

Arthritis Research UK Primary Care Centre

Winner of a Queen's Anniversary Prize
For Higher and Further Education 2009

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

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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), myotomes 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

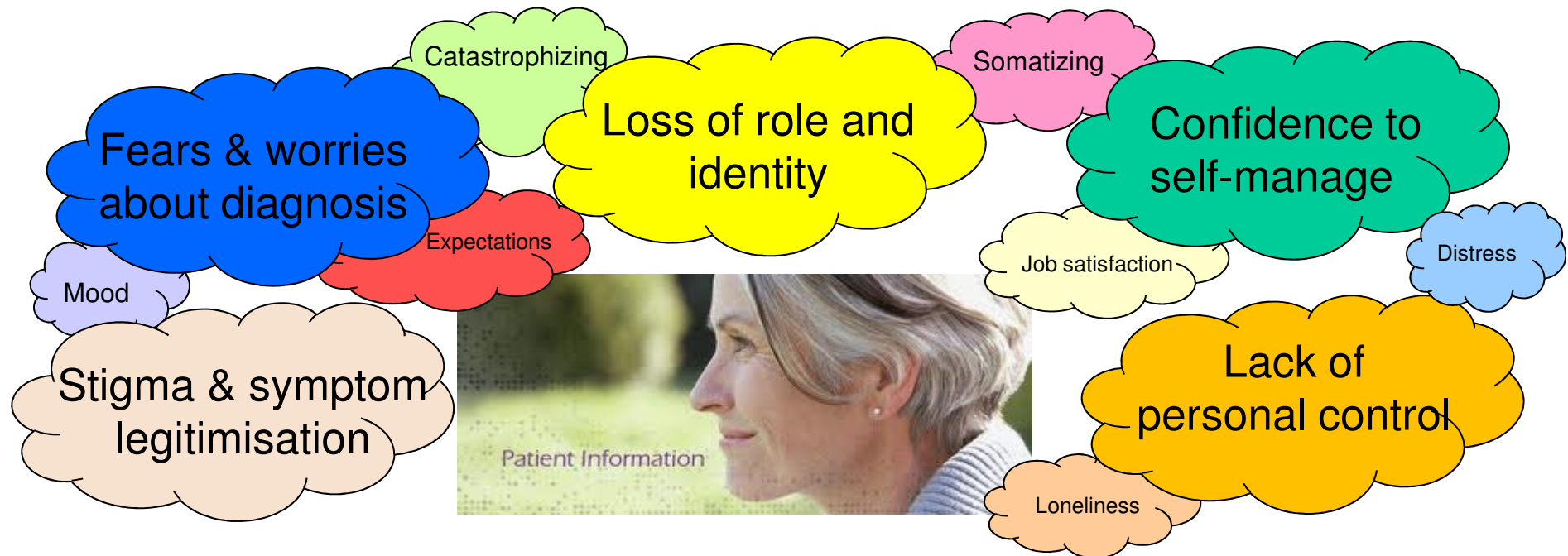


The case for screening

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):



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

The START Back Screening Tool

Patient name: _____ Date: _____

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

	Disagree	Agree
1. My back pain has spread down my legs in the last 2 weeks	<input type="checkbox"/>	<input type="checkbox"/>
2. I have had pain in the shoulder or neck at some time in the last 2 weeks	<input type="checkbox"/>	<input type="checkbox"/>
3. I have only walked short distances because of my back pain	<input type="checkbox"/>	<input type="checkbox"/>
4. In the last 2 weeks, I have done more slowly than usual because of back pain	<input type="checkbox"/>	<input type="checkbox"/>
5. It's not really safe for a person with a condition like mine to be physically active	<input type="checkbox"/>	<input type="checkbox"/>
6. Worrying thoughts have been going through my mind a lot of the time	<input type="checkbox"/>	<input type="checkbox"/>
7. I feel that my back pain is worse and it's more going to get any better	<input type="checkbox"/>	<input type="checkbox"/>
8. In general I have not enjoyed all the things I used to enjoy	<input type="checkbox"/>	<input type="checkbox"/>

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

Not at all	Slightly	Moderately	Very much	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Total score (all 9): _____ Sub-Score (Q8-9): _____

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

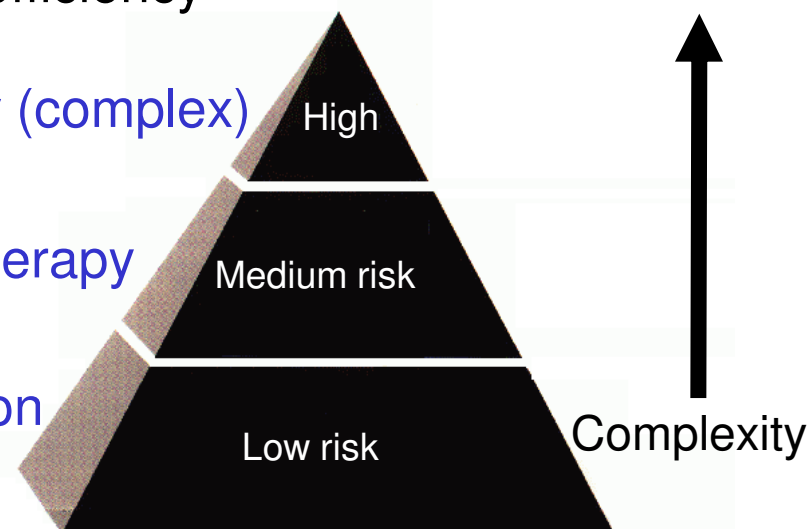
One complexity scale that integrates physical & psychosocial factors

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:

	Disagree 0	Agree 1
1 My back pain has spread down my leg(s) in the last 2 weeks	<input type="checkbox"/>	<input type="checkbox"/>
2 I have had pain in the shoulder or neck at some time in the last 2 weeks	<input type="checkbox"/>	<input type="checkbox"/>
3 I have only walked short distances because of my back pain	<input type="checkbox"/>	<input type="checkbox"/>
4 In the last 2 weeks, I have dressed more slowly than usual because of back pain	<input type="checkbox"/>	<input type="checkbox"/>
5 It's not really safe for a person with a condition like mine to be physically active	<input type="checkbox"/>	<input type="checkbox"/>
6 Worrying thoughts have been going through my mind a lot of the time	<input type="checkbox"/>	<input type="checkbox"/>
7 I feel that my back pain is terrible and it's never going to get any better	<input type="checkbox"/>	<input type="checkbox"/>
8 In general I have not enjoyed all the things I used to enjoy	<input type="checkbox"/>	<input type="checkbox"/>

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

Not at all	Slightly	Moderately	Very much	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
0	0	0	1	1

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

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The STarT Back Screening Tool

Example 2:
Score = 8

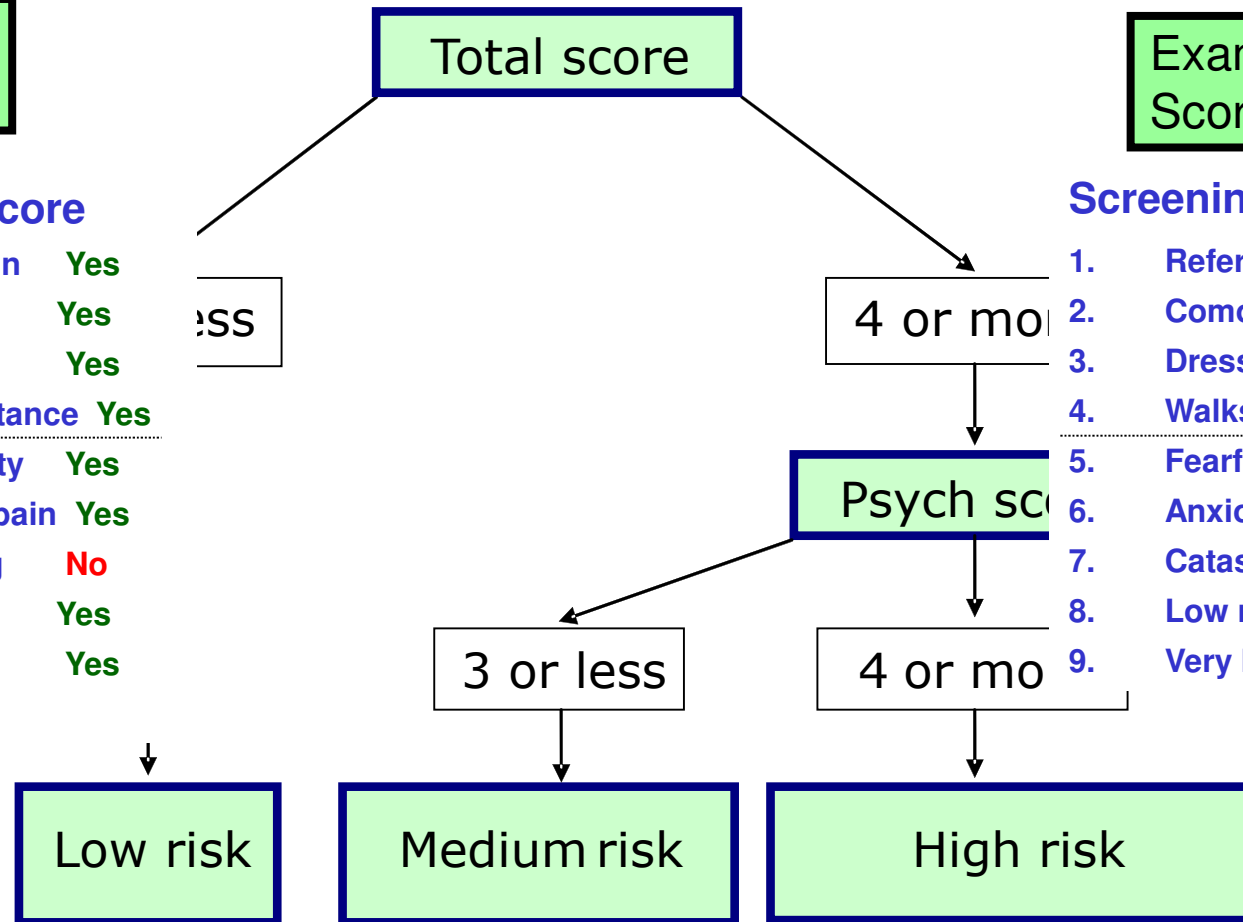
Example 1:
Score = 6

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 |

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 |



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)

Arthritis & Rheumatism (Arthritis Care & Research)
Vol. 59, No. 5, May 15, 2008, pp 632-641
DOI 10.1002/art.23563
© 2008, American College of Rheumatology

ORIGINAL ARTICLE

A Primary Care Back Pain Screening Tool: Identifying Patient Subgroups for Initial Treatment

JONATHAN C. HILL, KATE M. DUNN, MARTYN LEWIS, RICKY MULLIS, CHRIS J. MAIN,
NADINE E. FOSTER, AND ELAINE M. HAY

Comparison with Orebro (Steven Linton et al 1998)



The screenshot shows the website for the European Journal of Pain. At the top, there is a blue header with the journal's logo and the text 'Official Journal of the European Federation of IASP Chapters (EFIC)'. Below the header is a navigation menu with options like 'Articles and Issues', 'For Authors', 'Journal Info', 'Subscribe', 'EFIC', and 'More Periodicals'. A search bar is present with a dropdown menu set to 'All Fields' and a 'Go' button. The main content area displays the journal title 'European Journal of Pain', the volume and issue information 'Volume 14, Issue 1, Pages 83-89, January 2010', and the article title 'Subgrouping low back pain: A comparison of the STarT Back Tool with the Örebro Musculoskeletal Pain Screening Questionnaire'. The authors listed are Jonathan C. Hill, Kate M. Dunn, Chris J. Main, and Elaine M. Hay. Below the authors, there is a note about the article's submission and publication dates. At the bottom of the article preview, there are tabs for 'Abstract', 'Full Text', 'PDF', 'Images', and 'References'. The 'Abstract' tab is selected, showing the beginning of the article's introduction and aim.

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« Previous European Journal of Pain Volume 14, Issue 1, Pages 83-89, January 2010

Subgrouping low back pain: A comparison of the STarT Back Tool with the Örebro Musculoskeletal Pain Screening Questionnaire

[Jonathan C. Hill](#) [Kate M. Dunn](#) [Chris J. Main](#) [Elaine M. Hay](#)

Received 3 July 2008; received in revised form 11 December 2008; accepted 13 January 2009; published online 19 February 2009.

Abstract Full Text PDF Images References

Abstract

Introduction

Clinicians require brief, practical tools to help identify low back pain (LBP) subgroups requiring early, targeted secondary prevention. The STarT Back Tool (SBT) was recently validated to subgroup LBP patients into early treatment pathways.

Aim

To test the SBT's concurrent validity against an existing, popular LBP subgrouping tool, the Örebro Musculoskeletal Pain

(Hill et al,
Eur J Pain, 2009)

Subgroup characteristics

Observational primary care sample (n=1591)

Physical therapy sample (n=1016)

Low = 40%

Med = 40%

High = 20%

Group scores:

Pain VAS = 6.7

HADs dep cases = 71%

TSK>41 = 90%

RMDQ>7 = 97%

Referred leg pain = 55%

High risk

12%

Poor outcome

a) 59%

b) 32%

Medium risk

32%

Poor outcome

a) 35%

b) 12%

Low risk

56%

Poor outcome

a) 13%

b) 1%

Group scores:

Pain VAS = 2.6

HADs dep cases = 3%

TSK>41 = 31%

RMDQ>7 = 9%

Referred leg pain = 19%

Group scores:

Pain VAS mean = 5.3

HADs dep cases = 24%

TSK>41 = 62%

RMDQ>7 = 73%

Referred leg pain = 52%

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

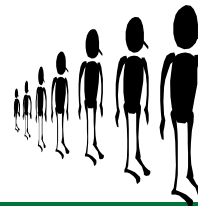
Psych subscale = 4/5

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



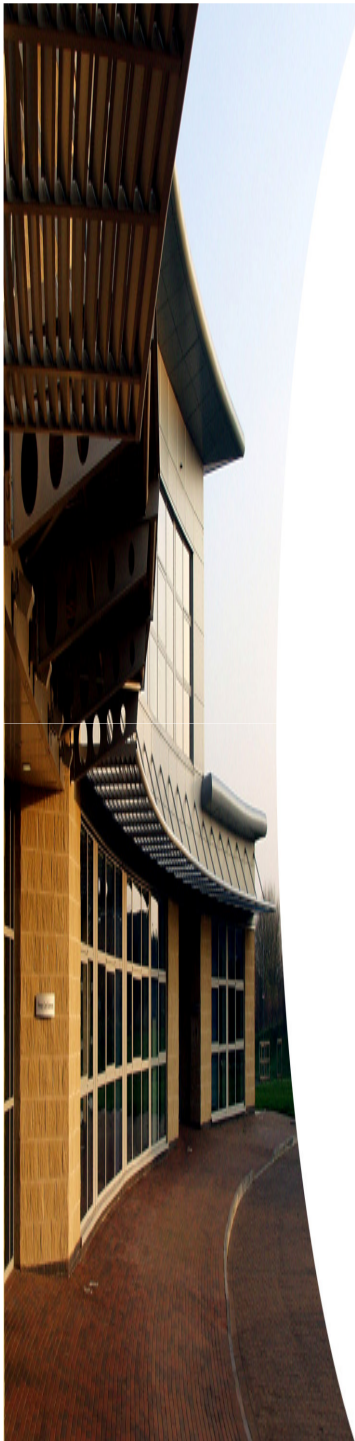
Arthritis Research UK Primary Care Centre

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

The STarT Back Screening Tool

Patient name: _____ Date: _____

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

	Disagree	Agree
1. My back pain has spread down my legs in the last 2 weeks	<input type="checkbox"/>	<input type="checkbox"/>
2. I have had pain in the shoulder or neck at some time in the last 2 weeks	<input type="checkbox"/>	<input type="checkbox"/>
3. I have only walked short distances because of my back pain	<input type="checkbox"/>	<input type="checkbox"/>
4. In the last 2 weeks, I have done more things than usual because of back pain	<input type="checkbox"/>	<input type="checkbox"/>
5. It's not really safe for a person with a condition like mine to be physically active	<input type="checkbox"/>	<input type="checkbox"/>
6. Worrying thoughts have been going through my mind a lot of the time	<input type="checkbox"/>	<input type="checkbox"/>
7. I feel that my back pain is worth it and it's worth going to get my better	<input type="checkbox"/>	<input type="checkbox"/>
8. In general I have not enjoyed all the things I used to enjoy	<input type="checkbox"/>	<input type="checkbox"/>

9. Overall, how do you rate your back pain based on the last 2 weeks?

Not at all	Slightly	Moderately	Very much	Extremely
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Total score (all 9): _____ Sub-Score (Q8-9): _____

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

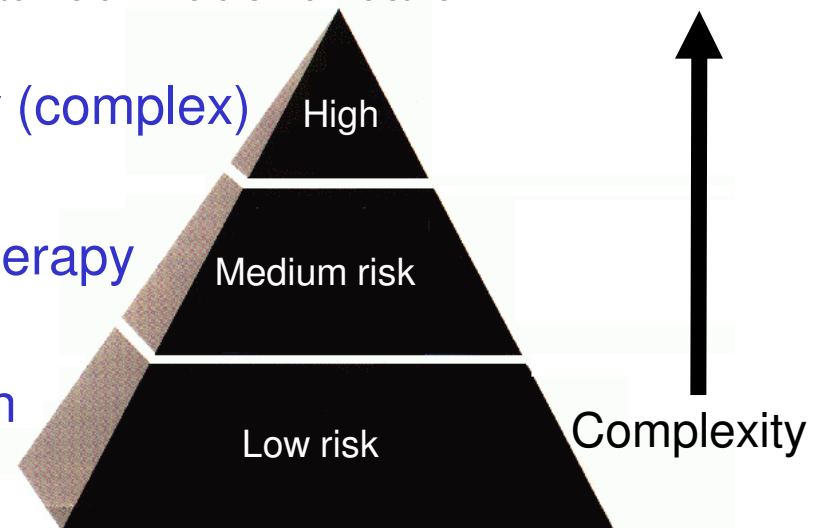
Limit more sophisticated resources to those that really need them

Organise initial referral according to this stratified model of care

Psychologically informed physiotherapy (complex)

Course of physiotherapy

Minimal treatment - advice & medication

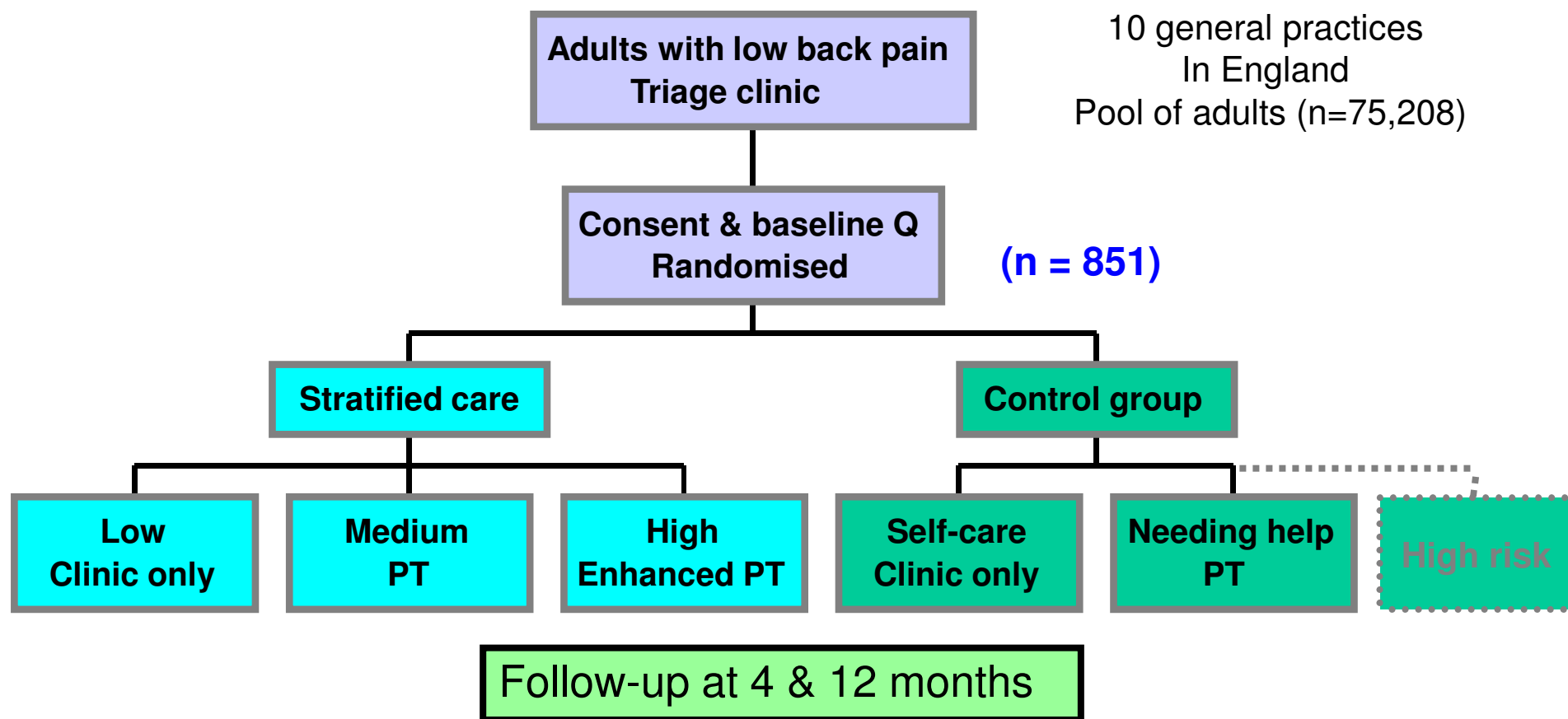


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STarT Back Trial Design

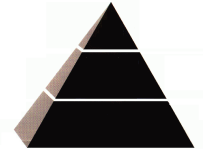


10 general practices
In England
Pool of adults (n=75,208)



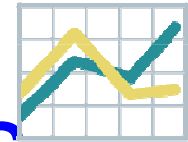
The design does not seek to determine whether risk-group level benefits are due to improved referral patterns, or improved treatment quality...

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



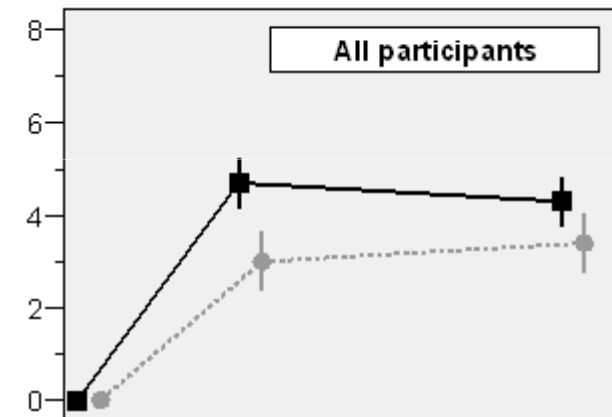
- | | |
|--------------------------------------|------------------------------------|
| 1. Physical function (RMDQ) | 5. Time (days) off work due to LBP |
| 2. Emotional function (PCS & TSK) | 6. Global improvement ratings |
| 3. Pain intensity | 7. Treatment satisfaction |
| 4. Quality of life (SF-12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

Results – overall



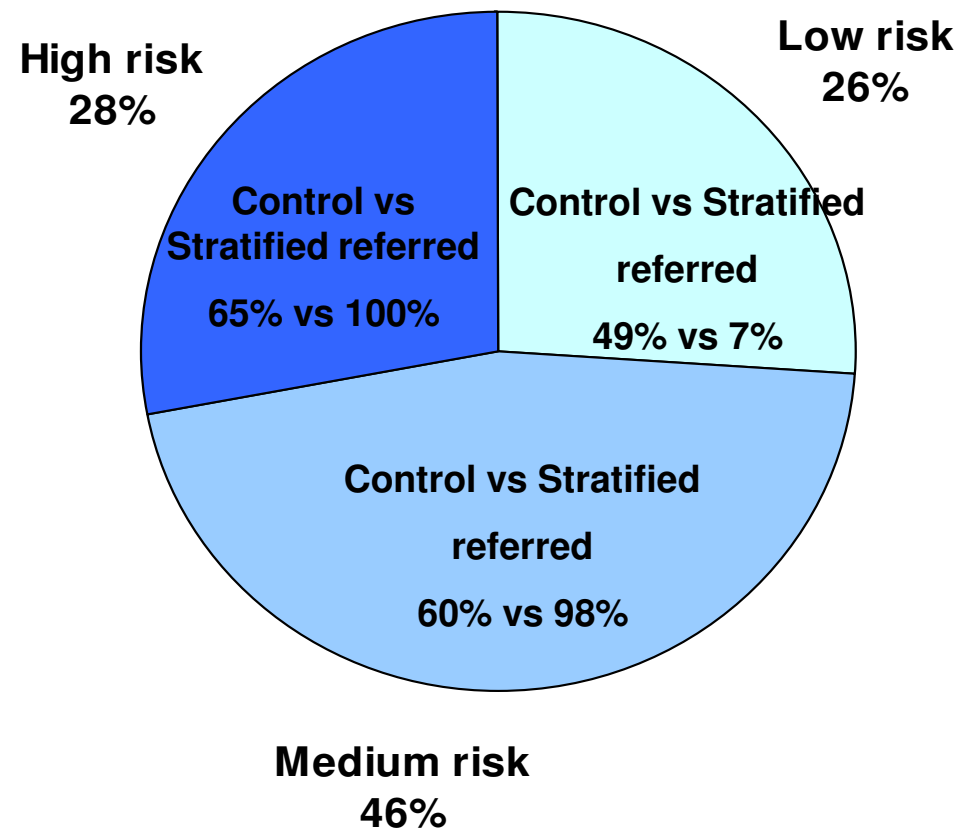
At 4 and 12 months there were significant improvements in:

- disability (RMDQ)
- fear avoidance beliefs
- time off work
- global improvement ratings
- patient satisfaction
- quality of life



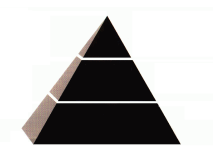
Targeted treatment was also cheaper

Referral patterns

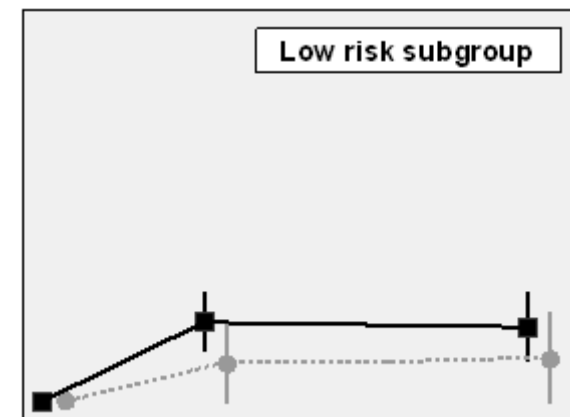


Overall referral rate:
1. Control: 58%
2. Stratified: 75%

Results – low risk group



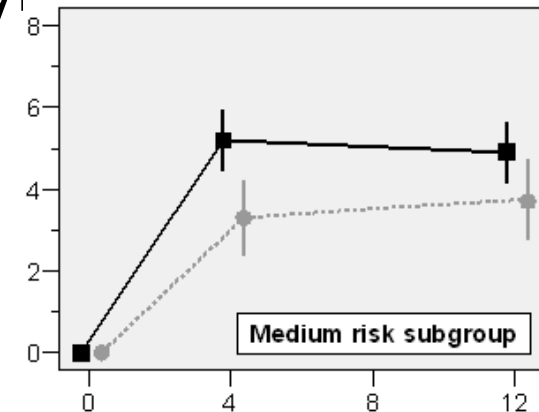
- Clinical outcomes were equivalent
 - Control: 49% referred for mean 5 treatments
 - Targeted: 7% referred for mean 5 treatments
- Small improvements secondary outcomes in favour of targeting:
 - better reductions in disability
 - less time off work (significant)
 - better patient satisfaction
 - better reductions in pain
- Much cheaper to target Tx



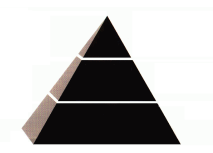
Results – med risk group



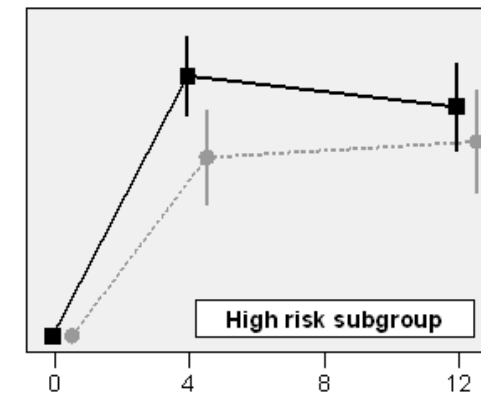
- Clinical outcomes were superior
 - Control: 60% referred (mean 4 sessions)
 - Targeted: 98% referred (mean 4 sessions)
- Consistent across secondary outcomes
- Differences were sustained at 4 and 12 months:
 - e.g. 4 days vs 18 days off work @ 1 yr
 - much more cost-effective



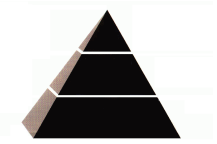
Results – high risk group



- 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

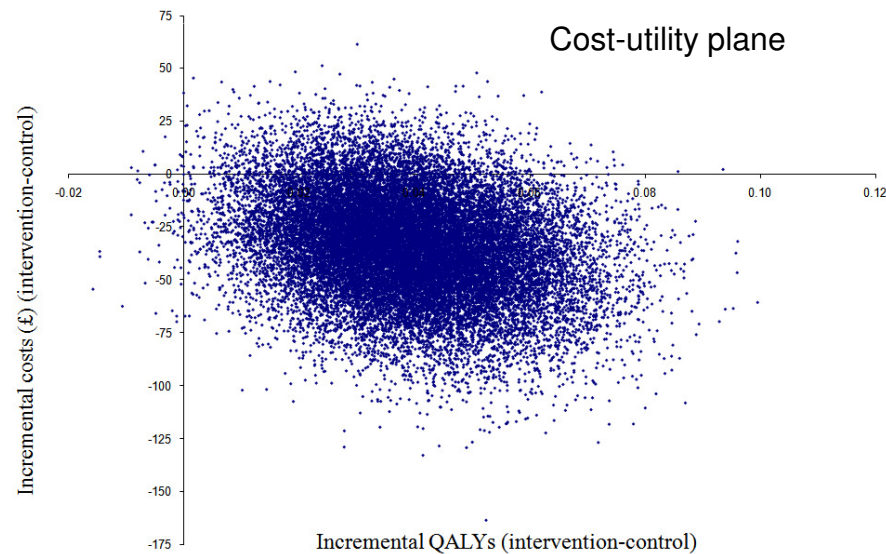


Results – costs



Stratified care was dominant:

- significant improvements in QALYs (0.04)
- reduction in health care utilisation
- reduction in societal costs (less time off work)



Trial Conclusions



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 **P**atient **C**are
through **T**argeted treatment for **B**ack pain

What are the barriers to implementation?

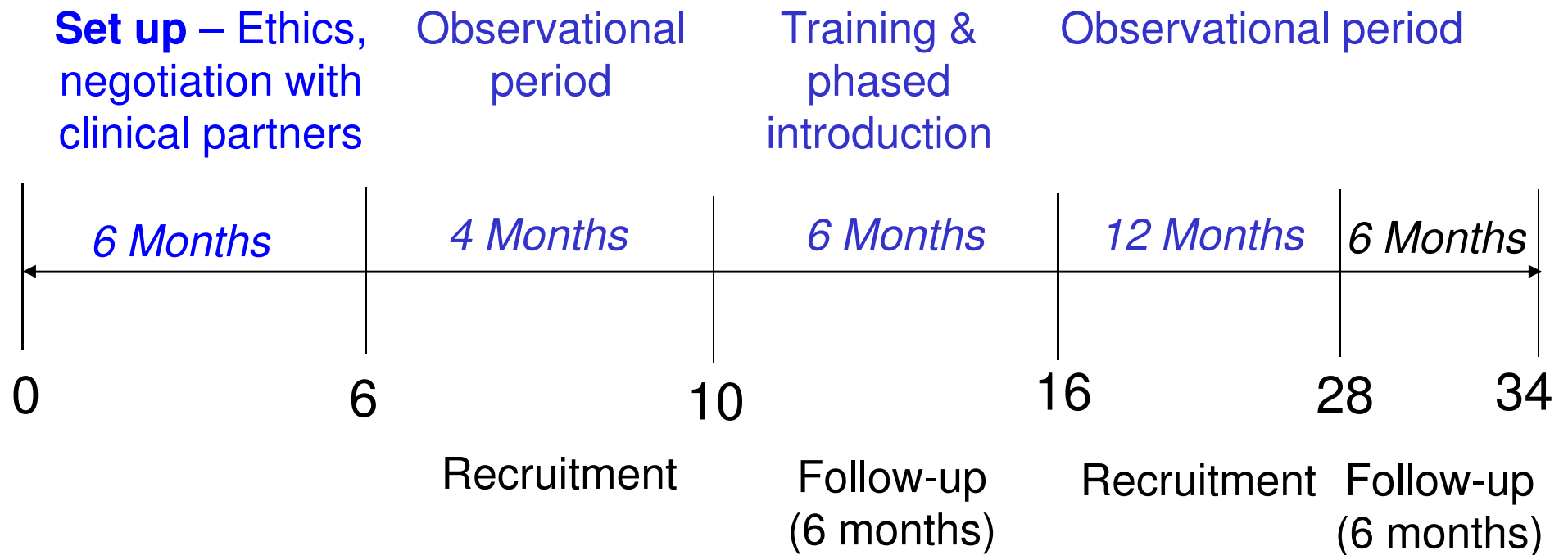
2007-2010

Led by Dr Nadine Foster



Timeline

Researchers / Clinicians



Patients

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 embeded 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

P Name: DOB: Title No: Physio: Date:

STarT Back: For these questions, please think about your back pain over the last few days.

1. How bothersome has pain spreading down your legs from your back been in the last few days?

Not at all Slightly Moderately Very much Extremely

2. How bothersome has pain in your shoulder or neck been in the last few days?

Not at all Slightly Moderately Very much Extremely

For each of the following please cross one box to show how much you agree or disagree with the statement thinking about the last few days.

3. In the last few days, I have dressed more slowly than usual because of my back pain.

Completely disagree Strongly agree

0 1 2 3 4 5 6 7 8 9 10

4. In the last few days, I have only walked short distances because of my back pain.

Completely disagree Strongly agree

0 1 2 3 4 5 6 7 8 9 10

5. It's really not safe for a person with a condition like mine to be physically active.

Completely disagree Strongly agree

0 1 2 3 4 5 6 7 8 9 10

6. Worrying thoughts have been going through my mind a lot of the time in the last few days.

Completely disagree Strongly agree

0 1 2 3 4 5 6 7 8 9 10

7. I feel that my back pain is terrible and that it is never going to get any better.

Completely disagree Strongly agree

0 1 2 3 4 5 6 7 8 9 10

8. In general in the last few days, I have not enjoyed all the things I used to enjoy.

Completely disagree Strongly agree

0 1 2 3 4 5 6 7 8 9 10

9. Overall how bothersome has your back pain been in the last few days?

Not at all Slightly Moderately Very much Extremely

1st Time Score 2nd Time Score Change score

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

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www.keele.ac.uk/startback

