ISRCTN15366334 https://doi.org/10.1186/ISRCTN15366334

The STarT MSK cluster trial

Submission date 06/04/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/04/2016	**Overall study status** Completed	
Last Edited 03/05/2024	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Current plain English summary as of 15/10/2019:
Background and study aims
Musculoskeletal pain such as back, knee, neck, shoulder, or multisite pain is very common. It is the number one reason why people take time off work and accounts for a fifth of all GP consultations. Most people soon recover, but about a third of patients still report disabling pain one year after consulting their GP. Early identification of this group of patients as well as finding more effective treatments for them is a high priority. Stratified care involves GPs using a short questionnaire to help identify patients who are at risk of having persistent disabling pain and providing recommended matched treatment options. This study aims to establish if stratified care is more clinically and cost effective compared to usual primary care for these common musculoskeletal conditions.

Who can participate?
Patients aged 18 and over with musculoskeletal pain consulting at participating GP practices

What does the study involve?
Participating GP practices are randomly allocated to either provide stratified or usual care for patients with musculoskeletal pain. The study involves completion of questionnaires so that the researchers can monitor patient outcomes and health care usage. Patients are asked to complete a questionnaire shortly after visiting their GP, answer three short questions every month (via text or postcard), and complete a final questionnaire 6 months after consulting their GP. With consent a small number of patients, GPs and physiotherapists will be interviewed about their experience of stratified care.

What are the possible benefits and risks of participating?
Although there is no direct benefit to the participants, we hope that the learning from the study will help people with pain conditions in the future. This is a low-risk study, and the treatments that the patients receive are all available in current practice. The questions patients are asked are similar to those that a GP or other healthcare professional might ask.

Where is the study run from?
Keele University (UK)

When is the study starting and how long is it expected to run for?
The pilot phase of the trial commenced recruitment in November 2016 and completed in May 2017. Recruitment for the main trial started in May 2018 and ended in July 2019.

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Jonathan Hill, j.hill@keele.ac.uk

Previous plain English summary:
Background and study aims
Musculoskeletal pain such as back, knee, neck, shoulder, or multisite pain is very common. It is the number one reason why people take time off work and accounts for a fifth of all GP consultations. Most people soon recover, but about a third of patients still report disabling pain one year after consulting their GP. Early identification of this group of patients as well as finding more effective treatments for them is a high priority. Stratified care involves GPs using a short questionnaire to help identify patients who are at risk of having persistent disabling pain and providing recommended matched treatment options. This study aims to establish if stratified care is more clinically and cost effective compared to usual primary care for these common musculoskeletal conditions.

Who can participate?
Patients aged 18 and over with musculoskeletal pain consulting at participating GP practices

What does the study involve?
Participating GP practices are randomly allocated to either provide stratified or usual care for patients with musculoskeletal pain. The study involves completion of questionnaires so that the researchers can monitor patient outcomes and health care usage. Patients are asked to complete a questionnaire shortly after visiting their GP, answer three short questions every month (via text or postcard), and complete a final questionnaire 6 months after consulting their GP. With consent a small number of patients, GPs and physiotherapists will be interviewed about their experience of stratified care.

What are the possible benefits and risks of participating?
Although there is no direct benefit to the participants, we hope that the learning from the study will help people with pain conditions in the future. This is a low-risk study, and the treatments that the patients receive are all available in current practice. The questions patients are asked are similar to those that a GP or other healthcare professional might ask.

Where is the study run from?
Keele University (UK)

When is the study starting and how long is it expected to run for?
The pilot phase of the trial commenced recruitment October 2016. The main trial is expected to be completed by June 2019.

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Steff Garvin,

s.garvin@keele.ac.uk
(updated 10/09/2019, previously: Stephanie Tooth, s.j.tooth@keele.ac.uk)

Contact information

Type(s)
Scientific

Contact name
Prof Nadine Foster

Contact details
School of Primary, Community and Social Care
Primary Care Centre Versus Arthritis
Keele University
Newcastle-under-Lyme
United Kingdom
ST5 5BG
+44 (0)178 273 3964
n.foster@keele.ac.uk

Type(s)
Public

Contact name
Dr Jonathan Hill

Contact details
School of Primary, Community and Social Care
Primary Care Centre Versus Arthritis
Keele University
Newcastle-under-Lyme
United Kingdom
ST5 5BG
+44 (0)178 273 3900
j.hill@keele.ac.uk

Additional identifiers

Protocol serial number
Nil known

Study information

Scientific Title
Stratified Primary Care for Musculoskeletal Pain: The STarT MSK feasibility and pilot cluster randomized controlled trial (patient-facing name the TAPS study)

Acronym

TAPS

Study objectives
To determine if stratified care involving use of the STarT MSK tool to allocate individuals into low, medium and high risk subgroups, and matching these subgroups to treatment options, results in improved pain outcomes for adults consulting in primary care for musculoskeletal pain with one of the five most common musculoskeletal pain presentations (back, neck, knee, shoulder and multisite pain).

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Nottingham 1 Research Ethics Committee, 07/07/2016, ref: 16/EM/0257

Study design
Current as of 31/08/2017: Multicentre cluster randomized controlled trial with external pilot phase (mixed-methods)
Previous: Multicentre cluster randomized controlled trial with internal pilot (mixed-methods)

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adult consulters in primary care with back, neck, knee, shoulder or multisite pain

Interventions
Current intervention as of 15/10/2019:
Approximately 24 GP practices in the UK will take part in the trial. 8 practices are recruited to a pilot phase before recruiting the remaining practices to the main trial. Practices will be randomised to either provide stratified or usual care for patients with back, neck, knee, shoulder or multi-site pain. Patients aged 18 and over consulting at participating GP practices will be invited to take part in the TAPS study. The TAPS study involves completion of questionnaires so that the researchers can monitor patient outcomes and health care usage during the trial. Patients will be asked to complete a questionnaire shortly after visiting their GP, answer 3 short questions every month (via text, or postcard) and complete a final questionnaire 6 months after consulting their GP. A small number of patients, GPs and radiotherapists will be interviewed to explore their experience of stratified care.

Previous intervention as of 17/07/2019:
Approximately 32 GP practices in the UK will take part in the trial. 8 practices are recruited to a pilot phase before recruiting the remaining practices to the main trial. Practices will be randomised to either provide stratified or usual care for patients with back, neck, knee, shoulder or multi-site pain. Patients aged 18 and over consulting at participating GP practices will be invited to take part in the TAPS study. The TAPS study involves completion of questionnaires so that the researchers can monitor patient outcomes and health care usage during the trial. Patients will be asked to complete a questionnaire shortly after visiting their GP, answer 3 short questions every month (via text, or postcard) and complete a final questionnaire 6 months after

consulting their GP. A small number of patients, GPs and radiotherapists will be interviewed to explore their experience of stratified care.

Previous intervention as of 31/08/2017:
Approximately 24 GP practices in the UK will take part in the trial. 8 practices are recruited to a pilot phase before recruiting the remaining practices to the main trial. Practices will be randomised to either provide stratified or usual care for patients with back, neck, knee, shoulder or multi-site pain. Patients aged 18 and over consulting at participating GP practices will be invited to take part in the TAPS study. The TAPS study involves completion of questionnaires so that the researchers can monitor patient outcomes and health care usage during the trial. Patients will be asked to complete a questionnaire shortly after visiting their GP, answer 3 short questions every month (via text, or postcard) and complete a final questionnaire 6 months after consulting their GP. A small number of patients, GPs and radiotherapists will be interviewed to explore their experience of stratified care.

Previous intervention:
Approximately 30 GP practices in the UK will take part in the trial. 8 practices will be recruited to a pilot phase before recruiting the remaining practices to the main trial. Practices will be randomised to either provide stratified or usual care for patients with back, neck, knee, shoulder or multi-site pain. Patients aged 18 and over consulting at participating GP practices will be invited to take part in the TAPS study. The TAPS study involves completion of questionnaires so that the researchers can monitor patient outcomes and health care usage during the trial. Patients will be asked to complete a questionnaire shortly after visiting their GP, answer 3 short questions every month (via text, email or postcard) and complete a final questionnaire 6 months after consulting their GP. Consent will be sought to record a small number of musculoskeletal consultations using the stratified care approach and interviews with consenting patients and GPs will explore contextual factors that may influence the acceptability of, and outcomes from, stratified care.

Intervention Type
Mixed

Primary outcome(s)
Pain intensity measured monthly over the study time period (0-6 months)

Key secondary outcome(s))
At baseline and 6 month follow-up secondary outcomes include:
1. Site-specific physical functional measures:
1.1. The Roland-Morris Disability Questionnaire (RMDQ) for patients with back pain
1.2. The Neck Disability Index (NDI), the Shoulder pain and disability index (SPADI)
1.3. The Knee Injury and Osteoarthritis Outcome Score Physical Function Short-form (KOOS-PS)
1.4. Physical function for patients with multi-site pain using the Short Form 12v2 Physical Component Scale
2. Other individual patient outcomes of interest include:
2.1. Patients' musculoskeletal risk status using the STarT MSK Tool
2.2. Symptom severity and impact from the musculoskeletal pain problem measured using the 14-item Musculoskeletal Health Questionnaire, which includes measures of pain interference with sleep, hobbies/leisure activities, work and daily routine, and quality of life with items for patients' confidence to manage their pain (self-efficacy), mood, and understanding of how to deal with their condition
2.3. Fear avoidance behaviours will be measured using the 11-item Tampa Scale of Kinesiophobia

2.4. Patient perceived level of reassurance from their GP will be captured using the Holt and Pincus et al reassurance scale, which has four sub-scales: information gathering, relationship building, generic reassurance and cognitive reassurance
2.5. A further quality of life scale EQ-5D-5L will be used to calculate quality adjusted life years (QALYs) used in the health economic evaluation
There will be single item questions to capture patient satisfaction with care received, whether they received written education material from their GP, physical activity level, and overall rating of change since their index GP visit.
3. To help describe the population recruited, additional baseline descriptors will capture:
3.1. health literacy using the Single Item Literacy Screener (SILS)
3.2. episode duration of musculoskeletal pain by asking time since last whole month free from this pain
3.3. Age
3.4. Gender
3.5. Employment
3.6. Socio-economic status
4. GP clinical behaviours that are being compared include the proportion of low, medium and high risk patients that are given:
4.1. Analgesic/opioid prescriptions
4.2. Referrals to other services (e.g. to physiotherapy and secondary care specialists)
4.3. Referrals for investigations (e.g. for radiographs, MRI/CT scans, blood tests)
4.4. Sick certifications (fit notes) issued
4.5. Receive further musculoskeletal related GP consultations
5. Questions on additional healthcare resource use and patient-borne costs including:
5.1. Musculoskeletal pain-related inpatient stays
5.2. Outpatient attendances
5.3. Other NHS and private practice healthcare appointments
5.4. Over-the-counter medicines and treatment
6. Work performance will be assessed through a single-item work presenteeism question, and time (days) off work will be aligned to occupational information to ascertain cost of absenteeism

Completion date
01/06/2020

Eligibility

Key inclusion criteria
Current inclusion criteria as of 31/08/2017:
1. Aged 18 years and over
2. Registered with a participating GP practice at the time of the specified study period
3. Read-coded relevant musculoskeletal consultation within the specified study period (this may be the first, or a repeat consultation)
4. Provided consent for the research team to have information from their GP medical records
5. A completed study template in the GP consultation
6. Consent to monthly follow-up
7. GP confirmation that the index pain is in the back, neck, shoulder, knee or is multi-site pain
8. Completion of the initial postal questionnaire within 4 weeks of their initial mailing date

Previous inclusion criteria:
1. Aged 18 years and over
2. Registered with a participating GP practice at the time of the specified study period

3. Read-coded relevant musculoskeletal consultation within the specified study period (termed the “index consultation”; this may be the first, or a repeat consultation)
4. Provided consent for the research team to have information from their GP medical records
5. A completed study template in the GP consultation
6. Consent to monthly follow-up
7. GP confirmation that the index pain is in the back, neck, shoulder, knee or is multi-site pain
8. Completion of the initial postal questionnaire within 4 weeks of their initial mailing date

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1237

Key exclusion criteria
1. Indications of serious ‘red flag’ pathology – for example, recent trauma with significant injury; acute, red, hot swollen joint; suspected fracture, joint infection or cancer; inflammatory arthropathy; crystal disease; spondyloarthropathy; polymyalgia rheumatic
2. Urgent care needs (e.g. Cauda Equina Syndrome)
3. Vulnerable patients, including any patients on the ‘Severe and enduring mental health register’ that GPs feel are not stable, or those who have a diagnosis of dementia, or those with a terminal illness, or those who have experienced recent trauma or bereavement
4. Those unable to communicate in English (both in reading and speaking)

Date of first enrolment
18/10/2016

Date of final enrolment
15/07/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Keele University
Arthritis Research UK Primary Care Centre
Primary Care Sciences
Keele University
Staffordshire
United Kingdom
ST5 5BG

Sponsor information

Organisation
Arthritis Research UK Primary Care Centre, Keele University

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from primarycare.datasharing@keele.ac.uk. The Institute's full statement on data sharing can be found at https://www.keele.ac.uk/pchs/datasharing.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/02/2020	13/02/2020	Yes	No
Results article	qualitative findings	15/07/2022	18/11/2022	Yes	No
Results article		16/12/2022	16/12/2022	Yes	No
Results article		01/06/2023	03/05/2024	Yes	No
Protocol article	protocol	05/07/2020	25/05/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	qualitative findings	11/02/2020	13/02/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes