



The University Of Utah
Division of Physical Therapy

Future directions for trials of interventions for musculoskeletal pain

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Introduction

- Musculoskeletal conditions are a major cause of disability around the world.
 - Developing and Emerging Nations are affected
 - Back pain is the most common source of disability and associated costs
 - Prompted declaration of the “Bone and Joint Decade” by the World Health Organization
- The situation does not appear to be improving
- Despite the prevalence and burden, research funding is low internationally

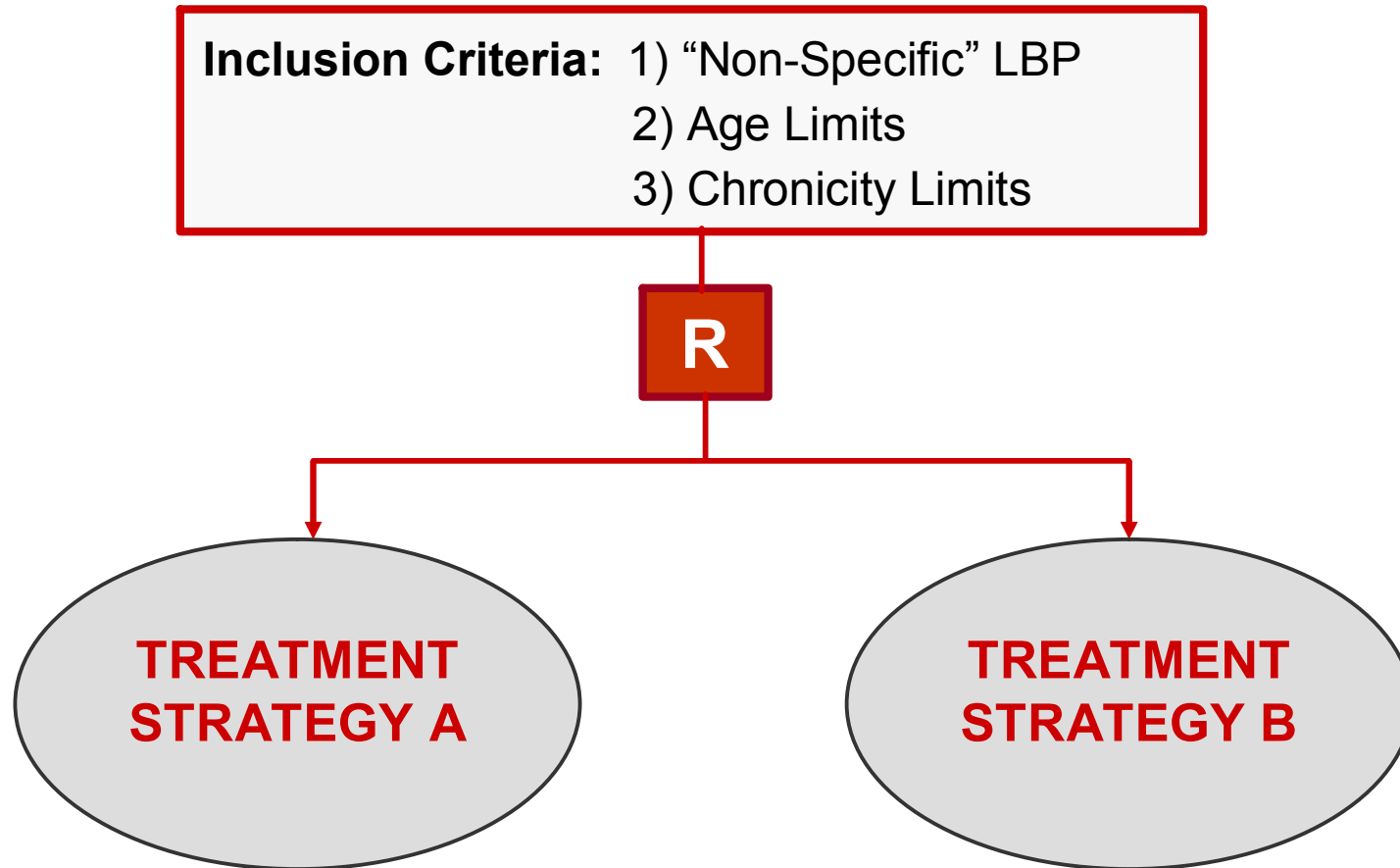


Emerging Directions for Research

- More powerful research designs
 - Stop chasing the “Magic Bullet”
- Translational research
 - Changing providers is a lot different than changing patients
- Economic analysis
 - Considering the costs



“Classic” RCT Design



“Because magic bullet approaches are far easier to design and implement in a classic RCT, they are more likely to lead to “methodologically sound” studies. But these approaches are rarely representative of real-world practice, where physical therapists spend considerable time examining patients and evaluating patient data with the presumed goals of matching multifaceted treatments based on their findings.”

(Delitto A, *Phys Ther*, 2005)



The Effects of Spinal Flexion and Extension Exercises and Their Associated Postures in Patients With Acute Low Back Pain

Inclusion Criteria: 1) Non-specific LBP with or without radiation
2) Acute LBP (<7 days)

R

FLEXION

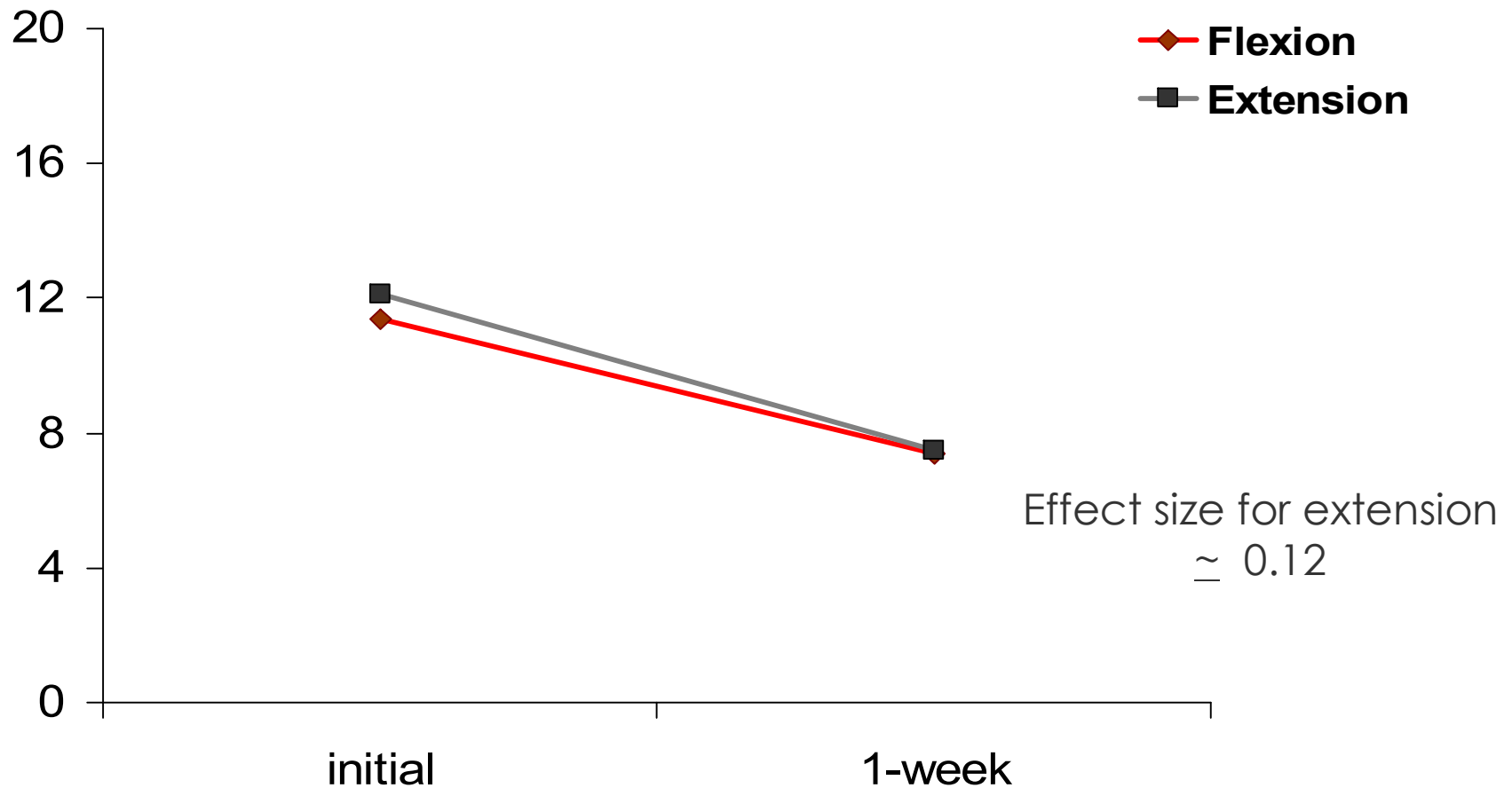
Pelvic tilts, partial sit-ups, double knee-to-chest

EXTENSION

prone-lying, press-ups
Postural instruction to maintain lordosis



Roland Disability Scores



What is the Alternative?

- However semantically correct, “non-specific” LBP is not a good clinical diagnosis. (*Waddell, 2004*)
- The apparent uncritical acceptance of “non-specific” LBP has adversely affected both research, practice, and national health policy. (*Abraham & Killacky-Jones, 2002*)
- The term fails to meet the expectations of the patient, doctor, or therapist. (*Waddell, 2005*)



What is the Alternative?

“For many, the Holy Grail of low back pain research is to find a way to sub-classify non-specific low back pain.” (*Waddell, 2005*)

The 1997 Agenda for Primary Care Research on Low Back Pain:

1. Identify different varieties and subgroups of LBP including criteria for membership



Sub-Grouping – Physical Therapy Perspective

- Numerous constructs can be used for sub-grouping patients with LBP.
 - Constructs vary for different professions
- Physical Therapist perspective:

“The process of classifying clinical data into named categories of clinical entities for the purpose of making clinical decisions regarding therapeutic management”

(Rose, 1989)



Sub-Grouping – Physical Therapy Perspective

“There is a time when the low back should be extended, and a time when it should be flexed; there are circumstances where both procedures should be applied, and ... it is possible to identify in advance those patients who will respond.”

(McKenzie, 1981)



Browder DA, et al. Effectiveness of an extension-oriented treatment approach in a subgroup of patients with low back pain: a randomized clinical trial.

Inclusion Criteria: 1) LBP with symptoms distal to buttock
2) Centralization with extension movement
3) Age 18-60

R

STRENGTHENING

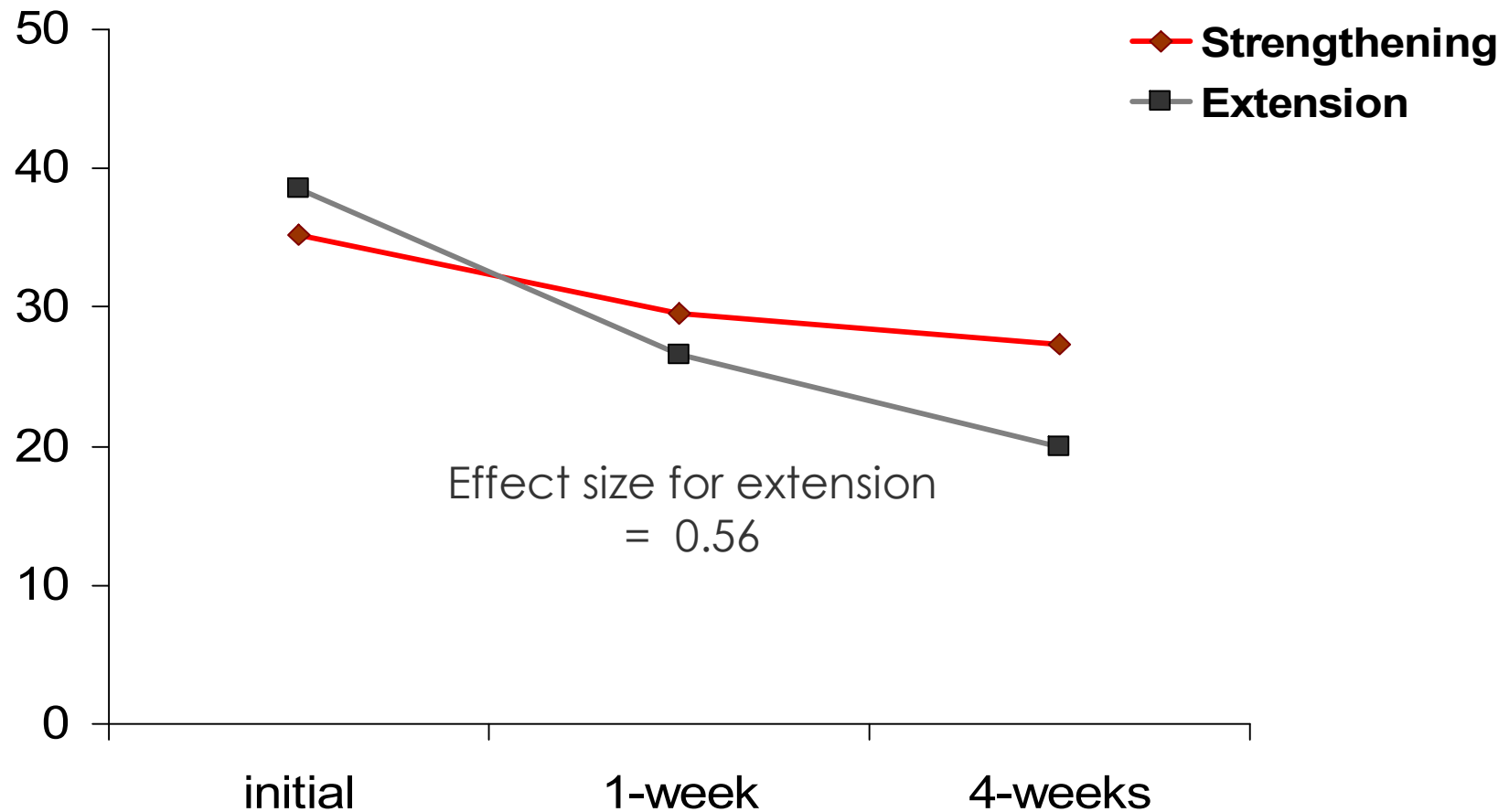
Trunk strengthening,
specific stabilization
exercise

EXTENSION

Prone-lying, press-ups
Postural instruction,
extension mobilization



Oswestry Disability Scores

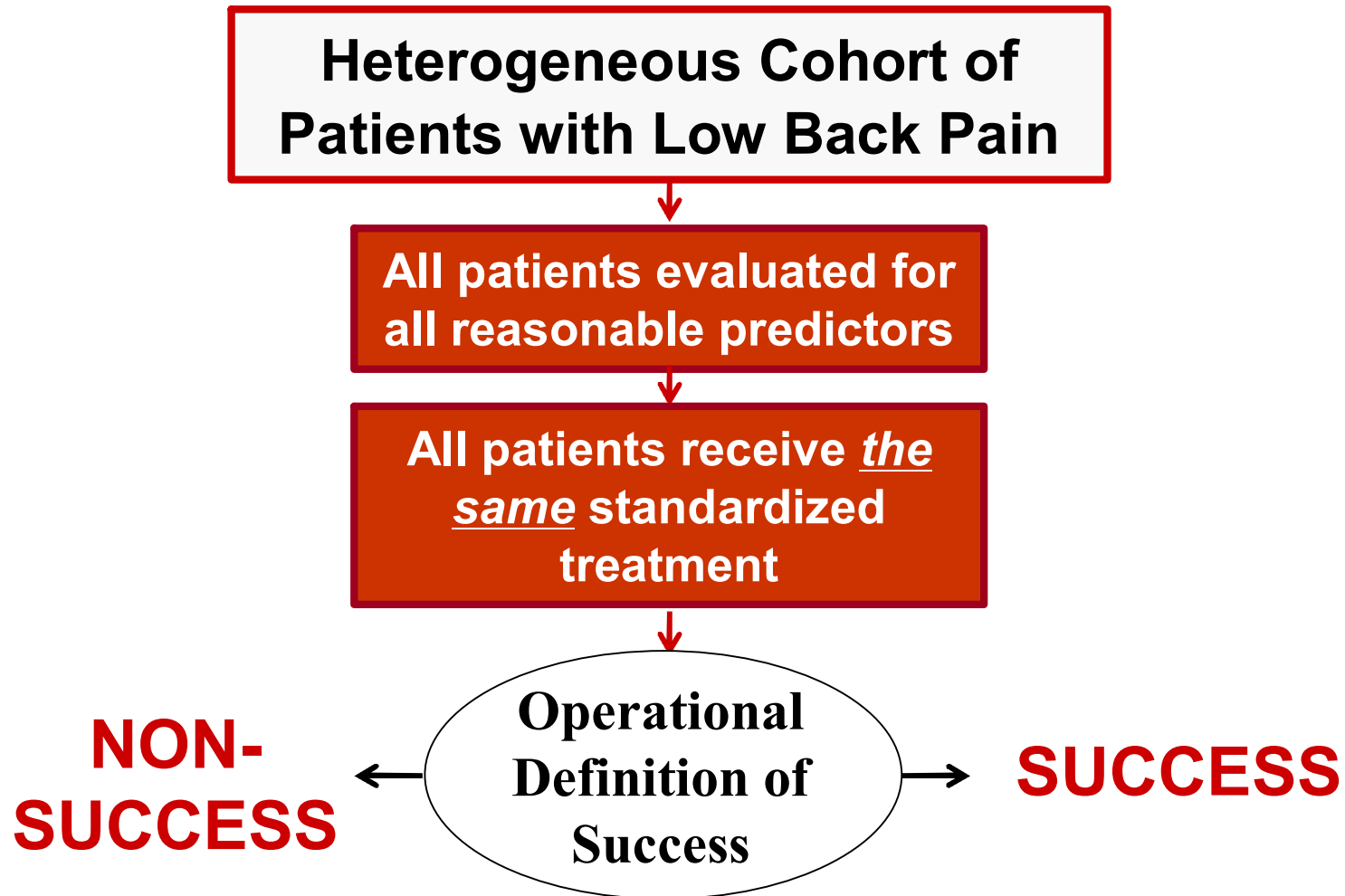


How Do We Identify Sub-Groups?

- Expert opinion and observation
- Single-group prospective studies to identify examination factors associated with better outcomes with a defined treatment.
- Secondary analysis of RCT results to identify examination factors associated with better outcomes with a defined treatment.



Prospective Cohort Designs



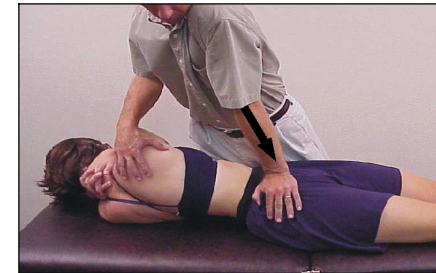
A Clinical Prediction Rule To Identify Patients with Low Back Pain Most Likely To Benefit from Spinal Manipulation: A Validation Study

Maj John D. Childs, PhD, PT; Julie M. Fritz, PhD, PT; Timothy W. Flynn, PhD, PT; James J. Irrgang, PhD, PT; Maj Kevin K. Johnson, PT; Maj Guy R. Majkowski, PT; and Anthony Delitto, PhD, PT

Heterogeneous Cohort of Patients with Low Back Pain

All patients evaluated for all reasonable predictors

All patients receive spinal manipulation with ROM exercise (max 2 sessions)



NON-SUCCESS

50% decrease on Oswestry?

SUCCESS

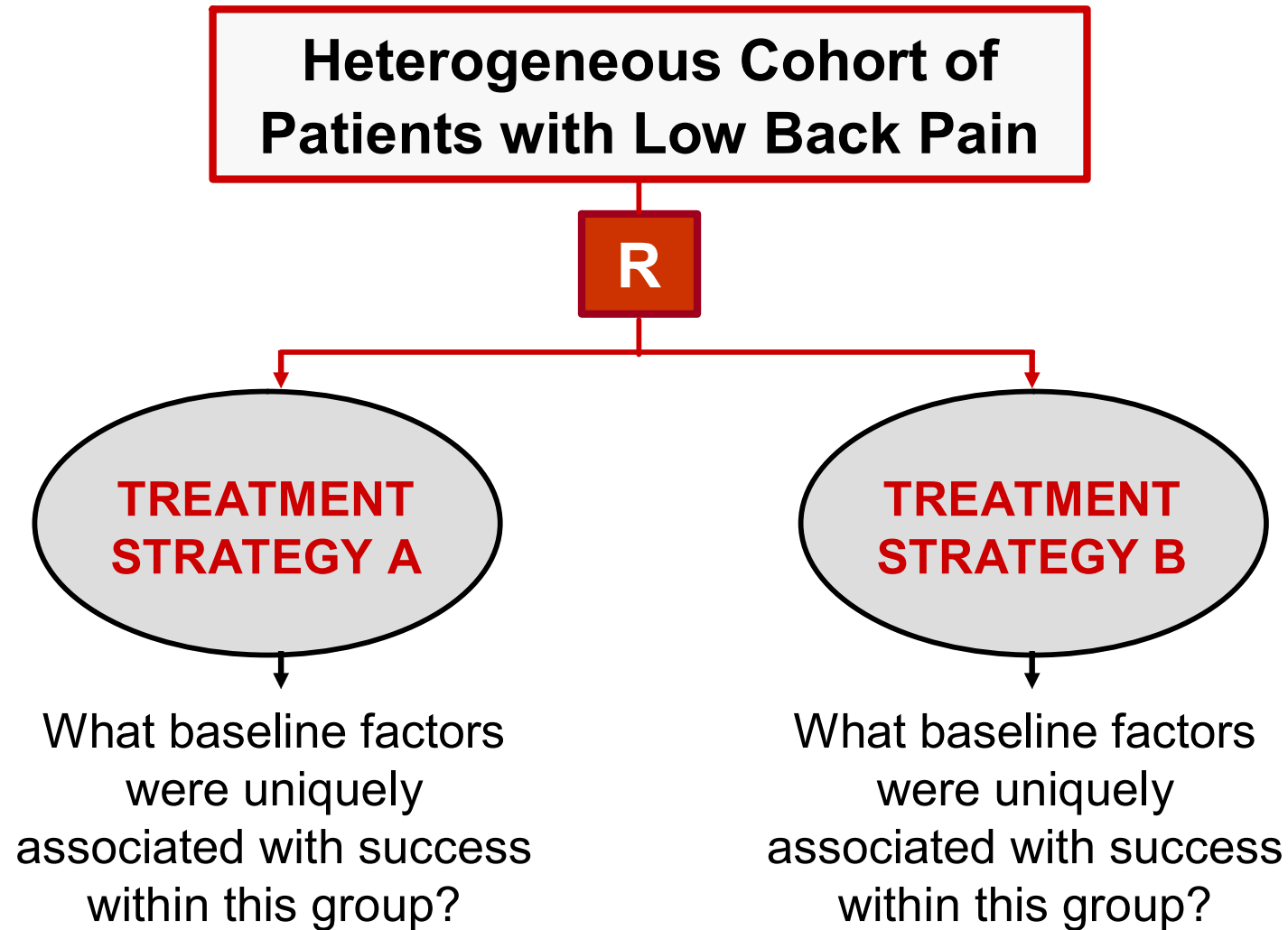


Five-Factor Decision Rule

- Duration of symptoms < 16 days
- FABQ work subscale 18 or less
- Symptoms not distal to the knee
- At least one hip internal rotation PROM > 35⁰
- Hypomobility at one or more lumbar levels with spring testing



Secondary Analysis of Randomized Trial



Predictors of Outcome in Patients With (Sub)Acute Low Back Pain Differ Across Treatment Groups

Petra Jellema, MSc,*† Henriëtte E. van der Horst, MD, PhD,*† Johan W. S. Vlaeyen, PhD,‡
Wim A. B. Stalman, MD, PhD,*† Lex M. Bouter, PhD,† and Daniëlle A. W. M. van der Windt, PhD*†

Inclusion Criteria: 1) “nonspecific” LBP
2) age 18-65
3) symptoms <12 wks

R

USUAL CARE

MINIMUM INTERVENTION

Success Associated With:

shorter duration of the LBP episode
few previous episodes
less pain catastrophizing
good perceived general health

Success Associated With:

More solicitous responses by others
less somatizing symptoms
lower perceived risk for chronic LBP
more fear avoidance beliefs
higher level of education
shorter duration of the LBP episode

Validation of Sub-Grouping Criteria

- Randomized trials using inclusion criteria or sub-group analyses to create homogenous sub-groups
- Randomized trials comparing management using sub-grouping procedures to alternative clinical decision-making approaches.



Translational Research

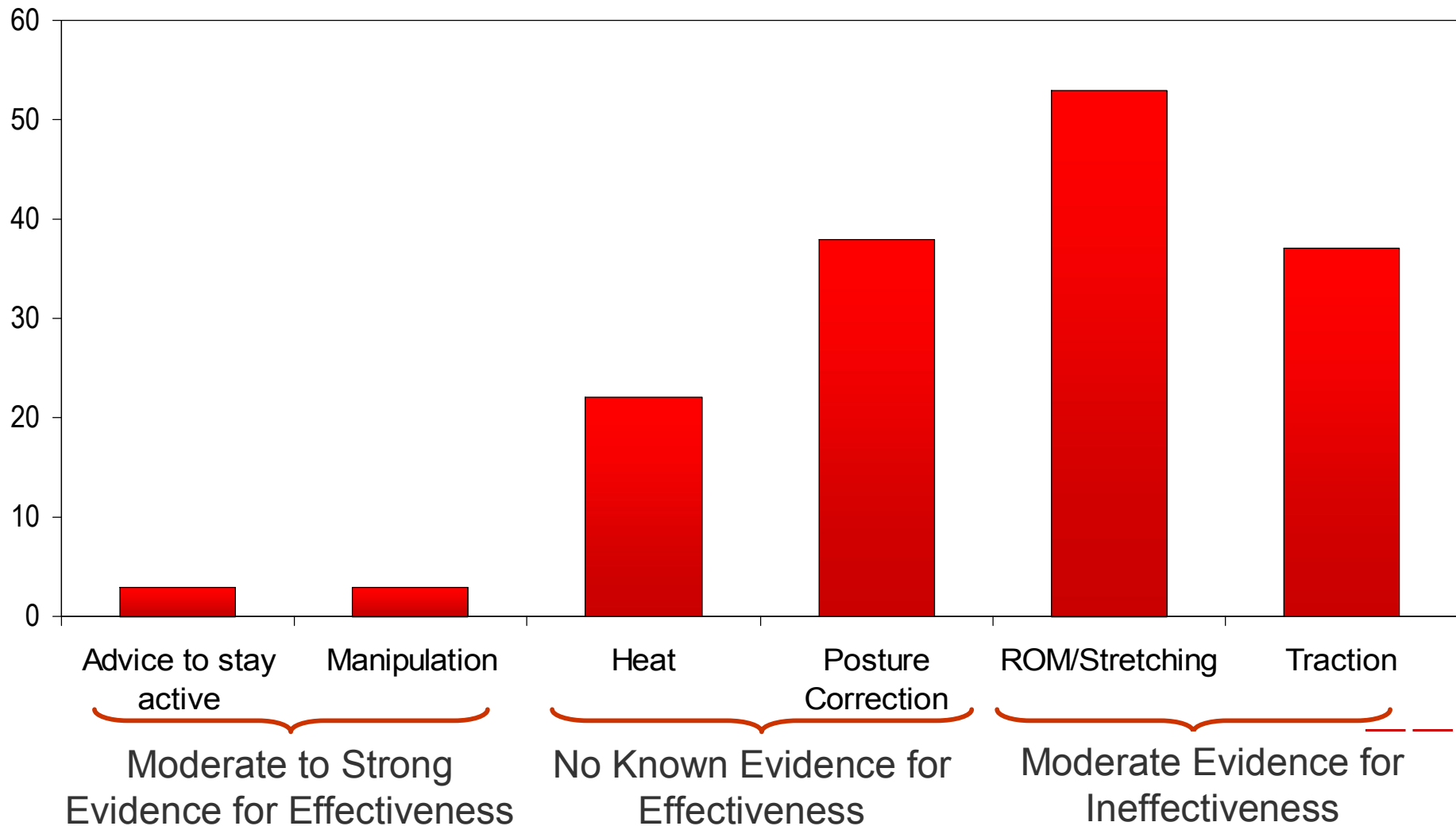
“The stark reality [is] that we invest billions in research to find appropriate treatments, we spend more than \$1 trillion on healthcare annually, we have extraordinary capacity to deliver the best care in the world, but we repeatedly fail to translate that knowledge and capacity into clinical practice”

(IOM, 2003 “Priority Areas for National Action”; Berg et al, 1997; Dickersin & Manheimer, 1998; Kamerow, 1997)



Prevalence of Recommended Interventions for Acute, Non-Specific LBP (100 therapists interviewed from Quebec, Canada)

Mikhail et al, *Physical Therapists' Use of Interventions with High Evidence...* Phys Ther 2005.



What is the Explanation?

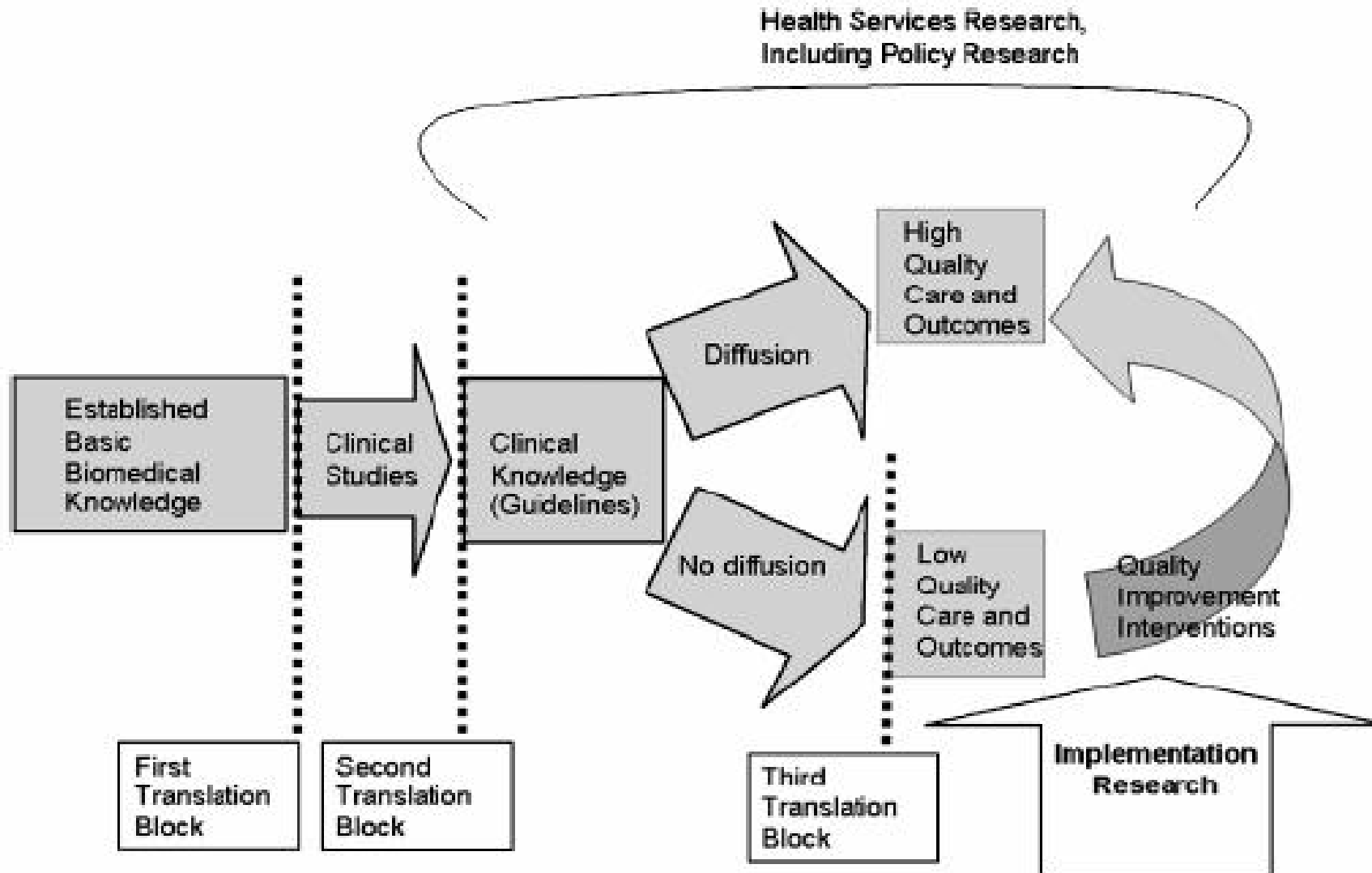
Change is Hard

“Faced with the choice between changing one’s mind and proving that there is no need to do so, almost everybody gets busy on the proof.”

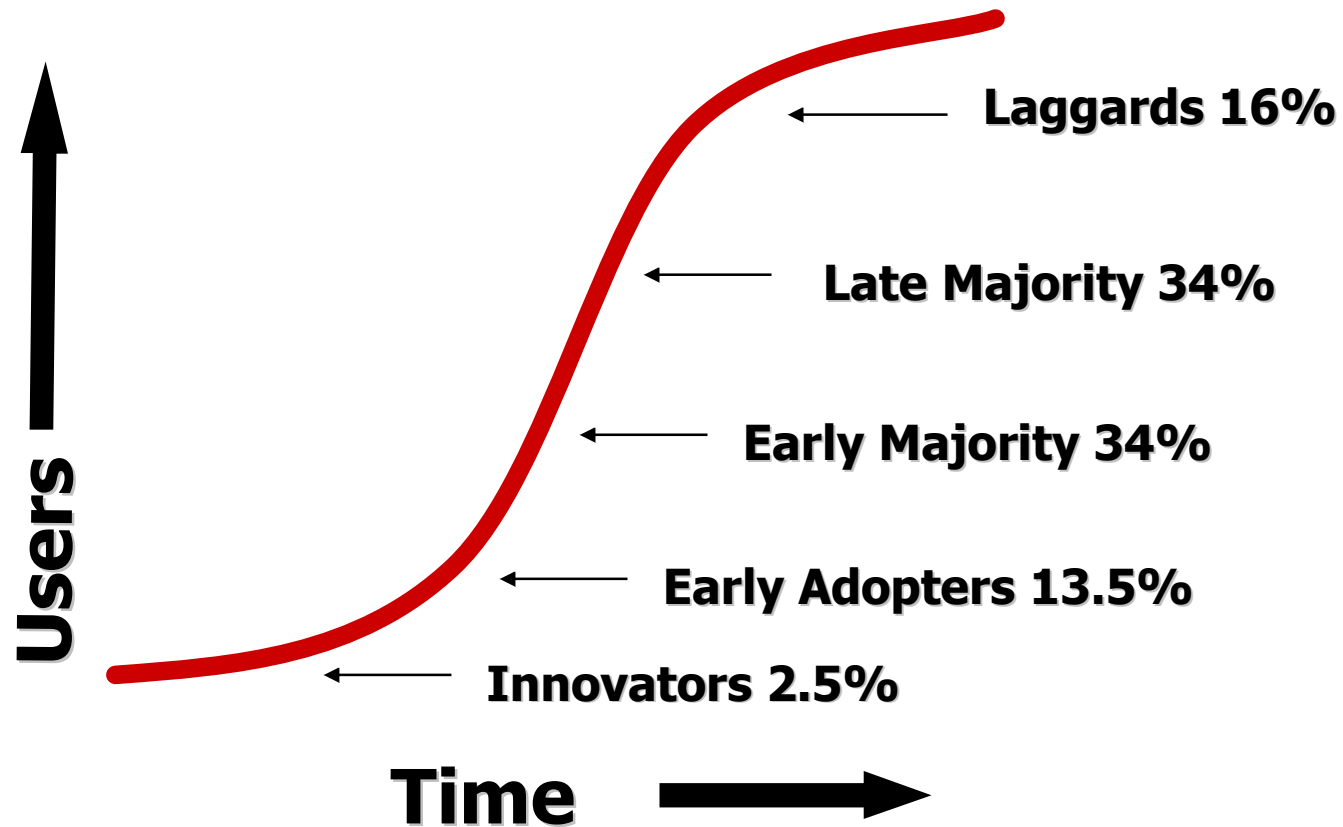
J. K. Galbraith American Economist



Translational Research



Innovation Diffusion



**“The gap between what we know works
and what is actually done is substantial
enough to warrant attention”**

(McGlynn et al. 2003)



Interventions to Change Behavior

- The process of implementing evidence or guidelines into practice requires significant behavior changes.
- Common educational approaches have been used in attempts to change provider behavior.
- These assume that key barriers relate to individual professional's knowledge and skills.
- Usually there are many barriers operating at multiple levels.



Which Interventions Work to Change Behavior?

■ Little Effect

- Passive dissemination: didactic lecture-based, mailed unsolicited materials

■ Moderately Effective

- Audit and feedback, especially if delivered by peers or opinion leaders

■ Relatively Effective

- Educational outreach, Reminder systems, and multi-faceted interventions



Interventions to Change Behavior

- Effective Strategies for Behavior Change:
- Active (interactive) learning opportunities
 - Learning takes place within the clinicians' environment
 - Longitudinal or sequenced learning
 - Methods to facilitate implementation in the practice setting (e.g., decision tools, etc.)



QUALITY IMPROVEMENT RESEARCH

Research designs for studies evaluating the effectiveness of change and improvement strategies

M Eccles, J Grimshaw, M Campbell, C Ramsay

Qual Saf Health Care 2003;12:47-52

■ **Non-Randomized Designs**

- Uncontrolled before and after studies
- Controlled before and after designs
- Time series designs

■ **Randomized Designs**

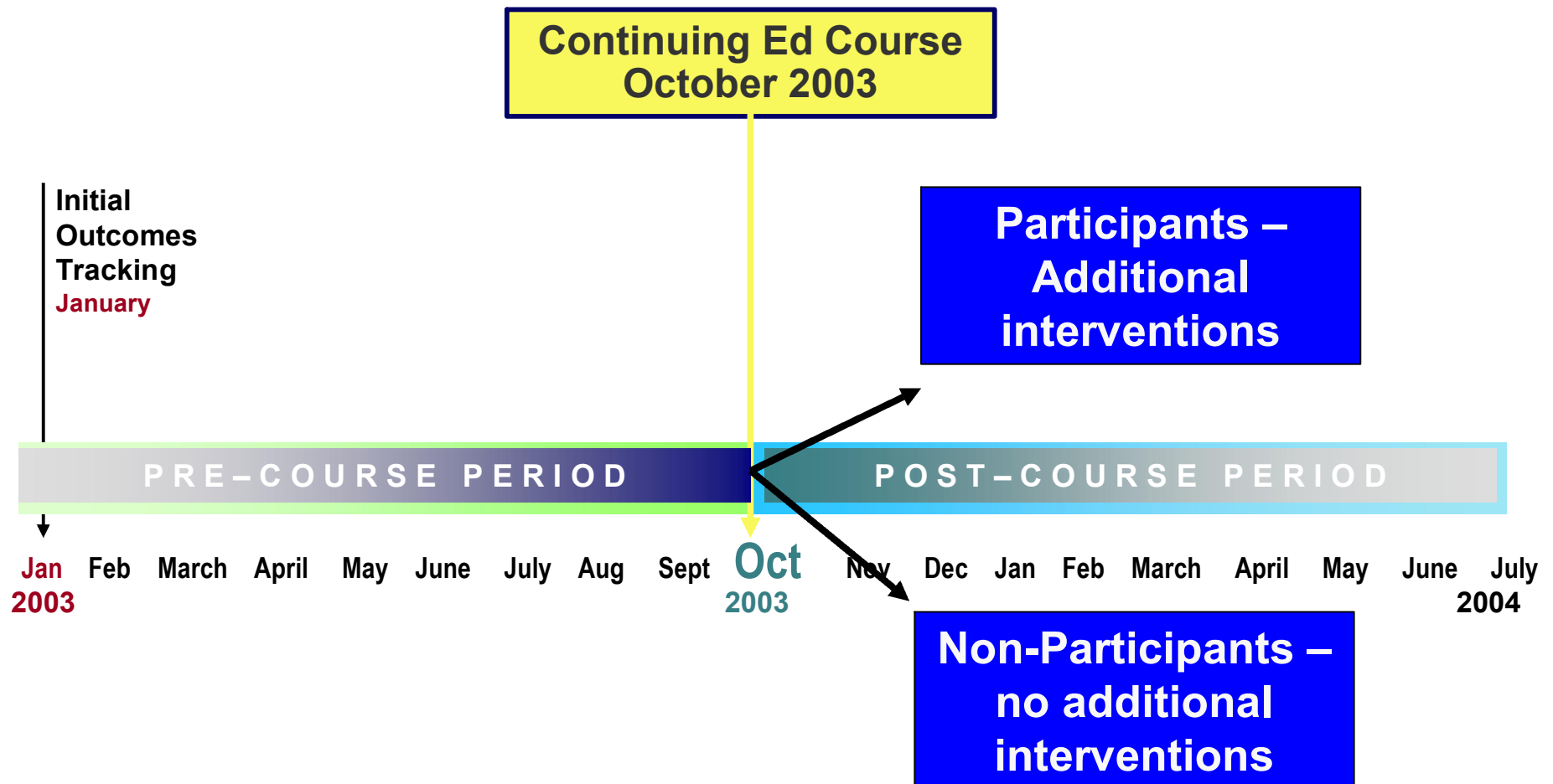
- Individual patient randomized designs
- Cluster randomized trials



Impact of Continuing Education Interventions on Clinical Outcomes of Patients With Neck Pain Who Received Physical Therapy

Gerard P Brennan, Julie M Fritz, Stephen J Hunter

Physical Therapy . Volume 86 . Number 9 . September 2006



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BEHAVIOR CHANGE INTERVENTION

NON-PARTICIPANTS:

- 2-day intensive continuing education course
- No longitudinal follow-up

BEHAVIOR CHANGE INTERVENTION

PARTICIPANTS:

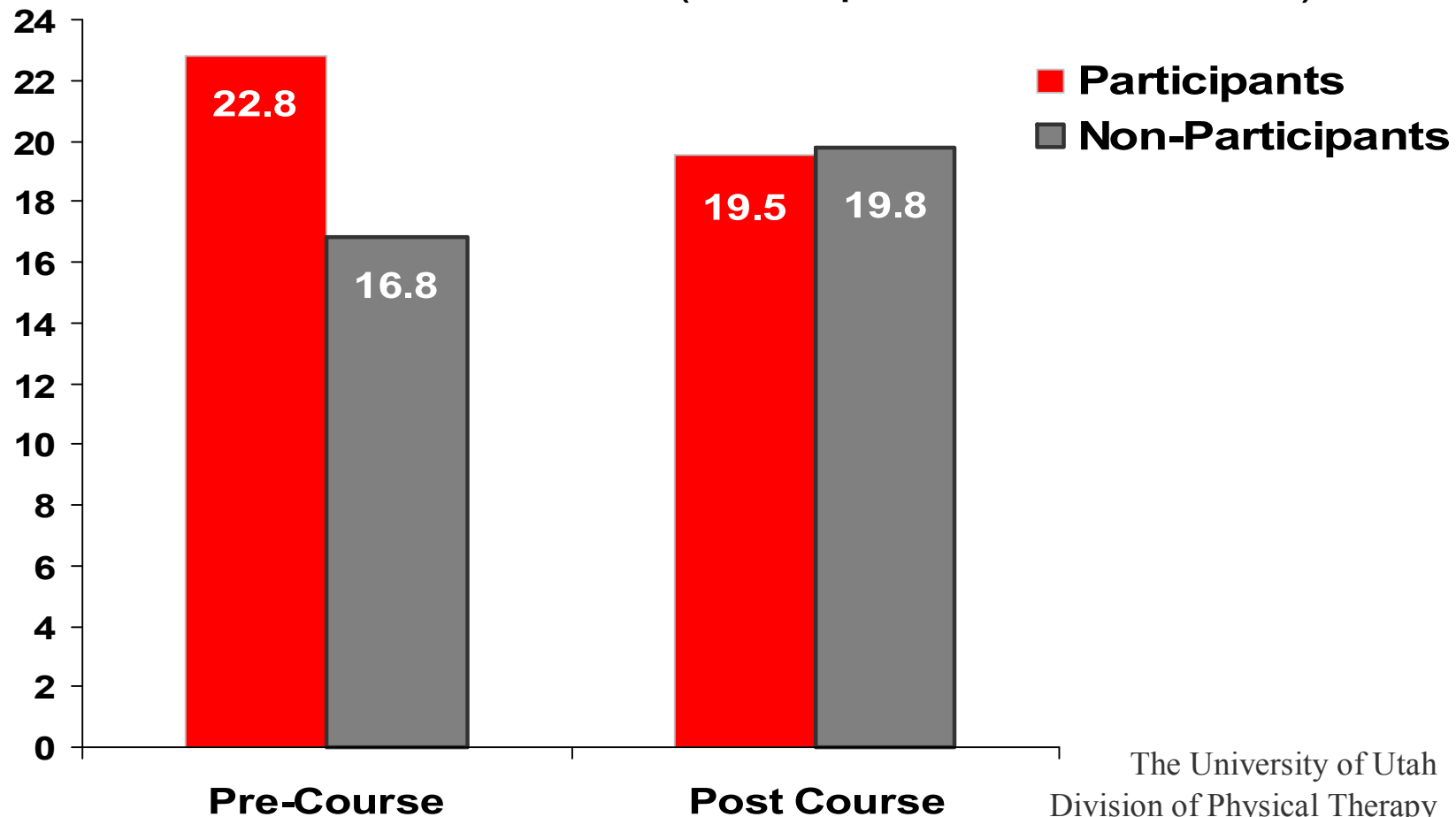
- 2-day intensive continuing education course
- Monthly follow-up meetings
 - GOAL: standardize evaluation, discuss the evidence
 - Clinician feedback
 - Modifications to the process
- Follow-up skills session after 6 months

Impact of Continuing Education Interventions on Clinical Outcomes of Patients With Neck Pain Who Received Physical Therapy

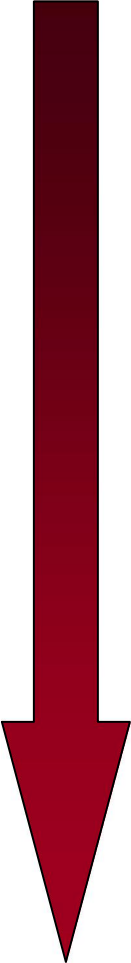
Gerard P Brennan, Julie M Fritz, Stephen J Hunter

Physical Therapy . Volume 86 . Number 9 . September 2006

Defect Rate (No improvement on NDI)



Research Questions

- 
- **Can it work?**
 - Efficacy
 - **Does it work?**
 - Effectiveness
 - **Should it be used, given limited healthcare resources?**
 - Economic Analysis



The Need for Economic Analysis

- Resources are limited
- Limited resources along with clinical uncertainty and risk have increased attention on cost-effectiveness
- The benefits of an intervention should justify its costs and its risks
- Care is optimized (for groups and individuals) when decisions are based on cost-effective



What are the costs to consider?

- Direct costs are economic costs within the health sector for prevention and treatment.
- Indirect costs are economic costs of lost time, lost quality of life, and lost wages associated with the disease.



From Whose Perspective?

- Perspective of government, payor, patient, etc., may be considered
 - Difficult to compare
 - Does not represent all aspects of the public interest
- Societal perspective is recommended
 - considers everyone affected by the intervention, and all health effects and costs that flow from it are counted, regardless of who would experience them



Types of Economic Analysis

- Cost identification analysis
- Cost minimization analysis
- Cost effectiveness analysis
- Cost benefit analysis
- Cost utility analysis



Economic Analysis

- **Cost-Benefit Analysis** provides an explicit decision about whether the cost of the practice is worth the benefit obtained from it by measuring both cost and benefit in the same units – typically, in monetary terms.
- **Cost-Effectiveness Analysis** measures the net cost of providing a service and also measures the outcomes obtained. Examples are cost per year of life gained or cost per case correctly diagnosed.



Cost-Effectiveness Analysis: When to use...

	New Strategy Costs <i>MORE</i>	New Strategy Costs <i>LESS</i>
New Strategy is <i>MORE</i> Effective	CEA Relevant	Adopt the New Strategy
New Strategy is <i>LESS</i> Effective	Reject the New Strategy	CEA Relevant

Cost-effectiveness of a graded exercise therapy program for patients with chronic shoulder complaints

International Journal of Technology Assessment in Health Care, 22:1 (2006), 76–83.
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Objectives: The present study evaluated the cost-effectiveness of a behavioral graded exercise therapy (GET) program compared with usual care (UC) in terms of the performance of daily activities by patients with chronic shoulder complaints in primary care.



Counting the Costs

- Intervention costs, direct health care costs, direct non–health-related costs, and indirect costs were assessed during the 12-week treatment period and the 52-week follow-up period.
- Intervention costs of the GET program included the costs of visits to physiotherapists for group treatment during the 12-week treatment period. The intervention costs for UC included the costs of visits to general practitioners, to physio-therapists for usual care, or to manual therapists or Cesar/Mensendieck exercise therapists during the 12-week intervention period.



Counting the Costs

- Other direct health-related costs for both groups during the 12-week treatment period included the costs of prescribed medication, hospitalization, and visits to physicians or alternative therapists. Direct health-related costs after the treatment period included the costs of visits to general practitioners, physiotherapists, manual therapists, Cesar/Mensendieck exercise therapists, physicians, and/ or alternative therapists; and costs of hospitalization and of prescribed medication during the 52-week follow-up period.



Counting the Costs

- Direct non–health-related costs included costs of professional home care, of paid housekeeping, of unpaid help from relatives or friends, of health-related activities (e.g., fitness training), and other out-of-pocket expenses (e.g., non-prescribed medication).
- Indirect costs included the costs of production losses due to sick leave from paid or unpaid work.



Counting the Costs

- Cost diaries filled in by the patients were used to assess direct health care costs, direct non–health-related costs, and indirect costs.
- Cost diaries were sent and returned by post



Data Analysis

- **Evaluation of Effectiveness:**
 - Mean change scores compared between groups
Independent-group t-tests,
mean used for missing data
- **Evaluation of Costs:**
 - Mean costs computed for each group
Non-parametric test used (Mann-Whitney)
Individual or group means used for missing data
- **Evaluation of Cost-Effectiveness:**
 - ICER calculated



Results – Cost-Effectiveness

ICER Values:

- Severity of Main Complaints: €17 (-4, 129)
- SDQ: €74 (-2, 101)
- The incremental costs for GET per unit improvement on these measures



Results – Cost-Effectiveness

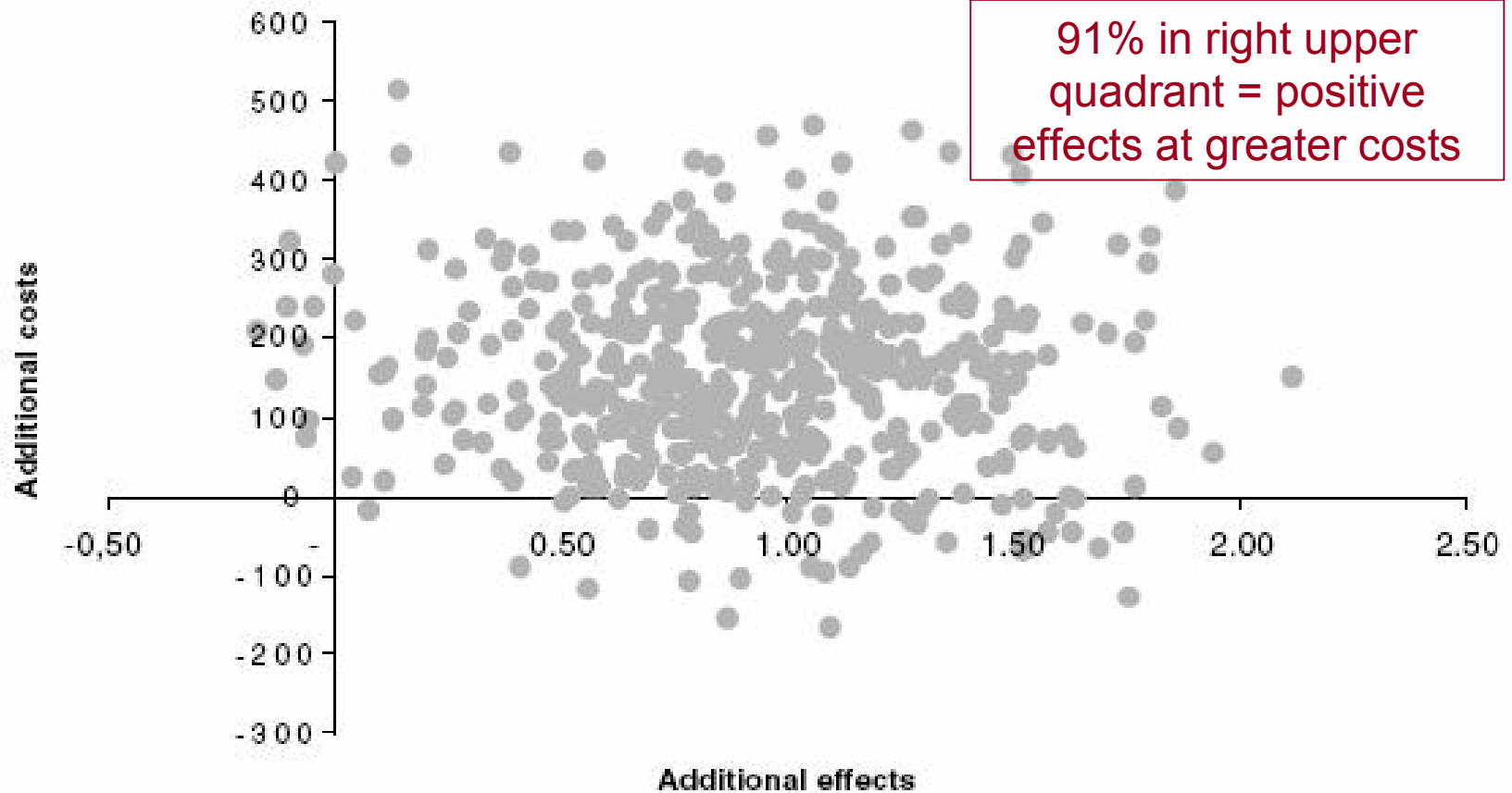


Figure 1. Cost-effectiveness plane for the main complaints after 52 weeks.

Conclusions

We conclude that GET is more cost-effective than UC for patients with chronic shoulder complaints in primary care. GET is clinically more effective than UC in restoring daily activities in these patients after the 12-week treatment period, and these effects last for at least 52 weeks. GET significantly reduces direct health care costs and direct non-health care costs in patients with chronic shoulder complaints. However, total costs during the one-year follow-up period were significantly higher due to the higher costs of the intervention itself.



Summary

