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A novel virtual reality-based theory of mind intervention for outpatients with schizophrenia: A proof-of-concept pilot study

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Abstract

Schizophrenia is a severe and highly disabling mental illness. Although several pharmacological solutions are available to alleviate symptoms of schizophrenia, they do not seem to provide solution for accompanying social dysfunctions. To handle this unmet clinical need, many innovative interventions have been developed recently. Considering the promising results on this field and the development trend, characterized by the growing proportion of included interactive technology, our research team developed a novel virtual reality (VR)-based targeted theory of mind (ToM) intervention (VR-ToMIS) for stable outpatients with schizophrenia. VR-ToMIS is a nine-session long structured and individualized method that uses cognitive and behavioural therapeutic techniques in an immersive VR environment. Our study was a randomized, controlled pilot study. Twenty-one patients have been recruited and randomly allocated to either VR-ToMIS or passive VR condition. Patients assigned to passive VR condition could use the same VR software as the VR-ToMIS group, but without any interventions. Effects on psychiatric symptoms, neurocognitive and social cognitive functions, pragmatic language skills and quality of life were evaluated by using analysis of covariance. According to our results, VR-ToMIS was associated with improvements in negative symptoms, in one neurocognitive field (immediate memory), ToM and pragmatic language skills, but no significant change in quality of life scores was detected. Significant changes in VR-ToMIS group were associated with moderate to large therapeutic effects ($\eta_p^2 = .24-.46$, $\phi = .55-.67$). On the background of the presented pilot results, VR-ToMIS is concluded to be feasible and tolerable.

KEYWORDS

schizophrenia, theory of mind, virtual reality

1 | INTRODUCTION

Schizophrenia is a severe and disabling mental illness, affecting 1% of the population (Saha, Chant, Welham, & McGrath, 2005). Although effective treatment of this disorder is usually associated with the

alleviation of positive and—to a lesser extent—negative symptoms, in most cases, social functioning remains impaired, causing long-lasting difficulties for the patients and their families and resulting in well-defined economic burden for the society as well (Gábor, 2011; Leifker, Bowie, & Harvey, 2009). As pharmacotherapy does not seem to offer

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a solution for the problem, researches aiming at exploring the potential underlying and treatable factors became the focus of attention in the past decades (Galderisi et al., 2014).

Although several trials have shown significant neurocognitive deficits in schizophrenia, these impairments explain only 10–40% of the variance of poor functional outcomes (Green, Horan, & Lee, 2015; Pinkham & Penn, 2006). Likewise, training programmes based on the improvement of neurocognitive functions led to contradictory results (McGurk, Twamley, Sitzer, McHugo, & Mueser, 2007). Cognitive processes however involve a wide range of functions, including those that are more directly related to social dysfunctions (Green et al., 2008). The aforementioned functions play a central role in the process of perceiving and interpreting social stimuli and are usually referred to collectively as 'social cognition' (Green et al., 2008). Raising the concept of social cognition was followed by a series of studies supporting that patients with schizophrenia consistently demonstrate deficits in various subdomains of social cognition (Green & Horan, 2010; Penn, Corrigan, Bentall, Racenstein, & Newman, 1997). Among these subfunctions, the ability of inferring mental states to another person (theory of mind [ToM]) was found to be the most relevant field, as it is assumed to influence functionality more directly than other fields of social cognition or neurocognition (e.g., Bell et al. supported the role of ToM as a main predictor of the success of employment) (Bell, Tsang, Greig, & Bryson, 2009; Brüne & Brüne-Cohrs, 2006; Couture, Granholm, & Fish, 2011). Signs of ToM deficit usually precede the onset of the illness and can be detected even in remission, where the impairment cannot be described as a consequence of symptomatology or general cognitive impairment in schizophrenia (Bora, Yucel, & Pantelis, 2009; Harrington, Siegert, & McClure, 2005; Herold, Tényi, Lénárd, & Tixler, 2002). It is also empirically supported that ToM deficit cannot be described as 'all or nothing' in nature but rather as a continuum between hypo-ToM (e.g., in case of negative symptoms) and hyper-ToM (e.g., in case of paranoid delusions) (Abu-Akel & Shamay-Tsoory, 2013).

Based on the significance of ToM in functional impairment in schizophrenia and the clinical experiences of relative inefficacy of medication on social dysfunctions, ToM deficit has recently become the focus of many psychosocial interventions (Vass, Fekete, Simon, & Simon, 2018). Reviews on randomized controlled trials of social cognitive and ToM interventions found that such treatment approaches can successfully modify the ability of attributing mental states, where the overall weighted mean effect size was in the range of small to moderate ($d = 0.46$, 95% confidence interval [CI]: 0.15–0.78) (Kurtz & Richardson, 2012; Vass et al., 2018).

In reflection to actual research findings, ToM interventions have changed much over time, not only in the underlying approach but also in the technologies applied.

Initially, interventions focused on general improvement of social cognition, without identifying any specific areas as treatment target, such as Social Cognition Interaction Training (SCIT) or Social Cognition Enhancement Training (SCET) (Kurtz & Richardson, 2012; Tan, Lee, & Lee, 2016; Vass et al., 2018). Then, in parallel with the extensive research of the field, an explicit change in the focus of the interventions from a broad-based towards a single targeted approach could be seen, and more interactive techniques were introduced.

Key Practitioner Message

- Theory of mind (ToM) deficit is considered as a barrier to successful social functioning in schizophrenia.
- Most existing ToM interventions use observer-focused tasks, where, in many cases, the interpersonal dimension of ToM is not emphasized enough.
- By encouraging patients to get involved in realistic virtual role plays, immersive virtual reality may help to place more emphasis on interpersonal processes.
- As illustrated in our study, including immersive virtual reality in psychotherapies holds promises even for patients suffering from severe and disabling mental disorders.

These changes were significantly fuelled by the contradictory results of the efficacy studies on the early attempts to improve ToM. One possible explanation of the inconsistent findings may be that the used training materials (e.g., story vignettes and comic strip task) made the learning environment somewhat artificial and—in some cases—limited the scope for development to one aspect of ToM (e.g., lower order ToM and cognitive ToM). Typically, in ToM tasks, patients need to imagine a situation based on the presented materials (story vignettes and comic strips) and report the attributed mental states to the therapist (Vass et al., 2018). Although residual paranoid symptoms and/or the awareness of deteriorated social skills often prevent the patient from participating in social interactions, using techniques during the treatment that help overcome such difficulties might be crucial. Immersive virtual reality (VR) can be a creative solution for this problem by providing a safe learning environment, where patients can not only observe realistic social interaction but are also encouraged to get involved in them (without any real-life consequences) (Vass et al., 2019).

To our knowledge, only one VR-based social cognitive training has been developed so far for patients with psychotic disorders. However, no results have been published yet (Nijman et al., 2019). Two further studies used cognitive behavioural techniques and immersive technology as part of social skills training, where virtual avatars helped the participants practice social interactions (Park et al., 2011; Rus-Calafell, Gutiérrez-Maldonado, & Ribas-Sabaté, 2014; Tan et al., 2016). These studies demonstrated significant improvement in communicative skills and social functioning and reported good tolerability and high patient satisfaction. Because these methods did not target any specific domains of social cognition, there are no data on the context behind the effect (Park et al., 2011; Rus-Calafell et al., 2014). Yet the strong association between social cognition and social functioning raises the question whether the indirect development of social cognition mediates the improvement or functionality can be improved without the amelioration of social cognitive deficits (Tan et al., 2016).

The aforementioned development trends and encouraging results confirm that finding a way to utilize immersive VR technologies in the remediation of ToM deficits can be a promising direction in the

development of interventions (Vass et al., 2018). Hence, our research team opted to develop an immersive VR-based targeted ToM intervention, especially designed for patients with schizophrenia (VR-ToMIS = VR-based ToM Intervention in Schizophrenia) (Vass et al., 2019). The current study aims to evaluate the feasibility and tolerability of VR-ToMIS with a randomized, controlled trial. We hypothesize that VR-ToMIS will be feasible, well tolerated and associated with more improvements in ToM, pragmatic language skills and negative symptoms.

2 | METHODS

2.1 | Subjects

After screening 54 patients, 21 outpatients with schizophrenia have been recruited from the Department of Psychiatry and Psychotherapy, Semmelweis University, Budapest, and from the Department of Psychiatry, Szabolcs Szatmár Bereg County Hospitals and University Teaching Hospital, Nyíregyháza. Patients were diagnosed by a trained psychiatrist using the criteria of DSM-IV-TR (First, France, & Pincus, 2004). Patients who had ToM deficit (Baron-Cohen Mind in the Eyes Test [BCMET] <22) have been recruited (Fernández-Abascal, Cabello, Fernández-Berrocal, & Baron-Cohen, 2013). Exclusion criteria were (i) changes in antipsychotic medication within the past 3 months; (ii) substance abuse or dependence; (iii) any neurological illness that could affect cognitive functions; (iv) epilepsy; (v) mental retardation; (vi) participation in any trials within the past 6 months; and (vii) ongoing psychotherapy. All patients signed a written informed consent form. Additionally, ethical approval for the development and further study of VR-ToMIS was granted by the local research ethics committee (reference number: SE-TUKEB 150/2016). (Based on the encouraging experiences of the current pilot study, we plan to continue the data collection on the efficacy of VR-ToMIS, in the form of a

randomized, controlled, single-blind study with a 3-month follow-up, which is planned to be finished in 2021.)

2.2 | Design

This is a 9-week randomized, controlled, single-blind, proof-of-concept pilot study. The included patients were randomly assigned to either VR-assisted ToM intervention (VR-ToMIS, $n = 9$) or passive VR condition (where patients used the same VR software without any interventions, $n = 8$).

2.3 | Interventions

VR-ToMIS was conducted by a trained psychotherapist over the course of 9 weeks (50 min per session per week) in individual setting. The programme included eight virtual simulation-based sessions and one extra session prior to the virtual ones with the aim of helping the patients understand the method. All VR sessions were highly structured and were based on cognitive and behavioural therapy principles. Active VR sessions were based on three consecutive steps, preceded a short warm-up that provided sufficient time for reviewing the activity between sessions (homework and monitoring behavioural changes) and key procedures for change—like 'how to keep up a conversation'—were revisited. The three mentioned steps were as follows: (i) In each session (2–9), the patient participated in simulated social interactions with an avatar in immersive VR environments (Environment, were provided by vTime [<https://vtime.net/>]; Figure 1). At this stage of the session, Samsung's Gear VR equipment was used, including a head-mounted display (HMD), a Samsung S7 smartphone and a Samsung Simple Controller. The backbone of the virtual conversations constituted of prewritten and pre-recorded structured dialogue elements, which were designed to be able to induce ToM impairment



FIGURE 1 Screenshots of two virtual reality (VR) environments used during the intervention (approved by vTime)

(by including double meaning sentences, overstatements and irony) and make them accessible for later cognitive interventions. (ii) With the aim of improving affective ToM and self-reflectiveness, each simulation was followed by a task, where the patient had to visualize the inferred emotions of the avatar by using Temporal Disc Controller (TDC) (Csukly, Simon, Kiss, & Takács, 2004). TDC is a software that displays an avatar's 3D face on a computer screen. The patients can visualize emotions on the avatar's face, by moving the mouse cursor over an underlying circular interface. If the mouse pointer is directed to the middle of the screen, a neutral face is displayed. Various mixtures of basic emotions can be visualized by moving the cursor towards the periphery (Figure 2). The task makes the result of mental state attribution visible, making incongruencies between the verbalized and visualized mental states observable. (iii) Experiences of the simulation were discussed with a trained psychotherapist right after each TDC task, where the therapist used cognitive and metacognitive techniques to help the patient in the recognition of consistencies between cognition and behaviour and in the development of adequate behavioural strategies. After the third step, the patient was granted the option to virtually test the learned reactions by repeating all the three steps as many times as possible within the frame of the session (Vass et al., 2019) (Figure 3). An average of three repetitions was requested by the patients, where the average duration was 50 min.

In passive VR condition, patients could freely explore the virtual destinations provided by vTime, but they could not contact any avatars and did not receive any interventions (<https://vtime.net>). A trained psychologist observed the patients' behaviour during the sessions providing only technical instructions if needed. The average duration of the sessions was 50 min.

2.4 | Assessment

The patients completed baseline and post-treatment assessments for psychopathology, neurocognitive skills, ToM, pragmatic language skills (non-literal language processing) and quality of life (QoL).

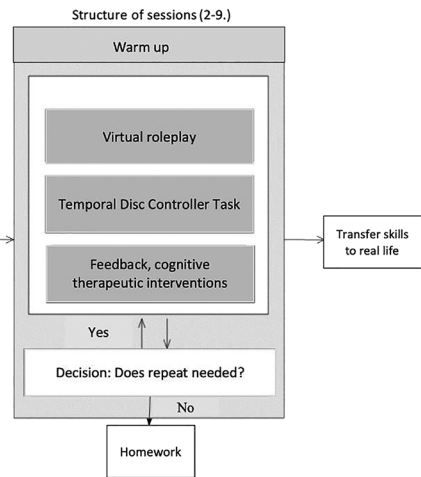
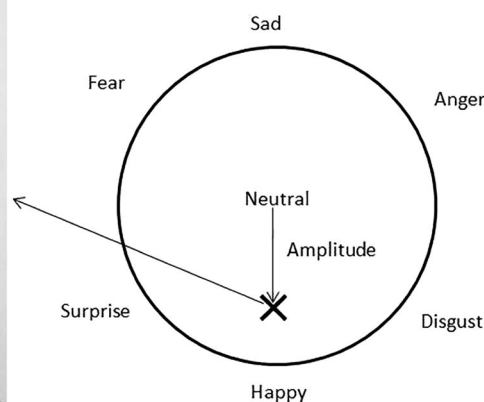


FIGURE 3 Main structure of VR-based ToM Intervention in Schizophrenia (VR-ToMIS)

Psychopathology was evaluated by Positive and Negative Syndrome Scale (PANSS), administered by a blinded, trained psychiatrist (Kay, Fiszbein, & Opler, 1987). However, the scoring method was modified. Our intention was to base our results methodologically on recently published findings. In 2019, a meta-analysis of 45 factor analyses identified a five-factor structure of the PANSS (positive symptoms, negative symptoms, affective symptoms, cognitive symptoms and activity/excitement) and suggested to change the scoring method to enhance its accuracy (Shafer & Dazzi, 2019).

Neurocognitive deficits were assessed by Repeated Battery for the Assessment of Neuropsychological Status (RBANS) and Wisconsin Card Sorting Test (WCST-64) (Lezak, 2004; Randolph, Tierney, Mohr, & Chase, 1998).

To cover the complexity of ToM, BCMET, faux pas test and cartoon stories task were administered to test the ability of mental state attribution (Brüne et al., 2008; Fernández-Abascal, Cabello, Fernández-Berrocal, & Baron-Cohen, 2013; Stone, 2002; Varga, Tényi, Fekete, & Herold, 2008).

FIGURE 2 Temporal Disc Controller (left side: avatar's face, visible for the patient; right side: circular interface, invisibly hidden under the face)

Pragmatic language skills were measured using the Hungarian metaphor and irony test, consisting of four subtests (metaphor, irony, implicatures and semantic subtest), each containing verbally presented short stories. In the metaphor and irony subtests, five stories were presented, and in the implicature subtest, four stories/types of implicature (quantity, quality, manner and relevance) were presented, as well as in semantic subtest. The overall 35 stories were presented in random order to the patients, where each one was followed by a question on the intended meaning. After implicature tasks, follow-up questions on possible linguistic inappropriateness were asked (Varga et al., 2019).

The patients were assessed for QoL by using Lancashire Quality of Life Profile (LQoLP) (van Nieuwenhuizen, Schene, Koeter, & Huxley, 2001).

All assessments for neurocognitive skills, pragmatic language skills and QoL were administered by a blinded trained psychologist.

After each VR session (2–9), the participants were assessed for symptoms of simulator sickness using the Simulator Sickness Questionnaire, administered by the therapist (Kennedy, Lane, Berbaum, & Lilienthal, 2009).

After the last session, all participants in the VR-ToMIS group were asked for their subjective opinion on the intervention. We also asked one relative of each patient to evaluate the perceived changes. In both cases, structured interviews—containing 5-point Likert scale questions—were used.

2.5 | Statistical analyses

Baseline differences in sociodemographic and main clinical characteristics of the sample were evaluated by Fisher's exact test, two-sample *t* test or Wilcoxon rank-sum test.

In line with recent findings, PANSS scores were calculated according to Shafer (Shafer & Dazzi, 2019). Regarding faux pas test, scores on 'faux pas' and 'no faux pas' stories were determined to represent hypo-ToM and hyper-ToM (lack of faux pas detection in 'faux pas stories' = hypo-ToM; faux pas detection in 'no faux pas stories' = hyper-ToM).

In accordance with the suggestion of recent studies, pretreatment to post-treatment changes between the treatment conditions (VR-ToMIS and passive VR) were compared with analysis of covariance (ANCOVA) by entering the post-treatment scores as dependent variables, pretreatment scores as covariates and treatment conditions as the categorical factor (Borm, Fransen, & Lemmens, 2007; Moritz, Veckenstedt, Randjbar, Vitzthum, & Woodward, 2011). When statistical expectation of normal distribution was not fulfilled, the Hettmansperger and McKean non-parametric linear model ANCOVA was used (Nakonezny & Shull, 2007).

In case of ANCOVA, Cohen's partial eta squared was calculated to evaluate the degree of change (η_p^2 : small, $\leq .01$; medium, $.06$ – $.14$; and large, $\geq .14$) Positive values of effect size estimations indicate more improvement (Aaker & Keppel, 1976). When Hettmansperger and McKean non-parametric linear model ANCOVA was used,

Cramer's phi was calculated to describe the degree of change ($\varphi = .1$, small effect; $\varphi = .3$, medium effect; and $\varphi = .5$, large effect).

Statistical Analysis System (SAS) Version 9.4 was used to perform statistical analyses. The significance of all statistical analyses was defined on a two-tailed significance level of $.05$; *p* values were adjusted by Bonferroni correction because of multiple comparisons.

3 | RESULTS

A total of 21 patients have been included in the study. Three patients have dropped out before the first session, during the baseline evaluation as they found the assessments time consuming and tiring. (None of them had experience with VR technology prior to the study.) One patient was excluded due to an adverse event, which was not in casual relationship with the intervention. No patient dropped out during the VR intervention. The final sample of 17 patients were randomly allocated to either VR-ToMIS (*n* = 9) or passive VR (*n* = 8) condition.

At baseline, no significant difference between the VR-ToMIS and passive VR group was found. Male and female patients were almost equally represented in the sample (eight male and nine female) and among the groups. The mean age of the participants was 43.7, within the range of 18 and 63 years. The duration of the illness varied in a similarly wide range (2.5–43 years), where the mean duration was 21.5 years (see Table 1 for more details on sample characteristics).

3.1 | Psychiatric symptoms

The VR-ToMIS group, compared with passive VR condition, was associated with significant improvements in negative symptoms on the PANSS score, with large effect size ($\eta_p^2 = .58$). Regarding positive and affective symptoms, non-significant but small effect size was noted ($\eta_p^2 = .19$ – $.22$). Similarly, in case of cognitive symptoms and activity scores, non-significant but medium effect sizes were detected (activity: $\eta_p^2 = .02$; cognitive: $\varphi = .13$) (Tables 2 and 3).

3.2 | Neurocognition

With respect to WCST-64 scores, only the number of correct responses showed VR-ToMIS-associated significant improvements. However, a trend towards significance was also shown in case of the rate of nonperseverative errors. Large effect size was found for each of the mentioned variables ($\eta_p^2 = .22$ – $.24$). As Table 3 shows, the patients' performance on visuospatial and attention subtest of RBANS significantly differed among VR-ToMIS and passive VR conditions, with medium effect size ($\varphi = .32$ – $.34$). Additionally, non-significant but large effect size was detected on immediate memory subscores ($\eta_p^2 = .24$). No further results of WCST-64 or RBANS subtests were found to be significant.

TABLE 1 Main demographic and clinical variables at baseline

Variable	VR-ToMIS (n = 9)	Passive VR (n = 8)	Active/control	p
			Statistics (Fisher's exact test, two-sample t test of Wilcoxon rank-sum test)	
Male/female	5/4	3/5	OR = 0.29	.63
Duration	20.8 (12.65)	21.5 (7.19)	t = -.13	.15
Age	38.6 (13.49)	48.8 (8.87)	t = -.93	.28
Education	14.3 (3.12)	13.6 (3.15)	z = -.25	.79
IQ	103.4 (12.13)	96.5 (16.21)	t = .99	.34
Baron-Cohen Mind in the Eyes Test	18.2 (2.9)	18.0 (3.25)	t = .15	.75
PANSS (Shafer & Dazzi, 2019)	58.1 (15.61)	60.1 (15.99)	t = -.24	.81
Negative symptoms	17.8 (6.38)	17.5 (4.89)	t = .12	.9
Positive symptoms	10.1 (2.85)	11.2 (3.32)	t = .69	.5
Cognitive symptoms	13.8 (4.22)	15.7 (4.55)	t = -.83	.42
Activity	4.8 (1.21)	6.3 (2.06)	z = -1.5	.13
Affective symptoms	9.1 (2.85)	9.2 (4.97)	z = .29	.76

Abbreviations: OR, odds ratio; PANSS, Positive and Negative Syndrome Scale; VR, virtual reality; VR-ToMIS, VR-based ToM Intervention in Schizophrenia.

3.3 | Theory of mind

With respect to ToM assessments, ANCOVA supported significant between-group differences in the first- and third-order ToM tasks and in many hypo-ToM tasks in favour of the VR-ToMIS group (cartoon test—first-order ToM task: $F(1, 16) = 4.62, p = .04, \eta_p^2 = .24$; cartoon test—third-order task: $\chi^2 = 5.24, \varphi = .55$; faux pas test overall scores of 'faux pas stories': $F(1, 16) = 12.69, p = .003, \eta_p^2 = .46$; faux pas empathy score of 'faux pas stories': $F(1, 16) = 8.33, p = .01, \eta_p^2 = .37$; faux pas detection score of 'faux pas stories': $F(1, 16) = 6.88, p = .02, \eta_p^2 = .32$; and metaphor-irony test—ToM subscore: $\chi^2 = 7.87, p = .005, \varphi = .67$). Similarly, VR-ToMIS-associated significant changes were noted regarding faux pas detection and understanding inappropriateness overall scores, with large effect size (faux pas detection overall scores: $F(1, 16) = 9.66, p = .007, \eta_p^2 = .40$; faux pas understanding inappropriateness overall scores: $\chi^2 = 4.62, p = .03, \varphi = .52$).

Although VR-ToMIS group showed remarkable changes in BCMET scores, no significant between-group differences were found. This contradiction, together with the small sample size, might explain the large effect size. A similar pattern can be seen concerning second-order ToM, faux pas overall scores, faux pas overall empathy scores and hypo-ToM subscores of false belief recognition. In each case, a noticeable improvement in VR-ToMIS group was accompanied by non-significant but large between-group effect sizes ($\eta_p^2 = .15-.22, \varphi = .43-.45$).

3.4 | Pragmatic language skills

Considering interpretation of metaphor and irony, remarkable change was only observed in case of metaphors, where significant between-

group differences were followed by large effect size ($\chi^2 = 4.23, p = .03, \varphi = .50$). The VR-ToMIS group showed apparent and greater change in detecting implicatures in all aspects, except from quantity implicature. However, a trend towards significance could be detected even in that case. Regarding each type of implicatures, effect sizes are considered as large ($\eta_p^2 = .22-.39$).

3.5 | Quality of life

No significant between-group differences were observed during the interventions. (Results are summarized in Tables 2 and 3.)

3.6 | Subjective feedbacks on VR-ToMIS

Subjective feedbacks on the tolerability of VR-ToMIS indicate that patients found this novel intervention interesting, engaging, easy and safe to use (Figure 4 shows the percentage of occurrences of the responses on the Likert scale).

Some examples of the patients' opinions:

It was really cool! Can I take the goggles home? (Male patient, 25 years old)

I think it was really interesting. I mean at least I was not afraid of these ... people, machines, or how do you call them? Avatars, or something like that. And ... I am not so scared of others either, live ones I mean. (Female patient, 50 years old)

TABLE 2 Preintervention and postintervention changes and non-parametric analysis of covariance (Hettm ANCOVA)

Variable	VR-ToMIS (n = 9)		Passive VR (n = 8)		Between group (ANCOVA), F (1, 16)	p (Bonferroni corrected)	Partial eta squared
	Preintervention	Postintervention	Preintervention	Postintervention			
BCMET	18.2 (2.90)	21.8 (4.64)	18.0 (3.25)	18.2 (5.23)	2.78	.11	.16
PANSS-S	58.1 (15.6)	48.1 (15.65)	60.1 (15.99)	61.2 (14.45)	2.19	.16	.13
Cognitive symptoms	13.8 (4.22)	11.2 (4.8)	15.7 (4.55)	16.2 (4.55)	2.14	.16	.13
Activity/excitement	4.8 (1.21)	6 (2.7)	6.3 (2.06)	6.6 (2.26)	0.33	.57	.02
WCST-64							
Correct responses	35 (12.62)	38.3 (10.85)	26.3 (16.15)	26 (8.48)	4.56	.05	.24
Nonperseverative errors	17.1 (19.58)	21.7 (22.73)	20.7 (20.37)	31 (18.2)	4.16	.06	.22
Perseverative errors	11.8 (9.2)	10.5 (9.02)	8.8 (12.10)	11.2 (14.53)	0.89	.36	.05
Perseverative responses	20.5 (15.02)	19.2 (12.73)	14.7 (17.45)	11 (17.37)	0.31	.58	.02
RBANS	200.3 (34.39)	210.2 (40.35)	166 (25.75)	170.1 (23.16)	1.07	.31	.07
Immediate memory	40.4 (11.71)	45.7 (9.94)	30.7 (7.99)	34.2 (7.49)	2.47	.13	.15
Visuospatial	37 (3.16)	36.1 (4.1)	32.7 (6.22)	30.8 (2.29)	7.25	.01	.34
Language	30.2 (5.47)	31.5 (6.08)	26.2 (3.91)	28 (4.20)	0.11	.75	.007
Attention	45.2 (12.79)	49.5 (9.61)	41.8 (8.69)	39.8 (8.50)	6.72	.02	.32
Delayed memory	47.4 (10.51)	55 (20.26)	34.3 (10.79)	36.7 (8.94)	0.43	.52	.02
Cartoon test	44.8 (10.06)	49.4 (12.58)	41.7 (6.58)	44.5 (10.87)	0.18	.67	.01
First-order task	3.8 (1.26)	4.5 (0.72)	3.3 (1.06)	3.3 (1.30)	4.62	.04	.24
Metaphor-irony test							
Quantity implicature	8 (4.24)	10.1 (2.99)	7.6 (4.50)	6.2 (3.53)	4.14	.06	.22
Quality implicature	8.2 (3.03)	10.2 (2.99)	4.1 (3.60)	3 (4.24)	6.88	.02	.32
Manner implicature	9.6 (3.93)	13.1 (3.78)	8.3 (3.46)	8.3 (3.73)	7.25	.01	.34
Relevance implicature	7.7 (3.96)	9 (4.52)	7.2 (3.15)	4.1 (3.04)	8.99	.009	.39
Language	15.1 (9.99)	19.8 (8.60)	9.8 (7.6)	8 (6.65)	7.27	.01	.34
Faux pas overall (FP)	0.71 (0.16)	0.78 (0.21)	0.70 (0.12)	0.68 (0.15)	2.58	.13	.15
FP stories	0.51 (0.31)	0.76 (0.27)	0.69 (0.25)	0.49 (0.30)	12.69	.003	.46
Faux pas detection	0.73 (0.20)	0.82 (0.23)	0.79 (0.13)	0.74 (0.17)	9.66	.007	.40
'No-FP' stories	0.92 (0.13)	0.93 (0.11)	0.76 (0.24)	0.86 (0.20)	0.48	.49	.03
FP stories	0.56 (0.33)	0.73 (0.40)	0.80 (0.28)	0.61 (0.36)	6.88	.02	.32
Attribution of intention							
FP stories	0.65 (0.17)	0.55 (0.35)	0.43 (0.41)	0.35 (0.35)	1.61	.22	.10
Recognize false belief	0.65 (0.17)	0.73 (0.23)	0.61 (0.34)	0.61 (0.18)	1.31	.27	.08
Empathy	0.67 (0.17)	0.75 (0.19)	0.71 (0.33)	0.60 (0.16)	4.16	.06	.22
FP stories	0.39 (0.35)	0.72 (0.27)	0.71 (0.33)	0.35 (0.39)	8.33	.01	.37
LQoLP							
Work	10.6 (2.91)	8.1 (4.64)	8.3 (4.13)	8.2 (3.61)	1.70	.21	.10

(Continues)

TABLE 2 (Continued)

Variable	VR-ToMIS (n = 9)		Passive VR (n = 8)		Between group (ANCOVA), F (1, 16)	p (Bonferroni corrected)	Partial eta squared
	Preintervention	Postintervention	Preintervention	Postintervention			
Free time activities	14.4 (4.69)	14.8 (5.25)	15.5 (4.8)	15.7 (5.87)	0.00	.94	.0003
Finances	10.3 (3.31)	9.2 (4.05)	8.8 (3.56)	7.5 (2.61)	0.28	.60	.01
Living situation	31.6 (8.13)	32.4 (8.21)	28.1 (5.3)	32.1 (4.85)	0.32	.57	.02
Family relations	12.7 (3.34)	12.2 (8.13)	13.1 (4.38)	13.6 (4.77)	0.15	.70	.01
Social relationship	7.3 (3.24)	8.2 (1.64)	9.1 (2.69)	9.1 (2.69)	0.10	.75	.007
Health	14.8 (2.26)	14.3 (3.87)	14.1 (3.9)	14.6 (2.06)	0.13	.72	.009
Subjective feelings	6.1 (0.92)	6.6 (2.12)	6.8 (2.10)	6.7 (2.60)	0.15	.70	.01
Perceived QOL index	6.7 (3.04)	6.9 (3.35)	6.9 (3.13)	7.7 (3.11)	0.33	.57	.02

Note: Significant results are highlighted in bold.

Abbreviations: ANCOVA, analysis of covariance; BCMET, Baron-Cohen Mind in the Eyes Test; LQoLP, Lancashire Quality of Life Profile; PANSS-S, modified Positive and Negative Syndrome Scale scores according to the meta-analysis of Shafer (Shafer et al., 2009); QoL, quality of life; RBANS, Repeated Battery for the Assessment of Neuropsychological Status; VR, virtual reality; VR-ToMIS, VR-based ToM Intervention in Schizophrenia; WCST-64, Wisconsin Card Sorting Test.

Do you remember that I started to take my medications to be allowed to participate? Maybe ... I will continue to do so. (Male patient, 18 years old)

Although in two cases we were unable to reach any relatives ($n = 7$), when close relatives were asked to evaluate the patients' change during the treatment, a decrease in the degree of distrust towards others and an observed increase of willingness to get involved and initiate a conversation can be highlighted (Figure 5 shows the percentage of the scores of the scale).

4 | DISCUSSION

Our pilot results provide initial support for the feasibility and tolerability of a novel targeted ToM intervention for patients with schizophrenia. In this randomized, controlled trial, the members of the VR-ToMIS group demonstrated significant improvements in negative symptoms, communicative-pragmatic skills, and in almost all types of ToM assessments, whereas passive VR condition had no effect on any of the examined variables.

Basically, our results showed that this new intervention can be used to modify ToM. To cover the complexity of ToM, we included several types of assessment tools, where (i) BCMET is approved to measure the affective subcomponent of ToM; (ii) the cartoon test used tasks that made it possible to distinguish between lower and higher order ToM; and (iii) faux pas test enables us to examine cognitive and affective subcomponents and underactive and overactive subtypes of ToM. Although other studies on the impact of ToM interventions could mainly show development in only one or two ToM areas, or led to contradictory results (Vass et al., 2018), VR-ToMIS seems to have promising effects on many aspects of ToM, supported

by medium to large within- and between-group effect sizes ($\eta_p^2 = .24-.46$, $\varphi = .52-.67$). Principally, being part of the VR-ToMIS group was in significant relationship with the amelioration of lower and higher order ToM, of both cognitive and affective subcomponents and underactive ToM/hypo-ToM (faux pas stories). Literature on the relationship between symptomatology and ToM may help us understand the detectable differences in the impact of our intervention on underactive and overactive types of ToM (Harrington et al., 2005). Literature data mostly support the hypothesis that there is a strong relationship between negative symptoms and the underactive type of ToM, whereas the overactive type of ToM is mainly associated with paranoid symptoms (Harrington et al., 2005; Sprong, Schothorst, Vos, Hox, & van Engeland, 2007). If we take a closer look at our data, it can be seen that most patients had higher scores on PANSS's negative symptoms subscale at baseline, regardless of which group they were assigned to (this was the case with each scoring method). However, no inclusion criteria for PANSS scores were specified. Regarding the clinical picture, only schizophrenia diagnosis based on DSM-IV and less than 22 points on BCMET test were named as criteria of involvement. It raises the question whether there is a connection between affective subtype of ToM assessed by BCMET and negative symptoms. The evaluation of this hypothesis by Spearman's rank correlation led to low correlation (PANSS negative symptoms scores: $r_s = -.16$; $p = .56$; PANSS negative symptoms scores according to Shafer: $r_s = -.4$; $p = .13$). Yet the negative value suggests that the higher the scores one achieved on PANSS negative symptoms scale, the lower scores they got on BCMET. However, although the increase of points on ToM outcome measures was accompanied by the decrease of negative symptoms, explanatory analysis using non-parametric multiple linear regression model did not support that baseline scores of negative symptoms would have an effect on the changes in ToM. Furthermore, no other characteristics of the sample,

TABLE 3 Preintervention and postintervention changes and non-parametric analysis of covariance (Hettmansperger and McKean model)

Variable	VR-ToMIS (n = 9)		Passive VR (n = 8)		Between group (Hettmansperger and McKean model), χ^2	p (Bonferroni corrected)	Cramer's phi
	Preintervention	Postintervention	Preintervention	Postintervention			
PANSS-S							
Negative symptoms	17.8 (6.3)	15 (4.16)	17.5 (4.89)	19.1 (5.58)	5.91	.01	.58
Positive symptoms	10.1 (2.85)	16.4 (21.27)	11.2 (3.32)	10.2 (3.53)	0.63	.42	.19
Affective symptoms	9.1 (2.85)	9.7 (5.93)	9.2 (4.97)	9.2 (4.13)	0.87	.34	.22
Cartoon test							
Second-order task	3.7 (0.97)	4.5 (0.72)	3.6 (0.91)	3.5 (1.30)	3.15	.07	.43
Third-order task	1.5 (0.88)	2.2 (0.97)	1 (1.06)	0.75 (0.88)	5.24	.02	.55
Metaphor-irony test							
Metaphor	8.1 (2.31)	8.5 (1.23)	5.2 (3.37)	4.8 (2.74)	4.23	.03	.50
Irony	7.7 (2.72)	9.1 (1.69)	5.7 (4.02)	5.2 (3.69)	3.49	.06	.46
Theory of mind	18.8 (9.53)	24.6 (8.73)	17.7 (7.14)	14 (7.28)	7.87	.005	.67
Faux pas overall (FP)							
'No-FP' stories	0.90 (0.13)	0.84 (0.32)	0.76 (0.22)	0.83 (0.26)	0.13	.70	.08
Understand inappropriateness	0.67 (0.18)	0.77 (0.22)	0.69 (0.12)	0.64 (0.18)	4.62	.03	.52
'No-FP' stories	0.90 (0.14)	0.83 (0.33)	0.73 (0.25)	0.83 (0.26)	0.17	.67	.1
FP stories	0.50 (0.30)	0.73 (0.31)	0.65 (0.31)	0.45 (0.39)	7.35	.006	.65
Attribution of intention	0.76 (0.32)	0.68 (0.21)	0.53 (0.09)	0.58 (0.15)	0.42	.51	.48
'No-FP' stories	0.45 (0.36)	0.83 (0.33)	0.65 (0.39)	0.81 (0.32)	0.07	.77	.06
Recognize false belief							
'No-FP' stories	0.81 (0.29)	0.83 (0.33)	0.68 (0.34)	0.83 (0.26)	0.31	.57	.1
FP stories	0.61 (0.31)	0.64 (0.36)	0.53 (0.34)	0.36 (0.35)	3.49	.06	.45
Empathy							
'No-FP' stories	0.93 (0.08)	0.75 (0.19)	0.61 (0.34)	0.83 (0.26)	0.71	.40	.20
LQoLP							
Religion	8.0 (4.84)	7.1 (5.62)	8.6 (3.77)	8 (4.27)	0.10	.73	.07
Legal and safety	12.3 (1.80)	11.8 (2.80)	9 (4.47)	11.5 (3.33)	0.26	.60	.1

Note: Significant changes are highlighted in bold.

Abbreviations: LQoLP, Lancashire Quality of Life Profile; PANSS-S, modified Positive and Negative Syndrome Scale scores according to the meta-analysis of Shafer (Shafer et al., 2009); VR, virtual reality; VR-ToMIS, VR-based ToM Intervention in Schizophrenia.

including the duration of the illness, type of medication, age, IQ and level of education, had detectable effect on ToM outcome measures.

With reference to the relationship between communicative-pragmatic skills and ToM, the published results are controversial. Whereas some studies showed correlation between the two notions, others suggest that the connection might be stronger and both abilities are needed to explain human communication. Furthermore, recent studies claim that pragmatic abilities should be considered as a subcomponent of ToM (Bosco, Tirassa, & Gabbatore, 2018; Sperber &

Wilson, 2002). Bosco et al. (2018) argue that ignoring the connection between the mentioned phenomena might lead to confusion in research methodology. In reflection to the above-mentioned literature data, we opted to use tasks to evaluate both ToM and pragmatic skills. As it was performed in the case of ToM, when choosing the assessment tool, the complexity of pragmatic skills was considered. Hence, we chose the Hungarian metaphor and irony task, which includes subtasks of detection of irony, metaphors and all types of known implicatures. According to our results, VR-ToMIS might help patients in using pragmatic skills more effectively during conversation

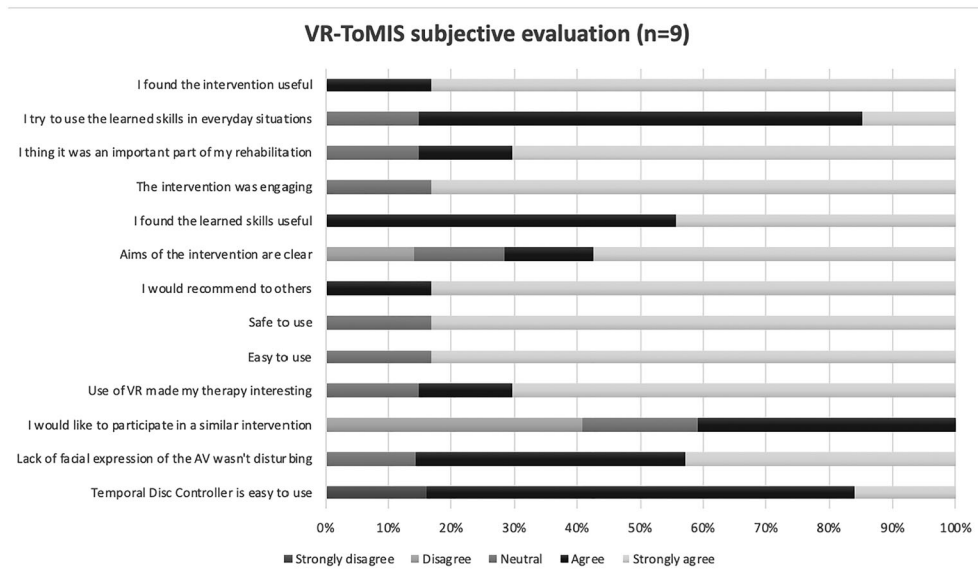


FIGURE 4 Patients' subjective evaluation of the intervention (percentage of occurrences of the responses on the Likert scale). VR, virtual reality; VR-ToMIS, VR-based ToM Intervention in Schizophrenia

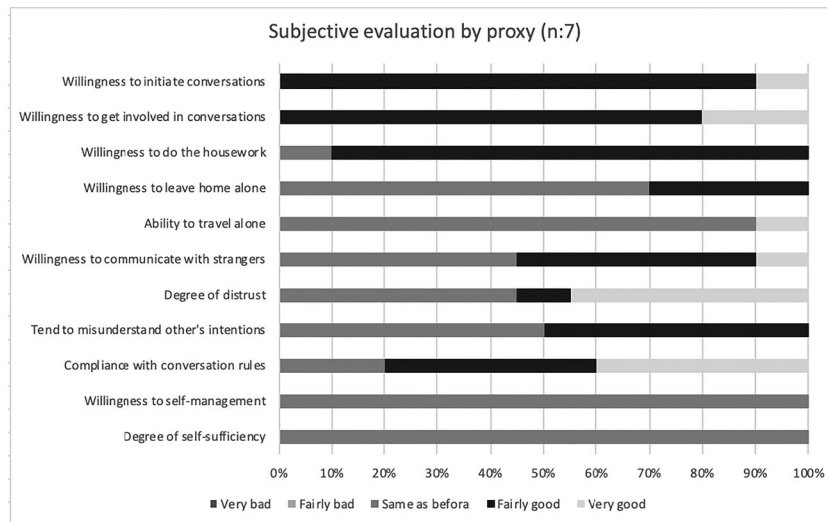


FIGURE 5 Relatives' evaluation on the effects of the intervention (percentage of occurrences of the responses on the Likert scale)

(Varga et al., 2019). This statement is supported not only by statistical analysis but also by the subjective feedback of the relatives of the included patients.

Regarding symptomatology by using the scoring method of Shafer, significant change was only shown concerning negative symptoms, but no other detectable changes were supported (Shafer & Dazzi, 2019).

With respect to neurocognition, significant effect of VR-ToMIS was detected only in case of visuospatial skills and attention, where, regarding visuospatial skills, changes in passive VR cognition pointed in the same direction. However, the changes in the control condition did not reach the level of significance according to a post hoc *t* test. Although these results support our hypothesis on the possible benefits of VR-ToMIS on neurocognitive skills, further study with larger sample sizes is needed to confirm its feasibility.

Our study did not support any significant changes in QoL scores. We suggest two possible reasons to explain the result on lacking such effect: (i) The intervention takes only 9 weeks, which period is not long

enough to witness noticeable changes in one's QoL. (ii) The changes of the life domains measured by LQoLP differ from the ones that are affected by the intervention. This assumption is in line with the subjective feedbacks of the patients' relatives, who observed positive changes in the attitudes of the patients and in their communicative skills. To see the effects of VR-ToMIS on different life domains, a larger sample size and adding a follow-up period to the study are needed.

According to the patients' subjective feedback, the intervention was engaging, interesting and safe to use. As no patients dropped out during the experimental intervention, and as some of them expressed verbally, improvement in compliance can also be considered as a possible effect of the intervention. Compliance in psychiatric care is critical, especially in the case of schizophrenia. Lack of compliance is usually considered as a barrier to recovery; hence, a method that has the potential to effectively support the patients' motivation to cooperate with health staff might be valuable. We think that VR-ToMIS has already shown the signs of this ability and can therefore hold a promising opportunity for rehabilitation.

Even though the pilot results are encouraging, some limitations of the study must be mentioned. First, the sample size is quite small. The main reason behind the small number of included patients was the high rate of screen failure (>50%), mainly due to the high scores on BCMET, which contradicts the literature data on incidence rate of ToM deficit in schizophrenia (Harrington et al., 2005). Nevertheless, the continuation of the present study and recruiting more patients are needed to assess the actual effects of VR-ToMIS. Second, no data on follow-up assessments were reported. In fact, our study is designed as a randomized controlled trial with a 3-month follow-up period, where promising pilot results are prerequisite for the continuation. Multiple testing might also be a problematic aspect of the study, as it inflates the Type I error rate. However, conservative Bonferroni correction was used to counteract the problem. Finally, it is possible that the tool chosen to assess QoL does not necessarily measure the domains that are affected by VR-ToMIS or are in direct relationship with ToM deficit. To address this limitation, we opted to collect information on the changes, observed by the patients' relatives. To get an accurate picture of the effects of VR-ToMIS, continuation of the current study is important.

In summary, the wide range of results on ToM assessment point in one direction even with such a small sample, which suggest that the identified progress is mainly accounted for by this novel intervention and not only for an unspecific effect of general rehabilitation.

Despite the limitations, in terms of the nature of changes caused by the intervention, our pilot results are in line with published results of other ToM interventions and support claim that VR-ToMIS might be a promising way of integrating VR technology in psychiatric care.

ETHICS STATEMENT

Ethical approval for the trial was granted by the local research ethics committee (reference number: SE-TUKEB 150/2016). All patients signed a written informed consent form.

AUTHOR CONTRIBUTION

M. E., L. L., Z. F. and B. K. collected the data on the patients. E. V. and L. S. led the interventions. E. V. and V. S. wrote the paper. All authors provided critical comments and approved the final version of the manuscript.

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CONFLICT OF INTERESTS

No conflicts of interest to declare.

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DATA AVAILABILITY STATEMENT

Data are available for sharing upon request.

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