Validation of the Philips EmoGraphy technology to measure sympathetic nervous system activity in an ambulatory setting

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON44295

Source
ToetsingOnline

Brief title
Autonomic nervous system activity and emotions in daily life.

Condition

- Other condition
- Psychiatric and behavioural symptoms NEC

Synonym
mood, stress

Health condition

Emotionele spanningen en stress

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,Philips,Philips BV

Intervention

Keyword: Ambulatory Assessment, Autonomic Nervous System, Emotion Research, Skin Conductance

Outcome measures

Primary outcome

Main study parameter/endpoint

The main study parameters of this study consist of the SNS activity and emotional tension measures. SNS activity is measured from the skin as SCL, nsSCRs, and from cardiac activity as pre-ejection period (PEP) and ECG T-wave amplitude (TWA). Emotional tension is quantified as scores on the visual analogue FS (during the laboratory section) and the 3MQ (during the ambulatory section).

Secondary outcome

Secondary study parameters/endpoints

Secondary study parameters consist of heart rate and heart rate variability measures as obtained from PPG and the ECG. Using additional information on respiratory behaviour, in the form of respiration rate (RR) and minute volume (VE), respiratory sinus arrhythmia (RSA) will be computed as a measure of parasympathetic nervous system (PNS) activity. This will allow a test of the added value of PNS activity to predict emotional tension.

Other study parameters

Other parameters will be measured that (1) can be of influence on our ambulatory SNS activity measures independent of emotional arousal, and (2) can modify the relationship between SNS activity and emotional tension across individuals.

The former consist of:

Physical activity and posture, measured by tri-axial accelerometry, energy expenditure measured by indirect calorimetry (VO2), and ambient temperature measured by a button worn on the outer clothing.

The latter consist of:

age, sex, educational attainment, medication and OC-use, (estimated) menstrual phase (women), BMI, waist-hip ratio, fat percentage, physical fitness level (estimated VO2 max), perceived physical and mental health, perceived stress level during the past year, smoking behaviour, alcohol use and regular exercise habits.

Study description

Background summary

In the past year Philips has been developing an ambulatory skin conductance sensor that can accurately monitor an individual*s skin conductance levels (SCL) over long periods of time. The intended application of this sensor is to develop a personal coaching system based on the association between fluctuations in an individual*s sympathetic nervous system (SNS) activity, measured by SCL parameters, and reflecting emotional tension. The scientific background on the association between SCL parameters and emotional tension in an ambulatory setting is limited, because the majority of the traditional emotional tension research is carried out in controlled laboratory situations. It has been frequently shown that laboratory measurements of mood and distress

correlate only modestly with daily life mood and distress measurements.

Study objective

The primary aim of this study is threefold. The first objective is to determine whether the SCL and the frequency of non-specific skin conductance response (nsSCRs) measured by the Philips GTEP Emography Bracelet are accurate measures of sympathetic nervous system activity. The second objective is to determine whether fluctuation in SCL parameters can predict an individual*s subsequent emotional tension in both a laboratory and ambulatory setting. The third objective is to determine whether the use of additional signals, like posture, physical activity, temperature and energy expenditure, can optimize the predictive value of SCL parameters for emotional tension.

Secondary aim
The relationship between SNS activity and emotional tension is likely to be variable across individuals. We will explore in ancillary analyses whether the predictive validity of the Emography can be increased by taking into account individual characteristics related to age, sex, educational attainment, hormonal status, body composition, perceived health and stress, and lifestyle behaviours.

Study design

The above defined objectives will be investigated using an experimental design consisting of a two and a half hour laboratory protocol containing mental and physical stressors followed by a ~22-hour ambulatory measurement in the natural environment of the subject. During both the laboratory protocol and the ambulatory measurement subjects will wear the Philips GTEP and the Vrije Universiteit Ambulatory Monitoring System (VU-AMS) that combines impedance cardiography and ECG recording using 7 surface electrodes. During part of the laboratory protocol, subjects will wear the portable CosMed K4 O2/CO2 sensor to measure their exact energy expenditure in parallel to wrist-based and hip-based accelerometry. In the laboratory emotional tension will be manipulated through exposure to various stressors and measured using the visual analogue Feeling Scale (FS). In the field study natural fluctuations in emotional tension will be measured every hour by the FS and the Maastricht Momentary Mood Questionnaire (3MQ) administered through an Ipod/smartphone applet. During the ambulatory measurement subjects will wear a button thermometer to measure ambient temperature.

Study burden and risks

The risks of participation to this study are minimal as all measurements are non-invasive. However, there is a non-trivial burden on the subjects as they participate in a prolonged (2.5 hours) laboratory session followed by an

ambulatory recording session in which they wear a belt-based (Holter sized) ambulatory recording device with a wrist-based smartwatch, and in which they are prompted once per hour to briefly fill in a diary.

Benefits of the study are the active contribution to research that could deliver evidence that a user-friendly strategy exists to validly measure emotional state and sympathetic nervous system activity in real life settings. This could be used to devise personalized preventive and intervention strategies that are based on real-time assessment of mood and physiological stress reactivity, i.e. they can be delivered *at the right time, at the right place*.

Participants will also receive feedback on their 24 hour heart rate, skin conductance level, and physical activity pattern, in an attractive visual form.

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 meet all of the following criteria:
- Between the age of 18 and 48
- Currently employed or in schooling trajectory
- Living or working in the Amsterdam Metropolitan Area.
- Female subjects are premenopausal; use of hormonal contraceptives is acceptable

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Serious heart, pulmonary, hepatic or renal diseases/impairment, malignant or haematological disease
- Known diabetes or diagnosed neuropathy
- Irregularity of menstruation in premenopausal women
- Medication influencing skin or cardiac SNS activity (hyperhidrosis related (e.g. glycopyrrolate), cardiac related (e.g. beta-blockers) or antidepressants (e.g. SNRIs))
- Metabolic disorders: uncontrolled thyroid and/or adrenal disease
- Current psychiatric illness including eating disorders and depression
- Alcohol abuse defined as: for men > 21 units/week, for women > 14 units/week
- Pregnancy or breast feeding
- Inability to understand the study protocol (including language barriers)
- Inability to give informed consent
- Inability to participate in all phases of the protocol due to a disability (visual, reading, physical etc.)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2017
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO

Date:	13-12-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL62442.029.17