CW-04 Randomized controlled trial in radiology research

15:00-15:20 201

Chairperson(s): Jeong Min Lee *Seoul National University Hospital, Korea*

RCT 설계와 진행의 개요

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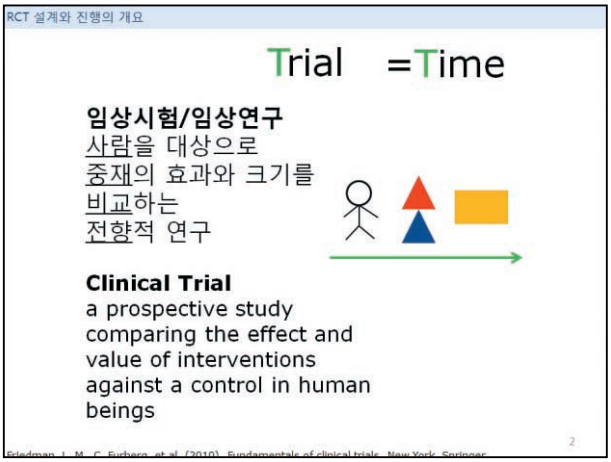

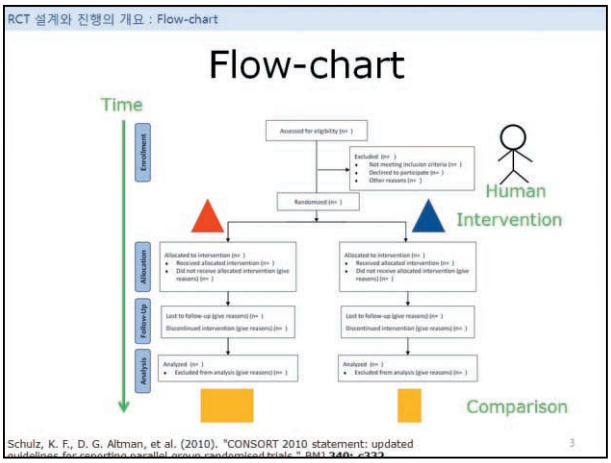

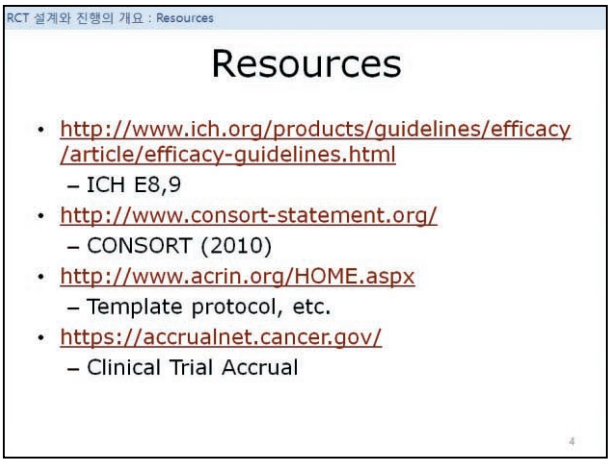

RCT 설계와 진행의 개요 : **Human** + Time : ID

ID

PT ID	Screening ID	Enrollment ID	Allocation (Random code)	Follow-up
1	1	1	1	1
2	2	2	2	2
3				
4	3	3	2	missing
5	4			
6	5	4	1	low quality

exclusions

(differential) withdrawals

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RCT 설계와 진행의 개요 : **Human** + Time : Participant Selection / Informed consent

Participant Selection

- Inclusion Criteria
- Exclusion Criteria
- Recruitment and Screening
- Inclusion of Women and Minorities

ACRIN template Protocol

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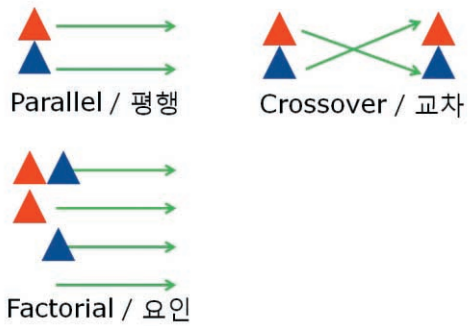
RCT 설계와 진행의 개요 : **Intervention** + Time : Design

Design



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RCT 설계와 진행의 개요 : **Intervention** + Time : Design

Parallel	Factorial	Cross-over
Most common clinical trial design for confirmatory trials	Varying combinations of the treatments	◦Bioequivalence of two formulations of the same medication ◦His own control for comparisons
Less complex	◦Interaction (joint effects) ◦Relatively Smaller sample sizes	◦Small sample size
	◦Add complexity ◦Adverse effect (poly-pharmacy)	◦Carry-over effect (wash-out period ; chronic and stable) ◦The loss of subjects

ICH E9

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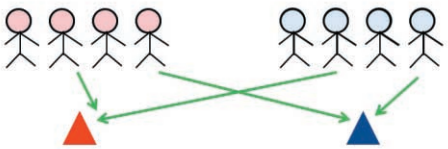
RCT 설계와 진행의 개요 : **Comparison** + Time : Bias

Comparison



To Minimize Bias?

1) Randomization
2) Blinding
3) Compliance

ICH E8

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RCT 설계와 진행의 개요 : **Comparison** + Time : Randomization

Randomization

- Units
  - Individual
  - Cluster (cluster randomization trial; more individuals, complexity)
- Steps
  - Sequence generation 배정 순서 생성
  - Allocation concealment mechanism 배정의 눈가림 방법
  - Implementation 배정의 시행

Schulz, K. F., D. G. Altman, et al. (2010). "CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials." BMJ **340**: c332.

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RCT 설계와 진행의 개요 : **Comparison** + Time : Randomization

Randomization

- Fixed Allocation Randomization
  - Simple
  - Block
  - Stratified
- Adaptive Randomization
  - Baseline adaptive randomization
  - Response adaptive randomization

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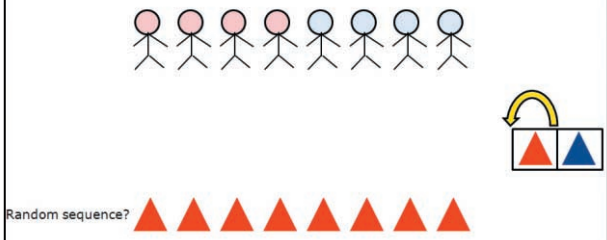
RCT 설계와 진행의 개요 : **Comparison** + Time : Simple Randomization

Simple Randomization



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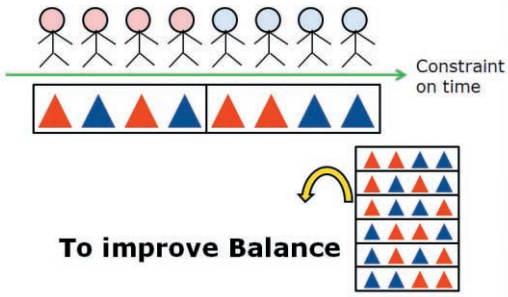
RCT 설계와 진행의 개요 : **Comparison** + Time : Blocked Randomization

Blocked Randomization
(permuted block randomization)



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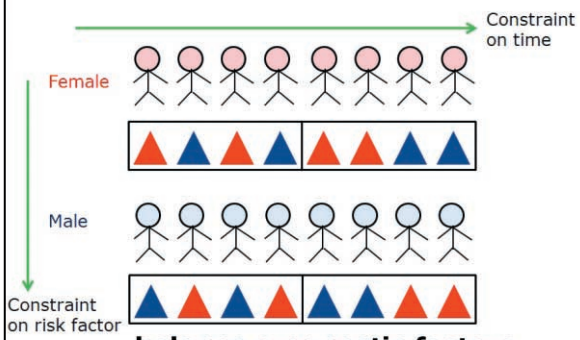
RCT 설계와 진행의 개요 : **Comparison** + Time : Stratified and Block Randomization

Stratified Randomization



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RCT 설계와 진행의 개요 : **Comparison** + Time : blinding

Blinding

	Healthcare providers		Data collectors	Outcome adjudicators
	physicians	Nurses		
Assignment	X	O	X	X
Outcome measurement	X	X	O	X
Analysis	X	X	X	O

-Vitamin C in the common cold
-Coronary artery bypass surgery v.s. medical treatment

Schulz, K. F., D. G. Altman, et al. (2010). "CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials." BMJ **340: c332**.

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RCT 설계와 진행의 개요 : **Comparison** + Time : Statistical analysis

Data anlaysis

- Pre-specification of the Analysis
- Analysis Sets
  - Full Analysis Set
  - Per Protocol Set
- Missing Values and Outliers
- Data Transformation
- Estimation, Confidence Intervals and Hypothesis Testing
- Adjustment of Significance and Confidence Levels
- Subgroups, Interactions and Covariates

ICH E9

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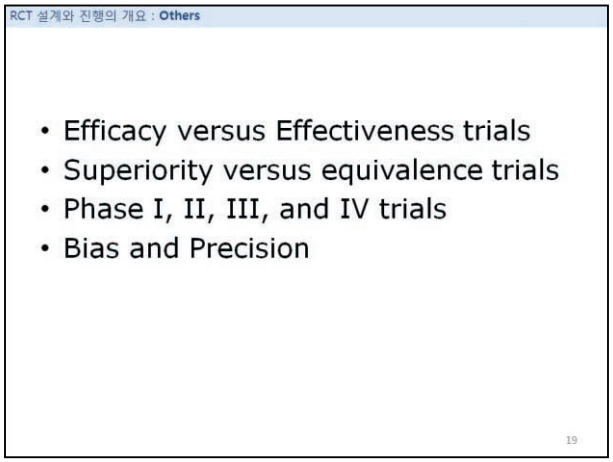
RCT 설계와 진행의 개요 : Others
• Efficacy versus Effectiveness trials
• Superiority versus equivalence trials
• Phase I, II, III, and IV trials
• Bias and Precision
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