

Evidence for CAM Interventions: In the eye of the beholder?



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Presentation Outline

- Examples: What is the evidence?
- What is Evidence?
 - Colloquial
 - Scientific
- Use of evidence in decision-making
 - Patients
 - Medicine
- A new perspective: CAM interventions as whole systems
- How should we study whether an intervention works?
- Discussion

Setting the Stage

Examples: What is the evidence?



Increasing well-being in HIV patients (1)*

Objective

- Assessing the effectiveness of a residential yogic breathing and meditation program on improving well-being for individuals living with HIV/AIDS

Methods

- RCT: Two randomized groups
- Outcomes: Mental Health Index, MOS-HIV health survey, Daily Stress Inventory
- Qualitative Interviews (perceptions of benefit of the program)

* Brazier, Mulkins, Verhoef, AJHP 2006;20:192-195

Increasing well-being in HIV patients (2)


Trial Results

- MHI: significant effect after one week, not at 6/12 weeks
- MOS: significant effect after one week (3 subscales only), not after 6/12 week
- DSI: Treatment group participants identified significantly more stressors and greater impact of the stressors on their life at each time

Increasing well-being in HIV patients (3)

Interview data

- Participants described a personal growth process (a new way of living): 'Living began to feel more meaningful and conscious'. It included
 - Engaging in life in new ways
 - Being 'okay'
 - Living positive
- However, positive changes were not always comfortable and can create pain




What is the evidence?

→ The intervention does not work, as the RCT does not show a difference

OR:


→ The intervention works, as the participants 'felt' it worked?



Increasing well-being in HIV patients (4)



Interpretation

- The personal growth process did not necessarily display a positive, linear change over time.
- Participants were learning to feel everything, pleasant and unpleasant with greater intensity.
- Participants' emotional reactions to new awareness were not always positive
- Early positive results may be due to nature of the program and high expectations




A Case Study: Sally

- Sally suffers from multiple symptoms and sees a TCM practitioner who prescribes Chinese herbs and provides acupuncture.
- Sally continues to feel better, but is that due to:
 - The acupuncture, the herbs or both?
 - The relationship with the practitioner, the time he takes and the way he explains how he treats both root and branch, her expectations or....??


What is evidence?




Views of evidence*


- Colloquial (within clinical, management and policy world)
- Scientific evidence (within research community)
 - Context free scientific evidence
 - Context sensitive scientific evidence

* Canadian Health Services Research Foundation, 2005



Colloquial evidence

- “Anything that establishes a fact or gives reason for believing something”
- Those using this type of evidence usually draw on multiple sources and define evidence broadly.




Assessing the role of evidence in patients' evaluation of complementary therapies*

- Qualitative study of cancer patients assessing
 - Type of information patients use
 - What types of information are accepted as evidence
 - Explore the role of scientific evidence in decision-making



*Verhoef, Mulkins, Carlson, Hilsden, Kania, 2007



Results

- In their own context patients will seek a wide range of sources of evidence of which scientific evidence is only part
- Choice of sources depended on experience with CAM use and stage of the disease




For example...

- New CAM users tended to value scientific evidence more than experienced users. They looked for credible sources and consistency of information
- Experienced CAM users considered CAM as part of their wellness regimen and believed strongly in CAM's positive effects. They were more likely to follow personal experience and their gut feelings



and...

- Late stage cancer patients saw CAM as a strategy to maintain hope, to gain control and to extend life. They were willing to try anything that sounded promising. For this group, risks associated with CAM treatments were usually not an important factor. They valued magazines, television programs and testimonials as evidence sources.



Sources of evidence identified by cancer patients...



1. Anecdotal evidence

- Learning about the CAM experiences of another person in a similar situation to them. A description of a specific example. Living proof.
- "I just kind of figured it would work well because it was a suggestion that I had heard from so many other people. A woman that I used to work with in the dry cleaners, she ended up getting cancer as well and she told me that her doctor and everyone had suggested the pot and that it really helped her through it."



2. Expert Opinion

- Advice/insight from conventional health care practitioners including physician, nurse and pharmacist.
- "I find that the pharmacist is an excellent source of information about CAM and they don't hesitate one minute. When they don't know the answer, they will go and look it up. They know."



3. Gut Feeling

- Following one's intuition. The 'right' thing to do. Results from own observations and experience.
- "I haven't seen evidence because I am not a researcher. I go by my intuition and gut feeling. It's my personal feel, from what I intuitively feel. I let it run through my head and if I feel comfortable with it, I go for it."



4. Popular Literature

- Includes articles in community newspapers, general books on CAM, information compiled by CAM Centers, Internet, Health food store
- "I have perused the internet. I get a monthly newsletter which is part of Prostate Calgary's publication. They also have a few magazines that I have been using for information on CAM. I do trust publications like this. It is what is deemed trusted information."



5. Trial & Error

- Trying a therapy and then observing the body for any physiological response.
- "After I started CAM, it was just trial and error. If it doesn't work, don't do it. If it works, keep doing it, right? For taking the pills to help me sleep or for the pot smoking and to have your body feel better, the pot was a lot better than the pills. So benefit-wise, it makes my body feel a lot better, helps me sleep at night, stops the night sweats, stops the aches and pains".



6. Testimonials


- Advertising messages that reflects opinions, beliefs, findings or experiences of a person other than the sponsoring advertiser. The messages are often vague statements or exaggerated claims by endorsers who are not easily identifiable.
- "I saw a commercial on the TV a couple of weeks ago where they had people singing the praises of this beverage which gets rid of any cancer and arthritis you might have. So I thought, what the heck and ordered a bottle."



7. Scientific Evidence

- Peer-reviewed journals and scientific reports. Reference to empirical analysis or to results of scientific experiments or investigations.
- "I will go to the library at the University and I will do searches in the medical journals for scientific trials with PC SPES or Saw Palmetto. You know with research that is done in an academic lab, that there is some degree of rigor to it. It is good reliable information."






Scientific evidence (1)

- Narrower and more restricted than colloquial evidence.
- Refers to “information generated through a prescribed set of processes and procedures recognized as scientific”.




* CHSRF, 2005




Randomized Trials (double blind – placebo controlled): The “Gold Standard”

- Intervention prior to post test
- Control group (time threats)
- Randomization (group threats)
- Blinding (contamination)
- Placebo control (excluding non-specific effects)



Use of RCTs results in scientific evidence that is

- Explicit
 - Systematic
 - Replicable
- Scientific evidence is determined through methodological testing rather than relevance (as colloquial evidence).




“Best” evidence is based on the Evidence “Hierarchy”

- Meta-analysis of randomized controlled trials
- Randomized controlled trials
- Non-randomized trials
- Observational studies
- Case series, case studies, qualitative research, anecdotes, expert opinion



However..

1. RCTs have major limitations with respect to CAM interventions
2. A broader description of EBM opens the door to a deeper understanding of evidence



1. Limitations of Randomized Controlled Trials

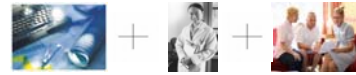
- Inappropriate to standardize many CAM interventions
- Difficulty finding a placebo
- Randomization is problematic
- Blinding usually impossible
- Inability to address the unique healing theory of intervention (e.g., diagnosis, patient provider relationship, range of outcomes)
- Interactions/synergy between components of the intervention cannot be addressed

Also:

- RCTs are about average patients
- The individual patient 'disappears' in RCTs:
 - exceptional patients
 - the impact of patients' choices, such as choice to be healed
- Potential for learning about complex intervention is minimal

2. Definition of EBM is broader than scientific evidence alone

- Evidence-based medicine is the integration of
 - best research evidence with
 - clinical expertise and
 - patient values (Sackett, 2000)



Clinical expertise/professional judgment, for example:

A health care provider may

- have detailed knowledge of a specific patient over a long time period
- have experience with a socio-demographic segment and with a specific socio-cultural context that leads her to recommend a specific intervention for this patient
- have knowledge of the availability and competence of CAM practitioners for a given therapy



Patient values, for example:

The patient may

- for example, know what treatments or interventions have been helpful in the past.
- be able to detect intuitively what sort of interventions are likely to be helpful.
- have strong treatment preferences based upon personal beliefs, values or ideology, and *ceteris paribus*, treatments that are consistent with patient preferences will tend to be more effective.



Ideally, according to this perspective

- Patients make treatment decisions that are informed by evidence, meet their values, beliefs and expectations and are supported by physicians' clinical judgment.



Scientific evidence - Two Views

- Science reveals universal truths – identified closely with Evidence Based Medicine. This provides a view of what might be achieved under ideal circumstances and creates *context-free guidance*
- Science has little meaning or importance for decision-making unless it is adapted to the specific circumstances. Such *context sensitive evidence* is embedded more strongly in social sciences.

An alternative to the Evidence Hierarchy: The Evidence House*

- In an "evidence house", different types of information and purposes are equally recognized but "housed" in different rooms.
- Because different types of questions are best answered by different types of evidence, one room could be for RCT's and systematic reviews, another for qualitative case reports, another for epidemiological outcomes and so on.

* Jonas, W.B. The Evidence House: How to build an inclusive base for complementary medicine. WJM 2001: 175

The Evidence House

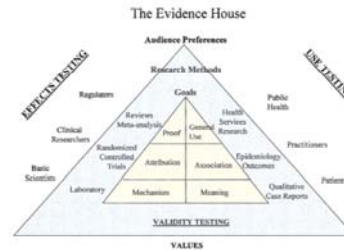


Figure 2 The evidence house affords greater accessibility to important information

A new perspective: CAM interventions as Whole Systems



What is a whole system? (1)

- A whole systems view would include all the factors involved and examine how they relate to each other and how they work as a whole. To deal with a whole system we can't leave anything out as irrelevant.
- Examples are naturopathy, TCM, Ayurveda, chiropractic..



Components of whole (therapeutic) systems include:

- Underlying assumptions/logic or therapeutic theory
- Process of the intervention
- Context
- Wide range of outcomes
- Interactions
- Meaning of the intervention



What is a whole system? (2)

- Whole systems are dynamic, they change, they move, they develop. Frozen pictures of how things are *supposed* to be might do us no good, we need to deal with the live systems, whichever surprising directions that might take us in.

How should we evaluate whole systems?

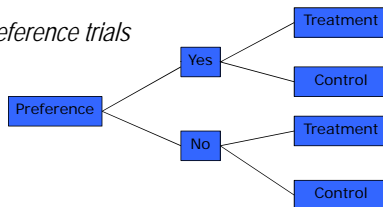


A Possible solution (1) : Modifications of RCTs

- *Pragmatic Trials* to assess how effective an intervention is in routine, everyday practice
- No standardization required
- Focus on effectiveness, versus efficacy

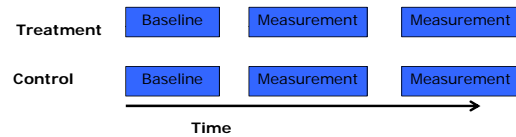
A Possible Solution (2) : Modifications of RCTs

- *Preference trials*



A Possible Solution (3):

Long-term, controlled observational studies




Possible **Better** solution: Combining Qualitative Methods and Quantitative Research

- Qualitative research - the investigation of phenomena, typically in an in-depth and holistic fashion, through the collection of rich narrative materials using a flexible research design.
- Quantitative research - the investigation of phenomena that lend themselves to precise measurement and quantification, often involving a highly controlled research design

Possible **Best** Solution: Whole Systems Research – A Mixed Methods Program

A process of:


1. Establishing available information/theory of the intervention
2. Careful exploration and description of all aspects of the intervention and desired outcomes
3. Describing process and context of the intervention
4. Identifying patterns of treatment/care
5. Developing testable explanations (theoretical models)
6. Testing these explanations



Early Phase Research*: Stages 1-4


- Usually small number of participants, large number of variables (minimize exclusion criteria)
- Optional use of control group: exploratory trials
- Describe treatment environment
- Explore treatment process
- Combining qualitative and quantitative research

* Aickin, Early Phase Research, 2007)



Early Phase Research


- To determine:
 - Is patient group appropriate for therapy?
 - Are they willing to be recruited?
 - Are outcome measures appropriate and reliable?
 - Are there multiple versions of a therapy?
 - Is placebo really placebo? Non-specific effects?
 - What is the impact depending on who delivers the intervention?
 - Timing of measurements



Early Phase Research


Ideally results in

- Identifying emerging patterns/classifications of treatment/care
- Making comparisons between the results and the existing literature or existing theories (from various disciplines)




Developing Testable Explanations: Stage 5

- Results will allow the formulation of hypotheses that address under which circumstances and for whom the intervention works.
- This is the most difficult CRUCIAL phase. It requires finding the balance between 'too much detail' and 'data that lack applicability and relevance'



Testing these Explanations: Stage 6

- Testing for effectiveness through controlled observational studies or variations of RCTs (pragmatic trials, preference trials, N-of-1 trials)
- Assessing a broad range of outcomes
- Combining with qualitative research to assess systems relationships and further refine theory



Discussion (1)

- Evidence is multidimensional
- In order to create evidence we need to take into account the person, the intervention and the context
- To some degree evidence is in the eye of the beholder, therefore we need to carefully examine what the best evidence-based approach is



Discussion (2)

- How can CAM practitioners find/gather evidence?
- How do we work together to create "best" evidence that does justice to the unique philosophy underlying the system?

