



From Herbal Formula to Palatable Food: A Prospective Observational Study on a Medicine-Food Homology Based Nutritional Product in Individuals with Metabolic Dysregulation

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Abstract

Background: Translating the wisdom of Traditional Chinese Medicine (TCM) “medicine-food homology” into enjoyable, everyday foods remains a challenge. This study evaluates a novel nutritional product developed by integrating a classic TCM formula, designed to “clear damp-heat and replenish qi-yin”, with whole grains and proteins.

Methods: A 4-week, multi-center, prospective observational study was conducted. Thirty-eight elderly participants with metabolic abnormalities consumed the product daily while maintaining their usual medication (95% were on drugs). Metabolic parameters and subjective experiences were monitored weekly.

Results: The product demonstrated excellent acceptability, with 89.5% (34/38) reporting favorable palatability (described as creamy cereal aroma with herbal notes). Safety was good, with mild, self-limiting initial reactions (e.g., dry mouth). In the context of ongoing pharmacotherapy, positive trends were observed: 57.6% (19/33) of hyperglycemic participants showed decreased blood glucose, and 65.0% (13/20) with hyperlipidemia had reduced triglyceride levels. Exploratory subgroup analysis of participants with milder baseline abnormalities (n=13) revealed even more pronounced positive trends: 76.9% (10/13) showed improvement in at least one metabolic parameter, and 69.2% (9/13) reported enhanced vitality, rates higher than the overall medicated group.

Conclusion: This study successfully demonstrates the feasibility of transforming a TCM formula into a well-accepted modern food product. The high acceptability and promising trends, especially in those with milder conditions, support its potential not only as a complementary tool for disease management but also as a preventive dietary intervention for “treating pre-disease” (*Zhi Wei Bing*).

Keywords: Medicine-Food Homology, Functional Food, Metabolic Syndrome, Preventive Nutrition, Product Acceptability, Traditional Chinese Medicine

Introduction

The rising global prevalence of metabolic syndrome, encompassing hyperglycemia, dyslipidemia, and hyperuricemia, poses a significant challenge to public health, particularly among the ag

ing population [1]. While pharmacotherapy is central to management, lifestyle modification, especially diet, is a cornerstone of both treatment and prevention [2]. Traditional Chinese Medicine (TCM)



offers a unique framework through its “medicine-food homology” (*Yao Shi Tong Yuan*) theory, which posits that many substances can serve both as food and medicine, using their properties to regulate bodily balance [3]. A classic example is the use of herbal formulas following the “Sovereign-Minister-Assistant-Courier” (*Jun Chen Zuo Shi*) principle for systematic intervention [4]. However, a significant barrier to integrating TCM dietary therapy into modern life is the often-challenging palatability and inconvenience of traditional preparations like decoctions. Therefore, a key innovation lies in skillfully embedding evidence-based TCM formulas into palatable, convenient, and nutritious food formats [5].

This study focuses on a proprietary formula comprising eight medicine-food homology ingredients: *Astragalus membranaceus* (Huangqi) and *Cichorium intybus* (Jujube) as Sovereigns for tonifying qi and clearing damp-heat; *Poria cocos* (Fuling), *Nelumbo nucifera* leaf (Heye), and *Morus alba* leaf (Sangye) as Ministers for promoting diuresis and clearing liver-heat; *Lonicera japonica* (Jinyinhua), *Zanthoxylum bungeanum* (Huajiao), and *Cinnamomum cassia* (Rougui) as Assistants/Couriers for harmonizing the middle energizer. This formula aims to achieve “clearing and tonifying in balance” (*Qing Bu Ping Heng*). We integrated the aqueous extract of this core formula with a matrix of 21 whole grains, plant proteins, fruits, and vegetables to create a composite nutritional powder.

The primary aim of this prospective observational study was to evaluate the real-world product experience, specifically its palatability and safety, in an elderly population with metabolic disorders. Secondary objectives were to observe trends in metabolic parameters and explore potential differential responses in subgroups to inform future applications, including preventive health (*Zhi Wei Bing*).

Methods

Study Design and Participants

A 4-week, multi-center, prospective, single-arm observational study was conducted. Participants were recruited from community stores across four Chinese provinces (Hebei, Shandong, Tianjin, Shanxi). Inclusion criteria were: age ≥ 50 years, a prior diagnosis of one or more conditions (hyperglycemia, hyperlipidemia, hyperuricemia), and willingness to maintain a stable medication regimen throughout the study. Exclusion criteria included severe renal or hepatic impairment and known allergies to any ingredient. All participants provided verbal informed consent. The study protocol followed observational research guidelines.

Product and Intervention

The investigational product was a powdered nutritional blend. Its core active component was a standardized extract from the eight-ingredient TCM formula mentioned above. This was combined with a nutrient base derived from 219 natural food sources, including 21 types of whole grains (e.g., oat, brown rice), multiple plant and dairy proteins, fruits, vegetables, and functional oils (e.g.,

olive oil, DHA algae oil) processed via techniques like enzymatic hydrolysis and microencapsulation. The proprietary medicine-food homology formula used in this product was designed by Professor Liu Yonggang’s research group at Beijing University of Chinese Medicine, ensuring its theoretical foundation in classical TCM principles. Participants were instructed to replace one or two meals per day with the product (25g per serving mixed with warm water) for 4 consecutive weeks, while continuing their usual diet, physical activity, and-critically-all prescribed medications.

Data Collection

Data were collected at baseline and weekly intervals.

- Objective Measures:** Fasting blood glucose, lipid profiles (focusing on triglycerides, TG), and uric acid (UA) were measured using portable devices or at local clinics as per routine practice.
- Subjective Measures:** A structured weekly questionnaire assessed: 1) Palatability (rated as good/acceptable/poor with open-ended descriptors), 2) Adverse sensations (dry mouth, thirst, skin itching, feeling hot), 3) Health perceptions (sleep quality, vitality/energy “Jing-Qi-Shen”, limb coldness/numbness).
- Compliance and Concomitant Medications:** Adherence was confirmed by weekly check-ins. Medication use was recorded at baseline and verified weekly.

Data Analysis

Given the exploratory, real-world nature of the study, descriptive statistics were primarily used. For metabolic parameters, the change from baseline to the final available measurement (Week 4) was determined. An “improvement” was defined as a decrease in the abnormal parameter. Improvement rates were calculated for the entire cohort and for specific subgroups. A pre-planned exploratory subgroup analysis was conducted on participants who: 1) were on medication, and 2) had baseline values indicating “milder” metabolic dysregulation. Criteria for “milder” were: fasting blood glucose between 6.1-7.8 mmol/L (pre-diabetes to mild diabetes), TG between 1.7-2.3 mmol/L (borderline high), or UA slightly above sex-specific upper limits. Subgroup improvement rates for metabolic markers and subjective vitality were compared descriptively to the overall medicated group rates.

Results

Baseline Characteristics

Thirty-eight participants (mean age ~ 70 years) were enrolled. Baseline metabolic profiles confirmed 33 (86.8%) with hyperglycemia, 20 (52.6%) with hyperlipidemia (elevated TG), and 12 (31.6%) with hyperuricemia. Thirty-six participants (94.7%) remained on stable regimens of hypoglycemic, lipid-lowering, or uric-acid-lowering drugs throughout the study.

Core Product Experience: Palatability and Safety

Palatability: Thirty-four participants (89.5%) rated the product's taste as "good" or "acceptable". The most common descriptors were "creamy cereal/milk flavor" and a "refreshing herbal aroma".

Safety and Tolerability: The product was well-tolerated. Some transient adverse sensations were reported initially: dry mouth (7 participants, 18.4% in Week 1) and skin itching/feeling hot (6 participants, 15.8% in Week 1). The incidence peaked in Week 2 (26.3% for dry mouth, 13.2% for skin reactions) and subsided markedly thereafter, with only 4 (10.5%) reporting dry mouth and 0 reporting skin reactions by Week 4. No serious adverse events occurred, and no participant discontinued due to intolerance.

Metabolic Parameter Trends in the Context of Medication

Against the background of continued pharmacotherapy, the following trends were observed from baseline to Week 4 among participants with the corresponding baseline abnormality:

Blood Glucose: Among 33 participants with hyperglycemia, 19 (57.6%) showed a decrease, 12 (36.4%) showed an increase, and 2 had no clear change.

Triglycerides: Among 20 participants with hyperlipidemia (el-

evated TG), 13 (65.0%) showed a decrease, 5 (25.0%) showed an increase, and 2 had missing data.

Uric Acid: Among 12 participants with hyperuricemia, 7 (58.3%) showed a decrease and 5 (41.7%) showed an increase.

Subjective Health Perceptions

By the end of the study, 21 participants (55.3% of total, 58.3% of medicated group) reported improved vitality ("Jing-Qi-Shen"), and 13 (34.2%) reported better sleep quality. Blood pressure remained stable in 34 participants (89.5%).

Exploratory Subgroup Analysis: Participants with Milder Baseline Abnormalities

Thirteen participants on medication met the criteria for "milder" baseline metabolic dysregulation.

Metabolic Improvement: In this subgroup, 76.9% (10/13) showed improvement (decrease) in at least one of their mildly abnormal parameters. Specifically, the improvement rate for borderline high TG was 83.3% (5/6), and for mild hyperglycemia was 62.5% (5/8).

Subjective Vitality: The proportion reporting improved vitality in this subgroup was 69.2% (9/13) (Table 1).

Table 1: Comparison of Improvement Rates between Overall Medicated Group and Milder Abnormality Subgroup.

Parameter	Overall Medicated Group (n=36)	Subgroup: Milder Abnormality (n=13)
TG Improvement	65.0% (13/20)	83.3% (5/6)
Blood Glucose Improvement	57.6% (19/33)	62.5% (5/8)
Subjective Vitality Improvement	58.3% (21/36)	69.2% (9/13)

Discussion

This prospective observational study demonstrates the successful translation of a TCM "medicine-food homology" formula into a modern nutritional product with high consumer acceptability and a favorable safety profile. The primary finding-89.5% palatability acceptance-is crucial, as long-term adherence is the fundamental challenge for any dietary intervention [6]. The product successfully masked potential herbal bitterness with a dominant pleasant cereal-milk flavor, proving the feasibility of this productization pathway. The observed trends in metabolic parameters must be interpreted cautiously within the study's limitations. The lack of a control group and near-universal use of concomitant medications preclude causal attribution of these changes to the product. They likely represent the combined outcome of sustained pharmacotherapy and dietary modification. However, these real-world results are promising and align with the theoretical actions of the core formula. Ingredients like *Cichorium intybus* and *Morus alba* leaf have documented preclinical hypoglycemic and lipid-modulating effects [7, 8], while *Astragalus membranaceus* is known for its immune-modulating

and anti-fatigue properties [9], potentially explaining the improved subjective vitality.

The most compelling insight comes from the exploratory subgroup analysis. Participants with milder baseline metabolic disturbances showed higher rates of improvement in both objective measures (especially triglycerides, 83.3%) and subjective vitality (69.2%) compared to the overall group. This suggests that the body's regulatory systems, when not severely compromised, may be more responsive to a gentle, balancing nutritional intervention rooted in TCM "harmonization" principles. This finding resonates strongly with the TCM concept of "*Zhi Wei Bing*" (treating pre-disease), which emphasizes intervention during the early, reversible stages of imbalance [10]. It positions this product not merely as a complementary aid for managed patients, but potentially as a primary tool for early-stage intervention and prevention.

The initial, self-limiting reports of dry mouth and mild heat sensations in a minority of participants are noteworthy. From a TCM perspective, this could reflect the "activating" nature of ingredients like *Cinnamomum cassia* and *Zanthoxylum bungeanum* in individ-

uals with certain constitutions (e.g., yin deficiency with effulgent fire). This highlights the potential for personalized nutrition based on TCM body constitution typing in future applications [11]. This study has several limitations, including its observational design, small sample size, short duration, lack of dietary intake standardization, and variability in lab measurement methods. The subgroup analysis is post-hoc and exploratory.

Conclusion

This study provides preliminary evidence that a classic TCM formula can be successfully integrated into a palatable, well-tolerated modern nutritional product. The high acceptance rate validates its market viability. While the observed metabolic benefits in this real-world setting are encouraging but confounded, the stronger positive signals in individuals with milder conditions offer a significant strategic direction. These results support the dual potential of this product: as a complementary nutritional support for individuals under medical management, and, more innovatively, as a promising candidate for early intervention and preventive health strategies targeting the large population in pre-disease states. Future randomized controlled trials focusing on pre-diabetic or borderline dyslipidemic populations are warranted to confirm its efficacy as a stand-alone lifestyle intervention tool.

Conflict of Interest

None.

Acknowledgment

None.

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