

Psychometric testing of the British English workplace activity limitations Scale in four rheumatic and musculoskeletal conditions

HAMMOND, Alison, TENNANT, Alan, CHING, Angela, PARKER, Jennifer, PRIOR, Yeliz, GIGNAC, Monique A.M., VERSTAPPEN, Suzanne M.M. and O'BRIEN, Rachel <<http://orcid.org/0000-0002-4720-1956>>

Available from Sheffield Hallam University Research Archive (SHURA) at:

<https://shura.shu.ac.uk/32054/>

This document is the Published Version [VoR]

Citation:

HAMMOND, Alison, TENNANT, Alan, CHING, Angela, PARKER, Jennifer, PRIOR, Yeliz, GIGNAC, Monique A.M., VERSTAPPEN, Suzanne M.M. and O'BRIEN, Rachel (2023). Psychometric testing of the British English workplace activity limitations Scale in four rheumatic and musculoskeletal conditions. *Rheumatology advances in practice*, 7 (1): rkad028. [Article]

Copyright and re-use policy

See <http://shura.shu.ac.uk/information.html>



Clinical science

Psychometric testing of the British English Workplace Activity Limitations Scale in four rheumatic and musculoskeletal conditions

Alison Hammond ^{1,*}, Alan Tennant², Angela Ching¹, Jennifer Parker¹, Yeliz Prior ¹,
Monique A.M. Gignac^{3,4}, Suzanne M.M. Verstappen^{5,6,7}, Rachel O'Brien⁸

¹Centre for Human Movement and Rehabilitation, School of Health and Society, University of Salford, Salford, UK

²Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, Leeds, UK

³Institute of Work and Health, Toronto, ON, Canada

⁴Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada

⁵Centre for Epidemiology Versus Arthritis, Centre for Musculoskeletal Research, Faculty of Biology, Medicine and Health, University of Manchester, Manchester, UK

⁶Manchester Academic Health Science Centre, Manchester, UK

⁷NIHR Manchester Biomedical Research Centre, Manchester University NHS Foundation Trust, Manchester, UK

⁸College of Health, Well Being and Life Sciences, Sheffield Hallam University, Sheffield, UK

*Correspondence to: Alison Hammond, Centre for Human Movement and Rehabilitation, School of Health and Society, Allerton, University of Salford, Frederick Road, Salford M6 6PU, UK. E-mail: a.hammond@salford.ac.uk

Abstract

Objectives: The aims were to validate a British English version of the Workplace Activity Limitations Scale (WALS) linguistically, then test this psychometrically in RA, axial spondyloarthritis (axSpA), OA and FM.

Methods: The WALS was forward translated, reviewed by an expert panel, and cognitive debriefing interviews were conducted. Participants completed a postal questionnaire booklet. Construct (structural) validity was examined by fit to the Rasch measurement model. Concurrent validity included testing between the WALS and the Work Limitations Questionnaire-25 (WLQ-25). Two weeks later, participants were mailed a second questionnaire booklet for test-retest reliability.

Results: Minor wording changes were made to the WALS, then 831 employed participants completed questionnaires: 267 men and 564 women; 53.5 (s.d. 8.9) years of age; with condition duration 7.7 (s.d. 8.0) years. The WALS satisfied Rasch model requirements, and a WALS Rasch transformation table was created. Concurrent validity was strong with the WLQ-25 (RA $r_s = 0.78$; axSpA $r_s = 0.83$; OA $r_s = 0.63$; FM $r_s = 0.64$). Internal consistency was consistent with group use ($\alpha = 0.80-0.87$). Test-retest reliability was excellent, with intraclass correlation coefficient (2,1) at ≥ 0.90 .

Conclusion: A reliable, valid British English version of the WALS is now available for use in the UK.

Lay Summary

What does this mean for patients?

Working people with arthritis can have difficulties doing work activities. If not identified and addressed, people can struggle to keep working and even give up work. The Workplace Activity Limitations Scale (WALS), developed in Canada, measures work difficulties. With help from 48 people with rheumatoid arthritis (RA), osteoarthritis (OA), axial spondyloarthritis (axSpA) or fibromyalgia (FM), we adapted the WALS into British English. They considered that the 12 questions of the WALS reflected their work problems well. We sent a questionnaire booklet, including the WALS and other work and health questionnaires (e.g. pain, fatigue, daily activity ability), to >800 people with RA, OA, axSpA or FM. Several weeks later, we again sent them the WALS to complete. We found a good relationship between WALS scores and other questionnaires; that is, the WALS is a valid, or realistic, measure of work difficulties. It is also reliable; people gave very similar answers second time round. The WALS could be used in clinics quickly (<5 min) to identify people with problems at work attributable to their arthritis. A score of seven or more indicates need for referral for work advice/rehabilitation to help resolve work problems, which could then help people to keep working.

Keywords: patient-reported outcomes, work, work rehabilitation, arthritis, musculoskeletal, rehabilitation

Key messages

- WALS content is considered highly relevant by working people with RA, OA, axSpA and FM.
- WALS has good reliability and construct (structural), concurrent and discriminant validity.
- WALS can be used to evaluate work difficulties, need for work rehabilitation and treatment outcomes.

Received: 14 October 2022. Accepted: 22 February 2023

© The Author(s) 2023. Published by Oxford University Press on behalf of the British Society for Rheumatology.

This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<https://creativecommons.org/licenses/by/4.0/>), which permits unrestricted reuse, distribution, and reproduction in any medium, provided the original work is properly cited.

Introduction

Work participation (i.e. paid work) is important for the health and well-being of people with rheumatic and musculoskeletal disorders (RMDs). Yet they have a shorter healthy working life expectancy [1] and are less likely to be employed compared with those without long-term health conditions [2]. Working people with RMDs can struggle to manage work, leading to presenteeism (i.e. reduced at-work productivity owing to health problems [3]). This is an important target for improvement in medical, rehabilitation and vocational interventions, and from the perspectives of people with RMDs [4]. Outcome measures assessing at-work productivity, tested across a range of RMDs, can help to direct and evaluate such interventions.

The OMERACT Work Productivity Group identified two patient-reported outcome measures of at-work productivity suitable for use in RMD [5, 6]. The Work Limitations Questionnaire-25 (WLQ-25) measures duration of difficulty with work activities (work productivity) [7]; and the Workplace Activity Limitations Scale (WALS) measures the amount of difficulty with work activities (work ability) [4, 8]. People with RA and OA preferred the WALS over the WLQ-25 as an outcome measure [9].

The WALS was developed and tested psychometrically in Canada and has been used there in studies in inflammatory arthritis [i.e. RA, PsA and axial spondyloarthritis (axSpA)], OA, lupus and scleroderma [10–15]. In RA and OA, it has the following characteristics: good content validity, comprehensibility and content relevance [9]; low respondent burden [16]; and concurrent validity with other work measures [6, 17]; although there is only limited evidence for its test-retest reliability [6]. It has potential for clinical and research use in the UK. The WALS was developed in Canadian English. Before use in the UK, it should be validated linguistically (i.e. translated and culturally adapted) into British English (a different form of the same language), then tested psychometrically [18]. Although most Canadian English is understandable in the UK, some words used in the WALS have different meanings, e.g. ‘subway’ means a rapid transport system in North America but an underpass for crossing roads in the UK. The aims of the present study were therefore as follows: to validate linguistically, investigate content validity, and evaluate the psychometrics of a British English WALS among employed people with RA, axSpA, lower limb OA and FM in the UK. Testing should include both classical testing and item response theory (e.g. Rasch analysis) to establish psychometric properties (e.g. reliability and validity) [19].

Methods

The study design used cross-cultural adaptation, followed by cross-sectional surveys to establish psychometric properties of the WALS. The COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklists were followed [19, 20]. Ethical approval was obtained from the National Research Ethics Service Committee East Midlands, Leicester South (17/EM/0409). All participants provided written, informed consent.

Participants and recruitment

Patients were recruited from 41 secondary care and six community National Health Service Trusts’ Rheumatology,

Orthopaedic or Therapy outpatient clinics, with some participants from our research group’s Arthritis Volunteer Register, in the UK. Participants were eligible if they were: ≥ 18 years of age, in paid employment ≥ 1 day per week, currently working or on < 4 weeks sick leave, with participation delayed until at work, and had a primary diagnosis of RA or undifferentiated inflammatory arthritis (UIA), axSpA, OA (knee and/or hip) or FM. Diagnoses were confirmed by a rheumatologist for RA, UIA and axSpA or by a rheumatologist, orthopaedic surgeon, general practitioner or extended scope physiotherapist for OA and FM. Participants needed to be able to read, write and understand British English and were ineligible if on long-term sick leave, because they were unable to complete the work measures. Patients were identified by research facilitators or therapists using these criteria and given a short study explanation and information pack. The latter included a reply form, including diagnosis, employment and sick leave status, to check eligibility criteria.

Data collection

In phase 1, linguistic validation and cross-cultural adaptation were conducted to ensure that the wording in the WALS was considered comprehensible by participants. Content validity (i.e. the degree to which the content of a patient-reported outcome measure is considered an adequate reflection of what is being measured) was also tested [18, 21] (see [Supplementary Data S1](#), available at *Rheumatology Advances in Practice* online).

In phase 2, for psychometric testing, participants were mailed a paper questionnaire booklet to complete at home [test 1 (T1)]. Two weeks after return of the questionnaire, they were mailed a second questionnaire [test 2 (T2)], to assess test-retest reliability. Participants were sent a reminder letter after 2 weeks, followed at 4 weeks by another reminder and questionnaire booklet, if needed.

The T1 booklet included demographic data: age, sex, living arrangements, education status, condition duration, medication regimen, employment status and job title, to allow coding to job skill level {1 = elementary occupations; 2 = requiring compulsory education/work-related training; 3 = post-compulsory education (sub-degree) or longer work experience; 4 = degree education or equivalent experience [22]}.

The T1 booklet also included the British English WALS, consisting of 12 items, measured on a scale of 0–3 for difficulty in performing work activities (0 = no difficulty; 3 = unable to do; [Supplementary Data S2](#), available at *Rheumatology Advances in Practice* online). The WALS includes: eight physical activity items; three about managing work; and concentration at work [12]. The instructions state that respondents should answer about their work performance without help from others or using special gadgets or equipment, in order that their answers are not confounded by the use of workplace behavioural coping strategies [10]. The recall period is not specified. Those items answered as ‘not applicable to my job’ are scored 0. Scoring allows up to three missing items, which can be imputed using the individual’s mean or median scores (depending on the data distribution). A summed score is calculated (0–36), with scores ≥ 9 being associated with greater absenteeism, job disruptions and need for work accommodations, compared with those scoring < 5 [13].

To test concurrent validity, several work and health measures were included in the T1 questionnaire booklet. Some of these were condition-specific measures, and therefore four

separate condition-specific T1 questionnaire booklets were used, with participants completing the booklet relevant for their condition. For all measures, a higher score indicates worse status. Three work measures were included. The WLQ-25 consists of 25 items in four subscales (1–5 scale), indicating the percentage time in the past 2 weeks that physical work, time, mental–interpersonal and output demands were limited [7]. From these, the WLQ Percentage Productivity Loss [7] and Summed scores [23] are created. Two forms of the Work Instability Scale (WIS) were used: the RA-WIS was included in those questionnaires for people with RA, OA or FM, and the AS-WIS for axSpA [24–26]. Both forms measure the degree of mismatch between the respondent's work abilities and their job demands. The RA-WIS includes 23 true/false items and the AS-WIS 20 items. Both have cut-points indicating low, moderate and high work instability (RA-WIS <10 and >17; AS-WIS <11 and >18). The third work measure was the Work Productivity and Activity Impairment (WPAI) (General Health) scale, which includes six items, from which a Percentage overall work impairment due to health (in the past 7 days) score is calculated [27].

For RA, the condition-specific health measures included in the T1 booklet were: the Rheumatoid Arthritis Impact of Disease (RAID) scale, consisting of seven 0–10 numerical rating scales (NRS; e.g. pain, fatigue, function) scored by summing weighted NRS scores [28]; and the HAQ, consisting of 20 daily activities rated 0–3 (0 = not at all difficult; 3 = unable to do) [29]. The HAQ was scored by summing all items (0–20 = mild; 21–40 = moderate; 41–60 = severe disability) without adjustment for using aids and devices [30]. For axSpA, the health measures were: the BASDAI, in which the average score (0–10) is calculated from six 10 cm visual analogue scales (VAS) of symptom severity (e.g. fatigue, spinal pain [31]); and the BASFI, in which an average score (0–10) is calculated from ten 10 cm VAS of physical function [32]. For OA, two subscales of the WOMAC were included [pain (five items) and physical function (17 items)]; both scored from 0 = none to 4 = extreme, with total scores for each subscale calculated [33]. Finally, for FM, the Revised Fibromyalgia Impact Questionnaire (FIQR) was included. This consists of three subscales rated on 0–10 NRS [overall impact (two items); symptoms (10 items); and function (nine items)]. Subscale and overall total scores were then calculated [34]. For all four conditions, an additional health question was about perceived health status: 'Considering all the ways that your condition affects you, how have you been over the past month?' (scored from 1 = very good to 5 = very poor).

At test 2, participants completed the WALs, perceived health status and also an item on perceived change in health status: 'Overall, how much is your arthritis/condition troubling you now compared with when you last completed this questionnaire?' (1 = much less; 3 = about the same; 5 = much more).

Sample size

Given that Rasch analysis was used to assess construct (structural) validity, a minimum of 150 cases are needed within each condition group [35]. We aimed to collect ≤ 250 to ensure a broad spread of responses. At least 79 sets of repeated responses were needed to demonstrate that a test–retest correlation of 0.7 differed from a background correlation (constant) of 0.45, with 90% power at the 1% significance level.

A test–retest reliability correlation of 0.7 is considered a minimum acceptable level [36].

Statistical analyses

Demographic, work and health measures were summarized descriptively, as appropriate. RUMM 2030+ software was used for Rasch analysis [37]. Given that all work and health measures either consisted of ordinal data or were not normally distributed, non-parametric statistical tests were conducted using the Statistical Package for the Social Sciences (SPSS) v.26 [38]. The following psychometric properties were assessed.

Compliance

Compliance (i.e. the amount of missing data) was assessed by identifying the number (percentage) of missing data items and also WALs which could not be scored.

Validity

Construct (structural) validity measures the degree to which the scores of a patient-reported outcome measure adequately reflect the dimensionality of the construct being measured (e.g. do all scale items measure the same construct, and are items independent of one another?). The first analytical strategy was testing the fit of the WALs for each condition to the Rasch measurement model [39]. The approach also tested cross-diagnostic validity to test for invariance (i.e. whether the scale can be used to assess group differences because items are being interpreted similarly across groups; e.g. across conditions, age groups and sex). For interested readers, full details of the analysis are given in [Supplementary Data S3](#) and [Table S1](#), available at *Rheumatology Advances in Practice* online, and described in detail elsewhere [40].

Concurrent validity (i.e. the degree to which scores are consistent with hypotheses, e.g. that scores on other relevant measures are correlated with the WALs) was assessed using Spearman's correlations with work and health measures. We hypothesized that there would be moderate to strong correlations between scores for the WALs and the three work measures and moderate correlations with perceived health status and condition-specific symptoms and physical function scales. Correlations of 0.4–0.59 are considered moderate and ≥ 0.6 are strong [41].

Discriminant validity (i.e. hypothesis testing that there would be significant WALs score differences between those reporting they had very poor/poor, fair or good/very good perceived health status). This was assessed using Kruskal–Wallis tests, with $P \leq 0.05$ considered significant.

Reliability

Internal consistency (i.e. the degree of interrelatedness between items within a scale) was assessed using Cronbach's α . Results ≥ 0.8 were deemed good to excellent; ≥ 0.9 is consistent with individual use; and > 0.7 with group-level use [41].

Test–retest reliability is the extent to which scores for participants who report that their health has not changed are the same for repeated measurements over time. This was assessed in those reporting perceived health as 'the same' at T2, using Spearman's correlations and intraclass correlation coefficient (ICC) (2,1): two-way random consistency, average measures model. An ICC of ≥ 0.75 is considered excellent and 0.5–0.74 moderate [42]. Reliability of individual WALs items was

calculated using linear weighted κ , with levels of agreement considered as: 0.41–0.60 = moderate; ≥ 0.61 = good [41].

Responsiveness

Sensitivity to change was assessed by calculating the standard error of measurement (SEM) and the minimal detectable change₉₅ (MDC₉₅) scores. The SEM represents the s.d. of repeated measures of one individual. The MDC₉₅ is a statistical estimate of the smallest detectable change corresponding to change in ability rather than a measurement error [43, 44].

Floor and ceiling effects were considered present if >15% of participants achieved either the lowest or highest scores in the WALs [45]. If present, these can have a negative effect on the quality of the measure, because responsiveness (i.e. the ability to detect change over time) will be limited.

Results

Phase 1

Linguistic validation, cross-cultural adaptation and content validity results are given in [Supplementary Data S1, Tables S2 and S3](#), available at *Rheumatology Advances in Practice* online. In cognitive debriefing interviews ($n=48$; participant characteristics are in [Table 1](#)), all items were considered very relevant and, following expert panel review, only minor changes in wording were needed.

Phase 2

Overall, 1359 people were referred to the study; 831 returned T1 and 622 T2 questionnaire booklets ([Supplementary Fig. S1](#), available at *Rheumatology Advances in Practice* online). The response rates were as follows: secondary care, 62% (696/1117); community hospitals, 53% (119/224); and volunteers, 89% (16/18). Participant characteristics are shown in [Table 1](#) and work and health measures in [Table 2](#). The median time between tests was 36 (IQR 28–47) days.

Compliance

There were 0.01% missing data. WALs scores could not be calculated for three participants (with 5–12 missing items each) in each of the RA, axSpA and OA groups. These participants were not included in analyses (i.e. the sample size was reduced to 822). All FM scores could be calculated. The frequency of ‘not applicable’ (re-scored as 0) and ‘missing’ data are shown in [Supplementary Table S4](#), available at *Rheumatology Advances in Practice* online.

Validity

Construct (structural) validity

[Table 3](#) displays the detailed analysis of fit to the Rasch model. The scale is unidimensional. The items most easily affirmed (i.e. the transition from no to some difficulty) were: ‘Lifting, carrying or moving objects’ (RA); ‘Crouching, bending or kneeling’ (axSpA and OA); and ‘Concentrating’ (FM). The items most difficult to affirm (i.e. the transition from a lot of difficulty to unable to do) was: ‘Working with your hands’ (RA, axSpA, OA and FM). Invariance was confirmed for age, sex, condition, disease duration, educational and work status. Full details of the results are given in [Supplementary Data S3](#), available at *Rheumatology Advances in Practice* online. A transformation table was created to convert WALs raw scores to interval level scores, if required ([Supplementary Table S5](#), available at *Rheumatology Advances in Practice* online). A

reference metric was also created to allow test equating of raw WALs scores with raw RA- and AS-WIS scores ([Supplementary Table S6](#), available at *Rheumatology Advances in Practice* online). Both the latter have clinically derived cut-points. Direct comparison with these cut-points suggests that WALs scores of 7 and 14 would indicate thresholds for moderate and high work instability, respectively, in these four RMDs.

Concurrent validity

As hypothesized, the WALs exhibited a moderate to strong positive correlation with work measures (total scores: $r_s=0.51$ – 0.84), perceived health status ($r_s=0.42$ – 0.71) and diagnosis-specific symptoms ($r_s=0.54$ – 0.68) and physical function measures ($r_s=0.55$ – 0.77) ([Table 4](#)).

Discriminant validity

As hypothesized, there were significant differences between the three levels of perceived disease severity for the WALs across all four conditions, with higher perceived disease severity subgroups scoring worse ([Supplementary Table S7](#), available at *Rheumatology Advances in Practice* online).

Reliability

Internal consistency

Cronbach’s α values across the four conditions were good to excellent, ranging from 0.80 (FM) to 0.87 (RA). All were consistent with group-level use ([Table 3](#)).

Test–retest reliability

At T2, 356 of 622 (57%) participants reported that their condition was ‘the same’ as at T1 and included in analyses. For all four conditions, correlations between T1 and T2 scores were strong to very strong ($r_s=0.80$ and above). The ICCs (2,1) were excellent, at 0.90 and above ([Table 5](#)). Item reliability was moderate to good ([Supplementary Table S8](#), available at *Rheumatology Advances in Practice* online).

Responsiveness

Sensitivity to change

The MDC₉₅ scores ranged from 3.17 (RA) to 5.08 (OA) in those stating that their health was ‘the same’ at T2 ([Table 5](#)).

Floor and ceiling effects

Fewer than 15% scored 0 for the WALs, indicating there was no floor effect: RA = 6 of 294 (2%); axSpA = 21 of 199 (10.40%); OA = 3 of 176 (1.70%); and FM = 1 of 156 (0.60%). There were no ceiling effects (i.e. score of 36) in the four conditions.

Discussion

A linguistically validated British English version of the WALs is now freely available for use in the UK ([Supplementary Data S2](#), available at *Rheumatology Advances in Practice* online and www.mskhub.com). This study provides new evidence that the British English WALs has good psychometric properties in RA, OA, axSpA and FM and can be used in the UK.

We ensured linguistic and cross-cultural validity of the WALs by using a standard translation process [21], with the approval of the WALs developer. Example activities were updated in three items: to reflect active travel options (in item 1); and in items 2 and 6 to increase relevancy to manual jobs.

Table 1. Phase 1 and 2 participant demographic data

Parameter	RA		axSpA		OA		FM	
	Phase 1	Phase 2	Phase 1	Phase 2	Phase 1	Phase 2	Phase 1	Phase 2
<i>n</i> =	12	294	10	199	13	173	13	156
Sex, <i>n</i> (%), male:female	5:7	76 (26.00):218 (74.00)	4:6	124 (62.30): 75 (37.70)	4:9	54 (31.00):119 (69.00)	2:11	10 (6.00): 146 (94.00)
Age, mean (s.d.), years	57.33 (6.77)	53.47 (8.97)	33.00 (14.62)	46.96 (10.24)	55.92 (6.70)	56.49 (7.21)	39.69 (9.11)	45.71 (10.05)
Job skill level, <i>n</i> (%)								
1 and 2	3	149 (51.00)	5	66 (33.10)	8	84 (48.60)	7	95 (61.00)
3 and 4	9	142 (48.00)	5	133 (66.90)	5	88 (50.80)	6	61 (39.00)
Missing	–	3 (1.00)	–	–	–	1 (0.70)	–	–
Disease duration, mean (s.d.), years	18.08 (11.93)	7.66 (7.97)	12.70 (9.78)	12.33 (10.40)	12.35 (10.60)	4.97 (6.83)	5.38 (3.55)	2.99 (4.17)
Phase 2 only								
Symptom duration, mean (s.d.), years		9.33 (8.52)		18.97 (11.75)		7.89 (8.50)		8.36 (7.16)
Living conditions, <i>n</i> (%)								
With spouse/family/significant other		241 (82.00)		179 (89.90)		143 (83.00)		139 (89.00)
Children <18 years old living at home, <i>n</i> (%)		69 (23.00)		68 (34.20)		31 (18.00)		56 (36.00)
Educational level, <i>n</i> (%), ISCED								
No formal qualifications		27 (9.20)		14 (7.00)		17 (10.00)		7 (4.00)
Secondary/post-secondary non-tertiary		148 (50.30)		100 (50.30)		91 (53.00)		76 (49.00)
Tertiary		117 (39.80)		84 (42.20)		61 (35.00)		73 (47.00)
Missing		2 (0.70)		1 (0.50)		4 (2.00)		–
Full-time:part-time work, <i>n</i> (%)	160 (54.40):134 (45.60)		150 (75.40):49 (24.60)		106 (61.30):67 (38.70)		70 (45.00):86 (55.00)	
Hours worked, mean (s.d.)	33.24 (12.47)		37.77 (10.44)		34.16 (11.66)		31.50 (10.56)	
Self-employed, <i>n</i> (%)	63 (21.40)		34 (17.10)		21 (12.10)		18 (11.50)	
Physical demands of job, <i>n</i> (%)								
None/a little		101 (34.40)		83 (41.70)		53 (30.70)		61 (39.10)
Noticeable		37 (12.60)		175 (8.90)		22 (12.70)		14 (9.00)
A lot/great deal		156 (53.00)		99 (49.80)		98 (56.60)		81 (51.90)
Medication regimen, <i>n</i> (%)								
None		2 (0.70)		19 (9.50)		33 (19.00)		23 (15.00)
NSAIDs ± analgesics		11 (3.70)		4 (2.00)		118 (69.00)		14 (9.00)
CSs ± NSAIDs		6 (2.00)		51 (25.60)		10 (6.00)		6 (4.00)
Single DMARD		103 (35.00)		10 (5.00)		–		–
Combination DMARD		97 (33.00)		2 (1.00)		–		–
Biologic/biosimilar		66 (22.40)		112 (56.30)		–		–
Neuropathic analgesics (e.g. gabapentin/pregabalin)		–		–		12 (7.00)		99 (64.00)
FM, opiate medication		–		–		–		12 (8.00)

axSpA: axial spondyloarthritis; ISCED: International Standard Classification of Education.

Table 2. Phase 2: participants' work and health measures

Parameter	RA (<i>n</i> = 294)	axSpA (<i>n</i> = 199)	OA (<i>n</i> = 173)	FM (<i>n</i> = 156)
Work measures				
WALS, 0–36, median (IQR)	9.00 (5.00–14.00)	6.00 (3.00–11.00)	10.00 (6.00–14.00)	16.00 (12.00–19.00)
WLQ-25, 0–100, median (IQR)				
Time management demands	30.00 (10.00–55.00)	25.00 (5.00–50.00)	30.00 (10.00–50.00)	60.00 (40.00–80.00)
Physical demands	37.50 (20.00–58.33)	37.50 (12.50–55.31)	41.67 (25.00–58.33)	58.33 (43.75–73.96)
Mental interpersonal demands	16.67 (5.55–36.11)	13.89 (2.78–30.56)	16.67 (5.56–36.11)	44.44 (27.78–61.11)
Output demands	20.00 (5.00–44.06)	10.00 (0–30.00)	20.00 (5.00–43.75)	45.00 (25.00–65.00)
WLQ-25 percentage productivity loss	6.92 (3.27–11.12)	5.40 (1.71–9.36)	6.65 (3.43–11.40)	13.26 (9.20–16.53)
WLQ-25 summed score	29.38 (14.17–43.70)	22.74 (7.08–40.03)	28.61 (15.21–45.36)	51.69 (37.30–64.62)
WIS (0–23 RA, OA, FM; 0–20 AS), median (IQR)	13.00 (7.75–18.00)	11.00 (4.00–15.00)	13.00 (8.00–17.00)	18.00 (15.00–20.00)
Low work instability, <i>n</i> (%)	95 (32.30)	99 (49.70)	59 (34.10)	6 (3.84)
Moderate work instability, <i>n</i> (%)	123 (41.80)	80 (40.20)	79 (45.70)	64 (41.00)
High work instability, <i>n</i> (%)	76 (25.90)	20 (10.10)	35 (20.20)	86 (55.16)
WPAI, median (IQR)				
Percentage overall work impairment owing to health	30.00 (10.00–60.00)	20.00 (0–40.00)	30.00 (10.00–58.11)	66.15 (50.00–80.00)
Health measures				
Perceived severity health last month (1–5), median (IQR), <i>n</i> (%)	3.00 (2.00–3.00)	2.00 (2.00–3.00)	3.00 (3.00–3.00)	4.00 (3.00–4.00)
Poor/very poor	45 (15.30)	21 (10.60)	37 (21.40)	83 (53.00)
Fair	133 (45.20)	78 (39.20)	95 (54.90)	63 (41.00)
Good/very good	116 (39.50)	100 (50.30)	41 (23.70)	10 (6.00)
RA				
RAID (0–10), median (IQR)	4.84 (3.15–6.42)	–	–	–
HAQ20 (0–60), median (IQR)	9.00 (3.00–18.00)	–	–	–
axSpA				
BASDAI (0–10), median (IQR)	–	3.93 (1.95–5.87)	–	–
BASFI (0–10), median (IQR)	–	2.97 (1.40–5.35)	–	–
OA				
WOMAC, median (IQR)				
Pain (0–20)	–	–	10.00 (7.00–13.00)	–
Physical function (0–68)	–	–	31.00 (21.00–41.50)	–
FM				
FIQR, normalized scores, median (IQR)				
Overall impact (0–20)	–	–	–	14.00 (10.00–17.00)
Symptoms (0–50)	–	–	–	34.50 (28.13–39.00)
Function (0–30)	–	–	–	19.33 (14.67–22.67)
FIQR total (0–100)	–	–	–	68.33 (54.20–77.50)
T1 to T2	<i>n</i> = 219	<i>n</i> = 156	<i>n</i> = 131	<i>n</i> = 116
Time between T1 and T2, median (IQR), days	40.00 (34.00–48.00)	38.00 (29.00–49.25)	30.00 (23.75–37.00)	33.00 (26.50–45.00)
Perceived change in health status at T2 vs T1, <i>n</i> (%)				
Much/somewhat less troublesome	36 (16.44)	24 (15.39)	16 (12.10)	14 (12.07)
The same ^a	136 (62.10)	99 (63.47)	78 (59.10)	54 (46.55)
Somewhat/much more troublesome	47 (21.46)	31 (19.88)	38 (28.80)	48 (41.38)
Missing	–	2 (1.00)	–	–

For all measures, higher scores indicate more work/health problems; WIS (RA-WIS used for RA, AS and FM; AS-WIS for AS). WIS cut-points: low instability: RA-WIS <10; AS-WIS <11; moderate instability: RA-WIS 10–17; AS-WIS 11–18; high instability: RA-WIS >17; AS-WIS = 19–20.

^a Participants included in test–retest reliability analysis.

axSpA: axial spondyloarthritis; FIQR: Fibromyalgia Impact Questionnaire—Revised; IQR: interquartile range; NRS: numerical rating scale; RAID: RA Impact of Disease; WALS: Workplace Activity Limitations Scale; WIS: Work Instability Scale; WLQ-25: Work Limitations Questionnaire-25; WPAI: Work Productivity Activity Impairment.

Participants considered the WALS comprehensive, comprehensible and easy to complete, indicating good content validity from the perspective of the patients in these four RMDs (i.e. comparable to findings in RA and OA in Canada [9]).

To our knowledge, this is the first study examining construct (structural) validity of the WALS in RA, axSpA, OA and FM, demonstrating fit to the Rasch model and making available a Rasch transformation table from WALS raw to interval scores. Given that the WALS is unidimensional, either

summed or (Rasch) standardized scores can be used. As hypothesized, the WALS demonstrated good concurrent validity with other work measures, except the WLQ-25 physical demands subscale in FM. Some participants can have difficulty completing this subscale, because instructions are reversed compared with the other three subscales [6]. Potentially, more participants with FM experience such difficulty, because >50% of people with FM report cognitive deficits, which is higher than that experienced by people with RA,

Table 3. Fit of the Workplace Activity Limitations Scale to the Rasch model: construct (structural) validity

Diagnosis	Residuals (s.d.)		χ^2		Reliability		Dimensionality	DIF	ECV	Latent correlation ^a
	Item	Person	Value (d.f.)	P-value	PSI	α	% <i>t</i> -tests (LCI)			
RA	0.01	0.84	28.10 (20)	0.11	0.83	0.87	2.70	None	0.97	0.93
axSpA	0.43	0.73	18.70 (15)	0.24	0.77	0.85	3.52	None	0.93	0.90
OA	0.17	0.92	22.80 (19)	0.24	0.80	0.83	1.80	None	0.96	0.92
FM	0.19	0.81	13.40 (18)	0.77	0.80	0.80	3.21	None	0.98	0.95
Across all four conditions	0.41	0.97	24.10 (23)	0.40	0.84	0.87	2.80	None	0.97	0.95
Ideal values	1.0	1.0	–	>0.05	>0.7	>0.7	<0.5	–	>0.9	>0.9

Bold text indicates ideal values.

^a Between parallel forms.

α : Cronbach's α ; axSpA: axial spondyloarthritis; DIF: differential item functioning; ECV: explained common variance; LCI: lower confidence interval; PSI: Person separation index.

Table 4. Concurrent validity of the Workplace Activity Limitations Scale with work and health measures

WALS (0–36) correlations with:	RA (<i>n</i> = 294) <i>r_s</i>	axSpA (<i>n</i> = 199) <i>r_s</i>	OA (<i>n</i> = 173) <i>r_s</i>	FM (<i>n</i> = 156) <i>r_s</i>
Work measures				
WLQ-25 (0–100)				
Time management demands	0.70**	0.75**	0.65**	0.57**
Physical demands	0.62**	0.73**	0.50**	0.39**
Mental interpersonal demands	0.68**	0.71**	0.62**	0.58**
Output demands	0.71**	0.71**	0.52**	0.56**
WLQ-25 percentage productivity loss	0.78**	0.83**	0.63**	0.64**
WLQ-25 summed score	0.79**	0.84**	0.67**	0.66**
WIS (0–23 RA, OA, FM; 0–20 axSpA)	0.77**	0.84**	0.73**	0.60**
WPAI (%)				
Overall work impairment owing to health	0.65**	0.80**	0.68**	0.51**
Health measures				
Self-reported health in last month (1–5)	0.61**	0.71**	0.53**	0.42**
RA				
RAID (0–10), median (IQR)	0.68**	–	–	–
HAQ20 (0–60), median (IQR)	0.73**	–	–	–
axSpA				
BASDAI (0–10), mean (s.d.)	–	0.68**	–	–
BASFI (0–10), mean (s.d.)	–	0.77**	–	–
OA				
WOMAC, median (IQR)				
Pain (0–20)	–	–	0.56**	–
Physical function (0–68)	–	–	0.55**	–
FM				
FIQR, normalized scores				
Overall impact (0–20)	–	–	–	0.43**
Symptoms (0–50)	–	–	–	0.54**
Function (0–30)	–	–	–	0.55**
FIQR total (0–100)	–	–	–	0.61**

** Correlation significant at 0.01 level.

axSpA: axial spondyloarthritis; FIQR: Fibromyalgia Impact Questionnaire—Revised; RAID: RA Impact of Disease; *r_s*: Spearman's correlations; WALS: Workplace Activity Limitations Scale; WIS: Work Instability Scale; WLQ-25 = Work Limitations Questionnaire-25; WPAI: Work Productivity Activity Impairment.

Table 5. Test–retest reliability and sensitivity to change of the Workplace Activity Limitations Scale

Condition	Number for test–retest ^a	Test 1 score ^a [median (IQR)]	Test 2 score ^a (median, IQR)	Spearman's correlation ^a , <i>r_s</i>	ICC (2,1) ^a (95% CI)	SEM ^a	MDC ₉₅
RA	136	8.00 (4.00–12.75)	7.00 (4.00–11.00)	0.83**	0.92 (0.90, 0.94)	1.15	3.17
axSpA	98	5.00 (2.00–9.00)	5.00 (1.75–7.25)	0.80**	0.90 (0.84, 0.93)	1.67	4.82
OA	78	8.00 (5.75–12.25)	7.00 (4.00–12.25)	0.81**	0.90 (0.84, 0.93)	1.83	5.08
FM	54	15.00 (10.00–19.25)	14.00 (11.00–19.00)	0.82**	0.90 (0.83, 0.94)	1.57	4.36

^a Participants indicating perceived health 'about the same' at T1 and T2, who had WALS scores available at both time points.

** Correlation significant at 0.01 level.

axSpA: axial spondyloarthritis; ICC: intraclass correlation coefficient; IQR: interquartile range; MDC₉₅: minimum detectable change; SEM: standard error of measurement.

for example [46, 47]. As hypothesized, correlations with physical function, symptom and health scales were moderate in OA and FM, but generally strong (i.e. higher than expected) in RA and axSpA. These findings are comparable to those in RA and OA in Canada [17]. We also demonstrated the WALs has good discriminant validity in the four RMDs, which had not been tested previously.

Internal consistency was good, and comparable to findings in RA and OA in Canada [6], meaning that the WALs can be used for group measurement in the four RMDs. Identifying that WALs scores of 7 and 14 equate to RA- and AS-WIS cut-points for moderate and high work instability indicates that the WALs could help not only to identify patients' work limitations but also who could benefit from work rehabilitation. The evidence for test–retest reliability is extended, and specific values of MDC₉₅ for each of the four RMDs are provided. These had previously been tested in only a small sample of 'workers with arthritis' [5, 6].

It is worth noting that across all four RMDs, the phase 2 results showed that those reporting they had 'fair' health status had average WALs scores exceeding the cut-off score for moderate work instability (i.e. 7) and also (apart from axSpA) those with poor/very poor health status had scores exceeding the cut-off for high work instability (i.e. 14). The FM group also had higher average WALs scores than the other three RMDs, despite being younger, with many experiencing high work instability. Health professionals working with employed people with RMDs reporting fair or poor health status, and especially those with FM, are recommended to screen for work problems and provide work advice and support, as relevant.

The WALs tests intrinsic work activity impairment (i.e. capacity in International Classification of Functioning, Disability and Health terms), because the instructions specify reporting difficulty without help from another person or use of gadgets or equipment. It might not therefore reflect the person's real ability to work (performance in International Classification of Functioning, Disability and Health terms; i.e. with ergonomic modifications, help and/or job accommodations). Under the UK Equality Act 2010, it is the duty of an employer to provide these (termed as 'reasonable adjustments') to employees with disabilities. Clinically, and in work rehabilitation studies, using a WALs omitting the instructions to answer 'without help or gadgets/equipment' could better identify whether improvement occurs following work rehabilitation and putting reasonable adjustments in place. Modified instructions could focus on how people usually do these activities. Additionally, there is no time frame in the instructions. Some work measures (e.g. the WLQ-25), ask about the last 2 weeks. A disadvantage of a short time frame is, firstly, that the measure can be completed only by people working for ≥ 1 day during that time. Those on sick, annual or other extended leave for > 2 weeks cannot complete it. Second, people with RMDs can experience episodic flares or worse health. A limited time frame means that completion might coincide with a period of unusual ill-health or good health. Avoiding a time scale overcomes this problem, because participants might either reflect on their difficulties when last at work or estimate difficulties. This could, however, be problematic in those on long-term sick leave if they estimate difficulties incorrectly. Particularly in intervention studies, it might be better to specify a time (e.g. 3 months). Future research could psychometrically test a WALs with modified instructions.

A strength of this study was that we had relatively large samples of people with RA, axSpA, OA and FM recruited from a wide variety of NHS outpatient clinics, meaning that the results are representative for people accessing secondary or community care. Limitations were that fewer people with FM had stable self-reported health between T1 and T2, compared with the other conditions, resulting in a smaller sample for test–retest reliability than required. Responsiveness (i.e. longitudinal validity) still needs testing, and minimal clinically important differences need to be established in the UK. Further testing in other RMDs is required.

Conclusions

Overall, psychometric testing of the British English WALs demonstrated good validity and reliability in employed people with RA, axSpA, OA and FM in the UK. The WALs meets most recommendations of the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklists for methodological quality and reporting [19, 20]. Accordingly, the British English WALs can be used in the UK for these four RMDs.

Supplementary material

[Supplementary material](#) is available at *Rheumatology Advances in Practice* online.

Data availability

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request, following completion of associated studies. The British English WALs is available in the [Supplementary Materials](#).

Contribution statement

A.H., A.T. and Y.P. contributed to the study conception and design. Phase 1: A.H. and Y.P. conducted data collection and analysis. A.H., A.T., M.G., Y.P., S.V. and R.O'B. were members of the Expert Panel. Phase 2: material preparation and data collection were performed by A.H., A.C., and J.P. Analyses were performed by A.T. (Rasch analysis) and A.H. (classical testing). The first draft of the manuscript was prepared by A.H., with A.T. drafting the construct (structural) validity/Rasch analysis sections. All authors contributed to and revised previous versions of the manuscript. All authors read and approved the final manuscript.

Funding

This work was part-supported by the European Alliance of Associations for Rheumatology (EULAR) grant number HPR035. NHS service support costs were secured from the NIHR Comprehensive Local Research Network.

Disclosure statement: The authors have no relevant financial or non-financial interests to disclose.

Acknowledgements

The authors wish to thank: all the study participants for their time in completing questionnaires. In phase 1: the expert

panel members for their time in supporting the linguistic validation process: John Grogan (J.G.; translator); Anita Prince (A.P.) and Stephen Kay (S.K.), patient research partners; Tracy White (T.W.; Senior Occupational Therapist, Wrightington Hospital) and Yvonne Hough (Y.H.; Senior Occupational Therapist, St Helens Hospital), clinical advisors. In phase 2: all the Local Collaborators (LC), rheumatology consultants, research facilitators, rheumatology nurses, occupational therapists and physiotherapists assisting with participant identification at the contributing NHS Trusts.

England: Yvonne Hough (LC), St Helens and Knowsley Teaching Hospitals NHS Trust; Tracy White (LC), Wrightington, Wigan and Leigh NHS Foundation Trust; Karen Crosby (LC), JoAnn Nicholson, Susannah Glasgow, Manchester University NHS Foundation Trust; Nicky Walker (LC), Mid Cheshire Hospitals NHS Foundation Trust; Sarah Wilson (LC), Sheffield Teaching Hospitals NHS Foundation Trust; Carol Graham (LC), Midlands Partnership NHS Foundation Trust; Anne Boulton (LC), Northumbria Healthcare NHS Foundation Trust; Clare Webb (LC), University Hospitals of Derby and Burton NHS Foundation Trust; Anne Bontoft (LC), Northern Lincolnshire and Goole NHS Foundation Trust; Deborah Wilson (LC), Phil Buckley, Sherwood Forest Hospital's NHS Foundation; Dr Roshan Amarasena (LC), Jayne Edwards, Theresa Grant, Lisa Burgess, The Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust; Sandi Derham (LC), Royal United Hospitals Bath NHS Foundation Trust; Sarah Small (LC), James Paget University Hospitals NHS Foundation Trust; Christina MacLeod (LC), Kevin Spear, Emily Porter, Hampshire Hospitals NHS Foundation Trust; Dr Shweta Bhagat (LC), Julie Blundell, Nyssa Muskett, West Suffolk NHS Foundation Trust; Sathish Govindarajalu (LC), Matthew Pearson, Samantha Nunn, Cambridgeshire Community Services NHS Trust; Dr David Coady (LC), Rona Ymballa, City Hospitals Sunderland NHS Foundation Trust; Susan Ellis (LC), East Lancashire Hospitals NHS Trust; Peter Swan (LC), Stephanie Howard, Wendy Neale, Norfolk Community Health and Care NHS Trust; Helen Jeffrey (LC), Jude Prince, Countess of Chester Hospital NHS Foundation Trust; Mr Kishore Mamidi (LC), Dr Marwan Bukhari (LC), Kathryn Allison, Jackie Toomey, Lynda Fothergill, University Hospitals of Morecambe Bay NHS Foundation Trust; Dr Karl Gaffney (LC), James Kennedy, Celia Woodhouse, Norfolk and Norwich University Hospitals NHS Foundation Trust; Dr Pamela Peterson (LC), Susan Pugmire, Gateshead Health NHS Foundation Trust; Dr Hanadi Sari-Kouzel (LC), Marina Oprea, Greta Van Duyvenvoorde, Allison Clarke, Blackpool Teaching Hospitals NHS Foundation Trust; Dr Suzanne Lane (LC), Cathleen Chabo, Sue Brixey, Ipswich Hospital NHS Trust; Dr Imran Riaz (LC), Ellie Gilham, Jayne Brown, The Queen Elizabeth Hospital, King's Lynn, NHS Foundation Trust; Suzannah Pegler (LC), Great Western Hospitals NHS Foundation Trust; Louise Hollister (LC), Dawn Simmons, Weston Area Health NHS Trust; Sue Smolen (LC), Mid Essex Hospital Services NHS Trust; David Sweeting (LC), East Coast Community Healthcare; Emma McLoughlin (LC), Anna Thornhill, Charlotte Dando, Solent NHS Trust; Dr Sophia Naz (LC), Lorraine Lock, Northern Care Alliance; Jonathan Price (LC), Joanne Holt, Birmingham Community Healthcare NHS Foundation Trust; Alison Bradshaw (LC), The Walton Centre NHS Foundation Trust; Dr Dobrina Hull and Dr Prabhu

Gandhimani (LCs), Kingston Hospital NHS Foundation Trust; Fiona Wright (LC), North Bristol NHS Trust; Dr Michael Green (LC), Samantha Roche, Holly Hancock, York Teaching Hospitals NHS Foundation Trust; Dr Cathy Lawson (LC), Pauline Fitzgerald, Lynsey Hall, Harrogate & District NHS Foundation Trust; Liz Lowe (LC), Jacqueline McCormick, Tameside and Glossop Integrated Care NHS Foundation Trust; Lee Hawthorn (LC), Bridgewater Community Healthcare NHS Foundation Trust; Dr Jill Firth (LC), Katherine Kinsey, Helen Light, Pennine MSK Partnership Ltd; Sharon Kerrison, Lara Smith, Jayne Budd (LCs), Stockport NHS Foundation Trust.

Wales: Laura Ingham (LC), Christine Samuel, Susan Pearson, Hayley Radford, Emma Williams, Shari Parker, Swansea Bay University Health Board.

Scotland: Janet Harkess (LC), NHS Fife; Justine Griffin (LC), NHS Greater Glasgow and Clyde.

Northern Ireland: Una McKenna (LC), Northern Health and Social Care Trust.

References

1. Lynch M, Bucknall M, Jagger C, Wilkie R. Healthy working life expectancy at age 50 for people with and without osteoarthritis in local and national English populations. *Sci Rep* 2022;12:2408.
2. Versus Arthritis. The State of Musculoskeletal Health. 2021. <https://www.versusarthritis.org/about-arthritis/data-and-statistics/the-state-of-musculoskeletal-health/> (11 October 2022, date last accessed).
3. Ravinskaya M, Verbeek JH, Langendam M *et al*. Extensive variability of work participation outcomes measured in randomized controlled trials: a systematic review. *J Clin Epidemiol* 2022;142:60–99.
4. Verstappen SMM, Lacaillle D, Boonen A *et al*. Considerations for evaluating and recommending worker productivity outcome measures: an update from the OMERACT worker productivity group. *J Rheumatol* 2019;46:1401–5.
5. Tang K, Boonen A, Verstappen SMM *et al*. Worker productivity outcome measures: OMERACT filter evidence and agenda for future research. *J Rheumatol* 2014;41:165–76.
6. Beaton DE, Dyer S, Boonen A *et al*. OMERACT filter evidence supporting the measurement of at-work productivity loss as an outcome measure in rheumatology research. *J Rheumatol* 2016;43:214–22.
7. Lerner D, Amick BC 3rd, Rogers WH *et al*. The Work Limitations Questionnaire. *Med Care* 2001;39:72–85.
8. Gignac MAM, Sutton D, Badley EM. Arthritis symptoms, the work environment, and the future: measuring perceived job strain among employed persons with arthritis. *Arthritis Rheum* 2007;57:738–47.
9. Tang K, Beaton D, Lacaillle D, Gignac MAM, Bombardier C, and Canadian Arthritis Network Work Productivity Group. Sensibility of five at-work productivity measures was endorsed by patients with osteoarthritis or rheumatoid arthritis. *J Clin Epidemiol* 2013;66:546–56.
10. Gignac MAM. Arthritis and employment: an examination of behavioral coping efforts to manage workplace activity limitations. *Arthritis Rheum* 2005;53:328–36.
11. Gignac MAM, Cao X, Lacaillle D, Anis AH, Badley EM. Arthritis-related work transitions: a prospective analysis of reported productivity losses, work changes, and leaving the labor force. *Arthritis Rheum* 2008;59:1805–13.
12. Gignac MAM, Cao X. "Should I tell my employer and co-workers I have arthritis?" A longitudinal examination of self-disclosure in the workplace. *Arthritis Rheum* 2009;61:1753–61.
13. Gignac MAM, Cao X, Tang K, Beaton DE. Examination of arthritis-related work place activity limitations and intermittent

- disability over four-and-a-half years and its relationship to job modifications and outcomes. *Arthritis Care Res (Hoboken)* 2011; 63:953–62.
14. Al Dhanhani AM, Gignac MAM, Beaton DE, Su J, Fortin PR. Work factors are associated with workplace activity limitations in systemic lupus erythematosus. *Rheumatology* 2014;53:2044–52.
 15. Jetha A, Johnson SR, Gignac MAM. Unmet workplace support needs and lost productivity of workers with systemic sclerosis: a path analysis study. *Arthritis Care Res (Hoboken)* 2021;73: 423–31.
 16. Tang K, Beaton DE, Boonen A, Gignac MAM, Bombardier C. Measures of work disability and productivity: Rheumatoid Arthritis Specific Work Productivity Survey (WPS-RA), Workplace Activity Limitations Scale (WALS), Work Instability Scale for Rheumatoid Arthritis (RA-WIS), Work Limitations Questionnaire (WLQ), and Work Productivity and Activity Impairment Questionnaire (WPAI). *Arthritis Care Res (Hoboken)* 2011;63: S337–49.
 17. Beaton DE, Tang K, Gignac MA *et al.* Reliability, validity, and responsiveness of five at-work productivity measures in patients with rheumatoid arthritis or osteoarthritis. *Arthritis Care Res (Hoboken)* 2010;62:28–37.
 18. Acquadro C, Joyce CRB, Patrick DL, Ware JE, Wu AW. Linguistic validation manual for Patient-Reported outcomes (PRO) instruments. Lyon: Mapi Research Trust, 2004.
 19. Mokkink LB, Terwee CB, Patrick DL *et al.* The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: an international Delphi study. *Qual Life Res* 2010;19:539–49.
 20. Gagnier JJ, Lai J, Mokkink LB, Terwee CB. COSMIN reporting guidelines for studies on measurement properties of patient reported outcome measures. 2021. https://www.cosmin.nl/wp-content/uploads/COSMIN-reporting-guideline_1.pdf (11 October 2022, date last accessed).
 21. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Recommendations for the Cross-Cultural Adaptation of the DASH & QuickDASH Outcome Measures. Toronto: Institute of Work and Health, 2007. https://dash.iwh.on.ca/sites/dash/files/downloads/cross_cultural_adaptation_2007.pdf (6 September 2022, date last accessed).
 22. Office for National Statistics. Standard Occupational Classification. 2010. <https://www.ons.gov.uk/methodology/classificationsandstandards/standardoccupationalclassificationsoc/soc2010> (11 October 2022, date last accessed).
 23. Roy JS, MacDermid JC, Amick BC *et al.* Validity and responsiveness of presenteeism scales in chronic work-related upper extremity disorders. *Phys Ther* 2011;91:254–66.
 24. Gilworth G, Chamberlain A, Harvey A *et al.* Development of a work instability scale for rheumatoid arthritis. *Arthritis Rheum* 2003;49:349–54.
 25. Tang K, Beaton DE, Lacaille D *et al.*; Canadian Arthritis Network Work Productivity Group. The Work Instability Scale for Rheumatoid Arthritis (RA-WIS): does it work in osteoarthritis? *Qual Life Res* 2010;19:1057–68.
 26. Gilworth G, Emery P, Barkham N *et al.* Reducing work disability in Ankylosing Spondylitis – development of a work instability scale for AS. *BMC Musculoskelet Disord* 2009;10:68.
 27. Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. *Pharmacoeconomics* 1993;4:353–65.
 28. Gossec L, Paternotte S, Aanerud GJ *et al.* Finalisation and validation of the rheumatoid arthritis impact of disease score, a patient derived composite measure of impact of rheumatoid arthritis: a EULAR initiative. *Ann Rheum Dis* 2011;70:935–42.
 29. Kirwan JR, Reeback JS. Stanford Health Assessment Questionnaire modified to assess disability in British patients with rheumatoid arthritis. *Br J Rheumatol* 1986;25:26–9.
 30. Wolfe F. Which HAQ is best? A comparison of the HAQ, MHAQ and RA-HAQ, a difficult 8 item HAQ (DHAQ), and a rescored 20 item HAQ (HAQ20): analyses in 2,491 rheumatoid arthritis patients following leflunomide initiation. *J Rheumatol* 2001;28: 982–9.
 31. Garrett S, Jenkinson T, Kennedy LJ *et al.* A new approach to defining disease status in ankylosing spondylitis: the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI). *J Rheumatol* 1994; 21:2286–91.
 32. Calin A, Garrett S, Whitelock H *et al.* A new approach to defining functional ability in ankylosing spondylitis: the development of the Bath Ankylosing Spondylitis Functional Index (BASFI). *J Rheumatol* 1994;21:2281–5.
 33. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1988;15:1833–40.
 34. Bennett RM, Friend R, Jones KD *et al.* The Revised Fibromyalgia Impact Questionnaire (FIQR): validation and psychometric properties. *Arthritis Res Ther* 2009;11:R120.
 35. Teresi JA, Kleinman M, Ocepek-Welikson K. Modern psychometric methods for detection of differential item functioning: application to cognitive assessment measures. *Stat Med* 2000;19:1651–83.
 36. Nunnally JC. Psychometric theory. New York: McGraw-Hill, 1978.
 37. Rumm Lab, RUMM2030. <https://www.rummlab.com.au> (11 October 2022, date last accessed).
 38. IBM Corp. IBM SPSS statistics for windows, version 26.0. Armonk: IBM Corp., 2019.
 39. Rasch G. Probabilistic models for some intelligence and attainment tests. Chicago: The University of Chicago Press, 1980.
 40. Tennant A, Conaghan PG. The Rasch measurement model in rheumatology: what is it and why use it? When should it be applied, and what should one look for in a Rasch paper? *Arthritis Rheum* 2007;57:1358–62.
 41. Evans JD. Straightforward statistics for the behavioural sciences. Pacific Grove: Brooks/Cole, 1996.
 42. Cichetti DV. Guidelines, criteria and rules of thumb for evaluating normed and standardised assessment instruments in psychology. *Psychol Assess* 1994;6:284–90.
 43. Donoghue D; Physiotherapy Research and Older People (PROP) group; EK. Stokes How much change is true change? The minimum detectable change of the Berg Balance Scale in elderly people. *J Rehabil Med* 2009;41:343–6.
 44. Stratford PW. Getting more from the literature: estimating the standard error of measurement from reliability studies. *Physiother Can* 2004;56:27–30.
 45. Terwee CB, Bot SDM, de Boer MR *et al.* Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol* 2007;60:34–42.
 46. Wolfe F, Rasker JJ, Ten Klooster P, Häuser W. Subjective cognitive dysfunction in patients with and without fibromyalgia: prevalence, predictors, correlates, and consequences. *Cureus* 2021;13:e20351.
 47. Galvez-Sanchez CM, de la Coba P, Colmenero JM, Reyes del Paso GA, Duschek S. Attentional function in fibromyalgia and rheumatoid arthritis. *PLoS ONE* 2021;16:e0246128.

A 2nd generation, JAK1 preferential inhibitor for moderate to severe RA¹⁻⁶

While 1st generation JAK inhibitors are relatively non-selective,²⁻⁶ JYSELECA has over 5x greater potency for JAK1 over JAK2/3 and TYK2^{1*}

Balancing sustained efficacy⁷⁻¹¹ with acceptable tolerability^{1,12}

Indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti-rheumatic drugs.¹ May be used as monotherapy or in combination with methotrexate.¹

*From biochemical assays, the clinical relevance of which is uncertain. JAK, Janus kinase; RA, rheumatoid arthritis; TYK, tyrosine kinase.

Learn more at
strengthofbalance.co.uk

Refer to Summary of Product Characteristics (SmPC) before prescribing, and for full prescribing information.

JYSELECA[®] filgotinib 100 mg or 200 mg film-coated tablets.

Indication: Jyseleca is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti-rheumatic drugs (DMARDs). Jyseleca may be used as monotherapy or in combination with methotrexate (MTX). **Dosage: Adults:** 200 mg once daily. Taken orally with/without food. It is recommended that tablets are swallowed whole. **Laboratory Monitoring:** Refer to the SmPC for information regarding laboratory monitoring and dose initiation or interruption. **Elderly:** A starting dose of 100 mg once daily is recommended for patients aged 75 years and older as clinical experience is limited. **Renal impairment:** No dose adjustment required in patients with estimated creatinine clearance (CrCl) \geq 60 mL/min. A dose of 100 mg of filgotinib once daily is recommended for patients with moderate or severe renal impairment (CrCl 15 to < 60 mL/min). Not recommended in patients with CrCl < 15 mL/min. **Hepatic impairment:** Mild/moderate hepatic impairment: no dose adjustment required. Severe hepatic impairment: not recommended. **Children (< 18 years):** Safety and efficacy not yet established. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Active tuberculosis (TB) or active serious infections. **Pregnancy/Warnings/Precautions:** See SmPC for full information. **Immunosuppression:** Combination use, with immunosuppressants e.g., ciclosporin, tacrolimus, biologics or other Janus kinase (JAK) inhibitors is not recommended as a risk of additive immunosuppression cannot be excluded. **Infections:** Infections, including serious infections such as pneumonia and opportunistic infections e.g. tuberculosis (TB), oesophageal candidiasis, and cryptococcosis have been reported. Risk benefit should be assessed prior to initiating in patients with risk factors for infections (see SmPC). Patients should be closely monitored for the development of signs and symptoms of infections during and after filgotinib treatment. Treatment should be interrupted if the patient

is not responding to antimicrobial therapy, until infection is controlled. There is a higher incidence of serious infections in the elderly aged 75 years and older, caution should be used when treating this population. **Tuberculosis:** Patients should be screened for TB before initiating filgotinib, and filgotinib should not be administered to patients with active TB. **Viral reactivation:** Cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies (see SmPC). If a patient develops herpes zoster filgotinib treatment should be temporarily interrupted until the episode resolves. Screening for viral hepatitis and monitoring for reactivation should be performed. **Malignancy:** Immunomodulatory medicinal products may increase the risk of malignancies. Malignancies were observed in clinical studies (see SmPC). **Fertility:** In animal studies, decreased fertility, impaired spermatogenesis, and histopathological effects on male reproductive organs were observed (see SmPC). The potential effect of filgotinib on sperm production and male fertility in humans is currently unknown. **Haematological abnormalities:** Do not start therapy, or temporarily stop, if Absolute Neutrophil Count (ANC) < 1×10^9 cells/L, ALC < 0.5×10^9 cells/L or haemoglobin < 8 g/dL. Temporarily stop therapy if these values are observed during routine patient management. **Vaccinations:** Use of live vaccines during, or immediately prior to, filgotinib treatment is not recommended. **Lipids:** Treatment with filgotinib was associated with dose dependent increases in lipid parameters, including total cholesterol, and high-density lipoprotein (HDL) levels, while low density lipoprotein (LDL) levels were slightly increased (see SmPC). **Cardiovascular risk:** Rheumatoid arthritis patients have an increased risk for cardiovascular disorders. Patients should have risk factors (e.g., hypertension, hyperlipidaemia) managed as part of usual standard of care. **Venous thromboembolism:** Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving JAK inhibitors including filgotinib. Caution should be used in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery, and prolonged

immobilisation. **Lactose content:** Contains lactose; patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take filgotinib. **Pregnancy/Lactation:** Filgotinib is contraindicated in pregnancy. Filgotinib should not be used during breast-feeding. Women of childbearing potential must use effective contraception during and for at least 1 week after cessation of treatment. **Driving/Using machinery:** No or negligible influence, however dizziness has been reported. **Side effects:** See SmPC for full information. **Common (\geq 1/100 to <1/10):** nausea, upper respiratory tract infection, urinary tract infection and dizziness. **Uncommon (\geq 1/1000 to <1/100):** herpes zoster, pneumonia, neutropenia, hypercholesterolaemia and blood creatine phosphokinase increase. **Serious side effects:** See SmPC for full information. **Legal category:** POM. **Pack:** 30 film-coated tablets/bottle. **Price:** UK Basic NHS cost: £863.10. **Marketing authorisation number(s):** Great Britain Jyseleca 100mg film-coated tablets PLGB 42147/0001 Jyseleca 200mg film-coated tablets PLGB 42147/0002 Northern Ireland Jyseleca 100mg film-coated tablets EU/1/20/1480/001 EU/1/20/1480/002 Jyseleca 200mg film-coated tablets EU/1/20/1480/003 EU/1/20/1480/004. **Further information:** Galapagos UK, Belmont House, 148 Belmont Road, Uxbridge UB8 1QS, United Kingdom 00800 7878 1345 medicalinfo@glog.com Jyseleca[®] is a trademark. **Date of Preparation:** January 2022 UK-RA-FIL-202201-00019

∇ Additional monitoring required

Adverse events should be reported.

For Great Britain and Northern Ireland, reporting forms and information can be found at yellowcard.mhra.gov.uk or via the Yellow Card app (download from the Apple App Store or Google Play Store).

Adverse events should also be reported to Galapagos via email to DrugSafety.UK.Ireland@glog.com or 00800 7878 1345

References: 1. JYSELECA SPC. Available at: www.medicines.org.uk. Last accessed: June 2022. 2. Angelini J, et al. *Biomolecules* 2020;10(7):E1002. 3. Banerjee S, et al. *Drugs* 2017;77:521-546. 4. O'Shea JJ, et al. *Nat Rev Rheumatol* 2013;9(3):173-182. 5. Traves PG, et al. *Ann Rheum Dis* 2021;01-11. 6. McInnes IB, et al. *Arthr Res Ther* 2019;21:183. 7. Combe B, et al. *Ann Rheum Dis* 2021;doi:10.1136/annrheumdis-2020-219214. 8. Genovese MC, et al. *JAMA* 2019;322(4):315-325. 9. Westhovens R, et al. *Ann Rheum Dis* 2021;doi:10.1136/annrheumdis-2020-219213. 10. Combe B, et al. *Arthritis Rheumatol* 2021;73(suppl 10). <https://acrabstracts.org/abstract/clinical-outcomes-up-to-week-48-of-filgotinib-treatment-in-an-ongoing-long-term-extension-trial-of-rt-patients-with-inadequate-response-to-mtx-initially-treated-with-filgotinib-or-adalimumab-during-th/>. Last accessed: June 2022. 11. Buch MH, et al. *Arthritis Rheumatol* 2021;73(suppl 10). <https://acrabstracts.org/abstract/clinical-outcomes-up-to-week-48-of-ongoing-filgotinib-ra-long-term-extension-trial-of-biologic-dmard-inadequate-responders-initially-on-filgotinib-or-placebo-in-a-phase-3-trial/>. Last accessed: June 2022. 12. Winthrop K, et al. *Arthritis Rheumatol* 2021;73(suppl 10). Available at: <https://acrabstracts.org/abstract/integrated-safety-analysis-update-for-filgotinib-in-patients-with-moderately-to-severely-active-rheumatoid-arthritis-receiving-treatment-over-a-median-of-2-2-years/>. Last accessed: June 2022.

Galápagos

June 2022 GB-RA-JY-202205-00033

JYSELECA, GALAPAGOS and the JYSELECA and GALAPAGOS logos are registered trademarks of Galapagos NV. © 2022 Galapagos NV. All rights reserved.