Reproducing a Randomised Controlled Trial

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Contents

1

Introduction

2

Data analysis in the workspace

R scripts
Built-in tools
ShinyApp

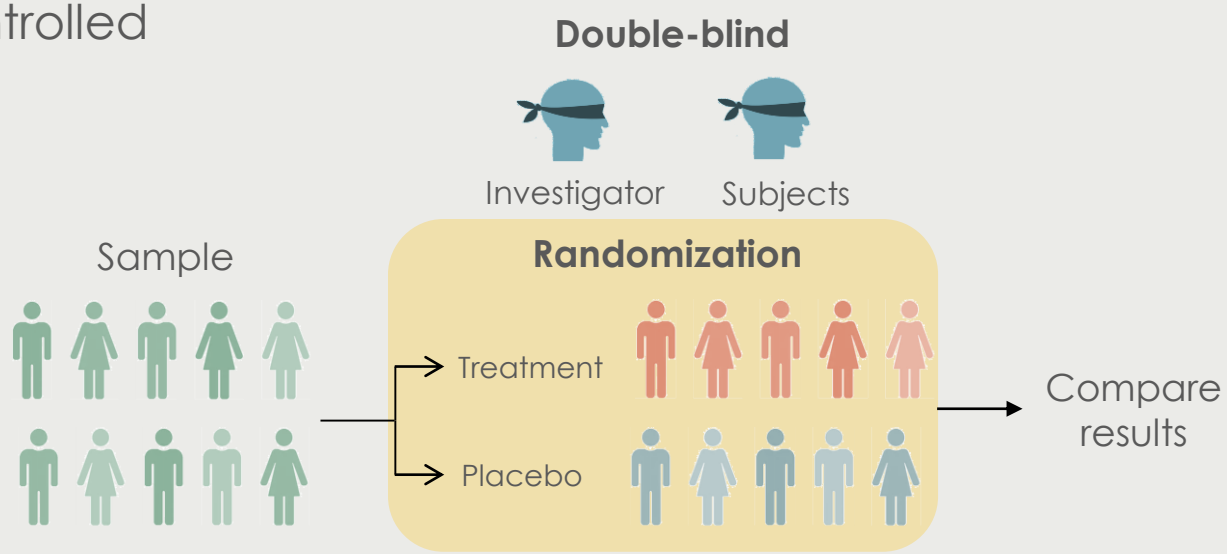
3

Comparison of the results

Randomised Controlled Trials (RCTs)

RCTs are planned experiments involving humans to **assess the safety and efficacy** of new approaches before applying them in healthcare.

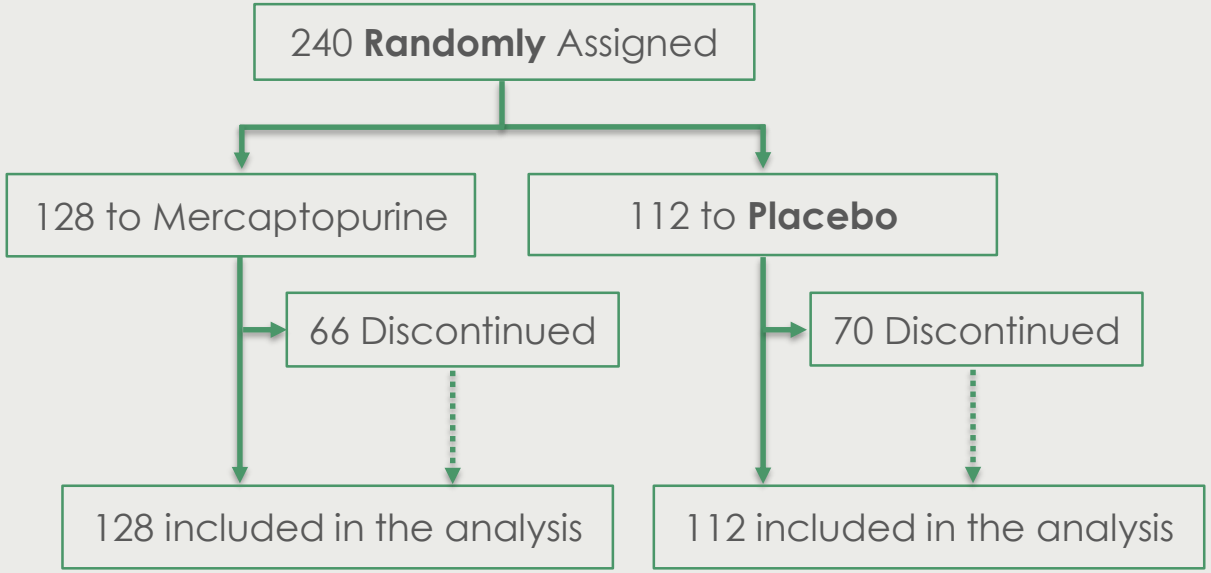
- Randomised
- Placebo-controlled
- Double blind



TOPPIC Study

Mercaptopurine Vs Placebo to Prevent Recurrence of **Crohn's Disease** After Surgical Resection.

- Crohn's Disease is a chronic, relapsing, inflammatory illness that can involve any segment of the gastrointestinal tract.



TOPPIC Study – Statistical Analysis Plan

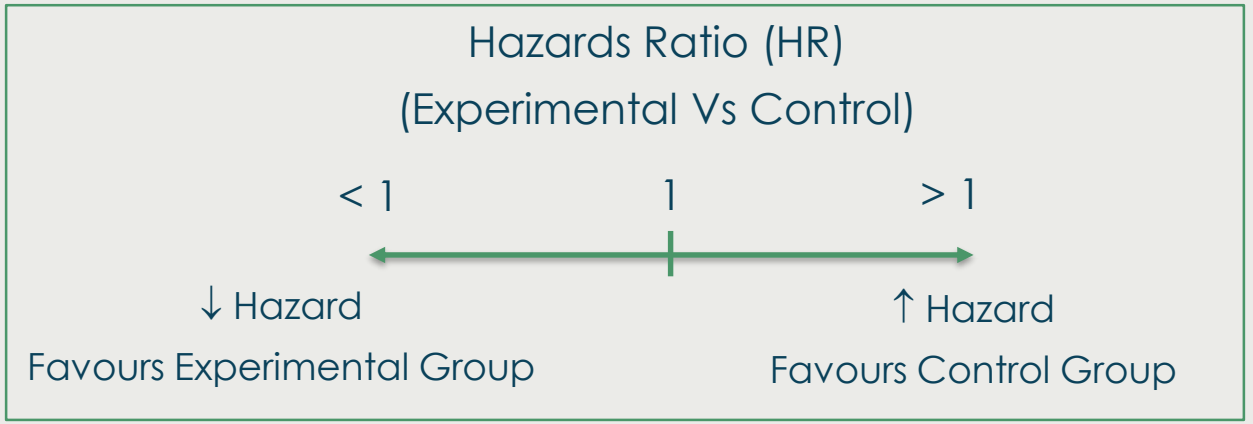
Null Hypothesis (H_0) = Both groups have equal recurrence

↓

Endpoint = Clinical recurrence of Crohn's disease

↓

Statistical Test = Cox Proportional Hazards Model



Data Analysis

Move to RCT Workspace

2

Comparison of the Results

	Adjusted HR	Unadjusted HR
	Surv(time, primary.endpoint) ~ treatmentno + azathioprine + sixmp + smoker + strata(a_centreno)	Surv(time, primary.endpoint) ~ treatmentno
Original	0.54 (0.27 – 1.06), p = 0.07	0.53 (0.28 – 0.99), p = 0.046
Replication	0.54 (0.27 – 1.10), p = 0.09	0.53 (0.28 – 1), p = 0.05

3

Conclusions

- Reproduction of the statistical analysis of was successful.
- We can only assume we have followed the same methods as the original study
  - ✓ Availability of the code allows reproducibility
  - ✓ Metadata allows faithful interpretation of the dataset

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