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

Submission date
23/11/2006

Recruitment status
No longer recruiting

Registration date
05/01/2007

Overall study status
Completed

Last Edited
08/10/2012

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

Study design
Pragmatic randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
1. Roland Morris Disability Questionnaire
2. Pain Catastrophising Scale

Secondary outcome measures
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])

Overall study start date
01/04/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
800

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
England

United Kingdom

Study participating centre
Keele University
Newcastle-Under-Lyme
United Kingdom
ST5 5BG

Sponsor information

Organisation
Keele University (UK)

Sponsor details
Keele
Newcastle-Under-Lyme
England

United Kingdom
ST5 5BG
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Sponsor type
University/education

Website
http://www.keele.ac.uk/

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (project grant 17741) (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	Protocol	22/04/2008		Yes	No
Results article	results	29/10/2011		Yes	No
Results article	results	01/06/2012		Yes	No
Results article	cost-utility results	01/11/2012		Yes	No