

An Online Lifestyle Diary with Personal Computer Assistant for Supporting Self-Regulation

Published: 20-05-2008

Last updated: 07-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32181

Source

ToetsingOnline

Brief title

Computer Assistance for Self-Regulation

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym

heaviness, Overweight

Health condition

overgewicht

Research involving

Human

Sponsors and support

Primary sponsor: TNO

Source(s) of monetary or material Support: SenterNovem (Economische Zaken)

Intervention

Keyword: Computer assistance, Digital diary, Lifestyle, Overweight

Outcome measures

Primary outcome

The main study parameter is the use of an online diary concerning duration, frequency and completeness of entries. Also, we will study if people adhere to their lifestyle goals.

Secondary outcome

Secondary parameter is the influence of the subjects* personal characteristics on the use of the online diary.

Study description

Background summary

There is an increasing number of people with overweight. Moreover, people experience problems adhering to a healthy lifestyle. In practice, treating overweight implies for people performing a number of treatment self-regulation tasks, such as keeping a diary of diet and physical activities. Following research on self-regulation, eHealth technology and personalized computer assistance, we designed an online lifestyle diary accompanied by a personal computer assistant that may stimulate the use of an online diary.

Study objective

Our main objective is to evaluate an online lifestyle diary accompanied by a personal computer assistant. The assistant provides people who are overweight feedback on their lifestyle goals. We want to study if it contributes positively to self-regulation, i.e., use of an online lifestyle diary. We expect that the the knowledge about and attitude towards a health ylifestyle

improves and that the subjects will adhere better to their lifestyle goals. Our secondary objective is to gain insight into the influence of personal characteristics on the use of the online diary.

Study design

We will conduct a randomized controlled trial of 4 weeks. Subjects fill in intake questionnaires, concerning demographics and personal characteristics. They are assigned, double blind, to the test or control group. Concluding, they fill in an exit survey.

Intervention

Subjects in the test group will be asked to set lifestyle goals, regarding keeping diary, diet and exercise, and fill in their diet and physical activities daily in an online diary. A computer assistant will monitor their diary data and indicate if the data filled in the diary correspond with the goals. The test group will be compared with the control group, which will be asked to set lifestyle goals and keep their diet and physical activities daily in an online diary, but without computer assistance monitoring.

Study burden and risks

To assess if the personal computer assistance contributes to improvement of self-regulation, we require the participation of overweight subjects for whom improvement of self-regulation is personally relevant. During the study, the subject will keep track of their diet and physical activities in an online diary. This implies we keep a database of the subjects' personal data. Burdens of the study are that confrontation with being overweight can be distressful. Also, subjects require having a home computer, which could bias the subjects' pool. Benefits of the study are that the project follows the existing development of eHealth, the online diary with computer assistant facilitates self-regulation, and results of our study can contribute to the development of scientific research models that support people and increase their self-efficacy while performing activities in complex task environments.

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

Overweight (25Male and female aged between 18 and 65;

Voluntary participation;

Having given written informed consent;

Have daily access to a computer with internet;

Willing to comply with the study procedures;

Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years.

Exclusion criteria

Have used the DieetInzicht website, independently, more than 3 times;

Treated periodically by specialist in hospital;

Having a history of medical or surgical events that may significantly affect the study outcome, including cardiovascular disease, hypertension (>160/95 at repeated measurements) and/or mental disorders;

Reported unexplained weight loss or gain of > 2 kg in the month prior to the pre-study screening;

Alcohol consumption [> 28 units/week for males and > 21 units/week for females];
Reported slimming or medically prescribed diet and physical activities;
Pregnant or lactating or wishing to become pregnant in the period of the study;
Personnel of TNO Defense, Safety and Security and the Leiden University Medical Center,
their partner and their first and second degree relatives.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-04-2008
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO	
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	NL22036.028.08