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# How does patient-initiated follow-up compare to standard care follow-up for people living with inflammatory arthritis?

**Submission date**
14/01/2025

**Recruitment status**
No longer recruiting

**Registration date**
17/01/2025

**Overall study status**
Ongoing

**Last Edited**
28/01/2026

**Condition category**
Musculoskeletal Diseases

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

## Plain English summary of protocol

Background and study aims
People with inflammatory arthritis usually require long-term treatment with arthritis drugs (medications) (though some manage without specific medication) and typically have routine follow-up appointments every 6-12 months. Some of these appointments may be unnecessary as people can be well at the time of the appointment, and people with inflammatory arthritis have told us they feel they are wasting their time and also NHS resources. NHS England has recently proposed that many people with inflammatory arthritis should no longer have routine follow-up appointments but instead be seen if and when they have a flare or need advice on managing their condition, using an approach called Patient Initiated Follow-Up or PIFU. Researchers working with the British Society for Rheumatology have produced a short video about PIFU which can be accessed via this link (https://bit.ly/3WcFDmf). They have also created a list of frequently asked questions and answers which may be helpful to read to find out more about PIFU. This can be found here: https://bit.ly/3PvfMCl. There is very little information about whether PIFU is better than routine follow-up appointments. This study aims to find out whether PIFU is better than standard routine follow-up for those with inflammatory arthritis in terms of the impact on patient's quality of life, disease activity and what this might potentially save the NHS.

Who can participate?
Adults who have been diagnosed with inflammatory arthritis (rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis, undifferentiated arthritis) for at least 2 years and whose health care team consider their disease to be generally well-controlled. Patients that have ever been on PIFU for their inflammatory arthritis, would not be eligible to take part.

What does the study involve?
Of those who agree to take part in the study, half will remain to have what is called standard care – this would mean that they would continue to come into the hospital approximately every 6-12 months to see their rheumatology care team, the other half will move to PIFU where they will not have any follow-up appointments made but instead be given a guide to PIFU and how to contact their care team if you need some advice or an appointment. Regardless of what

treatment group they are assigned to, participants would come to the clinic for an appointment at the start of the study and again at 24 months. These visits would include a routine disease assessment and several questionnaires for completion. Participants will also be sent questionnaires at 1 week and 6, 12 and 18 months to complete at home. If participants agree, they may be invited to take part in 1-2 interviews during the study to help us understand their experience of PIFU.

What are the possible benefits and risks of participating?
Participants may not directly benefit from taking part in this study but they will be making a significant contribution to research to help us to understand whether PIFU or standard care is better and which patients would benefit from PIFU. It is also hoped that study results will help to understand what PIFU costs the NHS compared to regular follow-up.

Where is the study run from?
The University of Oxford and 30 NHS secondary sites in the UK.

When is the study starting and how long is it expected to run for?
April 2024 to February 2028

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

Who is the main contact?
Gretchen Brewer, tailor@ndorms.ox.ac.uk

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Prof Laura Coates

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# Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)
329838

### Protocol serial number
CPMS 56645, NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC) Grant Codes: NIHR156922

# Study information

### Scientific Title
What is the clinical and cost-effectiveness of a patient-initiated follow-up (PIFU) strategy compared to traditional care pathways in people with inflammatory arthritis treated with long-term immune-suppressing therapies?

### Acronym
TaILOR

### Study objectives
The study aims to assess whether patient-initiated follow-up (PIFU) care is superior to standard care in terms of musculoskeletal quality of life (QoL) outcomes for patients with inflammatory arthritis.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 22/01/2025, South East Scotland Research Ethics Committee 1 (2nd Floor, Waverley Gate, Edinburgh, EH1 3EG, United Kingdom; +44 (0)7814 764 241; Sandra.Wyllie@nhs.scot), ref: 25/SS/0004

### Study design
Randomized controlled study

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Inflammatory arthritis

### Interventions
The study aims to recruit 438 patients with stable inflammatory arthritis from approximately 30 centres from varied demographic areas in the UK.

Patients will primarily be approached during their routine clinic visits or invited via letter ahead of their appointment. If a patient is assessed to be suitable for PIFU and is eligible and happy to join the study, informed consent will be requested ahead of study procedures.

Demographic, disease and treatment history information will be collected and recorded for the purposes of the study. Clinical data from patients' routine care will also be recorded from their medical notes (disease activity score including a physical exam and CRP measurement from blood draw) as well as hospital-reported resource use. Participants will complete questionnaires to collect patient-reported outcomes. Patient-reported outcomes include questionnaires about quality of life (musculoskeletal and overall), mental health, participation in health care decisions, and management of health care. Hospital-reported resource use will be collected for the 12 months prior to baseline. No additional procedures for the purpose of the study will take place at the baseline visit.

Patients will then be randomised 1:1 into either PIFU or standard care with routine remote or face-to-face follow-up appointments at 6-12 months in accordance with local practice. Patients randomised into the PIFU arm will be provided with information about PIFU and how to access rheumatology follow-up care if they become unwell due to their arthritis. The study team will not be blinded to intervention but the protocol requests, but does not insist on, a blinded assessor for participants' disease activity score which is assessed at the beginning of the start and month 24 of the study.

At week 1, all patients will be asked to complete remote, self-reported questionnaires about the decision-making process relating to taking part in the study as well as questions about time spent accessing patient education materials about managing their care.

At 6-8 weeks and 11 months, a member of the study team will confirm that patients have been assigned to the correct pathway (PIFU or standard care).

At months 6, 12 and 18 all patients will be asked to complete remote, self-reported questionnaires to assess quality of life, costs relating to medical care for their arthritis and flare information for the previous 6 months.

At 24 months, all patients will be seen in their rheumatology outpatient clinic as part of routine care for both PIFU and standard care. Patients will have been sent questionnaires to be completed remotely ahead of their visit. Clinical data from their visit will be recorded. Clinical data from patients' routine care will also be collected from their medical notes (disease activity score including a physical exam and CRP measurement from blood draw). At 24 months, hospital-reported flare information and resource use will be collected for the duration of the study.

The recruitment target of 438 participants allows for a 20% crossover/dropout rate. No interim analysis is planned but an independent data monitoring committee will review data every 6-12 months. Additionally, PROMS completion rates will be reported monthly to the TMG by the trial management group.

The grant includes a qualitative sub-study led by Prof Emma Dures from The University of the West of England, Bristol. She is a co-applicant on the main NIHR grant (also sponsored by Oxford University). She will lead both the anonymous survey to understand why potential participants choose not to take part in the TaILOR randomised clinical study (described in the following paragraph) and the qualitative interviews.

Patients who decline the study will be offered the opportunity to complete an anonymous electronic or paper survey. The survey aims to help us understand the reasons for not wanting to take part in the study as well as understand the demographics of these patients. As this is an anonymous survey that will not be collecting identifiable information, respondents will not be consented for this activity. Sites will provide the survey to patients who decline to take part (either via e-survey or paper survey to be posted back to CTU). No personal data will be collected.

The qualitative sub-study (interviews) aims to further understand the acceptability of PIFU by patients, healthcare professionals and administrators. Participants in the main study will be given the option to consent to be contacted by the qualitative team about taking part in interviews. Of those that consent to be contacted, 30-45 participants will be selected for interviews to take place at 2-12 weeks and/or 16-24 months post-randomisation. Additionally, 25 healthcare and service professionals from TaiLOR research sites will also be invited to tell us about their experiences with PIFU. These interviews will take place once the associated sites have been open to recruitment for 12 months through the last patient, and last visit. All qualitative interviews will take place over TEAMS or by telephone.

Three patient partners were extensively involved in the design of the study along with a project supported by the British Society for Rheumatology to develop a PIFU manual for hospital sites as well as educational materials for patients. Patient partners were involved in the selection of primary and secondary outcomes, the main metric they wanted was 'good care' where patients were satisfied with their care and disease management.

Four patient partners were involved with the development of the PIS, infographic, patient-facing letters and questionnaires. Specifically, patients provided critical feedback in the phrasing of instructions and questions of PROMS related to specific secondary outcomes. They will provide ongoing support with decisions relating to the execution of the study in relation to recruitment, site support and study burden. They will also assist in the interpretation of overall grant findings and dissemination.

## Intervention Type
Other

## Primary outcome(s)
Musculoskeletal quality of life is measured using MSK-HQ score over 24 months (measured at baseline, months 6, 12, 18 and 24)

## Key secondary outcome(s))
1. Musculoskeletal quality of life is measured using MSK-HQ score at baseline, months 6, 12, 18 and 24
2. Overall health-related quality of life is measured using EQ-5D-5L and EQ-VAS scores at baseline, months 12 and 24
3. Incremental cost measured using patient health resource use and costs at baseline, months 6, 12, 18 and 24
4. Incremental cost measured using hospital-reported health resource use and costs at 12 months prior to baseline through month 24
5. Cost-effectiveness measured using Cost per quality-adjusted life year (QALY) gained over the 24-month time horizon
6. Progression from no treatment to first-line DMARD measured using the proportion of patients starting a first-line DMARD during the study
7. Progression from conventional drugs to biologic therapies measured using the proportion of

patients starting a first biologic during the study
8. Disease activity is measured using disease-specific activity score (CDAI, DAS28-CRP, ASDAS, DAPSA) at baseline and 24 months
9. Disease activity is measured using the number of patient-reported flares from baseline to 24 months
10. Disease activity is measured using the number of hospital-reported flares from baseline to 24 months
11. Patient efficacy is measured using perceived efficacy in patient-physician interactions (PEPPI) score at baseline and 24 months
12. Depression is measured using PHQ-4 score at baseline and 24 months
13. Acceptability of PIFU to patients is measured using qualitative methods at Weeks 2-12 and Months 16-24
14. Acceptability of PIFU health professionals/service providers is measured using qualitative methods once the site has been open to recruitment for at least 12 months

### Completion date
28/02/2028

## Eligibility

### Key inclusion criteria
1. Age 18 years or over
2. Diagnosis of inflammatory arthritis (RA, PsA, axSpA, undifferentiated arthritis) for at least 2 years
3. Stable disease: defined as a level of disease control that the physician feels is suitable for PIFU; on the same conventional, targeted synthetic or biologic DMARD(s), or no treatment, for at least the previous 3 months; and with no escalation in therapy planned
4. Able to contact the Rheumatology team when required
5. Suitable for PIFU in the opinion of their consultant
6. Willing and able to give consent and comply with study procedures

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
100 years

### Sex
All

### Total final enrolment

438

### Key exclusion criteria
1. Currently or previously on PIFU for inflammatory arthritis
2. Safeguarding/consent/capacity concerns (using General Medical Council guidance)
3. Health literacy concerns from the treating clinician related to inflammatory arthritis
4. Women who are pregnant or planning to start a family
5. Currently undergoing radiotherapy, immunotherapy or chemotherapy for malignancy
6. Patients on end-of-life care pathways

### Date of first enrolment
21/03/2025

### Date of final enrolment
31/01/2026

## Locations

### Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

### Study participating centre
**John Radcliffe Hospital**
Headley Way
Headington
Oxford
England
OX3 9DU

### Study participating centre
**Queens Medical Centre**
Derby Road
Nottingham
England
NG7 2UH

### Study participating centre

**Lancashire & South Cumbria NHS Foundation Trust**
Sceptre Point
Sceptre Way
Bamber Bridge
Preston
England
PR5 6AW

**Study participating centre**
**Derriford Hospital**
Derriford Road
Plymouth
England
PL6 8DH

**Study participating centre**
**Belfast City Hospital**
51 Lisburn Rd
Belfast
Northern Ireland
BT9 7AB

**Study participating centre**
**Royal Berkshire Hospital**
London Road
Reading
England
RG1 5AN

**Study participating centre**
**City Hospital**
Dudley Road
Birmingham
England
B18 7QH

**Study participating centre**
**York Hospital**
Wigginton Road

York
England
YO31 8HE

**Study participating centre**
**The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust**
Gobowen
Oswestry
England
SY10 7AG

**Study participating centre**
**Royal Devon University Healthcare NHS Foundation Trust**
Royal Devon University NHS Ft
Barrack Road
Exeter
England
EX2 5DW

**Study participating centre**
**Royal United Hospitals Bath NHS Foundation Trust**
Combe Park
Bath
England
BA1 3NG

**Study participating centre**
**Kings College Hospital**
Denmark Hill
London
England
SE5 9RS

**Study participating centre**
**Cambridge University Hospitals NHS Foundation Trust**
Cambridge Biomedical Campus
Hills Road
Cambridge
England
CB2 0QQ

**Study participating centre**
**NHS Lothian**
Waverley Gate
2-4 Waterloo Place
Edinburgh
Scotland
EH1 3EG

**Study participating centre**
**Warwick Hospital**
Lakin Road
Warwick
England
CV34 5BW

**Study participating centre**
**Cumberland Infirmary**
Newtown Road
Carlisle
England
CA2 7HY

**Study participating centre**
**Betsi Cadwaladr University Lhb**
Executive Offices, Ysbyty Gwynedd
Penrhosgarnedd
Bangor
Wales
LL57 2PW

**Study participating centre**
**Northern General Hospital**
Northern General Hospital NHS Trust
C Floor, Huntsmnan Building
Herries Road
Sheffield
England
S5 7AU

**Study participating centre**
**Darlington Memorial Hospital**
Hollyhurst Road
Darlington
England
DL3 6HX

**Study participating centre**
**Leicester Royal Infirmary**
Infirmary Square
Leicester
England
LE1 5WW

**Study participating centre**
**Royal Surrey County Hospital**
Egerton Road
Guildford
England
GU2 7XX

**Study participating centre**
**Northampton General Hospital**
Northampton General Hospital NHS Trust
Cliftonville
Northampton
England
NN1 5BD

**Study participating centre**
**NHS Lanarkshire**
Kirklands
Fallside Road
Bothwell
Glasgow
Scotland
G71 8BB

**Study participating centre**
**Milton Keynes University Hospital NHS Foundation Trust**
Standing Way

Eaglestone
Milton Keynes
England
MK6 5LD

**Study participating centre**
**Queen Alexandra Hospital**
Southwick Hill Road
Cosham
Portsmouth
England
PO6 3LY

**Study participating centre**
**Western Isles**
37 South Beach
Stornoway
Scotland
HS1 2BB

**Study participating centre**
**Royal Cornwall Hospital (treliske)**
Treliske
Truro
England
TR1 3LJ

**Study participating centre**
**Harrogate & District NHS Foundation Trust**
Strayside Wing
Harrogate District Hospital
Lancaster Park Road
Harrogate
England
HG2 7SX

**Study participating centre**
**Bedfordshire Hospitals NHS Foundation Trust**
Lewsey Road

Luton
England
LU4 0DZ

**Study participating centre**
**University Hospitals Bristol and Weston NHS Foundation Trust**
Trust Headquarters
Marlborough Street
Bristol
England
BS1 3NU

# Sponsor information

**Organisation**
University of Oxford

**ROR**
https://ror.org/052gg0110

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health and Care 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 will be available upon request from Professor Laura Coates (laura.coates@ndorms.ox.ac.uk) and the Oxford Clinical Trials Research Unit (OCTRU; octrutrialshub@ndorms.ox.ac.uk) once the study findings have been published in full and for as long as this data is useful. Participant consent was obtained for sharing with researchers or collaborators (this may include commercial organisations), in the UK and abroad; however, some specific data items may not be shared in order to maintain participant anonymity.

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |