

# Tolerance of the regular intake of Duckweed plant based food products

Published: 15-08-2018

Last updated: 11-04-2024

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON45877

### Source

ToetsingOnline

### Brief title

Duckweed intake study

### Condition

- Other condition
- Gastrointestinal disorders

### Synonym

general health, intestinal discomfort

### Health condition

overige gezondheidsparameters

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Wageningen Universiteit

**Source(s) of monetary or material Support:** Wellcome trust funds

## Intervention

**Keyword:** consumer acceptance, Duckweed, intestinal discomfort, tolerance

## Outcome measures

### Primary outcome

The main study parameter frequency and severity of gastro-intestinal complains.

### Secondary outcome

Secondary outcome are intestinal health parameters derived from blood and urine samples taken before and after the intervention. And scores on consumer acceptance

## Study description

### Background summary

The rapid population growth and increasing standards of living are leading to an increasing demand for animal-derived protein. In order to provide sufficient dietary protein for human consumption, a transition towards more plant-based diets is required. Eendenkroos (*Lemna minor*) seems an interesting alternative protein source due to its high protein content and its enormous growth capacity. Last year we conducted a human trial in which we investigated the postprandial impact of a large portion (550 gram) Duckweed plant material on blood amino acids (AA). However, before duckweed can be included in a western diet, we need to investigate whether frequent intake of duckweed plant material, as part of a normal diet, would have effects on intestinal function and discomfort and investigate consumer acceptance. Therefore, the DISS-study aims to study the impact of frequent intake of 150-180 gram duckweed on gastrointestinal complains and several other health related biomarkers.

### Study objective

The primary objective is to investigate gastro-intestinal complains during 11

day duckweed consumption. Secondary objectives are to assess blood based parameters related to general health and urine based biomarkers for kidney function and to investigate consumer acceptance.

## **Study design**

The study has a randomised parallel design. Two different treatments will be evaluated e.g. a 11-day intervention with duckweed based meals and a 11-day intervention with control/spinach meals. At the start and at the end of the intervention we will collect a blood sample and a urine samples. Questionnaires about gut complains, stool consistency and frequency, wellbeing, health complains or other adverse effects will be collected daily during intervention and up to two days after the intervention.

## **Intervention**

A 11-day intervention in which subjects will receive a daily lunch with 150-180g wet weight duck weed or spinach. Products will be incorporated in food products such as pasta, curry, soup etc.

## **Study burden and risks**

This study is not related to a specific group. There are minor risks for the participants of this study. There are no direct benefits for the participants. The batch of duckweed that is going to be used for the study, has been analysed thoroughly on several safety parameters and no harm is expected. Literature about the use of duckweed as animal feed shows that fresh and dried duckweed has been fed successfully, indicating that duckweed can be part of the diet without adverse effects. Human consumption of duckweed is common in certain areas of Asia. Also the Pro-2 study indicated no extra gastro intestinal complaints after consumption of a very large dose (550 gram). Still due to its hard digestibility, consumption of duckweed may cause minor gastrointestinal discomfort, especially in the first few days of the intervention. The total amount of blood collected during the study is low and therefore not expected to cause any problems. Study subjects that will participate in the study will invest approximately 25 hours during the trial and need to visit the research facility daily during working days.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)  
Elderly (65 years and older)

### Inclusion criteria

- \* Apparently healthy men and women
- \* Age between 18 and 50 years
- \* Body mass index (BMI) between 18.5 and 24.9 kg/m<sup>2</sup>

### Exclusion criteria

- \* Any metabolic, gastrointestinal, inflammatory or chronic disease (such as diabetes, anaemia, hepatitis, cardiovascular disease)
- \* History of gastro-intestinal surgery
- \* History of liver dysfunction (cirrhosis, hepatitis) or liver surgery
- \* Kidney dysfunction (self-reported)
- \* Use of medication that may influence the study results, such as gastric acid inhibitors or laxatives
- \* Reported slimming, medically prescribed or vegan diet
- \* Current smokers
- \* Alcohol intake \*4 glasses of alcoholic beverages per day
- \* Pregnant, lactating or wishing to become pregnant in the period of the study (self-reported)
- \* Abuse of illicit drugs

- \* Food allergies for products that we use in the study
- \* Participation in another clinical trial at the same time
- \* Being an employee of the department Consumer Science & Health group of Wageningen Food & Biobased Research

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2018
Enrollment:	24
Type:	Actual

## Ethics review

Approved WMO	
Date:	15-08-2018
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

## Study registrations

## **Followed up by the following (possibly more current) registration**

No registrations found.

## **Other (possibly less up-to-date) registrations in this register**

No registrations found.

## **In other registers**

<b>Register</b>	<b>ID</b>
CCMO	NL66051.081.18