Work Rehabilitation in Inflammatory Arthritis -Effectiveness and cost effectiveness of an occupational therapy (OT) job retention intervention: a pilot randomised controlled trial

Submission date 20/09/2012	Recruitment status No longer recruiting	 Prospect Protocol
Registration date 21/09/2012	Overall study status Completed	[] Statistica[X] Results
Last Edited 15/05/2020	Condition category Musculoskeletal Diseases	[] Individua

-] Prospectively registered
- [] Statistical analysis plan
- Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 10521

Study information

Scientific Title

Work Rehabilitation in Inflammatory Arthritis - Effectiveness and cost effectiveness of an occupational therapy (OT) job retention intervention: a pilot randomised controlled trial

Study objectives

This is a feasibility study for a future randomised controlled trial evaluating the effectiveness of a vocational rehabilitation (VR) intervention provided by occupational therapists for employed people with inflammatory arthropathies (n=100). Patients are being recruited from 6 Rheumatology departments in England.

The study aims to identify the most appropriate primary work outcome measure and feasibility of recruitment procedures, VR provision and questionnaire completion. Participants, employers (following patient consent), therapists and therapy managers will also be interviewed to identify their views of the feasibility of the intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s) 11/EN/0103

Study design Randomised; Interventional; Design type: Treatment

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions

Participants are randomly allocated to receive VR or a stay at work information pack only.

Control group: An information pack including the National Rheumatoid Arthritis Society and Arthritis Care publications about Working with Arthritis

Vocational Rehabilitation: Up to x 1.5 hour appointments with an occupational therapist, trained in deliver:

1. Applying ergonomic, fatigue and stress management approaches to the workplace

2. Recommendations for assistive technology/equipment adaptation, workplace/work station modification, transport advice

3. Practical advice and support to enable participants to disclose their condition and negotiate job modifications with employers

4. Explaining rights under the Equality Act 2010 and the facilities available to

Follow Up Length: 9 month(s)

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

1. Work status 1.1. Work instability 1.2. Sickness absence

Measured at 0, 6 and 9 months

Secondary outcome measures

Health status
 Pain
 Fatigue
 Functional status
 NHS costs

Measured at 0, 6, 9 months

Overall study start date 01/10/2011

Completion date 31/10/2011

Eligibility

Key inclusion criteria

1. People with inflammatory arthritis (i.e., specifically early inflammatory arthritis [IA], rheumatoid arthritis [RA], psoriatic arthritis [PA])

2. Aged 18 years and over

3. Able to read, write and understand English and in paid work (full or parttime)

4. People who answer "yes" to:"Do you have any concerns about your health affecting your

ability to work over the next few years?" 5. Able to give informed consent 6. Male & Female; Upper Age Limit 65 years ; Lower Age Limit 18 years

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 100; UK Sample Size: 100; Description: People with inflammatory arthritis (i. e. specifically early inflammatory arthritis (IA), rheumatoid arthritis (RA), psoriatic arthritis (PA)

Key exclusion criteria

People who are:

1. On extended sick leave (i.e. > 3 months) or unemployed (including not normally in paid employment or student)

2. Planning to retire or take early retirement (through choice or ill health) within the next 12 months

3. Already receiving or awaiting work rehabilitation services

4. Planning to move out of area or expecting joint replacement surgery in the next 6 months

5. Other conditions affecting work apart from arthritis (e.g. uncontrolled medical/ psychiatric problems

Date of first enrolment

01/10/2011

Date of final enrolment 31/10/2011

Locations

Countries of recruitment England

United Kingdom

Study participating centre

Centre for Rehabilitation and Human Performance Research Salford United Kingdom M6 6PU

Sponsor information

Organisation University of Salford (UK)

Sponsor details Centre for Rehabilitation and Human Performance Research Allerton Building Frederick Road Salford England United Kingdom M6 6PU

Sponsor type University/education

ROR https://ror.org/01tmqtf75

Funder(s)

Funder type Charity

Funder Name Arthritis Research UK (UK)

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	21/07/2017		Yes	No
Results article	qualitative results with participants	01/01/2017	15/05/2020	Yes	No
	qualitative results with therapists		15/05/2020	Yes	No
Results article	therapist work rehabilitation training results	01/06/2013	15/05/2020	Yes	No