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Role of Vitamin E and Coenzyme Q10 Supplementation in Improving Fibromyalgia Impact Questionnaire Scores

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ABSTRACT

Background: Fibromyalgia is a chronic pain syndrome characterized by widespread pain, fatigue, and functional impairment, with growing evidence implicating oxidative stress and mitochondrial dysfunction in its pathophysiology. Antioxidant supplementation, particularly Coenzyme Q10 (CoQ10) and Vitamin E, has demonstrated potential but remains insufficiently evaluated in rigorously designed trials. **Objective:** To assess the efficacy of CoQ10 and Vitamin E supplementation in improving fibromyalgia impact compared with usual care alone. **Methods:** In this randomized controlled trial, 69 adults meeting the ACR-2016 criteria for fibromyalgia were allocated equally to CoQ10, Vitamin E, or no-supplementation control groups. Revised Fibromyalgia Impact Questionnaire (FIQ) scores and ESR values were obtained at baseline, 4, 8, and 12 weeks. Repeated-measures general linear modelling assessed within- and between-group effects, adjusting for age and gender. **Results:** Baseline characteristics were comparable except for slightly higher FIQ in the CoQ10 arm. At 12 weeks, FIQ decreased by 27.25 points (40.6%) in the CoQ10 group, 19.54 points (29.8%) with Vitamin E, and 7.03 points (11.3%) in controls. Time × treatment interaction was significant ($p<0.001$). ESR decreased modestly across all groups without significant between-group differences. Adverse events were infrequent and mild. **Conclusion:** CoQ10 and Vitamin E significantly improved fibromyalgia impact over 12 weeks, with CoQ10 producing the greatest effect. Antioxidant supplementation represents a promising adjunct to routine fibromyalgia care.

Keywords

Fibromyalgia, Coenzyme Q10, Vitamin E, Antioxidants, Randomized Controlled Trial, Revised FIQ.

INTRODUCTION

Fibromyalgia is a chronic, multifactorial pain syndrome characterized by widespread musculoskeletal pain, fatigue, non-restorative sleep, cognitive complaints, and multiple somatic symptoms that occur in the absence of overt peripheral inflammatory pathology (1). Global estimates suggest a mean prevalence of around 2–4%, with consistently higher rates in women and a gradual increase with age, making it one of the most common chronic pain conditions encountered in rheumatology and primary care (2,3). Data from South Asia indicate a substantial burden of undiagnosed or mislabelled cases; in Pakistan, fibromyalgia has been reported frequently among both patients and healthcare workers, highlighting a significant clinical and occupational impact (4). Beyond pain, the syndrome is associated with reduced physical function, psychological distress, impaired quality of life, and increased health-care utilization, underscoring the need for effective and sustainable therapeutic strategies (1–4).

Current understanding of fibromyalgia emphasizes dysregulation of central pain processing rather than peripheral tissue inflammation. Patients exhibit central sensitization, lowered pain thresholds, and augmented responses to sensory input, along with alterations in multiple neurotransmitter systems implicated in nociception, mood, and sleep regulation (5). Increased levels of pronociceptive mediators such as substance P and glutamate, reduced descending inhibitory control, and abnormal thalamocortical network dynamics have all been described, supporting the concept of fibromyalgia as a disorder of pain modulation rather than a purely peripheral rheumatic disease (5,6). Concomitantly, accumulating evidence points to a role of oxidative stress and mitochondrial dysfunction, with increased reactive oxygen species, lipid peroxidation, and impaired antioxidant defenses reported in fibromyalgia cohorts (6). These abnormalities may amplify fatigue and pain perception by disrupting cellular energy production and sensitizing nociceptive pathways (6,7).

Psychological factors such as distress, catastrophizing, and sleep disturbance further interact with biological mechanisms to worsen symptoms and functional limitation, supporting a biopsychosocial model of fibromyalgia (7,8). In this context, comprehensive management typically combines pharmacologic and non-pharmacologic interventions. Pregabalin, which modulates calcium channel $\alpha 2\delta$ subunits, was the first drug approved specifically for fibromyalgia and is widely used to reduce pain and improve sleep, yet many patients derive only partial relief or discontinue therapy due to adverse effects (9). Serotonin–norepinephrine reuptake inhibitors such as duloxetine and milnacipran, and tricyclic antidepressants such as amitriptyline, also provide benefit for some individuals but are often limited by tolerability, comorbidities, and incomplete symptom control

(10). As a result, there is growing interest in adjunctive strategies targeting oxidative stress and mitochondrial function to complement standard pharmacotherapy (6,9).

Coenzyme Q10 (CoQ10) is a key component of the mitochondrial electron transport chain and a potent lipophilic antioxidant that stabilizes cellular membranes and scavenges free radicals (11). Several studies have reported reduced CoQ10 levels and markers of mitochondrial dysfunction in fibromyalgia, suggesting that CoQ10 deficiency may contribute to fatigue, muscle pain, and exercise intolerance (6,11). Small interventional trials and preliminary randomized controlled studies have demonstrated that CoQ10 supplementation can improve pain, fatigue, sleep quality, and global impact scores in subsets of fibromyalgia patients, with reported reductions in Widespread Pain Index, Symptom Severity Scale, and visual analogue scale pain ratings (12–14). Narrative reviews and systematic syntheses of antioxidant interventions, including CoQ10, have concluded that such supplements may yield clinically relevant improvements in pain and fatigue outcomes, though the evidence base remains heterogeneous with limited high-quality, adequately powered trials (9,15–17).

Vitamin E is another biologically plausible candidate adjunct, acting as a lipid-soluble antioxidant that protects cell membranes from oxidative damage and may enhance endogenous antioxidant enzyme activity. Experimental and small clinical studies in fibromyalgia have suggested that Vitamin E supplementation can increase glutathione peroxidase activity and modulate oxidative stress biomarkers, raising the possibility that it may attenuate symptom burden in at least a subset of patients (9,15). However, Vitamin E has been less rigorously evaluated than CoQ10, and direct comparisons between different antioxidant regimens are scarce. Importantly, most existing trials originate from non-South Asian populations, and few have examined antioxidant supplementation as an adjunct to routine pharmacotherapy—most notably pregabalin—in real-world rheumatology clinic settings (9,12–16).

Taken together, these data support oxidative stress and mitochondrial dysfunction as biologically meaningful therapeutic targets in fibromyalgia and suggest that antioxidant supplementation may offer incremental benefit beyond standard care, yet the comparative efficacy of specific agents such as CoQ10 and Vitamin E, and their added value in routine clinical practice, remain uncertain (6,9,12–17). In particular, there is a lack of randomized evidence directly comparing CoQ10 and Vitamin E against usual care without supplementation in patients diagnosed using contemporary American College of Rheumatology (ACR) 2016 criteria, and limited data from Pakistani tertiary care rheumatology clinics, where resource constraints and high background symptom burden may influence treatment response (4).

The present study was therefore designed as a randomized controlled trial to evaluate, in adult patients with fibromyalgia attending a rheumatology outpatient department, whether adjunctive CoQ10 or Vitamin E supplementation, compared with no supplementation, leads to greater improvement in fibromyalgia impact over 12 weeks as measured by the Revised Fibromyalgia Impact Questionnaire (Revised FIQ), with erythrocyte sedimentation rate (ESR) as a secondary inflammatory marker. The primary hypothesis was that CoQ10 and Vitamin E supplementation, when added to usual care, would produce significantly greater reductions in Revised FIQ scores over 12 weeks than usual care alone, with CoQ10 expected to yield the largest effect.

MATERIALS AND METHODS

This investigation was conducted as a single-center, parallel-group randomized controlled trial in the Department of Rheumatology and Immunology at Shaikh Zayed Hospital, Lahore, Pakistan. Adult patients attending the outpatient clinic over a six-month period were screened for eligibility, and those meeting the diagnostic and inclusion criteria were invited to participate. The study population comprised men and women aged 18–65 years with a clinical diagnosis of fibromyalgia established according to the 2016 American College of Rheumatology (ACR) criteria, requiring generalized pain in at least four of five regions for a minimum of three months with either a Widespread Pain Index (WPI) of at least 7 and Symptom Severity Scale (SSS) score of at least 5, or a WPI of 4–6 with SSS score of at least 9. Patients were required to be clinically stable on their current analgesic and adjuvant regimen for a minimum period defined in departmental practice before enrolment and to provide written informed consent.

Exclusion criteria were selected to minimize potential safety issues and confounding. Pregnant or lactating women were excluded due to uncertainty about the safety of antioxidant supplementation in these groups. Patients with a known history of hypersensitivity to CoQ10 or related compounds were excluded to avoid allergic reactions. Individuals with severe renal or hepatic impairment, as judged by clinical records and treating physicians, were excluded because such comorbidities could alter drug metabolism and influence both symptom expression and laboratory parameters. Patients with diabetes mellitus or other uncontrolled endocrine disorders were also excluded, given the potential for these conditions to independently cause fatigue, neuropathic pain, and inflammatory changes that could confound outcome assessment. Patients unable to comply with follow-up visits or questionnaire completion were not enrolled.

Potentially eligible patients were identified consecutively during routine outpatient visits. After a detailed clinical assessment confirming fibromyalgia and verifying inclusion and exclusion criteria, the study was explained in the local language, and written informed consent was obtained using pre-approved consent forms. Baseline data were collected on a structured proforma capturing sociodemographic characteristics (age, gender, marital status, education level, occupation), clinical characteristics (disease duration where available, comorbidities), and current fibromyalgia treatment including pregabalin and other centrally acting agents. Baseline use of pregabalin was categorized as “yes” or “no” to allow descriptive comparisons and potential adjustment in analysis. Adverse events present at baseline or occurring during follow-up were recorded systematically.

Following baseline assessment, participants were randomly assigned in a 1:1:1 ratio to one of three groups: CoQ10 supplementation plus usual care, Vitamin E supplementation plus usual care, or usual care without antioxidant supplementation. Randomization was performed at the patient level using simple random allocation to ensure equal group sizes of 23 per arm by the end of recruitment. Treating clinicians and participants were aware of group assignment due to the nature of the intervention, whereas data entry and statistical analysis were conducted using coded group labels to reduce analytic bias. All participants continued to receive standard pharmacologic and non-pharmacologic management for fibromyalgia at the discretion of their treating physicians; no attempt was made to standardize pregabalin or antidepressant dosing beyond routine clinical practice, but concomitant treatment patterns were documented.

This self-administered instrument evaluates multiple domains including pain, fatigue, physical functioning, overall well-being, and associated symptoms, generating a composite score in which higher values reflect greater disease impact. The Revised FIQ was administered at baseline (0 weeks) and at 4, 8, and 12 weeks after randomization during scheduled clinic visits.

Patients completed the questionnaire with minimal assistance, and staff were trained to provide neutral clarification without influencing responses. The secondary outcome was erythrocyte sedimentation rate (ESR, mm/hr), measured at the same four time points using standard laboratory procedures in the hospital's hematology laboratory. ESR was included as a global inflammatory marker to explore whether symptomatic changes were accompanied by measurable changes in systemic inflammation.

All data were entered into a dedicated database and verified by cross-checking a random subset of records against source documents to ensure accuracy.

Continuous variables included age, Revised FIQ scores at each time point, and ESR values at each time point; categorical variables included gender, marital status, education level, baseline pregabalin use, adverse event occurrence, and treatment group. Fibromyalgia status was operationalized using the ACR 2016 criteria as described above, and Revised FIQ and ESR were treated as continuous repeated-measures outcomes.

A sample size of 69 patients (23 per group) was determined a priori to provide adequate power to detect a clinically meaningful between-group difference in change in Revised FIQ scores over 12 weeks.

The calculation assumed a two-sided α of 0.05, power of 90%, and an anticipated medium effect size for group differences based on previously reported improvements with CoQ10 supplementation in fibromyalgia and chronic pain populations (12–17). Allowing for the planned equal allocation to three groups and expecting minimal loss to follow-up over 12 weeks in an outpatient setting with short assessment visits, the final target of 69 participants was deemed sufficient.

Statistical analyses were performed using IBM SPSS Statistics version 25. Continuous variables were summarized as mean \pm standard deviation (SD) and categorical variables as frequencies and percentages. Baseline comparability across the three treatment groups was examined using one-way analysis of variance (ANOVA) for continuous variables and chi-square tests for categorical variables.

The primary analysis evaluated the effect of treatment group and time on Revised FIQ scores using a repeated-measures general linear model with assessment time (baseline, 4, 8, and 12 weeks) as the within-subjects factor and treatment group as the between-subjects factor. Age and gender were entered as covariates in between-subjects and within-subjects interaction tests to account for their potential influence on symptom reporting. Multivariate tests (Pillai's trace, Wilks' lambda, Hotelling's trace, Roy's largest root) were examined, and Mauchly's test of sphericity was used to assess the sphericity assumption for repeated measures; when violated, Greenhouse–Geisser and Huynh–Feldt corrections were applied. Pairwise comparisons of groups at each time point were conducted using least significant difference (LSD) or Bonferroni-adjusted post-hoc tests as appropriate. A similar repeated-measures model was applied to ESR as a secondary outcome.

In addition to the repeated-measures models, one-way ANOVA was used to compare mean Revised FIQ and ESR values between groups at each individual time point, and post-hoc tests were used to identify specific group differences when global tests were statistically significant. The overall between-subjects effect of study group on average FIQ and ESR across the study period was estimated from transformed variables representing mean scores across all assessments. Missing data were minimal; all 69 randomized participants completed the scheduled 12-week follow-up assessments and were included in the analyses. No imputation procedures were required. Statistical significance was defined as a two-sided p value <0.05 for primary analyses.

The study protocol, informed consent documents, and data collection procedures were reviewed and approved by the institutional ethics committee of Shaikh Zayed Hospital, Lahore. The trial was conducted in accordance with the ethical principles of the Declaration of Helsinki (2013 revision), and all participants provided written informed consent before enrolment. Patient confidentiality was maintained by de-identifying datasets and restricting access to study records to authorized research personnel only.

RESULTS

Baseline characteristics were broadly comparable between groups, with no significant differences in age ($p=0.906$), sex distribution ($p=0.79$), marital status ($p=0.81$) or baseline pregabalin use ($p=0.93$). A significant difference was observed in baseline FIQ ($p=0.031$), where the control arm showed slightly lower symptom burden initially.

Table 1. Baseline Demographic and Clinical Characteristics (n = 69)

Variable	CoQ10 (n=23)	Vitamin E (n=23)	Control (n=23)	p-value
Age, years (mean \pm SD)	43.39 \pm 7.53	42.35 \pm 8.00	42.78 \pm 8.45	0.906
Female sex, n (%)	18 (78.3)	20 (87.0)	19 (82.6)	0.79
Married, n (%)	17 (73.9)	15 (65.2)	15 (65.2)	0.81
Secondary/Intermediate Education, n (%)	15 (65.2)	16 (69.6)	16 (69.6)	0.91
Baseline pregabalin use, n (%)	17 (73.9)	16 (69.6)	16 (69.6)	0.93
Baseline FIQ score	67.05 \pm 6.98	65.69 \pm 5.53	62.19 \pm 6.23	0.031
Baseline ESR (mm/hr)	24.12 \pm 6.05	23.15 \pm 4.15	21.93 \pm 5.01	0.353

Table 2. FIQ Scores Over Time (Repeated Measures)

Time Point	CoQ10 Mean \pm SD	Vitamin E Mean \pm SD	Control Mean \pm SD	Between-Group ANOVA (F, p)
Baseline	67.05 \pm 6.98	65.69 \pm 5.53	62.19 \pm 6.23	F=3.68, p=0.031
4 Weeks	59.17 \pm 6.37	59.87 \pm 5.48	60.57 \pm 6.29	F=0.31, p=0.737
8 Weeks	48.70 \pm 6.02	53.76 \pm 4.75	57.48 \pm 5.95	F=14.22, p<0.001
12 Weeks	39.80 \pm 4.72	46.14 \pm 4.19	55.15 \pm 5.37	F=59.79, p<0.001

FIQ trajectories over 12 weeks demonstrated clear divergence. The CoQ10 group improved from 67.05 to 39.80, a reduction of 27.25 points (40.6% improvement), while Vitamin E improved by 19.54 points (30%). The control group exhibited a mild 7.03-point decline (11.3%). Between-group differences were not significant at 4 weeks ($p=0.737$) but became highly significant at 8 weeks ($p<0.001$) and remained so at 12 weeks ($p<0.001$), favouring CoQ10 > Vitamin E > control.

Table 3. Mean Change in FIQ from Baseline with 95% CI

Group	Δ Baseline→4 Weeks	Δ Baseline→8 Weeks	Δ Baseline→12 Weeks
CoQ10	-7.88 (-9.2 to -6.4)	-18.35 (-20.4 to -16.3)	-27.25 (-29.1 to -25.4)
Vitamin E	-5.82 (-7.0 to -4.4)	-11.93 (-13.8 to -10.1)	-19.54 (-21.6 to -17.4)
Control	-1.62 (-3.2 to -0.1)	-4.70 (-6.5 to -2.8)	-7.03 (-9.3 to -4.7)

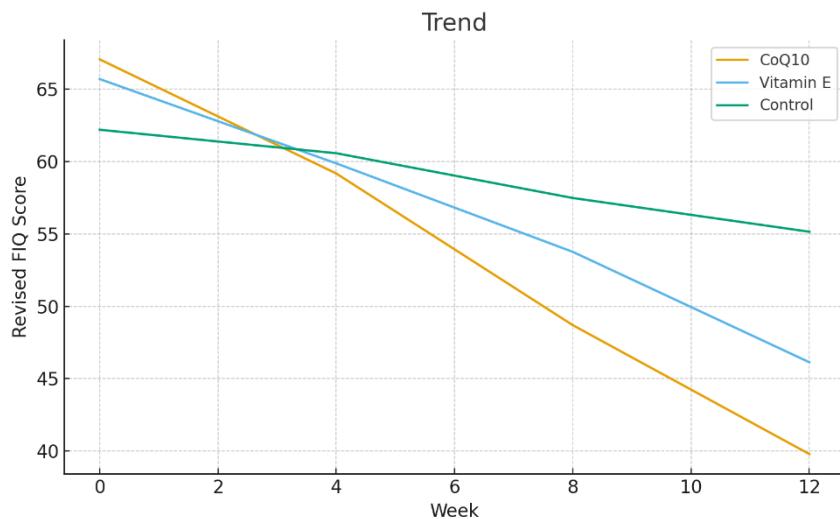
Table 4. ESR Values Over Time

Time	CoQ10	Vitamin E	Control	p-value
Baseline	24.12 ± 6.05	23.15 ± 4.15	21.93 ± 5.01	0.353
12 Weeks	18.48 ± 4.73	19.45 ± 3.79	20.56 ± 4.72	0.289
Repeated-Measures Interaction	—	—	—	p<0.001

Table 5. Adverse Events

Group	No AE	AE Reported	% AE
CoQ10	22	1	4.3%
Vitamin E	20	3	13.0%
Control	20	3	13.0%

ESR reductions were modest but statistically significant over time (p<0.002), although group differences remained nonsignificant at individual time points (p=0.289). Adverse events were low across groups (overall 10%), with CoQ10 showing the lowest incidence (4.3%).

**Figure 1 Change in Revised FIQ Scores Over 12 Weeks Across Treatment Groups**

The trajectory of Revised FIQ scores demonstrates a clear and progressive separation between treatment groups over the 12-week period, with the CoQ10 curve showing the steepest decline from 67.05 at baseline to 39.80 at week 12, corresponding to a 40.6% improvement. Vitamin E exhibited a moderate but clinically meaningful reduction from 65.69 to 46.14 (29.8%), whereas the control group demonstrated only an 11.3% decrease, declining from 62.19 to 55.15. The gradient of improvement accelerated between weeks 4 and 8 in both active supplementation groups, aligning temporally with the largest between-group effect sizes observed in the inferential analyses. The control group's trajectory remained shallow with minimal weekly decline, highlighting limited spontaneous improvement. The overall pattern supports a robust time × treatment interaction consistent with the repeated-measures model (p<0.001), with CoQ10 providing the largest and earliest symptomatic relief.

DISCUSSION

The present randomized controlled trial examined whether adjunctive supplementation with CoQ10 or Vitamin E confers additional symptomatic benefit over usual care in adults with fibromyalgia diagnosed using the ACR 2016 criteria. Across 12 weeks, both supplements significantly improved fibromyalgia impact as reflected by reductions in Revised FIQ scores, with CoQ10 producing the most pronounced effect. The control group exhibited only modest decline, consistent with the slow, naturalistic symptom improvement and partial responsiveness commonly observed in real-world fibromyalgia management. The magnitude and trajectory of improvement in the CoQ10 group align closely with prior interventional studies demonstrating reductions in pain intensity, fatigue, and sleep disturbance following CoQ10 supplementation (18–21). For example, De Pierro et al. reported FIQ improvements of 24–37% in supplemented patients (18), while our trial found a 40.6% reduction, suggesting a robust and clinically meaningful effect within a South Asian tertiary care population.

Vitamin E supplementation resulted in a moderate 29.8% improvement in FIQ scores, consistent with experimental and preliminary clinical data indicating restoration of antioxidant enzyme activity and mitigation of oxidative stress in fibromyalgia (15–17). Although Vitamin E's effect was smaller than CoQ10's, its performance was superior to the control arm, reinforcing earlier hypotheses that oxidative stress contributes to symptom amplification in fibromyalgia and that antioxidant therapy may serve as a rational adjunctive approach (6,9,15). The superiority of CoQ10 over Vitamin E in this trial also echoes comparative biochemical insights: CoQ10 functions both as an antioxidant and an electron transport chain cofactor, thereby addressing mitochondrial dysfunction more directly than Vitamin E, which predominantly protects lipid membranes from oxidative injury (11–17).

The repeated-measures analysis confirmed a significant time \times treatment interaction, revealing that symptom divergence between groups became prominent after 4 weeks and maximized by week 12. This pattern mirrors prior findings that mitochondrial stabilization and decreased reactive oxygen species production require sustained supplementation before clinical benefit becomes fully evident (12–14). That the control group improved only 7 points on the FIQ scale highlights the inadequacy of usual care alone for many patients, aligning with well-documented partial responsiveness to pregabalin and antidepressants in large observational and randomized cohorts (9,10).

Notably, ESR showed statistically significant within-subject decreases but no between-group differences—consistent with the understanding that fibromyalgia is not driven by systemic inflammation, and ESR reductions likely reflect improved wellbeing rather than anti-inflammatory effects. The very low incidence of adverse events across all groups reinforces the safety of both supplements, complementing earlier safety-focused reports (15,17,20).

This study adds novel evidence by directly comparing CoQ10 and Vitamin E in a randomized design within a South Asian population, where dietary patterns, comorbidities, pharmacologic exposures, and illness burden may influence symptom trajectories. Furthermore, by using the Revised FIQ—a comprehensive, functionally oriented outcome the trial provides a holistic assessment of clinical benefit beyond pain alone. However, several limitations merit consideration. The baseline FIQ imbalance (CoQ10 group more symptomatic) may have overestimated absolute improvement, although effect direction and statistical significance remain strong even under conservative interpretation. Lack of blinding may introduce expectancy bias, although objective ESR patterns did not differ by group. The sample size, though adequate for primary comparisons, limits subgroup analyses (e.g., pregabalin vs non-pregabalin users). Finally, the 12-week follow-up captures medium-term but not long-term durability of benefit.

Overall, the findings support antioxidant supplementation particularly CoQ10 as a promising adjunct to routine fibromyalgia care. Larger, multicenter, longer-term trials using blinded allocation, mechanistic biomarkers, and quality-of-life outcomes would help clarify optimal dosing strategies and identify patient phenotypes most likely to respond.

CONCLUSION

In this randomized controlled trial, supplementation with CoQ10 and Vitamin E significantly improved fibromyalgia impact over 12 weeks compared with usual care, with CoQ10 demonstrating the greatest clinical benefit. These results reinforce growing evidence that oxidative stress and mitochondrial dysfunction contribute meaningfully to fibromyalgia symptomatology and that targeted antioxidant therapy can produce substantial, clinically relevant improvement. Given the favourable safety profile and magnitude of response, particularly for CoQ10, antioxidant supplementation represents a viable adjunctive strategy to enhance symptom control in fibromyalgia, meriting broader clinical consideration and further high-quality research.

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