SHIFA-PC-RCT Statistical Analysis Plan v1.0

Structured Help for Families in Illness and Focused Assistance in Palliative Care: A Randomized Controlled Trial (SHIFA-PC-RCT)

Document	Statistical Analysis Plan
Version	1.0
Status	Pre-recruitment
Recruitment status at SAP creation	Not started

Study Title

Structured Help for Families in Illness and Focused Assistance in Palliative Care: A Randomized Controlled Trial (SHIFA-PC-RCT)

SAP Version

Version: 1.0

Status: Pre-recruitment

Recruitment status at SAP creation: Not started

Purpose

This Statistical Analysis Plan defines the planned analysis for SHIFA-PC-RCT before recruitment begins.

This SAP does not change the approved protocol, questionnaire, consent form, outcomes, sample size, intervention, control arm, or follow-up schedule.

Study Design

Single-centre, parallel-group randomized controlled trial.

Study Arms

Arm	Description	Planned Number
Intervention	Structured SHIFA-PC family education sessions	10 families
Control	Standard verbal counselling during routine care	10 families
Total		20 families

Randomization

Participants will be randomized in a 1:1 ratio using block randomization with variable block sizes of 4 and 6.

Allocation will be restricted and revealed only after:

1. Eligibility is confirmed.
2. Informed consent is completed.
3. Study ID is assigned.
4. Baseline assessment is completed.

Approved Assessment Timepoints

Timepoint	Description
Baseline	Before intervention/randomization
Immediate follow-up	After the third education session / equivalent control follow-up point
One-month follow-up	One month after the third education session / equivalent control follow-up point

Primary Outcome

The primary quantitative outcome is change in palliative care knowledge score from baseline to immediate follow-up.

Primary Outcome Score

Knowledge score is calculated as the sum of 9 approved symptom checklist items.

Measure	Rule
Minimum score	0
Maximum score	9
Higher score means	Greater recognition of symptoms managed in palliative care

Primary Analysis

The primary analysis will compare immediate knowledge change between the intervention and control groups.

Formula:

Immediate knowledge change = Immediate knowledge score − Baseline knowledge score

Because the sample size is small, the primary analysis will be interpreted as exploratory and estimation-focused.

The planned comparison will include:

- Mean change in each group
- Median change in each group
- Between-group difference in change
- 95% confidence interval where feasible
- Non-parametric comparison if distribution is clearly non-normal
- Exact p-value where feasible

Secondary Outcomes

Secondary outcomes include:

1. One-month knowledge score and one-month knowledge change.
2. Caregiver confidence in symptom management.
3. Caregiver burden using Zarit Burden Interview.
4. Satisfaction with structured education or standard counselling.
5. Session feedback and acceptability.
6. Open-ended qualitative responses.

Secondary Analysis

One-Month Knowledge Change

Formula:

One-month knowledge change = One-month knowledge score − Baseline knowledge score

This will be compared between groups descriptively and inferentially where appropriate.

Confidence

Confidence will be analyzed using:

- Yes/No confidence response
- 1 to 5 confidence rating

Group summaries will include frequency, percentage, mean, median, and range as appropriate.

Zarit Burden Interview

Zarit total score will be calculated from 22 items, each scored 0 to 4.

Measure	Rule
Minimum total score	0
Maximum total score	88
Higher score means	Greater caregiver burden

One-month burden change:

One-month Zarit total score − Baseline Zarit total score

A positive value means burden increased.

A negative value means burden decreased.

Satisfaction

Satisfaction items will be summarized descriptively.

Where identical satisfaction ratings exist across arms, between-group comparisons may be performed cautiously.

Arm-specific satisfaction items will not be overinterpreted as direct between-group comparisons.

Open-Ended Responses

Open-ended responses will be summarized using de-identified qualitative themes.

No identifiable quotes will be used.

Analysis Populations

Population	Definition
Intention-to-treat	All randomized participants, analyzed according to assigned group where outcome data are available
Per-protocol	Participants who completed assigned study procedures sufficiently for per-protocol assessment
Descriptive population	All consented participants with relevant process data

Baseline Characteristics

Baseline characteristics will be summarized by group.

No formal statistical testing of baseline differences will be emphasized due to small sample size.

Missing Data

Missing data will be reported transparently.

No primary imputation is planned because of small sample size.

Sensitivity analysis may be performed for Zarit scores if 1 or 2 items are missing using prorated scoring as defined in the scoring plan.

Statistical Significance

Because this is a small single-centre study, results will be interpreted with emphasis on:

- Direction of effect
- Magnitude of effect
- Confidence intervals
- Feasibility and acceptability
- Clinical relevance

P-values will be reported cautiously and not overinterpreted.

Software

Analysis may be performed using R, Python, SPSS, or equivalent validated statistical software.

The final software used should be documented before analysis.

Reporting

Final reporting should include:

- CONSORT flow diagram
- Baseline table
- Primary outcome table
- Secondary outcome table
- Missing data summary
- Protocol deviation summary
- Intervention completion/fidelity summary