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Effects of oral intake of collagen peptides on lower back discomfort: a randomized, double-blind, placebo-controlled, parallel-group comparison study

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ABSTRACT

Background: Lower back pain is a widespread problem that limits daily activities and lowers quality of life for many people. Collagen peptides, which support joint and tissue health, may help relieve this kind of discomfort.

Objectives: This study aimed to evaluate the effects of collagen peptides intake on lower back discomfort in healthy middle-aged and older adults reporting subjective symptoms of lower back discomfort.

Methods: We conducted a randomized, double-blind, placebo-controlled, parallel-group comparative study. Following screening, 49 healthy Japanese individuals experiencing lower back discomfort were randomized to receive either 10 g of a collagen peptides-containing drink (collagen group; n = 24) or a placebo drink (placebo group; n = 25) once daily for 12 weeks. The Japan low back pain evaluation questionnaire (JLEQ) was administered at baseline and at the end of the intervention.

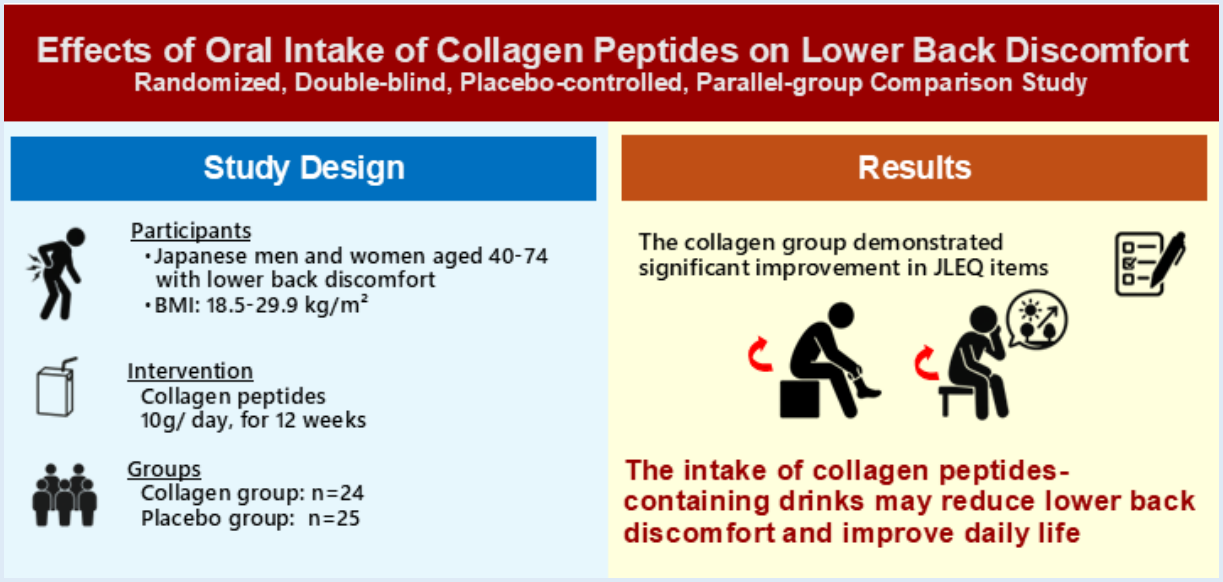
Results: Overall, 48 participants were included. The collagen group demonstrated significant improvement in JLEQ items, such as "How difficult has it been for you to put on underwear and stockings in the past few days because of your back pain?" and "During the past month, have you avoided going out to your neighborhood because of your back pain?".

Conclusions: Collagen peptides ingestion may alleviate lower back discomfort and improve daily functioning.

Novelty of the Study: This randomized controlled trial demonstrates that collagen peptides intake improves functional limitations associated with lower back discomfort in healthy individuals. The study indicates that utilizing collagen peptides can enhance quality of life by alleviating lower back discomfort.

Trial registration: The study protocol was registered with UMIN-CTR (ID: UMIN000055421).

Keywords: Collagen peptides, Bioactive peptides, Lower back discomfort, Musculoskeletal health, Functional food intervention, Randomized controlled trial, Biomarkers of pain, Quality of life



Graphical Abstract: Effects of oral intake of collagen peptides on lower back discomfort.

INTRODUCTION

Lower back discomfort, defined as 'pain, muscle tension or stiffness localized below the costal margin and above the inferior gluteal folds with or without leg pain' [1], is a common musculoskeletal complaint that affects individuals across age groups and sexes. The Global Burden of Disease Study 2021 (Global Burden of Diseases, Injuries, and Risk Factors Study) demonstrated that low back pain accounts for the greatest number of years lived with disability [2], affecting 619 million people worldwide in 2020, with a projected prevalence of 843 million by 2050 [3]. Higher prevalence rates of cases of low back pain have been identified in various countries [3]. According to the 2022 National Survey of Living Conditions conducted by the Ministry of Health, Labor, and Welfare, low back pain exhibits the highest

subjective symptoms among men and women. The etiology of low back pain involves multiple vertebral components, such as intervertebral discs, vertebral bodies, facet joints, ligaments, muscles, and fascia [4]. However, a specific source of nociception cannot be identified, and affected people are classified as having "non-specific" low back pain [5]. Additionally, factors associated with the etiology of low back pain include old age, female sex [6-7], smoking, obesity, and decreased levels of physical activity [8]. Importantly, low back pain restricts activities of daily life and reduces quality of life [9-10] by causing mental problems due to the pain-related stress [11-12]. Therefore, improving lower back function is essential for maintaining both physical and mental health.

For non-specific low back pain, interventions such as education and self-care, non-pharmacological therapies, pharmacotherapy, interventional procedures, and surgery are recommended [13]. In addition, there have been reports of low back pain improvement following ingestion of functional ingredients such as astaxanthin combined with piperine derived from long pepper [14], moringa seed extract [15], and L-serine with EPA [16].

Proteins constitute essential structural components of the human body and serve as indispensable nutrients for tissue formation. In recent years, the ingestion of specific bioactive peptides has been reported to confer various physiological and psychological benefits [17-18]. Collagen, which accounts for approximately one-third of total body protein, is a major component of the extracellular matrix in bones, joints, tendons, and ligaments. Collagen peptides are water-soluble because they are derived from collagen sources, such as pigs, fish, and cattle, through enzymatic hydrolysis, which reduces their molecular weight. Collagen peptides are widely used in the food industry. Regarding the usefulness of collagen peptides in humans, we have previously reported in clinical studies that they inhibit skin moisture evaporation [19], maintain skin elasticity [20], improve knee joint function [21], increase bone formation markers [22], and increase nail water and sphingosine [23]. Additionally, evidence from a comparison of the absorptivity of collagen using the hydroxyproline (Hyp) concentration in human plasma as an index indicates that collagen peptides are absorbed more quickly than gelatin [24]. Prolylhydroxyproline (Pro-Hyp) and glycylprolylhydroxyproline (Gly-Pro-Hyp) have been detected in circulation after oral ingestion of collagen peptides. These peptides migrate into the blood at concentrations that exhibit physiological functions, such as activation of fibroblasts [25–28]. We expect that collagen peptides may improve low-back discomfort, given that collagen peptides affect bone, joint, and muscle tissues [29]. In this study, we aimed to verify their effect on lower back discomfort by administering a collagen peptide-containing drink for 12 weeks to healthy middle-aged and older adult participants who experienced daily subjective symptoms of lower back discomfort.

MATERIALS AND METHODS

Clinical Trial Design: This study was conducted in accordance with the Declaration of Helsinki (October 2013 revision) and the Ethical Guidelines for Medical and Biological Research Involving Human Subjects. The protocol was approved by Shiba Palace Clinic Ethics Review Committee (IRB number: 16000008 on July 25, 2024). The study information was registered in a publicly accessible database (University Hospital Medical Information Network Clinical Trials Registry; UMIN000055421) before first participant enrollment date on September 6, 2024. All the participants were fully informed about the purpose, content, and methods of

the study, as well as their rights prior to participation; written informed consent was additionally obtained. Souken Co., Ltd. was responsible for participant recruitment, management, and study implementation. The study was performed from September to December 2024. No protocol changes were made after the approval of the Ethics Review Committee.

Participants: Participants who met the inclusion criteria but did not meet the exclusion criteria were selected.

Inclusion criteria: (1) Japanese males and females aged 40-74 years when providing informed consent, (2) Individuals with feelings of lower back pain on a daily basis and who are judged by an orthopedic surgeon as not requiring immediate treatment, (3) Individuals who have received enough explanation and understood about this study, and who can obtain informed consent, (4) Individuals who do not suffer from a specified disease and who do not receive medical treatment, medication, or treatment and judged appropriate for the study by the principal investigator, (5) Individuals with a BMI >= 18.5 and <=29.9.

Exclusion criteria: Individuals (1) using medical products, (2) who have a history of serious hepatopathy, kidney damage, heart disease, lung and blood disease, (3) who have a history of serious gastrointestinal disease, (4) who used or applied a drug for treatment of disease in the past 1 month, (5) who have joint pain due to rheumatism or gout, (6) who have undergone or need lower back surgery, (7) who have a history of lumbar fracture, acute low back pain, intervertebral disk herniation, or spinal stenosis, (8) who have received treatment of block injection in the lower back within 1 year, or will receive it during this test period, (9) whose BMI is < 18.5 or >= 30, (10) who have an irregular work pattern or perform physical labor, (11) who engage in strenuous exercise, (12) who regularly engage in activities that may affect the efficacy evaluation, (13) who are heavy alcohol drinkers, (14) who regularly use a cane, a supporter of the low back or a corset, (15) who regularly use drugs (including external medicine) or ingest health-promoting foods, foods for specified health uses, health foods, or supplements that have the function of improving joints and muscles in the past 3 months or will use or ingest them during the test period, (16) who had a habit of ingesting health-promoting foods, foods for specified health uses, health foods, or supplements containing ingredients of the test food in the past 3 months or will ingest them during the test period, (17) who participated in other clinical studies in the past 4 weeks, or will participate during this test period, (18) who are allergic to foods or medicines, (19) who are a smoker, (20) who are or are possibly pregnant, or are lactating, (21) who were hospitalized and received treatment in the past 6 months, (22) who will change life style during the test period, (23) who were judged inappropriate for this study by the principal investigator.

Test Samples: The test sample consisted of 125 mL of a drink containing 10 g of collagen peptides based on results from clinical trials on the knee joint function [21] and bone formation marker [22]. The amount of collagen peptides in the beverage was determined according to an analytical method validated by the Association of Official Analytical Chemists International [30]. The control sample comprised 125 mL of a drink without collagen peptides from the test sample. The nutritional compositions of the test samples are listed in Table 1. The test and control samples differed in protein, energy (caloric), and sodium contents due to differences in collagen peptide amounts. One bottle (125 mL) of the test or control sample was consumed once daily for 12 weeks. The independent allocation manager labeled each test sample and placebo sample separately to maintain blinding of participants and research staff in accordance

with a double-blind study manner. Taste, odor, appearance, color, and packaging were indistinguishable between test and control sample before and after the study.

Experimental Protocol: This was a randomized, double-blind, placebo-controlled, parallel-group trial. Overall,

Table 1. Sample nutritional composition.

	Placebo drink	Collagen drink
Energy (kcal)	32	72
Protein (g)	0	10
Lipid (g)	0	0
Carbohydrate (g)	8	8
Sodium (mg)	0–0.1	0–1
Collagen peptide (g)	0	10

100 participants were initially recruited, the Japanese low back pain evaluation questionnaire (JLEQ) was administered, and measurements of height and weight were conducted. Fifty-two participants were selected based on the criteria, the judgment of the doctors (orthopedist and study director), and the pain visual analog scale (VAS) score from JLEQ. At the second clinic visit, 49 participants underwent JLEQ (assessment at baseline), while three participants were absent on the second day. The target sample size was calculated based on the findings of Yamamoto et al. [21], who reported changes in JKOM IV scores after 12 weeks of intake as follows: −0.1 ± 1.1 and −1.3 ± 1.4 points in the placebo and test product groups, respectively. Assuming a significance level of 0.05 and 90% power, the required sample size was determined to be 26 participants per group (52 participants), considering potential dropouts and withdrawals.

The 49 participants were randomly allocated to two groups by stratification based on age, sex, BMI, pain VAS score, and total JLEQ score, ensuring that there were no differences between the groups at baseline. Allocation was concealed from the participants and investigators (double-blind). The allocation list was maintained as an electronic file, protected by a password, and managed by the allocation manager until completion of the statistical analysis. Each participant consumed one bottle per day of either the test sample (collagen group) or the control sample (placebo group) for 12 consecutive weeks, beginning on the second clinic visit date. All relevant information regarding physical condition and daily activities was prospectively recorded in the diaries of the participants. Participants were followed up by phone at the 6-week mark to ensure steady progress of the study. The JLEQ was performed on the day after the 12-week intake period completion as a post-intervention assessment.

Efficacy Evaluation: Efficacy was evaluated as the primary outcome using JLEQ, a disease-specific patient-oriented instrument. No secondary outcomes were set. The JLEQ is a quality of life assessment tool developed for patients with chronic low back pain, designed to reflect Japanese cultural factors while allowing for international comparisons [31]. First reported in 2007, it was jointly developed by the Japanese Orthopaedic Association, the Japanese Society of Motor Rehabilitation (currently the Japanese Society of Kinesiology), and the Japanese

Society of Clinical Orthopaedic Surgeons. The present study was conducted in Japanese participants and adopted the JLEQ. The JLEQ has been demonstrated to exhibit high validity and reliability and comprises four subscales (I–IV). Subscale I assesses the degree of low back pain using a 100-mm VAS, with the left end representing "no pain" and the right end representing "the most severe pain ever experienced." Subscales II ("Low Back Pain over Several Days"), III ("Problems in Daily Life Due to Low Back Pain over Several Days"), and IV ("Conditions over One Month") collectively include 30 items, each with five graded response options. Specifically, Subscale II comprises items 1–7, Subscale III comprises items 8–24, and Subscale IV comprises items 25–30. For each item, a score of 0 indicates the best functional condition and 4 indicates the worst functional condition, with intermediate responses scored 1–3. The total score, ranging from 0 to 120, is calculated as the sum of all item scores, with higher scores indicating greater impairment.

Statistical Analysis: Efficacy was evaluated by comparing the JLEQ subscale scores, total scores, and individual item scores at baseline and after 12 weeks of intervention. Baseline characteristics data of the participants are expressed as means ± standard deviation of the mean, and JLEQ scores are presented as means ± standard error of the mean. All statistical tests were two-sided, and a p-value < 0.05 was considered statistically significant. Between-group comparisons (collagen group vs. placebo group) were conducted using an independent-samples t-test for the VAS of the JLEQ and the Mann–Whitney U test for all other subscales and item scores. Within-group comparisons (pre- vs. post-intervention) were assessed using the Wilcoxon signed-rank test for all scores, except for the JLEQ VAS, for which a one-sample t-test was used. All statistical analyses were performed using IBM SPSS Statistics version 30. No adjustments for multiple comparisons were made as each item was considered a primary endpoint, and analyses were performed at specific time points.

Safety: Safety was evaluated by the study physician based on the diary-based questionnaires and telephone interviews conducted by the study sponsor at week 6 of the intervention. All adverse and unexpected events during the intake period were recorded as adverse events, and their relationship to the test product was assessed to determine causality. All randomized participants were included in the safety analysis.

RESULTS

Participant Selection and Analysis: Figure 1 displays the flow of participant selection, enrollment, and analysis. Overall, 49 participants were enrolled, and all initially commenced consumption of the assigned study drinks and completed the required schedules and assessments. Of these, one participant met the exclusion criterion and was excluded from the analysis owing to the excessive exercise, which had the potential to impact measurement outcomes. Consequently, 48 participants were included in the final analysis. The baseline characteristics of the participants are summarized in Table 2. There were no significant differences between groups regarding sex, age, height, weight, or BMI.

Analysis Results: The JLEQ scores, which served as the primary efficacy endpoints, are presented in Table 3. No significant difference was found between the collagen and control groups in subscale I ("Degree of low back discomfort"). Although the total scores for subscales II ("Low back discomfort for several days"), III ("Problems in daily life due to low back discomfort for several days"), IV ("Condition for 1 month"), and the combined JLEQ II–IV tended to improve in the collagen group compared to those in the placebo group, these changes were not significantly different between groups.

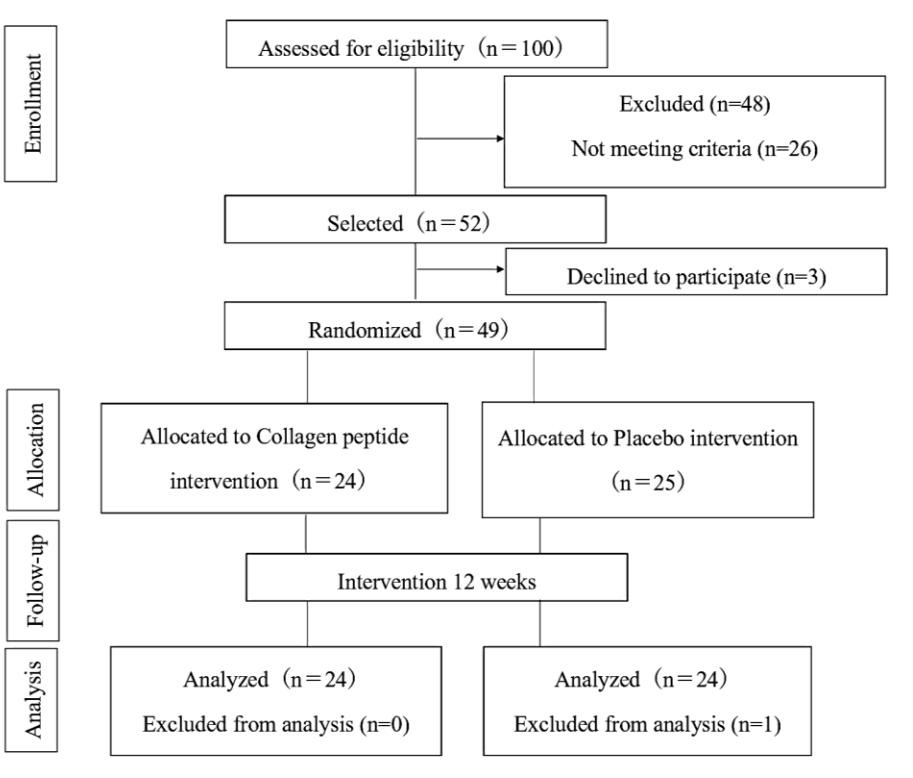


Figure 1. Flowchart of the study.

The individual item scores for each subscale are provided in Table 3. For the item "How difficult has it been for you to put on underwear and stockings in the past few days because of your back pain?" (Question 14), the collagen group demonstrated a significantly improved score compared to the placebo group ($P < 0.05$). Furthermore, the collagen group exhibited a significantly lower score on Question 25, "During the past month, have you avoided going out to your neighborhood because of your back pain?", than the placebo group ($P < 0.05$).

Safety: Safety was monitored for all 49 participants throughout the intervention period using diary-based questionnaires. Moreover, the physical condition of the participants was assessed through telephone interviews conducted by the study sponsor at week 6 of the intervention. No adverse events attributable to the test foods were observed. Additionally, no participants reported any adverse events during the study.

Table 2. Participant baseline characteristics

	Placebo group Mean ± SD (n = 24)	Collagen group Mean ± SD (n = 24)	P-Value
Male / Female	12 / 12	12 / 12	
Age (year)	55.3 ± 1.9	55.8 ± 1.5	0.849
Height (cm)	164.4 ± 1.6	163.8 ± 2.0	0.810
Weight (kg)	60.2 ± 2.3	61.3 ± 2.4	0.755
BMI	22.1 ± 0.6	22.7 ± 0.5	0.513

Values are expressed as means ± standard deviation. P-value was calculated using an independent samples t-test between groups. BMI, body mass index; SD, standard deviation.

Table 3. The JLEQ scores of participants.

		Pre-intervention	Between-group P value	Post-intervention	Within-group P value	Between-group P value
JLEQ I (mm)	Placebo	50.5 ± 3.9	0.74	32.5 ± 4.4	<0.001	0.86
	Collagen	52.3 ± 3.6		31.5 ± 3.6	<0.001	
JLEQ total score	Placebo	27.6 ± 3.5	0.66	17.1 ± 2.4	<0.001	0.24
	Collagen	26.5 ± 3.4		12.9 ± 1.8	<0.001	
JLEQ II score	Placebo	7.8 ± 0.8	0.88	5.3 ± 0.6	0.002	0.37
	Collagen	8.0 ± 0.8		4.7 ± 0.7	0.002	
JLEQ III score	Placebo	15.9 ± 2.2	0.58	9.3 ± 1.5	<0.001	0.19
	Collagen	14.5 ± 2.0		6.5 ± 1.0	<0.001	
JLEQ IV score	Placebo	3.9 ± 0.8	0.72	2.5 ± 0.5	0.017	0.41
	Collagen	4.0 ± 0.7		1.8 ± 0.3	0.002	
1	Placebo	2.0 ± 0.2	0.96	1.6 ± 0.1	0.007	0.59
	Collagen	2.0 ± 0.2		1.7 ± 0.1	0.073	
2	Placebo	2.3 ± 0.2	0.96	2.3 ± 0.2	0.004	0.73
	Collagen	2.3 ± 0.2		2.3 ± 0.2	0.018	
3	Placebo	2.0 ± 0.1	0.61	1.7 ± 0.1	0.071	0.67
	Collagen	2.2 ± 0.2		1.6 ± 0.1	0.015	
4	Placebo	2.3 ± 0.2	0.85	2.0 ± 0.1	0.07	0.16
	Collagen	2.2 ± 0.1		1.7 ± 0.0	0.008	
5	Placebo	1.8 ± 0.1	0.51	1.6 ± 0.1	0.206	0.37
	Collagen	2.0 ± 0.2		1.5 ± 0.1	0.04	
6	Placebo	2.2 ± 0.2	0.79	1.8 ± 0.1	0.012	0.26
	Collagen	2.1 ± 0.1		1.5 ± 0.1	0.002	
7	Placebo	2.3 ± 0.2	0.91	1.9 ± 0.1	0.09	0.56
	Collagen	2.3 ± 0.2		1.9 ± 0.2	0.122	
8	Placebo	2.7 ± 0.2	0.52	2.2 ± 0.2	0.02	0.39
	Collagen	2.8 ± 0.2		2.0 ± 0.1	0.002	
9	Placebo	1.8 ± 0.1	0.33	1.3 ± 0.2	0.002	0.94
	Collagen	1.7 ± 0.2		1.2 ± 0.1	0.013	
10	Placebo	2.0 ± 0.2	0.73	1.5 ± 0.1	0.001	0.15
	Collagen	2.0 ± 0.1		1.3 ± 0.1	0.002	
11	Placebo	1.7 ± 0.1	0.84	1.3 ± 0.1	0.008	1.00
	Collagen	1.7 ± 0.1		1.3 ± 0.1	0.032	
12	Placebo	1.7 ± 0.2	0.95	1.3 ± 0.1	0.033	0.15
	Collagen	1.4 ± 0.1		1.1 ± 0.1	0.005	
13	Placebo	1.9 ± 0.2	0.40	1.3 ± 0.1	0.005	0.93

		Pre-intervention	Between-group P value	Post-intervention	Within-group P value	Between-group P value
	Collagen	1.7 ± 0.1		1.3 ± 0.1	0.029	
14	Placebo	1.9 ± 0.2	0.97	1.8 ± 0.2	0.248	***0.041***
	Collagen	1.9 ± 0.2		1.3 ± 0.1	0.018	
15	Placebo	1.8 ± 0.2	0.95	1.4 ± 0.1	0.021	0.48
	Collagen	1.8 ± 0.2		1.3 ± 0.1	0.005	
16	Placebo	2.1 ± 0.2	0.99	1.8 ± 0.2	0.029	0.16
	Collagen	2.1 ± 0.2		1.5 ± 0.1	0.001	
17	Placebo	2.1 ± 0.2	0.70	1.7 ± 0.2	0.025	0.46
	Collagen	2.0 ± 0.2		1.5 ± 0.1	0.027	
18	Placebo	1.6 ± 0.1	0.36	1.4 ± 0.1	0.059	0.55
	Collagen	1.5 ± 0.1		1.3 ± 0.1	0.102	
19	Placebo	1.8 ± 0.1	0.80	1.5 ± 0.1	0.058	0.25
	Collagen	1.7 ± 0.1		1.3 ± 0.1	0.013	
20	Placebo	2.4 ± 0.1	0.61	2.1 ± 0.2	0.02	0.27
	Collagen	2.3 ± 0.1		1.8 ± 0.1	0.008	
21	Placebo	2.4 ± 0.2	0.45	1.8 ± 0.2	0.008	0.52
	Collagen	2.1 ± 0.2		1.6 ± 0.1	0.036	
22	Placebo	2.0 ± 0.2	0.37	1.5 ± 0.1	0.007	0.21
	Collagen	1.7 ± 0.2		1.3 ± 0.1	0.029	
23	Placebo	1.8 ± 0.2	0.81	1.3 ± 0.1	0.021	0.58
	Collagen	1.7 ± 0.2		1.1 ± 0.1	0.01	
24	Placebo	1.5 ± 0.2	0.91	1.3 ± 0.1	0.066	0.27
	Collagen	1.5 ± 0.1		1.1 ± 0.1	0.035	
25	Placebo	1.5 ± 0.2	0.43	1.2 ± 0.1	0.038	***0.039***
	Collagen	1.4 ± 0.2		1.0 ± 0.0	***0.041***	
26	Placebo	1.6 ± 0.2	0.49	1.4 ± 0.1	0.096	0.17
	Collagen	1.5 ± 0.1		1.2 ± 0.1	0.068	
27	Placebo	1.2 ± 0.1	0.95	1.1 ± 0.1	0.317	0.64
	Collagen	1.2 ± 0.1		1.1 ± 0.1	0.317	
28	Placebo	1.8 ± 0.2	0.28	1.6 ± 0.1	0.334	0.59
	Collagen	2.0 ± 0.2		1.5 ± 0.1	0.02	
29	Placebo	1.8 ± 0.2	0.77	1.6 ± 0.1	0.083	0.59
	Collagen	1.9 ± 0.2		1.5 ± 0.1	0.013	
30	Placebo	2.1 ± 0.2	0.66	1.7 ± 0.1	0.021	0.31
	Collagen	2.1 ± 0.1		1.5 ± 0.1	0.004	

Values are expressed as the means ± standard error of the mean. Between-group P-values were obtained using the dependent-samples t-test (JLEQ I: VAS) and the Mann–Whitney U test (JLEQ scores). Within-group P-values (pre- vs. post-intervention) were assessed using the one-sample t-test (JLEQ: VAS) and the Wilcoxon signed-rank test (JLEQ scores). A P-value < 0.05 was considered significant.

DISCUSSION

This randomized, double-blind, placebo-controlled, parallel-group study investigated whether consuming a drink containing 10 g of collagen peptides daily for 12 weeks affected lower back discomfort in healthy middle-aged and older adults who routinely experienced such symptoms. Our analysis identified significant improvement in the collagen group compared with the placebo group in two specific questions from the JLEQ assessed at week 12: Question 14 ("How difficult has it been for you to put on underwear and stockings in the past few days because of your back pain?") and Question 25 ("During the past month, have you avoided going out to your neighborhood because of your back pain?"). Furthermore, tendencies toward improvement were observed for the total JLEQ II, III, and IV scores and their combined score (JLEQ II–IV) in the collagen group, although the group differences were not statistically significant. Therefore, continuous intake of 10 g of collagen peptides may help alleviate lower back discomfort and related issues.

Regarding Question 14, the act of putting on or removing socks and stockings involves a wide range of lumbar flexion and coordinated movements of multiple joints, including the trunk and lower limbs. Previous research has highlighted a close association between everyday tasks and lumbar region flexibility [32]. Therefore, the improvement noted in this item suggests that consuming 10 g of collagen peptides may positively affect lumbar mobility, potentially facilitating routine functional movements. Moreover, this everyday task is related to the range of motion. Importantly, collagen intake has been shown to improve the shoulder range of motion in athletes and healthy individuals [33-34]. The duration of musculoskeletal discomfort is inversely proportional to the range of motion, suggesting that improved range of motion may alleviate low back pain during sock-related activities [35].

Furthermore, it has been established that escalation of lower back discomfort can limit daily functioning, such as walking and sitting, and deter individuals from engaging in activities outside the home. In turn, reduced physical activity may decrease muscle strength and place an additional burden on the lumbar region. The improvement observed in Question 25 suggests that supplementation with collagen peptides may support greater independence and outdoor activity among individuals with back discomfort, thereby enhancing quality of life and potentially extending a healthy lifespan.

Although statistically significant benefits were apparent for the two questionnaire items, some participants exhibited fluctuating symptoms of lower back discomfort. Accordingly, a post hoc analysis was performed on a subset of 43 participants whose combined changes in JLEQ I and II–IV total scores between recruiting and baseline exceeded one standard deviation of the entire sample. Covariate-adjusted analysis, using baseline JLEQ II–IV total scores as covariates, revealed a statistically significant improvement in JLEQ II scores following the intervention ($P=0.036$) and a trend toward significance in the combined JLEQ II–IV score ($P=0.054$). Considering the heterogeneous and sometimes intermittent nature of lower back discomfort, selecting participants with more persistent symptoms may allow for a more accurate evaluation of intervention effects in future trials.

The mechanisms by which collagen peptides alleviate lower back discomfort likely involve multifaceted effects on health of muscle, connective tissue, bone, and joint. Age-related degenerative changes in these tissues contribute to lower back discomfort. Loss of muscle mass in the core musculature (back and abdominal muscles) compromises postural support and increases the mechanical load on the lumbar spine, predisposing individuals to lower back symptoms.

Evidence indicates that individuals with lower back discomfort frequently exhibit diminished trunk muscle strength compared with healthy controls [36-37]. Collagen peptides are rich sources of proline and glycine, key amino acids necessary for muscle repair and regeneration. Recent interventions combining collagen peptide supplementation with resistance training have demonstrated improvements in muscle strength and body composition in older adult men with sarcopenia [38]. Furthermore, reports suggest that concurrent ingestion of collagen peptides with physical activity is associated with reduced lower back discomfort [39]. Collectively, these findings imply that the observed benefits on low back symptoms may be at least partly derived from the positive effects of collagen peptides on muscle metabolism and function.

Collagen is the principal structural protein of connective tissues such as skin, cartilage, bone, tendons, and ligaments, and its endogenous synthesis declines with age. Connective tissue alterations have been implicated in the development of chronic low back pain. Thickness and echogenicity of the connective tissue surrounding the lumbar musculature have been reported to be approximately 25% greater in patients with chronic low back pain, and abnormal connective tissue structures in the lumbar region have been documented [40]. Reduced elasticity of the lumbar fascia has also been observed in individuals with low back pain, and this loss of elasticity is strongly associated with pain severity [41]. Collagen is rich in amino acids essential for connective tissue collagen synthesis, including glycine and proline, and is thought to stimulate the metabolism of connective tissue cells, such as fibroblasts and chondrocytes, to increase endogenous collagen production [42-45]. Through promoting recovery of connective tissues, collagen may therefore contribute to the structural support of diverse bodily tissues.

Lumbar joint degeneration is another risk factor for lower back discomfort, as it may promote direct bony contact and nerve compression due to structural alterations. Animal studies have demonstrated that orally consumed collagen peptides are digested, absorbed, and subsequently incorporated into synovial cells and chondrocytes in articular tissue [46]. Additionally, collagen peptides have been implicated in modulating the gene expression relevant to chondrocyte maturation and promoting the synthesis of glycosaminoglycans, the primary components of the cartilage extracellular matrix, thereby supporting joint integrity [47]. Notably, human trials have reported beneficial effects on bone and joint health, including knee joint symptom improvement [21-22].

Further, evidence suggests collagen peptides play a role in modulating inflammatory responses. Collagen peptides have been shown to suppress the secretion of inflammatory cytokines and reduce oxidative stress [48-50], and in individuals with knee discomfort have been associated with reductions in C-reactive protein (CRP) [51] and in considered markers of synovial inflammation, such as interleukin-17A and hyaluronic acid [52].

Overall, collagen peptide intake may exert a broad spectrum of effects on musculoskeletal tissues, ultimately contributing to the relief of lower back discomfort.

This study had several limitations. The most significant limitation was that outcomes were assessed solely with the JLEQ, resulting in a lack of multidimensional evaluation. Improvement in lower back discomfort may be associated with increased lumbar range of motion and consequent gains in physical function and quality of life, but these endpoints were not assessed. We also did not measure inflammatory biomarkers reported to be related to low back pain, such as C-reactive protein (CRP), interleukin-1 (IL-1/IL-1β), interleukin-6 (IL-6), and tumor necrosis factor-α (TNF-α)

[53-54], therefore could not directly confirm a reduction in inflammation. Because the trial enrolled healthy participants, it remains to be determined whether lumbar range of motion and inflammatory biomarkers would improve in this population. Moreover, as mentioned before, pain perception changes may vary depending on the selection of participants because lower back discomfort is not uniform. Although various considerations are required in functional food science [55], dose-response effects of collagen peptides were not examined. In the present trial, daily intake of 10 g of collagen peptides for 12 weeks produced significant improvements in two subscale items; however, further research is needed to determine whether collagen peptides supplementation has a broader effect on lower back discomfort.

CONCLUSIONS

The intake of collagen peptides-containing drinks may reduce lower back discomfort and improve daily life restricted by discomfort in healthy middle-aged and older adults who regularly experience subjective symptoms, such as lower back discomfort.

Abbreviations: BMI: Body Mass Index, CRP: C-reactive protein, EPA: Eicosapentaenoic acid, Gly-Pro-Hyp: glycylprolylhydroxyproline, Hyp: hydroxyproline, IL: interleukin, JKOM: Japanese Knee Osteoarthritis Measure, JLEQ: Japan low back pain evaluation questionnaire, Pro-Hyp: prolylhydroxyproline, TNF-α: tumor necrosis factor-α, UMIN: University Hospital Medical Information Network Clinical Trials Registry, VAS: Visual Analogue Scale

Competing Interests: E.S., T.Y., M.I., R.T., H.M-U., E.N., and N.I. are employees of Morinaga & Co., Ltd. The funder had no role in the design, execution, interpretation, or writing of the study.

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