The effectiveness of game-based meditation therapy for traumatized adolescents in residential care: a randomized controlled trial (PREPRINT).

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Abstract

Aim: Many adolescents in residential care have experienced traumatic events and suffer from posttraumatic stress. This study examined the effectiveness of *Muse*, a game-based meditation intervention, as an addition to treatment as usual (TAU) for traumatized adolescents in residential care.

Methods: Seventy-seven traumatized adolescents (10 – 18 years old) received either *Muse* and TAU (n = 37) or treatment as usual alone (n = 40). TAU consisted of evidence-based treatments that did not specifically target posttraumatic symptoms. Outcomes were measured at T1, T2, and two-months follow-up (FU). Primary outcomes were posttraumatic symptoms (self-report and mentor-report) and stress (self-report) at T2. Secondary outcomes included anxiety, depression, and aggression at T2, and all outcomes at follow-up.

Results: The *Muse* group showed significantly greater improvements than the control group at T2 regarding self-reported posttraumatic symptoms, stress, anxiety, depression, and aggression. Mentor reports showed marginally significant decreases in posttraumatic stress at T2. There were no differences between the groups at FU, except for a marginally significant difference in self-reported posttraumatic symptoms, where the *Muse* participants showed larger decreases.

Conclusions: Game-based meditation therapy is a promising intervention that is more effective than treatment as usual alone. Implications of these findings for the role of game-based meditation interventions for traumatized adolescents in residential care are discussed.

Key words: Adolescents; Intervention; Meditation; Post-traumatic stress; RCT; Trauma

Introduction

Over 90% of institutionalized adolescents have been exposed to traumatic experiences at a young age. These include domestic violence, neglect or sexual, physical, or emotional abuse, and these different types of traumatic events frequently co-occur (Collin-Vézina et al., 2011). Often, these events occur in the primary caregiving environment. Caregiver support is a key factor for adolescent attachment, resilience, and stress adaptation, and thus, trauma can have a profound impact on adolescent function, leading to posttraumatic symptoms, including nightmares, flashbacks, and an ongoing feeling of alertness and hypervigilance (Cook et al., 2005). These symptoms increase the risk of psychological and behavioral problems (e.g., anxiety, depression, anger), sexual risk behavior and victimization, and delinquency (Collin-Vézina et al., 2011; Smith et al., 2006). The traumatization is more severe and pervasive if the traumatic event lasts for a longer period and as the number of traumatic events cumulate (Collin-Vézina et al., 2011).

Adolescents with a mild intellectual disability (MID) are especially vulnerable to experiencing traumatic experiences (Mevissen & de Jongh, 2010; Reiter et al., 2007). Among all the adolescents in residential institutions, 20-25% are diagnosed with an MID (Van Nieuwenhuizen, 2010). Adolescents with a MID have problems with social functioning and have a lower IQ compared to their typically developing peers. This makes these adolescents more likely to experience traumatic events, in particular physical and sexual abuse (Reiter et al., 2007). They are also more vulnerable to the adverse effects of trauma, since they lack the ability to cope with traumatic events. In addition, their limited capacities complicate treatment effectiveness (Mevissen & de Jongh, 2010).

Despite the high prevalence of traumatized adolescents in residential care and the devastating effects of trauma on their development (Van der Kolk, 2005), trauma often goes untreated. Trauma-focused treatments, such as cognitive behavioral therapy (CBT) and eye

movement desensitization and reprocessing (EMDR) are effective (Leenarts et al., 2013), but include exposure techniques and rely mostly on verbal expression and the regulation of cognition, emotions, and physiology (Warner et al., 2013). Yet, traumatized adolescents, and in particular those with an MID, often lack the capacity to control and regulate their impulses and emotions (Cook et al., 2005; Van der Kolk, 2005). Moreover, residential institutions tend to provide stressful living environments where instability, uncertainty, and a lack of trust impede the development of a therapeutic relationship and treatment progress (Cohen et al., 2012). Also, adolescents in residential institutions usually have had a substantial number of prior placements with concomitant therapies that did not work out for them (Baker & Curtis, 2006). As a result, the adolescents tend to doubt the value of therapy and are less motivated for future treatments (Greenwald, 2006). However, without the appropriate treatment, the adverse effects of the trauma are likely to continue over time (Hiller et al., 2016). Thus, this situation creates an evident need for additional or alternative forms of trauma treatments.

A novel approach that has recently gained popularity in the treatment of posttraumatic stress is mindfulness-based meditation intervention. Meditation-based approaches are thought to address emotional under- and overregulation, which are both core features of posttraumatic stress (e.g. hyperarousal or emotional numbing) (Boyd et al., 2018). There is little research on this topic among adolescents, but many studies among traumatized adults show reduced levels of posttraumatic stress and low dropout rates (Boyd et al., 2018). In addition, a recent feasibility study demonstrated the potential of a new innovative form of game-based meditation therapy (Angela A.T. Schuurmans et al., 2020). Therefore, in the present study, we aimed to test the effectiveness of *Muse*, which is a game-based meditation intervention, for traumatized adolescents in residential care.

Game-based interventions are a novel strategy to engage adolescents into treatment by making use of their intrinsic motivation to play games (Granic et al., 2014). Game-based bio-

or neurofeedback interventions among adolescents in residential care reported improved emotion-regulation, high user satisfaction, and low attrition (Kahn et al., 2009, 2013; Angela A.T. Schuurmans et al., 2015, 2018, 2020). These are promising results, because adolescents in residential care usually lack motivation for behavioral change (Van Binsbergen, 2003). which is a key predictor of treatment effectiveness (Harder et al., 2012). Moreover, learning by play a game suits adolescents better than didactic modes of learning (Vygotsky, 1978). which underlie most forms of traditional treatment (Weisz & Kazdin, 2010), and this is particularly true for those with an MID (Evmenova & Behrmann, 2011). The in-game environment offers the adolescents the opportunity to practice with acquired techniques, thereby promoting long-term learning and automatization into their daily lives (Rosas et al., 2003). The neurofeedback element of *Muse* provides the adolescents with real-time reports of their physical activity and rewards them each time they succeed in regulating their physical stress. This method of operant conditioning reinforces relaxation abilities and can reduce posttraumatic stress (Panisch & Hai, 2018).

The current study utilized a randomized controlled trial (RCT) to evaluate the effectiveness of *Muse* as an addition to treatment as usual (TAU) in traumatized adolescents with and without a MID in residential care. We predicted that playing *Muse*, as an addition to TAU, would result in a greater reduction of posttraumatic symptoms and stress compared to TAU alone (primary outcomes). We also hypothesized that playing *Muse* would lead to reduced anxiety, depression, and aggression, as well as improved executive functions (secondary outcomes).

Methods

The trial was registered in the Netherlands Trial Register under ID NL6689; NTR6859 and ethical review and approval were provided by the medical-ethical committee Arnhem-Nijmegen under protocol NL58674.091.16. Pre-registered primary outcomes were posttraumatic symptoms (self- and mentor-report) and stress (self-report) at T2 (Schuurmans et al., 2020).

Design, setting, and procedure

The present study was a multicenter RCT that examined the effectiveness of *Muse* as an addition to TAU in reducing posttraumatic symptoms (self- and mentor-report) and stress (self-report), compared with TAU alone in traumatized adolescents in residential care.

We recruited participants from three residential institutions in The Netherlands that provide open and secured residential care for adolescents with and without MID. At admission to these institutions, the Children's Revised Impact of Event Scale (CRIES-13) (Verlinden et al., 2014) was administered and was used as a screening tool for adolescents with clinical levels of posttraumatic symptoms (score ≥ 30). We included participants based on clinically relevant symptoms rather than a diagnosis of post-traumatic stress disorder (PTSD) due to the underdiagnosis of PTSD (Miele & O'Brien, 2010). The inclusion criteria were as follows: (1) CRIES-13 score ≥ 30 ; (2) age 10 to 18 years; (3) being able to comprehend and speak Dutch; (4) active informed participant assent; and (5) active parental or legal guardian consent when the adolescents are under the age of 16. The exclusion criteria were as follows: (1) negative clinician advice, for example, when the participant already received other forms of treatment and the clinician feared that treatment burden would become too heavy (at this stage, the participants were not randomized yet, so this exclusion criterium equally affected both conditions); (2) simultaneous participation in another clinical

intervention study; (3) acute psychotic symptoms; and (4) a current or recent (within the last three months) trauma treatment, specifically EMDR or CBT. There were no restrictions for concomitant interventions not targeting posttraumatic symptoms (e.g., medication, individual or group therapy). We kept track of the concomitant interventions and used these as covariates in the analyses.

The baseline measurement (T1) was conducted prior to the intervention (week 1). The posttreatment measurement (T2) was conducted immediately after the intervention (week 8). The follow-up measurement (FU) was conducted two months after the T2 (week 16). Participants received a gift voucher of €15 at T1, a gift voucher of €10 and a small stress ball as a present at T2, and a gift voucher of €15 at FU. The participants' mentors filled in the mentor-reported questionnaires during the same week that the participants' measurements were assessed.

Intervention

Muse. The participants in the *Muse* condition received the *Muse* intervention in addition to TAU. *Muse* is a game-based meditation application that is played on an iPad with a brain-sensing headband that utilizes neurofeedback. The intervention consisted of two 15-20 minutes gameplay sessions a week for six consecutive weeks. *Muse* includes ten relaxation tutorials that resemble elements of CBT (e.g. deep-breathing techniques) (Weisz & Kazdin, 2010). Each of the tutorials was followed by a three-minute meditation session. The gameplay sessions were supervised by research assistants who were trained to explain the tutorials according to the protocol. The participants completed at least two tutorials and two meditation sessions per intervention session. The brain-sensing headband provided real-time neurofeedback that was reflected by the intensity of the activity in the in-game environment that participants had selected previously (e.g., beach or rainforest). When participant's mind

was calm, the environment showed calm and settled winds, but these winds picked up and blew when participant's mind became more active. After each meditation session, the participants received feedback on their performance in the form of points and awards. These were saved and tracked over time so that participants could see their progress. A more detailed description of the intervention can be found in the pilot study evaluating *Muse* (Schuurmans et al., 2020).

Control condition. The participants in the control condition received TAU, which was the treatment as recommended by their clinicians, regardless of this study (e.g., medication, individual or group therapy). The types of TAU included a range of evidence-based interventions, except for trauma-focused treatments.

Measures

Posttraumatic symptoms were measured as reported by the participants' self-reports and as reported by their mentors. The *Child Report of Posttraumatic Symptoms* (CROPS) (Greenwald & Rubin, 1999) is a self-report questionnaire that consists of 24 items that rate symptoms on a three-point scale of intensity ('none', 'some', or 'lots'). The *Parent Report of Posttraumatic Symptoms* (PROPS) (Greenwald & Rubin, 1999) is a questionnaire with 32 three-point items that measures posttraumatic symptoms as reported by the parents or other caretakers. In this study, the participants' group home mentors filled out the questionnaire. The validity and reliability of both questionnaires was previously demonstrated (Greenwald et al., 2002).

Stress was examined using the seven-item 'stress' subscale from the *Depression Anxiety Stress Scales* (DASS-21) (De Beurs et al., 2001). The DASS-21 is a self-report

questionnaire that consists of 21 four-point items that range from ‘never’ to ‘almost always’. It has good validity and reliability, and the subscales have an excellent internal consistency (De Beurs et al., 2001).

Anxiety was measured using the seven-item ‘anxiety’ subscale from the DASS-21 (De Beurs et al., 2001).

Depression was measured using the seven-item ‘depression’ subscale from the DASS-21 (De Beurs et al., 2001).

Aggression was measured using the participants’ self-report as well as the mentor-reports. The *Reactive and Proactive Aggression Questionnaire* (RPQ) (Cima et al., 2013) is a self-report questionnaire that is composed of 23 three-point items ranging from ‘never’ to ‘often’. The RPQ consists of the subscales ‘proactive aggression’ and ‘reactive aggression’. Its validity and reliability are good, and both subscales have a good internal consistency (Cima et al., 2013). The *Parent-rating scale for Reactive and Proactive Aggression* (PRPA) (Kempes et al., 2006) is a questionnaire that is filled out by parents or other caretakers. The PRPA has eleven three-point items ranging from ‘never’ to ‘often’ and consists of the subscales ‘reactive aggression’ and ‘proactive aggression’. The PRPA total score and both its subscale scores have good validity (Kempes et al., 2006).

Motivation was assessed using the Intrinsic Motivation Inventory (IMI) (McAuley et al., 1988). The IMI consists of 37 seven-point items, including the following subscales: ‘interest/enjoyment’; ‘perceived competence’; ‘pressure/tension’; ‘value/usefulness’;

‘perceived choice’; and ‘effort’. The psychometric properties of the IMI show an adequate reliability and good validity (McAuley et al., 1988).

Randomization and masking

The participants were randomly allocated (1:1 ratio) into two conditions. The Python script randomization was executed by the first author and stratified by gender and MID (MID versus no MID) to ensure equal ratios in both conditions. The allocation of the conditions was not masked. It was not feasible to blind participants or mentors, but they were not informed about the specific hypotheses and were only told that *Muse* was designed to help participants cope with general stress.

Sample size calculation

The power calculation were performed using the program G*Power (Faul et al., 2007). An a priori power analysis for ANOVA: repeated measures, within-between interaction was conducted. Based on previous interventions for posttraumatic stress (Boyd et al., 2018; Kim et al., 2013; Panisch & Hai, 2018; K. Reiter et al., 2016), we expected a small-to-medium effect size of $d = 0.30$ and a repeated measures correlation of 0.60. To achieve a statistical power of at least 0.80, a sample size of 72 participants at T2 was required. We aimed at including 80 participants in total to allow for 10% attrition, as estimated from previous studies evaluating game-based interventions in this population (Schuurmans et al., 2015, 2018, 2020).

Statistical analyses

Our primary outcomes were immediate intervention effects on posttraumatic symptoms (self- and mentor-report), stress (self-report), and a clinical change in posttraumatic symptoms (self-report) at T2. The secondary outcomes were the long-term intervention effects on

posttraumatic symptoms (self- and mentor-report) and stress (self-report) at FU and the immediate and long-term intervention effects on anxiety (self-report), depression (self-report), aggression (self- and mentor-report), and executive functions (mentor-report) at T2 and FU.

The outcome data were missing for 5% of the self-reports and 14% of the mentor-reports at T2 and for 35% of the self-reports and 36% of the mentor-reports at FU. A logistic regression analyses indicated that the data were missing at random. The missing data were imputed using full information maximum likelihood estimation for Markov Chains (Graham, 2009) Both intention-to-treat analyses and completers-only analyses were conducted.

We calculated the descriptive statistics for the participants' demographic and clinical characteristics. To assess potential differences between the conditions at baseline, t-tests and chi square tests were conducted. To examine the intervention effect on our main outcome variables, we used a mixed-model repeated measures analysis of variance with time as within-groups factor and condition as between-groups factor. The analyses were conducted comparing the change from T1 to T2 and from T1 to two-months FU. In order to estimate the effect size, the partial eta squared (η^2p) was derived. Covariates included age, gender, IQ, type of residential care (open versus secured), medication use, and concomitant therapy.

The analyses showed a significant interaction between gender and intervention effectiveness. We conducted additional mixed-model analyses to evaluate gender as a potential moderator of the intervention effect on self-reported posttraumatic symptoms. This exploratory analysis was conducted among the participants in the intervention condition and included gender (male; female) and the baseline posttraumatic symptoms (low: ≤ 23 ; medium: 24-32; or high: ≥ 33). We included baseline scores to check whether it was gender that moderated the intervention effect or the differences in the baseline levels of the posttraumatic symptoms, since the females reported higher levels of posttraumatic symptoms compared to the males ($p = 0.036$).

Results

The recruitment of the participants took place between January 2018 and July 2019. Table 1 shows the demographic and clinical characteristics of the subjects. There were no significant differences at T1 between the two conditions based on the demographic or psychopathology variables.

As shown in Figure 1, 82 participants were enrolled in this study, of which 5 were transferred to another institution before the randomization, resulting in a sample size of 77 at baseline. Of these 77 participants, 73 (94.81%) completed the assigned intervention (TAU + *Muse* or TAU alone) and the T2 measurement. The two-months FU measurement was completed by 50 participants (64.94%).

Table 1. Demographic and diagnostic characteristics at baseline.

	<i>Muse</i> (n =38)		Control (n =39)	
Age (y), mean (SD)	14.93	2.63	15.31	1.91
Diagnosed ID, <i>n</i> (%)	16	42.11%	16	41.03%
IQ, mean (SD)				
Total sample	85.24	18.80	87.73	16.71
Sample no diagnosed ID	97.13	16.84	99.15	13.14
Subsample diagnosed ID	72.50	10.85	76.31	11.25
Gender, <i>n</i> (%)				
Male	23	60.53%	22	56.41%
Female	14	36.84%	16	41.03%
Transitioning			1	2.56%
Medication use	22	57.89%	19	48.72%
Concomitant therapy				

Animal assisted (e.g. dog, horse)	8	21.05%	5	12.82%
Creative (e.g. music, art)	4	10.53%	5	12.82%
Psychomotor therapy	7	18.42%	4	10.26%
CBT	4	10.53%	5	12.82%
Other individual therapy (e.g. emotion regulation/schema therapy)	4	10.53%	6	15.38%
Group therapy (e.g. resilience training)	1	2.63%	2	5.13%
Trauma- and stressor-related disorders				
PTSD	12	34.29%	10	28.57%
Reactive attachment disorder	14	40.00%	18	51.43%
Disinhibited social engagement disorder	0	0.00%	2	5.71%
ADHD/ADD	18	51.43%	21	60.00%
Neurodevelopmental disorders other than ADHD/ADD	4	11.43%	3	8.57%
Anxiety disorders	1	2.86%	1	2.86%
Autism spectrum disorders	13	37.14%	11	31.43%
Depressive disorders	2	5.71%	4	11.43%
Disruptive, impulse-control, and conduct disorders	12	34.29%	11	31.43%
Dissociative disorders	0	0.00%	1	2.86%
Obsessive-compulsive and related disorders	0	0.00%	1	2.86%
Comorbidity (>1 diagnosis)	25	71.43%	27	77.14%

Note. ADHD: attention-deficit/hyperactivity disorder, ADD: attention-deficit disorder, CBT: cognitive-behavioral therapy, ID: intellectual disability, PTSD: posttraumatic stress disorder, SD: standard deviation. One participant in the control condition was in an early stage of the

transitioning process from male to female. This participant was excluded in the gender interaction analyses. The data regarding the participants' diagnoses were retrieved from the file analysis. For 7 participants (Muse: $n = 3$, controls: $n = 4$), these data were missing. The percentages refer to the subjects who had complete diagnosis data.

Figure 1. CONSORT Diagram illustrating the flow of the participants through the study.

Primary outcomes

Table 2 shows the means and standard deviations for all the outcome variables per condition and the statistics of all the outcome analyses. Immediately after the intervention, the participants in the *Muse* condition reported lower levels of posttraumatic symptoms ($p < 0.001$) and stress ($p = 0.027$) compared to the participants in the control condition. The decrease in posttraumatic symptoms, as reported by their mentors, was marginally significant ($p = 0.074$).

Secondary outcomes

For all the self-reported secondary outcomes, we found a significant intervention effect at T2. The participants who played *Muse* reported decreased anxiety ($p = 0.004$), depression ($p = 0.004$), reactive aggression ($p = 0.039$), and proactive aggression ($p = 0.012$) compared to the participants in the control condition. None of the mentor-reported secondary outcomes, including aggression and executive functions, showed a significant intervention effect (See Table 2).

The long-term intervention effect on self-reported posttraumatic symptoms was marginally significant ($p = 0.052$) at FU. The effects on other outcomes were not maintained after two months (See Table 2).

Table 2. Psychopathological outcomes at baseline, posttreatment, and two-month follow-up.

	Descriptives		Statistical outcomes					
	<i>Muse</i>		Control condition					
	Mean	SD	Mean	SD	<i>F</i> (<i>df</i>)	<i>p</i>	η^2p	
Baseline (T1)								
Posttraumatic symptoms (SR)	26.03	9.74	23.92	9.87				
Stress (SR)	9.10	4.81	8.75	4.66				
Anxiety (SR)	6.25	4.11	5.30	3.28				
Depression (SR)	6.49	5.58	5.50	4.51				
Reactive aggression (SR)	12.05	4.70	11.83	4.21				
Proactive aggression (SR)	4.51	5.28	3.50	3.39				
Posttraumatic symptoms (MR)	27.58	9.76	26.08	10.52				
Reactive aggression (MR)	3.14	2.65	3.33	2.53				
Proactive aggression (MR)	6.97	3.91	6.40	2.92				
Executive functions (MR)	63.88	26.68	60.09	28.69				
Posttreatment (T2)								
Posttraumatic symptoms (SR)	19.40	10.64	24.54	8.85	21.64 (1, 75)	< .001	.22	
Stress (SR)	6.61	4.41	8.21	4.57	5.00 (1, 75)	.027	.06	
Anxiety (SR)	4.14	4.38	5.61	9.18	9.18 (1, 75)	.004	.11	
Depression (SR)	4.42	3.98	5.87	5.19	9.01 (1, 75)	.004	.11	
Reactive aggression (SR)	8.17	5.02	10.05	3.91	4.49 (1, 75)	.039	.06	
Proactive aggression (SR)	2.07	2.96	3.56	4.58	6.78 (1, 75)	.012	.08	
Posttraumatic symptoms (MR)	24.85	9.39	27.43	10.05	3.30 (1, 75)	.074	.04	
Reactive aggression (MR)	3.61	2.70	3.84	2.68	.030 (1, 75)	.885	.00	
Proactive aggression (MR)	6.83	3.10	6.82	3.12	1.24 (1, 75)	.290	.02	

Executive functions (MR)	63.24	27.68	63.40	30.41	.42 (1, 75)	.522	.01
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Follow-up (FU)							
Posttraumatic symptoms (SR)	18.57	7.53	20.54	7.76	6.18 (1, 75)	.052	.07
Stress (SR)	6.63	4.31	7.22	3.40	.80 (1, 75)	.401	.01
Anxiety (SR)	3.97	3.83	4.34	2.58	2.57 (1, 75)	.151	.03
Depression (SR)	3.55	4.48	4.10	3.13	1.88 (1, 75)	.189	.02
Reactive aggression (SR)	7.69	4.49	8.85	3.33	1.70 (1, 75)	.240	.02
Proactive aggression (SR)	2.07	2.96	3.56	4.58	6.76 (1, 75)	.183	.03
Posttraumatic symptoms (MR)	24.03	8.32	24.44	8.45	1.08 (1, 75)	.329	.01
Reactive aggression (MR)	3.54	2.60	3.67	2.45	.16 (1, 75)	.709	.00
Proactive aggression (MR)	6.73	3.14	6.96	2.73	1.97 (1, 75)	.183	.03
Executive functions (MR)	63.01	21.50	61.56	21.65	.17 (1, 75)	.687	.00

Note. MR = mentor-report, SR = self-report. The completers-only analyses showed minimal differences and led to the same statistical outcomes.

Exploratory analyses

No significant interaction between gender and baseline level of posttraumatic symptoms was found ($p = 0.510$). The main effects of both gender ($F = 5.26$ (1, 28), $p = .030$, $\eta^2p = .16$) and baseline posttraumatic symptoms ($F = 6.38$ (1, 28), $p = .005$, $\eta^2p = .31$) were significant (See Table 2). Specifically, although both groups experienced significant symptom reduction, the intervention effect was stronger for males than for females. Also, a stronger effect was found for the participants who reported higher levels of posttraumatic symptoms at baseline versus those with relatively lower levels of posttraumatic symptoms.

Motivation

Table 3 shows the means and standard deviations for the IMI outcomes. Since the intervention outcomes were moderated by gender, we provided motivation scores for the total sample and for the males and females separately. The analyses showed a significant difference between males and females with regard to interest/enjoyment ($t(31) = 2.49, p = 0.018, \eta^2 = 0.17$), indicating that playing *Muse* was enjoyed more by males than by females. No difference was found for the total score and other subscales of the IMI.

Table 3. Intrinsic Motivation Inventory outcomes for the participants who played *Muse*.

	Total sample		Males		Females	
	Mean	SD	Mean	SD	Mean	SD
Total score	136.64	32.24	143.00	22.13	126.84	4.73
Interest/enjoyment*	23.27	8.87	26.15	7.52	18.85	9.24
Perceived competence	25.52	10.85	26.85	10.27	23.46	11.81
Pressure/tension	19.30	4.50	19.90	3.93	18.38	5.28
Perceived choice	37.15	6.88	39.35	3.91	33.77	9.04
Effort	23.21	6.54	23.70	6.18	22.46	7.24
Value/usefulness	31.45	12.04	33.20	10.73	28.77	13.83

Note: SD: standard deviation. *Significant gender difference ($p < 0.05$).

Discussion

The present study evaluated *Muse* as a game-based meditation intervention for traumatized adolescents in residential care. The primary aim of this RCT was to test the immediate intervention effects on posttraumatic symptoms and stress. As predicted, the results indicated

that the participants who played *Muse* reported reduced levels of posttraumatic symptoms and stress compared to the participants in the control group. The mentor-reports showed only a marginally significant decrease in posttraumatic symptoms. At two-months follow-up, the participants in the *Muse* condition reported marginally significant lower levels of posttraumatic symptoms compared to the controls. Taken together, these results show that *Muse*, in addition to TAU, is more effective than TAU alone for traumatized adolescents in residential care, although caution is warranted with conclusions regarding the long-term effects and mentor-reports.

Secondary outcomes included the immediate intervention effects on anxiety, depression, reactive aggression, proactive aggression, and executive functions. We found larger decreases in self-reported anxiety, depression, reactive aggression, and proactive aggression for the participants in the *Muse* condition compared to those in the control condition. The mentor-reported results on reactive aggression, proactive aggression, and executive functions showed no differences between the conditions. The inconsistencies between the self-reports and the mentor-reports might be caused by differences in the perception of the adolescents themselves and their group home mentors. Many studies in residential youth care have reported differences in adolescent self-reported outcomes and those reported by their mentors (Bastiaansen et al., 2004; Grills & Ollendick, 2003; Schuurmans et al., 2018). One suggested explanation is that group care workers are more critical in adolescent progress assessments, which keeps them from noticing changes (Knorth et al., 2008). Thus, the mentors may not have noticed the expected improvements among the participants in the *Muse* condition.

Other secondary outcomes included long-term intervention effects measured two months after the intervention had ended. After two months, the intervention effect was only maintained on self-reported posttraumatic symptoms. However, caution is warranted

regrading this finding, since this effect only reached marginal significance ($p = 0.052$). Improvements in psychopathology symptoms did not disappear after the posttreatment (T2) measurement. Instead, the participants' symptoms remained stable or were even more improved. Also, our exclusion criteria included trauma therapy before or at T1, but due to ethical concerns, we did not withhold these traumatized adolescents from further treatment after the intervention had ended. Thus, between the T2 and FU measurements, some participants received trauma therapy. This may explain the decrease in posttraumatic symptoms in the control group at FU and have biased our outcomes. Yet, our main outcome from the self-reported posttraumatic symptoms still showed marginal significant differences between the conditions at the two-months FU measurement with a small-to-medium effect size. Previously, a pilot study exploring the feasibility of *Muse* in a sample of five participants showed that playing *Muse* not only resulted in immediate reduced posttraumatic symptoms, stress, and anxiety, but that these effects were maintained at one-month follow-up (Schuurmans et al., 2020). Considering that effect sizes for long-term RCT outcomes on posttraumatic symptoms are usually small (Gutermann et al., 2017) and that our sample size was sufficient, but not very large, reaching marginal significance at two-months follow-up might indicate the long-term effect of *Muse* on posttraumatic symptoms.

The results from the exploratory analyses to evaluate the moderators indicated two potential moderators that need further discussion, namely gender and the baseline level of the posttraumatic symptoms. There are several possible explanations for the moderating effect of gender. First of all, it is established that videogame play is more popular among males than among females (Bonanno & Kommers, 2005). Motivation outcomes in this study showed that the males reported higher enjoyment with playing *Muse* than the females did, which could have led to a stronger intervention effect among the males, since motivation is a key predictor of treatment effectiveness (Harder et al., 2012). Another explanation for the moderating effect

of gender may be found in sex-specific psychological, cognitive and biological mechanisms. Males, for example, tend to use a more active coping style to effectively deal with stress (Olf et al., 2007). This may not only lead to a lower risk of posttraumatic stress in males, but also contributes to their improvement in posttraumatic symptoms. A second moderating effect was participants' initial level of posttraumatic symptoms. We found a stronger intervention effect for the participants who reported higher levels of posttraumatic symptoms at baseline versus those with relatively lower levels. This finding is hardly surprising, because there is the tendency of regression to the mean: average scores tend to go down in the groups with the highest initial scores and tend to go up in the groups with the lowest initial scores (Barnett et al., 2005).

The biggest strength of the current study is that, to our knowledge, this is the first full-scale RCT investigating the effect of a game-based intervention in a clinical context. This study was conducted among a high-risk sample of adolescents in residential (secure) care with clinical levels of posttraumatic symptoms. We did not exclude potential participants based on minimal IQ-score, comorbid disorders, such as autism, medication use, or concomitant forms of treatment (other than trauma-focused treatment), which is common practice and impedes the external generalizability of study results. Our study sample reflects the real-world population of adolescents in residential care and results require minimal translation to be implemented into clinical care.

Another particular strength is the use of a multi-informant approach with the participant's self-report as well as the mentor reports. Also, we included participants based on clinical levels of posttraumatic symptoms rather than a diagnosis of PTSD due to underdiagnosis (Miele & O'Brien, 2010). This need was illustrated by the characteristics of our sample: all participants were included based on clinically relevant posttraumatic symptoms, but only 28.57% (22 out of 77) were diagnosed with PTSD.

Importantly, we would like to discuss some of the limitations of this study. Both conditions received TAU, while the experimental condition received the *Muse* intervention as an additional treatment. Consequently, the participants who played *Muse* received extra individual attention compared to the control condition. An active control group would have controlled for this, but active control groups are only more rigorous when the participants in both conditions do not differ in their attention and expectations of improvement (Boot et al., 2013). Residential institutions have tight restrictions when it comes to casual gameplay, which made it impossible to implement a control group who played a game with no expected mental health benefits. We want to emphasize, however, that in the clinical setting, where this study was conducted, TAU included a wide range of evidence-based forms of treatment. The participants were only excluded if they already received treatment specifically targeting posttraumatic symptoms, so most of the participants received some form of concomitant treatment. This indicated that *Muse* effectively reduces a range of psychopathology symptoms, on top of the other treatments that were provided. Also, our aim was not to test the intervention's superiority over other forms of treatment, but to test whether the intervention was a beneficial addition to TAU, which makes TAU a valid control condition (Freedland et al., 2011).

Although the results of this study show the effectiveness of *Muse*, it remains open which aspect of the intervention ensured this effectiveness: the use of neurofeedback, the game-based format of the intervention, the relaxation tutorials, or other nonspecific effects. This is an avenue to pursue in future research.

To conclude, this randomized controlled trial shows that *Muse* is a promising intervention for traumatized adolescents in residential care. Immediately after the intervention, not only were posttraumatic symptoms and stress reduced, but anxiety, depression, and aggression were also decreased. Unfortunately, most of these improvements

were not maintained at follow-up, leaving substantial room for intervention improvement and a need for future research. Thus, while additional studies are warranted, the present study provides strong support for the addition of game-based meditation approaches to traditional trauma-focused interventions.

Acknowledgements

The authors wish to thank the Dr. Couvee Fonds and the Innovatiefonds Zorgverzekeraars for funding this study and the participants, group care workers and research assistants for their invaluable contribution.

Declarations

Funding

This study has been funded by two charitable foundations: the ‘Couvée-stichting (the Netherlands) and the ‘Innovatiefonds Zorgverzekeraars’ (the Netherlands).

Competing interests

The authors declare that they have no competing interests.

Availability of data and material

Our study sample consisted of clinical adolescents in residential care. Due to the vulnerability of this population, the ethical committee requested private storage of all data.

Code availability

The syntaxes used to produce the reported results can be requested by the first author.

Ethics approval

The ethics committee of the CMO Arnhem-Nijmegen approved the trial prior to the start of the study under protocol NL58674.091.16.

Consent to participate

We obtained verbal and written assent from all participants, and when they were younger than the age of 16, also written consent from their legal guardians. Before participants are included, they are informed about the study design including the randomization procedure and that they can quit study participation at any moment without disadvantages.

Consent for publication

Participants and legal guardians provided informed consent and assent for anonymous publication of their data.

Author contributions

AS: Conceptualization, Methodology, Data curation, Data analysis, Writing: Original draft preparation, Writing: review and editing.

KN: Conceptualization, Methodology, Supervision, Writing: review and editing.

AP: Conceptualization, Methodology, Writing: review and editing.

RS: Conceptualization, Methodology, Writing: review and editing.

RO: Conceptualization, Methodology, Data analysis, Supervision, Writing: review and editing.

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