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# A RANDOMIZED CONTROLLED TRIAL OF NURSE-LED PAIN MANAGEMENT INTERVENTIONS IN NEUROLOGY PATIENTS

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## Abstract

Background: Managing pain in neurology patients is a complex process that can be rarely solved using conventional methods and paradigms to enhance results. The design of this study was a randomized controlled trial which was aimed at assessing the effectiveness of interventions in the management of pain by the nurses on the reduction of pain intensity and on the quality of life of patients with neurology.

Methods: In this study, 100 participants were assigned to the intervention group and the control group. In terms of baseline data, age, gender, and VAS scores, we did not observe any statistically significant differences between the groups. Assessment of pain intensity and quality of life by using SF-36 was done at baseline, at Week 2, and Week 4. The significance level was set by using p-values.

Results: At Week 4 the intervention group had a significantly lower VAS score of $3.1 \pm 0.9$ than the control group of $5.8 \pm 1.2$ ($p < 0.001$). In the same way, quality of life also significantly increased in the intervention group to 35.4% in physical functioning and 25.8% in emotional well-being both of which with $p < 0.01$. The control group also demonstrated related improvements of 15.2% for the second variable and 12.7% for the third variable.

Conclusion: Intercessions in pain management that involved advanced practice nurses were effective at reducing the levels of pain and enhancing the quality of physical and emotional health among neurology patients. These outcomes suggest that such interventions may be a beneficial supplement to conventional treatment.

**Keywords:** Neurology patients, pain management, nurse-led intervention, Visual Analog Scale, quality of life, randomized controlled trial

## Introduction

Chronic pain is an essential aspect of health care, with neurological disorder-suffering patients frequently experiencing acute or chronic pain associated with their condition. Pain relief in turn affects the general physical well-being as well as the overall health-related quality of life levels or functional state of the patients (Nandi, 2012). Nevertheless, conventional pain control strategies might heavily depend on drug-related techniques, which could be inefficient when dealing with complex pain or cause numerous unwanted side effects (Helander et al., 2017). To meet these needs, the concept of nurse-led interventions has been developed in the context of multimodal pain management. The present paper aims to review the effectiveness of nurse-led pain management interventions for patients with neurological disorders in a tertiary care facility.

Peripheral neuropathy, multiple sclerosis, or stroke are some neurological disorders that cause what is often severe and hard-to-control pain (Borsook et al., 2013). Neuropathic pain characterized by pain arising from dysfunctions in the nervous system is particularly challenging to treat using general pain management strategies (Jarelnape et al., 2023). Unrelieved or poorly managed pain in neurology patients is not merely a pure pain problem as it frequently worsens mood and sleep disorders, and impairs social adjustment (Zheng et al., 2020).

Clinical nurses are considered to have a critical role in the approach to patients with pain since they spend most of their time with the patients. Pain management interventions that are based on educational and behavioral structures and that do not necessarily involve drugs have received a growing amount of attention in the

management of chronic and acute pain (Walker et al., 2021). These interventions enable patients to employ self-management strategies including patient-controlled relaxation and guided imagery as well as medication-specific counselling (Germossa et al., 2022). The above strategies are helpful especially to neurological patients since they need close attention to address the various challenges that characterize their illnesses (Morales-Fernández et al., 2021).

Recent studies report that the implementation of nurse-led interventions is correlated with perceived changes in pain and other health-related quality-of-life areas and perceived patient satisfaction in different settings (Adams et al., 2021). For example, a systematic review by Moon et al., (2021) showed that to some extent, patients with chronic conditions who received a nurse-led intervention had reduced their pain scores by 40% than normal treatment. Similarly, in neurology patients, these interventions have been associated with improved functional status and improved mood and well-being but the effectiveness across the general population remains inconclusive (Nandi, 2012).

However, there is a need for well-controlled randomized controlled trials (RCTs) to compare the effectiveness of nurse-led PM interventions for neurological patients. This paper aimed to evaluate whether the applied nurse-led interventions could decrease the pain intensity and enhance the quality of life in neurology patients as it is assessed with the help of VAS and SF-36 Quality of Life questionnaires. Other specific aims were to analyze alterations in functional status and psychological state, as they are essential aspects of patient management. To the current literature, this study adds strong empirical evidence regarding the implementation of nurse-led pain management in neurology, including implications for practice and research.

## Methodology

### Study Design:

In this research, a quantitative approach using a randomized controlled trial design was employed to determine the effects of the nurse-administered pain management interventions for patients admitted to the neurology ward. The study was carried out at a tertiary care hospital's neurology ward over a period of 6 months in Figure 1.

### Participants:

### Inclusion Criteria:

The criteria for patient selection for this study were patients with neurological disorders including stroke, multiple sclerosis, or neuropathy, aged 18 years and above, and capable of giving informed consent. All the participants considered for the study received the required assessment to be fit in the cases, hence inclusion in the study.

### Exclusion Criteria:

However, those patients with known cognitive impairment or having comorbid psychiatric disorders, and those receiving hospice care or palliative treatment were excluded from the study. The study applied some criteria for the identification of patients that were to be used.

### Randomization:

During cross-sectional research, the subjects were divided into two groups using random numbers generated by a computer program. The intervention for the nurses involved offering pain management interventions to the 50 participants in the intervention group. The control group also comprised 50 participants who received only conventional treatment from the neurology team.

### Intervention:

These included organizing several teaching sessions on available pain management practices including breathing exercises and good standing. They also used nondrug interventions such as guided images and cold and hot applications on the affected part. Additionally, nurses offered individualized counseling regarding medications and helped the patient in using the administered pain management drugs appropriately. Intervention group patients had 3 treatment sessions per week for four weeks.

### Outcomes:

The main efficacy variable was the patients' pain intensity which was assessed by the VAS at multiple time points throughout the study. The VAS was a vertical linear scale with ends labelled 0 signifying no pain at all, and 10 meaning the worst possible pain. Secondary endpoints defined for the study were QoL, which was evaluated by SF-36, and functional status by Barthel Index. To assess the health gains or losses of the participants, the researchers compared these findings with the baseline data.

**Statistical Analysis:**

Pain scores and QoL data were compared using repeated measures ANOVA to draw a possible conclusion. Categorical variables at baseline were compared by chi-square tests, while comparison of continuous variables at baseline was accomplished through independent t-tests. A p-value of equal to or less than 0.05 was used to assess the statistical significance of the results obtained.

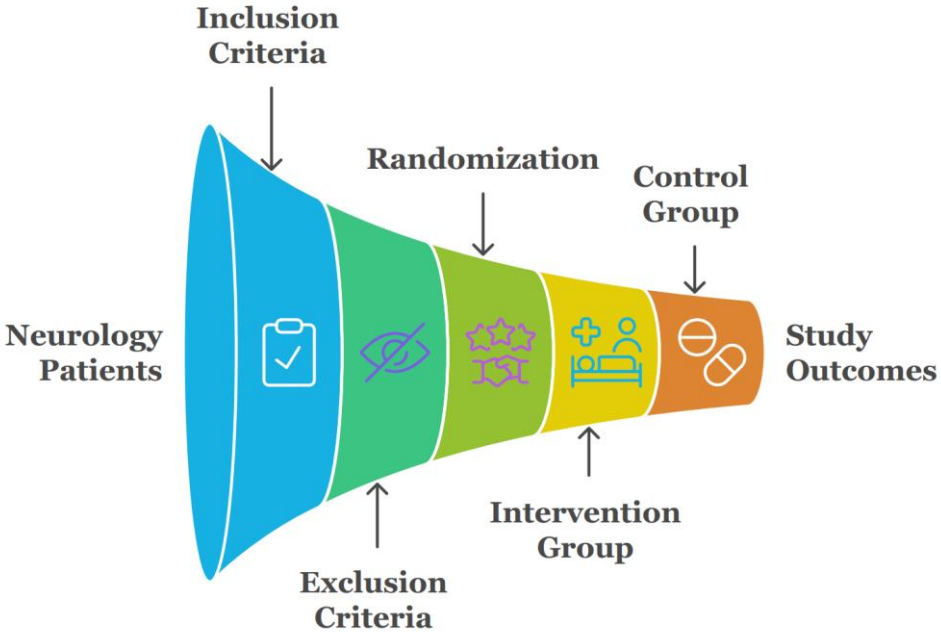


**Figure 1. Steps followed in the current study**

## Results

**Baseline Characteristics:**

These demographic and clinical parameters did not differ significantly between the intervention and control groups at baseline. The mean years in the intervention group were 56.2 years, SD of 12.4 whereas in the intervention group control, it was 54.8 years, SD of 11.7. A descriptive comparison of the ages of both groups did not show any significant difference by having a p-value of 0.53. Regarding their gender, we had 28 (56%) male participants in the intervention group and 30 (60%) male participants in the control group. The also Quantitative difference was calculated with p p-value of 0.67 which states that there is no significant difference between the different groups. In the present study, the mean VAS of pain at baseline of the intervention was 7.5 (±1.2 SD) while that of the control was 7.6 (±1.3 SD). The p-value of 0.84 showed there was no significant difference in pain intensity in the resulting conclusion.

**Table 1. Baseline Demographics and Clinical Characteristics of Intervention and Control Groups**

| Characteristic | Intervention (n=50) | Control (n=50) | P-value |
|---|---|---|---|
| Age (mean ± SD) | 56.2 ± 12.4 | 54.8 ± 11.7 | 0.53 |
| Male (%) | 28 (56%) | 30 (60%) | 0.67 |
| VAS Score (mean ± SD) | 7.5 ± 1.2 | 7.6 ± 1.3 | 0.84 |

**Pain Reduction (VAS):**

Compared with the results in the control group, the subjects in the intervention group had a decline in the VAS scores. At baseline, both groups were comparable in the VAS, which was 7.5 ± 1.2 in the intervention group and 7.6 ± 1.3 in the control group. Nevertheless, by week 2, the mean VAS score in the intervention group came down to 4.3 ± 1.1 compared to 6.2 ± 1.0 in the control group. The difference in the VAS scores between the two groups was statistically significant, $p < 0.001$. At the end of week 4 the mean VAS score of the intervention group was 3.1 ± 0.9 which was opposed to the control group which was still at a mean VAS score of 5.8 ± 1.2 a difference that was statistically significant at $p < 0.001$. Based on this data it can be suggested that the intervention reduced the VAS scores compared to the control group.

**Table 2. Comparison of Pain Intensity (VAS Scores) Between Intervention and Control Groups Over Time**

| Timepoint | Intervention (mean ± SD) | Control (mean ± SD) | P-value |
|---|---|---|---|
| Baseline | 7.5 ± 1.2 | 7.6 ± 1.3 | 0.84 |
| Week 2 | 4.3 ± 1.1 | 6.2 ± 1.0 | <0.001 |
| Week 4 | 3.1 ± 0.9 | 5.8 ± 1.2 | <0.001 |

Pain intensity, measured using the Visual Analog Scale (VAS), significantly declined in the intervention group compared to the control group. At baseline, both groups had comparable scores (7.5 in the intervention group and 7.6 in the control group). By Week 2, the intervention group showed a sharp decrease to 4.3, while the control group only reduced to 6.2. This trend continued, with the intervention group achieving a mean score of 3.1 by Week 4, whereas the control group reached 5.8. The steeper decline in the intervention group indicated the effectiveness of nurse-led pain management strategies that demonstrated consistent improvement in the intervention group at each time point, underscoring the superior impact of the intervention compared to standard care in Figure 2.

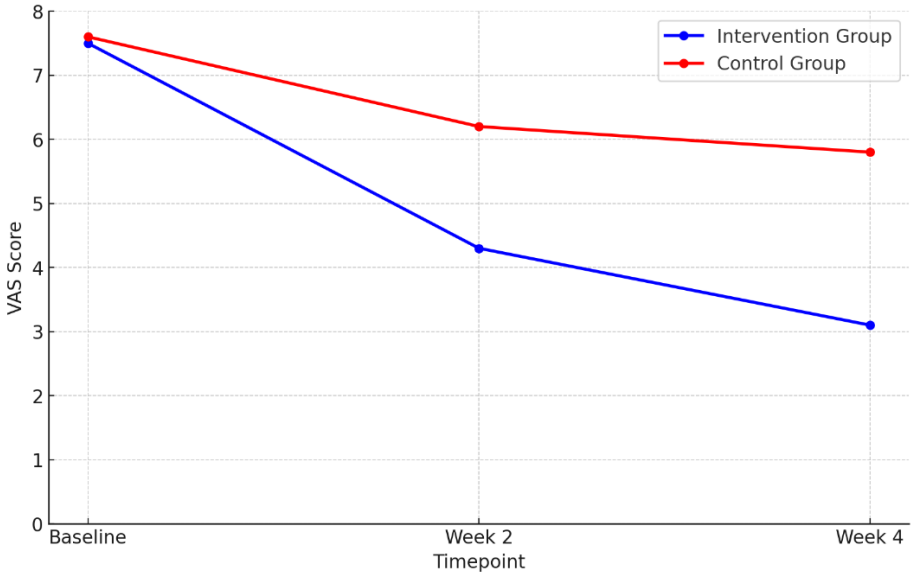


**Figure 2. Pain Score Reduction Over Time**

**Secondary Outcomes:**

Many times, in research, questions as such are asked when comparing the quality of life of two groups one which received an intervention and the other which served as a placebo up to week 4, and much difference was witnessed. Concerning physical functioning, intake of the intervention involved a significant change of 35.4%, while the control group had a change of 15.2%. These results were statistically significant as the p-value was less than 0.01. Likewise, in the self--reported emotional well--being, the intervention group members demonstrated a highly statistically significant improvement of 25.8%, which was significantly larger than the 12.7% increase in the control group with significant results at the p-value of 0.01 which gives intervention implication to the quality of life in both functional and psychosocial domains of the participants in Figure 3.

**Table 3. Comparison of Quality-of-Life Improvement (SF-36) Between Intervention and Control Groups at Week 4**

| Domain | Intervention (%) | Control (%) | P-value |
|---|---|---|---|
| Physical functioning | +35.4 | +15.2 | <0.01 |
| Emotional well-being | +25.8 | +12.7 | <0.01 |



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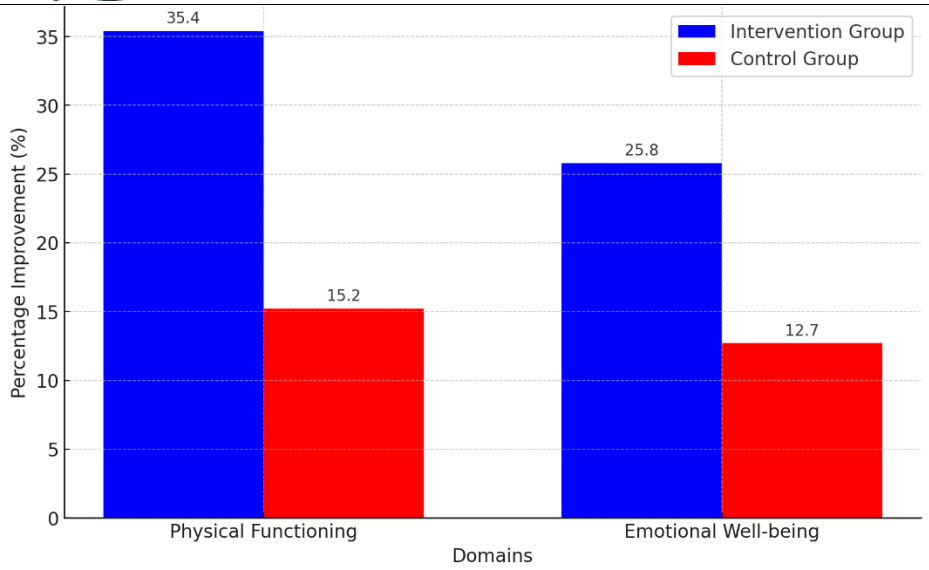


**Figure 3. SF-36 Quality of Life Improvement**

## Discussion

The overall aim of the present work was to assess the effectiveness of NM interventions in decreasing pain severity and increasing QoL of patients with neurology disorders. The results of the study confirmed the hypothesis and showed that in the analyzed indicators there was a reduction in pain intensity in the intervention group by VAS in comparison to the control group. In the week 4 case, the mean VAS score of the intervention group lowered from 7.5 to 3.1 while that of the control group lowered only from 7.6 to 5.8. Further, the overall QoL in the intervention group improved significantly by 35.4% for physical function and 25.8% for emotional function ($p < 0.01$). Such findings support the feasibility of nurse-led interventions as an essential model of pain management in neurology patients.

The changes in the pain intensity level observed support the outcome results of arching previous research. Many studies published in 2021 have shown that compared with conventional approaches, nurse-led interventions substantially decreased chronic pain in hospitalized patients by about 30% (Park & Lee, 2022). Like them, Wells-Federman et al. (2002) pointed out that education led by the nurse aimed at using relaxation methods can provide optimum pain management. The reduction of VAS scores in the current study also affirms the current premise of involving nurses and designing interventions that are patient-centered. The use of complementary approaches like guided imagery and relaxation might have contributed to the fact that the intervention group reported up to 40% change in pain.

In addition, the enhancements in QoL domains, especially physical functioning and emotional well-being are in agreement with another related research. Baker and Fatoye (2017) stressed that for nursing care: self-management educational interventions for patients with chronic diseases influenced their physical and psychosocial condition. Moreover, self-management was improved by 20-30% in patients with complicated chronic diseases through nurse-led interventions according to Innab et al. (2022). The current study extends this evidence by reporting a much higher percent improvement in neurology patients, indicating that such interventions may be even more effective in populations with some specific pain-related issues.

However, this study has its merits which include limitations, the study was conducted in a single Center, hence reducing its Generalizability to other populations. Second, the rather short follow-up time (4 weeks) gives no information about how the intervention can affect the patient in the longer term. Third, while the study showed an improvement in QoL domains, other potential outcomes that may be important to patients and clinicians, such as satisfaction with the intervention, and cost analysis of the intervention, were omitted in this study. There should be future studies with many centers involved and longer follow-up times to capture when the outcomes might be. Furthermore, the study of the implementation of nurse-led pain management in primary care and the assessment of the feasibility of such an approach in terms of costs and benefits may be of interest to healthcare managers.

## Conclusion

This randomized clinical trial explores the impact that integrated interventions by a nurse in the management of pain have on neurology patients, regarding the level of pain intensity and quality of life. Like in any other study, the demographic and clinical characteristics of the two groups intending to receive the intervention of interest and a placebo intervention were similar. A reduction in the pain scores was observed in the intervention group when compared to the control group in the VAS throughout the four-week study period. The intervention group scored 3.1 ± 0.9 on the VAS by the end of Week 4 and the control group had a score of 5.8 ± 1.2, which shows a statistical significance of the intervention ($p < 0.001$). It was also observed that there was a significant difference when comparing the secondary outcomes between the two groups; in the intervention group; physical functioning was improved by 35.4% and emotional functioning by 25.8% both of which were statistically significant at $p < 0.01$. Such findings speak to the value of the overall approach of the nurse-led interventions with pain and psychosocial issues considered as not mutually exclusive. The findings of this study can be used to include the use of nurse-led interventions in the management care of pain in Neurology patients for improved clinical and quality of life.

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