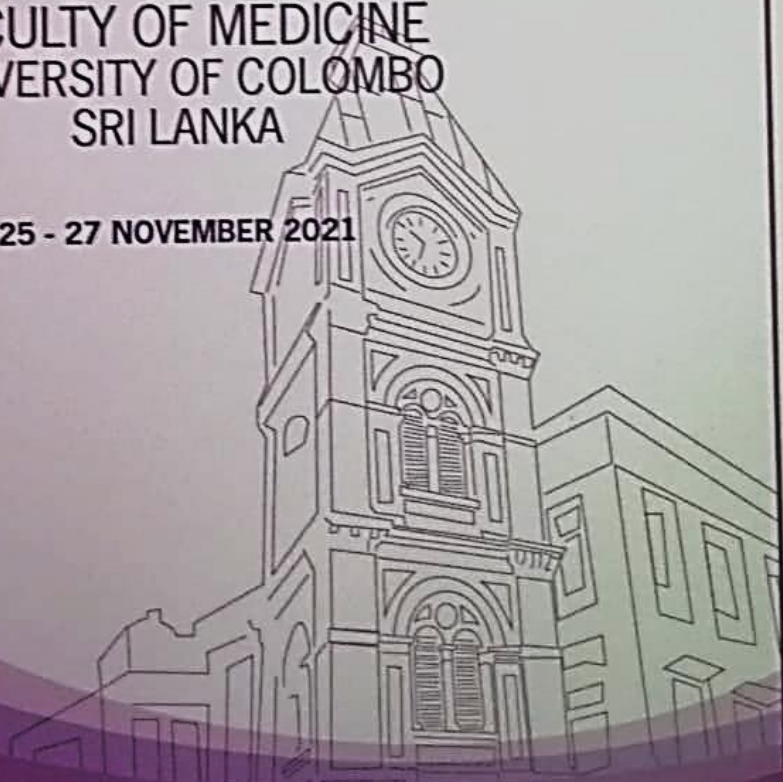


"NCD AND COVID 19: TACKLING TWO PANDEMICS THROUGH COLLABORATIVE RESEARCH"

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PP-12: Effects of meditation on physiological and metabolic parameters in patients with type 2 diabetes mellitus: Study protocol for a randomized controlled trial.

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Introduction: Sri Lanka is faced with the challenge of managing a high population with diabetes mellitus by 2030. Psychological stress plays a major role in disease outcome. Meditation-based interventions have positive effects on management of stress, mediated via modulation of neuro-humoral mechanisms and autonomic functions and are considered to be through reduction of stress hormones, improvement of insulin resistance and improvement of autonomic function.

Methods: Open label randomized controlled clinical trial will be conducted to investigate effects of meditation on glycaemic control, and possible mechanisms of how meditation affects glycaemic control in patients with type 2 diabetes. Study is approved by Ethics Review Committee of Faculty of Medicine, University of Colombo (ERC/2019/094). Patients attending professorial unit medical clinic with type 2 diabetes (86 in each arm) is recruited based on inclusion exclusion criteria. Patients who have never or rarely meditated (less than once in three months) will be randomized using block randomization to meditation and waitlisted arms (1:1 allocation ratio). Meditation arm will undergo mindfulness meditation programme (selected after studying several methods) by a qualified instructor, weekly for 12 weeks in addition to usual care while waitlisted arm will receive usual care. Daily meditation practices will be recorded in a diary. Primary outcome measures are fasting blood sugar, fructosamine and HbA1c. Secondary outcome measures are insulin resistance (calculated using fasting serum insulin), fasting serum cortisol, body mass index, cardiac autonomic reflex testing (Ewing's battery of tests) and oro-caecal transit time using hydrogen breath analysis. All assessments are done prior to commencement of intervention and after 3 months in both arms. Data will be analysed using SPSS V-23. Trial is registered at Sri Lanka Clinical Trial Registry (SLCTR/2021/015). Universal Trial Number (UTN) U1111-1166-8640.

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.

Keywords: Mindfulness meditation, diabetes mellitus, mechanisms of metabolic control