ISRCTN14277030 https://doi.org/10.1186/ISRCTN14277030

The Gait Rehabilitation in Early Arthritis Trial

Submission date
11/10/2017

Recruitment status
Suspended

Registration date
18/10/2017

Overall study status
Completed

Last Edited
08/06/2022

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Current plain English summary as of 04/02/2020:
Background and study aims
Rheumatoid arthritis (RA) is a long-term condition that causes pain, swelling and stiffness in the joints. Almost all patients with RA will develop foot and ankle pain and will experience difficulties with walking as a result. Patients walk slower and are more unsteady on their feet, and they often reduce their daily activities due to pain causing loss of muscle strength, balance and stability. During the first two years of RA, patients usually receive medications to control inflammation and may be referred to physiotherapy and/or podiatry for stretching /strengthening exercises and insoles. Whilst some patients improve, many continue to suffer from foot pain and difficulties walking and performing daily activities. Gait rehabilitation has been used with success in neurological conditions but its effectiveness in RA remains unknown. A new gait rehabilitation intervention has been developed for people with early RA which involves patients undertaking repetitions of walking tasks such as stepping over obstacles. This will be done under supervision by a physiotherapist or podiatrist initially, with support for completion of the walking tasks at home. The aim of this study is to find out whether adding this gait rehabilitation intervention to usual treatment results in any additional benefit.

Who can participate?
Patients aged 18 and over with early RA and foot and ankle pain

What does the study involve?
Participants are randomly allocated to one of two groups. One group receives usual rheumatology care including physiotherapy and podiatry as required. The other group receives the same as the first group plus gait rehabilitation, delivered over 2-4 sessions over 12 weeks and supplemented with a home programme. After 3, 6 and 12 months participants complete questionnaires to find out about their walking ability/lower limb function, ability to do daily activities, their quality of life, their ability to undertake exercise and their levels of physical activity. The amount of healthcare they have received is also assessed to work out the costs of the new and usual care interventions in relation to any benefits achieved.

What are the possible benefits and risks of participating?
The results of this study will establish whether or not gait rehabilitation should be offered to

people with early RA in future. Possible benefits for the participants include an improvement or slower decline in foot/ankle function. There is a very low risk of side effects associated with the intervention, which will be adapted according to individual needs.

Where is the study run from?
Glasgow Caledonian University

When is the study starting and how long is it expected to run for?
October 2017 to September 2022

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

Who is the main contact?
1. Miss Lisa Jolly (public)
2. Prof. Martijn Steultjens (scientific)
3. Mr Gordon Hendry (scientific)

Previous plain English summary:
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Rheumatoid arthritis (RA) is a long-term condition that causes pain, swelling and stiffness in the joints. Almost all patients with RA will develop foot and ankle pain and will experience difficulties with walking as a result. Patients walk slower and are more unsteady on their feet, and they often reduce their daily activities due to pain causing loss of muscle strength, balance and stability. During the first two years of RA, patients usually receive medications to control inflammation and may be referred to physiotherapy and/or podiatry for stretching /strengthening exercises and insoles. Whilst some patients improve, many continue to suffer from foot pain and difficulties walking and performing daily activities. Gait rehabilitation has been used with success in neurological conditions but its effectiveness in RA remains unknown. A new gait rehabilitation intervention has been developed for people with early RA which involves patients undertaking repetitions of walking tasks such as stepping over obstacles. This will be done under supervision by a physiotherapist or podiatrist initially, with support for completion of the walking tasks at home. The aim of this study is find out whether adding this gait rehabilitation intervention to usual treatment results in any additional benefit.

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Where is the study run from?
1. Gartnavel General Hospital (UK)
2. Glasgow Royal Infirmary (UK)
3. King's College London Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2017 to September 2022

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
1. Miss Lisa Jolly (public), Lisa.Jolly@ggc.scot.nhs.uk
2. Prof. Martijn Steultjens (scientific)
3. Mr Gordon Hendry (scientific)

Study website
https://www.great-trial.co.uk

Contact information

Type(s)
Public

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Type(s)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 15/165/04; V1.3 13 Jul 2018

Study information

Scientific Title
Gait Rehabilitation in Early Arthritis

Acronym
GREAT

Study objectives
Almost all patients with RA will develop foot and ankle pain and will experience difficulties with walking as a result. Patients walk slower and are more unsteady on their feet, and theyoften reduce their daily activities due to pain causing loss of muscle strength, balance and stability. During the first two years of RA, patients usually receive medications to control inflammation and may be referred to physiotherapy and/or podiatry for stretching/strengthening exercises and insoles. Whilst some patients improve, many continue to suffer from foot pain, walking difficulties and performing daily activities. Gait rehabilitation has been used with success in neurological conditions but its effectiveness in RA remains unknown. A new gait rehabilitation intervention has been developed for people with early RA which involves patients undertaking

repetitions of walking tasks such asstepping over obstacles. This will be done under supervision by a physiotherapist or podiatrist initially, with support for completion of the walking tasks at home. This study will evaluate whether adding this gait rehabilitation intervention to usual treatment results in any additional benefit compared to usual treatment alone in a randomised trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 04/02/2020:
For feasibility study:
Approved 26/02/2018, West of Scotland REC 3, no reference

For main trial:
Approved 20/12/2019, West of Scotland REC 3, ref: 19/WS/0189

Previous ethics approval:
West of Scotland REC 3, 26/02/2018

Study design
Multi-centre two-arm randomised control trial with internal pilot phase, process evaluation and health economic evaluation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not currently available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Early rheumatoid arthritis

Interventions
Current intervention as of 04/02/2020:
The Pilot phase of the main trial will be conducted to identify whether enough eligible patients can be recruited and kept in the study then the trial will be open up to investigate whether gait rehabilitation adds benefits to usual care. Adults with early RA and foot and ankle pain who meet other criteria for inclusion will be invited to take part and asked to sign a consent form.

Feasibility study:
42 participants will be recruited over 6 months from three NHS Trusts/Health Board regions in Scotland and England. They will all receive usual care plus gait rehabilitation over 12 weeks. Intervention acceptability, adherence and safety will be measured after 12 weeks using postal questionnaires and interviews with a small subgroup of participants as well as clinicians who delivered the intervention. 4 measurement tools will be compared to determine the best tool to measure change in response to the intervention in the main trial.

Trial:
550 patients will be recruited over 26 months from 12-15 NHS Trusts/Health Board regions in Scotland and England. Patients will be allocated by chance to one of two treatments:
1. Usual rheumatology care including physiotherapy and podiatry as required
2. The same as in 1 plus gait rehabilitation, delivered over 2-4 sessions over 12 weeks and supplemented with a home programme
At 3, 6 and 12 months patients will be asked to complete and return postal questionnaires to find out about their walking ability/lower limb function, ability to do daily activities, their quality of life, their ability to undertake exercise and their levels of physical activity. The amount of healthcare they have received will also be evaluated to work out the costs of the new and usual care interventions in relation to any benefits achieved. This data will be used to establish whether or not gait rehabilitation should be offered to people with early RA in future.

Previous intervention:
First, a feasibility study will be conducted of 42 participants with early RA (within 2 years of diagnosis) to identify the best way to measure the effectiveness of the gait rehabilitation intervention; determine its acceptability and safety; and determine whether it can be delivered as intended. Next, a miniature version of the main trial will be conducted to identify whether enough eligible patients can be recruited and kept in the study. Lastly, a large trial is planned to investigate whether gait rehabilitation adds benefits to usual care. Adults with early RA and foot and ankle pain who meet other criteria for inclusion will be invited to take part and asked to sign a consent form.

Feasibility study:
42 participants will be recruited over 6 months from three NHS Trusts/Health Board regions in Scotland and England. They will all receive usual care plus gait rehabilitation over 12 weeks. Intervention acceptability, adherence and safety will be measured after 12 weeks using postal questionnaires and interviews with a small subgroup of participants as well as clinicians who delivered the intervention. 4 measurement tools will be compared to determine the best tool to measure change in response to the intervention in the main trial.

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Intervention Type
Behavioural

Primary outcome measure
Feasibility phase:
1. The measurement properties (responsiveness, minimal important difference) of candidate outcome measures, to identify and select the most suitable primary outcome measure for the main trial. Measured using participant questionnaires and assessing walking capacity at 12 week follow up/visit 2
2. The acceptability of the new gait rehabilitation intervention, assessed by qualitative interviews with a subsample of participants and clinicians at 12 week follow up/visit 2
3. The safety of the new gait rehabilitation intervention, assessed by monitoring, recording and evaluating adverse effects/unintended outcomes using an adverse events reporting form as per the Glasgow CTU SOPs during each intervention session/unscheduled visit and week 12 visit
4. Participants' adherence to the new gait rehabilitation intervention and potential barriers /facilitators of adherence, assessed using Exercise Adherence Rating Scale (EARS) Questionnaire at unscheduled 12 week follow up/visit 2
5. Feasibility of participating physiotherapists and podiatrists delivering intervention as intended, assessed using semi-structured telephone-based interviews at end of feasibility phase
6. Review and refine if necessary the new gait rehabilitation intervention prior to final development of the new gait rehabilitation intervention manual and training programme for participating physiotherapists and podiatrists for the main trial.

Internal pilot trial phase:
1. Sample size calculation for the main trial using the feasibility phase sample variance on the selected primary outcome
2. The feasibility of recruitment and retention of patients with early RA, including willingness to be randomised, assessed using data from pilot trial stage at the end of this phase

Main trial phase:-
1. The clinical effectiveness of the new gait rehabilitation on lower limb function, measured using participant questionnaires and assessing walking capacity after the 12 month follow up visit
2. Cost-effectiveness, assessed using costing comparisions after the 12 month follow up visit
3. Participants’ views and experiences, assessed by various questionnaires and interview at 3 months, 6 months, and 12 month follow up visits
4. Clinicians’ views and experiences of the interventions and trial processes, assessed by interviews throughout the study

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2017

Completion date
30/09/2022

Eligibility

Key inclusion criteria

Current inclusion criteria as of 04/02/2020:
1. Aged 18 years or over
2. Clinician diagnosis of RA with disease duration less than 2 years from diagnosis
3. History of disease-related foot impairments defined as at least one of:
3.1. Self-reported foot pain
3.2. Presence of foot and/or ankle joint synovitis/tenosynovitis on clinical examination since diagnosis of RA
4. Willing to participate and provide written informed consent to participate in the study
5. Sufficient English language abilities to participate in a dialogue-based intervention and undertake completion of written questionnaires.

Previous inclusion criteria:
1. 18 years of age or over
2. Clinical diagnosis of RA (ACR 2010 criteria) with disease durations less than 2 years from diagnosis
3. Disease-related foot impairments defined as at least one of: self-reported foot pain, and/or the presence of foot and/or ankle joint synovitis/tenosynovitis detected during clinical examination by the rheumatologist or rheumatology nurse specialist
4. Willing to participate in the study and provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Feasibility stage: 42; main trial phase: 550

Key exclusion criteria
1. Not able to undertake or complete the intervention (e.g. due to severe comorbid disease) identified by their consultant rheumatologist prior to screening, or the research nurse at screening
2. Unable or unwilling to provide informed consent
3. Currently taking part in other non-medical intervention studies where the goal of the intervention is to improve lower limb function and/or gait

Date of first enrolment
01/02/2018

Date of final enrolment
01/10/2021

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
University Hospital Wishaw
50 Netherton St
Wishaw
United Kingdom
ML2 0DP

Study participating centre
King's College London Hospital
Denmark Hill
Brixton
London
United Kingdom
SE5 9RS

Study participating centre
Cannock Chase Hospital
Brunswick Rd
Cannock
United Kingdom
WS11 5XY

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Raigmore Hospital
Old Perth Road

Inverness
United Kingdom
IV2 3UJ

Sponsor information

Organisation
Glasgow Caledonian University

Sponsor details
Govan Mbeki Building
Cowcaddens Road
Glasgow
Scotland
United Kingdom
G4 0BA

Sponsor type
University/education

ROR
https://ror.org/03dvm1235

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal in June 2023.

Intention to publish date
01/06/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	feasibility study results	30/05/2022	08/06/2022	Yes	No
HRA research summary			28/06/2023	No	No