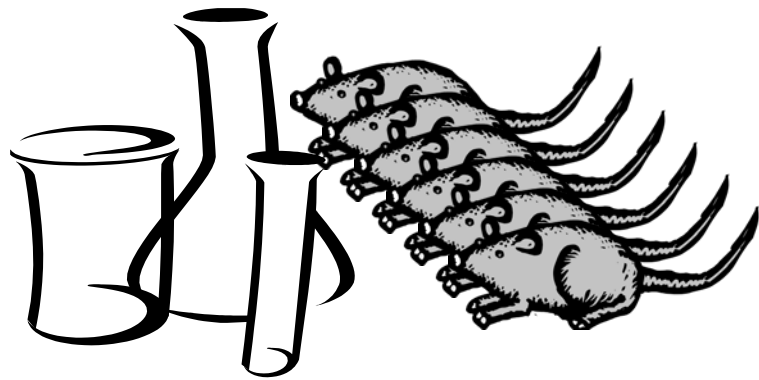


Intervention study *in the real world*



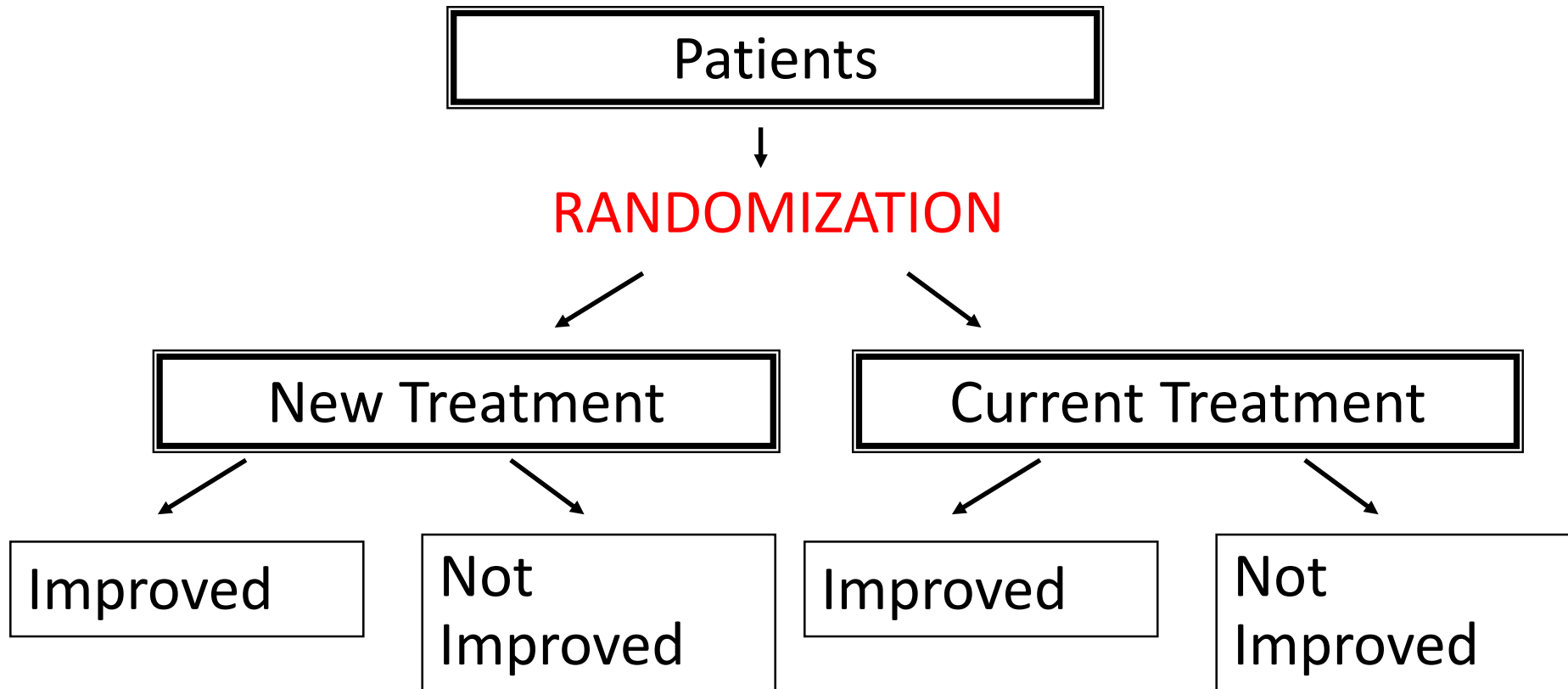
FUKUSHIMA
MEDICAL
UNIVERSITY

Aya Goto

Key concepts

- ❖ Intervention study should be **most carefully** planned and implemented.
- ❖ Randomization, blinding, and placebo.
- ❖ **Quasi-experimental study**

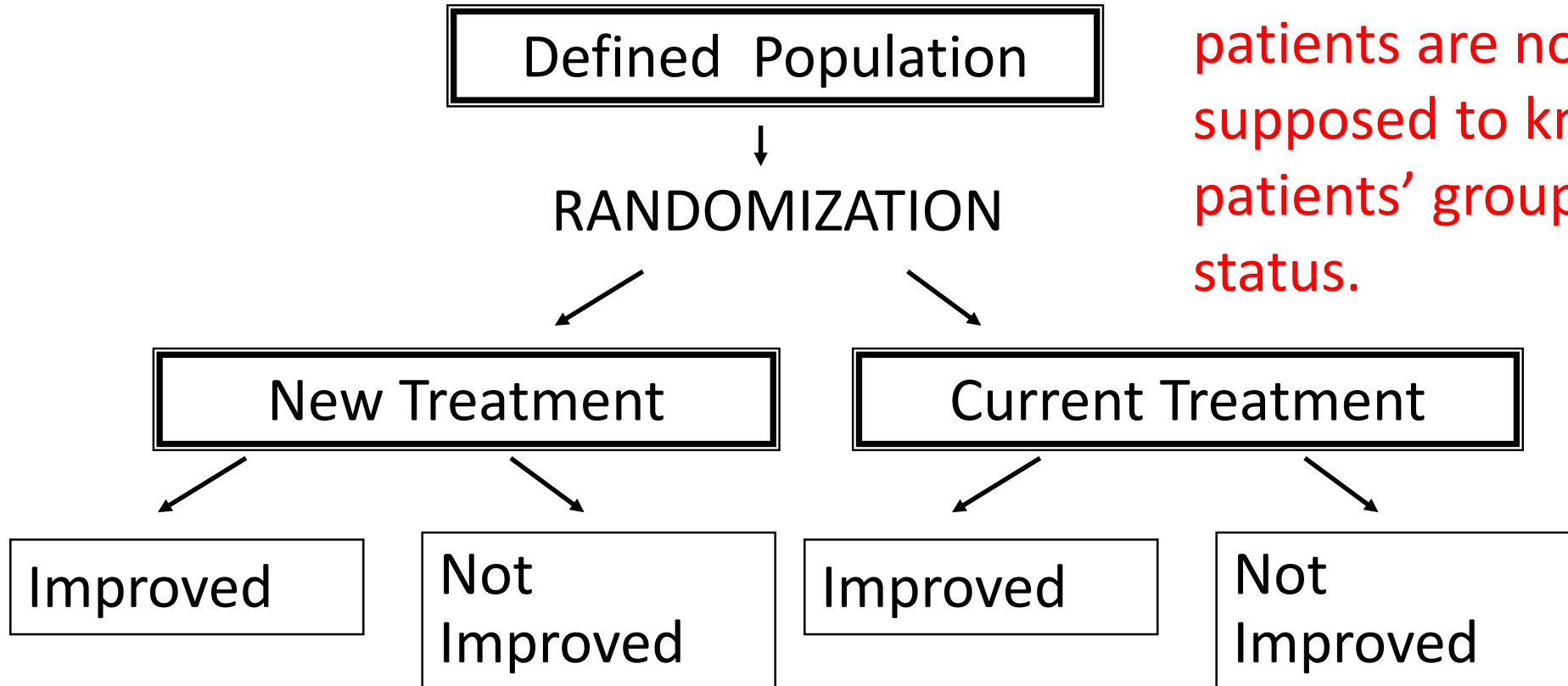
Intervention allocation - Randomization



- ❖ Make sure two groups are comparable in characteristics.
- ❖ Remove bias in allocation of intervention.

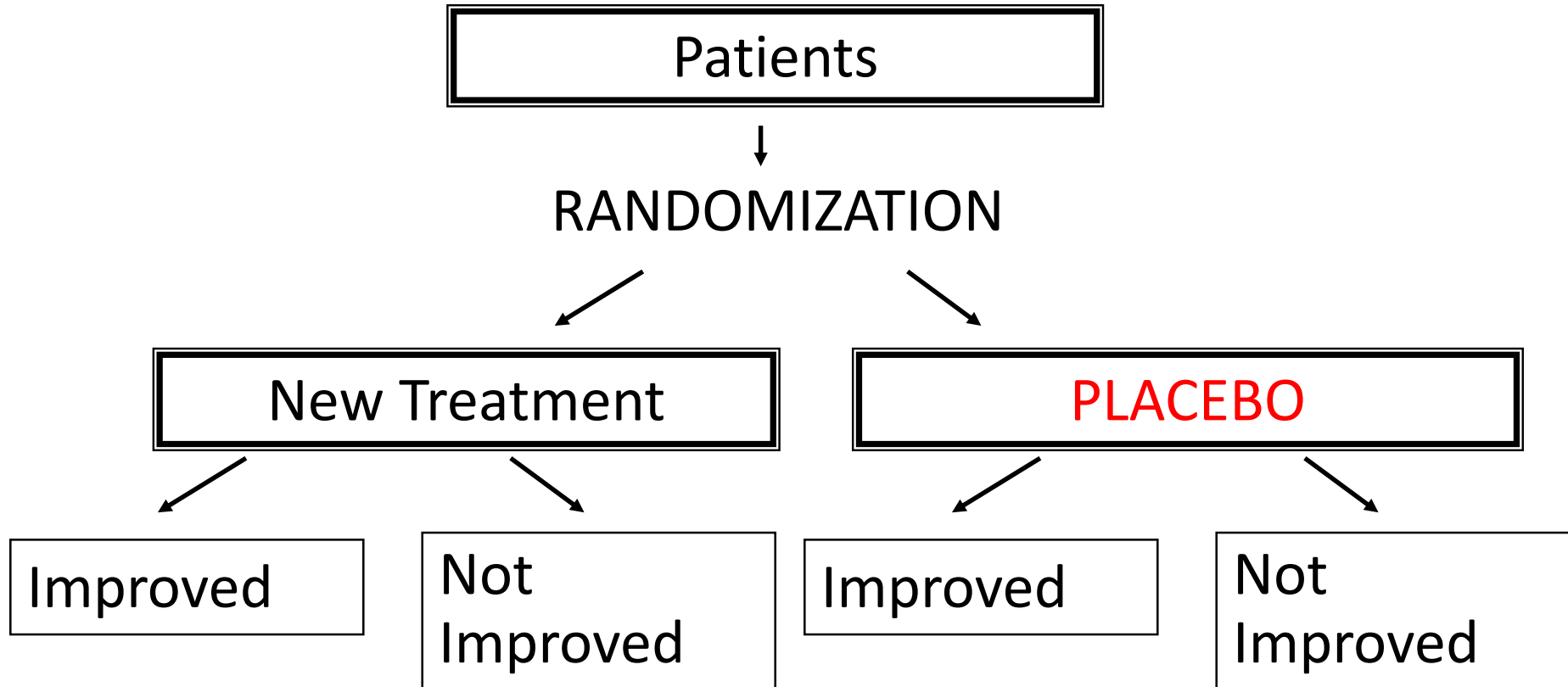
Double-blinding

Doctors and patients are not supposed to know patients' group status.



❖ Minimize observer and subject bias.

Placebo



- ❖ Prevent participants from knowing their group status.
- ❖ Eliminate *placebo effect*.

Important issues to consider before starting the study

❖ Ethical consideration

- Premise: You do not know about efficacy of the intervention.
- Obtain permission from an **ethical review** committee of your organization.
- Most importantly, obtain informed consent from participants.
- Discuss what if it becomes apparent, before the trial is over, that the new treatment is beneficial or toxic. (Stopping rule)

❖ Sample size

If the study finds no difference between compared treatments, do you believe it?

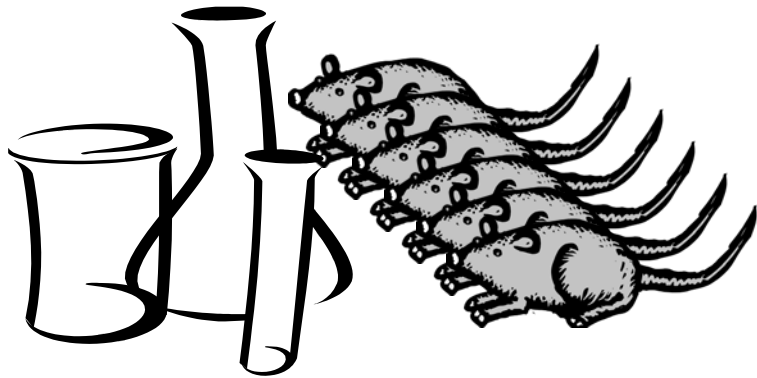
Was there a difference, but the study was not powerful enough to detect it? Calculate (or consult an epidemiologist about) sample size in the very beginning.

1. Check sample size in previous studies.
2. **Consult an epidemiologist**, calculate by statistical software or **web calculator**, or hand calculate.

OpenEpi

http://www.openepi.com/v37/Menu/OE_Menu.htm

❖ RCT evaluates **efficacy** in ideal setting. Program feasibility, acceptability and **effectiveness** are different issues in the real world.



Quasi-experimental study

Quasi-experimental study designs;

1. do not use control groups
2. use control groups without randomization
 - 1) no pretest
 - 2) with pretests

- Harris AD, et al. The use and interpretation of quasi-experimental studies in infectious diseases. Clin Infect Dis. 2004; 38(11): 1586-91.
- Harris AD, et al. The use and interpretation of quasi-experimental studies in medical informatics. J Am Med Inform Assoc. 2006; 13(1):16-23.



For advanced learners...

The lack of random assignment is the major weakness. Therefore one should be cautious in following three points when interpreting the obtained apparent association.

- ❖ **1) The difficulty in controlling for important confounders:** severity of illness and quality of medical and nursing care. The first variable could be addressed in multivariate analysis, but the second variable would be difficult to measure and control.
- ❖ **2) Regression to the mean** is a widespread statistical phenomenon. Statistically, decline/increase in an indicator (esp. extreme values) may happen even without intervention.
- ❖ **3) Maturation effect** is related to natural changes that patients experience with the passage of time.

The major advantage is...

- ❖ Quasi-experimental studies can sometimes provide a more natural, generalizable environment that better establishes **effectiveness** (as opposed to efficacy).

Free Online EBP course, University of Georgia

<http://ebp.uga.edu/ebp-modules/>



Example: Adaptation of a parenting program

1980s Nobody's Perfect was developed in Canada

1987 Introduced nationally

(Health Canada. *Working with Nobody's Perfect*. 2000.)

(B.C. Council for the Family. *Nobody's Perfect resource manual for facilitators*. 1995)

2002 JPN program manual was published.



Adapted to Japanese public health service setting

❖ Shorter duration

❖ Inexpensive

❖ Easier management

❖ Adapted to Asian culture

Goto A, Yabe J, Sasaki H, Yasumura D. Short-term operational evaluation of a group-parenting program for Japanese mothers with poor psychological status.

Health Care for Women International, 31, 636-651, 2010.

Result 1. Feasibility and acceptability

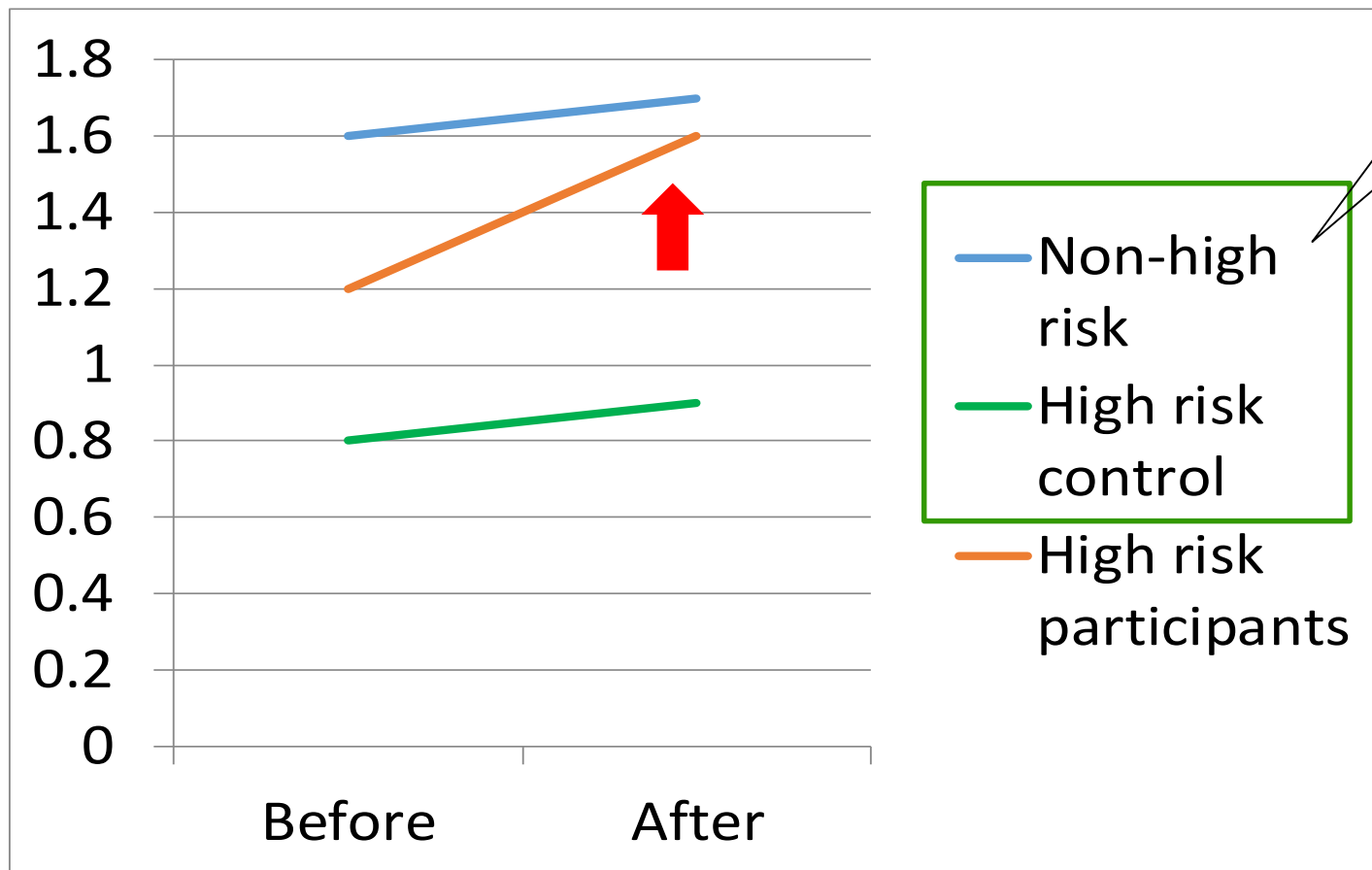
The program was;

- ✓ Feasible in a public health service setting, and organized by municipality public health nurses for three years.
- ✓ Well-accepted among first-time mothers with low psychological status; participation rate was 78% (no. participated 32 / no. registered 41) and 97% answered that the class was useful in parenting.



Result 2. Potential program effects

General self-efficacy (Social locus of ability)



Information of comparison groups was obtained from city database.

Controlling for background characteristics and the baseline level, above two indicators showed significant improvement compared to controls.

Cross-over design

Example

GROUP A	GROUP B
Pre-survey	Waiting list
Intervention	
Post-survey	Pre-survey
	Intervention
	Post-survey

Analysis

Compare changes between the pre- and post-survey (A+B).

Advantages

- Providing the service to all.
- Securing a sample size.

Disadvantages

- Contamination
- Unable to apply when the changes around the targeted health event is rapid.