether the absolute intake in grams, as measured by the Nutri+ module, is comparable to Compl-Eat for the 21 product groups. This will be explored both quantitatively (e.g., what percentage of intake is covered by the Nutri+ module compared with Compl-Eat) and qualitatively (e.g., where the differences between Compl-Eat and the Nutri+ module lie). These insights can be used to further improve the tool.

**Sub-objectives:**

- To investigate whether the results of the Nutri+ module are reproducible over time or whether time effects are present, with a correlation coefficient of ≥ 0.75 between two measurement points considered successful.
- To evaluate the Nutri+ module (dietary questionnaire) against the Compl-Eat 24-hour recall method. Specifically, we aim to examine whether the Nutri+ module can accurately classify at least 75% of individuals into three categories for the 21 product groups.
- To evaluate the visualization of the profile wheel by users of the Nutri+ module.

## 3 Study design

This is a longitudinal randomized study to evaluate the Nutri+ dietary intake module. The Nutri+ module can be completed by participants at home via an online portal; it is filled out only once and takes approximately 30 minutes to complete. As a reference method, Compl-Eat is used. This is an online 24-hour recall method developed by Wageningen University & Research (Meijboom et al., 2017). Participants in the study can complete this 24-hour recall themselves at home via a portal, recording everything they ate and drank in the previous 24 hours. Based on the submitted data, the Compl-Eat platform can determine for an individual how much and what was consumed at both the product group and individual product levels. Compl-Eat is completed by participants on four non-consecutive days—three weekdays and one weekend day (Saturday or Sunday)—to obtain an accurate representation of an individual's average intake. The 24-hour recalls are manually checked for completeness by a researcher afterwards.

A randomized cross-over design is used, in which one group of participants completes the Nutri+ module first, while the other group completes Compl-Eat first. The days on which participants complete

the Nutri+ questionnaire and the days on which Compl-Eat is completed are randomly selected. There is a minimum interval of 7 days between the Nutri+ module and the first or last day of Compl-Eat.

In addition, possible time effects in dietary recording and the reproducibility of the Nutri+ module results are examined. To this end, participants are invited again after three to six months to repeat the entire procedure of completing the Nutri+ module once and Compl-Eat four times. The first series of questionnaires is sent out in April; the second series begins in September.

See Figure 2 for a schematic overview of the study design.

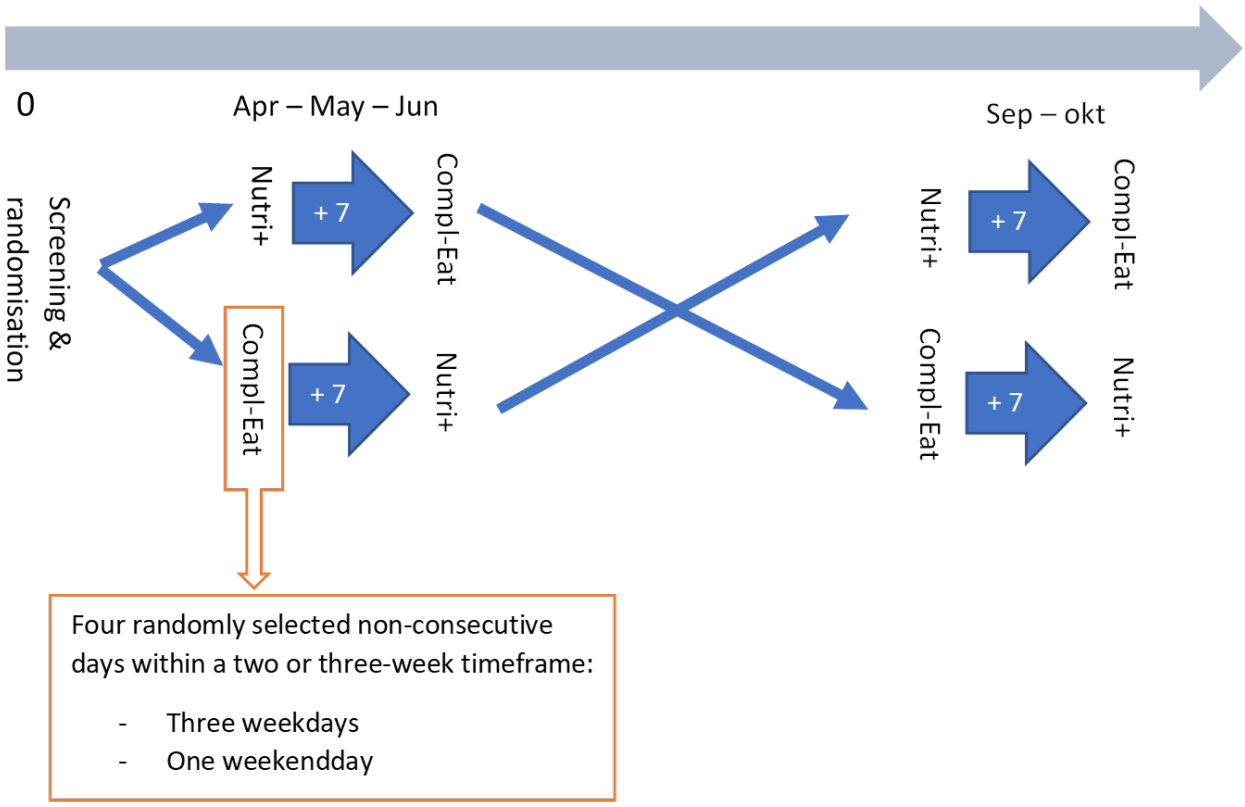


*Figure 2. Schematic overview of the study design of the evaluation study.*

## 4 Study population

A total of 200 participants will be recruited for this study. The target population consists of healthy men and women aged 35 to 80 years with normal weight, overweight, or obesity.

**Inclusion criteria for this study are:**

- BMI ≥ 20 and < 40 kg/m².
- Age 35–80 years.
- Good command of the Dutch language.
- Reasonable digital literacy and access to a PC or laptop.
- A fairly typical Dutch dietary pattern.

**Exclusion criteria for this study are:**

- Pregnant women or women who are breastfeeding.
- Recent unintentional weight loss of more than 5 kg.
- Under treatment for a serious (chronic) illness.
- History of myocardial infarction or stroke in the past 5 years.
- Previous or planned bariatric surgery.

In this study, we aim to perform subgroup analyses to examine whether there are differences in the usability of the Nutri+ module between men and women, across different age groups, between low and high socioeconomic status, and between individuals with normal weight and those with overweight or obesity. The rationale for this is the known differences in dietary intake among these subgroups and the potentially higher risk of over- or underreporting. Therefore, during recruitment, we will strive for a proportional distribution of sex (male/female), age (35–55 / 55–80), educational level (primary/secondary vocational or higher education/university), and BMI (20–25 / 25–30 / 30–40) in the study population. For sex, this will already be considered during screening: once 100 participants of a particular sex are recruited, only participants of the other sex will be admitted.

Recruitment will mainly take place via social media platforms (Facebook, LinkedIn, Instagram). If necessary, recruitment will be expanded through other channels, such as local newsletters and websites (e.g., “In de Buurt”). The number of participants represents our minimum target for data collection to ensure valid and reliable outcomes and to allow for subgroup analyses. Recruitment will therefore continue until the minimum number of participants is reached; additional participants are welcome (up to a maximum of 300). There will be no reserve participants.

## 5 Description of the study

**First Phase**

The first phase consists of preparatory activities, including the development of the Nutri+ module. During this phase, a pre-test is conducted with both participants and experts, which can take place either online or in person at a TNO location, depending on whether a visit to TNO is feasible. The aim of this pre-test is to assess the usability and comprehensibility of the Nutri+ module through a think-aloud protocol supervised by a researcher. This method involves asking participants and experts to verbalize all their thoughts, feelings, and opinions while performing a task. This provides the researcher with deeper insights into the user experience, the interpretation of the questions, the respondent’s thought process, as well as the completeness of the questionnaire, the alignment of response options with the questions, and the overall clarity and understandability of the questionnaire.

The think-aloud protocol is preferably conducted in a (digital) environment where the end user/respondent would normally complete the questionnaire; if this is not possible, it can also be carried out in a secluded, neutral room at TNO. Before starting, the researcher provides the participant or expert with an introduction to the study and requests consent for audio recording. The researcher remains passive while the participant or expert completes the questionnaire, but may remind them to continue verbalizing their thoughts if they fall silent. After completing the think-aloud protocol, several additional questions are asked regarding the experience of completing the questionnaire and the visualization of the profile wheel.

Both the target population of the Nutri+ module and a number of experts are involved in the pre-test. In total, approximately 10 participants are aimed for. Among the target population, the goal is to include a group with diverse characteristics in terms of age, sex, and educational level. Based on the results of this pre-test, the Nutri+ module will be further refined to prepare it for use in Phase 2.

*Table 1: Overview timeline and investment for participants pre-test*

| | How often and when | Total time investment |
|---|---|---|
| Go through the think-aloud protocol | 1 time filling out Nutri+ module<br>(spring 2022) | 1 time 30 minutes |
| Answering additional questions | 1 time directly after filling out Nutri+ module (spring 2022) | 1 time 15 minutes |

**Second Phase**

The second phase involves recruiting participants through social media campaigns and the completion of the Nutri+ module and Compl-Eat. Participants are recruited via social media advertisements, which link them to an online information sheet. After reading the information sheet, participants can provide online informed consent for participation in the study. They are then automatically directed to an online screening questionnaire (see inclusion and exclusion criteria). This screening questionnaire automatically assesses whether the individual meets the study's selection criteria. Candidates who do not meet the criteria are informed immediately. Candidates who do meet the criteria are directed to a baseline questionnaire to collect various baseline data (medication use, physical activity, adherence to any dietary or nutritional rules, and allergies or intolerances). Participants are then informed about the further study schedule and procedures.

The study uses a cross-over design, in which participants are randomly assigned to one of two sequences: starting with the Nutri+ module or starting with Compl-Eat. Participants who start with the Nutri+ module during the first series (autumn 2022) will start with Compl-Eat during the second series (spring 2023), and vice versa.

For all participants, the days on which the Nutri+ module and Compl-Eat must be completed are randomly selected. Both the Nutri+ module and Compl-Eat are completed at home using login credentials for the respective online platforms. Participants are not informed of the full schedule in advance to minimize potential influence on their dietary behavior. One day before a participant's first "assessment day," they are contacted by email by a researcher, requesting that they complete either the Nutri+ module or Compl-Eat the following day. Participants can respond to this email if the scheduled day does not fit their personal planning. In that case, the researcher reschedules the assessment day, and the participant is contacted again at a later time.

During the first series (autumn 2022), all participants complete Compl-Eat on four days within a two-week period and complete the Nutri+ module once. A minimum interval of seven days is maintained between completing Compl-Eat and the Nutri+ module to prevent interference between the methods.

After completing the first series (autumn 2022), participants are reminded that they will be contacted again in spring 2023 to complete the Nutri+ module and Compl-Eat. The same procedures are followed in spring 2023 as in autumn 2022.

Participants are also asked to complete an evaluation questionnaire regarding their experiences with completing the questionnaire and the visualization of the dietary profile wheel.

After data collection for the evaluation study is completed, the data are analyzed. Based on this analysis, recommendations will be made for adjusting the Nutri+ module (questionnaire, algorithms, and cut-off values) and for improving the visualization of the profile wheel.

*Tabel 2: Overview timeline and investment for participants evaluation study*

| | How often and when | Total time investment |
|---|---|---|

| | | |
|---|---|---|
| Nutri+ module | 1 time filling out autumn 2022<br>1 time filling out spring 2023 | 2 times, 20 minutes. 40 minutes in total. |
| Compl-eat | 1 time 4 days filling out autumn 2022<br>1 time 4 days filling out spring 2023 | 80 minutes per time. 160 minutes in total. |
| Evaluation questionnaire | 1 time filling out | 15 minutes |

## 6 Outcome variables

To evaluate the Nutri+ module in comparison with Compl-Eat, it is first necessary to assess the extent to which the food groups used in the Nutri+ module are also available in Compl-Eat. The outcomes listed below depend on the results of this mapping. In addition, Compl-Eat will need to apply the same food group classification based on the same cut-off values per product group as used in the Nutri+ module.

**Primary outcomes**

- Intake in grams for the 17 product groups that are quantitatively assessed (Fruit, Vegetables, Legumes, Nuts and Seeds, Fish, Dairy, Meat, Eggs, Soft Drinks, Alcohol, Coffee, Tea, Snacks, Sweet Spreads, Chips/Nuts/Party Snacks, Fast Food, Desserts/Ice Cream/Cakes) for both Compl-Eat and the Nutri+ module.

**Secondary outcomes**

- Evaluation overall and by subgroup (sex, BMI, etc.) for all product groups available in both Compl-Eat and the Nutri+ module, for which guidelines exist to assess reproducibility and classification. For Nutri+, these include: Fruit, Vegetables, Butter and Cooking/Frying Products, Dressings and Oils, Legumes, Nuts and Seeds, Fish, Dairy, Meat, Eggs, Cereal Products, Potatoes, Soft Drinks, Alcohol, Coffee, Tea, Snacks, Sweet Spreads, Chips/Nuts/Party Snacks, Fast Food, Desserts/Ice Cream/Cakes.
- Energy intake based on Compl-Eat
- Expected energy intake based on sex, age, weight, and physical activity
- Evaluation of the profile wheel

## 7 Description of incidents, safety, adverse events, side effects

The study for participants consists of completing dietary questionnaires and 24-hour dietary recalls. Due to the nature of the study, no incidents or adverse events are expected. Any complaints regarding the conduct of the study, the websites used, or other questions or remarks can be submitted via email or telephone, as indicated in the participant information.

## 8 Data-analysis and statistics

For Compl-Eat, all analyses will be based on the average intake per product group across the four assessment days within a single measurement series (spring or autumn).

Based on the Compl-Eat data, it will be assessed whether there is excessive under- or over-reporting in the study population. To this end, the number of calories consumed, as calculated by Compl-Eat, will be compared with the expected caloric intake based on participants' age, sex, height, and weight.

The agreement between classifications in Compl-Eat and the Nutri+ module will be evaluated by assessing the percentage overlap in categorization and subsequently examining correlations between the scores. The goal is for 75% agreement per product group between the Nutri+ module and Compl-Eat. If lower agreement is observed, the data will be qualitatively examined to identify areas for improvement in the Nutri+ module.

In addition, the intake in grams per product group as measured by the Nutri+ module and Compl-Eat will be examined. Correlation coefficients will be calculated to assess agreement between the Nutri+ module and Compl-Eat. These outcomes are primarily exploratory and aim to provide insight into where the largest differences between Compl-Eat and Nutri+ occur. These insights can be used to further improve the Nutri+ module.

To assess the reproducibility of the Nutri+ module, correlations between the spring and autumn measurements will be used.

Participants' opinions on the visualization of the profile wheel will be evaluated using descriptive information.

## 9 Risk analysis relating to the conduct of the study

Given the nature of the study, no health risks are expected (see Section 7). A potential risk during the study is insufficient participant recruitment. In that case, recruitment methods can be expanded from social media only to other channels, such as newsletters, local newspapers, and similar. However, based on previous positive experiences with social media recruitment, this is not expected to be necessary. Another risk is that the distribution of sex, age, and BMI may be insufficient to perform subpopulation analyses. Sex will be accounted for during screening; in other words, once 100 men have been recruited, only women will be admitted to the study. Unfortunately, it is not feasible to automate screening for multiple criteria. For other subgroups (age, BMI, and SES), a targeted recruitment campaign may be employed if the distribution is skewed. In the worst-case scenario, subpopulation analyses may not be feasible.

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