Targeted treatment for back pain: results of the STarT Back clinical trial

Dr Jonathan Hill
Arthritis Research UK Primary Care Centre
Keele University
Overview

- The selection of high-risk patients in practice
- The STarT Back Trial - results
- Implementation of the approach in practice
Differences in patients

Sarah
48 yr old with grown up children, works as an administrator (part time)
5 yr history of recurrent back pain flare-ups, usually settle
Present episode started 5 weeks ago, gradual onset
GP prescribed Diclofenac, noted OA in her hands and left knee, increased BP and Type II diabetes.
Current pain level is 5/10, localised to the lumbar spine, no referred pain
Main complaint is sleep difficulties and the lack of improvement over the past month
She is thinking about giving up part-time work, & has stopped her child care role for her grandson (2 days/wk)
O/E: Rather overweight, but posture OK. Reflexes, dermatomes, myotomes, slump, SLR – all NAD
Previous physiotherapy last year wasn’t particularly successful. She wants to have some answers why
she has so much pain and feels at a loss to know how to help herself get better

Dave
55 yr old man, works full time as a service engineer (in Stoke)
10 yrs ago had a similar back problem, but was pain-free in-between episodes
Present episode started 2 weeks ago, after a heavy lift at work – he felt it ‘go’
His GP prescribed Diclofenac & cocodamol, and gave him a 2 week sick note which is running out
Currently pain is 7/10, improving daily, but still severe down his right leg to back of calf
Main complaint is throbbing leg pain, particularly at night
He is not sure when to return to work as he has a lot of driving…..
O/E: A little overweight, moderate lateral shift of his spine to left, muscle spasm visible, reflexes OK,
dermatomes affected (dull sensation R side), myatomes OK, Slump & SLR positive right side (60°).
No red flags present, cough, sneeze, pins & needles were negative.
2 back pain cases

1. Where would you place Sarah and Dave on your waiting list? Who should get treatment first?

2. Which patient is likely to need the most number of treatments? Why?

3. Which patient requires the most expertise? (e.g. Supervision of Juniors/students)
Why screen psychosocial factors?

Treatment success for LBP is highly variable. Psychosocial factors help predict poor outcome.

Perceived disability, previous treatment experiences, depression, somatization, catastrophizing, fear avoidance beliefs, self-efficacy, coping strategies, and job satisfaction (Hilfiker et al., 2007)

Hypothesis: We should be better using this information to tailor treatment and improve clinical outcomes.
The case for screening

Screening tools help clarify the source of patient concerns
Some factors are difficult to identify without screening e.g. depression
Screening improves patient-centred care (issues important to pts):

- Fears & worries about diagnosis
- Stigma & symptom legitimisation
- Loss of role and identity
- Confidence to self-manage
- Lack of personal control
- Mood
- Expectations
- Catastrophizing
- Somatizing
- Job satisfaction
- Distress
- Loneliness

Patient Information

Arthritis Research Campaign National Primary Care Centre Keele University
Arthritis Research UK Primary Care Centre
Winner of a Queen’s Anniversary Prize 2009
Need for balance

Physical factors are also predictive of outcome:

• Pain intensity, referred leg pain, co-morbidity, etc…
• Even in chronic LBP patients - pain intensity & baseline function are usually more important predictors than individual psychosocial factors….
• Acute patients (with clear pathology) can score highly on psychosocial scales (fear, depression)

Recent paper by Heymans et al., 2010 (The Spine Journal)
This examined predictors/mediators of chronic disability
Scientific consensus

1. We need to move on from a ‘one-size fits all’ approach to LBP treatment
2. Methods to match pts to treatment need testing
3. We need to better target psychosocial factors that mediate treatment outcome

 e.g. self-efficacy has a strong influence on return to work….. So it makes sense to target self-efficacy during treatment
Scientific doubt

1. Should psychosocial issues be addressed in all patients or just among a small subgroup?

2. Are specific psychosocial treatments needed to actually address psychosocial factors?
   - Some say ‘Probably Not’ (Smeets 2006)
   - Others say ‘Probably Yes’ (George, 2003)

3. What level of therapist training is required?
Alternative approach… Differentiate on complexity

Identify patient’s level of risk for chronicity (using prognostic screening tool)

One complexity scale that integrates physical & psychosocial factors

Seeks to improve assessment & treatment efficiency

Augmented psychosocial physical therapy (complex)

Course of physical therapy

Minimal treatment of advice & medication
The STarT Back Screening Tool

Items included:

Referred leg pain
Comorbid pain elsewhere
Disability
Fear avoidance
Anxiety
Catastrophising
Depression
Overall impact

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Disagree</th>
<th>Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>My back pain has spread down my legs in the last 2 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have had pain in the shoulder or neck at some time in the last 2 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I have only walked short distances because of my back pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In the last 2 weeks, I have dressed more slowly than usual because of back pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>It's not really safe for a person with a condition like mine to be physically active</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Worrying thoughts have been going through my mind a lot of the time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I feel that my back pain is terrible and it's never going to get any better</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In general I have not enjoyed all the things I used to enjoy</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. Overall, how bothered has your back pain been in the last 2 weeks?

   Not at all | Slightly | Moderately | Very much | Extremely
   0         | 1        | 2          | 3         | 4

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

www.keele.ac.uk/startback
The STarT Back Screening Tool

**Screening tool score**
1. Referred leg pain  Yes
2. Comorbid pain Yes
3. Dresses slowly Yes
4. Walks short distance Yes
5. Fearful of activity Yes
6. Anxious about pain Yes
7. Catastrophising No
8. Low mood Yes
9. Very Bothered Yes

**Total score**
- 3 or less: Low risk
- 4 or more: Medium risk

**Psych score**
- 3 or less: Low risk
- 4 or more: Medium risk

**Screening tool score**
1. Referred leg pain Yes
2. Comorbid pain No
3. Dresses slowly Yes
4. Walks short distance Yes
5. Fearful of activity Yes
6. Anxious about pain Yes
7. Catastrophising No
8. Low mood No
9. Very Bothered Yes

**Example 1:** Score = 6
- Total score: Low risk

**Example 2:** Score = 8
- Total score: Medium risk

Arthritis Research Campaign National Primary Care Centre Keele University
Winner of a Queen’s Anniversary Prize 2009
Testing the instrument

- Evaluate screening tool’s measurement properties:
  - Content, discriminant, criterion, face validity
  - Item redundancy, internal consistency, floor & ceiling effects
  - Test-retest reliability
  - Paper published

(Hill et al, Arthritis Care & Research, 2008)
Comparison with Orebro (Steven Linton et al 1998)

(Hill et al, Eur J Pain, 2009)
Subgroup characteristics

Group scores:
- Pain VAS = 6.7
- HADs dep cases = 71%
- TSK>41 = 90%
- RMDQ>7 = 97%
- Referred leg pain = 55%

Low risk
- 56%

High risk
- 12%

Observational primary care sample (n=1591)

- Physical therapy sample (n=1016)
  - Low = 40%
  - Med = 40%
  - High = 20%

Medium risk
- 32%

Group scores:
- Pain VAS mean = 5.3
- HADs dep cases = 24%
- TSK>41 = 62%
- RMDQ>7 = 73%
- Referred leg pain = 19%

Poor outcome
a) 59%
b) 32%

Group scores:
- Pain VAS = 2.6
- HADs dep cases = 3%
- TSK>41 = 31%
- RMDQ>7 = 9%
- Referred leg pain = 19%

Poor outcome
a) 35%
b) 12%

Low risk
- 56%

Poor outcome
a) 13%
b) 1%

High risk
- 12%

6 month outcome: a) >= ‘very bothered’

12 month outcome: b) >30 days off work
Does it add to clinical intuition?

Study design

12 patients were video interviewed

Each video watched by a GP, physio and pain specialist – asked to subgroup patient into low, medium or high risk group

Patient Example

Age at interview: 35
Gender: Female
Background: Secretary (P/T)
Brief outline: 5 yr LBP – on & off.
New episode 4 wks ago with sciatica.
Pain was severe but is now improved.
Patient is back at work.
Has concerns about the cause due to an ongoing absent ankle jerk.
Clinicians comments:

- GP: Patient is currently under evaluation, wants to know what is causing the pain and how to deal with her symptoms – should improve. **Allocate to ‘low risk’**

- PM: Requires reassurance as she is worried about cause of the pain. States that her mood is good. Good work record. Supportive husband. **Allocate to ‘medium risk’**

- PT: Said that her back ‘cracked’…. & ‘I was nearly split in two’….. Also has had previous PT with no effect…. She is also frightened by her loss of ankle jerk. She is definitely high risk! **Allocate to ‘high risk’**

Screening tool score

1. Referred leg pain: Yes
2. Comorbid pain: Yes
3. Dresses slowly: Yes
4. Walks short distance: Yes
5. Fearful of activity: Yes
6. Anxious about pain: Yes
7. Catastrophising: Yes
8. Low mood: No
9. Very Bothered: Yes

Total score = 8/9
Psych subscale = 4/5
Allocate to ‘high risk’

Consistent allocation by all 3 experts in only 4 of 12 pts
No difference by profession
Summary so far

• Current early decision-making is inconsistent
• An ‘index of risk’ helps identify complex cases
• Back pain is multi-factorial…. so an assessment of overall ‘problematic-ness’ is needed to discriminate pts
• An integrated treatment approach is needed
• A brief screening tool for risk status has been validated
Arthritis Research UK
Primary Care Centre
Winner of a Queen’s Anniversary Prize
For Higher and Further Education 2009

The STarT Back Trial

Dr Jonathan Hill
On behalf of: Kate Dunn, Martyn Lewis, Liz Mason, Chan Vohora, Chris Main, Kika Konstantinou, Gail Sowden, Simon Somerville, David Whitehurst, Nadine Foster, and Elaine Hay.
RCT to test stratified primary care management approach

Identify patient’s level of risk for chronicity - Keele STarT Back Screening Tool

Limit more sophisticated resources to those that really need them

Organise initial referral according to this stratified model of care

Psychologically informed physiotherapy (complex)

Course of physiotherapy

Minimal treatment - advice & medication

www.keele.ac.uk/startback
STarT Back Trial Design

Adults with low back pain
Triage clinic

Consent & baseline Q
Randomised

10 general practices
In England
Pool of adults (n=75,208)

(n = 851)

Stratified care

Low Clinic only
Medium PT
High Enhanced PT

Control group

Self-care Clinic only
Needing help PT

Follow-up at 4 & 12 months

The design does not seek to determine whether risk-group level benefits are due to improved referral patterns, or improved treatment quality…
Methods

1. Pragmatic, phase III, 2-arm parallel RCT in UK
2. Protocol is published (Hay et al., 2008)
3. Remote telephone randomisation
   - Stratified by Centre & risk-group
4. Blinding of research nurses

Outcomes @ 4 & 12 months

1. Physical function (RMDQ)
2. Emotional function (PCS & TSK)
3. Pain intensity
4. Quality of life (SF-12 & EuroQol)
5. Time (days) off work due to LBP
6. Global improvement ratings
7. Treatment satisfaction
8. Economic evaluation
Results – overall

At 4 and 12 months there were significant improvements in:
- disability (RMDQ)
- fear avoidance beliefs
- time off work
- global improvement ratings
- patient satisfaction
- quality of life

Targeted treatment was also cheaper
Referral patterns

- **High risk**: 28%
  - Control vs Stratified referred: 65% vs 100%
- **Low risk**: 26%
  - Control vs Stratified referred: 49% vs 7%
- **Medium risk**: 46%
  - Control vs Stratified referred: 60% vs 98%

Overall referral rate:
1. Control: 58%
2. Stratified: 75%
Results – low risk group

- Clinical outcomes were equivalent
  - Control: 49% referred for mean 5 treatments
  - Targeted: 7% referred for mean 5 treatments

- Small improvements secondary outcomes in favour of targeting:
  - better reductions in disability
  - less time off work (significant)
  - better patient satisfaction
  - better reductions in pain

- Much cheaper to target Tx
Results – med risk group

- Clinical outcomes were superior
  - Control: 60% referred (mean 4 sessions)
  - Targeted: 98% referred (mean 4 sessions)

- Consistent across secondary outcomes
- Differences were sustained at 4 and 12 months:
  - e.g. 4 days vs 18 days off work @ 1 yr
  - much more cost-effective
Results – high risk group

• Clinical outcomes were superior at 4 months (RMDQ differences >2.5)
  • Control: 65% referred (mean of 5 sessions)
  • Targeted: 100% referred (mean of 4 sessions)

• RMDQ differences were **not** significant at 12 mths:
  - Only effective in the short-term
  - Significantly less health resource use
  - Improved patient satisfaction
Results – costs

Stratified care was dominant:
- significant improvements in QALYs (0.04)
- reduction in health care utilisation
- reduction in societal costs (less time off work)
A stratified management approach to primary care with screening and matched pathways – works.

Low risk patients only need minimal treatment

Systematic targeting of sophisticated treatment to med & high risk groups - leads to improved outcomes

The new systems approach was significantly better than a Rolls Royce usual care package, and was cheaper to provide.
Keele’s IMPaCT Back study

Implementation study to improve Patient Care through Targeted treatment for Back pain

What are the barriers to implementation?

2007-2010
Led by Dr Nadine Foster
Timeline

Researchers / Clinicians

Set up – Ethics, negotiation with clinical partners

Observational period

Training & phased introduction

Observational period

6 Months 4 Months 6 Months 12 Months 6 Months

0 6 10 16 28 34

Recruitment

Follow-up (6 months)

Recruitment (6 months)

Patients

Arthritis Research Campaign National Primary Care Centre
Keele University

Arthritis Research UK Primary Care Centre
Winner of a Queen’s Anniversary Prize 2009
Findings among GPs

- LBP is not seen as a priority
- Disposal approach is routine
- Lack of peer communication to drive innovation
- Sense - resource constraints impact sustainability
- Changing policy context, leading to apathy
- Not strong evidence it affects business model

- Overall uptake 60% but didn’t sustain post study
Findings among Physios

- Sense of readiness to change – skills are lacking
- Attitude that approach helps promote prof status
- Felt their skills/confidence improved beyond LBP
- Acknowledgment about inefficiencies of system
- Desire for GPs and PTs to give same messages
- Sense that care needs better coordination
Implementation research

External validation internationally
Julie Fritz - USA, tested tool in American PT sample
- found low-risk (30%) got same no. of Tx sessions
- high-risk discharged the earliest

Hanne Albert – is implementing tool - Southern Denmark
- has embedded the tool into 15 GP IT systems
- wants 1000 PTs trained in high-risk skills
New generic MSK tool

- Subgroup patients
- Provides audit data - PROMs
- Monitors treatment progress
- Flags non-responders
- Case mix adjustment
- Embedded in IT solution
What have we learnt?

- System level changes are needed
- Many UK physios fail high-risk pts and biopsychosocial training is needed
- The approach can be implemented and is very acceptable to patients
- UK GPs are slower to change than PTs
- Stratified care is very cost-effective particularly because it is systematic
Future directions

Implementation in increasing numbers of Centres in the UK and elsewhere

www.keele.ac.uk/startback

Website development – video clips, etc…

Now examining mediators of outcome
Exploring ways to achieve long-term outcomes
Identify non-responders at baseline
Expanding approach to musculoskeletal care
Thank you for listening

j.hill@cphc.keele.ac.uk  www.keele.ac.uk/startback