Neurawear: integrating physiological information into forensic care

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Ethical review	Approved WMO
Status	Pending
Health condition type	Personality disorders and disturbances in behaviour
Study type	Observational non invasive

Summary

ID

NL-OMON57051

Source
ToetsingOnline

Brief title
Neurawear

Condition

- Personality disorders and disturbances in behaviour

Synonym
Behavioral problems

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW,TBS klinieken

Intervention

Keyword: Dashboard, Forensic, Insight, Physiology

Outcome measures

Primary outcome

In the Neurawear project, the primary outcome measures are interoceptive awareness, emotion regulation and regulatory emotional self-efficacy. In addition, primary outcomes are individual target behavior (such as aggression or overstimulation) and the added value of Wearalyze to the daily activities and treatment of the client.

Secondary outcome

In the Neurawear project, the secondary outcomes measures are system usability and technology acceptance.

Study description

Background summary

Forensic psychiatry aims to reduce the risk of reoffending among patients who often exhibit uncontrolled aggressive and violent behavior (AVB). Although current interventions for AVB are found to be effective, the effect sizes are rather small (Gibbon et al., 2020; Iruthayarajah et al., 2018). Most interventions are currently focused on the cognitive and psychological factors that contribute to AVB, while biological and neurophysiological factors are important as well (Gibbon et al., 2020; Kozhuharova et al., 2019; Wong et al., 2020). Combining traditional psychosocial and cognitive behavioral treatment interventions with physiological information on sleep, stress and activity might thus provide numerous insights to improve interventions (Johnson & Picard, 2020).

Study objective

The proposed study aims to develop a new dashboard (Wearalyze) and design a new user interface in co-creation with therapists, patients and experts in

technology to enhance its usability and acceptability. In addition, we explore whether the use of Wearalyze is of added value on interoceptive awareness, emotion regulation and regulatory emotional self-efficacy. At last, we examine the usability and acceptance of Wearalyze.

Study design

The Neurawear project includes a multiple baseline across subjects A-B design.

Study burden and risks

The proposed study involves collecting data using questionnaires, experience sampling and interviews. In the Neurawear project, participants are asked two times to fill out three questionnaires which takes less than 15 minutes each to complete and one time daily over the course of the intervention to fill out a short questionnaire which takes approximately two minutes to fill out. In addition, participants participate in an interview which takes approximately 30 minutes to complete. Besides the time investment, no negative consequences due to answering the questionnaires are expected. The wearables are implemented in daily activities, therefore no loss of time due to this study component is expected. Wearing the devices could result in some discomfort over time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- patient in (inpatient) forensic care
- age 18 and above;
- permitted to work with a phone or tablet

Exclusion criteria

- experiencing an active psychotic episode;
- not understanding the Dutch language
- having a legal representative (because of a lack of capacity to make a will).

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2024
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO Date:	09-10-2024
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	NL87033.028.24