

THE SYNERGISTIC EFFECT OF WARM SALT FOOTBATH AND FOOT-ANKLE EXERCISES IN INDIVIDUALS WITH TYPE 2 DIABETES MELLITUS: A STUDY PROTOCOL FOR MULTICENTER RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Individuals with type 2 diabetes mellitus (T2DM) experience issues with their sleep quality and elevated level of the neutrophil-lymphocyte ratio (NLR). Warm salt footbaths and foot-ankle exercises play a significant role in addressing inflammation and improving sleep quality. Nevertheless, no studies have examined the synergistic effects of warm salt footbaths and foot-ankle exercises. This study aims to investigate the synergistic effects of warm footbath water and foot-ankle exercises on sleep quality and NLR. A randomized controlled trial with a total of 108 individuals with T2DM randomly assigned to one four groups: a warm salt footbath, a foot-ankle exercises, a combination of both interventions, or a control group. The interventions administered over a period of 4 weeks (three times per week). Evaluations were performed by blinded evaluators at baseline, as well as after 2 and 4 weeks of interventions. Chi-squared test, one-way analysis of variance, and generalized estimating equations were employed for data analysis. The results of this trial were expected to elucidate the synergistic effects of warm salt water footbath and foot-ankle exercises on sleep quality and NLR. Furthermore, the combination of warm salt water footbaths and foot-ankle exercises is more effective either intervention alone or conventional treatment.

Keywords: Foot-ankle exercises; synergistic effect; type 2 diabetes; warm salt footbath



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INTRODUCTION

Type 2 Diabetes Mellitus (T2DM) is a group of chronic metabolic disorders distinguished by abnormal insulin sensitivity and escalated blood glucose levels (American Diabetes Association, 2019; Buse et al., 2020). This condition can lead to increased inflammation (Halim & Halim, 2019; Rias, Gordon, et al., 2020; Rias, Kurniasari, et al., 2020) as well as sleep disturbances (Nanayakkara et al., 2020; von Schantz et al., 2021). Annually, it is estimated that four million deaths result from diabetes-related complications, which equates to one death every eight seconds (International Diabetes Federation, 2017). In Indonesia, the number of individuals with T2DM is projected to grow from 10.7 million in 2019 to 16.6 million by 2045 (Saeedi et al., 2019). To mitigate the increasing prevalence and reduce both macrovascular and microvascular complications associated

with T2DM, it is essential to understand and investigate individuals characteristics related to good exercise behaviors and relaxation techniques that may help prevent the development complications (Anusruti et al., 2020; Vaghasloo et al., 2020; Zhang et al., 2020).

Low levels of sleep quality have been identified as a risk factor for vascular complication associated with T2DM. While T2DM is a leading cause of mortality on its own, it exacerbates health problems when integrated with sleep disturbances. Increased neutrophil-to-lymphocyte ratio (NLR) levels in individuals with T2DM may result from the differential effects of hyperglycemia on neutrophils and lymphocytes, potentially contributing to the elevated levels of pro-inflammatory cytokines associated with insulin resistance (Mertoglu & Gunay, 2017). Currently, the physiological