Effectiveness of the serious game 'You & I' on the mentalizing abilities of adults with mild to borderline intellectual disabilities: a parallel superiority randomized controlled trial

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Method Article

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Abstract

Background: Persons with mild to borderline intellectual disabilities generally show dysfunctions in mentalization, including impairments in stress regulation, resulting in problematic social relationships and personal distress. Inteention programs can, however, improve mentalizing abilities. The aim of this study is to examine the effectiveness of the serious game 'You & I' on mentalizing abilities and stress regulation in adults with mild to borderline intellectual disabilities.

Methods: A two-arm, parallel, superiority randomized controlled trial will be used with 172 adults with mild to borderline intellectual disabilities. Participants will be randomly assigned to either the experimental group to play the serious game 'You & I' or a waitlist control group. Participants will be assessed at baseline, post-intervention (5 weeks after baseline), and follow-up (6 to 8 weeks after post-intervention). They also will fill in questionnaires measuring personal factors, personal development, and personal well-being, social validity, and autism spectrum quotient (demographic variables), mentalizing abilities (primary outcome measure), and stress regulation (secondary outcome measure).

Discussion: The serious game 'You & I' aims to improve mentalizing abilities in adults with mild to borderline intellectual disabilities, which is expected to lead to improved regulation of stress in social relationships. The study's unique feature is the use of a serious game to improve mentalizing abilities, which is expected to provide insight into the game's effectiveness for adults with mild to borderline intellectual disabilities. If the intervention is effective, the serious game can be implemented on a broad scale in Dutch care organizations for people with intellectual disabilities as an effective tool to improve mentalizing abilities. It will be made available online, free of charge.

Trial Registration: Nederlands Trial Register NTR7418 (registered 2 August 2018).

Keywords: Mentalization, stress regulation, intellectual disability, serious game.

Background

"*Seeing oneself from the outside and others from the inside*" [1]. This phrase is commonly used to describe mentalization, a concept that has become gradually more prevalent and extensive since Fonagy reintroduced it in the early 1990s. 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*" [2]. The capacity for mentalization is acquired in early childhood and is related to the development of all other domains, such as cognition, language, and social-emotional functioning [3]. Because of developmental delays in these domains, persons with mild to borderline intellectual disability (MBID) may have difficulties acquiring mentalizing abilities and be limited in their capacity to mentalize [3]. It is important to examine whether interventions can help improve the mentalizing capacity of people with MBID.

Our internal mental states drive human behavior – the way humans respond and act in certain situations. Mentalization is looking beyond overt behavior and being able to understand behavior in terms of those covert mental states [4]. This fundamental human ability allows us to understand our own behavior and that of others in terms of mental states such as beliefs, desires, intentions, goals, and emotions [5].

The ability to mentalize enables us to develop a stable sense of self because mentalizing allows us to accurately recognize our mental states and those of others. This recognition in turn results in increased social awareness and positive interpersonal relationships. Being able to mentalize is essential for successful coping with intense emotion such as stress: The ability to recognize your feelings makes it easier to cope with them [5]. Persons with MBID have a limited capacity to mentalize [3], with particular difficulties in attributing mental states to themselves and others. Consequently, they generally find it challenging to predict behavior based on such attributions [6][7][8]. These dysfunctions in mentalizing abilities may explain the social problems that persons with MBID can experience, such as not having many constructive social interactions or much reciprocity in social relationships [9][10]. Furthermore, because of limited social information processing as an executive function, people with MBID perceive more negative information, along with more difficulty remembering and processing information, limited working memory, and fewer problem-solving skills. The resulting stress makes learning mentalizing abilities more difficult [11] [12].

Within the construct of mentalization, three dimensions can be identified [13]. The first dimension is related to two modes of functioning, namely implicit and explicit functioning. Implicit mentalization refers to the unconscious, procedural, or automatic system of understanding others. Explicit mentalization involves a deliberate and conscious focus on mental content [14]. The second dimension is related to two objects, specifically the self and others. An individual can mentalize not only one's own mental states but also the mental states of others; moreover, a person can mentalize one's own relationships with other persons and correspondingly other persons' relationships with one another [15]. The third dimension of the mentalization concept relates to its cognitive and affective aspects. Mental states in oneself and others can be cognitively focused as well as affectively laden to varying degrees [13].

According to Fonagy and Bateman [14] and Fonagy [16], humans first acquire the capacity for mentalization in the context of early attachment relationships. More specifically, the child develops mentalizing abilities within a secure attachment relationship, when the caregiver accurately or contingently mirrors the internal states of the child [17][13]. The mirroring also needs to be *marked*. For example, when a child starts to cry because of distress, the caregiver shows concern in response to the distress rather than crying. The caregiver contingently mirrors the internal state of the child but differentiates by not spontaneously imitating the child's behavior [18]. This mirroring process enables the child to understand its own mental states and develop a stable sense of identity and, in turn, regulate its affect and distress [13][18]. By also naming the mental state of the child, the child learns to recognize and name their mental state and those of others, which will improve their mentalizing abilities [19][20].

Mentalization is not a static capacity but a dynamic, multifaceted ability whose development can be influenced by external factors such as stress [21][22]. As Allen [15] points out: "S*tress is the enemy of mentalization*". When high levels of stress are experienced, adequate mentalization becomes more difficult [23][24]. To be more precise, the capacity to understand someone else's mental states may be reduced, distorted, and less flexible when high levels of stress are experienced [22]. On the other hand, the better you have the abilities to mentalize, the lesser you will experience stress. In other words, good mentalizing abilities contribute to reducing stress and it is therefore important to improve these abilities.

Awareness and understanding of mental states can be developed gradually by explicitly educating someone about mental states [25]. Empirical evidence suggests that mentalizing abilities can be improved with treatment programs such as mentalization-based therapy [2]. In mentalization-based therapy (MBT), at therapist follows a therapeutic process to strengthen the patients mentalizing abilities: how do you think and feel about yourself and others, does this influence your behavior, can miscommunications in behavior and feelings lead to difficulties and how can you prevent and resolve those miscommunications? The therapist does not judge, is curious, asks in-depth questions, shows empathy and helps the patient reflect on what goes on in their mind [16]. Research shows that mentalization-based therapy leads to significantly fewer crisis situations, a strong decrease in depressive symptoms, less suicide attempts, a drop in self-injury and a strong improvement of interpersonal and social functioning [26][27][28]. So far, treatment programs such as mentalization-based therapy have mainly focused on persons with personality disorders, while methods to support the acquisition of mentalizing abilities for persons with MBID are still lacking. Moreover, current treatments for improving mentalizing abilities are time-consuming (treatment duration varying between 4 and 18 months), require supervision from qualified mental health professionals and, consequently, are quite costly [29][30][31].

A promising and innovative method to improve mentalizing abilities of people with MBID is serious gaming. Serious games are computer applications that combine serious aspects, such as learning, with playful gaming elements [32]. Serious games have become increasingly popular over the last years and results on their effectiveness are promising [33][34]. Studies have also shown that serious games can be deployed successfully in the care for persons with intellectual disabilities when it comes to learning new skills and the development of abstract concepts [35]. Furthermore, MBT key elements can be realized in the serious game: a voice-over can, just like a therapist, learn people with MBID indirectly (i.e. through interaction with an identifiable character) to recognize and name their mental state and those of others which will improve their mentalizing abilities. Serious games can support learning which is particularly helpful for people with MBID, who learn by making abstract concepts concrete and receiving and processing new information step by step [3]. 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 (un)likely to be realized in their daily lives [36][37].

Trial objective

The serious game ‘You & I’ (in Dutch: ‘Jij & Ik’) is a serious computer game, which is developed with and for adults with MBID. The aim of the game is to improve mentalizing abilities, including the regulation of stress, focusing specifically on the three above-mentioned dimensions of mentalization. In this study, the effectiveness of the serious game will be investigated, answering the following research questions: Is the serious game ‘You & I’ more efficacious in improving mentalizing abilities in adults with MBID compared to a wait list control group? Is the serious game ‘You & I’ more efficacious in improving the regulation of stress in adults with MBID compared to a wait list control group?

Hypotheses

The serious game ‘You & I’ is hypothesized to have a positive effect on the mentalizing abilities, including the regulation of stress, in adults with MBID. The primary hypothesis is that playing the serious game will be associated with an improvement of the mentalizing abilities in adults with MBID. The secondary hypothesis is that playing the serious game will be associated with an improvement of stress regulation in adults with MBID.

Methods

The aim of the present study is to examine the effectiveness of the serious game ‘You & I’ for adults with MBID. Primarily, efficacy is measured in terms of improved mentalizing abilities relative to the waiting list control group. Secondarily, efficacy is measured in terms of improved stress regulation. The efficacy will be examined by use of a parallel superiority randomized controlled trial (RCT) with a baseline, post-test after four weeks and follow-up assessment after six to eight weeks. The RCT includes two groups: an experimental group who play the serious game ‘You & I’ and a control group who will be placed on a waitlist. The method of this study is reported according to the Standard Protocol Items: Reccommendations for Interventional Trails (SPIRIT) Checklist (see Additional file 1).

Study population

A total of 172 adults with MBID, aged 18 years or above, will be recruited from the population of four Dutch care organizations that are specialized in disability care (Bartiméus, Ons Tweede Thuis, Cordaan and ASVZ). Furthermore, the possibility to participate will be mentioned on for example the website ‘www.socialerelatiesenict.nl’, on social media and at various meetings. So, it can occur that persons outside above mentioned organizations want to participate. These adults with MBID will also be included. A diagnoses of MBID (IQ ranging between 50 and 85) needs to be reported for instance by the care organizations where the participant receives care. Basic computer operation skills are eligible for participation in the study, just like having access to a computer and the internet. Adults need to give a written consent for participation in the study and, if necessary, also their legal representative. Excluded from participation in the study are adults who are deaf and/or blind or adults who have serious mobility impairments for whom computer operation is not possible.

Sample size calculation

Linear mixed effect modelling with two conditions and three repeated measures will be conducted to analyse the effect on mentalizing abilities and stress regulation. The sample size is estimated based on previous studies measuring mentalizing abilities and stress regulation among people with intellectual disabilities. Means and standard deviations were estimated. With an desired power of 0.90 and an alpha of .05, it is estimated that around 144 participants are needed, as calculated in GLIMMPSE [38]. Because there are three assessments, a drop-out of 20% will be taken into account. Thus, 172 participants will be recruited and randomized into two groups of approximately 86 participants in each group.

Study procedure and randomization

Individuals who sign up for the research via both the care organization as well as via the internet or via any other route and meet the inclusion criteria will receive an information brochure. Persons who want to participate in the study are asked to sign the consent form and return it to the researcher. In case of incapacitated participants, the legal representative of the participant are asked to sign a consent form and return this to the researcher.

Data collection for each participant takes 12 to 14 weeks. Participants will be assessed at: baseline (T0), post intervention (T1, five weeks after baseline), and follow up (T2, six to eight weeks after T1). During all three assessments, participants fill out a set of digital questionnaires (for all measurements, see Measures). The software program Qualtrics will be used to gather data through the digital questionnaires. Completing the questionnaires will take up to 90 minutes per assessment. Participants can fill out the questionnaires at home or in their care home. During all assessments, an independent researcher is present to assist the participants with the questionnaire. The researchers will follow a standard protocol on how to assist the participants.

After informed consent and baseline assessment, blind for intervention, participants will be individually randomized into two groups using stratified randomization in combination with block randomization with varying block sizes of 4 and 6. To ensure equality of the groups, randomization will be stratified with regard to care organization and intelligent quotient (IQ) (mild intellectual disability, i.e. IQ ranging from 50 to 70 and borderline intellectual disability, i.e. IQ ranging from 70 to 85). An independent researcher will produce the allocation schedule using a computerized random number generator and afterwards conceal the schedule for the researchers. Blinding is only possible by the baseline assessment and after that, both participants and the researchers know which group participants have been assigned to.

After randomization, participants within the experimental group will be offered the serious game ‘You & I’, while participants within the control group will be placed on a waitlist. Participants from the experimental group will be asked to play the serious game on their own computer device at home or on a computer device of their care home. They have to complete eight gaming levels within four weeks, playing the game twice a week. To remind the participants to play the game, they will receive an impersonal email twice a week asking them whether they already played the game. Participants adherence is not necessarily noted anywhere. Anonymous digital game statistics will measure the compliance of the participants (how often the computer game has been completed). After four weeks, post intervention

assessment is administered and six to eight weeks later, the participants complete follow-up assessment. Participants from the control group can play the serious game after they completed follow-up assessment.

Intervention

The intervention is a serious game called 'You & I' that focuses on the improvement of mentalizing abilities, including the regulation of stress. The second and last author in collaboration with adults with MBID and healthcare professionals developed the serious game. The serious game 'You & I' is based on the attachment theory [39], the practice-oriented book 'Mentalization in clinical practice' (in Dutch: Mentaliseren in de klinische praktijk) by Allen, Fonagy & Bateman [14] and the practice-oriented book 'Mentalization can be learned' (in Dutch: 'Mentaliseren kan je leren') by Dekker- van der Sande & Sterkenburg [3]. The participant with MBID can play the game independently 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 learns 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 [13]. Table 1 provides an overview of the themes and the domains of mentalization that are covered in each particular level. The first six gaming levels each cover a different domain of mentalization and levels seven and eight are so-called 'booster levels', implementing and repeating all domains of mentalization.

Measures

All data will be collected through computerized assessments at baseline, post-intervention and follow-up assessment. Participants can fill out the digital questionnaires at home or in their care home. When needed, participants will receive support of an independent researcher, who will be present during all assessments and who will follow a standard protocol on how to assist the participants. Figure 2 provides an overview of the measures and time of assessment.

Demographic variables

Minimal Dataset (MDS, T0)

To measure demographic variables, the minimal dataset (MDS) 'Basic MDS' and 'Basic MDS for adults with an intellectual disability' will be used, including the Personal Wellbeing Index – Intellectual Disability (PWI-ID) [40][41]. The MDS is a set of questions on demographic variables for everyone who collects data of persons with intellectual disabilities. The MDS focuses on questions in the following domains: personal factors, personal development and personal well-being. The questionnaire consists of 32 item. The first item of every subscale is: 'What is your date of birth?' (personal factors), 'What is the global IQ score?' (personal development) and 'How happy are you about your life in general?' (personal wellbeing).

Social Validity Scale (SVS, T0, T1)

The SVS [42] is a questionnaire consisting of 15 questions measured on a 5-point Likert scale to assess the desirability, applicability, clarity and efficiency of the intervention procedure. In this study, the scale will be used as described by Janssen, Riksen-Walvraven, & Van Dijk [43] and Jonker, Sterkenburg, & Van Rensburg [44]. During baseline assessment participants answer questions concerning their expectations of the serious game 'You & I' at the post intervention assessment questions concerning their experiences with playing the game.

Autism Spectrum Quotient (AQ-10, T0)

The AQ-10 [45] measures the degree to which adults with average intelligence exhibit autistic traits. The self-report questionnaire consists of 10 items measured on a 4-point Likert Scale with scores ranging from *definitely agree* (1) to *definitely disagree* (4). The first items of the measure are: 'I often notice small sounds when others do not' and 'I usually concentrate more on the whole picture, rather than the small details.' Within a normal developing population, the ASD performs well at discriminating between individuals with and without a clinical diagnosis of autism spectrum disorder [46]. The AQ-10 has not yet been used for adults with intellectual disabilities. Therefore, the items were adapted for persons with MBID. The adaptations were made by three authors (SW, MW, PS) and checked by collaborating researchers with MBID.

Mentalization

The primary outcome measure of this study is mentalizing abilities. Several questionnaires will be used to measure mentalization.

The Reflective Functioning Questionnaire (RFQ, T0, T1, T2)

The RFQ [47] is a brief self-report screening measure of mentalizing abilities. It consists of 8 items measured on a 7-point Likert scale with scores ranging from *strongly disagree* (1) to *strongly agree* (7). The first three items are: 'People's thoughts are a mystery to me', 'I don't always know why I do what I do', and 'When I get angry, I say things without really knowing why I am saying them'. Psychometric properties are good in a normal developing population and in patients with personality disorders. For the purpose of this study, the measure was adapted for adults with intellectual disabilities by removing unnecessary wording and simplifying concepts. The adaptations were made by the first three authors and checked by

collaborating researchers with MBID. Moreover, eight experimental items from the RFQ-54 were added to the questionnaire. The instrument was translated to Dutch by the second author. Then, it was translated back to English by the last author. Where necessary adjustments were made. Any ambiguity was discussed in mail conversation with the developers of the instrument. Therefore existing psychometric property data did not apply.

Radboud Faces Database (RaFD, T0, T1, T2)

The RaFD [48] is a set of pictures depicting different emotional expressions and is used to assess emotion recognition as a part of mentalization. Participants have to view 60 color photographs of unfamiliar faces portraying ten different Caucasian and Moroccan adults each displaying five emotions (anger, fear, happiness, sadness and neutral). A selection of 50 photographs has been made based on the percentage of agreement on emotion categorization, mean intensity, mean clarity, mean genuineness of the emotion and mean valence of the photograph [48]. The pictures include averted gaze orientations (left and right) as well as direct gaze orientations (frontal). Participants have to indicate for each photograph which one of five emotions the adult depicts. The RaFD has good psychometric qualities in a normal developing population with an average expression agreement between chosen and targeted emotions of 82% (median 88%, *SD* 19%) [48].

Subscale Perspective Taking (PT) of the Interpersonal Reactivity Index (IRI, T0, T1, T2)

The IRI [49] is a multidimensional tool measuring interpersonal reactivity. The self-report questionnaire consists of 28 items measured on a 5-point Likert scale with scores ranging from *does not describe me well* (1) to *describes me very well* (5). The measure has 4 subscales, each made up of 7 different items. In this study, only the PT subscale will be used. The PT subscale measures the tendency to take the psychological point of view of others. The first three items are: ‘I sometimes find it difficult to see things from the "other person’s point of view’, ‘I try to look at everybody's side of a disagreement before I make a decision’ and ‘I sometimes try to understand my friends better by imagining how things look from their perspective’. The reliability of the subscale is good with Cronbach’s α of .73 [50]. A modification of the subscale has previously been used in research on adults with moderate or mild intellectual disabilities, which also indicated adequate reliability for this population with Cronbach’s α of .71 [51].

Frith Happé Animations Test (T0, T1, T2)

The Frith-Happé Animations Test is added because this measure has been previously used with children with intellectual disabilities [52]. It is a non-verbal task to measure mentalizing abilities and therefore it is a good addition to the other verbal questionnaires. The Frith Happé Animations Test [52] consists of a series of computer-presented animations, lasting 34-45 seconds each. All animations feature one large red and one small blue triangle moving around the screen. There are three types of animations. First, Theory of Mind (ToM) animations in which it is suggested that the triangle anticipates or manipulates the ‘mental state’ of the other. Second, goal-direct action (GD) animations in which the interaction between

the triangles can be described in terms of behavioral interaction. Third, random (Rd) animations in which the triangles purposelessly move around without reference to interactions, goals or intentions.

After each animation participants were asked: 'What was happening in the animation?' Verbal descriptions are recorded and scored for complexity of mental state terms used (i.e. intentionality; 0-3) and accuracy of the answer given (i.e. appropriateness; 0-2). Participants are presented with two practice animations (GD and ToM) to ensure they understand the task.

Stress Regulation

The secondary outcome measure of this study is stress regulation.

Lifestress Inventory (LI, T0, T1, T2)

The LI [53] is a 30-item self-report questionnaire which can be used to measure general worry, negative interpersonal interactions and competency concerns. Participants are first asked to indicate whether they have experienced a stressor. If they do not, participants move on to the next item. If they do, they select one of four answers to indicate the impact of the stressor, ranging from no stress (1) to a great deal of stress (5). The first three items are: 'Do people treat you as though you are different?', 'Have you been getting on with your partner/girlfriend/boyfriend?' and 'Have you heard people you know arguing?'. The LI is suitable and has been validated for administration of people with ID, with a Cronbach alpha of .85 [53].

Perceived self-efficacy scale (stress, T0, T1, T2)

This is a short 9-item questionnaire which can be used to measure perceived self-efficacy regarding stress regulation. The questionnaire is designed by the researchers of this study and is specifically focused on the skills that have been learned in the serious game 'You & I'. Self-efficacy is concerned with people's belief in their capabilities, in this case stress regulation. We expect that if people believe that they are better in stress regulation, this will lead to a better stress regulation. This scale is very short and non-invasive. Participants are asked on a scale from 0 (not at all sure) to 10 (very sure) how certain they are about things they can do, know and feel. The first three items are: 'Feel in my body when I have stress', 'Deal with stress well' and 'Know that I have stress'.

Data analysis

All statistical analysis will be conducted using SPSS version 24.0. Partial intention-to-treat analysis will be performed: if data is missing at two measurement moments, the participant will be excluded from the analysis. All other participants who have been randomized will be included in the analysis.

Descriptive statistics will give insight in the characteristics of the participants. Demographic variables are used to test for differences in baseline characteristics between the experimental and control group. If necessary, results will be controlled for these differences. For social validity, average item scores are reported.

Primary and secondary outcome measures of the study (i.e. mentalizing abilities and stress regulation) will be assessed using linear mixed effects modeling. With Subject at the highest level and Group and Time and the Group x Time interaction will be entered as fixed effects, a mixed model fits in SPSS. Before running the analysis, it is checked whether the statistical assumptions are met. Furthermore, there will be controlled for compliance through anonymous digital game statistics (how often the computer game is completed) and it is tested whether there is dependency, for example for care organization.

Data Management and monitoring

Data will be collected using online survey software Qualtrics. Computerized data will be stored on a secured server of the Vrije Universiteit Amsterdam. The participant's privacy is guaranteed by assigning a unique identification number to every participant. Data will be processed using these identification numbers. All researchers who will work with the research data will sign a non-disclosure agreement, stating they will not share personal details of participants with a third party. The handling of the data will comply with the Dutch Personal Data Protection Act (in Dutch: De wet Bescherming Persoonsgegevens). A data management plan was submitted and accepted by the funding organization of the study (ZonMw), project number 845004004. This study is also embedded in the Amsterdam Public Health (APH) research institute. The quality committee of APH offers a handbook to safeguard the quality of the research and performs random audits.

Ethical considerations

The Medical Ethics Committee of the VU University Medical Center in Amsterdam, the Netherlands approved the study protocol (METc VUmc 2018.007, NL60353.029.17). Potential future changes to the study will be proposed to the Medical Ethics Committee as amendments, and will be described and discussed in publications of this study hereafter.

Discussion

This paper describes the study protocol of a parallel superiority randomized controlled trial for examining the effectiveness of the serious game 'You & I' in improving mentalizing abilities, including the regulation of stress, in adults with MBID. Participants in the experimental condition are offered to play 'You & I' for a duration of four weeks, while participants in the control condition are placed on a waitlist. It is hypothesized that participants in the experimental condition will show significant improvement in mentalizing abilities compared to participants from the waitlist control condition, as the experimental group is offered to play a serious game that is tailored for its specific purpose.

A unique feature of this study is the use of a serious game for the improvement of mentalizing abilities. This study is among the first to use a serious game specifically targeted at mentalizing abilities, particularly in adults with MBID. Serious games are promising within the healthcare for persons with intellectual disabilities since it can strengthen abilities and knowledge in an entertaining manner. Serious games can save costs and are noninvasive, easily applicable at home and require only the use of a

computer and internet access [54][36]. Consequently, implementation is straightforward and low in costs compared to real-life interventions such as mentalization-based therapy. If this study shows that the serious game has a positive effect on the abilities of the participants, serious games have the potential to become a standard service in the healthcare for persons with MBID.

In addition to an innovative psychological intervention, the study incorporates a large group of participants from a less frequently studied population. Only little research has been carried out on adults with MBID, while they actually represent the largest group within the population of persons with intellectual disabilities [55]. A randomized controlled trial with a large sample size is especially exceptional in this field of research. In this study, participants are recruited in close collaboration with four Dutch care organizations. Thus, if the serious game 'You & I' appears to be efficacious, the game can be instantaneously implemented as a component of already offered services for adults with MBID.

Participants who will be included in this study are recruited from a wide range of the population of adults with MBID. Only a few persons will be excluded from this study (i.e., persons who are deaf and/or blind, persons who cannot operate a computer, persons younger than eighteen). Hence, participants may be diagnosed with other comorbid disorders such as autism or borderline personality disorder, have different ethnic backgrounds, come from different socioeconomic situations and may have varying ages. This wide inclusion of participants has both advantages and disadvantages. The advantage is that external validity becomes a strong aspect of this study. The results will be easily generalizable to the population of MBID. Nevertheless, the disadvantage of little exclusion criteria is that the effects of this study may be smaller than expected, as the sample will be more heterogeneous.

Another limitation of this study is the use of measures that have not been specifically validated for the targeted population. As research on adults with MBID is scarce, little measures have been developed to study this population, especially when it comes to mentalizing abilities. Therefore it is possible that the questionnaires will be influenced by language abilities of the participants [56]. To overcome this limitation, for both the primary as well as the secondary outcome, both a verbal and a non-verbal measure have been selected, decreasing the chance of the results being confounded by the participants' vocabulary competence. Furthermore, some questionnaires have been adapted to make them more suitable for the population, minimizing the possible effect of language on the results. Other researchers might use the results on the measures in future research so that measures for this population can be further developed.

In conclusion, the present study is expected to provide valuable insight into the efficacy of the serious game 'You & I' for adults with MBID. If the intervention is efficacious, the serious game can be implemented on a broad-scale in the care organizations for people with intellectual disabilities. This may mean that fewer persons with MBID will suffer from problems related to mentalization deficits, such as social problems. Possibly this may lead to less social problems and more social inclusion of persons with MBID.

Abbreviations

MBID: Mild to borderline intellectual disabilities

MBT: Mentalization-Based Treatment

Declarations

Status of the trial

Protocol version 1, dated 18 January 2019. After being granted permission by the Medical Ethics Committee of the VU University Medical Center in Amsterdam, the first participants were included in September 2018. Currently, data is being collected, which will expectedly end at the end of July 2019. The main results are expected to be published at the end of 2019 or the beginning of 2020.

Ethics approval and consent to participate

The research was approved by the Medical Ethics Committee of the VU University Medical Center in Amsterdam, file VCWE 2018.007. Prior to data collection, informed consent will be obtained from all participants.

Consent for publication

In this manuscript, no data of individual persons are used.

Availability of data and materials

The dataset generated and/or analyzed during the current study will be available from the corresponding author on reasonable request.

Competing interests

Two authors of this paper are also authors of the intervention that is tested in this study. The research team commits reporting the trail findings without regard to outcome. The research funder will have no role in the study design, data collection, management, data analysis and interpretation, writing of subsequent reports, or decision to submit reports for publication.

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Authors' contributions

SW, SD, MW, CS and PS made substantial contributions to the conception and design of the study. SW and PS designed the intervention and started the implementation. SD coordinates the recruitment of the participants and data collection during the study. SW and SD drafted the present manuscript, and MW, PS and CS provided suggestions for the improvement of the manuscript. All authors read and approved the final manuscript and agreed both to be personally accountable for the author's own contributions and ensured that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

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Tables

Table 1 - Overview of themes and domains of mentalization for each level of the serious game ‘You & I’

Level nr.	Theme of the level	Dimensions of mentalization
1	The self	Cognitions & affections
2	Others	Cognitions & affections
3	Affective aspects	Affections, self & others
4	Cognitive aspects	Cognitions, self & others
5	Explicit functioning	Cognitions, affections, self & others
6	Implicit functioning	Cognitions, affections, self & others
7	Booster level	Cognitions, affections, self, others, implicit & explicit functioning
8	Booster level	Cognitions, affections, self, others, implicit & explicit functioning

Figures

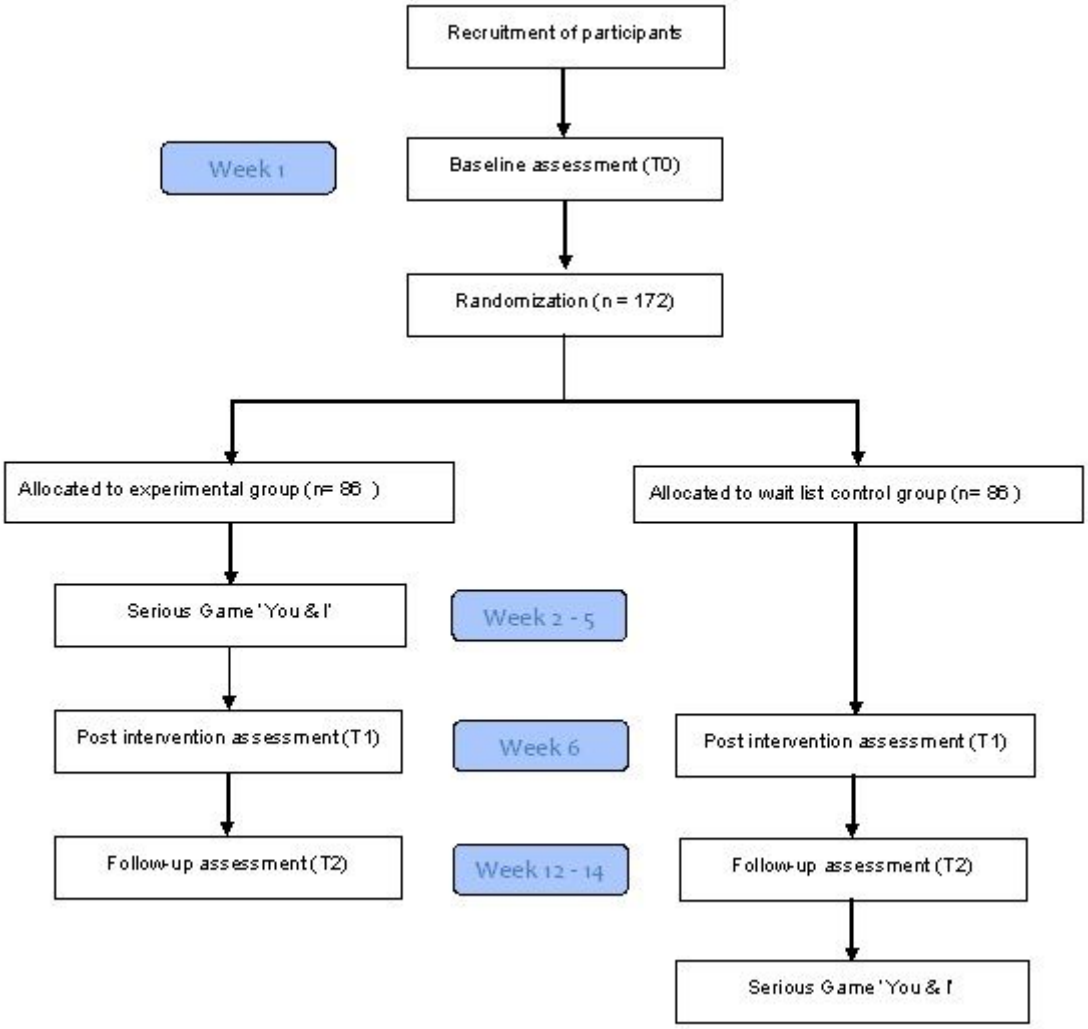

Figure 1

Overview of the study timeline.

	Enrolment	Allocation	Post-allocation	Close-out
TIMEPOINT	-T1	T0	T1	T2
ENROLMENT:				
Eligibility screen	x			
Registration	x			
Informed consent		x		
Allocation		x		
INTERVENTION:				
Serious Game 'You & I'		⟷	⟷	
ASSESSMENTS:				
Minimal Dataset (MDS)		x		
Autism Spectrum Quotient (AQ-10)		x		
Social Validity Scale		x	x	
Mentalization		x	x	x
Stress Regulation		x	x	x

Figure 2

Schedule of enrollment, allocation, intervention and assessments.

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