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Result of a Comparative RCT for the Assessment of Effectiveness and Safety Profile of the Two Siddha Medicines (*Nilavarai Chooranam* and *Sivathai Chooranam*) in the Treatment of Functional Constipation

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ABSTRACT Constipation is one of the digestive system issue prevalent in apparently common populations. The aim of this study was to investigate the efficacy and safety of the *Sivathai Chooranam* and *Nilavarai Chooranam* in patients with functional constipation. This study was a comparative (RCT) randomized controlled clinical trial. The participants (N=60) diagnosed with functional constipation were enrolled into 2 arms; Group A- *Nilavarai Chooranam* (Control Arm) and Group B - *Sivathai Chooranam* (Experimental Arm). Each group received prescribed quantities for 21 days medicines and patients were pursued for 1-week post-treatment for safety and to identify relapse incidents if any. The Bristol Stool Form Scale, Modified Longo Score, and Constipation Assessment Scale were used to evaluate efficacy as the study's main outcome measures on Day 0 (baseline), as well as Days 7, 14, 21, and 28 of the experiment. The secondary objectives were to evaluate the change in life quality, which was derived by using a questionnaire and safety profile of the study drugs. Finally, the data were analyzed using inferential and descriptive statistical tests. During the whole phase of the study, any adverse events (AEs) or serious adverse events (SAEs) were not registered. The results of this study exhibited that "*Sivathai Chooranam*" is an effectual, harmless, and Siddha Plant based laxative medicine in the treatment of functional constipation and superior (with no reported cases of relapse) to *Nilavarai Chooranam* in improving quality of life. Therefore, *Sivathai Chooranam* can be used as a safe treatment option for constipation management.