

INPLASY PROTOCOL

To cite: Zhou et al. The influence of fasting and caloric restriction on inflammation levels in humans: A protocol of a systematic review and meta-analysis. Inplasy protocol 202130026. doi: 10.37766/inplasy2021.3.0026

Received: 07 March 2021

Published: 08 March 2021

Corresponding author:
Ruihan Zhou

574829546@qq.com

Author Affiliation:
School of Health Preservation and Rehabilitation, Chengdu University of Traditional Chinese Medicine

Support: NSFC81674044.

Review Stage at time of this submission: The review has not yet started.

Conflicts of interest:
None declared.

The influence of fasting and caloric restriction on inflammation levels in humans: A protocol of a systematic review and meta-analysis

Zhou, RH¹; Hu, XM²; Liu, M³; Zhang, AR⁴.

Review question / Objective: Fasting and caloric restriction have a potential means of anti-inflammatory, as they can reduce inflammation levels in inflammatory disease models. Although encouraging results have been obtained in animal experiments, there is no consensus on whether these results are applicable to human. The objective of this systematic review and meta-analysis is to analyze the influence of fasting and caloric restriction on inflammation levels in humans.

Condition being studied: Fasting and caloric restriction striction diets are used in human subjects.

Information sources: We will search the following databases(The retrieval time is from the establishment of each database to December 2020.): PubMed, the Cochrane Library, Embase, Web of Science, China Biology Medicine (CBM), China National Knowledge infrastructure (CNKI), Wan Fang Data, the Chinese Science and Technology Periodical Database (VIP). The group of search words was a combination of human, inflammation and caloric restriction (or fasting or restriction caloric or low-calorie diet or intermittent fasting or hunger strike or time restricted feedings or fasting intermittent).

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 March 2021 and was last updated on 08 March 2021 (registration number INPLASY202130026).

INTRODUCTION

Review question / Objective: Fasting and caloric restriction have a potential means of anti-inflammatory, as they can reduce inflammation levels in inflammatory disease models. Although encouraging

results have been obtained in animal experiments, there is no consensus on whether these results are applicable to human. The objective of this systematic review and meta-analysis is to analyze the influence of fasting and caloric restriction on inflammation levels in humans.

Condition being studied: Fasting and caloric restriction striction diets are used in human subjects.

METHODS

Participant or population: Healthy adults or diseased patients undergoing intermittent fasting or caloric restriction. None restrictions about sex and ethnicity will be applied on the population of study.

Intervention: Intermittent fasting or caloric restriction.

Comparator: Healthy adults or diseased patients on a normal diet. None restrictions about sex and ethnicity will be applied on the population of study.

Study designs to be included: Randomized controlled trial.

Eligibility criteria: The participant, intervention, comparison, outcome, time, and study design (PICOTS) criteria was used to establish study inclusion criteria. EndNote X9 was used for citation management. Duplicates were excluded using the Endnote function “remove duplicates”. Two independent authors investigated the abstract of all articles to select eligible studies and they reviewed the full texts of relevant articles too. The following inclusion criteria were used: 1. Studies that have randomized controlled trial (RCT) design; 2. Studies on adult patients (age > 18 years); 3. The experimental group used calorie restriction diet or intermittent fasting, and the control group of the same original study used a normal diet; 4. Outcome indicators include inflammatory marker levels in baseline study and post-intervention, such as: IL-1 β , IL-6, TNF- α , high-sensitivity C-reactive protein (hs-CRP) and so on.

Information sources: We will search the following databases (The retrieval time is from the establishment of each database to December 2020.): PubMed, the Cochrane Library, Embase, Web of Science, China Biology Medicine (CBM), China National

Knowledge infrastructure (CNKI), Wan Fang Data, the Chinese Science and Technology Periodical Database (VIP). The group of search words was a combination of human, inflammation and caloric restriction (or fasting or restriction caloric or low-calorie diet or intermittent fasting or hunger strike or time restricted feedings or fasting intermittent).

Main outcome(s): The primary outcome will be inflammatory factors in the circulation, such as: IL-1 β , IL-6, TNF- α , high-sensitivity C-reactive protein (hs-CRP). Secondary results include the number of white blood cells, etc.

Quality assessment / Risk of bias analysis: Two researchers will select the quality assessment methods provided by Cochrane Handbook, including risk bias assessment form and Jadad modified scale. In case of disagreement, it will be decided by a third researcher. According to the methodology of randomized controlled trial, the following evaluation items will be adopted: random sequence generation, allocation concealment, blind methods, results data integrity, selective outcome reporting and other bias. As a result, the quality of evidence will be accepted as low risk, high risk, or ambiguous bias risk.

Strategy of data synthesis: Relevant data will be performed by Revman 5.3 software provided by the Cochrane Collaboration and Stata 14.0 statistical software. Relative risk (RR) will be used for dichotomy results with 95% confidence intervals, and Mean difference (MD) or normalized mean difference (SMD) will be used for continuous variables with 95% confidence intervals. The choice of random effect model or fixed effect model depends on the heterogeneity of the original research. In this study, the Cochrane Q test will be used to analyze the heterogeneity between studies, and I² will be used to evaluate the heterogeneity. If there is no heterogeneity (I² < 1), fixed effect model will be used in meta analysis. Otherwise, we will choose sensitivity analysis, subgroup analysis or meta regression to explore the causes of heterogeneity. If the cause cannot be found

and the degree of heterogeneity is acceptable, the random effect will be selected.

Subgroup analysis: Subgroup analysis was performed to identify the source of heterogeneity among trials. In this study, type of intervention (fasting or caloric restriction), percent of caloric restriction (less than 50% or more than 50% daily requirement caloric intake) and the health of the subject (healthy subjects or patients with disease) were considered as predefined source of heterogeneity.

Sensitivity analysis: Sensitivity analysis is to explore the impact of individual studies on aggregate results, which will be judged by the method of excluding studies one by one, so as to check the robustness of the comprehensive results.

Country(ies) involved: China.

Keywords: fasting; caloric restriction; Humans; Inflammation; meta-analysis; protocol; systematic review

Contributions of each author:

Author 1 - Ruihan Zhou - The author designed the experimental plan.

Email: 574829546@qq.com

Author 2 - Xiaomin Hu - The author has contributed to the development of selection criteria and the risk of bias assessment strategies.

Email: 563678338@qq.com

Author 3 - Mei Liu - The author contributed to the selection of the literature.

Email: 1020405812@qq.com

Author 4 - Anren Zhang - The author read, provided feedback and approved the final manuscript.

Email: 1518526780@qq.com