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Assessment of snacking behaviour in relation to mental well-being with the SnackBox

Submission date	Recruitment status	[ ] Prospectively registered
27/06/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/07/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/07/2022	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Given the rising prevalence of overweight and obesity, a considerable amount of research has been carried out on eating motives, especially what motivates people to eat in between regular meals (snacking behaviour). However, most research studying these motives is either performed in controlled laboratory settings or using some form of self-reported assessment. Both these methods are known for their lack of validity. Therefore, this study introduces the SnackBox as an automated and objective dietary assessment method for snacking behaviour. The main aim of this study is to validate the SnackBox as an automated dietary assessment method for snacking behaviour when compared to a dietary recall method and in relation to physiological and mood states assessed with two wearable sensors and ecological momentary assessments.

Who can participate?

Healthy volunteers with a stationary job (desk job) aged 18 to 49 years old

What does the study involve?

Participants are asked to install a SnackBox at home or work and asked to use it for five working days over a 2-week period. On each of these measurement days, the participants are asked to eat at least one snack and one drink from the SnackBox, to refrain from snacks not included in the SnackBox and to wear the Chill+ device and Garmin VivoSmart 4 for the entire day. Additionally, the participants receive several questionnaires throughout these days to assess their dietary behaviour and their mood states.

What are the possible benefits and risks of participating?

The burden for the participant, timewise, is one hour for the intake session, 30 minutes on each of the measurement days to complete all questionnaires and 30 minutes for the final session. The participants are asked to eat only the preselected snacks during the five measurement days and at least one snack and drink per measurement day. Risks or other discomforts are not expected. No benefit is expected for the participant either.

Where is the study run from?

Stichting IMEC Nederland (Netherlands)

When is the study starting and how long is it expected to run for?
November 2021 to August 2022

Who is funding the study?
Stichting IMEC Nederland (Netherlands)

Who is the main contact?
Alex van Kraaij, Alex.vankraaij@imec.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IA-21-WATS-TIP2-125

Study information

Scientific Title
Validation of the assessment of snacking behaviour with the SnackBox in relation to physiological and mood state aspects, assessed with wearable sensors and ecological momentary assessments

Acronym

Aphrodite

Study objectives
The primary objective of this study is to validate the SnackBox as an automated dietary assessment method for snacking behaviour when compared to a dietary recall method and in relation to physiological and mood state aspects, assessed with, respectively, two wearable sensors and ecological momentary assessments.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This study does not require medical ethics approval, the Daily Board of the Medical Ethics Committee Máxima MC (hereafter the Committee), has reviewed this research proposal. As a result of this review, the Committee decided that the rules laid down in the Medical Research involving Human Subjects Act (also known by its Dutch abbreviation WMO), does not apply to this research (ref: N21.099)

Approved 17/12/2021, the internal ethical committee of IMEC, Inmec (Holst Centre, imec the Netherlands, High Tech Campus 31, 5656 AE Eindhoven, The Netherlands; +31 (0)625335967; inmec@imec.nl), ref: IA-21-WATS-TIP2-125

Study design
Non-randomized non-blinded interventional study without control groups

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
http://oneplanetresearch.nl/resources/uploads/2022/04/Subject-Information-Sheet-2.pdf

Health condition(s) or problem(s) studied
Eating behaviour

Interventions
Participants are asked to install a SnackBox at home or work and asked to use it for 5 working days over a 2-week period. Each of these measurement days, the participants are asked to eat at least one snack and one drink from the SnackBox, to refrain from snacks not included in the SnackBox and to wear the Chill+ device and Garmin VivoSmart 4 the entire day. Additionally, the participants receive several questionnaires throughout these days to assess their dietary behaviour and their mood states.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
SnackBox

Primary outcome measure
The accuracy of the SnackBox in assessing snacking behaviour (snack event yes/no, grams) is measured by:
1. A comparison to a 5-hour dietary recall method (snack event yes/no, true:false positives and true:false negatives) at 11:30 a.m., 4:30 p.m. and 9:30 p.m. on each measurement day
2. A comparison to the weight of the overall consumed snacks (grams) measured using a scale at the end of the five measurement days
3. A comparison to the ecological momentary assessments (EMAs) prompted on participants' smartphones (snack event yes/no, true:false positives and true:false negatives) at random and snack-event triggered moments during a measurement day

Secondary outcome measures
1. Physiological data such as heart rate (mean and relative changes), skin conductance response rate (mean and rel. changes) , skin temperature (mean and relative changes) and acceleration (mean and relative changes) measured using a Garmin activity tracker (Vivosmart 4) and a Chill+ activity tracker throughout each measurement day
2. Mood state (fatigued-energized, relaxed-stressed, sad-cheerful, bored-interested, hungry-satiated) measured using the visual analogue score (VAS) at random and snack-event triggered moments during a measurement day

Overall study start date
01/11/2021

Completion date
31/08/2022

Eligibility

Key inclusion criteria
1. Between 18 years to 49 years old
2. The subject should have 5 days in which he/she works from a stationary location within a maximum period of 14 days. This can be either a complete working day from a desk at home or a complete working day from a desk at a work location.
3. The subject does not have COVID-19 and does not experience any remaining symptoms from previous exposure to COVID-19, such as loss of taste or smell
4. The subject has no interfering dietary restrictions, such as being on a diet
5. The subject is not allergic to stainless steel or Ag/AgCl electrodes
6. The subject is not pregnant (unknown potential effect of Chill+ device on the child)
7. The subject has no acute and/or chronic cardiovascular and metabolic conditions (including e. g. diabetes mellitus)
8. The subject has no broken skin, cuts, or wounds at the sensor placement sites (wrist, upper

arm)
9. The subject is not using medication with phototoxic side effects: tetracyclines, doxycycline, phenothiazines, dacarbazine, ketoprofen, lomefloxacin; to exclude the possibility of local skin irritation from prolonged irradiation by LED light
10. The subject is not wearing any other medical devices (e.g., Holter)
11. The subject does not have an implanted active device (e.g., device containing a battery)
12. The subject does not have any mental disorders

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. The subject does not like the snacks and/or drinks provided in the study (there is an option to taste samples during the intake session)
2. Allergic to the snacks and/or drinks provided in the study (the list of ingredients will be available for all snacks and drinks at all times)

Date of first enrolment
19/04/2022

Date of final enrolment
01/08/2022

Locations

Countries of recruitment
Netherlands

Study participating centre
OnePlanet Research Centre - Wageningen
Plus Ultra II, Bronland 10
Wageningen
Netherlands
6708 WE

Study participating centre
OnePlanet Research Centre - Nijmegen
Mercator II, Toernooiveld 300
Nijmegen
Netherlands
6525 EC

Sponsor information

Organisation
Stichting IMEC Nederland (Holst Centre)

Sponsor details
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Netherlands
PO Box 8550, 5605 KN
+31 (0)40 402 0400
contact@holstcentre.com

Sponsor type
Industry

Website
https://holstcentre.com/

Funder(s)

Funder type
Government

Funder Name
Province of Gelderland

Results and Publications

Publication and dissemination plan
Results will be published in multiple high-impact peer-reviewed journals.

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan

Informed consent forms will be stored at the imec building Plus Ultra II in Wageningen, NL for 15 years. The forms will be kept in the locked cabinet which can only be accessed by the Principal Investigator/research coordinator. Participants' contact information will be stored in the CastorEDC, which is a system that provides a full infrastructure for medical research studies, also complying with GDPR. CastorEDC allows specific access to specific people. Only the principal investigator in this study will have access to it and his access will be additionally secured by multi-factor authorization (2FA). The Principal Investigator must know which person belongs to which participant number during the trial to contact them in case of device malfunction/adverse event /participant's withdrawal etc. Three months after the study has ended, data fields containing personal data (first name, last name, email, telephone) will be discarded. The exemplary data fields that will be stored in separate spreadsheets per person with a Subject ID which is a number between 1-99, generated randomly.

IPD sharing plan summary

Stored in non-publicly available repository, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		23/03/2022	28/06/2022	No	Yes