BARABAZ Analyseert Biometrie

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21040

Source
NTR

Brief title
BAB

Health condition

Heart rate variability; galvanic skin response; oxygen saturation
Hartslagvariabiliteit; elektrische huid respons; zuurstofsaturatie

Sponsors and support

Primary sponsor: Kinetic Analysis
Pastoor Pottersplein 65
4815 BB Breda
Source(s) of monetary or material Support: BARABAZ
Hoogstraat 23
5061 ER Oisterwijk

Intervention

Outcome measures

Primary outcome

Heartrate variability

Galvanic skin response

Oxygen saturation

Secondary outcome

Gender; age; height; weight; medication

Study description

Background summary

The aim of this study is the validation of a new measurement system, BARABAZ®. BARABAZ® is a non-invasive measurement system that will be used for functional analyses of the human body, aiming to screen for disease/overload. To be able to do this, the BARABAZ® uses two separate measurement systems: a bio-impedance system and a digital pulse oximeter. In addition, BARABAZ® is equipped with two sets of sensors, which will be placed on the forehead of the patient. This allows BARABAZ® to collect data on heartrate variability, galvanic skin response and oxygen saturation. Each of these outcomoe measures will be compared to a validated alternative.

In this validation study it will be investigated whether the digital pulse oximeter of BARABAZ®, which uses Blood Volume Pulse (BVP) sensors, can be used to measure HRV. The BVP sensors use photoplethysmography (PPG): measuring changes in blood volume using an optic method that measures the amount of infrared light absorbed by the blood.
ECG is currently the gold standard to determine HRV, this data will be collected using the TMSi Mobi 8. Measuring the HRV with both measurement systems and comparing the data on several parameters (R-R intervals; N-N intervals; and RMSSD), allows us to make an educated conclusion whether the digital pulse oximeter of BARABAZ® is a valid alternative for determining HRV in a population of healthy subjects.

Secondly, it will be investigated whether the oximeter of BARABAZ® is a valid alternative to determine oxygen saturation. This will be done by comparing SpO2-values of BARABAZ® to those measured by a Nonin Onyx Vantage 9590 professional clinical pulse oximeter.
Lastly, it will be investigated whether the GSR data of BARABAZ® are a valid alternative for the GSR data measured with the Shimmer 3 GSR+.

Data of 62 participants will be collected for this study. All measurements will be performed 3 times for each of the outcome measures, to ensure a valid dataset. All measurement systems have a CE-certificate and measure non-invasive. Participants will not benefit from partaking in this study directly. However, there will not be any downsides to partaking either. Risks are

neglectable.

The study is initiated by BARABAZ, and will be executed by Kinetic Analysis.

Study objective

A new health system is being validated on heart rate variability; galvanic skin response and oxygen saturation.

Study design

All measurements will be done once, therefore there will be only one timepoint.

Intervention

This study is a validation study on HRV, GSR and oxygen saturation, therefore there is no actual intervention. All participants will be measured with all measurement systems to allow for a direct comparison on all parameters.

A standard measurement protocol will be instated to ensure measurements are done exactly the same way for every participant. This way of measurement is in line with the standard approach within the healthcare sector regarding measurement tools. In addition, the same setup will be used to minimise the influence of external factors, such as lighting.

In theory, the internal software of the measurement equipment should correct for external light sources, preventing external light sources from influencing the data. However, to ensure the influence of external light sources is equal in every trial, the measurements will be performed in the same space in the room every time.

All parameters will be measured 3 times for every participant to ensure a valid dataset. If the first trial appears to have a complete dataset, this trial will be used for analyses. However, if the dataset is incomplete or contains a measurement error, the second dataset will be used. In case the second set is incomplete or contains errors, data from the third trial will be used.

Contacts

Public
BARABAZ
Hoogstraat 23
Oisterwijk

[default] 5061 ER

The Netherlands
Scientific
BARABAZ
Hoogstraat 23
Oisterwijk

[default] 5061 ER
The Netherlands

Eligibility criteria

Inclusion criteria

Working age: between 18 and 67

In good health

Exclusion criteria

Coronary disease; pacemaker; damage to the skin; excessive sweating; incapable to remain seated without moving for 3 minutes; metal prosthetics in fingers or extremeties; pregnancy; medication which can influence heartrate; previous surgery in the upper extremeties

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	12-03-2018
Enrollment:	62
Type:	Anticipated

Ethics review

Positive opinion Date:	06-03-2018
Application type:	First submission

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
NTR-new	NL6888
NTR-old	NTR7075
Other	: 2018-20

Study results

Summary results
Data will be published in a relevant peer-reviewed magazine after all data has been collected and analysed.