MALAYSIAN HEALTH TECHNOLOGY ASSESSMENT SECTION

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Automated Virtual Reality Cognitive Therapy (gameChange) for Agoraphobia among Psychiatric Patients

EXECUTIVE SUMMARY

Agoraphobia or anxious avoidance of everyday situations such as public transport, shops or crowds, occurs across many different mental health disorders such as depression, social anxiety, panic disorder and psychosis. Combination of drugs with other modalities of treatment such as psychosocial such as cognitive behaviour therapy (CBT) and physical intervention are often needed. In recent years, immersive virtual reality-based cognitive behavioural therapy (VR CBT) has been identified as a potentially revolutionary tool for psychological treatment of patients with mental disorders. A recent advancement in stand-alone, self - guided, automated VR applications can make psychological therapy more readily available for many people, with reduced reliance to psychiatrists, psychologists and other mental health workers. gameChange is an automated VR application, intended for adults (age more than 16 years), aims for the participants to relearn safety beliefs and confidence by testing their fear expectations around other people. The software was developed by a multi-partner team led by researchers at the University of Oxford, UK and Oxford Health NHS Foundation Trust and is currently being tested in selected NHS mental health services and is planned for commercialisation soon. The gameChange therapy was designed to be delivered in approximately six sessions, each involving 30 min of VR, guided by a virtual coach, over a period of six weeks. Patient can select any of the six VR simulation of social scenarios; cafe, doctor's waiting room, pub, bus, opening the front door of the home onto the street, and small local shop. Evidence search was conducted using the scientific databases (Ovid Medline and Pubmed) and Google Scholar for up to 2 May 2022. There were three studies conducted on the effectiveness, satisfaction and safety of automated gameChange VR and three studies on other types of VR-CBT retrieved. Combination of automated gameChange VR therapy with usual care has the potential to safely reduce anxious avoidance particularly in patients with moderate to severe agoraphobia, compared to usual care alone. However, cost implication of this technology as a supplementary to the existing treatment needs to be further ascertained. In addition, its effect in an acute setting as well as in the long term are unknown and need further research. Since the acceptance in different society or age-group may also differ, piloting the technology before its introduction to our (Malaysian) population is encouraged. Automated delivery of psychology therapy may result in reduction in reliance on psychologists and other mental health workers. Hence, this technology may potentially scale-up the delivery of psychological therapy in the future.

Keywords: automated virtual reality, gameChange, cognitive-behavioural therapy, psychosis, agoraphobia, anxiety

INTRODUCTION

Mental disorders impose a large disease burden on the population with substantial economic costs incur to the society and health care systems.[1] The main contributors to societal costs are health care costs and productivity losses, but patients and their families also incur substantial costs.[2] Social avoidance, a common problem among these patients such as those with schizophrenia, hinders recovery in social participation and sustaining employment.[3]Poor social network, in turn, contributes to stigma and a lack of empowerment, resulting in more depressive symptoms and lower quality of life as well as more severe overall psychiatric and negative symptoms.[3]

There are now around 1 billion people worldwide who suffer from a mental disorder.[4] In total, poor mental health was projected to cost the world economy to $6 trillion by 2030, a huge rise from $2.5 trillion per year in poor health and reduced productivity in 2010.[4] In the European countries, treatment costs of psychotic disorders consume a significant part of their health care budgets.[5] In a survey of 1809 patients with non-affective psychosis who were attending mental health services in the UK National Health Service (NHS), anxious avoidance classed as agoraphobia was found in 64.5% of patients.[6]

There has been a dramatic increase in the prevalence of mental disorders over the past decade in Malaysia.[7] The prevalence has tripled from 10.7 in 1996 to 29.2 in 2016.[7] It is one of the leading causes of disability and health loss, accounting for 8.6% of total disability-adjusted life-years (DALYs).[8] In 2017, depressive (2.26% of total disability-adjusted life-years) and anxiety disorders (1.71% of total disability-adjusted life-years) were found to be among the top contributors to disability in Malaysia. The increasing prevalence of mental disorders in Malaysia is associated with an increased economic burden, with an economic analysis finding that mental health problems in the workplace were estimated to cost the Malaysian economy RM14.46 billion (£2.67 billion) in 2018.[8]

The country's current model of care is divided into in-patient and community care, with significant reforms to mental health legislation in Malaysia, from custodial care to community care.[9]There are 22 established community-based specialised mental health services (MENTARI) and 958 mental health day centres, in addition to four mental health hospitals and 47 psychiatric in-patient units attached to general hospitals.[9] However, a study in 2018 reported that there was significant deficit of psychiatrists and psychologists, with a ratio of 1.27 psychiatrists per 100 000 population.[10] Reduced access to general and mental healthcare, adverse socioeconomic conditions, combined with negative stigma, and the practice of seeking alternative care through religious practitioners or shamans, may have contribute to an increased risk for the development and barriers of mental health problems.[11]

In recent years, immersive virtual reality (VR) has been identified as a potentially revolutionary tool for psychological treatment of patients with mental disorders.[12] It provides an interactive three-dimensional computer-generated real-life simulation of everyday situations which patients with psychosis and agoraphobia perceived as threat to their safety leading to significant distress and social isolation.[13]

Early generation VR software and hardware enabled only simple simulations, mimicking real-world situations, and was mainly used for VR exposure therapy (VRET) for anxiety.[12] For patients with psychosis, VR has been used as a tool for CBT, cognitive remediation, improving job interview skills and social skills.[14] However, developments have been progressing rapidly, and more complex VR-based cognitive behavioural therapies (VR-CBTs) have emerged.

THE TECHNOLOGY

gameChange is an automated VR application that is recommended for adults (age more than 16 years), aims for the participants to relearn safety beliefs and confidence by testing their fear expectations around other people.[15] The therapy is not just a simple exposure therapy (participants asked to remain in situations until anxiety reduces), but instead, as repeated behavioural experiences in which defences are reduced in order to create belief change.[15]

The software was developed by a multi-partner team led by researchers at the University of Oxford, UK and Oxford Health NHS Foundation Trust, including staff from the University of Oxford spinout company Oxford VR, who managed the adoption of the technology in health services.[13] The hardware used was an HTC Vive Pro headset (HTC Corporation, New Taipei City, Taiwan) and Dell G5 15 5590 laptop (Dell Technologies, Round Rock, TX, USA) (Figure 1).[13] In its developmental process, a person-centred design approach was used, involving people with lived experience of psychosis, clinical psychologists, designers, and software developers.[15]

The therapy was designed to be delivered in approximately six sessions, each involving 30 min of VR, over period of six weeks.[15] A virtual coach, within the VR environments, guided the participant through the therapy. Patient can select any of the six VR simulation of social scenarios; cafe, doctor's waiting room, pub, bus, opening the front door of the home onto the street, and small local shop (Figure 2).[15] Each scenario comprised of five levels of difficulty (based on the number and proximity of people in the social situation and the degree of social interaction) and participants worked their way through each level. Throughout the sessions, participants responded to the questions from the virtual coach by moving a virtual slider or touching a virtual ball labelled with the option that appeared at the appropriate time. The VR sessions can be conducted in a clinic room with a mental health worker (either peer support worker, assistant psychologist, or clinical psychologist) present or in the patient's home.[15]

Figure 1: Automated VR gameChange

Figure 2: Six VR social scenarios in gameChange

gameChange is currently being tested and in use in selected NHS mental health services and is planned for commercialisation soon.

PATIENT GROUP AND INDICATION

gameChange was intended for adult patients aged 16 years or older, with a clinical diagnosis of schizophrenia spectrum psychosis (ICD-10 codes F20–29) or an affective diagnosis with psychotic symptoms (ICD-10 codes F31.2, 31.5, 32.3, 33.3) and those who had self-reported difficulties going outside the home primarily due to anxiety (for which they would like to have treatment).[13] Agoraphobia or anxious avoidance of everyday situations such as public transport, shops or crowds, occurs across many different mental health disorders such as depression, social anxiety, panic disorder and psychosis.[16]

According to the Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM-5), diagnostic criteria for agoraphobia include intense fear or anxiety prompted by the actual or predicted exposure to two or more of the following situations:[16]

- Using public transportation
- Being in open areas
- Being in closed-off areas
- Standing in line or a crowd
- Being alone outside of the house

Patient avoids the above situations because the individual believes they may become stuck or help might be unavailable in the event that the individual begins to panic and experience significant distress.[16] The fear the individual has is out of proportion to the possibility of danger and typically lasts for at least 6 months or longer and is not better explained by the symptoms of another medical disorder or a situational circumstance.[16]

Patients who were deemed unsuitable for gameChange include those with photosensitive epilepsy; substantial visual, auditory, or balance impairment; organic syndrome; primary diagnosis of alcohol or substance use disorder or personality disorder; clinically significant learning disability; or current active suicidal intent with plans.[13]

CURRENT PRACTICE

In treating patients with psychotic and anxiety disorders, several classes of medication are being prescribed, including selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, monoamine oxidase inhibitors, and benzodiazepines.[17]

Often, combination with other modalities of treatment such as psychosocial and physical intervention are needed. The most well-researched psychosocial approach is cognitive behaviour therapy (CBT), with clinical gains maintained at 2-year follow-up.[18] Cognitive behaviour therapy (CBT) is a structured, short-term, present-oriented psychotherapy.[19] It focuses on problem solving and modifying dysfunctional thinking and behaviour. The application of CBT is based on conceptualisation of individual person's belief, behaviour and emotional experience.[19]

In patients with anxiety with associated agoraphobia, combination of pharmacotherapy with cognitive-behavioural approach (CBT) has been found to be

superior to treatment alone during acute-phase treatment.[18] A meta-analysis of 124 studies found that CBT was at least as effective as pharmacotherapy and in some trials even significantly more effective.[19]

In patients with psychosis, CBT aims to normalise and make sense of individual's psychotic experiences and also reduce the associate distress and impact on functioning and is recommended in patients with schizophrenia with persistent positive symptoms and/or depression.[20]

Rapid advancement in medical technology has led to growing interest in the adoption of innovative digital technology such as virtual reality-based cognitive behavioural therapy (VR-CBT).[1] A recent advancement in stand-alone, self- guided, automated VR applications can make psychological therapy more readily available for many people, with reduced reliance to psychiatrists, psychologists and other mental health workers.[1]

SAFETY AND EFFICACY

Evidence search was conducted using the scientific databases (Ovid Medline and Pubmed) and Google Scholar for up to 2 May 2022. There were three studies conducted on the effectiveness, satisfaction and safety of automated gameChange VR and three studies on other types of VR-CBT retrieved.

a. Efficacy/Effectiveness

Effectiveness of gameChange AVR

In a recently released study, Freeman et al conducted a parallel-group, single-blind, randomised, controlled trial across nine National Health Service trusts in England to assess potential benefit of the automated VR therapy in patients with psychosis.[2] A total of 346 patients aged 16 years or older were enrolled, mean age was 37.2 years (SD 12.5) with a clinical diagnosis of a schizophrenia spectrum disorder or an affective diagnosis with psychotic symptoms, and had self-reported difficulties going outside due to anxiety. Around 174 patients were randomly assigned to the gameChange VR therapy group plus usual care and 172 to the usual care alone (antipsychotic medications, regular visits from a community mental health worker, and outpatient appointments with a psychiatrist). gameChange VR therapy was provided in approximately six sessions over 6 weeks. The primary outcome was avoidance of, and distress in, everyday situations, assessed using the self-reported Oxford Agoraphobic Avoidance Scale (O-AS) at 0,6 (primary endpoint), and 26 weeks after randomisation. Secondary outcomes were agoraphobia measured by the Agoraphobia Mobility Inventory-Avoidance scale as well as suicidal ideation, paranoia, paranoia worries, depression, activity levels and quality of life, all measured using relevant validated tools. The study found that compared with the usual care alone group, the gameChange VR therapy group had significant reductions in agoraphobic avoidance (O-AS adjusted mean difference –0.47, 95% CI –0.88 to –0.06; Cohen's d –0.18; p=0.026) and distress (–4.33, –7.78 to –0.87; n=322; –0.26; p=0.014) at 6 weeks. These beneficial effects were maintained at 26 weeks. The mediation analysis indicated that the VR therapy worked in accordance with the cognitive model by reducing anxious thoughts and associated protective behaviours. The moderation analysis indicated that the VR therapy

particularly benefited patients with severe agoraphobic avoidance, such as not being able to leave the home unaccompanied. There were no significant differences in the majority of secondary outcomes between the groups, although there were improvements in perceptions of recovery. In a nutshell, this study found that the greater the severity of anxious fears and avoidance, the greater the treatment benefits and the effects persisted for six months. There was no significant difference in the occurrence of serious adverse events between the gameChange VR therapy group (12 events in nine patients) and the usual care alone group (eight events in seven patients; p=0.37). Overall, this study is the largest RCT to date conducted on automated VR in agoraphobic psychotic patients and is deemed of high quality. However, it is unknown whether there are any longer-term benefits for patients beyond the 6-month time period assessed in this trial.[2]

Effectiveness of other types of VR-CBT

A randomised trial in 116 patients with paranoid ideation and social avoidance in patients with psychotic disorders that tested 16 sessions of VR-based cognitive behavioural therapy with a therapist did not find a significant end-of-treatment difference in social participation (assessed by time spent with other people) compared with a control group, but did find a significant difference at 6-month follow-up.[21]

A systematic review of reviews found an overall positive effect of virtual reality-based cognitive behavioural therapy (VR-CBT) as supplementary to the treatment of agoraphobic avoidance in patients with psychosis.[22]

b. Safety

Another recent study by Freeman et al investigated the safety effect and satisfaction among 122 psychotic patients who received gameChange VR therapy.[25]They completed a satisfaction questionnaire and the Oxford-VR Side Effects Checklist. The unwanted negative events that patients attributed to use of VR (hardware or software) may comprise potentially milder subjective experiences (e.g. eye strain, feelings of panic, increase in voices or paranoia), serious adverse events (e.g. death, life-threatening injury, hospitalisation) as defined by medical device trial guidelines. A total of 79 (65.8%) patients were very satisfied with VR therapy, 37 (30.8%) were mostly, 3 (2.5%) were indifferent/mildly dissatisfied, and 1 (0.8%) person was quite dissatisfied. The most common side effects were difficulties concentrating because of thinking about what might be happening in the room (n = 17, 14.2%); lasting headache (n = 10, 8.3%); and the headset causing feelings of panic (n = 9, 7.4%). The occurrence of side effects was not associated with number of VR sessions, therapy outcomes, or psychiatric symptoms. Difficulties in concentrating in VR were associated with slightly lower satisfaction. VR therapy provision and engagement made patients feel proud (n = 99, 81.8%); valued (n = 97, 80.2%); and optimistic (n = 96, 79.3%). Patients with psychosis were generally very positive towards the VR therapy, valued having the opportunity to try the technology, and experienced few adverse effects. Side effects did not significantly impact VR therapy.[25]

ESTIMATED COST

There was no evidence retrieved on cost/ cost-effectiveness on gameChange VR.

However, a trial-based cost utility analysis (CUA) was conducted on other VR-CBT among patients with psychotic disorders in seven outpatient mental health care services in the Netherlands, comparing it with usual treatment alone.[23] It aims to determine the short-term (6-month) cost-effectiveness of VR-CBT from a societal perspective in improving social participation among these patients. Societal costs were computed by adding (1) the direct medical costs of health care services use including the costs of antipsychotic medication and, in the experimental condition, the additional costs of adjunctive VR-CBT treatment; (2) direct non-medical costs of travel; and (3) indirect costs stemming from lower productivity. Patients were randomised into control group (n=58) who received usual care for psychotic disorders in accordance with the clinical guidelines and the experimental group (n=58) who received usual care complemented with add-on VR-CBT to reduce paranoid ideation and social avoidance, followed-up at 3- and 6-months post-randomisation. Treatment response was defined as a pre-post improvement of symptoms of at least 20% in social participation measures. Change in quality-adjusted life years (QALYs) was estimated by a change in the standardized mean difference of Green's Paranoid Thoughts Scale score on a corresponding change in utility. For VR therapy hardware, software and training costs were calculated. Total yearly costs for one VR system was €23,995 (RM 110,103.46; Exchange rate 1€ = RM4.58) according to CleVR BV, a company who builds VR sets. Yearly costs for training and supervision of the psychologists was €13,400 (RM61,512.42). Per-patient costs per 16 VR-CBT treatment sessions was €373.95 (RM1,716.61). The study found that the average mean incremental costs for a positive responder on social participation ranged between €8079 (RM37,086.48) and €19,525 (RM89,629.10), with 90.7% - 99.7% showing improvement. The average incremental cost per QALY was €48,868 (RM224,327.53) over the 6 months of follow-up, with 99.9% showing improved QALYs. Sensitivity analyses showed costs to be lower when relevant baseline differences were included in the analysis. Average costs per treatment responder now ranged between €6800 (RM31,215.26) and €16,597 (RM76,188.18), while the average cost per QALY gained was €42,030 (RM192,937.83). This study demonstrated that offering VR-CBT to patients with paranoid delusions is an economically viable approach toward improving patients' health in a cost-effective manner. However, long-term effects need further research.[23]

SOCIETAL / ETHICAL ISSUES

Views related to gameChange

A qualitative study was conducted by Brown et al to explore the views of patients and staff on the provision of gameChange VR therapy in psychiatric wards.[24] Focus groups or individual interviews were conducted with patients (n=19) and National Health Service staff (n=22) in acute psychiatric wards. Questions were derived from the non-adoption, abandonment, and challenges to the scale-up, spread, and sustainability framework. Expectations of VR therapy were discussed, and participants were then given the opportunity to try out the gameChange VR therapy before they were asked questions that focused on opinions about the therapy and feasibility of adoption. The study found positive attitude towards the use of gameChange VR therapy among study participants. It was considered as a tool to help build confidence, reduce anxiety, and managing transition between being in hospital and being discharged to the community. However, it was reflected that the VR therapy may not suit everyone, especially if they are acutely unwell.[24]

POTENTIAL IMPACT

Combination of automated gameChange VR therapy with the usual care has the potential to safely reduce anxious avoidance particularly in patients with moderate to severe agoraphobia, compared to usual care alone. However, cost implication of this technology as a supplementary to the existing treatment needs to be further ascertained. In addition, its effect in an acute setting as well as in the long term are unknown and need further research. Since the acceptance in different society or age-group may also differ, piloting the technology before its introduction to our (Malaysian) population is encouraged.

Automated delivery of psychology therapy may result in reduction in reliance on psychologists and other mental health workers. Hence, this technology may potentially scale-up the delivery of psychological therapy in the future.

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