A Software Tool for Planning Better Clinical Trials

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From Trial Setup to a Better Metric

Basic Setup of a Clinical Trial

In many studies, we compare two groups of patients:

- A **Treatment** group receiving a new medicine.
- A **Control** group receiving a placebo or standard care.

We then follow them over time to measure a **time-to-event** endpoint.

The Core Challenge: Study Design

Before starting, researchers must answer two critical questions:

1. **Sample Size:** "How many patients do we need for a reliable result?"
2. **Power:** "Given our patients, what is our chance of success?"

Why Traditional Methods Can Be Problematic

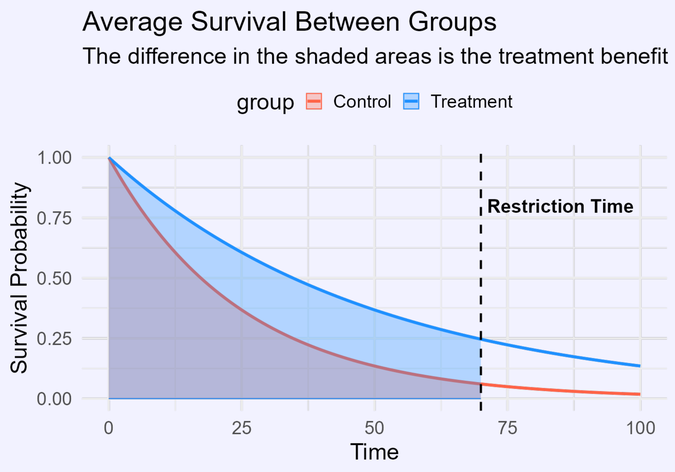
Traditional metrics like the **Hazard Ratio (HR)** rely on strong assumptions that are often violated in the real world, making results hard to interpret.

A Better Metric: RMST

Instead, we use **RMST** (Restricted Mean Survival Time). It directly measures the average "event-free" time patients experience.

✓ It is easy for everyone to understand.

✓ It provides a clear measure of treatment benefit.



Our Solution: The 'RMSTSS' Tool

Planning studies with RMST has been difficult. We made it easy. 'RMSTSS' is a free tool that helps researchers properly plan modern medical studies.

How to Use the App

The web application guides you through the process in a left-to-right flow:

Upload → Choose Model → Choose Goal → Get Results!

Features & Capabilities

- **Multiple Models:** Handles standard trials, multi-hospital studies, and more.
- **Clear Goals:** Calculate **Power** or search for the required **Sample Size**.
- **Flexible Methods:** Use a **Quick Check** (Analytical) or a **Deep Dive** (Bootstrap).

The 'RMSTSS' R Package

For statisticians and developers, 'RMSTSS' is available as a powerful and flexible R package for use in scripts and analysis pipelines.

Key Functions & When to Use Them

The package provides a suite of functions for different trial designs:

Function Group	Use Case
`linear.*()`	Standard clinical trials.
`additive.*()`	Multi-hospital trials (constant benefit).
`MS.*()`	Multi-hospital trials (proportional benefit).
`GAM.*()`	For complex, non-linear effects.
`DC.*()`	Studies with competing outcomes.

Installation Guide

Install the development version directly from GitHub:

```
remotes::install_github(
  "UTHSC-Zhang/RMSTSS-Package"
)
```

Project Website

Key References

Royston & Parmar (2013), Tian et al. (2014), Uno et al. (2014), Wang et al. (2018, 2019), Zhang & Schaubel (2012).