# Stepped care programme in primary care to prevent anxiety and depression: a randomised clinical trial

SYS Wong \*, WK Tang, WWS Mak, FMC Cheung, S Mercer, SM Griffiths, J Woo, DTF Lee, K Kung, AT Lam

#### KEY MESSAGES

- 1. Subthreshold depression and anxiety are prevalent in primary care. The probability of patients developing depression or anxiety in 1 year was 13.5%.
- 2. A stepped care programme was not superior to usual care in terms of preventing onset of depression or anxiety, reducing severity of symptoms, reducing health care utilisation, or improving quality of life in primary care patients with subthreshold depression or anxiety at 12 and 15 months.
- 3. A watchful waiting period or a less resourcedemanding intervention is suggested before initiating further intervention for subthreshold depression or anxiety. Patients considered to be severely depressed or anxious at baseline should be referred to a stepped care programme.

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<sup>1</sup> SYS Wong \*, <sup>2</sup> WK Tang, <sup>3</sup> WWS Mak, <sup>3</sup> FMC Cheung, <sup>4</sup> S Mercer, <sup>1</sup> SM Griffiths, <sup>5</sup> J Woo, <sup>6</sup> DTF Lee, <sup>1</sup> K Kung, <sup>7</sup> AT Lam

- <sup>1</sup> The Jockey Club School of Public Health and Primary Care, The Chinese University of Hong Kong
- <sup>2</sup> Department of Psychiatry, Faculty of Medicine, The Chinese University of Hong Kong
- <sup>3</sup> Department of Psychology, The Chinese University of Hong Kong
- <sup>4</sup> General Practice and Primary Care, University of Glasgow, Glasgow, United Kingdom
- <sup>5</sup> Department of Medicine and Therapeutics, Faculty of Medicine, The Chinese University of Hong Kong
- <sup>6</sup> The Nethersole School of Nursing, The Chinese University of Hong Kong
- <sup>7</sup> New Territories East Cluster, Hospital Authority, Hong Kong
- \* Principal applicant and corresponding author: yeungshanwong@cuhk.edu.hk

## Introduction

Anxiety and depressive disorders are associated with significant morbidity, disability, and health care utilisation.<sup>1</sup> Subthreshold depressive and anxiety symptoms are prevalent in primary care, and up to 35% of these patients will develop a major depressive or anxiety disorder within a year.<sup>2,3</sup> Therefore, preventing the onset and development of these disorders is of high priority. In Hong Kong, the waiting list for referral to non-urgent psychiatric care is long. A stepped care programme may be more costeffective.<sup>4,5</sup> This study evaluated the effectiveness of a stepped care programme in the prevention of depression and anxiety among patients in primary care with subthreshold depression and anxiety.

### Methods

This prospective, randomised, two-armed (1:1) study was conducted from June 2010 to February 2013. Patients aged  $\geq 18$  years who had subthreshold depression or anxiety (a score of  $\geq 16$  in the Center for Epidemiologic Studies Depression Scale [CES-D] or a score of  $\geq 6$  in the Hospital Anxiety and Depression Scale – anxiety section [HADS-A]) were recruited from the general out-patient clinics of the

New Territories East Cluster. Patients were excluded if they had any psychiatric disorders (according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition [DSM-IV]), insufficient command of the Chinese language, or were unwilling or unable to give informed consent.

A total of 240 participants were randomised to receive usual care (n=119) or the stepped care programme (n=121) that involved (1) watchful waiting, (2) telephone counselling, (3) problem solving therapy, and (4) family doctor treatment. Patients were assessed at baseline and at 3, 6, 9, 12, and 15 months by telephone interview. Primary outcome measures included incidence of major depression and generalised anxiety disorder according to the Structured Clinical Interview for DSM-IV. Secondary outcome measures included depressive and anxiety symptoms measured by the Chinese version of CES-D, HADS-A, Beck Anxiety Inventory, and Beck Depression Inventory-II. Quality of life was measured using the Chinese version of Short-Form Health Survey. Utilisation of health services and medication to improve mood or mood-related symptoms were also recorded. Satisfaction with delivered care was measured using the Consumer Assessment of Healthcare Providers

and Systems 2.0 Adult Questionnaire. Social support was measured using the Chinese version of Multidimensional Scale of Perceived Social Support.

#### Results

The stepped care group and usual care group were comparable in terms of demographics and baseline measures. The dropout rate at 15 months was 14.2% (n=34).

Of 121 participants in the stepped care group, 35 were eligible for telephone counselling and 24 accepted it. Of these 24, six were eligible for problemsolving treatment and three accepted it. Of these three, one subsequently received treatment from the family doctor. No adverse effects were reported.

At 15 months, 21 (17.4%) participants from the stepped care group and 18 (15.1%) participants from the usual care group developed DSM depression or anxiety. The cumulative probability of developing depression or anxiety was 13.5% at 12 months, and 21.8% at 15 months. The Cox proportional hazard model showed no significant difference between the two groups in terms of the risk of developing major depression or generalised anxiety at 15 months (hazard ratio=1.62; 95% CI, 0.82-3.18). Baseline comparison of participants with CES-D scores of <16 versus  $\geq$ 16 revealed a hazard ratio of 3.14 (95% CI, 1.53-6.44; P=0.002).

Using linear mixed models and repeated analysis of variance, the two groups did not differ significantly in terms of reduced depression or anxiety scores, health service utilisation (frequency and cost), or quality of life.

#### Discussion

The stepped care programme was not superior to usual care. First, a lower baseline level of severity and natural variation resulted in a lower proportion of participants who required further intervention following watchful waiting. Second, not all participants who were eligible for stepped care intervention accepted it. Third, the underestimated sample size had inadequate power to detect differences in the two groups. Fourth, participants in the usual care group might have sought help because they had higher self-motivation and awareness of depression and anxiety. Fifth, data were collected by telephone interview over time. As such, there may

have been attention bias, recall bias, and observation bias.

Subthreshold depression or anxiety is prevalent in Hong Kong primary care patients. Approximately 16.4% (464/2827) of recruited patients had subthreshold depression or anxiety. The probability of developing depression or anxiety disorders within a year was 13.5%. Further research on subthreshold depression and anxiety is needed to determine the magnitude of the problem in primary care. Future interventions for subthreshold depression or anxiety should include a watchful waiting period (eg 3 months) or less resource-demanding interventions before further interventions. Patients with high subthreshold depression or anxiety at baseline should be referred for intervention.

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