The potential of do-it-yourself devices for obtaining personal health data

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

Summary

ID

NL-OMON41081

Source
ToetsingOnline

Brief title
P4@TNO

Condition

- Other condition

Synonym
health and behaviour (change)

Health condition

algemeen gezondheid en gedrag

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: TNO

Intervention

Keyword: data collection, do-it-yourself devices, health behavior, self-monitoring

Outcome measures

Primary outcome

Potential of do-it-yourself devices for self-measuring health parameters by subjects will be assessed by the percentage of useful datasets. This should be at least 80%. Besides, the percentage of useful datasets for each individual device should be at least 80% to be considered eligible for do-it-yourself studies.

Effects of self-monitoring on actual behaviour change will be established by comparing baseline values for food intake and physical activity as measured by the Lifestyle-questionnaire with the values at the end of the study.
The hypothesis that awareness in own health status functions as motivational instrument for changing health behaviour will be tested with a questionnaire on attitude towards health behaviour. This questionnaire will be administered at baseline and at the end of the study.

Secondary outcome

All data collected with the devices for self-measured weight, physical activity, food intake, blood glucose, blood pressure and blood cholesterol will be analysed, to identify changes in these health parameters over time.

Usability of the devices will be assessed with a questionnaire and focus groups on user-experience with do-it-yourself devices in an at-home setting at the end of the study . This questionnaire and focus group will encompass questions on how often the devices are used, the context in which the device is used and, the satisfaction of the user with the device and the effects of the device on user behaviour.

The subjects will also fill out online-questionnaires on stress (DASS-21), vitality (Vita-16) and quality of life (RAND-36) at baseline and at the end of the study.

Study description

Background summary

There is an increasing number of possibilities for individuals to map their own health status. Smartphone Apps, Quantified Self devices and self-tests give individuals the opportunity to measure several aspects of their health, like food intake, weight, blood pressure, physical activity, blood sugar and cholesterol, with increasing accuracy. These measures can contribute to an individual*s awareness of health status and as such serve as a motivator to improve health. However, the usability of data resulting from self-monitoring devices for scientific purposes has not been investigated. Also, it is not known to which extent increased awareness in an individual*s health parameters contributes to behaviour change and improved health status.

Study objective

The first objective of this study is to evaluate the potential of do-it-yourself devices for self-measuring health parameters by subjects in obtaining interesting data.
The second objective of this study is to evaluate if increased awareness of own health status by self-measuring of health parameters leads to improved health behaviour.

Study design

The study is designed as an open, one-group, exploratory study.

During the three-month study, the subjects will use these do-it-yourself devices to self-monitor multiple health parameters in an at-home setting. The frequency by which the devices have to be used varies per device.

Intervention

The intervention in this study will consist of the use of do-it-yourself devices for self-monitoring health parameters in an at-home setting. The included devices are an activity tracker (Medisana ViFit), a blood pressure monitor (Medisana MTX), a blood glucose meter (Medisana MediTouch 2), a smart scale (Medisana Smart Scale) and a cholesterol meter (Mission Cholesterol 3-1 meter). Subjects will be supplied with these devices at the training day, except for the cholesterol meter. Subjects will use the cholesterol meter at a TNO location at the beginning and the and at the end of the study. Subjects will also be supplied with material and a manual for two do-it-yourself OGTT*s (oral glucose tolerance test). Devices have to be handed in again at the end of the study. Additionally, subjects will be given access to a food intake application Fatsecret.

Study burden and risks

Healthy volunteers participating in this study will monitor their own health status by using do-it-yourself devices for several health parameters for three months. We do not foresee any health risks in using the supplied devices for measuring health parameters. The products are commercially available and therefore, with normal use, considered safe.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Age ranging from 18 - 67 years
2. Desk-job and be less active than according to the Dutch activity guideline
3. Healthy as assessed by the: Health and lifestyle questionnaire (P9608 F02)
4. Body mass index : 20 - 30 kg/m2
5. Able to use self-monitoring devices
6. Voluntary participation
7. Having given written informed consent
8. Willing to comply with study procedures
9. Willingness to share anonymous data on bodyweight with Fatsecret (food intake app provider)
10. Willingness to share anonymous data on blood glucose, blood pressure, physical activity and bodyweight with Medisana (provider of measurement Toolkit)
11. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data by TNO
12. Have a desktop or laptop with internet access at home
13. Own a Smartphone with iOS or Android.

Exclusion criteria

1. Use of concomitant medication including medication known for its effects on blood glucose, cholesterol or insulin
2. Having a history of medical or surgical events that may significantly affect the study outcome, including physical limitations or cardio-vascular events
3. Having a pacemaker
4. Currently suffering from diabetes type I or type II as determined by the general practitioner

5. Reported slimming or medically prescribed diet
6. Physical, mental or practical limitations in using computerized systems
7. Exercise regularly and exceed the Dutch Standard of Healthy Physical Activity of 2.5 hours/week
8. Alcohol consumption > 28 units/week for males and > 21 units (drinks)/week for females
9. Reported unexplained weight loss or gain of > 2 kg in the three months prior to the pre-study screening
10. Not having one of the TNO locations in Delft, Den Haag or Rijswijk as posting
11. Partner or first or second degree relative from TNO personnel stationed at a TNO location in Zeist, Leiden, Hoofddorp or Soesterberg

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-06-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	03-06-2014
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	NL49064.028.14