Blood glucose monitoring, cognition, and wellbeing in relation to food intake @ work * a pilot study

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The primary objective of this pilot study is to investigate the relationship between glucose and cognition and wellbeing in an at-work setting. Additionally, this study aims to investigate the variability in intra- and inter individual glucose...

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

Summary

ID

NL-OMON44164

Source
ToetsingOnline

Brief title
Blood glucose, cognition and well-being @ work

Condition

- Other condition

Synonym
health, wellbeing

Health condition

algemeen welbevinden en gezondheid

Research involving
Human

Sponsors and support

Primary sponsor: TKI Agri Food
Source(s) of monetary or material Support: Google,Jumbo,Noldus,TKI Agri-Food,Wageningen Universiteit

Intervention

Keyword: Feedback, Health, Personalized, Work environment

Outcome measures

Primary outcome

The main outcome of this study is how food intake, glucose-levels, cognition and wellbeing of employees in the office relate to each other. With *daily* only week days, when employees are at the office, are meant. Participants are not required to do any measurements in the weekends.

* Daily food intake: this will be monitored with a food intake application (FatSecret) that can be accessed via smart phone or desktop. FatSecret converts selected food items into energy and macronutrients. Respondents are asked to keep track of their breakfast and food intake during working hours (incl. drinks).

* Daily glucose levels: daily glucose levels will be monitored using a continuous glucose monitoring device. Either the flash glucose monitoring system from FreeStyle® Libre* (FSL) or the Dexcom Continuous Glucose Monitor will be used. The choice will be made dependent on availability for the study. Both devices are factory-calibrated interstitial glucose monitoring systems, intended to be used instead of self-monitored blood glucose (Feldman et al.,

2003). The FSL or Dexcom sensor is placed on the skin (often upper arm) with a small cannula inserted in the interstitial fluid. A single sensor can measure glucose every 15 minutes for up to 14 days. Local storage is up to multiple hours but the sensor can be 'read' with a device that is held close to the sensor to obtain the data. The FSL and Dexcom sensor have been demonstrated to be feasible in human subjects, including individuals with diabetes I and provide an accurate estimation of blood glucose (Luijf et al. 2013; Bonora et al., 2016). Parameters obtained from the glucose sensor will be:

o Fasting glucose levels (e.g. in the morning after 8 hours of fasting, based on food intake reports)

o Glucose response profiles / postprandial glucose levels (peak, slopes, area under the curve).

* Daily cognition tests: 5-minute cognition tests will be offered twice per day (before lunch and one hour after lunch) via an online test platform. The tests are designed to assess specific aspects of memory, including working memory and memory recall. The specific tests include:

o Direct recall & delayed recall (1 minute): a task in which participants are presented with a random list of 10 items (out of a possible 500 items) for 20 seconds (i.e. a shopping list) and afterwards they are asked to write down the items that they remember from the list (immediate recall). After doing another cognitive task (see below) they are again asked to write down the items that they remembered from the list (delayed recall). This task has previously been shown to be sensitive to macronutrient manipulation

(Hoyland et al., 2008). For each recall task the number of correct and incorrect answers is scored.

o Free recall: out of the 26 letters of the alphabet 10 will be randomly selected and presented to the participant in a stream (e.g. 0,5 sec per letter). The participant gets 20-30 sec to enter the presented letters in the right order. The number of correct and incorrect answers is scored.

* Wellbeing: this will be measured via visual analogue scales (VAS) / ecological momentary assessment (EMA) questionnaire (smartphone), including five questions for *feeling energetic - tired, *feeling focused * distracted*, *feeling positive * negative* , *feeling motivated * unmotivated* , *feeling relaxed * stressed*. Filling in takes max. 30 seconds.
This questionnaire will be administered five times per day; two times in the morning, once five minutes before lunch (before with cognition test), once one hour after lunch (before cognition test) and once in the afternoon.

Secondary outcome

The secondary study parameters include social-psychological concepts as well as user evaluations. These will be measured mostly via questionnaires.

* Intention to eat healthy. It will be measured with three items (based on Poínhos et al., 2014; Ajzen, 1991; Oliver et al., 1997; Melnyk et al., 2011) that are rated on seven-point scales from totally disagree (1) to totally agree (7). The items are *I*m planning on eating healthy*, *I would consider to eat healthy* and *I*m absolutely going to eat healthy*.

* User experiences: user experiences will be measured in two ways, quantitatively (sef-efficacy and type of motivation) and qualitatively.

o Quantitative: Self-efficacy towards maintaining a healthy diet (Glynn & Ruderman, 1986) and type of motivation to eat healthy (intrinsic/extrinsic; Williams, Ryan & Deci, 1996) will be measured at baseline and end. Previous research shows that self-efficacy and intrinsic motivation are predictors of healthy diets. Self-efficacy will most likely decrease during the study. Adding external rewards can transform intrinsic motivation into extrinsic motivation.

o Qualitative assessment: measuring user experiences in four short surveys (baseline, day 1, in between, end) and in focus groups at the end of the study. Overall the survey includes self-constructed scales that measure user experience with the research in general, self-monitoring devices and personal feedback. Focus groups are needed to understand the reasoning behind the answers that employees give in the surveys and to validate initial analysis of the survey.

Study description

Background summary

Many people in the Western world have an unhealthy lifestyle, including an unhealthy dietary pattern. Numerous approaches have been taken to stimulate people to maintain a more healthy diet, but results are highly variable across studies and subjects. One explanation for this is that in many approaches the individuals' specific needs and the context they live and work in are not sufficiently taken into account. For an approach to be more effective, personal characteristics need to be taken into account. In other words, the approach needs to be tailored or personalised. When focussing on personalized nutrition and health in the work environment, the aspects of health that are included in the study should also be relevant for the work environment. Three main

parameters of interest are selected: (postprandial) blood glucose levels, cognition and (subjective) wellbeing.

The proposed research is part of a research program on Personalized Nutrition and Health (PNH). The ultimate goal of the program is to enhance the health and wellbeing of people by empowering consumers to choose and maintain an optimal personalized diet and lifestyle.

Study objective

The primary objective of this pilot study is to investigate the relationship between glucose and cognition and wellbeing in an at-work setting. Additionally, this study aims to investigate the variability in intra- and inter individual glucose responses to a certain food product or meal.

Secondary Objective(s):
- Does self-monitoring and feedback about food intake and wellbeing stimulate individuals to make healthier choices?
- What are the user experiences of employees to perform self-monitoring of and receive feedback on, glucose, wellbeing, food intake and cognition in the workplace?

Study design

This study will be designed as a randomized controlled trial with two groups, the feedback group and the control group. During the trial both groups will self-monitor their glucose levels (using a continuous glucose monitor), cognition (via online cognition tests) and their food intake and wellbeing (via a Smartphone app).
The feedback group will be provided with a personal feedback report on their collected data. The control group will do all measurements but will not get a feedback report.

The study will consist of two self-monitoring periods of two weeks. In between these two self-monitoring periods, the participants in the feedback group will be given feedback on their measurement data. The participants in the control group will not get any feedback on their data. The control group is required to see if only measuring is already causing an effect, and if providing feedback on data has added value to participants.
At baseline (before the start of the first self-monitoring period), after the first day of measuring, between the two self-monitoring periods and at the end of the study, questionnaires will be administered. At the end of the study also two focus groups will be organized to gather more in-depth experiences of study participants.
At the end of the study (after the focus groups), both the feedback and the control group will be debriefed and provided with a feedback report on their

personal data. Participants that do not take part in a focus group will be provided with the debrief and feedback report via email.

Intervention

The intervention consists of standardized meals during lunch, and personalized feedback.

Participants will be asked to consume standardized lunches at work days in the company restaurant at working days. These lunches will consist of food products that are regularly available at the company restaurant of the Jumbo headquarters in Veghel. All lunches will be offered at least twice to each participants, and the lunches will vary in macronutrient composition (e.g. sandwich lunch, salad lunch, warm meal). This will enable comparison of blood glucose responses with different types of meals between participants and within participants. During the second two-week measurement period study participants are free in their lunch choice in the company restaurant. Participants will be asked to register their food choice and take a picture of their lunch.

In between the two measurement periods, the feedback group will receive personalized feedback on their self-measured data. At the end of the second measurement period both the feedback group and the control group will receive a personalized feedback form, including a debriefing about the study.

The personalized feedback will contain a general explanation about glucose, cognition and wellbeing, healthy cut-offs and/or benchmark values, and why these measures are relevant for personal health and wellbeing. Also, a general explanation will be given about how glucose levels can be influenced. Also, the personalized feedback will contain the individual glucose response profiles, as well as graphs showing the wellbeing scores over time. The registered food intake will be mapped and linked to the glucose and wellbeing profiles. The results of the cognition test will also be shown as a mean score and will be linked to the individual profiles and food intake.
Once the content of the personalised feedback is defined, the communication form can be further aligned with personal socio-psychological characteristics. Literature shows that individuals differ intheir "Consideration of Future Consequences (CFC), i.e. whether they focus more on immediate or future outcomes. Individuals with a low score on CFC were more persuaded when positive consequences were short term and negative consequences were long term. The opposite was true for individuals with a high score on CFC. In this study we will use CFC to give either feedback with a focus on the future (e.g. your food choices ensure low risk of physical health problems in the future) or a focus on the present (e.g. your food choices give you energy to perform during the day), based on their responses.

Furthermore there are other points that we will consider when formulating the

feedback, including mentioning benefits, gain vs. pain-framing, etc.

Study burden and risks

The risks associated with participation can be considered negligible and the burden can be considered minimal. Glucose levels will be measured using a validated, commercially available minimally invasive glucose monitoring sensor. This sensor will be worn during each of the two two-week self-monitoring periods. Benefits include that participants learn to associate their daily food intake with glucose levels and with indicators of wellbeing and cognitive performance at their work place.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject:
* Must be present at Jumbo head-quarters during lunch at least four days/week and have access to their computer for one hour after lunch during the two 2-week self-monitoring periods.
* Must be frequent visitors of the company lunch restaurant (Jumbo food Café) (three or more times per week).
* Having giving written informed consent.
* Willing to comply with all study procedures.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Shift workers
* Diabetes type 2 patients
* Under treatment for neurological or psychiatric complaints, including eating disorders
* Specific dietary preferences, including vegan, raw food, paleo. Vegetarian, pescetarians and flexitarians can participate in the study.
* Allergies or intolerances, including coeliac disease, gluten intolerance, lactose intolerance, milk protein allergy
* Skin allergy or eczema

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	27-09-2017
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Continuous glucose monitoring device "FreeStyle Libre"
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-07-2017
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL61725.028.17