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PIONEERING AN INTEGRATED TREATMENT APPROACH FOR FUNCTIONAL NEUROLOGICAL SYMPTOM DISORDER: A RANDOMISED CONTROLLED TRIAL

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ABSTRACT

Background: Functional Neurological Symptom Disorder (FNSD), previously referred to as conversion disorder, presents with neurological symptoms that are inconsistent with structural neurological disease and are often associated with significant psychosocial distress and disability. Traditional treatment approaches have shown limited success due to the complexity of the disorder's biopsychosocial etiology. Cognitive Behavioural Therapy (CBT) has demonstrated efficacy in managing FNSD, and when combined with appropriate pharmacotherapy, may offer superior outcomes by addressing both cognitive-emotional and neurochemical dysregulation. However, integrated treatment models have not been widely tested in controlled trials.

Objectives

To evaluate the efficacy of an integrated treatment approach (CBT + pharmacotherapy) in reducing symptom severity in patients with Functional Neurological Symptom Disorder.

To assess improvements in functional outcomes and quality of life compared to standard care.

Methods: A single-center randomized controlled trial was conducted among **44 adult patients** (aged 18–60 years) diagnosed with FNSD according to DSM-5 criteria. Participants were randomized into two groups:

Intervention Group (n = 22): Received an 8-week structured CBT protocol alongside pharmacotherapy tailored to symptom profile.

Control Group (n = 22): Received standard care as per clinical practice guidelines.

Baseline assessments included the **PHQ-9**, **WHOQOL-BREF**, and **Sheehan Disability Scale (SDS)**. Follow-up assessments were conducted at **8 and 10 weeks**. Data were analyzed using repeated measures ANOVA and independent t-tests.

Results: The intervention group showed significant improvements in symptom severity, quality of life, and functioning at both 8 and 10 weeks. PHQ-9 scores reduced by an average of 8.3 points in the intervention group versus 3.2 in the control group (**$p < 0.001$**). WHOQOL-BREF domains showed marked enhancement in physical and psychological well-being ($p < 0.01$). SDS scores indicated greater improvement in work, social, and family functioning among intervention participants (**$p < 0.001$**).

Conclusion: The integrated treatment approach combining CBT and pharmacotherapy was significantly more effective than standard care in reducing symptom burden and improving overall functioning in patients with FNSD. These findings support the implementation of structured, multidisciplinary interventions in the routine management of functional neurological disorders.

Keywords: Functional Neurological Symptom Disorder, Conversion Disorder, CBT, Pharmacotherapy, Quality of Life, Randomized Controlled Trial

INTRODUCTION

Functional Neurological Symptom Disorder (FNSD), previously termed conversion disorder, is characterized by neurological symptoms—such as motor weakness, sensory disturbances, and non-epileptic seizures—that are incongruent with recognized neurological conditions but cause significant distress and functional impairment (3). FNSD remains a diagnostic and therapeutic challenge due to its complex biopsychosocial etiology, often involving maladaptive cognitive-emotional processing, psychological trauma, and altered brain network connectivity (2,4).

The condition is associated with high healthcare utilization and poor quality of life, yet standardized treatment models remain underdeveloped (5). While earlier views separated mind and body, recent conceptual frameworks support an integrated model of care, emphasizing neuropsychiatric overlap and the need for interdisciplinary approaches (6,7).

Evidence supports **Cognitive Behavioural Therapy (CBT)** as a cornerstone intervention in FNSD, particularly in addressing symptom-focused attention, maladaptive beliefs, and avoidance behaviors (3,8). Pharmacotherapy, especially when targeted toward comorbid anxiety and depression, has also shown adjunctive benefit (5). However, most patients are either under-treated or receive fragmented care, leading to suboptimal outcomes (1,4).

Recent studies advocate for **multidisciplinary and individualized treatment strategies**. For example, Petrochilos et al. (2020) demonstrated that a 5-week individualized multidisciplinary program significantly improved functional outcomes and symptom severity in FNSD patients (1). Keatley and Molton (2022) further emphasized the need to shift from diagnostic exclusion to proactive management, incorporating both psychological and pharmacologic modalities (7).

Despite these insights, few randomized controlled trials have examined the efficacy of combining CBT and pharmacotherapy in an integrated, structured format. Moreover, functional and quality-of-life outcomes remain underreported. Addressing this gap, the present study evaluates an integrated treatment approach for FNSD, combining CBT with symptom-specific pharmacotherapy, compared against standard clinical care.

MATERIALS AND METHODS

Study Design

This study was a randomized, parallel-group, controlled trial designed to evaluate the efficacy of an integrated treatment approach combining Cognitive Behavioural Therapy (CBT) and pharmacotherapy compared to standard clinical care in patients with Functional Neurological Symptom Disorder (FNSD). The study was conducted at Saveetha medical college and hospitalover a period of 10 weeks.

Study Population

Participants included adults aged 18 to 60 years diagnosed with FNSD based on **DSM-5 criteria**, confirmed by a psychiatrist and neurologist using positive diagnostic features. Patients were recruited from psychiatry and neurology outpatient departments.

Inclusion Criteria

- Age between 18 and 60 years
- Clinical diagnosis of FNSD as per DSM-5
- Ability to provide informed consent
- Willingness to comply with treatment and follow-up

Exclusion Criteria

- Presence of organic neurological illness
- Current psychosis, substance use disorder, or severe cognitive impairment
- Concurrent participation in other clinical trials
- Contraindications to pharmacotherapy or CBT

Sample Size and Randomization

A total of **44 participants** were enrolled and randomized in a 1:1 ratio into two groups using a **computer-generated random number sequence** with allocation concealment via sealed opaque envelopes:

- **Intervention Group (n = 22):** Received structured CBT plus pharmacotherapy
- **Control Group (n = 22):** Received standard clinical care as per routine outpatient protocols

Assessment Tools

At baseline, and again at 8 and 10 weeks, participants were assessed using:

- **PHQ-9 (Patient Health Questionnaire-9):** To evaluate depressive symptoms
- **WHOQOL-BREF:** To assess quality of life across physical, psychological, social, and environmental domains

- **Sheehan Disability Scale (SDS):** To measure functional impairment in work/school, social, and family life

Intervention Protocol

Integrated Treatment Group:

- **CBT sessions**: Conducted once weekly for 8 weeks by trained psychiatry residents under supervision, focusing on symptom reattribution, coping skills, stress management, and cognitive restructuring
- **Pharmacotherapy**: Tailored to individual symptom profiles, including SSRIs for affective symptoms or low-dose benzodiazepines for acute distress (as needed and supervised)

Control Group:

- Received routine care based on standard clinical judgment, including supportive counselling, symptomatic medications, and lifestyle advice as per standard outpatient practice.

Follow-up and Outcome Measures

Participants were evaluated at baseline and then re-evaluated at **8 weeks (end of treatment)** and again at **10 weeks** to assess maintenance of treatment effects.

Statistical Analysis

Data were analyzed using **SPSS version 23**.

Ethical Considerations

The study was approved by the Institutional Ethics Committee. Written informed consent was obtained from all participants. Confidentiality and the right to withdraw at any point were assured.

RESULT

The intervention and control groups were comparable across all socio-demographic variables, including age, gender, education, marital status, and employment (all $p > 0.05$), indicating successful randomization and baseline equivalence.

Table 1: Socio-Demographic Characteristics of Participants

Variable	Intervention Group (n = 22)	Control Group (n = 22)	p-value
Age (years)	33.7 ± 9.1	34.2 ± 8.6	0.78
Gender – Male (%)	9 (41%)	8 (36%)	0.76
Gender – Female (%)	13 (59%)	14 (64%)	
Education – < 10th (%)	6 (27%)	5 (23%)	0.82
Education – ≥ 10th (%)	16 (73%)	17 (77%)	
Marital Status – Married (%)	11 (50%)	10 (45%)	0.78
Marital Status – Unmarried (%)	11 (50%)	12 (55%)	
Employment – Employed (%)	7 (32%)	6 (27%)	0.74
Employment – Unemployed (%)	15 (68%)	16 (73%)	

At the 10-week endpoint, the **intervention group showed significantly greater improvements** in symptom severity, quality of life, and functioning compared to the control group.

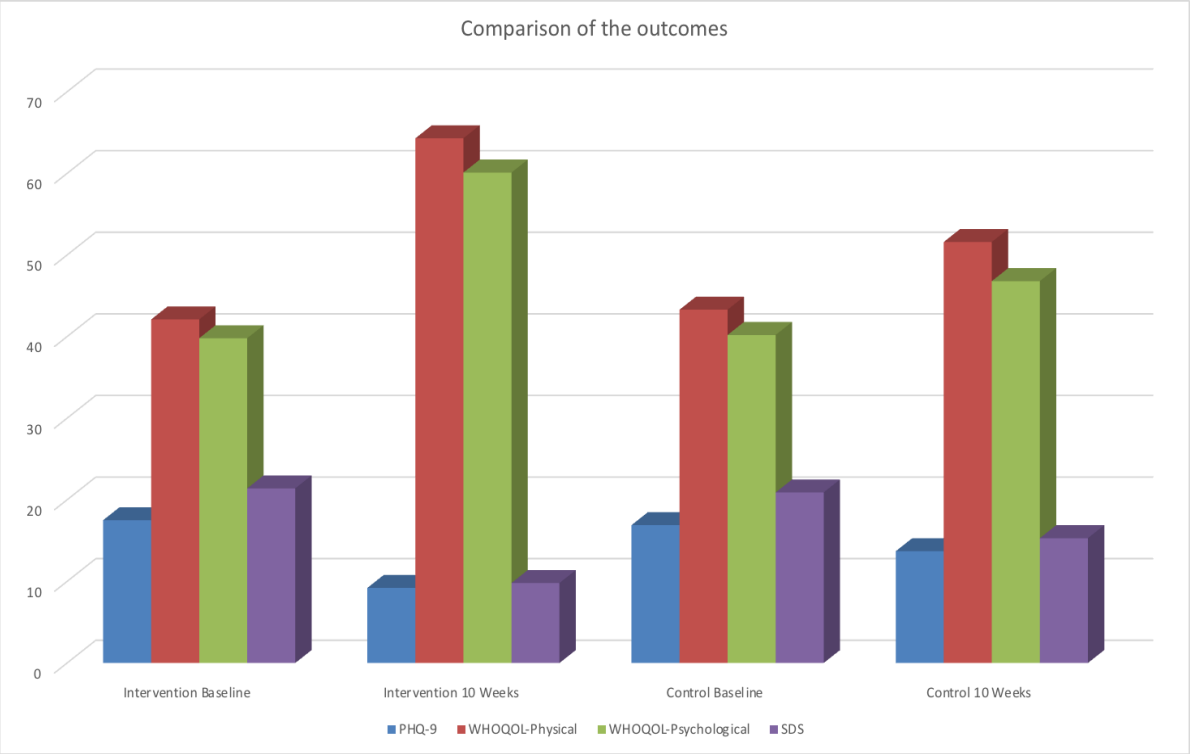
- **PHQ-9 scores** reduced markedly in the intervention group (from **17.5 ± 3.2 to 9.2 ± 2.8**, $p < 0.001$), whereas the control group showed a modest reduction (from **16.9 ± 3.4 to 13.7 ± 3.1**, $p = 0.02$). The between-group difference was significant ($p < 0.001$).
- In the **WHOQOL-BREF physical domain**, the intervention group improved from **42.1 ± 9.8 to 64.3 ± 10.2**, while the control group improved from **43.3 ± 10.1 to 51.6 ± 9.4** ($p < 0.001$ between groups).
- Similarly, in the **psychological domain**, scores increased from **39.8 ± 8.7 to 60.1 ± 9.3** in the intervention group and from **40.2 ± 8.4 to 46.8 ± 8.9** in the control group ($p < 0.001$ between groups).
- **SDS total scores**, reflecting disability, declined significantly in the intervention group (**21.4 ± 4.3 to 9.8 ± 3.6**, $p < 0.001$), compared to the control group (**20.9 ± 4.1 to 15.3 ± 3.9**, $p = 0.02$), again with a significant between-group difference ($p < 0.001$).

These results demonstrate that the integrated treatment approach (CBT + pharmacotherapy) was superior to standard care in improving emotional, functional, and quality-of-life outcomes in patients with FNSD over a 10-week period.

Table 2: Comparison of Outcomes Between Groups at Baseline and 10 Weeks

Outcome	**Group**	**Baseline**	**10 Weeks**	**p-value (within group)**	**p-value (between groups)**
PHQ-9 Score	Intervention	17.5 ± 3.2	9.2 ± 2.8	< 0.001	< 0.001
PHQ-9 Score	Control	16.9 ± 3.4	13.7 ± 3.1	0.02	
WHOQOL-BREF Physical	Intervention	42.1 ± 9.8	64.3 ± 10.2	< 0.001	< 0.001
WHOQOL-BREF Physical	Control	43.3 ± 10.1	51.6 ± 9.4	0.04	
WHOQOL-BREF Psychological	Intervention	39.8 ± 8.7	60.1 ± 9.3	< 0.001	< 0.001
WHOQOL-BREF Psychological	Control	40.2 ± 8.4	46.8 ± 8.9	0.03	
SDS	Intervention	21.4 ± 4.3	9.8 ± 3.6	< 0.001	< 0.001
SDS	Control	20.9 ± 4.1	15.3 ± 3.9	0.02	

Figure 1: Comparison of Outcomes Between Groups at Baseline and 10 Weeks



DISCUSSION

This randomized controlled trial demonstrated that an integrated treatment approach combining Cognitive Behavioural Therapy (CBT) with pharmacotherapy was significantly more effective than standard care in reducing symptom severity, improving quality of life, and enhancing functional outcomes in patients with Functional Neurological Symptom Disorder (FNSD).

Our findings support the growing evidence that FNSD is best managed using a **biopsychosocial framework**. Participants in the intervention group showed significant improvement in depressive symptoms (PHQ-9), quality of life (WHOQOL-BREF physical and psychological domains), and functioning (SDS), aligning with existing literature that underscores the multifactorial nature of FNSD and the need for integrated, multidisciplinary interventions (2,3,5). CBT has been shown to be effective in addressing the cognitive distortions, maladaptive illness beliefs, and avoidance behaviors that perpetuate functional symptoms (3,6). Pharmacotherapy, tailored to comorbid anxiety or depressive symptoms, further augments treatment by stabilizing affective states, as highlighted by Gilmour et al. (2020) and Espay et al. (2018) (3,5).

The degree of improvement observed in this study is comparable to that reported in previous multidisciplinary treatment models. For example, Petrochilos et al. (2020) demonstrated that a five-week individualized day-patient program significantly improved functional outcomes in FNSD, emphasizing the role of structured, integrated care (1). Our study builds on this evidence by using a controlled design and evaluating outcomes at 10 weeks, showing that even a brief outpatient intervention can be effective.

Moreover, recent insights from Hallett et al. (2022) and Mavroudis et al. (2024) advocate for neurobiologically informed interventions that target disrupted brain networks associated with emotion regulation and sensorimotor integration in FNSD (2,4). CBT, by facilitating cognitive reappraisal and behavioral change, may modulate these circuits, especially when reinforced by pharmacotherapy.

Despite these promising results, the study has limitations. The sample size was modest, which may limit generalizability. The follow-up duration was short, and longer-term effects remain to be evaluated. Also, the use of self-report measures, though standardized, may introduce bias.

Future research should explore **long-term outcomes**, cost-effectiveness, and the neurobiological correlates of treatment response, ideally through larger, multicentric trials. Integration of physical therapy and family psychoeducation may further enhance treatment impact (7,8).

CONCLUSION

This randomized controlled trial demonstrates that an integrated treatment approach—combining Cognitive Behavioural Therapy (CBT) with individualized pharmacotherapy—is significantly more effective than standard care in managing Functional Neurological Symptom Disorder (FNSD). Patients who received the integrated intervention showed marked reductions in symptom severity, as well as significant improvements in quality of life and functional capacity, within a relatively short treatment window of 10 weeks. These improvements were both statistically and clinically meaningful across emotional, physical, and psychosocial domains.

The results reinforce the central role of a **biopsychosocial model** in the understanding and treatment of FNSD. They support prior literature emphasizing the need for multimodal care, where psychotherapeutic strategies such as CBT help reframe maladaptive symptom-related beliefs, and pharmacotherapy concurrently addresses affective comorbidities such as anxiety and depression. In line with recent neurobiological models, this dual-targeted approach likely contributes to modulating brain circuits involved in emotion regulation, attention, and sensorimotor integration—networks that are increasingly implicated in the pathophysiology of FNSD (2,3,4).

Importantly, this study offers a practical, scalable model that can be implemented in resource-limited outpatient settings. Unlike inpatient multidisciplinary programs, which may not be feasible in many healthcare systems, this protocol demonstrates that even limited-session CBT with supportive pharmacotherapy can lead to substantial gains. This has significant implications for mental health policy and service delivery, particularly in low- and middle-income countries where FNSD is often misdiagnosed, stigmatized, or left untreated.

In summary, this study contributes strong evidence in favor of integrated, evidence-based care for FNSD. It advocates for shifting away from fragmented or purely symptomatic treatment toward structured, psychologically-informed, and neurobiologically grounded interventions. Implementing such models could transform outcomes for patients with this often-neglected but disabling condition.

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