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WORKWELL: Testing work advice for people with arthritis

Submission date
13/05/2019

Recruitment status
No longer recruiting

Registration date
06/06/2019

Overall study status
Completed

Last Edited
03/03/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Background and study aims
A third of people with inflammatory arthritis stop working within three years of diagnosis and half within ten years. This causes difficulties for people and their families socially, psychologically and financially. Before then, people struggle at work, physically and mentally, with the demands of their job because of their arthritis, especially due to pain and fatigue. People with job modifications (e.g. flexible hours; changes in equipment, job activities or workplace environment) are less likely to lose their job. Yet many with arthritis don't have access to advice on how to make such changes. This trial is investigating two methods of providing work advice and support to employed people experiencing work difficulties. These are a) a written self-help work information package about managing problems at work (SELF-HELP) and b) a written work self-help package PLUS practical advice and support from a work rehabilitation- trained occupational therapist (WORKWELL). The aims are to investigate:
1. Do employed people with inflammatory arthritis, who are concerned about staying in work, who receive WORKWELL (written information plus therapist support) have fewer work problems and less risk of job loss compared to those receiving written information?
2. Do employed people with arthritis receiving WORKWELL have better health compared to those receiving written information?
3. Is WORKWELL cost-effective?
4. What do people who receive WORKWELL think about it?

Who can participate?
Adults with rheumatoid, psoriatic or (early/undifferentiated) inflammatory arthritis; who are working; and currently experiencing difficulties managing at work

What does the study involve?
Following consent, participants are asked to complete a questionnaire booklet about their work, work difficulties and their health. Participants are then randomly allocated to one of the two methods of providing work rehabilitation (i.e. self-help or WORKWELL). Within a week, half of people with arthritis taking part receive written self-help information about ways to help them stay in work, with a flowchart to guide actions to take. The other half receive the same information plus WORKWELL (work rehabilitation) with a WORKWELL-trained therapist. In this, therapist and participant together identify the person's work problems, discuss possible

solutions and the therapist provides individualized advice and support to help resolve/improve work problems. On average, participants attend for up to 4 flexibly timed appointments (i.e. early or later in day around participant's work commitments), at about monthly intervals. If participants wish this, it is possible to conduct work visits and meet with employers to help further resolve work problems and make changes in the workplace. (Not all participants will want their employers to be involved and WORKWELL can be provided without this). At 6 and 12 months, participants are asked to complete another questionnaire booklet, to identify whether there have been any changes in their work status, work problems, health and health resource use. The researchers also interview a sample of people receiving WORKWELL to identify their views about the work advice and support received. In April 2022, our team received ethical approval to continue observing our study participants for an additional 36 months. We initiated this phase in June 2022 by notifying all 232 participants involved and providing them with detailed information about the next steps.

We anticipate completing the follow-up process by March 2024. Subsequently, our efforts will focus on organising the data, analysing the results, and composing scholarly articles to share our findings. We're also working on making the Workwell study materials available online, with input from patients and the public, to help more people get advice and support for work-related issues. We are confident that the study will be concluded within the planned timeframe and budget by December 2024.

What are the possible benefits and risks of participating?
Possible benefits are that the participant is able to make work and health-related changes to help resolve work problems and keep working. The researchers do not expect any risks associated with the self-help information pack or WORKWELL.

Where is the study run from?
The study is run from the Centre for Human Movement and Rehabilitation, School of Health and Society, University of Salford and co-managed with Lancashire Clinical Trials Unit. Participants are being recruited from 18 NHS Trusts around the UK: St Helens and Knowsley Teaching Hospitals NHSFT; Manchester University NHSFT; Worcestershire Acute Hospitals NHS Trust; Salford Royal NHSFT; Countess of Chester NHSFT; Newcastle upon Tyne Hospitals NHSFT; Barnsley Hospital NHSFT; Sherwood Forest Hospitals NHSFT; Northumbria Healthcare NHSFT; The Royal Wolverhampton Hospitals NHSFT; Leeds Teaching Hospitals NHSFT; Oxford University Hospitals NHSFT; North Devon NHS Healthcare Trust; Royal United Hospitals Bath NHSFT; North Bristol NHS Trust; Aneurin Bevan UHB; Cardiff and Vale UHB; NHS Fife.

When is the study starting and how long is it expected to run for?
May 2018 to April 2024

Who is funding the study?
Versus Arthritis: a medical charity

Who is the main contact?
1. Professor Yeliz Prior - y.prior@salford.ac.uk (Chief Investigator)
2. Dr Jennifer Parker - j.parker17@salford.ac.uk (Trial manager)

Study website
http://www.workwelluk.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
252583

ClinicalTrials.gov number
NCT03942783

Secondary identifying numbers
39604, IRAS 252583

Study information

Scientific Title
A randomised controlled trial of job retention vocational rehabilitation for employed people with inflammatory arthritis: the WORKWELL trial

Acronym
WORKWELL

Study objectives
The principal research question is whether there is a meaningful difference in presenteeism (work productivity or ability to work) between patients with RA, IA or PsA who receive either: a work self-help information pack (control); or a work self-help information pack PLUS job retention vocational rehabilitation (WORKWELL).

WORKWELL is provided by rheumatology occupational therapists or physiotherapists who will be given training in: assessing for work problems; identifying patients' priority problems; and recommending practical self-management solutions and job modifications to make people's working lives easier. All participants continue to receive usual care.

The secondary research questions include identifying if there are other differences between the two groups, such as in participants': amount of work difficulties; confidence in working; sick leave; use of job modifications; job satisfaction; physical and psychological status. We will investigate cost-effectiveness of WORKWELL. Additionally, the researchers will also conduct a process evaluation and:
1. Conduct interviews with WORKWELL participants, their employers, therapists and therapy line managers to investigate their views of WORKWELL. This will include the relevance of its content, how it helped (or not) the participants and its applicability for delivery in the NHS.
2. Evaluate the therapists' views of the WORKWELL training they received, through questionnaires and interviews.
3. Investigate the problems experienced by participants receiving WORKWELL, through analysis of the WORKWELL assessment and treatment notes/records and what are the common work solutions provided.
If the trial has positive outcomes, the objective is to develop the therapist training materials into an online resource to support other therapists in delivering WORKWELL. The researchers will also make the work solutions resources available online to people with arthritis and the public.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/11/2018, West Midlands - Solihull Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham , NG1 6FS, United Kingdom; +44 (0)207 104 8103; nrescommittee.westmidlands-solihull@nhs.net), ref: 18/WM/0327

Study design
Randomised; Both; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Physical, Rehabilitation, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Hospital

Study type(s)
Quality of life, 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
Inflammatory arthritis

Interventions
Current intervention as of 07/02/2022:
Design:
The WORKWELL multi-centre RCT will compare the effectiveness and cost-effectiveness of a written work self-help information pack and usual care (control group) compared to the pack, usual care PLUS WORKWELL job retention VR (intervention group). The study null hypothesis is that WORKWELL plus information pack will have the same effect on outcomes as the information pack only. The researchers chose this design because there have been no randomised controlled trials in the UK demonstrating whether a brief (i.e. approximately 4.5 hour) structured VR intervention has an effect on work , health outcomes or is cost-effective. The researchers are including a control group receiving the information pack only, because therapists in the feasibility trial considered the content reflected the work advice they would normally give; and they preferred not to treat the control group participants with simple work advice, as they considered once they knew how to provide VR, they would find it difficult to then provide only brief work advice to control group participants. The patient research partners also considered the information pack was comprehensive and contained more information than many patients received from hospital staff. Additionally, previous trials of VR have successfully used written information as the control.

Sample size:
The study will be recruiting 240 participants from at least 18 sites (and up to 21). Each site will screen employed adult patients with RA, UIA or PsA until the recruitment target for that site is reached, i.e. with at least 18 sites and a target of 240 participants this will be an average of 13-14 participants/ site, although the researchers will set a target of at least 17 per site (average + 1SD) to compensate for some low-recruiting sites. Thus, on average 1 participant/month at each site will need to be recruited; or at least 14 patients per month overall across all sites. Sites can recruit faster than this and/or exceed their target, if participants are identified more quickly and the WORKWELL therapist/s can provide the service for this rate of referral. Sites may also need to increase the number of patients recruited to compensate for sites that withdraw or fail to recruit to target. Based on the feasibility study, it is anticipated that approximately 10% of patients screened will be eligible and consent to participate in the trial. (Over half screened in the feasibility trial were ineligible). The researchers therefore plan to screen approximately 2,350 patients (but, conservatively based on the lower 60% confidence limit from our feasibility trial, possibly 2,640) in this trial. Consequently, at a conservative estimate, as we aim to recruit

for 18 months in at least 18 sites, each site will need to screen up to 146 patients overall or 8 patients/month to recruit 1 participant/month. (If the planned 21 sites take part, then the screening target for each site will be lower).

Participants will be randomly allocated to:
1. A control group receiving a written work self-help information pack. The content of this pack reflects the brief work advice that working patients may receive from occupational therapists, and includes work advice booklets published by arthritis charities.
2. The WORKWELL intervention. This will consist of, on average, 4 hours of face to face contact with a WORKWELL therapist (spread over 3 to 4 months), identifying work problems using a structured interview and providing individualised advice and training in work solutions, job modifications and self-management approaches to use at
work, which address the person's priority problems. This is followed up with a 30-minute telephone review, a month after the last face-to-face meeting, to see how the person is getting on with the recommended changes and job modifications. This is also supported with a written work self-help information pack. Patient research partners in our feasibility trial were involved in the modification of WORKWELL and the structured work interview for the UK.
Both groups will continue to receive usual care.

Therapist training:
Whilst obtaining HRA, ethics and site approvals, the therapists will be trained in WORKWELL delivery (months 6-8: October to December 2018) by two occupational therapists specialising in work rehabilitation. This training lasts 4 days and includes 2 days self-study and a 2-day training course of practical workshops, case studies and discussion.
At the training course, the researchers will also go through the key aspects of the study protocol relevant to them to ensure that the WORKWELL therapists understand how to follow the study procedures correctly to avoid any contamination of the control group. They will also be trained in how to conduct a structured work assessment, identify
work problems, work with participants to identify appropriate work solutions and enable participants to make changes in the workplace, and to liaise with their employers to obtain any needed job modifications. If the participant wishes the therapist to support this in the workplace (and it is appropriate), a work site visit with employer liaison is also possible as part of WORKWELL. The patient research partners are attending day 2 of the training course to meet the therapists and discuss their experiences of working with arthritis, employers' attitudes, the benefits of having job modifications at work, what has worked for them, and effective communication with line managers and employers. The therapists will also have received training in writing work reports for participants, that could then be provided to employers if the person decides to do so. The therapists will all continue to have support from an expert VR therapist mentor to discuss any issues arising when treating patients that they need advice with. Therapists will also receive one mentoring visit, observing them treating a participant and receiving feedback, and one monitoring visit, to observe whether they are delivering WORKWELL appropriately.

Site training:
The Trial Manager (or the Chief Investigator or Research Assistant) (TM) will conduct site training visits with the Principal Investigator, research facilitators (which also includes any therapy team embers assisting recruiting) (RF) and WORKWELL therapists prior to the site opening (planned for month 9: January 2019), explaining the study protocol and trial procedures, going through how to inform the potential participants about the study, how to take consent and complete study documentation and how to report on adverse events/ reactions and serious adverse events. Once the RFs are trained, and site approvals are completed, the screening and recruitment can start at these sites (after 1st January 2019). The

researchers have discussed the screening eligibility criteria with their patient research partners, as well as obtained their feedback on all patient-facing documents. They have been particularly helpful advising about when and how to inform potential participants about the possibility of employer contact during WORKWELL and employer interviews at the end of their participation.

Recruitment:
The normal procedures are that potential participants will be identified in Rheumatology, physiotherapy and/or occupational therapy clinics by members of the health care team; RFs or therapy team members (with training in recruitment and consent) will briefly explain the study and screen for eligibility; a full study explanation is provided to eligible and interested patients; and informed consent obtained if and when the patient decides to take part. The patient can take a week or so to decide or can agree to consent on the day if they wish to. The participant is provided with the baseline questionnaire to take home, complete in their own time (preferably within 1 to 2 weeks, and return in a Freepost envelope to the Trial Manager/ Research Assistant (referred to jointly as TM) at the University of Salford. There is optional support from the TM at the University of Salford, if the Research Facilitator/ therapy team member (referred to jointly as RF) have difficulty in contacting the patient (e.g. the patent only wants to be contacted in the evenings and site staff do not work evenings).

Randomisation and referral:
The participants' details will then be entered into the trial database (called REDCAp) by the Salford research staff. The Lancashire Clinical Trials Unit (CTU) will randomise the participant to either the intervention or control group. Within 2 working days of randomisation, the CTU will mail the participant the self-help information pack, with a cover
letter informing them: a) that they are receiving the pack and how to use this or b) they are receiving the pack, how to use this and that they have been referred to the therapy department at their hospital for WORKWELL. The CTU will then send an encrypted e-mail to the therapy department contact person at the participant's site to inform them of the participant's contact details, if randomised to WORKWELL. The WORKWELL therapist will acknowledge receipt of this email within two further working days and then contact and make an appointment with the participant within 5 working days and commence treating within 4 weeks (maximum) of the date of the CTU email (unless there are exceptional circumstances). The usual Therapy service time frame from referral to initial appointment may be longer than this in some departments. However, it is essential the time lag between baseline assessment and WORKWELL provision is not extended beyond 4 weeks (unless in exceptional circumstances) to ensure that the WORKWELL intervention can be completed before the 6-month follow-up. Given the sample size of 240 and number of participating departments (18 to 21 sites), most WORKWELL therapists are likely to be treating only 1 or 2 trial participants at the same time per month. Therefore this time requirement will not be unduly burdensome to therapy services. In case of exceptional circumstances, such as during periods when the WORKWELL therapist/s are on annual or sick leave, they will inform the Trial Manager as soon as possible by e-mail. An alternate named person at the Therapy department can then be contacted with the trial referral by the CTU. This person can then make the appointment on behalf of the WORKWELL therapist, for as soon as possible after their return, and if possible within the 4-week time frame.

WORKWELL provision:
At the first appointment, the WORKWELL therapist will complete the Work Experience Survey-Rheumatic Conditions (WES-RC: the structured work assessment) with the participant. The therapist and participant collaboratively identify priority problems to address, and start to plan work solutions. The therapist writes all treatment plans, notes and a record of the content and duration of the work interventions provided within the WES-RC assessment booklet. After the participant has attended their first treatment session, the WORKWELL therapist will complete

the WORKWELL Treatment Record Part 1, and send this to the CTU to confirm that treatment has started. They will also
complete the WORKWELL Treatment Record Part 2 at the end of the participant's treatment and return this to the CTU, to confirm that treatment has ended. The data manager at the CTU will monitor and check these treatment records to ensure they are completed accurately and treatment was provided to schedule. The WORKWELL therapist will also return a copy of the WES-RC to the research team at the University of Salford.

Follow-up data collection:
Each month for 12 months, the CTU will contact the participants by text, e-mail or telephone (as preferred by the participant) to ask if they took any sick leave days during the past month, and if yes, how many days. At 6 and 12 months, the second and third questionnaire booklets, respectively, will be mailed to the participant's home by the
CTU and the participant returns this to the CTU in a Freepost envelope. Participants will also have the option of receiving a link by e-mail to an online version of the questionnaire which they can complete instead.

Data analysis:
The researchers will analyse data using intention-to-treat analysis, meaning once participants are randomly allocated to one of the groups, we will collect and analyse their data, regardless of whether or not they received or completed WORKWELL/the information pack (intervention) or used the information pack (control). This method will help to avoid the effects of dropouts and a potential imbalance between the two groups.

Process evaluation:
Alongside this trial the researchers are conducting a process evaluation including: semi-structured interviews with selected WORKWELL participants (n=15) and participants' employers line managers (n=10) about their views of WORKWELL; interviews with WORKWELL participants who had to stop work (up to 7); content analysis of participants' WES-RCs to identify participants' common work problems and the work solutions provided by therapists; pre- and post-training questionnaires and interviews with WORKWELL therapists about their views of the training they received from us (all therapists approx.40); and interviews with therapists and their therapy line managers about WORKWELL and its implementation (one therapist (n=18-21) and line manager (n=18 -21) from each site). The researchers will also be analysing participants' questionnaire data to explore what personal and work-related contextual factors may influence outcomes of participants in either group. The interviews will take place at a mutually convenient place, such as the participant's home or a private room at the participating hospital site. We are also seeking to interview employers/ line managers (n= 10) of WORKWELL participants to obtain their views of how WORKWELL may have helped their employee and the workplace. Participants are informed about both these optional elements of the study within the Participant Information Sheet, and given an option to take part or not in the participant interview at the beginning of the study, when providing written consent. The researchers will inform them we will contact them about employer interviews at the end (12 months) and the participant can decide then whether or not they are interested in discussing this possibility with their employer/ line manager. This is left to the end so that participants don't feel that saying no would affect them taking part.

Trial oversight:
The trial management group (TMG) will meet quarterly and the trial steering committee (TSC) will meet annually throughout the trial, and the patient partners are also valuable members of both TMG and the TSC. They have and will play an important role in the decisions taken to run the trial, and most importantly help us to disseminate the findings in the wider patient and

public domain by contributing to the creating of lay summaries. The patient research partners are members of the TMG and TSC and contribute to all discussions about the trial. They will also be involved in advising about analysis and interpretation of results and report-writing and dissemination.

Timetable:
The trial is 56-months duration to completion of 12-month follow-up. A 3-year follow-up is now added (June 2022 – March 2024), with 3-year follow-up trial completion in December 2024, i.e., 80 months.
The trial was paused between March 2020 to July 2020, due to the COVID-19 pandemic, with sites progressively re-starting until January 2021, requiring an additional 11-month no-cost extension. From months 15 to 42 (July 2019 to October 2021) the researchers will be collecting 6-month follow-up questionnaires; and from months 21 to 47 (January 2020 to end March 2022) 12-month questionnaires. During this time (months 22-48) the researchers will complete interviews with purposively selected participants, and participants' employers/line managers, who consent to interviews. They will be conducting therapist and therapy line manager interviews from months 41-48 (Sept 2021 – March 2022). Process evaluation data (qualitative and quantitative will be analysed from month 46 onwards (Feb 2022) and reports written by month 56 (December 2022). Questionnaire data will be cleaned by month 48 (April 2022). Trial data analysis, contextual factor analysis and health economic analysis will commence from month 48 (April 2022) and report writing completed by month 56 (December 2022). In addition, the researchers are completing a 3-year follow-up, with a shorter questionnaire. This will occur between Months 50 - 71 (June 2022 – March 2024). A selected number of participants in the intervention group will also be interviewed during this time. Analysis will occur months 72-76 (April – August 2024), with reports completed by Month 80 (December 2024).

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Previous intervention:
Design:
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letter informing them: a) that they are receiving the pack and how to use this or b) they are receiving the pack, how to use this and that they have been referred to the therapy department at their hospital for WORKWELL. The CTU will then send an encrypted e-mail to the therapy department contact person at the participant's site to inform them of the participant's contact details, if randomised to WORKWELL. The WORKWELL therapist will acknowledge receipt of this email within two further working days and then contact and make an appointment with the participant within 5 working days and commence treating within 4 weeks (maximum) of the date of the CTU email (unless there are exceptional circumstances). The usual Therapy service time frame from referral to initial appointment may be longer than this in some departments. However, it is essential the time lag between baseline assessment and WORKWELL provision is not extended beyond 4 weeks (unless in exceptional circumstances) to ensure that the WORKWELL intervention can be completed before the 6-month follow-up. Given the sample size of 240 and number of participating departments (18 to 21 sites), most WORKWELL therapists are likely to be treating only 1 or 2 trial participants at the same time per month. Therefore this time requirement will not be unduly burdensome to therapy services. In case of exceptional circumstances, such as during periods when the WORKWELL therapist/s are on annual or sick leave, they will inform the Trial Manager as soon as possible by e-mail. An alternate named

person at the Therapy department can then be contacted with the trial referral by the CTU. This person can then make the appointment on behalf of the WORKWELL therapist, for as soon as possible after their return, and if possible within the 4-week time frame.

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complete the WORKWELL Treatment Record Part 2 at the end of the participant's treatment and return this to the CTU, to confirm that treatment has ended. The data manager at the CTU will monitor and check these treatment records to ensure they are completed accurately and treatment was provided to schedule. The WORKWELL therapist will also return a copy of the WES-RC to the research team at the University of Salford.

Follow-up data collection:
Each month for 12 months, the CTU will contact the participants by text, e-mail or telephone (as preferred by the participant) to ask if they took any sick leave days during the past month, and if yes, how many days. At 6 and 12 months, the second and third questionnaire booklets, respectively, will be mailed to the participant's home by the
CTU and the participant returns this to the CTU in a Freepost envelope. Participants will also have the option of receiving a link by e-mail to an online version of the questionnaire which they can complete instead.

Data analysis:
The researchers will analyse data using intention-to-treat analysis, meaning once participants are randomly allocated to one of the groups, we will collect and analyse their data, regardless of whether or not they received or completed WORKWELL/the information pack (intervention) or used the information pack (control). This method will help to avoid the effects of dropouts and a potential imbalance between the two groups.

Process evaluation:
Alongside this trial the researchers are conducting a process evaluation including: semi-structured interviews with selected WORKWELL participants (n=15) and participants' employers line managers (n=10) about their views of WORKWELL; interviews with WORKWELL participants who had to stop work (up to 7); content analysis of participants' WES-RCs to identify participants' common work problems and the work solutions provided by therapists; pre- and post-training questionnaires and interviews with WORKWELL therapists about their views of the training they received from us (all therapists approx.40); and interviews with therapists and their therapy line managers about WORKWELL and its implementation (one therapist (n=18-21) and line manager (n=18 -21) from each site). The researchers will also be analysing participants' questionnaire data to explore what personal and work-related contextual factors may influence outcomes of participants in either group. The interviews will take place at a mutually convenient place, such as the participant's home or a private room at the participating hospital site. We are also seeking to interview employers/ line managers (n= 10) of WORKWELL participants to obtain their views of how WORKWELL may have helped their employee and the workplace. Participants are informed about both these optional elements of the study within the Participant Information Sheet, and given an option to take part or not in the participant interview at the

beginning of the study, when providing written consent. The researchers will inform them we will contact them about employer interviews at the end (12 months) and the participant can decide then whether or not they are interested in discussing this possibility with their employer/ line manager. This is left to the end so that participants don't feel that saying no would affect them taking part.

Trial oversight:
The trial management group (TMG) will meet quarterly and the trial steering committee (TSC) will meet annually throughout the trial, and the patient partners are also valuable members of both TMG and the TSC. They have and will play an important role in the decisions taken to run the trial, and most importantly help us to disseminate the findings in the wider patient and public domain by contributing to the creating of lay summaries. The patient research partners are members of the TMG and TSC and contribute to all discussions about the trial. They will also be involved in advising about analysis and interpretation of results and report-writing and dissemination.

Timetable:
This is a 45-month trial. The first 8 months will include completing ethics and R&D approvals, training of therapists, training of research facilitators, and ensuring all the documentation is provided to the participating sites. From months 9 (January 2019) to 26 (June 2020: 18 months) the researchers will recruit from participating sites, participants will complete baseline questionnaires, be randomly allocated, all will receive the information pack and half receive WORKWELL from the therapists. WORKWELL will be completed by Month 31 (November 2020). From months 15 to 32 (July 2019 to December 2020) the researchers will be collecting 6-month follow-up questionnaires; and from months 21 to 38 (January 2020 to June 2021) 12-month questionnaires. During this time (months 22-38) the researchers will complete interviews with purposively selected participants, and participants' employers/line managers, who consent to interviews. They will be conducting therapist and therapy line manager interviews from months 30 to 34. They will be extracting data from WES-RCs from Month 15 to 35 (July 2019 to March 2021) and content analysing from months 36 to 39 (April to July 2021). Process evaluation data (qualitative and quantitative will be analysed from month 34 onwards (February 2021) and reports written by month 45 (January 2022). From months 27 to 39 (July 2020 to July 2021) questionnaire data will be cleaned. Trial data analysis, contextual factor analysis and health economic analysis will commence from month 40 (August 2021) and report writing completed by month 45 (January 2022). In addition, the researchers will seek funding for a further 3-year follow-up, which will involve sending out the same questionnaire to participants as used at 12 months.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 10/03/2022:
Presenteeism (work productivity) measured using Combined Work Activities Limitations Scale - Work Limitations Questionnaire-25 at 12 and 36 months

Previous primary outcome measure:
Presenteeism (work productivity) measured using Combined Work Activities Limitations Scale - Work Limitations Questionnaire-25; Timepoint(s): 12 months

Secondary outcome measures

Current secondary outcome measures as of 10/03/2022:
1. The degree of mismatch between functional abilities and workplace demands, measured using the Rheumatoid Arthritis Work Instability Scale at 0 and 12 months
2. Work status (full- or part-time work; early retired; retired; unemployed) measured at 0, 6, 12, and 36 months
3. Absenteeism (number of days sick leave/month) measured at monthly intervals for 12 months
4. Confidence about working measured using Work Self-Efficacy Scale at 0 and 12 months
5. Time off on sick leave or for any other reason, hours worked, health problems effect on work productivity and ability to do other daily activities, percentage absenteeism, all in the last 7 days, measured using Work Productivity and Activity Impairment Scale at 0 and 12 months
6. Physical and mental health measured using Short Form-12 (SF-12) Health Survey at 0, 6 and 12 months
7. Quality of life measured using EuroQol Five Dimensions Questionnaire (EQ5DL-5) at 0, 6 and 12 months
8. Impact of RA: coping, helplessness, fatigue, physical function, sleep, global assessment and pain, measured using Rheumatoid Arthritis Impact of Disease Scale at 0 and 12 months
9. Global disease activity during the past 6 months; current disease activity as measured by swollen and tender joints; current amount of arthritis pain (these three measured on 11-point NRS); current duration of morning stiffness (7-point verbal rating scale); and current number of tender joints in a joint list, measured using RA Disease Activity Index-5 at 0 and 12 months
10. Use of primary and secondary care, social care, private health care, measured using Health Resource Use Questionnaire at 0, 6 and 12 months
11. Managerial, co-worker and organisational support, measured using the Perceived Workplace Support Scale at 0, 12, and 36 months
12. Work disruptions due to arthritis, measured using the Work Transitions Index at 0 and 12 months
13. Ability to balance demands of work, health and personal life, measured using Work-Health - Personal Life Perceptions Scale: short form at 0 and 12 months
14. The number of job accommodations, policies and workplace practices employees have available in their workplace and how helpful they find each of these to manage health-related work difficulties (if used/available), measured using the Workplace Accommodations, Benefits, Policies and Practices Scale measured at 0 and 12 months
15. Any changes in job, and if this is due to arthritis, measured using a participant questionnaire at 36 months
16. Health status measured using a 5 point scale at 36 months
17. Hybrid working status measured using 1 item on a participant questionnaire at 36 months
18. Future job expectations measured using 2 items on a participant questionnaire at 36 months

Previous secondary outcome measures:
1. The degree of mismatch between functional abilities and workplace demands, measured using the Rheumatoid Arthritis Work Instability Scale at 0 and 12 months
2. Work status (full- or part-time work; early retired; retired; unemployed) measured at 0, 6 and 12 months
3. Absenteeism (number of days sick leave/month) measured at monthly intervals for 12 months
4. Confidence about working measured using Work Self-Efficacy Scale at 0 and 12 months
5. Time off on sick leave or for any other reason, hours worked, health problems effect on work productivity and ability to do other daily activities, percentage absenteeism, all in the last 7 days, measured using Work Productivity and Activity Impairment Scale at 0 and 12 months
6. Physical and mental health measured using Short Form-12 (SF-12) Health Survey at 0, 6 and 12 months
7. Quality of life measured using EuroQol Five Dimensions Questionnaire (EQ5DL-5) at 0, 6 and 12 months

8. Impact of RA: coping, helplessness, fatigue, physical function, sleep, global assessment and pain, measured using Rheumatoid Arthritis Impact of Disease Scale at 0 and 12 months
9. Global disease activity during the past 6 months; current disease activity as measured by swollen and tender joints; current amount of arthritis pain (these three measured on 11-point NRS); current duration of morning stiffness (7-point verbal rating scale); and current number of tender joints in a joint list, measured using RA Disease Activity Index-5 at 0 and 12 months
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13. Ability to balance demands of work, health and personal life, measured using Work-Health - Personal Life Perceptions Scale: short form at 0 and 12 months
14. The number of job accommodations, policies and workplace practices employees have available in their workplace and how helpful they find each of these to manage health-related work difficulties (if used/available), measured using the Workplace Accommodations, Benefits, Policies and Practices Scale measured at 0 and 12 months

Overall study start date
01/05/2018

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Adults (i.e. aged > = 18 years). (Upper age limit: Participants can be above the normal age for receiving their state pension as long as they are still in paid employment)
2. Diagnosed with RA, UIA or PsA by a Rheumatology Consultant. (Undifferentiated Inflammatory Arthritis is defined as: persistent synovitis in more than one small joint of the hand, without any other known cause, but the person does not yet meet all the diagnostic criteria for RA. Participants can have co-morbidities (which may also be related to having RA, UIA or PsA, for example, osteoarthritis, fibromyalgia, heart condition, mild to moderate anxiety or depression; or are unrelated, e.g. diabetes
3. In paid work (full or part-time, self-employed or regular contractual work) for at least 15 hours per week
4. Participants may be on sick leave at the time of screening BUT this must be for less than 4 weeks duration and not planned or likely to extend for longer than 4 weeks
5. Able to read and understand English. This is because:
5.1. The control group will only receive the written work self-help information and unfortunately it is not possible to translate the published booklets into multiple languages within the resources of this trial and
5.2. Data is being collected by self-report questionnaires and many of the measures included are not linguistically validated/ translated and psychometrically tested in other languages. Thus, translating them into Welsh, for example, will not provide valid, reliable results
6. Score > = 10 on the RA-Work Instability Scale (RA-WIS), a measure of mismatch between the person’s abilities and their job demands. A score of > = 10 is indicative of medium to high risk of

work instability and need for VR. This takes about 5 minutes to be completed and scored
7. Able to attend the participating site for WORKWELL appointments, if allocated to that group
8. Able to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 240; UK Sample Size: 240

Total final enrolment
249

Key exclusion criteria
Current participant exclusion criteria as of 07/02/2022:
1. On extended sick leave (i.e. > 4 weeks). The WORKWELL intervention is designed for people currently in work. Long-term sick leave is defined as being > 4 weeks [NICE, 2009b]. For that group, there is advice available through the UK Government Fit for Work service, with support for return to work plans. Many people with RA, UIA or PsA do not take long-term sick leave, as once on an effective medication regimen, short-term absences are more common than long-term absences due to the fluctuating nature of these conditions. (Most (95%) of UK absences amongst all workers last less than 20 days
2. Already planning to retire due to age or to take early retirement (for any health or non-health reason) within the next 12 months (i.e. within the trial follow-up period)
3. Already due to stop work for any other reason (e.g. planned redundancy, fixed term contract due to end) within the next 12 months (i.e. within the trial follow-up period)
4. Planning to move out of area within the next 3 months and therefore would be unable to attend for WORKWELL appointments if allocated to that group (as treatment may not be completed in time). (If patients move out of area at short notice, they will continue to be in the trial as this is an intent-to-treat analysis)
5. Already receiving or awaiting VR services from Access to Work or a Vocational Rehabilitation company. These services conduct work assessments as part of VR provision. (Those receiving work services from other sources (e.g. occupational health or human resources in their organisation, online advice from Fit for Work) may still be recruited as VR provision can be of varied quality and this will be considered as “usual care"
6. Employed in the armed forces (as they could be stationed overseas during the trial period. The armed services also have their own Vocational Rehabilitation service
7. On furlough or Self-Employment Income Support (i.e., currently unable to attend work or work from home)

Previous participant exclusion criteria:
1. On extended sick leave (i.e. > 4 weeks). The WORKWELL intervention is designed for people currently in work. Long-term sick leave is defined as being > 4 weeks [NICE, 2009b]. For that group, there is advice available through the UK Government Fit for Work service, with support for return to work plans. Many people with RA, UIA or PsA do not take long-term sick leave, as once on an effective medication regimen, short-term absences are more common than long-term absences due to the fluctuating nature of these conditions. (Most (95%) of UK absences amongst all workers last less than 20 days
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4. Planning to move out of area within the next 3 months and therefore would be unable to attend for WORKWELL appointments if allocated to that group (as treatment may not be completed in time). (If patients move out of area at short notice, they will continue to be in the trial as this is an intent-to-treat analysis)
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6. Employed in the armed forces (as they could be stationed overseas during the trial period. The armed services also have their own Vocational Rehabilitation service

Date of first enrolment
18/02/2019

Date of final enrolment
31/01/2021

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
Centre for Health Sciences Research
L701 Allerton (OT)
University of Salford
Frederick Road
Salford

United Kingdom
M6 6PU

Study participating centre
St Helens and Knowsley Hospital Services NHS Trust
Whiston Hospital
Warrington Road
Prescot
United Kingdom
L35 5DR

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Worcestershire Acute Hospitals NHS Trust
Worcestershire Royal Hospital
Charles Hastings Way
Worcester
United Kingdom
WR5 1DD

Study participating centre
Salford Royal NHS Foundation Trust
Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Countess Of Chester Hospital NHS Foundation Trust
The Countess Of Chester Health Park
Chester
United Kingdom
CH2 1UL

Study participating centre
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle-upon-Tyne
United Kingdom
NE7 7DN

Study participating centre
Barnsley Hospital NHS Foundation Trust
Gawber Road
Barnsley
United Kingdom
S75 2EP

Study participating centre
Sherwood Forest Hospitals NHS Foundation Trust
Mansfield Road
Sutton-in-Ashfield
United Kingdom
NG17 4JL

Study participating centre
Northumbria Healthcare NHS Foundation Trust
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
NHS Cannock Chase CCG
Block D
Beecroft Court
Beecroft Road
Cannock
United Kingdom
WS11 1JP

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Oxford University Hospitals NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Northern Devon Healthcare NHS Trust
North Devon District Hospital
Raleigh Park
Barnstaple
United Kingdom
EX31 4JB

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

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
Aneurin Bevan University LHB
Headquarters - St Cadoc's Hospital
Lodge Road
Caerleon Newport
Gwent
United Kingdom
NP18 3XQ

Study participating centre
Cardiff & Vale University LHB
Corporate Headquarters
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
NHS Fife
Springfield House
Cupar
United Kingdom
KY15 5UP

Sponsor information

Organisation
University of Salford

Sponsor details
c/o Jono Guildford
Research Contracts: Finance
Maxwell Building
The Crescent
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United Kingdom
M6 4WT
+44 (0)1612954551
j.guildford@salford.ac.uk

Sponsor type
University/education

ROR
https://ror.org/01tmqtf75

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK; Grant Codes: 21761

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
Current publication and dissemination plan as of 12/02/2024:

In 2021, the study protocol was published, outlining the research framework for the WORKWELL trial. This was followed by the publication of the process evaluation protocol in 2022. Furthermore, a detailed manuscript discussing the necessary modifications to the WORKWELL trial due to the COVID-19 pandemic's impact, as well as an evaluation of the efficacy of pre-notification of trial participants prior to the collection of self-reported outcome data to enhance retention rates, has also been disseminated.

The research team is currently preparing for the publication of the process evaluation outcomes in 2024. This will precede the publication of the trial findings, which is scheduled for 2025. The dissemination strategy encompasses a broad spectrum of stakeholders including participants, Rheumatology and Therapy departments, and individuals with RA/EIA/PsA via patient organisations.

Additionally, dissemination efforts will target professional organisations with vested interests in vocational rehabilitation. Manuscripts reporting the study findings will be submitted to peer-reviewed journals with a high impact factor within the domains of rheumatology and rehabilitation. Post-study, resources developed throughout the course of the research will be made available on the official study website https://www.workwelluk.org/ which has been co-designed with PPIE and digital learning specialists to ensure access by a wider population.

Previous publication and dissemination plan:

1. WORKWELL trial protocol article submitted for review in e.g. BMC Musculoskeletal Diseases circa May/June 2020
2. WORKWELL trial article planned publication in a high-impact peer-reviewed journal by end 2022
3. Process evaluation articles submitted during 2020-22, according to topic (e.g. WORKWELL Intervention and training 2020; participants' and therapists views of WORKWELL 2022)

The researchers will disseminate findings to: participants; Rheumatology departments; Therapy departments; people with RA/EIA/PsA via patient organisations; to professional organisations with interests in VR; and submit articles for publication in high impact rheumatology and rehabilitation journals. They also aim to make resources freely available at the end of the study on the University of Salford's research repository and www.mskhub.com – the research website designed to disseminate their research and self-management support people with musculoskeletal conditions and provide resources to health professionals.

Intention to publish date
03/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Yeliz Prior (Chief Investigator - y.prior@salford.ac.uk). Quantitative data selected from the questionnaire content will be available after publication of the trial results article for a period of 3 years. Access criteria: applicants should state the reason for the request; full study title, full names of research team; aims of the research and brief methodology; provide ethical approval for study; funder and sponsor details. The request will be reviewed by members of the research team. Fully de-identified dataset of summary key outcome variables.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/09/2020	15/09/2020	Yes	No
Protocol article	protocol for the process evaluation	09/11/2022	11/11/2022	Yes	No
Other publications	study adaption due to the COVID-19 pandemic	20/12/2022	30/03/2023	Yes	No
HRA research summary			26/07/2023	No	No
Results article		01/03/2025	03/03/2025	Yes	No