The NutriClock Study Protocol - Assessing the Impact of a Chrononutrition Intervention in Patients With Cardiometabolic Disturbances

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Objectives: The NutriClock Study aims to test the effect of a chronotype-based nutritional intervention in circadian homeostasis and in clinical and laboratory biomarkers of dysmetabolism.

Methods: The NutriClock Study is a randomised, controlled, parallel trial, conducted over 10 weeks (2 weeks of baseline assessments and 8 weeks of intervention), with a 3- and 6-months follow-up. The study includes 2 groups of patients with cardiometabolic disturbances: an experimental group with mealtimes defined according to their chronotype, without caloric restriction; and a control group benefitting only from treatment as usual, with no specific nutritional intervention. The primary endpoint is insulin sensitivity (HOMA Index), and secondary endpoints include cardiometabolic clinical and analytical features (body weight and composition, serum glucose, insulin, glycated haemoglobin, lipid profile, leptin, ghrelin), inflammatory biomarkers (CRP, IL-6, adiponectin) and chronobiological features (salivary clock gene Bmal1, Clock, Per1, Per2, Per3, Cry1, Cry2, Rev-erbα, Rev-erbβ, Dec1 expression, melatonin and cortisol). Circadian oscillations of target genes will be measured through bioinformatics and mathematical analysis of rhythmicity, period and amplitude. This method will be used to determine the participants' chronotype along with the Munich Chronotype Questionnaire and salivary cortisol and melatonin and will assist in optimizing mealtimes based on the circadian clock phenotypes. A sample size of 60 patients (30 per group) is required for a pairwise comparison with overall power of 80% to detect a true between-group difference of 20% in the primary endpoint after 8 weeks of intervention.

Results: Not applicable.

Conclusions: Chrononutrition emerges as an innovative intervention to enhance the health of patients with cardiometabolic diseases. This study will characterize circadian rhythms patterns in this population to set up an algorithm that defines pinpointed feeding intervals based on chronotype assessment.

Funding Sources: M. Lages holds a PhD Scholarship FCT/UIDB/05,704/2020.