Low back pain (FS-17)

Nadine Foster (United Kingdom)
Jonathan Hill (United Kingdom)
Peter O’Sullivan (Australia)
John Childs (United States of America)
Mark Hancock (Australia)
Stratified Models of Care for Low Back Pain

Nadine Foster
NIHR Research Professor
Current care for LBP

• First contact clinician
  – Diagnostic triage

• Predominant group ‘non-specific’ LBP
  • Managed with advice and analgesia
  • Stepped care to
    – Exercise, manual therapy, acupuncture
  • No systematic targeting of treatment
Clear trends in recent RCTs
Challenge

How to better ‘match’ patients to treatments in ways that ensure the right person gets the right treatment at the right time?
Stratified Care

- Involves targeting treatment to **subgroups of patients** based on their key characteristics
- Fast tracks patients to appropriate treatment
- Gets the right treatment to the right patient at the right time
Models of stratified care

• Patient’s prognosis
  – Matching treatment to patients risk of poor outcome (persistent pain and disability)

• Responsiveness to treatment
  – Matching treatment A to those who benefit most from treatment A

• Underlying mechanisms
  – Matching treatment to pathology or diagnosis
Symposium Plan

1. Patient’s prognosis - Dr Jonathan Hill
2. Responsiveness to treatment - Dr John Childs
3. Underlying mechanisms - Prof Peter O’Sullivan
4. Potential for integration - Dr Mark Hancock
5. Recommendations - Prof Nadine Foster

Discussion
Example 1: Stratified Care based on Prognosis

Dr Jonathan Hill
Keele University UK
Key underlying principles

• Clinical decisions are informed by prognosis (strong epidemiology)
• Prognostic subgroups guide management (e.g. low, medium, high)
• They are simple, brief and can be universally applied
• They aim to use healthcare resources more effectively & efficiently;
  - Low risk patients are not over-treated or medicalised
  - At ‘risk’ patients get access to the right person early on
  - Enhanced, comprehensive care is given for complex cases
• Examples:
  - The Orebro Musculoskeletal Screening Q (Linton & Halden 1998)
  - Chronic Pain Risk Prognostic Screen (von Korff et al 2013)
How does STarT Back work?

Prognostic Risk Tool + Matched Treatments
Keele STarT Back Tool

www.keele.ac.uk/sbst

9 questions:

1. Referred leg pain
2. Comorbid pain elsewhere
3. Disability (walking + dressing)
4. Fear of movement
5. Anxiety
6. Catastrophising
7. Depression/mood
8. Overall impact

Scoring the tool:
0-3 = low risk
4 or more total score = medium
4 or more sub score = high

Thinking about the last 2 weeks tick your response to the following questions:

1. My back pain has spread down my leg(s) in the last 2 weeks
2. I have had pain in the shoulder or neck at some time in the last 2 weeks
3. I have only walked short distances because of my back pain
4. In the last 2 weeks, I have dressed more slowly than usual because of back pain
5. It’s not really safe for a person with a condition like mine to be physically active
6. Worrying thoughts have been going through my mind a lot of the time
7. I feel that my back pain is terrible and it’s never going to get any better
8. In general I have not enjoyed all the things I used to enjoy
9. Overall, how much has your back pain (and related problems) affected your life in the last 2 weeks?

Scoring:
Disagree Agree
0 1

Total score (all 9): ____________ Sub Score (Q5-9): ____________

>=4/5 on subscore = Complex, high-risk

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Matched treatments

Psychologically informed physiotherapy with enhanced skills & more time

Evidence based Physiotherapy

Advice, reassurance, & medication. Avoid over treatment & investigation

Complexity

- Low risk: 26%
- Medium risk: 46%
- High risk: 28%
- Very high risk: 12%
Evidence for this approach

- **Validated prognostic tool**
  - Hill et al 2008 (n=500)
  - Published validation & translation studies
    - Brazilian & Portugal Portuguese
    - Children’s version, Danish, Finnish
    - French, German, Iranian, Japanese
    - Mandarin, Persian, Spanish, Swedish

- **Proof of principle RCT**
  - Hill et al 2011 (n=851)
  - Funded replication RCTs
    - Dan Cherkin – Seattle USA
    - Tony Delitto – 5 Centres across USA
    - Lars Morsoe – Southern Denmark

- **Implementation & Qualitative research**
  - Foster et al 2014 (n=922)
  - Implementation research planned
    - Simon French – Canada
    - Martin Jensen – Denmark
    - Sven Karstens – Germany
    - Jaro Karpinnen - Finland
So what do we know about this model of stratified care?

• Strong data - it is both clinically and cost effective
• It improves early clinical decision-making so more patients get appropriate first-line care
• It focuses the minds of service providers particularly about managing hard to treat, complex patients
• Complexity has long been recognised - but previously it didn’t lead to patients getting a different treatment approach
• Patients and clinicians like it – they ‘get it’ & feel it ‘adds value’
• It can be implemented into routine care and makes a difference
HEALTH WARNING!
Myths about STarT Back

1. Low risk patients do not need treating ×
2. The tool is used without the matched treatment options ×
3. Managers use the approach to ration rather than re-allocate treatment resources ×
4. It reduces clinical autonomy & clinical reasoning ×
5. High-risk patients are all chronic psychological cases ×
6. The tool is not working if patients change subgroup ×
Limitations of STarT Back

1. It is designed for primary care
2. It is validated for non-specific low back pain
3. The tool’s predictive abilities have a sweet spot
4. Prediction is strongly influenced by treatment
5. It does not direct specific treatment only broad management
6. Training to upskill therapists to treat high-risk pts is scarce
7. The trial design does not tell us if it was the subgrouping or matched treatments (or both) which caused the effect
Future directions for prognostic stratified care

Promising early results – but more research is needed

For example:

- replication studies (internationally)
- sciatica patients (Keele SCOPIC trial)
- back pain in the elderly
- back pain in children (Simons et al 2015)
- other musculoskeletal conditions
Acknowledgements

The STarT Back & IMPaCT Back study teams
GP practices and physiotherapy services
Study participants

Full information on website [http://www.keele.ac.uk/sbst/](http://www.keele.ac.uk/sbst/)
With DVDs explaining the approach
Training course (5 days) s.weir@keele.ac.uk
Jonathan Hill’s email: j.hill@keele.ac.uk
Example 2: Responsiveness to treatment

John D. Childs, PT, PhD, MBA
CEO, Evidence in Motion &
Associate Professor & Director of Research
U.S. Army-Baylor University
Low Back Pain Sub-groups

- **Manipulation**
  - Classification Criteria
  - Manipulation and exercise

- **Specific Exercise**
  - Classification Criteria
  - Activities to Promote Centralization

- **Stabilization**
  - Classification Criteria
  - Stabilization exercises

- **Traction**
  - Classification Criteria
  - Mechanical/autotraction
Clinical Prediction Rule

Steps in Development:

1) Creating or deriving the rule
2) Testing or validating the rule
3) Assessing the impact of the rule on clinical behavior
A Clinical Prediction Rule for Classifying Patients with Low Back Pain Who Demonstrate Short-Term Improvement With Spinal Manipulation

Timothy Flynn, PT, PhD,*† Julie Fritz, PT, PhD,† Julie Whitman, PT, DSc,† Robert Wainer, PT, PhD,*† Jake Magel, PT, DSc,† Daniel Rendeiro, PT, DSc,† Barbara Butler, PT,† Matthew Garber, PT, DSc,† and Stephen Allison, PT, PhD*
Patient Admitted

Evaluation

MANIPULATION

50% Reduction in Oswestry? yes → SUCCESS

no → MANIPULATION

50% Reduction in Oswestry? yes → SUCCESS

no → FAIL
Spinal Manipulation CPR

**Physical Exam**
- Hip IR > 35 degrees
- Lumbar hypomobility

**History**
- Symptoms < 16 days
- No symptoms distal to the knee
- FABQWK < 19
131 Patients with LBP in Physical Therapy

- Mean age 33.9 years
- 42% female
- Median duration of sx = 27 days

Mean Oswestry = 41.2
24% sx distal to knee

Manipulation Group
n=70

- +CPR
  n=23
- -CPR
  n=47

Exercise Group
n=61

- +CPR
  n=24
- -CPR
  n=37

Clinical Prediction Rule Validation Study

ODQ Score

+ CPR (manip)
- CPR (manip)
+ CPR (exercise)
- CPR (exercise)

*P<0.001

• Based on classification algorithm:
  – manipulation (42.0%)
  – specific exercise (30.8%)
  – stabilization (17.6%)
  – traction (9.6%)
• 66.0% had clear classification
• 34.0% had unclear classification
Assessment of diclofenac or spinal manipulative therapy, or both, in addition to recommended first-line treatment for acute low back pain: a randomised controlled trial

Mark J Hancock, Chris G Maher, Jane Latimer, Andrew J McLachlan, Chris W Cooper, Richard O Day, Megan F Spindler, James H McAuley

Lancet 2007; 370: 1638–43
“Consistent with contemporary best clinical practice, the therapist adjusted the treatment to the clinical presentation of the patient rather than applying the same treatment to all patients.”

"Most participants had several low-velocity mobilisation techniques (232/239, 97%) with a small proportion also having high-velocity thrust techniques (12/239, 5%).“

What about exercise?
Bringing it together – future research

• 25% met more than one subgroup = what treatment should they get?
• 25% didn’t meet any subgroup = should we use the algorithm with them? Need additional treatments?
Example 3:
Stratified care based on underlying mechanisms

Peter O’Sullivan
Key underlying principles

- Patients matched to treatments based on underlying mechanism/s that drive pain and / or disability

  Pathoanatomy    Pain mechanisms    -ve thoughts / distress    Provocative behaviours

- Provides direction for targeted care
- Examples:
  - Pathoanatomic Based Classification approach (Peterson et al 2003)
  - Mechanical Diagnosis and Treatment approach (McKenzie 2003)
  - Multi-dimensional behavioural approach (O’Sullivan 2005, 2012)
Bio-psycho-social profile

Low back pain

THREAT RESPONSE

Trigger
Symptom provoking functional behaviours
Activity avoidance

Thoughts / distress....

It's dangerous to move.....
It's never going to get better..
I feel anxious and depressed...

O’Sullivan JOSPT 2012
Negative **beliefs about LBP**, **fear of movement**, ↑**distress** & ↓**self efficacy** are predictive of disability

Influences pain perception and functional behaviours

(Sullivan Pain 2009)
Pain provoking functional behaviours

Flexion pattern of provocation

Extension pattern of provocation

Provocative functional behaviours – sitting

<table>
<thead>
<tr>
<th></th>
<th>Sacral angle</th>
<th>Lx C</th>
<th>Lower LxC</th>
<th>Upper LxC</th>
</tr>
</thead>
<tbody>
<tr>
<td>No-LBP</td>
<td>-11.22</td>
<td>-10.85</td>
<td>-8.42</td>
<td>-2.49</td>
</tr>
<tr>
<td>Flexion Pattern</td>
<td>2.27</td>
<td>3.24</td>
<td>2.51</td>
<td>2.1</td>
</tr>
<tr>
<td>Active Extension</td>
<td>-17.41</td>
<td>-22.87</td>
<td>-18.43</td>
<td>-9.16</td>
</tr>
</tbody>
</table>

(Dankaerts Spine 2006, Sheeran Spine 2012)
Provocative functional behaviours – forward bending

3 groups classified with 96% accuracy based on EMG and kinematics

(Dankaerts Spine 2009)
Can we reliably identify these features?

Beliefs and levels of distress
(Fersum Man Ther 2009)

Provocative functional behaviours
(Dankaerts Man Ther 2006
Fersum Man Ther 2009)

Screening questionnaires

Örebro Musculoskeletal Pain Screening Questionnaire (Modified) (Linton & Hallden, 1998)

Name: ______________________ Date of Birth: ____________

Are you:

☐ Male
☐ Female

1. How long have you had your current pain problem? Tick (✓) one.


Interview

Physical examination
Cognitive functional therapy for targeted management of LBP

- Personalised understanding of LBP
- Reassurance
- Pain ≠ harm / damage
- Goal setting

- ↑ body awareness
- Functional training specific to individual
- Provocative and feared activities targeted
- ↑ pain control and confidence
- Protective behaviours discouraged
- Integrate into ADL

- Healthy lifestyle choices
- Graded physical activation
- Based on patient preference

Strong therapeutic alliance is central

-ve thoughts and distress

Symptom provoking functional behaviours

Activity avoidance
MINDSET CHANGE
"DON’T PANIC"

Trigger

Low back pain

Bio-psycho-social profile

+ve thoughts

My back is strong
Movement is good
Pain ≠ damage

Healthy movement & lifestyle behaviours

Curtin University
Evidence for this approach

Efficacy of classification-based cognitive functional therapy in patients with non-specific chronic low back pain: A randomized controlled trial

K. Vibe Fersum¹, P. O'Sullivan², J.S. Skouen¹,², A. Smith², A. Kvåle¹

1. Physiotherapy Research Group, Department of Public Health and Primary Health Care, University of Bergen, Norway
2. School of Physiotherapy, Curtin University, Bentley, Western Australia, Australia
3. The Outpatient Spine Clinic, Department of Physical Medicine and Rehabilitation, Haukeland University Hospital, Bergen, Norway

Cognitive Functional Therapy vs Manual Therapy/Exercise

N= 121
12 week intervention
Disability - ODI

(Fersum EJP 2013, 2015 unpublished)

Cognitive Functional Therapy
Manual Therapy

<table>
<thead>
<tr>
<th>Time</th>
<th>Cognitive Functional Therapy</th>
<th>Manual Therapy</th>
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</thead>
<tbody>
<tr>
<td>Pre P=0.164</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post P&lt;0.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 months post P&lt;0.000</td>
<td></td>
<td></td>
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<tr>
<td>36 months post P&lt;0.000</td>
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Patient pathways

Retain biomedical beliefs

Control over pain

Function

non-responders

Acceptance of biopsychosocial understanding

Achieving Independence

Control over pain

Return to normal

responders

McEvoy, Bunzli et al 2015
Where to next?

Hypothesized approach

Clinical validation

Laboratory validation

Outcome validation

Cost benefits

Replication

Implementation

Training required

Understand mediators of change/barriers to recovery

Questions:

Where to next?
Who is CFT not for?

Red Flags

Acute radiculopathy

Acute trauma

Limitations of CFT

Time constraints

Level of training required

Readiness for change
What do we know about this model of stratified care?

- Targets beliefs and behaviours
- Facilitates patient centred care
- Strong clinical alliance is central
- Builds confidence in clinicians
- Patients like it – empowering
- Primary and secondary care
- Can be integrated with:
  - screening tools
  - other interventions (medical /psychological)
Acknowledgements

Kjartan Fersum  Wim Dankaert  Alice Kvåle  Sture Skouen  Leon Straker  Anne Smith  Kieran O’Sullivan  Sam Bunzli  Sarah McEvoy

www.pain-ed.com
What is still unknown?
Which approach should I use next week?

A/Prof Mark Hancock
Overlap between approaches?

- Mechanisms
- Prognosis
- Rx response
Biology and stratification?

Albert et al ESJ 2013
Prognosis ≠ Rx effect

Should we provide treatment to those with better or worse prognosis?

- Good prognosis
  - Small Rx effect
- Poor prognosis
  - Large Rx effect

Pain intensity vs Time graph

- Good prognosis (Small Rx effect)
- Poor prognosis (Large Rx effect)
Prognosis ≠ Rx effect

Should we provide treatment to those with better or worse prognosis?

![Graph showing pain intensity over time for good and poor prognosis with different Rx effects.]

- Good prognosis: Large Rx effect
- Poor prognosis: Small Rx effect
Prognosis (patient focussed?)

Clinical prediction rule for probability of recovery

<table>
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<tr>
<th>Predictors present</th>
<th>Proportion recovered week 2</th>
<th>Proportion recovered week 12</th>
</tr>
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<tbody>
<tr>
<td>0</td>
<td>24.5</td>
<td>74.7</td>
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<tr>
<td>1</td>
<td>34.8</td>
<td>87.7</td>
</tr>
<tr>
<td>2</td>
<td>51.2</td>
<td>97.2</td>
</tr>
<tr>
<td>3</td>
<td>77.9</td>
<td>99.9</td>
</tr>
</tbody>
</table>

1. baseline pain (≤7/10);
2. duration of current symptoms (≤5 days);
3. number of previous episodes of low back pain (≤1).

Hancock et al EJP 2009, Williams EJP 2014
Treatment response

How generalizable are the findings?
• Different patients
• Treatment delivered differently
• Different comparison treatment

Maybe treatment is just not effective?
Mechanisms

Does the treatment work in the manner we think?

Motor control vs McKenzie method
Which approach should you use?

No approach is meant to completely remove clinician decision making

In which patients/setting is there evidence/logical rationale?

- Prognosis (STarT Back):
- Treatment response (Treatment based classification):
- Mechanisms (CFT):
Can we integrate existing approaches?

Acute/subacute NSLBP

STarT Back approach
- Min Care
- PT
- PT+

T-B Class Algorithm
- Manips
- Specific (MDT)
- Stabilization

Do not recover

Cognitive functional therapy

Chronic NSLBP
Recommendations for practice, education and research

Nadine Foster
NIHR Research Professor
Clinical practice

• 3 examples based on good quality evidence of at least one randomised clinical trial
  – but 1 RCT is still only 1 RCT
  – the evidence base needs further development

• These models don’t replace clinical reasoning or experience, but
  – they do warrant judicious exploration in clinical practice in appropriate settings

• Clinical training requirements
Education

• Evidence base warrants inclusion of stratified care into physical therapy education
  – qualifying / undergraduate – awareness, introduction and early skill development
  – post-qualifying / postgraduate – training and expert skill development

• Desire to avoid unhelpful confusion
  – may be realistic to focus on one approach as a detailed example and raise awareness of other approaches
Research

• Use published guidance about the methods of stratified care research
  – high quality randomised trial design
  – care needed in selection of control group for these trials

• Broad validation studies of the most promising approaches are needed
  – more than developing multiple new approaches
  – impact analysis studies are needed
Discussion