Principal Investigator: Winnie Wing Sze MAK / Version 1.1 / Date: 13 Aug 2019
Using Virtual Reality (VR) to reduce social avoidance: A pilot and a randomized controlled trial
of a virtual reality cognitive behavioral therapy based program for social avoidance.
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Introduction

The World Health Organization (WHO) puts mental illness among the leading causes of disease and disability globally. By 2020, mental ill-health is expected to rank second behind heart disease. The effects of mental illness goes beyond the inflicted individuals, but also their families, colleagues and others they come across with. A review of 45 studies showed that mental illnesses place tremendous economic burden to the society (Doran, & Kinchin, 2019).

In Hong Kong, about 1 in 7 adults in the general population have common mental disorders, namely anxiety, depression, or a combination of the two (Lam et al., 2015). Research has also showed that anxiety and depression tend to co-occur and to share similar risk factors for onset and common transdiagnostic processes for maintenance (Topper, Emmelkamp, & Ehring, 2010). Although effective treatments have been developed for anxiety and depression, only about a quarter of the individuals ever seek help due to stigma, access, and costs (Lam et al., 2015).

A common condition among individuals experiencing depression and anxiety is social avoidance. People may find themselves difficult to relax in social situations, particularly when interpersonal interaction is needed. Avoiding anxiety-provoking situation may alleviate discomfort in short term, it may deter people from seeking professional and social support, which ends up delaying treatment and aggravates psychological distress.

An effective treatment for social avoidance is cognitive behavioural therapy (CBT). CBT focus on changing how individual thinks and behaves. The most powerful change happens when people are directly presented with the situations that cause them distress and learn in that moment how to respond more constructively instead of resorting to behavioural avoidance. Yet, taking the treatment into the actual environment can be time-consuming and sometimes impractical. Meanwhile, technological innovations such as virtual reality (VR) offers an innovative solution to tackle such challenge.

Over the past 25 years, VR has been used to complement therapist-delivered psychological interventions, primarily exposure therapy for anxiety related disorders. Meta-analyses revealed a large (Cohen's d=1.1) treatment effect size (Freeman et al., 2018). VR renders real-world social interactions simulation, which allows users to experience an anxiety provoking situation with a greater sense of control (Riva, 2005). Meanwhile, therapists can also adjust the simulated environment to cater for the needs and progress of their clients with convenience inside of their offices. In Hong Kong, with the lack of mental health professionals being a perennial problem, VR-based interventions offer the potential to substantially reduce the treatment time and cost, as well as to increase access to evidence-based psychological interventions.

In this study, we aim to examine a VR social avoidance intervention. The intervention is based on cognitive-behavioral approach with a virtual coach acting as the therapist. The intervention will be delivered using consumer VR devices. We hypothesize that, comparing with usual care (i.e. waitlist control), the intervention group will experience a significant reduction on social avoidance symptoms after treatment and this benefit will persist till 4-week follow-up.

This project is in compliance with Declaration of Helsinki.

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Method

Intervention Design

The current VR intervention will be designed to help people feel safer and more confident in social situations. Participants will be guided by a virtual coach through a series of graded tasks in different environments that reflect everyday situations (e.g., café, bus, street, doctor's waiting room) for people who might avoid social situations. This program will be designed in tandem with input from Hong Kong users to ensure the scenario can resonate with them. By testing beliefs that inhibit confidence in a safe and controlled environment, participants will complete tasks with increasing difficulty and learn that they can cope in situations that they previously avoid. This program is intended for use by adults who are 18 or above.

Participants

Recruitment will be done via mass email, social media, newsletter and AXA's client network.

Inclusion criteria

- Age 18 or above
- Can read traditional Chinese and understand Cantonese
- Self report on experiencing social avoidance symptoms

Exclusion criteria

- People who are currently receiving psychological intervention for social avoidance
- People who have participated in the pilot study of this project
- History of photosensitive epilepsy
- Impairment of stereoscopic vision
- Balance problems

Procedures

When signing up for the VR intervention, potential participants will need to first complete an online screening survey to determine their eligibility. Qualified participants will be further validated on the inclusion and exclusion criteria over the telephone prior scheduling their first face-to-face appointment. At baseline, participants' demographic information and level of social avoidance will be collected.

The VR intervention will consist of a software application which delivers using a consumer VR head-mounted display that has associated hand controllers and headset tracking. Participants will also wear headphones with a microphone.

For pilot trial, participants will be asked to evaluate the usability of the VR program and treatment protocol. After the pilot trials, participants recruited for the RCT will be randomized into intervention or wait-list control groups. The intervention group will go through roughly six to eight 30-minute VR sessions over a period of 3 to 6 weeks. Participants will undergo each intervention session with a research assistant in the room to assist with putting on headset and other logistic arrangement. A virtual

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coach within the VR program will guide through the intervention from initial assessment, providing encouragement and retrieving participant feedback. Participants will be asked to complete certain homework assignment in-between sessions to apply what they learn in real life. Assessments will be conducted at baseline, post-intervention, and 1-month follow-up. Wait-list control group will complete the questionnaires in the same interval as the intervention group, with promise of receiving VR intervention after 1-month follow-up is over. Participants who complete all required sessions and assessments will receive HK\$300 as participatory incentives.

Measures

Demographics. Participants' demographic information, such as age, gender, educational attainment, occupational background will be obtained during screening.

Mobility Inventory for Agoraphobia (Chambless, Caputo, Jasin, Gracely, & Williams, 1985). This 27-item inventory measures self-reported agoraphobic avoidance behavior and panic attack frequencies when respondents are being alone and with companion. It is rated on a 5-point Likert scale, with higher score indicating higher tendency of avoidance.

Liebowitz Social Anxiety Scale (LSAS; Heimberg et al., 1999). This 24-item questionnaire intends to assess participants' fear and avoidance on a range of social interaction and performance situations. LSAS consists of two subscales; 13 items measure performance anxiety and 11 items pertain to various social situation. LSAS has been found to be psychometrically valid and reliable for measuring social phobia (Heimberg et al., 1999).

Social Interaction Anxiety Scale (SIAS; Mattick, & Clarke, 1998). This 20-item scale measures individuals' self-report distress when interacting with others. It runs on a 5-point Likert scale (0 to 4). It has been widely used in clinical setting, with reliable and valid psychometric properties (Mattick, & Clarke, 1998).

Brief Avoidance Scale (BAS; Freeman, & Lambe, 2019). This is a 7-item scale to assess if individuals may experience anxiety in situations which the current VR intervention targets. Situations include walking down the street, riding on bus, placing order in a café, going to the pub, waiting in a medical clinic, and buying something in a convenient store. Participants have to rate how anxious they feel going into each of the above situations, from 0 (not at all anxious) to 5 (extremely anxious). Another item asks participants if they are interested in getting help in reducing anxiety in any of those situations.

Oxford Behavioural Avoidance Task (OBAT; Freeman, & Lambe, 2019). This is a 44-item scale to assess the extent of which participants feel anxious in everyday situations, and the extent of which they try to avoid those situations. Situations such as standing outside of one's home, walking down a busy street, etc... Scale ranges from 0 (no distress) to 10 (extremely distress).

Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001). To assess the extent of which respondents are bothered by depression related symptoms using a 4-point Likert scale from 0 (not at all) to 3 (nearly every day). It has shown to have an internal consistency of .89 (Li et al., 2014).

Generalized Anxiety Disorder Assessment (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006). To assess the extent of which respondents are bothered by anxiety related symptoms using a 4-point Likert scale

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from 0 (not at all) to 3 (nearly every day). It has shown to have an internal consistency of .92 (Li et al., 2014).

Work and Social Adjustment Scale (WSAS; Mundt, Marks, Shear, & Greist, 2002). This 5-item scale measures the extent of which respondent's psychological problem impact their various aspect of life. It is rated on an 8-point Likert scale ranges from 0 (not at all impaired) to 8 (severely impaired).

Statistical analysis

For pilot trial, we expect to recruit 50 participants to provide qualitative feedback on the localized VR program and intervention protocol.

For the RCT, a target sample size of 208 will enable the study to detect a small intervention effect (0.1) with 85% power, at a significance level of 0.05, two conditions (i.e. VR intervention group and waitlist control group), three measurements (i.e. baseline, post-intervention, 1-month follow-up), correlation of repeated measurements at 0.6. Repeated measure (within-between interaction) ANOVA or linear mixed effects model will be used to examine intervention effect over time.

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