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Research report

Prevention of anxiety and depression in Chinese: A randomized clinical trial testing the effectiveness of a stepped care program in primary care ☆

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ABSTRACT

Background: Despite empirical evidence demonstrating the effectiveness of collaborative stepped care program (SCP) in Western countries, such programs have not been evaluated in the east, which has a different services system structure and cultural nuances in seeking help for mental illness. Furthermore, only a few studies have used SCP for depression and anxiety prevention. We conducted a trial to test its effectiveness in preventing major depressive disorder and generalized anxiety disorder among primary care patients with subthreshold depression and/or anxiety in Hong Kong.

Methods: Subthreshold depression and/or anxiety patients were randomized into the SCP group ($n=121$) or care as usual (CAU) group ($n=119$). The SCP included watchful waiting, telephone counseling, problem solving therapy, and family doctor treatment within one year. The primary outcome was the onset of major depressive disorder or generalized anxiety disorder in 15 months. The secondary outcomes were depressive and anxiety symptoms, quality of life and time absent from work due to any illness.

Results: Survival analysis showed no differences between the SCP and CAU groups (the cumulative probability of onset at 15 month was 23.1% in the SCP group and 20.5% in the CAU group; Hazard Ratio=1.62; 95% Confidence Interval: 0.82–3.18; $p=0.16$). No significant differences were found in secondary outcomes.

Limitations: Sample size might not have been large enough.

Conclusions: SCP did not show beneficial effect on depression/anxiety prevention compared with CAU in Hong Kong primary care. As a large majority of patients improved overtime without any intervention, we are not able to exclude the possibility that the intervention might be effective. Future studies would need to have a larger sample size and conduct on patients with more severe symptoms or perform a second screening.

1. Introduction

Anxiety and depressive disorders are associated with significant morbidity, disability and healthcare utilization. (Roy-Byrne et al., 1999; Sherbourne et al., 1996; Simon et al., 1995). Subthreshold depressive and anxiety symptoms are prevalent in primary care (Ansseau et al., 2004; Blazer et al., 1988; Nisenson et al., 1998; Pini et al., 1997) and evidence shows that up to 35% of these patients developed a major depressive or anxiety disorder within one year (Beekman et al., 1998, 1997a). Therefore, preventing the onset and development of these disorders should receive a high priority particularly in the primary care settings (Lam et al., 2009; Pietrzak et al., 2013). Prevention is a prerequisite in minimizing the adverse consequences and decreasing the disease burden from

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a public health perspective (Beekman et al., 2010; Cuijpers et al., 2005b). Evidence from meta-analysis showed that well-designed indicated interventions were (cost-) effective and could reduce the incidence of depression and anxiety (Christensen et al., 2010; Glasgow et al., 1999; Munoz et al., 2010; Smit et al., 2006). As a result, indicated prevention using stepped care models that target at individuals at high risk of developing anxiety or depressive disorders should be tested (Bower and Gilbody, 2005; Sobell and Sobell, 2000; van't Veer-Tazelaar et al., 2009).

Stepped care models may be the most cost-effective models in health system where the effectiveness of the intervention is maximized by making the best use of resources adequately available at the right time (Haaga, 2000; Hunkeler et al., 2006; van't Veer-Tazelaar et al., 2006). The stepped care model seems to be a logical approach from both clinical and economic perspectives and several countries like the United Kingdom (NICE, 2005, 2007, 2009) and New Zealand (Dowell et al., 2009) have implemented guidelines for stepped care model for managing common mental disorders, including depression and anxiety. However, surprisingly, very few studies have used it for prevention of depression and anxiety and these were conducted on the older adults in the Netherlands (Dozeman et al., 2012; van't Veer-Tazelaar et al., 2009; van der Weele et al., 2012). The first trial on 170 older adults recruited in primary care found the stepped care program (SCP) halved the incidence of depression and anxiety disorders from 24% to 12% in 12 months (van't Veer-Tazelaar et al., 2009) with demonstrated cost-effectiveness (Van't Veer-Tazelaar et al., 2010) and the positive effects were sustained at 24 months (van't Veer-Tazelaar et al., 2011). Two other trials published in 2012 (Dozeman et al., 2012; van der Weele et al., 2012) did not have strong evidence in supporting the beneficial effect of SCP on depression and anxiety prevention and the intervention was not cost-effective (Bosmans et al., 2014) when compared to the usual care in the Netherlands, although subgroup analysis has showed beneficial effects on depression (Dozeman et al., 2012) or only with short-term benefits (van der Weele et al., 2012; van Schaik et al., 2014), which reduces the confidence in the finding. In addition, a trial on 120 primary care attendees aged 18–65 years with minor or major DSM-IV depressive and/or anxiety disorders did not find stepped care was more effective than care as usual in the Netherlands (Seekles et al., 2011).

No studies tested the stepped care model for managing common mental disorders so far among the Chinese population with a different culture. Chinese people have different health services utilization patterns such as doctor shopping, and tend to present somatic symptoms during the help-seeking despite of being aware of emotional disturbances (Cheung et al., 1981, 1984; Leung et al., 2005; Lo et al., 1994). The performance of the stepped care model is yet to be examined in such a different cultural context and health care system.

We conducted a randomized controlled trial (RCT) to test the effectiveness of a stepped care program (SCP) to prevent the onset of major depressive disorder (MDD) and generalized anxiety disorder (GAD) among Chinese people with subthreshold anxiety and depression symptoms in primary care, comparing with care as usual (CAU) in Hong Kong.

2. Methods

This was an individually randomized two-arm (1:1) controlled trial comparing a SCP with CAU, with the assessors blinded to the group assignment.

2.1. Subjects and recruitment

The study was carried out in public primary care clinics in Hong Kong. Participants were recruited in the General Outpatient Clinics (GOPCs) of the New Territories East Cluster (NTEC) in Hong Kong where these public primary care and family medicine clinics usually serve patients with chronic conditions, people at an older age and with low socioeconomic status.

Inclusion criteria: 1) aged 18 years or above; 2) having a Center for Epidemiologic Studies Depression Scale (CES-D) score ≥ 16 or a Hospital Anxiety and Depression Scale - Anxiety section (HADS-A) score ≥ 6. Exclusion criteria: 1) Meeting the DSM-IV (the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition) criteria for major depression or/and clinical anxiety disorders (These individuals were referred directly to a family physician for treatment for ethical reasons); 2) insufficient mastery of Chinese language; 3) unwilling or unable to give informed consent.

Two methods were used for patient recruitment. First, patients in GOPCs were approached by the trained research assistant to assess for eligibility. Second, the staff from the clinics helped to distribute the questionnaires and patients who returned their questionnaires were checked for eligibility by the research assistant. Eligible participants completed the baseline assessments from the beginning of January to the end of April, 2011.

2.2. Randomization, concealment and blinding

The randomization scheme was derived by computer and managed independently by a statistician and the results were disclosed to participants upon providing informed consent and after baseline data collection. Therapists were informed about the randomization outcomes, but the trained research assistants who performed the interviews were kept blinded to the allocation during the study.

2.3. Intervention: stepped care program (SCP)

This SCP lasted for one year. Participants were stepped up to the next step of the SCP if they had a score at or above the cut-off point (CES-D score ≥ 16 or HADS-A score ≥ 6) and without the SCID (the Structured Clinical Interview for DSM-IV) diagnosed MDD or GAD at every 3 months' assessments.

The SCP consisted of four steps including watchful waiting, self-help instruction coached by a social worker via telephone, face-to-face problem solving therapy (PST), and treatment by family medicine doctors (Fig. 1).

Step 1 Watchful waiting: After randomization, participants were given 3 months' watchful waiting to see if their depression and anxiety symptoms persisted which warranted further intervention.

Step 2 Telephone counseling - self-help instruction coached by a professional: If there was persistent presence of clinically significant depressive or anxiety symptoms, as defined by CES-D score ≥ 16 or HADS-A score ≥ 6, participants were offered self-help instruction coached by two trained social workers with at least three years' counseling experience with a protocol delivered through telephone (Corey, 2005; Kottler, 2002; Minuchin et al., 2007). The counseling was initially weekly and then bi-weekly depending on needs with a maximum of 6 sessions, to a) assess type, severity and causes of symptoms; b) discuss any social or medical related problems they had and information they needed to deal with their social and medical related problems, c) reflect on emotional symptoms through an initial brief non-directional exploration, discussion and brief