

Efficacy of Psychological Intervention in Children with Cancer: A Randomized Controlled Trial (RCT)

14-August-2024

SUMMARY OF PROCEDURES & STATISTICAL ANALYSIS PLAN

1. The study will be conducted at the Pediatric Oncology Unit of the Children's Hospital, PIMS Islamabad.
2. The study will involve 80 children aged 8-13 years who have been diagnosed with malignancies and are receiving chemotherapy.
3. Newly diagnosed pediatric cancer patients aged 8-13 years
4. Children must be receiving chemotherapy as part of their treatment plan.
5. Ability to participate in CBT sessions and complete assessment scales.
6. Single-blinded, two-arm randomized controlled trial (RCT).
7. **Experimental Group:** Receives five weekly sessions of Cognitive Behavioral Therapy (CBT).
8. **Control Group:** Receives usual care (UC), which includes standard medical and psychological support provided by the oncology unit.
9. Potential participants are identified by the oncology healthcare team at the time of cancer diagnosis.
10. Parents or guardians of eligible children are approached for consent, and assent is obtained from the children.
11. Randomization occurs immediately after enrollment.
12. Participants are randomly assigned to either the experimental group (CBT) or the control group (UC).
13. Randomization is conducted using a computer-generated random number sequence to ensure unbiased allocation.

14. **Allocation Concealment:** Allocation is concealed from the participants and the healthcare providers administering the usual care to minimize bias. However, the psychologist administering CBT cannot be blinded to group allocation.
15. Baseline assessments are conducted **immediately after randomization** and before any intervention begins.
16. Revised Child Anxiety and Depression Scale (RCADS): Used to assess levels of anxiety and depression in the children.
17. Pediatric Quality of Life Inventory (PedsQL) Generic Core Score 4.0: Used to assess the quality of life.
18. A trained psychologist or researcher administers the scales to the children.
19. The baseline assessment data provide a reference point for comparing post-intervention outcomes.
20. The CBT intervention begins immediately after the baseline assessment for those in the experimental group.
21. The CBT consists of five weekly sessions.
22. Duration: Each session lasts 30-35 minutes.
23. Content: The sessions focus on cognitive restructuring, relaxation techniques, coping strategies, and problem-solving skills tailored to the child's age and psychological needs.
24. Control Group: Children in the control group continue to receive usual care without any additional psychological intervention.
25. The endline assessment is conducted **one month after the completion of the CBT intervention**.

26. For participants in the experimental group, this is typically six weeks after baseline (allowing for five weeks of intervention and one-week post-intervention).
27. The same timeline applies to the control group, with the endline assessment conducted at a comparable time point.
28. The same trained psychologist or researcher who conducted the baseline assessment will administer the endline assessments to ensure consistency.
29. The primary outcomes (anxiety, depression, and quality of life) will be compared between the experimental and control groups using statistical methods appropriate for RCTs (e.g., ANCOVA adjusting for baseline values).
30. The analysis will determine whether the CBT intervention significantly reduces anxiety and depression and improves quality of life compared to usual care.

Variables Typically Collected in an RCT for CBT Intervention in Pediatric Oncology Patients

1. Demographic and Baseline Characteristics:

- **Age:** Continuous variable (years).
- **Gender:** Categorical variable (Male, Female).
- **Type of Malignancy:** Categorical variable (e.g., Leukemia, Lymphoma, Solid Tumor).
- **Stage of Cancer:** Categorical variable (e.g., Early, Intermediate, Advanced).
- **Baseline Anxiety Score:** Continuous variable, measured by RCADS.
- **Baseline Depression Score:** Continuous variable, measured by RCADS.
- **Baseline Quality of Life (QoL) Score:** Continuous variable, measured by PedsQL.

2. Intervention-Related Variables:

- **Group Assignment:** Categorical variable (CBT Intervention, Usual Care).
- **Attendance of CBT Sessions:** Categorical variable (Number of sessions attended).
- **Adherence to Usual Care:** Categorical variable (Yes, No).

3. Outcome Variables:

- **Post-Intervention Anxiety Score:** Continuous variable, measured by RCADS.
- **Post-Intervention Depression Score:** Continuous variable, measured by RCADS.
- **Post-Intervention Quality of Life (QoL) Score:** Continuous variable, measured by PedsQL.

4. Additional Variables:

- **Dropout Rate:** Categorical variable (Yes, No).
- **Adverse Events:** Categorical variable (None, Mild, Moderate, Severe).

Baseline Characteristics Table:

| Variable | CBT Group (n=40) | Usual Care Group (n=40) | p- value |
|--|-----------------------------|------------------------------------|---------------------|
| Age (years, mean \pm SD) | | | |
| Gender, n (%) | | | |
| Male | | | |
| -Female | | | |
| Type of Malignancy, n (%) | | | |
| - Leukemia | | | |
| - Lymphoma | | | |
| - Solid Tumor | | | |
| Stage of Cancer, n (%) | | | |
| - Early | | | |
| - Intermediate | | | |
| - Advanced | | | |
| Baseline Anxiety Score | | | |
| Baseline Depression Score | | | |
| Baseline QoL Score | | | |

Post-Intervention Outcome Table:

| Outcome | CBT Group (n=40) | Usual Care Group (n=40) | p- value |
|---|-----------------------------|------------------------------------|---------------------|
| Post-Intervention Anxiety Score | | | |
| Post-Intervention Depression Score | | | |
| Post-Intervention QoL Score | | | |
| Dropout Rate, n (%) | | | |
| Adverse Events, n (%) | | | |
| - None | | | |
| - Mild | | | |
| - Moderate | | | |
| - Severe | | | |

3. Adherence and Session Attendance Table (for CBT Group Only)

| Variable | CBT Group (n=40) | Usual Care Group (n=40) |
|-----------------|-----------------------------|------------------------------------|
| | | |

| | | |
|---|--|--|
| Attendance of CBT Sessions (mean ± SD) | | |
| Adherence to Usual Care, n (%) | | |