Ian Appleyard MBAcC

Course Director: Acupuncture
LSBU - Confucius Institute for TCM

Become what you want to be
Warm Needle Acupuncture vs. Needle Acupuncture for Osteoarthritis of the Knee: a Pilot Study
Background rationale

Evidence that acupuncture is effective for chronic pain Vickers et al 2012, 2017

Moxibustion was not used

Acupuncture = zhenjiu 针灸

Acupuncture is a complex intervention

Component efficacy trial
Components of acupuncture

Psychologically mediated constructs
- Time
- Attention
- Credibility
- Expectation
- Belief about acupuncture
  - Theory
  - Advice
  - Illness narrative
  - Symbolic work

Physically mediated variables
- Needles
  - Gauge
  - Length
  - Metal
- Acu-points
  - Number
  - Location
- Stimulation
  - Manual manipulation
  - Electro-acupuncture
- Insertion time
- Depth
- Cupping
- Palpation
- Massage
- Moxibustion
  - Warm needle
  - Direct moxibustion
  - Moxa stick

Generic psychological components

Characteristic psychological components

Physical components
Aim - to develop an RCT protocol to test the hypothesis:

Warm needle acupuncture leads to greater clinical benefits for those with osteoarthritis of the knee than the use of needle acupuncture alone
Components of acupuncture

Psychologically mediated constructs
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Generic psychological components

Characteristic psychological components

Physical components

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Background rationale continued

Test physical component → not purely psychological
  i.e. *not a placebo*

Semi–flexible protocol ≈ Usual practice
  *Osteoarthritis of the knee*

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Objectives of the pilot study

- Test the integrity of the study protocol.
- **Assess the safety** of warm needle acupuncture for OA of the knee
- Assess the **acceptability of warm needle acupuncture** among **UK patients**
- Collect **qualitative data from participants** and staff to support the development of the protocol for an adequately powered RCT
- Provide an initial indication of the effectiveness of warm needle acupuncture compared to needle acupuncture to inform a **sample size calculation** for an adequately powered RCT
METHODS

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Basics

12 treatments in 8 weeks
  • 4 weeks of x 2 treatments/week
  • 4 weeks of x 1 treatments/week

4 Data collection points
  • Baseline week 0
  • Mid point week 4
  • End of treatment week 8
  • Follow-up week 16

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Basics

Outcome measures

• WOMAC® NRS 3.1
• RAND-36 (version 1.0) [SF-36]

Plus

• Question on group allocation (blinding)
• Expectation questions
• Adverse events
• Qualitative interviews

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Blinding procedures:

• Participants
• Acupuncturists
• Outcome assessors

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Become what you want to be
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### Baseline demographic characteristics and pattern differentiation

<table>
<thead>
<tr>
<th>Variable</th>
<th>Warm mean (SD)</th>
<th>Needle mean (SD)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants n</td>
<td>8</td>
<td>6</td>
<td>14</td>
</tr>
<tr>
<td>Women n</td>
<td>6</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>Mean age (SD) years</td>
<td>56.9 (10.3)</td>
<td>51.0 (13.2)</td>
<td>54.4 (12.0)</td>
</tr>
<tr>
<td>Mean duration of pain (SD) years</td>
<td>9.6 (9.6)</td>
<td>11.2 (5.4)</td>
<td>10.3 (8.1)</td>
</tr>
<tr>
<td>Range duration of pain years</td>
<td>1-30</td>
<td>5-21</td>
<td>1-30</td>
</tr>
<tr>
<td>Both knees affected n</td>
<td>6</td>
<td>4</td>
<td>10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bi-syndrome pattern</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cold Bi</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Damp Bi</td>
<td>4</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Cold Damp Bi</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Qi and Blood Stagnation</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>
Do you think you are receiving warm needle acupuncture or needle acupuncture?

Answer options:
- a. Warm needle
- b. Needle acupuncture
- c. Don’t know

Asked twice:
- Mid point - week 4
- End of treatment - week 8

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Blinding Success

• 12/14 thought they were in the warm needle group - at some point
• Needle group had more ‘don’t knows’
• One person said needle acupuncture

Bangs Index

• Blwarm = 0.75 (CI 0.5 - 1)
• Blneedle = -0.33 (CI -0.75 - 0.12)
For future trials - part 1

Qualitative interviews:

• Need to improve the acting skills of those who light the moxa

• May need to use larger, slightly thicker skin guards
WOMAC® NRS 3.1

Warm needle group
Needle group

95% Confidence Intervals

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RAND-36 (v1.0) [SF36]

Mental Health Composite

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Individual Mental Health Composite (MHC)

Warm needle group

Needle acupuncture group

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Individual: WOMAC % change

Warm needle group

WOMAC Total Score Percentage Change

Needle group

50% Improvement responder rate line

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Future trials - part 2

The semi-flexible protocol may not have been appropriate for all participants

Baseline

Experiment/ Warm needle

Control 1/ Warm needle

Mid-point

Control 2/ Unrestricted acupuncture

End of treatment

Follow up

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Personal reflections

Semi-flexible protocols can be difficult to administer

- Conflict of interest desire to give best treatment vs. need to collect data

Hyper vigilant

Outcome measures

- Very subjective, apparent disability did not match score

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Outcome measure issues

• One scale can be limiting - pain or function

• WOMAC - slight confusion ‘sitting or lying’

• RAND V1 - too many ceiling and basement scores for 8 scales

• Sensation 1 hour after treatment - predict success?
Funding

The pilot study was supported by

• British Acupuncture Council Research Grant - BACCRG_2014IA
• Facilities of the Confucius Institute for Tradition Chinese Medicine - London South Bank University
• Moxa supplied at cost by AcuPrime Exeter EX2 8RU

Protocol


The trial is registered at ClinicalTrials.gov Ref: NCT02680912
Any questions?

THANK YOU

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