Individual behavioural factors are associated with compliance and response to a wholegrains and nuts intervention - a proof of principle interventional N-of-1 study

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Inter-individual variations in response to dietary interventions are common, which can be affected by both physiological and behavioural factors. N-of-1 studies enable examination of response at an individual level, by collecting multiple measurements over time in a single volunteer[1]. With significant blood pressure (BP) response heterogeneity to wholegrains (WGs) seen in a previous study[2], the goal of the MI-DIET study was to examine behavioural factors associated with compliance to a Dietary Approaches to Stop Hypertension (DASH)-style intervention with WGs and nuts, and subsequent BP response, through a series of N-of-1 interventional studies.14 volunteers with mildly elevated BP (120/80–140/90mmHg) who were low consumers of WG foods (≤7 portions/wk) were recruited. Each volunteer carried out a 24-week N-of-1 study, composed of three 8-week periods (observation, intervention, and follow-up). Throughout the study, volunteers responded to semi-personalised morning and evening questionnaires using a wrist-worn device (PRO-Diary, CamNtech Ltd.) which measured activity via actigraphy, and measured their BP daily using a wireless monitor (QardioArm, Qardio Inc.). These daily measurements provide sufficient statistical power for individual N-of-1 dynamic modelling analysis, a form of regression controlled for autoregressive time trends[3]. During the intervention phase, volunteers were provided with and asked to consume 3–4 portions of WGs and a handful of nuts each day, in line with DASH dietary recommendations. Every four weeks, volunteers completed an online 24 h diet diary (Intake24) and visited the institute to measure their weight and provide a fasted blood sample for analysis of cholesterol concentrations and WGs intake biomarkers.12 volunteers completed the study. The results from dynamic modelling analysis to date reveal that for each volunteer, different factors are significantly associated with portions of WGs consumed and BP. These include consumption of cakes ($p < 0.01$) and chocolate ($p < 0.05$) being associated with lower WGs consumption in one volunteer, while a later time to sleep was associated with lower WGs consumption in another volunteer. Later time to sleep was additionally associated with higher diastolic BP in one volunteer ($p < 0.01$), while for another volunteer, being woken up during sleep was associated with higher systolic BP ($p < 0.01$). Ongoing analysis includes addition of actigraphy data for objective markers of physical activity and sleep quality into the dynamic regression models, combining questionnaire data collected from more than one volunteer for aggregated N-of-1 analyses, and analysis of WG intake biomarkers as confirmation of consumption.The results from this study highlight how compliance and BP response to a dietary intervention can be influenced by different factors at an individual level, and additionally demonstrates the successful application of a novel interventional N-of-1 methodology to a nutrition trial.

References

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