

# INPLASY

## The Efficacy and Safety of ketogenic diet in The Treatment of polycystic ovary syndrome: A Systematic Review and Meta-Analysis

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### ADMINISTRATIVE INFORMATION

**Support** - None.

**Review Stage at time of this submission** - Preliminary searches.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202470024

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 July 2024 and was last updated on 08 July 2024.

### INTRODUCTION

**Review question / Objective** The purpose of this study was to systematically evaluate the effect of ketogenic diet on glucose and lipid metabolism in PCOS patients.

**Condition being studied** Polycystic ovary syndrome (PCOS) is a prevalent hormonal disorder affecting women of reproductive age, marked by high androgen levels, anovulation, and ovarian cysts. It often coexists with insulin resistance and obesity, linked to metabolic diseases. Globally, PCOS affects 5%-20% of women, with increasing prevalence. Factors like genetics, environment, oxidative stress, and inflammation contribute to its development, with insulin resistance and obesity being key. Lifestyle interventions, particularly weight loss, are crucial for management, with up to 80% of patients having central obesity. While no cure exists, symptomatic treatment and health management are the focus. Recent studies suggest the ketogenic diet, which is high in fat and low in carbs, effectively aids weight loss and

insulin sensitivity, making it a recommended treatment for PCOS patients.

### METHODS

**Participant or population** Patients with polycystic ovary syndrome, do not limit the patient's age, course of disease, etc.

**Intervention** Clinical study of ketogenic diet as an intervention measure.

**Comparator** The control group of randomized controlled trials was non-ketogenic diet, and there was no control group in the single-arm study.

**Study designs to be included** The types of studies included randomized controlled trials and non-controlled single-arm trials.

**Eligibility criteria** Ketogenic diet intervention for 8 weeks or 12 weeks.

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**Information sources** The following online databases will be comprehensively searched including: The Cochrane Library, PubMed, EMBASE, Chinese Biomedical Literature Database, Chinese National Knowledge Infrastructure Database, Chinese Science and Technique Journals Database (VIP), and the Wanfang Database. All the literature retrieved is from the inception of the database to 21 June 2024. There are no language restrictions or regional restrictions. The subject words mainly include: polycystic ovary syndrome, Ketogenic diet.

**Main outcome(s)** Blood glucose levels, insulin levels, insulin resistance index, triglycerides, body mass index, sex hormones, etc.

**Quality assessment / Risk of bias analysis** The quality of the literature was evaluated using the Cochrane bias risk tool V.1.0. and ROBINS-I.

**Strategy of data synthesis** Meta-analysis was performed using Stata17.0 software. The odds ratio (OR) was used as the effect analysis statistic for the count data, and the mean difference (MD) or standardized mean difference (SMD) was used as the effect analysis statistic for the measurement data. The 95 % confidence interval (CI) was calculated for all effect quantities. The heterogeneity between the results of the included studies was analyzed by  $\chi^2$  test (test level  $\alpha = 0.1$ ), and the heterogeneity was quantitatively judged by  $I^2$ . When  $P \geq 0.10$  and  $I^2 \leq 50\%$ , the heterogeneity between studies was small, so the fixed effect model was used for analysis. When  $P < 0.10$  and  $I^2 > 50\%$ , it suggested that the heterogeneity between studies was large, so the random effect model was used for analysis.

**Subgroup analysis** If there is significant heterogeneity between studies, subgroup analysis will be performed on patients of different ages and genders.

**Sensitivity analysis** Furthermore, if necessary, a sensitivity analysis will be performed.

**Country(ies) involved** China (Shanghai Kangshi Food Technology Co., Ltd).

**Keywords** Ketogenic diet, Polycystic ovary syndrome.

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