GACD
GLOBAL ALLIANCE FOR CHRONIC DISEASES
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MODULE 5 | LECTURE 5B

Study designs for implementation research (1)

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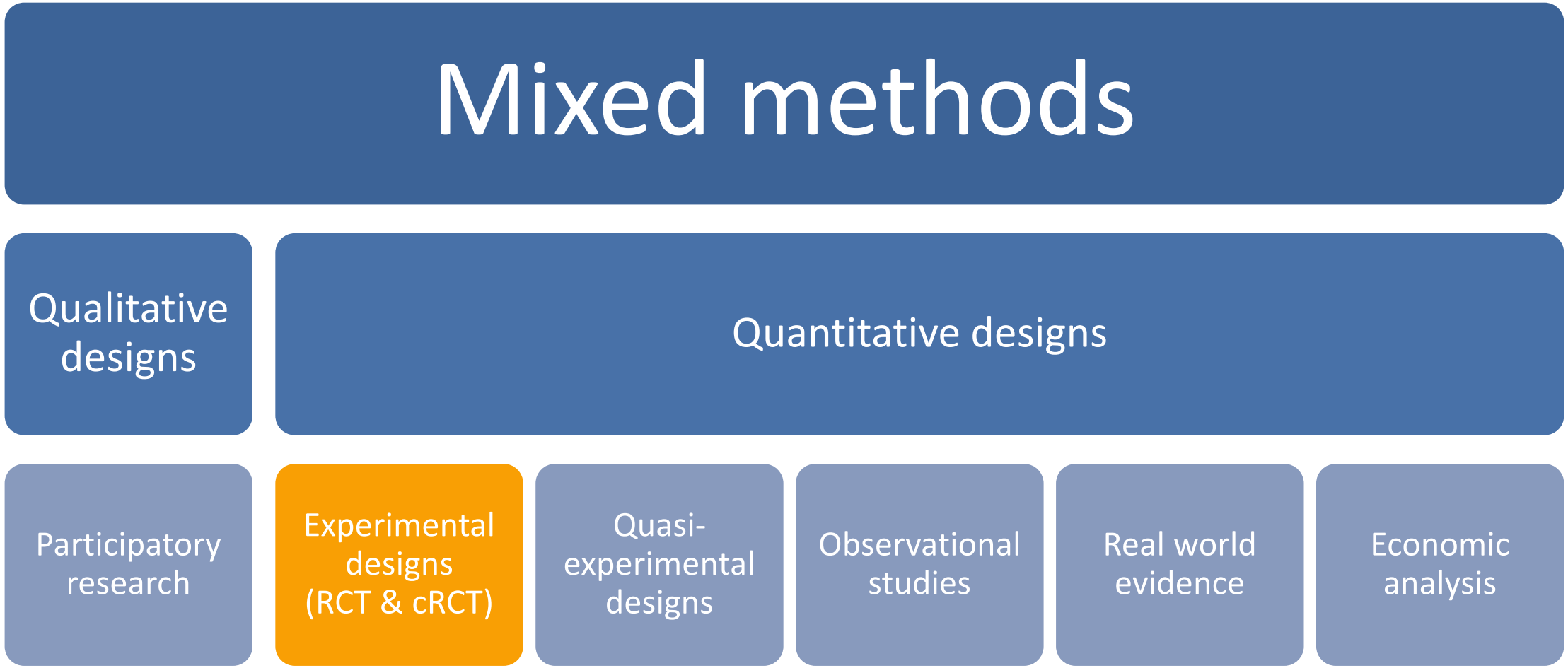
Lecture overview

- [x] Describe the most common study designs in implementation research
- [x] Explain pragmatic trials
- [x] Understand hybrid designs

What study designs are used in IS?



Pragmatic trials are often used in IS

Traditional trials	Pragmatic trials
More inclusion criteria: low external validity	Few exclusion criteria: higher external validity
Limited range of patients, providers, and settings	Wide range of patients, providers, and settings
Mostly placebo-controlled	Active comparators
Clinical or physiological outcome measures	People-centred outcomes; process measures
Shorter follow up with more intensity	Longer follow up with less intensity
Often double blinded	Often not blinded
Often individual-randomised	Often cluster randomised

What are hybrid studies?

- Studies that simultaneously consider clinical/health outcomes **and** implementation evaluation

- Hybrid studies are unique to implementation science

There are 3 types of hybrid studies

Hybrid Type 1

Test clinical / health effectiveness

Gather implementation information

Hybrid Type 2

Test clinical / health effectiveness

Test implementation strategies

Hybrid Type 3

Test implementation strategies

Gather data on clinical/ health effectiveness

There are 3 types of hybrid studies

Hybrid Type 1

Primary aim: Clinical / health outcomes

Secondary aim: Gather data on implementation

Hybrid Type 2

Co-primary aims:
Implementation outcomes
+
Clinical/health outcomes

Hybrid Type 3

Primary aim:
Implementation outcomes

Secondary aim: Gather data on clinical / health effects

Key messages

1. In implementation science, we use a broad range of study designs, both quantitative and qualitative, and most often, mixed-method approaches.

2. Hybrid studies have a dual focus on implementation evaluation and clinical/health outcome effectiveness.

3. There are three types of hybrid studies (1, 2 and 3). The difference between them rely on the hierarchy of clinical/health versus implementation outcomes.

Reference list

- Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. Med Care. 2012 Mar;50(3):217-26. doi: 10.1097/MLR.0b013e3182408812. PMID: 22310560; PMCID: PMC3731143.

- Brown CH, Curran G, Palinkas LA, Aarons GA, Wells KB, Jones L, Collins LM, Duan N, Mittman BS, Wallace A, Tabak RG, Ducharme L, Chambers DA, Neta G, Wiley T, Landsverk J, Cheung K, Cruden G. An Overview of Research and Evaluation Designs for Dissemination and Implementation. Annu Rev Public Health. 2017 Mar 20;38:1-22. doi: 10.1146/annurev-publhealth-031816-044215. PMID: 28384085; PMCID: PMC5384265.

- Drazen, Jeffrey M.; Harrington, David P.; McMurray, John J.V.; Ware, James H.; Woodcock, Janet; Ford, Ian; Norrie, John . (2016). Pragmatic Trials. New England Journal of Medicine, 375(5), 454–463. doi:10.1056/NEJMra1510059