Evaluating the efficacy of I-fiber pearl on reducing body fat accumulation in obese females: A randomized, double-blind, and placebo-controlled trial

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Abstract

Obesity is a growing public health challenge worldwide, strongly linked to metabolic syndrome, type 2 diabetes, and cardiovascular disease. Inulin, a soluble, fermentable fiber derived mainly from Jerusalem artichoke and chicory, has been reported to improve weight management and metabolic health. This randomized, double-blind, placebo-controlled trial evaluated the effects of inulin-enriched tapioca pearls (I-fiber pearl) on body composition and lipid parameters in obese women. Methods: Fifty women (BMI ≥27 or waist >80 cm; age 20−50 years) were randomized to receive either I-fiber pearl or placebo (2 packs/day, 100 g/pack) for 12 weeks. Anthropometric indices, body composition, and blood biochemistry were assessed pre- and post-intervention. Results: After 12 weeks, the I-fiber group showed significant reductions in body weight, BMI, body fat mass, visceral fat, total cholesterol, and LDL cholesterol. I-fiber pearl improved body composition and lipid profiles, suggesting potential benefits as a functional supplement for obesity management.

Keywords: I-fiber pearl, Inulin, Obesity management, Randomized controlled trial

1. Introduction

Obesity is a critical global public health concern; according to the WHO, 16% of adults (890 million) were obese in 2022. Recognized as a chronic disease since 1997, it fundamentally results from an imbalance between energy intake and expenditure [1]. Factors like sedentary lifestyles and energy-dense diets drive this prevalence, causing excess energy storage and adipocyte hypertrophy [2]. As a multifactorial condition involving genetic and metabolic interactions, obesity heightens health risks [3−6]. Compared to healthy-weight individuals, those with obesity face a threefold higher risk of type 2 diabetes and metabolic syndrome, and a twofold higher risk of cardiovascular diseases. Visceral fat accumulation promotes chronic inflammation and oxidative stress, inducing a vicious cycle of insulin resistance and metabolic dysfunction [7,8].

Effective management is paramount, as losing just 5% of body weight significantly improves comorbidities like hypertension and sleep apnea [9]. When lifestyle changes are insufficient, pharmacotherapy is an option, though long-term use poses safety concerns [10−12]. Among current strategies—including surgery and exercise—dietary supplements are increasingly popular due to their convenience and favorable safety profile, serving as a

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widely accepted adjunctive approach for weight management.

Bubble tea, which originated in Taiwan during the 1980s, has become one of the nation's most iconic cultural and economic exports. Tapioca pearls (or boba), traditionally made from cassava starch, are central to this beverage's appeal. The industry has seen dramatic expansion; by the end of 2023, the number of beverage shops in Taiwan reached over 28,000, with annual revenues exceeding NT$128.5 billion [13]. Furthermore, the global demand for tapioca pearls remains high, with export values reaching nearly USD 84 million in 2023 (Taiwan Customs Administration, 2024). Despite their popularity, traditional pearls are often viewed as calorie-dense and labor-intensive to prepare. Recently, "ready-to-eat" frozen pearls with fewer additives have emerged as a convenient alternative to the complex cooking processes traditionally required by vendors.

Inulin is a soluble, fermentable, and non-digestible polysaccharide naturally present in over 36,000 plant species, most sourced from Jerusalem artichoke tubers and chicory roots [14–16]. Functionally, inulin undergoes fermentation in the colon and acts as a prebiotic. Several clinical studies have demonstrated its efficacy in regulating lipid metabolism, lowering blood glucose, supporting weight management, and alleviating constipation [14]. However, its effectiveness can vary depending on dosage, duration, and individual responsiveness, necessitating further study in specific food matrices. Further studies are therefore necessary to clarify the optimal conditions under which inulin supplementation most effectively supports weight, fat mass, and body composition management.

Traditional tapioca pearl preparation is labor-intensive and technically demanding, requiring precise control over cooking process. Furthermore, their short shelf life after cooking often leads to significant waste. Ready-to-eat frozen pearls address these challenges by simplifying the process, reducing the need for additives and minimising operational costs through enhanced convenience.

Building upon these market trends and nutritional benefits, the present trial evaluates a novel functional food product, "I-fiber pearl." This innovation incorporates inulin into a ready-to-eat pearl formulation, reducing the need for traditional food additives while providing a high-fiber alternative. This formulation allows consumers to enjoy the sensory appeal of bubble tea while simultaneously supplementing dietary fiber to help reduce fat accumulation. Accordingly, we conducted a randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy of I-fiber pearl in improving body weight, body fat, and metabolic parameters in obese female subjects.

2. Methods

2.1. Test product: I-fiber pearl

The investigational product, I-fiber pearl, and its placebo were provided by Ying-Hui Biotechnology Co., Ltd. The formulation of I-fiber pearl consisted of cassava starch, purified water, modified starch, chicory inulin, carboxymethyl cellulose, and sucralose. The placebo product contained cassava starch, purified water, acetylated distarch phosphate (as the modified starch), carboxymethyl cellulose, and sucralose. Sucralose was included as a Class XI sweetener permitted for food use. Both I-fiber pearl and placebo were packaged in identical transparent sachets (100 g per pack), making them indistinguishable to participants and ensuring blinding throughout the trial. Nutritional analysis revealed the following composition per 100 g: 134 kcal energy, 33.5 g carbohydrate, 4.6 mg sodium, and non-detectable levels of protein, fat, saturated fat, trans fat, and sugars. Triplicate sampling confirmed the inulin content of I-fiber pearl, with an average of 4.15 g per 100 g. Thus, participants in the I-fiber pearl group consumed approximately 8.3 g of chicory inulin daily (two packs/day). The macronutrient composition of the placebo was matched to that of I-fiber pearl, with the sole difference being the absence of dietary fiber. Participants were instructed to consume two packs of either I-fiber pearl or placebo daily for 12 consecutive weeks. Products could be consumed with tea, coffee, other beverages, or food, or ingested alone. Participants were advised to consume the product before noon. The recommended preparation method was as follows: (1) open the package and pour the frozen pearls into a cup; (2) reconstitute with 400 mL of hot water at 85 °C per 100 g serving; and (3) stir until thawed before consumption. Long-term stability testing indicated that I-fiber pearl remained stable under frozen storage for up to 24 months.

2.2. Clinical trial design

This study was a randomized, double-blind, placebo-controlled clinical trial conducted in obese females. The protocol was approved by the Institutional Review Board (IRB) of Chung Shan Medical University Hospital (CSMUH No: CS2-23093) and registered at ClinicalTrials.gov (Identifier: NCT06203834). Prior to randomization, participants

were required to maintain stable body weight for two weeks by following their usual lifestyle, dietary caloric intake, and physical activity patterns. A total of 50 eligible women were randomly assigned in equal numbers (n = 25 per group) to either the I-fiber pearl or placebo group. Participants consumed two packs daily (100 g/pack) of the assigned product for 12 consecutive weeks. Study visits and assessments: In-person assessments were performed at baseline (week 0) and post-intervention (week 12). These visits included blood sampling, urine collection, anthropometric measurements [bioelectrical impedance analysis (BIA), waist-to-hip ratio, subcutaneous fat thickness], blood pressure, heart rate, respiratory rate, dietary interviews, trial product dispensation, and returned product counts. Each blood draw involved 15 mL of venous blood, which was analyzed for hematology, glucose metabolism, lipid profile, renal and hepatic function, thyroid function, and electrolyte balance. Remote assessments were conducted via online interviews at screening (2 weeks before baseline) and during the trial at weeks 0, 2, 4, 6, 8, 10, and 12. These interviews included weekly home-based body weight and waist-to-hip measurements, dietary records (weeks 0, 4, and 12), physical activity and subjective well-being questionnaires (weeks 0 and 12), as well as product distribution or shipment confirmation. Randomization and blinding: Both I-fiber pearl and placebo products were packaged in identical transparent sachets and assigned distinct product codes to ensure blinding. Neither the investigators nor participants were aware of product allocation. Each participant received sachets labeled with a fixed product code for the entire trial, ensuring consistent treatment exposure. Unblinding and data analysis: At the conclusion of the 12-week intervention, anthropometric data, body composition results, blood biochemistry, and urinalysis outcomes were compiled and analyzed by the study team. Unblinding of group allocation was subsequently conducted by Ying-Hui Biotechnology Co., Ltd., after completion of statistical analyses.

2.3. Participants

2.3.1. Inclusion criteria

Eligible participants were required to meet all the following conditions: (1) Female, aged 20–50 years. (2) Overweight or obese, defined as BMI $\geq$27 kg/m^2 (3) Waist circumference >80 cm. (4) Ability to understand the study procedures and the potential risks and benefits as described in the informed consent form, and willingness to provide written informed consent. (5) Willingness and ability to adhere to dietary control during the intervention period.

2.3.2. Exclusion criteria

Participants were excluded if they met any of the following conditions: (1) Pregnant or lactating women. (2) Diagnosed with endocrine disorders, major organ diseases, or psychiatric illnesses (as determined by a physician). (3) Secondary obesity attributable to medical conditions or treatments (as determined by a physician). (4) Intolerance or adverse reactions to the study product identified during the trial. (5) Noncompliance with study requirements, including inconsistent consumption of the test product or deviationsin diet and physical activity. (6) Development of new illnesses or use of medications/supplements during the study that could affect the trial outcomes. (7) Use of any medications or supplements affecting fat metabolism within the past 6 months. (8) Use of medications for endocrine disorders within the past 6 months. (9) Current adherence to extreme dietary regimens.

2.4. Sample size and study duration

Based on previous research, supplementation with 10 g/day of inulin for 8 weeks resulted in a reduction in body weight from 76.0 ± 12.4 kg to 72.9 ± 12.0 kg [17]. Drawing on these findings, the present study calculated the required sample size with an effect size of 0.9, a two-tailed type I error (α) of 0.05, and a statistical power (1-β) of 0.8. Using G*Power software (Version 3.1.9.6, Franz Faul, Universität Kiel, Germany), the minimum sample size was determined to be 21 participants per group, resulting in a total of 42 participants. To account for an anticipated dropout rate of 20%, the sample size was increased to 50 participants (42 × 1.2 = 50), with 25 participants randomly allocated to the I-fiber pearl group and 25 to the placebo group. The clinical trial protocol was contracted on June 1, 2023, and received ethical approval from the Institutional Review Board (IRB) of Chung Shan Medical University Hospital on October 23, 2023 (CSMUH No: CS2-23093). The study was conducted from trial initiation through to IRB closure on September 18, 2024.

2.5. Study product and dosage

The investigational product, I-fiber pearl, and the placebo pearls were provided by Ying-Hui Biotechnology Co., Ltd. (Taipei, Taiwan). The formulations of the two products were identical, except that I-fiber pearl was additionally fortified with chicory inulin. The inulin was extracted directly

from natural plant sources using aqueous extraction methods. I-fiber pearl had a mildly sweet flavor and a chewy texture indistinguishable from that of conventional tapioca pearls (placebo). Both products were packaged in identical transparent sachets to maintain blinding, preventing participants from distinguishing between the test and placebo products. Participants were instructed to consume two packs daily (100 g per pack) of either I-fiber pearl or placebo pearls for a duration of 12 weeks.

2.6. Biochemical and urinalysis assessments

Biochemical and hematological analyses were performed by Saiya Health Medical Laboratory (Taichung, Taiwan). Serum parameters were measured using a cobas pro e801 automated chemiluminescence immunoassay analyzer (Roche Diagnostics). The following biomarkers were assessed: uric acid, creatinine, blood urea nitrogen (BUN), thyroid-stimulating hormone (TSH), triiodothyronine (T3), thyroxine (T4), aspartate aminotransferase (AST), alanine aminotransferase (ALT), gamma-glutamyl transferase (γ-GT), albumin, glucose, insulin, triglycerides (TG), total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), sodium (Na), potassium (K), chloride (Cl), calcium (Ca), and phosphorus (P). Hematological parameters were measured using a XN-1000 automated hematology analyzer (Sysmex). The following were included: white blood cell count (WBC), red blood cell count (RBC), hemoglobin (Hb), hematocrit, mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), platelet count, neutrophils, lymphocytes, monocytes, eosinophils, and basophils. Glycated hemoglobin (HbA1c) was analyzed using a Premier Hb9210 HbA1c analyzer (Trinity Biotech). Urinalysis was performed with an AX-4060 automated urine chemistry analyzer, measuring pH and specific gravity. Free fatty acids were analyzed using the RANDOX NEFA standard assay.

2.7. Dietary assessment and analysis

Dietary intake was assessed using 24-h dietary recall records at weeks 0, 4, and 12. For each time point, participants were asked to complete records for three non-consecutive days via an online form. Completion of dietary questionnaires was verified through online interviews and during on-site visits. A registered dietitian instructed participants on how to appropriately substitute the investigational products (I-fiber pearl or placebo) within their daily diet. During follow-up visits and interviews, participants were also asked to confirm their compliance with home-based body weight and waist-to-hip ratio measurements, as well as their adherence to product consumption. Dietary recall records submitted via Google Forms were verified with participants and subsequently consolidated into Excel spreadsheets for analysis. Nutrient intake was analyzed using the Simplified Nutrition Calculation Table published by the Taiwan Dietitian Association in 2023. The following dietary components were quantified: adjusted energy intake, crude protein, water, crude fat, total carbohydrates, and dietary fiber.

2.8. Subjective well-being and physical activity questionnaires

At baseline (week 0) and post-intervention (week 12), participants completed self-administered questionnaires via online forms. These assessments were used to compare changes in subjective well-being and physical activity before and after the 12-week intervention. Physical activity was assessed using the International Physical Activity Questionnaire (IPAQ)—Short Form, Taiwan version, authorized for use by the Health Promotion Administration, Ministry of Health and Welfare, Taiwan. The IPAQ evaluates weekly physical activity levels and reports results as metabolic equivalent of task minutes per week (MET-min/week), calculated as: MET score × minutes of activity per day × days per week. Daily activities were categorized into vigorous activity (8.0 METs), moderate activity (4.0 METs), and walking (3.3 METs), while sedentary time (sitting) was excluded from scoring. Total minutes of activity per week were summed to generate overall physical activity scores [18].

2.9. Anthropometric and body composition assessments

Anthropometric and physiological parameters were measured, including height, waist circumference, hip circumference, subcutaneous fat thickness, blood pressure, heart rate, respiratory rate, and body composition indices (body weight, body mass index [BMI], total body water [TBW], fat-free mass [FFM], body fat mass [BFM], percent body fat [PBF], and visceral fat level [VFL]). Waist circumference was measured with the participant standing relaxed at the end of normal expiration. The midpoint between the lower margin of the last rib and the upper edge of the iliac crest was identified, and a measuring tape was placed horizontally

around the abdomen at this level. Hip circumference was measured at the maximum circumference over the buttocks with the participant standing relaxed. Blood pressure and heart rate were measured on the non-dominant upper arm using an automated sphygmomanometer (NISSEI, DS-G10J; Ministry of Health and Welfare, Import Medical Device License No. 031516). Systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate were recorded after participants rested for at least 5 min in a seated position. Respiratory rate was measured by counting complete inspiration–expiration cycles over 1 min using a timer. Body composition was assessed using a multifrequency bioelectrical impedance analyzer (InBody 270, Biospace, Korea), providing measurements of body weight, BMI, TBW, FFM, BFM, PBF, and VFL. Skinfold thickness was measured at seven anatomical sites (chest, midaxillary line, triceps, subscapular, abdomen, suprailiac, and thigh) using Lange skinfold calipers. The sum of the seven measurements (mm) was used, together with age, to estimate body density with the following equation:

2.10. Statistical analysis

All data are expressed as mean ± standard deviation (SD) or percentages (%), as appropriate. Statistical analyses were performed using IBM SPSS Statistics, version 22.0 (IBM Corp., Chicago, IL, USA). The Shapiro–Wilk test was applied to assess data normality. Within-group differences between baseline and post-intervention were analyzed using the paired-sample t-test, while independent-sample t-tests were used to compare differences between groups. Repeated-measures ANOVA was employed to evaluate dietary intake across baseline, mid-intervention, and post-intervention time points. A p-value of <0.05 was considered statistically significant.

3. Results

3.1. Participants recruitment and attrition

A total of 50 participants were enrolled in this trial and randomly assigned to either the I-fiber pearl group (n = 25) or the placebo group (n = 25). Some participants discontinued the intervention due to difficulties complying with the study requirements. By the end of the 12-week intervention, 21 participants in the placebo group and 20 participants in the I-fiber pearl group had completed the trial, yielding a total of 41 participants included in the final analysis (Fig. 1). Compliance during the intervention was high in both groups. After 12 weeks, adherence rates were 97.17% in the placebo group and 99.26% in the I-fiber pearl group, with no statistically significant difference between groups ($p > 0.05$).

3.2. Effects of I-fiber pearl on physiological parameters, body composition, and subcutaneous fat

3.2.1. Baseline comparisons

As shown in Tables 1 and 2, baseline physiological and body composition parameters of the 41 obese participants—including height, age, body weight, BMI, total body water (TBW), fat-free mass (FFM), body fat mass (BFM), percent body fat (PBF), visceral fat level (VFL), waist circumference, and hip circumference—did not differ significantly between the I-fiber pearl and placebo groups at week 0 ($p > 0.05$). Similarly, baseline subcutaneous fat thickness was comparable between groups ($p > 0.05$).

3.2.2. Within-group changes from baseline to week 12

After 12 weeks of intervention, no significant changes were observed in the placebo group for any anthropometric or body composition variables ($p > 0.05$). In contrast, participants in the I-fiber pearl group demonstrated significant reductions in body weight, BMI, BFM, PBF, VFL, waist circumference, and hip circumference ($p < 0.05$). Regarding subcutaneous fat, both groups showed reductions. In the placebo group, significant decreases occurred at the chest, midaxillary, suprailiac, and triceps sites ($p < 0.05$). In the I-fiber pearl group, significant reductions were observed at the midaxillary, suprailiac, thigh, abdomen, subscapular, and triceps sites ($p < 0.05$).

3.2.3. Between-group comparisons of changes

Between-group comparisons revealed that changes in body weight, BMI, BFM, and VFL were significantly greater in the I-fiber pearl group than in the placebo group ($p < 0.05$). However, changes in TBW, FFM, PBF, waist circumference, and hip circumference did not differ significantly between groups ($p > 0.05$). Furthermore, between-group comparisons of changes in subcutaneous fat thickness at specific sites did not reach statistical significance ($p > 0.05$).

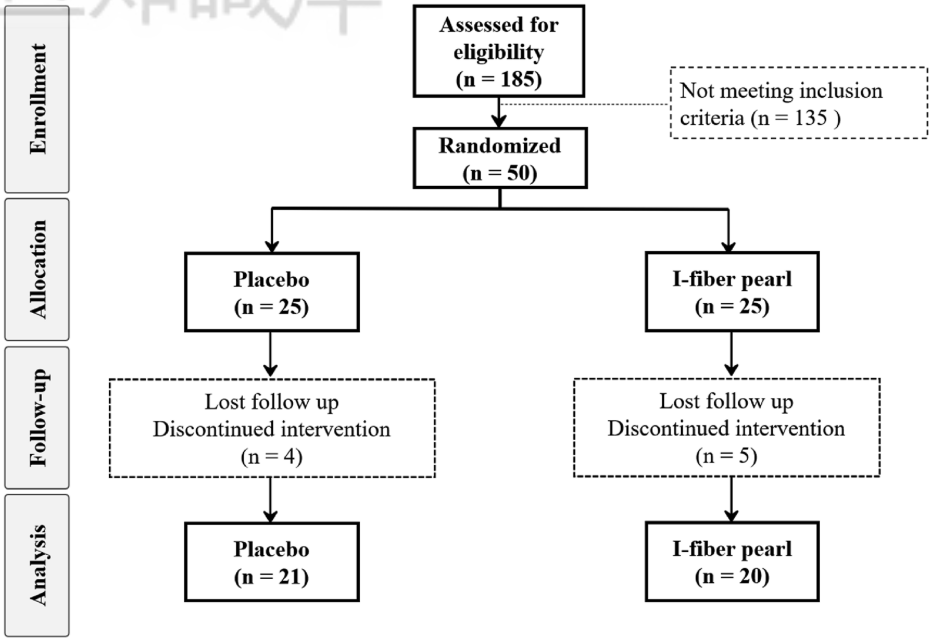

Fig. 1. Result flow chart.

Table 1. A comparative analysis of the biological characteristics and bioelectrical impedance analysis results of the obese females in the placebo and I-fiber pearl groups between week 0 and week 12.

Measure	Placebo (n = 21)			I-fiber pearl (n = 20)		
	Week 0	Week 12	Change	Week 0	Week 12	Change
Height (cm)	157.83 ± 5.62	157.83 ± 5.62	0.00 ± 0.00	159.53 ± 6.94	159.53 ± 6.94	0.00 ± 0.00
Age (years)	31.71 ± 9.54	31.71 ± 9.54	0.00 ± 0.00	30.10 ± 7.94	30.10 ± 7.94	0.00 ± 0.00
Weight (kg)	74.57 ± 9.83	74.15 ± 10.19	−0.42 ± 1.84	78.77 ± 13.38	76.80 ± 12.66**	−1.97 ± 2.15†
BMI (kg/m^2)	29.94 ± 3.79	29.78 ± 3.98	−0.16 ± 0.75	30.81 ± 3.63	30.05 ± 3.51**	−0.76 ± 0.85†
TBW (L)	31.29 ± 3.34	31.33 ± 3.16	0.04 ± 0.88	32.26 ± 5.25	32.05 ± 5.43	−0.21 ± 0.87
FFM (kg)	42.71 ± 4.59	42.74 ± 4.32	0.03 ± 1.20	44.08 ± 7.19	43.81 ± 7.45	−0.27 ± 1.20
BFM (kg)	31.85 ± 6.96	31.40 ± 7.26	−0.45 ± 1.70	34.69 ± 7.92	32.99 ± 7.10**	−1.70 ± 2.14†
PBF (%)	42.45 ± 4.16	42.00 ± 4.00	−0.44 ± 1.70	43.87 ± 4.70	42.89 ± 4.70*	−0.98 ± 1.74
VFL (Level)	15.29 ± 3.02	15.05 ± 2.99	−0.24 ± 0.94	16.50 ± 3.24	15.55 ± 3.00**	−0.95 ± 1.23†
Waist (cm)	94.70 ± 10.68	94.40 ± 11.16	−0.30 ± 1.71	93.46 ± 10.34	92.58 ± 10.40*	−0.88 ± 1.56
Hip (cm)	104.57 ± 8.20	104.67 ± 9.17	0.10 ± 2.07	108.31 ± 9.19	107.63 ± 8.90*	−0.68 ± 1.07

The reported values are means ± SD. *Mean significant difference compared to week 0 within the same group using the paired *t*-test, *$p < 0.05$, **$p < 0.0$. †Mean significant difference in the change (Week 12 minus Week 0) between the I-fiber pearl and placebo groups using analyzed by paired sample *t*-test, †$p < 0.05$. BMI, body mass index. TBW, total body water. FFM, fat free mass. BFM, body fat mass. PBF, percent body fat. VFL, visceral fat level.

Table 2. A comparative analysis of the subcutaneous fat of the obese females in the placebo and I-fiber pearl groups between week 0 and week 12.

Measure	Placebo (n = 21)			I-fiber pearl (n = 20)		
	Week 0	Week 12	Change	Week 0	Week 12	Change
Chest (mm)	18.71 ± 5.43	16.79 ± 4.35*	−1.93 ± 3.09	18.28 ± 4.49	17.33 ± 3.45	−0.95 ± 2.91
Mid-axillary (mm)	20.74 ± 4.98	17.10 ± 4.48**	−3.64 ± 4.67	20.75 ± 6.97	18.15 ± 4.15**	−2.60 ± 3.63
Supraspinale (mm)	10.74 ± 5.72	8.98 ± 4.95*	−1.76 ± 3.23	10.68 ± 7.70	9.58 ± 6.72**	−1.10 ± 1.18
Front thigh (mm)	24.93 ± 9.47	23.67 ± 6.03	−1.26 ± 4.89	26.40 ± 5.38	24.73 ± 5.53***	−1.68 ± 1.60
Abdominal (mm)	21.52 ± 6.38	19.36 ± 5.03	−2.17 ± 5.33	23.19 ± 5.89	20.23 ± 4.72***	−2.96 ± 2.87
Subscapular (mm)	23.57 ± 19.86	16.63 ± 3.58	−6.94 ± 19.83	18.58 ± 4.25	16.98 ± 2.87**	−1.60 ± 2.41
Triceps (mm)	28.74 ± 6.83	26.14 ± 6.00**	−2.60 ± 3.80	28.38 ± 7.03	26.03 ± 5.25*	−2.35 ± 4.05

The reported values are means ± SD. *Mean significant difference compared to week 0 within the same group using the paired *t*-test, *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$.

Table 3. A comparative analysis of the blood pressure, heart rate, and respiratory rate of the obese females in the placebo and I-fiber pearl groups between week 0 and week 12.

Measure	Placebo (n = 21)			I-fiber pearl (n = 20)		
	Week 0	Week 12	Change	Week 0	Week 12	Change
SBP (mmHg)	122.33 ± 15.65	119.17 ± 16.06	−3.17 ± 13.41	121.78 ± 10.31	118.28 ± 9.64	−3.50 ± 8.53
DBP (mmHg)	77.62 ± 10.60	76.31 ± 13.22	−1.31 ± 8.20	77.43 ± 10.47	75.78 ± 8.49	−1.65 ± 9.86
Heart rate (bpm)	75.81 ± 9.88	77.62 ± 9.28	1.81 ± 12.35	78.60 ± 11.88	79.58 ± 14.23	0.98 ± 9.51
RR (times/min)	17.76 ± 4.13	19.14 ± 8.00	1.38 ± 5.84	16.35 ± 5.91	16.70 ± 5.80	0.35 ± 2.21

The reported values are means ± SD. SBP, systolic blood pressure. DBP, diastolic blood pressure. RR, Respiratory rate. min, minutes.

3.3. Effects of I-fiber pearl on blood pressure, heart rate, and respiratory rate

3.3.1. Within-group changes and between-group comparisons

As shown in Table 3, baseline measurements of systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate, and respiratory rate did not differ significantly between the I-fiber pearl and placebo groups ($p > 0.05$). After 12 weeks of intervention, respiratory rate remained comparable between groups ($p > 0.05$). Within-group comparisons from baseline to week 12 revealed no significant changes in SBP, DBP, heart rate, or respiratory rate in either the placebo or I-fiber pearl group (all $p > 0.05$). Furthermore, between-group comparisons of changes in these parameters showed no statistically significant differences ($p > 0.05$).

3.4. Effects of I-fiber pearl on serum biochemical parameters and urinalysis

3.4.1. Within-group changes from baseline to week 12

As shown in Table 4, baseline serum biochemical parameters related to renal function (uric acid, creatinine, and BUN), liver function (AST, ALT, γ-GT, and albumin), and thyroid function (TSH, T3, and T4) did not differ significantly between the I-fiber pearl and placebo groups ($p > 0.05$). Within-group analyses showed no significant changes in the placebo group ($p > 0.05$). In contrast, the I-fiber pearl group showed significant increases in uric acid, creatinine, albumin, and T4 ($p < 0.05$), although all remained within clinically normal ranges. Regarding lipid profiles, the I-fiber pearl group showed significant within-group reductions

Table 4. Effects of placebo and I-fiber pearl on kidney, liver, and thyroid parameters, blood glucose and blood lipid profiles of obese females between week 0 and week 12.

Measure	Placebo (n = 21)			I-fiber pearl (n = 20)		
	Week 0	Week 12	Change	Week 0	Week 12	Change
Uric acid (mg/dL)	5.26 ± 1.28	5.18 ± 1.12	−0.08 ± 1.18	5.19 ± 1.04	5.59 ± 1.15**	0.40 ± 0.58
Creatinine (mg/dL)	0.65 ± 0.08	0.67 ± 0.06	0.02 ± 0.07	0.64 ± 0.10	0.70 ± 0.14**	0.06 ± 0.08
BUN (mg/dL)	11.57 ± 3.53	10.95 ± 2.18	−0.62 ± 3.29	10.50 ± 2.52	9.90 ± 2.25	−0.60 ± 2.50
AST (U/L)	18.86 ± 8.88	20.57 ± 12.43	1.71 ± 5.09	19.55 ± 8.41	17.90 ± 5.49	−1.65 ± 5.03†
ALT (U/L)	20.76 ± 21.26	23.67 ± 27.98	2.90 ± 8.89	22.30 ± 18.64	20.15 ± 12.52	−2.15 ± 9.49
γ-GT (U/L)	14.81 ± 10.46	16.57 ± 10.36	1.76 ± 4.07	21.40 ± 17.52	20.30 ± 18.48	−1.10 ± 5.99
Albumin (g/dL)	4.54 ± 0.26	4.66 ± 0.21	0.11 ± 0.25	4.57 ± 0.16	4.68 ± 0.17**	0.11 ± 0.17
TSH (ng/dL)	2.00 ± 1.15	1.83 ± 1.05	−0.17 ± 1.28	2.61 ± 2.06	2.32 ± 2.68	−0.29 ± 1.24
T3 (ng/dL)	117.19 ± 21.85	113.59 ± 23.98	−3.60 ± 24.08	115.67 ± 15.36	117.12 ± 21.33	1.45 ± 16.49
T4 (μg/dL)	8.06 ± 1.35	8.35 ± 1.43	0.29 ± 0.96	7.51 ± 0.74	8.26 ± 1.74*	0.75 ± 1.46
HbA1c (%)	5.57 ± 0.34	5.65 ± 0.37	0.08 ± 0.27	5.63 ± 0.42	5.61 ± 0.33	−0.02 ± 0.21
Glucose (mg/dL)	93.48 ± 12.73	89.14 ± 6.82	−4.33 ± 10.73	91.80 ± 8.04	89.75 ± 7.84	−2.05 ± 6.30
Insulin (μIU/mL)	27.75 ± 38.28	15.75 ± 7.29	−12.00 ± 36.92	13.55 ± 5.66	12.01 ± 8.43	−1.54 ± 7.96
TG (mg/dL)	117.52 ± 44.13	99.14 ± 34.88	−18.38 ± 50.17	98.35 ± 35.36	101.00 ± 35.50	2.65 ± 18.89
TC (mg/dL)	190.86 ± 37.17	196.86 ± 38.35	6.00 ± 22.20	190.10 ± 32.32	182.70 ± 21.18	−7.40 ± 18.66†
HDL-C (mg/dL)	54.33 ± 14.81	56.10 ± 12.10	1.76 ± 9.01	54.20 ± 11.51	51.50 ± 12.83*	−2.70 ± 5.04
LDL-C (mg/dL)	123.95 ± 35.46	127.57 ± 36.13	3.62 ± 21.35	124.05 ± 33.27	115.85 ± 24.06*	−8.20 ± 14.59†
AIP	0.41 ± 0.48	0.38 ± 0.81	−0.03 ± 0.41	0.24 ± 0.21	0.28 ± 0.22	0.04 ± 0.10
FFA (mmol/L)	1.12 ± 0.61	0.75 ± 0.77	−0.37 ± 1.02	0.90 ± 0.15	0.66 ± 0.16***	−0.24 ± 0.24

The reported values are means ± SD. *Mean significant difference compared to week 0 within the same group using the paired *t*-test, *$p < 0.05$, **$p < 0.01$. †Mean significant difference in the change (Week 12 minus Week 0) between the I-fiber pearl and placebo groups using analyzed by paired sample *t*-test, †$p < 0.05$. BUN, blood urea nitrogen. AST, aspartate aminotransferase. ALT, alanine aminotransferase. γ-GT, gamma glutamyl transpeptidase. TSH, thyroid-stimulating hormone. T3, triiodothyronine. T4, tetraiodothyronine. TG, triglyceride. TC, total cholesterol. HDL-C, high-density lipoprotein-cholesterol. LDL-C, low-density lipoprotein-cholesterol. AIP, Atherogenic Index of Plasma. FFA, Free fatty acid. AIP = $\log_{10}$ (TG/HDL-C).

in free fatty acids (FFA), HDL-C, and LDL-C ($p < 0.05$), while the placebo group remained stable.

As shown in Table 5, within-group analyses revealed several significant physiological fluctuations over the 12-week period. In the placebo group, serum potassium decreased significantly while calcium levels increased ($p < 0.05$). In the I-fiber pearl group, significant increases were observed in sodium, chloride, and calcium levels compared with baseline ($p < 0.05$). Regarding hematological parameters, basophil percentage decreased significantly in the placebo group, while mean corpuscular hemoglobin (MCH) increased significantly in the I-fiber pearl group ($p < 0.05$). For urinary parameters, no significant within-group changes were observed in pH or specific gravity ($p > 0.05$). Importantly, all aforementioned changes remained within normal clinical reference ranges, indicating no adverse metabolic or physiological impact.

3.4.2. Between-group comparisons of changes

After 12 weeks, there were no significant between-group differences in renal or thyroid function markers ($p > 0.05$). Notably, between-

Table 5. Effects of placebo and I-fiber pearl on serum electrolytes, hematological parameters, and urinary parameters of obese females between week 0 and week 12.

Measure	Placebo (n = 21)			I-fiber pearl (n = 20)		
	Week 0	Week 12	Change	Week 0	Week 12	Change
Na (mmol/L)	137.67 ± 2.03	138.67 ± 2.76	1.00 ± 3.00	137.00 ± 1.92	139.10 ± 1.94**	2.10 ± 2.27
K (mmol/L)	4.86 ± 0.74	4.45 ± 0.44*	−0.41 ± 0.76	4.64 ± 0.69	4.40 ± 0.28	−0.24 ± 0.59
Cl (mmol/L)	101.86 ± 1.85	102.33 ± 2.39	0.48 ± 2.11	101.80 ± 1.64	103.15 ± 2.21**	1.35 ± 2.06
Ca (mg/dL)	9.15 ± 0.44	9.42 ± 0.40*	0.28 ± 0.48	9.22 ± 0.41	9.42 ± 0.34**	0.20 ± 0.27
P (mg/dL)	3.78 ± 0.56	3.83 ± 0.40	0.05 ± 0.55	3.71 ± 0.55	3.79 ± 0.43	0.08 ± 0.40
MCH (pg/cell)	27.27 ± 3.42	27.33 ± 3.13	0.06 ± 0.77	27.33 ± 3.43	27.01 ± 3.43*	−0.32 ± 0.51
MCHC (g/dL)	31.84 ± 1.81	31.81 ± 1.85	−0.02 ± 0.85	32.11 ± 1.24	31.88 ± 1.35	−0.24 ± 0.74
MCV (fL)	85.38 ± 8.23	85.74 ± 7.22	0.37 ± 2.32	84.91 ± 8.41	84.50 ± 8.60	−0.41 ± 1.83
Hb (g/dL)	12.79 ± 1.55	13.00 ± 1.25	0.22 ± 0.86	12.97 ± 1.56	12.75 ± 1.62	−0.22 ± 0.55
WBC count ($\times 10^3/\mu L$)	7.03 ± 1.21	7.60 ± 2.68	0.57 ± 2.41	8.33 ± 2.28	7.37 ± 2.16	−0.96 ± 2.09
Platelet ($\times 10^3/\mu L$)	314.19 ± 78.00	326.19 ± 81.85	12.00 ± 40.05	325.05 ± 61.51	338.30 ± 77.82	13.25 ± 48.64
RBC count ($\times 10^6/\mu L$)	4.70 ± 0.36	4.79 ± 0.45	0.08 ± 0.28	4.77 ± 0.48	4.74 ± 0.46	−0.03 ± 0.19
Basophilic (%)	0.87 ± 0.43	0.64 ± 0.24*	−0.23 ± 0.42	0.75 ± 0.27	0.81 ± 0.25	0.06 ± 0.26†
Eosinophilic (%)	2.48 ± 1.94	2.07 ± 1.34	−0.41 ± 1.52	3.44 ± 2.41	3.66 ± 2.75	0.23 ± 1.74
Hematocrit (%)	40.08 ± 4.06	40.83 ± 2.73	0.76 ± 2.75	40.33 ± 4.08	39.91 ± 4.19	−0.42 ± 1.81
Lymphocyte (%)	31.32 ± 7.30	29.50 ± 9.02	−1.83 ± 8.84	28.84 ± 6.58	30.31 ± 7.36	1.47 ± 6.17
Monocyte (%)	5.19 ± 1.26	5.41 ± 1.47	0.23 ± 1.28	4.82 ± 1.02	4.84 ± 1.08	0.02 ± 1.15
Neutrophil (%)	60.14 ± 9.15	62.38 ± 9.75	2.24 ± 10.15	62.16 ± 6.93	60.39 ± 8.57	−1.78 ± 7.34
pH	6.24 ± 0.58	6.36 ± 0.50	0.12 ± 0.82	6.23 ± 0.70	6.08 ± 0.49	−0.15 ± 0.81
Specific gravity	1.02 ± 0.01	1.02 ± 0.01	0.00 ± 0.01	1.02 ± 0.01	1.02 ± 0.01	0.00 ± 0.01

The reported values are means ± SD. Comparison of different groups using analyzed by independent sample *t*-test. *Mean significant difference compared to week 0 within the same group using the paired *t*-test, *$p < 0.05$, **$p < 0.01$. †Mean significant difference in the change (Week 12 minus Week 0) between the I-fiber pearl and placebo groups using analyzed by paired sample *t*-test. Significant differences ($p < 0.05$). Na, sodium. K, potassium. Cl, chloride. Ca, calcium. P, phosphorus. MCH, mean corpuscular hemoglobin. MCHC, mean corpuscular hemoglobin concentration. MCV, mean corpuscular volume. Hb, Hemoglobin. WBC count, white blood cell count. RBC count, red blood cell count.

Table 6. Effect of placebo and I-fiber pearl on dietary data of obese females at week 0, week 4, and week 12.

Variable	Groups	Number of cases	Week 0	week 4	week 12
Total energy (Kcal)	Placebo	21	4389.87 ± 1343.55	4123.84 ± 1380.06	4423.23 ± 1421.61
	I-fiber pearl	20	4758.88 ± 1083.56	4447.45 ± 1576.16	4625.51 ± 1275.69
Protein (g)	Placebo	21	207.73 ± 43.21	181.17 ± 61.90	188.25 ± 65.47
	I-fiber pearl	20	225.28 ± 42.93	190.90 ± 75.27	204.15 ± 56.75
Fat (g)	Placebo	21	192.30 ± 66.95	146.24 ± 67.81	164.61 ± 74.71**
	I-fiber pearl	20	203.93 ± 57.00	151.59 ± 80.39	181.59 ± 66.75***
Carbohydrate (g)	Placebo	21	474.21 ± 180.21	537.96 ± 183.97	564.51 ± 188.07
	I-fiber pearl	20	524.32 ± 152.09	593.18 ± 190.61	561.05 ± 168.69
Dietary fiber (g)	Placebo	21	30.78 ± 7.77	30.33 ± 14.87	31.76 ± 15.41
	I-fiber pearl	20	34.44 ± 10.45	49.46 ± 11.56#	50.91 ± 14.65#,***

The reported values are means ± SD. Comparison of different groups using analyzed by independent sample *t*-test. Comparison of different groups using analyzed by repeated measures ANOVA. #Mean significance compared to the placebo group within the same week using the paired *t*-test, #$p < 0.05$. *Mean significance compared to week 0 within same group using the paired *t*-test, **$p < 0.01$, ***$p < 0.001$.

group comparisons revealed that changes in AST were significantly lower in the I-fiber pearl group compared with placebo ($p < 0.05$). For lipid parameters, the I-fiber pearl group demonstrated significantly greater reductions in TC and LDL-C compared to the placebo group ($p < 0.05$).

At baseline, there were no significant differences between the I-fiber pearl and placebo groups in terms of serum electrolytes, hematological parameters, or urinary pH and specific gravity ($p > 0.05$). After 12 weeks of intervention, no significant between-group differences were observed in electrolyte changes or urinary parameters ($p > 0.05$). Electrolytes (Na, K, Cl, Ca, P) were monitored primarily as safety markers to ensure that the 12-week consumption of I-fiber pearl did not cause metabolic disturbances or influence fluid balance. Although we observed minor fluctuations, all values remained within clinical reference ranges, confirming the safety of the product. However, significant differences between the two groups were observed in the white blood cell count, as well as the percentages of basophils and eosinophils ($p < 0.05$). Despite these statistical differences, all hematological values for both groups remained within physiological norms, and no clinically relevant abnormalities were identified.

3.5. Effects of I-fiber pearl on dietary intake and physical activity

3.5.1. Within-group changes from baseline to week 12

As shown in Table 6, dietary fiber intake in the I-fiber pearl group increased significantly after 12 weeks ($p < 0.05$), whereas no change was observed in the placebo group ($p > 0.05$). According to Table 7, no significant changes in daily physical activity (vigorous, moderate, or walking) were observed within either group throughout the study.

3.5.2. Between-group comparisons

Between-group comparisons revealed significant differences in fiber intake at the mid-point and end of the trial ($p < 0.05$) due to the intervention product. However, energy, protein, fat, and carbohydrate intake did not differ significantly between groups ($p > 0.05$). The Tapioca pearls themselves (both I-fiber and placebo) contain cassava starch, providing approximately 33.5 g of carbohydrates per 100 g pack. Since participants consumed two packs daily, an increase in daily carbohydrate intake of approximately 67 g was expected and reflected in the dietary assessment. Baseline physical activity levels were comparable, and no between-group differences emerged during the trial. Based on the IPAQ results, there were no statistically significant differences in physical activity between the two groups at baseline ($p > 0.05$). Any slight numerical differences were within the range of individual variability and did not impact the study's overall findings.

3.6. Effects of I-fiber pearl on safety indicators

As shown in Table 8, no significant differences were observed between the I-fiber pearl and placebo groups in assessments of mental status, sleep quality, anorexia, or gastrointestinal symptoms at baseline or after 12 weeks of intervention ($p > 0.05$).

4. Discussion

Previous studies have highlighted the health implications of differential fat distribution. Abdominal fat accumulation is strongly associated with metabolic syndrome, whereas gluteofemoral fat deposition is often the result of subcutaneous adipocyte hypertrophy, which may be relatively protective and less strongly associated with metabolic risk [19,20]. Our findings indicate that 12 weeks of I-

Table 7. Effects of placebo and I-fiber pearl on physical activity data of obese females between week 0 and week 12.

Measure	Placebo (n = 21)			I-fiber pearl (n = 20)		
	Week 0	Week 12	Change	Week 0	Week 12	Change
Vigorous (MET-min/week)	908.57 ± 2692.54	960.00 ± 2720.59	51.43 ± 235.68	480.00 ± 952.87	1030.00 ± 2667.79	550.00 ± 2798.67
Moderate (MET-min/week)	245.71 ± 541.30	217.14 ± 550.72	−28.57 ± 151.34	571.00 ± 807.27	676.00 ± 1394.48	105.00 ± 1180.56
Walking (MET-min/week)	555.50 ± 1336.47	660.79 ± 1375.10	105.29 ± 550.48	1607.10 ± 3841.69	1546.88 ± 3174.46	−60.23 ± 1678.30
Total (MET-min/week)	1709.79 ± 3414.63	1837.93 ± 3386.09	128.14 ± 626.56	2658.10 ± 4020.28	3252.88 ± 5571.74	594.78 ± 4420.02

The reported values are means ± SD. Physical activity score using IPAQ. Vigorous intensity means 8 METs. Moderate intensity means 4 METs. Walking means 3.3 METs. Expressed as MET-min per week: MET level × minutes of activity × events per week. Total MET-minutes/week = walk (METs × min × days) + mod (METs × min × days) + vig (METs × min × days).

Table 8. Effects of placebo and I-fiber pearl on safety indicators of obese females between week 0 and week 12.

Measure (Grade 0–4)	Placebo (n = 21)			I-fiber pearl (n = 20)		
	Week 0	Week 12	Change	Week 0	Week 12	Change
	Median (Range)	Median (Range)	Median (Range)	Median (Range)	Median (Range)	Median (Range)
Feeling anxious	0 (0 to 3)	0 (0 to 3)	0 (−1 to 1)	1 (0 to 3)	0 (0 to 2)	0 (−2 to 2)
Fatigued, lacking energy	1 (0 to 3)	1 (0 to 3)	0 (−2 to 1)	1 (0 to 3)	1 (0 to 3)	0 (−2 to 1)
Difficulty sleeping	0 (0 to 3)	0 (0 to 3)	0 (−1 to 1)	1 (0 to 3)	1 (0 to 3)	0 (−2 to 1)
Poor appetite	0 (0 to 2)	0 (0 to 2)	0 (−1 to 1)	0 (0 to 2)	0 (0 to 2)	0 (−2 to 1)
Bloating or stomach pain	0 (0 to 3)	1 (0 to 3)	0 (−2 to 2)	0 (0 to 2)	0 (0 to 2)	0 (−1 to 1)
Acid reflux	0 (0 to 3)	0 (0 to 2)	0 (−1 to 1)	0 (0 to 3)	0 (0 to 3)	0 (−1 to 1)
Frequent indigestion	0 (0 to 2)	0 (0 to 2)	0 (−1 to 2)	0 (0 to 2)	0 (0 to 2)	0 (−1 to 1)
Constipation or irregular bowel movements	1 (0 to 3)	1 (0 to 3)	0 (−2 to 2)	1 (0 to 3)	1 (0 to 3)	0 (−2 to 1)
Overall bowel condition	1 (0 to 3)	1 (0 to 3)	0 (−1 to 1)	1 (0 to 3)	1 (0 to 3)	0 (−1 to 1)

The parameters were assessed using a 5-point Likert scale (Grade 0: None; Grade 1: Very mild; Grade 2: Mild; Grade 3: Moderate; Grade 4: Severe). As these are non-parametric data, results are expressed as Median (Minimum–Maximum).

fiber pearl supplementation produced favorable effects on body weight, BMI, BFM, and VFL. Importantly, within-group comparisons showed a significant reduction in abdominal fat in the I-fiber pearl group, suggesting potential benefits for lowering the risk of metabolic syndrome. These results are consistent with prior evidence that inulin supplementation reduces visceral adipose tissue and improves glucose tolerance, likely through modulation of gut microbial metabolites, supporting its role in regulating obesity and metabolic abnormalities [21]. Moreover, dietary fiber is known to reduce energy intake by increasing chewing effort, stimulating saliva and gastric secretions, promoting gastric distension and satiety, and slowing intestinal absorption, while also enhancing fat binding and reducing dietary fat absorption-mechanisms that collectively contribute to weight reduction and obesity improvement [22,23]. In this study, the I-fiber group demonstrated significant within-group reductions in subcutaneous fat thickness at several sites (thigh, abdomen, and subscapular). However, the between-group differences remained statistically non-significant, likely due to a parallel decrease in specific fat sites (triceps and mid-axillary) within the placebo group. Fundamental factors may include limited statistical power due to the small sample size and substantial inter-individual variability in fat distribution [24]. Furthermore, the psychological impact of trial enrollment—the Hawthorne effect—may have led participants in both groups to adopt healthier habits, resulting in the observed parallel shifts and reducing the statistical difference between the groups. Cizza et al. (2014) reported that obese individuals with insufficient sleep increased their sleep duration simply by enrolling in a clinical trial, even before the formal intervention commenced. This self-initiated behavioral shift was associated with notable improvements in insulin resistance and lipid profiles, illustrating the potential impact of trial participation on physiological outcomes [25].

Our findings suggest that 12 weeks of I-fiber pearl supplementation did not adversely affect blood pressure, heart rate, or respiratory rate in obese participants. This is consistent with previous research demonstrating that supplementation with soluble dietary fiber does not negatively influence cardiovascular parameters such as blood pressure or heart rate [26]. Similarly, studies supplementing inulin and fructooligosaccharides have reported no significant alterations in heart rate or respiratory rate [27,28]. Notably, epidemiological evidence has suggested that higher intakes of chicory-derived inulin may help reduce the risk of hypertension [29]. In addition, a randomized, double-blind, placebo-controlled trial showed that daily supplementation with 15 g of inulin for 21 days effectively reduced SBP and prevented SBP elevation [30]. These findings indicate that while the present study did not observe changes in hemodynamic parameters, chicory inulin may have potential benefits in specific populations or under different supplementation regimens.

The beneficial effects observed in our study may be attributed to the chicory inulin contained in I-fiber pearl. Inulin is a soluble dietary fiber and an indigestible carbohydrate that functions as a prebiotic. Previous studies have shown that inulin fermentation in the gut slows gastric emptying, thereby attenuating postprandial glucose increases and improving glycemic control, partly through stimulation of GLP-1 secretion [31–33]. Meta-analyses have also reported that inulin supplementation can significantly reduce fasting glucose and fasting insulin in individuals with prediabetes or

type 2 diabetes, although such effects may not be observed in healthy individuals [33]. Moreover, fermentation of dietary fibers and oligosaccharides produces short-chain fatty acids (SCFAs), particularly propionate, which suppresses hepatic gluconeogenesis and fatty acid synthesis, while plasma fatty acid concentrations can indirectly modulate glucose metabolism [32,33]. Taken together, our findings suggest that supplementation with I-fiber pearl not only maintained normal renal, hepatic, and thyroid function but also exerted favorable effects on lipid metabolism, particularly through reductions in TC and LDL-C, potentially mediated by the prebiotic properties of inulin.

Our results are consistent with previous safety evaluations of inulin-type fructans. For example, in a randomized, double-blind, placebo-controlled trial, supplementation with 0.8 g/day of inulin-enriched infant formula for 4 months showed no adverse events, with serum chloride levels slightly higher than those in standard formula-fed infants but lower than those in breastfed infants; all values remained within normal ranges [27]. Additionally, a controlled trial in nine healthy adult men showed that 28 days of chicory inulin supplementation significantly increased calcium absorption from 21.3% to 33.7%, indicating a beneficial effect of inulin on mineral metabolism [34]. Furthermore, Prior research suggests that dietary patterns rich in vegetables can increase urinary pH, reduce urinary acidity, and lower bone resorption markers, indicating benefits for acid–base balance and skeletal health [35]. However, supplementation with inulin-type soluble fiber alone, without broader dietary modifications, may not be sufficient to alter urinary pH values.

These results indicate that consumption of I-fiber pearl did not produce adverse effects on psychological status, sleep, appetite, or gastrointestinal tolerance. This finding is consistent with previous evidence. Smith et al. (2015) reported that supplementation with 5 g of inulin/oligofructose in healthy adults did not negatively impact mood, psychological well-being, gastrointestinal comfort, or hunger sensation [36]. Taken together, these results support the safety and tolerability of I-fiber pearl as a functional dietary supplement.

After 12 weeks of intervention, participants in the I-fiber pearl group demonstrated significantly greater reductions in body weight, BMI, body fat mass ($p = 0.044$), visceral fat level, aspartate aminotransferase, total cholesterol, and LDL cholesterol compared with the placebo group. Importantly, no adverse effects were observed in physiological parameters, hematological and biochemical markers, dietary intake, or physical activity levels, indicating that I-fiber pearl was well tolerated and safe. In conclusion, these findings suggest that I-fiber pearl supplementation for 12 weeks can effectively improve body composition and lipid metabolism in obese individuals. Therefore, I-fiber pearl may serve as a promising dietary supplement for reducing body fat accumulation and supporting obesity management. In conclusion, the 12-week intervention with I-fiber pearl demonstrated significant improvements in primary metabolic and anthropometric outcomes compared to the placebo group. Specifically, the I-fiber pearl group achieved a significant reduction in body weight (mean change: −3.37 kg; 95% CI: −4.36 to −2.38 kg) and BMI (mean change: −1.33 kg/m^2; 95% CI: −1.72 to −0.94 kg/m^2), whereas the placebo group showed no such improvements.

Regarding body composition and lipid profiles, the I-fiber pearl intervention led to a substantial decrease in body fat mass (BFM) (mean change: −2.30 kg; 95% CI: −3.12 to −1.48 kg) and LDL-cholesterol (mean change: −11.95 mg/dL; 95% CI: −18.25 to −5.65 mg/dL). The inclusion of 95% confidence intervals reinforces the clinical significance of these findings, suggesting that I-fiber pearl is an effective functional food for weight management and lipid regulation in obese individuals. These results support the potential of incorporating inulin into popular beverages to improve metabolic health without compromising sensory indulgence.

A limitation of this study is the reliance on multi-frequency BIA for body composition assessment. While imaging techniques like DEXA or MRI offer superior precision for fat quantification, BIA was utilized due to its non-invasive nature, cost-effectiveness, and high feasibility for large-scale clinical screening. Despite its lower absolute accuracy compared to gold-standard imaging, BIA remains a validated and reliable tool for tracking longitudinal trends and relative changes. Thus, it is sufficient for evaluating the efficacy of the I-fiber pearl intervention on body fat distribution over the 12-week study period. Another limitation of this study is the reliance on self-reported dietary records and physical activity levels, which are inherently susceptible to recall bias and social desirability bias. To mitigate this, we employed registered dietitians for participant training, conducted frequent online follow-up interviews to ensure data consistency, and utilized the validated IPAQ for activity assessment. While these measures strengthened data reliability, some degree of subjective reporting bias remains a possibility. Third limitation, the priority of young female consumers in Taiwan when

purchasing bubble tea is mouthfeel and sensory appeal. This demographic trend justifies our selection of 20–50-year-old females as the primary study population and underscores the market potential for functional ingredients like I-fiber pearl, which maintains the desired texture while offering health benefits. For future studies, we suggest including male participants and older adults to enhance external validity.

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Conflicts of interest

The authors declare that no conflicts of interest exist.

References

[1] Safaei M, Sundararajan EA, Driss M, Boulila W, Shapi'i A. A systematic literature review on obesity: understanding the causes & consequences of obesity and reviewing various machine learning approaches used to predict obesity. Comput Biol Med 2021;136:104754.
[2] Sergi G, De Rui M, Stubbs B, Veronese N, Manzato E. Measurement of lean body mass using bioelectrical impedance analysis: a consideration of the pros and cons. Aging Clin Exp Res 2017;29:591–7.
[3] Fock KM, Khoo J. Diet and exercise in management of obesity and overweight. J Gastroenterol Hepatol 2013; 28(Suppl 4):59–63.
[4] Hwalla N, Jaafar Z. Dietary management of obesity: a review of the evidence. Diagnostics (Basel) 2020;11.
[5] Omer TAM. The causes of obesity: an in-depth review. Adv Obes Weight Manag Control 2020;10:90–4.
[6] Wharton S, Lau DCW, Vallis M, Sharma AM, Biertho L, Campbell-Scherer D, et al. Obesity in adults: a clinical practice guideline. CMAJ 2020;192:E875–91.
[7] Meldrum DR, Morris MA, Gambone JC. Obesity pandemic: causes, consequences, and solutions-but do we have the will? Fertil Steril 2017;107:833–9.
[8] Salmon AB. Beyond diabetes: does obesity-induced oxidative stress drive the aging process? Antioxidants (Basel) 2016;5.
[9] Taiwan HPA. In: Taiwan HPA, editor. Obesity is a chronic disease! improve diet and exercise life is the best prescription; 2018.
[10] Apovian CM, Aronne LJ, Bessesen DH, McDonnell ME, Murad MH, Pagotto U, et al. Pharmacological management of obesity: an endocrine society clinical practice guideline. J Clin Endocrinol Metab 2015;100:342–62.
[11] Patel D. Pharmacotherapy for the management of obesity. Metabolism 2015;64:1376–85.
[12] Pokushalov E, Ponomarenko A, Garcia C, Pak I, Shrainer E, Seryakova M, et al. The impact of glucomannan, inulin, and psyllium supplementation (Soloways (TM)) on weight loss in adults with FTO, LEP, LEPR, and MC4R polymorphisms: a randomized, double-blind, placebo-controlled trial. Nutrients 2024;16.
[13] Taiwan MoF. Sales at beverage stores are expected to reach new heights in 2014. In: Taiwan MoF; 2024.
[14] Qin YQ, Wang LY, Yang XY, Xu YJ, Fan G, Fan YG, et al. Inulin: properties and health benefits. Food Funct 2023;14: 2948–68.
[15] Shoaib M, Shehzad A, Omar M, Rakha A, Raza H, Sharif HR, et al. Inulin: properties, health benefits and food applications. Carbohydr Polym 2016;147:444–54.
[16] Wan X, Guo H, Liang Y, Zhou C, Liu Z, Li K, et al. The physiological functions and pharmaceutical applications of inulin: a review. Carbohydr Polym 2020;246:116589.
[17] Aliasgharzadeh A, Khalili M, Mirtaheri E, Pourghassem Gargari B, Tavakoli F, Abbasalizad Farhangi M, et al. A combination of prebiotic inulin and oligofructose improve some of cardiovascular disease risk factors in women with type 2 diabetes: a randomized controlled clinical trial. Adv Pharm Bull 2015;5:507–14.
[18] IPAQ. Guidelines for data processing and analysis of the international physical activity questionnaire (IPAQ) - short form. IPAQ; 2004.
[19] Després JP, Lemieux I, Tchernof A, Couillard C, Pascot A, Lemieux S. Fat distribution and metabolism. Diabetes Metab 2001;27:209–14 [In fre].
[20] Illouz YG. Study of subcutaneous fat. Aesthetic Plast Surg 1990;14:165–77.
[21] Nakajima H, Nakanishi N, Miyoshi T, Okamura T, Hashimoto Y, Senmaru T, et al. Inulin reduces visceral adipose tissue mass and improves glucose tolerance through altering gut metabolites. Nutr Metab (Lond) 2022;19:50.
[22] He Y, Wang B, Wen L, Wang F, Yu H, Chen D, et al. Effects of dietary fiber on human health. Food Science and Human Wellness 2022;11:1–10.
[23] Slavin JL. Dietary fiber and body weight. Nutrition 2005;21: 411–8.
[24] Harper ME, McPherson R, Dent R. Interindividual variability in weight loss in the treatment of obesity. Am J Clin Nutr 2021;114:824–5.
[25] Cizza G, Piaggi P, Rother KI, Csako G. Hawthorne effect with transient behavioral and biochemical changes in a randomized controlled sleep extension trial of chronically short-sleeping obese adults: implications for the design and interpretation of clinical studies. PLoS One 2014;9:e104176.
[26] Hartley L, May MD, Loveman E, Colquitt JL, Rees K. Dietary fibre for the primary prevention of cardiovascular disease. Cochrane Database Syst Rev 2016;2016:Cd011472.
[27] Closa-Monasterolo R, Gispert-Llaurado M, Luque V, Ferre N, Rubio-Torrents C, Zaragoza-Jordana M, et al. Safety and efficacy of inulin and oligofructose supplementation in infant formula: results from a randomized clinical trial. Clin Nutr 2013;32:918–27.
[28] De Giani A, Sandionigi A, Zampolli J, Michelotti A, Tursi F, Labra M, et al. Effects of inulin-based prebiotics alone or in combination with probiotics on human gut microbiota and markers of immune system: a randomized, double-blind, placebo-controlled study in healthy subjects. Microorganisms 2022;10.
[29] Golzarand M, Bahadoran Z, Mirmiran P, Azizi F. Inulin intake and the incidence of cardiometabolic diseases: a prospective cohort study. Food Funct 2022;13:10516–24.
[30] Becerril-Alarcón Y, Campos-Gómez S, Valdez-Andrade JJ, Campos-Gómez KA, Reyes-Barretero DY, Benítez-Arciniega AD, et al. Inulin supplementation reduces systolic blood pressure in women with breast cancer undergoing neoadjuvant chemotherapy. Cardiovasc Ther 2019;2019: 5707150.
[31] Guo J, Zhang M, Wang H, Li N, Lu Z, Li L, et al. Gut microbiota and short chain fatty acids partially mediate the beneficial effects of inulin on metabolic disorders in obese ob/ob mice. J Food Biochem 2022;46:e14063.
[32] Kellow NJ, Coughlan MT, Reid CM. Metabolic benefits of dietary prebiotics in human subjects: a systematic review of randomised controlled trials. Br J Nutr 2014;111:1147–61.
[33] Wang L, Yang H, Huang H, Zhang C, Zuo HX, Xu P, et al. Inulin-type fructans supplementation improves glycemic control for the prediabetes and type 2 diabetes populations:

results from a GRADE-assessed systematic review and dose-response meta-analysis of 33 randomized controlled trials. J Transl Med 2019;17:410.

[34] Coudray C, Bellanger J, Castiglia-Delavaud C, Rémésy C, Vermorel M, Rayssignuier Y. Effect of soluble or partly soluble dietary fibres supplementation on absorption and balance of calcium, magnesium, iron and zinc in healthy young men. Eur J Clin Nutr 1997;51:375–80.

[35] Cao JJ, Roemmich JN, Sheng X, Jahns L. Increasing vegetable intake decreases urinary acidity and bone resorption marker in overweight and obese adults: an 8-week randomized controlled trial. J Nutr 2021;151:3413–20.

[36] Smith AP, Sutherland D, Hewlett P. An investigation of the acute effects of oligofructose-enriched inulin on subjective wellbeing, mood and cognitive performance. Nutrients 2015;7:8887–96.