Wearables and challenging behaviour in geriatric psychiatry

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

Summary

ID

NL-OMON48071

Source
ToetsingOnline

Brief title
Wearables & challenging behaviour

Condition

- Other condition
- Dementia and amnestic conditions

Synonym
challenging behaviour, dementia, stress

Health condition

neuropsychiatrische symptomen

Research involving
Human

Sponsors and support

Primary sponsor: Fontys Hogescholen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Challenging behaviour, Geriatric psychiatry, Wearables

Outcome measures

Primary outcome

Relationship between challenging behaviour (frequency, type, duration, intensity) and biomedical parameters as measured by the wearable (temperature, movement, heart rate variability, blood volume pulse and skin conductance.

Secondary outcome

* Determine the reaction of people with dementia regarding the putting on and wearing of the wearable. Do they show discomfort?
When putting on and wearing the wearable it is registered if and how the subjects react to the wearable (both verbally as nonverbally). In addition, skin rash/irritations are registered.

* The identification of environmental factors preceding challenging behaviour and/or increase in stress-related parameters as measured by the wearable.
In case of challenging behaviour and/or increase in stress-related parameters, the environmental factors (e.g. envorinmental temperature, sounds, enterling/leaving of persons, events) 15 minutes prior to the challenging behavior and/or increase of stress-related parameters will be scored.

Study description

Background summary

In nursing homes, dementia is often (up to 80%) accompanied by challenging behaviour, such as anxiety, agitation, apathy, delusions, aberrant motor behaviour, nighttime behaviour disturbances and disinhibition. Stress plays an important role in the cause of challenging behaviour. This negatively influences the quality of life of the specific resident and his environment.
The cause of challenging behaviour can be treated psychosocially, by means of a thorough analysis of behaviour and context. However, behavioural analysis is very complex, among other things caused by the client*s limited communicative capabilities. They cannot indicate themselves what they experience as being stressful. This hampers the identification of the stressors which cause challenging behaviour. By measuring biomedical variables, such as movement, temperature, heart rate variability, blood volume pulse and skin conductance, by means of a wearable (wristband), stress-related parameters can be measured easily and continuously.

Study objective

The purpose of this research is to determine the usability of a wearable regarding the care of people with dementia showing challenging behaviour in a nursing home (geriatric psychiatry department). The relationship between biomedical data and behavioural observations will be investigated.

Study design

Multiple case-study, observational research (cross sectional / diagnostic)

Study burden and risks

Burden/risk: Current literature shows that wearables can cause skin rash. Because the subjects will be wearing the wearable for a relative short amount of time (3x 4 hours), the risk of skin rash is estimated as low. In case of skin rash, the subject will be removed from the study and (if necessary) the skin rash will be seen and treated by the nursing home*s doctor. It is possible that the subjects find the moment of putting on the wearable uncomfortable. In case of the expression of objection (as described a priori by the legal representative and/or described in the code of conduct *The expression of objection by incapacitated (psycho)geriatric patients in the context of the WMO*) related to wearing or putting on the wearable, the subject*s study participation will be terminated.

Benefit: The subject*s gain is potentially high. Challenging behavior can, by

facilitating a psychosocial approach (instead of a pharmacological approach, often accompanied with many side effects and often insufficiently effective), be prevented/reduced.

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

- diagnosed with dementia (NCS)
- living in a nursing home
- show challenging behaviour (as indicated by medical staff): delusions, hallucinations, agitation/aggession, depression/dysophoria, apathy, disinhibition, irritable/lability, aberrant motor behavior and/or appetite and eating abnormalities

Exclusion criteria

- Circumstances which cause an unrepresentative situation (e.g. in case of an infection)
- known allergies to any of the materials used in the medical device, which may come in contact with the skin while wearing.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2019
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Wearable (wristband): Empatica E4
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-05-2019
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 19930
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL67835.015.19
Other	NL7604
OMON	NL-OMON19930