Sham and placebo in manual medicine research: What works?

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Is manual medicine effect all placebo?

What is Placebo? (latin for "I shall please")

The placebo effect is:
• measurable, observable, or felt improvement in health
• not attributable to treatment
• a medication / treatment believed inert or innocuous
• often considered a mind-body relationship

Leuchter & Witte: Am J of Psychiatry 2002

n = 26 Placebo
n = 25 Antidepressant

Depression

Percent Responding

0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

Hamilton Depression Scale < 10

Antidep Placebo

Prefrontal Lobe:
• Antidepressant: Decreased
• Placebo: Increased

Pet Scan Brain activity

Leuchter & Witte: Am J of Psychiatry 2002
Wager et al, Science 2004

From Substantia nigra –
Respond maximally to noxious, mechanical and thermal cutaneous stimuli!

“These findings show us that there are different pathways to improvement for people suffering from depression,” Leuchter adds. “Medications are effective, but there may be other ways to help people get better!”
Placebo analgesia related to decreased brain activity in pain-sensitive brain regions, including the thalamus, insula, and anterior cingulate cortex, and was associated with increased activity during anticipation of pain in the prefrontal cortex. (Wager et al 2004)

Is manual medicine effect all placebo?

Effects are “hands-on” plus … but, what is the “active agent”?

Manual Placebo / Sham, multifaceted issues

Selection of a good placebo / sham requires the same insights as those of good magicians!

….the best made plans!

Placebo Selection:

- What is the condition?
  - Heterogeneity / Homogeneity
  - Natural / Treatment history
- What is the research question?
  - What are the characteristics of treatment
    - Type of massage
    - Dosage
    - Duration
    - Threshold
    - Physical characteristics
Placebo Selection:
- Must have
  - What is the condition?
    - Degenerative Induced

Placebo Selection:
- Must have
  - Natural / Treatment history

Back Pain Presence
Low back natural history with relapses.
Average 1 - 3 in 12 months.

Selecting Outcomes: what to measure?
- Depends on the suspect mechanism of action.
  - Mechanical
  - Reflexive
  - Neurologic
  - Psychologic

Initial 1 week 12 weeks 26 weeks

Pain
Back Pain Presence

Ideal Tx Hx Ineffective Tx Hx

Weekly Dosage

Physical characteristics
- Friction
- Rhythm
- Rate
- Pressure
- Amplitude
- Concentration
- Direction

Tissue Load

Deployed Load

Direction

ROM
Selecting Outcomes: what to measure?
- Depends on the suspect mechanism of action.
- & on Intended effects
  - Reduce pain
  - Reduce adhesions
  - Promote flexibility
  - Promote Sedation
  - Mobilize fluids
  - Muscular relaxation
  - Vasodilation

Extrafusal Muscle spindle
Intrafusal

The Evidence of Skill:
- It’s easy to tell a technically poor surgical performance….
- Can we tell about good?
- About manual treatment?

The Evidence of Skill:
- Evidence on the “Gestalt” for manual methods
  - Fattaposta et al 1996 - rehearsal alters neuromotor control architecture.

The Evidence of Skill:
- Ten year experience of measurements.
  - Triano and Schultz 1994
  - Cervical SMT control factors
  - Triano et al 1995
  - Experienced patients and operators strongly agree on performance.
  - Rogers 2000
  - Biomechanical measures are valid and responsive to change.
  - Triano and Schultz 1997
  - Procedure / posture control factors
  - Triano 1998
  - Lumbar and cervical transmitted loads
  - Quantitative feedback and rehearsal result in predictable changes.

The Evidence of Skill:
- “I’m an expert, he’s expert, you’re an expert, too!”

Is it generalizable?
The Evidence of Skill:

- Are operators consistent?

Is it generalizable?

The Evidence of Skill:

Impulse Duration

The Evidence of Skill:

Speed

The Evidence of Skill:

Peak Load Amplitude

The Evidence of Skill:

Load / Operator Stature

Comparability of physician – patient contact time.

- SMT Group: 3 sessions per week / 15 minutes
- SMT mimic: 3 sessions per week / 15 minutes
- Back school: 3 sessions per week / 15 minutes
Blinding: Investigators, use “Silos”

- Principle Investigator
- Recruiters
- Patient Randomized
- Evaluators
- Outcomes

Blinding: The procedure mimic – sham itself?
- Physician performance training & periodic monitoring

Independent physiologic markers:

- Thoracic Curr.
- Variance

Sham | Treatment

Similarity in patient positioning:

- Open Shoulder - girdle
- Single knee - flex
- Double knee - flex

Summary:

- Measure Target Functions
- Directly
  - The Treatment
  - The Effects
  - Relaxation

Patient Exit Interviews:

Ask them: What treatment did you have?
Summary:

• Clearly define the question.
• Know the characteristics of the test treatment.
• Address psychological factors.
• Train, test and verify.
• Use Independent markers.
• Directly measure treatment and results.
• Exit interviews.

Thankyou.