2023年度

嘉義基督教醫院EBM文獻查證競賽



林口X嘉義X高雄長庚紀念醫院聯隊









長 庚 大 學 中 西 醫 雙 主 修 學 系

高長PGY

林長PGY

高長PGY

嘉長PGY









高長放射腫瘤科 R1



























長庚 Webex 視訊系統通知 ^{星期二 下午 04:17}

劉芷廷君您好:

以下為您申請的視訊會議資料:

會議類型:一般會議 會議主題:discussion

會議時間: 2023/05/18 21:30

會議網址: https://cgmh.webex.com/cgmh/j.php? MTID=m936347b181cd84feb94f7facfde2e40d

主持人金鑰: 225902 會議室ID: 25196079728 會議密碼: xP8by775

備註:大型會議廳、簡報室視訊主機可撥號至: 210.4.202.4,並輸入會議室ID後按#以進入會議,

詳細說明請參閱登記網頁文件。

純安

4/25, 26 20:00 下次討論

@葉日中你25可以嗎?

大家分別找出3個PICO跟對應的SR or MA





以上

APR 20, 9:47 PM

- ◆ 日中 replied to 純安
- @葉日中你25可以嗎?



25可以 如果大家方便比較希望 21:30 如果不行就 20:00



瀚陽

先詢問一下大家對於實證的了解程度大概到哪邊?都不懂 沒關係,只是想抓一下要從哪邊開始講起 ं 怕耽誤大家時間



◆ 日中 replied to 瀚陽

先詢問一下大家對於實證的了解程度大概到哪邊?都不懂沒關係, 只是想抓一下要從哪邊開始講起 😂 怕耽誤大家時間



大概就 PICO 金字塔 然後 CASP 十個問題評讀論文 沒了 😂



瀚陽



哈囉各位 想問大家明天討論如果改後天方便嗎

瀚陽

我從昨天半夜開始 大爆咳 低燒



今天先回去篩一下吃個藥,想說明天看看情況,後天再約?

瀚陽



如果跟現在一樣我可能會邊講邊咳🤐



純安

我都可以



我周四才<mark>值班</mark>

APR 24, 6:02 PM

日中



我後天值班 🥯







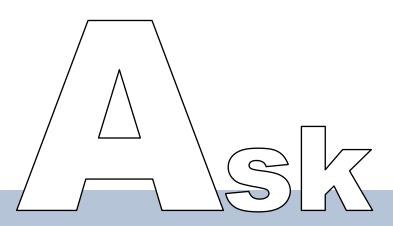


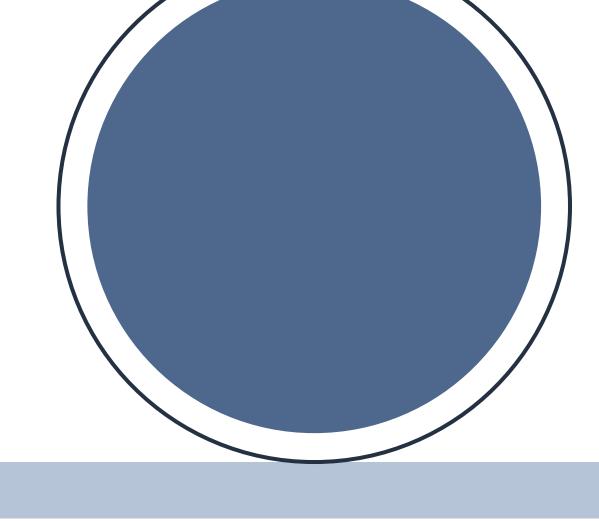


設定PICO 文獻搜尋



評讀證據 效益評估







問題









臨床情境 ▶ 消景資訊 ▶ 提出問題

65歲的江先生曾經中風過,雖然不嚴重,但過去五年都在家休養,最近因為反覆性泌尿道感染,住院接受抗生素治療,才剛出院不久。

前天因為發燒、腹痛、腹瀉到醫院急診,醫師診斷為感染性腹瀉,因為長期使用抗生素,醫師懷疑與困難梭狀桿菌 (Clostridium difficile) 有關。

除了症狀與病徵之外,其他檢驗,包括糞便細菌培養及毒素檢驗都在進行中,他想問根據這些症狀與病徵,可不可以預測這位病人罹患困難梭狀桿菌的機率?有一種叫做**風險評估模式 (risk prediction model)** 的工具,準確嗎?另外,他之前聽到一種新療法,叫做**糞便菌叢移植法 (fecal microbiota transplantation)** 將新鮮糞便純化後的菌叢,用口服或管灌的方式移植到病人身上,對付難治療的困難梭狀桿菌感染。

他想問,這種治療有效嗎?會不會有副作用?做這項治療需要做哪些事?注意什麼? 病人與家屬對於一直用抗生素治療效果不佳感到焦慮,對於新療法也有嘗試的意願。

A問題

臨床情境

▶ 背景資訊 ▶ ▶

提出問題





曾住院接受 抗生素治療

江先生

健康狀況:65/M,曾中風,反覆泌尿道感染

病狀:抗生素治療後不久,因發燒、腹瀉,

診斷為感染性腹瀉,疑似困梭桿菌感染



可以**根據症狀與病徵,預測**罹患困梭 桿菌感染的機率嗎?



糞便菌叢移植法的治療效果如何?

副作用如何?有哪些注意事項呢?





臨床情境



提出問題

根據



資料顯示

診斷為困難梭狀桿菌感染

需要有「症狀」+「檢驗結果positive」



Making the Diagnosis

- diagnosis based on clinical and laboratory findings ^{1,3}
 - symptoms
 - usually diarrhea, defined as ≥ 3 unformed stools in ≤ 24 hours
 - diarrhea may be absent in patients with ileus
- o confirmation by either of
 - stool test positive for Clostridioides (Clostridium) difficile toxins or toxigenic C. difficile
 - pseudomembranous colitis indicated by histopathology or lower gastrointestinal endoscopy (rarely needed)



尚未確診困梭感染



臨床情境



提出問題

根據



資料顯示

A檢索

可以依據「WBC」,「Creatinine」,「臨床症狀」

區分嚴重程度

A評讀 **ppraise**

- Infectious Diseases Society of America and Society for Healthcare Epidemiology of America (IDSA/SHEA) guideline categorizes Clostridioides (Clostridium) difficile disease as nonsevere, severe, or fulminant ¹
- nonsevere disease defined as both
- leukocytosis with white blood cell count ≤ 15,000 cells/mL and
- serum creatinine level < 1.5 mg/dL
- severe disease defined as either
- leukocytosis with white blood cell count ≥ 15,000 cells/mL or
- serum creatinine level > 1.5 mg/dL
- fulminant disease defined as presence of
 - hypotension or shock
- ileus
- megacolon



嚴重度未知





臨床情境



提出問題

根據

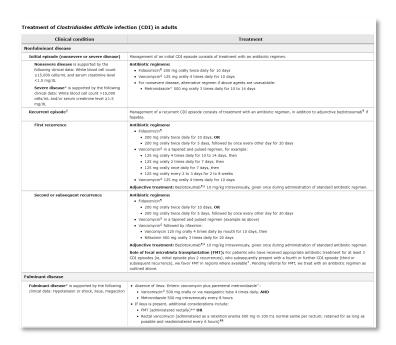
UpToDate®

資料顯示

確診困梭感染後的治療流程







第一步:停用不必要的抗生素

第二步:Supportive care

第三步:一線治療給抗生素 Vancomycin/ Fidaxomicin

第一次復發考慮「Bezlotoxumab」

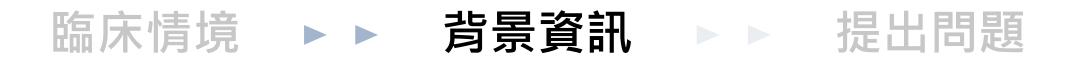
再次復發考慮「糞便移植」

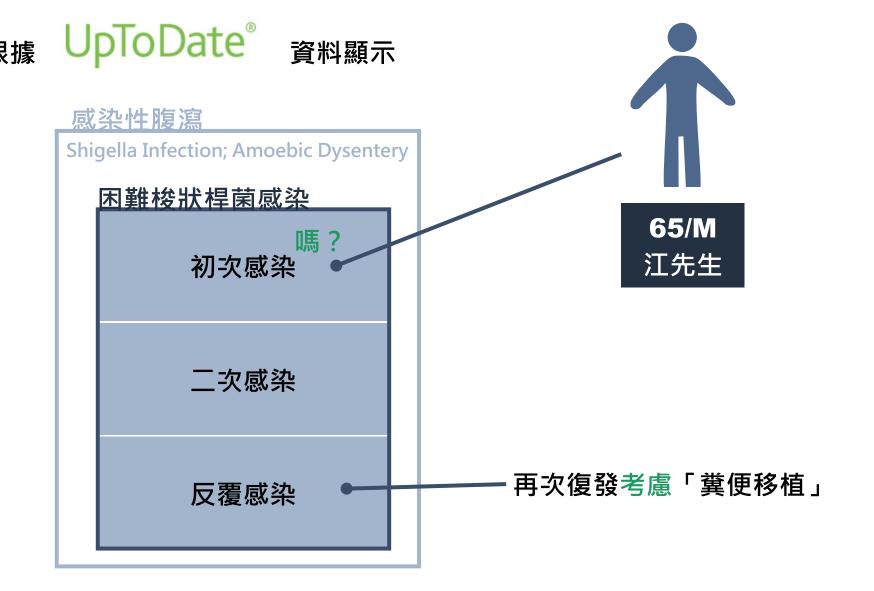


A檢索 Acquire

A評讀 Appraise

> A應用 Apply





A問題 Sk

臨床情境

背景資訊

提出問題



檢索 cguire







疑似困難梭狀桿菌感染 成年男性,中風病史

依據臨床症狀診斷

依據糞便培養結果診斷

診斷困難梭狀桿菌感染 的準確率,likelihood ratio

這是一個 診斷型 的問題

第二個PICO

確診困難梭狀桿菌感染 成年男性・中風病史

使用糞便菌叢移植法 治療的病人

使用抗生素或是安慰劑的病人

有效性(疾病治癒率 NNT)、 安全性(副作用 NNH)

這是一個 治療型 的問題

A問題

臨床情境

背景資訊

▶ 提出問題











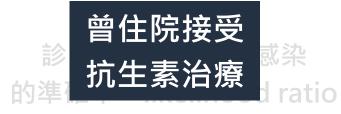




第一個PICO

是似用希望盡快康復 不要再用抗生素





這是一個 診斷型 的問題

第二個PICO

確診困難梭狀桿菌感染 成年男性,中風病史

使用糞便菌叢移植法 治療的病人

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有效性(疾病治癒率 NNT)、 安全性(副作用 NNH)

這是一個 治療型 的問題

A問題

臨床情境 ▶ ▶

背景資訊

▶ 提出問題

A檢索 cquire

A評讀 Appraise

> A應用 Apply



<u> 感染性腹瀉</u>

困難梭狀桿菌感染

初次感染

二次感染

反覆感染

這是一個 診斷型 的問題

第二個PICO

確診困難梭狀桿菌感染 成年男性,中風病史

使用糞便菌叢移植法 治療的病人

使用抗生素或是安慰劑的病人

有效性(疾病治癒率 NNT)、 安全性(副作用 NNH)

這是一個 治療型 的問題





搜尋時的關鍵字設定

中文

安全性(副作用)

A 檢索 Acquire	P	成年男性 困難梭狀桿菌感染	Adults, male, Primary Clostridium difficile infection	First/ Initial/ First episode Clostridium infection	Clostridium Infections
A評讀 ppraise	I	糞便菌叢移植	Fecal microbiota transplantation	Fecal transplant, Donor feces infusion, Intestinal microbiota transplant	Fecal microbiota transplantation
	C	安慰劑, 萬古黴素	Placebo, Vancomycin	Placebo, Vancomycin Hydroc hloride, Vancomycin Sulfate	Placebo, Vancomycin
A應用 pply		有效性(疾病治癒率)、	Effectiveness	Efficacy, Clinical, Effectiveness,	Treatment

英文

Adverse effect

同義字

Treatment

自然語言

Outcome

MeSH term



檢索策略



CDSS

UpToDate, DynaMed, BMJ clinical evidence

EBM, EBN, DARE, EBMH

Cochrane review, PLUS

ACP journal club

Pubmed, EMbase

Systems

Summaries

Synopses of Syntheses

Syntheses

Synopses of studies

Studies

從次級資料庫 查找背景知識







從初級資料庫

選擇最佳文獻評讀

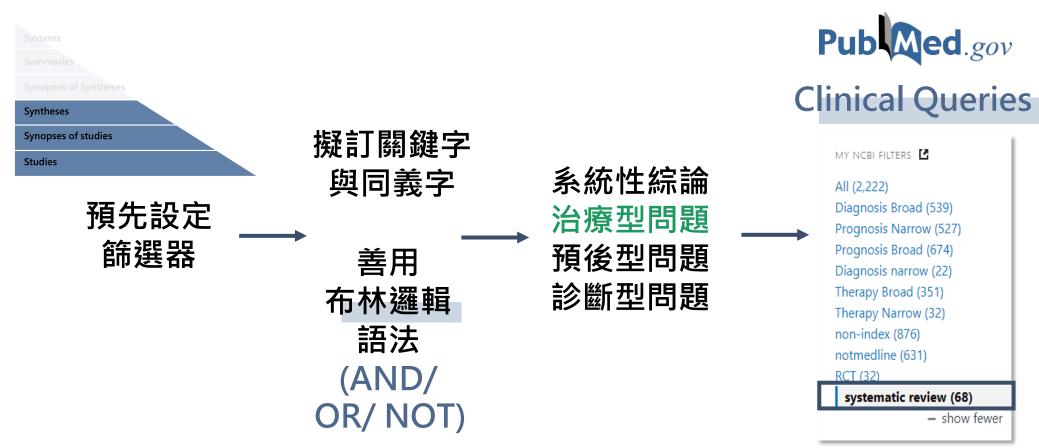


使用檢索技巧提升搜索效率









各資料庫搜尋結果交叉比對

語法引用自





搜尋初次感染的meta analysis and SR





Meta-Analysis > J Clin Gastroenterol. 2022 Nov-Dec;56(10):881-888 doi: 10.1097/MCG.000000000001610. Epub 2021 Sep 9.

Fecal Microbiota Transplantation and Medical Therapy for Clostridium difficile Infection: Meta-

Tanveer Singh ¹, Prabhjot Bedi ², Karandeep Bumrah ², Darshan Gandhi ³, Tanureet Arora ⁴, Nikita Verma ⁵, Mary Schleicher ⁶, Manoi P Rai ⁷, Raiat Garg ¹, Beni Verma ¹,

PMID: 34516460 DOI: 10.1097/MCG.000000000001610

analysis of Randomized Controlled Trials



bias 過高 且異質性高(I2=78% & 82%)









Letters in Applied Microbiology ISSN 0266-8254

REVIEW ARTICLE

Effectiveness of fecal microbiota transplant for the treatment of Clostridioides difficile diarrhea: a systematic review and meta-analysis

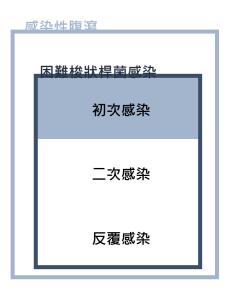
R.Á. Pomares Bascuñana¹, V. Veses² (D) and C.C. Sheth¹ (D)

- 1 Department of Medicine, Faculty of Health Sciences, Universidad Cardenal Herrera, CEU Universities, Valencia, Spain
- 2 Department of Biomedical Sciences, Faculty of Health Sciences, Universidad Cardenal Herrera, CEU Universities, Valencia, Spain



並沒有把primary 以及 recurrence 分開討論





搜尋初次感染的RCT

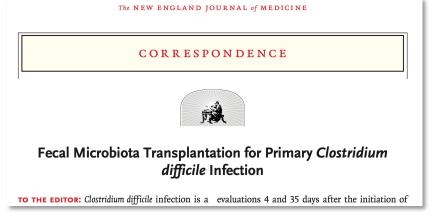












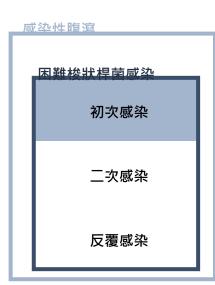
letter to the editor 總收案數僅20人 有待未來trial

Faecal microbiota transplantation for first or second Clostridioides difficile infection (EarlyFMT): a randomised, double-blind, placebo-controlled trial

Simon Mark Dahl Baunwall, Sara Ellegaard Andreasen, Mette Mejlby Hansen, Jens Kelsen, Katrine Lundby Høyer, Nina Rågård,
Lotte Lindgreen Eriksen, Sidsel Støy, Tone Rubak, Else Marie Skjøde Damsgaard, Susan Mikkelsen, Christian Erikstrup, Jens Frederik Dahlerup,
Christian Lodberg Hvas

lost f/u rate 38% 控制組failed, interim analysis



















Search	Actions	Details	Query	Results	Time
#27	•••	>	Search: (#18) NOT (#19 OR #20 OR #21) Filters: Randomized Controlled Trial, in the last 5 years	11	20:46:58

Search	Actions	Details	Query	Results	Time
#26	•••	>	Search: (#18) NOT (#19 OR #20 OR #21) Filters: Meta-Analysis, Systematic Review, in the last 5 years	13	20:26:07
#25	•••	>	Search: (#18) NOT (#19 OR #20 OR #21) Filters: Meta-Analysis, in the last 5 years	6	20:26:03
#24	•••	>	Search: (#18) NOT (#19 OR #20 OR #21) Filters: in the last 5 years	154	20:25:38
#23	•••	>	Search: (#18) NOT (#19 OR #20 OR #21)	285	20:25:33
#22	•••	>	Search: #19 OR #20 OR #21	158,887	20:24:56
#21	•••	>	Search: immunocompromised[Title/Abstract]	41,717	20:24:39
#20	•••	>	Search: Inflammatory Bowel Diseases[MeSH Terms]	96,175	20:23:53
#19	•••	>	Search: inflammatory bowel disease[Title/Abstract]	56,643	20:23:42

Search	Actions	Details	Query	Results	Time
#18	•••	>	Search: #12 AND #17	374	20:15:52
#17	•••	>	Search: #13 OR #14 OR #15 OR #16	4,918	20:15:35
#16	•••	>	Search: Infusion Donor Feces	4,918	20:14:47
#15	•••	>	Search: fecal microbiota transplantation[MeSH Terms]	2,717	20:13:50
#14	•••	>	Search: "fecal microbiota transplantation"	4,331	20:13:29
#13	•••	>	Search: fecal microbiota transplantation	4,902	20:13:16
#12	•••	>	Search: #6 AND #11	6,460	20:12:53
#11	•••	>	Search: #7 OR #8 OR #9 OR #10	6,403,219	20:12:29
#10	•••	>	Search: first episode	63,280	20:11:50
#9	•••	>	Search: initial	1,744,046	20:11:38
#8	•••	>	Search: primary	2,031,561	20:11:26
#7	•••	>	Search: first	3,386,986	20:11:18
#6	•••	>	Search: #1 OR #3 OR #4 OR #5	39,466	20:10:59
#5	•••	>	Search: clostridium infections[MeSH Terms]	32,582	20:10:27
#4	•••	>	Search: clostridium infection*	20,396	20:09:4
#3	•••	>	Search: "clostridium infections"	10,622	20:09:20
#1	•••	>	Search: clostridium infection	39,057	20:08:37



Cochrane















和Pubmed相同的4篇

#17	#3 AND #7 AND #14 AND [randomized controlled trial]/lim AND ([adolescent]/lim OR [adult]/lim OR [young adult]/lim OR [middle aged]/lim OR [aged]/lim OR [very elderly]/lim) AND [humans]/lim AND [2018-2023]/py	38
#16	#3 AND #7 AND #14 AND ([cochrane review]/lim OR [systematic review]/lim OR [meta analysis]/lim) AND ([adolescent]/lim OR [adult]/lim OR [young adult]/lim OR [middle aged]/lim OR [aged]/lim OR [very elderly]/lim) AND [humans]/lim AND [2018-2023]/py	20
#15	#3 AND #7 AND #14	910
#14	#10 OR #11 OR #12 OR #13	7,885,445
#13	first AND episode	58,413
#12	initial	1,276,531
#11	primary	2,883,667
#10	first	4,609,260
#9	#3 AND #7 AND ([systematic review]/lim OR [meta analysis]/lim) AND [humans]/lim AND [2018-2023]/py AND ([adult]/lim OR [young adult]/lim OR [middle aged]/lim OR [aged]/lim OR [very elderly]/lim)	44
#8	#3 AND #7	2,851
#7	#4 OR #5 OR #6	60,384
#6	clostridium AND infection	35,355
#5	'clostridium infection'	2,186
#4	'clostridium infection'/exp	48,111
#3	#1 OR #2	10,119
#2	fecal AND microbiota AND transplantation	10,119
#1	'fecal microbiota transplantation'/exp OR 'fecal microbiota transplantation'	9,447



へ 檢索

A評讀



搜尋時的關鍵字設定

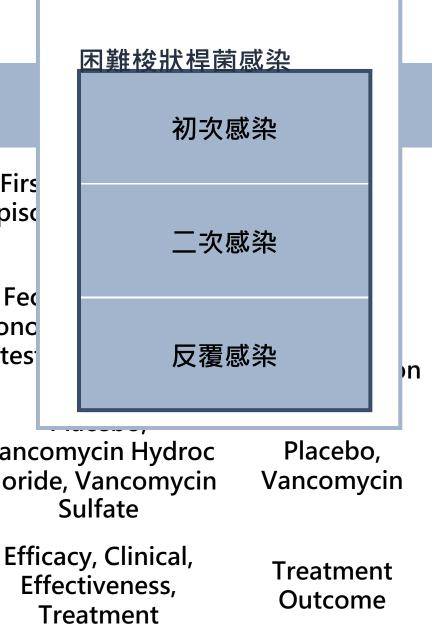
有效性(疾病治癒率)、

安全性(副作用)

	自然語	語言	
	中文	英文	
P	成年男性 困難梭狀桿菌感染	Adults, male, Primary Clostridium difficile infection	Firs episc
I	糞便菌叢移植	Fecal microbiota transplantation	Fed Donc Intes
C	安慰劑, 萬古黴素	Placebo, Vancomycin	Vanc hloric

Effectiveness

Adverse effect



感染性腹瀉



MeSH descriptor 聯集原單字



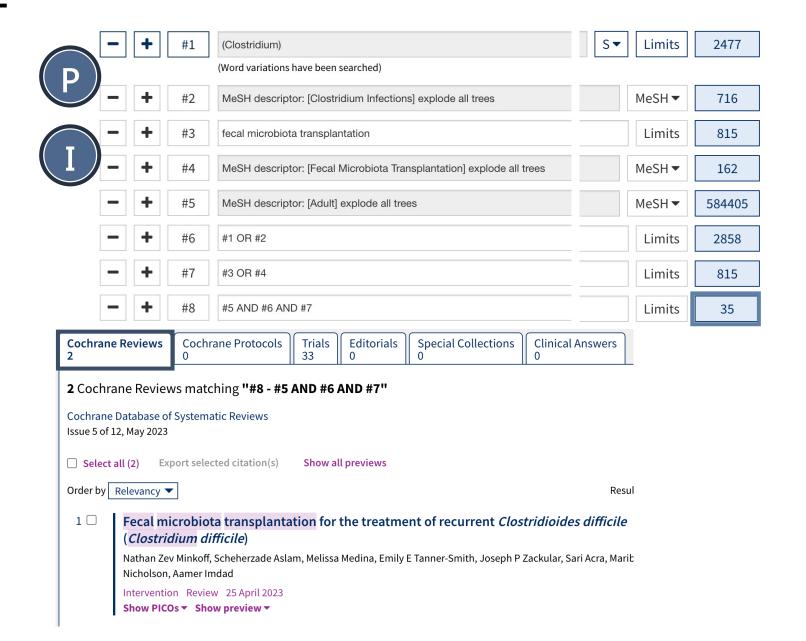














A 檢索 Cquire









Embase





MeSH terms 聯集原單字

Search	Actions	Details	Query	Results	Time
#13	•••	>	Search: #5 AND #10 Filters: Systematic Review, in the last 5 years	43	11:07:26
#12	•••	>	Search: #5 AND #10 Filters: in the last 5 years	720	11:07:22
#11	•••	>	Search: #5 AND #10	1,531	07:26:18
#10	•••	>	Search: #6 OR #7 OR #8 OR #9	6,522	07:22:13
#9	•••	>	Search: fecal microbio* transplantation	6,522	07:13:56
#8	•••	>	Search: "fecal microbiota transplantation"	4,313	07:13:40
#7	•••	>	Search: fecal microbiota transplantation	4,882	07:13:26
#6	•••	>	Search: fecal microbiota transplantation[MeSH Terms]	2,713	07:12:46
#5	•••	>	Search: #1 OR #2 or #3 OR #4	39,452	06:59:24
#4	•••	>	Search: clostridium infection*	20,387	06:58:14
#3	•••	>	Search: "clostridium infections"	10,617	06:58:02
#2	•••	>	Search: clostridium infections	36,142	06:57:30
#1	•••	>	Search: clostridium infections[MeSH Terms]	32,572	06:57:02



Emtree/exploded聯集原單字





#3 AND #7 AND ([systematic review]/lim OR [meta analysis]/lim) AND [humans]/lim AND [2018-2023]/py AND ([adult]/lim OR [young adult]/lim OR [middle aged]/lim OR [aged]/lim OR [very elderly]/lim)

2,851

2,186





#9

#7

#4

60,384





#4 OR #5 OR #6











#3 #1 OR #2





#2 fecal AND microbiota AND transplantation

'clostridium infection'/exp

I	10,11
---	-------



#1 'fecal microbiota transplantation'/exp OR 'fecal microbiota transplantation'

9,447













Pub Med.gov









Systematic Review 符合 臨床問題



A 檢索 Cquire





搜尋結果









Pub Med.gov









交叉比對後



Embase



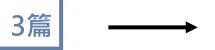




...



















不選擇其他篇的理由

Journal	Title	Year	IF	解釋
Cochrane Database Syst Rev	Fecal microbiota transplantation for the treatment of recurrent Clostridioides difficile (Clostridium difficile)	2023	9.27 Q1	納入文獻全收錄RCT 年份新 Q1
Dig Dis Sci	Systematic Review with Meta-Analysis: Fecal Microbiota Transplantation for Severe or Fulminant Clostridioides difficile.	2022	3.2 Q3	侷限討論 fulminant and severe CDI 與case情形較不符
J Clin Gastroent erol	Oral Fecal Microbiota Transplant Capsules Are Safe and Effective for Recurrent Clostridioides difficile Infection: A Systematic Review and Meta- Analysis.	2021	3.06 Q3	侷限討論 oral FMT 納入非RCT研究
PLoS One	Fecal microbiota transplantation for treatment of recurrent C. difficile infection: An updated randomized controlled trial meta-analysis.	2019	3.24 Q2	侷限於 fresh FMT 年代相對較舊
J Clin Gastroent erol	Fecal Microbiota Transplantation and Medical Therapy for Clostridium difficile Infection : Meta- analysis of Randomized Controlled Trials	2022	3.06 Q3	有收初次以及反覆感染 收錄RCT之ROB較高









不選擇其他篇的理由

Journal	Title	Year	IF	解釋
Cureus	Role of Fecal Microbiota Transplantation in Reducing Clostridioides difficile Infection- Associated Morbidity and Mortality: A Systematic Review	2022	-	Without IF 納入非RCT研究
Cureus	Fecal Microbiota Transplant in Recurrent Clostridium Difficile Infections: A Systematic Review.	2022	-	Without IF 無收錄RCT
Lett Appl Microbiol	Effectiveness of fecal microbiota transplant for the treatment of Clostridioides difficile diarrhea: a systematic review and meta-analysis.	2021	2.86 Q3	納入非RCT研究
Clin Infect Dis	Low Cure Rates in Controlled Trials of Fecal Microbiota Transplantation for Recurrent Clostridium difficile Infection: A Systematic Review and Meta-analysis.	2019	9.08 Q1	主要納入非RCT研究 年代相對較舊
E Clinical Medicine	Faecal microbiota transplantation for recurrent Clostridioides difficile infection: An updated systematic review and meta-analysis	2020	3.59 Q1	納入非RCT研究









不選擇其他篇的理由

Journal	Title	Year	IF	解釋
United European Gastroent erol J	A network meta-analysis of randomized controlled trials exploring the role of fecal microbiota transplantation in recurrent Clostridium difficile infection.	2019	5.09 Q2	NMA 年代相對較舊
Eur J Gastroent erol Hepatol	Comparing fecal microbiota transplantation to standard-of-care treatment for recurrent Clostridium difficile infection: a systematic review and meta-analysis.	2018	2.54 Q4	年代相對較舊 Q4
Eur J Gastroent erol Hepatol	Safety and efficacy of encapsulated fecal microbiota transplantation for recurrent Clostridium difficile infection: a systematic review	2018	2.57 Q4	年代相對較舊 Q4
Expert Rev Anti Infect Ther	Fecal microbiota transplantation for treatment of patients with recurrent Clostridioides difficile infection.	2020	5.09 Q2	僅為專家建議









最佳文獻

Cochrane Database of Systematic Reviews | Review - Intervention

Fecal microbiota transplantation for the treatment of recurrent Clostridioides difficile (Clostridium difficile)

Nathan Zev Minkoff, Scheherzade Aslam, Melissa Medina, Emily E Tanner-Smith, Joseph P Zackular, Sari Acra, Maribeth R Nicholson, Aamer Imdad Authors' declarations of interest

Version published: 25 April 2023 Version history

https://doi-org.lib3.cgmh.org.tw:30443/10.1002/14651858.CD013871.pub2

理由: ☑最符合臨床問題

☑最佳研究設計: Systematic Review

☑發表年份較新:2023.04.25

☑有全文可供評讀

☑發表在較佳之期刊: Cochrane Database of

Systematic Reviews, IF: 9.27, Q1





評讀









我們的評讀流程



Fecal microbiota transplantation for the treatment of recurrent Clostridioides difficile (Clostridium difficile) (Review)

Systematic

review

Minkoff NZ, Aslam S, Medina M, Tanner-Smith EE, Zackular JP, Acra S, Nicholson MR, Imdad A









「結果 重要性」



評估證據等級



Version: 3.2.2

評估證據品質













反覆的困梭桿菌感染



Objectives

To evaluate the benefits and harms of donor-based fecal microbiota transplantation for the treatment of recurrent *Clostridioides difficile* infection in immunocompetent people.



有效性及安全性

我們的個案是初次感染?

針對初次感染尚無證據力足夠之文獻

A 評讀 ppraise

Selection criteria

We considered randomized trials of adults or children with rCDI for inclusion. Eligible interventions must have met the definition of FMT, which is the administration of fecal material containing distal gut microbiota from a healthy donor to the gastrointestinal tract of a person with rCDI. The comparison group included participants who did not receive FMT and were given placebo, autologous FMT, no intervention,

or antibiotics with activity against *C difficile*.



「證據 可信度」 對照組:安慰劑、自體糞便菌叢移植、

不做介入、給抗生素









2.是否尋找適當研究型態的文獻?

Criteria for considering studies for this review

Types of studies

We included RCTs assessing FMT for the treatment of rCDI. We included trials with multiple arms, as long as these included an intervention and comparison group that addressed the primary question for this review. We planned to include both cross-over and cluster-randomized trials; however, there were none that met criteria for inclusion. We reports, and case series.

共收納六篇,皆為RCT, 排除觀察性研究、病例報告等類型的文獻

Included studies

Six RCTs assessed FMT for the treatment of rCDI (Cammarota 2015; Hota 2017; Hvas 2019; Kelly 2016; Rode 2021; van Nood 2013). See Characteristics of included studies table for full details.





Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

Question	Step 1 (Level 1*)	Step 2 (Level 2*)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic reviet that allow match circumstances*
Is this diagnostic or monitoring test accurate? (Diagnosis)	Systematic review of cross sectional studies with consistently applied reference standard and blinding	Individual cross studies with con applied reference blinding
What will happen if we do not add a therapy? (Prognosis)	Systematic review of inception cohort studies	Inception cohor
Does this intervention help? (Treatment Benefits)	Systematic review of randomized trials or <i>n</i> -of-1 trials	Randomized tria or observational dramatic effect
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, <i>n</i> -of-1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual rando or (exceptionall study with dram
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or <i>n</i> -of-1 trial	Randomized tria or (exceptionall study with dram
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials	Randomized tria



3.所有重要且相關的研究都被納入?



足夠的資料庫

Electronic searches

We searched the following databases from their inception using the methods in the Cochrane Handbook for Systematic Reviews of Interventions (Lefebvre 2022):

- Cochrane Central Register of Controlled Trials (CENTRAL, via Ovid; Issue 3, 2022) (Appendix 2);
- 2. MEDLINE (1946 via Ovid) (Appendix 3);
- 3. Embase (1974 via Ovid) (Appendix 4);
- Conference Proceedings Citation Index (Appendix 5);
- ISRTN Registry (www.isrctn.com/; Appendix 5).

The literature was conducted on 16 February 2021, and updated on 31 March 2022. We searched the Cochrane Gut Group Specialized Register in February 2021 only and not in March 2022.

Searching other resources

We searched ClinicalTrials.gov (www.clinicaltrials.gov/) for ongoing trials. We also searched the reference sections of previously published randomized trials and meta-analyses on this topic. We contacted authors of published and ongoing studies to seek new or additional data when needed. Of note, ICTRP and ClinicalTrials.gov are both indexed in CENTRAL.

有和各作者聯繫,也有搜尋未發表的文獻 未收錄非英文文獻













At least two review authors (SHA and MM) answered the signaling questions in the RoB 2 tool for each domain to assess the risk of bias separately for all included studies, for all outcomes reported in the summary of findings table, and the authors compared their assessments. The overall risk of bias was determined based on

使用ROB 2.0評估,收錄六篇文獻皆為中上品質 且有兩位以上作者參與評估

			Bias			
Study	Randomisation process	Deviations from intended interventions	Missing outcome data	Measurement of the outcome	Selection of the reported results	Overall
Cammarota 2015	Ø	Ø	Ø	©	②	Ø
Hota 2017	0	Ø	Ø	Ø	Ø	Ø
Hvas 2019	0	Ø	②	Ø	②	Ø
Kelly 2016	Ø	②	②	②	Ø	Ø
Rode 2021	Ø	②	②	②	Ø	Ø
van Nood 2013	Ø	②	Ø	Ø	②	Ø













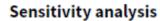
有評估異質性

也有針對I² > 60%的部分進行次族群分析



Assessment of heterogeneity

We assessed the clinical, methodologic, and statistical heterogeneity amongst studies. We assessed methodologic heterogeneity by comparing components of the risk of bias assessment. We assessed statistical heterogeneity based on forest plots, the I² statistic, and the P value for the Chi² test. We considered heterogeneity to be significant if the P value for Chi² was less than 0.10 or the I² statistic was greater than 60%. We planned to explore potential explanations for heterogeneity using subgroup analyses to explore the distribution of important factors such as maximum number of doses of FMT, route of administration, and the source of FMT, but the number of studies was too small to complete the planned subgroup analyses.



We planned the following a priori sensitivity analyses.

- Fixed-effect model versus random-effects model.
- Studies with high risk of bias versus those with low risk of bias/ some concerns.

None of the included studies were at high risk of bias so the second of these planned sensitivity analyses was not conducted.

A 評讀 ppraise

作者有設計敏感性分析,

但收錄的文獻並沒有需要進行分析的

high risk of bias文章·故沒有進行敏感性分析















Figure 2. Forest plot of comparison: 1 Fecal microbiota transplantation (FMT) vs control for the treatment of recurrent *Clostridioides difficile* infections (rCDI), outcome: 1.1 Resolution of rCDI.

	FM	Т	Cont	rol		Risk Ratio	Risk Ratio	Risk of Bias
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI	ABCDEF
Cammarota 2015	18	20	5	19	11.9%	3.42 [1.59 , 7.36]		
Hota 2017	7	16	7	14	12.0%	0.88 [0.41, 1.88]		2
Hvas 2019	17	24	11	40	16.3%	2.58 [1.46, 4.53]	-	2
Kelly 2016	20	22	15	24	22.6%	1.45 [1.04, 2.04]	-	
Rode 2021	26	34	30	64	23.1%	1.63 [1.18, 2.25]	-	
van Nood 2013	15	17	7	26	14.1%	3.28 [1.70, 6.32]		
Total (95% CI)		133		187	100.0%	1.92 [1.36, 2.71]	•	
Total events:	103		75				. •	
Heterogeneity: Tau ² = 0	0.11; Chi ² = 1	3.45, df =	5 (P = 0.02); I ² = 63%	ó	0.	01 0.1 1 10 1	100
Test for overall effect:	Z = 3.68 (P =	0.0002)				0.	Favors control Favors FMT	
Test for subgroup differ	rences: Not a	pplicable						

有效性outcome: $I^2 = 63\%$,異質性較高 ->進行次組群分析













Analysis 1.2. Comparison 1: Fecal microbiota transplantation (FMT) versus control for the treatment of recurrent Clostridioides difficile infections (rCDI), Outcome 2: Resolution of rCDI: sensitivity analysis: fixed-effect model

	FM	T	Cont	trol		Risk Ratio	Risk Ratio	Risk of Bias
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI	ABCDEF
Cammarota 2015	18	20	5	19	8.3%	3.42 [1.59 , 7.36]		
Hota 2017	7	16	7	14	12.1%	0.88 [0.41, 1.88]		2 0 0 0 0 0
Hvas 2019	17	24	11	40	13.4%	2.58 [1.46, 4.53]		2
Kelly 2016	20	22	15	24	23.3%	1.45 [1.04, 2.04]	•	
Rode 2021	26	34	30	64	33.8%	1.63 [1.18, 2.25]	-	
van Nood 2013	15	17	7	26	9.0%	3.28 [1.70, 6.32]	-	
Total (95% CI)		133		187	100.0%	1.92 [1.58 , 2.34]		
Total events:	103		75					
Heterogeneity: Chi ² = 1	13.45, df = 5 ((P = 0.02);	$I^2 = 63\%$			0.0	1 0.1 1 10 10	00
Test for overall effect:	Z = 6.45 (P <	0.00001)					Favors control Favors FMT	
Test for subgroup differ	rences: Not a	pplicable						

$$I^2 = 63\%$$

Analysis 1.4. Comparison 1: Fecal microbiota transplantation (FMT) versus control for the treatment of recurrent *Clostridioides difficile* infections (rCDI), Outcome 4: Resolution of rCDI: sensitivity analysis: excluding immunocompromised participants

	FM	T	Cont	trol		Risk Ratio	Risk Ratio	Risk of Bias
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI	A B C D E F
Cammarota 2015	18	20	5	19	14.4%	3.42 [1.59 , 7.36]		•••••
Hota 2017	7	16	7	14	14.5%	0.88 [0.41, 1.88]		2
Kelly 2016	20	22	15	24	26.8%	1.45 [1.04, 2.04]	_	
Rode 2021	26	34	30	64	27.3%	1.63 [1.18, 2.25]	_	
van Nood 2013	15	17	7	26	17.0%	3.28 [1.70 , 6.32]	-	• • • • •
Total (95% CI)		109		147	100.0%	1.81 [1.23 , 2.66]	•	
Total events:	86		64				•	
Heterogeneity: Tau ² = 0	0.11; Chi ² = 1	1.37, df =	4 (P = 0.02); I ² = 65%	6	0.	01 0.1 1 10 1	00
Test for overall effect:	Z = 3.02 (P =	0.003)					Favors control Favors FMT	••
Test for subgroup diffe	rences: Not a	pplicable						

$$I^2 = 65\%$$



	FM	T	Cont	rol		Risk Ratio	Risk R	atio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Randor	n, 95% CI
Cammarota 2015	18	20	5	19	12.2%	3.42 [1.59 , 7.36]		-
Hota 2017	7	16	7	12	12.8%	0.75 [0.36 , 1.56]	_	
Hvas 2019	17	24	11	40	16.2%	2.58 [1.46, 4.53]		-
Kelly 2016	20	21	15	24	22.0%	1.52 [1.10, 2.11]	4	-
Rode 2021	26	34	30	62	22.1%	1.58 [1.15 , 2.17]	-	-
van Nood 2013	15	16	7	25	14.6%	3.35 [1.76 , 6.36]		-
Total (95% CI)		131		182	100.0%	1.89 [1.31 , 2.73]	,	•
Total events:	103		75					•
Heterogeneity: Tau ² = 0	0.13; Chi ² = 1	5.62, df =	5 (P = 0.00	8); I ² = 68	1%		0.01 0.1 1	10 100
Test for overall effect:	Z = 3.42 (P =	0.0006)					Favors control	Favors FMT
Test for subgroup diffe	rences: Not a	pplicable						

 $I^2 = 68\%$

進行次組群分析,I²仍高













Figure 3. Forest plot of comparison: 1 Fecal microbiota transplantation (FMT) vs control for the treatment of recurrent *Clostridioides difficile* infections (rCDI), outcome: 1.2 Serious adverse events.

	FM	T	Cont	trol		Risk Ratio	Risk Ratio	Risk of Bias
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI	ABCDEF
Cammarota 2015	2	20	2	19	10.6%	0.95 [0.15, 6.08]	-	
Hota 2017	2	16	3	14	13.0%	0.58 [0.11, 3.00]		2
Hvas 2019	5	24	10	40	27.9%	0.83 [0.32, 2.15]	10 <u>-11</u>	2
Kelly 2016	2	22	3	24	12.4%	0.73 [0.13, 3.95]		
Rode 2021	3	34	22	64	22.4%	0.26 [0.08, 0.80]		
van Nood 2013	4	17	2	26	13.8%	3.06 [0.63, 14.90]	+•	•••••
Total (95% CI)		133		187	100.0%	0.73 [0.38, 1.41]	•	
Total events:	18		42				T	
Heterogeneity: Tau ² = (0.17; Chi ² = 6	5.74, df = 5	(P = 0.24)	; I ² = 26%		0	.01 0.1 1 10	100
Test for overall effect:	Z = 0.94 (P =	0.35)					Favors FMT Favors contro	
Test for subgroup differ	rences: Not a	pplicable						

不良事件outcome: $I^2 = 26\%$

但有效性outcome進行次組群 分析後I²仍高,故無法評斷研究 結果若進行合併是否合理











評讀統整



「證據 可信度」 是否問了一個清楚、明確的問題?

是否尋找適當研究型態的文獻?

所有重要且相關的研究都被納入?

是否評估所納入研究文獻的品質?

作者將研究結果進行合併是否合理?



-> 值得評讀



「結果 重要性」







使用FMT比起對照組,有較佳的有效性及較高的安全性 且證據品質中等以上

Key results

Stool transplantation probably leads to a larger increase in resolution of repeated infections of *C difficile* than the other treatments studied. Other treatments included antibiotics such as vancomycin, which are commonly prescribed for this infection. These same studies looked at the rate of serious side effects and risk of death from FMT. Fecal microbiota transplantation likely leads to a small decrease in serious side effects; however, these effects were few. Fecal microbiota transplantation may decrease the risk of death in people with rCDI; however, there were few deaths in either group. Elimination of one study that included some immunocompromised people did not alter these conclusions, but, based on the low number of immunocompromised people enrolled in the included studies, conclusions could not be drawn about the benefits or harms of FMT for rCDI in the immunocompromised population at this time.







Outcomes	Anticipated abso	olute effects* (95%	Relative effect (95% CI)	№ of partici- pants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with con- trol	Risk with fe- cal microbiota transplantation (FMT)		,	, , , , , , , , , , , , , , , , , , , ,	
Resolution of rCDI follow-up: range 8 weeks to 17 weeks	401 per 1000	770 per 1000 (545 to 1000)	RR 1.92 (1.36 to 2.71)	320 (6 RCTs)	⊕⊕⊕⊙ Moderate ^{a,b,c}	FMT likely results in a large increase in resolution of rCDI.
Serious adverse events follow-up: range 8 weeks to 17 weeks	225 per 1000	164 per 1000 (85 to 317)	RR 0.73 (0.38 to 1.41)	320 (6 RCTs)	⊕⊕⊕⊝ Moderate ^d	FMT probably results in a slight reduction in serious adverse events; however, the CIs around the summary estimate were wide and included a possibility of increased risk of serious adverse events.
All-cause mortality follow-up: range 8 weeks to 17 weeks	96 per 1000	55 per 1000 (21 to 140)	RR 0.57 (0.22 to 1.45)	320 (6 RCTs)	⊕⊕⊝⊝ Low ^e	FMT may result in a reduction in all-cause mortality; however, the CIs around the summary estimate were wide and possible risk of increased mortality could not be ruled out.
Colectomy	0 per 1000	0 per 1000 (0 to 0)	Not estimable	(0 studies)	-	None of the included studies reported this outcome.









Cammarota 2015

Primary outcome

Resolution of diarrhea associated with C difficile infection (disappearance of diarrhea, or persistent diarrhea explicable by other causes, with 2 negative stool tests for C difficile toxin) 10 weeks after end of treatments. For participants in FMT group who required > 1 infusion of feces, follow-up was extended to 10 weeks after the last infusion.

Secondary outcome

 Toxin negative without recurrent C difficile infection (diarrhea unexplainable by other causes, with or without positive stool toxin) 5 weeks and 10 weeks after end of treatments.

Hota 2017

Primary outcome

1. Recurrence of symptomatic, laboratory-confirmed CDI within 120 days of the intervention

Secondary outcomes

- 1. Recurrence of CDI symptoms within 14 and 120 days (not laboratory-confirmed)
- 2. Recurrence of CDI within 120 days of crossover
- 3. Days of diarrhea in the 120 days of follow-up
- 4. CDI requiring hospital admission

Hvas 2019

Primary outcome

 Combined clinical resolution and a negative C difficile test result without the need for rescue FMT or colectomy 8 weeks after the initial treatment.

Secondary outcome

 Clinical resolution at week 8, a negative CD test result at week 8, combined clinical resolution and negative CD test result at week 1, clinical resolution at week 1, and a negative CD test result at week 1

Safety outcomes

- 1. AEs
- SAEs
- 3. Immediate complications in 24 hours



Kelly 2016

Primary outcome

Clinical cure 8 weeks after FMT or at the time of early withdrawal. Clinical cure defined as resolution of diarrhea (i.e. < 3 unformed stools for 2 consecutive days), with maintenance of resolution for 8-week follow-up period and no further requirements for anti-infective therapy for C difficile infection regardless of results of follow-up stool testing for C difficile

Secondary outcome

 Clinical failure during the 8-week period after FMT. Clinical failure defined as the persistence or development of diarrhea and the need for additional anti-infective therapy for CDI with or without positive stool testing (PCR) for C difficile

Safety endpoints

- SAEs
- AEs
- Death
- 4. New medical conditions or diagnoses, or changes in medical conditions at 6-month follow-up

Rode 2021

Primary outcome

1. Clinical cure within 90 days after ended treatment. Clinical cure defined as absence of *C difficile* infection (i.e. absence of diarrhea or diarrhea with a negative *C difficile* test)

Secondary outcome

1. Clinical cure within 180 days after ended treatment

Safety outcomes

- 1. AEs
- SAEs
- 3. 180-day mortality (all-cause and possibly C difficile-related mortality)

van Nood 2013

Primary outcome

 Cure without relapse within 10 weeks after initiation of therapy. If a patient required a second infusion of donor feces, follow-up was extended to 10 weeks after the second infusion for primary outcome assessment. Cure defined as absence of diarrhea or persistent diarrhea that could be explained by other causes with 3 consecutive negative stool tests for C difficile toxin

Secondary outcome

 Cure without relapse after 5 weeks. Relapse defined as diarrhea with a positive stool test for C difficile toxin









<u>有效性</u>

- 1. 治療後1、2、5、8、10週、90天、120天等等時間點是否有復發情形,評估項目包含不再有腹瀉症狀、C difficile toxin test 陰性等等
- 2. 部分研究C difficile toxin test需連續三次陰性才可認定為cure或有效

安全性

- 治療後各時間點內若有復發,腹瀉 復發天數、是否需住院治療等等
- 2. 治療過程中不良事件
- 3. 治療過程中嚴重不良事件
- 4. 治療後24小時內立即產生之併發症
- 5.180天內死亡事件











Figure 2. Forest plot of comparison: 1 Fecal microbiota transplantation (FMT) vs control for the treatment of recurrent *Clostridioides difficile* infections (rCDI), outcome: 1.1 Resolution of rCDI.

	FM	т	Cont	trol		Risk Ratio	Risk Ratio		R	sk of	Bias	3
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI	A	В	С	D I	F
Cammarota 2015	18	20	5	19	11.9%	3.42 [1.59 , 7.36]		•	•		9 6	
Hota 2017	7	16	7	14	12.0%	0.88 [0.41, 1.88]		?			9 (
Hvas 2019	17	24	11	40	16.3%	2.58 [1.46, 4.53]	-	?			9 (
Kelly 2016	20	22	15	24	22.6%	1.45 [1.04, 2.04]		•			9 (
Rode 2021	26	34	30	64	23.1%	1.63 [1.18, 2.25]	-	•	•		9 (
van Nood 2013	15	17	7	26	14.1%	3.28 [1.70, 6.32]		•	•	•	9 (•
Total (95% CI)		133		4.0	1 00	1 26 2 71	1					
Total events:	103		1	1.3	94	1.36, 2.71						
Heterogeneity: Tau ² = 0	0.11; Chi ² = 1	3.45, df =	5(P=0)				1 10	100				
Test for overall effect:	Z = 3.68 (P =	0.0002)				F	Favors control Favors FMT					
Test for sub-moun diffe	noncon Moto	naliashla										

有效性:FMT優於對照組 RR 1.92,經計算後NNT=3 且95%信賴區間不包含1

Figure 3. Forest plot of comparison: 1 Fecal microbiota transplantation (FMT) vs control for the treatment of recurrent *Clostridioides difficile* infections (rCDI), outcome: 1.2 Serious adverse events.

	FM	Т	Cont	rol		Risk Ratio	Risk Ratio	Risk of Bias
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI	ABCDEF
Cammarota 2015	2	20	2	19	10.6%	0.95 [0.15, 6.08]	·	
Hota 2017	2	16	3	14	13.0%	0.58 [0.11, 3.00]		2
Hvas 2019	5	24	10	40	27.9%	0.83 [0.32, 2.15]		2
Kelly 2016	2	22	3	24	12.4%	0.73 [0.13, 3.95]		
Rode 2021	3	34	22	64	22.4%	0.26 [0.08, 0.80]		
van Nood 2013	4	17	2	26	13.8%	3.06 [0.63, 14.90]	-	•••••
Total (95% CI)		133		187	100.0%	0.73 [0.38, 1.41]		
Total events:	18		42					
Heterogeneity: Tau ² = 0	0.17; Chi ² = 6	5.74, df = 5	(P = 0.24)	I ² = 26%		0.0	01 0.1 1 10	100
Test for overall effect:	Z = 0.94 (P =	0.35)					Favors FMT Favors contro	
Test for subgroup diffe	rences: Not a	pplicable						

安全性:FMT在各項嚴重副 作用並沒有多於對照組











Figure 2. Forest plot of comparison: 1 Fecal microbiota transplantation (FMT) vs control for the treatment of recurrent *Clostridioides difficile* infections (rCDI), outcome: 1.1 Resolution of rCDI.

	FM	Т	Cont	trol		Risk Ratio	Risk Ratio	Risk of Bias
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI	ABCDEF
Cammarota 2015	18	20	5	19	11.9%	3.42 [1.59 , 7.36]		
Hota 2017	7	16	7	14	12.0%	0.88 [0.41, 1.88]	_	20000
Hvas 2019	17	24	11	40	16.3%	2.58 [1.46, 4.53]	-	2
Kelly 2016	20	22	15	24	22.6%	1.45 [1.04, 2.04]	-	
Rode 2021	26	34	30	64	23.1%	1.63 [1.18, 2.25]	-	
van Nood 2013	15	17	7	26	14.1%	3.28 [1.70, 6.32]	-	
Total (95% CI)		133		187	100.0%	1.92 [1.36, 2.71]	•	
Total events:	103		75				· ·	
Heterogeneity: Tau ² = 0	0.11; Chi ² = 1	3.45, df =	5(P = 0.02)); I ² = 63%	6	0.0	01 0.1 1 10 1	100
Test for overall effect:	Z = 3.68 (P =	0.0002)					Favors control Favors FMT	
Test for subgroup diffe	rences: Not a	pplicable						

				Effect size
Outcome or subgroup title	No. of studies	No. of partici-	Statistical method	
		pants		1.92 [1.36, 2.71]
1.1 Resolution of rCDI: intention-to-treat analysis	6	320	Risk Ratio (M-H, Random, 95% CI)	
1.2 Resolution of rCDI: sensitivity analysis: fixed-effect model	6	320	Risk Ratio (M-H, Fixed, 95% CI)	1.92 [1.58, 2.34]
1.3 Resolution of rCDI: sensitivity analysis: as-available analysis	6	313	Risk Ratio (M-H, Random, 95% CI)	1.89 [1.31, 2.73]
1.4 Resolution of rCDI: sensitivity analysis: excluding immunocompromised partici-	5	256	Risk Ratio (M-H, Random, 95% CI)	
pants			3370 (1)	1.81 [1.23, 2.66]

FMT有效性優於對照組, 且在所有次族群分析的 outcome中,RR的95% 信賴區間裡皆沒有包含1, 有顯著的差異。











7. 結果精準嗎? ☑ YES



Analysis 1.1. Comparison 1: Fecal microbiota transplantation (FMT) versus control for the treatment of recurrent Clostridioides difficile infections (rCDI), Outcome 1: Resolution of rCDI: intention-to-treat analysis

	FM	T	Cont	rol		Risk Ratio	Risk Ratio	Risk of Bias
Study or Subgroup	Events Total		Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI	ABCDEF
Cammarota 2015	18	20	5	19	11.9%	3.42 [1.59 , 7.36]		
Hota 2017	7	16	7	14	12.0%	0.88 [0.41, 1.88]	I →	? • • • •
Hvas 2019	17	24	11	40	16.3%	2.58 [1.46, 4.53]		? • • • •
Kelly 2016	20	22	15	24	22.6%	1.45 [1.04, 2.04]	-	
Rode 2021	26	34	30	64	23.1%	1.63 [1.18, 2.25]	₌	
van Nood 2013	15	17	7	26	14.1%	3.28 [1.70 , 6.32]		•••••
Total (95% CI)		133		187	100.0%	1.92 [1.36 , 2.71]	•	
Total events:	103		75				*	
Heterogeneity: Tau ² = 0	0.11; Chi ² = 1	3.45, df =	5 (P = 0.02); I ² = 63%	ó		0.01 0.1 1 10 100	
Test for overall effect:	Z = 3.68 (P =	0.0002)					Favors control Favors FMT	
Test for subgroup differ	rences: Not a	pplicable						ı

Total 95% CI 1.36~2.71



信賴區間是窄的→精準









7. 結果精準嗎? **☑ YES**



Figure 3. Forest plot of comparison: 1 Fecal microbiota transplantation (FMT) vs control for the treatment of recurrent Clostridioides difficile infections (rCDI), outcome: 1.2 Serious adverse events.

	FM	T	Cont	rol		Risk Ratio	Risk Ratio	Risk of Bias
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI	ABCDEF
Cammarota 2015	2	20	2	19	10.6%	0.95 [0.15 , 6.08]		
Hota 2017	2	16	3	14	13.0%	0.58 [0.11, 3.00]		? • • • • •
Hvas 2019	5	24	10	40	27.9%	0.83 [0.32, 2.15]		? • • • • •
Kelly 2016	2	22	3	24	12.4%	0.73 [0.13, 3.95]		$\bullet \bullet \bullet \bullet \bullet \bullet$
Rode 2021	3	34	22	64	22.4%	0.26 [0.08, 0.80]	_ -	
van Nood 2013	4	17	2	26	13.8%	3.06 [0.63 , 14.90]	+-	•••••
Total (95% CI)		133		187	100.0%	0.73 [0.38 , 1.41]		
Total events:	18		42				I	
Heterogeneity: Tau ² = 0).17; Chi ² = 6	.74, df = 5	(P = 0.24)	$I^2 = 26\%$			0.01 0.1 1 10 100	
Test for overall effect: 2	Z = 0.94 (P =	0.35)					Favors FMT Favors control	
Test for subgroup differ	rences: Not a	pplicable						

Total 95% CI 0.38~1.41











評估證據等級

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)
How common is the problem?	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
Is this diagnostic or monitoring test accurate? (Diagnosis)		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
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)	Systematic review of randomized trials or <i>n</i> -of-1 trials	ramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control s of-1 trial with the patien raising the question aboobservational study with dramatic effect		t佳→維持Level	case-control, y controlled	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	Randomized trial	Non -randomized controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning



A問題

△檢索





使用 GRADEprofiler 評估證據品質

					the evidence (GRADE)
Outcomes	Anticipated abso	olute effects* (95%	Relative effect (95% CI)	№ of partici- pants (studies)	
	Risk with con- trol	Risk with fe- cal microbiota		(Studies)	
		transplantation (FMT)			⊕⊕⊕⊝ .
Resolution of rCDI follow-up: range 8 weeks to 17 weeks	401 per 1000	770 per 1000 (545 to 1000)	RR 1.92 (1.36 to 2.71)	320 (6 RCTs)	Moderate ^{a,b,c}
Serious adverse events follow-up: range 8 weeks to 17 weeks	225 per 1000	164 per 1000 (85 to 317)	RR 0.73 (0.38 to 1.41)	320 (6 RCTs)	⊕⊕⊕⊚ Moderate ^d
3					



Certainty of

A問題







評讀統整



「證據 可信度」



「結果 重要性」

是否問了一個清楚、明確的問題? 是否尋找適當研究型態的文獻? 所有重要且相關的研究都被納入? 是否評估所納入研究文獻的品質? 作者將研究結果進行合併是否合理?

結果精準嗎?

整體結果為何?

YES ☑ YES YES ☑ YES Can't tell

療效:FMT顯著優於對照組;嚴重副作用無顯著差異













應用



8. 是否可應用到當地的族群?









Country

The included studies were conducted in five different countries, with two studies conducted in Denmark (Hvas 2019; Rode 2021), and one each in Canada (Hota 2017), the Netherlands (van Nood 2013), Italy (Cammarota 2015), and the US (Kelly 2016).

未收入亞洲文獻











8. 是否可應用到當地的族群?

Article Open Access | Published: 29 January 2021

Ethnicity influences the gut microbiota of individuals sharing a geographical location: a cross-sectional study from a middle-income country

Jacky Dwiyanto ⊡, M. H. Hussain, D. Reidpath, K. S. Ong, A. Qasim, S. W. H. Lee, S. M. Lee, S. C. Foo, C. W. Chong & Sadequr Rahman ⊡

Scientific Reports 11, Article number: 2618 (2021) | Cite this article



不同的飲食習慣會導致 不同的腸道菌叢

而不同的種族會有不同 的飲食及生活習慣

In conclusion, the influence of ethnicity on the gut microbiota was detected from a community living in the same geographical region. This influence could be traced to the collective effect of multiple lifestyle factors exerting subtle yet distinct differences across ethnicity. Ethnicity, therefore, serves as a proxy for lifestyle and dietary variations across different ethnic groups living in the same community. Future studies on the GM should consider the impact of ethnicity to ensure valid interpretation of their study outcome.



「應用」

Dwiyanto, J., Hussain, M.H., Reidpath, D. et al. Ethnicity influences the gut microbiota of individuals sharing a geographical location: a cross-sectional study from a middle-income country. Sci Rep 11, 2618 (2021). https://doi.org/10.1038/s41598-021-82311-3









8. 是否可應用到當地的族群以及本案例?



Cochrane Database of Systematic Reviews

Fecal microbiota transplantation for the treatment of recurrent Clostridioides difficile (Clostridium difficile) (Review)

Minkoff NZ, Aslam S, Medina M, Tanner-Smith EE, Zackular JP, Acra S, Nicholson MR, Imdad A



健康狀況:65/M,曾中

風,反覆泌尿道感染

抗生素治療後感染性腹瀉

	收錄的各篇平均52~73歲	年龄	65歲
	男女比例相近	性別	男性
_	未知	共病	中風病史
	未知	經濟狀況	未知
P	「應用 歐洲及美洲	種族	亞洲人



9. 是否所有重要臨床結果都有被考量?





Primary outcomes

- Proportion of participants with a resolution of rCDI: we considered a participant fulfilling the definition of resolution of rCDI if studies reported either of the two criteria: diarrheal symptoms did not recur after treatment or repeat C difficile testing was negative.
- Serious adverse events, as per the author's definition of a serious adverse event.

Secondary outcomes

A priori planned secondary outcomes:

- Treatment failure: symptoms of CDI did not resolve after FMT treatment or that reoccurred within two weeks post-FMT.
- 2. All-cause mortality.

- Proportion of participants who withdrew from the study.
- Rate of new CDI infection after a successful FMT, with renewal of diarrheal symptoms and a repeat positive test for C difficile more than eight weeks after the previous positive test (McDonald 2007; McDonald 2018).
- Any adverse event.
- 6. Quality of life score.
- Colectomy.

We considered the primary and secondary outcomes at the longest follow-up before the trial was open for analysis. We anticipated that trials would have a follow-up period of at least six weeks. Additional details on definitions of certain primary and secondary outcomes discussed in protocol are available in Appendix 1.





長期的預後及副作用沒被考慮一需要更多研究來探討





10. 付出的傷害和花費換得的益處是否值得?







糞便菌叢移植法

抗生素或是安慰劑







利弊

平衡

費用

資源

金錢

醫療 現況

病人 期望

效果

副作用

時間

可近性

最在意 的問題

顯著優於對照組

無顯著差異

需自費

只需治療一次!

有做糞便菌叢移植法 的醫院相對較少

能改善感染性腹瀉, 且副作用低

健保給付

一天需口服四次,7-14天

台灣的醫學中心 皆有對應的抗生素









評讀統整



「證據 可信度」



「結果 重要性」



「應用」

是否問了一個清楚	VES YES					
是否尋找適當研究	✓ YES					
所有重要且相關的	✓ YES					
是否評估所納入研	VES YES					
作者將研究結果進	√ Can't tell					
整體結果為何?	整體結果為何? 療效:FMT顯著優於對照組;					
結果精準嗎?	結果精準嗎? 等級1,品質中					
可否應用到當地族	✓ NO					
所有重要結果都考	✓ YES					
益處是否大於傷害	VES YES					

64



共享決策

超級比一比

您在意的因素有哪些?重要度為何?







	不在意				很在意
症狀緩解	1	2	3	4	5
副作用	1	2	3	4	5
經濟考量		2	3	4	5
方便性	1	2	3	4	5
生活品質	1	2	3	4	5





考量病人觀點且有效說明

A問題

A檢索 Cquire

A評讀 Appraise

Apply



糞便菌叢移植法的治療效果如何?

副作用如何?有哪些注意事項呢?

65/M, 中風病史 首次感染性腹瀉

江先生您好,根據我們團隊實證查證的結果, 糞便移植法的確有良好的治療效果喔!









一篇證據品質良好的歐美文獻證實,反覆困難梭菌感染的病患,使用傳統治療跟糞便移植法比較時,糞便移植的治療效果比較好! 而副作用跟傳統抗生素治療比沒有比較高! 長期的效果仍有待觀察,但目前整體看起來,效果跟安全性都是不錯的喔!

不過,江先生您目前懷疑是初次困難梭菌感染,我們 建議您先以傳統抗生素治療,若是有強烈副作用或無法 配合服藥,我們才建議嘗試糞便移植法。而且目前糞便 移植為自費項目,費用比較高,您可以再評估一下喔!



謝

謝

您

的

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