

VOLUNTEER PARTICIPANT INFORMATION SHEET:

WORKWELL: Testing work advice for people with arthritis

Part One: Introduction

We would like to invite you to take part in a research study. The study is being run by the Centre for Health Sciences Research, University of Salford. The Lancashire Clinical Trials Unit, University of Central Lancashire, is also supporting the trial. Before you decide, you need to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. **The research team will be happy to talk through this information sheet with you. We can answer any questions you have.** Our Trial Research team (0161 295 2120 and workwell@salford.ac.uk) can do this by telephone or online. Please ask if there is anything that is not clear to you or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of this study?

Working people with inflammatory arthritis (i.e. rheumatoid arthritis, early inflammatory arthritis or psoriatic arthritis) may find that they have some difficulties doing their job because of their arthritis. Work issues might be: physical, managing the effects of arthritis at work, psychological; relationships with co-workers or managers; and/or balancing work, health and personal life.

The advice and help available for working people with arthritis about work issues varies considerably between Rheumatology departments and between people's workplaces. In this study we want to **test two ways** of providing working people with arthritis with advice

and support about how to manage any work problems they may have. These are for people who have concerns about their health affecting their ability to work over the next few years.

We are testing:

- a) A work self-help information pack: Information booklets, specifically designed for working people with arthritis, with practical advice about work issues and how to manage these. **Plus** written guidance on identifying your work issues, where you can get support and any actions or changes you can make yourself, if you wish to.
- b) The self-help information pack **plus** practical advice from a therapist. The therapist will offer between 2 to 4 appointments of about 45 to 60 minutes each. These will be provided by telephone or online (using Microsoft Teams). The number of appointments depends on your work-related needs. These are usually about a month apart and flexibly timed around your work commitments (for example, appointments can be earlier or later in the day). The therapist will work with you to identify your work issues, discuss possible practical solutions and help you with any changes you decide on.

A member of the WORKWELL research team will provide your treatment. Staff are experienced, qualified occupational therapists with training/experience in delivering WORKWELL and who are Health and Care Professions Council registered. Staff are employed by the University of Salford, which provides Professional Indemnity Insurance.

People taking part are allocated by chance (by a computer) to one or other of these two types of work advice. We are asking about 240 working people with inflammatory, rheumatoid or psoriatic arthritis to take part. You are asked to fill out a questionnaire booklet before receiving one of the two types of work advice. We will then ask you to fill out a questionnaire booklet 6 months later and again 12 months later. Each month, we will also ask if you took any days off due to ill-health. You would therefore be taking part in the study for about a year.

There is little research in the UK about whether work advice helps people with arthritis to reduce their work problems or stay in work. Two studies in the USA have shown work advice can help people stay in work for longer, but two studies in the Netherlands showed it made little difference. However, the USA and the Netherlands are very different to the UK. We want to see if this work advice helps working people with arthritis in the UK and whether it is value for money to provide this in NHS Rheumatology departments. We are asking for your help with this study.

Why have I been invited?

You have either: a) previously taken part in one of our Research Centre's studies and agreed we can contact you with information about other studies; or b) have seen information about this study on a patient organization's website or social media.

We are asking people to take part who:

1. Have **one** of three types of arthritis:

- Early (undifferentiated) inflammatory arthritis (EIA); Rheumatoid arthritis (RA) or Psoriatic arthritis (PsA).

2. Are **employed** (i.e. have a work contract or self-employed) for 15 hours or more (on average) per week and are currently working, this includes working from home or working at a different site to your normal workplace. (Please also see numbers 4 and 5).

3. Are experiencing some work difficulties due to arthritis.

4. Are **not on sick leave**. BUT if you are on short-term sick leave (that is, due back at work soon and you won't be off work for more than 4 weeks altogether), you can still take part. You will need to have been back at work for at least a few days first. This is because some questions in the questionnaire booklet ask how you have been managing at work "within the last 2 weeks" If you are interested in taking part but you are on sick leave, please discuss

this with us - the research team at the University of Salford (see contact details at end of this information sheet). We can discuss with you about joining the study when you are back at work, if you wish.

5. If you are currently on **furlough/ Self-Employment Income Support Scheme /other income support/ shielded or strict social distancing** and **unable** to attend work, you can still take part when you are back at work (including working from home or in a different location to normal). If you are interested in taking part, you can discuss this with us - the research team at the University of Salford (see contact details at end of this information sheet). We can discuss with you about joining the study when you are back at work.

6. Are **not** planning to retire or take early retirement (through choice or ill-health) in the next 12 months.

7. Are **not** already receiving or recently received work rehabilitation from a work rehabilitation service, such as Access to Work. If you have received / are receiving advice from your occupational health or human resources department at work, or previously received work advice from a therapist, you **can** still take part.

Do I have to take part?

It is up to you to decide. Take your time to do so. Please discuss it with family or friends if you wish. Please call us (the **WORKWELL Trial Research Staff**) and we will be happy to explain the study to you and answer any questions. You can also send us the Contact Details Form in the FREEPOST envelope enclosed, if you are interested and want more information. We can then call you.

If you are interested in taking part, we will explain further about the study and first check if you are eligible to take part (i.e. trial screening). We will be using the fully anonymized

information from this screening to summarize, for example, the ages, gender and types of jobs of people who express an interest in taking part.

If you decide not to take part, this will not affect the standard of care you receive. If you decide to take part, you can still withdraw at any time. You do not need to give a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?

1. **If you decide to take part:** we will ask you to sign a consent form to show you agreed. This will be completed by telephone. The WORKWELL research team member can also formally record your verbal consent.

You can complete trial screening and /or consent by telephone and mail with the WORKWELL Trial staff. We will need your contact details to do this. Please mail your contact details to us on the Contact Details Form enclosed, using the FREEPOST envelope. Or scan and e-mail the form to return to us. We can then call you to discuss the study, check to see that you are eligible and answer any questions you may have before you decide to complete your consent.

On the Contact Details Form: please provide both your land-line and mobile telephone numbers (if you have them); and your e-mail address (if you have one).

- **Let us know** the best time/days to contact you. **If we can** call/text/e-mail you at any reasonable time of the day/ early evening: state “anytime.”

This will make it much easier for us to get in touch with you. We can leave text/ voicemail/ e-mail messages to arrange talking to you. We can call you early evenings if you are out at work all day.

If you decide to take part, we may also use your contact details later if we need to get in touch about your study questionnaires (for example, if you missed out anything by mistake). If you are referred to the WORKWELL programme, the therapist will also receive your contact details so they can make an appointment with you. Knowing your day-time availability, or that messages can be left on your mobile/ e-mail, will make it much easier for them to get in touch with you.

2. Following consent, we will give/mail you a **questionnaire** to complete to do in your own time. If you prefer to do this **online**, we can e-mail you a link to a secure online questionnaire, only accessible to you and the research team. This questionnaire will ask about, for example, your age, diagnosis and medication. It will also ask about your work, what work difficulties you have, how your health is affecting your work, your work-life balance and other health-related information. The questions are mostly answered using tick boxes/ circling numbers. It takes about 45-60 minutes to fill in. You do this in your own time at home (paper or online). Then you post it back to us in the FREEPOST envelope provided (i.e. at no cost to yourself).

3. Within one week of returning the questionnaire, you will receive the work self-help advice pack through the post from the Lancashire Clinical Trials Unit. A letter with this will let you know if you will also receive the WORKWELL programme.

4. If it was decided by chance that you receive the self-help information advice pack to use on your own, we ask that you read the guidance and information. Please identify the work problems you are experiencing and who you could discuss these with (e.g. family, friends, employer, GP). Take time to talk to people and think about solutions. Write down your own Action Plan. Then make any changes you decide will help.

5. If it was decided by chance that you will receive the pack plus the WORKWELL programme, within 1 to 2 weeks a therapist will get in touch to make the first appointment

with you. This will be by remote consultation (telephone or online). When you are referred, we will send the therapist your contact details to help the therapist contact you. They can offer appointments earlier or later in the day to reduce the impact on your working day. In the first meeting, the therapist helps you identify your work problems. In the following meeting(s), the therapist discusses and agrees with you any changes you want to make and gives practical advice about how to make changes. Usually the WORKWELL programme lasts 2 to 4 meetings. Each can be up to one hour, and each are about a month apart. The therapist will call you a few weeks later to ask how you are getting on. **Sometimes**, the therapist **might** suggest a work site visit would also be helpful to see what your problems are. This would be done remotely. **If** this would be helpful, the therapist will discuss this with you. It is up to you if you want this to happen or not. If yes, the therapist would need your line manager/ employer's permission. We understand that not everyone has told their employer/ people at work that they have a health condition.

A work visit will be done remotely (i.e. telephone or online). It **may** be helpful for you to send digital photographs of your workplace/of you working to your WORKWELL therapist to allow a better understanding of your work. If you do so, we ask that you: first check with your employer/ line manager that it is alright to do so. Please avoid including identifying features of other workers or yourself in the photograph (e.g. turn head away, keep face out of picture, any documents on a desk or computer screen are closed). If you choose to send photographs, the therapist will store these securely as part of your treatment record. Photographs will be stored on the University of Salford central server and only accessible to the research team. You may be asked later if the photographs can be used for educational and/or non- commercial purposes, in reports, presentations, publications, websites and/or exhibitions connected to the WORKWELL project. Your written consent will be asked for first. If you decide to consent (for any/all purposes), you can choose which photographs are used. Identifying details of yourself, people and workplace will be removed. If applicable, your employer's approval will be requested.

At the end of the WORKWELL programme, the therapist will write a report for you about the main work issues identified and advice given. You can use this to remind yourself about what you have done/ can do. You may find it helpful to discuss this with your line manager/ employer. It is up to you.

- **Optional:** we would like to audio-record the first appointment that your Workwell therapist has for one volunteer. You **might** be asked if the therapist can record your first appointment. This is so we can later listen to how the therapist provides treatment; and we will take notes about what is said. You can let us know if you agree to this on the consent form. Not everyone will be asked by the therapist. You can still change your mind at any time. The audio-recordings will be transferred securely to the research team. The therapist then deletes their copy. Recordings will only be accessed by our research team. Your name is not identified in any notes or reports. We delete the recordings afterwards.

6. Six months after you complete the first questionnaire, we will mail you a second one. This is shorter and asks about: work-related problems, health-related information and what you thought about the type of work advice you received. This takes about 30 minutes. You do this in your own time at home. Then you post it back to us in the FREEPOST envelope provided. If you prefer to do this **online**, we can e-mail you a link to a secure online questionnaire, only accessible to you and the research team.

7. Another six months later (12 months from the start), we ask you to complete the third questionnaire. This is also about: any work difficulties you may have, how your health may have affected your work, work-life balance, other health-related information, and any other treatment you had in the last 6 months. This takes about 45 to 60 minutes. You do this in your own time at home. Then you post it back to us in the FREEPOST envelope provided. If you prefer to do this **online**, we can e-mail you a link to a secure online questionnaire, only accessible to you and the research team.

8. **Each month for the 12 months: we will ask if you have been off work because of ill-health that month, and if yes, how many days it was.** We can do this by text, e-mail or phone, as you prefer.

After the final questionnaire (at 12 months):

9. **Optional:** we would like to interview about **15 people who received the WORKWELL programme (i.e. just over 10%)**. You can let us know if you are interested on the consent form. If you prefer not to be interviewed, it's not a problem. We don't need everyone to help. If you do agree to the interview, you can still change your mind at any time. In the interview, we ask your views about the work advice you received. The interview will normally be by telephone, or may be in person, and at a time and place that suits you (e.g. your home or hospital you usually go to) and will last up to 45 minutes. We would like to audio-record it to help us later in writing down accurately what you said. The recordings are only listened to by our research staff. Your name is not identified when these are typed up. We delete the recordings once the content is written down. We will not ask about any private information. (Please do not disclose such information to the interviewer).

10. **Optional:** we will write to some people who attended the WORKWELL programme to ask if they are interested in us interviewing their employer/ line manager about what their views of the work advice you received and if they think there are any benefits for the company/ organization you work for. This is a 15-20-minute telephone interview. We **only** need about **10%** of people to help us contact their employer/ line manager. Therefore, if you don't want to do this, it's not a problem. It does not affect you taking part in the study now in any way. **If** in a year's time you are interested, we will give you more information, you can think about it and take time to decide. **If** you are interested, we ask if you will talk to your line manager/ employer about being interviewed, and to help put us in touch if they are. We send them information to think about and they can decide then.

11. **Lastly**, we would like to see how you get on in the future with your working life. We would like to send you another copy of the questionnaire in **three years' time from now**. You can decide then if you want to complete this.

We will send you a thank you letter when you have finished the third questionnaire (at 12 months). We will ask you, in the thankyou letter, if you would be interested in letting us know about what you thought about taking part in the trial and your ideas about how the treatments, we are testing could best be put into practice when we know the results. You can decide then if you want to do this. Our "Workwell Patient Group" is leading this. We will also let you know the results of the study when it has ended (which will be in 2022).

Expenses and payments

There is no expense in completing the questionnaires, as we provide FREEPOST envelopes for the reply. If you are due to be treated by a WORKWELL therapist, the therapist will start any telephone calls so there is no expense to you.

As a "thank you," on returning each of the questionnaires we send you at 6 and 12 months, we will enter you into a **Prize Draw** at the end of the study (late 2021/ early 2022). Returning both questionnaires will mean you have two Prize Draw entries. There are five prizes worth the equivalent of **£50** each. Please let us know if you would like to be entered or not (by answering this question at the end of the first questionnaire).

What are the possible benefits of taking part?

The study may help you, if you choose to make changes suggested in the work information pack or WORKWELL programme, although it may not help. The information you give us will help us understand any effects the information pack and WORKWELL programme may have on people with arthritis' work problems, and if one method of providing work advice is better than the other. In future, this will help therapists plan work-related treatment for

people with arthritis. It can help the NHS plan appropriate work-related services for people with arthritis.

What are the possible disadvantages and risks of taking part?

The work advice pack contains information available to people with arthritis, if they know where to find it. The WORKWELL programme is provided by a therapist who has received training in this. We do not expect there are any disadvantages or risks to you in taking part, as you choose what changes (if any) to make. If you choose to take part in the interview, we will arrange this at a place and time to suit you.

If the information in Part 1 has interested you and you are considering taking part, please read the additional information in Part 2 before making any decision.

Part Two: Further information

Will my taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice. We will handle all information about you in confidence. We will store it securely at the University of Salford and the Lancashire Clinical Trials Unit. All information which is collected about you during the course of the research will be kept strictly confidential. We only identify you in any interview recording by a number. You have the right to check the accuracy of the data held and correct any errors. Only staff involved in the research study see your information. Any direct quotes from the audio-recordings we use in reports, will not identify you in any way.

How we will use your personal data and your rights under the law.

The University of Salford is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting **Prof Alison Hammond** and on our website: <https://www.workwelluk.org/privacy-notice>

The only people in the University of Salford and the Lancashire Clinical Trials Unit who will have access to information that identifies you will be people who need to contact you to (for example to discuss the study, find out any missing information, provide treatment, arrange an interview) or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

The research team at the University of Salford will also keep identifiable information about you from this study for 6 years after the study has finished. Your information will be stored in locked cabinets and then a data archive store within the Centre for Health Sciences Research and only accessible to members of the research team. After this date, your identifiable information, questionnaires (paper and any scanned information) will be confidentially destroyed or purged from the University server.

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time, and your care will not be affected. We will use the data collected up until your withdrawal unless you tell us not to.

What will happen if there is a problem?

If you have problems with the WORKWELL programme, please contact and discuss this with the therapist who you saw. If you have any queries or problems about the work advice pack,

the study, questionnaires or interview, please contact our WORKWELL Research Staff who will do their best to help.

If you have any complaint about the way you have been dealt with during the study, or any possible harm you might suffer, we will address this. If you have a concern about any aspect of this study, you should ask to speak first to: the researchers and, if appropriate, the therapist who provided the WORKWELL programme to you. We will do our best to answer your questions (contact our WORKWELL Research Staff – see below).

If you remain unhappy and wish to complain formally, you can do this through the School of Health Sciences, University of Salford. Please contact:

Dr Andrew Findlow, Chair of the Health Research Ethics Panel, PO49, Brian Blatchford Building, Frederick Road Campus, University of Salford, Salford, M6 6PU.

Tel: 0161 295 0037. Email: a.h.findlow@salford.ac.uk

In the event that something does go wrong and you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the University of Salford, but you may have to pay your legal costs.

What will happen to the results of the research study?

We will send you a summary of the findings when the study is fully completed. When you finish taking part, we will send you a letter saying when this is likely to be. We will write up the findings and submit them for publication. This will help Rheumatology and Therapy departments learn from our experiences. You will not be identified in any report or publication. We will present the study results at national and international rheumatology conferences. We will inform arthritis charities so they can choose whether to make the findings available to other people with arthritis via their websites/ magazines.

Who is organizing and funding the research?

The Centre for Health Sciences Research, University of Salford and the Lancashire Clinical Trials Unit are organizing this trial. We are also working with researchers at the: University of Manchester, University of Lancaster, University of Southampton and Sheffield Hallam

University. The study is funded by Versus Arthritis (formerly Arthritis Research UK). The Chief Investigator is Professor Alison Hammond. The Centre for Health Sciences Research, University of Salford is part of the Versus Arthritis/ Medical Research Council's National Centre for Musculoskeletal Health and Work Research.

Who has reviewed the study?

All research in the NHS is looked at by independent groups of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favorable opinion by West Midlands-Solihull Research Ethics Committee. The Research Ethics Committee at the University of Salford and University of Central Lancashire have also approved the study.

Further information and contact details

If you have any questions about the study, wish to discuss taking part or have any concerns; please contact the researchers:

Trial Manager: Dr Angela Ching

Trial Research Administrator: Dr Jennifer Parker

Chief Investigator: Prof. Alison Hammond

Tel: 0161 295 2120; workwell@salford.ac.uk

Centre for Health Sciences Research, University of Salford

L701 Allerton, Frederick Road, Salford M6 6PU.

We can be contacted by mail at:

Workwell Trial, PO Box 296, NANTWICH CW5 9DZ

Information about the study is also available from our website: www.workwelluk.org

General information about taking part in research is available on the INVOLVE website (www.invo.org.uk). **INVOLVE** is a national advisory Group, funded by the Department of

Health, which supports active public involvement in NHS, public health and social care research.

Finally

Thank you for considering taking part. Please keep this information sheet. We will ask you to sign a consent form if you agree to take part.