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# Effectiveness of a Nurse-Led Home Care Package for Caregivers of Children with Hydrocephalus: A Randomized Controlled Trial Running Title: Nurse-Led Home Care in Pediatric Hydrocephalus

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# Abstract

### Objectives

Hydrocephalus is characterized by abnormal cerebrospinal fluid accumulation, resulting in increased intracranial pressure and neurological complications. Children require long-term care and monitoring for shunt malfunction and infection. Caregivers often experience psychological distress and inadequate knowledge and skills. This study evaluated the effectiveness of a nurse-led home care package on hospitalization, complications, psychological status, quality of life, and caregiving skills.

### Methods

A randomized controlled trial was conducted among 60 caregivers of children with hydrocephalus attending the Pediatric Surgery units of PGIMER, Chandigarh. Caregivers were randomized into control (n = 30) and experimental (n = 30) groups using block randomization. Psychological status was assessed using DASS-21, quality of life using WHOQOL-BREF, and caregiving skills using an observational checklist. The experimental group received a nurse-led home care package. Outcomes were assessed after 45 days.

### Results

The mean age of children was 11.58 ± 13.00 months in the control group and 21.35 ± 36.74 months in the experimental group. Most children had congenital hydrocephalus (93.3% and 96.7%, respectively). The experimental group showed lower hospitalization (6.7% vs. 10%) and fewer complications, although the differences were not statistically significant ($p > 0.05$). Anxiety [median 9.5 (5–14) vs. 14 (11–16); $p = 0.034$] and stress [median 14 (11.5–16) vs. 16 (14–18); $p < 0.001$] were significantly reduced. Competent caregiving skills increased from 6.7% to 73.3%, and quality of life improved significantly in the physical, psychological, and environmental domains.

### Conclusion

The nurse-led home care package significantly improved caregivers' psychological status, quality of life, and caregiving skills. Although hospitalization and complications were reduced, the differences were not statistically significant.

### Trial Registration

Clinical Trials Registry–India (CTRI)


# Introduction

Hydrocephalus is a neurological disorder characterized by abnormal accumulation of cerebrospinal fluid (CSF) within the ventricular system due to an imbalance between CSF production, circulation, and absorption, resulting in ventricular dilatation and increased intracranial pressure. It is broadly classified

as congenital or acquired and further categorized into obstructive and communicating hydrocephalus according to the underlying mechanism of CSF flow disturbance. If left untreated, hydrocephalus may lead to progressive neurological impairment, developmental delay, and long-term disability.[1]

Clinical manifestations vary according to the child's age and severity of the disease. Infants commonly present with rapidly increasing head circumference, bulging anterior fontanelle, vomiting, poor feeding, irritability, seizures, developmental delay, and the characteristic "sun-setting" sign. Older children may present with headache, nausea, vomiting, visual disturbances, gait abnormalities, cognitive decline, and other features of raised intracranial pressure. Diagnosis relies on clinical assessment, serial head circumference measurement, neurological examination, and neuroimaging, including cranial ultrasonography, computed tomography, and magnetic resonance imaging. Ventriculoperitoneal shunt placement remains the standard treatment, while endoscopic third ventriculostomy with or without choroid plexus cauterization is an alternative for selected patients.[2]

Despite advances in surgical management, children remain at risk of shunt malfunction, infection, recurrent hospitalization, and neurological complications, necessitating lifelong monitoring and follow-up. Nurses play a pivotal role in early identification of complications, perioperative management, caregiver education, neurological assessment, and discharge planning. Comprehensive home care, including shunt care, head circumference monitoring, recognition of warning signs, medication adherence, infection prevention, developmental stimulation, and regular follow-up, is essential for improving long-term outcomes and quality of life.[3]

Caregivers are primarily responsible for providing continuous home-based care but often experience inadequate knowledge, limited caregiving skills, and psychological distress, which may adversely affect the child's recovery and increase the risk of preventable complications. Therefore, strengthening caregiver competence through structured nurse-led educational interventions is essential. However, evidence regarding the effectiveness of nurse-led home care interventions for caregivers of children with hydrocephalus remains limited. Hence, the present study was undertaken to evaluate the effectiveness of a nurse-led home care package for caregivers of children with hydrocephalus on selected child and caregiver outcomes.[4]

## Materials and Methods

# Study Design and Setting

A randomized controlled trial (RCT) with a parallel-group design was conducted to evaluate the effectiveness of a nurse-led home care package for caregivers of children with hydrocephalus. The study was carried out in the Pediatric Surgery Units (wards and outpatient department) of A tertiary care teaching hospital in North India,, between July and September 2025.

## Participants

The study included caregivers of children (newborn to 12 years) diagnosed with hydrocephalus attending the Pediatric Surgery Units of A tertiary care teaching hospital in North India,. Caregivers who were willing to participate, able to understand Hindi or Punjabi, and available for follow-up assessment were included. Caregivers of critically ill children with hydrocephalus and those unwilling to participate were excluded.

## Sample Size and Sampling

A total of 60 caregivers were enrolled based on feasibility and participant availability. Approximately 30–40 children with hydrocephalus attend the Pediatric Surgery Units each month; therefore, a feasible sample of 60 caregivers was considered adequate for the present trial. Participants were allocated equally to the experimental (n = 30) and control (n = 30) groups.

## Randomization and Allocation

Eligible participants were randomly assigned to either the experimental or control group using fixed block randomization with a block size of four to ensure balanced allocation throughout recruitment. Six possible allocation sequences (EECC, ECEC, ECCE, CEEC, CECE, and CCEE) were generated before participant enrollment. Fifteen blocks were used to allocate all 60 participants. Participants were enrolled consecutively and assigned according to the predetermined allocation sequence.

## Intervention

Caregivers in the experimental group received a structured nurse-led home care package in addition to routine hospital care. The intervention was developed through an extensive review of current literature, consultation with experts in pediatric surgery, neurosurgery, pediatric nursing, and nursing research, and the investigator's clinical experience. The package included individualized teaching sessions, demonstration and return demonstration, an illustrated educational booklet, and follow-up reinforcement through telephone calls.

The educational content covered hydrocephalus and VP shunt care, head circumference measurement, recognition of early warning signs and shunt-related complications, infection prevention, medication adherence, positioning techniques, nutritional care, developmental support, and follow-up recommendations. Caregivers in the control group received routine hospital care and the standard discharge education provided by the treating team.

# Outcome Measures

Baseline socio-demographic and clinical characteristics of children and caregivers were collected using self-structured data collection forms. The primary caregiver outcomes included psychological status,

quality of life, and caregiving skills, whereas child-related outcomes included the frequency of hospitalization and incidence of hydrocephalus-related complications during the 45-day follow-up period.

Psychological status was assessed using the Depression Anxiety Stress Scale-21 (DASS-21), a standardized self-report instrument comprising 21 items distributed across three subscales: depression, anxiety, and stress. Each item is scored on a four-point Likert scale, with higher scores indicating greater emotional distress. The DASS-21 has demonstrated excellent psychometric properties, with reported Cronbach's alpha coefficients of 0.91 for depression, 0.84 for anxiety, and 0.90 for stress.[5]

Caregivers' quality of life was assessed using the World Health Organization Quality of Life-BREF (WHOQOL-BREF) questionnaire. The instrument consists of 26 items covering four domains: physical health, psychological health, social relationships, and environmental health. Domain scores were transformed according to the WHO scoring guidelines, with higher scores indicating better perceived quality of life. Reported Cronbach's alpha coefficients range from 0.68 to 0.82 across domains.[6]

Caregiving skills were evaluated using a 24-item observational checklist developed by the investigator to objectively assess essential home care practices for children with hydrocephalus. The checklist included positioning techniques, head circumference measurement, ventriculoperitoneal shunt care, identification of early warning signs, wound care, hygiene practices, medication administration, and follow-up care. Each correctly performed step was scored as one and incorrectly performed or omitted steps were scored as zero, yielding a total score ranging from 0 to 24. Caregiving competency was categorized as competent (21–24), satisfactory (17–20), needs improvement (13–16), and incompetent (≤ 12).

The incidence of complications and frequency of hospitalization were assessed using a self-structured checklist developed specifically for the study. Complications monitored during the 45-day follow-up included vomiting, irritability, lethargy, seizures, rapid head enlargement, sun-setting sign, strabismus, shunt-site redness or swelling, shunt-site discharge, fever, abdominal pain or swelling, altered responsiveness, speech delay, motor developmental delay, and signs of shunt obstruction.

## Validity and Reliability

The self-developed research tools and nurse-led home care package underwent content validation using the Delphi technique. A panel of seven experts from pediatric surgery, neurosurgery, pediatric nursing, and nursing research independently evaluated the relevance, clarity, and comprehensiveness of each item using a four-point relevance scale. Items with a Content Validity Index (CVI) of ≥ 0.80 were retained following expert review. The overall Scale Content Validity Index (S-CVI) of the intervention package was 0.90, indicating excellent content validity.

The observational checklist demonstrated good content validity (CVI = 0.91) and internal consistency reliability (Cronbach's α = 0.86). The incidence of complications checklist demonstrated satisfactory content validity (CVI = 0.89), with reliability coefficients of 0.82 for the complications section and 0.84 for

the hospitalization section. Standardized instruments (DASS-21 and WHOQOL-BREF) demonstrated acceptable reliability in previous validation studies.[5–7]

## Pilot Study

A pilot study was conducted in June 2025 at the Pediatric Surgery Units (wards and outpatient department), to assess the feasibility and practicability of the study protocol. Approximately 10% of the total sample (n = 6) was included. The pilot study evaluated participant recruitment, data collection procedures, randomization, implementation of the nurse-led home care package, and suitability of the research tools. The findings confirmed that the study procedures were feasible and no major modifications to the intervention or data collection tools were required before the main study.

# Ethical Considerations

**Ethical approval**

was obtained from the Institutional Ethics Committee of the Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, before commencement of the study. Administrative permission was obtained from the concerned departments, and the study was registered with the Clinical Trials Registry–India (CTRI). Written informed consent was obtained from all caregivers before enrollment, and assent was obtained from children whenever applicable. Participation was voluntary, and participants were informed of their right to withdraw from the study at any stage without affecting the child's treatment. Confidentiality and anonymity of participant information were strictly maintained throughout the study.

# Data Collection Procedure

Eligible caregivers attending the Pediatric Surgery Units were screened according to the predefined inclusion and exclusion criteria. After obtaining written informed consent, baseline assessment was performed using the study instruments to collect socio-demographic and clinical information, psychological status, quality of life, caregiving skills, previous hospitalization, and hydrocephalus-related complications.

Following baseline assessment, participants were randomly allocated to the experimental or control group using fixed block randomization. Caregivers in the experimental group received the nurse-led home care package in addition to routine hospital care, whereas caregivers in the control group received routine hospital care and standard discharge education. Follow-up reinforcement was provided to caregivers in the experimental group through scheduled telephone contacts. Outcome assessment was performed 45 days after the intervention using the same standardized and self-developed assessment tools.

# Statistical Analysis

Data were entered into Microsoft Excel and analyzed using the Statistical Package for the Social Sciences (SPSS) version 26.0. Descriptive statistics, including frequency, percentage, mean, standard deviation, median, and interquartile range, were used to summarize participant characteristics and study variables. The normality of continuous variables was assessed before analysis. Between-group comparisons were performed using the Mann–Whitney U test for continuous variables and the Chi-square test or Fisher's exact test for categorical variables, as appropriate. Within-group comparisons between baseline and follow-up were performed using the Wilcoxon signed-rank test. A two-tailed p-value < 0.05 was considered statistically significant.

A total of 76 caregivers of children with hydrocephalus were assessed for eligibility. Sixteen participants were excluded (14 critically ill children and 2 caregivers who refused participation). The remaining 60 caregiver–child dyads were randomized equally into the experimental group (n = 30) and the control group (n = 30). Baseline assessment was completed for all participants. The experimental group received the nurse-led home care package in addition to routine care, whereas the control group received routine care only. Follow-up assessment was conducted on the 15th day, and endline assessment was completed on the 45th day. No participant was lost to follow-up, and all 60 participants were included in the final analysis (Fig. 1).

## Results

# Baseline characteristics

Table 1
Baseline demographic and clinical characteristics of children and caregivers (N = 60)

| Variable | Control (n = 30) | Experimental (n = 30) | p-value |
|---|---|---|---|
| Child age (months), Mean ± SD | 11.58 ± 13.00 | 21.35 ± 36.74 | 0.964 |
| Male sex | 50.0% | 80.0% | 0.015* |
| Congenital hydrocephalus | 93.3% | 96.7% | 0.554 |
| Previous hospitalization (> 6 months) | Comparable | Comparable | 0.039* |
| Developmental delay | 70.0% | 80.0% | 0.642 |
| Caregiver age (years), Mean ± SD | 26.13 ± 4.12 | 27.40 ± 5.58 | 0.437 |
| Female caregivers | 66.7% | 53.3% | 0.292 |
| Joint family | 96.7% | 86.7% | 0.161 |
| Rural residence | 76.7% | 70.0% | 0.740 |
| Socioeconomic status | Comparable | Comparable | 0.025* |

The baseline characteristics of children and caregivers were largely comparable between the two study groups. Most children were diagnosed with congenital hydrocephalus and had developmental delay. Mothers constituted the majority of caregivers in both groups. Significant differences were observed only in gender distribution of children and socioeconomic status of caregivers, while all other baseline variables were comparable between groups.

# Hospitalization and complications

Table 2
Hospitalization and complications among children with hydrocephalus after 45 days

| Outcome | Control n (%) | Experimental n (%) | p-value |
|---|---|---|---|
| No hospitalization | 27 (90.0) | 28 (93.3) | NS |
| Hospitalized once | 3 (10.0) | 2 (6.7) | NS |
| Vomiting | 1 (3.3) | 0 | 0.313 |
| Irritability | 1 (3.3) | 0 | 0.313 |
| Rapid head enlargement | 3 (10.0) | 0 | 0.076 |
| Sunset eyes | 1 (3.3) | 0 | 0.313 |
| Shunt site redness/swelling | 1 (3.3) | 0 | 0.313 |
| Fever | 1 (3.3) | 2 (6.7) | 0.554 |
| Shunt obstruction | 2 (6.7) | 1 (3.3) | 0.554 |

At the end of the 45-day follow-up, hospitalization was slightly lower in the experimental group than in the control group. Similarly, fewer complications such as vomiting, irritability, rapid head enlargement, sunset eyes, and shunt-site infection were observed among children receiving the nurse-led intervention. However, none of these differences reached statistical significance ($p > 0.05$).

Table 3
Comparison of DASS-21 scores between the control and experimental groups at baseline and endline (N = 60)

| Domain | Baseline Median (IQR) Control | Baseline Median (IQR) Experimental | p-value | Endline Median (IQR) Control | Endline Median (IQR) Experimental | p-value |
|---|---|---|---|---|---|---|
| Depression | 20 (18–24) | 22 (20–24) | 0.326 | 19 (16–22) | 16 (13.5–20) | 0.200 |
| Anxiety | 14 (12–18) | 14 (12–18) | 0.811 | 14 (11–16) | 12 (9.5–14) | 0.034* |
| Stress | 18 (16–22) | 18 (15.5–20) | 0.344 | 16 (14–18) | 14 (11.5–16) | < 0.001* |
| Intragroup comparison (Wilcoxon signed-rank test) | | | | | | |
| Domain | | | Control p-value | | Experimental p-value | |
| Depression | | | 0.025* | | < 0.001* | |
| Anxiety | | | 0.004* | | < 0.001* | |
| Stress | | | 0.007* | | < 0.001* | |

At baseline, depression, anxiety, and stress scores were comparable between the control and experimental groups ($p > 0.05$). At the endline assessment, caregivers in the experimental group demonstrated significantly lower anxiety ($p = 0.034$) and stress ($p < 0.001$) scores than those in the control group, whereas the reduction in depression was not statistically significant ($p = 0.200$). Within-group analysis showed significant reductions in all three DASS-21 domains in both groups; however, the magnitude of improvement was greater in the experimental group, indicating the beneficial effect of the nurse-led home care package.

Table 4
Comparison of WHOQOL-BREF scores between the control and experimental groups at baseline and endline (N = 60)

| **Domain** | **baseline p-value** | **Endline p-value** |
|---|---|---|
| Physical | 0.114 | 0.732 |
| Psychological | 0.027* | 0.281 |
| Social | 0.724 | 0.400 |
| Environmental | 0.010* | 0.176 |
| Intragroup comparison (Wilcoxon signed-rank test) | | |
| Domain | Control p-value | Experimental p-value |
| Physical | 0.040* | < 0.001* |
| Psychological | 0.026* | < 0.001* |
| Social | 0.317 | 0.102 |
| Environmenta | 0.046* | < 0.001* |

Baseline WHOQOL-BREF scores showed significant differences in the psychological and environmental domains, while physical and social domains were comparable. Following the intervention, no statistically significant differences were observed between the groups in any quality-of-life domain, suggesting comparable endline scores. Within-group analysis demonstrated significant improvements in physical, psychological, and environmental domains in the experimental group, whereas the social domain did not improve significantly. The control group showed only modest improvements, supporting the effectiveness of the nurse-led home care package in enhancing caregivers' quality of life.

Table 5
Comparison of caregiver skill levels at baseline and endline (N = 60)

| **Skill level** | **Control Baseline** | **Control Endline** | **Experimental Baseline** | **Experimental Endline** |
|---|---|---|---|---|
| Competent | 3.3% | 10.0% | 6.7% | 73.3% |
| Satisfactory | 23.3% | 26.7% | 20.0% | 20.0% |
| Needs improvement | 50.0% | 40.0% | 46.7% | 6.7% |
| Incompetent | 23.3% | 23.3% | 26.6% | 0% |

At baseline, most caregivers in both groups required improvement in caregiving skills. After 45 days, only minimal changes were observed in the control group. In contrast, caregivers in the experimental group demonstrated marked improvement, with the proportion of competent caregivers increasing from 6.7% to 73.3%, while those requiring improvement declined from 46.7% to 6.7%. No caregiver in the

experimental group remained in the incompetent category at the endline, demonstrating the effectiveness of the nurse-led home care package in improving practical caregiving skills.

## Discussion

# Socio-demographic Profile of Children with Hydrocephalus

Most children in both groups were aged 0–11 months (66.7%). The mean age was 11.58 ± 13.00 months in the control group and 21.35 ± 36.74 months in the experimental group, indicating that hydrocephalus was more common during infancy. Similar findings were reported by Dewan MC et al. (2018)[8] and Isaacs AM et al. (2018).[9]

Gender distribution was equal in the control group, whereas males predominated in the experimental group (80%), with a statistically significant difference ($\chi^2$=5.934, p = 0.015). This finding is consistent with Dewan MC et al. (2018), who also reported a slight male predominance among children with hydrocephalus.

# Clinical Profile of Children with Hydrocephalus

Most children had congenital hydrocephalus (93.3% in the control group and 96.7% in the experimental group), with no significant difference between the groups (p = 0.554). Similar findings were reported by Isaacs AM et al.[9] (2018), indicating that congenital hydrocephalus is the most common type in children.

Most children were diagnosed within 0–11 months of age. The mean age at diagnosis was 4.30 ± 7.34 months in the control group and 7.27 ± 23.68 months in the experimental group.

Regarding hospitalization in the previous six months, significant differences were observed between the groups ($\chi^2$=6.387, p = 0.039). Similar findings were reported by Vinchon M et al. (2018)[10] and Simon TD et al. (2018)[11], who documented frequent hospital admissions among children with hydrocephalus due to shunt-related complications.

Most children had delayed developmental milestones in both groups, although the difference was not statistically significant (p = 0.642). This finding is consistent with Stone SS et al. (2017),[12] who reported developmental delay in children with hydrocephalus despite surgical treatment.

# Socio-demographic Profile of Caregivers of Children with Hydrocephalus

Most caregivers were mothers (66.7% in the control group and 53.3% in the experimental group), which is consistent with Okoronkwo I et al. (2021),[13] who reported that mothers are the primary caregivers of children with neurological disorders.

Most caregivers belonged to the 20–30 years age group, with mean ages of 26.13 ± 4.12 years and 27.40 ± 5.58 years in the control and experimental groups, respectively. Similar findings were reported by Malekani F et al. (2023).[14]

Female caregivers predominated in both groups, consistent with Okoronkwo I et al. (2021). Most caregivers belonged to the Hindu religion, had completed higher secondary education, were unemployed, and resided in rural areas, with no significant differences between groups. However, socioeconomic status differed significantly ($\chi^2$=10.808, p = 0.025), with most caregivers belonging to the middle and lower-middle classes.

# Frequency of Hospitalization among Children with Hydrocephalus

Most children remained free from hospitalization during the follow-up period (90% in the control group and 93.3% in the experimental group). Zimmerman RA et al. (2020)[15] also reported that effective home care and monitoring may reduce hospital admissions among children with hydrocephalus.

Incidence of Complications among Children with Hydrocephalus

Children in the control group experienced complications such as rapid head enlargement, vomiting, irritability, and sunset eyes, whereas only minimal complications were observed in the experimental group. Similar findings were reported by Vinchon M et al. (2018), highlighting the importance of early identification of complications and caregiver education.

# Psychological Outcomes (DASS-21)

The present study demonstrated significant reductions in anxiety (p = 0.034) and stress (p < 0.001) among caregivers in the experimental group, while the reduction in depression was not statistically significant. These findings are consistent with Alhassan A et al. (2022),[16] who reported that structured interventions improve caregivers' psychological well-being.

# Quality of Life of Caregivers of Children with Hydrocephalus

Quality of life improved in both groups; however, significant intragroup improvement was observed in the experimental group in the physical, psychological, and environmental domains. Similar findings were reported by Bawa M et al. (2017),[17] Zimmerman RA et al. (2020), who reported that caregiver education and support improve quality of life.

# Caregiving Skills of Caregivers of Children with Hydrocephalus

Caregiving skills improved markedly in the experimental group, with competent caregivers increasing from 6.7% to 73.3%, while no caregiver remained in the incompetent category. Similar improvements were reported by Keklik B et al. (2025),[18] and Tavares M et al. (2020),[19] demonstrating the effectiveness of structured educational interventions in improving caregiver skills.

## Conclusion

The present randomized controlled trial demonstrated that the nurse-led home care package was effective in improving caregivers' psychological well-being, quality of life, and practical caregiving skills. Caregivers who received the intervention showed significantly greater reductions in anxiety and stress, significant improvements in the physical, psychological, and environmental domains of quality of life, and substantial enhancement of caregiving skills compared with those receiving routine care alone. Although lower rates of hospitalization and hydrocephalus-related complications were observed among children in the experimental group, these differences were not statistically significant, possibly because of the relatively short follow-up period and limited sample size.

Overall, the findings support the integration of structured nurse-led caregiver education into routine pediatric neurosurgical practice. Strengthening caregiver competence through evidence-based educational interventions may improve home-based management, facilitate early recognition of complications, enhance adherence to follow-up, and ultimately contribute to better health outcomes for children with hydrocephalus. Further multicenter studies with larger sample sizes and longer follow-up are recommended to confirm these findings and evaluate the long-term effectiveness of the intervention.

## Declarations

# Ethics Approval

The study was approved by the Institutional Ethics Committee (Intramural), Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, India.

# Author Contribution

1.Suman PokhriyaConceptualization; Methodology; Investigation; Data curation; Formal analysis; Visualization; Writing – original draft; Writing – review & editing2. Dr. MonalizaConceptualization; Methodology; Supervision; Validation; Project administration; Writing – review & editing3. Dr. Jai Kumar MahajanResources; Supervision; Validation; Writing – review & editing4. Mrs. Anupama ChoudharyMethodology; Supervision; Validation; Writing – review & editing

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# Figures

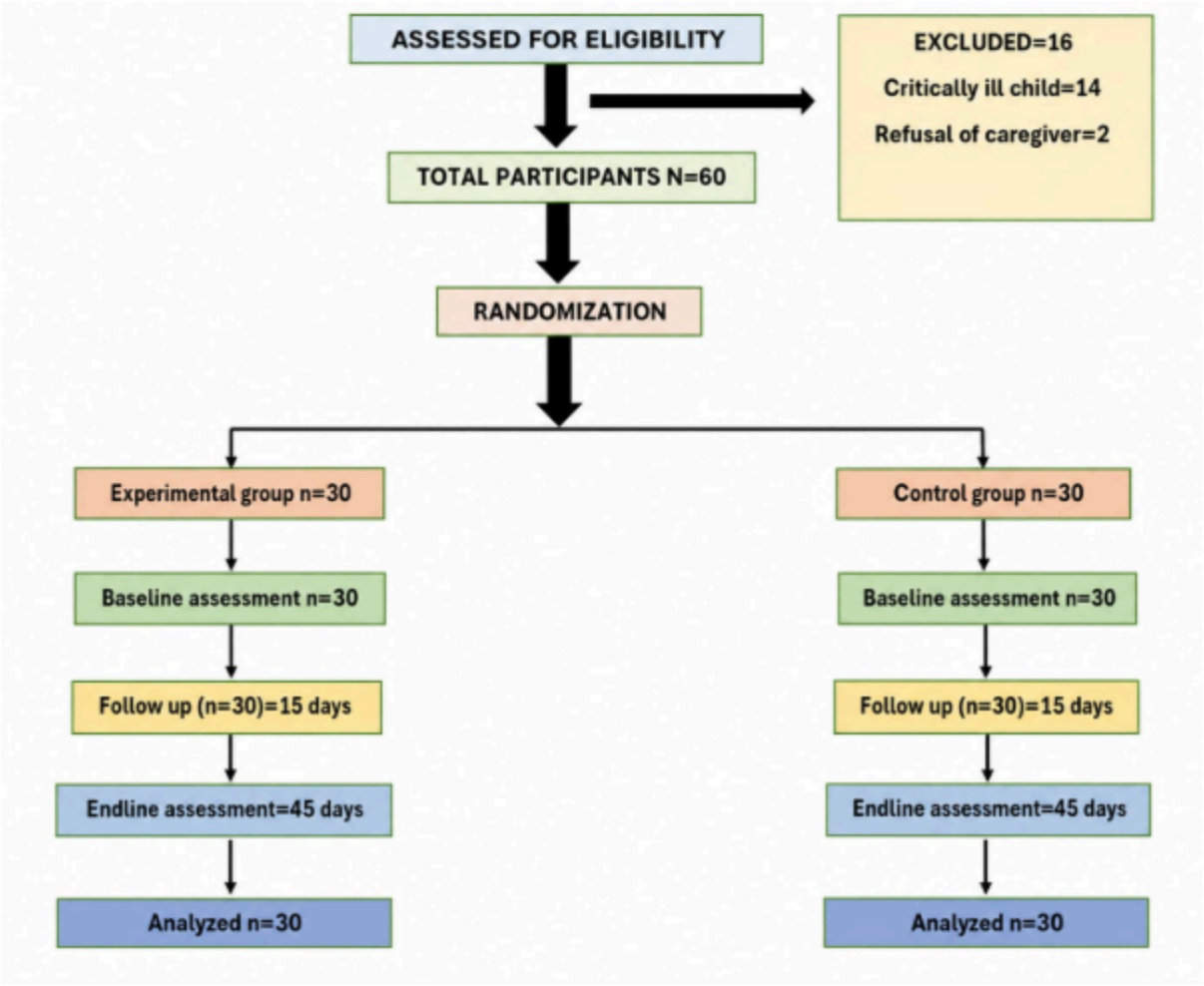



**Figure 1**

**Consort Flow Diagram**

# Supplementary Files

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