

# Evaluation of the Warwick Axial Spondyloarthritis Fatigue and Energy questionnaire (e-WASTEd)) in rheumatology clinical practice.

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| <b>Submission date</b><br>18/09/2023   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
|  |   | <input checked="" type="checkbox"/> Protocol         |
| <b>Registration date</b><br>19/10/2023 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>01/08/2024       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data |
|  |   | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Axial Spondyloarthritis (axSpA) is relatively common, affecting 3 in every 1,000 UK adults. There is no cure. Pain, stiffness, reduced mobility, and severe fatigue are important problems. Patients have said that they would like more help coping with fatigue. However, the current way patients are asked about fatigue can undervalue its importance and impact. The study team worked with patients to complete the first steps towards making a new questionnaire to assess fatigue. However, this work needs to be completed before it can be used in clinical practice. This study aims to work with patients to refine and test this new questionnaire about fatigue in axSpA to help patients tell clinicians about their fatigue and get the treatment they need. An online version will be made which will be completed using a computer or tablet. Guidance will be provided to improve the use of online questionnaires.

### Who can participate?

People aged 18 years old and over with axSpA

### What does the study involve?

A new online system is being used by NHS clinicians to support questionnaire completion by rheumatology patients. The system will be used to test the study questionnaire and to find out what patients and clinicians think about it. For example, its ease of use and whether it helps in meetings between patients and clinicians. This will help the study team both to improve the system and ultimately improve patient care.

### What are the possible benefits and risks of participating?

Participants may benefit from being able to track several aspects of their health over the course of the study. There are no risks to participation.

### Where is the study run from?

The University of Warwick (UK)

When is the study starting and how long is it expected to run for?  
August 2022 to July 2024

Who is funding the study?  
The National Institute for Health and Care Research (NIHR) through the Research for Patient Benefit (RfPB) Programme (UK)

Who is the main contact?  
Prof Kirstie Haywood, k.l.haywood@warwick.ac.uk

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Kirstie Haywood

### ORCID ID

<https://orcid.org/0000-0002-5405-187X>

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

310098

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

IRAS 310098, CPMS 53089, IDEATE 69591

## Study information

Scientific Title

Measuring fatigue in Axial Spondyloarthritis (axSpA): refinement, application and evaluation of a new electronic patient-reported outcome measure (the Warwick Axial Spondyloarthritis Fatigue and Energy questionnaire (e-WASTEd)) in rheumatology clinical practice.

## **Acronym**

WASTEd

## **Study objectives**

The electronic version of the WASTEd PROM is a reliable and valid method to identify fatigue and energy levels in patients with axial spondyloarthritis

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 08/12/2022, Preston Research Ethics Committee (HRA NRES Centre, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8364; preston.rec@hra.nhs.uk), ref: 22/NW/0211

## **Study design**

Multicentre longitudinal mixed methods study

## **Primary study design**

Observational

## **Study type(s)**

Diagnostic, Quality of life

## **Health condition(s) or problem(s) studied**

Axial spondyloarthritis

## **Interventions**

Stage 1: Refining the WASTEd-Short Form

1.1. Qualitative interviews (paper version of WASTEd): Three rounds of semi-structured interviews (online/by phone) with people with axial spondyloarthritis, providing the first opportunity to check the content and face validity of the 'short-form' 18-item WASTEd.

1.2. Develop the e-WASTEd: We will create an electronic (e) version which is compatible with online completion using computers and tablets via the British Society of Rheumatology's (BSR) electronic patient-reported outcome measure (ePROM) platform. We will not change the PROM item structure or content.

1.3. Pilot the e-WASTEd - qualitative interviews: We will conduct up to 10 semi-structured interviews (online/phone) to check the usability, acceptability, and feasibility of the eWASTEd.

Stage 2: Evaluating the e-WASTEd:

A cohort of people with axial spondyloarthritis (n=380) will complete a suite of ePROMs at baseline and follow-ups at week 2 and month 3. The principle ePROM of interest is the Warwick Axial Spondyloarthritis Fatigue and Energy questionnaire (e-WASTEd)).

Stage 3: Exploring the experiences of patients and clinicians using the BSR ePROM platform

To explore patient and clinician experiences of using ePROMs accessed via the ePROM platform

to provide information to help to improve the ePROM platform and ultimately to improve patient care. We estimate requiring up to 10 patients and 10 health professionals (clinicians, physiotherapists, nurses) to participate in focus groups.

Note: The WASTEd is currently only available in the English language, so the ability to understand written English is a study requirement. The WASTEd has a readability level of 11-13 years; hence, patients with significantly limited literacy levels are excluded. This extends to patients with significant co-morbidities.

### **Intervention Type**

Mixed

### **Primary outcome(s)**

Fatigue and energy measured using the WASTEd 18-item questionnaire at baseline, 2-week and 3-month follow-up

### **Key secondary outcome(s)**

The following secondary outcome measures are assessed at baseline, 2-week and 3-month follow-up:

1. Health-related quality of life measured using the EQ-5D five questionnaire descriptive system and the EQ visual analogue scale (EQ VAS)
2. Self-reported fatigue and its impact upon daily activities and function measured using the Functional Assessment of Chronic Illness Therapy – Fatigue Scale (FACIT-Fatigue) 5-point Likert-type scale comprising 13 items
3. Anxiety and depression symptoms measured using the Hospital Anxiety and Depression Score (HADS) 4-point Likert-type scale comprising 14 items
4. Pain measured using a single measure of pain severity using an 11-point numerical rating scale
5. Four domains of physical function, disease activity, emotional well-being and social participation measured using the Evaluation of Ankylosing Spondylitis Quality of Life (EASi-QoL) 5-point Likert-type scale comprising 20 items
6. Functional and disease activity indices measured using the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) comprising a 0 - 10 scale measuring discomfort, pain, and fatigue (0 being no problem and 10 being the worst problem) in response to six questions
7. Functional anatomical limitations due to the course of this inflammatory disease and the patient's ability to cope with everyday life measured using the Bath Ankylosing Spondylitis Functional Index (BASFI) comprising 10 VAS questions

### **Completion date**

01/07/2024

## **Eligibility**

### **Key inclusion criteria**

Patients:

1. Adults aged 18 years old and over
2. A confirmed diagnosis of axSpA
3. Registered with participating rheumatology centres
4. Access to a computer or tablet device to allow for receipt of the e-mail and e-WASTEd completion

Health professionals:  
Experience of using the BSR ePROM portal with their patients

**Participant type(s)**

Patient, Health professional

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

272

**Key exclusion criteria**

1. Ability to understand written English to a readability level of 11-13 years
2. Patients with significant co-morbidities

**Date of first enrolment**

26/09/2022

**Date of final enrolment**

30/04/2024

## **Locations**

**Countries of recruitment**

United Kingdom

England

Scotland

Wales

**Study participating centre**

**Haywood Hospital**

Burslem

Stoke-on-trent

United Kingdom

ST6 7AG

**Study participating centre**  
**Gartnavel General Hospital**  
1053 Great Western Road  
Glasgow  
United Kingdom  
G12 0YN

**Study participating centre**  
**University Hospitals Coventry and Warwickshire NHS Trust**  
Walsgrave General Hospital  
Clifford Bridge Road  
Coventry  
United Kingdom  
CV2 2DX

**Study participating centre**  
**Royal Berkshire NHS Foundation Trust**  
Royal Berkshire Hospital  
London Road  
Reading  
United Kingdom  
RG1 5AN

**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**  
**North Wales Clinical Research Centre, Wrexham**  
Unit 4-8  
Gwenfro Units  
Wrexham Technology Park  
Wrexham  
United Kingdom  
LL13 7YP

**Study participating centre**  
**Glan Clwyd General Hospital**  
Ysbyty Glan Clwyd  
Sarn Lane  
Bodelwyddan  
Rhyl  
United Kingdom  
LL18 5UJ

**Study participating centre**  
**Betsi Cadwaladr University Health Board**  
North Wales Clinical Research Centre NWCRC  
Unit 15 Gwenfro  
Wrexham  
United Kingdom  
LL13 7YP

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

## **Sponsor information**

**Organisation**  
University of Warwick

**ROR**  
<https://ror.org/01a77tt86>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**

Research for Patient Benefit Programme

### Alternative Name(s)

NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

Interview data from stages 1 & 3 will not be made available. The dataset generated during stage 3 is not expected to be made available as this data is held by the British Society of Rheumatology within their ePROM portal.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

| Output type                   | Details     | Date created | Date added | Peer reviewed? | Patient-facing? |
|-------------------------------|-------------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol file</a> | version 1.5 | 07/06/2023   | 10/10/2023 | No             | No              |