Nutrition 46 (2018) 143–152

Contents lists available at ScienceDirect

Nutrition

journal homepage: www.nutritionjrnl.com

Pilot study

A nonrandomized controlled clinical pilot trial on 8 wk of intermittent fasting (24 h/wk)

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ARTICLE INFO

Article history:
Received 2 March 2017
Accepted 6 August 2017

Keywords:
Fasting
Fast
Caloric restriction
Buchinger fasting
Traditional European medicine

ABSTRACT

Objective: The aim of the study was to evaluate whether intermittent fasting (IF) is an effective preventive measure, and whether it is feasible for healthy volunteers under every day conditions.
Methods: A nonrandomized controlled clinical trial on IF was performed with healthy volunteers over a period of 8 wk, and a subsequent 4-mo follow-up. Outcomes were assessed at baseline, after 8 wk, and after 6 mo. Volunteers who were not interested in fasting served as a control group. Participants in the fasting group were asked to continue their regular nutritional habits on the nonfasting days, whereas the control group maintained their habitual nutrition throughout the whole period. Outcomes included changes of metabolic parameters (insulin, glucose, insulin resistance, insulin-like growth factor-1, brain-derived neurotropic factor, lipids, liver enzymes, hemoglobin A1c) and coagulation markers; bioelectrical impedance analysis; body mass index; abdominal girth; blood pressure; general quality of life (five-item World Health Organization Well-Being Index [WHO-5] questionnaire), as well as mood and anxiety (Hospital Anxiety and Depression Scale [HADS], Profile of Mood States, Flourishing-Scale, visual analog scale, Likert scales). The intervention consisted of a fasting day, which was repeated every week for 8 wk, with abstinence from solid food between 00:00 and 23:59 at minimum and a maximum caloric intake of 300 kcal on each fasting day. A per-protocol analysis was performed. $P < 0.05$ was considered significant.
Results: Thirty-six volunteers were included; 22 allocated themselves to the fasting group, and 14 to the control group. Thirty-three data sets were included in the final analysis. Although significant in-group changes were observed in both groups for a number of outcomes after 8 wk and 6 mo, no significant between-group differences were observed for any outcome other than overall body fat mass after 8 wk as well as for the HADS total score and the WHO-5 total score after 6 mo, all in favor of the fasting group. However, none of the between-group differences were clinically relevant.

This study was funded by the Irmgard Deutsch Foundation, Berlin, Germany. All decisions on design; data collection, analysis, and interpretation; and publication were completely independent of the funding source. C.K., R.S., A.M., and N.S. conceptualized the research project and developed the methodology and the trial protocol. R.S. and A.M. took part in the acquisition of the financial support for the project leading to this publication. R.S., M.J., and N.S. conducted the investigation process. C.K. and R.S. coordinated the research activity planning and execution. C.K. and N.S. wrote the initial draft of the manuscript. N.S. performed the formal statistical analysis. M.S., A.S., and F.R. participated in editing the manuscript and performed data entry and data curation. C.K. and N.S. had full access to all of the data in the study and take full responsibility for the integrity of the data and the accuracy of the data analysis. They affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained. Statistical code is available from N.S. (e-mail: Nico.steckhan@charite.de). Certain portions of the analytical data set are available to approved individuals through written agreements with the authors. The authors have no conflicts of interest to declare.

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http://dx.doi.org/10.1016/j.nut.2017.08.004
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Conclusions: We did not find any clinically relevant differences between groups in this controlled clinical pilot trial of 8 wk of IF in healthy volunteers. Further clinical research in this field is warranted to further analyze mechanisms and effects of IF.

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Introduction

Intermittent fasting (IF) has increasingly become a focal point for research. This is due to the fact that the benefits of constant caloric restriction (CR) can be achieved while reducing certain risks [1]. The fact that CR is always linked to a constant restriction of food causes a decreased acceptance of CR. So, IF seems to be a promising technique to achieve the known beneficial effects of CR [2,3]. *Intermittent fasting* is an umbrella term describing different kinds of regimens [4]. Currently, the most common methods include 5:2 fasting [5,6], the hypocaloric 2-d diet [5], the alternate-day fasting [7,8] or the every-other-day diet [9,10] as well as time-restricted feeding (e.g., with a 16/8 h rhythm) [11,12]. The nutritional definition of fasting days varies between moderate reduction of caloric intake (600–800 kcal), stricter reduction of energy intake (200–400 kcal), and zero-calorie fasting. Furthermore, there is increasing evidence supporting the use of fast-mimicking diets [13–15]. In Europe, particularly in German-speaking countries, the most popular tradition is the practice of block fasting (e.g., 7–14 d) with a maximum intake of 300 to 400 kcal of liquids as vegetable juice or broth, as prescribed by the Buchinger technique, formulated by Otto Buchinger and others [16].

A variety of animal studies have shown beneficial effects of different kinds of CR/IF [17,18]. The effects of IF on longevity were the same as in CR, but compared with IF, caloric-restricted mice had a higher body weight [19]. Other animal studies indicate that IF has a beneficial effect on breast [20], prostate [21], and pancreatic cancers [22]; cardiovascular and cerebrovascular diseases [23,24]; dementia [25]; other brain functions [26,27]; and type 2 diabetes [13]; which are at least equal to or better than the results of CR.

A range of possible mechanisms underlying the apparent benefits of IF has been proposed. These include increased efficiency of metabolic fuel usage, decreased systemic inflammation, reduced circulating insulin-like growth factor (IGF)-1 and increased cell survival via modulation of apoptosis and enhanced cytoprotection [13,24,28]. However, studies in humans and key molecular mechanisms are currently being investigated [29].

In present human studies, similar cardioprotective effects have been proved in obese women and thus confirm the results from animal studies [30]. A study with healthy, nonobese young adults indicates effects on expression of genes linked to aging and metabolism. The positive effect on glucose metabolism by lower insulin levels may have an antidiabetic effect [3,31]. On the one hand, IF reduces IGF-1, insulin, and glucose levels. On the other hand, it causes increased levels of IGF binding protein 1 and ketone bodies. The combination of both reduction and gain could build a protective environment that reduces DNA damage, cancerogenesis, and increases apoptosis of precancerous cells [32,33].

To our knowledge, this is the first study to examine the effects of a 1-d/wk IF on metabolic profile, psychometric measures, and quality of life.

Methods

Design

The present study was designed as a nonrandomized controlled clinical trial with two arms, involving healthy volunteers only. The study protocol was reviewed and approved by the Ethics Committee of the Charité-University Medical Center, Berlin, Germany. Patients were enrolled between September 12 and September 22, 2014; interventions and follow-up were completed by March 2015. Study procedures and data collection were carried out at the outpatient department of the Immanuel Hospital Berlin, Department of Internal and Complementary Medicine. The trial followed the Declaration of Helsinki and Good Clinical Practice guidelines for trial conduct. Participants provided written informed consent before taking part and were not reimbursed for participation.

Participants

Healthy volunteers of both sexes were eligible if they were between 18 and 65 y of age and had given written informed consent. We excluded individuals if they suffered from any chronic disease, eating disorders, were pregnant or breastfeeding, or if they participated in another clinical trial.

Interventions

Intervention group

All participants in the fasting group received a 60-min group training session about fasting in the 2 wk preceding the start of the IF by a board-certified nutritional counsellor. Participants were instructed to observe one fixed fasting day per week over a period of 8 wk, a fixed week day (e.g., Monday) was requested to facilitate adherence to the protocol (see later). Individual patient adherence was defined by fasting for ≥6 of the 8 d of fasting during the 8-wk intervention period (the maximum 2 missed fasting days could be any of the 8 scheduled fasting days). A fasting day was defined as abstinence from solid food for at least the period between 00:00 and 23:59 on the individually chosen weekly fasting day, and by a maximum intake of 300 kcal/d resulting from defined fasting beverages: standard fruit and/or vegetable juices (maximum 2 × 200 mL/d); clear vegetable broth (maximum 300 mL/d); ≥750 mL/d hot, unsweetened herbal teas; ≥1500 mL/d of non-sparkling, respectively tap water at room temperature. In case of intolerance to fruit or vegetable juices, grain-based liquids (linseed, rice, millet, and quinoa) were allowed for up to a maximum of 4 × 150 mL/d as alternatives to juices and broth; for better compliance cardamom, vanilla, and cinnamon were allowed in small quantities to enhance the taste of grain-based liquids. Unsweetened black tea, green tea, and black coffee were also allowed in small quantities (maximum two servings). Participants were instructed to prepare the vegetable broth by themselves, preferably by prolonged boiling of fresh organic vegetables (≥1 h) or by using high-quality organic broth concentrates. Enrichment with fresh green herbs (e.g., basil leaves, parsley leaves), and mild seasoning with salt and pepper was also allowed. Thus, a sample fasting day could consist of 200 mL fruit or vegetable juice in the morning, 300 mL vegetable stock for lunch, 200 mL vegetable or fruit juice in the evening plus 2250 mL of tea and water distributed throughout the entire day. Laxative measures before, during, and after fasting days were not part of the protocol (e.g., standard polyethylenglycol solution, Glauber or Epsom salt). During the intervention, participants were asked to consume the vegetable stock on Mondays at lunch in a group setting and in the presence of a physician experienced with fasting patients. Here, any problems with the intervention could be counseled, while maximum adherence to the intervention was assured, particularly the adherence to a caloric intake of maximum 300 kcal per fasting day.

Control group

Participants in the control group received two group counseling sessions for a healthy diet according to current guidelines of the German Nutrition Society by a board-certified nutritional counselor. Based on this, the participants were instructed to follow a regular healthy diet over the 8-wk study period. Moreover, they were offered the opportunity to perform the IF intervention (as outlined previously) after the end of the 6-mo observational period (waiting-list control group design).

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