ISRCTN64318436 https://doi.org/10.1186/ISRCTN64318436

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

Submission date
18/09/2023

Recruitment status
No longer recruiting

Registration date
19/10/2023

Overall study status
Completed

Last Edited
01/08/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
Warwick Research in Nursing
Division of Health Sciences
Warwick Medical School
University of Warwick
Coventry
United Kingdom
CV4 7AL
+44 (0)7972374204
k.l.haywood@warwick.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
310098

Central Portfolio Management System (CPMS)
53089

Protocol serial number
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

Primary study design
Observational

Study design
Multicentre longitudinal mixed methods study

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 questionniare 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?
Protocol file	version 1.5	07/06/2023	10/10/2023	No	No