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D1.3 Final Protocols of Evaluation Studies

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Author(s)/Contributor(s):	Authors: Ioannis Ioakeimidis (KI), Monica Mars (WU) Contributors: Janet van de Boer (WU), Phil Spires (IEGS)
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Version	Peer Review Date	Reviewed By
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[1] Please use a new number for each new version of the deliverable. Use "0.#" for Draft and Peer-Reviewed. "x.#" for Submitted and Approved", where x>=1.Add the date when this version was issued and list the items that have been added or changed.

[2] A deliverable can be in one of these stages: Draft, Peer-Reviewed, Submitted and Approved.

[3] Only for deliverables that have to be peer-reviewed

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Abbreviations and Acronyms

Abbreviation	Explanation
WPX	SPLENDID work package X
DoW	SPELNDID description of Work
DX.X	SPLENDID deliverable X.X
TX.X	SPELNDID work task X.X
QX	Yearly quarter X
EMG	Electromyography
PPG	Photoplethysmograph
BMI	Body mass index
VAS	Visual analogue scale
IPAQ	International Physical Activity Questionnaire
NQplus	Cohort study which currently being conducted in Wageningen and surrounding municipalities

Executive Summary

SPLENDID aims to provide personalized lifestyle guidance services helping individuals to adopt healthy eating behaviours and activity. In order to ensure that the final SPLENDID system has the necessary technological quality and usability and that it is being used in a proper scientific fashion, a number of evaluation studies, spreading across the whole duration of the project, are scheduled.

"Final Protocols of Evaluation Studies" covers the work in the first ten months of the Task 1.3 of the SPLENDID project with the title "Protocols for the evaluation studies". It describes the protocols, the scope, the objectives and the data use for all the evaluation studies in the SPLENDID project.

In the current version of the document (Version 1.0, July 2014), the reader is taken through the detailed protocols for the first-year studies: i) the *Chewing sensor prototype study*, ii) the *Activity sensor studies* and iii) the *Mandometer study*.

Concerning these studies, this report presents detailed information on their i) *objectives*, ii) the relevant *research settings* and *study materials*, iii) their *timing*, iv) the *characteristics of the study participants*, v) their *detailed procedures* and vi) the *collection, handling, reporting* and *use of the outcome data*.

The *chewing sensor prototype study* will be run by WU in the Netherlands. It will test the sensitivity and validity of the chewing sensor signals with 17 different foods being eaten by 20 young adults in a controlled environment, while exploring the possibility to use those signals to distinguish among the different food categories. At the same time, the study will evaluate the comfort of the first prototypes of the chewing sensor.

The *activity sensor* and the *Mandometer* studies take place in Stockholm, Sweden, and will be jointly run by KI and Mando, in a common sample of approximately 15 young subjects. The *activity sensor* will validate the prototype activity sensor against a commercially available sensor in a set of scripted activities in a controlled environment. Additionally, 24h accelerometry datasets will be collected with the commercial sensors, in order to help to the development of the algorithms for the extraction of physical activity behavioural indicators from real-life environment measures. The *Mandometer study* will test the sensitivity and the validity of the Mandometer signals in meals with a wide range of food types. The produced datasets will be combined with past experimental datasets for meals with another 5 food types, provided by KI, and will be used to investigate the possibility of use the Mandometer signal to identify different food types being eaten.

Additionally, in this document, the *System V1 and System V2 evaluation studies* are outlined, with more detailed presentation of the *V1 evaluation study in adolescents*, which is projected to take place during 2015, at Internationella Engelska Skolan in Stockholm, Sweden, including approximately 40 high school students. This study aims to evaluate the feasibility of the stand-alone, V1 sensors in a school setting, and to collect feedback on different elements of the system by the participants. The student-specific datasets will be later used to improve the algorithms developed for the extraction of behavioural indicators and for the assessment of the risk for the development of eating disorders and obesity.

Two updated versions of this report will progressively add more information concerning the protocols of the SPLENDID studies which are scheduled for the second and the third year of the project.

This document can be used by the SPLENDID partners as a detailed guide for all the planned studies of this project. To the external reader, this document is a blueprint of the evaluation procedures in SPLENDID and a statement to the quality of the work involved in this project.

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1 Introduction

SPLENDID aims to provide personalized services helping individuals to adopt healthy eating behaviours and activity. For this, the SPLENDID technological solution requires the development of novel sensors, of signal processing and decision support algorithms and of users' applications, in an integrated usable system. In order to ensure the necessary system quality and usability, as well as the proper scientific use of the system, a number of evaluation studies have been foreseen, spreading across the whole duration of the project.

As the project matures and the development on every level of the system progresses, the focus of the required studies will shift. Therefore, the early studies concentrate on validating and standardising the raw data output from stand-alone sensors, on providing appropriate datasets for algorithm development and on collecting data on the fundamental usability of the system. Progressively, the studies will focus more on the integrated versions of the system, testing the full range of its usability and its functionalities, in real life environments. Thus, it is logical that at this point in time (see section 1.2.3) the current document includes more detail on the earlier evaluation studies. As the project progresses, and the integrated system versions are implemented, the protocols of the later studies will get finalised.

It is very important that the scheduled studies are conducted with the appropriate experimental samples and protocols, representing the target users and uses, *SPLENDID @ School* and *SPLENDID for Adults (defined* in D1.1*)*. Additionally, the two scientific partners in the SPLENDID consortium (WU and KI) are closely involved in the design, the realisation and the analysis of the outcomes of all the studies, ensuring that the evaluation procedures adhere to the highest scientific standards.

1.1 Purpose of the document

Deliverable D1.3: *Protocols of Evaluation Studies* constitutes the third, and final, deliverable of Work Package 1: *User requirements and health evaluation protocols*. The scope of this Deliverable is to describe the protocols, the general scope and the specific objectives of the scheduled evaluation studies in SPLENDID.

This is a key report in SPLENDID since it is the theoretical basis for the realisation of WP6: *Evaluation*. WP6 is responsible for all the testing and evaluation in SPLENDID and it will feed information to all the other work packages to accommodate further developments toward the final version of the system.

1.2 Methodology

The decisions concerning the protocols, the requirements and the aims of the presented studies were taken jointly by KI, WU, Mando and IEGS, based largely on the information provided in DoW, in the D1.1: *User Requirements* report as well as on feedback by the technical teams AUTH, CSEM and TSB. KI, together with WU, were then responsible for the composition of the available information into this report.

1.2.1 Evaluation studies in SPLENDID

Table 1 presents all the projected studies, their objectives and the use of their results in other work packages of SPLENDID. Table 2 provides all the currently available information on the

settings, the timing and the size of the experimental samples for all the projected SPLENDID evaluation studies.

Table 1. List of the projected evaluation studies, their objectives and their contributions in SPLENDID development

Study name	Objectives	Use of results in SPLENDID development
Chewing sensor prototype study	i. Compare the prototype chewing sensors vs EMG	WP2, WP3
	ii. Evaluate the comfort of the prototype chewing sensors	WP2, WP5
	iii. Test the sensitivity and validity of the signals with different foods	WP3
	iv. Investigate the possibility to distinguish among different food structures with the chewing sensors	WP3
Activity sensor studies	i. Compare the prototype physical activity sensor vs currently accepted sensor	WP2, WP3
	ii. Collect free-living physical activity datasets for extraction of activity behavioural indicators	WP3
Mandometer study	i. Test the sensitivity and validity of the Mandometer signals with different foods	WP3
	ii. Investigate the possibility to distinguish among different food structures with the Mandometer sensor	WP3
1st system version (V1) evaluation study		
In adolescents	i. Test the feasibility of the use of V1 in a school environment	WP2, WP4, WP5
	ii. Collect student-specific sensor datasets in a school environment for evaluation of indicators and risk assessment algorithms	WP3, WP6
In adults	i. Test the feasibility of the use of V1 in young adults	WP2, WP4, WP5
	ii. Collect young adult-specific sensor datasets in a school environment for evaluation of indicators and risk assessment algorithms	WP3, WP6
2nd system version (V2) evaluation study		
In adolescents	i. Test the intergraded V2 system in real-life (school) environment	WP2, WP3, WP4, WP5
	ii. Test the screening capabilities of the intergraded V2 system for students	WP3, WP5, WP6
	iii. Test the Personalised Guidance system on students	WP3, WP4, WP5, WP6
In adults	i. Test the intergraded V2 system in real life (everyday) environment	WP2, WP3, WP4, WP5
	ii. Test the Personalised Guidance system on young adults	WP3, WP4, WP5, WP6

Table 2. Information on the setting, the timing and the size of study samples in SPLENDID studies

Study name	Setting	Timing	Subjects
Chewing sensor prototype study	WU *Controlled environment*	July-August 2014	20
Activity sensor studies [1]			
Sensor validation	KI, Mando *Controlled environment*	May-July 2014	15
Collection of free-living physical activity data	KI, Mando *Real-life environment*	May-July 2014	15
Mandometer study [1,2]	KI, Mando – *Controlled environment*	May-July 2014	15
1st system version (V1) evaluation study			
In adolescents	IEGS (KI, Mando) *Semi-controlled environment*	Spring 2015	≈ 40
In adults	WU *TBD*	Spring 2015	TBD
2nd system version (V2) evaluation study			
In adolescents	IEGS (KI, Mando) *Real-life environment*	2016, date TBD	TBD
In adults	WU *Real-life environment*	2016, date TBD	TBD

[1] These two studies, while described as two separate entities, in practice will be run in parallel, using a common pool of participants, except if the protocol-specific exclusion criteria prohibit it

[2] the results will be combined with 25 compatible past datasets provided by KI

The evaluation studies in SPLENDID have been designed in accordance to the research principles presented in detail in the SPLENDID *Ethics and Safety manual I* (deliverable 8.2). Since overlapping information will not be repeated here, it is advised that the reader should consult report D8.2 when needed.

1.2.2 Study supervision and coordination

In all the cases the detailed protocols of the studies are/will be approved by the Dutch and Swedish ethical authorities (*D8.2: Ethics and Safety manual I*).

In *Netherlands* the scheduled evaluation studies (Table 1) are run exclusively by WU. Therefore, WU will be solely responsible for the procedural and ethical monitoring of the study protocols, record keeping and data handling in Dutch studies.

In *Sweden*, the scheduled studies (Table 1) require the participation of two (KI, Mando) or three (KI, Mando and IEGS) partners. In all the scheduled studies KI has a supervisory and advisory role, working closely with Mando and IEGS (when involved), in order to ensure that the studies fulfil the required scientific, procedural and ethical requirements of general

scientific practice and SPLENDID. KI is/will be responsible for authoring the required ethical applications for all the studies, ensuring that the presented information correspond with the scheduled study protocols. Also, KI is responsible to educate and supervise all the involved personnel for adhering to good scientific practices and for following the described protocols.

KI will also dictate the specifics of data collection, data formatting and data in-house analysis. Thus, after the studies are completed, all the collected/produced data are going to be passed along from Mando/IEGS to KI for storage/analysis. At this phase, special emphasis will be given to the de-identification of the data, as described in *D8.2: Ethics and Safety manual I*, and the identification keys will be stored in KI computers (no other partner will have access to those files). Afterwards, KI will use the usual Swedish and in-house practices (*D8.2: Ethics and Safety manual I*), developed through their long experience in running scientific studies, for storing and analysing data. KI will be then responsible to pass data along and communicate in-house analysis findings to the rest of the consortium as needed.

Furthermore, each involved investigator, irrespective of the partner, is personally responsible to follow these practices to the letter.

1.2.3 Report updates

SPLENDID studies follow the progress of the technical developments. Therefore, month 10 would be too early for the finalization of all the study protocols, especially for the V1 and V2 evaluation studies that have been planned for the 2nd and 3rd project year respectively. For this reason D1.3 has been identified already from the start of the project as a live deliverable (see D8.1: *Project Management and Quality Control Plan*). In addition to the current version, two follow-up versions are planned:

D1.3, Version 1.0: Current version including the detailed protocols for the first year studies, namely the chewing sensor, the activity sensor and the Mandometer studies and the outline of the System V1 and System V2 evaluation studies; delivery in project month 10.

D1.3, Version 2.0: Section 5 of the document will be updated with the finalized evaluation protocols for the V1 evaluation study; planned delivery in February 2015.

D1.3, Version 3.0: Section 6 of the document will be updated with the finalized evaluation protocols of the System V2 evaluation study; planned delivery in February 2016.

1.3 Who should read this document

The obvious intended audience of this document is the whole consortium of the SPLENDID, since the evaluation studies will produce results that will be used in every facet of the SPLENDID development. The results of these studies will also help in the dissemination and exploitation activities planned in WP7.

Since this is a public document, the external reader should consult this document in order to gain in-depth information on the details and the quality of the evaluation protocols in SPLENDID.

1.4 Document overview

Section 2 presents the Chewing sensor studies currently running in the Netherlands.

Sections 3 and 4 present the parallel, *Activity Sensor* and *Mandometer studies* currently running in Sweden.

Section 5.1 presents a detailed plan for *testing of the 1st system version (V1) in a semi-controlled school environment* in Sweden. Similarly, section 5.2 presents a (less detailed) plan for *testing of the 1st system version (V1) in young adults* in the Netherlands.

Finally, Section 6 presents the basic requirements of *testing of the 2nd, intergraded system version (V2) in real life environments in students* (Sweden) and *young adults* (the Netherlands).

2 Chewing sensor prototype study

The chewing sensor study in Wageningen combines elements from two tasks (Figure 1), i.e., Task 6.2a and Task 6.3. Task 6.2a addresses the standardisation and validation of the chewing sensors vs EMG (electromyography). Task 6.3 aims to test the sensitivity and validity of the signals with different foods but also to investigate whether it is possible to distinguish different food structures with the chewing sensors. The protocol also aims to evaluate the comfort of the first prototype of the chewing sensors.

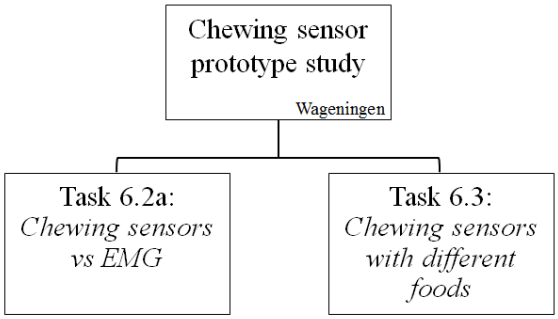


Figure 1. Schematic overview of the chewing (i.e. acoustic and PGG) sensor prototype study in Wageningen

2.1 Chewing sensors

At this stage of the project, two options are currently being considered for the first prototype of the chewing sensor: an *acoustic* and a *photoplethysmograph* (PPG) sensor.

The *acoustic sensor* uses a miniature microphone placed at the ear to detect sounds produced by eating. Several studies have already been performed with such sensors for eating detection [e.g., 1-4]. The results of these studies are promising. However, the sensors presented here are not yet sufficiently developed for monitoring of eating behaviour in everyday live. In the current study two types of acoustic sensors will be tested: i) an in-ear and ii) bone conduction version.

The *PPG* sensor detects changes in blood volume in the microvascular bed of tissue. With this technique it is possible to make non-invasive measurements at the skin surface. It has already been applied for several purposes, like measuring heart rate, blood pressure, blood oxygen saturation, cardiac output and respiration [5]. Using PPG for detection of eating is a new promising application. It is assumed that PPG will detect eating by measuring increasing blood volume in the area involved in oral processing during eating.

In order to decide which of the sensors should be incorporated into the system, they will both be validated against EMG, which is currently the *golden-standard* for measuring chewing activity by measuring the electrical potentials of the facial muscles involved in chewing. The reported comfort of the sensors will also be considered in the final decision.

The results from this study will play a major role in the decision on the eating detection sensor to be used. Furthermore, the produced dataset will be used to develop algorithms (i.e. step-by-step procedures for calculations) that will enable automatic detection of eating behaviour with the sensors.

2.2 Study objectives

The primary goal of the study is to investigate whether it is possible to detect when someone is eating using the signals produced by the two chewing sensors (helpful for the development in WP2 and WP3). Additionally, the study will provide a dataset with a wide variety of signals from the sensors that will then be used by WP3 to develop algorithms for detection of eating.

Additionally, we will collect information on the wearing comfort of the eating detection sensors (related to developments in WP2 and WP5). As mentioned before, these results will play a major role in the decision on the eating detection sensor to be used in the system.

The secondary objective of the study is to investigate whether it is possible to distinguish different food structures in the signals produced by the eating detection sensors. The collected study dataset will be used by WP3 to test the possibility to develop signal analysis algorithms which automatically categorize food on the basis of its texture characteristics.

2.3 Research setting and timing of the study

Data collection including recruitment and screening has been scheduled for July – August 2014. The current study will be conducted in the *Restaurant of the Future* of Wageningen University and Research Centre, housed in the Futurum facility (Figure 2). In this controlled environment scientists can observe restaurant guests for a prolonged period of time. Moreover, it houses specialised labs, such as the oral lab where the current study will be carried out. In the oral lab we have the opportunity to use EMG and use build in video cameras.

Figure 2. The *Restaurant of the Future*. **A** & **B**: outside of the restaurant. **C**: view in the restaurant from one of the build in cameras. **D**. Oral lab.

2.4 Subjects

The study population will include 10 male and 10 female healthy volunteers, between 18 and 30 years old. Subjects will be recruited in Wageningen and surroundings using the volunteer

database at the division of Human Nutrition. Recruitment of these participants is not expected to be a problem. The projected sample characteristics are presented in the Table 3.

Table 3. Sample characteristics for the chewing sensor prototype study

Age (years)	18-30 (i.e., young adults)
BMI	any
Gender	Male, female
Target sample size	20 individuals
Gender ratio	1 : 1
Protocol-specific exclusion criteria	Self-reported bad overall health
	Food aversion or dislike
	Food specific allergies/intolerances
	Chewing/swallowing discomforts
	Excessive facial hair (e.g. beard/moustache)

Subjects will give written informed consent (can be seen in Annex A, A) and will get financial compensation for participation. The study protocol was approved by the Medical Research Ethical Committee of Wageningen University (Annex B).

People who show interest in the study will receive additional information (i.e., the information letter and an example of the informed consent form) and will be invited to attend an information meeting. At this meeting they will be further informed on the study, covering all elements discussed in the information letter. At the end of the meeting they will receive a printed copy of the information letter and the informed consent form. If they decide to participate they will be asked to sign both, either at the information meeting or at a later point. The investigator will also sign these. After signing the informed consent form and the information letter they are asked to fill in a screening questionnaire and their height and weight will be measured. Based on this information the investigators will decide on who will participate. Finally, the eating sessions will be scheduled together with the participants.

Upon completing the study the participants receive a financial compensation of €32.50. If their participation in limited to the information meeting (i.e., excluded from the study by the investigators), they will receive a financial compensation of €5.

2.5 Study procedure

Every participant will come to the university once for a test session of about 2 hours (Figure 3). At the start of the session, the procedure will be explained and the sensors (i.e. acoustic, PPG sensor and EMG) will be placed. Before starting the actual measurements, some data will be collected as control measurements and for the purpose of calibration. These include recordings while the participant talks (i.e. reads a book section), swallows with an empty mouth, coughs and does nothing.

Afterwards the participant will receive small portions of commonly consumed food products (section 2.6.4), varying in structure, in random order. The participants are requested to consume these foods the way they would normally do. However, they need to take at least 5 bites/sips of the food product or eat from it for at least 2 minutes. Therefore the participants do not need to finish any of the portions, but they can if they want to. The total amount of food products provided to the participants, excluding drinks, will not exceed 500g. Additionally, simple activities will be included at random moments during the measurements; either while eating a food (i.e., talking and drinking water in case of solids and semi-solids), or in between foods (i.e., the same activities as during the control measurements).

Finally, at the end of a test session, participants will fill in a questionnaire including questions about the level of comfort experienced when wearing the sensors and whether they were able to eat like they would normally do.

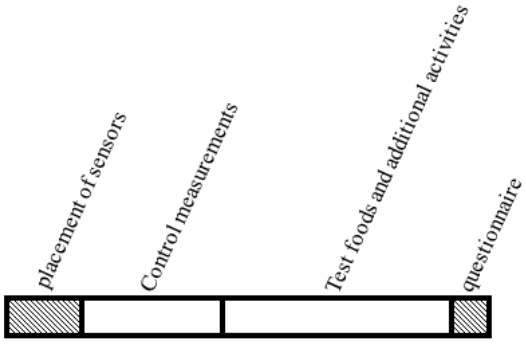


Figure 3. Overview (left to right) of the procedure of a test session in the chewing sensor prototype study

2.6 Study material

2.6.1 Acoustic chewing sensors

Two types of *acoustic sensors* will be tested; one measuring air vibrations (i.e. sound) and one measuring bone conducted vibrations. In both cases the acoustic sensor for eating detection consists of a small microphone placed near the ear (Figure 4, A). Here it collects vibrations/sounds that are produced as a result of eating (Figure 4, B). However, also other vibrations/sounds will be collected, this is called 'noise'. Therefore the placement of the microphone was chosen in such a way the signal intensity from eating is optimized and the signal intensity from 'noise' is limited. This should enable detection of eating. In order to automate this, we plan to develop detection algorithms using the produced dataset.

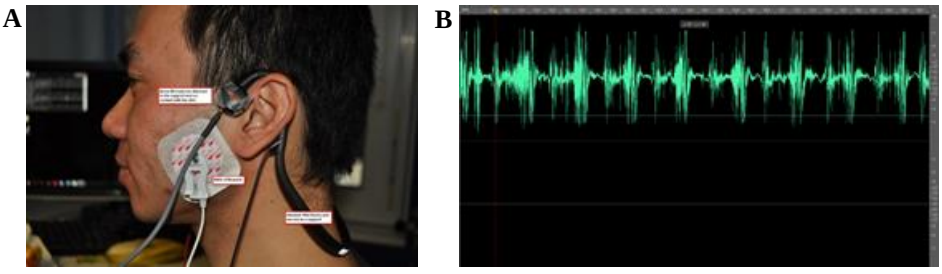


Figure 4. The acoustic sensors (**A**) and their visualised signal (**B**).

2.6.2 PPG chewing sensor

The PPG sensor uses an optical technique for the detection of eating. This PPG sensor is embedded into an earhook of an earphone (Figure 5, A); a LED light is attached near the inside of the ear and covered by a soft foam cushion, and a photodiode is attached near the back of the ear. The LED light transmits light into tissue of the ear. On the other side of that tissue a photodiode is placed to detect how much light has been able to pass the tissue (for an example see Figure 5, B). This amount reflects the blood volume in the microvascular bed of the tissue of the ear, but indirectly also the blood volume in the tissue that is involved in oral processing. The blood volume in these tissues will increase during eating, as the increased activity in these tissues will require additional blood supply. As a result measuring these changes in blood volume should allow for detection of eating. In order to automate this, we plan to develop detection algorithms using the dataset produced during this study.

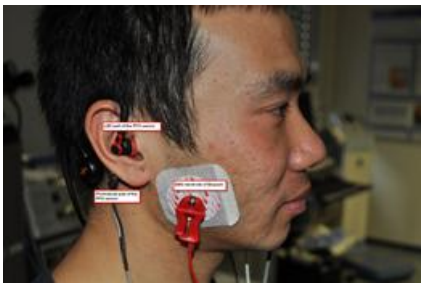
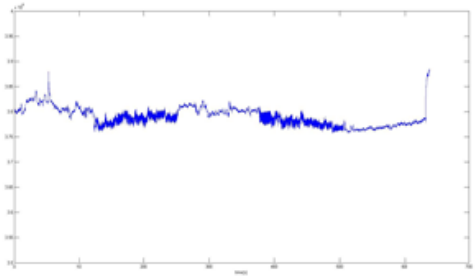
A  **B** 

Figure 5. The PPG sensor (**A**) and its visualised signal (**B**).

2.6.3 EMG

During this study EMG (electromyography) will function as the *golden-standard* for the detection of eating, being the accepted method for monitoring the microstructure of eating behaviour [6]. With electrodes placed on the skin overlaying the muscles involved in the oral processing of foods, bioelectrical activity of these muscles is measured. Sophisticated software (developed in MatLab) is used to identify swallows and chews from these signals. This is a procedure that already has been used at WU several times (Figure 6).

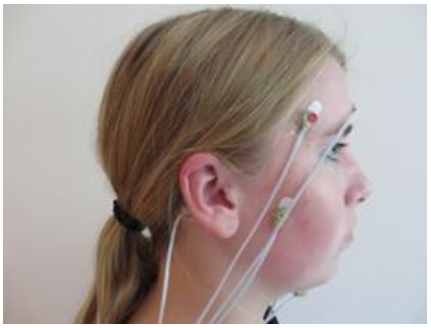
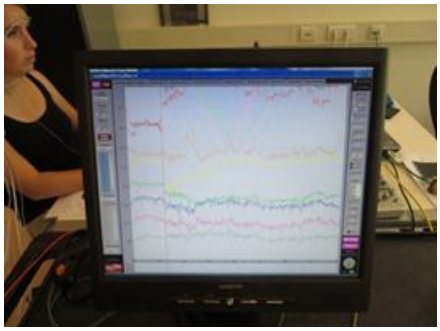
A  **B** 

Figure 6. The EMG sensors (**A**) and their visualised signals (**B**).

2.6.4 Food products

A series of commercially available, commonly consumed, food products were chosen from three different food texture groups: solid foods, semi-solid foods and liquids. The oral

processing of these food groups are characterized by stereotyped patterns (Table 4; [6]). The list of foods is shown in Table 5, Figure 7. It will be tested whether the acoustic and PPG chewing sensors will be able to differentiate between these food groups based on these differences in oral processing.

Table 4. Food textures and their corresponding oral processing patterns [6]

Texture	Oral processing
Solids, hard and soft	Rhythmic jaw opening and closing
Semi-solids	Tongue compression movements
Fluids, thin and thick	Transport via oral lingual, pharyngeal, and oesophageal musculature

Furthermore, the chosen food products will only include foods that do not need preparation. This will reduce variability between food products, reduce the risks involved when eating them and will simplify the procedure. Foods will be offered in randomized and balanced order (Annex C).

Table 5. List of food product and combination of food products and activities to be tested.

Food products	Estimated amount
Water	100 g
Diet coke	100 g
Apple juice	100 g
Yoghurt (thick and creamy)	75 g
Vanilla custard	75 g
Pureed apple	75 g
Potato chips	15 g
Cookie	25 g
Apple	50 g
Lettuce	25 g
Bread	35 g
Cake	30 g
Banana	50 g
Strawberry	50 g
Candy bar	25 g
Toffee	15 g
Chewing gum	-

2.6.5 Liking of the food products

After consumption of the specific foods the subjects would indicate its palatability on an x-point Likert scale [7].

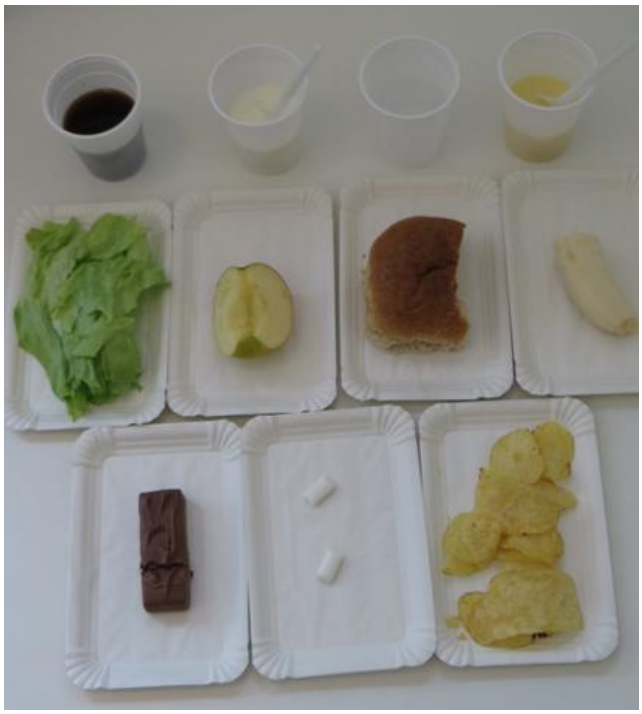


Figure 7. Picture of some of the foods tested in the study.

2.6.6 Video recordings

During this study the participants will be filmed by two cameras; one capturing the upper body of the participants and one providing an overview of the room in which the study will be conducted. The recordings of these cameras will function as a back-up data. Video will only be checked in cases when the chewing sensors have produced abnormal signals that cannot be explained either by the study procedure, the study logbook, or the EMG signals. So, the recordings will only by looked at when there is no other option for explaining abnormal findings, and only the investigators will have access to them.

2.6.7 Comfort of the system

At the end of the test session subjects will fill out a questionnaire on the level of comfort which they experienced while eating with the sensors.

2.6.8 Complementary study material

Inclusion questionnaire. At the beginning of each study, the participants will be asked to fill in an inclusion questionnaire. This questionnaire will contain questions on self-reported health, food preferences, allergies, etc. The obtained data will be used test whether subjects meeting the inclusion criteria of the studies and in order to describe the study population.

Mood, appetite and taste ratings. All the participants will be asked to rate their mood and appetite (i.e., hunger, fullness, desire to eat, prospective consumption, thirst, on a 100 mm visual analogue scale (VAS), from "not at all" (score=0) to "extremely/very" (score=100) [8]. These questionnaires are usually filled out before the meals and at fixed time points after the meal.

Anthropometric measures. The participants will be weighted on a calibrated weighing scale [9], and their length will be measured with a calibrated stadio-meter [9]. The obtained data will be used to describe the study population.

2.7 Data collection and reporting of results

The study will yield a dataset of chewing sensor and EMG signals, as well as answers to the questionnaires. All data will be described in D6.2: *Annotated database for sensors Standardisation and indicator extraction algorithms*. The user comfort questionnaire analysis will be included in D6.2 as well. The outcome of the signal processing analysis addressing the feasibility of automatic chewing detection and food structure categorization will be included in D3.1: *Signal processing algorithms for extraction of eating and activity related indicators*.

3 Activity sensor studies

The activity sensor studies in Stockholm will be realised under work task 6.2b: *Activity sensor versus commercially available sensor*. Task 6.2b addresses the validation of the first prototype of the SPLENDID activity sensor vs a currently accepted commercial sensor. The designed study aims to compare the sensitivity and the validity of the raw accelerometry signals during a set of scripted activities. Additional, 24h accelerometry datasets will be collected with the commercial sensors, in order to help to the development of the algorithms for the extraction of physical activity behavioural indicators from real-life environment measures.

3.1 Objectives and structure of the studies

The designed protocol is divided into two parallel subprotocols (Figure 8). The first subprotocol aims to validate the first SPLENDID activity prototype sensor by comparing it with the Bodymedia Armbands (relevant with the development processes in WP2 and WP3), which are widely used accelerometers and have been used widely by KI and Mando for the collection of experimental and clinical data [10]. The activity meters will be compared using a scripted set of activities (see 3.9.1). The second sub-protocol will collect data in a *free-living environment*, without supervision (see 3.9.2), using only the Bodymedia armbands. Those datasets will be used to complement the datasets provided by D6.1 aiming in providing adequate information (for WP3 development) for the extraction of physical activity indicators from a free living setting. Note that these studies will run in parallel with the Mandometer study (section 4), using the same research setting and a common pool of participants, when possible.

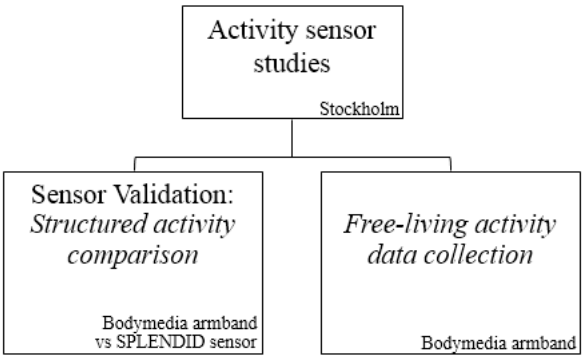


Figure 8. Schematic overview of the activity sensor (i.e., SPLENDID activity prototype & Bodymedia armband) studies in Stockholm

3.2 Research setting

KI's Division of Applied Neuroendocrinology in Stockholm, Sweden, is housed in research facilities adjacent (but separate) to the Mandolean clinic. The dedicated KI facilities include a sensor laboratory (Figure 9, A), food preparation and data processing facilities. For the SPLENDID studies, the research personnel will have access to Mando's clinical infrastructure for experimental use. The participants will be received in the common area of the Mandolean clinic (Figure 9, B). For serving and recording meals in the Mandometer study (section 5), *eating labs* (i.e., secluded rooms for serving individual meals) located inside the Mandolean

clinics (Figure 9, C) will be fitted with extra sensors (e.g., cameras and research Mandometers). The scripted physical activities will be recorded both in Mandolean's exercise facilities (Figure 9, D) and in the Karolinska Institute's personnel gym that is housed in the same building.

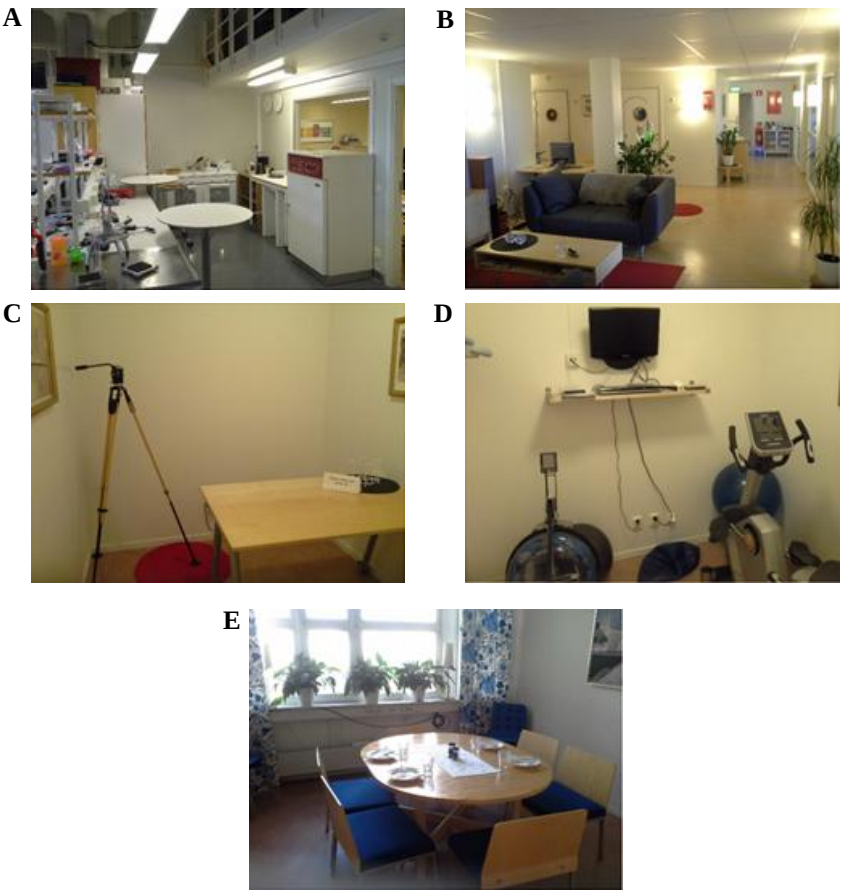


Figure 9. Some of the facilities to be used in the semi-controlled SPLENDID evaluation studies in Sweden. **A**: Sensor laboratory and Food preparation facilities (KI), **B**: Reception area (Mando), **C**: Eating lab (Mando), **D**: Exercise facility (Mando), **E**: Common dining area (Mando)

3.3 Complementary past data

KI has previously collected a large number of experimental free-living data using Bodymedia armbands, from experimental populations directly comparable with the target study sample population. Additionally, Mando have been using the Bodymedia armbands for collecting clinical data for the quantification of physical activity in obese and eating disorder patients. A large part of these data have already been made available to the SPLENDID consortium (ethical permission: D6.1, Annex A) and are described in detail in the report for D6.1. Additionally, small scale in-house testing for the comparison of the SPLENDID and the Bodymedia sensors were completed in January 2014 (Figure 10). The accumulated experience from collecting those data types have been considered for the formulation of the presented protocol.

3.4 Subjects

Healthy subjects (both genders, ages 18-30 years old) are to be recruited for participation both in the *sensor validation* and *free living* sub-protocols (Figure 8). The participants will be recruited through advertisement on nearby university campuses and through the Swedish digital recruiting portal www.studentkaninen.se [11]. Table 6 presents the target characteristics of the selected experimental sample. The selection was made based on the relevance of the sample to the expected user population of the SPLENDID platform, the ease of recruitment and the outcome data compatibility with previously selected experimental data collected by KI which have already been made available to the SPLENDID consortium.

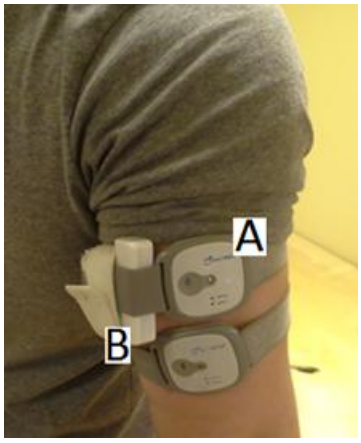


Figure 10. Placement of the sensors during the in-house testing of SPLENDID activity sensor (**A**) against the Bodymedia armband (**B**)

Table 6. Projected sample characteristics for both *sensor validation* and *free living* subprotocols

Age (years)	18-30 (i.e., young adults)
BMI	18-28 kg/m^2
Gender	Male, female
Target sample size	15 individuals
Gender ratio	1 : 1
Protocol-specific exclusion criteria	Self-reported bad overall health History of eating disorders Movement impairing medical conditions

Subjects will give written, informed consent (can be seen in Annex A, B). The study protocol was approved by the Stockholm Ethical Review Board (Annex D), together with the protocol of the Mandometer study (section 4).

3.5 Timing of the studies

The described studies have already initiated during May 2014 and will be completed before the end of July 2014. In case of problems in collecting the required number of datasets (e.g.,

due to drop outs and/or limited participation) the data collection will be completed during August 2014.

3.6 Introductory & debriefing meetings and compensation

After volunteers express their interest in the study an introductory meeting is planned. KI and Mando personnel are going through both subprotocols in detail and a printout of the study information sheet is provided. If the volunteers are interested in participating, firstly they fill in the consent form (Annex A, B) and then they fill in the onetime screening questionnaires. If the participants fulfil the inclusion criteria they are assigned a study identification code, their identification info is added to KI's key files. They are then contacted by phone and the first study session is scheduled.

At the end of the two protocols, if the participants require it, they are given a personal printout (i.e., a Bodymedia sensor generated energy expenditure vs time graph) of their physical activity performance for both protocols. These data are prepared by KI personnel. At the end the participants are compensated with one cinema ticket coupon (approximately worth 12€) for their participation.

3.7 Study material

3.7.1 Physical activity sensors

A) Bodymedia Armband. Accelerometry data will be collected exclusively using the 3-axis capacitive accelerometer included in the MF-SW model of the devices (BodyMedia, Inc, Pittsburgh, PA, USA) [10]. In all the protocols the devices will be placed on the dominant arm of the participants, according to the directions of the manufacturer. To facilitate comparisons with the SPLENDID activity sensor, in the *sensor validation* subprotocol the device will be set to collect data at a frequency of 32Hz from all axes and save them in a raw, unfiltered format. In the *free-living* subprotocol the data sampling frequency will be set to 1 measurement / minute to allow for longer term recordings. The proprietary Bodymedia daily energy expenditure values will also be stored in order to be compared (WP3: *Information Processing and Inference*) with energy expenditure calculations derived by SPLENDID algorithms. The device and the correct position on the arm can be seen in Figure 11, A.

B) First SPLENDID activity prototype sensor. CSEM has provided KI with one unit of the first SPLENDID activity prototype. The device is a 3-axis capacitive accelerometer with a set-up sampling frequency of 25Hz for each axis. During in-house testing at AUTH, it was shown the activity sensor should be worn in the waist. When worn in the waist, the accuracy, precision, sensitivity and specificity on activity type detection were higher compared to arm and chest positions. The outcome of this analysis will be included in D3.1. Thus, in the *structured activity subprotocol*, the first SPLENDID activity sensor prototype will be worn on the waist, to simulate the planned sensor placement in the intergraded SPLENDID platform (Figure 11).

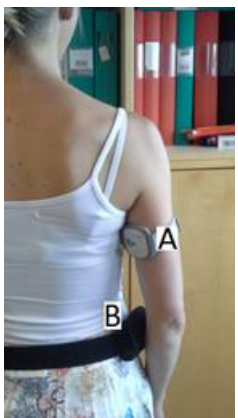


Figure 11. Placement of the Bodymedia (**A**) vs the SPLENDID (**B**) sensors for the structured activity (**A & B**) and the free-living activity (only **A**).

3.7.2 Self-reporting physical activity diary

In the *free-living* subprotocol of the study, the participants will have to use a self-reporting physical activity diary in parallel with the Bodymedia armband. The participants have to fill in information about the type of activities they are doing during a weekday, including wakeup and falling to sleep times. Also they have to justify any periods that the activity sensor was not worn (e.g., taking a shower, etc.). The diary is given to the participants in paper format and they are responsible to fill it in for the duration of the study. Periodic (twice a day) reminders to fill in the diary are provided by automated sms phone messages. This format of the diary has been previously used by KI in similar experimental procedures and a modified version of it has been used by Mando for collection of clinical self-reported data from patients. An excerpt of the diary (in Swedish) can be seen in Annex E.

3.7.3 Complementary study material

Health status and eating habit questionnaires. At the beginning of each study, the participants will be asked to fill in a standardised KI form concerning the general health of the participant. This questionnaire contains questions on self-reported health, history of eating disorders, food preferences, allergies, etc. The obtained data will ensure that the subjects meet the inclusion criteria.

International Physical Activity Questionnaire (IPAQ): at the beginning of all the studies the participants will be asked to feel in IPAQ [12] in order to have an individual estimate of the general levels of physical activity for each participant. The collected data will be used to identify/explain possible outliers in the recorded physical activity datasets (e.g., individuals with abnormally sedentary and/or active lifestyles).

Anthropometric and body composition measures. In all the studies the subjects will be weighted by Tanita scales [13]. Apart from the weight, these scales use bio-electrical impedance analysis to calculate the fat mass, fat-free mass and total body water of the individual. The height of the participants will be counted using a standard height scale.

3.8 Study procedure

3.8.1 *Sensor validation* subprotocol

The experimental session for the structured activity is scheduled any available time of the day. The participants are received first in the Mandometer reception area, where the two accelerometers are fitted (Figure 11). Then the participants have to go through a total of nine scripted activities (3 minutes each), separated in 3 subgroups (3 activities in each group). During the activities the participants are supervised by the investigators in order to make sure that the protocol is followed correctly. The investigators are also required to keep a log of

activities per participant, time-stamping the begging and the end of each activity. The order of the activities inside each group is randomised. The order of the groups is also randomised per participant. A list of the selected activities and the script of the subprotocol can be seen in detail in Table 7 and Figure 12 respectively. The list of structured activities cover a wide range of possible free-living activities of varying intensities. The list have been decided in close communication with AUTH, based on the needs of WP3 (*Information Processing and Inference*).

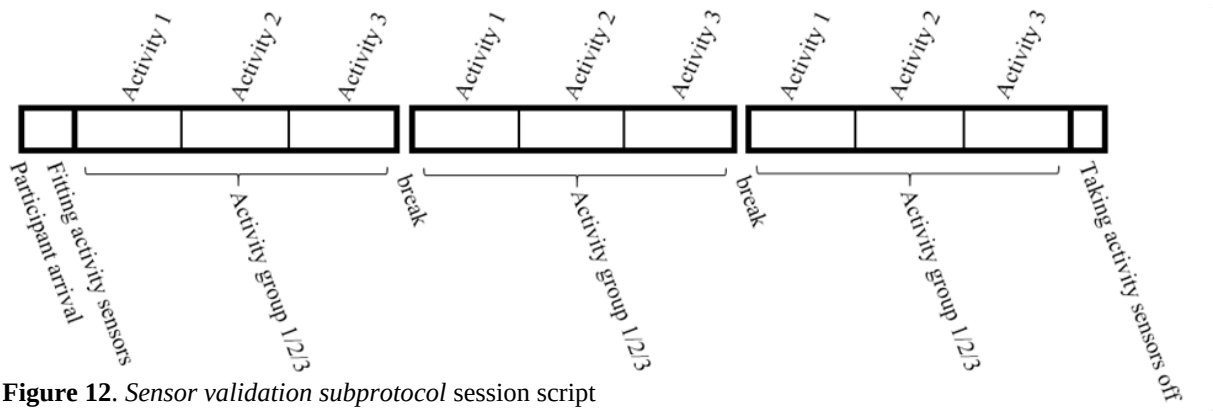


Figure 12. *Sensor validation subprotocol* session script

Table 7. List of scripted physical activities (3 min long) in the *Sensor validation* subprotocol

Activity group*	Activity**	Extra information	Location
1	Walking	Speed: ≈ 4 km/hour	Karolinska Institute's personnel gym
	Jogging	Speed: ≈ 7 km/hour	
	Walking up and down stairs	≈ 3 complete cycles	
2	Row machine	≈ 2.7 min/500m	Mandolean's exercise facilities
	Slow cycling	≈ 50 rpms/resistance 2	
	Moderate cycling	≈ 50 rpm/resistance 5	
3	Eating while seating	Vanilla ice cream[14]	Mandolean's reception & common dining area
	Using an Android Tablet device	Playing Candy Crush[15]	
	Watching TV while seating	-	

* Activity groups are randomised per participant

**Activities inside each group are randomised per participant

3.8.2 *Free-living* physical activity subprotocol

The experimental session for the free-living activity quantification is scheduled directly after lunch (around 12:00 am) during a weekday. The Bodymedia accelerometers are fitted on the participants' arm based on handiness (right- vs left-handed; Figure 13) and they are given the *self-reporting physical activity diary* (Annex E). The participants are advised to keep the activity sensor on for 24 consecutive hours, including periods of sleep. Automated sms

messages (20:00 the same night and 09:00 the following morning) are used to remind the participant to fill in the complementary activity diary. Another message signifies the end of the session following lunch the next day. The script of the subprotocol can be seen in detail in Figure 13.

3.9 Data collection, handling and reporting

After the completion of each subprotocol the data are extracted from the activity sensors (coded by the participant's study identification code) and stored in KI's computers for further formatting. After the free-living subprotocol, the activity diary is scanned and stored in KI's computers. The outcome activity datasets are annotated in excel either based on the log of the investigator (*sensor validation subprotocol*) or based on the self-reporting activity diary of the participant (*free-living activity subprotocol*). Finally, the datasets are reformatted according to SPLENDID requirements (for more details see the reports for D6.1 and D6.2), preparing them for sharing with the rest of the SPLENDID consortium. The outcome of the signal processing analysis addressing the accuracy of the automatic detection of activity behaviour indicators will be included in D3.1: *Signal processing algorithms for extraction of eating and activity related indicators*.

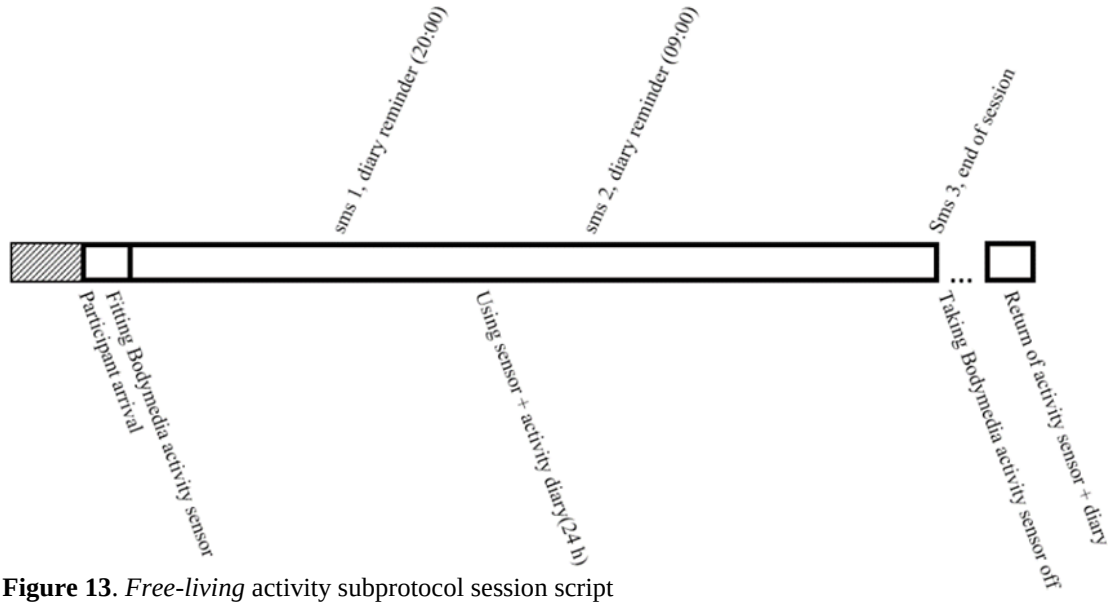


Figure 13. *Free-living* activity subprotocol session script

4 The Mandometer study

The Mandometer study in Stockholm is part of the task 6.3: *Sensor testing with different foods*. The designed study will test the sensitivity and the validity of the Mandometer in meals with a wide range of food types. Additionally, the produced datasets will be used to investigate the possibility of use the Mandometer signal to identify different food types being eaten.

4.1 Objectives and structure of the studies

The primary objective of this study is to provide data on the sensitivity of the device with different food item types (relevant with the WP3 development). In order to achieve this goal, the current version of the Mandometer (V4) will be tested with three different types of foods. The produced data will be combined with previously collected data (KI) on users eating another 5 types of food. The combination of past and novel data will allow for a wider variety of food types to be analysed as it is not realistic to collect novel data for more than 3 food types in the available SPLENDID timeframe.

A secondary objective of this study is to use (in WP3) the combined dataset (novel and past data) to test the possibility to develop signal analysis algorithms which automatically categorize the food on the basis of its texture characteristics.

The structure of the final dataset is presented in Figure 14. Note that the Mandometer study protocol is scheduled to run in parallel with the Activity sensor studies, in the same research setting (section 3.2).

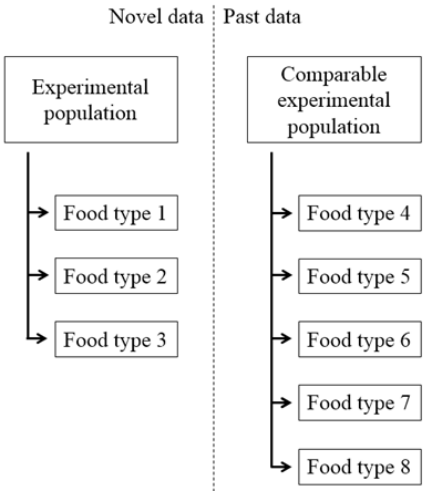


Figure 14. Structure of the final T6.3b dataset. **Novel data**: Data to be collected under the scope of SPLENDID. **Past data**: Comparable data collected in the past by KI. The order of the meals is randomized per participant

4.2 Past data

In the past, KI has collected a large number of data, using Mandometer V4, from meal with different food types, as part of many different experimental procedures (e.g., [16]). Approval for data use in SPLENDID have been granted by the Regional Ethics Committee of Stockholm shortly after the initiation of the project (see D6.1, Annex A). After communication with AUTH it has been jointly decided that five datasets (for a total of 25 datasets), originating form a comparable experimental sample, from each food type are required in order to cover the desired range of foods. The presented Mandometer study

protocol is directly comparable to experimental protocols used before [17], ensuring the compatibility of the outcome data. Thus, the protocol is only presented for the new experimental procedure. In the following sections more information for the past datasets is presented as needed. The Mandometer study protocol has been approved by the Stockholm Ethical Review Board (Annex D), together with the protocol of the Activity sensor studies (section 3).

4.3 Subjects

The participants for the Mandometer study are recruited from a common pool of interested volunteers with the Activity sensor studies, using identical recruiting methodologies (sections 3.4). Subject selection is also similar, with small differences in procedure-specific exclusion criteria. Table 8 presents the target characteristics of the experimental sample, as well as the selected ranges for past datasets to be shared.

Table 8. Target sample characteristics for both *Novel* and *Past* datasets

	Novel datasets	**Past datasets**
Age (years)	18-30 (i.e., young adults)	18-30 (i.e., young adults)
BMI	18-28 kg/m^2	18-28 kg/m^2
Gender	Male, female	Female
Target sample size	10 individuals	5 individuals/food type
Gender ratio	1 : 1	-
Protocol-specific exclusion criteria	History of eating disorders	History of eating disorders
	Bad oral health	Bad oral health
	Vegetarian	Vegetarian
	No food-specific allergies	No food-specific allergies

4.4 Introductory meal and compensation

In order to familiarise with the environment and the experimental procedures, all the participants will participate in an introductory meal session, on a separate day, at the beginning of the procedure. During this session, the experimental script is followed unchanged, but no data are collected.

At the end of the study protocols, the subjects can participate in an optional debriefing meeting where they are given a personal printout of their meal data. At the end of the study, the participants are compensated with three cinema tickets coupons (approximately worth 36€) for their participation.

4.5 Study material

4.5.1 Mandometer V4

The Mandometer device has been described in detail before (DoW, Part B, page 16), so it is not presented here again. The V4 of the device that is used for the described protocols is a standalone apparatus, including a custom controller and input unit (Figure 15). For the collection of the novel datasets the devices will be configured for a sampling rate of 1Hz.

Figure 15. The Mandometer V4, used for the collection of *Novel* and *Past* datasets in the Mandometer study

4.5.2 Served food

For the preparation of all the food in the study widely consumed, commercially available ingredients are used. When possible, the ingredients are pre-cooked, ordered in big quantities from the same manufacturer. In every case the food preparation is standardised, ensuring minimal variations in the quality/taste of the food items. Additionally, when the food is served, special care is given to keeping the temperature of a dish stable across sessions. The list of served meals are presented in Table 9.

4.5.3 Video recordings of meals

All the meals are recorded with a video camera placed approximately 2m away from the subject, with clear view of the subjects' temporomandibular area and the table where the meal is taking place.

4.5.4 Complementary study material

In addition to the material presented in the section, the participants will have to fill in various *mood, appetite and taste questionnaires*. Before the meals the participants will be asked to rate their mood (i.e., happiness, relaxation, tension, anxiety, restlessness and nausea) and appetite (i.e., thoughts about food, desire to eat, hunger and smell pleasantness) on a 100 mm visual analogue scale (VAS), from "not at all" (score=0) to "extremely/very" (score=100). Using a similar scheme, after the meals, the participants will rate their appetite and the taste characteristics of the served food (i.e., overall taste, saltiness, sweetness, spiciness, fatness, sourness and bitterness). The collected data will be used, by KI, for the identification of outliers in the datasets (e.g., identifications of problems with the served food etc.). Those datasets will not be shared with the rest of SPLENDID.

Table 9. List of foods in *Mandometer study*. **Novel** data from 3 food types will be combined with **past** data from another 5 food types.

Food type	Nutritional characteristics (/100g)	Picture
Novel Data		
Vegetables with chicken in cubes	384kJ 9.6g protein, 8.2g carbohydrates 2.0g fat	
Finely grinded meat and tomato soup	327kJ 2.1g protein 5.9g carbohydrates 4.6g fat	
Hamburger	758kJ 7.6g protein 17.2g carbohydrates 8.9g fat	
Past Data		
Curry rise with chicken in cubes	598kJ 5.5g protein 18g carbohydrates 5.7g fat	
Macaroni with minced meat and sauce	754kJ 6.3g protein 17.8g carbohydrates 9g fat	

Meatballs and whole potatoes with tomato sauce	587kJ 9.4g protein 8.5g carbohydrates 6.8g fat	
Minced meat and potato purée with tomato sauce	587kJ 9.4g protein 8.5g carbohydrates 6.8g fat	
Oat porridge	496kJ 4.2g protein 20.9g carbohydrates 2.1g fat	

4.6 Study procedure

All the experimental meals are served during lunch time. Consecutive meals are separated by approximately one week. The participants are asked to refrain from eating for at least three hours before the meal and their breakfasts are standardised the days of the experimental sessions. No reading materials or use of electronic devices are allowed during the meals, in an effort to minimize the external effects on eating behaviour. For each of the meals, amounts of food enough to create an ad libitum feeling (from 700g to 1.5kg depending on the kind of food), is presented on an external food tray (i.e., not placed on the Mandometer). The subject is then asked to add food on the plate placed on the Mandometer scale and they are also informed that they are allowed to add food freely during the meal. Before the meal is initiated the participants have to fill in the *mood* and *appetite questionnaires*. Then the meal initiates and the investigators exit the room. When the meal is concluded the *appetite* and *taste questionnaires* are filled in again. The script for a typical experimental meal session can be seen in Figure 16.

4.7 Data collection, handling and reporting

After the completion of each experimental session the Mandometer data are stored in KI's computers for further formatting. Similarly, the video files and the questionnaire datasets are transferred to the KI computers. The video-files are then time-stamped for removal of food from the plate, for occurrence of bites and chewing cycles throughout the meal, allowing for

validation and expansion of the weight-loss data obtained from the Mandometer [17]. The datasets (raw and reanalysed data) are reformatted according to SPLENDID requirements (for more details see the reports for D6.1 and D6.2), preparing them for sharing with WP3. The outcome of the signal processing analysis addressing the automatic detection of eating behaviour indicators will be included in D3.1: *Signal processing algorithms for extraction of eating and activity related indicators*.

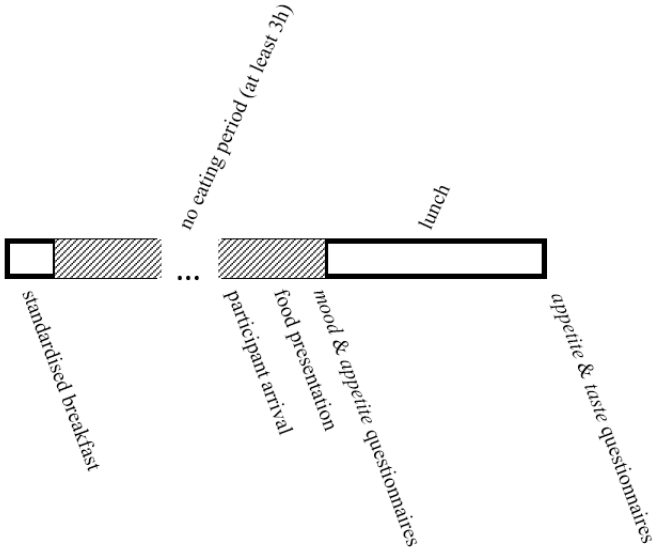


Figure 16. Experimental meal session script for the *Mandometer study*

5 First system version (V1) evaluation study

After the completion of the initial evaluation studies (sections 2 to 4), the analysis of their outcome data by the relevant WPs (Table 1) and the conclusion of the technical system developments, the (non-intergraded) V1 of the SPLENDID system will become available and it will be evaluated in adolescents and young adults in two separate studies, in Sweden and the Netherlands respectively. The two studies will have similar, but not identical, protocols, adapted to the requirements of the two study sites. The studies will utilize all the developed, but not intergraded, sensors, analysing both eating and physical activity behaviours in both sites. The collected data from the planned studies in this task will feed back into various WPs (Table 1) to help for the development of the V2 of the SPLENDID system.

The protocols have already been drafted but are not finalized yet (see section 1.2.3). Also, the involved partners (KI, IEGS, WU and Mando) will apply for ethical permissions based on a mature version of these protocols during Q4 of 2014. Due to the complexity of the studies and the sensitivity of the target subjects, it is possible that the local ethical authorities might require changes on the proposed procedures. Based on the received feedback, it is expected that this section will be finalised during February 2015 (document version 2.0). Consequently, in the sections below, the studies are described in general terms, expressing the main plan rather than a schedule set in stone.

5.1 V1 evaluation study in adolescents

This section of the document will be finalised in the document version 2.0, in February 2015 (see section 1.2.3).

In order to evaluate the use of the V1 sensors in a school environment, used by students, this study will take place in the IEGS School in Stockholm. This study aims to evaluate the feasibility of the stand-alone, V1 sensors in a school setting, and to collect feedback on different elements of the system by the participants. The student-specific datasets will be later used to improve the algorithms developed for the extraction of behavioural indicators and for the assessment of the risk for the development of eating disorders and obesity.

For this study, the presented protocol is already quite detailed. KI, Mando and IEGS have started working early on the specifics of this study, due to the sensitivity of the target subject group and the challenging nature of the setting of this study (i.e., students and school environment respectively). The protocol will not incorporate evaluation of screening of students and in-study risk assessments. Instead, this study will aim to collect reliable information from all the sensors in the target environment that will be fed into WP3 for the development of follow-up risk-calculating algorithms, after the completion of the study

5.1.1 Objectives and structure of the study

The primary goal of this study is to test all the V1 sensors in the school environment by the maximum possible number of students. To achieve the above the main elements of the study will be: i) *eating school meals with the Mandometer*, ii) *using the chewing sensor and the physical activity sensor while in school*, iii) *using the chewing sensor to identify a semi-random snacking event* and iv) *collecting feedback from students and school personnel for the components of the system under development*. The designed protocols will also function as a

rehearsal for successfully running the *V2 evaluation study in adolescents* (section 6.1) the following year of the project.

The study is expected to include two full classes from IEGS's Natural Science program (approximately 60-70 students). While the precise number of participants cannot be confirmed at this point, the inclusion of two classes in the study should ensure that at least 40-50 students will accept to participate in the study. The participants will be divided into two groups, of at least 20 (but probably more) subject each, which will go through different protocols.

The first group of students will use all the sensors, following the protocol described here. The other group will follow a complementary scientific protocol, which will be designed outside the scope of SPLENDID. The reason for this decision is that it is not deemed appropriate to engage only a smaller subgroup of students in a study, as this is going to increase the chances of stigmatisation for the participants. It is possible that the second protocol produces data from school meals with the Mandometer only. The structure of the final dataset is presented in Figure 17. The presented study structure has been discussed in detail among KI, Mando and IEGS, in a meeting at the beginning of June 2014 and is regarded realistic.

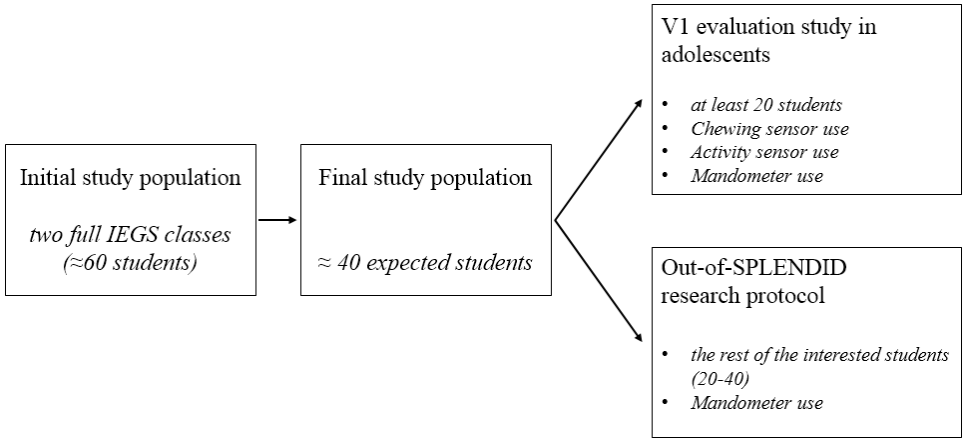


Figure 17. Projected structure of the *V1 evaluation study in adolescents* in the school environment.

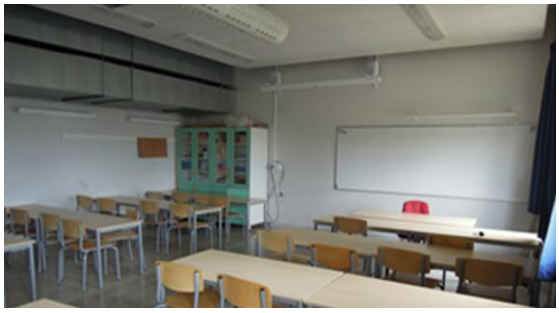
5.1.2 Research setting

IEGS is an international high school located on Södermalm downtown Stockholm area. The student's in IEGS (around 700 in total) are aged between 15 and 19 years and they are divided (age-wise) in three consecutive classes. Of special interest for SPLENDID, is the active Natural Science program in IEGS, which is going to be the main pool of participants for the *V1* and *V2 evaluation studies*. The program usually has 60-70 students per year (i.e., two classes).

IEGS has an in-school dining area which serves free-of-cost, buffet breakfast (optional) and lunch to all the students in the school. The buffet area (Figure 18, A) will be used to serve the food in the *V1* and *V2 evaluation studies*. An adjacent, semi-independent room is going to be reserved for SPLENDID use, and it will be fitted with all the required equipment for recording the meals. The same room will be used at different times of the day for briefing and debriefing meetings with the participating students. For the *V1 evaluation study*, IEGS will also reserve one of the available Natural Science classrooms (Figure 18, B) and/or the school Drama room (Figure 18, C), which will be fitted with the required equipment for recording snacking.

A

B



C

Figure 18. Some of the school facilities (IEGS) to be used in the *V1* and *V2 evaluation studies in adolescents*. **A**: School buffet area, **B**: Natural Science classroom, **C**: Drama room

5.1.3 Subjects and compensation

The students will be randomised in the two parallel studies, until the target number of 20 students is completed in the SPLENDID protocol (Figure 17). The rest of the students will be included in the other study. The finalized criteria for participating in the SPLENDID study will be decided in communication with IEGS personnel, but the set of criteria will not be very restrictive, since our intention is to test the sensors in as many available students as possible. Table 10 presents the projected subject characteristics.

Table 10. Projected subject characteristics for V1 evaluation protocol in adolescents

Age (years)	15-16 (i.e., first year students in IEGS)
BMI	any
Gender	Male, female
Target sample size	20 individuals
Gender ratio	1 : 1
Protocol-specific	none

exclusion criteria

For their participation, the students will be compensated with one cinema ticket coupon. Alternatively (if so desired by IEGS administration and the students) some more relevant form compensation will be decided (e.g., contribution for a class activity etc.).

5.1.4 Study material

5.1.4.1 SPLENDID sensors

In this study the sensors that will be used are the ones included in V1 of SPLENDID, described in detail in D5.1: *Services, Components and System Specification*. In summary, in this version of the system, the sensors and the algorithms are not integrated. Thus the different sensors will be used as standalone apparatuses.

5.1.4.1 Video recordings

In communication with IEGS it has been agreed that the semi-controlled experimental parts of the protocol will be videotaped in order to validate the nature of the recorded sensor data. If concerns for the use of cameras in a school setting are raised by the local ethical authorities and/or the cameras limit the participation in the studies, the cameras will be replaced by external observers (i.e., KI, Mando and IEGS personnel), externally logging study-related behaviours. If the latter proves the case, an appropriate behavioural logging scheme will be selected based on scientific literature.

5.1.4.2 Served food and snacking items

In communication with IEGS, KI researchers will come in contact with the catering company providing food for the school lunches and a range of representative, yet study-appropriate food items will be prepared the days of the experimental sessions and served exclusively to the participating students in a buffet setting. Special attention will be given to accommodating various food related student requirement (e.g., food-specific allergies, vegetarians etc.).

The list of food items for the semi-random snacking events will be decided jointly among KI, IEGS and WU. It will probably include typical Swedish snacking items (e.g., apples, sweets, biscuits etc.). The final list of items will be finalized during Q4 2014. Once again, student food-related requirements will be analysed and accommodated.

5.1.4.3 SPLENDID user acceptance and satisfaction questionnaires

The precise nature of the desired feedback from the *V1 evaluation study in adolescents* and the final format of the questionnaires to be used, will be decided during Q4 2014, jointly among KI, Mando, AUTH, WU, IEGS and TSB. The questionnaires will be directed to both students and involved school personnel (e.g., teachers, school nurses etc.). The general aim of these questions will be to collect sensor specific feedback, but also to feedback related to the feasibility of using the envisioned SPLENDID system in a school setting. Additionally, mock ups of the available system screens (web and mobile) will be presented and feedback will be collected.

5.1.5 Timing of the studies SPLENDID presence in IEGS

It is projected that the study will be run in IEGS during the end of February or the beginning of March 2015 and they will last two to three weeks. The precise timing of the studies will be decided after the beginning of the 2014-2015 school year. Due to the available number of V1 sensors, the daily experimental script will be repeated for two/three consecutive days with different groups of students, until the desired number of datasets is collected.

5.1.6 SPLENDID presence in IEGS

i. To prepare the school community for the V1 and V2 evaluation studies, it has been agreed that KI and Mando will participate in the 2014 educational program of the Natural Science program in IEGS. Thus the involved personnel will give a short series of lectures (Q4 2014) to the targeted classes about the general scientific and clinical interests of the two groups. That will create the opportunity for the investigators to familiarise with the school environment and for the students to acclimatize with the presence of the research personnel in the school.
ii. KI and Mando personnel will also meet with the Natural Science teaching team (around December 2014) in order to allow the integration of the protocol into the teaching schedule of the program.
iii. During January 2015 the investigators will hold an informational meeting with the students from the two participating classes, during which detailed information about the project will be presented and the consent and assent forms will be distributed for the students and the parents. IEGS will then be responsible to collect the required consent and assent forms from the students.
iv. Around the same period of time the investigators will hold an "open room session" (probably after school hours) at IEGS, when parents and non-participating school personnel/students will be encouraged to attend in order to receive information about the studies to follow and SPLENDID in general.
v. The days/week before the initiation of the experimental protocols, KI, IEGS and Mando personnel will meet with the participating students to demonstrate in detail the use of sensors, go through the specifics of the upcoming experimental session script and fill in all the questionnaires required for the initiation of the study.

5.1.7 Study procedure

At the beginning of the experimental days, the investigators will meet with the participating students, who they will be fitted with the activity sensors and will fill in the daily questionnaires. Then the students will go through their usual school activities. At lunch time, they will be served the prearranged food (section 5.1.4.2) and they will be guided to the pre-arranged eating stations where they will answer the eating-related questionnaires and they will eat their meals using Mandometers V4. Approximately 1 hour after the end of the lunch, they will be received in an especially prepared area where they will remain for at least 1.5 hours, wearing the *V1 chewing sensor*. At a time point, randomised during the last 1/3 of this time period, the students will be directed to visit the *snacking station* and receive a snack (section

5.1.4.2), that will be consumed while wearing the chewing sensor (if it is deemed practically possible the Mandometers V4 will also be used). At the end of the experimental day, the students will be debriefed in a final meeting, when the activity sensors will be removed and the *acceptance* and *satisfaction questionnaires* (section 5.1.4.3) will be answered. The students will also be encouraged to contact KI (through email) if they wish to receive personal printouts of their performance during the tests. The projected structure of the daily experimental script can be seen in Figure 19.

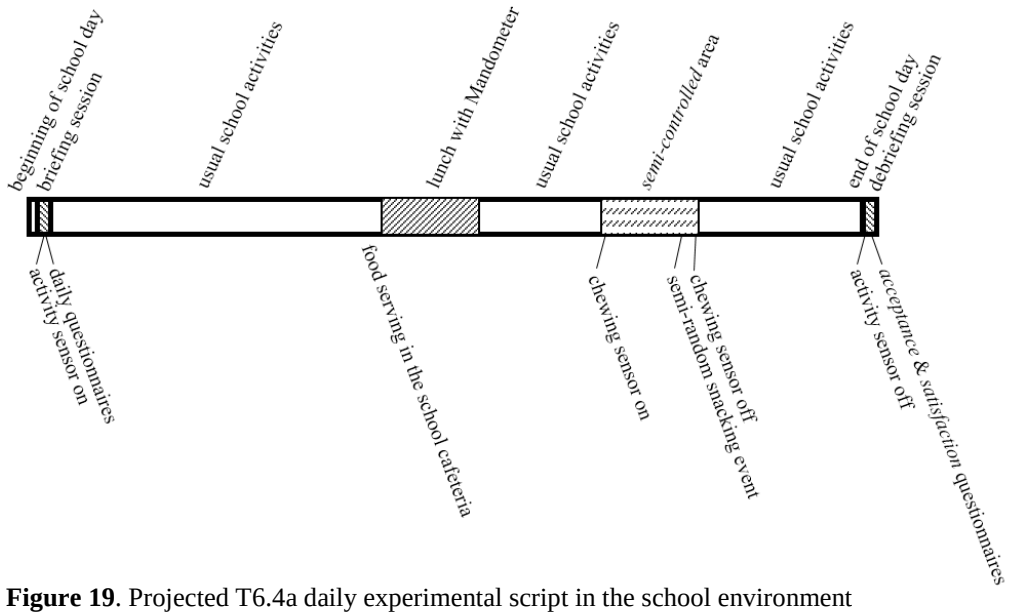


Figure 19. Projected T6.4a daily experimental script in the school environment

5.1.8 Data collection, handling and use

After the completion the daily experimental script the Mandometers data, the accelerometry and chewing data, the questionnaire answers and the video files (if existent), will be stored in KI computers for further formatting and analysis. The precise data formatting and pre-analysis procedures will be finalized later, but they will be roughly equivalent to the procedures that were described in the section 3 and 4. The produced datasets (raw and reanalysed data) will be reformatted according to SPLENDID requirements and they will be passed along to the relevant WPs (Table 1). Signal processing analysis addressing the automatic detection of eating behaviour indicators will be conducted in WP3. The results will be presented in D6.3 "Preliminary evidence on objective assessment of eating and activity behaviour of Swedish adolescents and Dutch adult population at risk for weight gain: Results of the evaluation of the first system version (V1)".

5.2 V1 evaluation study in young adults

This section of the document will be finalised in the document version 2.0, in February 2015 (see section 1.2.3).

This study aims to evaluate the feasibility of the stand-alone, V1 sensors by young adults. The outcome datasets will be later used to improve the algorithms developed for the extraction of behavioural indicators and for the assessment of the risk for the development of eating

disorders and obesity. The study will also collect updated feedback from the participants, concerning the different elements of the system.

Currently, fewer decisions have been taken about the protocol of this study than about the one of the *V1 evaluation study in adolescents*. However, it is expected that the two protocols will be similar. WU, KI and Mando will be working together during Q3 2014 to finalize the experimental procedures to be followed.

5.2.1 Objectives and structure of the study

The primary objective of this study will be to test the feasibility of using the first (V1) version of the system in young adults. As before, the V1 sensors will be intergraded into the protocol as standalone apparatuses. It is projected that the protocol will include: i) *eating meals with the Mandometer V4*, ii) *using the chewing sensor and the physical activity sensor for longer periods of time*, iii) *using the chewing sensor to identify a snacking events* and iv) *collecting feedback from the users for the components of the system under development*. The study will also function as a rehearsal for running the *V2 evaluation study in young adults* (section 6.2) the following year of the project.

5.2.2 Timing, research setting and subjects

It is projected that this study will start after the termination of the *V1 evaluation study in young adults*. Due to the fact that the same set of V1 sensors will be used in both V1 evaluation studies, it is foreseen that the data collection of the study will start in April/May 2015. The starting date will also depend on the ethical approval by the Dutch Medical Research Ethical Committee. Due to the available number of V1 sensors, the daily experimental script will be repeated for several days with different subjects, until the desired number of datasets is collected

The study will be conducted at the Biotechnion building in Wageningen (Figure 20). This building has a dining room and professional kitchen that can provide meals for large groups of subjects (up to 60). The kitchen is run by a group of dieticians that can develop and prepare standardized meals for different types of experiments.

A

B

C

Figure 20. Biotechnion building (**A**), professional kitchen (**B**) and common dining area (**C**)

Subjects for the study will be recruited from the NQplus cohort [18], a study which currently being conducted in Wageningen and surrounding municipalities. From the total pool of individuals in NQplus, overweight young adults, the target user population of the system, will be selected to participate in the study.

5.2.3 Preliminary experimental procedure

Subjects will come to the dining room about one hour before lunch. The subject will receive instructions and the physical activity sensors will be placed. After this instruction, the subject will fill out questionnaires. The subject will then eat his or her lunch with the V4 MANDO system in an isolated booth. After lunch the subjects will get the chewing sensor and they can spend the rest of the afternoon freely in the university building. The subjects will take a snack box with them and they get instructions to eat certain foods at certain times. Subjects will then return to the dining room for their dinner, which they will also eat with the Manometer. At the end of the experimental day, the participants will be debriefed in a final meeting, when the activity sensors will be removed and the acceptance and satisfaction questionnaires will be answered.

5.2.4 Study material

Since both the V1 evaluation studies will have similar protocols, the main study materials will be very similar (section 5.1.4).

5.2.4.1 SPLENDID user acceptance and satisfaction questionnaires

The general aim of these questionnaires will be to collect sensor-specific feedback, but also to feedback related to the feasibility of using the envisioned SPLENDID system in real-life. Additionally, mock ups of the available system screens (web and mobile) will be presented and feedback will be collected. In this case, the questionnaires will be tailored to Dutch young adults. The questionnaires will be finalised during Q4 2014.

5.2.4.2 Served food and snacking items

The meals will be prepared by dieticians from the division of Human Nutrition, according to all hygiene codes. The exact type of meals and snacks will be decided together with KI. The foods will probably include typical Dutch snacking items (e.g., apples, sweets, biscuits etc.). The final list of items will be finalized during Q4 2014.

5.2.5 Data handling, formatting and pre-analysis

After the completion of the study the produced datasets will be passed along to the relevant WPs (Table 1). Signal processing analysis addressing the automatic detection of eating behaviour indicators will be conducted in WP3. The results will be presented in D6.3 “Preliminary evidence on objective assessment of eating and activity behaviour of Swedish adolescents and Dutch adult population at risk for weight gain: Results of the evaluation of the first system version (V1)”.

6 Second system version (V2) evaluation study

During the last year of SPLENDID the intergraded, close to final, V2 of the SPLENDID system will be evaluated in adolescents and young adults. Again, the evaluation will take place in Sweden and the Netherlands, for adolescents and young adults respectively. The two main characteristics of these studies will be: i) *the use of the intergraded system in real-life environments* and ii) *the longer term testing of the Personalised Guidance in the target populations (in real-life environments again).* The evaluation of the studies' outcomes will lead to the final version of the system (Version 3, developed in T5.4).

It is expected that this section will be finalised during February 2016 (document version 3.0).

The outcomes of the V2 evaluation studies are considered very important for this project and they will be reported with D6.4 (September 2016).

6.1 V2 evaluation study in adolescents

This section of the document will be finalised in the document version 3.0, in February 2016 (see section 1.2.3).

This study will be jointly run by KI, Mando and IEGS in Sweden. For the first time in the project, adolescents who are at risk of developing either eating disorders or obesity will be identified from a larger sample (≈100) of IEGS students. Those individuals will be identified in a screening session, organised in IEGS School, using the Mandometer. The selected individuals (expected n≈30) will be asked to use the SPLENDID behavioural recording system for one week. Afterwards, those individuals will be asked to the use sensors together with the personalised guidance system for 3 weeks.

Before and after the personalised guidance phase, parameters of eating and physical activity behaviour will be measured. During the personalised guidance behavioural and compliance data will be collected continuously by the system. Another group of students (i.e., the control group, n≈30) will undergo the before and after measurements, without using the personalised guidance system. The outcome datasets will be compared within and between groups in a before-after fashion, aiming into identifying differences in eating and physical activity, facilitated by the use of the personalised guidance system.

Using the personalised guidance system for such a short period of time is not expected to facilitate weight changes for the users. However, the successful modification of key eating and physical activity behaviours in the group of students using the personalised guidance system, will point to a potential weight changes after longer use of the system.

6.2 V2 evaluation study in young adults

This section of the document will be finalised in the document version 3.0, in February 2016 (see section 1.2.3).

This study will be run by WU in the Netherlands. Young adults at risk of developing obesity will be identified and recruited through the NQplus cohort study [18]. The selected young adults (expected n≈30), much like the students, will be asked to use the SPLENDID behavioural recording system for one week. Afterwards, they will be asked to the use sensors together with the personalised guidance system for 3 weeks.

Similarly to the *V2 evaluation study in adolescents* (section 6.1), the protocol will include measurements before and after and during the personalised guidance phase. Only before and after measurements will be taken from a control group of participants (n≈30), without using the personalised guidance system.

The outcomes of this study will be analysed similarly to the *V2 evaluation study in adolescents*, aiming in identifying changes in key eating and physical activity behaviours pointing to possible weight loss after using the personalised guidance system for a longer period of time.

7 Conclusions

The present report, entitled "Final Protocols of Evaluation Studies", describes the protocols, the overall scope and the objectives for the evaluation studies in the SPLENDID project. Those protocols reflect the need to evaluate the systems' quality and usability, but also its correct scientific use.

This version of the document (Version 1.0, July 2014) includes the detailed protocols for the three first-year studies: i) the *Chewing sensor prototype study*, ii) the *Activity sensor studies* and iii) the *Mandometer study*. It also outlines the System *V1 and System V2 evaluation studies*. The updated versions of the report (2.0 and 3.0, which are to be delivered in February 2015 and 2016 respectively), will progressively add more detailed information concerning the protocols of the SPLENDID studies planned for the second and the third year of the project.

This report can be used by the SPLENDID consortium, and specifically by the partners involved in running the evaluation protocols, as a detailed guide for all the planned studies of this project. Additionally, to the external reader, this document is a blueprint of the evaluation procedures in SPLENDID and a statement to the quality of the work involved in this project.

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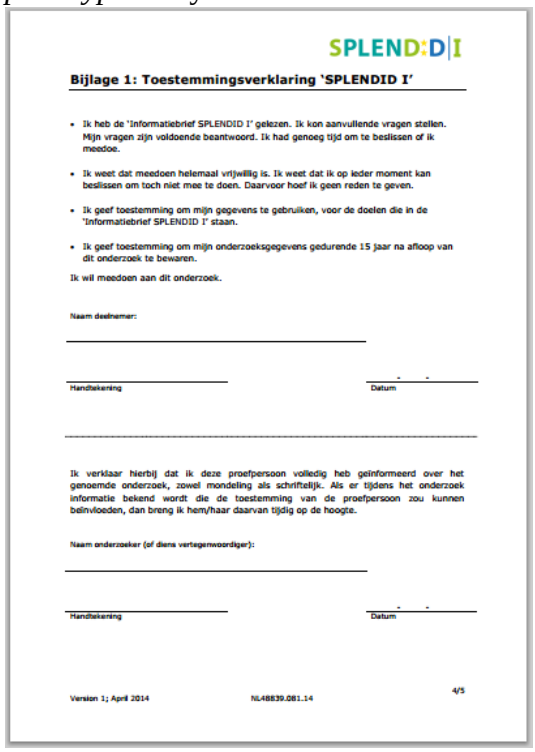
Annex A

A: Extract from the written, informed consent forms used by WU for the *Chewing sensor prototype* study



SPLEND:D|I

Bijlage 1: Toestemmingsverklaring 'SPLENDID I'

- Ik heb de 'Informatiebrief SPLENDID I' gelezen. Ik kon aanvullende vragen stellen. Mijn vragen zijn voldoende beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.
- Ik weet dat meedoen helemaal vrijwillig is. Ik weet dat ik op ieder moment kan beslissen om toch niet mee te doen. Daarvoor hoef ik geen reden te geven.
- Ik geef toestemming om mijn gegevens te gebruiken, voor de doelen die in de 'Informatiebrief SPLENDID I' staan.
- Ik geef toestemming om mijn onderzoeksgegevens gedurende 15 jaar na afloop van dit onderzoek te bewaren.

Ik wil meedoen aan dit onderzoek.

Naam deelnemer:

Handtekening Datum

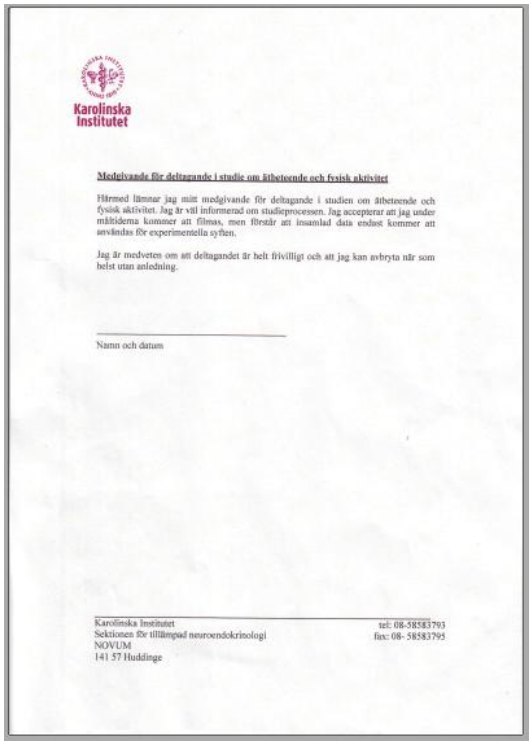
Ik verklaar hierbij dat ik deze proefpersoon volledig heb geïnformeerd over het genoemde onderzoek, zowel mondeling als schriftelijk. Als er tijdens het onderzoek informatie bekend wordt die de toestemming van de proefpersoon zou kunnen beïnvloeden, dan breng ik hem/haar daarvan tijdig op de hoogte.

Naam onderzoeker (of diens vertegenwoordiger):

Handtekening Datum

Version 1; April 2014 NL48839.081.14 4/5

B: Extract from the written, informed consent forms used by KI for the *Activity sensor* and the *Mandometer* studies



Karolinska Institutet

Medgivande för deltagande i studie om ätbeteende och fysisk aktivitet

Härmed lämnar jag mitt medgivande för deltagande i studien om ätbeteende och fysisk aktivitet. Jag är väl informerad om studieprocessen. Jag accepterar att jag under måltiderna kommer att filmas, men förstår att insamlad data endast kommer att användas för experimentella syften.

Jag är medveten om att deltagandet är helt frivilligt och att jag kan avbryta när som helst utan anledning.

Namn och datum

Karolinska Institutet
Sektionen för tillämpad neuroendokrinologi
NOVUM
141 57 Huddinge
tel: 08-58583793
fax: 08- 58583795

Annex B

Extract from the approval decision (in Dutch) for the protocols in *Chewing sensor prototype studies*

WAGENINGEN UR
METC-WU

BESLUIT
Primaire beoordeling

NL nummer:	NL48839.081.14	**METC nr.**	14/12
Titel onderzoek:	SPLENDID I: Development of a sensor for the detection of eating.		

Contactgegevens: Dr. M. Mars, Wageningen University, Division of Human Nutrition, Wageningen.
Verrichter: Wageningen University, Division of Human Nutrition

Besluit
De medisch-ethische toetsingscommissie METC-WU heeft zich, op grond van artikel 2, tweede lid, sub a van de *Wet medisch wetenschappelijk onderzoek met mensen* (WMO), beraden over bovengenoemd onderzoeksdossier.

De commissie oordeelt positief over de uitvoering van het onderzoek in het volgende centrum: Wageningen University, building Futurum (hoofdonderzoeker: Dr. M. Mars).

Documenten
Het oordeel baseert de METC-WU op de documenten, waarover zij bij de beoordeling de beschikking heeft gehad. Een overzicht van de documenten is opgenomen in Bijlage 1 bij dit besluit.

Achtergrond
Op donderdag 3 april 2014 is het onderzoeksdossier ter beoordeling bij de METC-WU ingediend. Het onderzoeksdossier is besproken in de plenaire vergadering van dinsdag 15 april 2014: zie Bijlage 2 voor de aanwezige leden op deze vergadering.

Overwegingen
De METC-WU is van oordeel dat aan de voorwaarden in artikel 3 van de WMO is voldaan. De belangrijkste vragen ten aanzien van het onderzoeksdossier betroffen: *het is geen observationeel onderzoek, maar een cross-over interventiestudie, er zijn geen hypothesen geformuleerd, sample size berekening ontbreekt, onduidelijkheid over uitkomstmaten, onduidelijkheid in exclusiecriterium, begrijpelijkheid PIF, privacy issues.*

WAGENINGEN UR
METC-WU

De verboden die genoemd worden in de artikelen 5 en 6, eerste
WMO zijn niet van toepassing op het onderzoeksdossier.
De commissie is van mening dat is voldaan aan de voorwaarden
vijfde t/m negende lid, van de WMO. De proefpersonen (en/of d
mede/in hun plaats bevoegd zijn tot het geven van toestemming
deelname aan het onderzoek), worden op gepaste, volledige en
begrijpelijke wijze schriftelijk over het onderzoek geïnformeerd.

Verzekeringen
De METC-WU heeft geconstateerd dat is voldaan aan de
verzekeringsplicht. De commissie is van oordeel dat de plicht tot
afsluiten van een WMO-proefpersonenverzekering vervalt op gro
artikel 5, vijfde lid, van de WMO. Gezien het type onderzoek lope
deelnemende proefpersonen volgens de commissie geen risico's
De METC-WU heeft geconstateerd dat een aansprakelijkheidsver
afgesloten zoals bepaald in artikel 7, negende lid van de WMO.

Ten slotte wijst de METC-WU u op de voorwaarden en verplichti
Bijlage 3 zijn vermeld.

Hoogachtend,

Namens de METC-WU,
Dr. C. Dullemeijer, ambtelijk secretaris

Wageningen, 23 juni 2014

Beroepsprocedure
Tegen dit besluit kan een belanghebbende op grond van artikel 2
WMO binnen zes weken na de dag waarop het besluit is bekend
administratief beroep instellen bij de Centrale Commissie Mensg
Onderzoek (CCMO). Het beroepschrift dient u te adresseren aan
Postbus 16302, 2500 BH Den Haag.

Annex C

Randomisation protocol for the *Chewing sensor prototype studies*

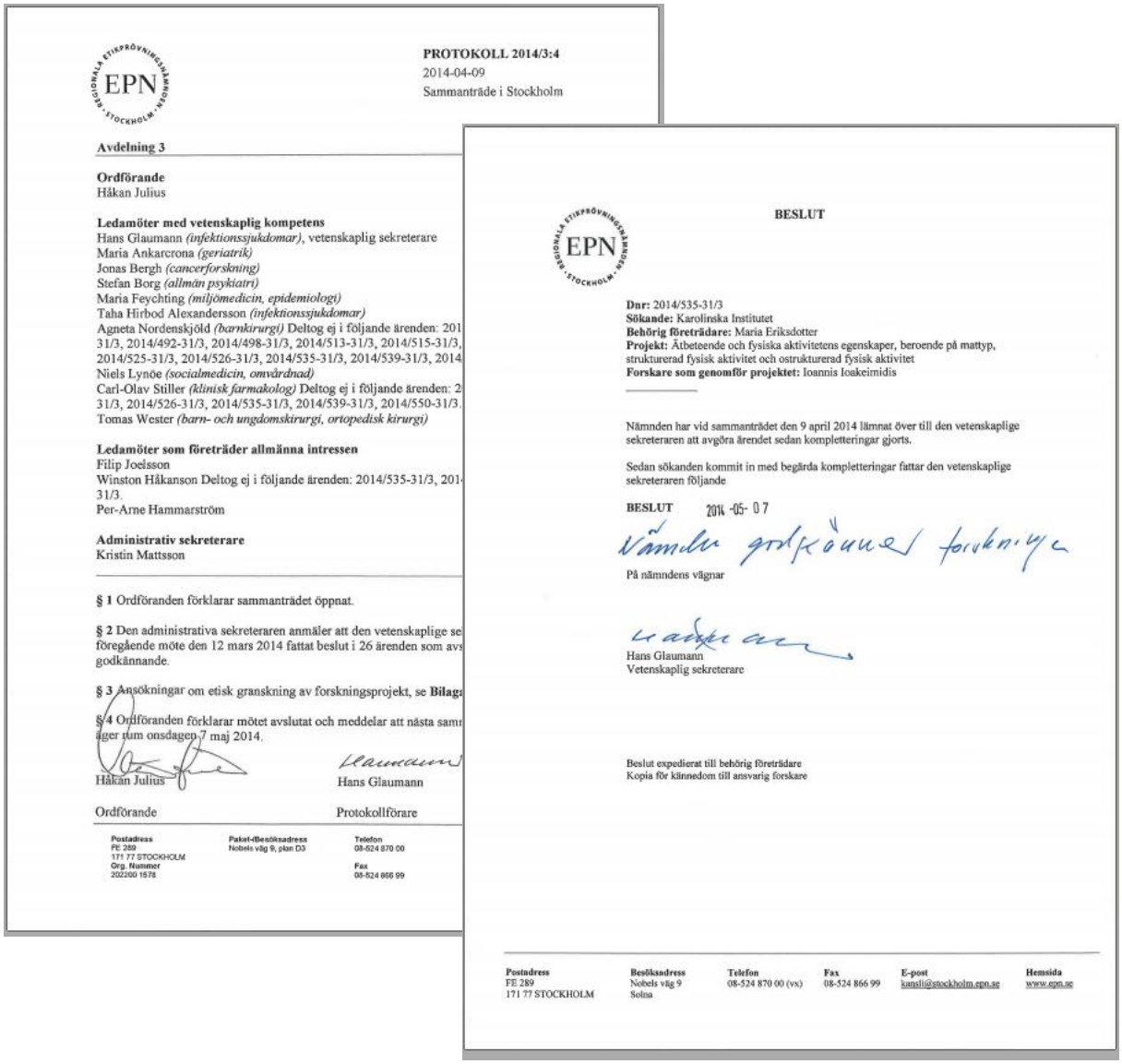
		Males										Females									
		1	2	3	4	5	6	7	8	9	10	1	2	3	4	5	6	7	8	9	10
Activities																					
Reading a book section out loud		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Swallowing with empty mouth		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Coughing		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Doing nothing		x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Food products	**Estimated amount**																				
Water	100 g	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Diet coke	100 g						x	x	x	x	x						x	x	x	x	x
Milk	100 g	x	x	x	x	x						x	x	x	x	x					
Apple juice	100 g						x	x	x	x	x						x	x	x	x	x
Yoghurt (thick and creamy)	75 g	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Vanilla custard	75 g	x	x	x	x	x						x	x	x	x	x					
Pureed apple	75 g						x	x	x	x	x						x	x	x	x	x
Potato chips	15 g	x	x	x	x	x						x	x	x	x	x					
Cookie	25 g						x	x	x	x	x						x	x	x	x	x
Apple	50 g	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Lettuce	25 g	x	x	x	x	x						x	x	x	x	x					
Bread	35 g	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Cake	30 g						x	x	x	x	x						x	x	x	x	x
Banana	50 g	x	x	x	x	x						x	x	x	x	x					
Strawberry	50 g						x	x	x	x	x						x	x	x	x	x
Candy bar	25 g	x	x	x	x	x						x	x	x	x	x					
Toffee	15 g						x	x	x	x	x						x	x	x	x	x
Chewing gum	-	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Food products & Activities	**Estimated amount**	(T=talking, D=drinking)																			
Water	100 g	T										T									
Diet coke	100 g		T										T								
Milk	100 g			T										T							
Yoghurt (thick and creamy)	75 g				T			D							T			D			
Pureed apple	75 g					T	D									T	D				
Potato chips	20 g					D	T									D	T				
Apple	50 g				D						T				D						T
Bread	35 g			D					T					D					T		
Banana	50 g		D							T			D							T	
Toffee	15 g	D						T				D						T			
Chewing gum	-								D	T									D	T	
Mystery conditions																					
.....		x		x			x				x	x		x			x				x
.....			x			x		x					x			x		x			
.....				x	x				x					x	x				x		
.....			x		x					x			x		x					x	
.....		x				x					x	x				x					x
Total																					
Number of drinks		3	3	3	2	2	3	3	3	3	3	3	3	3	2	2	3	3	3	3	3
Grams of drinks		300	300	300	200	200	300	300	300	300	300	300	300	300	200	200	300	300	300	300	300
Number of foods		9	9	9	10	10	10	10	9	9	9	9	9	9	10	10	10	10	9	9	9
Grams of food		365	400	385	400	370	450	445	390	405	405	365	400	385	400	370	450	445	390	405	405
Number of conditions		19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19	19

At the start of the measurements, in random order

Main part of the measurements, in random order, with random breaks in between

Annex D

Extract from the approval decision (in Swedish) for the protocols in *Activity Sensor* and *Mandometer studies*



EPN

PROTOKOLL 2014/3:4
2014-04-09
Sammanträde i Stockholm

Avdelning 3

Ordförande
Håkan Julius

Ledamöter med vetenskaplig kompetens
Hans Glaumann *(infektionssjukdomar)*, vetenskaplig sekreterare
Maria Ankarcrona *(geriatrik)*
Jonas Bergh *(cancerforskning)*
Stefan Borg *(allmän psykiatri)*
Maria Feychting *(miljömedicin, epidemiologi)*
Taha Hirbod Alexandersson *(infektionssjukdomar)*
Agneta Nordenskjöld *(barnkirurgi)* Deltog ej i följande ärenden: 201
31/3, 2014/492-31/3, 2014/498-31/3, 2014/513-31/3, 2014/515-31/3,
2014/525-31/3, 2014/526-31/3, 2014/535-31/3, 2014/539-31/3, 2014
Niels Lynöe *(socialmedicin, omvårdnad)*
Carl-Olav Stiller *(klinisk farmakolog)* Deltog ej i följande ärenden: 2
31/3, 2014/526-31/3, 2014/535-31/3, 2014/539-31/3, 2014/550-31/3.
Tomas Wester *(barn- och ungdomskirurgi, ortopedisk kirurgi)*

Ledamöter som företräder allmänna intressen
Filip Joelsson
Winston Håkanson Deltog ej i följande ärenden: 2014/535-31/3, 201
31/3.
Per-Arne Hammarström

Administrativ sekreterare
Kristin Mattsson

§ 1 Ordföranden förklarar sammanträdet öppnat.

§ 2 Den administrativa sekreteraren anmäler att den vetenskaplige se
föregående möte den 12 mars 2014 fattat beslut i 26 ärenden som avs
godkännande.

§ 3 Ansökningar om etisk granskning av forskningsprojekt, se **Bilag**

§ 4 Ordföranden förklarar mötet avslutat och meddelar att nästa samr
äger rum onsdagen 7 maj 2014.

Håkan Julius
Ordförande

Hans Glaumann
Protokollförare

Postadress FE 289 171 77 STOCKHOLM Org. Nummer 202100 1578
Paket-/Besöksadress Nobels väg 9, plan D3
Telefon 08-524 870 00
Fax 08-524 866 99

EPN

BESLUT

Dnr: 2014/535-31/3
Sökande: Karolinska Institutet
Behörig företrädare: Maria Eriksdotter
Projekt: Ätbeteende och fysiska aktivitetens egenskaper, beroende på mattyp, strukturerad fysisk aktivitet och ostrukturerad fysisk aktivitet
Forskare som genomför projektet: Ioannis Ioakeimidis

Nämnden har vid sammanträdet den 9 april 2014 lämnat över till den vetenskaplige sekreteraren att avgöra ärendet sedan kompletteringar gjorts.

Sedan sökanden kommit in med begärda kompletteringar fattar den vetenskaplige sekreteraren följande

BESLUT 2014 -05- 07
Nämnden godkänner forskningen

På nämndens vägnar

Hans Glaumann
Vetenskaplig sekreterare

Beslut expedierat till behörig företrädare
Kopia för kännedom till ansvarig forskare

Postadress FE 289 171 77 STOCKHOLM
Besöksadress Nobels väg 9 Solna
Telefon 08-524 870 00 (vx)
Fax 08-524 866 99
E-post kansli@stockholm.epn.se
Hemsida www.epn.se

ANNEX E

Example of self-reporting physical activity questionnaire to be used in the *free-living physical activity data* subprotocol of the *Activity sensor studies*

Instruktion

Du skall bära en aktivitetsmätare under 3 dygn och samtidigt skall Du fylla i denna dagbok över Din fysiska aktivitet.

Det är viktigt att Du skriver dagboken i anslutning till aktiviteten, och inte vid slutet av dagen eller senare. Ha alltså dagboken till hands hela tiden!

Dag	Klockslag	Utförd aktivitet	Tid (min)