

THERAPY II

Traditional Chinese Medicine (Herbal Medicine)

Objectives:

At the completion of this unit, participants will be able to assess how trustworthy the results of a randomized controlled trial(RCT) are, and how these results might apply to patient care.

At the completion of this unit you will be able to:

1. Assess the risk of a RCT addressing a question of therapy.
2. Interpret the measures of effect of the intervention in terms of magnitude, precision, and patient-important (e.g. mean, RR, RRR, ARR, NNT, and 95% CI of these measures).
3. Determine the applicability of the results to your patients.
4. Evaluate the trade-offs between benefits and harms (desirable vs undesirable consequences) of alternative courses of actions.

Reference (readings):

Listed chapters (below) in: Guyatt GH, Rennie D, Meade M, Cook DJ. Users' Guides to the Medical Literature: A Manual for Evidence Based Clinical Practice, 3rd Edition, New York, NY: The McGraw-Hill Companies, Inc. 2015.

- The Foundations
Chapter 4, P19, What Is the Question?
- Part Therapy
Chapter 7, p.59, Randomized Trials
Chapter 9, p.87, Does Treatment Lower Risk? Understanding the Results
Chapter 10, p.95, Confidence Intervals: Was the Single Study or Meta-analysis Large Enough?
Chapter 11, p.103, Advanced Topics in the Validity of Therapy Trials
Chapter 12, p.189, Advanced Topics in the Results of Therapy Trials
Chapter 13, p.235, Advanced Topics in Applying the Results of Therapy Trials

Problem Based Educational Strategy:

1. Read the Clinical Scenario
2. Compose a well-built clinical (foreground) question about the clinical problem.
3. Read the Users' Guides to the Medical Literature reference articles.
4. Complete the attached Critical appraisal sheet.
5. Decide whether you will recommend "*Tong Xie Yao Fang*" or individualized herbal treatment to the patient.

Scenario:

You are a traditional Chinese medicine (TCM) doctor working in the Department of Traditional Chinese Medicine of a general hospital in China. Today a 40-year-old lady came to you to seek treatment. Six months ago she was diagnosed with irritable bowel syndrome (IBS) based on her symptoms and medical history and all other possibilities were ruled out by a colonoscopy examination. The physician working in the gastroenterology department prescribed the antidepressant medication fluoxetine and the fiber supplement Metamucil for her, and also advised her to engage in more physical exercise. After six months of this treatment, her condition did not improve. Because of lack of benefit, she had discontinued her medications.

After a complete TCM diagnostic procedure, you prescribed *Tong Xie Yao Fang*, a very old and classical formula, which uses the original dosage of individual herbs and based on one dose per day for seven days. After the meeting with the patient, your senior colleague Jun Wang, who is a senior TCM doctor who is sharing the same clinic room with you in your hospital, came to you and discussed her case with you. He thought it would be more suitable to prescribe an individualized formula based on *Tong Xie Yao Fang*, according to her specific symptoms and not based on the typical symptoms. You are not comfortable with this course of action and suggested that the original herb ingredients and dosage should be followed because you were using it before and it was effective for your patients.

To support your argument, you decided to seek evidence regarding this question by conducting an electronic search in some online medical databases. You identified the following trial:

Alan Bensoussan, Nick J. Talley, Michael Hing, Robert Menzies, Anna Guo, MengNgu. Treatment of Irritable Bowel Syndrome with Chinese Herbal Medicine – A Randomized Controlled Trial. *JAMA*, 1998, 280 (18): 1585-1598.

Since it is highly relevant to your discussion of this pressing topic, you decided to review the trial closely. The results appear to favour individualized treatment, which supported your colleague's opinion. You then decided to critically appraise this paper using the "User's Guide" for a Therapy paper since you wanted to be more certain regarding the confidence you can have in the results. After critically appraising this paper, will you recommend individualized TCM herbal medicine for the patient or standardized TCM herbal medicine "*Tong Xie Yao Fang*"?

Enclosed Materials:

Alan Bensoussan, Nick J. Talley, Michael Hing, Robert Menzies, Anna Guo, Meng Ngu. Treatment of Irritable Bowel Syndrome with Chinese Herbal Medicine – A *Randomized Controlled Trial*. *JAMA*, 1998, 280 (18): 1585-1598.