



# Assessing the number, characteristics and quality of randomized controlled trials conducted in Japan

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## Background

The randomized controlled trial (RCT) is the most powerful research tool for evaluating health technologies and formulating evidence-based healthcare. The number of RCT is rapidly increasing internationally. Despite the rapid increase in research in Japan, little is known about comprehensive information of RCTs conducted there.

## Objectives

To assess the number and characteristics, and evaluate quality of RCTs conducted in Japan.

## Methods

All RCTs conducted in Japan and published in 2010 were searched using the Japanese database and international databases. Inclusion criteria and identification of studies.

- Database : Japan Medical Abstract, MEDLINE, EMBASE, CINAHL, PsycINFO
- Original articles about RCTs and the affiliation of the first authors from Japan published in 2010

Among 2,975 studies located, 1,022 studies were identified as RCTs by reviewing their abstracts and/or original papers. Characteristic of these RCTs were analyzed according to a subset of criteria. 102(10%) of the RCTs identified were randomly selected and their quality was reviewed by two independent reviewers, using the risk of bias (van Tulder) scale.

## Results

Table1: Characteristics of RCTs

N=1022		
Type of control groups		
Head to head	460	(45.1%)
Placebo	397	(38.8%)
Dose	165	(16.1%)
Study design		
Parallel	771	(75.4%)
Crossover	205	(20.1%)
Factorial	46	(4.5%)
Number of arms		
2	833	(81.5%)
3	168	(16.5%)
>=4	21	(2.0%)
Journals		
Japanese journals	634	(62%)
International journals	388	(38%)
Registered to clinical registry system (n=102)	9	(9%)

Figure1: Sample size of RCTs in Japan

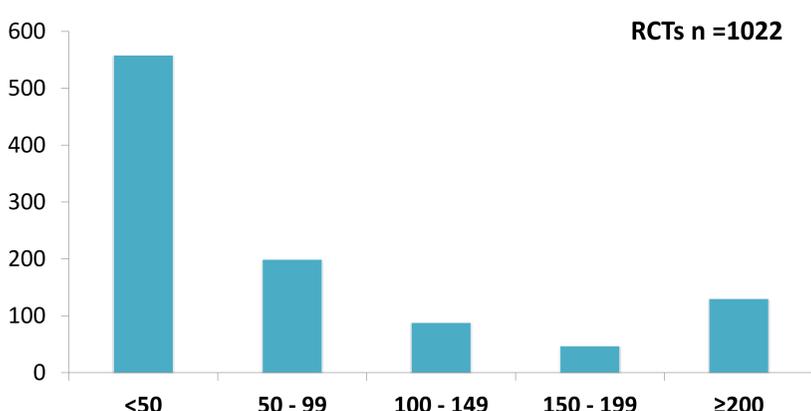


Figure2: Type of interventions in Japan

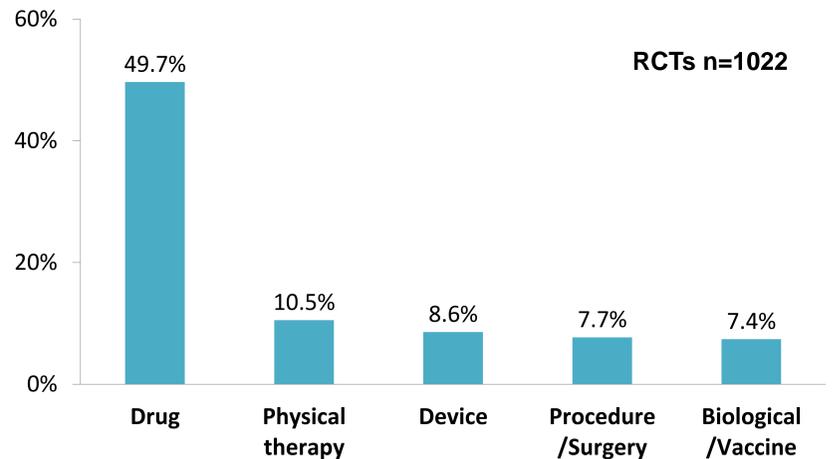


Figure3: Disease and conditions in Japan

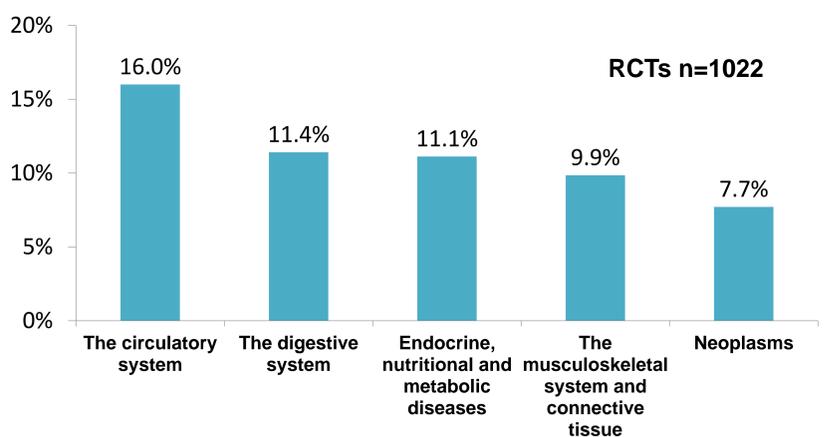
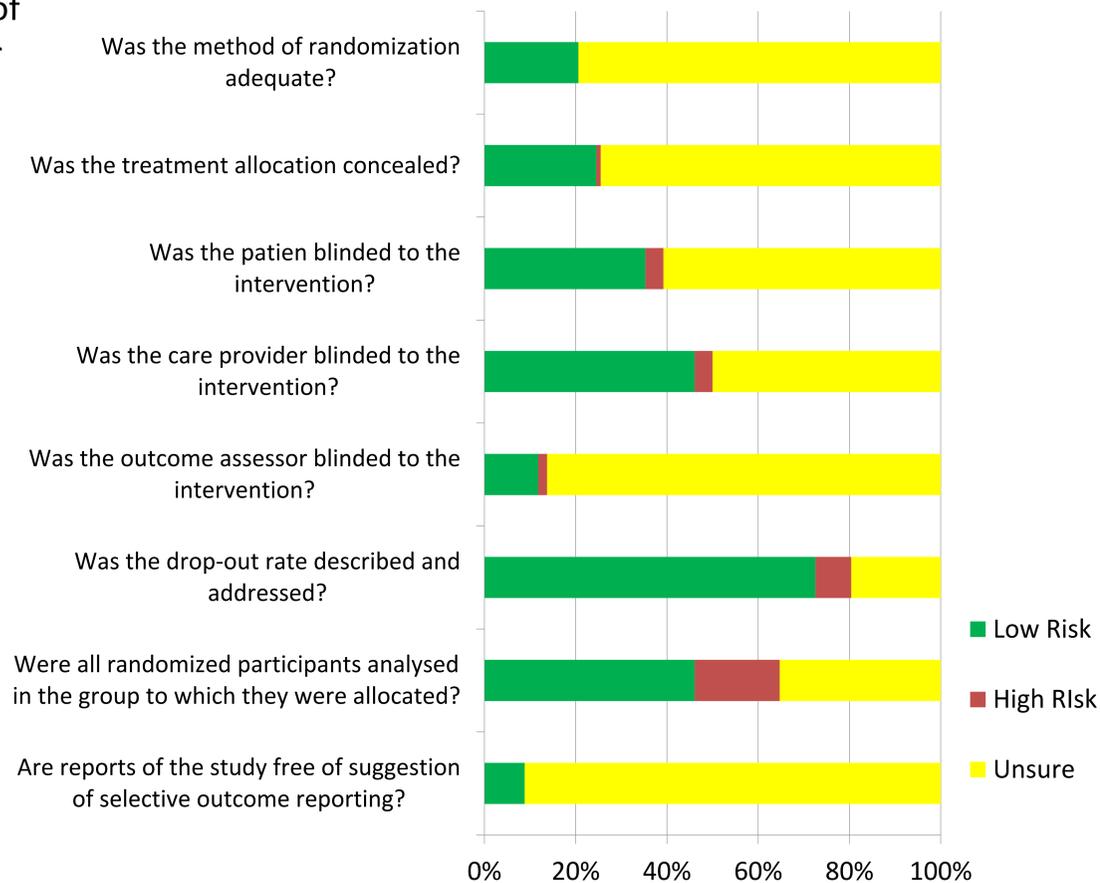


Figure4: Risk of bias



## Conclusions

Although 1022 of RCTs was conducted in 2010, the existing international databases failed to capture them.

Moreover, most of the trials were small sample size with parallel design and their quality was insufficient to clarify the true effect of health interventions.

CONSORT should be endorsed to promote and improve the quality of RCTs. Institutional review boards and journals should require trial investigators for clinical trial registration before implementation.

Improvement and promotion of RCTs are urgently needed.