RMSTSS: A New Tool for Planning Better, Faster Medical Studies

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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, such as time to recovery or survival time.

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?"

Answering these questions correctly is essential for an ethical and cost-effective study.

Why Traditional Methods Can Be Problematic

For decades, clinical trials have relied on two main approaches:

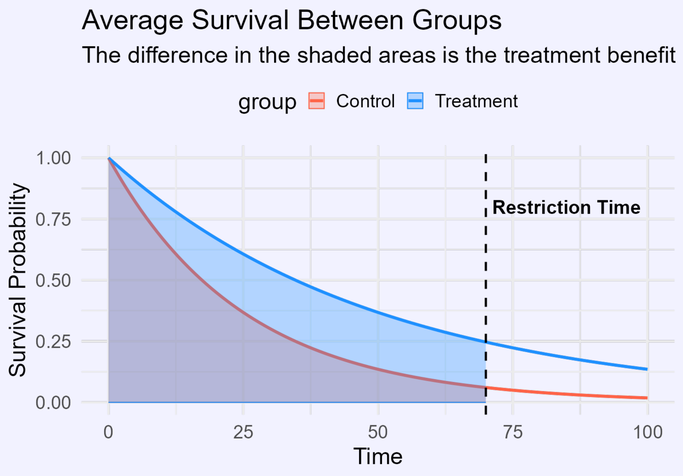
- **Hazard Ratio (HR):** This popular metric relies on a strong statistical assumption (proportional hazards) that is often violated in the real world. When this happens, the HR loses its clear meaning.
- **Direct Survival Modeling:** Comparing survival at a single point (e.g., 5-year survival) ignores the patient's journey and can be misleading.

A Better Metric: RMST

Instead of complex metrics, we can use **RMST** (Restricted Mean Survival Time). It directly measures the average "event-free" time patients experience. It is a good measure because it:

✓ Is easy for everyone to understand.

✓ 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 Data → Choose Model → Choose Target → Get Results

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:

Features & Capabilities

A Full Suite of Modern Models

Our tool handles many real-world research scenarios:

- **Linear Model**: For standard clinical trials.
- **Stratified Models**: For studies run at many different hospitals.
- **GAM Model**: For studies where factors like patient age have complex effects.
- **Dependent Censoring**: For studies with competing outcomes, like transplants.

Choose Your Goal

- **Power Calculation**: Find the chance of success for a given study size.
- **Sample Size Search**: Find how many patients you need to succeed.

Choose Your Method

- **Quick Check (Analytical)**: A fast answer for exploring ideas.
- **Deep Dive (Bootstrap)**: A powerful simulation for a more accurate result. Our tool can run these simulations in parallel to be faster!

Function Group & Use Case	
`linear.*()`	& Standard clinical trials with linear effects.
`additive.*()`	& Multi-hospital trials with a constant treatment benefit.
`MS.*()`	& Multi-hospital trials with a proportional treatment benefit.
`GAM.*()`	& When factors like patient age may have complex, non-linear effects.
`DC.*()`	& Studies with competing outcomes, such as organ transplants.

Installation Guide

Install the development version directly from GitHub with this command:

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

Access Links