

SYS Wong 黃仰山 ■

Effect of mindfulness-based stress reduction programme on pain and quality of life in chronic pain patients: a randomised controlled clinical trial

Key Message

A mindfulness-based stress reduction programme may not be superior to an education programme in terms of improving disability and pain in patients with a moderate degree of chronic pain.

Introduction

Chronic pain is a prevalent health problem and a frequent cause of disability and suffering. It is also associated with significant health care costs. Although psychological interventions are alternatives to traditional medical approaches, many individuals with chronic pain do not benefit from these treatments.

Mindfulness-based stress reduction (MBSR) is a clinical programme to increase self-acceptance coping and reduce suffering in patients with medical illness using mindfulness meditation as a self-regulated approach for stress reduction and emotion management. Preliminary evidence demonstrated that MBSR may reduce pain and improve mood symptoms. However, no definitive conclusion could be drawn as no randomised controlled trial with an active control group had been carried out. The objective of this trial was to compare the effectiveness of MBSR with an education programme in terms of reduction of pain and improvement in quality of life for chronic pain patients.

Methods

This study was conducted from October 2006 to September 2007. A total of 100 participants were recruited from primary care, geriatric and pain clinics in the community and hospitals that most chronic pain patients attended.¹ Patients included were aged 18 to 65 years, with any chronic pain for at least 3 months. The pain had to be moderate to severe (scoring at least 4 out of 10 in an 11-point Numeric Rating Scale) verified by a trained research assistant and confirmed by a family physician. The patients had to agree not to receive other new treatments (including topical, over-the-counter, and non-pharmacological medication) during the intervention. Patients were excluded if they (1) received concurrent treatment other than medications for pain or psychological symptoms, (2) had a concurrent diagnostic and statistical manual of mental disorders axis-I diagnosis, (3) participated in an MBSR group, engaged in current or prior practice of meditation or relaxation techniques including MBSR, or (4) were illiterate and unable to complete the meditation diary. All participants gave written informed consent, and the study was performed according to the Good Clinical Practice guideline. This trial was also registered with the Centre for Clinical Trials of the Chinese University of Hong Kong, and was approved by the ethics committee of the university.

Study instruments

Outcome measures were collected at baseline, 8 weeks (end of intervention), 3 and 6 months after the intervention. Primary outcome measures were self-reported pain intensity measured by the 11-point Numeric Rating Scale² and the Dual Visual Analogue Sensation of Pain and Distress Scales.³ Both scales have been demonstrated to be reliable and sensitive measurements of pain. Secondary outcome measures were mood status and symptoms assessed using the Profile of Mood States, the validated Chinese version of the Centre for Epidemiological Studies-Depression Scale, and the State Trait Anxiety Inventory. Health-related quality of life was measured by the validated Chinese version of the Short-Form

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Department of Community and Family
Medicine, The Chinese University of Hong
Kong
SYS Wong

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Principal applicant and corresponding author:
Prof Samuel Yeung-shan Wong
4/F, Department of Community and Family
Medicine, The Chinese University of Hong
Kong, School of Public Health, Prince of
Wales Hospital, Shatin, NT, Hong Kong
SAR, China
Tel: (852) 2252 8774
Fax: (852) 2606 3500
E-mail: yeungshanwong@cuhk.edu.hk

Health Survey (SF-12).

Results

Before intervention, patients in both the MBSR and education programme groups did not differ with regard to demographics, pain intensity, mood symptoms, health-related quality of life scores, the amount of sick leave taken, or the use of services and analgesics. After intervention, patients in both groups had significant improvements in pain intensity, which was sustained until 6 months post-intervention.

There were no significant differences in the SF-12 scores between the two groups at baseline, 8 weeks, and 3 and 6 months post-intervention. At 3 months after intervention, physical and mental component scores of SF-12 improved significantly in both groups. Nonetheless, only the physical component score improved further at 6 months post-intervention. There was a significant difference in the Profile of Mood States activity subscale between the two groups at the end of intervention, but the difference was not sustained thereafter.

The mean anxiety state scores of both groups improved 2.4 (95% confidence interval [CI]=0.3-4.5, $P=0.027$) at 3 months and 3.1 (95% CI=1.9-4.3, $P=0.005$) at 6 months post-intervention, compared with baseline scores. There were no significant differences between the two groups at baseline, 8 week, and 3 and 6 months post-intervention. Depressive symptoms (according to the Centre for Epidemiological Studies-Depression Scale) were not significantly different between the two groups and did not change over time.

Discussion

The randomised clinical trial design was used to study the effects of MBSR on chronic pain intensity with an active control group that could be adjusted for the confounding

effects of group attention and therapist time. The effects of MBSR on chronic pain in a non-Caucasian population were also studied. The MBSR programme was not superior to multidisciplinary education programme based on the principles for management of chronic pain. We could not show that MBSR was not effective per se for improving quality of life or some of the mood symptoms, as we observed significant improvement in both groups.

There were several limitations to this study. First, the unexpectedly high dropout rate in the MBSR group and the low proportion of subjects who completed all 10 sessions might have contributed to the negative results of this intervention. As a result, the study could have had a type-II error. Second, for the MBSR group, only a proportion of subjects practiced daily for the recommended amount of time. Thus, MBSR might not be effective for those who attended the class only. If all those who attended the class also practised daily at home as instructed by the therapist, the results could have been different.

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