





中榮官網

網 中榮 日

實證醫學基本課程文獻評讀與數據擷取

實證決策管理委員會 實證醫學中心 何鴻鋆

進行方式:課前線上學習、現場討論

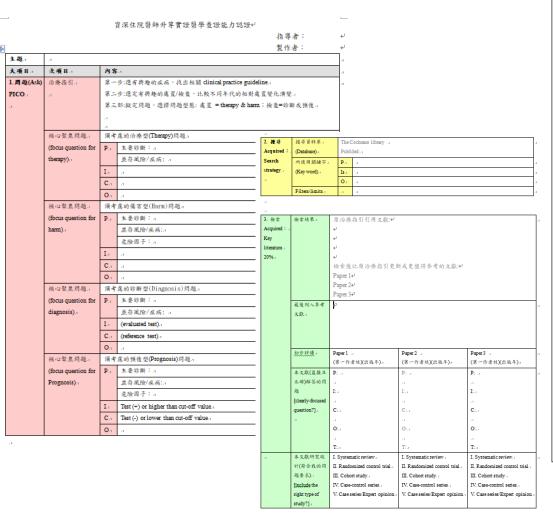


- 先找好科部內兩位指導老師,撰寫CAT過程中若有疑問,先與指導老師討論。特別是專科知識討論與未來進一步研究方向。
- 請按進度先自行完成線上影音學習,於上課前完成提 交初稿,以利指導者課前審視。上課時將直接針對相 關進度繳交之CAT內容討論。
- 請按照預約時段準時到場,逾時不候,亦無法補課, 未完成之進度遞延至下一梯次。兩梯次內未完成則需 重新報名等候安排。
- 為讓您接收訊息更快速直接,學員間也可以互相討論 取暖,請加入Line群組! _____
- http://line.me/R/ti/g/70EJpEycyf

呈現介面使用表格



201707 R4 EBM CAT模板.doc



Paper 1	就度 Validity/编数	Bias.		
条介へ各担	a			
Randomization. 分本過程是各係密 編差危險性 病/本確之/他 病/本確之/他 病/本確之/他 病/本確之/他 病/本確之/性 病/本症性 病/本確之/性 病/本確之/性 病/本確之/性 病/本症/性 病/本症/性 病/本症/性				
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高/不確定/依、				
Concealment, 一局治多無條件是				
開始多無條件是否 編並危險性		高/不確定/低。	高/不確定/低。	高/不確定/低。
照理人員是否不知证	一開始各組條件是	:否 偏差危險性	偏差危險性。	偏差危險性。
# 上			高/不確定/低。	高/不確定/低。
staff (PD)。 受試者是否不知道	照護人員是否不知	道 偏差危險性	偏差危險性	偏差危險性。
 会式者是否不知道键 编差危险性 高/不確定/依 高/不確定/依	谁是實驗組 Blind	to 高/不確定/低.,	高/不確定/低。	高/不確定/低。
是實驗推 Blind to participants ,				
participants .	受試者是否不知道	雄 偏差危險性	偏差危險性	偏差危險性。
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er loss to follow up. 是音稱用意向性治療 分析 Intention-to-treat analysis. 参州人製是音是內 Enough participants (power calculation). 報音或基於過數 Report ling bias or Others: 基名為慢質 NT · 若不是、組織下列 Bias 發達: 基在發性. 為/不確定/依. 為/本征述/依. 為/本征述/依. 為/本征述/依. 為/本征述/依. 為/本征述/依. 為/本述述/表述/表述述述述述述述述述述述述述述述述述述述述述述述述述述述述述述			14.	147 1 21-01
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是否為發質 NT · 若不是 · 繼續下列 Bias 禁續: - 多細年後因素控制是 · 傷差危險性. · 傷子來確定他. · 傷子不確定他. · 傷子不確定性. · 傷子不能性. · 傷子不能性. · 傷子不能性. · 傷子不確定性. · 傷子不確定性. · 傷子不確定性. · 傷子不確定性. · 傷子不能性. · 傷子不能.			177	147
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多知除了控制或置不 编差危險性. 編差危險性. 編差危險性. 編光を確定/他. 編/不確定/他. 編/本確定/他. 編/本述/他. M.		高/不確定/低。	高/不確定/低。	高/不確定/低。
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* Measurement of exposure. ***********************************				
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Level of evidence. #				
Level of evidence			4.4	
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Precise of results. Absolute Risk reduction: Mean' median differences: Odds ratio: Hazard ratio: Paper 2: Paper 3:			confidence interval /p valve/]	
Absolute Risk reduction: Mean/median differences Odds ratio Hazard ratio Paper 2: Paper 3:				
Mean/mediam differences: Odds ratio Hazard ratio Pager 2: Pager 3:	Precise of results.			
Odds ratio: Hazard ratio:. Paper 2: Paper 3:				
Hazard ratio . Pager 2: Pager 3: Pager 3:				
Paper 2: Paper 3:				
Paper 3:				
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進度



- 1. 題目設定與形成及精準搜尋與證據選定
- 2. 證據研究方法評讀
- 3. 證據數據擷取
- 4. 證據應用評估
- 5. FINAL CAT (Critical Appraisal Topic) 產出

2. 證據研究方法評讀



- 2.1 選定證據文獻
- 2.2 評讀表選定
- 2.3 bias評讀 (Validity)

2.1 選定證據文獻



3. 檢索	检索结果,	原治療指引引用文獻:↓
Acquired :		the state of the s
Key		the state of the s
literature.		4 ¹
20%.,		the state of the s
		檢索後比原治療指引更新或更值得參考的文獻:4
		Paper 1↔
		Paper 24 ^J
		Paper3€
	最後列入参考	₽
	文獻。	

初步評讀↩	Paper 1 ↔	Paper2 ↔	F
	(第一作者姓)(出版年)₽	(第一作者姓)(出版年)₽	(
本文獻(直接且	P : ← ¹	P: ←	F
正確)解答的問	4	4	+
題	I:₊ ^j	I:4 ^j	I
[clearly-focused	4	4	+
question?]₽	C:⊎	C:↔	C
φ	4	4	+
	O:4 ¹	O:4	d
	4	4	+
	T:₽	T:₽	1
本文獻研究設	I. Systematic review ⁴	I. Systematic review	Ι
計(符合我的問	II. Randomized control trial↓	II. Randomized control trial↓	I

檢索結果(可考慮列入評讀文獻)

- 原CPG或UpToDate在相關章節的參考文獻
- 在DataBase搜尋到的文獻

最後列入(評讀)參考文獻: 出略篩 選文獻符合我們臨床問題的 PICO

初步評讀: (需寫出文獻PICOT與研究設計)

選定文獻「必要條件」:

- 文獻PICO符合我們臨床問題的PICO
- 較能解決該類型問題的研究設計
- · 通過的文獻才進入真正評讀

2.1 選定證據文獻



a									
3. 檢索	檢索結果。	原治療指引引用文獻:↓							
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20%.1		₽							
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		Paper 1↔							
		Paper 2↔							
		Paper 34 ²							
	最後列入參考	þ							
	文獻。	'							
	初步評讀。	Paper 1	Paper 2	Paper 3					
	**********	(第一作者姓)(出版年)、	(第一作者姓)(出版年)、	(第一作者姓)(出版年)。					
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	正確)解答的問	al .	al	.i					
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	question?].	C:	C:	C:					
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	計(符合我的問	II. Randomized control trial.	II. Randomized control trial.	II. Randomized control trial.					
	acm, by	III. Cohort study.	III. Cohort study.	III. Cohort study.					
	题要求)	III. Colloit study.							
	概要求)。 [include the	IV. Case-control series.	IV. Case-control series.	IV. Case-control series.					
		•		IV. Case-control series. V. Case series/Expert opinion.					

建議文獻選擇考量:

- 列出參考guideline/UpTodate中 相關參考文獻
- 列出在PubMed/EmBase找到的文獻
- 依據與緣設定PICO最符合、證據 等級較高、發表年較近緣則選擇
- 將選定評讀文獻中研究方法:收 案對像(P),探討的處置(I)、對 照組處置(C)與outcomes列出。另 外處置使用時間/觀察時間(T)列 出。假如無法找到對應項目列出 ,前在這篇文獻不是適當文獻。
- · 研究設計方法為何?除非罕見疾病 ,否則無對照組研究不會列入評 讀。

範例



t)	Chen et al.₽	Morelli et al.₽	Wong et al.₽
發表年份♥	2017₽	2013₽	2010₽
本文獻直接且正確解答我的問題↓	Yes+ P: 80 Taiwan patients with endometriomas undergoing laparoscopic cystectomy followed by 6 cycles of gona dotropin- releasing hormone agonist treatment + I: LNG-IUS+ C: without LNG-IUS+ T: 30 months+ O: endometrioma recurrence 30 months after surgery; dysmenonhea (VAS), CA125 levels, noncyclic pelvic pain, and side effects+	Yes. P: patients who had chronic pelvic pain due to endometriosis after conservative laparoscopic surgery. I: LNG-IUD (n=44). C: estradiol valerate + dienogest estrogenprogestin (EP) therapy (n=48). T: at least 24 months for the last woman operated. O: pain relapse (VAS) and disease recurrence rate at 12 and 24 months after treatment; patient satisfaction with the therapy	Yes. P: 30 Hong Kong patients after conservative surgery (within 5 years) endometriosis without lesion recurence (If evidence of bone loss or gross osteoporosis during the study, the patient was advised to withdraw) I: LNG-IUD C: Depot MPA, three-monthly T: 3 years O: symptom control, recurrence, compliance and change in bone mineral density (BMD)
本文獻研究設計 符合我的問題要 求₽	Yes, randomized control trial↓ (definition of recurrence: endometrioma>2cm from USG)↓	Yes, retrospective case series, (definition of recurrence: elevated CA125 and/or USG evidence of endometrioma and/or palpable rectovaginal septumnodule)	Yes, randomized control trial. ↓ (definition of recurrence: endometrioma>=3cm from USG)↓

2.2 評讀表選定



	ger (RCT, cohort er love			Systemat	ic Review/Meta-analysis.	-		stomatic review		(A) 效度 Validity/供替Binn:									
	效度 Validity 機器 Bio	3 .7		4.挥簧.;	放皮 Validity 機器 Binn.		4.纤维.1	效度 Validity 模質 Binara			Paper La	Paper 2.	Paper 3.1						
nal S		Pager 1 a	Pa	Appeared		Paper La	Appraisal		Pap	本文獻直播卫亚瑞鲜茶栽的	P:	P:	P:						
	受效者继续分配支持 整介人各组 Randomination.1	佛盖危險性 為/不確定/他』	梅花		用外标提文章的标准是专组者 Eligibility criteria: appropriate & relevant to the Review question?。	偶基危险性 名/不確定/他		(A) Are the results of the: Screening Questions	revier	周組 7a	li:	le .	li:						
1	分派性权之を任念 Allocation concealment.:	佛盖危險性 為/不確定/依	傷名		是香度有為技術與 企業的 文章 Search design: comprehensive& systematic? important, relevant	佛基危險性 為 / 不確定/像		1. Did the review address a clearly fecused question?	是/		C(reference standard):	C(reference standard):	C(reference standard)						
	一 間 故 各組條件是否 相 同 組 選 人 員是否不知道	為 / 不 確定/他	梅花		studies were missed (publication bias)?				C		т:	T:	т:						
	地元黄始組 Blind to staff (FI):1	為 / 不 確定/他	*		被納入文章的評估標準是否可 被重複檢視?文章收納、評估 是否有的他以上寫象得立刻	病基危险性 药/不確定/像		2. Did the authors look for the right type of papers?	Æ/. Rex	是香灣通常多時標準檢查 (reference standard)被對照?	₹/ ₫ a	是/香 a	£/≨ a						
	受試者是否不知道権 是實验組 Blind to participants:	病基危险性 药/不確定/他	傷		86 ? Search process: study selection.			用外部强文章的标准是香道書 Elipibility criteria:		是香機模拌值?。 是香所有各與者都稳全社會		供益危险性	供益危险性						
ı	於展集物會是香不納 遺物是實验經Blind		梅		extraction of data & assessment of validity done independently by at least 2 reviewers?			appropriate 2 relevant to the Review question?	0 D:	新性检查高多考得等检查?; 止诊断性检查标果是适合变 多考得等检查标果影響?;	為/不確定/他 供益危险性 為/不確定/他	為/不確定/他 佛基危險性 為/不確定/他	為 / 不 確定/他 供 基 危險性 為 / 不 確定/他						
	程模分配接的李高會 是否如納人最後分辨 Withdraw, incomplete	偶基危險性 為/不確定/他	梅		被納入的文章品質是委员好 Validity of included studies: Did reviewers do enough to assess the validity of included studies?	偶基危险性 高/不確定/他		Is It worth continuing? Do you think all the	供益	全州各高者推群的高高校歷 是否有清楚相述?。	倘基危险性 药/不確定/他	内/不恒之/% 供益危险性 名/不確定/他	病 / 不 性定/版 病 基 危險性 药 / 不 难定/版						
-	or loss to follow up.: 是多級用金布性均差 分析 Intention-to-treat	供益危险性	供水		無線等級 Level of evidence			ingortant, relevant studies were included? 是否结构结构是多的文章	為八	執行这些检查的方洛是否数 选到 學知? (5) 致 是 Impact	满基危险性 高/不確定/他	偶基危险性 名/不確定/他	偶基危险性 名/不確定/他 1						
	englysis :	尚/不堪定/依	~		放英 Impact.i 企業故機可能是否定件故会会	2/5		Scarch design:		Main result	华夏公全/元金60国1000	confidence interval/ Pvalue]&	iπ?.						
	多名人教える足夠 Enough participants (power calculation).:	佛基危險性 為/不確定/他	梅		新 业 系 机性回题如何分析研究简	Q statistics: v2 test.;				:	comprehensive & systematic? important, relevant studies		(size of effect)表 Precise of results	Sensitivity .: Specificity Positive predict rate	Commence and a Principal	1121.1			
	組合成其他傳送 Reporting bias or Others:	佛基危險性 為/不確定/依	傷名		申其常性(httmanicit)。	D test P value Q statistics:	12 test P value	12 test	Î2 test	12 test	12 test	12 test	12 test	were missed (publication biss)? Did the review's authors	供益		Negative predict rate Likehood, ratio		
ı	是 香 為優賞 RT·蘇不	是,機模下列 Bias 纤维:	_		本文章的人研究開有沒有異質 性存在							do enough to sesses the	卷八	许饭 维加少品物	ROC curve				
	各組手種B全板制定 番牌 含 Control for confounders :	佛基危险性 器/不確定/他	英		Tere	12 test P value		guslity of the included studies?。 終編入文章的存機器集長を可		(C) & A A		全查货用高级组织与何?;;							
	各組除了控制起置不 同外其他治療是香糖 世 Measurement of exposure.)	佛基危險性 為/不確定/像	為		以本文章的品質並真質性流行 統合分析是否合理			被重複檢視?艾章收納、評估 是否有兩位以上享數猶立則 辦?		这种展是否可以应用到你的 病 怎或相能换群?。 这检查是否可以应用到你的									
	性核等性。 Level of evidence 放艮 Impact				若有效合分析,本系统性可能 收集到的研究以而一種機能分 持 (fixed effect model 或 random	Fixed effect model/Random effi model		Search process: study selection, extraction of data & assessment of validity done independently by		病 息或相關機群?。 这多数於展對他人或相關機 群是 香金藝(有金藝)?。	是/不確定/香口								
ŀ		,	_		effect model)?核用機組是多值 会?	是/香		at least 2 reviewers? it in 人的专业品等是否多数		在你的病息或相關機群使用 這檢查的效益(impact)無何?									

- 依照第一次上課認定所選主題為何種型態選擇模板中的表格
- origin paper用p3的,他們就不用再分RCT, cohort, case series。 SR 兩者選一。診斷型的只有CASP
- 假如發現評讀文章時,無法順利竹項填入,要不是選錯文獻,要不 選錯表格。

2.3 bias評讀 (Validity)

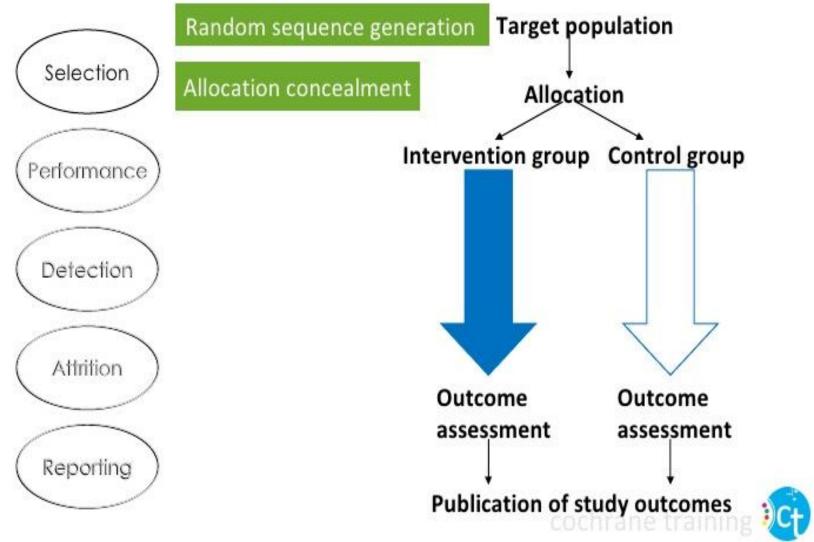


Critical Appraisal

Source	Protection
Baseline imbalance	Randomization
Performance	Blinding of caregivers, careful monitoring & analysis
Placebo-effect	Blinding of patients
Attrition	Careful follow-up & ITT analysis
Detection	Valid measurement Blinding of outcome assessors
Analytical	Careful analyses
Reporting	Report all relevant planned measurements

Sources of bias

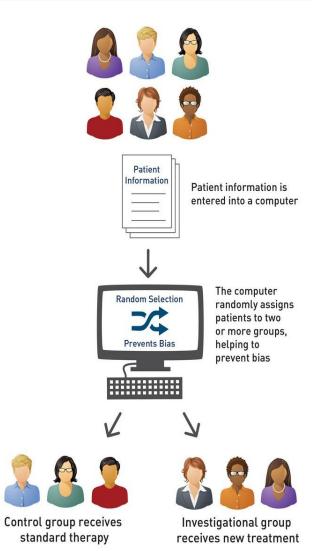




第一關: Randomization







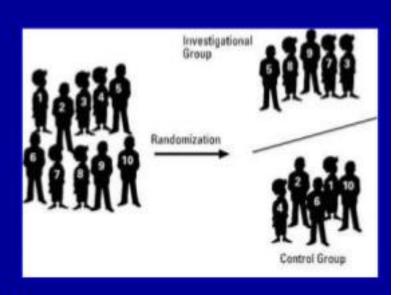


常見Randomization的方法



- Simple randomization
- Random table
- Block randomization
- Stratified randomization
- · Minimization method
- Unequal randomization
- Allocation concealment

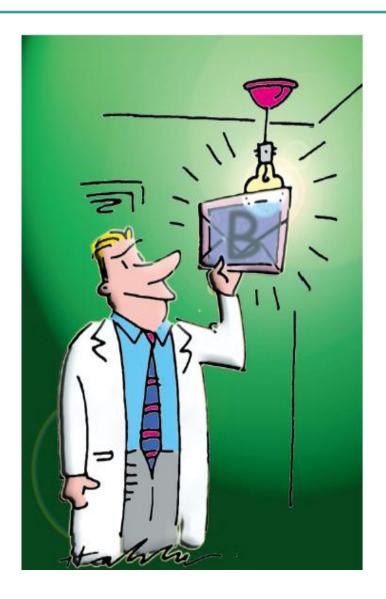
Inacceptable



Preferred

Allocation Concealment



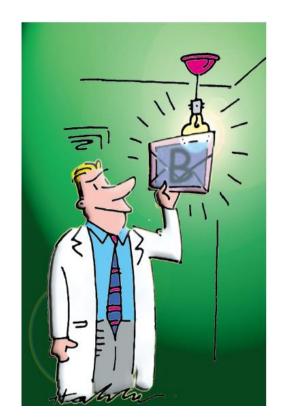


Allocation Concealment



Minimum criteria for adequate allocation concealment schemes

- Sequentially numbered, opaque, sealed envelopes (SNOSE)
- Sequentially numbered containers
- Pharmacy controlled
- Central randomisation



Allocation Concealment



Minimum description of
adequate allocation
concealment scheme
Sequentially numbered,
opaque, sealed envelopes
(SNOSE)

Additional descriptive elements that provide greater assurance of allocation concealment Envelopes are opened sequentially only after participant details are written on the envelope. Pressuresensitive or carbon paper inside the envelope transfers that information to the assignment card (creates an audit trail). Cardboard or aluminum foil inside the envelope renders the envelope impermeable to intense light. All of the containers were tamperproof, equal in weight, and similar

in appearance.

Indications that the researchers developed, or at least validated, a proper randomisation scheme for the pharmacy. Indications that the researchers instructed the pharmacy in proper allocation concealment.

The mechanism for contact—eg. telephone, fax, or e-mail-the stringent procedures to ensure enrolment before randomisation. and the thorough training for those individuals staffing the central randomisation office.

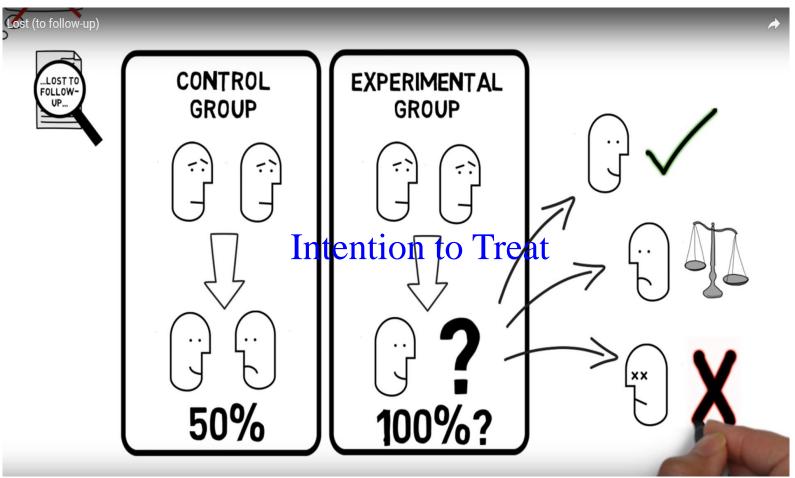
Sequentially numbered containers

Pharmacy controlled

Central randomisation

Lost Follow-up -- Attrition





Lost Follow-up -- Intention to Treat



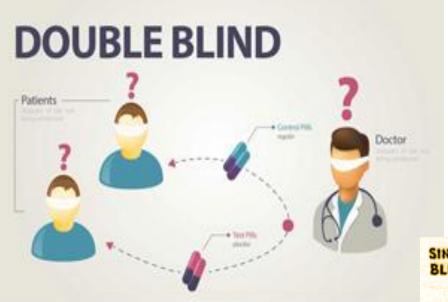
FICTIONAL STUDY

TRUTH NO DIFFERENCE GOOD OUTCOME 75%

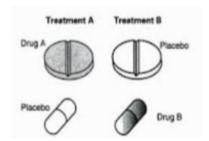


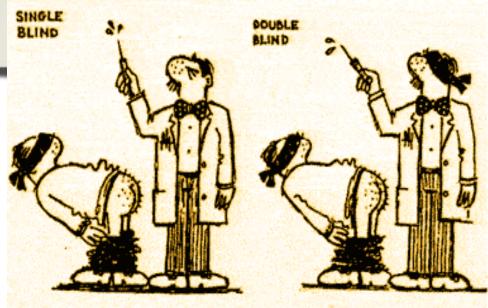
Blind





Double dummy technique

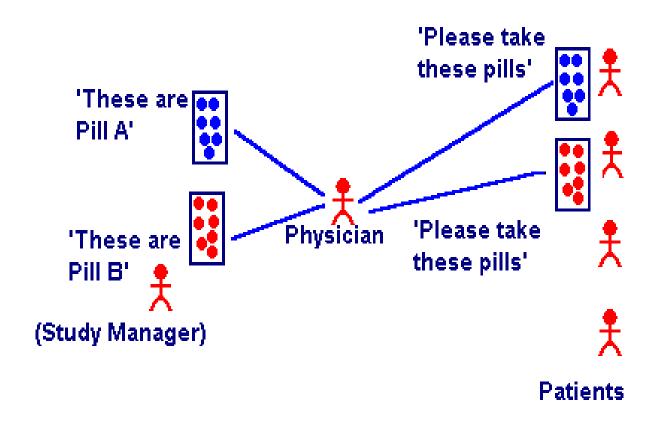






研究設計 Double-Blind





http://library.downstate.edu/EBM2/2300.htm

Blinding



A)Single blind trial: the trial is so planned that the participant is not aware whether he belongs to the study group or control group.

B)Double blind trail: The trial is so planned that neither the investigator nor the participant is aware of the group allocation and the treatment received.

c)Triple blind trial: The participant, the investigator and the person analyzing the data are all blind.

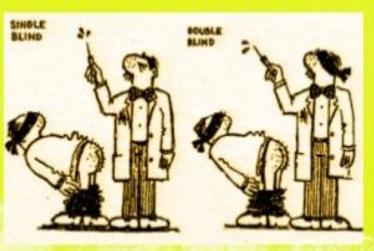




Fig. 3. A distrible-billed placelte controlled clinical total for CAM therapies.

Detection bias



Valid measurement



A good measure should be

- Valid
- Reliable
- Sensitive

Valid exist when

- "testing for the right thing"
- A valid measure actually measures what it is intend to measure

Criteria for Measurements



A good measure should be

- Valid
- Reliable
- Sensitive

Valid exist when

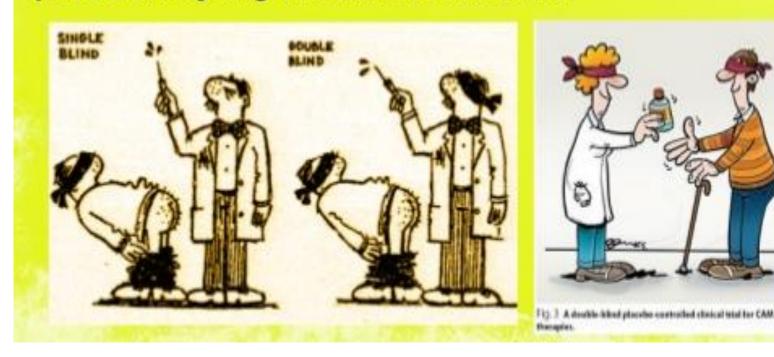
- "testing for the right thing"
- A valid measure actually measures what it is intend to measure

Detection bias



- Valid measurement
- Blinding of outcome assessors

c)Triple blind trial: The participant, the investigator and the person analyzing the data are all blind.



Analytical bias



- Analyzing the data incorrectly
- Due to the way that the results are evaluated

Reporting bias/ Selective reporting



Type of reporting bias	Definition
Publication bias	The publication or non-publication of research findings, depending on the nature and direction of the results
Time lag bias	The rapid or delayed publication of research findings, depending on the nature and direction of the results
Multiple (duplicate) publication bias	The multiple or singular publication of research findings, depending on the nature and direction of the results
Location bias	The publication of research findings in journals with different ease of access or levels of indexing in standard databases, depending on the nature and direction of results.
Citation bias	The citation or non-citation of research findings, depending on the nature and direction of the results
Language bias	The publication of research findings in a particular language, depending on the nature and direction of the results
Outcome reporting bias	The selective reporting of some outcomes but not others, depending on the nature and direction of the results

https://www.youtube.com/watch?v=dMfC-SSBZi0

填寫要求範例



4.評讀↓	效度 Validity/偏誤 Bia	S**		
Appraisal↔	評讀文章₽	Chen et al. 2017€	Morelli et al. 2013₽	Wong et al. 2010₽
評讀工具:↓	受試者隨機分配至治 療介八各組₽	Yes p. 2. Computer-generated random numbers in sequentially sealed opaque envelopes were used to randomly allocate the patients into either the control group (n=40) or the intervention group (n=40).€	No, retrospective chart review₽	Yes, p.247 Achart was prepared with 30 slots of randomly allocated treatment regime of either LNG-IUS or Depot MPA and each patient was assigned to each slot and the corresponding therapy in chronological order.
	分派過程是否保密₽	Yes p.2. Computer-generated random numbers in sequentially sealed opaque envelopes were used to randomly allocate the patients into either the control group or the intervention group 43	No, retrospective chart review₽	Yes, p.274 Achart was prepared with 30 slots of randomly allocated treatment regime of either LNG-IUS or Depot MPA and each patient was assigned to each slot and the corresponding therapy in chronological order.
	一開始各組條件是否 相 同↓	No, p.4 Table 14 Intervention group older (>3 y/o), higher weight (>2kg), higher BMI (>1), higher ASRM score, smaller diameter (<2mm), higher dysmenorhea VAS, 4	Unclear, Table 1 did not provide enough data p. 987: Table 1. As shown, no differences were found between the two groups in terms of age, body mass index (BMI), CA125 levels, ASRM stages and VAS scores (Table 1)	Yes, p. 275 table 1, ↓ There was no significant difference in the demographic data (including meanage, meanhighest rAFS score in previous operation and BMI) (Table 1), nature of previous operation(Table 1), starting Symptom Scores (Fig. 2), baseline DEXA T-score (Fig. 3), BMD of lumbar spine and hip (Table 2) between the two groups of patients√
	照護人員是否不知道 誰是實驗組₽	No, p.3 The surgeons and participants were not blinded to study allocation.	No₽	No↔

進度



- 1. 題目設定與形成及精準搜尋與證據選定
- 2. 證據研究方法評讀
- 3. 證據數據擷取
- 4. 證據應用評估
- 5. FINAL CAT (Critical Appraisal Topic) 產出

評讀最終目的在數據 讀結論決定相信數據的程度

數據要如何呈現



數據有那些



Raw Data type

- Binary
- •Continuo us
- Survival/ Time to event

Group Summary

- •Risk /
 Proportio
 n
- Mean/Median
- Rate

Group Comparison (Rx effect)

- Difference
- Ratio
 - Risk ratio
 - Oddsratio
 - Hazard ratio

Reporting g precision

- Confide nce interval
- p-value
- Hypothesis test

要整理條列,不是把圖或表貼進來



範例:

效益 Impact⊕		
SOC SEE THIS DOCK	U # U = # # 1	U # U # # # # # # # .
结果₽	治療效果有多大↓	治療效果有多精準↓
	Paper1 Chen et al. 2017↔	Paper1 Chen et al. 2017. ←
	LNG-IUD vs control ↔	LNG-IUD vs expectant management 🖟
	1.Endometrioma recurrence rate at 30 months	
	25% vs 37.5%, hazardratio = 0.60€	95% CI, [0.27, 1.33], P=.209₽
	2.dysmenorrhea recurrence rate ↔	2. dysmenorrhea recurrence rate↔
	hazardratio=0.32↔	95% CI, [0.12, 0.83], P=.019₽
	3. visual analog scale score ↔	3. VAS,95% CI, [1.9, 16.1], P=.014↔
	39.1±10.9 vs 30.1±14.7↔	4
	33.1210.3 1330.1214.71	L.
	*	Paper2 Morelli et al. 2013↔
	Paper2 Morelli et al. 2013↔	EPvs LNG-IUD-
	EP vs LNG-IUD↔	
	1. VAS score at 24 months ↔	1. VAS score at 24 months, P < 0.05
	19.08±0.37 vs 28.98±10.79 ↔	2. Recurrence rate at 24 months, P=0.30↔
	2. Recurrence rate at 24 months ↔	€.
	12.5 % vs 20.5% ↔	+ 1
	LI LI	+ 1
	Barrar 2 Warrant at 2010 d	+ 1
	Paper 3 Wong et al. 2010.	Paper 3 Wong et al. 2010⊌
	LNG-IUS vs Depot MPA	LNG-IUS vs Depot MPA↓
	1. Pain Score (total=6) only 36 months (0.1	1. Pain Score only 36 months P<0.0025↔
	vs 0.6) significant difference, All other visits	+
	showed no significant difference	4
	2. recurrence of endometriosis lesion>3cm ↔	ت د
	none of both groups had recurrence ↓	T
	₽	

評讀最終目的在數據 評讀結論決定相信數據的程度

證據等級 (LEVEL OF EVIDENCE)



Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

				licht	Service light
Question	Step 1		Step 3	Step 4	Step 5 (Level 5)
	(Level 1*)		(Level 3*)	(Level 4*)	
	Local and current random sample		Local non-random sample**	Case-series**	n/a
problem?	surveys (or censuses)	that allow matching to local			
		circumstances**			
Is this diagnostic or			Non-consecutive studies, or studies without	Case-control studies, or	Mechanism-based
monitoring test	1		consistently applied reference standards**	"poor or non-independent	reasoning
		applied reference standard and		reference standard**	
(Diagnosis)	standard and blinding	blinding			
What will happen if	Systematic review	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case-	n/a
we do not add a	of inception cohort studies			control studies, or poor	
therapy?				quality prognostic cohort	
(Prognosis)				study**	
			Non-randomized controlled cohort/follow-up	Case-series, case-control	Mechanism-based
intervention help?	of randomized trials or n-of-1 trials	or observational study with	study**	studies, or historically	reasoning
(Treatment Benefits)		dramatic effect		controlled studies**	
What are the	Systematic review of randomized	Individual randomized trial	Non-randomized controlled cohort/follow-up	Case-series, case-control,	Mechanism-based
			study (post-marketing surveillance) provided		reasoning
•	,	,	there are sufficient numbers to rule out a	studies**	
	of-1 trial with the patient you are		common harm. (For long-term harms the		
	raising the question about, or		duration of follow-up must be sufficient.)**		
	observational study with dramatic				
	effect				
What are the RARE	Systematic review of randomized	Randomized trial			
		or (exceptionally) observational			
(Treatment Harms)		study with dramatic effect			
,		•			
Is this (early	Systematic review of randomized	Randomized trial	Non -randomized controlled cohort/follow-up	Case-series, case-control,	Mechanism-based
	trials		study**		reasoning
worthwhile?				studies**	
(Screening)					

^{*} Level may be graded down on the basis of study quality, imprecision, indirectness (study PICO does not match questions PICO), because of inconsistency between studies, or because the absolute effect size is very small; Level may be graded up if there is a large or very large effect size.

^{**} As always, a systematic review is generally better than an individual study.

Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

				lich	20日本
Question	Step 1		Step 3	Step 4	Step 5 (Level 5)
	(Level 1*)	(Level 2*)	(Level 3*)	(Level 4*)	
problem?	surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this diagnostic or monitoring test accurate? (Diagnosis)	of cross sectional studies with		Non-consecutive studies, or studies without consistently applied reference standards**	Case-control studies, or "poor or non-independent reference standard**	Mechanism-based reasoning
What will happen if we do not add a therapy? (Prognosis)	Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case- control studies, or poor quality prognostic cohort study**	n/a
Does this intervention help? (Treatment Benefits)	of randomized trials or <i>n</i> -of-1 trials	or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	reasoning
What are the COMMON harms? (Treatment Harms)	trials, systematic review	study with dramatic effect	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or <i>n</i> -of-1 trial	Randomized trial or (exceptionally) observational study with dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials		Non -randomized controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning

^{*} Level may be graded down on the basis of study quality, imprecision, indirectness (study PICO does not match questions PICO), because of inconsistency between studies, or because the absolute effect size is very small; Level may be graded up if there is a large or very large effect size.

^{**} As always, a systematic review is generally better than an individual study.