Shu's 3 minutes cooking

3 minutes screening sheet for Clinical trial, EV

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When you are too busy to read articles in restricted time, or the journal club will be start in next ten minutes, you would like to read an article in very short time.

Read the article with the quick check list as following. Because you read in three minutes, you can only read as screening. It is not sufficient to apply to your faced patients with this method. **Note this sheet is for SCREENING and it is at risk to make decision directly on the final evaluation of the articles. Especially it is absolutely dangerous that beginners only use this sheet to master the skills of critical appraisal.** If you would like to do real critical appraisal, you may use JAMA Users' guides to the Medical Literature[1,2] or CASP appraisal tool for randomized controlled trials[3] as references.

If you have any comment or recommendation about this sheet, please contact me as e-mail.

PRINCIPLE：SEARCH THE WORDS. If you can get the information from title, you need not to read abstract. You may read text of article only you cannot get the information from abstract.

quick check list for screening

1. Read the title.
2. Is the main result significant?
   -> If not significant, check the sample size.
3. Is there the word of 'random'?
   -> If unclear, you may not go ahead.
4. Is there the word of 'ITT' or 'intention-to-treat'?
5. Is follow up rate 0.8 or more?
6. Is there any difference in baseline characteristics?
7. What is the PICO of the article?
   -> If all items are clear, you are recommended to read in detail.

8 Evaluation of the result (only for the main outcome).

Comments

1. Read the title.

Make out the brief PICO of the article from the title.

The first you have to do in screening articles is making out the PECO. But it takes a long time to recognize details of PICO. So you should understand in rough by the title. The details of PICO will be maked out after screening.

2. Is the main result significant?

☐significant
☐not significant

Find out the word of 'significant', 'prefer', 'more effective', 'reduce', 'better', or 'marked' in the *Conclusion* of the abstract. You may not regard the results of sub-study.

In case of not significant, there is sometimes luck of power. If the result is significant, the sample size must be enough.

In case of not significant; Is the sample size enough?

☐enough
☐not enough

Look at the head of *Statistical analysis* in the text. To calculate sample size, the values of α, power, estimated effectiveness(usually in relative risk reduction) must be written on the article. If the sample size at the time of analysis is bigger than the calculation, it will be truly not significant. Otherwise, there must be luck of power.

3. Is there the word of 'random'?

☐randomized
☐non-randomized

Find out the word of 'randomized' or 'randomization' in title, abstract or text.

The word is in the head of *Intervention* or *Methods* when it is in the abstract.

-> If unclear, you may not go ahead.

4. Is there the word of 'ITT' or 'intention-to-treat'?

☐Intention-to-treat analysis
☐Per-protocol analysis

Try to find the word of 'ITT' or 'intention-to-treat' in *abstract* first. Otherwise, search in the text. In case of written in the *abstract* the most case is in the end of *Intervention* or *Methods*. When it is in the text, there is in *Statistical analysis*.

If you cannot make it sure, compare the numbers of participants in tables of baseline and result. If they are identical, the analysis must be intention-to-treat.
The aim of ITT is maintenance of randomization.

5. Is follow up rate 0.8 or more?

Calculate follow up rate if the analysis is based on ITT principle

follow up rate=the number of result/the number of allocation
=

If follow up rate is under 80%, we cannot keep randomization and the study has insufficient internal validity. But the number of 0.8 is not absolute. ACP Journal Club adopts follow up rate as 0.8 or more.

6. Is there any difference in baseline characteristics?

☐no significant difference
☐significant difference

Because allocation is due to randomized, all the groups must be similar. But since they are sometimes different, you have to check the baseline characteristics are really similar.

7. What is the PICO of the article?

P(Patient) :

I(Intervention) :

C(Comparison) :

O(Outcome) :

P is showed in *Participants*, I and C is in *Intervention*, and O is involved in *Main Outcome Measures.* Or sometimes they are all included in *Methods*.

-> If all items are clear, you are recommended to read in detail.

8 Evaluation of the result (only for the main outcome)

incidence rate of intervention group=

incidence rate of comparison group=

RRR(Relative Risk Reduction)=

NNT(Number Needed to Treat)=

If there is a table which shows the result, let see it.

You may read the result of main outcome(primary endpoint) only.

It is important for interpretation of the result to make sure the duration of interventions. It is written in the head of *Result* or *Findings* of abstract. If you cannot find out, it is described as 'Mean follow-up was…' in *Result* of text.

Note the p-value if the article show it.

The important thing is whether effect is clinically significant or not.

e.g.:therapy of hyperlipidemia for secondary prevention of myocardial infarction

EVENT	Placebo (n=4502)	Pravastatin (n=4512)	Reduction in Risk (95%CI)	P value
Death due to CHD	373(8.3)	287(6.4)	24(12-35)	<0.001

for follow up period of 6.1yrs;
RRR=24%(12-35)
ARR=8.3ー6.4=1.9%
NNT=1/(1.9%)=53

data from LIPID study, *N Engl J Med* 1998;339:1349

参考文献

1) Guyatt GH, Sackett DL, Cook DJ, for the Evidence-Based Medicine Working Group: Users' guides to the Medical Literature. II: How to Use an Article About Therapy or Prevention. A. Are the Results of the Study Valid? JAMA 1993;270(21):2598-2601.

2) Guyatt GH, Sackett DL, Cook DJ, for the Evidence-Based Medicine Working Group: Users' guides to the Medical Literature. II: How to Use an Article About Therapy or Prevention. B. What Were the Results and Will They Help Me in Caring for My Patients? JAMA 1994;271(1):59-63.

3) CASP NHS. http://www.phru.org.uk/%7ecasp/rcts.htm

4) **開原成允, 浅井泰博, 治療や予防に関する文献の使い方,** JAMA **医学文献の読み方, 中山書店** 2001 **年,** 11-35**.**

5)Ttrain ML. http://www.egroups.co.jp/group/Ttrain/.

6)**厚生省医薬安全局審査管理課長, 臨床試験のための統計的原則** E9**,** 1998 **年.**

7) Bedenoch D **他著, 斉尾武郎監訳,** EBM **の道具箱, 中山書店** 2002 **年,** 16-24**.**

3 minutes CAT sheet for Clinical trial

1. article

title:

author:

citation:

2. Is the main result significant?

☐significant
☐not significant ○sample size is enough
○sample size is not enough

3. Is there the word of 'random'?

☐randomized
☐non-randomized

-> If unclear, you may not go ahead.

4. Is there the word of 'ITT' or 'intention-to-treat'?

☐Intention-to-treat analysis
☐Per-protocol analysis

5. Is follow up rate 0.8 or more?

follow up rate=the number of result/the number of allocation
=

6. Is there any difference in baseline characteristics?

☐no significant difference
☐significant difference

7. What is the PICO of the article?

P(Patient) :
I(Intervention) :
C(Comparison) :
O(Outcome) :

8 Evaluation of the result (only for the main outcome)

incidence rate of intervention group=
incidence rate of comparison group=
RRR(Relative Risk Reduction)=
NNT(Number Needed to Treat)=

Critical appraisal date / / **Signature**

改訂履歴

1.4→1.5（2002/11/19）

ITT 解析に関する解説を強化．ITT，FAS，Per protocol analysis の概念を説明．

補足の項を新設．「ランダム割付け」の意義の強調，ITT の補足説明，masking の除外理由を解説．

1.5→1.6（2002/11/19）

著作権に関する記載を追加．

参考文献に「臨床試験のための統計的原則 E9」を追加．

1.6→1.7（2002/11/21）

Ttrain の議論より，3 分読みを批判的吟味を代表する読み方としてとらえることの危険性を指摘，シートに記述することで強調した．3 分読みのみで論文の評価とすることを禁じた．

副題として，「南郷 3 分間クッキング」と命名．

1.7→2.0(ebh 研究会例会 2002/11/24)

このシートで論文の善し悪しを結論してしまうのは危険であり，スクリーニング用に用いた方がよいだろうという意見を踏まえ，タイトルを変更．

3 分で判定するには単語の拾い読みが最も易しく効果的ということを再認識．このため，各項目で単語の記載場所を可能性の高いもの順に記載．

PECO が少しも分からないと論文を読みようがないとの意見で，タイトルから最低限の情報だけ引き出すというのを始めに持ってくることにした．

このシートを使う場面を明示．

abstract しか読まないのであれば情報として不十分である可能性があることを記載．

差がない論文の時の読み方を追加．→サンプルサイズを読ませる．

結果の解釈に観察期間が重要であることを明示．

参考文献に「EBM の道具箱」を追加．

更新履歴を記載．

2.0→2.1

CAT シートを新設．

2.1→EV1.0

Translated to English version.