ISRCTN12765345 https://doi.org/10.1186/ISRCTN12765345

Integrating and improving care for patients with inflammatory rheumatological disorders in the community

Submission date
15/11/2017

Recruitment status
No longer recruiting

Registration date
29/11/2017

Overall study status
Completed

Last Edited
08/01/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Inflammatory rheumatic conditions are disorders related to inflamed joints, muscles and tissues that connect or support the organs and other internal body parts. They include rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, polymyalgia rheumatica and giant cell arteritis. Patients with these conditions are also at an increased risk of cardiovascular (heart) disease, osteoporosis (bone weakness) and depression. At present, people with rheumatoid arthritis are advised to have an “annual review” with an assessment of their condition plus assessment for linked illness. Such an annual review would seem to be one way to improve care for these patients. Even for patients with rheumatoid arthritis, care is fragmented between primary and secondary care, meaning some tests are done twice, whilst others are missed. Nurse-led care is increasingly advocated for management of chronic inflammatory arthritis. To date much of this has been delivered in specialist secondary care rheumatology services, but given the expertise in primary care, developing new nurse-led models of care in primary care may improve outcomes for these patients. The aim of this study is to assess the feasibility and acceptability of a nurse-led integrated care review for people with inflammatory rheumatic conditions in primary care.

Who can participate?
Patients aged 18 and over with any of the following conditions: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, polymyalgia rheumatica and giant cell arteritis

What does the study involve?
Participating GP practices are randomly allocated to one of two groups: the control group or the intervention group. Control group practices provide best current standard care only. At intervention group practices, participants are also offered a 30-minute nurse-led integrated care review (called the 'INCLUDE review') at their practice. The nurse assesses their health specifically checking for symptoms and risk of cardiovascular disease, osteoporosis, depression and/or anxiety. Participants receive tailored advice and signposting to additional services where appropriate. With consent from the participant, a small number of these appointments are audio-recorded to assess how the intervention was delivered. Intervention participants and

practitioners are also invited to an informal interview to share their perceptions and experiences of the INCLUDE review. All participants are asked to complete three postal questionnaires over 6 months and are invited to consent to a review of their GP medical records at 12 months.

What are the possible benefits and risks of participating?
All participants, including those in the control group, continue to receive the best current standard care. Intervention practice participants may benefit by receiving a more integrated and holistic care consultation (the INCLUDE review) which may identify additional and treatable conditions such as high blood pressure. Where relevant, identified conditions are flagged to their care team for follow up or participants are given advice and signposted to additional services. This study will directly inform a larger study and it is hoped that the insight gained will help to inform how best to treat patients with inflammatory rheumatological conditions in the future. There will be some burden with regards to time for the participants. All participants complete three postal questionnaires (all postage costs are covered). Participants in the intervention group are asked to attend a 30-minute INCLUDE review appointment at their practice. A small number of participants are invited to take part in the audio-recording of their INCLUDE review. The informed consent process adds 10 minutes to their appointment. A small number of participants from intervention group practices are invited to take part in an informal interview of up to 45 minutes to explore their views and experiences of receiving the INCLUDE review.

Where is the study run from?
Keele Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
January 2017 to December 2019

Who is funding the study?
1. Haywood Rheumatism Research and Development Foundation (UK)
2. National Institute of Health Research Collaborations for Leadership in Applied Health Research and Care West Midlands (NIHR WM CLAHRC) (UK)

Who is the main contact?
Mrs Kendra Cooke

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Sponsor ref: RG-0013-16-IPCHS

Study information

Scientific Title
The INCLUDE study: INtegrating and improving Care for patients with infLammatory rheUmatological DisordErs in the community: a pilot randomised controlled trial

Acronym
INCLUDE

Study objectives
This study is to assess the feasibility and acceptability of a nurse-led integrated care review in primary care for patients with inflammatory rheumatological conditions, specifically rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), polymyalgia rheumatica (PMR) or giant cell arteritis (GCA).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 5, 08/01/2018, ref: 17/WA/0427

Study design
Two-arm cluster pilot randomised controlled multi-centre trial in primary care with a nested qualitative study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Other

Participant information sheet

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

Health condition(s) or problem(s) studied
Inflammatory rheumatological disorders: rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), polymyalgia rheumatica (PMR) or giant cell arteritis (GCA)

Interventions
Participating GP practices are randomly allocated to one of two groups:
1. Intervention practices: in addition to best current standard care, participants are offered a 30-minute nurse-led integrated care review (called the 'INCLUDE review') at their practice. The nurse will provide a holistic assessment of their health specifically assessing for symptoms and risk of cardiovascular disease, osteoporosis, depression and/or anxiety. Participants will receive tailored advice and signposting to additional services where appropriate. With consent from the participant, a small number of these appointments will be audio-recorded to assess how the intervention was delivered. Intervention participants and practitioners will also be invited to consent to an informal interview to share their perceptions and experiences of the INCLUDE review
2. Control practices: best current standard care only

All participants are asked to complete three postal questionnaires over 6 months and invited to consent to a review of their GP medical records at 12 months.

Intervention Type
Other

Primary outcome measure
The feasibility of recruitment, retention and acceptability of the INCLUDE intervention

To help identify the most appropriate measure for a main trial, this pilot will use the three measures below to assess the feasibility and acceptability of the INCLUDE intervention:
1. Patient Activation Measure (Hibberd at al, 2005) via postal questionnaires at 0 and 6 months
2. Bristol Multi-morbidity Treatment Burden Questionnaire (Salisbury & Duncan, 2017) via postal questionnaires at 0, 3 and 6 months
3. Treatment Acceptability and Credibility (Borkovec & Nau, 1972) via postal questionnaire at 3 months

Secondary outcome measures
The following outcomes will be assessed for their feasibility:
1. Response rate of general practices to participate in the trial
2. Proportion of patients with a code for one of the five conditions who are eligible for inclusion into the trial
3. Overall recruitment to the trial
4. Follow-up rates at 6 months, overall and per arm
5. Completion rates of the INCLUDE computer template and the self-reported outcome measures*
6. Acceptability of the integrated care review from the perspectives of practitioners and patients participating in review (qualitative study)

*Self-report outcome measures are as follows:
1. Pain is measured using the Numerical Rating Scale (0-10) via postal questionnaires at 0, 3 and

6 months
2. Self efficacy is measured using the Self-Efficacy for Managing Chronic Disease measure via postal questionnaires at 0 and 6 months
3. GP practice service provision is measured using the General Practice Assessment Questionnaire (GPAQ, National Primary Care Research and Development Centre, University of Manchester and Safran/NEMCH) via postal questionnaire at 3 months
4. Quality of life is measured using EQ-5D-5L (Herdman et al., 2011) via postal questionnaires at 0, 3 and 6 months
5. Physical function is measured using the Modified Health Assessment Questionnaire MHAQ (Maska et al., 2011) via postal questionnaires at 0 and 6 months
6. Fatigue is measured using the Modified Functional Assessment of Chronic Illness Therapy (FACIT) - Fatigue (Cella et al., 2002) via postal questionnaires at 0 and 6 months
7. Anxiety is measured using the Generalized Anxiety Disorder Assessment (GAD-7) (Spitzer et al., 2006) via postal questionnaires at 0 and 6 months
8. Depression is measured using the Modified Patient Health Questionnaire (PHQ-8) (Kroenke, 2001) via postal questionnaires at 0 and 6 months

Overall study start date
01/01/2017

Completion date
31/12/2019

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. GP Read code for any of the following conditions - rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), polymyalgia rheumatica (PMR) or giant cell arteritis (GCA)
3. Registered with a participating GP practice
4. Ability to understand and capable of giving written informed consent in English

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2 clusters, 100 participants per cluster

Total final enrolment
339

Key exclusion criteria
1. Vulnerable patients (e.g. patients on the practice register for severe enduring mental ill health (such as unstable schizophrenia / bipolar disorder), significant cognitive impairment (such as dementia) and/or terminal illness
2. Those that reside in a nursing home (as care pathways are different)

Date of first enrolment
05/02/2018

Date of final enrolment
12/07/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Keele Clinical Trials Unit
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Sponsor information

Organisation
Keele University

Sponsor details
Directorate of Research, Innovation & Engagement
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Sponsor type
University/education

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ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
Haywood Rheumatism Research and Development Foundation

Funder Name
National Institute of Health Research Collaborations for Leadership in Applied Health Research and Care West Midlands (NIHR WM CLAHRC)

Results and Publications

Publication and dissemination plan
The study protocol will be published. Research results will be published in scientific journals and the relevant manuscripts made available in the public domain.

Intention to publish date
31/12/2020

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. Core data will be available immediately after main publication. A data request form is required to be completed and must outline the type of data to be obtained, the reason for obtaining this data (research question /objective), the timing for when the data is required to be available (start date/end date). Checks will be performed by a Data Custodian and Academic Proposals (DCAP) committee at Keele to ensure that the data set requested is appropriately suited to answer the research question /objective and that the request fits with the original ethical approval and participant consent and adheres to funder and legal restrictions. Only de-identified data are available for request in aggregated format or at the level of the individual participant.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	02/08/2018	06/01/2021	Yes	No
Results article	results	06/01/2021	08/01/2021	Yes	No
HRA research summary			28/06/2023	No	No