

# Using mobile technology to support relationship development, well-being and social participation of adults with a visual and intellectual disability.

Published: 12-04-2011

Last updated: 27-04-2024

The key objectives of the study are:(1) to assess the effect on the quality of client-caregiver interaction by a treatment protocol designed around a specially developed mobile device. Moreover, attention will also be given to differentiation among...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Anxiety disorders and symptoms
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON36452

### Source

ToetsingOnline

### Brief title

Mobile technology to support relationship development

### Condition

- Anxiety disorders and symptoms

### Synonym

anxiety, separation anxiety

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit

**Source(s) of monetary or material Support:** ZonMW InZicht

## **Intervention**

**Keyword:** mobile technology, relationship development, social participation, visual and intellectual disability., well-being

## **Outcome measures**

### **Primary outcome**

All messages sent by the client and the caregivers will be registered on a webbased computerized data collection system. The kind of emotional message sent and the frequency of these in the different phases of the research will be used to examine the increasing quality of client-caregiver interaction and differentiation among caregivers.

### **Secondary outcome**

Outcome variables: Instruments

First it is important to note that although quite a variety of instruments are mentioned, caregivers will only be asked to fill out the items that are of concern to this study. Secondly, the care organizations which employ caregivers will receive compensatory funding for the time they need for completing the questionnaires. The client's mentor will be asked to answer the questionnaires. An independent caregiver will support the client in completing some of the questionnaires.

Outcome variables: Separation distress, loneliness & challenging behaviour

- The Psychopathology Inventory for Mentally Retarded Adults (PIMRA) (Matson,

Van Minnen & Hoogduin, 1994): It is one of the most widely administered and researched instruments in assessing psychopathology in individuals with developmental disabilities. This scale consists of 56 true/false items within eight subscales: Schizophrenia, Affective Disorder, Psychosexual Disorder, Adjustment Disorder, Anxiety Disorder, Somatoform Disorder, Personality Disorder, and Inappropriate Adjustment. The psychometric properties have been widely studied and suggest that overall it is a reliable and valid screening measure of psychopathology in persons with ID. Only the 7 items on \*anxiety disorder\* will be used with a scoring time of approximately 3 minutes.

- The health of the nation outcome scales learning disabilities (Honos-LD)

(Roy, Matthews, Clifford,

Fowler & Martin, 2002) will be used to measure risk and vulnerability of mental health problems

that suits the needs of people with learning disabilities. Only item 3D

(Anxiety, phobias, obsessive

or compulsive behavior) will be used with a scoring time of approximately 1 minute.

- Sociale redzaamheidschalen verstandelijk gehandicapten (SRZ/SRZi). SRZ/SRZi

Social ability scales for people with ID (Kraijer, Kema, & Bildt, 2004): The

SRZ has a Cohen's kappa for reliability of between  $r = .66$  and  $.89$  and adequate validity. Only the 5 items on \*social functioning\* will be used with a scoring time of approximately 2 minutes.

- The Dutch version of the Adult Behavior Checklist (ABCL) for the ages 18 to

59 (Achenbach & Rescorla, 2003): scales for adaptive functioning, empirically

based syndromes, substance use, internalising, externalising, and total problems. There are six scales to gain characteristics consistent with DSM-IV categories: Depressive Problems, Anxiety Problems, Somatic Problems, Avoidant Personality Problems, Attention Deficit/Hyperactivity Problems, and Antisocial Personality Problems. The ABCL was found to be a reliable and valid measure to assess psychopathology in persons with mild intellectual disabilities or low IQ, admitted for treatment in facilities for adults with mild intellectual disability and severe challenging behaviour (Tenneij & Koot, 2007). The observer rating scale will be used with a scoring time between 5 and 20 minutes.

-Residential observation: The professional caregivers in the participants' residential homes will be instructed to record the frequency of the challenging behaviours (e.g. distress, behavioural problems, clamping behaviour). An online web-based computerized data collection system \*Thesis Tools\*, will be used for the daily reporting of challenging behaviour. A computerized reminder for filling out the lists will be added and will be visible on the computer on which caregivers daily check their e-mail. The daily scoring time will take around 5 minutes. An earlier study with a paper and pencil version achieved responses rates of 100% over periods of 9 to 12 months of daily scoring (Sterkenburg et al., 2008).

-The Symptom Checklist-90-R SCL-90-R is a questionnaire frequently used as an instrument to determine the experienced degree of psychopathology and for the evaluation of treatment. The reliability and validity of the instrument is described as good (COTAN evaluation) (Arrindell & Ettema, 2003). The items are divided in eight scales: Fear, Agoraphobia, Depression, Somatic complaints,

Insufficient way of thinking and reacting, Suspicion and interpersonal sensitivity, Anger-hostility, and Sleeping problems. The shortened version, the Brief Symptom Index (BSI) (De Beurs & Zitman, 2005) often used to measure therapy effect, will be used. The 53 item list will be scored by the client assisted by an independent researcher. The BSI is a easy to score list with a duration of approximately 15 minutes.

Outcome variable: feeling of well-being

- The IDQOL Intellectual Disability Quality of Life (Hoekman et al. 2001) is a short questionnaire (quickscan) to examine the quality of life of persons with a moderate to mild intellectual disability. The 16-item questionnaire with its 5-point scale (using smileys) has a Cronbach\*s Alpha for internal consistency of between .72 and .86. The items cover the range from personal well-being, social well-being and well-being in the caregiving situation. It will take between 5 and 20 minutes to complete the questionnaire. An independent caregiver will support the client.

## Study description

### Background summary

Experiencing separation anxiety is a normal reaction for persons with a developmental age between 0 and 48 months. For these persons anticipating the return of a loved person and the ability to imagine the whereabouts of the missing person is difficult. For persons with a visual and intellectual disability (ID) this may be even more difficult. Prevalence studies indicate that separation anxiety among children with ID is four times higher than among their non-ID peers. For persons with a visual disability and ID the prevalence of separation anxiety disorder is unknown. However, anxiety symptoms are

widespread: in 30% of the cases anxiety and fear were reasons to apply for treatment at the Psychotherapy department of Bartiméus. Furthermore, research among children and adolescents has indicated that anxiety disorders do not spontaneously disappear and can cause comorbid disorders such as depression and behaviour problems. Consequently this may lessen their possibilities of integration in community and decreases independent citizenship. Hardly any research has been done on the treatment of separation anxiety among persons with a visual disability and ID. In order to overcome separation anxiety, persons with visual and intellectual disabilities may be given the experience that their caregivers continue to exist and keep their client in their minds, even when they are separated in space and time. Mobile technology offers new ways of treating separation anxiety and isolation. However, research on the use of mobile technology in the intervention of separation anxiety of persons with a visual disability and ID is lacking.

## **Study objective**

The key objectives of the study are:

- (1) to assess the effect on the quality of client-caregiver interaction by a treatment protocol designed around a specially developed mobile device. Moreover, attention will also be given to differentiation among different caregivers.
- (2) to assess the effect of the treatment protocol on the client. Endpoints are: reduced separation distress; reduced signs of loneliness; reduced challenging behaviour; increased well-being.
- (3) to assess the social validity of treatment with mobile technology. Can mobile technology be used while providing care to another client? Does mobile technology for the client lead to less, not more signals of distress?

## **Study design**

A series of single case studies with a multiphase design (ABCBC) with a three-week post-intervention check will be used.

## **Intervention**

A treatment protocol that is designed around a specially developed mobile device (an adapted iPhone Touch).

## **Study burden and risks**

Although the burden of participation is expected to be negligible, clients may experience the mobile device as troublesome. Efforts will be made to reduce this to a minimum.

## 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

Criteria for participation in this study are: being at least 18 years of age; having a visual disability in accordance to WHO criteria (blind persons are excluded); having an IQ between 40 and 70 (moderate to mild) acquired their disability before adulthood; regularly becoming distressed when left alone as shown on the PIMRA (see instruments); the capacity to physically use the touch-screen of the mobile device.

### Exclusion criteria

Adults with the diagnoses Autism Spectrum Disorder will be excluded from this study as well as persons who are deaf.

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 09-07-2011

Enrollment: 6

Type: Actual

## Ethics review

Approved WMO

Date: 12-04-2011

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	NL33646.029.11