



Appraisal

Trial Protocol: The use of mindfulness-based intervention for improving bracing compliance for adolescent idiopathic scoliosis patients: protocol for a randomised, controlled trial

Benjamin Hon Kei Yip^a, Xue Li^a, Christine Hiu Yan Leung^a, Ting Gao^a, Vincent Chi Ho Chung^a, Fiona Wai Ping Yu^{b,c,d}, Tsz Ping Lam^{b,c,d}, Jack Chun Yiu Cheng^{b,c,d}, Samuel Yeung Shan Wong^a

^aSchool of Public Health and Primary Care, Faculty of Medicine, The Chinese University of Hong Kong; ^bJoint Scoliosis Research Center of the Chinese University of Hong Kong and Nanjing University; ^cBone Quality and Health Centre, Department of Orthopaedics and Traumatology, Faculty of Medicine, Prince of Wales Hospital, The Chinese University of Hong Kong; ^dSH Ho Scoliosis Research Laboratory, Faculty of Medicine, Prince of Wales Hospital, The Chinese University of Hong Kong, Hong Kong

Abstract

Introduction: Adolescent idiopathic scoliosis (AIS) is the most prevalent deforming orthopaedic condition; it causes significant disability when spinal curves progress beyond 45 deg. Bracing is the primary treatment prescribed for adolescents with an immature skeleton who have spinal curves between 25 and 45 deg. New evidence suggests that compliance with bracing significantly decreases the progression of high-risk curves to the threshold for surgery. Nonetheless, bracing is a stressful experience. Therefore, interventions that mediate health-related quality of life for AIS patients are of great interest. In the past few decades, numerous studies have documented the benefits of mindfulness training on chronic pain, stress management, anxiety and emotional disorders. Mindfulness might additionally provide AIS patients with psychosocial support. **Research questions:** This study will investigate the effects of a mindfulness-based intervention on bracing compliance and quality of life among AIS patients with poor bracing compliance. The study also plans to evaluate if the mindfulness-based intervention effect is sustained after the intervention period. The potential mechanism by which mindfulness affects bracing compliance will be explored. **Design:** Single-blind, two-arm, randomised, controlled trial. **Participants and setting:** The study will recruit 120 AIS patients aged between 10 and 15 years with non-satisfactory bracing compliance. Patients who have previously practised or are currently practising meditation or mindful yoga or who cannot finish the whole intervention will be excluded. The study will take place at the Jockey Club School of Public Health and Primary Care building. **Intervention:** Patients in the mindfulness-based intervention group will join weekly sessions for 8 weeks. This program is a short version of a mindfulness-based stress relaxation program to address the specific issues of AIS patients. Two to three experienced instructors will deliver the program. **Control:** Control group patients will participate in an 8-week physiotherapy exercise program as recommended in the International Scientific Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) 2011 guideline. **Measurements:** The primary outcome is

the 6-month post-intervention total score of bracing compliance. Secondary measures are non-bracing-specific quality of life, bracing-specific quality of life, self-compassion, emotional regulation, mindful awareness and acceptance, self-efficacy, perception of stress, and general measure of health outcome. **Procedure:** 120 participants will be assigned to either an intervention or control arm by simple randomisation, and the randomisation result will only be revealed once participants have confirmed availability to attend intervention classes. Clinicians of the scoliosis clinic and research staff will be blinded to the treatment allocation. **Analysis:** ANCOVA will be conducted to compare the effect of mindfulness-based intervention versus physiotherapy exercise on the outcome measures. To investigate significant change over time, linear mixed models analyses will be conducted following the intention-to-treat principle. The R-package lavaan will be used to conduct structural equation modelling to study the potential mechanism of mindfulness. **Discussion/significance:** This will be the first psychosocial intervention study conducted on braced AIS patients with the aim of improving patients' bracing compliance and quality of life. The results from this study will potentially carry significant impact on future AIS treatment by emphasising psychosocial care for braced AIS patients.

Trial registration: Chinese Clinical Trial Register (ChiCTR). **Registration number:** ChiCTR-IOR-16010299. **Was this trial prospectively registered?** Yes. **Date of trial registration:** 30 December 2016. **Funded by:** University Grants Committee Research Grants Council. **Funder approval number:** 14614416. **Anticipated completion date:** 31 December 2018. **Correspondence:** Dr Benjamin Hon Kei Yip, School of Public Health and Primary Care, Faculty of Medicine, The Chinese University of Hong Kong, Hong Kong. Email: benyip@cuhk.edu.hk

Provenance: Not invited. Peer reviewed.

Full protocol: Available on the eAddenda at <https://doi.org/10.1016/j.jphys.2018.02.019>

<https://doi.org/10.1016/j.jphys.2018.02.019>

1836-9553/© 2018 Australian Physiotherapy Association. Published by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).