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### Scenario

### 52歲女性

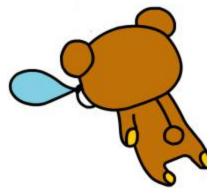
- ·醫生,我有纖維肌痛症的問題,在你們總院看好久的西醫,吃了好多藥,請問我平常能不能做些什麼運動呢?
- · 我朋友兼獸約我一起去打太極拳,請問合不合適?
- · 我朋友超強,他都打108招,我怕打不到 108招就沒效.....
- 我找到一則簡報,好像很有趣:

# 中國太極拳輔助治頑疾獲權威認可堅持練楊式太極可緩解纖維肌痛

《健康時報》(2011-08-15 第01版)

- 首都醫科大學附屬宣武醫院風濕免疫科李小霞主任的門診中,大約有一半的纖維肌痛患者都有心理問題,有的就是抑郁症患者。他們沒有任何器質性疾病,但就是覺得渾身疼,一問原因,不是懷疑坐月子受了風,就是覺得是更年期落下的病根。
- 至於打太極拳有助於緩解纖維肌痛,李小霞主任認為,因為太極拳是一種需要精心凝神來做的運動,一邊運動一邊調養心情,當患者認認真真、全神貫注地打太極拳時,他對於身體疼痛的關注度就會降低,這樣一來,從感覺上就會從一定程度上忽略疼痛。

• 唉呀,隨便啦,輕鬆一點,不要太激烈就可以了。



# 5A step 1 - Asking 問問題(可以回答的問題)

PICO
Problem, Intervention,
Comparison, Outcome

# Background question

### 纖維肌痛症 fibromyalgia

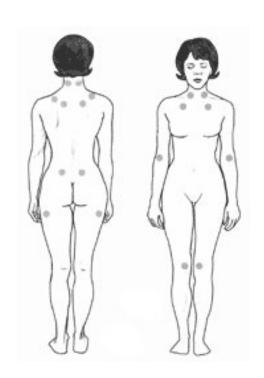
- 流行病學(ACR 統計資料)
  - 一般人口的發病率是3~5%
  - 男女比率為1:9,白人居多,好發年齡層在20-50
  - 約佔免疫風濕科門診病患的14%或前三名。
- 症狀:
  - 疼痛: Chronic, widespread pain, fatigue, and allodynia (80%)--Widespread musculoskeletal pain
  - 自律神經失調(Dysautonomia)導致各種心身症狀,如 失眠、頭痛、經痛、手部發麻、憂鬱,以及過敏性胃 腸症狀(Irritable Colon)等





# Background question

- 診斷標準: ACR 1990
  - A history of widespread pain > 3 months
    - affecting all four quadrants of the body, i.e., both sides, and above and below the waist.
  - > 11 of 18 tender points
- 治療:
  - 物理、藥物及心理治療
    - Psychological/behavioural therapies
    - Pharmaceuticals:
      - Tramadol, Muscle relaxants, Antidepressant, Anti-seizure medication, Dopamine agonists, Opioids



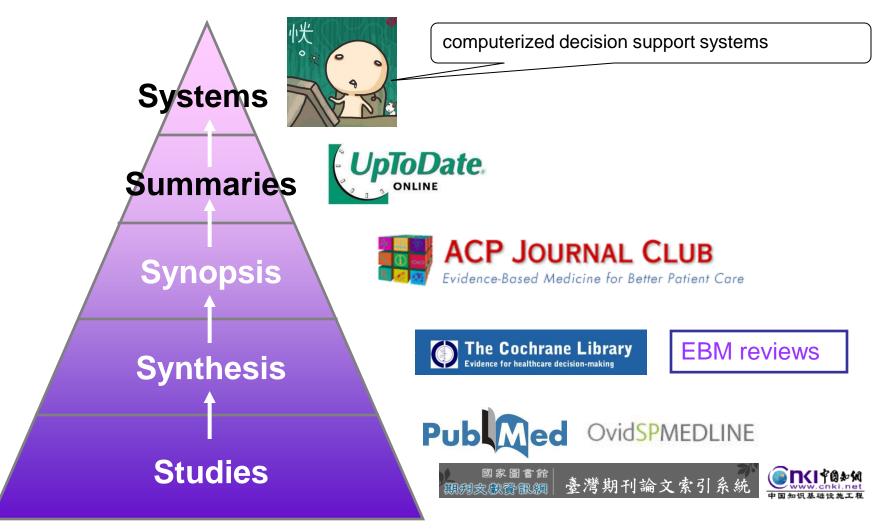
# PICO

Р	Fibromyalgia				
I	Tai chi OR tai ji				
С	Placebo OR conventional treatment				
O	Symptoms reduction				

# 5A step 2 - Accessing 找資料 (可獲得最好的證據資訊)

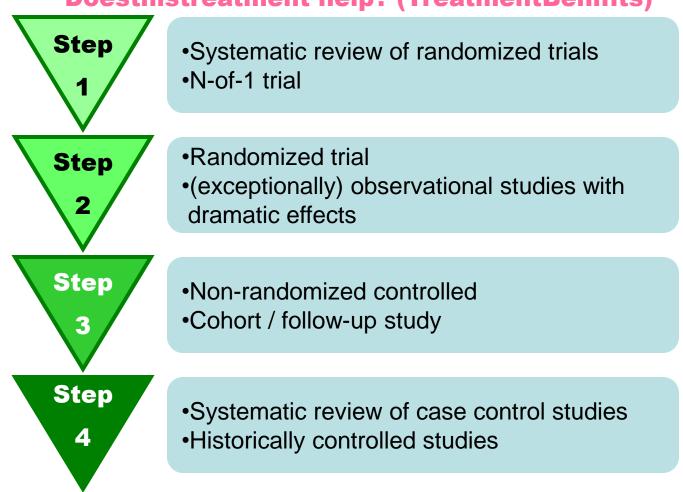
Search strategy

### The "5S" evolution of information services for evidencebased healthcare decisions

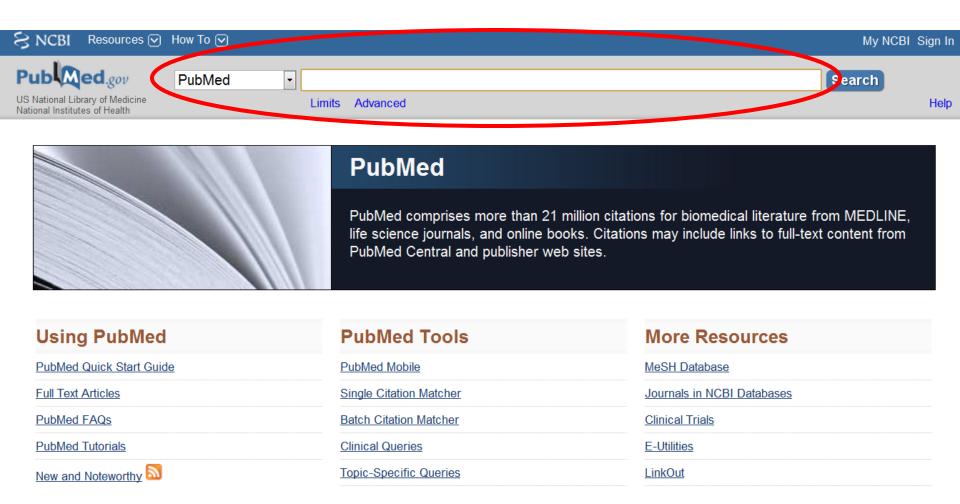


## Steps in finding evidence (levels)

#### **Doesthistreatment help? (TreatmentBenifits)**

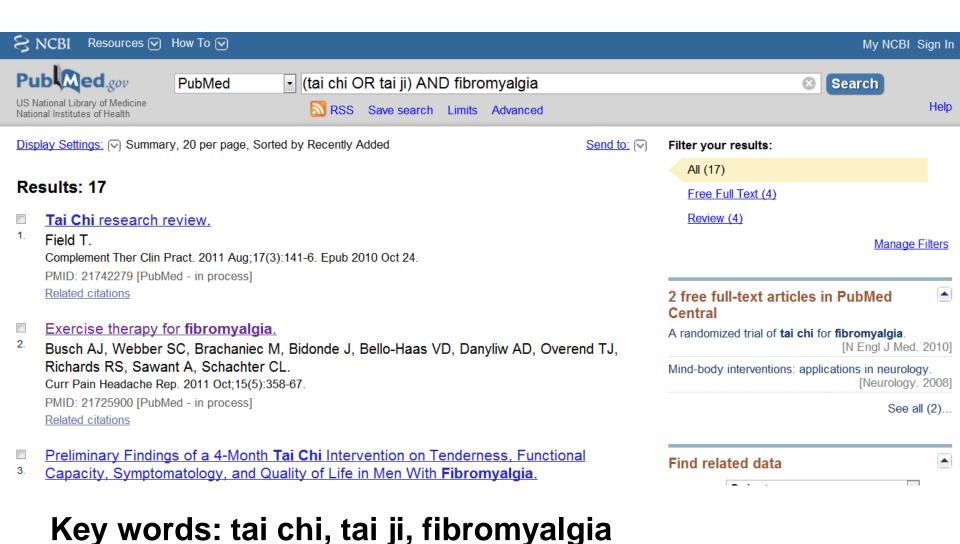


### Search strategy



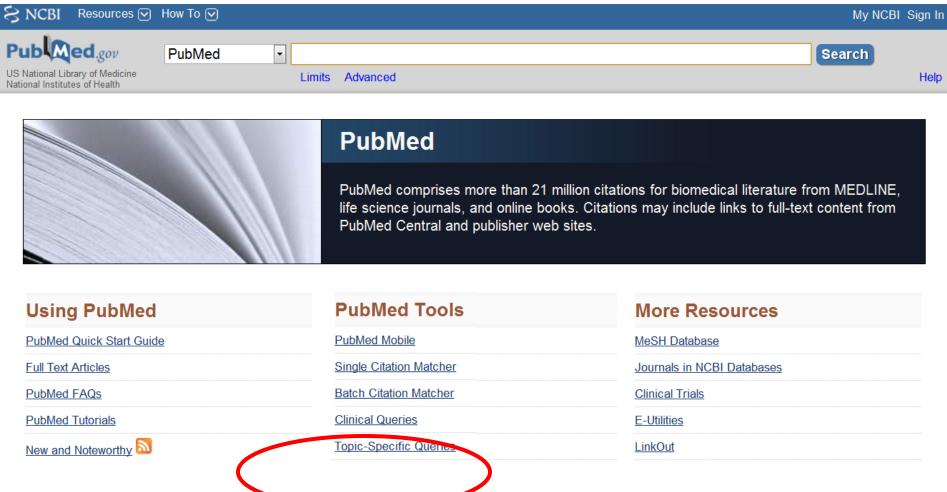
# Key words

Р	Fibromyalgia			
I	Tai chi OR tai ji			
С	Placebo OR conventional treatment			
0	Symptoms reduction			
(Cochrane OR meta-analysis OR Systematic review)				

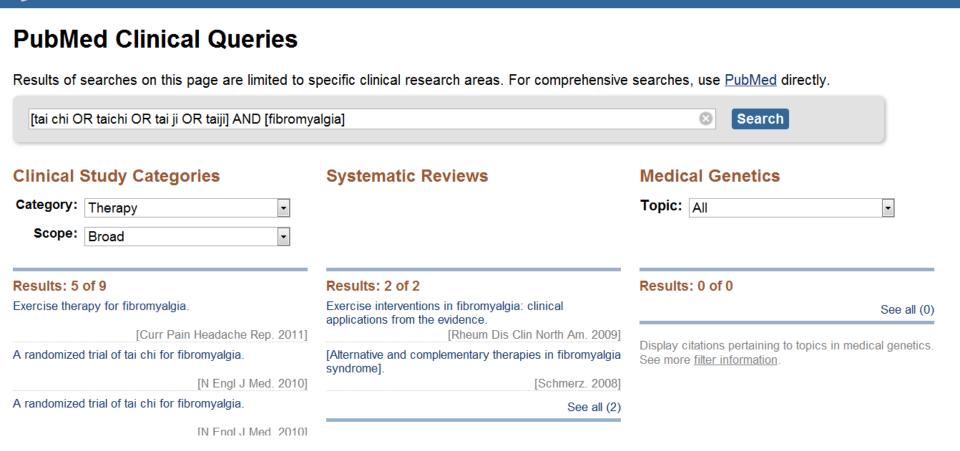


Results: free full text (4), reviews(4)

# Search strategy (Clinical Queries)



## Clinical queries



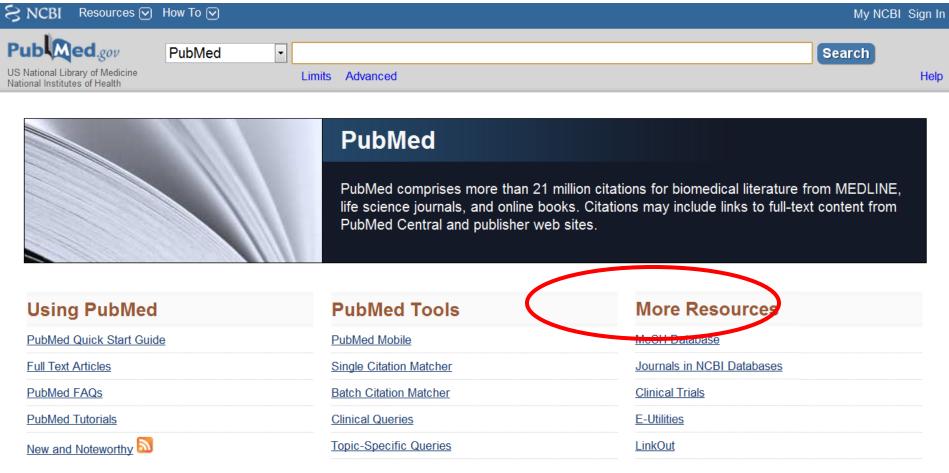
Key words: tai chi, tai ji, fibromyalgia Results: free full text (3), reviews(1)

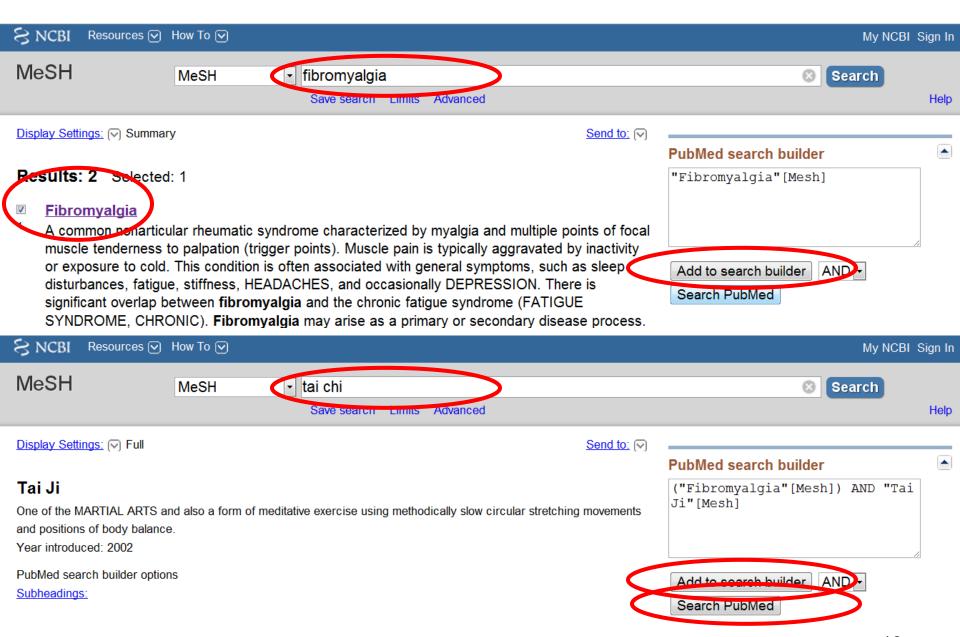
S NCBI

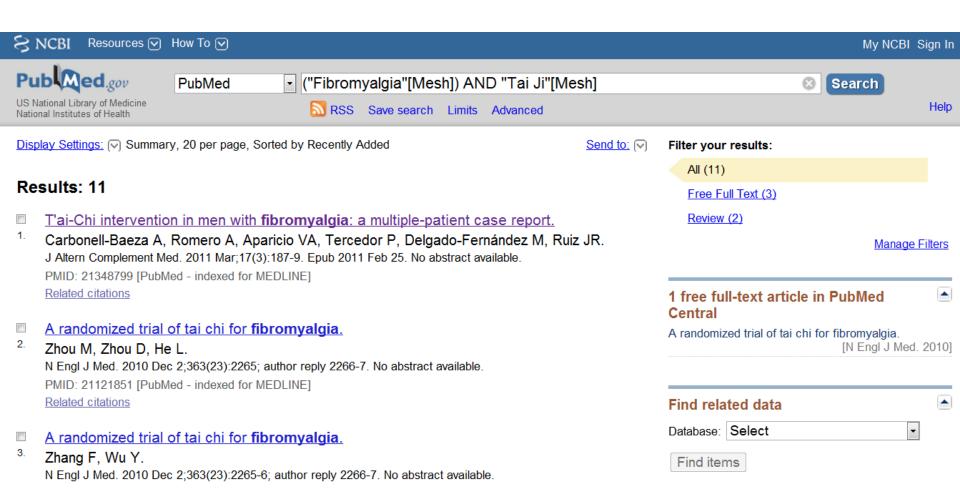
Resources (V) How To (V)

My NCBI Sign In

# Search strategy (MeSH)







### Results: free full text (3), reviews(2)

# Final result (best)

The NEW ENGLAND JOURNAL of MEDICINE

#### ORIGINAL ARTICLE

### A Randomized Trial of Tai Chi for Fibromyalgia

Chenchen Wang, M.D., M.P.H., Christopher H. Schmid, Ph.D., Ramel Rones, B.S., Robert Kalish, M.D., Janeth Yinh, M.D., Don L. Goldenberg, M.D., Yoojin Lee, M.S., and Timothy McAlindon, M.D., M.P.H.

Level: 1b

### Evidence levels

1a	SR (with homogeneity) of RCTs
1b	Individual RCT (with narrow Confidence Interval)
1c	All or none
2a	SR (with homogeneity) of cohort studies
2b	Individual cohort study (including low quality RCT)
2c	"Outcomes" Research; Ecological studies
3a	SR (with homogeneity) of case-control studies
3b	Individual Case-Control Study
4	Case-series (and poor quality cohort and case-control studies)
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

Oxford Centre for Evidence-based Medicine Levels of Evidence (March 2009)

# 5A step 3 - Appraising 評讀 (文獻的效度與重要性)

5A step 4 - Applying 臨床應用 (整合四大層面)



# Critical appraisal



- Critical Appraisal for Therapy Articles
  - CAT maker
  - Critical appraisal sheets: RCT
    - Are the results of the trial valid? (Internal Validity)
    - What were the results?
    - Will the results help me in caring for my patient? (ExternalValidity/Applicability)



# Therapy study - validity

### Internal validity

- Yes 1a. R- Was the assignment of patients to treatments randomised?
- Yes 1b. R- Were the groups similar at the start of the trial?
- Yes 2a. A Aside from the allocated treatment, were groups treated equally?
- Yes 2b. A Were all patients who entered the trial accounted for? and were they analysed in the groups to which they were randomised?
- Yes 3. M Were measures <u>objective</u> or were the patients and clinicians kept "<u>blind</u>" to which treatment was being received?

# 1a. Was the assignment of patients to treatments randomised?

使用電腦進行 隨機分配

Yes

#### STUDY DESIGN

We assigned participants to tai chi or the control intervention in three randomization cycles, using computer-generated numbers. The randomized treatment assignments were sealed in opaque envelopes and were opened individually for each patient who agreed to be in the study.

The sponsors had no role in the design and conduct of the study; the collection, management, analysis, or interpretation of the data; or the preparation, review, or approval of the manuscript. The study was conducted in accordance with the trial protocol.

### 1b. Were the groups similar at the start of the trial?

Table 1. Baseline Characteristics of the Study Participants.*		
Variable	Tai Chi Group (N=33)	Control Group (N = 33)
Female sex — no. of patients (%)	28 (85)	29 (88)
Age — yr	49.7±11.8	50.5±10.5
White race — no. of patients (%)†	20 (61)	17 (52)
High-school or higher education — no. of patients (%)	31 (94)	30 (91)
Body-mass index:	33.9±8.9	31.5±7.4
Duration of fibromyalgia-related pain — yr	11.8±6.9	10.0±7.2
Medications taken before intervention — no. of patients (%)		
Analgesics	29 (88)	24 (73)
Antidepressants	17 (51)	15 (45)
Anticonvulsants	9 (27)	5 (15)
Muscle relaxants	9 (27)	4 (12)
Benzodiazepines	5 (15)	3 (9)
Self-reported coexisting illness — no. of patients (%)		
Heart disease	0	0
Hypertension	12 (36)	6 (18)
Diabetes	6 (18)	1 (3)
FIQ score§	62.9±15.5	68.0±11
Visual-analogue scale¶		
Patient's global assessment	5.8±2.3	6.3±1.8
Physician's global assessment	5.7±1.9	5.6±2.4
PSQI score	13.9±3.1	13.5±3.7
SF-36 score**		
Physical component	28.5±8.4	28.0±7.8
Mental component	42.6±12.2	37.8±10.5

Table 1. (Continued.)					
Variable	Tai Chi Group (N=33)	Control Group (N=33)			
CES-D score††	22.6±9.2	27.8±9.2			
CPSS score;;	5.2±1.9	4.6±2.2			
6-Minute walk test — yd∭	522.1±102.7	501.2±106.6			
Outcome Expectations for Exercise score $\P\P$	3.7±0.8	3.9±0.7			

#### BASELINE CHARACTERISTICS OF THE PATIENTS

Table 1 shows baseline data for the 66 participants before randomization. Participants had a mean age of 50 years, 86% were women, and 56% were white; the mean body-mass index (the weight in kilograms divided by the square of the height in meters) was 32.7. On average, participants had had fibromyalgia for 11 years. Baseline characteristics were reasonably well balanced between the two groups, except that the tai chi group had a lower CES-D score. The average score on the physical component of the SF-36 was about 2 SD below normal, indicating a cohort with poor health.



# 2a. Aside from the allocated treatment, were groups treated equally?

### Tai chi group:

- 老師: a tai chi master

- 上課: 一週兩次,一次60分鐘,一共12周

- 在家: 每天至少20分鐘太極拳

- 12週~24週: 看DVD自己做

### Control group:

- 老師: research staff

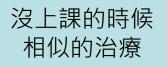
上課: 一週兩次,一次60分鐘(40+20),一共12周

- 在家: 每天20分鐘伸展操

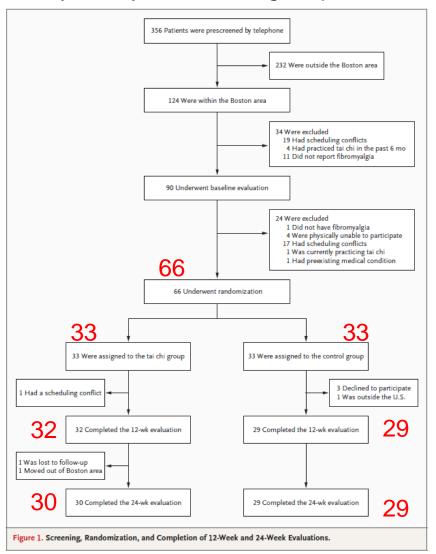
- 12週~24週: 自己做

- 1. 在這12週之內不要做其他運動
- 2. 沒上課的要補課!!!!!!!





2b. Were all patients who entered the trial accounted for? – and were they analysed in the groups to which they were randomised?



Effects were evaluated on an intention-to-treat basis, and participants who did not complete the follow-up period were considered not to have had any changes in scores.

研究結果分析 包含原先列入研究 之所有對象之結果



- 3. Were measures <u>objective</u> or were the patients and clinicians kept "<u>blind</u>" to which treatment was being received?
- Single-blinded RCT
- Why not double-blinded RCT?

研究結果分析 包含原先列入研究 之所有對象之結果

Yes



Chenchen Wang

- Sham Tai Chi?
- 怎麼把身心的動作分開?

## 其他避開bias的方法

- 怎麼預防大師效應? (possible placebo effect)
  - Deemphasizing tai chi
  - -告訴病人是"比較兩種不同訓練計畫的效果"
  - 打太極拳的組別, 不包含衛教

Table 1. (Continued.)					
Variable	Tai Chi Group (N=33)	Control Group (N=33)			
CES-D score††	22.6±9.2	27.8±9.2			
CPSS score‡‡	5.2±1.9	4.6±2.2			
6-Minute walk test — yd∬	522.1±102.7	501.2±106.6			
Outcome Expectations for Exercise score¶¶	3.7±0.8	3.9±0.7			

### What were the results?

- 1. How large was the treatment effect?
  - 治療效果的大小: Number needed to treat
- 2. How precise was the estimate of the treatment effect?
  - 療效的估計精準度: 95% Confidence interval

### Treatment effect(治療效果的大小)

- Relative Risk (RR)
- Relative Risk Reduction (RRR)
- Absolute Risk Reduction (ARR)
- Number Needed to Treat (NNT)
  - 在研究試驗期間,需要治療多少病人,才能預防一個壞結果

## 哪些量表?



#### Fibromyalgia Impact Questionnaire(FIQ)

- physical function, common symptoms, and general wellbeing in patients with fibromyalgia
- 0 100, higher scores indicating more severe symptoms



#### **Global status**

- assessed separately by participant and physician
- visual-analogue scale (0 10), with higher scores indicating greater pain



#### Scores on the Pittsburgh Sleep Quality Index (PSQI)

0 - 21, higher scores indicating worse sleep quality



#### The 6-minute walk test

- objective assessment of mobility (a proxy for physical function)
- higher scores indicating improved functional conditioning



#### Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36)

0 - 100, higher scores indicating better health status



#### **Center for Epidemiologic Studies Depression (CES-D)**

- 0 - 60, with higher scores indicating greater dysphoria



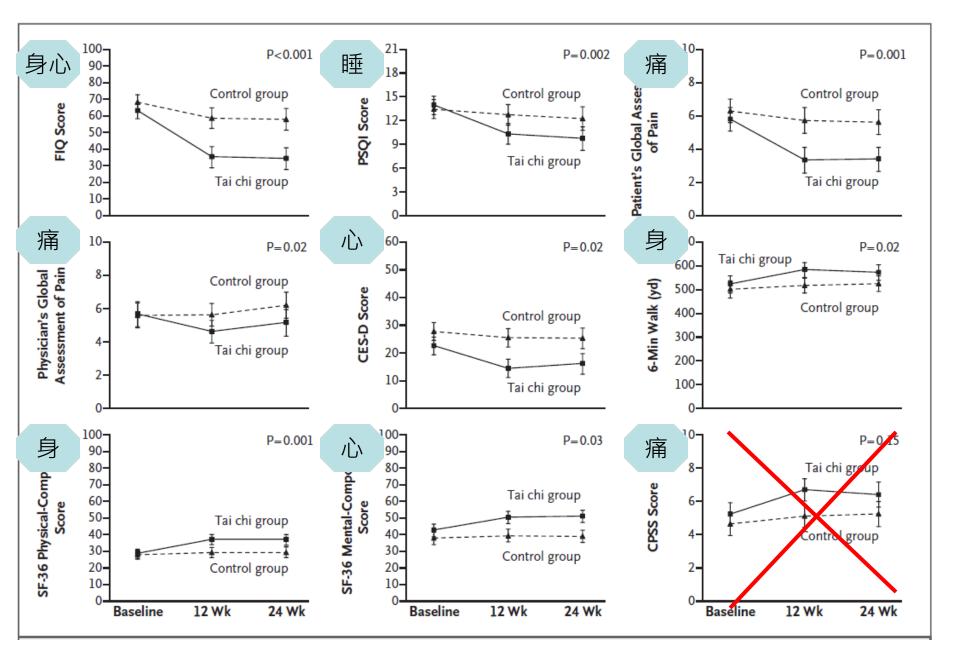
#### **Chronic Pain Self-Efficacy Scale (CPSS)**

- measures patients' confidence in their ability to perform a particular task
- 1 10, higher scores indicating improved status

		Tai chi	Control	Р	NNT	NNT	
FIQ							
	12 wks	26	13	0.001	2.54	3	
	24 wks	27	17	0.009	3.3	3	
Patient' s g	lobal asse	ssment					
	12 wks	18	9	0.02	3.67	4	
	24 wks	18	9	0.02	3.67	4	
PSQI							
	12 wks	13	4	0.01	3.67	4	
	24 wks	15	6	0.02	3.67	4	
CES-D	CES-D						
	12 wks	24	16	0.04	4.13	4	
	24 wks	23	13	0.01	3.3	3	
SF-36 physi	SF-36 physical						
	12 wks	18	5	0.001	2.54	3	
	24 wks	17	5	0.002	2.75	3	
SF-36 mental							
	12 wks	14	8	0.12	5.5	6	
	24 wks	16	8	0.04	4.3	4	

Table 2. Changes in Primary and Secondary Outcomes.*						
Variable	Mean Change from	Baseline (95% CI)	Between-Group Difference (95% C			
	Tai Chi Group (N=33)	Control Group (N=33)	Tai Chi Group vs. Control Group	P Value†		
FIQ score:						
Week 12	-27.8 (-33.8 to -21.8)	-9.4 (-15.5 to -3.4)	-18.4 (-26.9 to -9.8)	< 0.001		
Week 24	-28.6 (-34.8 to -22.4)	-10.2 (-16.4 to -4.0)	-18.3 (-27.1 to -9.6)	< 0.001		
Patient's global assessment score()						
Week 12	-2.5 (-3.3 to -1.7)	-0.6 (-1.4 to 0.2)	-1.9 (-3.1 to -0.7)	0.002		
Week 24	-2.4 (-3.1 to -1.7)	-0.7 (-1.4 to 0.01)	-1.7 (-2.7 to -0.8)	0.001		
Physician's global assessment score	§					
Week 12	-1.0 (-1.7 to -0.4)	0.02 (-0.6 to 0.7)	-1.1 (-1.9 to -0.2)	0.02		
Week 24	-0.5 (-1.2 to 0.1)	0.6 (0.03 to 1.2)	-1.1 (-2.0 to -0.2)	0.02		
PSQI score¶						
Week 12	-3.6 (-4.8 to -2.4)	-0.7 (-1.9 to 0.5)	-2.9 (-4.6 to -1.2)	0.001		
Week 24	-4.2 (-5.8 to -2.7)	-1.2 (-2.7 to 0.4)	-3.0 (-5.2 to -0.9)	0.007		
6-Minute walk test (yd)						
Week 12	60.6 (37.9 to 83.3)	16.3 (-6.4 to 38.9)	44.4 (12.3 to 76.4)	0.007		
Week 24	49.8 (25.9 to 73.8)	23.2 (0.8 to 47.1)	26.7 (-7.2 to 60.5)	0.12		
Body-mass index**						
Week 12	0.02 (-0.4 to 0.4)	-0.2 (-0.5 to 0.2)	0.2 (-0.3 to 0.7)	0.47		
Week 24	-0.2 (-0.7 to 0.3)	-0.3 (-0.8 to 0.2)	0.1 (-0.6 to 0.8)	0.76		
SF-36 score††						
Physical component						
Week 12	8.5 (5.7 to 11.3)	1.4 (-1.5 to 4.2)	7.1 (3.1 to 11.1)	0.001		
Week 24	8.4 (5.6 to 11.3)	1.5 (-1.4 to 4.3)	7.0 (2.9 to 11.0)	0.001		
Mental component						
Week 12	7.7 (3.9 to 11.6)	1.6 (-2.2 to 5.4)	6.1 (0.7 to 11.6)	0.03		
Week 24	8.5 (4.6 to 12.4)	1.2 (-2.7 to 5.0)	7.3 (1.9 to 12.8)	0.009		
Table 2. (Continued.)						
Variable	Mean Change from Baseline (95% CI)		Between-Group Difference (95% C			
	Tai Chi Group (N=33)	Control Group (N=33)	Tai Chi Group vs. Control Group	P Value†		
CES-D score‡‡						
Week 12	-8.1 (-10.9 to -5.3)		−5.9 (−9.8 to −1.9)	0.005		
Week 24	-6.5 (-9.4 to -3.6)	-2.4 (-5.3 to 0.5)	-4.1 (-8.2 to 0.1)	0.05		
CPSS score∭						
Week 12	1.5 (0.7 to 2.2)	0.5 (-0.3 to 1.2)	1.0 (-0.03 to 2.0)	0.06		
Week 24	1.2 (0.4 to 1.9)	0.6 (-0.2 to 1.4)	0.6 (-0.5 to 1.6)	0.28		

### 治療效果 估計精準度



### Will the results help my patient?

### **External validity / Applicability**

- No 我的病人會不會跟這個研究差很多?
  - 不會,可以應用
- Yes 治療是否合理可行?
  - 很合理
- Yes 我的病人可能從治療中得到什麼好處?
  - 使用NNT評估得到的好處
  - Ex: FIQ NNT 12 weeks = 3
    - 叫3個病人打太極拳12周,就能預防一個病人的FIQ變壞喔
- Yes 我的病人如何看待治療結果?
  - 正向(不痛又沒副作用)

### **CAT** maker



## 其他人的評論



周醫師,成都華西醫科大學醫院

●治療組跟對照組差異甚大(duration, 師資, 在家運動)



張醫師,上海華山醫院

- •治療組跟對照組差異甚大(duration, 師資, 在家運動)
- •怎麼知道在家裡有沒有運動?
- •楊氏太極85式,選哪10式?理由?



Yvonne,荷蘭Maastricht University Medical Center

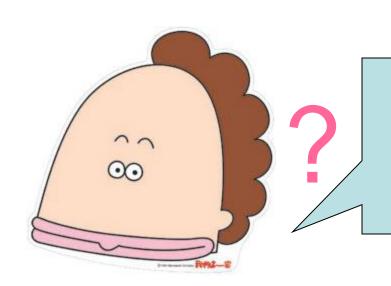
- •貴計畫的療效實在史無前例(unprecedented)
- •妳這效果也太扯了!

## 作者的回答



- •針對身心運動設計sham組別很困難
- •Education = attention control = placebo control,與時間無關
- •太極拳,百家爭鳴,其理一也;招式變化萬千,也 沒SOP
- •已經盡量減低bias;效果是真的狠好

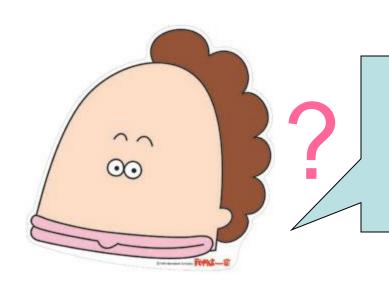
# 5A step 5 - Auditing 評估成果



# 我全身都好痛,睡都睡不好請問我可以打太極拳嗎?

有一篇研究結果顯示, 打太極拳對纖維肌痛症有 生理上與心理上的幫助





### 真的喔,那一定要打滿 108招嗎?

這個研究只有打十招, 12週就可以見效了



### Thanks for attention!!



長庚醫院中醫科部關心您的健康