實證文獻評析--隨機對照研究

台北榮民總醫院護理部
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101.05.26

Ask Acquire Appraise Apply Assess

問問題、搜尋、評讀、應用、評核

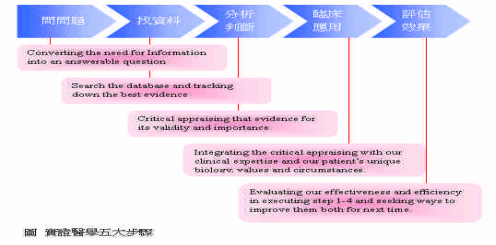
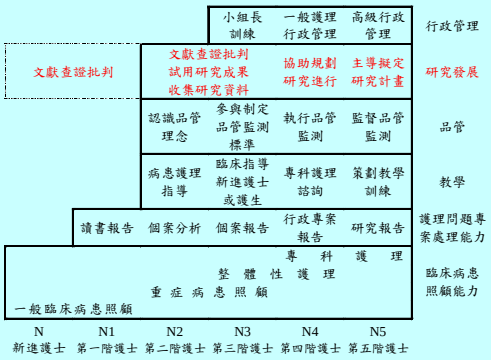


圖 實證醫學五大步驟



圖一 醫學中心各階護理人員角色功能與職責

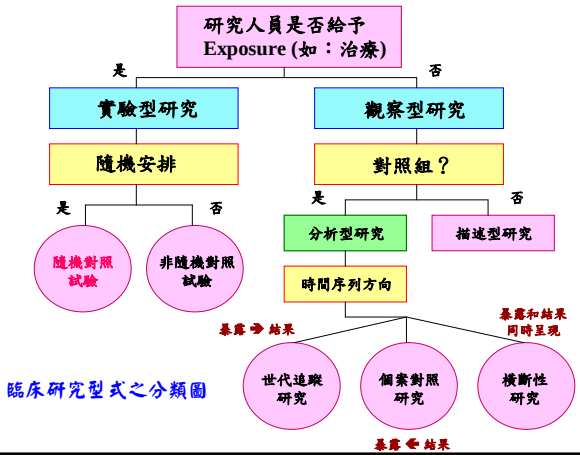
研究設計種類

就描述性或實驗性而言：

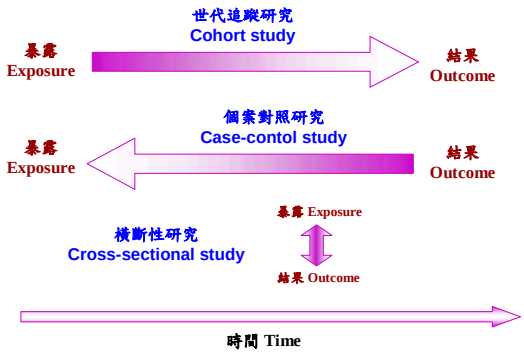
- 描述性或相關性研究設計
- 實驗性或類實驗性研究設計

就回溯性或前瞻性而言：

- 橫斷面研究法 (Cross-sectional study)
- 個案對照研究法(Case-control study)
- 追蹤研究法(Cohort study)



臨床研究型式之分類圖



三種研究設計的時間方向概要圖說明

描述性調查型研究設計

- **A descriptive survey research** is the method of gathering data from respondents thought to be representative of some population. Researchers use an instrument composed of closed structure or open-ended questions. This is the usual form of data collection in the social sciences, providing for efficient collection of data over populations, reachable to administration in person, by phone, or using the Internet.
- 例：欲瞭解護理人員營養認知、態度、飲食行為與健康狀況

描述性比較型或相關型研究設計

- **Comparative surveys** compare the experiences of two or more groups of respondents.
- **Correlational descriptive surveys** let the researcher to measure the scope to which levels of one event correspond to levels of another.
- A comparative survey is different from a correlational survey.
- In a correlational survey a sample representing a cross-section of a single population of interest is studied; in the comparative survey samples from two or more populations are compared.
- 例：欲瞭解老人癡呆症之子女身為主要照顧者，其孝道觀念與其照護負荷間狀況與相關性，此種研究屬於描述相關性研究設計

描述性縱貫型研究設計

- **Descriptive longitudinal study** is designed to test stability or variation over time and includes repeated observations. Its purpose is to characterize the course of a phenomenon such as human development or adaptation.
- 例：欲調查罹患癌症兒童其父親的調適過程，以家庭調適量表於罹病頭2週、六個月、一年及兩年，追蹤同一個案，收集一系列之資料，此研究設計屬於縱貫式研究設計

橫斷面研究法 (Cross-sectional study)

- **Cross-sectional designs** involve selecting a representative sample from the population of interest and observing all the phenomena, including the putative cause and effect, of interest at the same point in time.
- 例：探討某醫學中心護理人員在98年4月時之工作滿意度

個案對照研究法(Case-control study)

- **Retrospective designs** begin with the selection of representative samples from at least two groups. Usually one group has the effect that is being studied, and the other does not. The participants are studied regarding the putative causes.
- 例：收集自97年1月至97年12月所有住院病人曾發生跌倒之資料，預測影響住院病人跌倒之高危險因子

追蹤研究法(Cohort study)

- **Prospective designs** involve sampling from a population of interest to obtain a representative group and observing the sample on at least two occasions. The key difference between cross-sectional and prospective designs is that prospective designs follow the participants into the future for a designated period of time. The investigator is particularly interested in learning that will experience the effect during the period of the study.
- 例：收集自98年4月至99年4月所有住院病人資料(含有無跌倒)，預測影響住院病人跌倒之高危險因子

實驗性研究設計

- Experimental designs, quasiexperimental designs, and many variations on experimental designs also can be used to test hypotheses. Experiments are studies in which the investigator manipulates a putative cause and measures an effect.
- There are three critical features of experiments: (1) random allocation of participants to the treatment and control groups, (2) manipulation of the causal variable, and (3) control through comparison of participants who did and did not receive the treatment or causal variable.
- 例：The effectiveness of different combinations of pulmonary rehabilitation program components: a randomized controlled trial.

類實驗性研究設計

- Quasiexperiments have the features of manipulation and control, but participants are not randomly assigned to the treatment and control groups.
- 例：欲瞭解提供臨床護理人員以登階訓練進行健康體能促進，其改善護理人員輪班、體能狀況與其睡眠及生活型態之影響效果

組別	前測	介入活動	一週後測	兩週後測	三週後測	四週後測
實驗	→ O1 →	實驗處置	→ O2	→ O3	→ O4	→ O5
對照	→ O1 →		→ O2	→ O3	→ O4	→ O5

Randomised Controlled Trials

評讀重點

隨機對照試驗
Randomized Controlled Trial (RCT)

- 樣本數計算
- 隨機分派--勿以隨機之名行非隨機之實
- 隱匿分配 (allocation concealment)--勿好奇而破解分派機制
- 組別間樣本數不均等的迷思
- 退出、流失、反覆--依最初分配組別分析(意圖治療分析，intent-to-treat)
- 盲性作業--研究者應明確敘述如何操作盲性作業，非僅賣弄術語(如單盲、雙盲、三盲)

Randomised Controlled Trials

- RCT - ideal design for experimental studies
- Used to determine the effect of an intervention compared to another treatment option, whether it be placebo, another treatment, or usual care
- Provide the best evidence on effectiveness of an intervention when designed well and appropriately performed
- Most rigorous method to determine the existence of a cause-effect relationship
- Properly performed RCTs reduce bias, confounding factors, and results by chance
- Poorly conducted RCTs are susceptible to bias and may produce misleading information or exaggerated treatment effects

Sampling

- Selecting participants from population and including them in the trial
- Inclusion/exclusion criteria – set to define a specific study group for the trial
- Sample should represent the population – most important to consider when selecting a sample
- Random sample – all members of a population should have equal chance of being selected

Sampling Methods

- **Probabilistic (Random) sampling** - random sampling of individuals from the target population
- **Consecutive** - consecutive sampling of every patient who meets the inclusion criteria from the population over a period of time
- **Systematic** - sampling occurs where samples are decided on a system, such as every third patient is to be enrolled in the trial
- **Convenience** - sampling by convenience

Randomisation

- Randomisation reduces bias
- Selection bias occurs when the groups in a research study are not comparable, which can impact on the treatment effect for the groups and produce misleading results
- Randomisation provides equal chance of all participants to be assigned to a particular group

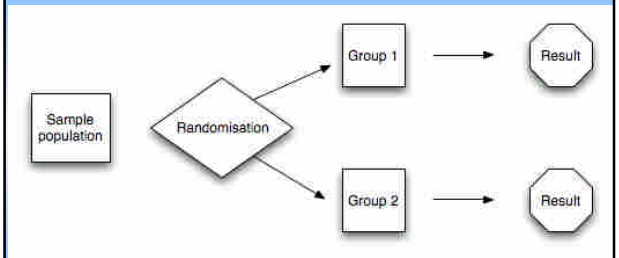
Valid Methods of Randomisation

- Coin flipping, dice, computer generated tables etc
- Important to assess randomisation
  - Trials all state randomisation
  - Need valid method
  - Quasi or pseudo-randomisation
- Valid randomisation
  - the investigator should not be able to determine what group the individual will be in - allocation concealment,
  - not to be confused with blinding, which occurs following allocation

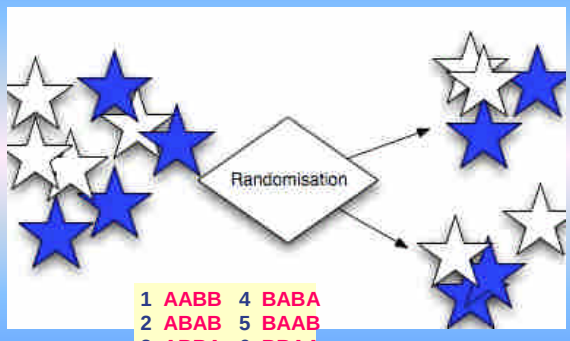
Randomisation Issues

- Simple methods may result in unequal group sizes
  - Tossing a coin or rolling a dice
- True randomisation results in similar group sizes
  - Block randomisation
- Confounding factors due to chance imbalances
  - stratification – prior to randomisation
  - ensures that important baseline characteristics are even in both groups

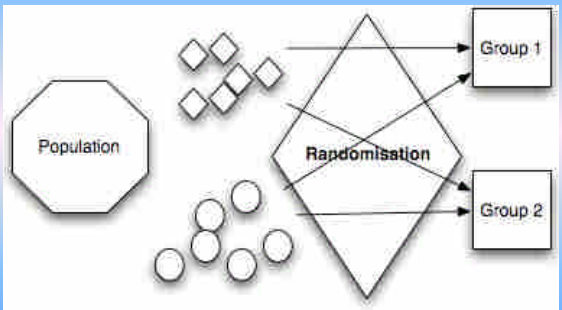
Randomisation



Block Randomisation



Stratified Randomisation



Blinding

'The RCT is a very beautiful technique, of wide applicability, but as with everything else there are snags. When humans have to make observations there is always the possibility of bias'

(Cochrane AL. 1972:2)

Blinding

- Method to eliminate bias from human behaviour
- Applies to participants, investigators, assessors etc
- Blinding of allocation
  - Those involved in the trial do not know which group has been assigned
- Single, double blinded
  - Are terms used to state whether blinding has occurred for both the participant and/or investigator

成功遮盲所得之潛在效益

遮盲對象	潛在效益
參試者	▪較不可能對治療的心理或生理反應懷有成見 ▪較可能順從試驗藥物用法 ▪較不可能找尋其他的附屬治療 ▪較不可能未提供結果資料，就半途離開試驗導致追蹤期間樣本流失
研究者	▪較不可能將他們的傾向或態度轉移至參試者 ▪較不可能差別實施輔助治療 ▪較不可能差別調整劑量 ▪較不可能差別排除參試者 ▪較不可能差別地鼓勵或勸阻參試者持續參加試驗的進行
評估者	▪較不可能懷有成見地影響結果評定，尤其是對主觀評定的試驗結果

Schulz, 2002

Sources of Bias

- Selection
- Performance
- Detection
- Attrition

Selection Bias

- Systematic differences between participant characteristics at the start of a trial
- Systematic differences occur during allocation to groups
- Can be avoided by blinding of investigators and/or participants to group

Performance Bias

- Systematic differences in the intervention of interest, or the influence of concurrent interventions
- Systematic differences occur during the intervention phase of a trial
- Can be avoided by blinding of investigators and/or participants to group

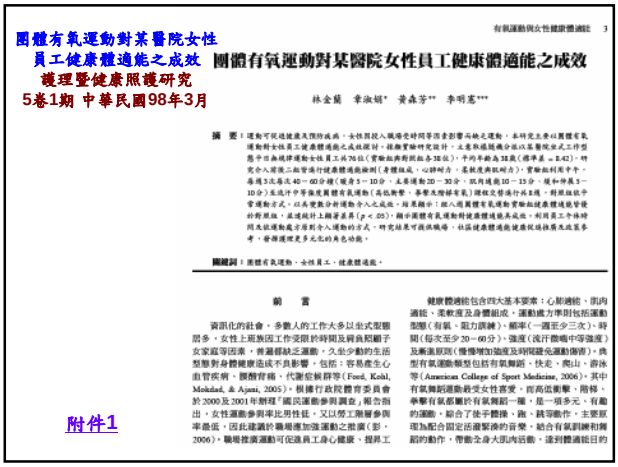
Detection Bias

- Systematic differences in how the outcome is assessed between groups
- Systematic differences occurs at measurement points during the trial
- Can be avoided by blinding of outcome assessor

Attrition Bias

- Systematic differences in loss to follow up between groups
- Systematic differences occur at measurement points during the trial
- Can be avoided by:
  - Accurate reporting of losses
  - Use of ITT analysis

團體有氧運動對某醫院女性員工健康體適能之成效
護理暨健康照護研究
5卷1期 中華民國98年3月



團體有氧運動對某醫院女性員工健康體適能之成效

林金蘭　章淑娟*　黃森芳**　李明憲***

摘　要

關鍵詞：團體有氧運動、女性員工、健康體適能。

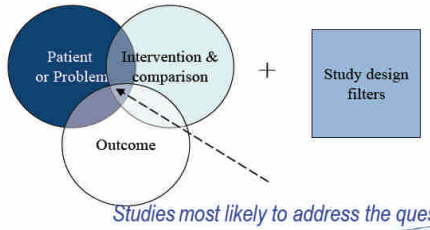
前　言

健康體適能包含四大基本要素：心肺適能、肌肉適能、柔軟度及身體組成。運動處方準則包括運動型態（有氧、阻力訓練）、頻率（一週至少三次）、時間（每次至少20－60分）、強度（漸汗微喘中等強度）及漸進原則（慢慢增加強度及時間避免運動傷害）。典型有氧運動類型包括有氧舞蹈、快走、爬山、游泳等（American College of Sport Medicine, 2006）。其中有氧舞蹈運動最受女性喜愛，而高低衝擊、階梯、拳擊有氧都屬於有氧舞蹈一種，是一項多元、有趣的運動，結合了徒手體操、跑、跳等動作，主要原理為配合固定活潑緊湊的音樂，結合有氧訓練和舞蹈的動作，帶動全身大肌肉活動，達到體適能目的

附件1

A focused question helps in searching for studies

PICO + STUDY DESIGN FILTER



Studies most likely to address the question

JBI-MAStARI – Assessment:
The critical appraisal criteria
單一隨機(或類隨機)研究文獻評析

原　則	是	否	不清楚
1.分派至實驗組是否是真正的隨機分配？			
2.參加者是否不知自己在實驗組或對照組?			
3.分配者是否將分派結果保持未知？			
4.分析結果時是否描述樣本流失並納入分析？			
5.評估結果者是否不知實驗的組別？			
6.實驗組和對照組在進入試驗時是否相當？			
7.實驗組和對照組是否被等同對待？			
8.實驗組和對照組測量是否一致？			
9.測量方法是否可靠？			
10.統計方法是否適當？			

Cochrane Assessing Risk of Bias (1)

Domain	Description (provide evidence from text and any further comments)	Judgement
Adequate sequence generation 分派是否隨機 Was the allocation sequence adequately generated?		Yes Unclear No
Allocation concealment 分派隱匿，分組機會相似 Was allocation adequately concealed?		Yes Unclear No
Blinding 盲化 Was knowledge of the allocated interventions adequately prevented during the study?	Patients: 病人、研究人員對分派不清楚 Caregivers: 兩組病人均被同等對待 Outcome assessors: 結果分析者也不能分辨組別	Yes Unclear No

Cochrane Assessing Risk of Bias (2)

Domain	Description (provide evidence from text and any further comments)	Judgement
Incomplete outcome data addressed 追蹤是否完整、不完整資料是否同樣分析 Were incomplete outcome data adequately addressed?		Yes Unclear No
Free of selective reporting 不會選擇性報告結果 Are reports of the study free of suggestion of selective outcome reporting?		Yes Unclear No
Free of other bias 沒有其他偏見 Was the study apparently free of other problems that could put it at a high risk of bias?		Yes Unclear No

本部
讀書報告
寫作格式
-- RCT

RCT 文獻：

篇　名	作者（年份）、標題、期刊（名稱、卷期、頁數）	
研究方法 (Design)	RCT	
研究對象 (Participant)	-	
介入措施 (Intervention)	-	
比較措施 (Comparison)	-	
成果指標 (Outcome)	-	
評析項目	評析結果	評析根據
分派是否隨機	☐Yes ☐No ☐Unclear	-
分派過程隱匿，分組機會相似	☐Yes ☐No ☐Unclear	-
兩組病人均被同等對待	☐Yes ☐No ☐Unclear	-
病人、研究人員對分派不清楚	☐Yes ☐No ☐Unclear	-
追蹤是否夠久、夠完整	☐Yes ☐No ☐Unclear	-
主要研究成果	-	

分組練習