EBM and Research Publications

Crash Course
on
Getting Research Published
to
support
Evidence-based Medicine

Course Manual

Contents

Welcome

This is your course handout for the Patient-oriented Research Crash Course. It contains:

- The overall aim and objectives
- A session-by-session timetable
- An outline of the teaching and learning strategy
- Relevant methodological and clinical papers

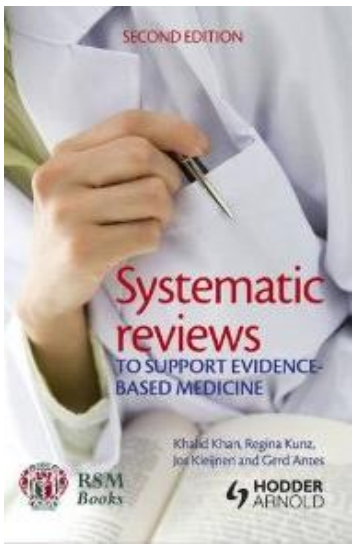
The handout is carefully designed to serve as a resource in the future, and to give you some preparatory work to complement the teaching and learning strategy.

Your Tutors

Dr. Carmen Amezcua Prieto, Lecturer and Researcher in the Department of Preventive Medicine and Public Health, University of Granada, is Assistant Editor in BMC Pregnancy and Childbirth journal, and Guest Editor for the special issue 'Physical activity in women' in IJERPH journal. Her research areas of interest are perinatal epidemiology, women's health and artificial intelligence in health.

Dr. Sandra Martín Peláez, Lecturer and Researcher in the Department of Preventive Medicine and Public Health, University of Granada. Graduated in Biology and in Food Science and Technology by the University of Granada, she obtained her PhD in Animal Nutrition in the Autonomous University of Barcelona. Topic Editor and Guest Editor for the special issue "Dietary Bioactives, Gut Microbiota, and Human Health" in Nutrients journal. As a researcher, she is mainly interested in the role of gut microbiota on health, and how we can influence it through the diet.

Professor Khalid Saeed Khan, a former Editor of BJOG, EBM-BMJ and BMC Med Educ, has published over 400 peer-reviewed papers and supervised over 25 higher-degree theses. His research is highly cited with an h-index>100. He graduated in medicine from the Aga Khan University and higher training at McMaster University led him to an academic career, focusing on patient-oriented clinical research. Khalid has contributed to many trials and meta-analyses and is the lead author of Systematic Reviews to Support Evidence-Based Medicine, which won a BMA Medical Book award.



Introduction

Research design conduct and publication should underpin evidence-based medicine. Funders, ethics committees, editors, peer-reviewers, thesis examiners, clinicians, patient representatives, policymakers and health insurance providers all look for features that help achieve this end.

Evidence-based medicine involves systematically finding, appraising and using contemporaneous research findings as the basis of healthcare decisions. It follows four steps: formulate a clear clinical question to address a patient's problem; search the literature for relevant clinical articles; evaluate (critically appraise) the evidence for its quality (validity, reliability) and importance (usefulness); implement useful findings in practice. To undertake research and write in a way that facilitates the above is challenging.

Checklists for reporting exist for different publications types. Following these closely from the start will help you conduct good research. At the time of publication, this approach will help you compete with other submissions being assessed at the same time as your own. This way, your research will succeed, and its manuscript will successfully pass through the various hurdles faced with editors and peer-reviewers. More importantly, it will have a real chance of making a difference to patient outcomes.

The teaching and learning strategies employed in this course include pre-course independent learning, lectures and interactive small group work. This approach is meant to be participant-centred, problem-based, systematic and integrated as far as possible.

This manual aims to assist the course participants to get the maximal educational benefit from their course and help the tutors and administrators run the course effectively.

Any suggestions for improvement of this manual and the course are welcome. Please address these directly to the course organisers or via the anonymous evaluation form given at the end of the course.

Timetable

Day1:

Session 1: Write abstract first
Lecture: Writing for publication vs Evidence-based medicine
Group work: Framing questions, title, abstract and study design

Session 2: Selecting a journal
Lecture: The basic journal metrics
Group work: Drafting introduction

Day 2:

Session 3: Avoiding rejection
Lecture: The editorial and peer-review process
Group work: Writing methods and results

Session 4: Handling revisions and rejections
Lecture: Responding to peer-review
Group work: Writing discussion

Day 3:

Session 5: What editors want
Lecture: Post-publication dissemination
Group work: Group presentations

The structure of each session will include:

Tutor-led session:
Lead-in self-assessments
Lecture/presentation

Student group work:
Introductions, group discussions
Preparation of presentations

Student presentations:
Production and defence of work

Evaluation:
Feedback and future plans

Group work overview

Participants' role: Clarify the task. Identify a facilitator and presenter. Listen attentively. Discuss what could be improved.

Facilitators' role: Determine if participants agree on the task. Facilitate interaction. Encourage those who are quiet. Identify and help participants resolve conflicts. Seek input from tutor if appropriate. Time keeping.

Tutor's role: Support facilitators. Provide guidance and hints (but do not dictate) referring to the content presented. Comment briefly and honestly.
(see next page)

Curriculum Outline

Aim

To familiarise participants with the principles of design and reporting of systematic reviews and clinical trials studies for promoting evidence-based medicine.

Objectives

To prepare participants to:

A. Understand the editorial assessment process.
B. Develop an approach directed towards reporting guidelines for preparing protocols and manuscripts,
C. Learn about critical appraisal of the evidence collated in systematic reviews (meta-analysis) and primary research concerning effectiveness and accuracy,
D. Become comfortable with enhancing the applicability of research findings using clinically meaningful measures of effect and accuracy for incorporating research into practice,

Learning outcomes

The participants should have the following competencies:

1. Design, register, conduct and write-up a paper involving a systematic review or primary research,
2. Assess (and transparently report) the quality of systematic reviews or primary research,
3. Use clinically meaningful measures to present results to enhance the applicability of findings in clinical practice,
4. Incorporate the above learning into the preparation of a manuscript for publication,

Learning Resource

Webinar re publications: https://www.youtube.com/watch?v=oo3dGrapXdc
Open peer review article:
https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-6-177

Learning/Teaching Methods

The teaching and learning strategy will involve:

- Lectures/presentations: Understanding the methodological principles
- Small group work: Evaluating published manuscripts using reporting guidelines
- Participant directed learning: Independent study pre- and post-course

Educational format of group work

What is a student group? A small number of course participants (ideally 4-10) will come together to undertake learning tasks.
How will it work? The learning task will be provided and agreed at the start of the group session. Participants will:

- Learn each other's names, interests and objectives
- Agree on the roles of the group members (facilitator, presenter, etc.)
- Mutually support individual and group roles, keep to time
- Discuss and share knowledge to carry out the agreed task
- Listen (concentrate and analyse) and talk (consolidate/summarise)
- Maintain confidentiality
- Deliver and defend the presentations

How will it succeed?

- By taking responsibility (individually and as a group) for identifying, monitoring, and reinforcing positive, and correcting negative, elements of the group work.
- By observing attentively, identifying behaviours (not motives), encouraging non-participants while politely discouraging over-participants, and focusing on strategies for correcting/improving the situation.
- By evaluating self, each other, the group, the session, and the tutor with candour and respect, celebrating what went well and identifying what could have been done better.

Contact time

20 hours Teaching sessions during course and independent study

Assessments

Self-assessment pre-course (Test 1) and post-course (Test 2)

Self-Study / Group Work

STROBE and a cohort study
Reporting guideline: equator-network.org/reporting-guidelines/strobe/
Study: doi.org/10.1111/1471-0528.14536

In trials eligible for prospective registration (i.e., before the first patient is randomised), some researchers may forget to register their study.

The structured question:
Participants – Sample of published RCTs
Intervention – Prospective registration
Comparator – No registration
Outcome – Journal quality
Design – Cohort study

Self-study: Please fill out the STROBE checklist for the cohort study.

Relative risks (rate ratio or RR) calculation:

Construct a 2x2 table and answer the following questions using Table 1:

a) Among prospectively registered studies, what is the rate of publication in general (high impact) journals?
b) Among studies not prospectively registered, what is the rate of publication in general (high impact) journals?
c) Does prospective registration increase the chances of publication in high impact journals? If so, by how much?

Table 1. Compliance of published RCTs with prospective registration rule and differences between journals

Factor	Total RCTs, *n* (%)	RCTs published in general journals,* *n* (%)	RCTs published in specialist journals,** *n* (%)	*P*-value***
Total eligible for prospective registration				
Yes	75	22	53	
Prospective registration				
Yes	51 (68)	21 (95)	30 (57)	0.001
Sample size achieved****				
Less in reported versus registered	31 (61)	11 (52)	20 (67)	0.304

*General = *BMJ*, *N Engl J Med*, *JAMA* and *Lancet*.
**Specialist = *Acta Obstet Gynecol Scand*, *BJOG*, *Obstet Gynecol* and *Am J Obstet Gynecol*.
***see Figure 2 for details. Using chi-squared test.
****Concordance between registered and reported sample size in the 51 prospectively registered RCTs.

CONSORT and a randomised study

Reporting guideline: equator-network.org/reporting-guidelines/consort/
Study: biomedcentral.com/articles/10.1186/1471-2288-1-12

Amongst healthcare providers, questionnaire surveys have a poor response rate.

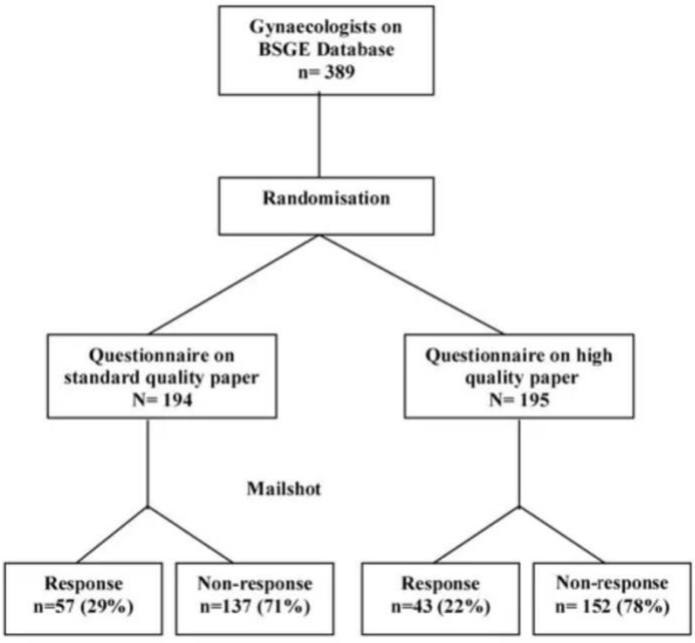
The structured question:
Participants – Doctors taking a postal questionnaire survey
Intervention – High quality paper
Comparator – Standard
Outcome – Response rate
Design – Randomised trial

Self-study: Please fill out the CONSORT checklist for the randomised study attached.

Odds ratio (OR) calculation:

Construct a 2x2 table and answer the following questions using Figure 1:

a) When the questionnaire is printed on high quality paper, what are the odds of there being a response?
b) When the questionnaire is printed on standard quality paper, what are the odds of there being a response?
c) Does high quality paper increase the odds of a response? How much.



GRIPP2 and a pilot trial

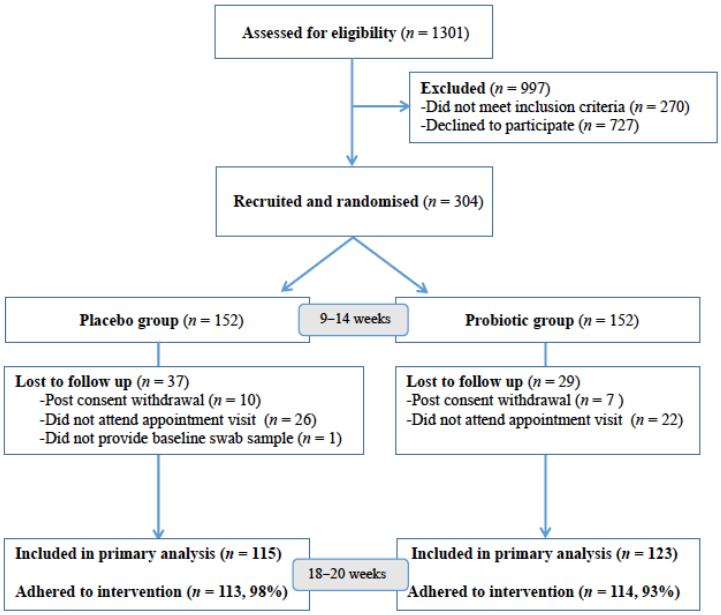
Reporting guideline: https://www.bmj.com/content/358/bmj.j3453
Study: https://obgyn.onlinelibrary.wiley.com/doi/epdf/10.1111/1471-0528.15675

Evidence of benefit from oral probiotics is lacking in pregnancy.

The structured question:
Participants – Healthy pregnancies.
Intervention – Oral probiotics.
Comparator – Usual care.
Outcome – Primary: vaginal microbiome; Secondary: preterm birth.
Design – Randomised pilot trial.

Self-study: Please fill out the GRIPP2 checklist for the randomised study attached.

2x2 table construction:
Please construct a 2x2 table for the outcome preterm birth using the text provided from the results section.



> Although the secondary outcomes did not differ between the two groups, this trial was not powered to assess these adequately. There was one miscarriage in the placebo group and three in the probiotic group, all occurring between 9–14 weeks' and 18–20 weeks' gestation. There were nine and eight PTBs in the placebo and probiotic groups, respectively, giving PTB rates of 8.2% and 6.7%; these rates are consistent with the 7.7% PTB rate reported for England and Wales in 2015.[35] In each group, the mean duration of pregnancy was 39 weeks, and in those who delivered preterm, 36 weeks.

Concerning GRIPP2 checklist:

- What is missing from the paper that appears on the checklist?
- Is the rationale for patient engagement (or absence of it) clearly explained?
- Did the write-up demonstrate the study truly engaged patients?
- What would authors need to consider if they proceeded to a full-scale trial?

PRISMA and a systematic review

Reporting guideline: equator-network.org/reporting-guidelines/prisma/
Study: doi.org/10.1111/1471-0528.14528

A large proportion of patients never get a chance to take part in research.

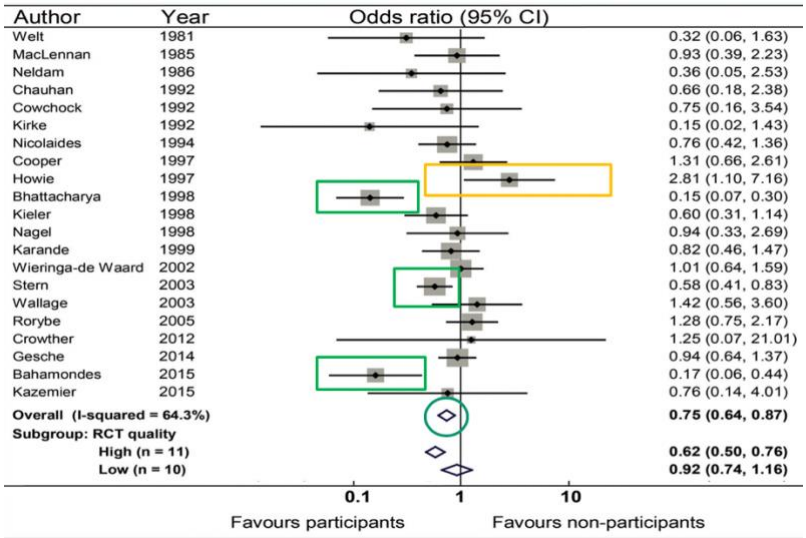
The structured question:
Participants – Women patients
Intervention – Participation in RCT
Comparator – No participation
Outcome – Improved health
Design – Systematic review

Self-study: Please fill out the PRISMA checklist for the systematic review.

Meta-analysis interpretation:

Answer the following questions using Figure 4:

a) How many studies show conclusively that participation in trials, compared to usual care, is beneficial?
b) How many studies show conclusively that participation in trials, compared to usual care, is harmful?
c) On average, what are the relative odds of there being a benefit? What is the range?
d) Is the main finding supported by studies with high quality RCTs?



Self-assessment

Below are a series of terms of direct and indirect relevance to reviews and research. Please circle the number that most closely fits your understanding of terms, using the scale below

TERM	BEFORE (Circle one number)						AFTER (Circle one number)				
Likelihood ratio	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
Test accuracy	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
Cohort Study	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
Economic evaluation	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
Cross-sectional study	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
Absolute risk	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
Medline	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
p-value	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
Decision analysis	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
Publication bias	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
Randomised trial	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
Probability	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
Confidence interval	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
Logistic regression	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
Systematic review	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
Relative risk	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5
Meta-analysis	*1*	*2*	*3*	*4*	*5*		1	2	3	4	5

THE SCALE:
1.Unaware of the term
2.Know something about the term, or have come across it before
3.Would understand the term when used in its correct context by others, but would not use it myself
4.Understand it and might use the term myself, but would need to refer to a colleague or a book before defining it
5.Understand it and could define it now

Course Evaluation

Please help us to evaluate this course by providing any comments/suggestions

On a scale of 1-5 (1=poor, 5=excellent) please indicate your opinion of the following.

Please tick the appropriate box.

ITEM						USE AGAIN	
	1	2	3	4	5	Yes	No
Lectures							
Small group work							
Course handout							

Do you have any comments? If so, please give details

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Thank you for attending the course!