Mood radar: A technical aid in monitoring upcoming challenging behavior. Discovering dependable predictors of upcoming challenging behaviour in people with a mental disability. Measuring physiology of clients and their caretakers in natural situations. Viewing Challenging behaviour from a bio-physiological transactional model.

No registrations found.

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

Summary

ID

NL-OMON28283

Source
Nationaal Trial Register

Brief title
Mood Radar: A technical aid in monitoring upcoming challenging behavior.

Health condition

challenging behavior

Sponsors and support

Primary sponsor: De twentse Zorg centra

Intervention

Outcome measures

Primary outcome

Skin conductance, heart rate variability and occurrence of challenging behaviour will be measured on both the client and the caretaker in the natural situation.

Secondary outcome

N/A

Study description

Background summary

Challenging behaviors (CB) are a serious problem in the daily care of people with a mental or intellectual disability. Besides the negative effects of CB for the individual displaying this behavior (e.g institutionalization, medication use, restriction in behavior) the CB affects all people surrounding them. The occurrence of challenging behaviour can be viewed from a multi-component "bio physiological" model. Client, caretaker and environment characteristics can be distinguished as interacting factors setting the stage for challenging behaviors to occur. In this research we aim to identify physiological signs within the clients and their caretakers that reliably precede an outburst of challenging behaviors. What specific patterns in physiology of client and caretaker can be found in the onset, ongoing and ending of CB ? Can physiology patterns help in predict upcoming CB?

The primary objective of this study is to investigate the physiology of clients with ID and their caretakers in naturalistic situations in relationship to the occurrence of challenging behavior. The level of arousal in daily situations will be objectively measured by measuring output from the autonomous nervous system: heart rate variability and galvanic skin response. The aim of Mood Radar is to find reliable physiological predictors for the occurrence of challenging behaviour which can be translated into a simple non-technical warning signal when the occurrence of challenging behaviour in the near future is likely. This warning signal helps caretakers to direct focused attention to this client and establish whether action is required to prevent escalation.

Mood radar is a explorative, observational study with an ideographic approach.

Mood radar will include both clients with an intellectual disability, that are known to show severe challenging behaviours and their caretakers . 10 client-caretaker couples will be formed.

Study objective

Fysiological changes in client and or catertaker preceed the actual occurence of challenging behavior.

Study design

Measurements will take place during 12 weeks: three times a week during a three hour period. Measurements will be made in the natural situations.

Intervention

None. Mood radar is an explorative, observational study. No interventions will be made.

Contacts

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Eligibility criteria

Inclusion criteria

For the clients the main inclusion criteria is the actual occurrence of challenging behaviour. This is operationalized through scores of 3 or 4 on the "Consensprotocol Ernstig Probleemgedrag" (Kramer, 1995).

For the caretakers the inclusion criteria is having to work with the above mentioned client group.

Exclusion criteria

Medication use which severely and directly influence arousallevels for example lang term working benzodiazepines.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	N/A: single arm study

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2011
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-08-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35961
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2897
NTR-old	NTR3043
CCMO	NL37314.044.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35961

Study results

Summary results
N/A