

# 實證競賽

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內科部 專科護理師

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# 團隊



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## 臨床情境

在一群中年（45-60歲）有輕度至中度慢性阻塞性肺病（COPD，肺功能 FEV1 為預測值的50%-80%）的病人中，醫療團隊正在討論是否應先以肺康復治療（包括運動訓練、呼吸肌訓練、教育）作為初期主要治療，與直接以長效支氣管擴張劑起始治療相比。請參賽者探索：對於這樣病人族群，肺康復治療相比直接使用長效支氣管擴張劑，是否能在降低急性加重次數、改善生活品質、延緩肺功能惡化方面取得較佳成效？並評估於台灣教學醫院內部實施的可行性。

## 醫療團隊關心的問題

加入 **LAMA** 後，是否比「肺復原 + LABA」更能改善：

- **6 分鐘行走距離（6MWD）**
  - **身體活動量（步數、METs、能量消耗）**
- 是否能促進更快、更顯著的體能改善？

## 病人及家屬關心的問題

走路、爬樓梯會不會比較輕鬆？  
運動耐力（6 分鐘走路）會提升多少？  
LABA + LAMA 是否健保給付？  
每月藥費大概多少？  
肺復原要不要額外付費？

# 背景知識

## 1. COPD 45–60 歲族群仍處於活躍年齡

- 多需工作、照顧家庭，運動耐受力下降會影響生活與就業。
- 輕中度 COPD 雖氣流受限不如重度嚴重，但「活動量下降」已可造成顯著功能退化。

## 2. LABA 與 LAMA 皆為 GOLD 推薦的支氣管擴張藥物

- **LABA**：改善呼吸氣流，減少喘。
- **LAMA**：減少氣道阻力、降低過度充氣（hyperinflation）。
- ☞ **雙擴張（LABA + LAMA）** 在研究中常優於單一 **LABA**。

## 3. 肺復原是提升體能最有效的介入之一

- 肺復原可改善：
  - 運動耐受力（6MWD）
  - 肌力與心肺功能
  - 身體活動量
- 若結合支氣管擴張劑，可達到「更能運動 → 更願意運動 → 效果更強」的良性循環。

## 4. 運動能力與身體活動量都是預後指標

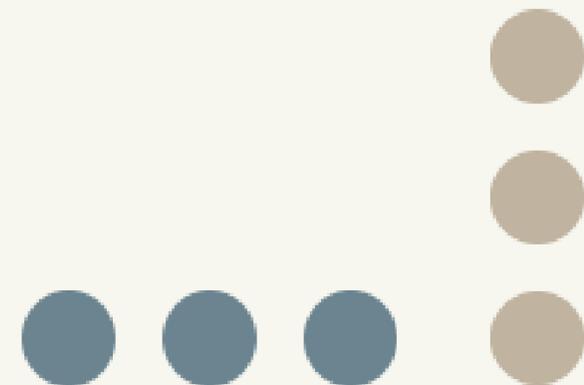
- 6MWD 下降與死亡率、住院率上升有關。
- 身體活動量低與急性加重風險增加相關。



# 5A-1 ASK 提出問題

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# 根據臨床問題形成第一個PICO

	英文關鍵字	MeSH terms	中文關鍵字
P	(middle-aged OR adult*) AND (COPD OR "chronic obstructive pulmonary disease") AND (mild COPD OR moderate COPD OR "FEV1 50-80%")	Pulmonary Disease, Chronic Obstructive[Mesh] Middle Aged[Mesh]	45-60歲，輕中度 COPD
I	pulmonary rehabilitation OR lung rehabilitation) AND (exercise training OR respiratory muscle training) AND (LABA OR LAMA OR bronchodilator) AND (combination therapy OR PR + LABA + LAMA)	Pulmonary Rehabilitation[Mesh] Exercise Therapy[Mesh] Bronchodilator Agents[Mesh]	肺復原治療 + LABA + LAMA
C	pulmonary rehabilitation) AND (LABA OR long-acting beta agonist) AND (monotherapy OR standard LABA treatment)	Adrenergic beta-2 Receptor Agonists[Mesh] Bronchodilator Agents[Mesh]	肺復原治療 + LABA
O	exercise capacity OR functional capacity) AND ("six-minute walk distance" OR 6MWD) OR (physical activity OR step count OR METs)	Exercise Tolerance[Mesh] Walking[Mesh] Motor Activity[Mesh]	運動耐受力 (6分鐘行走距離) 身體活動量 (Steps/day, METs, 能量消耗)

- 治療/預防型問題
- 診斷型問題
- 癒後型問題
- 傷害/病因型問題

# 根據臨床問題形成第二個PICO

	英文關鍵字	MeSH	中文關鍵字
P	(middle-aged OR adult*) (COPD OR "chronic obstructive pulmonary disease") (mild COPD OR moderate COPD OR "FEV1 50-80%") stable COPD	Pulmonary Disease, Chronic Obstructive[Mesh] Middle Aged[Mesh] Severity of Illness Index[Mesh]	45-60歲 · 輕中度 COPD
I	home-based pulmonary rehabilitation, tele-rehabilitation, remote rehab	"Pulmonary Rehabilitation"[Mesh] "Telemedicine"[Mesh]	居家基礎 (Home-based) 或遠距醫療輔助 (Tele-rehab) 肺康復
C	hospital-based pulmonary rehabilitation, center-based rehab	"Rehabilitation Centers"[Mesh] "Pulmonary Rehabilitation"[Mesh]	傳統醫院內 (Hospital-based) 肺康復
O	exercise capacity, 6-minute walk distance, 6MWD	"Exercise Tolerance"[Mesh] "Walking"[Mesh]	運動耐受力 (6分鐘行走距離 6MWD)

- 治療/預防型問題
- 診斷型問題
- 癒後型問題
- 傷害/病因型問題





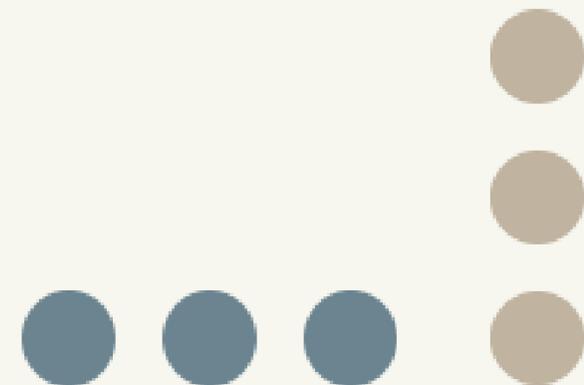
# 5A-2

## Acquire

### 搜尋資料

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# 檢索策略

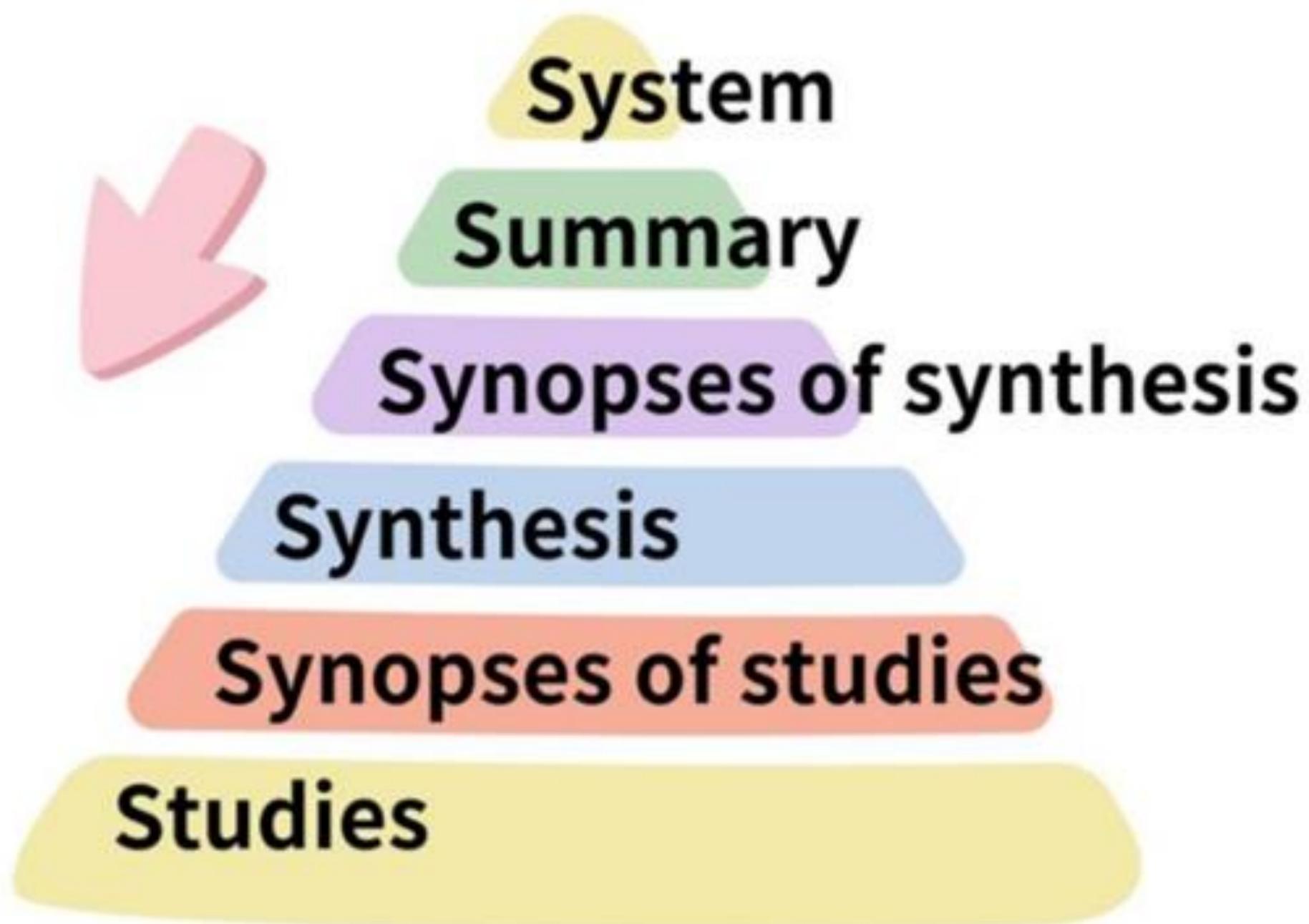
## 首選Level1 : SR of RCT

Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

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

Systematic Review、Meta-Analysis[Major] Randomized Controlled Trial/Cohort Study

# 資料庫



DynaMed<sup>™</sup> UpToDate  
Powered by EBSCOhost

PubMed  
Embase

Cochrane  
Library

airiti Library

華藝線上圖書館

# 搜尋Cochrane library



**filter your results**

Date i

Publication date

The last 3 months

The last 6 months

The last 9 months

The last year

The last 2 years

Custom Range:

01/12/2020 to 31/12/2025

Apply Clear

Status i

Conclusions changed ..... 2

New search ..... 2

Available Translations i

Español 5

Cochrane Reviews 22

Cochrane Protocols 0

Trials 460

Editorials 1

Special Collections 0

Clinical Answers 0

Date: Custom date range ✕

5 Cochrane Reviews matching (COPD OR chronic obstructive pulmonary disease\*) AND (pulmonary rehabilitat\* OR exercise therap\* OR inspiratory muscle training) AND (bronchodilator\* OR LABA\* OR LAMA\*) in Title Abstract Keyword

Did you mean: *cod* | *coed* | *cold*

Cochrane Database of Systematic Reviews  
Issue 12 of 12, December 2025

輸入關鍵字、適當使用Truncation  
使用Limit功能  
限定『Review』之文章  
限定『2020-2025』之文章

2  Chronic non-invasive ventilation for chronic obstructive pulmonary disease

Tim Raveling, Judith Vonk, Fransien M Struik, Roger Goldstein, Huib AM Kerstjens, Peter J Wijkstra, Marieke L Duiverman

Free access Intervention Review 9 August 2021 New search Conclusions changed

Show PICOs Show preview

# 搜尋Pubmed

The screenshot shows the PubMed search page with the following elements:

- Search Bar:** Contains the query: ("Pulmonary Disease, Chronic Obstructive"[MeSH] OR COPD OR "chronic ob..."). A "Search" button is to the right.
- Buttons:** "Advanced", "Create alert", "Create RSS", "Save", "Email", "Send to", and "Sort by:".
- Filters Applied:** A green bar indicates: "Filters applied: in the last 5 years, Full text, Meta-Analysis. [Clear all](#)".
- Filters:**
  - PUBLICATION DATE:** Radio buttons for 1 year, 5 years (selected), 10 years, and Custom Range.
  - ARTICLE TYPE:** Checkboxes for Books and Documents, Clinical Trial, Meta-Analysis (checked), Randomized Controlled Trial (checked), Review, and Systematic Review (checked).
  - TEXT AVAILABILITY:** Checkboxes for Abstract, Free full text (checked), and Full text (checked).
  - SPECIES:** Checkboxes for Humans (checked) and Other Animals.
- RESULTS BY YEAR:** A bar chart showing results for the year 2020.

Annotations in the image provide the following instructions:

- Top Right Box:** 輸入關鍵字、適當使用Truncation  
適當使用布林邏輯運算  
『 AND 』 『 OR 』
- Bottom Right Box:** 限定文章類型  
『 System review 』 『 Meta-analysis 』  
『 Randomized controlled trial 』  
限定適當搜尋範圍  
限定 『 5年 』 內之文章  
限定 『 Full text 』 有全文可供評讀  
限定 『 Human 』 species

# 查詢結果



輸入『P』、『I』、『O』及適當同義詞，搭配各資料庫限定或filter之功能

940results

360results

20results

選擇『System review』之文章

27results

35results

1results

選擇『5年內』之文章

6results

22results

1results

選擇『符合臨床問題』之文章

1results

1results

0results

# 選擇最佳文獻

Miravittles et al. *Respiratory Research* (2022) 23:347  
<https://doi.org/10.1186/s12931-022-02268-3>

Respiratory Research

RESEARCH

Open Access

## Exercise capacity and physical activity in COPD patients treated with a LAMA/LABA combination: a systematic review and meta-analysis



Marc Miravittles<sup>1\*</sup>, Juan Luis García-Rivero<sup>2</sup>, Xavier Ribera<sup>3</sup>, Jordi Galera<sup>4</sup>, Alejandra García<sup>5</sup>, Rosa Palomino<sup>5</sup> and Xavier Pomares<sup>6</sup>

## 選擇理由

- 1.符合所設定的PICO
- 2.出版於近5年內
- 3.為SR of RCT



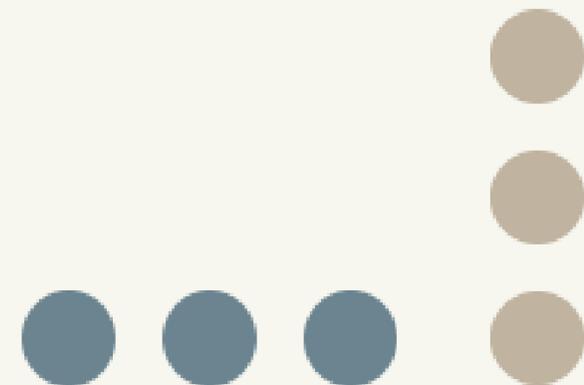
# 5A-3

# Appraise

# 評讀文獻

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# 嚴格評讀：以 CASP 工具進行系統性檢驗



## 工具介紹

CASP (Critical Appraisal Skills Programme)  
Systematic Review Checklist

一套標準化工具，用以系統性地評估文獻的  
有效性 (Validity)、結果 (Results) 與臨床  
適用性 (Applicability)。

我們將透過 CASP 的10個問題，逐一檢驗此  
篇文獻的每一個細節。



# 1.此回顧是否問了一個清楚、明確的臨床問題？

P

We included randomized clinical trials in patients aged  $\geq 40$  years diagnosed with COPD, with a post-bronchodilator forced expiratory volume at 1 s ( $FEV_1$ )/forced vital capacity (FVC)  $< 0.7$  and treated with a combination of LAMA/LABA inhaled bronchodilators compared with placebo or monotherapy with LAMA or LABA. To be included, the trials had to evaluate at least one variable related to exercise capacity or physical activity.

I

C

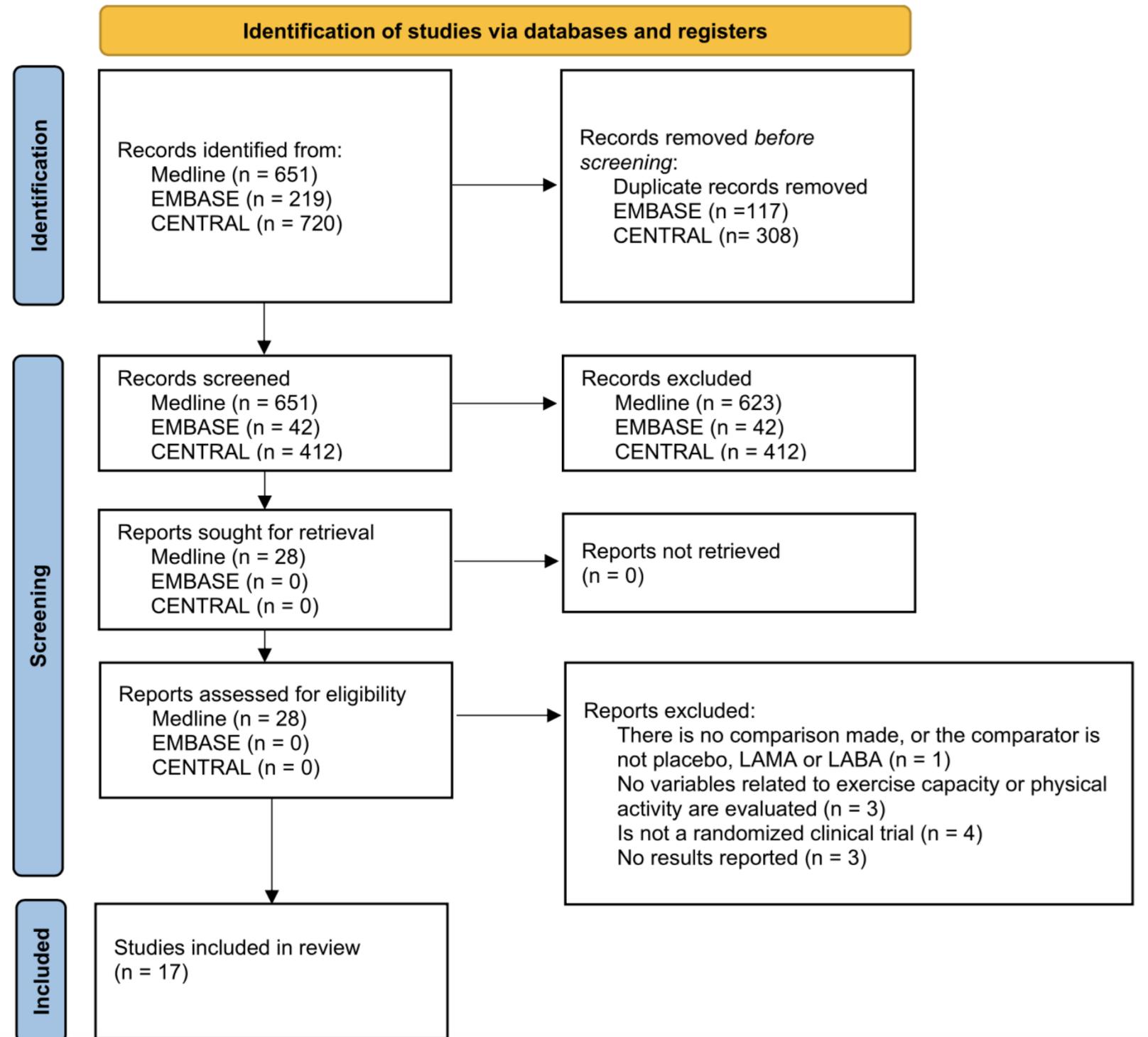
O

■ Yes □ Can't tell □ No

符合臨床問題  
PICO清楚定義



## 2. 作者是否收納適當研究類型？



■ Yes □ Can't tell □ No

收錄符合問題RCT  
清楚定義納入排除條件



### 3.重要、相關的研究是否皆被納入？

A search strategy was designed for MEDLINE (through PubMed), CENTRAL and EMBASE using appropriate controlled terms related to COPD, LAMA, LABA, exercise capacity, physical activity and lung function in articles published between the 1st January 2012 and the 31st December 2021 as the first LAMA/LABA combination inhaler was approved in 2013 and prior 2012 there was no evidence about double bronchodilators (Additional file [2](#): Table A1). There were no limitations regarding language. Additionally, references to selected articles were also reviewed to identify other articles that met the inclusion and exclusion criteria.

搜尋各種資料庫  
Protocol說明納入排除  
不限語言  
與專家聯繫  
包含已/未發表文獻  
搜尋英文/中文文獻  
從參考資料再搜尋

Yes  Can't tell  No





## 4. 作者是否有評估收納研究的品質？

### Assessment of risk of bias

The risk of bias assessment was carried out according to the Cochrane Manual for Systematic Reviews and Meta-Analysis of Interventions criteria [11] and evaluated the generation of the randomization sequence, concealment of the assignment, blinding of patients and researchers, blinding of the results of the variables to be evaluated, data on incomplete results, bias of scientific information, and other biases. The risk of bias was assessed by one reviewer and validated by a second on a detailed form. Review Manager 5.4 was used for the risk of bias assessment.

2個作者獨立評讀

### Cochrane Risk of Bias tool

**過程嚴謹：**二位分別評讀  
**結果報告：**作者在結果中報告了風險評估的狀況，指出除了「結果盲性」和「分組隱匿」部分研究風險不明確外，其他領域的偏差風險均較低

■ Yes □ Can't tell □ No

# 作者是否有評估收納研究的品質？

過程嚴謹：二位分別評讀結果報告：作者在結果中報告了風險評估的狀況，指出除了「結果盲性」和「分組隱匿」部分研究風險不明確外，其他領域的偏差風險均較低。

作者使用了標準的 **Cochrane Risk of Bias tool** 來評估偏差風險。

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Canto., 2012	+	?	+	?	+	+	+
Ichinose., 2018	+	+	+	+	+	+	+
Jayaram., 2013	+	-	+	?	+	+	+
Maltais., 2014	+	+	+	?	?	+	+
Maltais., 2018	+	?	+	?	-	+	+
Maltais., 2020	+	?	+	?	+	+	+
Minakata., 2019	+	+	+	+	+	+	+
O'Donnell., 2017	+	?	+	?	+	+	+
O'Donnell., 2018	+	?	+	?	?	+	+
Riley., 2018	+	+	+	?	+	+	+
Singh., 2018	+	?	+	?	?	+	+
Stringer., 2021	+	+	+	?	+	+	+
Takahashi et al., 2020	+	-	-	?	+	+	+
Troosters., 2018	+	?	-	?	+	+	+
Tufvesson., 2021	+	?	+	?	+	-	?
Watz., 2016	+	?	+	+	+	+	+
Watz., 2017	+	?	+	?	+	+	+

□ Yes □ Can't tell □ No





「證據  
可信度」

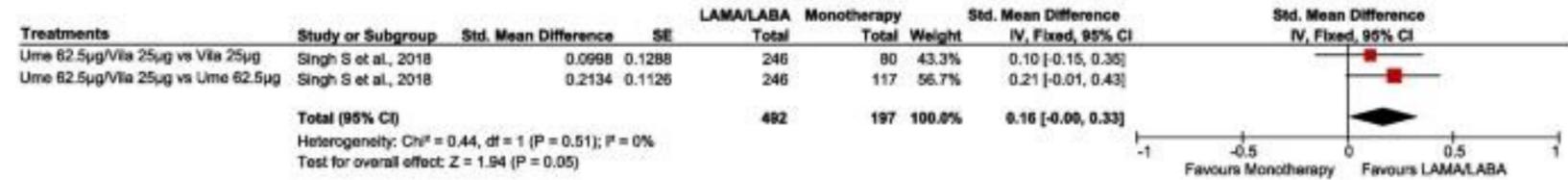
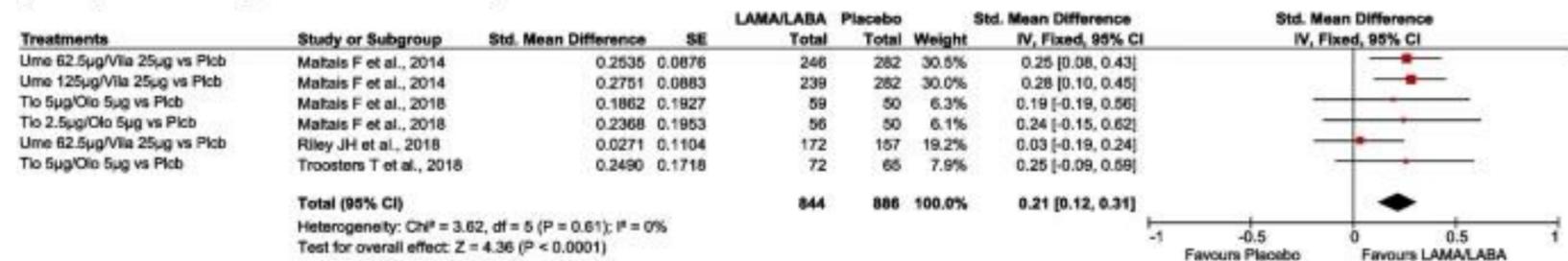
# 5. 作者將研究結果進行合併，這樣的合併是否合理？

主要結果-\_\_yes\_\_

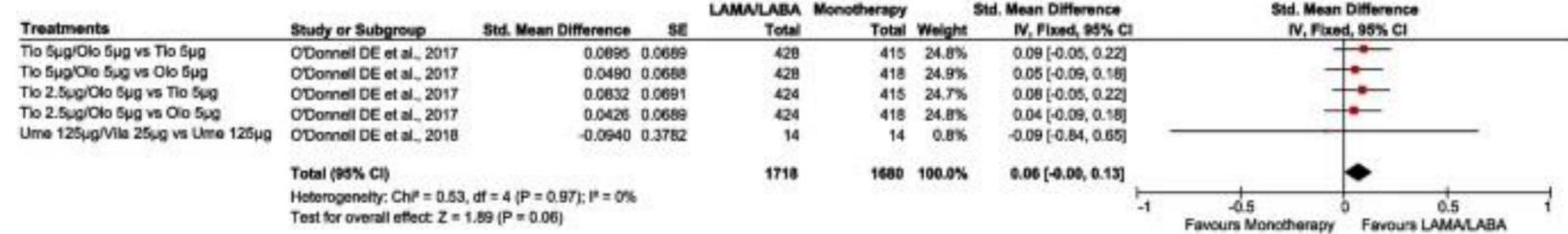
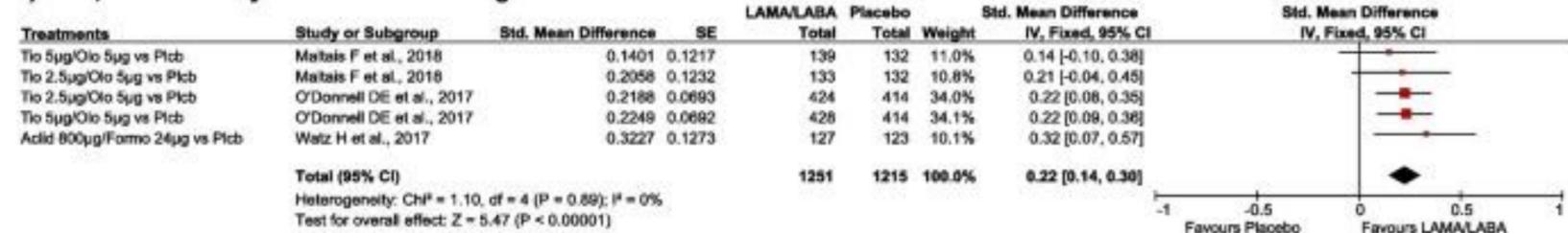
■ Yes □ Can't tell □ No

異質性：為顯著異質性低度(I2 : 0%)  
敏感性測試

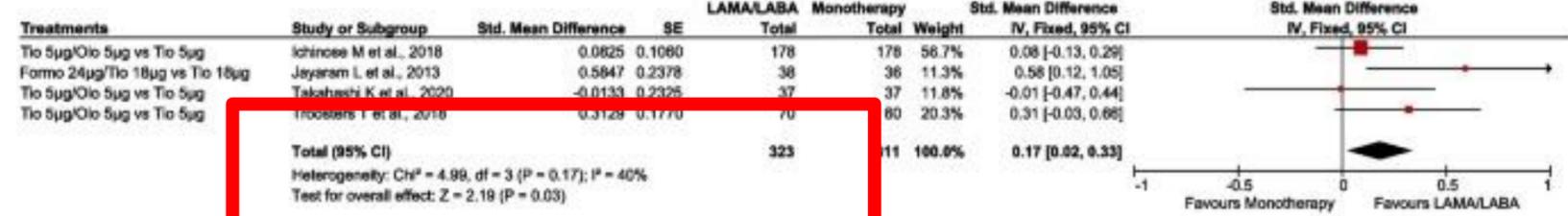
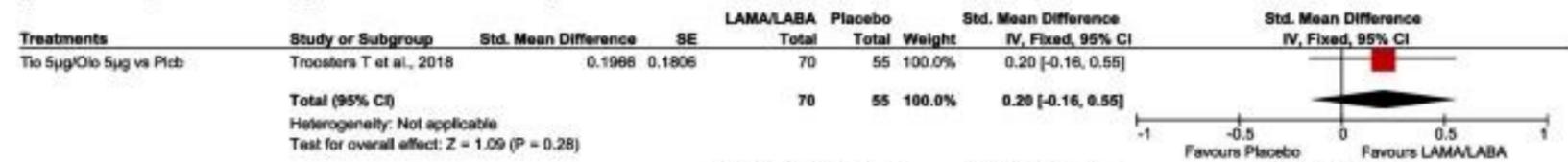
a) EET, measured by ESWT: mean change from baseline



b) EET, measured by CWRE: mean change from baseline



c) Distance, measured by 6MWT: mean change from baseline



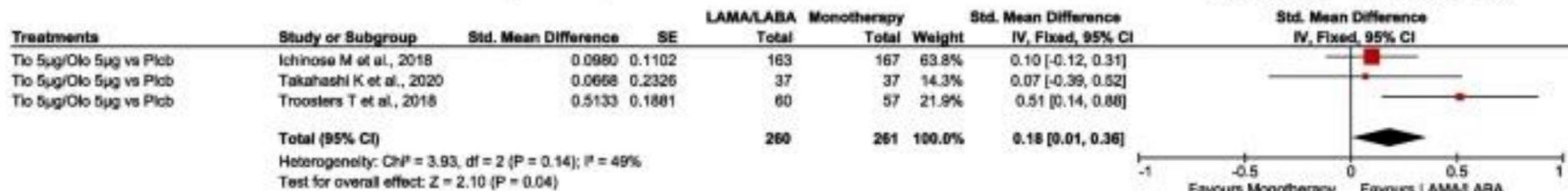
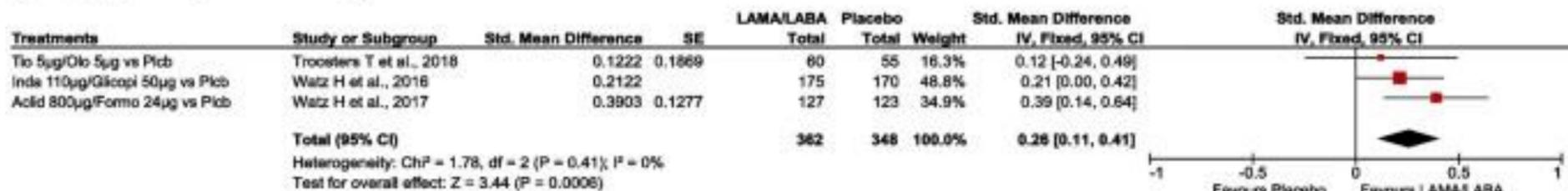


# 5. 作者將研究結果進行合併，這樣的合併是否合理？

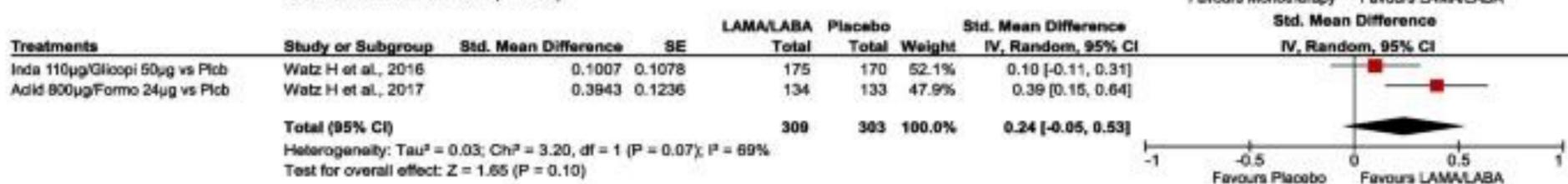
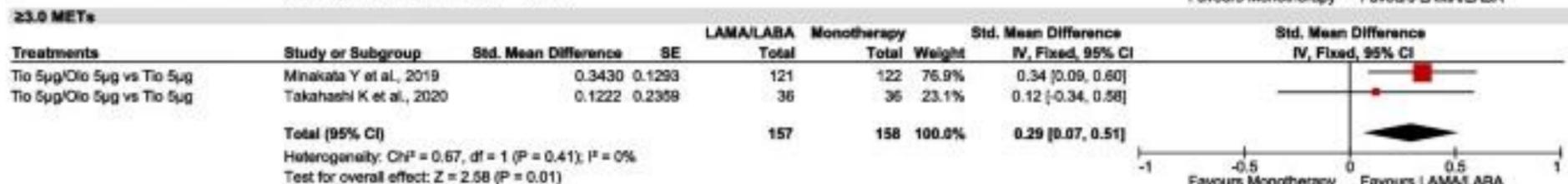
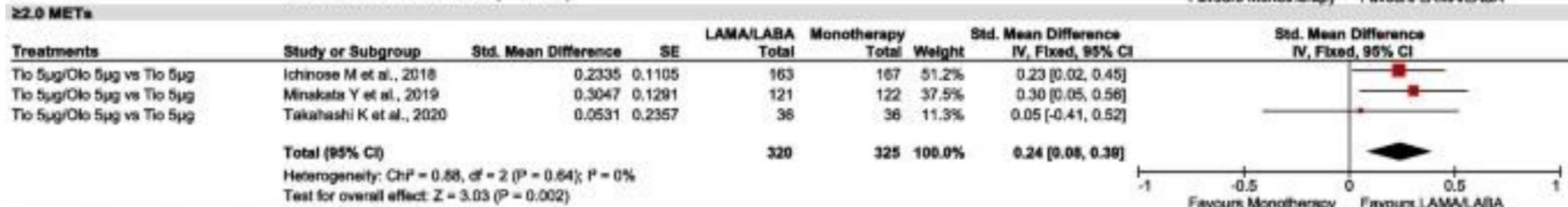
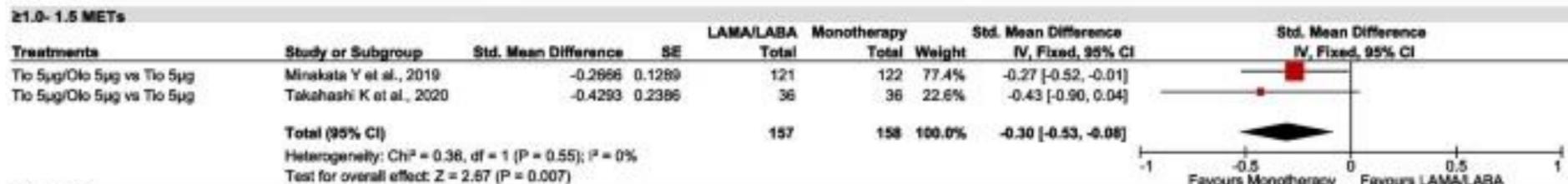
主要結果-\_\_yes\_\_

■ Yes □ Can't tell □ No

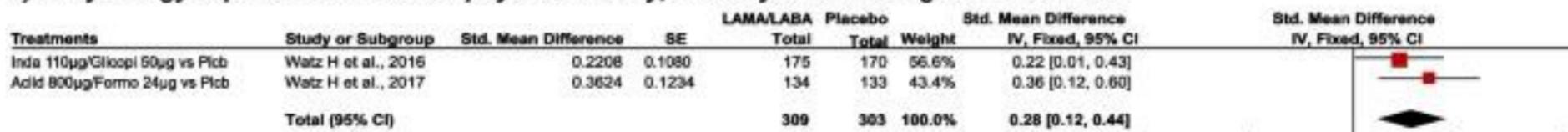
a) Steps per day: mean change from baseline



b) Daily duration of activity (≥1.0-1.5, ≥2.0 and ≥3.0 METs), minutes: mean change from baseline



c) Daily energy expenditure related to physical activity, kcal/day: mean change from baseline



# 評讀統整

	CASP評讀統整	Y/N
1	此系統性回顧是否問了一個清楚、明確的臨床問題？	Y
2	作者是否尋找適當研究型態的文獻？	Y
3	你認為所有重要且相關的研究都被納入？	Y
4	作者是否評估所納入研究文獻的品質？	Y
5	作者將研究結果進行合併，這樣的合併是否合理？	Y

## 值得評讀



「證據  
可信度」



「結果  
重要性」

## 6. 這篇系統性文獻回顧的整體結果為何？

■ Yes □ Can't tell □ No

### Effectiveness of the intervention in physical activity

When measured in steps per day, LAMA/LABA combinations were significantly superior to both placebo and monotherapy (Fig. 3a). Regarding daily duration activity, patients treated with LAMA/LABA combination reduced the duration of  $\geq 1.0$ – $1.5$  METs activity than patients treated with monotherapy. On the other hand, for moderate physical activity, the results favoured LAMA/LABA therapy by increasing the duration of  $\geq 2.0$  METs activities. For vigorous physical activity ( $\geq 3.0$  METs), LAMA/LABA therapy was superior to both monotherapy and placebo, although the latter results were not statistically significant when standardized under a random effects model (Fig. 3b). Daily activity-related energy expenditure was higher in the LAMA/LABA group than in the placebo group (Fig. 3c). Finally, more inactive patients ( $< 6000$  steps/day) were observed in the placebo group than in the LAMA/LABA combination group (OR [95% CI]: 0.27 [0.14–0.51]; 1 study, N = 267) [15]. In Troosters et al. [12] walking intensity and walking time per day were also evaluated at week 12, results for average daily walking time mirrored those of steps per day and there was a small but significant increase in average daily walking intensity with SMBM plus placebo compared with baseline (1.97 vs. 1.90 m/s<sup>2</sup>, p = 0.006) and with SMBM + tiotropium/olodaterol (1.99 vs. 1.91 m/s<sup>2</sup>; p < 0.05) [12].

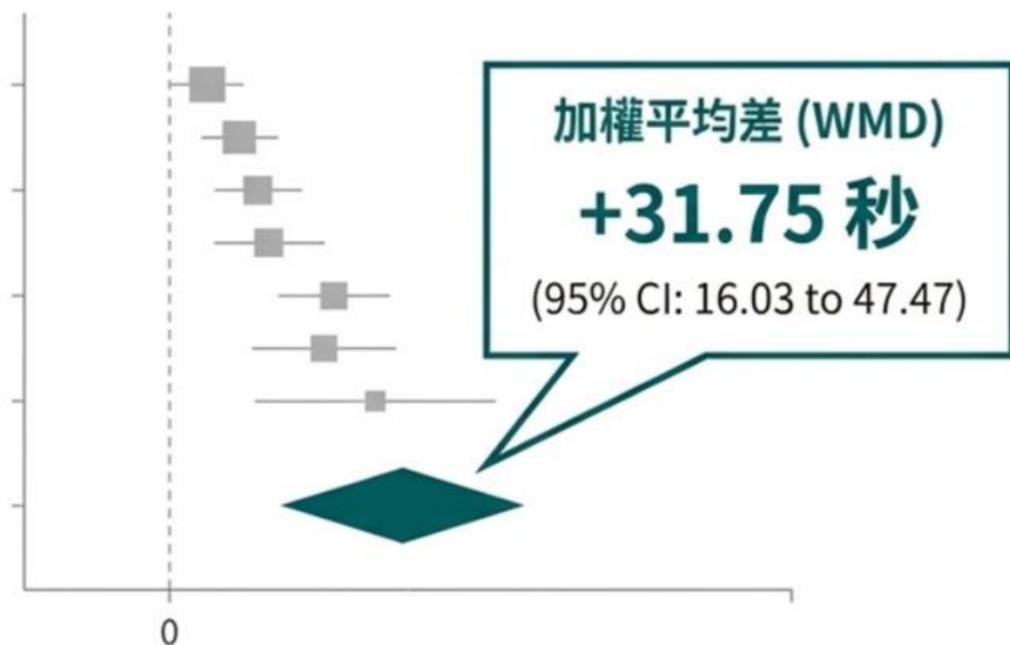
In Watz et al. [15] the D-PPAC questionnaire total score (LSM [95% CI]: 2.7 [1.3–4.1]; p = 0.0002), amount (3.4 [1.4–5.4]; p = 0.0008), and difficulty (2.3 [0.3–4.4]; p = 0.0258) domains improved significantly in the LAMA/LABA combination group versus placebo at

P值<0.05有顯著差異

# LAMA/LABA 療法顯著優於安慰劑，有效提升患者的運動耐受時間

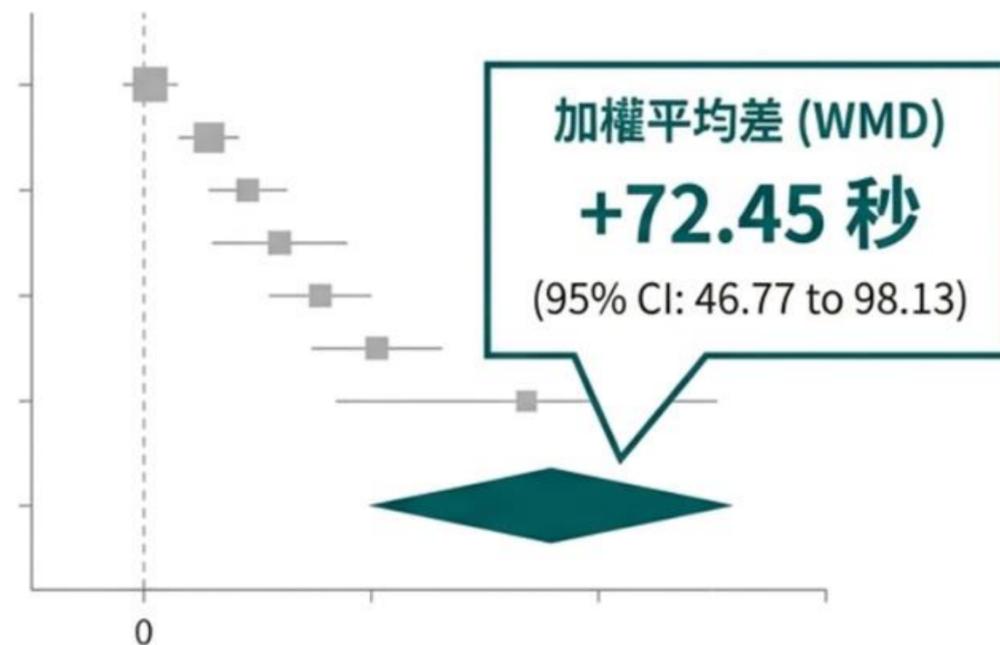
## 關鍵運動耐力指標：與安慰劑比較

耐力折返步行測試  
(Endurance Shuttle Walk Test, ESWT)



統計學上顯著改善

固定功率腳踏車運動  
(Constant Work Rate Cycle Ergometry, CWRCE)

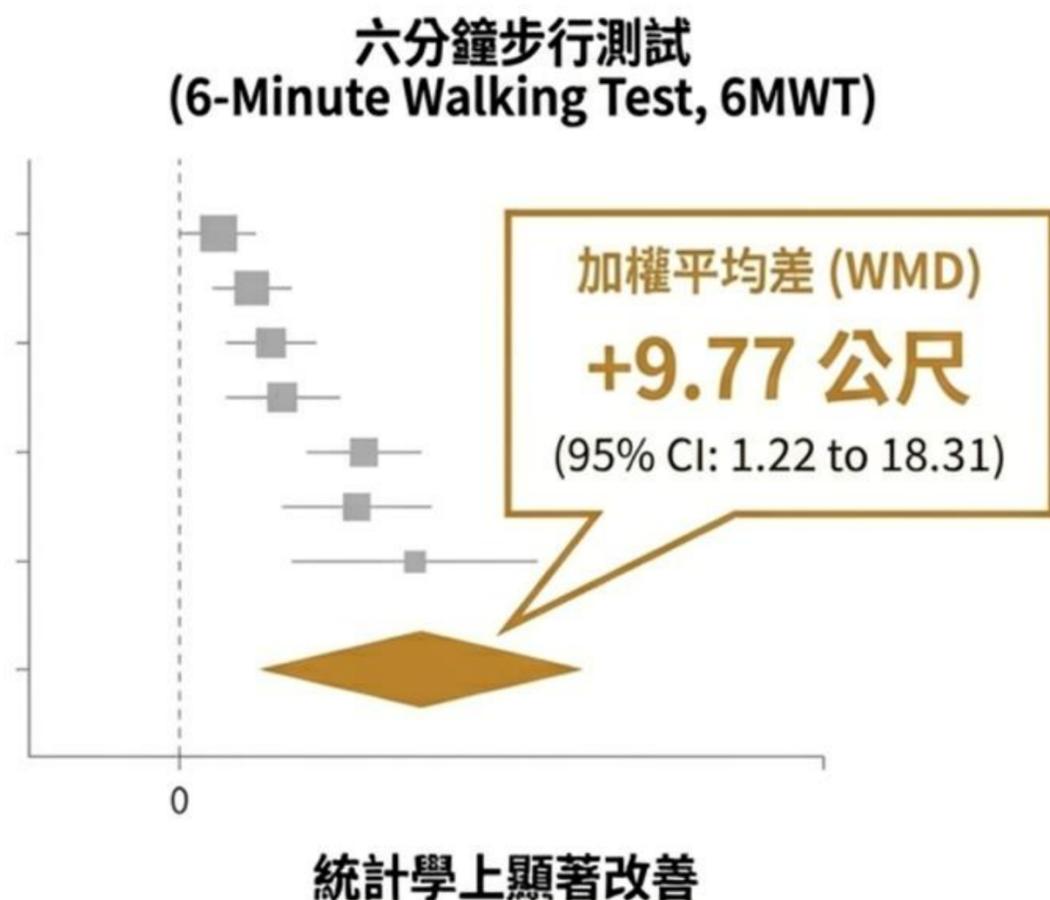


統計學上顯著改善

Source: Table 2 & Figure 2 from Miravittles et al. (2022).

與單方治療相比，LAMA/LABA 複方療法在六分鐘步行測試中展現出統計學上的優越性

更進一步：與單方支氣管擴張劑比較



在 ESWT 與 CWRCE 方面，結果同樣有利於 LAMA/LABA 複方，但未達統計學顯著差異。

這可能反映了從單一有效藥物升級至複方時，其效益增加的幅度較安慰劑為基準時更為細微。

Source: Table 2 & Figure 2 from Miravittles et al. (2022).

# 7. 結果精準嗎？

■ Yes □ Can't tell □ No

## Results

The search strategies yielded 1590 articles, of which 17, including 4,041 patients, met the inclusion criteria, 2964 of the patients were treated with the LAMA/LABA combination, 1901 treated with placebo, 1070 treated with LAMA and 755 treated with LABA (Fig. 1) [12–28]. The reference search yielded no further articles.

**Table 2** Summary of meta-analysis comparisons and main results in weighted mean differences (WMD) and standardised mean differences (SMD)

	LAMA/LABA comparator	Characteristics		Weighted results		Standardized results	
		Number of CT	N	MD	95% CI	MD	95% CI
ESWT	Placebo*	4	1730	31.75 s	16.03 s to 47.47 s	0.21	0.12 to 0.31
	Monotherapy	1	689	11.36%	– 0.03% to 22.74%	0.16	– 0.00 to 0.33
CWRCE	Placebo*	3	2466	72.45 s	46.77 s to 98.13 s	0.22	0.14 to 0.30
	Monotherapy	2	3398	24.23 s	– 0.86 s to 49.32 s	0.06	– 0.00 to 0.13
$T_{lim}$ CWRT	Monotherapy*	1	38	43.80%	38.77% to 48.83%	5.42	3.99 to 6.86
6MWT	Placebo	1	125	11.87 m	– 9.32 m to 33.06 m	0.20	– 0.16 to 0.55
	Monotherapy*	4	634	9.77 m	1.22 m to 18.31 m	0.17	0.02 to 0.33
Steps/day	Placebo*	3	710	471.89 steps/day	206.08 steps/day to 737.71 steps/day	0.26	0.11 to 0.41
	Monotherapy**	3	521	398.48 steps/day	– 264.40 steps/day to 1061.36 steps/day	0.18	0.01 to 0.36
≥ 1.0–1.5 METs	Monotherapy*	2	315	– 9.93 min	– 17.91 min to – 1.95 min	– 0.30	– 0.53 to – 0.08
≥ 2.0 METs	Monotherapy*	3	645	5.59 min	2.13 min to 9.05 min	0.24	0.08 to 0.39
≥ 3.0 METs	Placebo***	2	612	7.73 min	3.07 min to 12.39 min	0.24	– 0.05 to 0.53
	Monotherapy*	2	315	2.60 min	0.74 min to 4.46 min	0.29	0.07 to 0.51
Energy expenditure	Placebo*	2	612	39.33 kcal/day	17.95 kcal/day to 60.71 kcal/day	0.28	0.12 to 0.44

\* Statistically significant differences, both in WMD and SMD. \*\*Statistically significant differences in SMD. \*\*\*Statistically significant differences in WMD

CI confidence interval, CT clinical trial, CWRCE constant work rate cycle ergometry, ESWT endurance shuttle walk test, kcal kilocalories, LABA long-acting beta-2 agonists, LAMA long-acting muscarinic antagonists, m meters, MD mean difference, MET metabolic equivalent of task, min minutes, N number of patients, s seconds, SMD standardized mean difference,  $T_{lim}$  CWRT tolerance limit in constant work rate test, WMD weighted mean difference, 6MWT 6-min walking test

Sample size : 4041

95%CI : 0.21(0.12, 0.31) 無碰到統計無效線  
 95%CI : 0.22 (0.14, 0.33) 無碰到統計無效線



# 評定證據等級

## 證據等級Level 1

問題	等級1級*	等級2級*	等級3級*	等級4級*	等級5級*
這問題有多普遍？	本地和當前的隨機抽樣調查(或人口普查)	契合當地情況調查的系統性文獻回顧**	區域非隨機樣本**	病例報告(Case-series)**	n/a
診斷或監測是否準確？(診斷)	採用一致性參考標準品和盲法的橫斷面研究之系統性文獻回顧	採用一致性參考標準品和盲法的個別橫截面研究	非連續研究或沒有採用一致性參考標準品的研究**	病例對照研究(Case-control studies)，或低品質或非獨立參考標準品的研究**	基於機制的推斷
如果不治療會有何後果？(預後)	初始世代研究(Inception cohort studies)之系統性文獻回顧	初始世代研究(Inception cohort studies)	世代研究(Cohort studies)或隨機對照試驗的控制組*	病例報告或病例對照研究，或低品質的預後世代研究**	n/a
這種介入有幫助嗎？(治療益處)	隨機對照試驗(RCT)或單人交叉臨床試驗(N-of-1 trials)的系統性文獻回顧	隨機對照試驗(RCT)或效果顯著的觀察性研究	非隨機對照的世代/追蹤性研究**	病例報告，病例對照研究或歷史對照研究**	基於機制的推斷
有哪些常見的傷害？(治療傷害)	隨機對照試驗(RCT)的系統性文獻回顧，重疊病例對照研究，對您提出問題的患者進行的單人交叉臨床試驗(N-of-1 trials)或具有顯著效果的觀察性研究之系統性文獻回顧	單篇試驗(單篇RCT)或(異常)效果顯著的觀察性研究	非隨機對照的世代/追蹤性研究(上市後監測)，前提是有足夠的樣本數量可以排除常見的傷害。(對於長期傷害，追蹤時間必須足夠。)**	病例報告，病例對照或歷史對照研究**	基於機制的推斷
罕見的傷害是什麼？(治療傷害)	隨機對照試驗(RCT)或單人交叉臨床試驗(N-of-1 trials)之系統性文獻回顧	隨機對照試驗(RCT)或(異常)效果顯著的觀察性研究	非隨機對照的世代/追蹤性研究(上市後監測)，前提是有足夠的樣本數量可以排除常見的傷害。(對於長期傷害，追蹤時間必須足夠。)**	病例報告，病例對照或歷史對照研究**	基於機制的推斷
早期診斷值得嗎？(篩檢)	隨機對照試驗(RCT)的系統性文獻回顧	隨機對照試驗(RCT)	非隨機對照的世代/追蹤性研究**	病例報告，病例對照或歷史對照研究**	基於機制的推斷

# 評讀統整

1	此系統性回顧是否問了一個清楚、明確的臨床問題？	Y
2	作者是否尋找適當研究型態的文獻？	Y
3	你認為所有重要且相關的研究都被納入？	Y
4	作者是否評估所納入研究文獻的品質？	Y
5	作者將研究結果進行合併，這樣的合併是否合理？	Y
6	這篇系統性文獻回顧的整體結果為何？	Y
7	結果精準嗎？	Y

## 可以應用



「證據  
可信度」

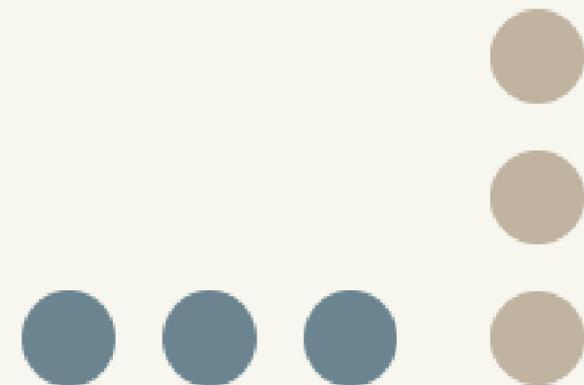


「結果  
重要性」

# 5A-4

# Apply

# 臨床應用



# 8. 此研究結果是否可應用到當地的族群？

Yes  Can't tell  No

**Table 1** Characteristics of studies included

Abbreviated reference and countries	Study type, number of arms and randomized patients
Troosters et al. 2018 [12] Australia, Austria, Belgium, Canada, Denmark, Germany, New Zealand, Poland, Portugal, United Kingdom, United States	Parallel, 4 arms, 304 patients
O'Donnell et al. 2017 [13] United States, Argentina, Australia, Austria, Belgium, Canada, Chile, Germany, Italy, Netherlands, New Zealand, Russia, Sweden	Crossover 5 arms, 586 patients

**Table 1** (continued)

Abbreviated reference and countries	Study type, number of arms and randomized patients	Duration	Inclusion criteria	Intervention	Comparator	Outcomes selected for analysis	Main results
Ichinose et al. 2018 [14] Japan	Crossover 2 arms, 184 patients	6 weeks	Japanese patients ≥ 40 years, with history of smoking > 10 pack-years, with COPD and stable airway obstruction, post-bronchodilator FEV1 < 80% of predicted; post-bronchodilator FEV1/FVC < 0.7 at visit 1; mMRC ≥ 1; 6MWD < 400 m; and a score ≥ 4 on Borg's modified scale following the 6MWD test on visit 2	Tiotropium 5 µg/Olodaterol 5 µg	Tiotropium 5 µg	6MWT, steps/day, duration of activity	Adjusted mean (SD), 6MWT: - At Beginning: - All treatments: 293.8 (93.3) - At 6 weeks: - Tiotropium 5 µg/Olodaterol 5 µg: 311.5 (n.a) - Tiotropium 5 µg: 307.4 (n.a) Adjusted mean (95%CI) treatment difference at 6 weeks, 6MWT: 4.2 (-6.2-14.5) Adjusted mean, steps/day: - At Beginning: - All treatments: 3723.0 - At 6 weeks: - Tiotropium 5 µg/Olodaterol 5 µg: 3871.1 - Tiotropium 5 µg: 3793.6 Adjusted mean (95%CI) treatment difference at 6 weeks, steps/day: 77.5 (-92.7-247.7) Adjusted mean (SD), ≥ 2 METs: - At Beginning: - All treatments: 181.4 (82.0) - At 6 weeks: - Tiotropium 5 µg/Olodaterol 5 µg: 191.5 (n.a) - Tiotropium 5 µg: 186.5 (n.a) Adjusted mean (95%CI) treatment difference at 6 weeks, ≥ 2 METs: 5.0 (0.39-9.69)

包含數個國家，包含亞洲地區



## 9. 是否所有重要的臨床結果都被考量到？

■ Yes □ Can't tell □ No

### Assessed outcomes

The identified outcome variables are defined as:

- 6-min walking test (6MWT), measuring the distance walked in 6 min in meters.
- Endurance Shuttle Walk Test (ESWT) measured in seconds (one study measured it in mean percentage change from baseline).
- Constant Work Rate Cycle Ergometry (CWRCE) measured in seconds.
- Steps per day (steps/day), examined by accelerometer and evaluated as average number of steps per day.
- Energy expenditure of  $\geq 1.0$ – $1.5$ ,  $\geq 2.0$ ,  $\geq 3.0$  Metabolic Equivalent of Task (METs), consisting on the average daily duration (in minutes) of  $\geq 1.0$ – $1.5$ ,  $\geq 2.0$  and  $\geq 3.0$  METs. Periods of sedentary time were categorized as an energy expenditure of  $1.0$ – $1.5$  METs, whereas periods of physical activity performed at more than light (i.e., moderate, or vigorous) and

此回顧將其評估的結果變項明確定義為與運動能力 (Exercise Capacity) 和身體活動量 (Physical Activity) 相關的結果。由於研究的目標就是評估 LAMA/LABA 在這些領域的效益，因此作者納入了這些領域中公認且重要的客觀和主觀測量指標。

# 10. 付出傷害和花費換得介入措施的益處是否值得？

■ Yes □ Can't tell □ No

介入措施	花費
介入系統性運動復健	掛號費100-300 1027點(台灣常規最高可計價)
優點	副作用
生活品質顯著改善 減輕症狀	無明顯副作用

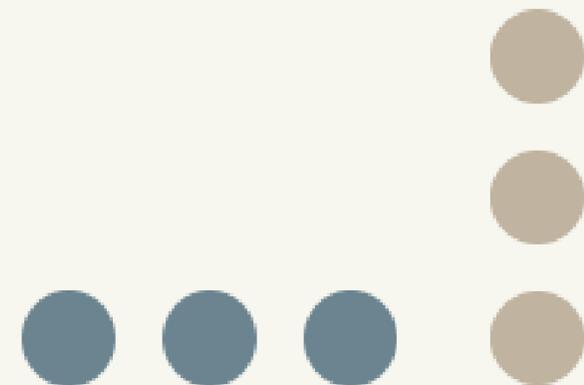
# 10. 付出傷害和花費換得介入措施的益處是否值得？

■ Yes □ Can't tell □ No

診療項目代碼	診療項目中文	支付點數	支付價生效起迄
47090B	高頻胸壁振盪模式呼吸道清潔(每次至少三十分鐘)	247	111.03.01~999.12.31
診療項目代碼	診療項目中文	支付點數	支付價生效起迄
57010B	呼吸運動 (次)	85	084.03.01~999.12.31
診療項目代碼	診療項目中文	支付點數	支付價生效起迄
57011B	誘發性深呼吸運動	70	084.03.01~999.12.31
診療項目代碼	診療項目中文	支付點數	支付價生效起迄
57012B	復原運動	140	106.10.01~999.12.31
17004C	標準肺量測定 (包括FRC測定)	485	106.05.01~999.12.31

	<b>CASP question</b>	<b>Y/N</b>
1	此系統性回顧是否問了一個清楚、明確的臨床問題？	Y
2	作者是否尋找適當研究型態的文獻？	Y
3	你認為所有重要且相關的研究都被納入？	Y
4	作者是否評估所納入研究文獻的品質？	Y
5	作者將研究結果進行合併，這樣的合併是否合理？	Y
6	這篇系統性文獻回顧的整體結果為何？	Y
7	結果精準嗎？	Y
8	此研究結果是否可應用到當地的族群？	Y
9	是否所有重要的臨床結果都被考量到？	Y
10	付出傷害和花費換得介入措施的益處是否值得？	Y

# 5A-5 Audit 執行決策



# 共享決策Share decision making

醫療現況 ( 實證醫學 )	病人治療的偏好
<ul style="list-style-type: none"><li>• 證據等級：CEBM ( LEVEL 1 )</li><li>• 建議：<b>選項</b>雙重支氣管擴張劑 (LABA+LAMA) <b>搭配</b> 肺康復計畫。 包含：有氧耐力訓練、肌力強化與呼吸技巧指導 ( 可選醫院療程或居家 App 輔助 ) 。</li></ul>	<p>希望體能改善到可以<b>勝任戶外休閒活動</b> ( 不只是坐著不喘，而是能動 ) 。</p> <p>極力希望能<b>預防急性惡化住院</b>。</p> <p>雖然認同復健有效，但擔心「<b>頻繁回診</b>」會造成<b>請假困難</b>。</p> <p><b>偏好「自我掌控度高</b>」的治療模式 ( 例如：學會方法後自己在家練，而不是一定要去醫院 ) 。</p>
利弊平衡	費用資源
<p><b>利 (符合期待)：</b></p> <p><b>提升活動力：</b> 實證顯示能顯著增加行走距離與耐力，直接達成病人「增加戶外活動」的目標。</p> <p><b>改善生活：</b> 相比單純用藥，生活品質與呼吸困難感改善更明顯。</p> <p><b>弊 (潛在風險)：</b></p> <p><b>副作用：</b> 需注意口乾、心悸等藥物副作用。</p> <p><b>生理負擔：</b> 復健初期可能會有肌肉痠痛或疲憊感。</p>	<p><b>時間成本 (關鍵痛點)：</b></p> <p>標準復健需每週 2-3 次回診，對 45-60 歲上班族來說，<b>請假與交通的時間成本極高</b>。</p> <p><b>金錢花費：</b></p> <p>長期使用雙重擴張劑的部分負擔，加上復健療程的掛號與交通費。</p>

# 臨床應用-回覆病人問題

先生您好，經過我們團隊縝密的實證搜尋後，目前現有最佳證據是由**系統性回顧文獻**的研究支持，使用 **雙重支氣管擴張劑 (LABA+LAMA)** 搭配肺康復治療可預期有效的協助 **增加您的6分鐘走路距離**，達成您想增加戶外活動的心願，且花費是 **藥物有健保給付**，但標準復健需投入每週**2-3次往返醫院的時間成本**，因為你的狀況是 **輕中度肺阻塞**，且希望能積極維持生活品質 所以建議您接受 **藥物與運動訓練並進** 的治療。

另外平常須注意 **居家自我運動訓練** 證據是由**系統性回顧文獻**的研究支持，使用 **居家或App輔助的肺康復計畫** 治療可預期有效的協助 **克服工作忙碌無法回診的困難**，維持心肺耐力，且花費是 **時間彈性高**，省去**交通費與掛號費**，因為你的狀況是 **仍在工作**，時間較難配合醫院療程 所以建議您接受 **混合照護模式（醫院指導後改為居家訓練）**。



# Thank You

For your attention

