Developing a Healthy Human Clinical Trial Unit to Advance Post-prandial Glycaemic Response Research in an Academic Institution

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The post-prandial glycaemic response (PPGR) is a valuable indicator of carbohydrate-rich diets that are used to assist people to manage their blood glucose levels and improve overall health. The healthy human clinical trial unit (CTU) in glycaemic index (GI) studies has a competing demand to conduct advanced research in many academic institutions. However, there is no commercially established, accredited CTU for GI testing exists in Sri Lanka. This study was conducted to establish a healthy human CTU to analyze the PPGR of food. Initially, 301 undergraduate students of the Faculty of Agriculture, University of Peradeniya were recruited in the age group of 21-25 years, and anthropometric and demographic parameters were collected. The recruited participants were screened based on anthropometric and demographic parameters. Then 97 participants were screened and trained for clinical trials in GI studies. Finally, 50 interested and available participants were chosen as the "healthy human CTU for GI studies". Moreover, the bio-clinical evaluation of participants was conducted. The CTU consisted of participants aged between 22-25 years, mean body mass index of 20.9 ± 1.7 kg m^{-2} and a mean waist-to-hip ratio of 0.8 ± 0.1. The randomly selected participants' fasting blood glucose level and oral glucose tolerance test results were 85.7 ± 6.5 mgdL^{-1} and 70.6 ± 19.1 mgdL^{-1} respectively. This research results consist of a guidebook (ISBN 978-624-94637-0-7). The research outcome generates a harmonized and standardized procedure for research investigators and other stakeholders in different academic institutions to advance PPGR research in educational activities or in regulatory services. Therefore, the established healthy human CTU can be used in future GI studies of the food industry to analyze the GI of available food structures and to facilitate GI labelling of food products. Moreover, the guidebook provides the long-term sustainability of this procedure in an academic institution.

Keywords: Clinical trial unit, GI labelling, Glycaemic index, Glycaemic load, Post-prandial