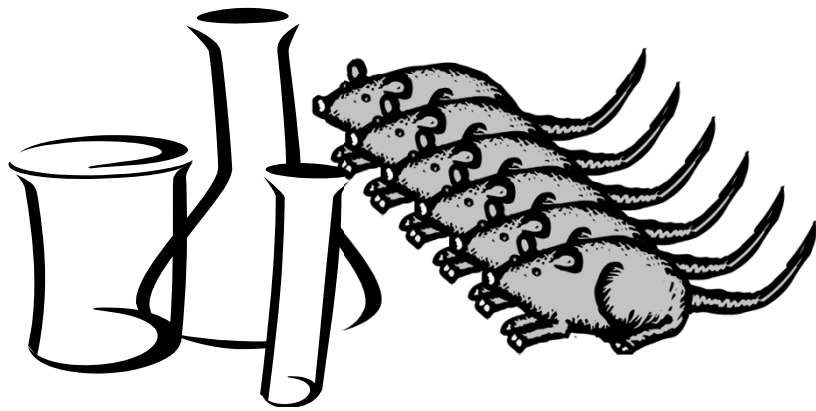


# Intervention study *in the real world*

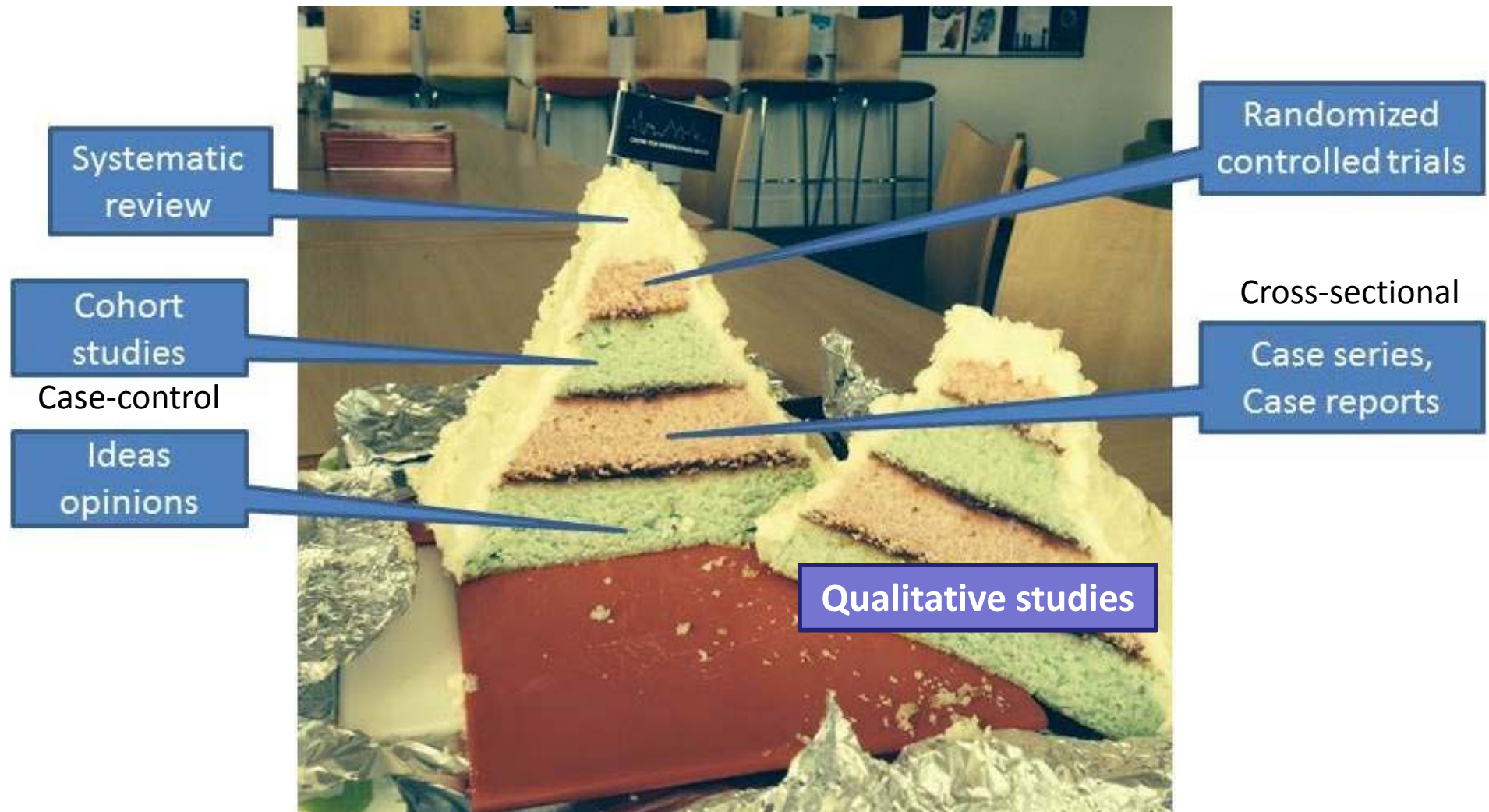
## Program adaptation



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# Levels of evidence



<http://www.cebm.net/wp-content/uploads/2014/07/Slide11.jpg>

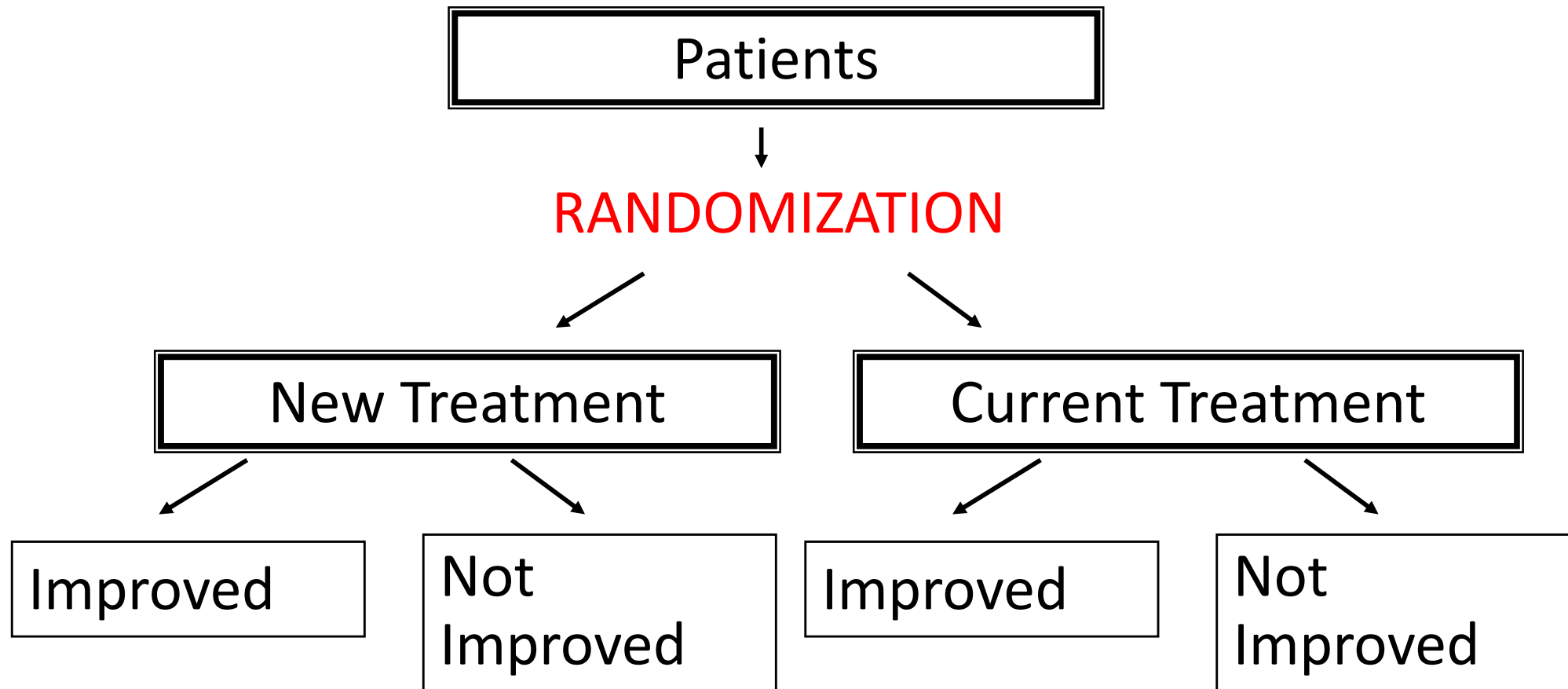
# Key concepts

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

# Observational and Experimental study

- ❖ Observational study: Cross-sectional, case-control, and cohort studies.
- ❖ **Experimental study** = Intervention study:  
This is a special type of cohort study in which exposure is specified by an investigator.

# Intervention allocation - Randomization



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

## ❖ How to randomize:

1. Classic envelop method
2. Computer

. list ID	
+-----+	
	ID
	----
1.	8
2.	6
3.	1
4.	9
5.	3
+-----+	

STATA 10.0 Copyright 1984-2007  
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4905 Lakeway Drive  
College Station, Texas 77845 USA  
800-STAT-PC <http://www.stata.com>  
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Notes:  
1. C:\mt op  
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edit  
list ID

ID
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sample - Draw random sample

Main by/if/in

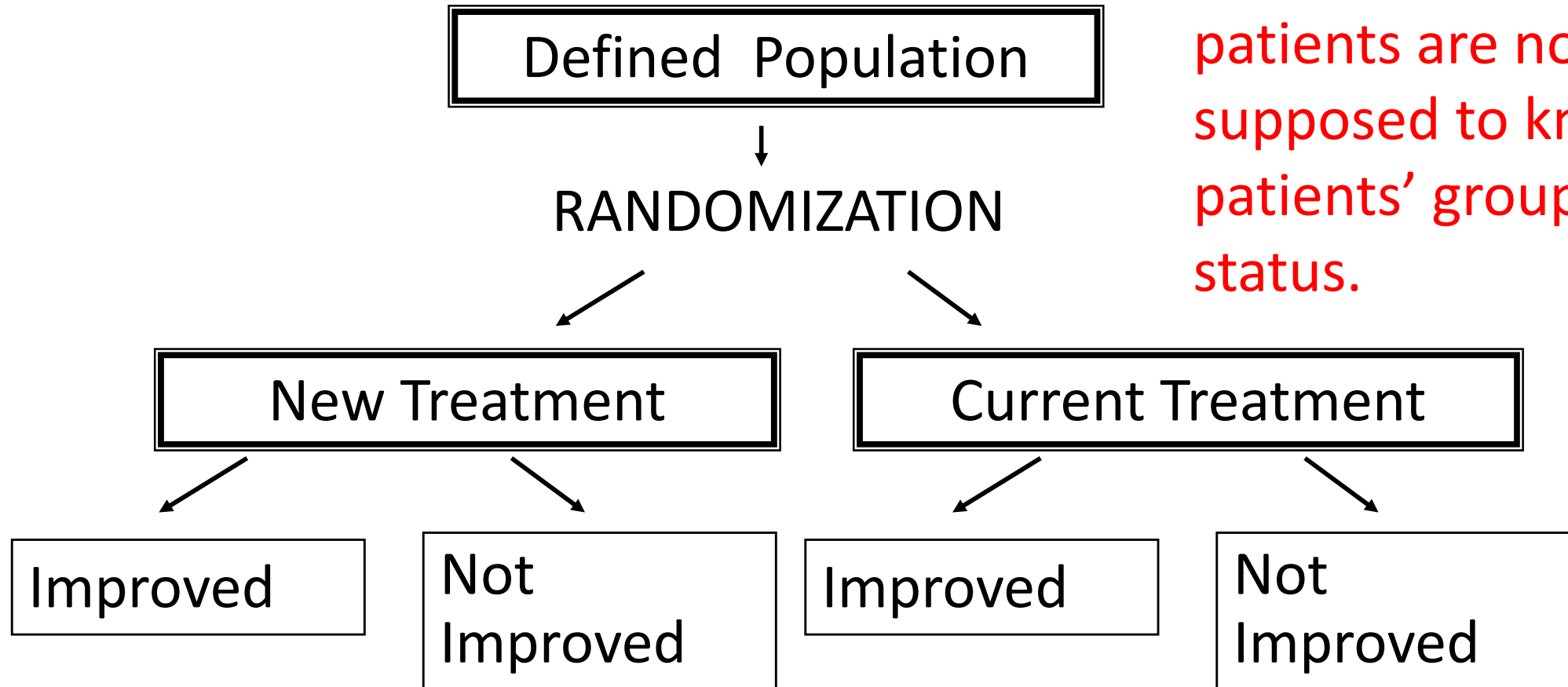
☐ Percentage of current data to sample

☒ Sample size 3

OK Cancel Submit

# Double-blinding

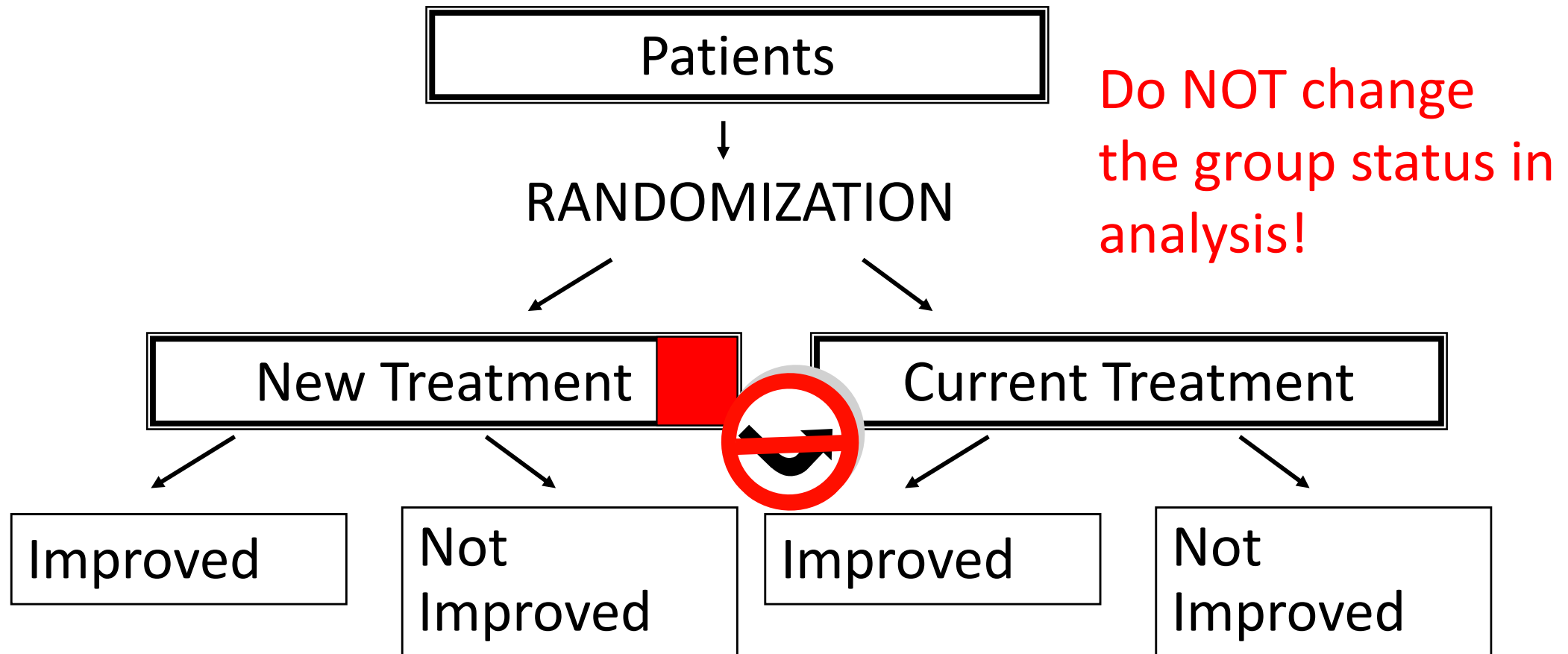
Doctors and patients are not supposed to know patients' group status.



❖ Minimize observer and subject bias.



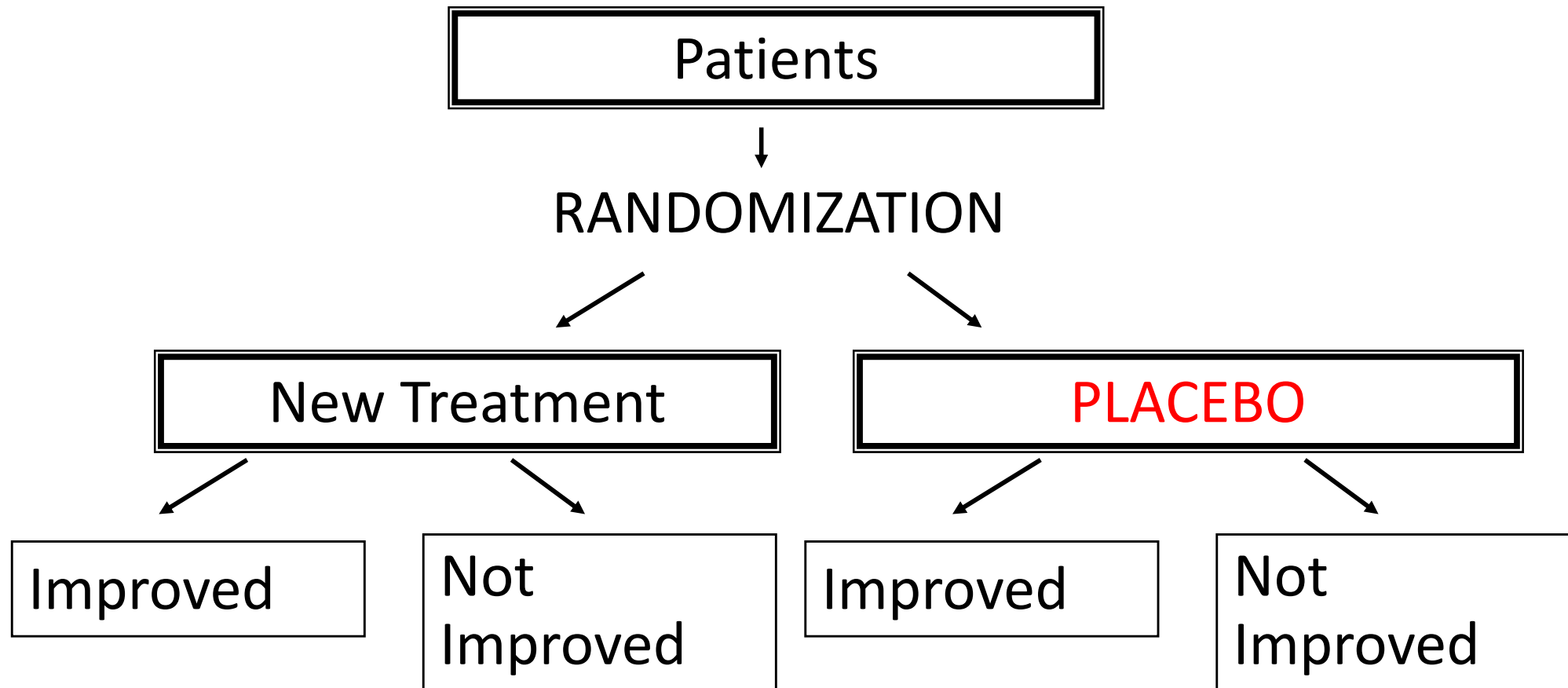
# Once randomized, always analyzed



- ❖ Avoid overestimation of intervention effects
- ❖ Real life setting



# 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?

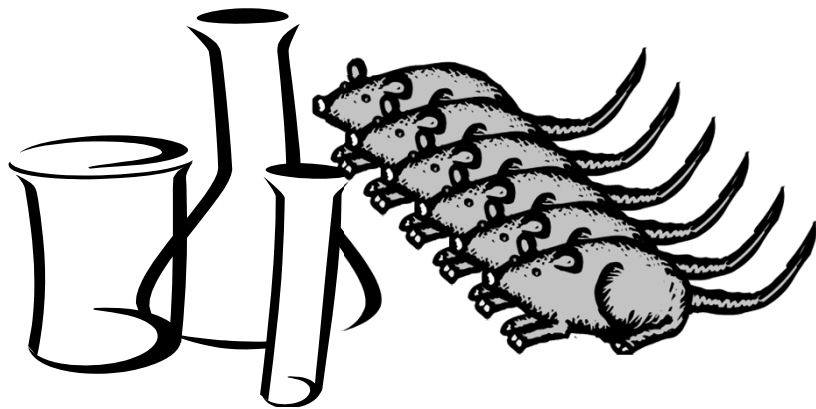
Was there a difference, but the study was not powerful enough to detect it? Calculate (or consult an epidemiologist about) sample size in the very beginning.

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](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/>



# Question

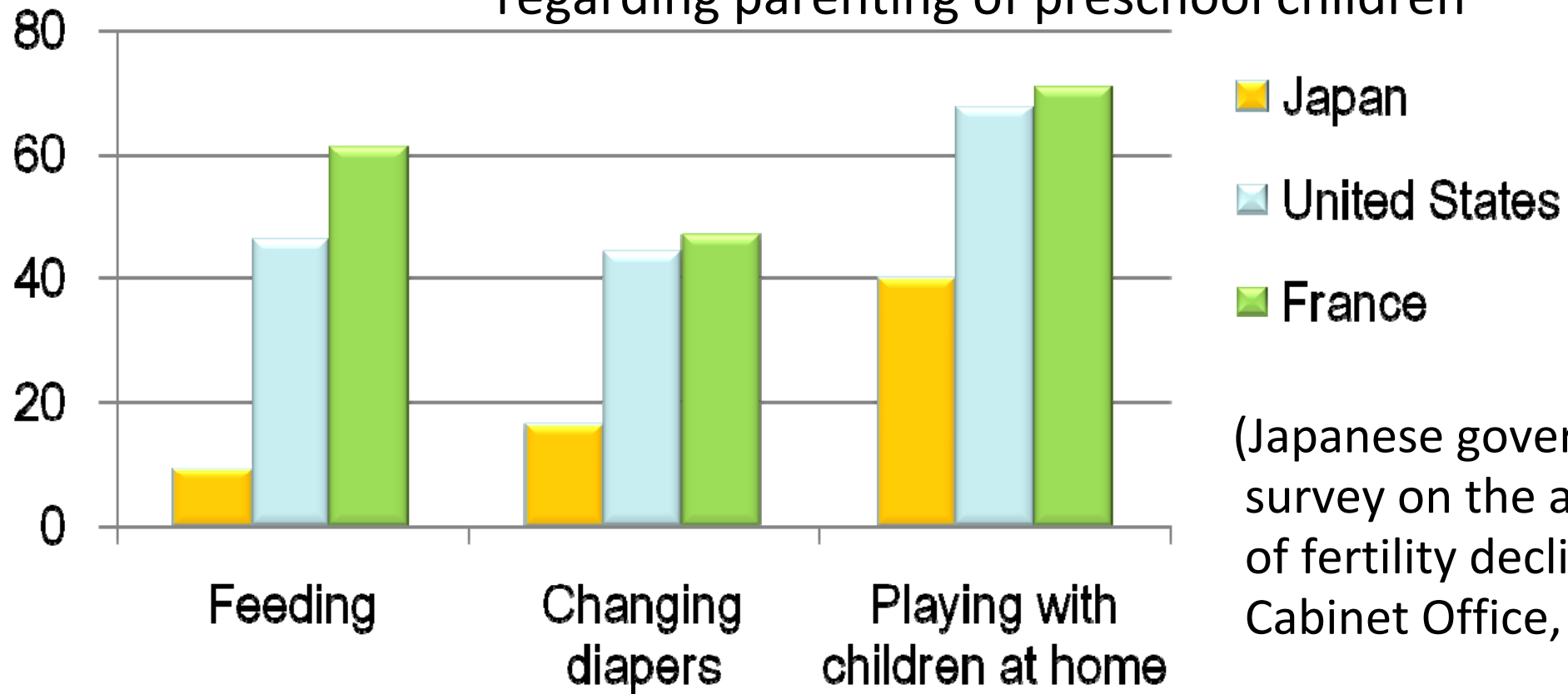
When you find a model program from overseas, how do you apply in your country?



Example: Group-parenting program for mothers with poor psychological status

# Background: Traditional gender role in Asia

**JAPAN** Proportion of “father does the task mainly or equally as mother” regarding parenting of preschool children



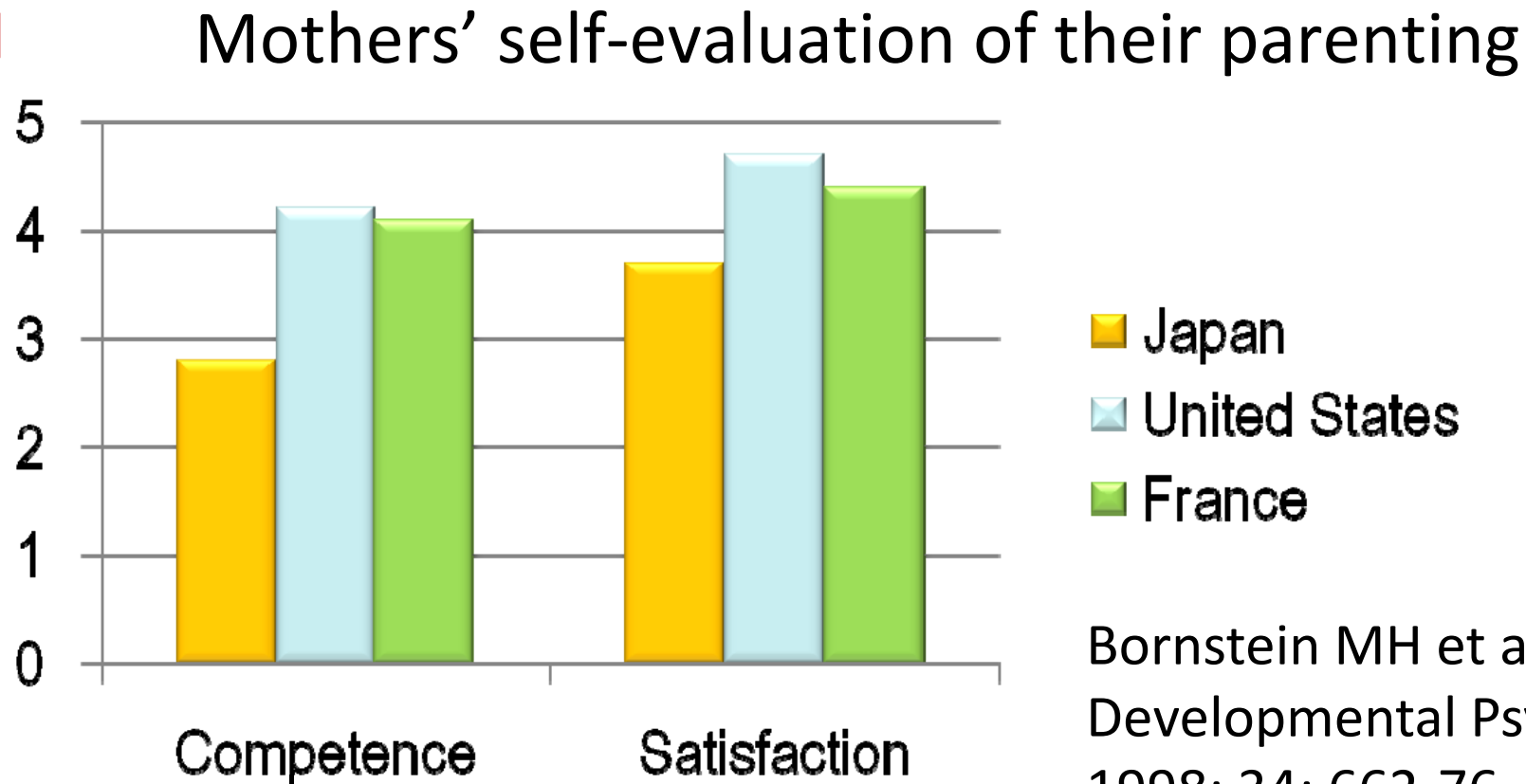
(Japanese government survey on the awareness of fertility decline. Cabinet Office, 2006.)

**VIETNAM** “Women continues overwhelmingly to be responsible for taking care of children.”

(Vo PH, et al. Community, Work and Family 2007; 10: 179-199.)

# Background: Asian mothers' low mental health

## JAPAN

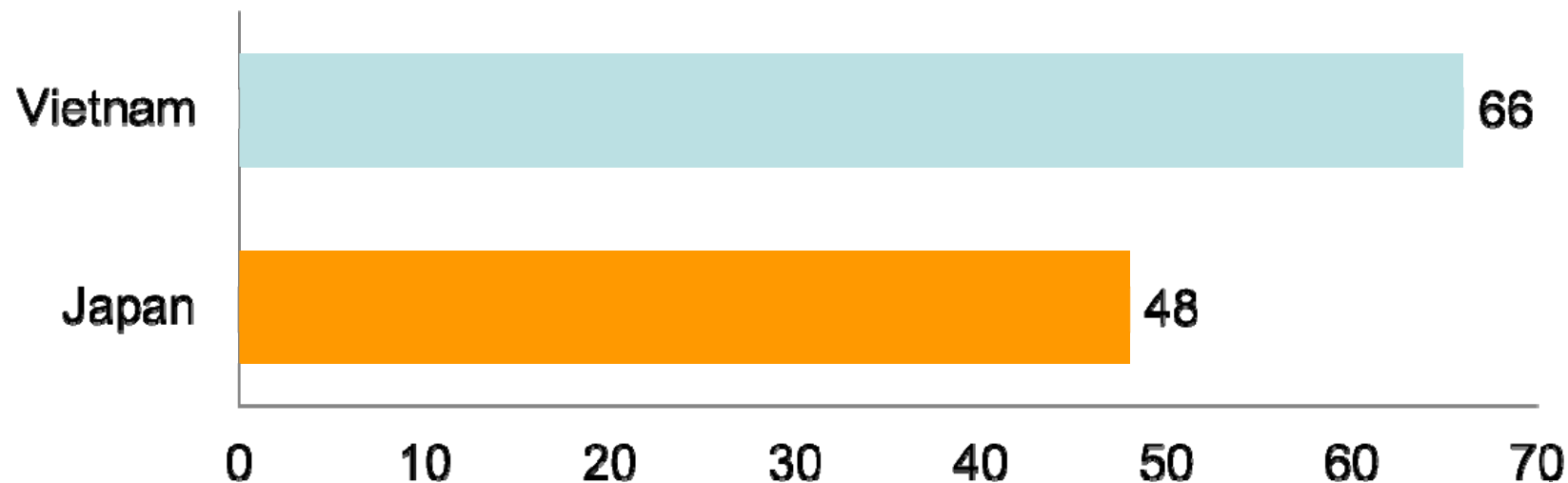


Bornstein MH et al.  
Developmental Psychology  
1998; 34: 662-76.

## VIETNAM

Little published evidence about mental health problems in general.  
Reported prevalence of postpartum depression was as high as 33%.  
(Fisher JR, et al. BJOG 2004; 111: 1353-1360.)

# Proportion of Japanese and Vietnamese mothers who are not confident in child rearing at around 1 month postpartum



Japan: Matern Child Health J. 2008; 12(5): 613-9.

Vietnam: J Child Fam Stud. 2010; 19(1): 118-127.

# Rationale of parenting support

❖ Maternal mental health affects child development.

International Child Development Steering Group  
Lancet 2007; 369: 229–42.

# Model program and modifications

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

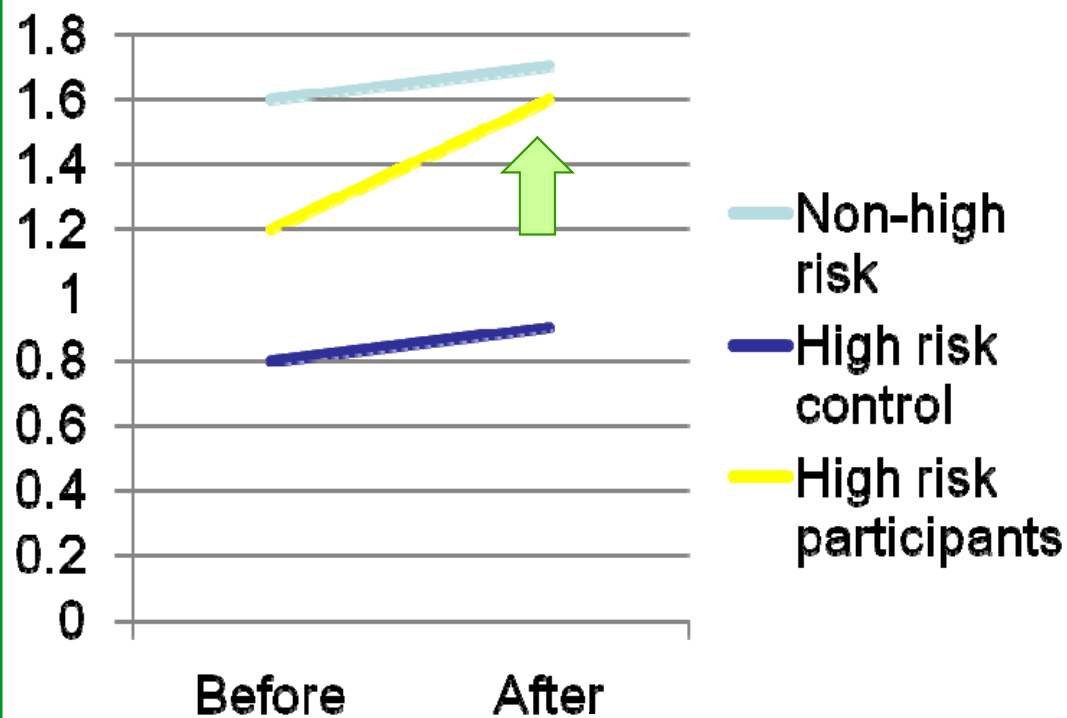
The program was;

- ✓ 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.

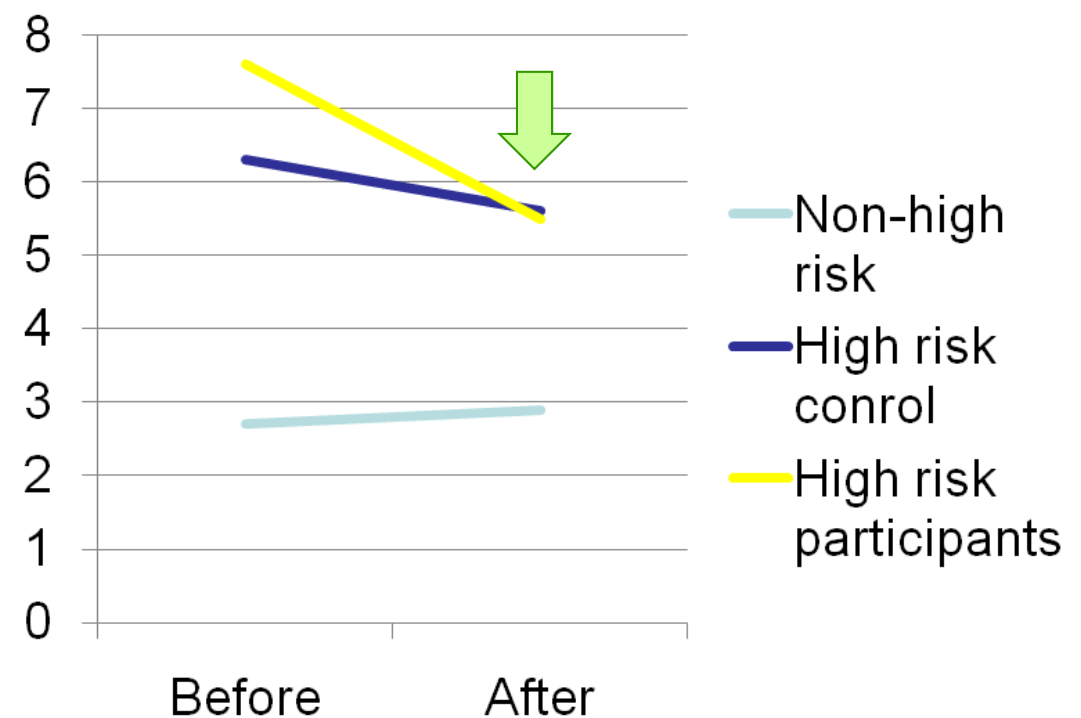


## Result 2. Potential program effects

General self-efficacy  
(Social locus of ability)



Mood



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

# Further adaptations to VN hospital setting

- ❖ Shorter duration
- ❖ Ready-made sessions → Easier management
- ❖ Inexpensive
- ❖ Adapted the content to Vietnamese culture/customs, health issues  
e.g. Use music, include accident prevention

Goto A, Suzuki Y, Nguyen QV, Nguyen TTV, Trinh HP, Pham NM, Nguyen TM, Yasumura S, NDGD Parenting Support Team. Pilot study on a group-based parenting program in a Vietnamese public hospital. **Asia-Pacific Psychiatry**, 4: 76-83, 2012.



# Modified version: Vietnamese public hospital

## Screening and invitation

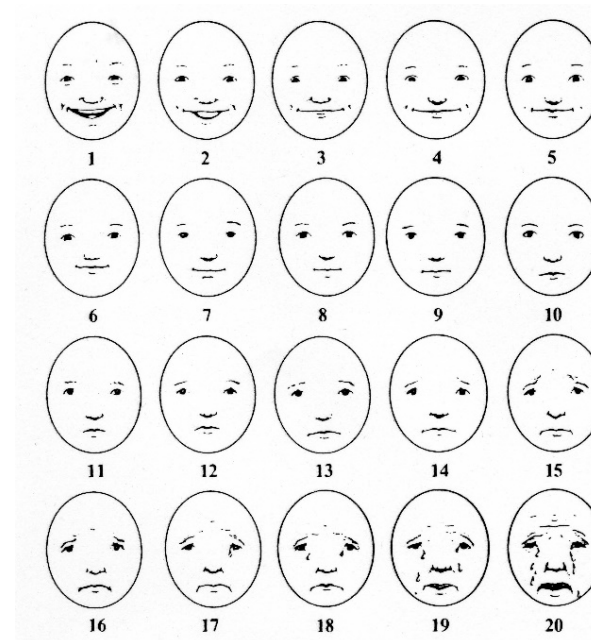
First-time mothers with low psychological status defined as;

1. scoring 11 or higher on the face-scale mood test
2. marking either or both of two-question depression case-finding instrument
3. not having confidence in child rearing

But, not...

When mother's depression level requires individual psychological counseling.

The faces go from very happy at the top to very sad at the bottom. Check the face which best shows the way you have felt inside today.



Lorish CD, Maisiak R.  
Arthritis Rheumatism  
29: 906-909, 1986

During the past month, have you often been bothered by feeling down, depressed, or hopeless? 1. Yes 2. No

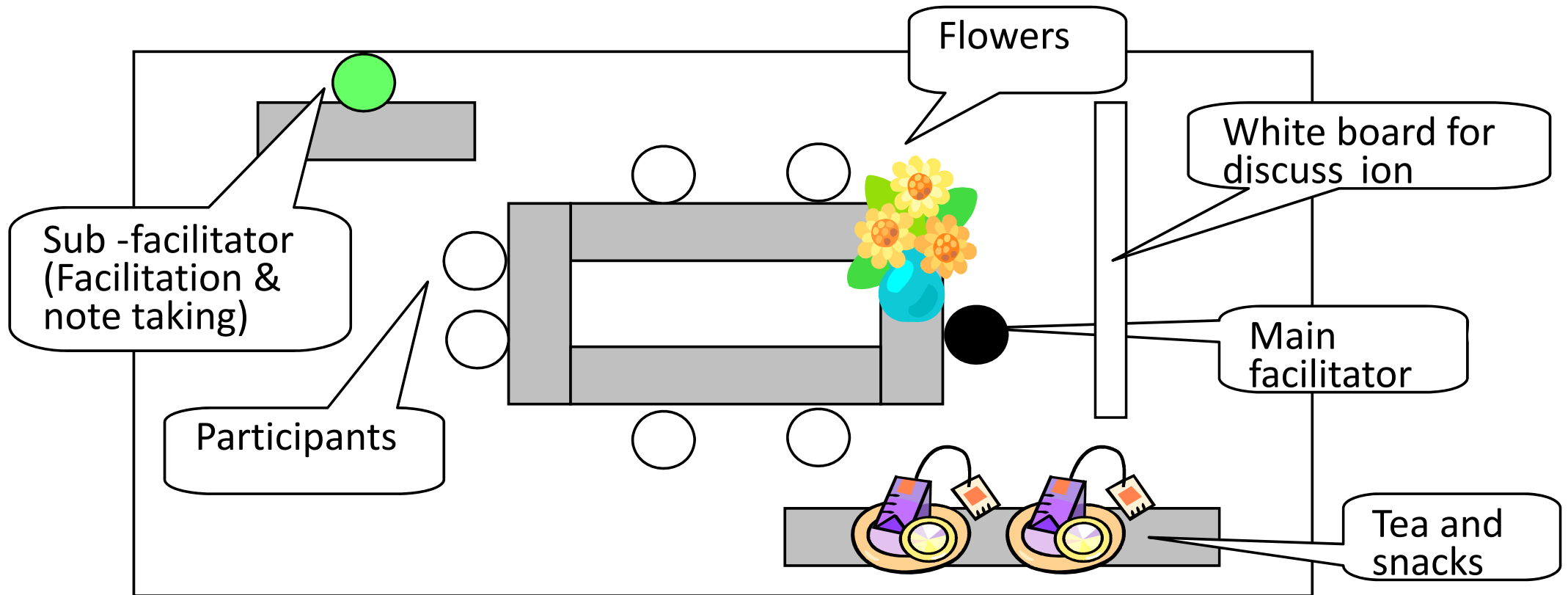
During the past month, have you often been bothered by little interest or pleasure in doing things? 1. Yes 2. No

Are there any moments when you don't feel confident about childrearing? 1. Yes 2. No 3. Not sure



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# For mothers



Facilitators are listeners, not teachers. "Can you tell us more about that?"  
Facilitators bring people together. "What do others think about that?"  
Facilitators help people find their strengths. "Good idea!"

# For babies

Midwives. One staff is needed for every three babies less than one-year old.

Baby beds or mattresses

Toys

Mothers' bags containing milk, snacks, diapers, clothes, etc.

Hot water for milk

Before session, a mother writes baby's name, months, feeding time and other necessary notes on a nursery card and hand it to midwives. After session, she receives a small note from midwives reporting how her baby spent the time during her absence.

# Two-day class content

First day	
8:30-9:00	Staff meeting, registration of participants and babies
9:00-9:20	Introductory session (Explanation of the parenting class, self-introduction)
9:20-9:50	Session 1
9:50-10:00	Tea break
10:00-10:30	Session 2
10:30-11:00	Summary of the day
11:00-	Mothers pickup their babies



Second day	
8:30-9:00	Staff meeting, registration of participants and babies
9:00-9:30	Session 3
9:30-9:40	Tea break
9:40-10:10	Session 4
10:10-10:30	Filling a questionnaire
10:30-11:00	Summary of the day, giving certificates
11:00-	Mothers pickup their babies

Topics	Activities	Preparations
<b>Before and after</b>	<ul style="list-style-type: none"> <li>➤ Write changes in your life after birth.</li> <li>➤ Present and discuss about the notes.</li> </ul>	<ul style="list-style-type: none"> <li>➤ Paper, pencils</li> <li>➤ Handout</li> </ul>
<b>Child nutrition</b>	<ul style="list-style-type: none"> <li>➤ Small lecture on child nutrition</li> <li>➤ Taste baby food and talk about child nutrition</li> </ul>	<ul style="list-style-type: none"> <li>➤ Baby food</li> <li>➤ Contact a nutritionist</li> <li>➤ Handout</li> </ul>
<b>Mother's mental health</b>	<ul style="list-style-type: none"> <li>➤ Small lecture on mental health</li> <li>➤ Discussion with a psychiatrist</li> </ul>	<ul style="list-style-type: none"> <li>➤ Contact a psychiatrist</li> <li>➤ Handout</li> </ul>
<b>Child safety</b>	<ul style="list-style-type: none"> <li>➤ Make an inexpensive toy</li> <li>➤ Discuss about child play, safety and development</li> </ul>	<ul style="list-style-type: none"> <li>➤ Plastic bottles, colorful stickers, markers, beads, tapes</li> <li>➤ Handout</li> </ul>

# Program evaluation

1. How many mothers came to participate?
  - Activity record
2. How many mothers completed?
  - Activity record
3. Were participants satisfied with the class?
  - Evaluation form
    - Did you like the program?
    - Did you become more positive about parenting?
    - Are lessons from the class useful in parenting?
4. Did their psychological status improve?
  - Follow-up telephone survey with mental health measurements

# Program adaptation procedures

## Preparations

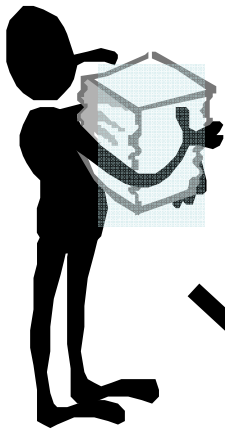
- ❖ Site selection and visit to check facility and current services
- ❖ Team selection; nice mix of professionals from different fields and levels e.g. Obstetrics, public health, nutrition, psychiatry e.g. Staff, unit chiefs
- ❖ **Translate/revise** tools
- ❖ Explain about the program to authorities and obtain approval



# Back-translation

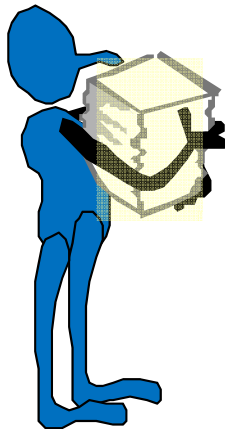
## Step 1

Translation  
Eng. to VN



## Step 2

Back-Translation  
VN to Eng.



## Step 3

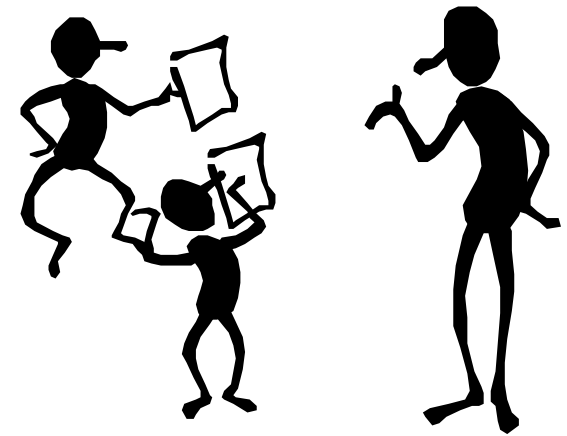
Compare original and back-translated versions, and address any differences.



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## Pilot testing & training

- ❖ Arrange schedule
- ❖ Secure place and staff's time
- ❖ Test-run the program and check...
  - logistics and operation
  - acceptance among participants and staff
- ❖ Discuss future expansion



Date	Pilot testing and training				
Nov 16 (Mon)	Preparation meeting				
17 (Tue)		Screening of participants			
18 (Wed)					
19 (Thu)					
20 (Fri)			Staff training		
21 (Sat)				Parenting class	
22 (Sun)					
23 (Mon)					Summary meeting

# Summary

## Steps for adapting an intervention

