

# Improving the effectiveness of primary care for low back pain: the Sub-grouping for Targeted Treatment (STarT Back) trial

<b>Submission date</b> 23/11/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/01/2007	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 08/10/2012	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

17741

## Study information

### Scientific Title

**Acronym**

STarT Back

**Study objectives**

1. Patients at low risk can be managed effectively with a brief intervention and will remain at low risk subsequently.
2. Patients at high risk who are managed within a framework that targets modifiable physical and psychosocial risk factors will have reduced risk of future disabling chronic back pain.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approval received from the North Staffordshire LREC in February 2007 (ref: 07/Q2604/5).

**Primary study design**

Interventional

**Study design**

Pragmatic randomised controlled trial

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Low back pain

**Interventions**

1. Targeted treatment arm:

The new intervention to be tested in this trial is targeted treatment, which will be allocated according to the sub-grouping tool, and administered on a stepped-care basis. As described above, all patients randomised to this treatment arm will be seen on their first visit to the Community Back Pain Clinic by a study physiotherapist who will provide an initial 30-minute standard intervention and inform them of their treatment plan according to the results of the screening tool. Treatment allocation will be as follows:

- a. Group one (low risk): Initial 30-minute physiotherapy intervention alone
- b. Group two (medium risk): Initial 30-minute physiotherapy intervention plus medium risk group intervention
- c. Group three (high risk): Initial 30-minute physiotherapy intervention plus high risk group intervention

2. Non targeted treatment:

Current best practice physiotherapy

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

1. Roland Morris Disability Questionnaire
2. Pain Catastrophising Scale

**Key secondary outcome(s)**

1. Recurrence of back pain
2. Fear avoidance (Tampa Scale of Kinesiophobia)
3. Back pain bothersomeness
4. Anxiety and depression (Hospital Anxiety and Depression Scale)
5. Self-reported global change in back problem
6. Pain intensity
7. Patient perceptions of their low back pain
8. Patient satisfaction
9. Overall health status (EuroQol instrument [EQ5D], Short Form health survey version two [SF12 vs2])

**Completion date**

01/06/2010

**Eligibility****Key inclusion criteria**

1. Males and females age 18 and over with non-specific low back pain
2. Able to give informed and written consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**Key exclusion criteria**

1. Persons with red flags indicative of possible serious spinal pathology
2. Serious co-morbidity
3. Psychiatric illness/personality disorder
4. Recent spinal surgery (less than six months)
5. Pregnancy
6. Already receiving treatment for this episode of back pain

**Date of first enrolment**

01/04/2007

**Date of final enrolment**

01/06/2010

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Keele University**

Newcastle-Under-Lyme

United Kingdom

ST5 5BG

## Sponsor information

**Organisation**

Keele University (UK)

**ROR**

<https://ror.org/00340yn33>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Arthritis Research Campaign (project grant 17741) (UK)

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	29/10/2011		Yes	No
<a href="#">Results article</a>	results	01/06/2012		Yes	No
<a href="#">Results article</a>	cost-utility results	01/11/2012		Yes	No
<a href="#">Protocol article</a>	Protocol	22/04/2008		Yes	No