實證護理研究設計概論

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實證醫學五步驟(5A)

- 提出問題(Ask: PICO)

提問: 由個案的臨床資料提出可回答的臨床問題

- 搜尋證據(Acquire)

尋找最佳的實證文獻〔各種文獻資料庫，未/發表的資料〕

- 嚴格評讀(Appraisal: VIP)

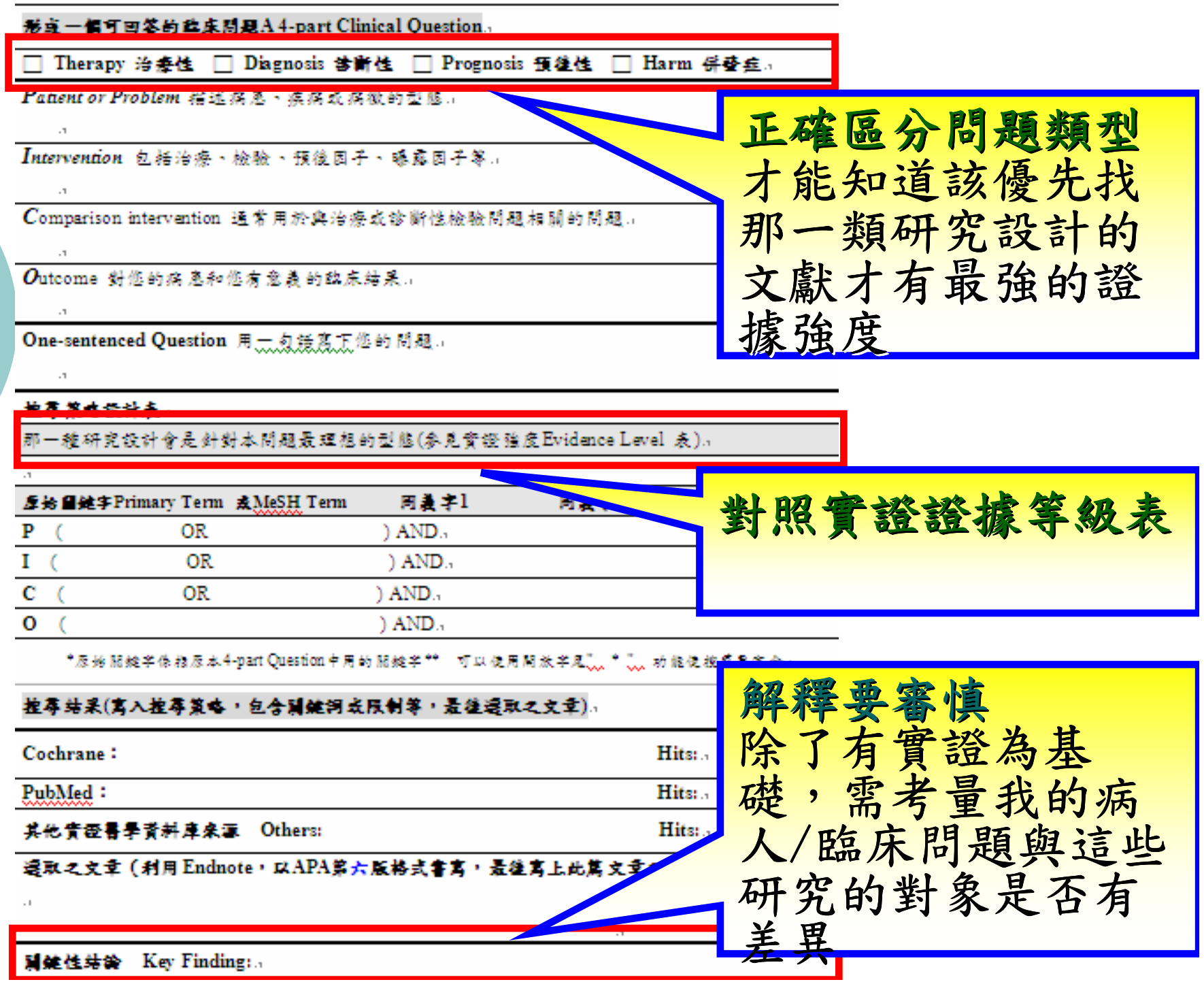
評估最佳實證醫學文獻的可信度、臨床重要性、可應用性

- 臨床運用(Apply:3E)

整合並應用於實際患者的治療決策

- 效果評估(Audit)

溝通用病人可聽懂語言，告知各種處置之可能利益與風險



正確區分問題類型
才能知道該優先找那一類研究設計的文獻才有最強的證據強度

對照實證證據等級表

解釋要審慎
除了有實證為基礎，需考量我的病人/臨床問題與這些研究的對象是否有差異

綱要

- 研究設計確認
- 研究結果判讀
- 實證文獻等級判讀

解答不同類型臨床問題之最佳研究設計

Question type (問題類型)	Suggested best type of study (研究設計)
Therapy	SR＞RCT＞Cohort ＞ Case control ＞ Case series
Diagnostic test 診斷性檢驗或檢查	Prospective, blinded cross-sectional study comparing with gold standard 前瞻性、盲法、與黃金標準進行比較之斷面研究
Etiology /Harm 病因/傷害	SR＞Cohort ＞ Case control ＞ Case series
Prognosis 預後	SR＞Cohort ＞ Case control ＞ Case series 系統性回顧 ＞世代研究 ＞ 病例對照 ＞ 病例系列研究
Prevention 預防	SR＞RCT ＞Cohort＞ Case control ＞ Case series
Cost	Economic analysis

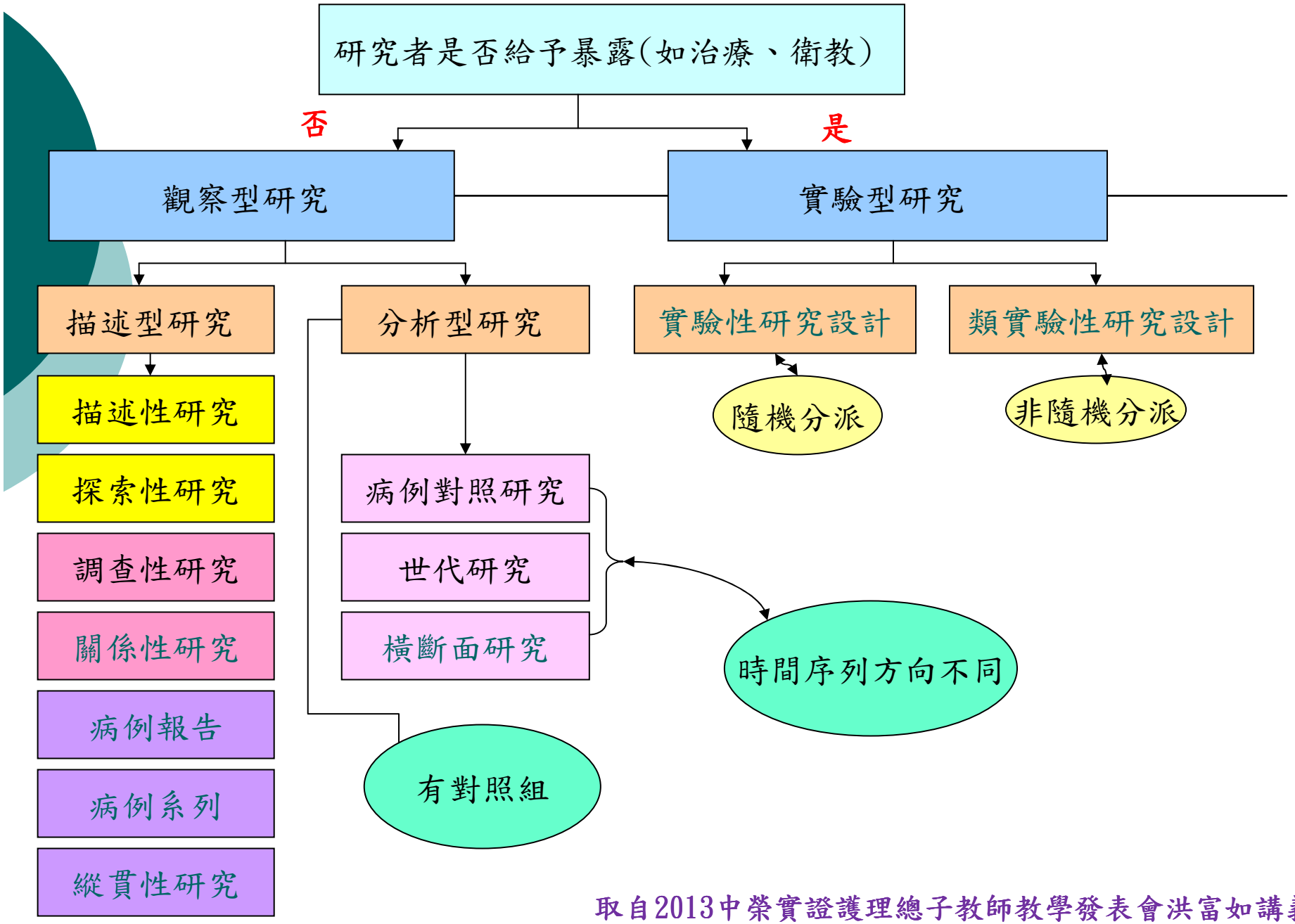
所選文獻資料之研究設計類型是否適合用來回答你的臨床問題(PICO)?

決定要不要繼續讀下去?

1.這篇研究是否問一個清楚的問題?
(與我的PICO比較)
2.這篇研究設計是否為回答此問題的最佳等級?
3.研究結果是否適用於我們的病人?

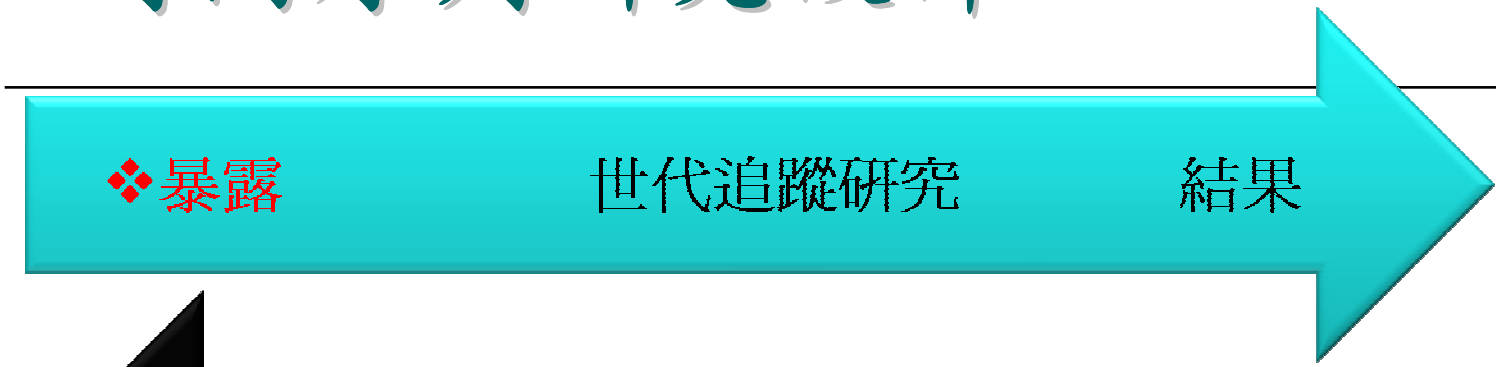
臨床文獻的結構

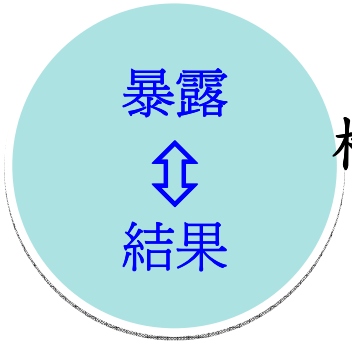
- **Abstract**
- **Introduction & Background (Why)**
- **Methods (Who & How)**
- **Results, Descriptive and analytical (What)**
- **Discussion (So What)**
- **References**



取自2013中榮實證護理總子教師教學發表會洪富如講義

時間序列研究設計



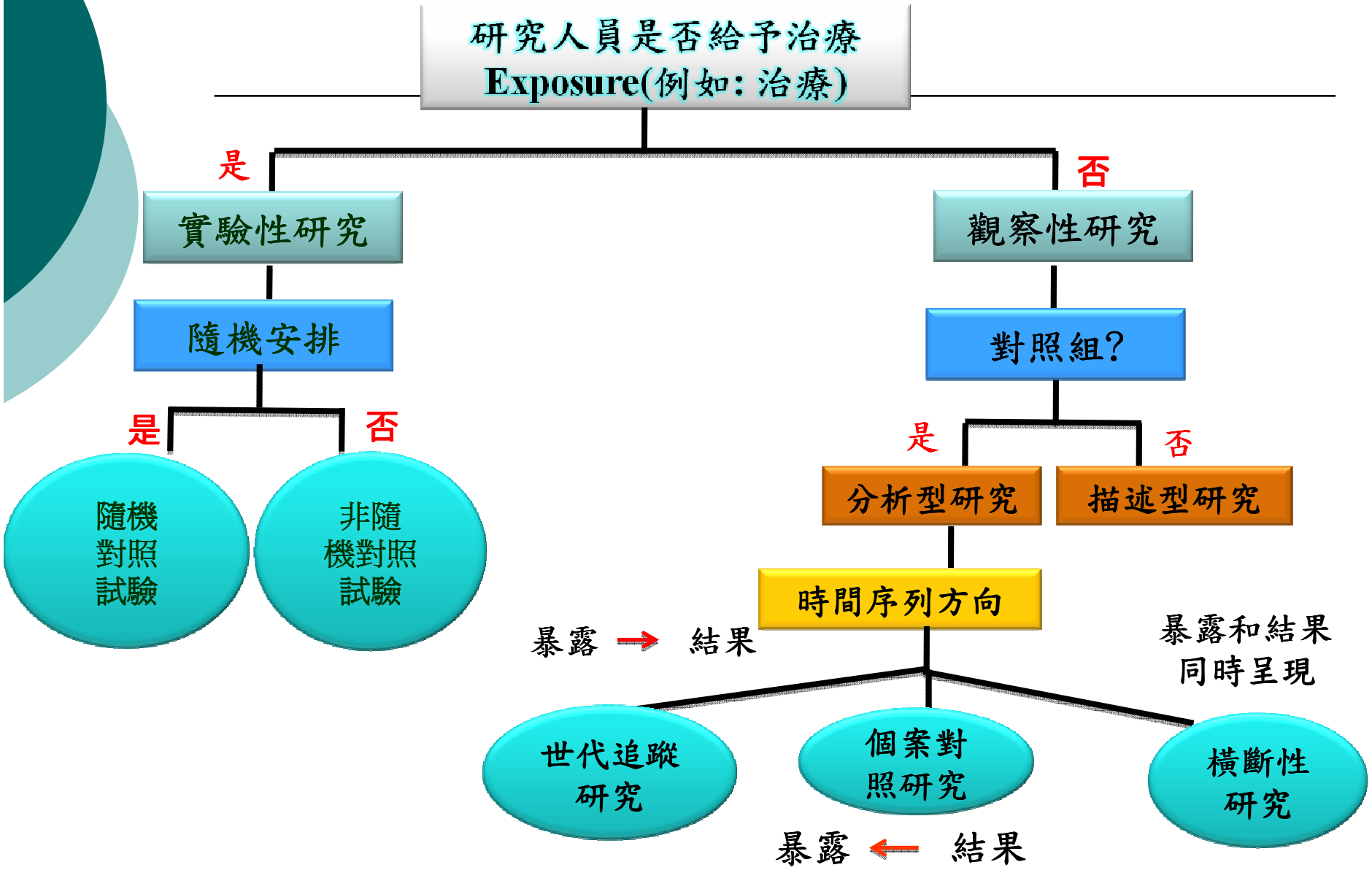


橫斷性研究

時間

舒茲，格里米斯，& 林菁華.（2008）

醫學領域常見的研究設計



臨床常用的研究設計簡介

- 隨機對照臨床試驗(RCT)
- 世代研究(Cohort)
- 系統性回顧(SR)

隨機對照臨床試驗 (RCT)
Randomized controlled clinical trial

○名詞解釋:受試者被隨機分派到實驗組或對照組，並後續追蹤群組間的變異數和結果。

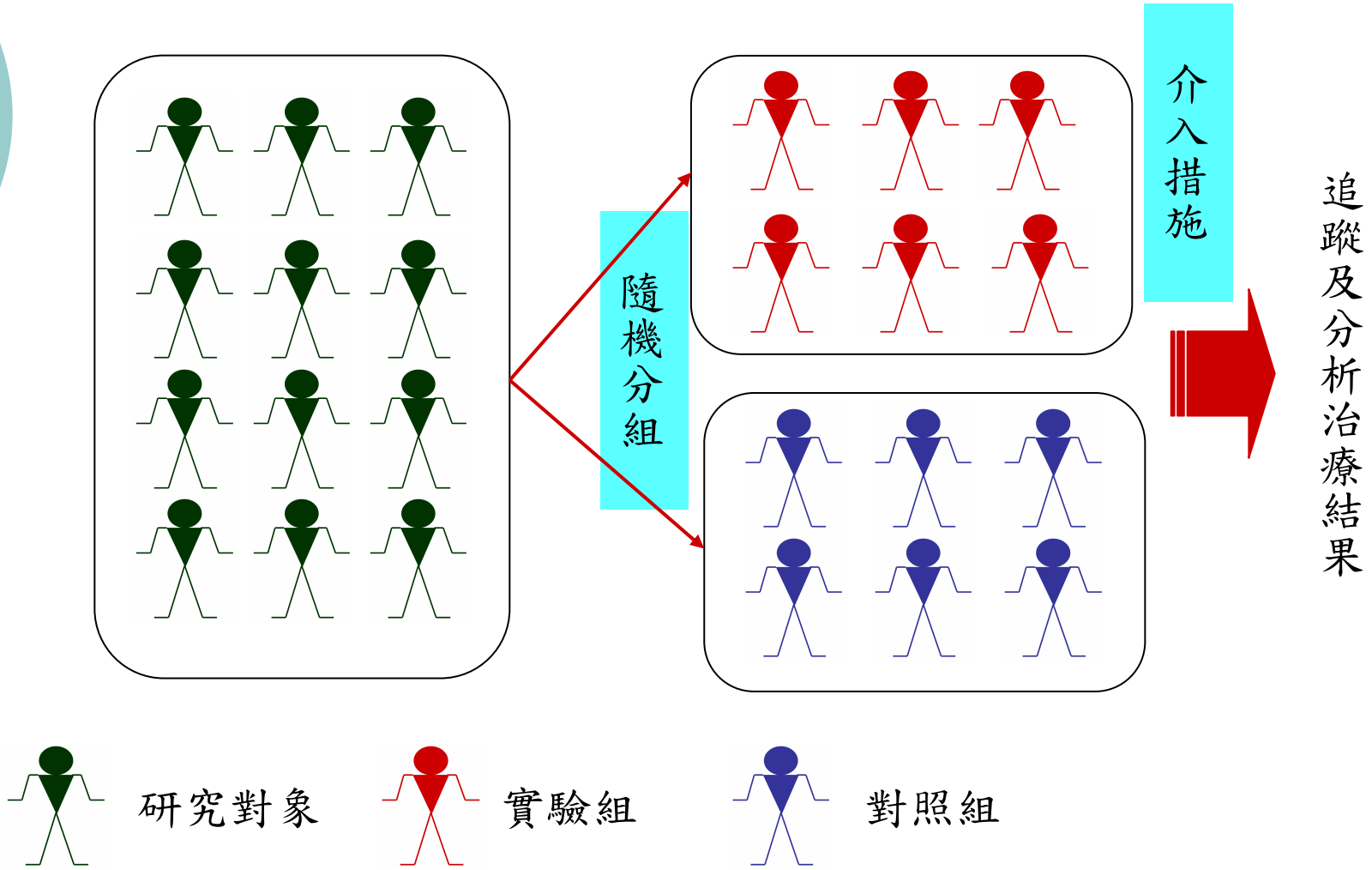
○研究特點

1.在研究中導入了實驗/處置

2.固定其他的條件，兩組之間只有處置不同

3.隨機方式使兩組的干擾因素相似，使兩組病人能充分的相提並論(可比較性comparable)

RCT研究架構



介入　（治療、衛教）

- 在的效益　，　用或　性
- 強度、　量、　數
- 可能　到標準　，　到合理的　定性

考自2012實證護理師資　　張　如講義

隨機 (Randomization)

- 一受試者被分派 實驗 組機會 等
- 使介入 的 因子在各組分
- 可 除因隨 分派所 的 差
- 可對等比較之組 ，提 結果正確性
- 方法:
  1. 隨機 數
  2. 隨機表
  3. 理方法: 、 子

(control)

- 研究
- 實驗組的變
- 對照組、　　組

盲　（　　）

- 盲試驗:受試者
- 盲試驗:受試者、照顧者、評量者
- 盲試驗:　　資料分析者

隨機對照臨床試驗 (RCT)

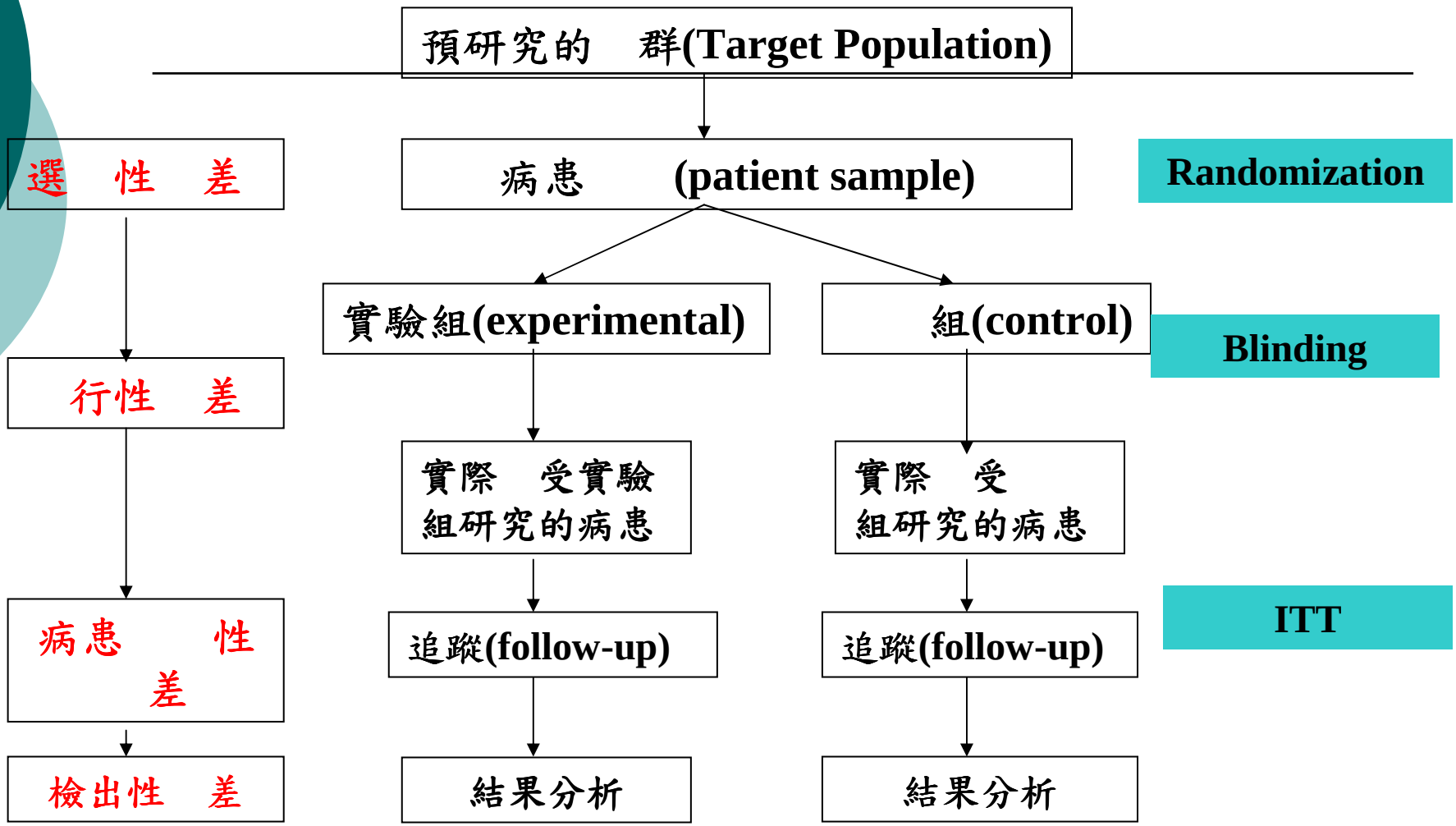
優點:

- 因果關係清楚
- 可　預　與

點:

- 干擾因素在自　　下不　估　　度
- 隨機分　不　證兩組的　　一定會一　。
- 　　者的　差

研究的　差來　　解決方式


預研究的　群(Target Population)
選　性　差
病患　(patient sample)
Randomization
實驗組(experimental)
組(control)
Blinding
行性　差
實際　受實驗組研究的病患
實際　受組研究的病患
病患　性差
追蹤(follow-up)
追蹤(follow-up)
ITT
檢出性　差
結果分析
結果分析

個　隨機試驗的證據是有效的　？

- 病人的治療分派是隨機的
- 隨機分派　　使否
- 對照組與實驗組在進入試驗時是否相似
- 病人的追蹤是否　　、　　整
- 所有的病人　被　到　先分派的組　　分析
- 病人、醫師、研究　是否對治療分派不知
- 對照組與實驗組是否被同等對

PICO: 治療能否 分

病人 性

The additional therapeutic effect of group music therapy for schizophrenic patients: a randomized study

Ulrich G, Houtmans T, Gold C. The additional therapeutic effect of group music therapy for schizophrenic patients: a randomized study.

Objective: Schizophrenia is one of the most serious mental disorders. Music therapy has only recently been introduced as a form of treatment. The aim of this study was to examine the effect of music therapy for schizophrenic in-patients needing acute care.
Method: Thirty-seven patients with psychotic disorders were randomly assigned to an experimental group and a control group. Both groups received medication and treatment indicated for their disorder. Additionally, the experimental group (n = 21) underwent group music therapy.
Results: Significant effects of music therapy are found in patients' self-evaluation of their psychosocial orientation and for negative symptoms. No differences were found in the quality of life.
Conclusion: Musical activity diminishes negative symptoms and improves interpersonal contact. These positive effects of music therapy could increase the patient's abilities to adapt to the social environment in the community after discharge from the hospital.

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Key words: schizophrenia; music therapy; randomized controlled trial; negative symptoms; quality of life

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研究設計與我們臨床實際　　差異

In a meta-analysis (7) evidence is found that music therapy as an addition to standard care can help patients with schizophrenia to improve their global state, mental state, and social functioning in the short-to-medium term. The most important studies (8, 9) show effects of music therapy on social function and negative symptoms. Hayashi et al. (10) also found effects of music therapy on quality of life (QOL). However, these last three studies are Asian studies and it is not clear whether the standard of care in Asia is comparable with that in European countries and therefore whether the effects found in these studies would be the same in European countries. The present study is a replication and integration of the previous studies.

Aims of the study

The aim of the study was to examine the effectiveness of music therapy in increasing interpersonal contact, reducing negative symptoms and enhancing QOL of schizophrenic acute care in-patients in a European context.

Material and methods

Design

To examine the effect of group music therapy sessions for schizophrenic patients, a randomized controlled trial in a pretest–post-test design was used. In this study, a control group and an experimental group were compared. The control group received the standard treatment used in the clinic (11). The experimental group underwent music therapy in addition to the standard treatment. Most patients of the control group were involved in another activity during the time the experimental group underwent music therapy. The study spanned a period of 8 months. During this time, patients and nurses filled in questionnaires prior to and after music therapy sessions.

Sampling

Content of music therapy

On average, the experimental group had 7.5 sessions of music therapy (SD 3.5). This amounts to 1.6 therapy sessions a week. Each session took 45 min. During these sessions, the main activity of the patients was playing together on rhythm instruments. These instruments can be played relatively easily. The sound stops as soon as the player stops playing. This implies that the player is responsible for his actions. The music therapist uses musical techniques (13) to structure, emphasize or bait the playing. During the sessions, structured or semi-structured musical exercises were often used. Playing and singing famous rock and pop songs were also used frequently. Besides playing music, there were group discussions used for reflection.

In music therapy sessions, orthopedagogical techniques and a supportive way of working were often used (14, 15). An important issue during the sessions was stimulating the social interactions and learning to deal with problems in the social interactions. The main focus of the music therapy was learning how to work together with others in a social setting. To achieve this goal, the music therapist uses the available resources of the patient. The therapeutic method was eclectic with behaviouristic accents. Ultra-sensitive listening attitude (16) was used.

Assessment

Because the patients stayed in different wards, there were a total of eight nurses and one medical specialist who assessed them. Before the start of the study, they were trained in the use of observer instruments to achieve high inter-rater reliability. For every patient, the observer instruments were filled in by two raters in pre- and post-tests. In the analysis, the means of the two raters were used.

Interpersonal contact was assessed by subscales 1, 5 and 6 of the Gießentest (17). With this German test, the self-assessment and the observer assessment of social relations can be compared easily. Aspects of closeness with and dependency on other people are important in this test. Subscales, such as

Randomization- Yes

Results

Procedure

The procedure is presented in Fig. 1. When the neuroleptic medication had stopped the psychotic symptoms, patients were eligible to join music therapy sessions. At this point, the medical specialist asked each patient if he/she was interested in music therapy. Forty-seven patients who indicated that they wanted to participate in music therapy were then randomly assigned to either the control or experimental group by throwing a die. After patients were assigned to either the experimental or control group, they were asked whether they were

這個有效　重要的證據　來自RCT)適用於我們的病人

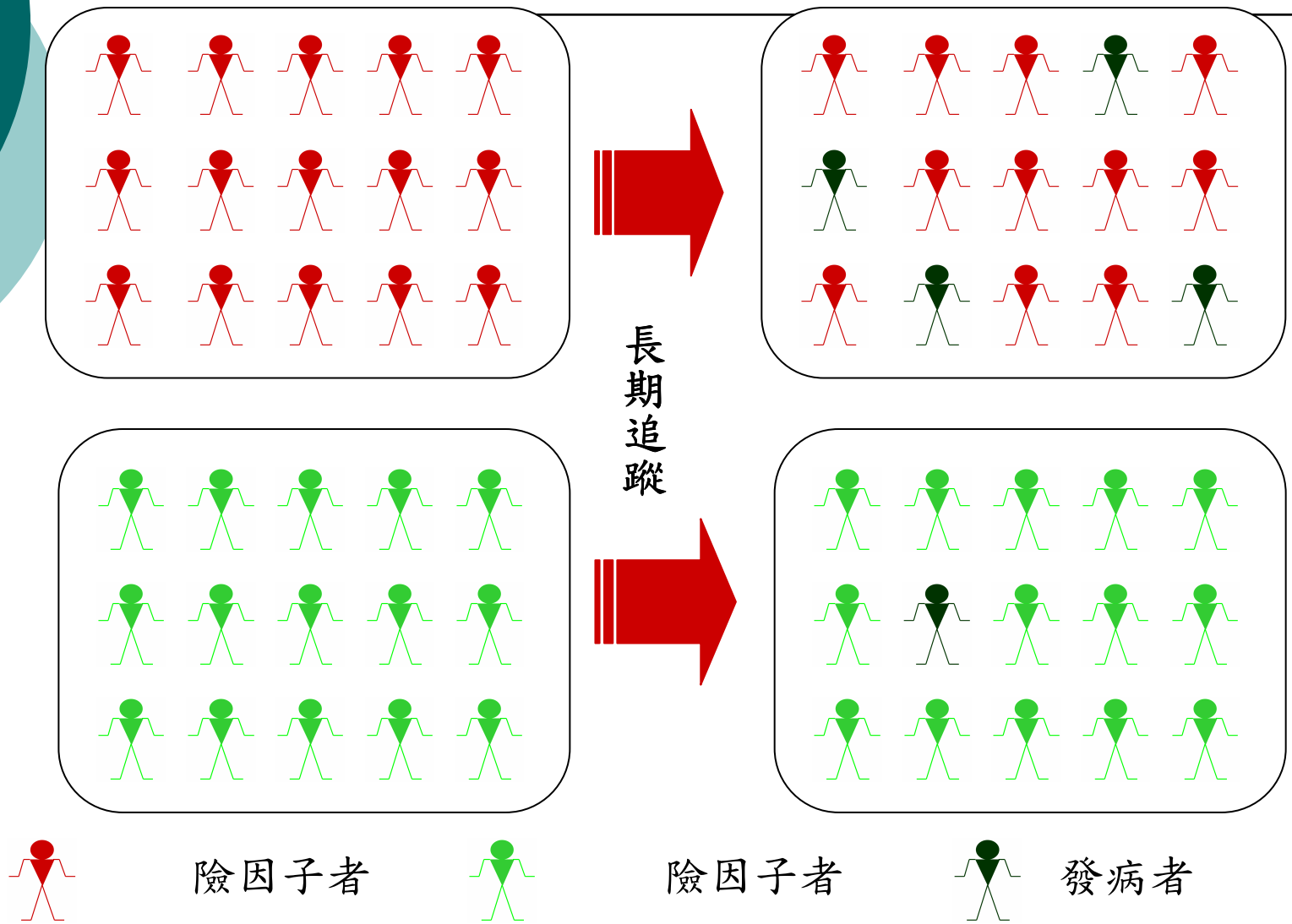
- 我們的病人與研究中的病人　否非常不同，於　法應用這個研究結果
- 這個治療適用於我們的臨床
- 我們的病人可能　治療中　到　　處或　處
- 對於我們要預防的結果　我們所提　的治療，病人的　　觀和期　　為

世代研究(Cohort)

○名詞解釋:分　兩組不同的病人，一組　受介入　/暴露，　一組　有，後續追蹤兩組在未來發　的結果。

○研究特點:　是前瞻性的研究

世代研究 (Cohort Study)



探討危險因子的角色

世代研究(Cohort)

- 研究對象

  資料庫中找出　　露　　有　露於研究標　　或因素的兩個　群

- 研究

  研究者不　入　　處置，　　追蹤　了解兩個　群的結果　預後

- 　選領域

  探　　預期風險因素對預後

世代研究 (Cohort Study)

優點:

- 較　　理的顧
- 可對兩組受試者的條件　　對
- 　入條件　結果評估能標準
- 較RCT在行　　較為簡

點:

- 對照組可能不
- 可能　　干擾因素
- 　　盲性
- 　　隨機分組
- 研究　見　病時　需　　的個案數　或長　的追蹤時間

世代研究的證據是有效的　？

- 　特定、　代表性的病人　　，是否　處於同一病　　？
- 研究中的病人是否追蹤　　、　　整?
- 研究結果是否有　觀的標準?
- 不同的預後　群組分析中，是否　對重要預後因子　調整?

系統性文獻回顧 (Systematic review, SR)

○名詞解釋:對醫學文獻的整理，運用　確的方法進行　整的文獻搜尋和個　研究的嚴格評讀，　適時　運用適　統計學分析整合這些有效的研究。

○研究特點:

1.　合　個　的和方法　分相　的研究報告整合在一　進行分析

2　整研究的統計分析方法　為 meta-analysis (後設分析)

系統性文獻回顧或描述型回顧?

Etiology and management of esophageal impaction in children: A **review** of 11 years.

1. Alrazzak BA, Al-Subu A, Elitsur Y.
Avicenna J Med. 2013 Apr;3(2):33-6. doi: 10.4103/2231-0770.114113.
PMID: 23930240 [PubMed] **Free PMC Article**
Related citations

Surgery for cataracts in people with age-related macular degeneration.

1. Casparis H, Lindsley K, Kuo IC, Sikder S, Bressler NB.
Cochrane Database Syst Rev. 2012 Jun 13;6:CD006757. doi: 10.1002/14651858.CD006757.pub3. **Review**.
PMID: 22696359 [PubMed - indexed for MEDLINE] **Free PMC Article**
Related citations

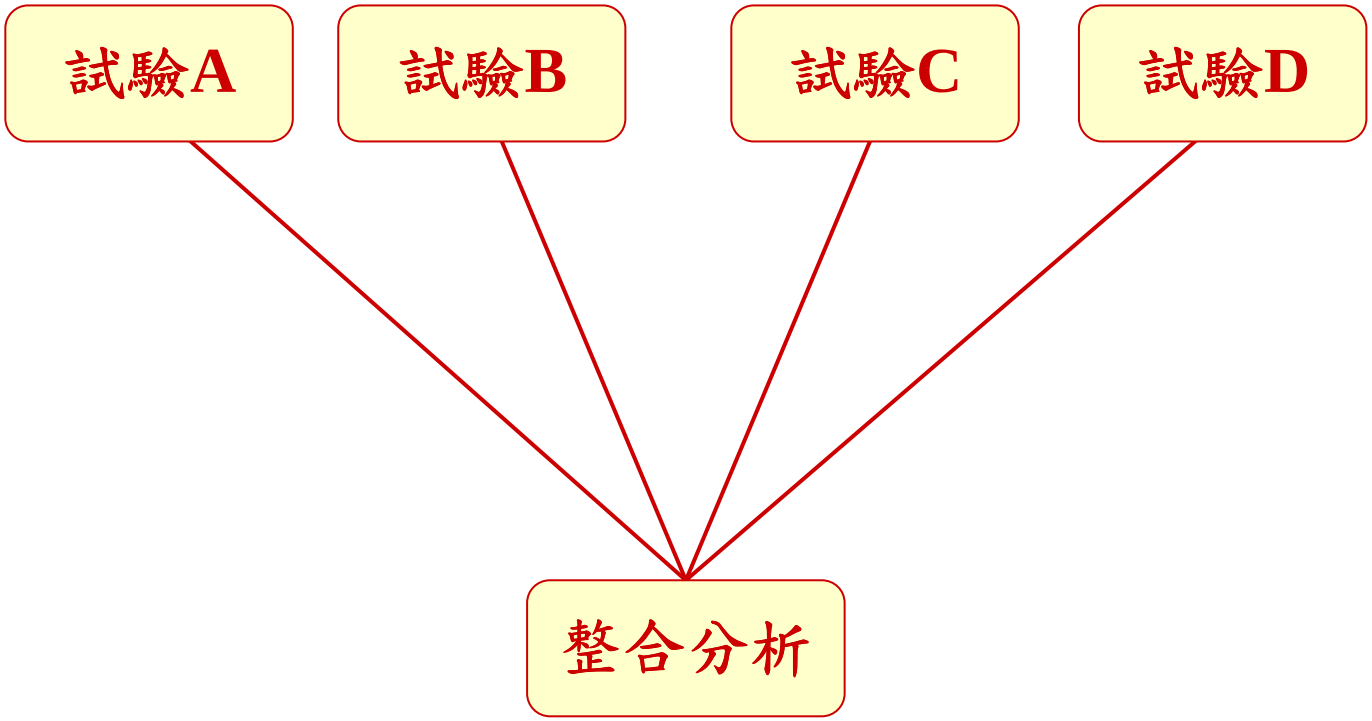
Acupuncture for treatment of irritable bowel syndrome.

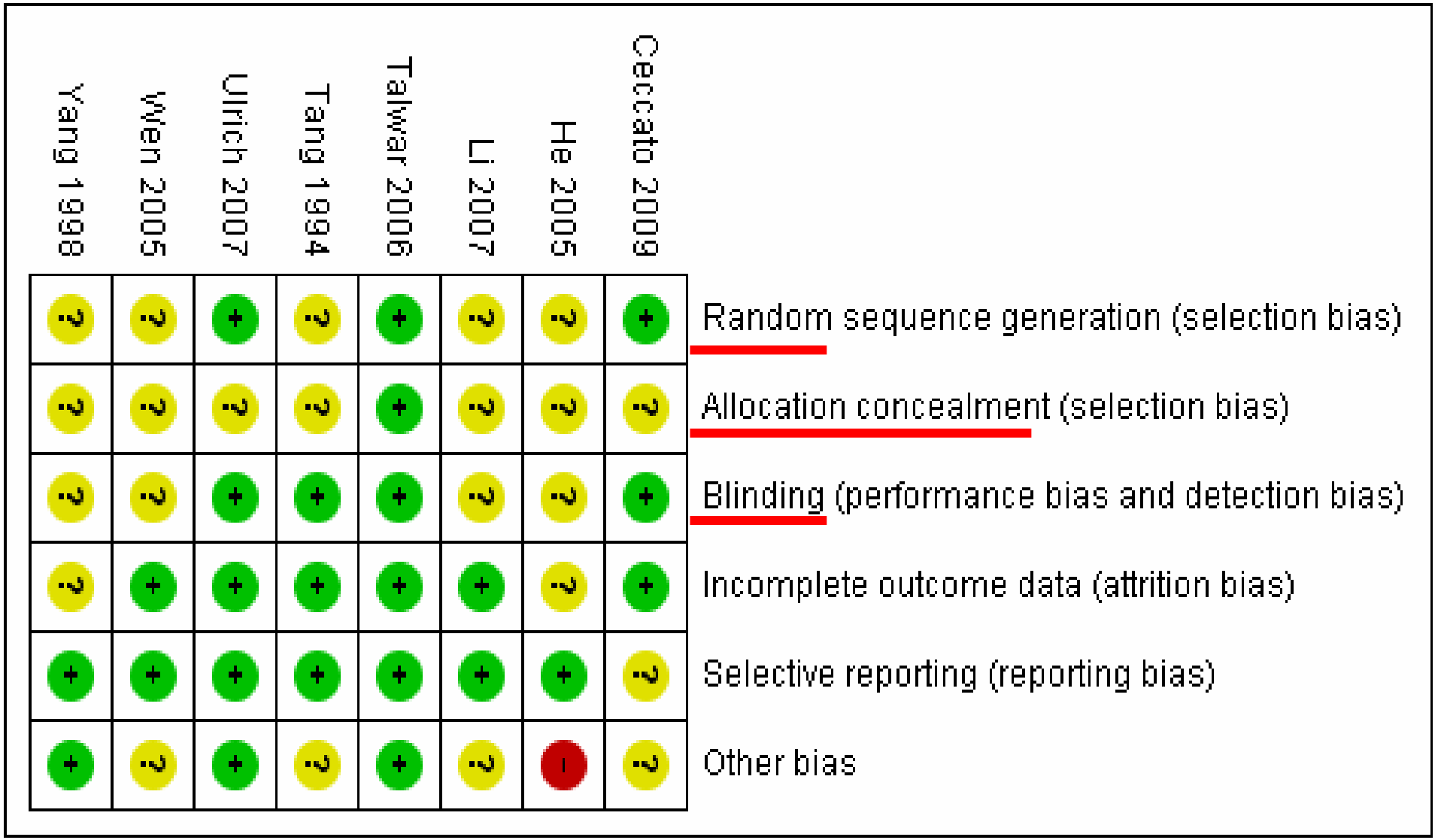
2. Manheimer E, Cheng K, Wieland LS, Min LS, Shen X, Berman BM, Lao L.
Cochrane Database Syst Rev. 2012 May 16;5:CD005111. doi: 10.1002/14651858.CD005111.pub3. **Review**.
PMID: 22592702 [PubMed - indexed for MEDLINE] **Free PMC Article**
Related citations

Ayurvedic treatments for diabetes mellitus.

3. Sridharan K, Mohan R, Ramaratnam S, Panneerselvam D.
Cochrane Database Syst Rev. 2011 Dec 7;(12):CD008288. doi: 10.1002/14651858.CD008288.pub2 **Review**.
PMID: 22161426 [PubMed - indexed for MEDLINE] **Free PMC Article**
Related citations

系統性文獻回顧(SR)




Caccato 2009
He 2005
Li 2007
Talwar 2006
Tang 1994
Ulrich 2007
Wan 2005
Yang 1998
Random sequence generation (selection bias)
Allocation concealment (selection bias)
Blinding (performance bias and detection bias)
Incomplete outcome data (attrition bias)
Selective reporting (reporting bias)
Other bias

來自此SR的證據是有效/重要　？

- 這是一個RCT的系統性回顧
- 對相關試驗所　的搜尋，其描述是否　整

- 個　研究是否　　效度評估
- 分析中是否使用個　研究的病人的數據(或使用　整的數據)
- 這些結果在不同的研究之間是否一　？
- 療效有　　？
- 對於療效的描述有　　準?

來自SR中的這個有效　重要的證據適用於我們的病人

- 我們的病人是否與研究中病人的差異　　，　於　法應用其結果
- 該　治療在我們的診療　　中是否可行
- 我們的病人可能　治療中受　或受害
- 　對我們　要預防的結果和該　治療可能　　的傷害，我們的病人的　　觀和期　為

PICO: 治療能否 分 病人 性

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

MUSIC THERAPY versus

Patient or population: pe
Settings:
Intervention: MUSIC THE

Outcomes	Quality of the evidence (GRADE)	Comments
Mental state: Negative symptoms SANS Follow-up: 1-3 months	⊕⊕⊕⊕ **high**[1,2]	SMD -0.74 (-1 to -0.47)

ABSTRACT

Background

Music therapy is a therapeutic method that uses musical interaction as a means of communication and expression. The aim of the therapy is to help people with serious mental disorders to develop relationships and to address issues they may not be able to using words alone.

Objectives

To review the effects of music therapy, or music therapy added to standard care, compared with 'placebo' therapy, standard care or no treatment for people with serious mental disorders such as schizophrenia.

Search methods

We searched the Cochrane Schizophrenia Group Trials Register (December 2010) and supplemented this by contacting relevant study authors, handsearching of music therapy journals and manual searches of reference lists.

Selection criteria

All randomised controlled trials (RCTs) that compared music therapy with standard care, placebo therapy, or no treatment.

Data collection and analysis

Studies were reliably selected, quality assessed and data extracted. We excluded data where more than 30% of participants in any group were lost to follow-up. We synthesised non-skewed continuous endpoint data from valid scales using a standardised mean difference (SMD). If statistical heterogeneity was found, we examined treatment 'dosage' and treatment approach as possible sources of heterogeneity.

Main results

We included eight studies (total 483 participants). These examined effects of music therapy over the short- to medium-term (one to four months), with treatment 'dosage' varying from seven to 78 sessions. Music therapy added to standard care was superior to standard care for global state (medium-term, 1 RCT, n = 72, RR 0.10 95% CI 0.03 to 0.31, NNT 2 95% CI 1.2 to 2.2). Continuous data

Study Design			研究開始		問題 (用途)
研究種類	時間性	過去 ⇐	現在 ⬭	未來 ⇒	
Cross-sectional (prevalence)	橫斷性觀察		▼收集資料▼ Case & non-Case		盛行率、診斷
Cohort (longitudinal)	縱向性(前瞻)		定義世代並評估危險因子	觀察結果Y*N	發生率、病程預後、病因
Clinical Trial (experimental)	縱向性(前瞻)		作治療〔治療組與對照組〕	觀察結果Y*N	藥物療效評估
Case control (retrospective)	縱向性(回溯)	評估危險因子 Exposure: Y*N	界定病例組與非病例組		病因〔尤其罕病〕
Repeated cross-sectional	橫斷性觀察		收集資料▼	重複收集▼▼	隨時間改變

實證醫學中　證據等級簡要表

等級	證據等級	文獻研究設計　證據
A	1a	同　性的隨機對照試驗統合分析的系統性回顧文獻 (RCTs)
	1b	篇隨機對照試驗 (　的信　區間) (RCT)
	1c	有或　試驗* (All or none)
B	2a	同　性的世代研究的系統性回顧文獻 (cohorts)
	2b	篇世代研究:　的隨機對照試驗 (cohort、RCT)
	2c	預後研究:世代研究 (cohort study)
	3a	同　性的病例對照研究的系統性回顧文獻 (case series)
	3b	篇病例對照研究(case report)
C	4	系列病例報告:　世代研究或病例對照研究[a] (case series)
D	5	未　嚴格評判的　見: 或基於　理學、實驗　研究或基理之

*　有: 未介入治療時，所有病人　，介入治療後有　分　。
:未介入治療時，　分病人　，介入治療後　有病人　。

[a]　有　確定義的比較對象，對暴露因子或預後量　方法不　觀(暴露組與對照組)，　有　可能的干擾因子，追蹤時間不　長到　觀察到預後發　。

實證證據等級

	Level 1 證據力最高	Level 2	Level 3	Level 4
Therapy Harm	RCT	Cohort	Case-control	Case-series
Prognosis	Prospective Cohort	Retrospective Cohort	----------	Case-series
Diagnosis	Validating Cohort	Exploratory Cohort	Non-consecutive	Case-control
Differential Diagnosis	Prospective Cohort	Retrospective Cohort	Non-consecutive Cohort	Case-series