Whole Systems Research: Researching the Way We Practice

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Whole Systems Research in Health Care: A Scoping Review

Abstract

Objectives: This scoping review evaluates two decades of methodological advancements made by "whole systems researchers" to improve the quality and translation of outcomes from complex clinical interventions. Whole systems research (WSR), a methodological approach in which the entire health care system is considered, has gained traction since the early 2000s. The aim of this review is to provide an overview of WSR findings, focusing on the evolution of research methods and outcomes. This review aims to identify the methods used to study complex interventions, assess the feasibility of applying mixed-methods approaches, and highlight methodological challenges.

Methods: A systematic search of electronic databases (PubMed, Embase, CINAHL, and Cochrane) was conducted, followed by article selection and data extraction. The data was analyzed using thematic analysis to identify common themes and trends.

Results: The reviewed WSR methodology involves a wide range of methodological approaches. Traditional quantitative methods, such as randomized controlled trials, are increasingly being supplemented with qualitative methods to enhance understanding of complex interventions. The use of mixed-methods approaches has also grown, with studies often reporting both quantitative and qualitative findings to provide a comprehensive view of the research.

Conclusions: Whole systems research is essential in guiding the implementation of complex interventions. Mixed-methods approaches are increasingly being used to study the complexity of health care systems, and future research should continue to explore the effectiveness of these methodologies.
## Methodological Dissonance?

<table>
<thead>
<tr>
<th></th>
<th>Biomedicine (Classical RCT)</th>
<th>TCIM Interventions (Typical)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FOCUS</strong></td>
<td>Disease</td>
<td>Patient (multimorbidity)</td>
</tr>
<tr>
<td></td>
<td>Symptom management</td>
<td>Balance / health restoration</td>
</tr>
<tr>
<td><strong>DIAGNOSTICS</strong></td>
<td>Biomedical</td>
<td>Paradigm specific +/- biomedical</td>
</tr>
<tr>
<td><strong>INTERVENTION</strong></td>
<td>Singular / isolated</td>
<td>Complex / multimodal</td>
</tr>
<tr>
<td></td>
<td>Standardized / static</td>
<td>Individualized / tailored / dynamic</td>
</tr>
<tr>
<td><strong>OUTCOMES</strong></td>
<td>Objective biomarkers</td>
<td>Subjective, holistic assessment</td>
</tr>
<tr>
<td></td>
<td>Single endpoint</td>
<td>Progressive tracking</td>
</tr>
<tr>
<td><strong>TRAJECTORY</strong></td>
<td>Evidence precedes practice</td>
<td>Practice precedes evidence</td>
</tr>
<tr>
<td><strong>PLACEBO DESIGN</strong></td>
<td>Inert control</td>
<td>Often active / non-credible placebos</td>
</tr>
<tr>
<td><strong>RESEARCH PRIORITY</strong></td>
<td>Efficacy / mechanism of action</td>
<td>Real world effectiveness</td>
</tr>
<tr>
<td><strong>RESEARCH AIMS</strong></td>
<td>Explain effects and validate best practices</td>
<td>Evaluate marginal therapies to foster health systems integration</td>
</tr>
</tbody>
</table>

*Adapted from Ijaz et al 2019*
Competing Models of Evidence


“Evidence House” - Jonas 2001

“Circular Model” - adapted from Walach et al 2006
Model Validity

A good fit between research design, the studied intervention, and the underlying paradigm.
WSR Scoping Review Overview

- **Aim:** To map the *range* of clinical research features pertaining to model validity principle
  - Study design
  - Intervention selection
  - Outcome measures

- **Initial Process:** Expert consultative process + supplemental searches

- **Inclusion criteria**
  - *Completed peer-reviewed studies* reporting TCIM clinical outcomes
  - *Focus on model validity including minimum two of the following:* a) complex intervention; b) individualized care; c) salutogenic / behavioral focus; d) multimorbid patients; e) dual diagnosis.
WSR Exemplars (n=41)

Study size range: 1 – 3000 patients

Thirteen disciplines represented:
• Anthroposophy
• Ayurveda
• Chinese medicine
• Chiropractic
• Complementary/integrative medicine
• Energy medicine
• Homeopathy
• Naturopathy
• Midwifery
• Preventive/restorative biomedicine
• Swedish massage
• T’ai chi
• Yoga therapy

Study duration range: 1 day to several years

Areas of clinical focus include:
• Acute and chronic illness (including arthritis, cancer cardiovascular, diabetes, headache, insomnia, tinnitus)
• Mental health concerns
• Musculoskeletal disorders
• Reproductive conditions
• Medically unexplained symptoms
• Quality of life
• Prevention and rehabilitation
Most Common Study Designs

- **Pragmatic comparative effectiveness trials**
  - Whole systems (WS) intervention vs. Usual care
  - Usual care + WS intervention vs. Usual care
  - Factorial designs
    - E.g. acupuncture vs acupuncture plus herbal medicine
  - Mixed methods (qualitative methods, economic evaluations)
- **Allocation:** Mainly randomized but some ‘pragmatic’
  - Patient preference, matched pairs (EMR)
- Open label: virtually no double blinding
- Active controls rather than placebo/sham

- Pre-post observational studies (single arm)
- N-of-1 series
- Retrospective designs
Intervention Designs

FIG. 8. Primary features of whole systems research interventions.

Intervention Development Process for a Pragmatic Randomized Controlled Trial: The Thoracic Peri-Operative Integrative Surgical Care Evaluation Trial

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Elen McDonnell, ND,
Anna Fazekas, MA,
Linh Zhao, PhD,
Tim Asmis, MD,
Rebecca C. Auer, MD, MSc,
Dean Ferguson, MPH, PhD,
Salmaan Kanji, PharmD,
Donna E. Maziak, MD, MSc,
Tim Ramsay, PhD,
Paul Chamberland, PT,
Chris Spooner, ND,
Jennifer Threader, PhD,
and Andrew Seely, MD, PhD

Development of a manualized protocol of massage therapy for clinical trials in osteoarthritis

After All, Janet Koh, Lisa Rosenberger and Adam I. Petriwan

Abstract

Background: Clinical trial design of manual therapies may be especially challenging as techniques are often individualized and practitioner-dependent. This paper describes our methods in creating a standardized Swedish massage protocol tailored to subjects with osteoarthritis of the knee while respectful of the individualized nature of massage therapy, as well as implementation of this protocol in two randomized clinical trials.

Methods: The manualization process involved a collaborative process between methodologic and clinical experts, with the explicit goals of creating a reproducible semi-structured protocol for massage therapy, while allowing some latitude for therapists’ clinical judgment and maintaining consistency with a prior pilot study.

Results: The manualized protocol addressed identical specified body regions with distinct 30- and 60-min protocols, using standard Swedish strokes. Each protocol specifies the time allocated to each body region. The manualized 30- and 60-min protocols were implemented in a dual-site 2×2 randomized dose-finding trial in patients with osteoarthritis of the knee, and is currently being implemented in a three-site 2×2 week efficacy trial of manualized Swedish massage therapy. In the dose-finding study, therapists adhered to the protocols and significant treatment effects were demonstrated.
Individualization Spectrum

FIG. 2. Spectrum of clinical individualization strategies.
Dual Diagnosis

A Pilot Whole Systems Clinical Trial of Traditional Chinese Medicine and Naturopathic Medicine for the Treatment of Temporomandibular Disorders

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ELIZABETH SUTHERLAND, N.D., 5 JOSEPH LEBEN, D.D.S., 9 LYNN DEBAR, Ph.D., 7
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APPENDIX 1. TRADITIONAL CHINESE MEDICINE PROTOCOL

<table>
<thead>
<tr>
<th>Syndrome diagnosis</th>
<th>Points</th>
<th>Base herbal formula(s)</th>
<th>Symptoms</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver qi stagnation</td>
<td>GB41, GB40, GB34, LV14, LV13</td>
<td>Xiao yao san or chai ju shu gan tang</td>
<td>Headache</td>
<td>GV20, taiyang, GB41, ST41, TW5</td>
</tr>
<tr>
<td>Liver blood xu</td>
<td>GB39, BL18, BL20</td>
<td>Jia weyi si wu tang</td>
<td>Insomnia</td>
<td>HT7 or PC6, anmian</td>
</tr>
<tr>
<td>Liver yin xu</td>
<td>SP6</td>
<td>Yi guan jian</td>
<td>Ear pain</td>
<td>TW3, TW17</td>
</tr>
<tr>
<td>Liver Wind, liver yang, or liver Fire rising due to injury</td>
<td>LV2, GB40</td>
<td>Zheng gan xi feng tang or tianma gouteng yin</td>
<td>Fibromyalgia</td>
<td>SP21, scalp points: upper, middle, and lower jiao</td>
</tr>
<tr>
<td>Heart blood xu</td>
<td>BL15</td>
<td>Aih xi</td>
<td>Depression and/or anxiety</td>
<td>GV24, GV20, CV17, CV12, CV6</td>
</tr>
<tr>
<td>Spleen qi xu and Damp retention</td>
<td>ST36, SP9</td>
<td>Xiao hao huo dan or tong qiao hou xue tang</td>
<td>Neck/shoulder pain or tightness</td>
<td>BL43, BL12, ST3</td>
</tr>
<tr>
<td>Kidney qi xu</td>
<td>BL23, KD3</td>
<td>Jin gui shen qing tang</td>
<td>Low back pain</td>
<td>BL23, shiqizhui, BL40</td>
</tr>
<tr>
<td>Kidney jing xu</td>
<td>BL52</td>
<td>Zuo gai yin</td>
<td>Difficulty moving the jaw</td>
<td>During last 5 minutes remove all local points and stimulate LI4 while patient attempts to move her jaw</td>
</tr>
<tr>
<td>Kidney xin xu</td>
<td>SP6, KD6</td>
<td>Zhi dai di huang tang, or Bu weiyi di huang tang</td>
<td>TCM differentiations (most salient)</td>
<td></td>
</tr>
<tr>
<td>Kidney yang xu</td>
<td>GV4, CV4</td>
<td>You gai wan</td>
<td>Liver Qi Constraint</td>
<td>47.5 53.8 34.9 47.6</td>
</tr>
<tr>
<td>Wind-Cold invasion</td>
<td>TW5</td>
<td>Yuan yang tang, Yi yang ren tang, or Gui zhi wu ren tang</td>
<td>Qi and Blood Stagnation</td>
<td>37.5 38.5 51.2 38.1</td>
</tr>
<tr>
<td>Other‡</td>
<td>15.0 7.7 13.9 14.3</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comparative Effectiveness of Traditional Chinese Medicine and Psychosocial Care in the Treatment of Temporomandibular Disorders—Associated Chronic Facial Pain

Cheryl Ritenbaugh,* Richard Hammerschlag,† Samuel F. Dworkin,‡ Mikel G. Aickin,† Scott D. Mist,* Charles R. Elder,§ and Richard E. Harris**
Outcome Measures

• Most common:
  – Patient-reported outcomes for:
    • Symptom severity
    • QOL / psychosocial
    • Some ‘patient-generated’ outcomes
  – Some concurrent objective outcome measures

FIG. 11. Outcome assessment in whole systems research.
Next Frontiers:
Paradigm-specific outcome measures
Harmonization into Broader Research Schemes

Hierarchies of evidence applied to lifestyle Medicine (HEALM): introduction of a strength-of-evidence approach based on a methodological systematic review

D. L. Katz1,2,3, M. C. Karlsen1,4*, M. Chung5, M. M. Shams-White6, L. W. Green7, J. Fielding8, A. W. Willett9,10,11

Abstract

Background: Current methods for assessing strength of evidence prioritize the contributions of controlled trials (RCTs). The objective of this study was to characterize strength of evidence (S), identify their application to lifestyle interventions for improved longevity, vitality, or success, assess implications of the findings.

Methods: The search strategy was created in PubMed and modified as needed for four additional databases, Embase, AnthropologyPlus, PsycINFO, and Agerine, supplemented by manual searching. Systematic reviews of intervention trials or observational studies relevant to lifestyle intervention were identified. The quality and characteristics of each study were assessed and then categorized into levels using the strength of evidence (S).

Results: A total of 21 studies were included in the review. The level of evidence varied widely, with some studies providing strong support for the effectiveness of lifestyle interventions, while others showed limited evidence.

Conclusion: The strength of evidence approach provides a useful framework for evaluating the effectiveness of lifestyle interventions. Further research is needed to validate the strength of evidence categories and to develop more rigorous methods for assessing the quality of evidence from different types of studies.

Encompassing Cultural Contexts Within Scientific Research Methodologies in the Development of Health Promotion Interventions

Daniel Dickerson1, Julie A. Baldwin2, Annie Belcourt3, Lorenda Belone4, Joel Gittelsohn5, Joseph Keaweaimoku Kaholokula6, John Lowe7, Christi A. Patten4, Nina Wallerstein7

Abstract

American Indians/Alaska Natives/Native Hawaiians (AI/AN/NHs) disproportionately experience higher rates of various health conditions. Developing culturally centered interventions targeting health conditions is a strategy to decrease the burden of health conditions among this population. This study analyzes the use of Indigenous-based methods and knowledge systems in the development of health promotion interventions. The aim of the study was to (a) identify and describe the use of Indigenous-based methods and knowledge systems in the development of health promotion interventions; (b) assess the effectiveness of these interventions; and (c) explore the challenges and opportunities associated with using Indigenous-based methods and knowledge systems in the development of health promotion interventions. The study was conducted using a qualitative approach, with data collected through interviews with Indigenous and non-Indigenous stakeholders. The findings revealed that Indigenous-based methods and knowledge systems are used in the development of health promotion interventions, but there are challenges and opportunities associated with their use.

Keywords: American Indians, Alaska Natives, Native Americans, Native Hawaiians, Culture, Interventions
WSR as a Distinctive Field

• Common features with ‘pragmatic’ research
  – BUT: there are distinctions that unite this work
    • Combination of features (whole as more than parts)
    • Dual diagnosis

• Training new generation of TCIM (clinician)-scientists in model valid methodologies

• Further development of complex analytic models

• **Big questions:** what other ‘measurables’ are relevant?