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The effect of Shexiang Tongxin Droping Pills on CMVD among those with mental disorder and NOCAD: a study protocol

Background Coronary microcirculation dysfunction, highly prevalent among patients with mental disorder (anxiety or depression), is closely related to adverse cardiac events, including hospitalization, sudden cardiac death, and myocardial infarction. Shexiang Tongxin Droping Pills (STDP), a tradition Chinese medicine, exerts endothelial protective function by anti-inflammation, anti-oxidative stress, and promoting blood circulation. STDP protects against CMVD in previous fundamental studies. Objective The present trail is aiming at evaluating the effect of STDP on CMVD among depressed/anxious patients with non-obstructive coronary artery disease (NOCAD). Method 160 depressed or anxious patients diagnosed with NOCAD combined with CMVD utilizing coronary artery angiography and stress cardiac magnetic resonance (CMR) will be recruited in the present study. These patients will be randomized into two groups, namely, Nicorandil group (Nicorandil combined with routine medicine), and STDP groups (STDP combined with routine medicine). The absolute myocardial blood flow and myocardial reperfusion will be assessed by CMR 6-month after discharge. Major cardiac events (MACEs) and quality of life will be recorded at 1-, 3-, 6-, 9-, 12-month of follow-up. The change of CMVD is defined the primary endpoint. PHQ9, GAD-7, and Seattle Angina Scale (SAQ) will be recorded at 1-, 3-, 6-, 9-, 12-month of follow-up. Conclusion This study will first evaluate the efficacy of STDP on CMVD among patients with mental disorder and NOCAD, and discuss the potential mechanisms, providing therapeutic evidence for the useful of STDP for these patients.