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Recommendations

ASAS recommendations on reporting axial spondyloarthritis clinical trials

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ABSTRACT

Objectives: This study aims to develop recommendations on reporting baseline features and outcomes from axial spondyloarthritis (axSpA) clinical trials based on the recently updated instrument set of the Assessment of SpondyloArthritis international Society (ASAS) core outcome set (COS).

Methods: A steering group (SG) convened a workgroup (WG), consisting of 13 ASAS members including rheumatologists, methodologists, epidemiologists, and 2 Young ASAS members. Recommendations on reporting axSpA trials baseline features and outcomes were developed in 3 steps: (1) the SG identified relevant baseline features from key axSpA clinical trials and formulated a proposal on how outcomes related to the instruments in the ASAS COS should be presented. (2) The SG proposal was presented, discussed, and modified in WG meetings. (3) WG proposal was discussed and voted on by ASAS members during the 2024 annual ASAS workshop.

Results: Forty-two baseline features relevant for all axSpA clinical trials and 8 additional features for disease-modifying drug trials were defined including descriptions on how to report them. Additionally, recommendations on how to report 20 trial outcomes at baseline and follow-up

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timepoints were put forward. Finally, recommendations on how to report 11 outcomes of instruments additionally endorsed by ASAS but not in the COS were formulated. Proposals for baseline features, COS outcomes, and outcomes not in COS were approved by ASAS members (with 84%, 85%, and 93% of members in favour, respectively).
Conclusions: These ASAS-endorsed recommendations on axSpA clinical trial reporting provide a standardised approach to reporting both baseline features as well as outcomes from axSpA clinical trials.

INTRODUCTION

A clinical trial is the best method for assessing the effect of an intervention. Moreover, clinical trials are crucial for regulatory decision-making and the introduction of therapies into clinical practice. To improve the overall quality of clinical trials, Consolidated Standards of Reporting Trials (CONSORT) published the CONSORT statement providing a set of recommendations for reporting randomised trials. The statement offers a standard way for trialists to prepare reports of trial findings regardless of the disease studied. The most recent version of the Statement—the CONSORT 2010 Statement—contains a 25-item checklist focusing on reporting how the trial was designed, analysed, and interpreted and a flow diagram displaying the progress of participants through the trial [1].

Apart from initiatives to improve the general reporting of trial methodology, for many conditions including rheumatic and musculoskeletal diseases, disease-specific core outcome sets (COS) have been developed aimed at encouraging researchers to measure a consistent set of clinical endpoints in studies. A COS is an agreed standardised minimum set of outcomes that should be measured and reported in all clinical trials in a specific area and is intended to lead to research measuring relevant outcomes. In addition, the use of COS as an agreed standardised set of outcomes facilitates not only comparing trial outcomes but also combining trial data such as in meta-analyses [2].

The Assessment of SpondyloArthritis international Society −Outcome Measures for Arthritis Clinical Trials COS for ankylosing spondylitis was developed almost 3 decades ago and reflecting the progress made in the field, this original COS was recently updated into a COS for the entire axial spondyloarthritis (axSpA) spectrum. For the updated ASAS COS, first the domain set, which instructs what to measure, was updated and thereafter the instrument set, which tells how to measure, was updated [3,4]. The current core domain set includes 7 mandatory domains for all studies and 3 additional mandatory domains for studies evaluating disease-modifying antirheumatic drugs (DMARDs). In the core instrument set, 7 mandatory instruments were selected for all trials and 9 additional mandatory instruments for DMARD trials. Furthermore, 11 extra instruments were also endorsed by ASAS and can be used in addition to those included in the COS [4].

While initiatives like the CONSORT statement aid in trial methodology and the updated ASAS COS provide axSpA trialists guidance on which instruments to use in axSpA clinical trials, recommendations on how to report the outcomes of axSpA clinical trials are not available. Moreover, recommendations on which baseline features should be reported, as well as how to report them to adequately describe the study population are lacking.

The aim of this ASAS project was to develop expert recommendations on which baseline features to collect, how to report baseline features, and how to present axSpA trial outcome data in text, tables, and graphs.

METHODS

The project took place under the auspices of ASAS, the worldwide organization of SpA experts. Following project approval in September 2023, the steering group (FAvG, VN-C, and DvdH) convened a workgroup consisting of 8 additional ASAS members (XB, RL, PMM, HM-O, DP, LSG, SR, and FvdB). The workgroup was complemented by 2 Young ASAS members (IH, VRR).

The project consisted of 3 steps. First, the steering group collected a limited set of recent publications of clinical trials in axSpA covering the entire spectrum of the disease and treatment armamentarium, including trials aimed at disease modification. The aim of the scoping literature search was to provide the steering group with an overview to be used in workgroup discussion of possible relevant baseline features and examples of how baseline features and outcomes are reported. For this, a literature search was performed on 23 January 2023 in the Web of Science database using the keywords ‘spondyloarthritis’ and ‘clinical trial’ [5]. After limiting results to the last 10 years and ranking these by highest cited trials, all publications were selected until at least 2 examples of clinical trials in radiographic axSpA, 2 in nonradiographic trials, and 2 axSpA disease-modifying antirheumatic drug (DMARD) trials with imaging outcomes had been included (Supplementary Table S1).

The steering group then identified relevant baseline features based on the discussion of the literature review and made a proposal on how baseline features and outcomes can be reported as clearly and informatively as possible. As a second step, after having received the proposals prior via e-mail, the workgroup discussed and modified the proposals in 2 online meetings in November 2024.

The proposals as agreed on by the workgroup were sent to all ASAS members 1 week before the annual ASAS workshop on the 12 and 13 January 2024, in Barcelona. During the workshop, the proposals were discussed, additional proposals could be made, and final proposals were voted on by ASAS members with full membership.

RESULTS

Baseline features for all trials

Table 1 shows the recommended baseline features for all trials including DMARD trials and how to present them. Of the recommended 42 baseline features, the majority were selected by the steering group from published axSpA clinical trials (Supplementary Table S1).

The first 6 baseline features are demographics including sex and age. Smoking and body mass index were added as recommended baseline features by the workgroup. Highest level of education completed as a baseline feature was added to the steering group proposal by the ASAS members at the annual meeting (89 votes with 70% in favour, 28% against and 2% abstaining) (Supplementary Table S2).

Baseline features 7 to 20 provide details on the presence or SpA features and disease duration based on axial symptoms. As

Table 1
Baseline features for all trials including disease-modifying antirheumatic drug (DMARD) trials

Demographics	How	Comment
1. Biological sex	*n* (%)	-
2. Age	Mean years (SD)	-
3. Highest completed level of education	*n* (%) of primary, secondary, and tertiary	According to ISCED levels (see Supplementary Table 2)
4. Geographic location	*n* (%) per country	Geographic location could be text only
5. Smoking	*n* (%) current/never/past	If collected report mean (SD) pack years
6. Body mass index	Mean kg/m^2 (SD)	-
Spondyloarthritis symptoms and features	How	Comment
7. Duration axial symptoms since disease onset	Mean years (SD)	
8. Symptom duration ≤2 y	*n* (%)	According to ASAS SPa EARLy (SPEAR) definition
9. Duration since diagnosis	Mean years (SD)	-
10. History of IBP	*n* (%)	Definition according to ASAS classification criteria
11. History of peripheral arthritis	*n* (%)	According to physician
12. History of enthesitis	*n* (%)	According to physician
13. History of dactylitis	*n* (%)	According to physician
14. History of uveitis	*n* (%)	According to physician
15. History of IBD	*n* (%)	According to physician
16. History of psoriasis	*n* (%)	According to physician
17. HLA-B27 positivity	*n* (%)	-
18. Radiographic sacroiliitis (ever)	*n* (%)	Report if collected (mandatory for DMARD trials)
19. Inflammation on MRI-SIJ (ever)	*n* (%)[c]	Report if collected (mandatory for DMARD trials)
20. Structural lesions on MRI-SIJ (ever)	*n* (%)[c]	Report if collected
Previous and current treatment	How	Comment
21. Previous b or tsDMARD	*n* (%) + mean /median number per patient	-
22. Previous TNFi	*n* (%)	-
23. Previous IL-17A-i or IL-17A/F-i	*n* (%)	
24. Previous JAKi	*n* (%)	-
25. Previous 2 b/tsDMARD classes	*n* (%)	-
26. Previous 3 b/tsDMARD classes	*n* (%)	-
27. Current NSAID	*n* (%)	Report ASAS NSAID score if collected
28. Current TNFi	*n* (%)	-
29. Current IL-17A-i or IL-17A/F-i	*n* (%)	-
30. Current JAKi	*n* (%)	-
31. Current csDMARD	*n* (%)	-
Clinical and laboratory measures	How	Comment
32. ASDAS	Mean score (SD)	-
33. ASDAS disease status[a]	*n* (%) per category	-
34. Patient global disease activity	Mean (SD)	-
35. Total back pain (BASDAI Q2)	Mean (SD)	-
36. Severity/duration stiffness (BASDAI [Q5 + Q6]/2)	Mean (SD)	-
37. Fatigue (BASDAI Q1)	Mean (SD)	-
38. BASFI	Mean (SD)	-
39. ASAS health index	Mean (SD)	-
40. ASAS health index status[b]	*n* (%) per category	-
41. CRP (mg/L)	Mean (SD)	Last CRP value from clinical care may be used
42. Elevated CRP (≥5 mg/L)	*n* (%)	-

ASAS, Assessment of SpondyloArthritis international Society; ASDAS, Axial Spondyloarthritis Disease Activity Score; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Functional Index; bDMARD, biological DMARD; CRP, C-reactive protein; csDMARD, conventional synthetic DMARD; DMARD, disease-modifying antirheumatic drug; IBD, inflammatory bowel disease; IBP, inflammatory back pain; SIJ, sacroiliac joints; NSAID, nonsteroidal anti-inflammatory drug; i, inhibitor; Q, question; tsDMARD, targeted synthetic DMARD.

[a] ASDAS categories: ≤1.3 inactive disease, >1.3 and ≤2.1 low disease, >2.1 and ≤3.5 high disease, >3.5 very high disease activity.

[b] ASAS health index categories: good ≤ 5, moderate <5 to <12, poor ≥12.

[c] Definitions according to current ASAS classification criteria.

commented in Table 1, current but also past extramusculoskeletal manifestations (EMM) such as inflammatory bowel disease and musculoskeletal manifestations like dactylitis should have been diagnosed by a physician. As baseline features, the imaging items radiographic sacroiliitis, magnetic resonance imaging (MRI) inflammation, and MRI structural lesion were already proposed mandatory by the steering group for DMARD trials but in workgroup meeting it was decided that these are also useful to be reported for trials other than DMARD trials. However, while these imaging items set as mandatory for DMARD trials (Table 2), they are optional for non-DMARD trials (ie, 'report if collected').

Eleven features (items 21-31) in Table 1 are on current and past pharmacological treatment of axial SpA with the steering and workgroup having added several items not reported in published clinical trials such as previous use of 3 biological or targeted synthetic DMARD classes and previous use of Janus kinase inhibitor (JAK) inhibitors.

Items 32 to 42 in Table 1 are baseline values of instruments like the Axial Spondyloarthritis Disease Activity Score (ASDAS), a composite index to assess disease activity, the ASAS health index (ASAS HI) for overall health and functioning, and results from C-reactive protein (CRP) laboratory test. Apart from a CRP value (≥5 mg/L), all baseline features in the 'Clinical and laboratory measures' category are also baseline values of the outcomes in Tables 3 and 4.

Additional baseline features for DMARD trials

Table 2 lists recommended extra baseline features for trials aimed at showing disease modification. In addition to the baseline features for all trials from Table 1, for DMARD trials, it is

Table 2
Additional baseline features for disease-modifying antirheumatic drug (DMARD) trials

Item	How	Comment
1. SPARCC MRI activity of the SIJ	Mean (SD)	-
2. SPARCC MRI activity of the spine	Mean (SD)	-
3. 44 swollen joint count	*n* (%) patients with ≥1 swollen joint and mean (SD) in patients with ≥1 swollen joint	-
4. MASES	*n* (%) patients with score ≥1 and mean (SD) in patients with score ≥1	-
5. Dactylitis count	*n* (%) patients with ≥1 and mean (SD) in patients with ≥1	-
6. mSASSS	Mean (SD)	-
7. Syndesmophytes	*n* (%) patients with ≥1 syndesmophyte	-
8. Radiographic sacroiliitis	*n* (%) bilateral ≥grade 2 or unilateral ≥grade 3	Grading according to modified New York criteria

MASES, Maastricht Ankylosing Spondylitis Enthesitis Score; mSASSS, modified Stoke Ankylosing Spondylitis Spinal Score; SIJ: sacroiliac joints; SPARCC, Spondyloarthritis Research Consortium of Canada.

Table 3
Reporting outcomes of instruments in the ASAS Core Outcome Set

Item	At baseline	At follow-up timepoint(s)
For all trials		
1. ASDAS	Mean (SD)	Mean (SD) and mean (SD) CFB and *n* (%) of pts with improvement of ≥1.1 (clinically important-) and ≥2.0 (major- improvement)[a]
2. ASDAS disease activity status	*n* (%) per category[b]	*n* (%) per category and *n* (%) <2.1 and ≥2.1
3. Patient global disease activity	Mean (SD)	Mean (SD) and mean (SD) CFB
4. Total back pain (BASDAI Q2)	Mean (SD)	Mean (SD) and mean (SD) CFB
5. Mean stiffness severity (BASDAI Q5) and duration (BASDAI Q6)[c]	Mean (SD)	Mean (SD) and mean (SD) CFB
6. Fatigue (BASDAI Q1)	Mean (SD)	Mean (SD) and mean (SD) CFB
7. BASFI	Mean (SD)	Mean (SD) and mean (SD) CFB
8. ASAS 20 and ASAS 40 responses	Not applicable	*n* (%)
9. ASAS health Index	Mean (SD)	Mean (SD) and mean (SD) CFB and *n* (%) of pts with improvement ≥3
10. ASAS health Index status[d]	*n* (%) per category	*n* (%) per category
Mandatory for DMARD trials only		
11. SPARCC MRI-SIJ activity	Mean (SD)	Mean (SD) and mean (SD) CFB
12. SPARCC MRI-spine activity	Mean (SD)	Mean (SD) and mean (SD) CFB
13. Acute anterior uveitis	*n* (%) with history	*n* (%) since baseline/rate per 100 pt yrs and split by pts with and without history
14. Psoriasis	*n* (%) with history	*n* (%) since baseline[e]/rate per 100 pt yrs and split by pts with and without history
15. IBD	*n* (%) with history	*n* (%) since baseline/rate per 100 pt yrs and split by pts with and without history
16. 44 swollen joint count	Mean (SD)	Mean (SD) and mean (SD) CFB[f]
17. MASES	Mean (SD)	Mean (SD) and mean (SD) CFB[f]
18. Dactylitis count	Mean (SD)	Mean (SD) and mean (SD) CFB[f]
19. mSASSS	Mean (SD)	Mean (SD) and mean (SD) CFB
20. Syndesmophytes	*n* (%) with ≥1	*n* (%) with ≥1 syndesmophyte and *n* (%) with a new syndesmophyte

ASAS, Assessment of SpondyloArthritis international Society; ASDAS, Axial Spondyloarthritis Disease Activity Score; BASFI, Bath Ankylosing Spondylitis Functional Index; CFB, change from baseline; IBD, inflammatory bowel disease; MASES, Maastricht Ankylosing Spondylitis Enthesitis Score; mSASSS, modified Stoke Ankylosing Spondylitis Spinal Score; pt, patient; Q, question; SPARCC, Spondyloarthritis Research Consortium of Canada.
[a] If flares are reported: *n* (%) of pts. with ASDAS of ≥0.9.
[b] ASDAS categories: ≤1.3 inactive disease (ASDAS-ID), >1.3 and ≤2.1 low disease (ASDAS-LDA), >2.1 and ≤3.5 high disease (ASDAS-HDA), >3.5 very high disease activity (ASDAS-VHDA).
[c] BASDAI (Q5 + Q6)/2.
[d] ASAS health index categories: good ≤5, moderate <5 to <12, poor ≥12.
[e] For psoriasis 'since baseline' is restricted to new-onset since baseline.
[f] In pts with swollen joint count>0, MASES > 0 or dactylitis count>0 at baseline.

recommended to report the 44 swollen joint count, Maastricht Ankylosing Spondylitis Enthesitis Score (MASES) and dactylitis count as baseline features. Moreover, while radiographic sacroiliitis and inflammation on MRI of the sacroiliac joint according to Table 1 are not mandatory and can be reported if collected, for DMARD trials it is recommended to report radiographic sacroiliitis with grading according to modified New York criteria and Spondyloarthritis Research Consortium of Canada (SPARCC) MRI activity score of the sacroiliac joint.

Grading according to the modified New York criteria (88 votes with 81% in favour and 19% against) was proposed by the ASAS members.

Additional imaging as a baseline feature recommended for DMARD trials is to report the mean SPARCC MRI activity score of the spine, mean modified Stoke Ankylosing Spondylitis Spinal Score (mSASSS), and the number of patients with at least 1 spinal syndesmophyte at baseline

With the exception of the number of patients with at least 1 syndesmophyte, all these baseline features are also trial outcomes. However, for swollen joint count, MASES and dactylitis count there are subtle differences in reporting. As a baseline feature, the 44 swollen joint count is recommended to be reported as the number of patients with at least 1 swollen joint plus the mean number of swollen joints in patients with at least 1 swollen joint, but as an outcome only the mean number of swollen joints in patients with at least 1 swollen joint is to be reported (Table 3). This is similar for MASES and dactylitis count.

Table 4
Reporting outcomes of instruments additionally endorsed by ASAS but not in the Core Outcome Set

<If collected present this way> *Item*	*At baseline*	*At follow-up timepoint(s)*
1. BASDAI	Mean (SD)	Mean (SD) + mean (SD) change from baseline
2. CRP (mg/L)	Mean (SD)	Mean (SD) + mean (SD) change from baseline
3. Berlin MRI-SIJ activity	Mean (SD)	Mean (SD) + mean (SD) change from baseline
4. Berlin MRI-spine activity	Mean (SD)	Mean (SD) + mean (SD) change from baseline
5. Back pain at night	Mean (SD)	Mean (SD) + mean (SD) change from baseline
6. Severity morning stiffness (BASDAI Q5)	Mean (SD)	Mean (SD) + mean (SD) change from baseline
7. Duration morning stiffness (BASDAI Q6)	Mean (SD)	Mean (SD) + mean (SD) change from baseline
8. SF-36 (PCS, MCS)	Mean (SD)	Mean (SD) + mean (SD) change from baseline
9. 66 swollen joint count[a]	Mean (SD)	Mean (SD) + mean (SD) change from baseline
10. SPARCC enthesitis[a]	Mean (SD)	Mean (SD) + mean (SD) change from baseline
11. SPARCC MRI SSS for erosion	Mean (SD)	Mean (SD) + mean (SD) change from baseline

BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; CRP, C-reactive protein; MCS, mental component summary; PCS, physical component summary, Q, question; SF-36, 36-item Short Form Health Survey; SIJ, sacro-iliac joint; SPARCC, Spondyloarthritis Research Consortium of Canada; SSS, Sacroiliac joint Structural Score.
[a] In pts with swollen joint count>0, or enthesitis>0 at baseline.

Study outcomes

Table 3 presents recommendations on how outcomes from the instruments in the COS should be reported. The first 10 outcomes are for all clinical trials and the second 10 are outcomes for DMARD trials only. In the second column of the table, the outcomes are listed, in the third column how to report the outcomes at baseline, and in the fourth column how to report at 1 or more follow-up timepoints in the study. The most commonly recommended format for outcomes is to report the mean plus the SD at baseline and the mean value plus SD at other timepoints of the study while adding the mean change with SD from baseline for each timepoint. When more appropriate—for example, for outcomes with a highly skewed distribution—the geometric means may also be used.

While the recommendation to report the mean also applies to the ASDAS and the ASAS HI, it is recommended for these outcomes to also report the number and percentage of patient that achieve a specific improvement, namely a decrease of ≥1.1 (clinically important [CI]) and ≥2.0 units (major improvement [MI]) for the ASDAS and a decrease in the score of ≥3 for the ASAS HI. In addition, if disease activity flares are reported, the recommended threshold of an increase of 0.9 units for the ASDAS should be used. For both ASDAS and ASAS HI, it is recommended to also report the number and percentage of patients with specific status at each timepoint. For ASDAS, this is the number and percentage of patients with ASDAS inactive (≤1.3) (ASDAS-ID), low (>1.3 and ≤2.1) (ASDAS-LDA), high (>2.1 and ≤3.5) (ASDAS-HDA), and very high (>3.5) disease activity (ASDAS-VHDA) plus the number and percentage of patients with an ASDAS score of <2.1 (ie, ASDAS-ID or LDA) and ≥2.1 (ie, ASDAS-HDA or VHDA). For ASAS HI, the number and percentage of patients with a good (≤ 5), moderate (<5 to <12), and poor (≥12) status should be reported.

For ASAS20 and ASAS40 responses, it is recommended to report the number and percentage of patients meeting response criteria. ASAS 20 and 40 are improvement criteria than can be calculated from patient global disease activity, total back pain (Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] Q2), Bath Ankylosing Spondylitis Functional Index (BASFI) and severity and duration stiffness (mean of BASDAI questions 5 and 6).

Psoriasis, acute anterior uveitis and inflammatory bowel disease are EMMs of axSpA and new occurrences or flares are recommended to be reported as the number and percentage of patients with flare or (re)occurrence since baseline plus the rate per 100 patient-years while also splitting the results by patients with and without a history of that particular EMM.

For spinal syndesmophytes, it is recommended to report the number and percentage of patients with at least 1 at baseline and outcomes plus the number and percentage of patients with a newly developed syndesmophyte which, if not scored on radiographs separately, can be derived from the mSASSS scoring with a vertebral unit over time developing an mSASSS score of 2 or 3 from a score less than 2 counting as the development of a syndesmophyte.

Table 4 lists the recommendations on how instruments additionally endorsed by ASAS but not in the COS should be reported at both baseline and at follow-up timepoints. All outcomes are recommended to be reported as mean with the SD of the mean at baseline and at follow-up timepoints the mean with the SD plus the mean changes from baseline with SD.

Voting

The final proposals were voted in by a majority of ASAS members in 3 separate votes: 85 members voting on the proposal for baseline features (Tables 1 and 2) with 84 % in favour, 11% against, and 6% abstaining, 81 members voting on the proposals for reporting outcomes of COS instruments (Table 3) with 85% in favour, 9% against, and 6% abstaining, and 85 members voting on reporting items of additional instruments not in the COS (Table 4) with 93% in favour, 2% against and 5% abstaining.

Presentation

All recommendations can be applied to reporting baseline characteristics and outcomes in text and tables but also in graphs. Figures 1-3 contain graph examples of 3 outcomes from Table 3 in a bar graph, a line graph, and a cumulative probability plot, respectively.

Figure 1 shows a bar graph of BASFI responses over time. While the use of the bars allows the reader to immediately see the difference between the 2 groups, the actual mean values can be found including the mean changes over time. Without these numbers, it would otherwise be difficult to accurately estimate the exact results by eye (or even ruler) using the height of the bars against the *Y*-axis. Apart from providing a more exact outcome, this greatly facilitates the reuse of the data into, for example, meta-analysis.

Similarly, in Figure 2, a line graph presents the mean ASDAS over 52 weeks' time in 2 groups of patients. While it is clear just by looking at the graphs that over time the mean ASDAS decreases in both groups, the exact means for each time point can be found in the box below the graphs with the change from baseline in the figure at each timepoint. Finally, Figure 3 shows cumulative probability plots of the change in mSASSS for patients receiving 2 different treatments.

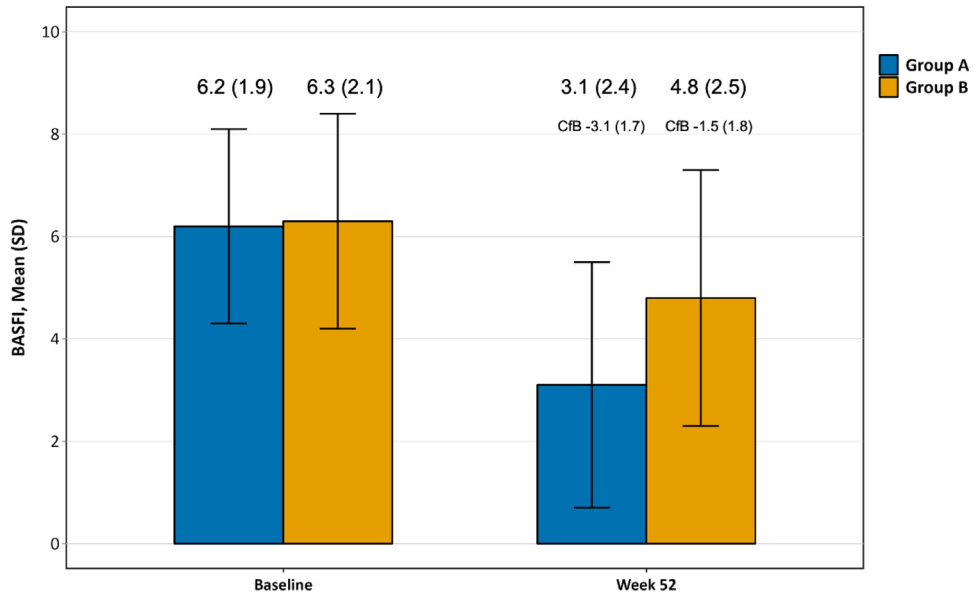
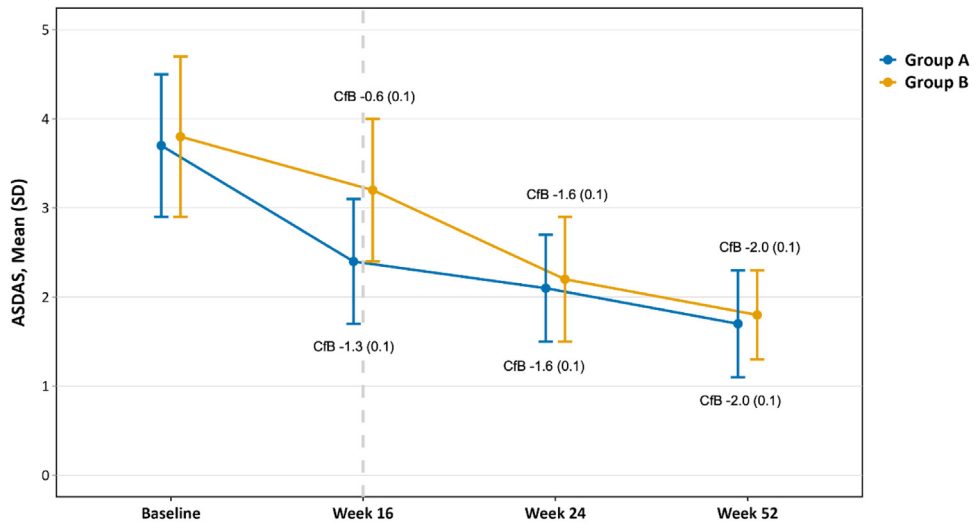


Figure 1. Bar graphs of hypothetical data showing the mean Bath Ankylosing Spondylitis Functional Index (BASFI) at baseline and 52 weeks in 2 groups of patients. For both groups the mean baseline values plus SD at baseline, 52 weeks, and the change over 52 weeks can be found directly above the graph. CfB, change from baseline.



Group	Baseline	Week 16	Week 24	Week 52
Group A	3.7 (0.8)	2.4 (0.7)	2.1 (0.6)	1.7 (0.6)
Group B	3.8 (0.9)	3.2 (0.8)	2.2 (0.7)	1.8 (0.5)

Figure 2. Line graphs of hypothetical data showing the mean Axial Spondyloarthritis Disease Activity Score (ASDAS) in 2 groups of patients over time with the mean scores and SD at all timepoint in the box below the graphs with the change in ASDAS between baseline and the other timepoints in the graph itself. CfB, change from baseline.

Each symbol represents the change score of an individual patient ordered from the lowest to the highest change score by treatment group and the mean scores at baseline, mean scores at outcome, and mean change from baseline are shown in the graph.

DISCUSSION

Recommendations on reporting axSpA clinical trials based on a high degree of consensus from a large group of SpA experts are presented, consisting not only of recommendations on which baseline features to collect and how to report them but also which outcomes from instruments in the ASAS COS to present and how to present these outcomes.

While the recommendations on reporting outcomes build and expand upon the updated COS instruments set, the recommendations on the baseline features for clinical trials are novel. Baseline data should adequately describe the population in a trial including demographic variables, disease characteristics, and known factors that influence the outcomes (including past and current medications taken by participants). AxSpA is a heterogeneous disease and that is reflected in the number of clinical features listed in the baseline features table. Moreover, the relatively large number of items concerning pharmacological treatment reflect the recent increase in the number of treatments available for axSpA including whole new classes of biological and target synthetic DMARDs [6]. That said, while the number of recommended baseline features is substantial in particular

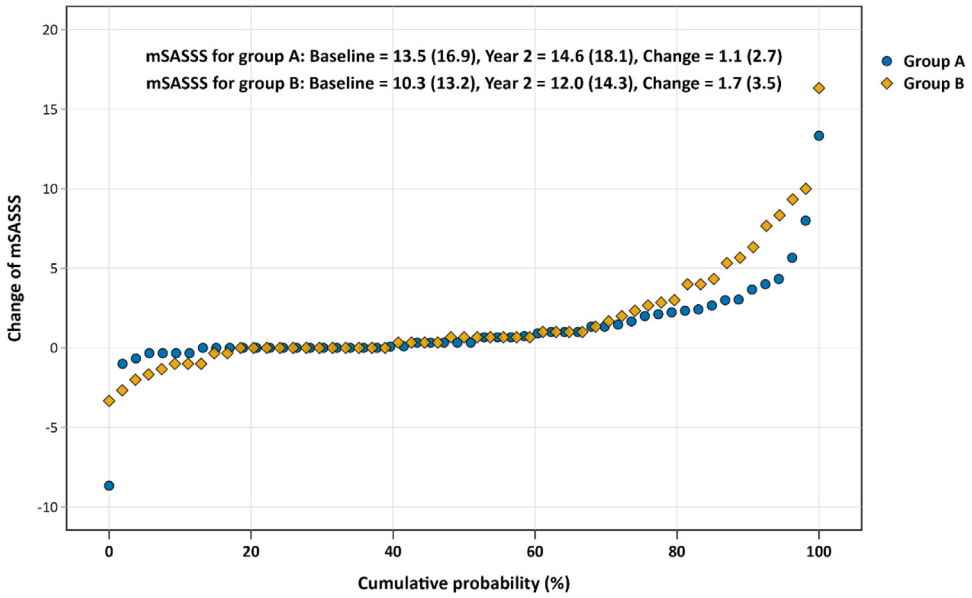


Figure 3. Cumulative probability plot of change in modified Stoke Ankylosing Spondylitis Spinal Scores (mSASSS) over 2 years in 2 groups of patients with mean scores plus SD at baseline, 2 years and the change over 2 years in the graph. Each symbol represents the change score of an individual patient ordered from the lowest to the highest change score by treatment group.

specific items describing pharmacological treatment options may not be applicable to all trials for obvious reasons, for example, previous bDMARD use in a trial aimed at bDMARD-naïve patients. However, given that information on the background of patients participating in a clinical trial is needed for correct interpretation of the results, it is important that the appropriate information on baseline features—like the study outcomes—can be found in the main manuscript and not only in an appendix.

A limitation of the process of drafting the baseline recommendations was that the number of publications consulted by the steering group was relatively small based on reviewing highly cited axSpA clinical trial publications. However, the recommendations were reviewed and commented on by a large number of experts making it unlikely that important items are missing. Nevertheless, apart from the recommended mandatory features, trialists may want to add specific baseline items and this should be analysed in future evaluations of these recommendations.

Per clear recommendation of ASAS members, educational level was added as a baseline feature. The steering group operationalized this by recommending the highest completed level of education in terms of primary, secondary, and tertiary education. The International Standard Classification of Education which offers uniform and internationally agreed definitions on education should be used to properly classify educational achievements despite substantial differences in educational systems around the world (Supplementary Table S2) [7].

The recommendation to report the number and percentage of axSpA with axial symptoms of less than 2 years as a baseline feature reflects the progress made in recent years in making earlier diagnoses. Diagnostic delay is far longer in axSpA than in other inflammatory disease and for many patients it can take years before being diagnosed. Recently, ASAS has adopted a definition of early axSpA as a duration of ≤2 years of axial symptoms and data from the SPondyloArthritis Caught Early cohort were published showing that rheumatologists are able to diagnose axSpA in patients with chronic back pain with less than 2 years of symptom duration [8,9].

In addition to for the first time providing recommendations on baseline features for axSpA trials, the project is a clear extension of the recently updated axSpA COS. The recommendations expand on the publication of the updated COS domains and instruments by advising how to actually report outcomes from the COS instruments.

Notably, while in the COS there are 16 instruments (7 mandatory instruments for all trials and 9 additional for DMARD trials), Table 3 shows 20 items to report: 10 for all trials and 10 additional items for DMARD trials. While most COS instruments correspond with 2 outcomes (eg, mean and mean change from baseline), other instruments such as ASAS HI [10] and mSASSS [11] but in particular the ASDAS inform more outcomes. Apart from a COS instrument, ASDAS is the recommended instrument for monitoring patients in clinical practice [6] and this is one of the reasons that outcomes of the ASDAS are recommended to be extensively reported including mean values at timepoints, change from baseline, patients with CI and MI and flare [12,13]. In addition, CRP, the laboratory test in the ASDAS and an objective marker of inflammation may be reported separately as an endorsed instrument but not in the COS.

Overall, these recommendations contain a substantial number of different axSpA features, definitions, and instruments. Important background information on these items including how to correct use instruments can be found in the original publications such as the ASAS20 and 40 improvement criteria [14,15] but also the ASAS handbook available on the ASAS website and which is currently in the process of being updated [16,17].

There is a growing recognition that sufficient attention must be paid to the outcomes measured and reported in clinical trials. Having a COS available as an agreed minimum standardised set of outcomes that should be measured is an important step in reducing trial heterogeneity but so is consistent and precise reporting of trial outcomes. With COSs having been developed for most major rheumatic and musculoskeletal diseases, to our knowledge not many include recommendations on reporting outcomes of clinical trials. However, recommendations on reporting clinical trials have been published before, for example,

the European Alliance of Associations for Rheumatology (EULAR)/American College of Rheumatology (ACR) collaborative recommendations on reporting disease activity in clinical trials of patients with rheumatoid arthritis and the EULAR recommendations for the reporting of clinical trial extension studies [18,19].

While this study is focused on recommendations for available data, reporting missing data in clinical trials are a critical aspect of ensuring transparency, reproducibility, and the integrity of study findings. Both the European Medicines Agency and the International Conference on Harmonization (ICH) (ICH E9) provide comprehensive guidelines on how to not only handle but also report missing data in clinical trials [20,21].

Finally, the readership of clinical trials is diverse and may include researchers, policy makers, patients, and clinicians. Therefore, ensuring clinical trial reports are accessible to readers with different training and educational backgrounds is important and may—for example—require explaining context or implications to nonclinicians and explanation of the interpretation of advanced methodology to readers with less extensive statistical training.

In summary, as the final step in updating the axSpA COS, we present ASAS-endorsed expert recommendations for collecting and reporting baseline features and presenting outcomes of axSpA clinical trials using instruments from the COS with the overall aim of improving the quality of evidence-based knowledge in axSpA. Adherence to these recommendations will standardise presentation of results and thereby provide better insight into trial outcomes and facilitate comparing outcomes across studies.

Competing interests

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CRediT authorship contribution statement

Floris A. van Gaalen: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Victoria Navarro-Compán:** Writing – review & editing, Supervision, Investigation, Formal analysis, Data curation, Conceptualization. **Xenofon Baraliakos:** Writing – review & editing, Investigation, Formal analysis. **Filip van den Bosch:** Writing – review & editing, Investigation, Formal analysis. **Lianne S. Gensler:** Writing – review & editing, Investigation. **Ihsane Hmamouchi:** Writing – review & editing, Investigation, Formal analysis. **Robert Landewé:** Writing – review & editing, Investigation, Formal analysis. **Pedro M. Machado:** Writing – review & editing, Investigation, Formal analysis. **Helena Marzo-Ortega:** Writing – review & editing, Investigation, Formal analysis. **Valeria Rios Rodriguez:** Writing – review & editing, Visualization, Investigation, Formal analysis. **Denis Poddubnyy:** Writing – review & editing, Investigation, Formal analysis. **Sofia Ramiro:** Writing – review & editing, Investigation, Formal analysis. **Désirée van der Heijde:** Writing – review & editing, Supervision, Methodology, Investigation, Data curation, Conceptualization.

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