Oligonol® Increases the Distance Covered in the 12-Minute Run Test in Long-Distance Runners: A Randomized, Double-Blind, Placebo-Controlled, Parallel Trial

Original Research

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Abstract

Introduction: Oligonol® which is a standardized oligomerized-polyphenol from *Litchi chinensis* fruit extract (OPLFE), has been reported to have multiple beneficial effects on exercise performance. This study evaluated the effects of OPLFE on endurance performance in long-distance runners.

Methods: A randomized, double-blind, placebo-controlled, parallel trial was conducted in which 34 long-distance runners (male and female adults aged 45–64) were assigned to receive 200 mg/day of OPLFE or placebo as the intervention for 60 days. The 12-minute run tests were conducted at the initial and final visits to evaluate the primary outcome (running distance), and secondary outcomes included heart rate, rating of perceived exertion (RPE) score, and body composition. Statistical significance was set at $*P < 0.05$.

Results: The primary outcome of running distance in the 12-minute run test was significantly increased in the OPLFE group compared to the placebo group (OPLFE: 2.97 ± 0.36 km vs. placebo: 2.95 ± 0.36 km, $P = 0.038$), based on an analysis of covariance with baseline value as the covariate and group as the factor. The secondary outcome of RPE score also showed a significant decrease in the OPLFE group compared to the placebo group (OPLFE: 14.5 ± 2.0 vs. placebo: 16.4 ± 2.0, $P = 0.003$). No differences were observed in the other secondary outcomes.

Conclusions: OPLFE intake increased the distance covered in the 12-minute run test and reduced RPE. These findings suggest that OPLFE may improve endurance performance in middle-aged male and female adults.

Key Words: endurance performance; lychee fruit polyphenol; running distance

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Introduction

In recent years, the supplement market has been growing rapidly worldwide [1]. As supplements have become more popular, their uses have also diversified. They are intended to improve overall well-being, support physiological functions, and help fill nutritional gaps, ultimately contributing to better health and disease prevention. The sports industry is also increasingly focusing on the functional benefits of supplements, and their usage is on the rise [2]. In Japan, it has been reported that more than 80% of Olympic athletes use supplements during both the summer and winter seasons [3]. Furthermore, a survey of track and field athletes revealed that the primary purposes for supplement use were recovery (71%), improving health (52%), enhancing performance (46%), and treating an injury (40%) [4].

Therefore, the use of supplements has become an essential component for athletes in maintaining intense training regimens and achieving optimal performance.

Polyphenols are antioxidants synthesized by plants to protect themselves from ultraviolet (UV) radiation and other environmental stresses. These also provide antioxidant benefits to humans and animals through the regular consumption of polyphenol-rich foods such as fruits and vegetables [5]. Since oxidative stress and subsequent inflammation caused by exercise or sports are primary contributors to fatigue and pain, as well as obstacles to achieving peak exercise performance, polyphenols in various foods have become the subject of extensive research [6]. Previous studies on polyphenol-rich fruits and exercise have reported that cocoa improves physical fitness in professional soccer players [7], that berry fruits aid in recovery and protect against oxidative stress-induced damage [8], and that tart cherry reduces biomarkers of muscle and cardiac damage caused by exercise-induced oxidative stress [9]. Furthermore, studies focusing on specific polyphenol types have found that quercetin [10] and anthocyanins abundant in haskap [11] enhance running performance. As such, the antioxidant properties of polyphenols in plants clearly have beneficial effects in the field of exercise and sports.

Although polyphenols are known for their antioxidant properties, most naturally occurring polyphenols found in fruits and vegetables have a high molecular weight and are poorly absorbed upon ingestion [12]. Oligonol® (Amino Up Co., Ltd., Sapporo, Japan) is a standardized oligomerized-polyphenol from *Litchi chinensis* fruit extract (OPLFE) is a functional food containing high concentrations of low-molecular-weight polyphenols. It consists of more than 70% total polyphenols, including over 20% flavanol monomers and dimers. Compared to common fruit-derived polyphenols, OPLFE contains much higher amounts of low-molecular-weight polyphenols, which have been shown to be efficiently absorbed by the body [13] and to act as antioxidants within an organism [14,15].

Previous studies have shown that OPLFE reduces exercise-induced inflammation, enhances recovery, and increases endurance performance. Nishizawa et al. [16] reported that intake of OPLFE at 100 mg/day for two months reduced exercise-induced IL-6 and increased TGF-β. In addition, Kang et al. [17] observed an increase in anaerobic threshold (AT) in young men following intake of OPLFE at 200 mg/day for 30 days. In this study, male and female adults aged 45–64 participated, and we hypothesized that taking 200 mg of OPLFE daily for 60 days would increase the running distance in the 12-minute run test. As running distance was designated as the primary outcome, participants were allowed to freely increase their speed but were not allowed to decrease their speed during the test, this was intended to ensure that the distance covered reflected their maximal capacity. This approach was intended to reduce variability attributable to pacing strategy while capturing endurance capacity in a controlled setting.

Methods

Study design

This study was designed as a randomized, double-blind, placebo-controlled, parallel trial. To address potential adverse events, a response desk was established, and health status interviews were conducted at each visit. The study protocol was approved by the TACTICS Ethics Committee (Approval No. 2020-150, June 9, 2020) and was conducted in accordance with the Ethical Guidelines for Medical Research Involving Human Subjects (Notification No. 3, 2014, Ministry of Education, Culture, Sports, Science and Technology and Ministry of Health, Labor and Welfare) and the Declaration of Helsinki.

Participants

Participants were recruited from amateur running clubs in Sapporo between June 9 and July 21, 2020, through the clubs' online communities. All applicants received a written explanation of the study protocol and provided informed consent prior to participation. Participants attended one to two club training sessions per week, and even those with lower monthly mileage ran at least 100 km per month, while higher-mileage runners covered up to approximately 250 km per month, and they were also accustomed to treadmill use as they use regularly. To minimize confounding by training effects, participants were instructed to maintain their usual training throughout the intervention and not to modify training volume. Weekly training volume during the ~60-day intervention was not systematically logged. Dietary intake, including energy, carbohydrate, and antioxidant consumption, was not monitored or controlled during the intervention.

Eligibility criteria for inclusion in this study required participants to meet several conditions. Participants were males or females aged 45 to 64 years at the time of the initial visit. All individuals were assessed by the study administrator and determined to be in good general health and engaged in generally healthy lifestyle practices. Participants were also

required to be available to attend both days of the designated two-day evaluation, including the initial and final visits. Additionally, participants needed to be willing and able to discontinue the use of polyphenol supplements during the study period and for at least two weeks prior to the initial visit. A total of 34 participants, including 21 males and 13 females, were successfully enrolled in the study.

Intervention

Table 1 presents the details of the test foods used in the intervention of this study. Participants took OPLFE capsules containing OPLFE, a low molecular weight polyphenol derived from lychee fruit, and PINEDEX® #1 dextrin (Matsutani Chemical Industry Co., Ltd., Japan) as an excipient, or placebo capsule containing only dextrin. OPLFE and placebo were filled into hard capsules (opaque, No. 1 dark caramel: Capsugel Inc., Japan) at Amino Up Co., Ltd. OPLFE and placebo were provided to participants with neither the capsules nor the outer packaging being distinguishable. During the 60-day intervention period, participants took one capsule of OPLFE (100 mg/capsule) or placebo after each meal, morning and evening (two capsules/day), and on the final day, they took two capsules after breakfast.

Table 1. Compositions for the test foods per capsule

Ingredients	Unit	OPLFE capsule	Placebo capsule
OPLFE	mg	100	-
Calcium stearate	mg	5	-
Dextrin	mg	195	300

Outcome and Schedule

Figure 1 presents an overview of the study, and Figure 2 presents the details of the evaluation for each visit date. Participants were scheduled for a total of two visits. At the initial visit (Day 0), the following assessments were conducted in sequence: body composition, levels of advanced glycation end products (AGEs), and estimated hemoglobin (Hb) levels in peripheral blood, followed by a 12-minute run test and the RPE score. At the final visit (Day 60), the same procedure as at the initial visit was conducted for the evaluation. Two 12-minute run tests were conducted on July 26, 2020, and September 27, 2020. This study did not involve the drawing of blood samples.

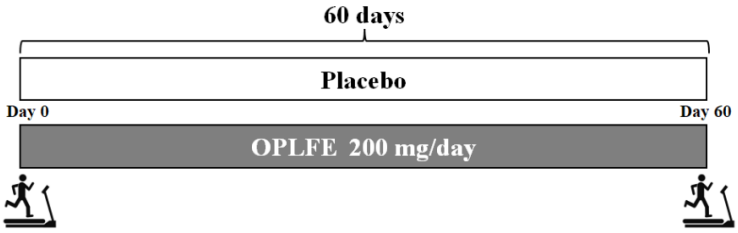

Figure 1. Study design and timeline. Participants were randomly assigned to either the OPLFE group or the placebo group and took the assigned capsules for 60 days. Assessments were conducted at two visits: the initial visit (Day 0) and the final visit (Day 60), including the 12-minute run test at both time points.

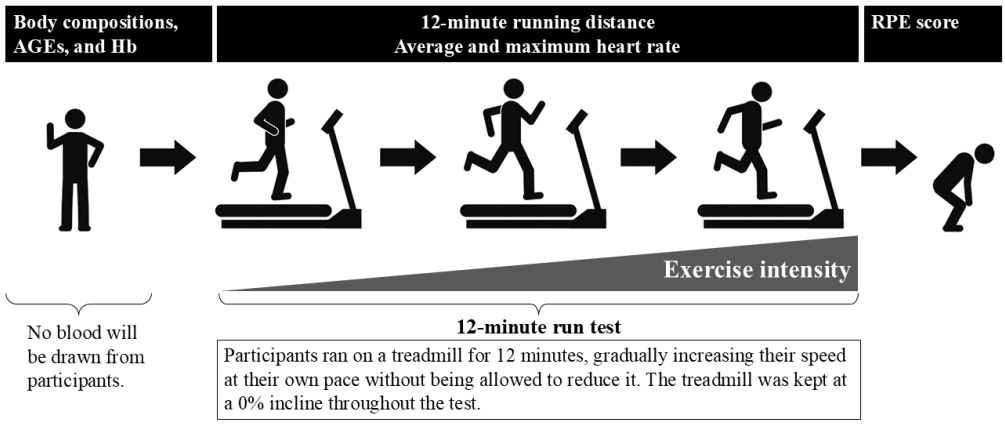

Figure 2. Detailed flow of assessment day. The figure shows the sequence of assessments conducted at each visit. The assessment day began with measurements of body composition, followed by the evaluation of AGEs and estimated Hb levels. After these assessments, a 12-minute run test was performed on a treadmill, and the RPE score was evaluated immediately upon completion.

Primary Outcome

Participants' endurance performance was assessed by conducting a 12-minute run test, with the running distance as the primary outcome. The test was performed on a treadmill (Johnson Health Tech Japan, Tokyo: MATRIX treadmill RR-JHJ-2-TIX100v) with a fixed 0-degree incline. Participants did not undergo a familiarization trial, did not receive standardized pacing instructions, and were allowed to increase their speed at any time during the 12-minute run test according to their running style and pace, but they were not allowed to decrease their speed. Consistent with evidence that more even pacing benefits prolonged efforts, we implemented this principle on the treadmill by permitting speed increases while prohibiting speed decreases. We set these prespecified conditions not to allow participants to decrease their speed and to maintain a sustainable optimal pace through to the finish so that participants' best possible performance could be evaluated [18].

Secondary Outcomes

At the beginning of both the initial and final visit days, body composition parameters, including body weight, body water content, muscle mass, body fat percentage, and body mass index (BMI), were measured using the InnerScan DUAL RD-800/RD-E04 (Tanita Corporation, Japan). AGEs were non-invasively measured from the left middle finger using the RQ-AG01J sensor (Sharp Corporation, Japan). Blood Hb concentration was estimated using the ASTRIM FIT device (Sysmex Corporation, Japan). During the 12-minute run test, average and maximum heart rates were recorded using both the Garmin HRM4-Run™ and the Garmin ForeAthlete 945 (Garmin Japan K.K., Japan), which were fitted to participants prior to the test. The RPE score was assessed immediately after the run using the Borg scale [19].

Sample Size

The primary outcome of this study was the running distance in the 12-minute run test, which reflects endurance performance and has been shown to be associated with AT [17]. Regarding the relationship between OPLFE and endurance performance, Kang et al. reported that OPLFE intake significantly increased AT, an indicator of endurance performance, with an effect size (Cohen's *d*) of 0.895 [17]. Based on this effect size, we calculated the required sample size using a significance level of one-sided $\alpha = 0.05$ and a statistical power of 80%. Since a decrease in endurance performance due to OPLFE intake was not anticipated, a one-sided test was applied. As a result, the required sample size was estimated to be 17 participants per group.

Randomization and Allocation

Participants were stratified and randomly assigned to two groups (1:1 ratio) based on gender and half marathon time, with identification numbers listed by the person responsible for allocation. Randomization was performed using a pre-generated random number table. The two groups were assigned to the OPLFE group (n=17) and the placebo group (n=17) by the person responsible for group assignment. Test foods were provided to participants at the initial visit by the study investigator, according to the list of identification numbers. The study investigators, the person responsible for group assignment, and the participants were blinded to the contents of the test foods until analysis was completed.

Statistical Analysis

All confirmatory hypothesis tests were two-sided ($\alpha = 0.05$), and one-sided *P* values are presented in Table 3 only as sensitivity outputs corresponding to the a priori power calculation. Data are presented as mean ± standard deviation (mean ± SD), and differences in least-squares means are reported as between-group differences (Δ). Analysis of between-group comparisons (OPLFE group vs. placebo group) for the initial visit used Mann–Whitney's U test, for the final visit used Analysis of covariance (ANCOVA) with values at the initial visit as covariates and group as factors. Statistical significance levels were defined as $*P < 0.05$. All statistical analyses were performed with EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). More precisely, it is a modified version of R Commander designed to add statistical functions frequently used in biostatistics [20]. Primary analyses used a per-protocol set (PPS). In addition to the PPS primary analyses, a sensitivity analysis using the intention-to-treat (ITT) population was performed with a linear mixed-effects model including group, visit, and their interaction as fixed effects and participant as a random effect (REML; two-sided $\alpha = 0.05$).

Results

Participant Flow

The participation flow of the study is presented in Figure 3. One female participant in the OPLFE group withdrew consent after the initial visit and was excluded from all subsequent analyses. One male participant in the OPLFE group discontinued the evaluation during the 12-minute run test at the final visit, resulting in missing data for the primary outcome and the secondary outcomes of heart rate and RPE score. Consequently, 32 participants were included in the analysis: 17 in the placebo group (11 males and 6 females) and 15 in the OPLFE group (9 males and 6 females). Table 2 provides the participant backgrounds. For the analysis, Table 3 and Table 4 present the results for running distance, RPE score, and heart rate, and for body compositions, AGEs, and Hb.

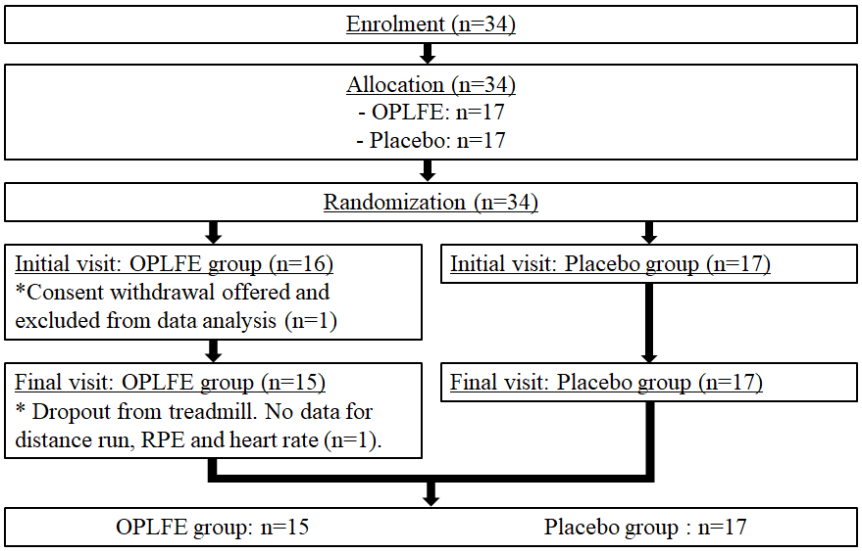

Figure 3. Flow diagram of the progress through the phases of a parallel randomized trial of two groups.

Table 2. Backgrounds for the participants

Items		OPLFE (n=15)	Placebo (n=17)
Gender	**Male**	n=9 (60.0%)	n=11 (64.7%)
	Female	n=6 (40.0%)	n=6 (35.2%)
Age		50.7 ± 4.7	52.3 ± 4.5
Height (cm)		166.4 ± 7.5	168.2 ± 10.5
Weight (kg)		58.3 ± 7.8	59.9 ± 10.2
BMI		20.8 ± 1.6	21.0 ± 1.7

Table 3. Mean values of running distance, RPE score, and heart rates.

		OPLFE (n=15)	Placebo (n=17)			Group comparison			
		Mean ± SD	Mean ± SD	Δ	SE	95% CI-	95% CI+	*P* value (two-tailed)	Effect size
Running distance (km)	**initial**	2.86 ± 0.36	2.91 ± 0.35					0.940	
	final	2.97 ± 0.36	2.95 ± 0.36	0.07	0.03	0.0	0.1	0.038*	0.77
RPE score	**initial**	15.5 ± 1.9	15.2 ± 2.0					0.576	
	final	14.5 ± 2.0	16.4 ± 2.0	-2.0	0.6	-0.8	-0.2	0.003**	-1.15
Average heart rate (bpm)	**initial**	149.3 ± 19.3	148.8 ± 14.6					0.584	
	final	158.0 ± 8.4	156.5 ± 10.9	1.4	3.0	-4.8	7.6	0.652	0.16
Max heart rate (bpm)	**initial**	171.7 ± 16.9	171.3 ± 15.0					0.925	
	final	174.5 ± 8.9	177.1 ± 10.4	-2.7	3.0	-0.5	-0.1	0.372	-0.32

Data for each group were expressed as the arithmetic mean ± standard deviation. In between-group comparisons, Δ is the group difference in the least-squares mean for the data at final visit. Analysis of between-group comparisons for initial visit used Mann-Whitney's U test, for final visit used ANCOVA with baseline as covariate and group as factor. Effect size was calculated as Cohen's d. All *P* values are two-tailed. One-sided *P* values are also shown only as sensitivity outputs corresponding to the a priori sample size calculation.

Primary Outcome

The running distance in the 12-minute run test of 32 participants (OPLFE group: 15 and placebo group: 17) showed a significant between-group difference at the final visit based on ANCOVA adjusting for baseline. Baseline-adjusted least squares means (LS means) were 2.99 ± 0.02 km for the OPLFE group and 2.92 ± 0.02 km for the placebo group, corresponding to an adjusted between-group difference of +0.07 km (P = 0.038). Two-sided 95% confidence intervals, Cohen's *d*, and fully adjusted estimates are reported in Table 3. At the final visit, baseline-adjusted least-squares means (LS means) were 2.92 ± 0.02 km (placebo group) and 2.99 ± 0.02 km (OPLFE group), corresponding to an adjusted between-group difference of +0.07 km (*P* = 0.038). The sensitivity analysis using the ITT population was supportive of the result, yielding a similar between-group difference (0.07 km; *P* = 0.0345).

Table 4. Mean measured values of body composition, AGEs, and Hb levels.

		OPLFE (n=15) Mean ± SD	Placebo (n=17) Mean ± SD	Group comparison *P* value
Body weight (kg)	**initial**	58.3 ± 7.8	59.9 ± 10.2	0.794
	final	57.7 ± 7.7	59.6 ± 10.2	0.585
BMI (kg/m²)	**initial**	20.8 ± 1.6	21.0 ± 1.7	0.865
	final	20.8 ± 1.2	21.0 ± 1.7	NA †
Muscle mass (kg)	**initial**	47.2 ± 8.0	47.9 ± 9.4	0.970
	final	46.1 ± 7.5	47.1 ± 9.2	0.573
Body fat (%)	**initial**	14.5 ± 6.7	15.7 ± 5.9	0.473
	final	15.7 ± 6.8	16.7 ± 5.8	0.942
Body water (%)	**initial**	61.2 ± 6.9	59.3 ± 5.8	0.450
	final	58.9 ± 5.4	56.9 ± 4.8	0.460
AGEs score	**initial**	0.43 ± 0.11	0.46 ± 0.09	0.610
	final	0.42 ± 0.10	0.45 ± 0.09	0.765
Hb levels (g/dL)	**initial**	14.8 ± 1.4	14.3 ± 1.4	0.257
	final	14.7 ± 1.7	14.5 ± 1.3	NA †

Data for each group were expressed as the arithmetic mean ± standard deviation. Analysis of between-group comparisons for initial visit use Mann-Whitney's U test, for final visit use ANCOVA with baseline as covariate and group as factor. † means that there is a significant interaction between the covariate and factor.

Secondary Outcomes

The OPLFE group demonstrated a statistically significant decrease of 2.0 points in RPE score compared to the placebo group (*P* = 0.003). No significant differences were observed between groups in average or maximum heart rates during the 12-minute run test. Additionally, no significant differences were found between groups in body composition parameters, AGEs, or estimated Hb levels (Tables 3 and 4). No adverse events related to the intake of the test foods were reported during the study period.

Discussion

In this study, the running distance covered in the 12-minute run test significantly increased in the OPLFE group, supporting our hypothesis that taking 200 mg of OPLFE daily for 60 days can improve endurance performance. In order to clarify the mechanism by which OPLFE intake improves the endurance performance of runners, this study also measured body composition, blood Hb concentration, and AGEs using non-invasive methods. It has been reported that endurance performance improves with lower body fat mass [21–23] and adequate muscle mass [24]. Regarding muscle mass, it has also been reported that AGEs accumulation leads to skeletal muscle atrophy [25]. Furthermore, a higher blood Hb concentration enables more efficient oxygen transport throughout the body, resulting in higher endurance performance [26, 27]. However, in this trial involving long distance runners, OPLFE intake did not alter these parameters. Therefore, the findings cannot be fully accounted for by the variables measured in this study, suggesting involvement of other mechanisms.

Because this study did not evaluate mechanistic indices such as mitochondrial function, ATP metabolism, or lactate kinetics, the following discussion is presented as hypothesis. Specifically, Chang et al. reported that OPLFE may enhance mitochondrial function, increase ATP production, and thereby stabilize energy supply during exercise [28]. Toward the end of the test, participants were likely exercising near or above the AT. At this intensity range, glycolytic activity increases and lactate accumulation becomes prominent [29]. Additionally, Kawamura et al. reported that OPLFE

intake increased power output and reduced lactate accumulation during high-intensity exercise [30]. Taken together, OPLFE intake may enhance energy metabolism efficiency, which could explain the reduction in RPE score observed in this study.

To determine whether the improvement observed in this study was practically meaningful, the percentage change in running distance was compared with the smallest worthwhile change (SWC) criterion. In endurance performance research, SWC is typically defined as half of an athlete's typical competition-to-competition variability in performance, expressed as a percentage (coefficient of variation, CV), which corresponds to approximately 0.5–1% [31]. The observed +0.07 km increase in this study corresponded to 2.4%, exceeding a CV of 1%, and may therefore be interpreted as a meaningful increase under the SWC criterion. Under the treadmill conditions of this study, participants were not allowed to decrease their speed to avoid pacing effects arising from speed fluctuations. Allowing participants to adjust their speed freely typically introduces behavioral variability due to pacing and makes it harder to reflect purely physiological capacity [18, 32]. By restricting speed adjustments, this design prevented decreases in speed during the late stage of the run, allowing a more direct assessment of fatigue resistance. The observed increase in distance may therefore reflect improved fatigue resistance. These findings should be interpreted with caution when applying them to outdoor running, due to the specific treadmill conditions used in this study [33, 34].

This study has several limitations. Dietary intake and training volume were not controlled, and neither formal familiarization trials nor standardized pacing instructions were implemented, which may have influenced running distance and RPE score. Furthermore, the sample was restricted to runners aged 45–64 years, limiting the generalizability of the findings to this age range. Future directions, to improve the external validity of performance inferences regarding OPLFE, future studies should incorporate standardized field tests such as the Cooper test [35] together with key physiological measures such as VO_{2max}. In addition, reproducibility under real-world conditions should be examined by prospectively recording outdoor race times and comparing these to laboratory and field performance outcomes.

Conclusions

The results of this study demonstrate that OPLFE intake increased the distance covered in the 12-minute run and reduced perceived exercise intensity. These findings suggest that OPLFE may contribute to the enhancement of endurance performance in middle-aged male and female adults.

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Conflict of Interest. Amino Up Co., Ltd. founded the trial and provided the test foods. However, the company had no involvement in the study design, data analysis, or manuscript preparation.

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