Southern Cross University

Developing a testable model of the osteopathic intervention in patients with chronic NSLBP using surveys, focus group and patient interviews.

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Outline

- Integrating evidence into practice
- Pragmatic trials
- PhD research narrative
- Proposal for authentic trial method

FRUSTRATION with EBM

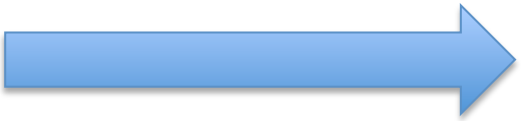
Building the house of evidence

- *develop a complete understanding of what the service entails.*

- *the intervention and outcome measures should be authentic and meaningful to the clinician and their patients.*

PRAXIS

The synthesis of theory and practice, without presuming the primacy of either. Definitions.com

RESEARCH  PRACTICE

PRAXIS

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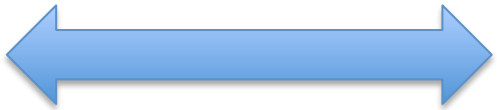
RESEARCH  PRACTICE

Researching practice

- Authenticity

  having the origin supported by unquestionable evidence; verified, reliable, trustworthy. *Dictionary.com*

  – SMT trials?

  – Exercise trials?

  – Massage trials?

  – Combination?

  "OMT is not chiropractic or simple SMT"

  Licciardone et al, Osteopathic manipulative treatment for low back pain: a systematic review and meta-analysis of randomized controlled trials. BMC Musculoskeletal Disorders (2005) 6;43

- Efficacy V Effectiveness

  ➔ Pragmatic trials

Pragmatic clinical trials

- Reflecting real world practice
- "whole practice"
- Pragmatic V explanatory

"how effective an intervention is in everyday practice"

MacPherson, H. (2004) Complementary Therapies in Medicine, 12;136-140.

  - wide inclusion criteria
  - control with credible intervention
  - intention to treat
  - Black Box/protocol

Pragmatic trials

- balance between external validity (generalizability of the results) and internal validity (reliability or accuracy of the results)
- seeks to maximize external validity to ensure that the results can be generalized.
- the danger is that internal validity may be overly compromised in the effort to ensure generalizability.

Godwin et al. Pragmatic controlled clinical trials in primary care: the struggle between external and internal validity *BMC Medical Research Methodology* 2003, 3:28 doi:10.1186/1471-2288-3-28.

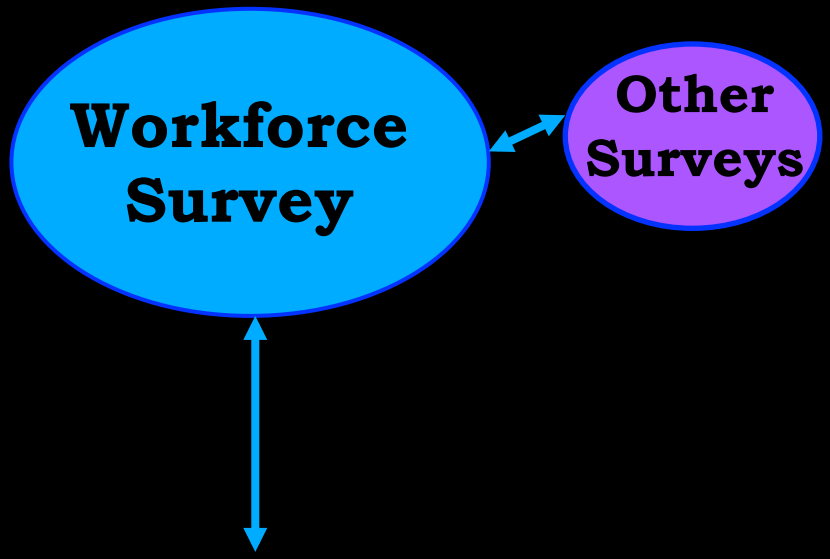
Burning question

- What is the effectiveness of the osteopathic intervention in the most common presenting complaint?

BUT

- What **is** the osteopathic healthcare intervention as practiced?

What is the osteopathic intervention
in the most common presenting conditions ?



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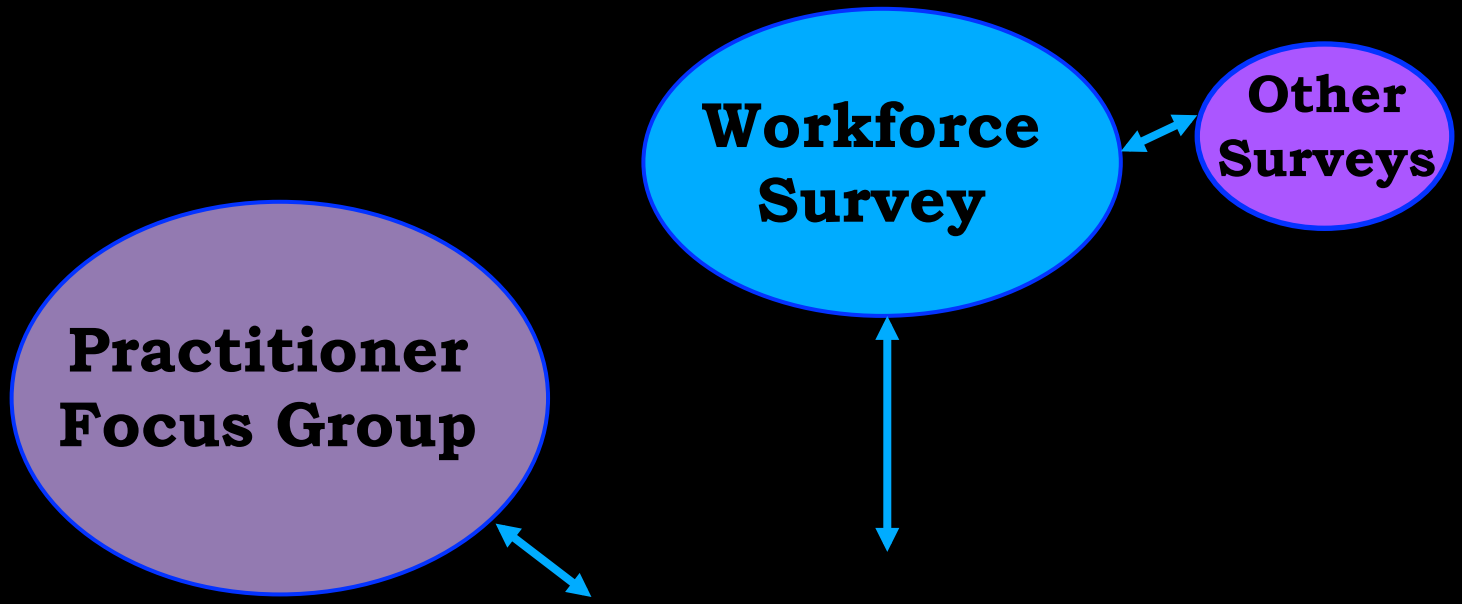

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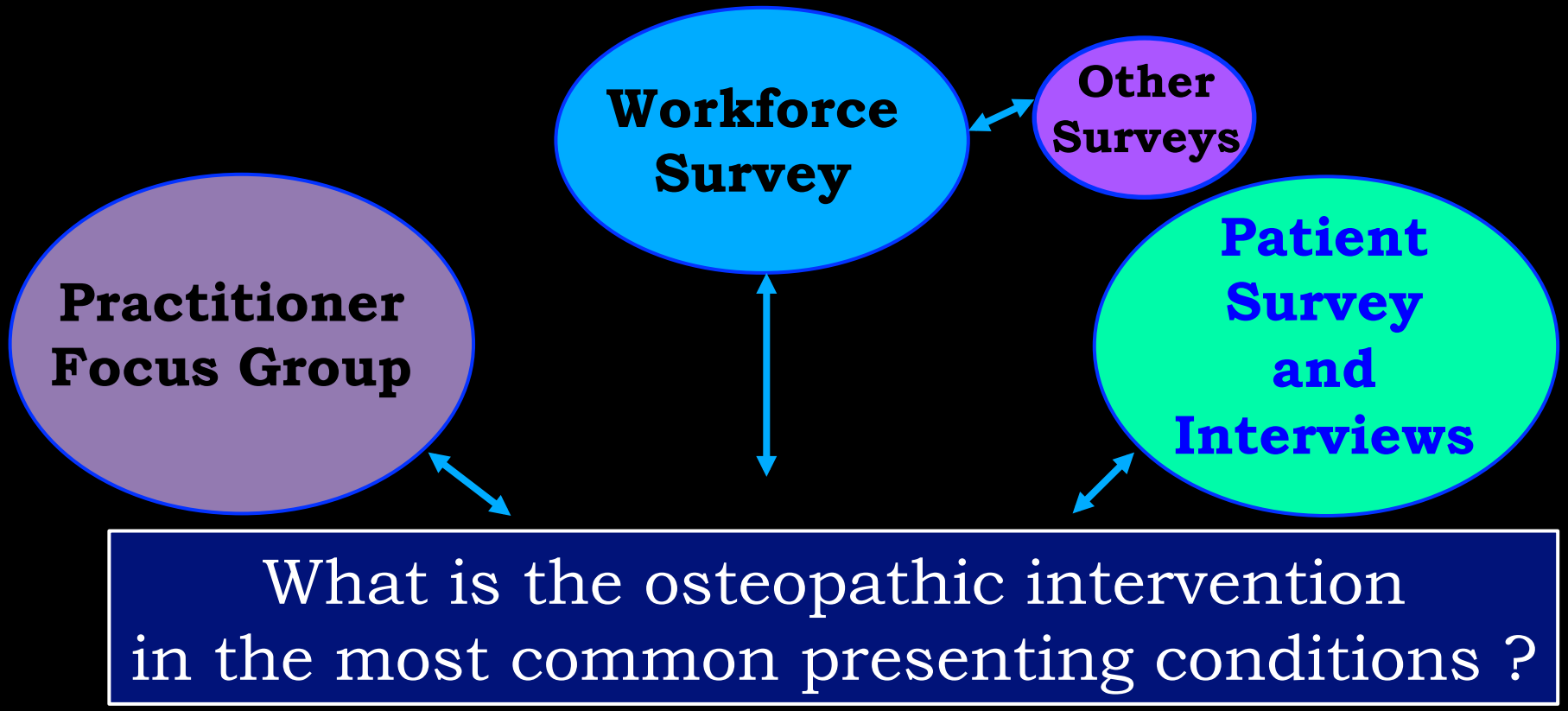

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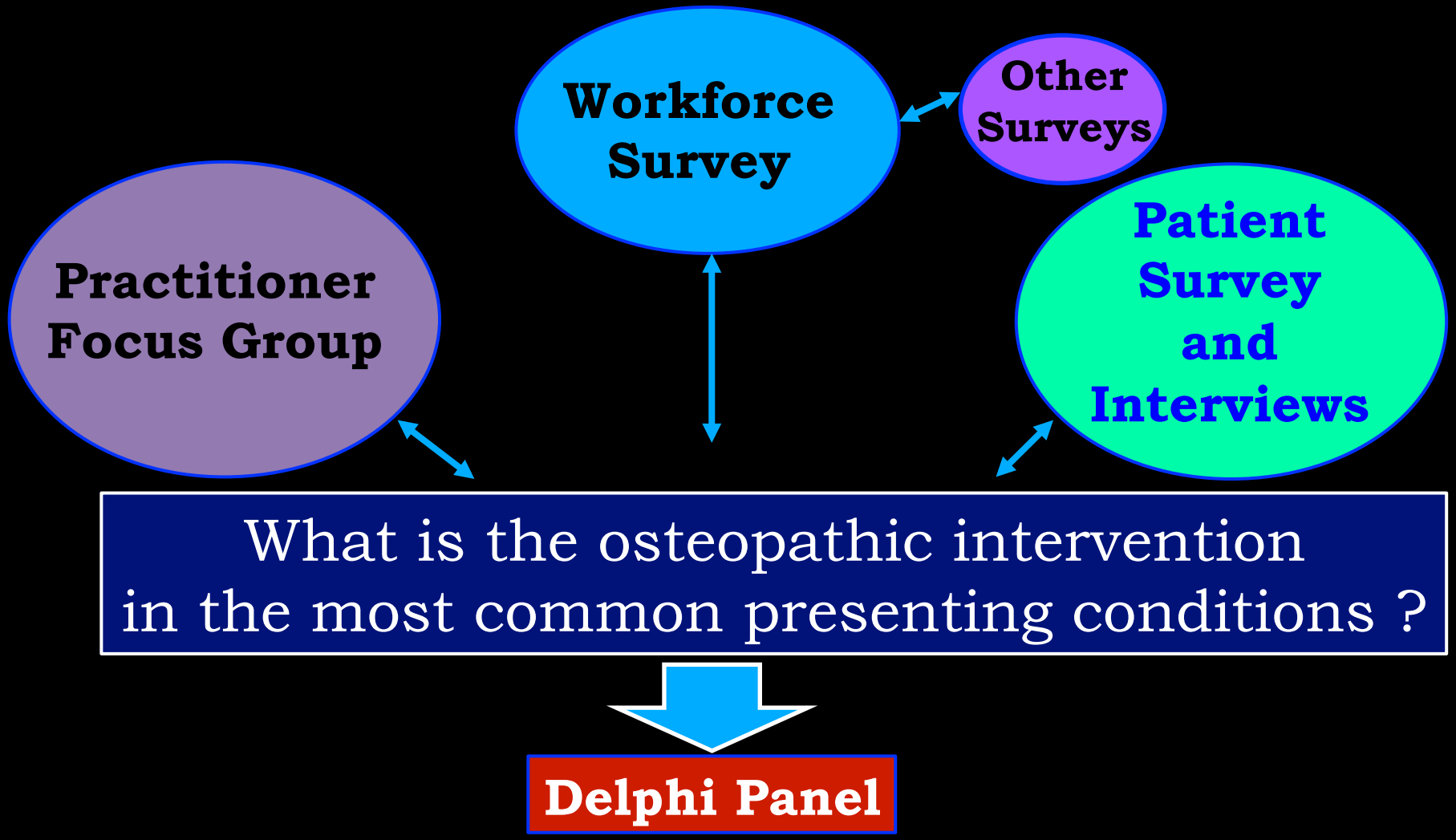
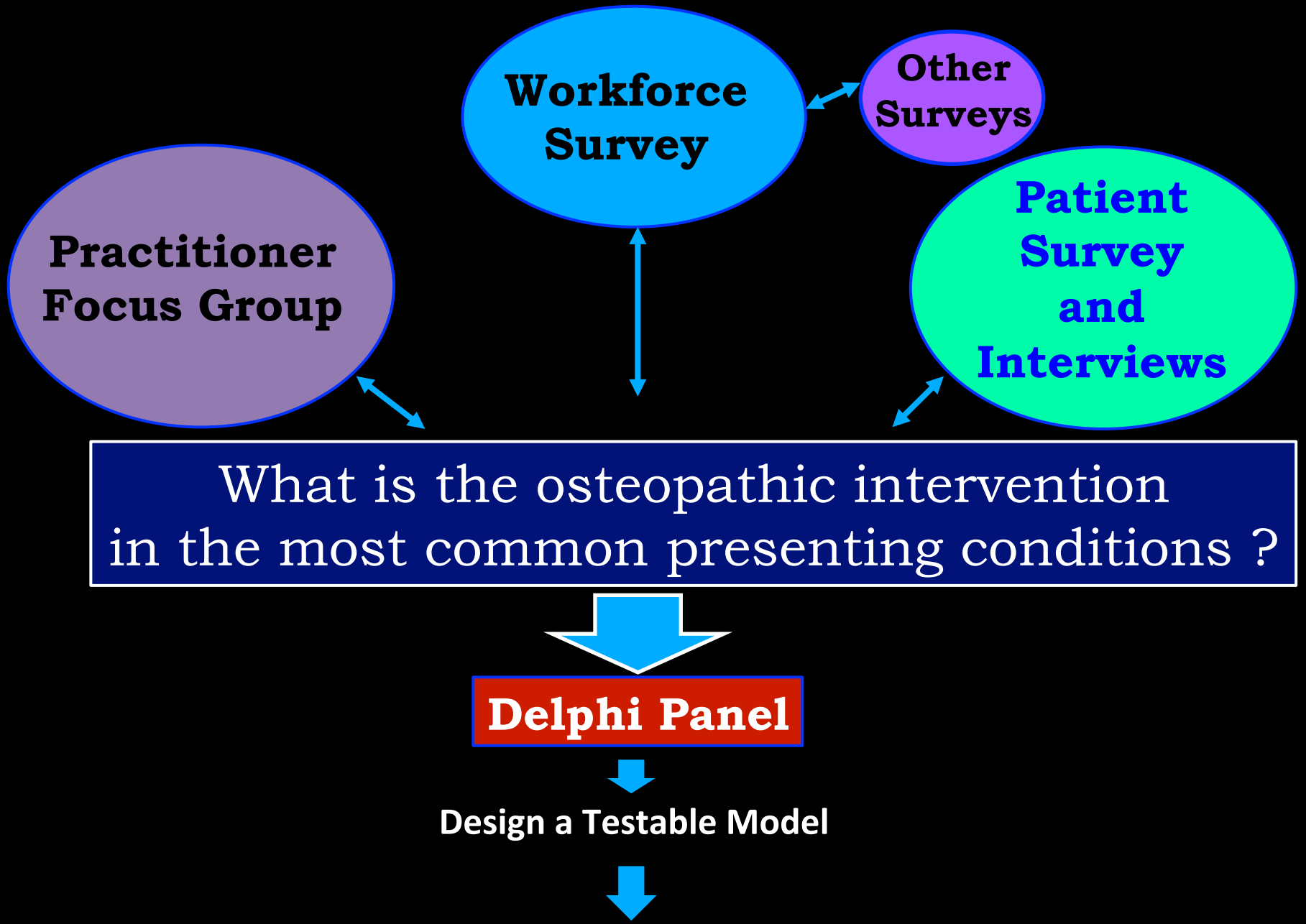

Workforce Survey
Other Surveys
Practitioner Focus Group
Patient Survey and Interviews
What is the osteopathic intervention in the most common presenting conditions ?
Delphi Panel


Workforce Survey
Other Surveys
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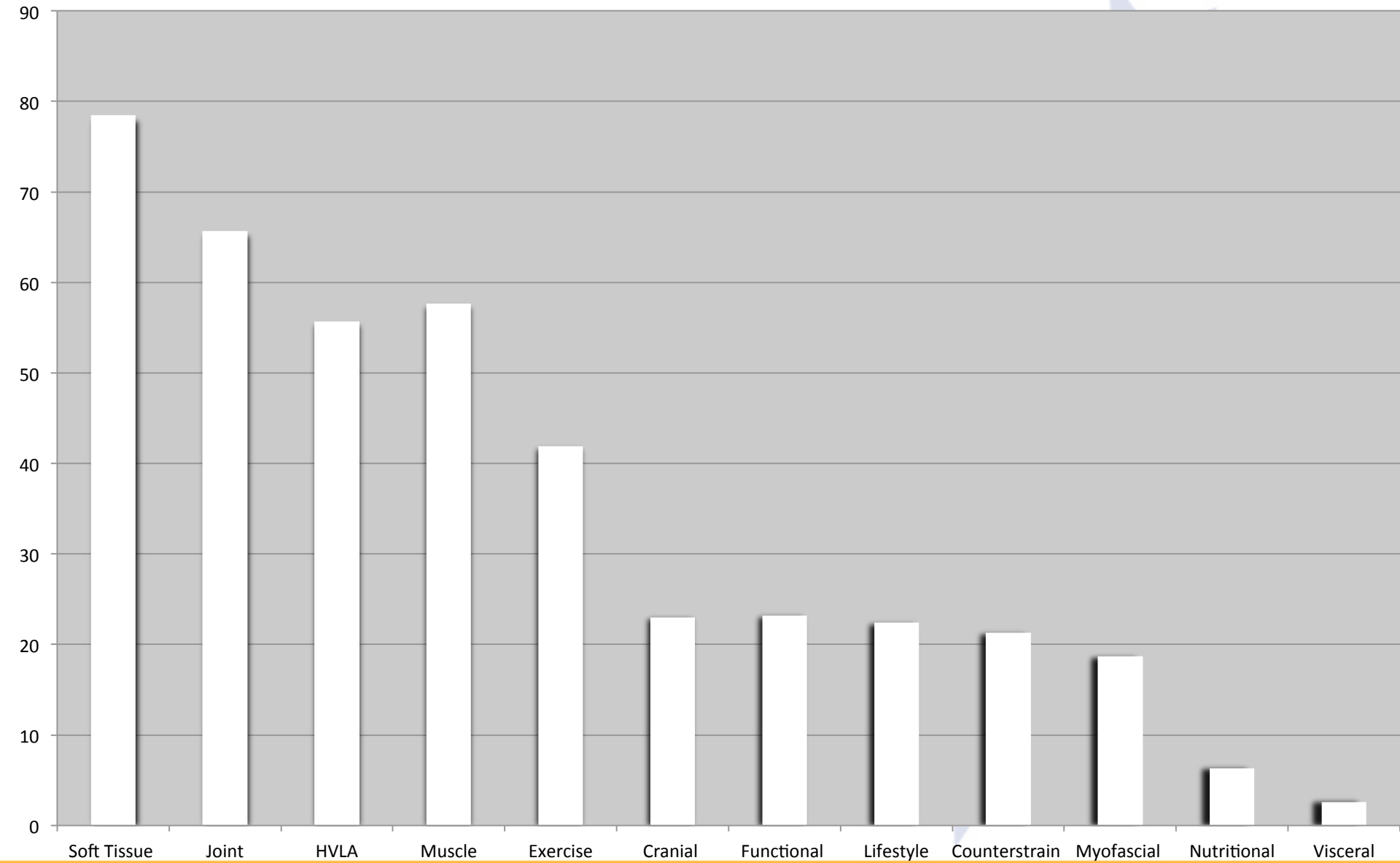
What is the osteopathic intervention in the most common presenting conditions ?
Delphi Panel
Design a Testable Model
Pragmatic Clinical Trial

Workforce survey

Osteopathic Census results

- 52% of members of AOA (then over 70% of registered osteopaths), snapshot of patients
- 2238 patients seen on one day
- 2104 patients had full records of presenting symptoms
- 1001 patients had PS (1,2 or 3) of “pain” in “lumbar spine” and/or “pelvis”
- 537 patients had this PS for longer than 12 weeks

Pain - Low back/pelvis – 12 weeks and over - modality use



Focus Group

Osteopathic Management of CNSLBP

- Email invitation within region
- Osteopathic clinicians
- Opportunistic/purposive sample
- N=7 plus observer/scribe
- Thematic analysis of transcript
- Pictogram and researcher reflections

FOCUS GROUP findings

Definition of chronic non-specific low back pain (CNSLBP)

- Diagnosis of exclusion
- Lack of clarity regarding "*non-specific*" label

Focus Group findings

Prevalence

- Common presentation
- Common as a co-morbidity whatever the presenting complaint

Why osteopathy?

- Tried everything else

Focus group findings

Factors influencing prognosis/management

- Co-morbidity presence and severity
- Age
- Degenerative status
- Occupational aggravators
- Medication use
- Psychosocial stressors
- Insurance claim history
- History of previous treatment
- "Instability"
- Non-compliance with advice

Focus group findings

Approach

- Broad
- How to start when diagnosis is vague
- Co-management is important
- Self management is a major goal
- Individualisation
- Educational

Focus group findings

Psychosocial issues

- Loss of hope
- Told that they have to live with it
- Referral to psychologist considered
- Advice needs to be simple, concise, repetitive
- Expectations

Focus Group

- FG5 re is there a protocol?
- *“look at the patient in totality - osteopathically, for lack of a better term, and individualise their treatment – that’s the protocol”.*

RESULTS – patient survey

- 160 completed surveys were collected
  (Limited sample designed to give an impression and recruit)
- Majority female (58.8%)
- Majority middle aged (67.7% between 40 and 69 yoa)
- Predominantly self-referred (73.3%),
  - 6.8% were referred by their GP
  - 3.7% were attracted to the clinic by an advertisement
- Majority have had more than one condition treated
  - Largest "4 or more conditions" category at 32.3%.
- The current presenting condition
  - 0-4 weeks in 23%
  - over 12 weeks in 66.5%

Return patient survey

Opportunistic in 9 practitioner waiting rooms, n=161
Characteristics of age, gender, condition, stage similar to national

Outcome	Number "yes"	%
Reduced pain	150	94.9
Increased range of motion	127	80.4
Increased flexibility	113	71.5
More able to complete daily tasks	95	60.1
Improved posture	74	46.8
More strength	55	34.8
More energy	44	27.8
More concentration/mental clarity	42	26.6
Improved breathing	26	16.5
Improved digestion	15	9.5

Patient interview results

Purposive from survey with CNSLBP, semi-structured, n=11, phenomenology

Four themes became apparent:

1. patient decision-making
2. patient shared experiences of the osteopathic healthcare consultation
3. tailored patient-centred care
4. therapeutic relationship in healthcare

Patient interview results

Shared experiences

- Comprehensive assessment and review at each session
- Searching for a cause
- Consistently applied manual and adjunctive therapies
- Education about the condition
- Lifestyle advice for self management

Patient interview results

(the osteopath) asks how is it interfering (with life), *then looks at my feet and shoes, how I walk, about the desktop ergonomics, even sexual function and such; so she asks questions and I give her the answers. (PI4)*

Patient interview results

a combination of information, communication, and treatment, a complete package. (PI8)

Patient interview results

Individualised/tailored care

- Encounter is tailored to patient
- Individualised plan is matched to patient
- Goals of plan are patient centred
- Co-management

Patient interview results

(after assessment) *…he might repeat some of the things he's done before … or then he might expand upon his repertoire and do a whole lot of different things. (PI3)*

When a certain technique's not working, osteopaths are happy to look elsewhere and try new things. (P10)

Patient interview results

Patient centred outcome goals

- *physical stress relief … which would translate into just personal wellbeing. (PI1)*
- *maintain performance…. days off work means you go backwards financially (PI1)*
- *improved breathing (PI7)*
- *it's definitely put my energy and my strength up,– also sleeping…. I'll sleep right through again (PI2)*
- *It was like taking off a heavy coat…….. I'd gone from nothing to two kilometres* (of walking) (PI8)

Delphi panel

- Invited group of researchers
  - US, Canada, UK, Australia
  - Senior professors with clinical trial experience
  - Academics with clinical trial statistical expertise
  - Osteopathic clinicians with research experience
- Emailed document with discussion circulated
- Two rounds (so far)
- Level of agreement = 80%

Delphi results

Study Condition

- NSLBP – difficult definition
- Severity
- Radiating pain?
- Exclude
  - Previous knowledge of OI (cost/numbers)
  - Co-morbidities that confound
- CNSLBP "that's can be treated by OI" – do we know what can be?

Delphi results

Design

- Parallel
- Keep simple
- Cost
- Sub grouping pre or post-hoc

Delphi results

Control

- Usual or best care?
  - Inconsistent internationally
  - Exclude or randomise GP/physician referral to PT/ SMT?
- Therapeutic relationship?

Delphi results

Intervention

- Establish from preceding research
- Expert group decide on package based on research findings?

Delphi results

Outcome measures

- Pain VAS
- Roland Morris Disability Questionnaire
- Patient Reported Outcome Measures
- Cost effectiveness
- Patient Global Impression (Improvement)

Delphi results

Blinding

- Assessor
- Analyst/statistician

Delphi results

Statistical analysis

- Intention To Treat
- Report effect sizes (Cochrane Back Review Group) and minimally important changes

Delphi results

Follow up

- 3, 6, 12, 26 weeks
- 12 months?
- Withdrawals

SUMMARY

- Significant progress towards a pragmatic trial design based on research of the intervention
- Triangulated data demonstrates commonalities of osteopathic healthcare
- Plan to pilot this design and run a collaborative trial

THANK YOU OIA