**INTRODUCTION**

Review question / Objective: Diabetic nephropathy is the most common and serious microvascular complication of diabetes and one of the main causes of end-stage renal disease. Diabetic nephropathy has an insidious onset and a rapid course of disease. If it is not controlled and treated in time, it will seriously affect the quality of life of patients. At present, for the treatment of DN, western medicine mainly uses angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers to reduce urinary protein to protect the kidneys, and there is no precise targeted therapy for DN. At present, traditional Chinese medicine has good advantages and good therapeutic effects in the treatment of diabetes and its complications. It is widely used in today’s clinical practice and has positive and important significance for the treatment of diabetic nephropathy. This study systematically evaluated the efficacy of Wuling Powder on diabetic nephropathy patients, and the control group was given conventional diabetes drugs or placebo. Outcome variables included total response rate, 24-h urine volume, 24-h urine protein volume, serum creatinine, blood urea nitrogen, fasting blood glucose, plasma albumin, cholesterol, triacylglycerol, high-density lipoprotein, low-density lipoprotein; research methods for randomised controlled trials.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 April 2022 and was last updated on 12 April 2022 (registration number INPLASY202240071).
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Condition being studied: Diabetic nephropathy is one of the common microvascular complications of diabetes, an important type of chronic kidney disease, and a common cause of end-stage renal failure. About 20%-40% of diabetic patients in China have DKD, which has now become the main cause of CKD and end-stage renal disease. The disease is difficult to cure, and will seriously affect the quality of life of patients. Once the disease progresses to renal failure, it is difficult to reverse, which will bring serious mental and economic burdens to patients.

METHODS

Participant or population: Diabetic nephropathy.

Intervention: Wuling Powder.

Comparator: Conventional diabetes medication or placebo.

Study designs to be included: RCT.

Eligibility criteria: Inclusion criteria: patients who meet the internationally recognized diagnostic criteria for diabetic nephropathy at the time of the study, or patients who have been diagnosed with diabetic nephropathy by a clinician. Exclusion criteria: (1) Not meeting the diagnostic criteria for diabetic nephropathy. (2) It is not an RCT or it cannot be determined whether the literature is an RCT. (3) Repeated published literature. (4) Document data records are incomplete, and document information cannot be extracted normally.

Information sources: Two researchers searched PubMed, Embase, Cochrane Library, Chinese Biomedical Literature Database, Chinese National Knowledge Infrastructure, Chinese Scientific Journal Database, and Wanfang database etc.

Main outcome(s): Outcome variables included total response rate, 24-h urine volume, 24-h urine protein volume, serum creatinine, blood urea nitrogen, fasting blood glucose, plasma albumin, cholesterol, triacylglycerol, high-density lipoprotein, low-density lipoprotein.

Additional outcome(s): Adverse event.

Data management: EndNote.

Quality assessment / Risk of bias analysis: Cochrane TOOL.

Strategy of data synthesis: Review Manager and Stata software were selected for meta-analysis. Effect indices were expressed as dominance ratios (OR) and 95% confidence intervals (95% CI). Fixed-effects models were used if there was statistical homogeneity between studies (I² < 50%). When heterogeneity between studies was significant (I² ≥ 50%), a substratum analysis was required to find the cause of heterogeneity. If the heterogeneity was too large or the source of heterogeneity was unknown, qualitative heterogeneity was used. Risk of publication bias was analyzed using funnel plots. When the funnel plot was significantly
asymmetric, it indicated the presence of publication bias.

**Subgroup analysis:** Subgroup studies were conducted based on factors such as patient age, control treatment, and disease duration.

**Sensitivity analysis:** After deleting any one of them, the combined results of the remaining documents are not much different from those without deletion, which means that the sensitivity analysis has passed.

**Country(ies) involved:** China.

**Keywords:** Wuling Powder, diabetic nephropathy.

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