# SPLENDID II; Development of a system for monitoring eating and physical activity behavior

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON42124

**Source**
ToetsingOnline

**Brief title**
SPLENDID II

### Condition

- Other condition

**Synonym**
Overweight

**Health condition**

Overgewicht (BMI>25)

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Wageningen Universiteit
**Source(s) of monetary or material Support:** Europese Unie

## Intervention

**Keyword:** detection of eating, detection of physical activity, monitoring behavior, sensor development

## Outcome measures

### Primary outcome

How well the eating detection sensor is able to detect food consumption;

precision and recall

### Secondary outcome

- How well the Mandometer is able to register meal intake; precision and recall

- How well the activity meter is able to monitor physical activity; precision

an recall

- Wearer-comfort and user-friendliness of sensors (i.e. results questionnaire)

(- Dataset with sensor signals for algorithm development)

# Study description

### Background summary

The overall goal of SPLENDID, an EU-funded project, is to develop a system of sensors that can be used for the prevention of obesity and eating disorders. Initially it will be used for mapping behavioral patterns regarding eating and physical activity of the individuals that are wearing the system. Consecutively it will provide them real-time feedback on how to improve these patterns. The system will act like a personal coach.

This system includes, among others, sensors that will map the eating- and physical activity behavior of its wearers. These sensors and/or the corresponding algorithms are still under development and include:

- an eating detection sensor (i.e. a sensor, that is worn as an hearing aid, that registers if and when someone is eating),
- the Mandometer (i.e. a scale, that is placed underneath the plate while eating, that registers the intake of food throughout the meal)
- en een accelerometer (i.e. a sensor, that is worn at the hip, that registers acceleration of the body)

The corresponding algorithms are step-by-step procedures for calculations that enable automatic detection of behaviors (e.g. if someone is eating or the level of physical activity a person is engaging in) using the singals produced by the sensors.

**Study objective**

The main objective of the current study is to see how well the current versions of the sensors (mainly the eating detection sensor) function/ how useful the produced signals are. The sensors have already shown to produce valuable signals in controlled settings and we would like to see if in a semi-controlled setting the produced signals are still informative.

Furthermore, the produced signals will be used to 'feed' the algorithms. If more/different signals are fed to the algorithms they will learn to better understand the signals and will become better at detecting behaviors from those signals.

Additionally we want to see how wearing/using the sensors is experienced by the participants, mainly with regards to wearer-comfort and user-friendliness.

**Study design**

The study is a semi-controlled experiment. Participants will participate in two testing days at the university. While wearing/using the sensors of the SPLENDID-system they will perform predetermined *daily life-activities*; i.e. have lunch, spend some free-time, have snack(s), do moderate exercise and have diner. However, the participants will have quite some freedom in choosing the 'content' of these activities. They will be able to compose their own lunch, choose what snacks to consume and choose what (physical) activities to perform.

**Intervention**

At predetermined moments participants are expected eat a food product of choice or perform an (physical) activity of choice (see 'study design').

**Study burden and risks**

The participants of 'SPLENDID II' will visit the university 3 times; once for

an information meeting (±60 min) and twice for a testing day (±7 hours). During the information meeting the participants will fill out some questionnaires and their weight and height will be measured. Furthermore, in the two hours prior to the testing days the participants are requested not to eat or drink anything (except for water). During the actual testing days the participants will fill out some short questionnaires, but the main focus will be on performing *daily life-activities* which will be monitored non-invasively with the SPLENDID sensors. Examples of such activities are having lunch, snacking, relaxing, taking the stairs and cycling on a hometrainer. This is not expected to provide too much burden for the participants.

Furthermore, participation in the study is not expected to put an individual at risk. Previous experiences with the separate SPLENDID-sensors have not shown any adverse effects. Additionally, the sensors are non-invasive, which reduces the potential damage they can cause. Finally, there are always risks associated with the consumption of foods and moderate excercise, but also this is expected to be limited.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

- 18-30 years old
- Overweight (BMI>25)
- Dutch speaking

## Exclusion criteria

- Vegetarian
- Hypersensitivity (i.e. allergy and/or intollerance) food products provided during the study
- Currently experiencing discomfort or difficulty with eating
- Currently experiencing discomfort or difficulty with exercising moderately

# Study design

## Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Prevention |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-06-2015 |
| Enrollment: | 20 |
| Type: | Actual |

# Ethics review

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|---|---|
| Approved WMO Date: | 05-03-2015 |
| 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

| Register | ID |
|---|---|
| CCMO | NL52100.081.15 |