

Evidence-based Homeopathy?

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Homeopathy: A popular alternative

- Homeopathy is the most frequently used form of CAM in 5 out of 14 surveyed countries in Europe
- 1 of the 3 most frequently used in 11 out of 14 surveyed countries (NOU 1998)
- Between one quarter and one fifth of all EU citizens use homeopathic medicines (EU commission statement, 1997)



Homeopathy under attack

- As the popularity of homeopathy increases so does the number and intensity of attacks
- There have been many highly publicised objections in the UK media over the past few years.



The Lancet

- Are the clinical effects of homeopathy placebo effects?
- Shang et al
- Lancet 2005;366 (9487):726-733



Evidence Based Medicine: Implications for homeopathy

- The call for an evidence base is not limited to allopathic medicine
- There is tangible pressure on all forms of CAM to provide the kind of evidence that is deemed of high value from randomised controlled trials and reviews of these trials.



EBM: A paradigm shift?

- Proponents of EBM have described it as a 'paradigm shift' that will change medical practice in the years ahead (Guyatt et al 2002)
- Physicians who violate its precepts should ultimately face licence suspension (Muney, 2002)



Others are more critical:

- There is no evidence that EBM provides better care. It is simply following its own political agenda (Goodman, 1999)
- EBM emphasises exclusively the *science* of medicine whilst denying completely the *art* of medical practice (Miettinen, 2001)



What evidence do we have?

1. Experimental research
Efficacy of ultra high dilutions in vitro or in vivo
2. Basic Research
Mechanism of action – how does it work?
3. Clinical Research
Pathogenic trials
Therapeutic trials
Systematic reviews



1. Experimental research

Efficacy of ultra high dilutions in vitro or in vivo

“numerous effects and anomalies have been reported. However no single model has been sufficiently widely replicated”

(Walach et al Research on Homeopathy: state of the art. JACM 2005:11 (5):813-829



2. Basic Research

Plausible theory of the mechanism of action

“encouraging results but again, series of independent replications are missing”

(Walach et al Research on Homeopathy: state of the art. JACM 2005:11 (5):813-829



3. Clinical Research

- Pathogenetic trials (provings)
- Therapeutic trials

“ of 200 reports on clinical trials, few series have been conducted for single conditions.

Some series document clinically useful effects and differences against placebo and some series do not.

Observational research documents consistently strong therapeutic effects and sustained satisfaction in patients”

(Walach et al Research on Homeopathy: state of the art. JACM 2005:11 (5):813-829



Clinical trials in homeopathy

- Started in 1821 and still continuing
- 300+ clinical trials between 1821 - 1998
 - Open observation
 - Case Series
 - Pragmatic comparison
 - Explanatory trial
 - Placebo controlled trials (1st one 1829)



- Historically the CAM research community have attempted to address the call for evidence
- Many have undertaken the challenge to provide the holy grail, gold standard RCT research that the EBM movement demands



- Experience of this has taught us many important lessons including the following 2



Lesson 1

- That homeopathy, as a whole person treatment, does not lend itself well to testing through the placebo-controlled randomised trial
- Many researchers have begun to look for alternative methodologies that are more suited to researching this complex intervention (Weatherley-Jones et al,2004)



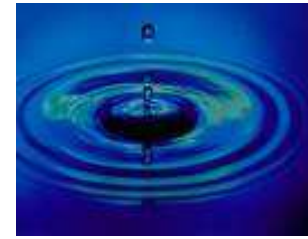
Lesson 2

Even when trials have produced positive results they are dismissed as flukes, or subject to researcher bias



Example

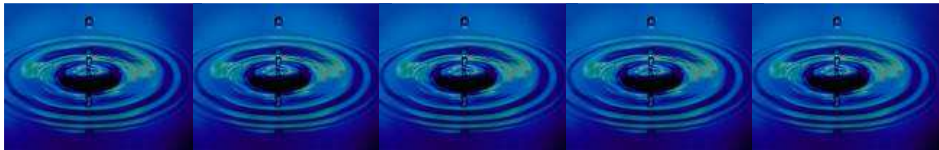
- David Taylor Reilly et al. – Repeated trials with hay fever, asthma and perennial rhinitis that demonstrated a significant difference between the placebo and homeopathic groups
- (Reilly et al, 1986; Reilly et al 1994; Taylor et al, 2000)



Paradigm clash

The high dilution problem

- Not surprising that homeopathy is accused of being no more than placebo
- A completely logical conclusion from the perspective of a person who thinks and works within the current prevailing scientific paradigm.



- Positive results from placebo-controlled trials of homeopathy are doubted because critics claim that remedies are composed of nothing more than water.
- *To accept that homeopathic remedies have an effect would entail revision of much of our basic scientific conception of chemistry and the body.*
- (Sehon & Stanley, 2003)

- The history of science tells us that there have always been things that could not be explained according to currently held scientific opinion



Thomas Kuhn termed these *anomalies* as they cannot be explained within the framework of current scientific opinion

Homeopathy might be considered an example of an anomaly.



Homeopathy: Public enemy?

- It is normal for people who try to work with these anomalies to be marginalised
- The emergence of a new paradigm is painful for those with vested interests in the existing paradigm



Until we have a reasonable explanation for mechanism of action of high dilutions it will not matter how many positive trials there are



So what can we do? What are we doing?

- Research does not have to be focused upon the *efficacy* of an intervention
- Much of allopathic medicine is not evidence-based
- The majority of research into allopathic clinical procedures is focused upon how to *improve* practice rather than trying to *prove* efficacy



Political agenda

- How does the intervention compare with existing treatment options?
- Is it cost effective?
- Is it safe?
- Do patients want it?
- Can we offer it within the existing healthcare framework?



Improving practice

- The profession needs to find ways of assessing practice that are sympathetic to and reflective of the way homeopaths work
- There is very little existing research into homeopathy as practised by the majority of practitioners and experienced by their patients



A practical example: UK homeopaths service evaluation

To gather basic data about:

- Types of conditions & symptoms for which patients are seeking homeopathic treatment
- Patients' perceptions of the benefits received from treatment

Simple study

Volunteer homeopaths collected information from patients from the first appointment using:

- the outcome measure MYMOP2 (Measure Yourself Medical Outcome Profile Paterson 1996)
- an additional form designed to collect data about homeopaths' perceptions of the case and their prescriptions

MYMOP2

- Patient chooses up to 2 symptoms
- Activity limited by symptoms
- General well being
- Grades on a 7 point Likert scale
- Duration of symptoms
- Medication status and importance of reducing or avoiding medication

• Choose one or two symptoms (physical or mental) which bother you the most. Write them on the lines. Now consider how bad each symptom is, over the last week, and score it by circling your chosen number.

• **SYMPTOM 1:**0 1 2 3 4 5 6
As good as it As bad as it
could be could be

• **SYMPTOM 2:**0 1 2 3 4 5 6
As good as As bad as it
could be could be

• Now choose one activity (physical, social or mental) that is important to you, and that your problem makes difficult or prevents you doing. Score how bad it has been in the last week.

• **ACTIVITY:**0 1 2 3 4 5 6
As good as it As bad as it
 could be could be

• Lastly how would you rate your general **feeling of wellbeing** during the last week?

0 1 2 3 4 5 6
 As good as it As bad as it
 could be could be

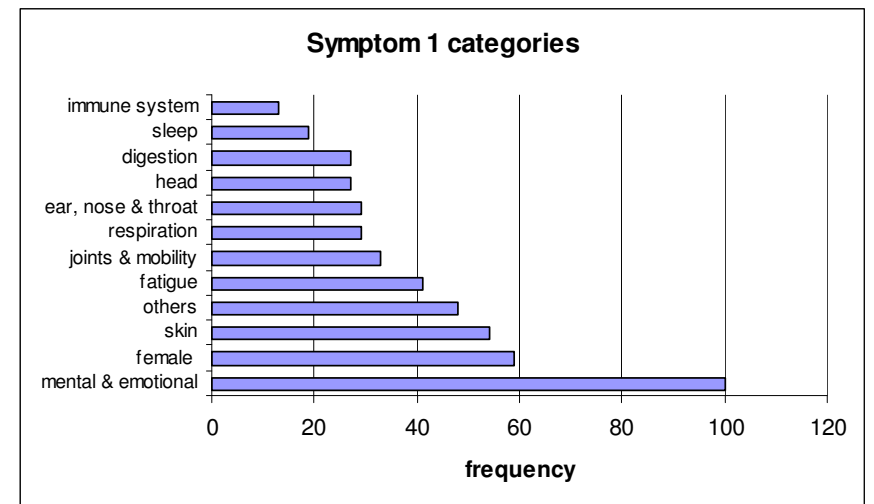
MYMOP2 SCALE

0 1 2 3 4 5 6
 As good as it As bad as it
 could be could be

RESULTS

- 482 patients, 1419 consultations
- Follow up data for 86% of patients
- 79% Female, 21% Male
- 44% 40 – 59 years old

RESULTS - Symptoms



RESULTS

- 82.7% of patients reported a positive improvement in symptom 1
- 63.5% expressed an improvement of 2 points or above.
- 10.2% reported no change
- 7% reported a worsening of symptoms; no patients experienced a worsening above 3 MYMOP points

RESULTS

- Change in primary symptom – mean improvement of 2.26 (0.8 suggested to indicate clinically significant improvement Guyatt 1998)
- MYMOP Profile score change – mean improvement of 1.9

Implications

- Generated a lot of valuable data about:
 - the conditions for which patients consult homeopaths
 - the benefit they receive from homeopathic treatment
- Results show possible rich seams for future homeopathy research - e.g. mental & emotional pathology



Next stage

- Survey of 200 homeopaths asking for their experience and opinions about treating people with a wide range of mental health concerns
- Broad survey using International Classification of Diseases (ICD) codes to find out more precisely why people are visiting homeopaths
- Safety study



Pilot safety survey

(Clare Relton)

Research question

- What is the type and frequency of adverse event after homeopathic treatment?
- What are the other risks associated with homeopathic treatment?
 - Delayed or missed diagnosis as a result of homeopathic treatment
 - Premature stopping of other medication or treatment on the advice of the homeopath



Pilot safety survey

Research Methods

- 40 homeopaths randomly selected
- Baseline questionnaire
 - Consent
 - Duration of condition
 - Other medication/ consultations
 - MYMOP score
 - Rx



Pilot safety survey

- Six week questionnaire
 - MYMOP score
 - Cause of change in score
 - Well-being
 - Other consultations
 - Medication
 - Homeopath advice
 - Adverse effects
 - Outcome of adverse effect
 - Cause of adverse effect
 - Discuss adverse effect



Summary

- Homeopathy is increasing in popularity
- As popularity increases so do attacks
- EBM calls for 'scientific evidence'
- But orthodox methods are not suitable for researching a complex intervention
- We cannot *prove* that homeopathy works through clinical trials
- But we can seek to improve our practice through research
- We can also address the political agenda