

Critical Appraisal of a Therapy Paper (Randomized Controlled Trial)

Goal:

Participants will be able to critically appraise an article addressing therapy.

Objectives:

1. Learn how build a PICO question (See “Creating a searchable clinical question using PICO”)
2. Assess the validity of an article on therapy
3. Interpret the measures of effect of the intervention for both magnitude (how big the difference is between the treatments), precision (how accurate the comparison), and clinical relevance
4. Determine the applicability of the results to your patients
5. Evaluate the trade-offs between benefits and harms of the interventions

Reference (Further Reading):

Guyatt GH, Rennie D, Meade M, Cook DJ. Editors. Users’ Guides to the Medical Literature: A Manual for Evidence Based Clinical Practice, 3rd Edition, New York, NY: The McGraw-Hill Companies, Inc.

Available here:

<http://jamaevidence.mhmedical.com/book.aspx?bookID=847>

- Chapter 7, Therapy (Randomized Trials)
- Chapter 9, Does Treatment Lower Risk? Understanding the Results
- Chapter 10, Confidence Intervals: Was the Single Study or Meta-Analysis Large Enough?
- Chapter 13.1, Applying Results to Individual Patients
- Chapter 13.2, Numbers Needed to Treat

Educational Exercise:

1. Read the Users’ Guides to the Medical Literature reference chapters (listed above)
2. Read the Clinical Scenario (below)
3. Read “Creating a searchable clinical question using PICO” and compose a well-built clinical (PICO) question about the problem from the scenario
4. Complete a literature search using the headings from your PICO question
5. Read the relevant article and complete the appraisal worksheet (and decide whether you would recommend the suggested treatment for this scenario)

Clinical Scenario:

You are seeing patients in an outpatient clinic. Susie Smith is a 10-week-old former term infant. Her mother has brought her to the clinic for an acute care visit due to excessive crying. Susie is exclusively breastfed. She has been growing well and has developed a social smile. However, over the past several weeks she has developed progressively longer periods of crying, for several hours a

day, every day. The crying occurs throughout the day but is significantly worse in the afternoon and evening. Susie's mother feels that this is colic and has tried everything her friends and family have recommended for colic, but nothing is working. She recently read in a parenting magazine that probiotics may help "cure" colic. She is desperate and asks you to prescribe probiotics for Susie. You perform a history and physical exam and determine that Susie meets accepted criteria for colic. You give Susie's mother your clinic's handout for parents on surviving colic and recommend new strategies for Susie's mother to try. You also provide a recording sheet to record Susie's crying times and other symptoms for the next week. You then schedule her back in one week to follow up and report on how Susie is doing, with her colic record.

PICO question from above scenario:

P (patient or problem)

I (intervention)

C (comparison)

O (outcome)

After going to PubMed 'clinical queries' and putting in your search terms: colic and probiotics, you find the article:

Szajewska H, et al. Lactobacillus reuteri DSM 17938 for the management of infantile colic in breastfed infants: a randomized, double-blind, placebo-controlled trial. J Pediatr. 2013 Feb;162(2):257-62.

You scan the article and it appears relevant to your clinical scenario.



CRITICAL REVIEW FORM: THERAPY (RCT)

Identify and outline your clinical question in plain language:

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Build a PICO:

P	
I	
C	
O	

Preferred Resource:

- Meta-analysis/Systematic Review RCT Cohort Case Control

Databases Searched:

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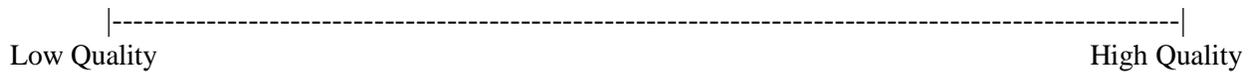
Resource Acquired:

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Did intervention and control groups start with the same prognosis?	
Were patients randomized?	
Was group allocation concealed?	
Were patients in the study groups similar with respect to known prognostic variables?	

Was prognostic balance maintained as the study progressed?	
To what extent was the study blinded?	
Were the groups prognostically balanced at the study's completion?	
Was follow-up complete?	
Were patients analyzed in the groups to which they were first allocated?	
What are the results?	
How large was the treatment effect?	
How precise was the estimate of the treatment effect?	
What were the confidence intervals?	

Strength of Evidence:



How does this apply to your patient?



CRITICAL REVIEW FORM: THERAPY (RCT)

Identify and outline your clinical question in plain language:

Do probiotics help with infantile colic?

Build a PICO:

P	Colic
I	Probiotics
C	N/A
O	Decreased colic symptoms (crying time)

Preferred Resource:

- Meta-analysis/Systematic Review
 RCT
 Cohort
 Case Control

Databases Searched:

PubMed

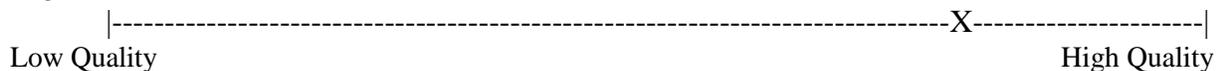
Resource Acquired:

Lactobacillus reuteri DSM 17938 for the management of infantile colic in breastfed infants: a randomized, double-blind, placebo-controlled trial

Did intervention and control groups start with the same prognosis?	
Were patients randomized?	Yes. A computer-generated randomization list was used. Patients were randomized in blocks of 6.
Was group allocation concealed?	Yes. An independent person prepared the randomization schedule and oversaw the packaging and labeling of the study products.
Were patients in the study groups similar with respect to known prognostic variables?	No. Table 1 shows that the experimental group had more patients with a family history of allergy in it. Otherwise, yes.

Was prognostic balance maintained as the study progressed?	
To what extent was the study blinded?	The parents and all study caregivers were unaware of the group allocation.
Were the groups prognostically balanced at the study's completion?	
Was follow-up complete?	Yes. All but 2 patients turned in the study diary and were analyzed.
Were patients analyzed in the groups to which they were first allocated?	Yes. Intention to treat analysis was followed.
What are the results?	
How large was the treatment effect?	Median difference at 14 days 4.3, NNT 2 Median difference at 21 days 2.6, NNT 2 Median difference at 28 days 1.6, NNT 3
How precise was the estimate of the treatment effect?	
What were the confidence intervals?	At 14 days 95% CI=2.3,8.7 p-value: <0.001 At 21 days 95% CI=1.8,4.0 p-value: <0.001 At 28 days 95% CI=1.3,2.1 p-value: <0.001

Strength of Evidence:



How does this apply to your patient?

-Your patient matches the study inclusion criteria. The crying time was significantly reduced in the probiotic group compared to the placebo group. As no adverse events associated with the probiotic therapy were reported, the benefits appear to be worth the potential harms. However, cost was not addressed. If cost is not an issue and parents want to alter the course of this self-limiting condition, the use of *L reuteri* DSM 17938 could be discussed as a treatment option for infantile colic.