

Effect of the serious game 'You & I' on the mentalizing abilities of adults with mild to borderline intellectual disabilities

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23829

Source

NTR

Health condition

Mild to borderline intellectual disability, mentalization, stress regulation.

Licht verstandelijke beperking, mentaliseren, stressregulatie.

Sponsors and support

Primary sponsor: Vrije Universiteit Amsterdam

Cordaan

ASVZ

Bartimeus

Ons Tweede Thuis

Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The primary outcome measure of this study is mentalizing abilities. Several questionnaires will be used to measure mentalization. There are 3 timepoints for all the measures, T0 (baseline), T1 (posttest, 4 weeks later after finishing the serious game 'You & I') and T2 (follow up, 6-8 weeks after T1).

- The Reflective Functioning Questionnaire (RFQ)
- Radboud Faces Database (RaFD)
- Subscale Perspective Taking (PT) of the Interpersonal Reactivity Index (IRI)
- Frith Happé Animations Test
- Questions based on the Social Information Processing Test (In Dutch: Sociale InformatieverwerkingsTest (SIVT))

Secondary outcome

The secondary outcome measure of this study is stress regulation.

- Lifestress Inventory (LI), measured at T0, T1, T2

Study description

Background summary

This randomized controlled trial aims to study the effect of the serious game 'You & I' on the mentalizing abilities and stress regulations in adults with mild to borderline intellectual disabilities. Participants will be assessed at baseline, posttest (four weeks after baseline) and follow-up (six to eight weeks after baseline) using several questionnaires.

Study objective

The primary hypothesis is that playing the serious game 'You & I' will be associated with an improvement of the mentalizing abilities in adults with mild to borderline intellectual disabilities.

The secondary hypothesis is that playing the serious game 'You & I' will be associated with an improvement of stress regulation in adults with mild to borderline intellectual disabilities.

Study design

T0: baseline

T1: posttest (4 weeks after baseline)

T2: follow-up (6-8 weeks after T1)

Intervention

The intervention is a serious game called 'You & I' that focuses on the improvement of mentalizing abilities, including the regulation of stress. The game was developed by researchers of the Vrije Universiteit Amsterdam in collaboration with healthcare professionals and adults with MBID. The serious game is based on the attachment theory (Bowlby, 1982), the practice-oriented book 'Mentalization can be learned' (in Dutch: 'Mentaliseren kan je leren') by Dekker & Sterkenburg (2015) and the practice-oriented book 'Mentalization in clinical practice' (in Dutch: 'Mentaliseren in de klinische praktijk') by Allen, Fonagy & Bateman (2008). The game can be played independently by the participant on a tablet or computer.

The serious game revolves around a main character called Mo, who the player follows throughout the game by watching videos. In the first level, the player finds out that Mo is sad because he misses his friend Emily, who moved to the United States. He decides to visit her and travel to the United States. The player will follow Mo on his adventure, while he leaves his house, takes the bus, the airplane and finds his way through a foreign country to finally be able to visit Emily. By watching videos, playing games and answering questions, the player will improve its mentalizing abilities and learn how to cope with stress better.

The game consists of eight gaming levels, which will take about 30 to 45 minutes to complete. The participant is asked to play the game twice a week, completing one level every time. Each level has the same structure consisting of eight different elements. That is, videos following Mo's journey, multiple choice questions, an emotion picture game, a stress measurer and a game about stress. The gaming levels cover different domains of mentalization, as described by Choi-Kan & Gunderson (2008).

Contacts

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Eligibility criteria

Inclusion criteria

- Mild to borderline intellectual disability, as diagnosed by one of the participating care organizations (IQ range of 50 to 85 and social adaptation problems).
- 18 years or older
- Computer and internet access
- Basic computer operation skills

Exclusion criteria

- Deaf-blindness
- Blindness
- Serious mobility impairments for whom computer operation is not possible
- No written consent from the participant and/or their legal representative

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	172
Type:	Anticipated

Ethics review

Positive opinion	
Date:	02-08-2018
Application type:	First submission

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
NTR-new	NL7219
NTR-old	NTR7418
Other	2018.007, NL60353.029.17 : METc VUmc

Study results

Summary results

not yet