

# Effect of the serious game 'You & I' on the mentalizing abilities of adults with mild to borderline intellectual disabilities: A randomized controlled trial

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The first objective of this study is to research the efficacy of the serious game \*You & I\* in improving mentalizing and stress regulating abilities of adults with mild to borderline intellectual disabilities compared to a wait list control...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON50524

### Source

ToetsingOnline

### Brief title

Effect serious game on mentalization in intellectually disabled adults

### Condition

- Other condition

### Synonym

Intellectual disabilities/special needs/learning disabilities

### Health condition

volwassenen met een licht verstandelijke beperking

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit

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

## Intervention

**Keyword:** Mentalizing abilities, Mild to Borderline intellectual disability, Serious Game, Stress regulation

## Outcome measures

### Primary outcome

The primary study parameter is mentalizing abilities. Mentalization will be measured using:

- Reflective Functioning Questionnaire (RFQ)
- Radboud Faces Database (RaFD)
- Subscale Perspective Taking (PT) of the Interpersonal Reactivity Index (IRI)
- Frith Happé Animations Test

### Secondary outcome

The secondary parameter is stress regulation. Stress regulation will be measured using:

- Lifestress Inventory (LI)
- Self-efficacy questionnaire

Help of caregivers while jointly playing the serious game 'You & I', measured using:

- Audio recordings coded for the degree of mentalizing support

# Study description

## Background summary

\*Seeing oneself from the outside and others from the inside.\* A phrase that is commonly used to describe the term mentalization. Mentalization refers to \*the mental process by which an individual implicitly and explicitly interprets the actions of himself or herself and others as meaningful on the basis of intentional mental states such as personal desires, needs, feelings, beliefs, and reasons\* (Bateman & Fonagy, 2004). It is a fundamental human ability that allows us to understand our own behavior and the behavior of others in terms of mental states (Fonagy, 2006). In relation to the self, the ability to mentalize enables the development of a stable sense of identity, essential to the regulation of strong emotions, such as stress (Fonagy, Gergely, Jurist, & Target, 2002). On the other hand, in relation to others, the ability to mentalize is crucial for the establishment of healthy reciprocal social relationships (Allen, Fonagy, & Bateman, 2008).

Persons with mild to borderline intellectual disabilities (MBID) generally show reduced abilities to mentalize (Baglio et al., 2016; Yirmaya, Erel, Shaked, & Solomonica-levi, 1998; Owen, Browning, & Jones, 2001). This inadequacy results in a number of difficulties experienced by this population, including a poor sense of self, no constructive social interaction, no reciprocity in social relationships and a poor regulation of emotions, including stress (Fonagy, 2006). Empirical evidence (Busch, 2008) suggests, however, that mentalizing abilities can be improved with treatment programs such as mentalization-based therapy (Bateman & Fonagy, 2004). So far, these treatment programs have mainly focused on persons with borderline personality disorders, while methods to support the acquisition of mentalizing abilities for persons with MBID are still lacking. Yet, it seems particularly important for this population to enhance mentalization, as persons with MBID face many difficulties related to the mentalization deficit, such as small social networks and poor emotion regulation skills (Bigby, 2008; McClure & Donahue, 2009).

A promising method to improve mentalizing abilities of people with MBID is serious gaming (Connolly, Boyle, MacArthur, Hainey, & Boyle, 2012). Serious games are computer applications that combine serious aspects, such as learning, with playful gaming elements (Alvarez & Djaouti, 2011). Serious games have become increasingly popular over the last years and results on their effectiveness are promising (Connolly et al., 2012). Studies have shown that serious games can be deployed successfully in the care for persons with intellectual disabilities when it comes to learning new skills and when it comes to the development of abstract concepts (Den Brok & Sterkenburg, 2014). Moreover, serious games are cost-effective and provide a unique learning environment wherein persons are allowed to practice new skills in a setting

that is unlikely to be realized in their daily lives (Cheng, Chen, Cu, & Chen, 2015).

To address the intervention gap in clinical practice, the serious game \*You & I\* has been developed. The game is intended to improve mentalizing abilities, including the regulation of stress, in adults with MBID. For scientific relevance, the efficacy of the serious game will be investigated, answering the following research questions: Is the serious game \*You & I\* efficacious in improving mentalizing abilities in adults with MBID compared to a wait list control group? Is the serious game \*You & I\* efficacious in improving the regulation of stress in adults with MBID compared to a wait list control group?

In addition, research will be conducted into the serious game 'You & I' in a research group of adults with MBID who played the serious game together with their caregiver. Although the game is ideally suited to be played only by adults with MBID, adding a social link (some kind of social support) can improve the process of behavioral change (Sort & Khazaal, 2017). For adults with mild to borderline intellectual disabilities, care providers regularly provide (social) support and their involvement in playing a serious game can benefit the learning experience of this group. Moreover, previous research by Witvliet et al. (2015) and Douma (2018) has shown that caregivers can motivate people with MBID and increase their self-confidence while performing a task. The accompanying research questions are therefore: Is the serious game 'You & I' more efficacious in improving mentalizing abilities in adults with MBID when they play the game together with their supervisor compared to playing the game alone or the waiting list control group? Is the serious game 'You & I' more efficacious in improving the regulation of stress in adults with MBID when they play the game together with their supervisor compared to playing the game alone or the waiting list control group?

## **Study objective**

The first objective of this study is to research the efficacy of the serious game \*You & I\* in improving mentalizing and stress regulating abilities of adults with mild to borderline intellectual disabilities compared to a wait list control group. The primary research question of this study is: Is the serious game \*You & I\* efficacious in improving mentalizing abilities in adults with mild to borderline intellectual disabilities compared to a wait list control group? The secondary research question of this study is: Is the serious game \*You & I\* efficacious in improving the regulation of stress in adults with mild to borderline intellectual disabilities compared to a wait list control group?

The second objective of this study is to research the efficacy of the serious game \*You & I\* when the game is played by adults with mild to borderline intellectual disabilities together with their caregiver. The primary research question is: Is the serious game \*You & I\* more efficacious in improving

mentalizing abilities in adults with mild to borderline intellectual disabilities when playing the game together with caregivers compared to playing the game alone or the wait list control group? The secondary research question is: Is the serious game \*You & I\* more efficacious in improving the regulation of stress in adults with mild to borderline intellectual disabilities when playing the game together with caregivers compared to playing the game alone or the wait list control group?

Moreover, the aim is here also to gain (more) insight in the process of jointly playing the serious game 'You & I' by caregivers and adults with mild to borderline intellectual disabilities. It is expected that caregivers also apply what is central and is taught in the serious game in their help to the clients while playing the serious game. Therefore, the additional research question is: To what extent do caregivers support learning by promoting mentalization while playing the serious game \*You & I\* with adults with mild to borderline intellectual disabilities?

## **Study design**

The first research question will be answered using a two arm parallel superiority randomized controlled trial (RCT). The RCT includes an experimental group, who will be offered to play the serious game \*You & I\*, and a wait list control group, who will get the chance to play the serious game after the follow up measurement. Both participants and researchers are not blinded, as this is not possible due to the design of this study. Thus, both the participants and the researchers know which group the participants have been assigned to.

The second research question will be answered using a single-arm trial in which clients play the serious game 'You & I' with their caregivers. Because this single-arm trial will start later than the RCT, the participants in this study will be matched with the participants in the RCT. To gain (more) insight into how the participants play together with their caregivers, the caregivers will be asked to make two audio recordings.

## **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 experienced researchers in the period of June 2017 until August 2018. 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 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, so it takes four weeks to complete the game. Each level has the same structure consisting of six different gaming elements, such as a memory game, videos, questions, puzzles and statements.

### **Study burden and risks**

To test the efficacy of the serious game \*You & I\*, multiple measures are included in the design. At every assessment, participants are asked to fill out several questionnaires. These questionnaires will take up to 1.5 hours each time. Participants who are assigned to the experimental group have to play the serious game \*You & I\* twice a week for 30 to 45 minutes throughout 4 weeks. The two audio recordings that are made during the playing moments of the group participants who play together with their caregiver, take little to no extra time.

The burden of the participants can be considered in proportion to the potential benefits of the research project for the subject. We expect an improvement in mentalizing abilities and stress regulation. Participants in the control condition encounter the same possible benefits as the participants in the experimental conditions because they are invited to play the serious game \*You & I\* after the follow-up assessment.

No risks are expected.

## **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

- 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:	Active
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2018
Enrollment:	258
Type:	Anticipated

## Ethics review

Approved WMO	
Date:	18-07-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	02-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	22-12-2020
Application type:	Amendment
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

CCMO

### ID

NL60353.029.17