An analysis on the effect of time restricted eating on body weight and fasting glucose in participants with obesity: results of a randomized, controlled, virtual clinical trial

Background

Time restricted eating (**TRE**) is an emerging dietary intervention strategy for weight management[1,2,3,4]. Common TRE schedules consist of fasting for 12–18 h each day, beginning in the evening or nighttime[3,5]. Restricting the non-fasting (eating) duration to 12 h or less during waking hours has been shown to improve measures of cardiometabolic health, and is increasing in popularity as a unique method for weight loss[1,2,3,4].

Limiting the portion of the day where eating occurs allows greater opportunity for the beneficial effects of fasting to take place. During the overnight fast, fuel utilization shifts from glucose to ketones, which are produced by the liver from fatty acids[6,7]. Ketogenesis and ketosis are maintained in the absence of dietary carbohydrate[8]. This daily metabolic switch from glucose to ketones reinforces metabolic circadian rhythms, reduces oxidative stress and inflammation, and has numerous other benefits[1,2,3,4,8,9,10]. Studies of TRE suggest that extending the duration of the daily fast to periods longer than 12 h may yield further cardiometabolic benefits[3]; however, daily fasting for durations of 16 h or longer usually necessitates missing a meal, which can reduce adherence[1,2]. Because fasting is difficult by nature, foods designed to mimic the ketogenic effect of fasting (i.e., high fat, low carbohydrate, and low protein) have been demonstrated by Longo and colleagues to have potential in providing relief from the hunger while maintaining ketosis, or metabolic fasting[1,11,12]. A low calorie, high fat, low carbohydrate, low protein, "fasting snack" introduced during the daily fast may be useful in assisting individuals to adhere to longer metabolic fasting durations (i.e., greater than 12 h), during TRE by preventing the metabolic shift from ketones to glucose that occur with consumption of a mixed meal.

Objective

This study investigated the effect of engaging in a commercial weight loss program and a TRE schedule of 14 h of metabolic fasting each day, beginning in the evening immediately after the dinner meal, on the change in body weight in individuals with obesity. We also investigated if eating a high fat, low protein, low carbohydrate "fasting snack" at hour 12 in the group would affect blood glucose levels. The macronutrient composition of the fasting snack was designed to avoid an increase in blood glucose levels and maintain ketosis, or metabolic fasting. The commercial weight loss program included customized meal plans (controlled for daily caloric intake and macronutrient composition) and weekly coaching / troubleshooting sessions.

Methods

Participants were recruited and eligible individuals who enrolled in the Jenny Craig® Rapid Results™ Weight Loss Plan in the United States on or after June 22, 2020 were invited to participate in the study and were screened for eligibility by the study doctor (PM Peeke). Eligible participants were adult men and women between 18 and 65 years of age with a BMI ≥ 30 kg/m^2, body weight less than 192.8 kg (425 lbs, the limit of the smart scale), had a tablet/smartphone with a camera and internet access, were not taking any medications for weight loss or diabetes, had no history of serious food allergies, no current eating or severe psychiatric disorders, were not currently taking psychiatric medications, had no special dietary requirements, and were not currently pregnant or breastfeeding. Participants were required to enroll in the existing Jenny Craig® Rapid Results™ Weight Loss Plan (enrollment is free) and to purchase weekly food. This study was conducted remotely due to physical distancing regulations and increased the use of telemedicine during the COVID-19 pandemic.

This pilot study was a randomized, comparator-controlled, clinical trial comparing a 14:10 TRE (intervention) with a 12:12 TRE (active control) over the course of 8 weeks. Eligible participants were randomized by the study coordinator in a 1:1 ratio by screening day to the 14:10 or the 12:12 groups. An equivalent number of men were assigned to each group. Participants were blinded to the nature of the intervention and control groups. The 14:10 group consisted of a 14-h metabolic fast that began after dinner (between 5 and 8 pm) and ended with consumption of breakfast 14 h later. Participants in the 14:10 group were also instructed to eat a low-calorie fasting snack consisting of high fat, low carbohydrate, low protein, 12 h after the start of the fast for 5 days each week. The 12:12 (control) group consisted of a daily 12-h fast that began after dinner (between 5 and 8 pm) and ended with consumption of breakfast 12 h later. No fasting snack was administered in the 12:12 group. Dietary regimens for both the 14:10 and 12:12 groups were based on the existing Jenny Craig® Rapid Results™ Weight Loss Plan and were reduced in energy relative to expenditure for baseline body weight (approximately 500–1000 kcal/day deficit). The overall macronutrient composition of the diets was approximately 25–35% fat, 45–55% carbohydrate, and 20–30% protein. Participants were provided with prepackaged meals and snacks from the Jenny Craig weekly menu.

Results

Subjects lost a significant amount of weight by the end of week 4, with participants in the 14:10 group losing on average 6.08kg (95% CI 5.09kg to 7.08kg) and the 12:12 group on average 5.24kg (95% CI 4.40kg to 6.09kg). See below figures for full results of the 14:10, now known as the Rapid Results Max Weight Loss Plan.

Conclusions

In participants with obesity who completed the Rapid Result Max Weight Loss Plan which consisted of:

(a)   a commercial weight loss program (in this case, with Jenny Craig);
(b)   14:10 TRE schedule (consisting of 14 hours of fasting and 10 hours of non-fasting);
(c)   a fasting snack at 12 hours (consisting of high fat, low protein, low carbohydrate),

there was statistically significant and clinically meaningful weight loss at both 4 weeks and then again at 8 weeks. As demonstrated in Figure 1 and Figure 2 below, the *average* weight loss achieved at the 4-week period was 13.4 pounds or 6.08kgs.
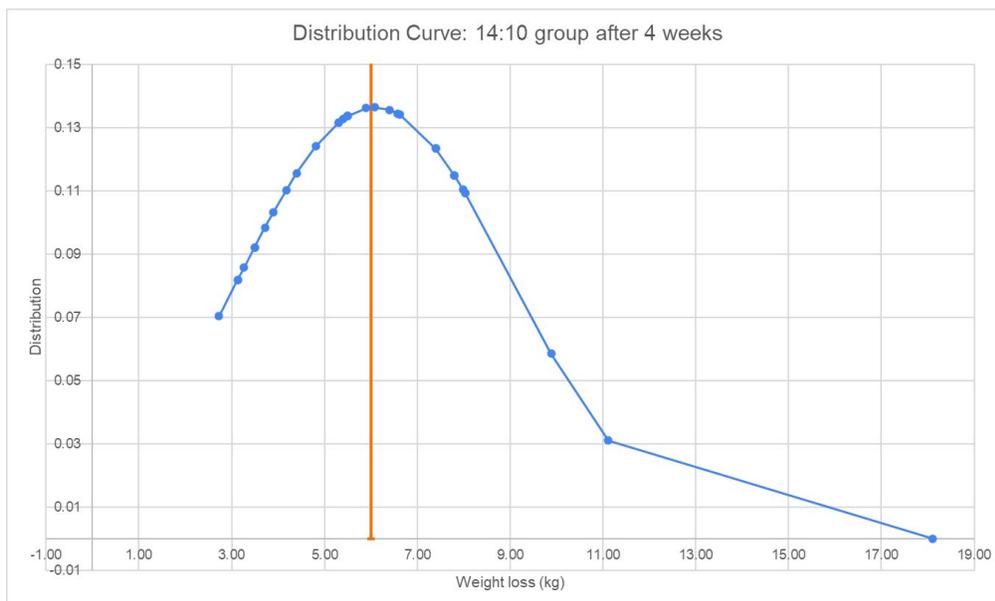
Fig. 1: Weight loss after 4 weeks in the 14:10 group

Conversion (lbs to kg)	0.453592

Male & Female Weight Loss	lbs	kg
Avg. Weight Loss	13.41	6.08
Lower 95% Confidence Interval	11.21	5.09
Upper 95% Confidence Interval	15.61	7.08

Clients that lost >= 13.2 lbs (~ 6.0 kg)	
13 out of 33	39.4%

Fig. 2: Graph

Distribution Curve: 14:10 group after 4 weeks

References

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