

Virtual-reality-based cognitive behavioural therapy versus waiting list control for paranoid ideation and social avoidance in patients with psychotic disorders: a single-blind randomised controlled trial

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Summary

Background Many patients with psychotic disorders have persistent paranoid ideation and avoid social situations because of suspiciousness and anxiety. We investigated the effects of virtual-reality-based cognitive behavioural therapy (VR-CBT) on paranoid thoughts and social participation.

Methods In this randomised controlled trial at seven Dutch mental health centres, outpatients aged 18–65 years with a DSM-IV-diagnosed psychotic disorder and paranoid ideation in the past month were randomly assigned (1:1) via block randomisation to VR-CBT (in addition to treatment as usual) or the waiting list control group (treatment as usual). VR-CBT consisted of 16 individual therapy sessions (each 1 h long). Assessments were done at baseline, after treatment (ie, 3 months from baseline), and at a 6 month follow-up visit. The primary outcome was social participation, which we operationalised as the amount of time spent with other people, momentary paranoia, perceived social threat, and momentary anxiety. Analysis was by intention to treat. This trial was retrospectively registered with ISRCTN, number 12929657.

Findings Between April 1, 2014, and Dec 31, 2015, 116 patients with a psychotic disorder were randomly assigned, 58 to the VR-CBT group and 58 to the waiting list control group. Compared with the control, VR-CBT did not significantly increase the amount of time spent with other people at the post-treatment assessment. Momentary paranoid ideation ($b=-0.331$ [95% CI -0.432 to -0.230], $p<0.0001$; effect size -1.49) and momentary anxiety (-0.288 [-0.438 to -0.1394]; $p=0.0002$; -0.75) were significantly reduced in the VR-CBT group compared with the control group at the post-treatment assessment, and these improvements were maintained at the follow-up assessment. Safety behaviour and social cognition problems were mediators of change in paranoid ideation. No adverse events were reported relating to the therapy or assessments.

Interpretation Our results suggest that the addition of VR-CBT to standard treatment can reduce paranoid ideation and momentary anxiety in patients with a psychotic disorder.

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Introduction

People with psychotic disorders often avoid public and social activities. Their social networks are generally small and they spend more time alone than people without a psychotic disorder.¹ Many people with psychotic disorders do not have romantic partners, and the unemployment rate is high.^{2,3} As many as 90% of patients have paranoid ideation to some degree.⁴ Often, such ideation is strong and manifests as paranoid delusions, which are characterised by unfounded anticipation of intentional harm inflicted by other people. The anxiety resulting from paranoid ideation strongly contributes to social avoidance. This conditioned avoidance is not always affected by use of antipsychotic medication.⁴ Cognitive behavioural therapy (CBT) is the most effective psychological treatment for people with psychotic disorders.⁵ The effect sizes of CBT on paranoid delusions and social functioning are small to medium, but can be

improved by more emphasis on behavioural rather than cognitive change, and by more person-specific exposure⁵—a key element of CBT.

Exposure-based therapeutic exercises for paranoid ideation have several limitations. First, the social environment and reactions of others cannot be controlled by the therapist—relevant events might not occur, or unwanted events can suddenly occur. Second, exposure takes place between therapy sessions, and thus therapist feedback is retrospective and based on patient reports, which could be inaccurate because of biases.⁶ Finally, many patients are reluctant or unable to undergo exposure because of strong paranoid fears or negative symptoms.

These limitations could be overcome through virtual reality. The virtual social world is a controlled environment and exercises are done with the guidance of a therapist. Virtual reality is effective and safe for treating anxiety.⁷

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Research in context

Evidence before this study

Paranoid ideation is common in patients with psychotic disorders. The anxiety resulting from paranoid ideation strongly contributes to social avoidance. Cognitive behavioural therapy is the most effective psychological treatment for this symptom, but effects sizes are small to medium at best. The positive results of using virtual reality to treat anxiety disorders suggest that virtual reality might be used to improve treatment for anxiety and avoidance of social situations resulting from paranoid ideation. We searched MEDLINE with the terms (Virtual Reality) AND (Delus* OR Paranoi* OR Psychosis OR Psychotic OR Schizophren*) for articles published in any language before Sept 14, 2017. We identified 94 peer-reviewed papers. Research showed exposure of patients with a psychotic disorder to immersive virtual environments is safe and that virtual reality can be used to elicit paranoid ideation and anxiety in patients with a psychotic disorder, which suggests that the creation of virtual environments for treatment is feasible. Only one of the identified papers was a randomised controlled trial of virtual reality therapy for reducing paranoid

ideation. This small (n=30) experimental study showed large reductions in delusional conviction and real-world distress.

Added value of this study

We did the first randomised controlled trial (to our knowledge) of virtual-reality-based cognitive behavioural therapy with the aim of improving social functioning and reducing paranoid ideation in patients with psychotic disorders. We found that the addition of virtual reality cognitive behavioural therapy to standard therapy reduced paranoid ideation, anxiety, and use of safety behaviours in social situations compared with standard therapy alone. Results of the mediation analysis supported the importance of reducing safety behaviours and modifying social cognition in the treatment of paranoid delusions.

Implications of all the available evidence

Virtual-reality-based cognitive behavioural therapy is safe and effective in patients with psychotic disorders. Future research should compare virtual-reality-based cognitive behavioural therapy with standard cognitive behavioural therapy in terms of treatment effects and cost-effectiveness.

It is safe to use in people with psychotic disorders,⁸ and studies suggest promising results for several virtual reality interventions, including for social skills training, auditory hallucinations, and paranoid ideation.^{9,10} These findings suggest that virtual-reality-based CBT (VR-CBT) could be an effective, affordable, acceptable, and accessible form of treatment for patients with paranoid ideation and social withdrawal.

We did a randomised controlled trial to establish the effectiveness of VR-CBT, compared with treatment as usual, in improving the quantity and quality of social participation in patients with psychotic disorders who experience paranoid ideation and social avoidance. The primary hypothesis was that VR-CBT would lead to more time spent with other people, and a decrease in momentary paranoia, perceived social threat, and anxiety during real-life social activities. Our secondary hypotheses were that safety behaviours and paranoid ideation would be reduced by VR-CBT, that levels of social anxiety, depression, stigma, cognitive biases, and cognitive limitations would decline, and that social functioning, quality of life, and schematic beliefs would improve. Furthermore, we hypothesised that changes in safety behaviour and cognition (biases and mental schemas) would mediate the reduction in paranoia. Cost-effectiveness analyses will be reported in a separate paper.

Methods

Study design and participants

We did a single-blind randomised controlled trial of VR-CBT plus treatment as usual versus treatment as usual only in outpatients at seven Dutch mental health

centres. Details of the study protocol have been published.¹¹ Inclusion criteria were a DSM-IV diagnosis of a psychotic disorder based on the Mini-International Neuropsychiatric Interview,¹² the Schedules for Clinical Assessment in Neuropsychiatry,¹³ or the Comprehensive Assessment of Symptoms and History¹⁴ (varied by centre); avoidance of either shops, streets, public transport, or bars or restaurants; paranoid ideation in the past month (defined as a score greater than 40 on the Green et al Paranoid Thoughts Scale¹⁵); and age 18–65 years. Exclusion criteria were an IQ of 70 or lower (established by a valid instrument such as the Wechsler Adult Intelligence Scale or the Wechsler Intelligence Scale for Children); insufficient mastery of the Dutch language; and history of epilepsy. The protocol was approved by the medical ethical committee of VU University Medical Center Amsterdam (METC number NL37356.058.12). Patients were informed about the study by their treating psychiatrist, psychologist, or psychiatric nurse. If a patient was eligible and willing to participate, written informed consent was obtained.

Randomisation and masking

After a baseline assessment, patients were randomly assigned. Research assistants blinded to treatment allocation did the post-treatment and follow-up assessments. Assessors were instructed to stop the assessment in case of unblinding, and the assessment was repeated by another research assistant. (An assessor had to be replaced on three occasions.) Block randomisation was used to allocate patients (1:1) to the VR-CBT or control group. Each block had six assignments

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