Principal Investigator: Winnie Wing Sze MAK / Version 2.0 / Date: 07 May, 2020
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 go 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 focuses on changing how an 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 scenarios 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, non-governmental organisations 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
- Hearing and/or vision problems
- 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 then schedule a face-to-face or an online initial appointment for the validation on the inclusion and exclusion criteria, and completion of baseline measurements. During the initial appointment, participants who fulfil all eligiblity criteria and consent to participate in the study will be invited to provide demographic information and complete baseline measurements concerning ones' level of social avoidance.

The VR intervention will consist of a software application which delivers the VR program 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

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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 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 have learnt in real life. Assessments will be conducted at baseline, post-intervention, and 1-month follow-up. Wait-list control group will complete the questionnaires at the same interval as the intervention group, with promise of receiving VR intervention after completion of the 1-month follow-up survey. 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 (MIA; Chambless, Caputo, Jasin, Gracely, & Williams, 1985). This 27-item inventory measures self-reported agoraphobic avoidance behavior 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.

Social Interaction Anxiety Scale-6 (SIAS-6; Peters, Sunderland, Andrews, Rapee & Mattick, 2012) This 6-item scale, which is a shortened version of the 20-item SIAS (Mattick, & Clarke, 1998), measures individuals' self-report distress when interacting with others. It runs on a 5-point Likert scale (0 -not at all characteristics or true of me to 4- extremely characteristics or true of me). Significant correlations between the brief and the original long format at pre-, post- treatment and 3-month follow up have been reported (Peters et al., 2012). The internal reliability of SIAS-6 (i.e. alpha values of SIAS-6 in different studies ranged from .75 to.92) along with its ability to detect changes associated with treatment targeting social phobia have been supported (Johnston et al., 2011; Le Blanc et al., 2014; Peters et al., 2012).

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).

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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 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).

Brief Fear of Negative Evaluation Scale (bFNE; Leary, 1983). This is a 12-item scale that measures the fear associated with being evaluated unfavorably while anticipating or participating in a social situation, including apprehension about receiving negative evaluation, avoidance of being evaluated, and the expectation of being negatively evaluated with a 5-point Likert-type rating scale, ranging from 1 (not at all characteristic of me)to 5 (extremely characteristic of me). Leary (1983) has demonstrated that scores on the bFNE were highly correlated (r =.96, p<.0001) with the scores on the original long form— Fear of Negative Evaluation Scale (Watson & Friend, 1969), and reported satisfactory internal reliability (α =.90) and acceptable test—retest reliability (α =.75) (Leary, 1983).

Social Anxiety Session Change Index (SASCI; Hayes Miller, Hope, Heimberg & Juster, 2008) SASCI is a 4-item self-reported measurement that monitors session by session changes across treatment of social anxiety on four dimensions: anxiety, avoidance, concern about humiliation and embarrassment, and interference, using a 7-point Likert-type scale ranging from 1 (much less than the start of treatment) to 4 (not different from the start of treatment) to 7 (much more than the start of treatment).

As suggested by the authors (Hayes et al.,2008), the scale can be adapted (i.e. by changing the wordings of the questions) to monitor other psychological condition, which is social avoidance in our current study.

In the current study, the scale will be administered to track the intermediate changes for the VR sessions (i.e. a per session update of improvement/ deterioration of level of social avoidance)

Satisfactory psychometric properties of the scale have been reported by Hayes and colleagues (2008). The value of Cronbach's Alpha of SASCI ranged from .84 to .94. Meanwhile, changes on the SASCI were shown to be significantly related to improvement on established measures of social anxiety symptoms (e.g. SIAS, Liebowitz Social Anxiety Scale etc.) and were not correlated with measures examining unrelated construct (e.g. anxiety sensitivity or depression) (Hayes et al.,2008),

Oxford Behavioural Avoidance Task – HK (OBAT-HK). This is a 16-item scale, a local adaptation of Freeman's OBAT to assess the extent of which participants feel anxious in everyday situations, and the extent of which they try to avoid those situations. Examples of the situations are: approach another pedestrian to ask for direction, ask the bus driver about which stop you should get off etc. Participants first answer a question concerning if they could do a specific task right now and then rate the level of distress if they have to perform the task straightaway from 0 (no distress) to 10 (extremely distress).

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Preliminary data from the local population supported the psychometric properties of the scale and its sub-scales with satisfactory internal reliability (values of Cronbach's Alpha ranged from .724 to .951) and convergent validity demonstrated via correlations of moderate strength in expected direction with established scales (i.e. MIA and bFNE) measuring avoidance and anxiety in social situations.

General Digital Working Alliance Inventory (D-WAI). This is an 8-item scale, adapted from Henson et al. (2019), intends to evaluate users' overall feeling and thoughts toward the working alliance established during the digital therapeutic program. The 8 items fall into three sub-factors: goals, tasks, and bonding. Scale points range from 1 (never) to 7 (always). Acceptable psychometric properties were provided (Henson et al., 2019).

Working Alliance Inventory applied to VR and AR (WAI-VAR). This is a 12-item scale designed to assess therapeutic alliance between the virtual/augmented reality program and the users. It is a unidimensional scale. Scale points range from 1 (never) to 7 (always). Psychometric properties were well validated (Miragall et al., 2015).

Gatineau Presence Questionnaire. This is a 4-item scale designed to assess the feeling of presence experienced in a virtual environment. Sample items include "the impression of being here", "appraising the experience as being real". Scale point ranges from 0 to 100. Psychometric properties were well validated (*Laforest et al.*, 2016).

Treatment acceptability. This is a 4-item scale intends to examine the overall user satisfaction toward the digital psychological intervention. Each item has its own scale point. The scale has been used widely and validated by studies involving internet-based psychological treatments (DaPonte et al., 2018; Titov et al., 2013).

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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