Official Title: Effectiveness of social virtual-reality on enhancing social interaction skills in children with attention-deficit/hyperactivity disorder: a three-arm pilot randomised controlled trial

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Study Protocol

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Background

Attention deficit/hyperactivity disorder (ADHD) is one of the most common neurodevelopmental disorders frequently diagnosed in school-aged children. It is characterised by pervasive symptoms of inattention, hyperactivity, and impulsivity. There are three main types of ADHD: inattentive type, hyperactive-impulsive type, and combination type. ADHD impacts the children's emotions, behaviours and ability in learning. The hyperactivity and inattention levels of children with ADHD are noticeably higher than expected, causing distress or problems at home, at school and with peers. The global prevalence rate of ADHD is about 5% to 7%. According to the data from the Family Council in Hong Kong, there are 14,580 students with ADHD in Hong Kong, which is the second-highest number among the nine types of special education needs (SEN). Children with ADHD's executive functions can be delayed by up to 32% compared with peers. Such delay may cause difficulty in self-control, managing emotion, paying attention and holding information in working memory, and likely to talk excessively and interrupt others. Hence, children with ADHD have challenges in understanding social cues and behaviour problems while entering a social setting. For example, they are difficult to comprehend some nonverbal expressions (body language, eye contact and facial expressions) and spoken communication (pitch, speed, tone, and volume), leading to difficulty in listening to others, sharing scattered thoughts and rapid speaking. The social skill deficit causes becoming hard to build friendships and integrate into society. ADHD has been associated with a wide range of detrimental impacts on affected subjects and with a severe financial burden to families and society. Several studies reported that the economic burden of raising a child with ADHD was five to six times more than the counterpart and parents of those with ADHD tended to be fired and have low work efficiency. Therefore, adequate and appropriate treatments should be provided to alleviate their behaviours and costly dysfunctional outcomes in the community. The commonly used social skill training in children with ADHD are tradidactic instructions, modelling, role-play activities and behaviour rehearsal; however, these methods are limited to time and space and short of real-life scenarios.

Virtual reality (VR) has emerged in plenty of domains as a promising tool for therapy and rehabilitation. Numerous studies adopted VR in improving cognitive behaviours in children

with ADHD; however, the focuses of these studies were cognitive functioning of daily living context, attentional performance and impulsivity. None of these studies utilised VR to improve social interaction competence and appropriateness in children with ADHD. Furthermore, VR provides controllable immersive environments to engage children, sustain their attention and allow them to effectively gain skills in a safer environment. VR systems generally consist of a head-mounted display and screen so that the therapy can be conducted in a relatively low spatial limitation. Although no study has investigated VR social interaction skills in children with ADHD, evidence has proposed the use of VR social skill training in children with Autistic Spectrum Disorder (ASD). Most of the studies regarding children with ASD also used some real-life scenarios, for example, classrooms, transportation and supermarket, in their social skills training program. The differences in social skills between ADHD and ASD are that children with ADHD are easy to be distracted, avoid or dislike concentrating on one thing and are more likely to interrupt others' speaking; those with ASD are less aware of others around them, overly attached to one object that they like and hard to give meaning to their speech. Due to these discrepancies, the design of social VR intervention in this study will be put in more instantaneous events, objects and avatars in each scenario to improve the distraction problems of children with ADHD. In addition, social VR, which allows more than one user to appear as avatars in a lifelike environment and connect with other users in real-time, will be adopted in this study instead of VR to enhance engagement and interaction among children with ADHD.

Considering the prevalence and advantages of social VR, we plan to develop a social VR training program that contains three real-life scenarios and compare the effects of social VR training and traditional social skills training on social interaction skills, inhibitions, emotional control, behavioural and emotional difficulties and conduct disorders for children with ADHD in Hong Kong using receiving no training as a control.

Cultivating sufficient and appropriate social interaction skills for children with ADHD is a vital step to assist them in integrating into the community. The real-life scenarios created by VR offer a more effective alternative to therapeutic strategies for children with ADHD. However, no previous study adopted social VR to assess social interaction competence and appropriateness in children with ADHD and no randomised controlled trial (RCT) compared the effectiveness of social VR training and traditional social skills training on enhancing the social interaction skills in children with ADHD. The traditional social skills training for

children with ADHD lacked the provision of real-life scenarios and was limited by time and space. Social VR allowing real-time connection and interaction between patients and the virtual instructor was absent in previous studies. To fill these research gaps, we proposed to conduct a three-arm RCT to answer the research question of whether social VR training has higher effectiveness than traditional social skills training in enhancing the social interaction skills of children with ADHD in Hong Kong. The findings of this study are expected to unveil the clinical impacts and compliance and acceptability of social VR training for enhancing social interaction skills among children with ADHD.

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Aims and hypotheses

The study targets children with diagnosed ADHD and aims to (1) develop a social virtual reality-based intervention, (2) investigate its effects on improving the social skills and executive functioning of inhibitions, emotional control and attention of the children compared to traditional social skills training and (3) evaluate the subjects acceptability and compliance with social VR training for enhancing social interaction skills. It is hypothesised that the social interaction skills of the participants in the social VR training group are likely to perform better than those in the traditional social skills training group. Participants in the waitlist control group will receive no change in social interaction skills compared with the two intervention groups.

Methods/ Design

The study will be a three-arm randomised controlled trial comparing the effects of a social VR-based intervention with traditional social skills training on social skills and executive functioning of children with ADHD. Participants in the social VR intervention group and traditional social skill training group will receive 12 training sessions for 3 weeks (4 sessions per week), and participants in the waitlist control group will be asked to retain their usual lifestyles for 3 weeks. The overall design of the study is illustrated in Figure 1. Ethical

approval for the study has been obtained by the Human Subjects Ethics Application Review Committee of The Hong Kong Polytechnic University.

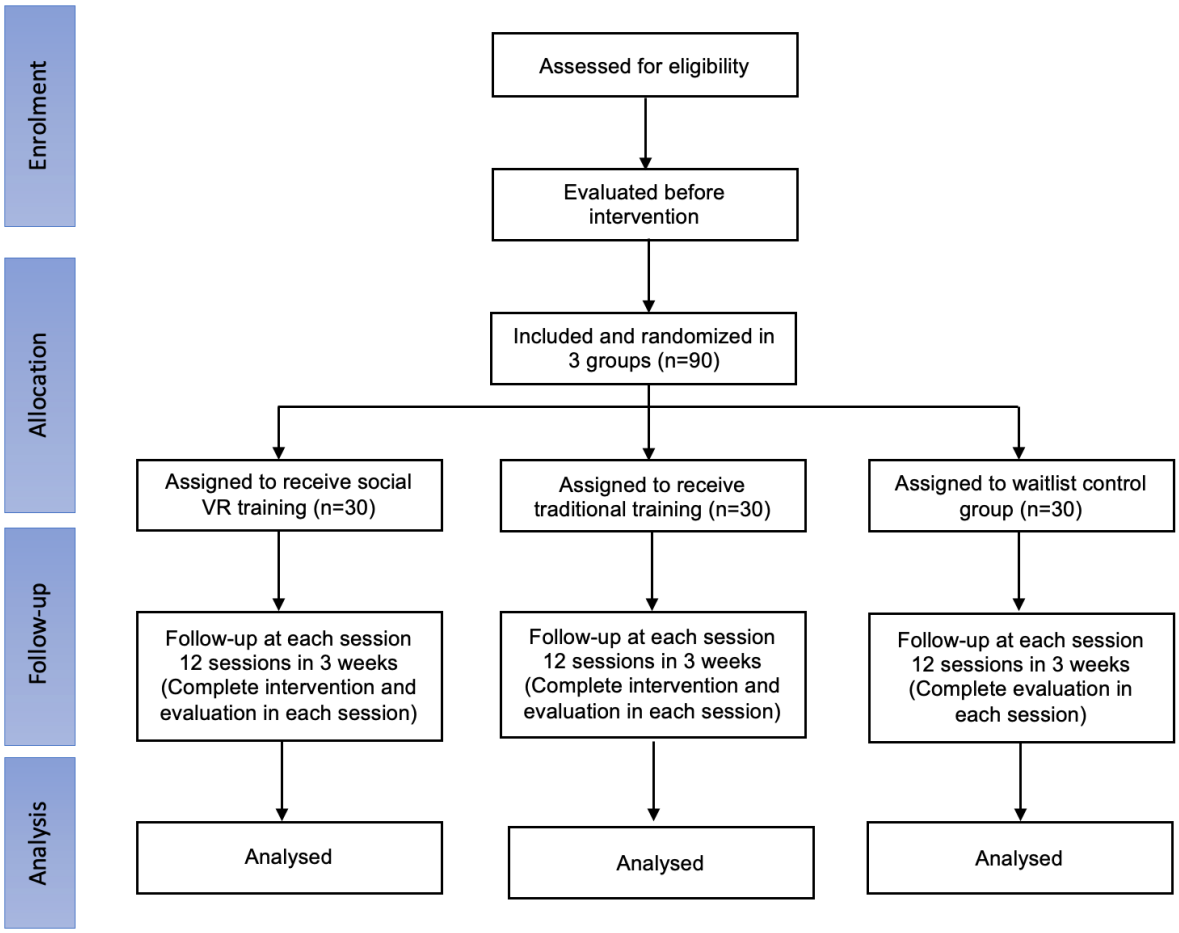

Figure 1. Study design

Participants

Individuals who meet the inclusion criteria will be recruited. The criteria are as follows: 1) aged between 6 and 12 years; 2) ethnic Chinese; 3) residing in Hong Kong; 4) having received a diagnosis of ADHD by Child Assessment Service in Hong Kong or via private practice; 5) stable on pharmacological and/or psychological treatment for ADHD 8 weeks before baseline (determined by health care professionals on the basis of medication data and behavioural observation); 6) no initiation or change of pharmacological treatment for ADHD during the intervention period; 7) ability to read Chinese, and speak and listen to Cantonese by the child and by at least one of their parents or legal guardian; 8) willing to provide informed consent by both participants and one of their parents or legal guardian.

Exclusion criteria are as follows: 1) comorbid autism; 2) mental retardation; 3) an estimated

IQ lower than 85 (using the Wechsler Intelligence Scale for Children – Fourth Edition (Hong Kong) (WISC-IV(HK))); 4) autism spectrum disorder (previously diagnosed by health care professionals), 5) comorbid acute psychiatric disorder (previously diagnosed by health care professionals); and 6) with a severe physical disability (e.g., blindness, deafness) or learning disability (e.g., dyslexia).

Sample size

The guidelines of Whitehead et al. (2016) suggested that recommended that at least 16 subjects per group for medium effect size in pilot RCT and 15% attrition over time can be expected. A total of 90 participants will be recruited which fulfils the minimum number suggested by Whitehead et al. (2016). 30 participants in the social VR group, 30 in the traditional social skills group and 30 in the waitlist control group. This sample size is comparable to those used in the published pilot study on children with ADHD. For instance, van der Oord et al. (2014) recruited 40 participants (20 in the control group and 20 in the interventional group) to examine the efficacy of computerized executive functioning remediation training with game elements in children with ADHD.

Procedure

Recruitment

Participants will be recruited from six primary schools and community centres. Interested participants or parents who provide written informed consent will be further evaluated for inclusion and exclusion criteria by a trained research assistant. Participants who meet the inclusion criteria in the study will be invited to perform an IQ test at the university at baseline.

Randomisation

Eligible participants will be randomized to the social VR (Social VR) group, traditional social skills training group or waitlist control group. A computer-generator randomiser will be used to generate the random allocation list. The randomisation will be undertaken by another research assistant not directly involved in the study. A number generated by the computer will be assigned to each eligible subject who will be randomly allocated to the three different groups by using the number. The participants and their parents or legal guardians will be blind to the assignment process. Parents or legal guardians will receive an email and a telephone call with notification to Group 1, Group 2 or Group 3.

Social VR Intervention

Social VR intervention is developed to enhance the social interaction skills of children. The participants will wear a head-mounted display (HMD) for the Social VR intervention. Each session of the Social VR intervention lasts for a maximum of 20 minutes to ensure the participants focus on the intervention and prevent causing any physical effect. The duration will be adjusted depending on the emotion of the participants during the intervention. The Social VR intervention will mainly help the participant to enhance their social interaction skills and executive function. The intervention contains three real-life virtual scenarios, including (1) classroom and playground, (2) MTR station and compartment, and (3) street and building. One scenario will be adopted in each session. The sequences of the scenarios used in each session will be the same for all participants. During the Social VR intervention, one RA will also appear as one avatar in the scenario to guide the participants to complete a series of tasks. Each intervention session will be conducted in a classroom independently for each participant.

Traditional social skills training

An experienced SEN teacher will teach the participants social interaction skills through tradidactic instructions and role-play activities. Four modules will be covered in the 3-week training: (1) how to introduce yourself and basic social skills; (2) how to listen to others; (3) how to share with others; (4) learn to know how people feel and how to empathise. These modules have been applied in many studies. The content of this training will be as similar as possible to the Social VR training. The training lasts 20 minutes which depends on the emotion of the participants. Each training session will be conducted in a classroom independently for each participant.

Waitlist control group

The participants in this group will receive no training and they can participate in the social VR training after the intervention period. To ensure consistency of the experiment, the participants are not allowed to initiate or change their pharmacological treatment during the 3-week intervention period.

Measures

Questionnaires

The parents or legal guardians of the participants will complete a structured questionnaire at the baseline and after the last session. Demographic information, including age, gender, Medication, ADHD symptoms and game experience will be recorded at the baseline. The questionnaires include questions about social skills and executive functioning. The satisfaction of the participants and their parents or legal guardians towards the training program will be assessed at week 3. The VR sickness of the participant will be evaluated after each session. The assessor will be blind to the treatment condition. The questionnaires will include the following scales:

Primary outcome measure

1. Process evaluation

   The process evaluation of the training will be assessed by investigating: (i) training acceptability as measured by the participants' attendance and compliance; (ii) recruitment rate; (iii) participant completion.

   (i) Assessment of training acceptability and compliance

   The attendance of the participants during the trainings will be recorded. To verify the validity of the findings, training non-adherence of the participants will be terminated which will be stated in the consent form. The absence of any training session will be considered as non-adherence. The participants will be asked about their willingness of partaking in this kind of training by one 7-point Likert scale question which is used to reflect the acceptability to the intervention. The retention rate should be at least 85% according to the feasibility RCT.

   The compliance with the training program will be evaluated by the communication log which the parents record their children's daily activity and emotion in the 3-week intervention period. The participants' parents will be reminded to attend the training through telephone in the first four training sessions and WhatsApp or WeChat in the fifth and eighth training sessions. No reminder follow-up will be made in the remaining four sessions. These data will be used to evaluate their compliance.

   (ii) Recruitment rate

   The recruitment rate is at least 48.5% of all referrals according to the feasibility study.

   (iii) Participant completion

   Participants attending at least nine (i.e., 75%) of the 12 sessions are considered to have completed the program.

Secondary outcome measure

1. Social Skills Rating Scale (SSRS-P)

   The social skills of the children will be assessed by Chinese-translated SSRS-P which will be scored by the participants' parents before the first session and after the last session. This scale consists of 3 subscales, including self-control, assertiveness and initiative and cooperation, with a total of 31 items. A 3-point Likert scale (never, sometimes, often) is used to score. The SSRS-P is a validated instrument that has been commonly adopted in clinical trials of psychiatric and neurological disorders.

2. Child psychologist's assessment

   One child psychiatrist will score the performance of the participants in the 5-minute tasks to obtain an objective evaluation. Broken blinding is unavoidable in child psychiatrist's assessment. To minimise unblinding bias during the assessment, each participant will be identified by a case number.

3. Behaviour Rating Inventory of Executive Function (BRIEF)

   Chinese-translated BRIEF used to assess the executive functioning of children which will be scored by the participants' parents before the first session and after the last session. The subscales of inhibitions (16-item) and emotional control (10-item) will be adopted in this study. A 3-point Likert scale (never, sometimes, often) is used to score.

4. Satisfaction

   Satisfaction is measured by a 7-point Likert scale, 'What grade would you give to this training program?'. Both participants and parents/ guardians have to answer.

5. Simulator Sickness Questionnaire (SSQ)

   The SSQ measures motion sickness or physical discomfort of participants in VR environment. Nine items will be measured, including discomfort, fatigue, headache, eyestrain, sweating, nausea, difficulty concentrating, blurred vision and dizziness, with yes or no questions for each item.

6. Assessment of safety

   a) Adverse events

   RA1 will ask participants' parents/ guardians, using open-ended questions, whether the participants experienced any adverse events during training. The severity and relationship of the adverse event to the intervention will be documented and investigated.

   b) Reasons for withdrawal

   When a subject withdraws before completing the study, the reasons for withdrawal will be recorded.

Statistical analysis plan

All statistical analyses will be performed in SPSS version 26.0 software (IBM Corp, Armonk, NY, USA) and are two-sided with a level of significance of < 0.05. Demographic information of the participants will be summarised with frequency and percentage for categorical variables. The continuous variables will be summarised by mean and standard deviation. The change between baseline and week 3 within each arm will be tested using t-tests. To examine the between-group difference in terms of measure outcomes from baseline to week 3, repeated analyses of covariance (ANCOVA) with adjustment of baseline characteristics will be conducted. To evaluate the improvement during the intervention period among the three groups, f-tests will be performed on primary and secondary outcome measures at the beginning of the first session and at the end of the last session. An intention-to-treat analysis will be performed. This analysis is regarded as the most appropriate approach to analyse RCT data by the highest-quality journals, which have utilised the CONSORT standard.

THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

CONSENT TO PARTICIPATE IN RESEARCH

EFFECTIVENESS OF SOCIAL VIRTUAL-REALITY ON ENHANCING SOCIAL INTERACTION SKILLS IN CHILDREN WITH ATTENTION-DEFICIT/HYPERACTIVITY DISORDER: A THREE-ARM PILOT RANDOMISED CONTROLLED TRIAL

The study aims to develop a social virtual reality-based intervention for children with ADHD and investigate its effects on improving the social skills and executive functioning of inhibitions, emotional control and attention of the children with ADHD compared to traditional social skills training. The social VR training program is important for children with ADHD because the innovativeness of the VR technology may engage and enhance children with ADHD's learning ability. The findings will provide healthcare professionals with the most effective mean for mental health services for ADHD in Hong Kong. These findings will facilitate the development of the social VR training program that is tailor-made for Hong Kong children with ADHD, resulting in the improvement of these children's social skills and psychological wellbeing that will be beneficial in integrating them into society.

During the social virtual reality training session, participants had to wear head-mounted display devices for an approximately 20-minute session. In the traditional social skills training process, the instructor will lead the participants in the 20-minute session.

All data collected this time will only be used for scientific research and will be analyzed anonymously, and all personal data will be kept strictly confidential.

I _____ hereby consent to participate in the captioned research conducted by the researcher of School of Nursing at The Hong Kong Polytechnic University.

I understand that information obtained from this research may be used in future research and published. However, my right to privacy will be retained, i.e. my personal details will not be revealed. Participating in this study may cause physical discomfort to me, such as headaches, eyestrain, dizziness, and nausea after using the headset.

The procedure as set out in the attached information sheet has been fully explained. I understand the benefit and risks involved. My participation in the project is voluntary. I acknowledge that I have the right to question any part of the procedure and can withdraw at any time without penalty of any kind.

If you have any questions, you may contact Dr Harry Jin Qin (email: harry.qin@polyu.edu.hk).

Name of participant _____

Name of Parent or Guardian _____

Signature of Parent or Guardian _____

Name of researcher _____

Signature of researcher _____

Date _____

Hung Hom Kowloon Hong Kong 香港 九龍 紅磡
Tel 電話 (852) 2766 5111 Fax 傳真 (852) 2784 3374
Email 電郵 polyu@polyu.edu.hk
Website 網址 www.polyu.edu.hk