INPLASY PROTOCOL

To cite: Jiang et al. The effectiveness of intermittent fasting, caloric restriction and time-restricted feeding for the blood pressure management in general healthy adults: Protocol for a systematic review and meta-analysis. Inplasy protocol 2020120031. doi: 10.37766/inplasy2020.12.0031

Received: 05 December 2020

Published: 05 December 2020

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Support: **No.JCY J20180703145202065.**

Review Stage at time of this submission: **Data analysis.**

Conflicts of interest:
All authors have no conflicts to declare.

The effectiveness of intermittent fasting, caloric restriction and time-restricted feeding for the blood pressure management in general healthy adults: Protocol for a systematic review and meta-analysis

Jiang, Z[1]; Qu, Z[2]; Miao, F[3]; Wu, H[4]; Li, Y[5].

Review question / Objective: **Are intermittent fasting, caloric restriction, or time-restricted feeding interventions effective for blood pressure management in generally healthy adults, compared with no intervention?**
Condition being studied: **The increasing prevalence of hypertension has become a global burden. As the most important independent factor, blood pressure management is essential to reduce the risk and mortality of cardiovascular diseases and requires intervention even in the generally healthy population. Among all the non-drug interventions, fasting interventions have attracted increasing attention and formed several mainstream fasting regimens. The objective of this systematic review and meta-analysis was to assess the pooled effects of three mainstream fasting interventions on BP management in generally healthy adults.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 December 2020 and was last updated on 05 December 2020 (registration number INPLASY2020120031).

INTRODUCTION

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METHODS

Participant or population: Generally healthy adults (at least 18 years old) without any major diseases. Exclusion criteria: (1) drug-dependent patients for hypertension; (2) participants with diabetes or pre-diabetes; (3) pregnant or nursing-women; (4) medication or other treatment known to affect body weight.

Intervention: The intervention will include any kind of fasting regimen (caloric restriction, intermittent fasting, alternate day fasting, fasting-mimiking diet, or time-restricted feeding) that implicates voluntary food abstinence for a limited period of time.

Comparator: The interventions will be compared with controls with no intervention or with usual dietary advice only.

Study designs to be included: Randomized Controlled Trials (RCTs) which utilized the fasting regimen as an intervention in generally healthy adults.

Eligibility criteria: Inclusion criteria: (1) the design of study was an RCT on humans; (2) participants were generally healthy adults (at least 18 years old) without any major diseases; (3) including at least one fasting intervention group; (4) the control group maintained a regular diet with no intervention, or only accepted usual dietary advice; (5) reports of outcomes including changes in SBP or DBP. Exclusion criteria: (1) randomized clinical crossover trials without before-crossover data; (2) inclusion of drug-dependent patients for hypertension; participants with diabetes or pre-diabetes; pregnant or nursing-women; medication or other treatment known to affect body weight; (3) combining with other types of interventions (such as Mediterranean diet or exercise); (4) lack of numerical data on BP changes.

Information sources: PubMed、EMBASE、Cochrane Library and CNKI(China National Knowledge Infrastructure).

Main outcome(s): Changes in systolic and diastolic blood pressure.

Quality assessment / Risk of bias analysis: A 5-point Jadad scale will be used to assess the quality of selected studies, which included assessment of the following items: randomization, blinding, description of dropout and withdrawal, and evaluation of randomization and blinding.

Strategy of data synthesis: The net effect size will be defined as the difference of blood pressure change before and after fasting intervention between the intervention group and the control group, which will be presented as the mean with standard deviation (SD). A random-effect model will be used to calculate pooled estimates of the net effect sizes, which will be presented as weighted mean difference (WMD) and 95% confidence intervals (CI).

Subgroup analysis: We plan to conduct subgroup analysis from the following characteristics: (1) intervention duration (long-term or short-term); (2) participants with different obesity status (obese status or non-obesity); (3) participants with different average BP baseline status (reaching the threshold of stage 1 hypertension or not); (4) the different types of fasting interventions (intermittent fasting, caloric restriction or time-restricted feeding); (5) the different types of

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intervention interval (continuous or intermittent).

Sensibility analysis: We will conduct a sensitivity analysis to determine the influence of a single study and robustness of overall estimates by excluding each study sequentially from the meta-analysis.

Country(ies) involved: China.

Keywords: fasting intervention; blood pressure; meta-analysis; calorie restriction; intermittent fasting; time-restricted feeding; alternate day fasting; fasting-mimicking diet.

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