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Feedback on snacking behaviour, assessed with the SnackBox in relation to mood

Submission date
13/07/2023

Recruitment status
No longer recruiting

Registration date
23/08/2023

Overall study status
Completed

Last Edited
05/10/2023

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
To investigate snacking behaviour and how to affect it in relation to mood and physiology, the study team developed the SnackBox. The SnackBox accurately tracks snacking behaviour without actions of the researcher or user and then uses this information to trigger ecological momentary assessments to assess perceived mental well-being or just-in-time-adaptive interventions (JITAIs) to support healthy snacking behaviour. This study will investigate the effect of JITAIs on snacking behaviour. The primary objective of this study is to validate the effect of JITAIs (Just-In-Time-Adaptive Interventions) on snacking behaviour, assessed with the SnackBox. As secondary objectives, the study investigates the effect of the JITAIs on participants' mood, and if and which factors (demographics, eating behaviour scores, mental well-being scores and physiology) affect JITAI outcomes.

Who can participate?
Adults aged between 18 and 49 years old who have at least eight days in which he/she works from a location with a stationary place to take breaks (f.e. desk or canteen) within a maximum period of 14 days.

What does the study involve?
Participation will consist of a pre-screening questionnaire, an intake session, 10 measurement days (divided over 14 days) and a hand-over session. Participants are asked to set up the Snackbox at their desk at home or at the office/break room for 10 days spread over 14 days at maximum. In the evenings you are asked to bring the SnackBox to your living room or other location you spend your evening. You will also wear the Garmin only on those 10 days.

What are the possible benefits and risks of participating?
In this study, no discomforts or side effects are expected. If you do experience such issues, immediately contact the principal investigator. It is important that you properly consider the possible advantages and disadvantages before you decide to participate. You will not personally receive any advantage from taking part in this study. Your participation may contribute to more knowledge about SnackBox. Disadvantages are possible discomforts of the measurements in the study, the main burden for the participant is expected to be the refrainment from other snacks on measurement days and the numerous questionnaires that need to be filled out.

Where is the study run from?
OnePlanet Research Center (Netherlands)

When is the study starting and how long is it expected to run for?
December 2022 to November 2023

Who is funding the study?
Province of Gelderland (Netherlands)

Who is the main contact?
Alex van Kraaij (Principal Investigator), Alex.vankraaij@imec.nl

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IM-NL-SP-2023-0004-A001

Study information

Scientific Title
Feedback on snacking behaviour, assessed with the SnackBox in relation to mood

Acronym
Aphrodite II

Study objectives
The primary objective of this study is to validate the effect of a just-in-time-adaptive intervention (JITAI) on snacking behaviour in daily life, assessed with the SnackBox.

Ethics approval required
Ethics approval not required

Ethics approval(s)
The study has no medical grounds and does not fall under the medical scientific research act. We have sought an opinion on ethics approval both internally, with colleague Fabian Beutel from the internal medical ethical committee (INMEC) of Imec, and externally with the ‘Medische Ethische Toetsings Commissie” (METC) Veldhoven.

Study design
Randomized controlled single-blind interventional study

Primary study design
Interventional

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
Overweight and obesity

Interventions
Participants are asked to install a SnackBox at the place where they usually snack (home and/or work) and to use it on their work days for a two-week period. On each of these measurement days, the participants are asked to take all in-between-meal food and drinks from the SnackBox, to refrain from snacks not included in the study and to wear the Garmin Vivosmart 5 the entire day. Additionally, the participants receive several questionnaires throughout each of these days to assess their meals, their mood states and some contextual information. The second week is the feedback week, where participants in the intervention group, in addition to the aforementioned questionnaires, receive the just-in-time-adaptive intervention (JITAI) on their smartphones.

SnackBox:
The SnackBox, a device developed within OnePlanet, will be used to record the snacking behaviour of the child during the measurement period. The device contains three weighing stations where different types of snacks can be weighted. Snacks will be weighted in special designed boxes. These compartments can be closed with an airtight lid. The SnackBox is placed on the participant's home and must be connected to a power socket for power supply. Each of the three weighing stations exists of a load cell that measures the weight of its content. A Raspberry Pi (RBPi) computer, placed inside the station, collects and stores the weight data as well as data from the accelerometer located on the bottom of the weight station. The SnackBox also identifies when a snack compartment is not placed back on its weighing station and provides feedback to the user by using a blinking LED light and a buzzer sound. Lastly, the SnackBox registers which snack is placed on each of the weighing stations by registering its NFC tag. All snack compartments are labelled with NFC tags by the researchers prior to the measurements.

Randomisation:
For men and women separately, intervention is randomly assigned by drawing either 'Intervention' or 'Control' cards from a pool.

Intervention Type
Behavioural

Primary outcome(s)
Grams consumed from "healthy" and "unhealthy" snacks measured using the SnackBox at week 1 and week 2

Key secondary outcome(s))
The effect of the JITAI messages on mood measured using the difference in mood Visual Analogue Scores (VAS) at random times of the day between the intervention week with JITAI messages and the baseline week without JITAI messages (corrected for that same difference in the control group)

Completion date
30/11/2023

Eligibility

Key inclusion criteria
1. The participant must be between 18 years to 49 years old.
2. The participant should have at least eight days in which he/she works from a location with a stationary place to take breaks (f.e. desk or canteen) 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, or a complete working day where breaks are taken at a canteen (at least three times a day).
3. The participant 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 participant has no interfering dietary restrictions, such as being on a diet and has a restricted eating score lower than 3.13.
5. The participant is likely to snack, expressed in having an emotional eating score higher than 1.08.
6. The participant likes to snack on at least 1 or more of the high-caloric snack options on the list in section 7.1.
7. The participant is not allergic to stainless steel or Ag/AgCl electrodes.
8. The participant has no acute and/or chronic cardiovascular and metabolic conditions (including e.g. diabetes mellitus).
9. The participant has no broken skin, cuts, or wounds at the sensor placement sites (wrist, upper arm).
10. The participant is not using medication with phototoxic side effects: tetracyclines, doxycycline, phenothiazines, dacarbazine, ketoprofen, and lomefloxacin; to exclude the possibility of local skin irritation from prolonged irradiation by LED-light.
11. The participant is not wearing any other medical devices (e.g., Holter).
12. The participant does not have an implanted active device (e.g., a device containing a battery).
13. The participant does not have any mental disorders.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
49 years

Sex
All

Key exclusion criteria
1. Participant does not like the snacks and/or drinks provided in the study
2. Is allergic to the snacks and/or drinks provided in the study

Date of first enrolment
01/05/2023

Date of final enrolment
01/11/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
OnePlanet Research Centre - Wageningen
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Study participating centre
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Toernooiveld 300
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6525 EC

Sponsor information

Organisation
OnePlanet Research Centre

Funder(s)

Funder type
Government

Funder Name
Province of Gelderland

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Alex van Kraaij (Principal Investigator), Alex.vankraaij@imec.nl

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	07/03/2023	26/07/2023	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes