

# A Software Tool for Planning Better Clinical Trials

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## The Challenge & A Better Metric

### The Challenge of Trial Design

Researchers must answer two key questions for an ethical and cost-effective study.

- How many patients do we need? (Sample Size) and
- What accuracy can be achieved for a given cohort? (Power).

In survival studies, we then follow the individuals over time to measure a **time-to-event** endpoint.

### 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.

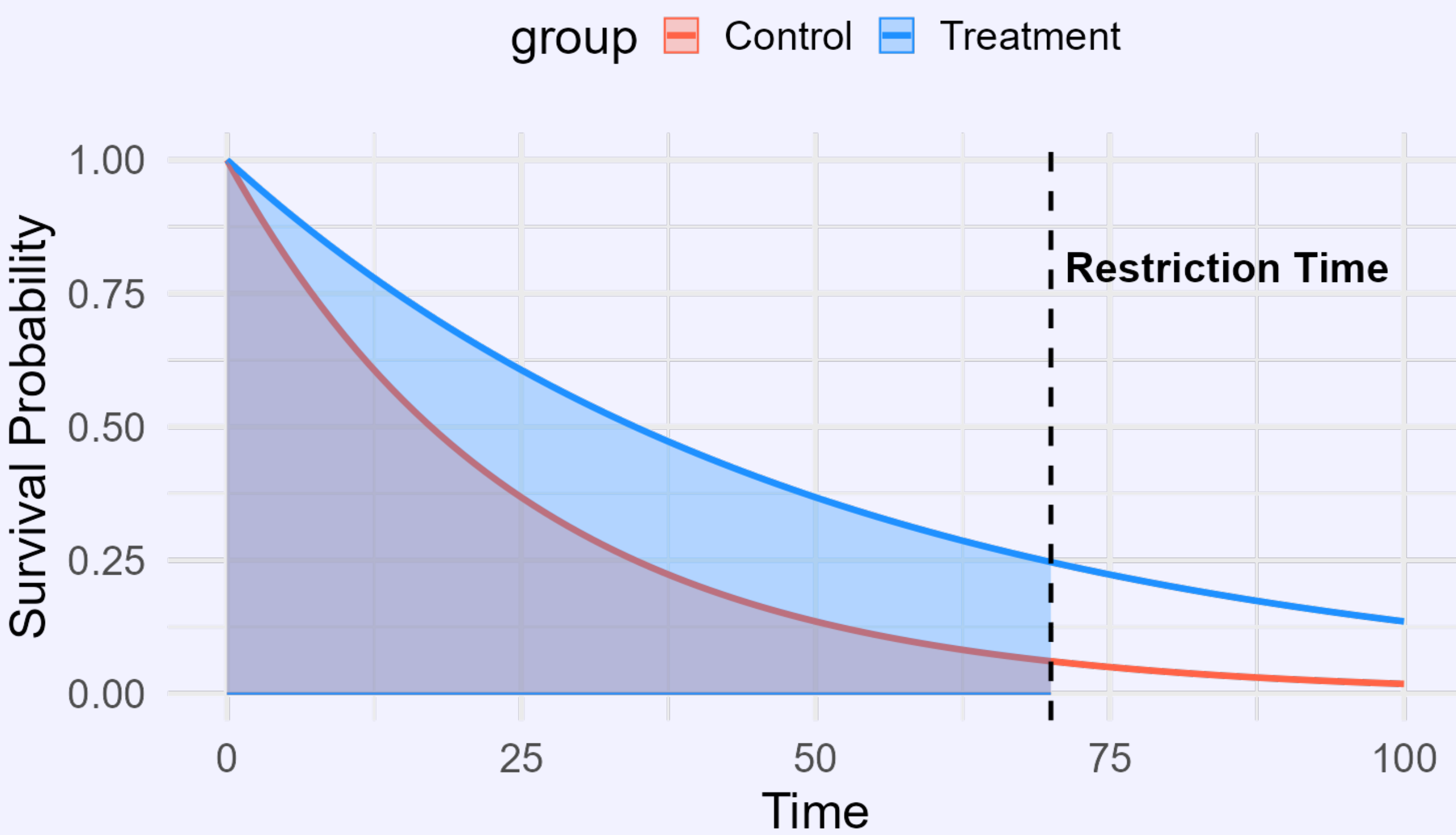
### A Better Metric: RMST

We use **RMST** (Restricted Mean Survival Time). It directly measures the average “event-free” time.

- ✓ It’s easy for everyone to understand.
- ✓ It provides a clear measure of treatment benefit.

#### Average Survival Between Groups

The difference in the shaded areas is the treatment benefit



RMST difference provides causal interpretation which hazard ratios failed to provide.

## 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 app guides you through a simple left-to-right flow:

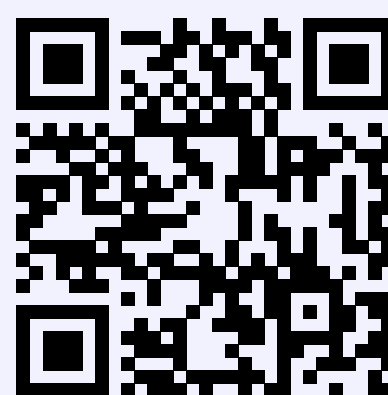
**Upload → Model → Target Quantity → Results!**

The app allows you to prepare a downloadable report with all the analysis results and console outputs.

### App Features

- **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).

## App Website



## The ‘RMSTSS’ R Package

For statisticians and developers, ‘RMSTSS’ is a powerful 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
<code>linear.*()</code>	Standard clinical trials.
<code>additive.*()</code>	Multi-hospital trials (constant benefit).
<code>MS.*()</code>	Multi-hospital trials (proportional benefit).
<code>GAM.*()</code>	For complex, non-linear effects.
<code>DC.*()</code>	Studies with competing outcomes.

## Installation and Usage Guide

Install directly from GitHub:

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

After installing the package the app can be used in local machine using the following code.

```
RMSTSS::run_app()
```

## Project Website

