ISRCTN79085082 https://doi.org/10.1186/ISRCTN79085082

Maintained physical activity and physiotherapy in the management of distal arm pain

Submission date
31/01/2012

Recruitment status
No longer recruiting

Registration date
17/02/2012

Overall study status
Completed

Last Edited
30/07/2019

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Arm pain is a common cause of disability, demand for health care and lost work time. Arm pain in the community is more likely to become chronic if accompanied by poor mental health, adverse psychosocial factors, including a somatising tendency (tendency to be distressed over common physical symptoms), and aspects of beliefs concerning health and activity.
Distal arm pain is defined as pain in the elbow, forearm, wrist or hand and comprises a number of specific and non-specific musculoskeletal conditions. Although distal arm pain is clinically important, and costly, the best approach to managing symptoms is unclear. Patients are often advised to rest, to avoid purported harmful activities, and are commonly referred to physiotherapy. However, none of these strategies are evidence-based and there are reasons to suppose that rest may be inferior to remaining active. Well-conducted studies are needed to resolve these uncertainties and to improve the outcome for these patients.
The study aims are:
To investigate whether, among patients awaiting physiotherapy for distal arm pain, advice to remain active results in a long-term reduction in arm pain and disability compared with advice to rest the painful arm.
Among the same patient population, to investigate whether immediate ("fast-track") physiotherapy results in a long-term reduction in arm pain and disability, compared with physiotherapy delivered at the usual time - typically, after a waiting list period of 7 weeks.

Who can participate?
Males and females of >18 years of age who are referred to physiotherapy for distal arm pain from primary care may be recruited into the study.

What does the study involve?
Recruited patients undergo telephone screening in the first instance followed by a pre-study assessment by a research nurse to confirm eligibility. Eligible patients are randomly allocated to one the following groups:
1. Immediate physiotherapy
2. Advice to remain active or

3. Advice to rest
Patients are followed up by self-complete postal questionnaire at 6, 13, and 26 weeks post randomisation.

What are the possible benefits and risks of participating?
The risks from participating in the trial are minimal. Early physiotherapy and / or active advice may lead to pain / discomfort in short-term. However, there may be a decrease in pain and increase in function in the longer term. The is also a risk of intrusion / inconvenience / changes to participants' lifestyle for all groups, resulting from the physical (arm) examination during the initial assessment appointment and the follow up questionnaires. However, we have ensured where possible that the questionnaire does not ask intrusive questions.
The benefit from participating in this trial is that all patients who attend an initial assessment appointment will receive an examination of their condition earlier than they would otherwise receive, and some will also receive earlier treatment.

Where is the study run from?
The study is run from the University of Aberdeen.

When is the study starting and how long is it expected to run for?
Recruitment started on January 30th 2012 and is expected to last until July 2013.

Who is funding the study?
Arthritis Research UK.

Who is the main contact?
Dr Gareth Jones
gareth.jones@abdn.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Gareth Jones

Contact details
Epidemiology Group
Institute of Applied Health Sciences
University of Aberdeen
School of Medicine and Dentistry
Polwarth Building
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
pRGF/059/09

Study information

Scientific Title
Maintained physical activity and physiotherapy in the management of distal arm pain: a randomised controlled trial

Acronym
Arm Pain Trial

Study objectives
We hypothesise that among patients awaiting physiotherapy for distal arm pain (pain in the elbow, forearm, wrist or hand), advice to remain active and maintain usual activities results in a long-term reduction in arm pain and disability, compared with advice to rest.

In addition, among the same patient population, we hypothesise that immediate ("fast-track") physiotherapy results in a long-term reduction in arm pain and disability, compared with physiotherapy delivered at the usual time - typically, after a waiting list period of 7 weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and South West Hampshire Research Ethics Committee, 03/06/2011; ref: 11/SC/0107

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Distal arm pain

Interventions
Advice to remain active:
Participants randomised to receive advice to remain active will receive a leaflet focusing on shifting beliefs about activity, and including practical advice. The messages will be reinforced verbally by a research nurse using a brief standardized script. The experimental leaflet has been developed from the findings of a recent HSE Research Report of a comprehensive review of the issues around arm pain: this research confirmed that biopsychosocial principles apply to the management of upper limb disorders and a number of evidence-based messages were proposed, key among which were:
1. Upper limb pain is common
2. Early return to work is helpful
3. Lasting damage is rare
4. Recovery and return to full activities can be expected
5. Some cases need treatment but many settle with self-management
6. Maintaining activity is probably helpful

These messages are very similar to those that apply to back pain and can be presented in written form - similar to The Back Book. Cognitive behavioural principles underlie the patient-centred information and advice, which focuses on the benefits of remaining active. The text has been prepared by Kim Burton (co-investigator) who has experience of producing this sort of patient educational material, with input from other members of the research team. The leaflet has also undergone further review from a number of peers, and from a focus group of end users, to ensure accuracy and general acceptability and clarity.

Advice to rest:
Participants randomised to receive advice to rest the arm will receive a leaflet similar in length, design and appearance to the booklet for the advice to remain active group. This leaflet is based on material currently available via NHS Direct: it covers a range of diagnoses, can be taken to reflect current clinical practice, and contrasts with the approach adopted for the experimental leaflet. The style is solidly biomedical and the advice is about rest and avoidance (as well as treatment) rather than maintaining activity.

Immediate physiotherapy:
Participants randomised to receive immediate physiotherapy are fast-tracked to treatment and receive the earliest mutually convenient appointment. Whilst this trial is intended to be pragmatic in so far as it is reflective of usual physiotherapy practice, we have undertaken additional work to ensure that the treatment programmes are compliant with both the Medical Research Council's and the CONSORT organisation's guidance on developing and reporting complex interventions. In the early phases of the study we documented and developed the intervention to ensure it represents best usual care. This involved a review of appropriate treatment guidelines and the literature to ascertain, as far as possible, best practice. It also included discussions with physiotherapists involved in the trial in order to establish current practice and, if any differences were encountered, reconciliation of the findings of the literature with actual clinical practice. A broad set of guidelines were developed which gave therapists the flexibility to treat patients on an individual basis without being overly prescriptive. Further, it is important that the interventions are documented so that they can be reported and replicated, and that the physiotherapists who deliver the intervention are involved in this process (to facilitate compliance with the treatment protocol). Treatments are recorded using a

standardised pro forma and record, for example, treatment modality, number and timing of appointments attended, and time to discharge.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The proportion of patients free of disability at 26 weeks post-randomisation, as determined by the modified - Disabilities of the Arm, Shoulder and Hand (DASH)

Secondary outcome measures
1. Determine the proportion of participants who still seek physiotherapy at 6 weeks
2. Collect information on the type of treatments given, and time to discharge
3. Arm pain and function
4. Coping
5. Fear of movement
6. Ability to function at work
7. Aspects of general health and quality of life

Measured at 6, 13, and 26 weeks post-randomisation by self complete postal questionnaire using validated instruments

Overall study start date
30/01/2012

Completion date
31/07/2013

Eligibility

Key inclusion criteria
1. Entry on to out-patient physiotherapy waiting list for treatment for distal arm pain / disability following self-referral or referral from primary care and
2. Aged ≥18 years at the time of screening

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
555

Key exclusion criteria
1. Previous physiotherapy for distal arm pain (within the past 12 months)
2. Pain for which physiotherapy of the distal arm is not the primary treatment (e.g. referred pain from the neck / shoulder)
3. Arm pain arising from fracture or systemic inflammatory disease
4. Pain arising from cancer
5. Complex Regional Pain Syndrome (CRPS)
6. Specific condition for which advice to remain active is contraindicated (e.g. evidence of florid tenosynovitis)
7. Classed as an emergency appointment
8. Embroiled in legal dispute regarding arm pain

Date of first enrolment
30/01/2012

Date of final enrolment
31/07/2013

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Epidemiology Group
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
c/o Ms Elizabeth Rattray
Research and Innovation
King's College
Aberdeen
Scotland

United Kingdom
AB24 3FX

Sponsor type
University/education

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

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK ref: 19231

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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?
Results article	results	10/03/2014		Yes	No
Results article	cost-utility results	20/03/2019	30/07/2019	Yes	No