Effects of a bioresponse system for caregivers of adults with visual and severe or profound intellectual disabilities

Published: 27-11-2015
Last updated: 19-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42433

Source
ToetsingOnline

Brief title
Effects of a bioresponse system for caregivers

Condition

- Other condition

Synonym
challenging behaviour, development stimulation

Health condition

volwassenen met een visuele- en (zeer) ernstige verstandelijke beperking

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Vereniging van Instellingen voor mensen met een Visuele beperking (VIVIS)

Intervention

Keyword: caregiver-client interaction, challenging behaviour, sensitivity, visual and severe or profound intellectual disabilities

Outcome measures

Primary outcome

The sensitivity and responsiveness of the caregiver. Instrument: NICHD-scales.

Secondary outcome

The client's challenging behavior. Instruments: ABCL, SGZ.

The quantity of caregiver-client interactions. Instruments: ESCS, Pianta scales.

The user-friendliness of the bioresponse system. Instrument: Social Validity

Scale.

Study description

Background summary

Individuals with profound intellectual and multiple disabilities (PIMD) (of whom 70% also has a visual impairment (Van Splunder, 2003)) experience high levels of stress on a daily basis. Poppes, van der Putten & Vlaskamp (2010) found in their study that 45% of the individuals with PIMD show aggressive and destructive behavior and that this behavior occurs on a weekly or daily basis. This challenging behavior in combination with high levels of stress hinders the development and self-management of individuals with PIMD.

Caregivers in residential institutes are often not sufficiently responsive to the client's signals, due to the difficulty of understanding the non-verbal behavior of individuals with PIMD (Maes, 2011). Special training programs are developed for caregivers to learn to understand subtle behavioral signals within the context and to react sensitive and responsive to these signals (among others Janssen et al., 2003, Damen et al., 2011). These programs are intensive and expansive, and can only be taught to selected caregivers. Next to the high costs, the turnover in staff in group homes are large, two to three new caregivers for each client per year (Buntinx, 2003), which causes a loss of the newly gained expertise.

Emotional arousal causes changes in biological signals. Through monitoring these biological signals, using a bioresponse system, enables caregivers to 'read' and understand the signals of individuals with visual and severe or profound intellectual disabilities. A bioresponse system is a low-cost aid product to share knowledge with regards to the client's subtle stress signals among colleagues. The empathy for the client can be increased with a shorter and thus a less expensive training program.

Study objective

The objective of the study is to test the effectiveness of the bioresponse system. To verify this objective, a few research questions have to be answered. The first research question concerns the ability of the bioresponse system to monitor the emotional arousal and to clearly communicate this arousal to caregivers. Other research questions will test the influence of the system on the caregiver's sensitivity and responsiveness and the influence of the system in combination with heightened sensitivity of the caregiver, on the client's challenging behavior. The expected decrease in challenging behavior leads to a new research question: to verify the system's influence on the quantity of caregiver-client interactions. The last research question concerns the user-friendliness of the system.

Study design

This study involves a randomized multiple baseline study design. During the study, 21 video recordings will be made for each client: 7 video recordings during the baseline phase, 7 during the intervention phase and 7 during the follow-up phase. Weekly two or three recordings will be made by a research assistant. The duration of each video recording will be in total 35 minutes: 10 minute of play; 10 minute of daily care; and 15 minute of semi-structured caregiver-client interaction based on the *The Three Boxes Procedure* (NICHD, 2003). The length of the baseline phase will be randomized. The follow-up phase will start three weeks after finishing the intervention. After the study, the baseline videos, the intervention videos and the follow-up videos will be scored according to the NICHD-scales, ESCS, ABCL & Pianta scales by independent

observers blind to phase.

Intervention

The caregivers will be presented with the bioresponse system, an user manual and an instruction video on how to use the system. The bioresponse system exists of a small bracelet which measures skin temperature, a sensor sock that measures skin conductance, a small band for the ankle and an app on a tablet PC. The intervention requires the caregivers to use the bioresponse system two times a day for 90 minutes over a period of 12 weeks.

Caregivers are requested to enter their observations of their client*s behavior on the tablet PC. In the Netherlands, every client with a visual and severe or profound intellectual disability has his own behavior signaling observation lists, in Dutch it is called: *signaleringsplan*. These observation lists show an individualized description of the behavior of the client indicating emotion from *relaxed* to *very high levels of stress*. Color coded buttons, that correspond to the colors used in the signaling observation lists, are displayed on the tablet PC. The caregivers will be asked to score (on the tablet PC) their interpretation of the bioresponse signal and the behavior of the client.

Study burden and risks

During the video recordings the clients will interact with their caregiver, following a semi-structured approach. They will wear a small bracelet, a sensor sock (a normal sock with two small and soft fabric electrodes) and a small elastic band with a clip for the sensor around the ankle. Several straps hold the sock and ankle band in their position. These straps are fastened with Velcro. It might occur that these straps are fastened too tight and are pinching off. Caregivers are advanced on this risk and stimulated to check with every use whether the straps are not fastened too tight.

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

- Adults with a visual and severe or profound intellectual disability
- Adults living in a group home (from Bartiméus or Royal Dutch Visio)
- Adults older than 18 years
- Adults receiving care from a professionally trained caregiver
- Written consent given by the parents for the client's participation in this study
- Written consent given by the caregiver for his/her own participation

Exclusion criteria

- Clients with serious medical problems
- If the client's parent/representative does not approve for participation
- If the caregiver does not sign for approval

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-01-2016
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	27-11-2015
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	NL53963.029.15