

STUDY PROTOCOL

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Effects of meditation on physiological and metabolic parameters in patients with type 2 diabetes mellitus “MindDM”: study protocol for a randomized controlled trial

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Abstract

Background: Sri Lanka is faced with the challenge of managing a large population with diabetes mellitus by 2030. Psychological stress plays a major role in disease outcome by exerting physiological, psychological and social effects on individuals with chronic disorders.

Meditation-based interventions have positive effects on the management of stress and diabetes, which are mediated via modulation of neuro-humoral mechanisms and autonomic functions, among others. Mechanisms of bio-physiological effects of meditation are considered to be through reduction of stress hormones, improvement of insulin resistance and improvement of autonomic dysfunction.

Methods: This study will be conducted as an open-label, randomized controlled clinical trial in the Faculty of Medicine, University of Colombo. The aim is to investigate the effects of meditation on glycaemic control and possible mechanisms of how meditation affects glycaemic control in patients with type 2 diabetes. The study was approved by the Ethics Review Committee of the Faculty of Medicine, University of Colombo (ERC/2019/094). Patients who are attending the professorial unit medical clinic with type 2 diabetes (172 in total) will be recruited based on inclusion-exclusion criteria. Patients who have never meditated or rarely meditated (less than once every three months) will be randomized using block randomization to meditation and waitlisted arms (1:1 allocation ratio). The meditation arm will undergo a mindfulness meditation program (selected after studying several meditation methods) conducted by a qualified instructor weekly for a period of 12 weeks in addition to usual care, while the waitlisted arm will only receive usual care. Daily meditation practices will be recorded in a diary. The primary outcome measure is HbA1c. Secondary outcome measures are fasting blood sugar, fructosamine, insulin resistance (calculated using fasting serum insulin), 24-h urinary cortisol, body mass index, cardiac autonomic reflex testing (Ewing’s battery of tests) and oro-cecal transit time using hydrogen breath analysis. All these will be done prior to commencement of the intervention and after 3 months in both arms. Data will be analysed using SPSS V-23.

Discussion: This study aims to identify the effect of mindfulness meditation on glycaemic control and the possible mechanisms (neuro humoral and autonomic functions) by which beneficial effects are mediated.

Trial registration: Registered under Sri Lanka Clinical Trial Registry: SLCTR/2021/015

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