

Clinical Trials Corner

Dear Readers,

Welcome to the second edition of the Clinical Trials Corner of *Nutrition and Healthy Aging*. The aim of this section is to inform readers of upcoming clinical trials and highlight new findings. If you would like to draw attention to a specific topic and upcoming clinical trials, please email me: leonie.heilbronn@adelaide.edu.au

Intermittent fasting (IF) is a nutritional strategy that consists of a period with zero, or minimal food intake, followed by a period where food is freely available. Like moderate daily caloric restriction (CR), intermittent fasting increases life- and health- span in many species including yeast, flies, and mice [1]. Thus, there is potential for intermittent fasting as a viable alternative to CR to improve health in humans. However, the clinical data as to the safety, efficacy and durability of intermittent fasting is currently limited.

To date, four randomised controlled trials [2-5] have compared various forms of intermittent fasting with moderate daily caloric restriction (CR), over 2-12 months. These studies suggest that intermittent fasting is as efficacious to reduce body weight, and may provide greater metabolic benefit vs. CR. There is also accumulating preclinical evidence to show that intermittent fasting protects normal cells against the perils of chemotherapy.

Currently, there are more than 20 clinical trials registered that are examining various modes of intermittent fasting in various cohorts, including teens, overweight, older adults, those with pre-diabetes and undergoing chemotherapy. Highlighted below are 6 of these trials, and we await the outcomes of these studies with great interest.

Yours Sincerely,

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References

- [1] Mattson M et al. Impact of intermittent fasting on health and disease processes. *Ageing Res Rev*, S1568-1637(16)30251-3. doi: 10.1016/j.arr.2016.10.005.
- [2] Trepanowski et al. Weight loss, weight maintenance, and cardioprotection among metabolically healthy obese adults. *JAMA Intern Med*. 2017;177(7):930-938. doi:10.1001/jamainternmed.2017.0936
- [3] Harvie et al. The effects of intermittent or continuous energy restriction on weight loss and metabolic disease risk markers: a randomised trial in young overweight women. *Int J Obes (Lond)*. 2011;35(5):714-27. doi: 10.1038/ijo.2010.171.
- [4] Harvie M. et al. The effect of intermittent energy and carbohydrate restriction v. daily energy restriction on weight loss and metabolic disease risk markers in overweight women. *Br J Nutr* 2013;110(8):1534-47. doi: 10.1017/S0007114513000792.
- [5] Catenacci VA. et al. A randomised pilot study comparing zero-calorie alternate day fasting to daily caloric restriction in adults with obesity. *Obesity (Silver Spring)* 2016; 24(9):1874-83.

<https://www.clinicaltrials.gov/>

A). Study Title: Impacts of intermitted fasting on energy balance and associated health outcomes.

Clinicaltrials.gov identifier: NCT02498002

Sponsor: University of Bath, UK

Primary Outcome: Body Fat Percentage, Lean Body Mass, Fasting Plasma Glucose Concentration, Fasting Plasma Insulin Concentration, Fasting Plasma Triglyceride Concentration, Fasting Total Cholesterol Concentration, Fasting LDL Cholesterol Concentration, Fasting HDL Cholesterol Concentration [Time Frame: Baseline - Pre - Post (7 weeks)]

B). Study Title: Intermittent Calorie Restriction, Insulin Resistance and Biomarkers of Brain Function.

Clinicaltrials.gov identifier: NCT02460783

Sponsor: National Institute on Aging (NIA), USA

Primary Outcome: Exosomal p-S312-IRS-1/p-panY-IRS-1 ratio (index of brain insulin resistance) [Time Frame: 0, 8 weeks]

C). Study Title: Can Intermittent Fasting Mimic the Metabolic and Cardiovascular and Anti-aging Effects of Calorie Restriction?

Clinicaltrials.gov identifier: NCT01964118

Sponsor: Washington University School of Medicine

Primary Outcome: Change in high sensitivity C-reactive protein at 6 and 12 months [Time Frame: Every 6 months- baseline, 6 month and 12 month]

D). Study Title: Metabolic and Hormonal Effects of 5:2 Intermittent Fasting

Clinicaltrials.gov identifier: NCT02450097

Sponsor: Karolinska University Hospital

Primary Outcome: Change from baseline in fasting serum insulin in 6 months. [Time Frame: 6 months]

E). Study Title: Intermittent Fasting Accompanying Chemotherapy in Gynecological Cancers - a Randomized, Controlled, Two-armed Intervention Study With Additional Observational Control Group

Clinicaltrials.gov identifier: NCT03162289

Sponsor: Charite University, Berlin, Germany

Primary Outcome: Functional Assessment of Cancer Therapy - General (FACT-G) [Time Frame: Date of inclusion (baseline), day -2 and +7 at each chemotherapy (CT) in triweekly cycles/-2 days at each CT in weekly cycles and +7 after the last weekly CT, 4 months after inclusion, 3 weeks after end of CT and 1, 2 and 3 years after inclusion]

F). Dietary restriction as an adjunct to neoadjuvant chemotherapy for HER2 Negative Breast Cancer (DIRECT)

Clinicaltrials.gov identifier: NCT02126449

Sponsor: Leiden University Medical Center

Collaborators: Borstkanker Onderzoek Groep, Pink Ribbon Inc., Amgen

Primary Outcome: The percentage of patients with grade III/IV toxicity according to the National Cancer Institute Common Terminology Criteria for Adverse Events version (NCI CTCAE) v4.03. [Time Frame: 2 years]