General Psychiatry

Virtual reality-based cognitive–behavioural therapy for the treatment of anxiety in patients with acute myocardial infarction: a randomised clinical trial

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ABSTRACT

Background The presence of mental health conditions is pervasive in patients who experienced acute myocardial infarction (AMI), significantly disrupting their recovery. Providing timely and easily accessible psychological interventions using virtual reality-based cognitive–behavioural therapy (VR-CBT) could potentially improve both acute and long-term symptoms affecting their mental health.

Aims We aim to examine the effectiveness of VR-CBT on anxiety symptoms in patients with AMI who were admitted to the intensive care unit (ICU) during the acute stage of their illness.

Methods In this single-blind randomised clinical trial, participants with anxiety symptoms who were admitted to the ICU due to AMI were continuously recruited from December 2022 to February 2023. Patients who were Han Chinese aged 18–75 years were randomly assigned (1:1) via block randomisation to either the VR-CBT group to receive VR-CBT in addition to standard mental health support, or the control group to receive standard mental health support only. VR-CBT consisted of four modules and was delivered at the bedside over a 1-week period. Assessments were done at baseline, immediately after treatment and at 3-month follow-up. The intention-to-treat analysis began in June 2023. The primary outcome measure was the changes in anxiety symptoms as assessed by the Hamilton Anxiety Rating Scale (HAM-A).

Results Among 148 randomised participants, 70 were assigned to the VR-CBT group and 78 to the control group. The 1-week VR-CBT intervention plus standard mental health support significantly reduced the anxiety symptoms compared with standard mental health support alone in terms of HAM-A scores at both post intervention (Cohen's d=−1.27 (95% confidence interval (CI): −1.64 to −0.90, p<0.001) and 3-month follow-up (Cohen's d=−0.37 (95% CI: −0.72 to −0.01, p=0.024). Of the 70 participants who received VR-CBT, 62 (88.6%) completed the entire intervention. Cybersickness was the main reported adverse event (n=5).

Conclusions Our results indicate that VR-CBT can significantly reduce post-AMI anxiety at the acute stage of the illness; the improvement was maintained at the 3-month follow-up.

Trial registration number The trial was registered at www.chictr.org.cn with the identifier: ChiCTR2200066435.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Anxiety is common in people who experienced acute myocardial infarction (AMI) and significantly impacts their recovery and all-cause mortality. Although internet-based cognitive–behavioural therapy (CBT) has proven effective in reducing anxiety in people during their AMI recovery stage, evidence has indicated that the anxiety level is much higher at the time of the cardiac event compared to the recovery stage after hospital discharge.

WHAT THIS STUDY ADDS

⇒ This study is the first randomised controlled trial to report that a timely, 1-week virtual reality-based CBT (VR-CBT) is efficacious for the treatment of anxiety in post-AMI patients within the intensive care unit (ICU) environment. The VR-CBT intervention significantly reduced the anxiety symptoms compared with standard mental health support at both post intervention and the 3-month follow-up.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The use of VR-CBT in the ICU setting is efficacious, safe and readily deliverable for reducing post-AMI anxiety.

INTRODUCTION

Acute myocardial infarction (AMI) is a severe and life-threatening coronary heart disease (CHD) affecting more than 3 million people yearly worldwide.[1] In individuals aged over 60 years, the global prevalence of AMI can be around 10%.[1] AMI is a stressful, traumatic event, and over one-third of patients

who experienced AMI develop mental health conditions, including anxiety, depression and post-traumatic stress disorder (PTSD).[2 3] Post-AMI anxiety and depression symptoms can remain elevated for months after hospital discharge and are associated with a higher risk of subsequent adverse cardiac events and all-cause mortality.[4 5] Suicide risk peaks during the first month following discharge and is 20 times higher in patients with AMI who have a history of psychiatric disorders than in patients without such history.[6] The presence of mental health conditions has also been linked with poor compliance and attendance in cardiac rehabilitation programmes, resulting in a worse AMI prognosis and a lower quality of life.[7 8]

Evidence-based psychological treatment, for example, cognitive–behavioural therapy (CBT), has shown effectiveness in reducing mental health symptoms in patients with CHD.[9] Although recommended by the American Heart Association, psychological intervention is not routinely included in conventional cardiac rehabilitation programmes.[10 11] The limited availability of mental health professionals and the high costs of mental healthcare are global challenges for the treatment of mental disorders. Internet-delivered CBT (ICBT) partially resolves the limited access to therapists, and some preliminary studies have suggested that 8–14 weeks of ICBT is efficacious in reducing anxiety and depression in people during their AMI recovery stage.[12 13] However, evidence has shown that the incidence of mental health conditions in patients with AMI, particularly anxiety, is much higher at the time of the cardiac event than during the recovery stage after hospital discharge.[14 15] The above findings suggest that providing timely psychological intervention may be beneficial for both the acute stage and the long-term recovery of patients with AMI. The emergence of virtual reality-based CBT (VR-CBT) provides a flexible, accessible and cost-effective treatment approach involving less workload for mental health professionals. VR-CBT has been successfully used in treating anxiety-related disorders, including specific phobias, panic disorder and social anxiety disorder, with promising efficacy and safety.[16] In the present study, we tested the effectiveness of VR-CBT for post-AMI anxiety symptoms delivered at the bedside for patients admitted to the intensive care unit (ICU) immediately after an AMI event. We hypothesised that patients receiving the VR-CBT interventionhave lower levels of anxiety compared with patients receiving standard mental health support. Our secondary hypotheses were that VR-CBT could improve sleep quality, cognitive function, perceived well-being and somatic symptom severity.

METHODS

Study design

In this single-blind randomised clinical trial, participants were continuously recruited from the ICU of the cardiology department of Zhongshan Hospital, Fudan University, in Shanghai, China, from December 2022 to February 2023. The trial was registered at www.chictr.org.cn with the identifier ChiCTR2200066435. The complete protocol is available in the online supplemental material 1. The reporting of this study followed the Consolidated Standards of Reporting Trials guidelines. Permuted block randomisation was used with a block size of 4. One nurse assistant unassociated with the study opened the next sequentially numbered opaque envelope that contained the allocation sequence. The random allocation sequence was generated using R V.4.1.2. (R Project for Statistical Computing). Participants were randomly allocated in a 1:1 ratio to receive VR-CBT plus the standard mental health support (intervention group) or to receive the standard mental health support only (control group) for 1 week. A research assistant who registered the participants and assigned them to the intervention or the control groups was aware of the allocation sequence. Due to the nature of the study, the participants and the clinicians were not blinded, whereas the outcome assessors and data analysts were blinded to the allocation. Data were collected at baseline, 1 week post intervention and 3-month follow-up.

Participants

Eligible participants were aged 18–75 years, had an AMI diagnosis based on the American Heart Association or World Heart Federation guidelines and had a Hamilton Anxiety Rating Scale (HAM-A) Score above 7.[17] Individuals who were receiving psychotropic medications, who had a history of any psychiatric disorders, including major depression, bipolar disorder, anxiety disorders, psychotic disorders, obsessive-compulsive disorder, PTSDs, substance use disorders or significant active suicidal ideation or behaviours, or who experienced severe visual or hearing impairment were excluded through an initial screening assessment. All participants were informed about the study, and participation in the study was voluntary. Participants had the right to leave the study at any time without affecting their treatment.

Intervention

The VR equipment included both hardware and software. The intervention group participants could sit or lie in bed while wearing a head-mounted display (HMD) connected to a movable control station (**see** online supplemental material 1). The software was designed by the MED-VISION company (www.med-vision.cn) and contained four modules: hypnotherapy (day 1), mindfulness cognition (days 2 and 3), music therapy (days 4 and 5) and relaxation therapy (days 6 and 7). Each module contained several scenarios from which the participants could choose 1–2 per day. The VR-CBT intervention took approximately 30 min every day for a total of 7 days. The standard mental health

support included brief mental health-related education and daily mental healthcare delivered by trained nurses. Specifically, before the intervention began, a nurse would give a 10 min introduction to the patients regarding the mental health-related problems they may encounter and let the patients know how they could get help. The daily mental healthcare, which took 5–10 min, mainly included verbal communication which included encouragement and support for the patient, assistance for building the patient's confidence, orientation to increase familiarity with the ICU environment and coping measures to address fear and worry.

Sample size determination

We determined our sample size using pilot study data, and it was based on an effect size of 0.4 for the standard mental health support and 0.6 for the VR-CBT, 85% power and $\alpha \leq 0.05$. This resulted in a required sample of 144 participants. In planning the final sample size, we included a dropout rate of 10%.

Outcome measures

At enrolment, participants self-reported sociodemographic characteristics (age, sex, marital status, educational attainment, employment, drinking and smoking status and physical comorbidities) and the use of mental health services (current and in the past 12 weeks).

The two groups were compared at baseline, 1 week post intervention and 3-month follow-up. The primary outcome was changes in anxiety symptoms assessed with the HAM-A scores by a blinded psychiatrist investigator. Secondary outcomes were self-evaluated anxiety symptoms assessed using the State-Trait Anxiety Inventory (STAI),[18] cognitive dysfunction using the Perceived Deficits Questionnaire for Depression (PDQ-D)[19] and sleep quality using the Pittsburgh Sleep Quality Index (PSQI).[20] Patients' perception of well-being and quality of life was evaluated with the Short Form-12 (SF-12).[21] Subscales of the SF-12, including mental and physical component scores, can be calculated and represent a patient's mental and physical health state. The Patient Health Questionnaire-15 (PHQ-15) assessed patients' self-evaluated somatic symptom severity.[22] Participants completed questionnaires at baseline, 1 week post intervention and 3-month follow-up.

Statistical analysis

Baseline demographic and clinical characteristics were analysed using a t-test for normally distributed variables; if normality was violated, we used the Mann-Whitney test. Fisher's exact test was used for categorical variables. We used the intention-to-treat (ITT) principle to analyse all post-intervention and follow-up data according to participant randomisation. The repeated measurements of the outcome variables were analysed using linear mixed models with restricted maximum likelihood estimation. Treatment group, time and group-by-time interactions were included as fixed effects, and the participant level was included as random effects. The treatment effect was estimated with the group-by-time interactions. Post-intervention and follow-up data were each compared with the baseline data. The variance–covariance model for the repeated measures was selected using the unstructured model. Effect sizes were estimated as Cohen's d using the results from the independent sample t-test (M_1-M_2/S_p, M: mean of each group, S_p: pooled SD). Significance was set as a two-tailed $p<0.05$. All analyses were conducted in SPSS V.27 (IBM).

RESULTS

Sample characteristics

Of the 180 patients admitted to the Zhongshan Hospital ICU after AMI during the study period, 20 were ineligible and excluded from participation. In total, 160 participants completed the baseline assessments and were randomly assigned to the VR-CBT group (n=80) or the control group (n=80). Among these participants, ten in the VR-CBT group and two in the control group never started the intervention, and all were due to unknown personal reasons (see figure 1). Of the eight patients in the VR-CBT group who dropped out of the intervention, five were due to unknown personal reasons and three were discharged from the ICU before the completion of the treatment. Likewise, four patients in the control group discontinued the intervention because of ICU discharge. Retention rates at 3 months were 82.9% and 87.2% in the VR-CBT and control groups, respectively. All participants were Han Chinese. The baseline characteristics were comparable between the two groups and are described in table 1.

Primary outcome

At baseline, no significant differences were seen in measured outcomes between the VR-CBT and control groups, except in the HAM-A scores, which was significantly lower in the control group (t=−2.78, p=0.006, see online supplemental table 1). The baseline HAM-A score was thus included as a covariate in the analyses. The ITT analysis indicated that the treatment effect significantly reduced the anxiety symptoms in the VR-CBT group as assessed using HAM-A, both at 1 week post intervention (B=−9.38 (95% confidence interval (CI): −11.55 to −7.22), p<0.001) and at 3-month follow-up (B=−2.18 (95% CI: −4.08 to −0.28), p=0.024) compared with the baseline score (table 2). The HAM-A score decreased by 57.3% from baseline to 1 week post intervention in the VR-CBT group, while it increased by 15.7% in the control group (table 3). Larger reductions in anxiety symptoms were also observed at the 3-month follow-up in the intervention group compared with those in the control group (Cohen's d=−0.37, tables 2 and 3).

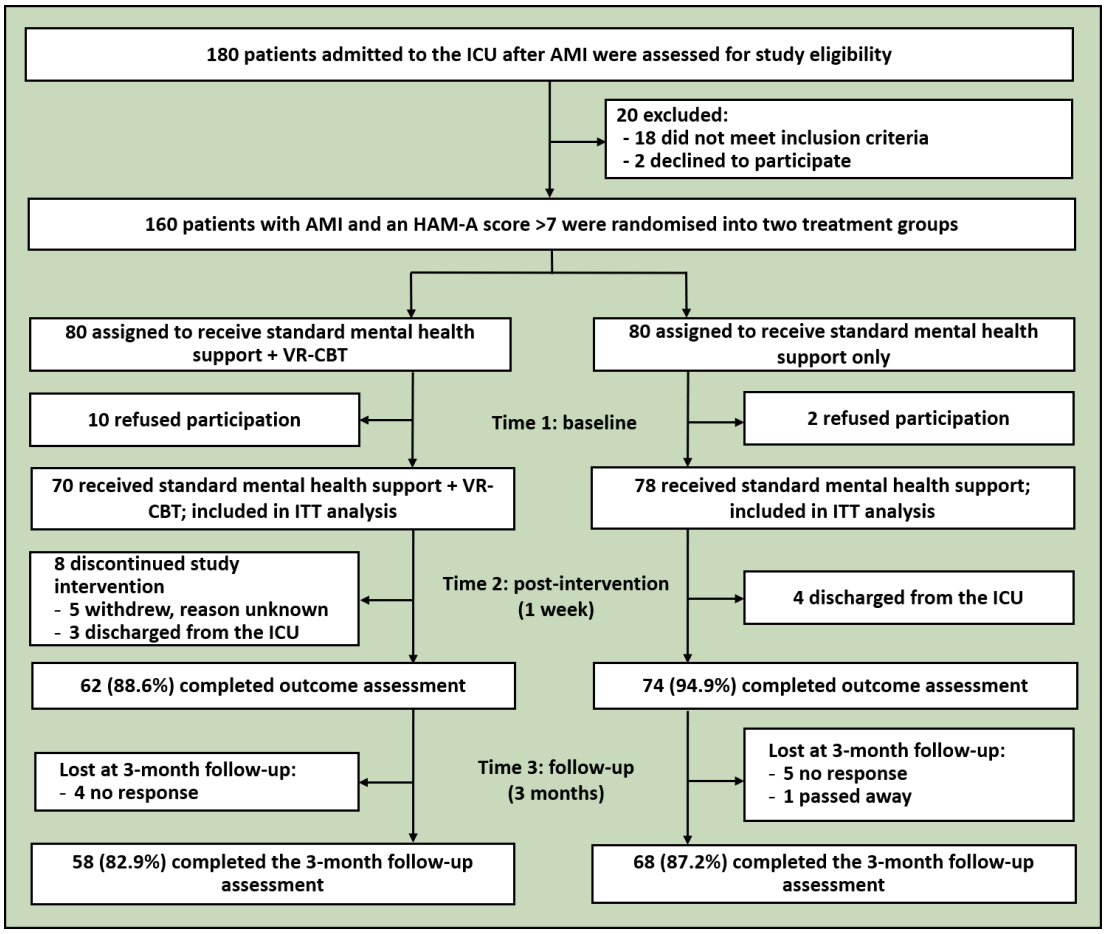

Figure 1 Consolidated Standards of Reporting Trials flowchart. AMI, acute myocardial infarction; HAM-A, Hamilton Anxiety Rating Scale; ICU, intensive care unit; ITT, intention-to-treat; VR-CBT, virtual reality-based cognitive–behavioural therapy.

Secondary outcomes

Between baseline and the postintervention assessment, significant intervention effects were seen on self-reported anxiety symptoms (STAI-S: B=−4.21 (95% CI: −6.14 to −2.27), p<0.001; STAI-T: B=−5.61 (95% CI: −7.49 to −3.73), p<0.001), sleep quality (PSQI: B=−5.15 (95% CI: −6.85 to −3.45), p<0.001), somatic symptom severity (PHQ-15: B=−5.92 (95% CI: −7.55 to −4.29), p<0.001) and the mental health component of the perceived well-being (SF-12 MCS: B=−6.62 (95% CI: −9.77 to −3.47), p<0.001). The treatment effect over the 1-week VR-CBT was not significant on self-evaluated cognitive dysfunction (PDQ-D: B=−1.34 (95% CI: −3.32 to 0.64), p=0.181) and the physical health component of the perceived well-being (SF-12 PCS: B=−1.29 (95% CI: −3.46 to 0.88), p=0.242) (table 2). Specifically, a larger reduction was noted in STAI-S (Cohen's d=−0.71), STAI-T (Cohen's d=−0.99), PSQI (Cohen's d=−1.09), PHQ-15 (Cohen's d=−1.21) and SF-12 MCS (Cohen's d=−0.68) in the VR-CBT group than in the control group (tables 2 and 3). Treatment effects at the 3-month follow-up were not significant for any of the secondary outcomes (table 2).

Adverse events

The only reported adverse effect was cybersickness (n=5), including uncomfortableness due to wearing the HMD (n=3), a feeling of derealisation (n=1) and headache (n=1). However, none of the participants discontinued the study because of these effects. No other severe adverse events were reported.

DISCUSSION

Main findings

To our knowledge, this study is the first randomised controlled trial of using VR-CBT to treat anxiety symptoms in post-AMI patients during the in-hospital acute stage. Our results revealed that an immediate 1-week VR-CBT significantly improved anxiety symptoms on the clinician-rated primary outcome in the intervention group compared with the control group, both post intervention and at the 3-month follow-up assessment. Significant improvements were also found at one week post intervention in self-evaluated anxiety symptoms, sleep quality, somatic symptom severity and the mental health component of the SF-12 questionnaire. Since all participants were admitted to ICU due to AMI, a serious physical disease, we did not expect the SF-12 PCS to improve significantly simply after the 1-week VR-CBT intervention. Moreover, the purpose of the intervention was to improve mental health outcomes, and no specific session addressing physical symptoms

Table 1 Demographic and clinical characteristics of patients with acute myocardial infarction in the ICU by treatment group

Characteristics	N (%)		T/χ^2	P value
	Standard mental health support and VR-CBT (n=70)	Standard mental health support alone (n=78)		
Age, mean (SD), years	58.3 (9.3)	59.9 (9.5)	1.01*	0.316
Sex			0.001†	0.975
Female	10 (14.3)	11 (14.1)		
Male	60 (85.7)	67 (85.9)		
Education level, mean (SD), years	12.0 (3.5)	11.0 (3.2)	–1.87*	0.063
Employment status			0.02†	0.902
Full time	20 (28.6)	23 (29.5)		
Retired/no stable work	50 (71.4)	55 (70.5)		
Married/common law	66 (94.3)	72 (92.3)	0.23†	0.632
Has children	54 (77.1)	58 (74.4)	0.16†	0.693
BMI, mean (SD)	25.0 (3.6)	25.3 (3.1)	0.57*	0.572
Smoking history	46 (65.7)	51 (65.4)	0.002†	0.966
Drinking >5 days per week	23 (32.9)	28 (35.9)	0.15†	0.698
Physical comorbidities‡				
0	6 (8.6)	8 (10.3)	0.14†	0.932
1–2	50 (71.4)	54 (69.2)		
≥3	14 (20.0)	16 (20.5)		
Emergent PCI	65 (92.9)	73 (93.6)	0.03†	0.859

*T value.
†Pearson χ^2.
‡Physical comorbidities included but were not limited to cerebrovascular disease, hypertension, diabetes, coronary heart disease, glaucoma, cataract, thyroid dysfunction and brain trauma.
BMI, body mass index; ICU, intensive care unit; PCI, percutaneous coronary intervention; VR-CBT, virtual reality-based cognitive–behavioural therapy.

had been designed. The failure to detect significant improvement in somatic symptoms was similar to the finding reported by Schneider *et al*.[12] As expected, because the baseline levels of self-evaluated cognitive dysfunction were low, the treatment effect was not significant over time in the VR-CBT group compared with the control group. In addition, we did not detect a treatment effect in the STAI and PSQI between the VR-CBT and control groups at the 3-month follow-up. One possible explanation might be that our 1-week intervention exerted only an acute and relatively short-term effect on these domains. A previous study also indicated that internet-based CBT intervention was not superior in reducing self-reported symptoms of anxiety or depression compared with the control group.[13]

Our results are in line with previous VR-CBT studies for the treatment of anxiety-related disorders, in which significant reductions in anxiety symptoms were observed after the intervention.[16] Previous VR studies have reported a high frequency of dropouts due to the inability to become immersed in the programme or cybersickness.[23] However, none of the patients discontinued for these reasons in this study, despite five patients (7.1%) reported experiencing cybersickness. The advances in VR technology in recent years have significantly improved image quality and immersive feeling; therefore, cybersickness is less likely to be problematic for this type of utilisation. In our study, the main reason for discontinuation was early discharge from the ICU, considering the average time for monitoring post-AMI patients in ICU in China is approximately 1 week.

AMI is a life-threatening and distressing traumatic event. Patients' intense sense of pain, helplessness and the risk of death during the event, as well as the fearful experience of various treatments, such as percutaneous coronary interventions (PCI), could lead to the immediate occurrence of anxiety symptoms, which are likely to occur twice the rate of depression during the acute stage of the illness.[15] From patients' perspectives, the ICU is often experienced as a hostile environment because of excessive noise, loss of self-autonomy and a lack of contact with relatives and friends, further augmenting the patients' stress

Table 2 Group×time interactions for primary and secondary study outcomes of patients with acute myocardial infarction in the ICU who received 1 week of VR-CBT treatment in addition to standard mental health support

	Post intervention				3-month follow-up			
Outcomes	B (95% CI)*	T value	P value	Cohen's d (95% CI)†	B (95% CI)*	T value	P value	Cohen's d (95% CI)†
HAM-A	−9.38 (−11.55 to −7.22)	−8.50	**<0.001**	−1.27 (−1.64 to −0.90)	−2.18 (−4.08 to −0.28)	−2.26	**0.024**	−0.37 (−0.72 to −0.01)
STAI-S	−4.21 (−6.14 to −2.27)	−4.31	**<0.001**	−0.71 (−1.06 to −0.36)	−2.12 (−4.99 to 0.76)	−1.46	0.147	−0.20 (−0.55 to 0.16)
STAI-T	−5.61 (−7.49 to −3.73)	−5.91	**<0.001**	−0.99 (−1.35 to −0.64)	−1.46 (−4.03 to 1.12)	−1.12	0.265	−0.14 (−0.49 to 0.21)
PDQ-D	−1.34 (−3.32 to 0.64)	−1.37	0.181	−0.31 (−0.65 to 0.04)	0.11 (−2.04 to 2.27)	0.11	0.917	0.06 (−0.29 to 0.42)
PSQI	−5.15 (−6.85 to −3.45)	−5.98	**<0.001**	−1.09 (−1.47 to −0.70)	0.98 (−0.54 to 2.50)	1.26	0.208	0.20 (−0.17 to 0.57)
PHQ-15	−5.92 (−7.55 to −4.29)	−7.18	**<0.001**	−1.21 (−1.58 to −0.84)	0.71 (−0.80 to 2.22)	0.93	0.354	0.20 (−0.15 to 0.55)
SF-12 MCS	−6.62 (−9.77 to −3.47)	−4.15	**<0.001**	−0.68 (−1.03 to −0.33)	−0.98 (−4.66 to 2.70)	−0.53	0.601	−0.08 (−0.43 to 0.27)
SF-12 PCS	−1.29 (−3.46 to 0.88)	−1.18	0.242	−0.10 (−0.44 to 0.24)	−0.52 (−2.59 to 1.55)	−0.50	0.620	−0.01 (−0.36 to 0.34)

*Age, sex and baseline HAM-A were included as covariate in all analyses.
†Cohen's d for unadjusted group means based on the baseline to post-test difference.
B, beta coefficient; HAM-A, Hamilton Anxiety Rating Scale; ICU, intensive care unit; PDQ-D, Perceived Deficits Questionnaire for Depression; PHQ-15, Patient Health Questionnaire-15; PSQI, Pittsburgh Sleep Quality Index; SF-12 MCS, 12-Item Short Form Health Survey Mental Component Score; SF-12 PCS, 12-Item Short Form Health Survey Physical Component Score; STAI-S, State-Trait Anxiety Inventory-State; STAI-T, State-Trait Anxiety Inventory-Trait; VR-CBT, virtual reality-based cognitive–behavioural therapy.

Table 3 Changes from baseline to post-test and follow-up in primary and secondary outcomes* in a comparison of patients with acute myocardial infarction in the ICU

	Standard mental health support and VR-CBT (n=70)			Standard mental health support alone (n=78)		
Outcomes	Baseline	Post intervention	3-month follow-up	Baseline	Post intervention	3-month follow-up
HAM-A	12.86 (12.80–12.91)	5.49 (3.63–7.34)	6.72 (5.33–8.10)	12.84 (12.78–12.89)	14.85 (13.13–16.56)	8.90 (7.60–10.19)
STAI-S	41.62 (39.95–43.29)	38.80 (37.16–40.43)	40.31 (38.77–41.84)	41.83 (40.26–43.41)	43.21 (41.70–44.73)	42.81 (41.38–44.24)
STAI-T	41.02 (39.39–42.66)	36.67 (35.24–38.09)	40.83 (39.34–42.32)	41.48 (39.94–43.01)	42.73 (41.41–44.05)	42.89 (41.51–44.27)
PDQ-D	1.93 (0.14–3.71)	−0.32 (-1.56–0.91)	2.27 (0.69–3.85)	2.63 (0.94–4.32)	1.72 (0.57–2.88)	3.23 (1.76–4.71)
PSQI	6.77 (5.83–7.71)	5.04 (3.94–6.13)	9.47 (8.51–10.43)	7.02 (6.12–7.93)	10.44 (9.46–11.43)	8.54 (7.64–9.43)
PHQ-15	7.01 (6.06–7.96)	3.09 (1.93–4.24)	6.00 (4.96–7.03)	6.69 (5.79–7.58)	8.68 (7.62–9.74)	4.83 (3.86–5.79)
SF-12 MCS	56.52 (54.24–58.81)	56.64 (54.44–58.84)	61.93 (59.43–64.43)	55.64 (53.49–57.79)	62.38 (60.34–64.42)	61.80 (59.48–64.13)
SF-12 PCS	37.38 (36.04–38.72)	35.10 (33.65–36.55)	35.32 (33.95–36.69)	37.90 (36.64–39.16)	36.91 (35.58–38.25)	36.37 (35.10–37.64)

*Data were represented as estimated marginal means and 95% CI, with age, sex and baseline HAM-A adjusted using linear mixed models.
HAM-A, Hamilton Anxiety Rating Scale; ICU, intensive care unit; PDQ-D, Perceived Deficits Questionnaire for Depression; PHQ-15, patient health questionnaire-15; PSQI, Pittsburgh Sleep Quality Index; SF-12 MCS, 12-Item Short Form Health Survey Mental Component Score; SF-12 PCS, 12-Item Short Form Health Survey Physical Component Score; STAI-S, State-Trait Anxiety Inventory-State; STAI-T, State-Trait Anxiety Inventory-Trait; VR-CBT, virtual reality-based cognitive–behavioural therapy.

and anxiety. Although, for many patients, some of the early mental health symptoms resolve during the first few months after hospital discharge, the prevalence of generalised anxiety disorder, major depression and panic disorder is still higher in patients with CHD than in the general population.[24–26] Moreover, the majority of our subjects admitted to the ICU underwent emergent PCI, which is also associated with a higher risk for later development of PTSD.[27] It is difficult to monitor whether mental health problems become fully developed in-hospital or are established only weeks after discharge. Therefore, conducting timely psychological interventions during the in-hospital acute stage can potentially reduce the risk of symptoms of anxiety and depression that emerge later or persist into the convalescent stage at home. Our results supported that an immediate, 1-week bedside VR-CBT delivered in the ICU environment can effectively reduce the patient's anxiety symptoms, not only in the acute stage but also extending to the 3-month follow-up. VR-CBT is easily accessible, flexible and significantly more cost effective than traditional psychotherapy.[28] VR-CBT also seems to be more favourable to people compared with conventional face-to-face therapy.[29] Meanwhile, it has a similar effect size as ICBT in the treatment of anxiety and depression.[16]

Strengths and limitations

A strength of our study is that we provided VR-CBT soon after ICU admission (1–2 days), minimising the influence of the ICU's untoward environmental factors on the patients' experience. The timing of the ICU-VR intervention is suggested as a key relevant factor for its therapeutic effect.[30] We also provided several scenarios in each VR-CBT module so that the patients could experience better self-control, considering that private mobile devices are not permitted in the ICU setting in China. Our study provided one of the largest sample sizes in the investigation of VR-CBT-based treatment of anxiety-related disorders. The study findings can be used as an evidence-based intervention protocol to improve the literature and make a noticeable contribution to the treatment of mental distress in post-AMI patients.

The current study had several limitations. First, despite our randomisation procedure, there were statistical differences in the primary outcome measures between groups at baseline. Second, the long-term effects of the 1-week VR-CBT are unknown since we only set up a 3-month follow-up assessment. Long-term follow-up data are required in future studies to evaluate the impact of VR-CBT for post-AMI patients comprehensively. Third, the generalisation of results from this study may be limited since patients were recruited from only one study centre; whether VR-CBT conducted in the ICU could be applied for the reduction of anxiety symptoms of other acute diseases remains unknown. Finally, the study has a single-blind design in which only participants were blinded to the details. The disadvantage of this design was that the attending experimenter might consciously or subconsciously affect participants' responses and might conduct the standard mental health support unequally between the control and intervention groups.

Implications

Our findings support the hypothesis that a timely VR-CBT intervention strongly reduces post-AMI anxiety in patients admitted to the ICU. The use of VR-CBT in the ICU setting remains in the primary stage. More study is needed to increase the evidence regarding the effectiveness of this technology and its long-term effect on the mental health of patients with serious illness conditions.

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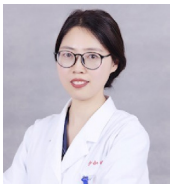

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