An introduction to research in integrative medicine

Dr Ava Lorenc
Co-Chair
Research Council for Complementary Medicine

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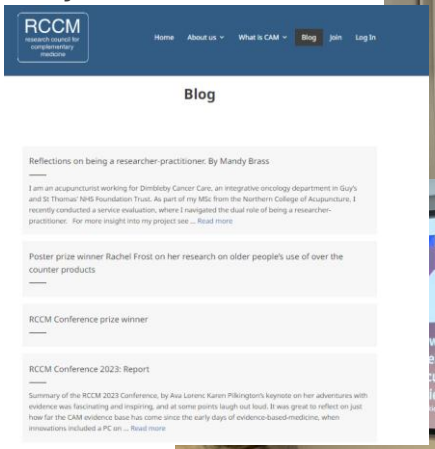
Introduction

RCCM:

- UK's leading authority on TCIM (Traditional Complementary and Integrative Medicine) research.
- To support, nurture and advise on delivering high-quality research within the TCIM community.
- Trustees
- Members
- Conference



Ava Lorenc

- Editor in Chief, EuJIM
- Co Chair, RCCM
- Research Fellow, University of Bristol

Overview of session

- Searching for evidence
- Critical appraisal
- Research designs for TCIM practitioners
- Publication and dissemination
- What RCCM can offer

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How to search for and retrieve research papers

- Databases
- Open access journals/papers
- Email author
- Pay per view
- Research Gate
- Copyright

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How to search for and retrieve research papers

Databases:

- ❑ Pubmed/medline: www.ncbi.nlm.nih.gov/pubmed/
- ❑ Google scholar: https://scholar.google.co.uk/
- ❑ Cochrane library: http://cochranelibrary-wiley.com/cochranelibrary/search
- ❑ AMED
- ❑ OVID
- ❑ Cinahl (nursing & allied health)
- ❑ PsycInfo
- ❑ Embase (biomedical)

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How to search for and retrieve research papers

Other types and sources of literature

- Reference lists
- NHS Evidence
- Citations & related articles – google scholar, article websites
- Grey literature (non journal)
- Protocols
- Conference abstracts
- Registries (for ongoing research) e.g. UKCRN, Health service research projects in progress, Prospero
- Theses (index to theses)

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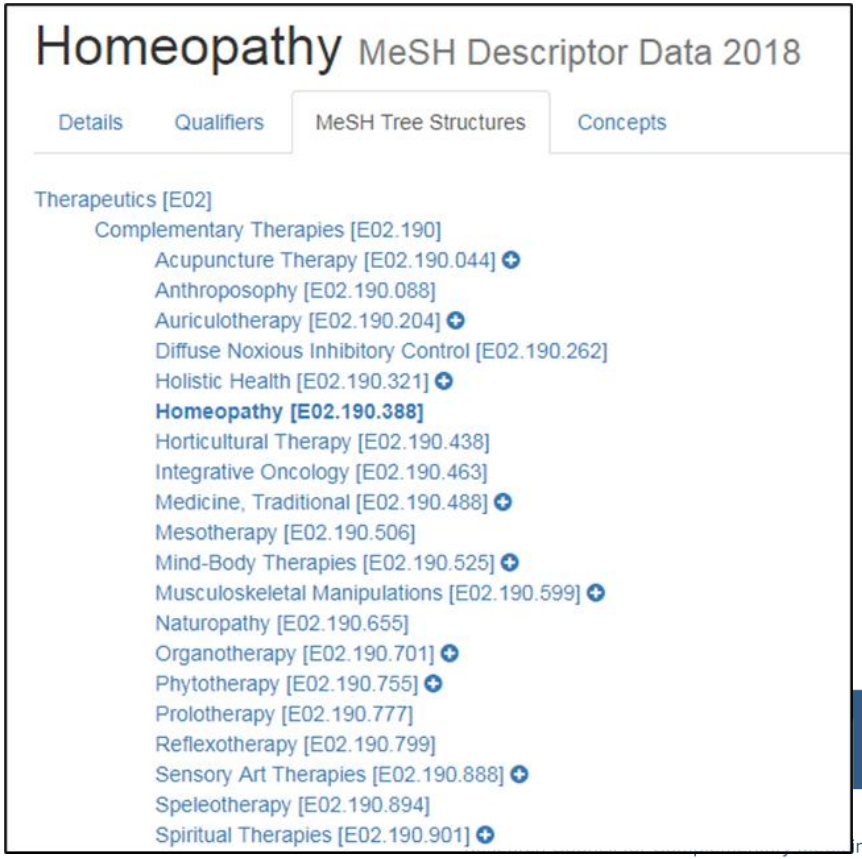
How to search for and retrieve research papers

Searching:

- Keyword/search terms – MeSH terms; Advanced Search Results - PubMed (nih.gov)
- Date limits?
- Language limits?
- PICO(TS): population, intervention, comparator, outcomes, timing, and setting.
- Combining search terms



Critical appraisal of different study designs

Study type	Reporting checklist	Quality assessment	
RCT	CONSORT (+ extensions) e.g. STRICTA	Cochrane Risk of Bias Jadad	CASP (Critical Appraisal Skills Programme) Equator
Systematic review	PRISMA GRADE	AMSTAR 2 ROBIS	
Feasibility study	CONSORT + extension		
Qualitative	COREQ SRQR (Standards for Reporting Qualitative Research)		
Protocols	SPIRIT		

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Critical appraisal

- Date of publication
- Country
- Setting (clinical etc)
- Study design
- Quality
- Size of study
- Impact factor of journal

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Critical appraisal

Key points to look for (RCTs):

- Randomisation (randomisation process, concealment of allocation etc)
- Sample size estimation
- Blinding
- Withdrawals/dropouts
- Publication bias

Guidance:

- Cochrane handbook
- BMJ EBM Toolkit http://bestpractice.bmj.com/info/toolkit/ebm-toolbox/ includes critical appraisal, statistics, glossary, resources

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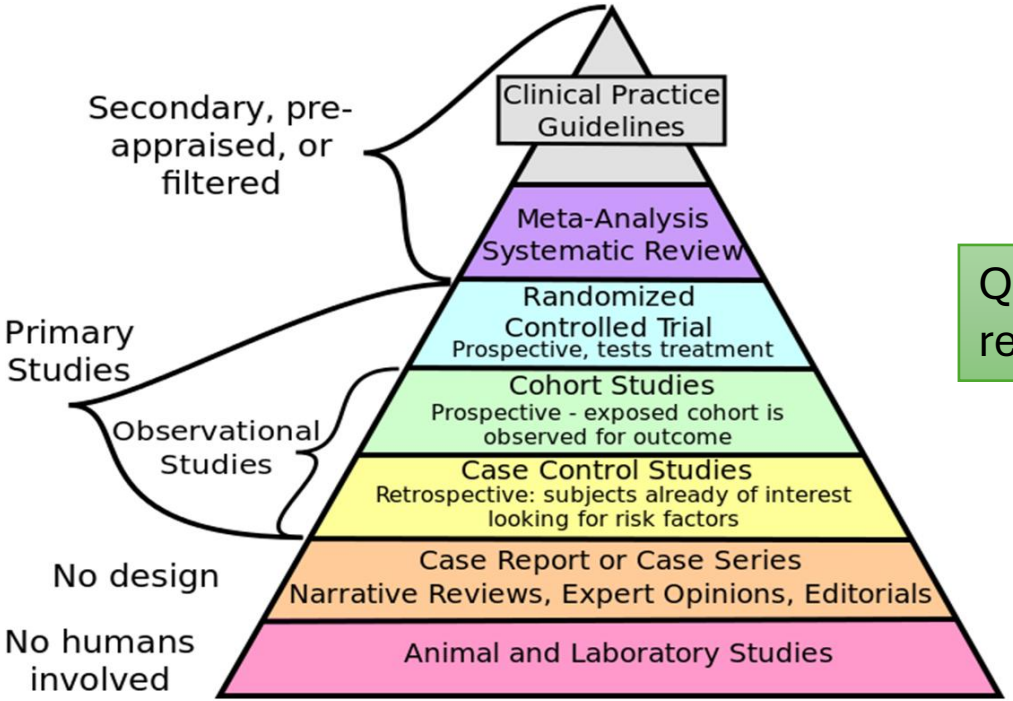
Methodological approaches for studying integrated medicine



Qualitative research

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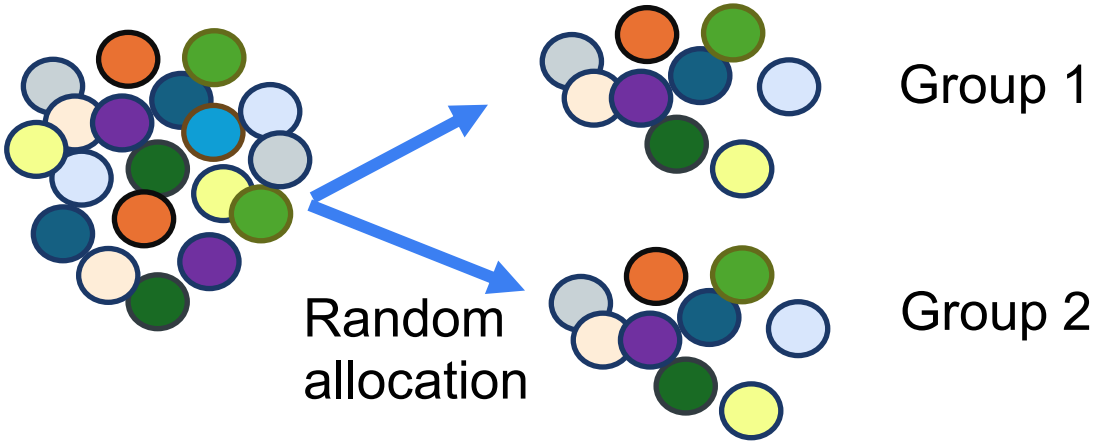
Methodological approaches for studying integrated medicine

The supposed ‘gold standard’ of the double blind randomised controlled trial



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Challenges with the RCT design for integrated medicine: Model validity

- Concordance of trial intervention vs clinical practice.
- Complex interventions
- Low model validity may = false negative findings

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An example

Author	Population	Design	Treatment administered	Criteria for assessing improvement	Findings
David et al (1999)	56 patients with definite or classical RA, recruited from a hospital based rheumatology outpatient clinic.	Randomised placebo-controlled cross over design. Participants randomly assigned to receive either five weekly treatments of acupuncture or placebo. This was followed by a wash-out period of six weeks, after which each participant received the alternative intervention. The trial was participant and assessor blind.	Acupuncture treatment consisted of LI3 needled bilaterally. The needles were inserted for four minutes and manipulated on two minutes for five seconds. The placebo treatment consisted of holding a needle introducer on point LI3 for four minutes without pressure or skin puncture.	-Measurement of inflammatory markers (ESR and CRP) -VAS of pain -VAS of patient's global assessment -28 swollen joint count -28 tender joint count -Number of analgesic tablets taken daily -General health questionnaire 28 -Modified Disease activity score (DAS) index	No significant effect from acupuncture treatment on any of the outcome variables.
Man and Baragar (1974)	20 patients with classical or definite RA for five or more years, seropositive for RF, and in whom pain in both knees was a major problem.	Double-blind randomised controlled trail. Group 1 (ten patients), intra-articular corticosteroids on one knee, other knee treated once with true acupuncture. Group 2 (ten patients) intra-articular corticosteroids on one knee, other knee treated once with sham acupuncture. The study was participant and assessor blind.	True acupuncture consisted of needles inserted at points GB34, SP9, and, S43 and connected to a 6.26 electro-stimulator at 5mA for 15 minutes. Sham acupuncture consisted of the insertion of three acupuncture needles inserted on the patella of the knee and 5cm above and 5cm below the first needle on the longitudinal line of the leg. Needles connected to a 6.26 electro-stimulator at 5mA for 15 minutes.	-Pain relief at rest, during flexion, extension, weight bearing, and walking on a five point scale -Local heat and swelling -Analgesic intake	Acupuncture effective in relieving pain for up to three months, but had no anti-inflammatory effect.

Hughes, JG (2007) Acupuncture for rheumatoid arthritis and the impact of acupuncturist affiliation to a traditional or western theoretical framework: exploring the perceptions of acupuncturists and patients (PhD thesis). Manchester Metropolitan University

An example

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Does not reflect treatment for arthritis as reported in a qualitative study with acupuncturists

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Challenges with the RCT design for integrated medicine: model validity

Integrated medicine trials need to ensure model validity, using appropriate methods.

- Mixed methods approach
- Systematic review examining previous treatments used in papers
- Workshop with experts.
- Informed by the systematic review and their clinical expertise experts devise and agree the trial intervention.

European Journal of Integrative Medicine 21 (2018) 56–62

Contents lists available at ScienceDirect

European Journal of Integrative Medicine

journal homepage: www.elsevier.com/locate/eujim

Ensuring model validity in a feasibility study of acupuncture to improve quality of life in cancer patients undergoing radiotherapy treatment

John Hughes[a,*], Mike Cummings[a], Jacqueline Filshie[b], Sosie Kassab[a], Graham Long[c], Peter Mackereth[d], Hugh MacPherson[e], Beverley de Valois[f], Peter Fisher[a]

ARTICLE INFO

Keywords:
Acupuncture
Model validity
Cancer
Randomised controlled trial
Radiotherapy

ABSTRACT

Introduction: A feasibility study of acupuncture for quality of life in cancer patients is planned. The pragmatic randomised controlled trial will aim to assess the feasibility of training radiographers to administer acupuncture to their patients undergoing radiotherapy intended to cure their cancer. The preliminary phase covered in this paper aimed to develop the trial acupuncture intervention and ensure its model validity.

Methods: A mixed methods approach will be adopted. Systematic review conducted examining the treatments administered in papers reporting acupuncture treatment for cancer patients. Subsequently, one-day workshop held with an acupuncture expert panel. Informed by the systematic review and their clinical expertise the expert panel devised and agreed the trial acupuncture intervention.

Results: The acupuncture expert panel came to a consensus on the trial acupuncture intervention. Trial radiographers will treat patients for 30 min, with needles inserted for approximately 20 min of this time. The trial will employ a standard treatment protocol for constitutional symptoms (fatigue, hot flushes, mood problems, anxiety, depression, and sleep problems) consisting of non traditional ASAD (anxiety, sickness and dyspnoea) acupoints, LI4, LR3, SP6 and ST36. Additional acupoints can be utilised for nausea/vomiting and pain. Guidelines on safe practice were also agreed.

Conclusions: Few clinical trials of acupuncture, and complementary medicine interventions generally, document details of the process by which they ensured the model validity of their trial intervention. It is recommended that researchers in acupuncture, and other forms of complementary medicine, adopt appropriate methodological approaches to ensure model validity.

Challenges with the RCT design for integrated medicine: Placebo/control interventions

- Placebo = indistinguishable from the true intervention, yet physiologically inert.
- Challenging in TCIM
- E.g. acupuncture: needles at ‘wrong’ places; retractable ‘stage dagger’ needles; or inactivated TENS.
- In TCIM often leads to ‘no difference’ in effect = both are effective
- Pragmatic trial designs

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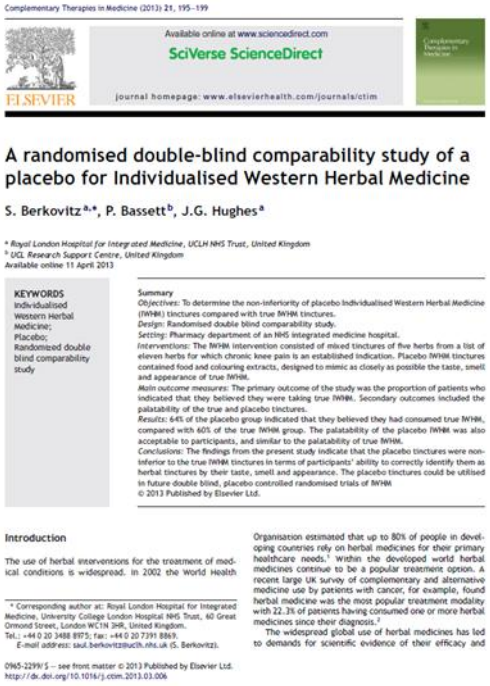
Challenges with the RCT design for integrated medicine

Even in integrated medicine modalities amenable to the randomised placebo controlled trial design, such as herbal or homeopathic interventions, pre trial research needs conducting to ensure the placebo intervention is indistinguishable to the real intervention.



Complementary Therapies in Medicine (2013) 21, 195–199

Available online at www.sciencedirect.com

SciVerse ScienceDirect

journal homepage: www.elsevierhealth.com/journals/ctim

A randomised double-blind comparability study of a placebo for Individualised Western Herbal Medicine

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Available online 11 April 2013

KEYWORDS
Individualised Western Herbal Medicine;
Placebo;
Randomized double blind comparability study

Summary
Objectives: To determine the non-inferiority of placebo Individualised Western Herbal Medicine (IWHM) tinctures compared with true IWHM tinctures.
Design: Randomised double blind comparability study.
Setting: Pharmacy department of an NHS integrated medicine hospital.
Interventions: The IWHM intervention consisted of mixed tinctures of five herbs from a list of eleven herbs for which chronic knee pain is an established indication. Placebo IWHM tinctures contained food and colouring extracts, designed to mimic as closely as possible the taste, smell and appearance of true IWHM.
Main outcome measures: The primary outcome of the study was the proportion of patients who indicated that they believed they were taking true IWHM. Secondary outcomes included the palatability of the true and placebo tinctures.
Results: 64% of the placebo group indicated that they believed they had consumed true IWHM, compared with 60% of the true IWHM group. The palatability of the placebo IWHM was also acceptable to participants, and similar to the palatability of true IWHM.
Conclusions: The findings from the present study indicate that the placebo tinctures were non-inferior to the true IWHM tinctures in terms of participants' ability to correctly identify them as herbal tinctures by their taste, smell and appearance. The placebo tinctures could be utilised in future double blind, placebo controlled randomised trials of IWHM

Introduction

The use of herbal interventions for the treatment of medical conditions is widespread. In 2002 the World Health Organisation estimated that up to 80% of people in developing countries rely on herbal medicines for their primary healthcare needs.[1] Within the developed world herbal medicines continue to be a popular treatment option. A recent large UK survey of complementary and alternative medicine use by patients with cancer, for example, found herbal medicine was the most popular treatment modality with 22.3% of patients having consumed one or more herbal medicines since their diagnosis.[2]

The widespread global use of herbal medicines has led to demands for scientific evidence of their efficacy and

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0965-2299/$ – see front matter © 2013 Published by Elsevier Ltd.
http://dx.doi.org/10.1016/j.ctim.2013.03.006

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Challenges with the RCT design for integrated medicine: outcome measures

- Can only detect what you measure
- Traditional outcome measures designed for conventional (typically pharmacological) interventions.
- Some outcome measures capture the wider effects of TCIM
  - MYMOP
  - Warwick Holistic Health Questionnaire
- Embedded qualitative study to capture patients' experiences/unexpected outcomes

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Qualitative research

- Understanding and meaning
- Processes or factors which influence a phenomena
- Approches include:
  - Thematic analysis
  - Phenomenology
  - Ethnography
  - Grounded theory
  - Narrative
  - Framework
- Can detect outcomes
- Not only within a trial

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Publication and dissemination of your research

Why disseminate?

- ✓ Required by funder
- ✓ Research is no use sitting on a shelf!
- ✓ Make an impact
- ✓ Change practice/policy
- ✓ Open discussions
- ✓ Raise awareness

Research is of no use unless it gets to the people who need to use it

Professor Chris Whitty, Chief Scientific Adviser for the Department of Health

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Publication and dissemination of your research

Where to publish?

- Journals
- Magazines/non peer-reviewed journals
- Social media
- Blogs
- Mainstream press
- Lay summary

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Publication and dissemination of your research

TCIM Journals

- EuJIM
- BMC CAM – Open access
- Complementary therapies in clinical practice
- Complementary therapies in medicine
- Journal of complementary and integrative medicine
- Evidence based CAM
- Alternative Therapies in Health and Medicine
- FACT
- Journal of holistic nursing
- Journal of holistic healthcare
- Therapy specific

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Publication and dissemination of your research

Choosing a journal:

- ✓ **Best audience for your message**
- ✓ Open access or pay per view?
- ✓ Scope
- ✓ Impact factor, CiteScore and other metrics
- ✓ Word count
- ✓ Type of papers published
- ✓ Visibility, social media presence etc.
- ✓ Turnaround time

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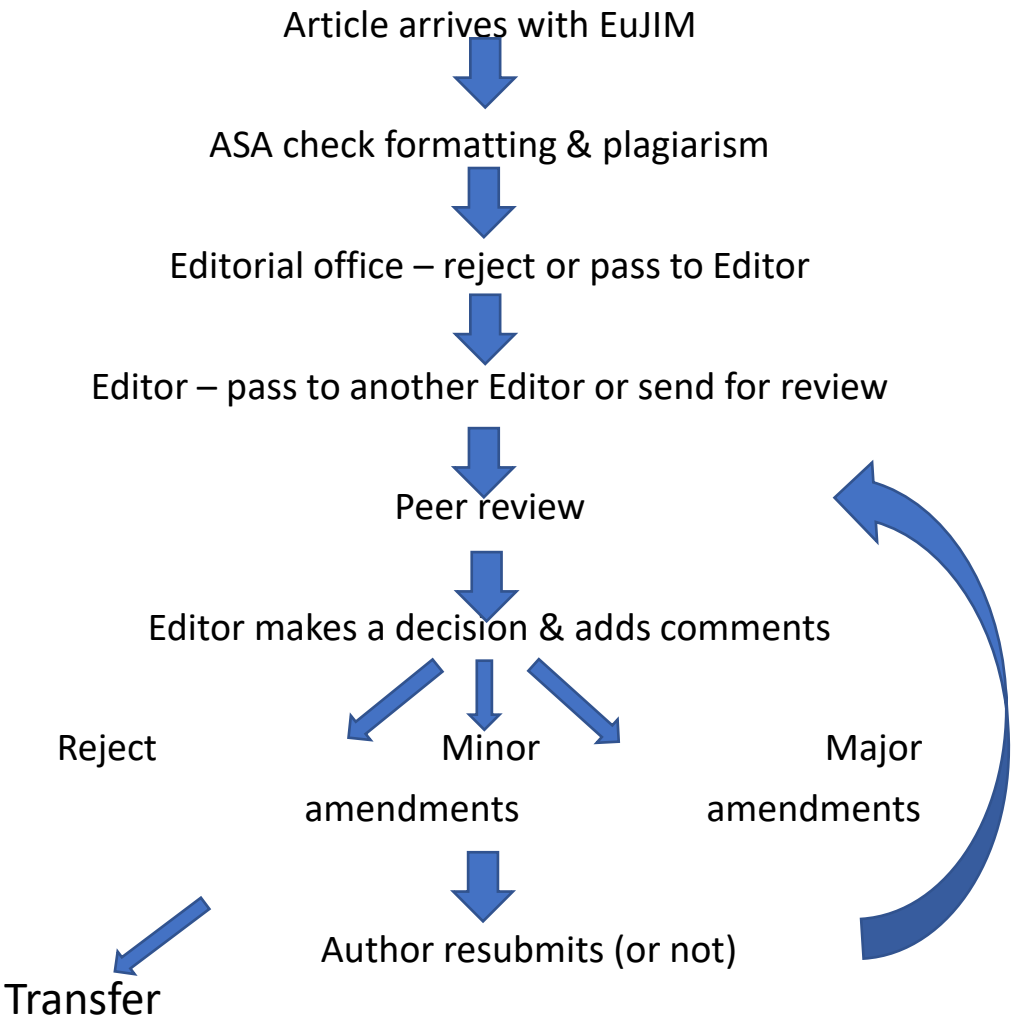

Acceptance

Proofing

Publication

Dissemination – email, social media etc

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How not to get rejected

- ✓ Reporting checklists e.g. Consort, Prisma, Coreq
- ✓ Format for the journal
- ✓ Good English, concise
- ✓ Title and abstract are important
- ✓ Likely to be cited
- ✓ Interest to readers

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What can the RCCM offer?

www.rccm.org.uk
info@rccm.org.uk

Free newsletter

Membership

Full Member (£50 p/a)
- ✓ Discounted events
- ✓ RCCM Connect networking sessions
- ✓ Advice from trustees
- ✓ Website members-only resources
- ✓ Linkedin group

Corporate Member (£200/pa)
- ✓ Discounted events
- ✓ Representation
- ✓ Profile on website
- ✓ Access to resources

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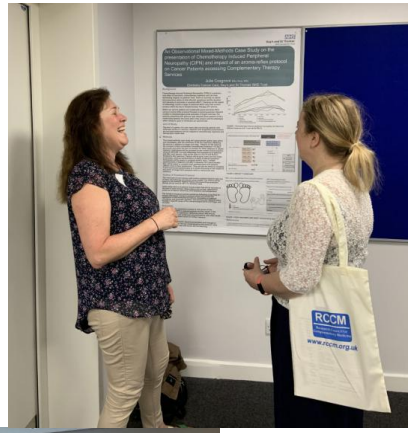
Annual conference

- Thursday 24th September
- Online with local hubs encouraged
- Theme: **Supporting clinical practice through evidence**

https://rccm.org.uk/news-and-events/events/rccm-conference-2026/



EVIDENCE BASED ACUPUNCTURE

Meaningful Measures

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Recommended reading

- MRC Complex interventions guidance
- CAM and trial design:
  - Mason, S., et al. (2002). "Evaluating complementary medicine: methodological challenges of randomised controlled trials." BMJ 325(7368): 832-834.
  - Verhoef, M. J., et al. (2005). "Complementary and alternative medicine whole systems research: Beyond identification of inadequacies of the RCT." Complementary therapies in medicine 13(3): 206-212.
- Feasibility studies
  - Eldridge, S. M., et al. (2016). "Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework." PLoS ONE 11(3): e0150205.
- Pragmatic trials
  - Macpherson, H. (2004). "Pragmatic clinical trials." Complementary therapies in medicine 12(2-3): 136-140.
- Research methods in health by Ann Bowling

- https://www.bbc.co.uk/programmes/m0004l7k

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