



A multicentre observational psoriatic arthritis cohort study addressing real-life outcomes of a treat to target approach in routine clinical practice - Randomised trials are included in the cohort (TwICS design)

Statistical Analysis Plan (SAP)

Data Definitions and Tables

Version 1.0 – 24Apr2024

Based on Protocol Version 10.0 – 23Feb2023

Oxford Clinical Trials Research Unit (OCTRU)

and

Centre for Statistics in Medicine (CSM)



CONTENTS

1. Introduction	3
2. Generation of outcomes	3
2.1 Primary outcome	3
2.2 Secondary Outcome Definitions	12
3. Definitions of Population	15
4. Presentation of Key Cohortdata	17
4.1 Baseline characteristics.....	17
4.2 Treatment compliance & details of the interventions.....	29
4.3 CohortResults.....	29
4.3.1 Primary outcome	29
4.3.2 Secondary outcomes.....	30
4.4 Safety	30
5. Other	30
6. References	30
7. Glossary of abbreviations.....	30

1. INTRODUCTION

This document details how the key outcomes will be generated from raw data and reported. This document has been developed in collaboration with the trial team in order to ensure that the data being collected is appropriate, not excessive, and can be reported in a sensible way. The tables and figures are primarily aimed at the final statistical report, funder reports and publications, but may also guide reporting to trial oversight committees.

2. GENERATION OF OUTCOMES

Data will use from OpenClinica database. The OpenClinica application resides on a webserver hosted and managed by Oxford University's Medical Sciences Division IT Services department. Data will be downloaded from the OpenClinica database by the IT Services. In Cambridge site: Patients will complete their PROMs on a tablet computer using a software called MyChart, that is an extension of EPIC; a fully integrated electronic patient record system. MyChart transmits PROMS data securely to EPIC.

2.1 Primary outcome

The primary outcome will be the proportion of patients achieving a good response level (reduction from baseline of ≥ 1.6 and final score of ≤ 3.2) measured by the PsA Disease Activity Score (PASDAS) at 48 weeks. The PASDAS is a weighted index comprising assessments of joints, function, acute-phase response, quality of life (QOL), and patient and physician MD by VAS. It is represented by the formula:

$$\text{PASDAS} = (((0.18 \times \sqrt{\text{Physician global VAS}}) + (0.159 \times \sqrt{\text{Patient global VAS}}) - (0.253 \times \sqrt{\text{SF36} - \text{PCS}}) + (0.101 \times \text{LN}(\text{Swollen joint count} + 1)) + (0.048 \times \text{LN}(\text{Tender joint count} + 1)) + (0.23 \times \text{LN}(\text{Leeds Enthesitis Count} + 1)) + (0.377 \times \text{LN}(\text{Dactylitis count} + 1)) + (0.102 \times \text{LN}(\text{CRP} + 1)) + 2) \times 1.5$$

where LN = natural logarithm, PCS = physical component summary scale of SF36, CRP = C-reactive protein in mg/l, SF36 = Medical Outcomes Study Short Form-36. All VAS scores are 0–100 mm. Swollen joint count is 66 joints, and tender joint count 68. The score range of the PASDAS is 0–10, with worse disease activity represented by higher scores.

SJC	lateralhumerusright, lateralhumerusright2*, lateralhumerusright3*, medialfemurleft, medialfemurleft2*, medialfemurleft3*, medialfemurright, medialfemurright2*, medialfemurright3*, proximalachillesleft, proximalachillesleft2*, proximalachillesleft3*, proximalachillesright, proximalachillesright2*, proximalachillesright3*, swollentmjleft, swollentmjright, swollensternoclavleft, swollensternoclavright, swollenacjleft, swollenacjright, swollenshoulderleft, swollenshoulderright, swollenelbowleft, swollenelbowright, swollenwristleft, swollenwristright, swollentmjleft1*, swollentmjright1*, swollensternoclavleft1*, swollensternoclavright1*, swollenacjleft1*, swollenacjright1*, swollenshoulderleft1*,	R CUH OP RHEUM ENTHESITIS LATERAL HUMERUS (Left/Right)				
		R CUH OP RHEUM ENTHESITIS MEDIAL FEMUR (Left/Right)				
		R CUH OP RHEUM ENTHESITIS PROXIMAL ACHILLES (Left/Right) SWOLLENLTMJ SWOLLENRTMJ SWOLLENLSTERNOCLAV SWOLLENRSTERNOCLAV SWOLLENLACJ SWOLLENRACJ SWOLLENLSHOULDER SWOLLENRSHOULDER SWOLLENLELBOW SWOLLENRELBOW SWOLLENLWRIST SWOLLENRWRIST SWOLLENLMCP1 SWOLLENLMCP2 SWOLLENLMCP3 SWOLLENLMCP4 SWOLLENLMCP5 SWOLLENRMCP1 SWOLLENRMCP2 SWOLLENRMCP3				

	swollenshoulderright1*, swollenelbowleft1*, swollenelbowright1*, swollenwristleft1*, swollenwristright1*, swollenmcpleft_ms_id_1, swollenmcpleft_ms_id_2, swollenmcpleft_ms_id_3, swollenmcpleft_ms_id_4, swollenmcpleft_ms_id_5, swollenmcpright_ms_id_1, swollenmcpright_ms_id_2, swollenmcpright_ms_id_3, swollenmcpright_ms_id_4, swollenmcpright_ms_id_5, swollenmcpleft1_ms_id_1*, swollenmcpleft1_ms_id_2*, swollenmcpleft1_ms_id_3*, swollenmcpleft1_ms_id_4*, swollenmcpleft1_ms_id_5*, swollenmcpright1_ms_id_1*, swollenmcpright1_ms_id_2*, swollenmcpright1_ms_id_3*, swollenmcpright1_ms_id_4*, swollenmcpright1_ms_id_5*, swollenipleft_ms_id_1, swollenipleft_ms_id_2, swollenipleft_ms_id_3, swollenipleft_ms_id_4, swollenipleft_ms_id_5, swollenipright_ms_id_1, swollenipright_ms_id_2, swollenipright_ms_id_3,	SWOLLENRMCP4 SWOLLENRMCP5 SWOLLENLPIP1 SWOLLENLPIP2 SWOLLENLPIP3 SWOLLENLPIP4 SWOLLENLPIP5 SWOLLENRPIP1 SWOLLENRPIP2 SWOLLENRPIP3 SWOLLENRPIP4 SWOLLENRPIP5 SWOLLENLDIP2 SWOLLENLDIP3 SWOLLENLDIP4 SWOLLENLDIP5 SWOLLENRDIP2 SWOLLENRDIP3 SWOLLENRDIP4 SWOLLENRDIP5 SWOLLENLKNEE SWOLLENRKNEE SWOLLENLANKLE SWOLLENRANKLE SWOLLENLMIDTARSAL SWOLLENRMIDTARSAL SWOLLENLMTP1 SWOLLENLMTP2 SWOLLENLMTP3 SWOLLENLMTP4 SWOLLENLMTP5 SWOLLENRMTP1 SWOLLENRMTP2 SWOLLENRMTP3				
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swollenipright_ms_id_4, swollenipright_ms_id_5, swollenipleft2_ms_id_1*, swollenipleft2_ms_id_2*, swollenipleft2_ms_id_3*, swollenipleft2_ms_id_4*, swollenipleft2_ms_id_5*, swollenipright2_ms_id_1*, swollenipright2_ms_id_2*, swollenipright2_ms_id_3*, swollenipright2_ms_id_4*, swollenipright2_ms_id_5*, swollendipleft_ms_id_2, swollendipleft_ms_id_3, swollendipleft_ms_id_4, swollendipleft_ms_id_5, swollendipright_ms_id_2, swollendipright_ms_id_3, swollendipright_ms_id_4, swollendipright_ms_id_5, swollendipleft1_ms_id_2*, swollendipleft1_ms_id_3*, swollendipleft1_ms_id_4*, swollendipleft1_ms_id_5*, swollendipright1_ms_id_2*, swollendipright1_ms_id_3*, swollendipright1_ms_id_4*, swollendipright1_ms_id_5*, swollenkneeleft, swollenkneeright, swollenankleleft, swollenankleright, swollenmidtarsalleft, swollenmidtarsalright,	SWOLLENRMTP4 SWOLLENRMTP5 SWOLLENLFOOTIP1 SWOLLENLFOOTIP2 SWOLLENLFOOTIP3 SWOLLENLFOOTIP4 SWOLLENLFOOTIP5 SWOLLENRFOOTIP1 SWOLLENRFOOTIP2 SWOLLENRFOOTIP3 SWOLLENRFOOTIP4 SWOLLENRFOOTIP5				
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swollenkneelleft1*, swollenkneeright1*, swollenankleleft1*, swollenankleright1*, swollenmidtarsalleft1*, swollenmidtarsalright1*, swollenmtpleft_ms_id_1, swollenmtpleft_ms_id_2, swollenmtpleft_ms_id_3, swollenmtpleft_ms_id_4, swollenmtpleft_ms_id_5, swollenmtpright_ms_id_1, swollenmtpright_ms_id_2, swollenmtpright_ms_id_3, swollenmtpright_ms_id_4, swollenmtpright_ms_id_5, swollenipfootleft_ms_id_1, swollenipfootleft_ms_id_2, swollenipfootleft_ms_id_3, swollenipfootleft_ms_id_4, swollenipfootleft_ms_id_5, swollenipfootright_ms_id_1, swollenipfootright_ms_id_2, swollenipfootright_ms_id_3, swollenipfootright_ms_id_4, swollenipfootright_ms_id_5, swollenmtpleft1_ms_id_1*, swollenmtpleft1_ms_id_2*, swollenmtpleft1_ms_id_3*, swollenmtpleft1_ms_id_4*, swollenmtpleft1_ms_id_5*, swollenmtpright1_ms_id_1*, swollenmtpright1_ms_id_2*, swollenmtpright1_ms_id_3*,					
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TJC	swollenmtpright1_ms_id_4*, swollenmtpright1_ms_id_5*, swollenipfootleft2_ms_id_1*, swollenipfootleft2_ms_id_2*, swollenipfootleft2_ms_id_3*, swollenipfootleft2_ms_id_4*, swollenipfootleft2_ms_id_5*, swollenipfootright2_ms_id_1*, swollenipfootright2_ms_id_2*, swollenipfootright2_ms_id_3*, swollenipfootright2_ms_id_4*, swollenipfootright2_ms_id_5*, tendertmjleft, tendertmjleft1*, tendertmjright, tendertmjright1*, tendersternoclavleft, tendersternoclavleft1*, tendersternoclavright, tendersternoclavright1*, tenderacjleft, tenderacjleft1*, tenderacjright, tenderacjright1*, tendershoulderleft, tendershoulderleft1*, tendershoulderright, tendershoulderright1*, tenderelbowleft, tenderelbowleft1*, tenderelbowright, tenderelbowright1*, tenderwristleft, tenderwristleft1*,	TENDERLTMJ TENDERRTMJ TENDERLSTERNOC LAV TENDERRSTERNOC LAV TENDERLACJ TENDERRACJ TENDERLSHOULDER TENDERRSHOULDER TENDERLELBOW TENDERREL BOW TENDERLWRIST TENDERRWRIST TENDERLMCP1 TENDERLMCP2 TENDERLMCP3 TENDERLMCP4 TENDERLMCP5 TENDERRMCP1 TENDERRMCP2 TENDERRMCP3 TENDERRMCP4 TENDERRMCP5				
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tenderwristright, tenderwristright1*, tenderhipleft, tenderhipleft1*, tenderhipright, tenderhipright1*, tenderkneeleft, tenderkneeleft1*, tenderkneeright, tenderkneeright1*, tenderankleleft, tenderankleleft1*, tenderankleright, tenderankleright1*, tendermidtarsalleft, tendermidtarsalleft1*, tendermidtarsalright, tendermidtarsalright1*, tenderipleft_ms_id_1, tenderipleft_ms_id_2, tenderipleft_ms_id_3, tenderipleft_ms_id_4, tenderipleft_ms_id_5, tenderipleft_ms_ni, tenderipright_ms_id_1, tenderipright_ms_id_2, tenderipright_ms_id_3, tenderipright_ms_id_4, tenderipright_ms_id_5, tenderipright_ms_ni, tenderipleft2_ms_id_1*, tenderipleft2_ms_id_2*, tenderipleft2_ms_id_3*, tenderipleft2_ms_id_4*,	TENDERLHANDIP1 TENDERLHANDIP2 TENDERLHANDIP3 TENDERLHANDIP4 TENDERLHANDIP5 TENDERRHANDIP1 TENDERRHANDIP2 TENDERRHANDIP3 TENDERRHANDIP4 TENDERRHANDIP5 TENDERLDIP2 TENDERLDIP3 TENDERLDIP4 TENDERLDIP5 TENDERRDIP2 TENDERRDIP3 TENDERRDIP4 TENDERRDIP5 TENDERLHIP TENDERRHIP TENDERLKNEE TENDERRKNEE TENDERLANKLE TENDERRANKLE TENDERLMIDTARSAL TENDERRMIDTARSAL TENDERLMTP1 TENDERLMTP2 TENDERLMTP3 TENDERLMTP4 TENDERLMTP5 TENDERRMTP1 TENDERRMTP2 TENDERRMTP3				
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tenderipleft2_ms_id_5*, tenderipleft2_ms_ni*, tenderipright2_ms_id_1*, tenderipright2_ms_id_2*, tenderipright2_ms_id_3*, tenderipright2_ms_id_4*, tenderipright2_ms_id_5*, tenderipright2_ms_ni*, tenderipfootleft_ms_id_1, tenderipfootleft_ms_id_2, tenderipfootleft_ms_id_3, tenderipfootleft_ms_id_4, tenderipfootleft_ms_id_5, tenderipfootleft_ms_ni, tenderipfootright_ms_id_1, tenderipfootright_ms_id_2, tenderipfootright_ms_id_3, tenderipfootright_ms_id_4, tenderipfootright_ms_id_5, tenderipfootright_ms_ni, tenderipfootleft2_ms_id_1*, tenderipfootleft2_ms_id_2*, tenderipfootleft2_ms_id_3*, tenderipfootleft2_ms_id_4*, tenderipfootleft2_ms_id_5*, tenderipfootleft2_ms_ni*, tenderipfootright2_ms_id_1*, tenderipfootright2_ms_id_2*, tenderipfootright2_ms_id_3*, tenderipfootright2_ms_id_4*, tenderipfootright2_ms_id_5*, tenderipfootright2_ms_ni*	TENDERRMTP4 TENDERRMTP5 TENDERLFOOTIP1 TENDERLFOOTIP2 TENDERLFOOTIP3 TENDERLFOOTIP4 TENDERLFOOTIP5 TENDERRFOOTIP1 TENDERRFOOTIP2 TENDERRFOOTIP3 TENDERRFOOTIP4 TENDERRFOOTIP5				
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*These are the same variables with the same names, but they are in the different CRF versions.

2.2 Secondary Outcome Definitions

The secondary outcomes in MONITOR are as follows:

- Time from baseline to first achieving minimal disease activity (MDA) and PASDAS good response.
- Proportion achieving PASDAS good response at 24, 48 and 96 weeks.
- Proportion achieving PASDAS moderate response at 24, 48 and 96 weeks.
- Change in PsA impact of disease (PSAID) score from baseline to follow up.
- Proportion achieving PSAID patient acceptable symptom state (≤ 4) at follow up.
- Change in work productivity (absenteeism, presenteeism and productivity loss)
- EQ-5D-5L (6) converted into multi-attribute utility scores using established algorithm and resource use data to record direct medical costs and nonmedical costs. Unit cost data will be obtained from national databases such as the BNF and PSSRU Costs of Health and Social Care
- Side effects reported at each time point, combined with the Treatment satisfaction questionnaire for medication.
- Explore immune response in patients with PsA and how this relates to clinical effectiveness with standard therapies.

Table 2: Defining Secondary outcomes.

Outcome	Variable names	Time points	CRF heading on database	Range of possible values & interpretation	Scoring instructions (including reference to scoring manual)
MDA	TJC SJC Enthesitis count PSASI Patient Global VAS Patient pain VAS HAQ	Baseline, 12 weeks, 24 weeks, 36 weeks, 48 weeks, 72 weeks, 96 weeks	Baseline, 12wk_followup 24wk_followup, 36wk_followup, 48wk_followup, 72wk_followup, 96wk_followup	MDA is scored 'Not achieved' (0) or 'Achieved' (1).	TJC ≤ 1 SJC ≤ 1 Enthesitis count ≤ 1 PSASI ≤ 1 Patient Global VAS ≤ 20 Patient pain VAS ≤ 15 HAQ ≤ 0.5 Minimal Disease Activity (MDA) is acceptable when 5 of the above 7 items are achieved. Reference: Defining minimal disease activity in psoriatic arthritis: a proposed objective target for treatment - PubMed (nih.gov)

PASDAS	See Table 1	See Table 1	See Table 1	See Table 1	See Table 1
PSAID	psaid	Baseline, 12 weeks, 24 weeks, 36 weeks, 48 weeks, 72 weeks, 96 weeks	Baseline, 12wk_followup, 24wk_followup, 36wk_followup, 48wk_followup, 72wk_followup, 96wk_followup	PSAID range from 0 to 10. PsAID1 (pain) (range 0–10) PsAID2 (fatigue) (range 0–10) PsAID3 (skin) (range 0–10) PsAID4 (Work and/or leisure activities) (range 0–10) PsAID5 (function) (range 0–10) PsAID6 (discomfort) (range 0–10) PsAID7 (sleep) (range 0–10) PsAID8 (coping) (range 0–10) PsAID9 (anxiety) (range 0–10) PsAID10 (embarrassment) (range 0–10) PsAID11 (social life) (range 0–10) PsAID12 (depression) (range 0–10)	PsAID final value = (PsAID1(pain)x3) + (PsAID2(fatigue)x2) + (PsAID3(skin)x2) + (PsAID4(Work and/or leisure activities) x2) + (PsAID5(function)x2) + (PsAID6(discomfort)x2) + (PsAID7(sleep)x2) + (PsAID8(coping)x1) + (PsAID9(anxiety)x1) + (PsAID10(embarrassment)x1) + (PsAID11(social life) x1) + (PsAID12 (depression)x1). The total is divided by 20. Reference: A patient-derived and patient-reported outcome measure for assessing psoriatic arthritis: elaboration and preliminary validation of the Psoriatic Arthritis Impact of Disease (PsAID) questionnaire, a 13-country EULAR initiative - PubMed (nih.gov)
EQ-5D-5L	eqmobility, eqselfcare, equsualactivities, eqpaindiscomfort, eqanxietydepression, eq5d5lq01, eq5d5lq02, eq5d5lq03,	Baseline, 24 weeks, 48 weeks,	Baseline, 24wk_followup, 48wk_followup, 72wk_followup, 96wk_followup	Utility score: –0.594 (worse than death) to 1 (perfect health). Visual analogue scale: 0 (worst imaginable health state) to 100 (best imaginable health state).	The utilities can be calculated using the 'eq5d5l' command in Stata based on the England value set. The VAS score can be reported as a continuous value based on eq5d_vas. Reference: Development and preliminary testing of the new

EQ-5D VAS	eq5d5lq04, eq5d5lq05 eqhealthscore	72 weeks, 96 weeks			five-level version of EQ-5D (EQ-5D-5L) - PubMed (nih.gov)
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3. DEFINITIONS OF ANALYSIS POPULATION

Adult participants with newly diagnosed PsA who have not previously received treatment with synthetic or biologic disease-modifying anti-rheumatic drugs (DMARDs) for their articular disease.

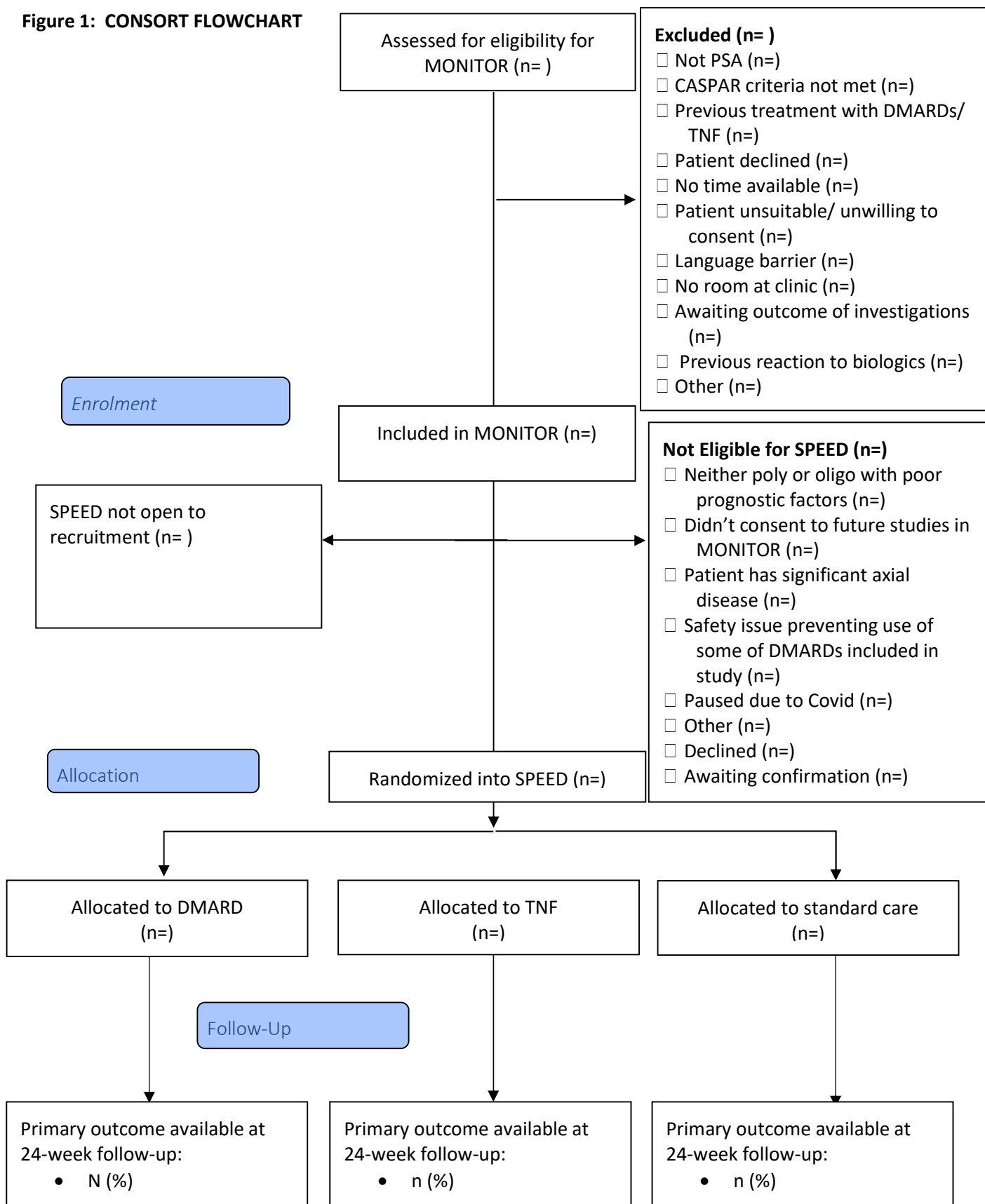
Inclusion Criteria

- Participant is willing and able to give informed consent for participation in the study.
- Male or Female
- Aged 18 years or above.
- Clinical diagnosis of PsA based upon the Classification of Psoriatic Arthritis (CASPAR) criteria(23))
- Active PsA defined by ≥ 1 tender or ≥ 1 swollen joint or ≥ 1 enthesis (site of attachment of tendon to bone)
- Not previously received treatment with synthetic or biologic disease-modifying anti-rheumatic drugs (DMARDs) for their articular disease.
- In the Investigator's opinion, is able and willing to comply with all study requirements.

Exclusion criteria

- Current or previous treatment of arthritis with synthetic DMARDs (including methotrexate, leflunomide or sulfasalazine) or biologic DMARDs (including TNF, IL12/23 or IL17 inhibitor therapies) or targeted synthetic DMARDs (PDE4 or JAK inhibitor therapies).
- Use of investigational therapies within 1 month or 5 biological half-lives of the baseline study visit (whichever is longer)

Figure 1: CONSORT FLOWCHART



4. PRESENTATION OF KEY COHORT DATA

4.1 Baseline characteristics

Table 3: Recruiting sites.

Recruitment site	N (%)
Bath	
Cambridge	
Coventry	
Newcastle	
Oxford	
Christchurch Hospital	
Torbay and South Devon	
Royal National Orthopaedic Hospital	
Ipswich Hospital	
Haywood Hospital	
Royal Wolverhampton	
County Durham	
Wirral	

Table 4: Demographic Characteristics

	Polyarticular N =	Oligoarticular N =	Total N =
Age (years)			
Missing			
Height (m)			
Missing			
Weight (kg)			
Missing			
Body Mass Index (BMI; kg/m²)			
Underweight			
Normal			
Overweight			
Sex			
Female			
Male			
Dominant hand			
Left			
Right			
Missing			
Education Level			
GCSE			
A Level			
College			
University			
Missing			
Occupation			
Non-Manual			
Light-Manual			
Heavy-Manual			
Not in Work			
Missing			
Smoker			
Never			
Ex			
Current			
Missing			
Alcohol			

No
Yes
Missing

*Categorical variables summarised with n (%)

*Continuous variables summarised with mean (SD), median (IQR)

An individual is classified as Polyarticular if the joints involved are greater or equal than 5 and classified as Oligoarticular if the joints involved are less than 5.

Joints involvement is calculated by all the measurements of SJC and TJC. (See table 1)

Table 5: Observation, Lab values

	Polyarticular N =	Oligoarticular N =	Total N =
Systolic Blood Pressure			
Missing			
Diastolic Blood Pressure			
Missing			
Pulse (bpm)			
Missing			
CRP			
Missing			

Variables summarised with mean (SD), median (IQR)

Table 6: Symptoms

	Polyarticular N =	Oligoarticular N =	Total N =
Inflammatory Back Pain¹			
No			
Yes			
Missing			
Duration > 3 months			
No			
Yes			
Missing			
EMS² > 30 minutes			
No			
Yes			
Missing			
Waking in second half of night			
No			
Yes			
Missing			
Alternating buttock pain			
No			
Yes			
Missing			

Variables summarised with n (%)

¹ Inflammatory Back Pain (IBP) is calculated by checking five components:

Age at onset <40 years, Insidious onset, Improvement with exercise, no improvement with rest, Pain at night (with improvement upon getting up).

"Yes" represents individuals that have 4 out of the 5 components.

² Early morning stiffness

Table 7: Clinical Assessment

	Polyarticular N =	Oligoarticular N =	Total N =
Tender Joint Counts (TJC) (mean, SD, median IQR)			
Missing			
Tender Joints < 28¹ (mean, SD, median, IQR)			
Missing			
Swollen Joint Counts (SJC) (mean, SD, median IQR)			
Missing			

Swollen Joints < 28¹ (mean, SD, median IQR) Missing			
Tender TMJ* No Yes Missing			
Tender ACJ* No Yes Missing			
Tender Shoulder* No Yes Missing			
Tender Sternoclav* No Yes Missing			
Tender Elbow* No Yes Missing			
Tender Wrist* No Yes Missing			
Tender MCP* No Yes Missing			
Tender Hand IP* No Yes Missing			
Tender Hand DIP* No Yes Missing			
Tender Knee* No Yes Missing			
Tender Ankle* No Yes Missing			
Tender Midtarsal* No Yes Missing			
Tender MTP* No Yes Missing			
Tender Foot IP* No Yes Missing			
Swollen TMJ (Left, Right or both) * No Yes Missing			
Swollen ACJ* No Yes Missing			
Swollen Shoulder*			

No			
Yes			
Missing			
Swollen Sternoclav*			
No			
Yes			
Missing			
Swollen Elbow*			
No			
Yes			
Missing			
Swollen Wrist*			
No			
Yes			
Missing			
Swollen MCP*			
No			
Yes			
Missing			
Swollen Hand IP*			
No			
Yes			
Missing			
Swollen Hand DIP*			
No			
Yes			
Missing			
Swollen Knee*			
No			
Yes			
Missing			
Swollen Ankle*			
No			
Yes			
Missing			
Swollen Midtarsal*			
No			
Yes			
Missing			
Swollen MTP*			
No			
Yes			
Missing			
Swollen Foot IP*			
No			
Yes			
Missing			
Proportion with any enthesitis			
Missing			
Mean Leeds enthesitis index (LEI) in all patients			
Missing			
Mean enthesitis score in all patients			
Missing			
Mean LEI in patients with any enthesitis			
Missing			
Mean enthesitis score in those with any enthesitis			
Missing			
Proportion with any dactylitis			
Missing			
Mean dactylitis count in all patients			
Missing			
Mean dactylitis count in patients with any dactylitis			
Missing			
PASI			
How active do you feel the patient's arthritis has been in the last week?			
BASMI²			

Assessor Global VAS Missing			
Joint Activity VAS Missing			
Skin Activity Missing			
Nail disease VAS Missing			
Enthesitis sites			
First costochondral 0 1 2 Missing			
Seven costochondral 0 1 2 Missing			
Supraspinatus 0 1 2 Missing			
Lateral humerus 0 1 2 Missing			
Medial humerus 0 1 2 Missing			
Posterior spine 0 1 2 Missing			
Anterior spine 0 1 2 Missing			
Iliac crest 0 1 2 Missing			
Greater trochanter1 0 1 2 99			
Medial femur 0 1 2 Missing			
Quadriceps patella 0 1 2 Missing			
Inferior patella 0 1			

2 Missing			
Tibial tubercle 0 1 2 Missing			
Proximal Achilles 0 1 2 Missing			
Insertion fascia 0 1 2 Missing			
5th lumbar process 0 1 2 Missing			
Dactylitis sites			
dactylitis_hand2 0 1 2 Missing			
dactylitis_hand3 0 1 Missing			
dactylitis_hand4 0 1 Missing			
dactylitis_hand5 0 1 Missing			
dactylitis_hand_thumb 0 1 Missing			
dactylitis_foot2 0 1 2 Missing			
dactylitis_foot3 0 1 Missing			
dactylitis_foot4 0 1 2 Missing			
dactylitis_foot5 0 1 2 Missing			
dactylitis_foot_hallux 0 1 2			

Missing			
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* These joints are presented as the proportion of patients with each joint involved (Yes: either left or right or both joints involved, n, %)

¹ 28 joint counts only include shoulders, elbows, wrists, MCPs, PIPs and knees.

² Calculated just for patients who have Axial disease (these are the patients that filled in the BASMI section, n=90)

Categorical variables summarised with n (%)

Continuous variables summarised with mean (SD), median (IQR)

Table 8: PROMS

	Polyarticular N =	Oligoarticular N =	Total N =
Psoriasis VAS			
Missing			
Arthritis VAS			
Missing			
Both VAS			
Missing			
Pain VAS			
Missing			
SF-36 (PCS)			
Missing			
Peripheral EMS			
Missing			
Axial EMS			
Missing			
BASDAI*			
Missing			
BASFI*			
Missing			
PsAID			
Missing			
Pain			
Missing			
Fatigue			
Missing			
Skin			
Missing			
Work leisure			
Missing			
Functional capacity			
Missing			
Discomfort			
Missing			
Sleep disturbance			
Missing			
Coping			
Missing			
Anxiety fear			
Missing			
Embarrassment			
Missing			
Social participation			
Missing			
Depression			
Missing			
Are you currently employed (working for pay)?			
No			
Yes			
Missing			
Work hours missed			
Missing			
Leisure hours missed			
Missing			
Work hours			
Missing			
WPAI:			
1) Percent work time missed due to health			
Missing			
2) Percent impairment while working due to health			
Missing			
3) Percent overall work impairment due to health			

Missing
4) Percent activity impairment due to health
Missing
HAQ - Standard disability index
Missing
EQ-5D-5L
Missing
EQ-5D VAS
Missing
PASDAS
Missing
Duration of Psoriatic arthritis (months)
Missing
Duration of Psoriasis (months)
Missing

* Calculated just for patients who have Axial disease (BASDAI: n = 74, BASFI: n = 75)
Categorical variables summarised with n (%)
Continuous variables summarised with mean (SD), median (IQR)

Table 9: Pain and family history

	Polyarticular N =	Oligoarticular N =	Total N =
Neck pain			
Current			
Ever			
Never			
Missing			
Back pain			
Current			
Ever			
Never			
Missing			
Chest pain			
Current			
Ever			
Never			
Missing			
Enthesitis pain			
Current			
Ever			
Never			
Missing			
Plantar pain			
Current			
Ever			
Never			
Missing			
Dactylitis			
Current			
Ever			
Never			
Missing			
Uveitis			
Current			
Ever			
Never			
Missing			
Uveitis family history			
No			
Yes			
Missing			
Psoriasis			
Current			
Ever			
Never			

Missing
Psoriasis family history
 No
 Yes
 Missing
Crohn's
 Current
 Ever
 Never
 Missing
Crohn's family history
 No
 Yes
 Missing
Spa
 Current
 Ever
 Never
 Missing
Spa family history
 No
 Yes
 Missing
Hypertension
 No
 Yes
 Missing
Angina
 No
 Yes
 Missing
Myocardial infarction
 No
 Yes
 Missing
Stroke
 No
 Yes
 Missing
Diabetes
 No
 Yes
 Missing
DVT/PE
 No
 Missing
Dyslipidemia
 No
 Yes
 Missing

Variables summarised with n (%)

Table 10: Clinical factors

	Polyarticular N =	Oligoarticular N =	Total N =
HLAB27			
Negative			
Positive			
Missing			
Hemoglobin			
Missing			
WBC			
Missing			
PLT			
Missing			
Neutrophil			
Missing			
ALT			
ALT > 45			
ALT <= 45			
EGFR			
Missing			
CASPAR criteria			
Current psoriasis			
No			
Yes			
Missing			
Personal history			
Psoriasis			
No			
Yes			
Missing			
Family history			
No			
Yes			
Missing			
Nail dystrophy			
No			
Yes			
Missing			
Current dactylitis			
No			
Yes			
Missing			
Rheumatoid negative			
No			
Yes			
Missing			
Rheumatoid Factor			
Normal			
Positive			
Missing			
ACPA			
Negative			
Positive			
Missing			

*Categorical variables summarised with n (%)

*Continuous variables summarised with mean (SD), median (IQR)

Table 11: Radiographic

	Polyarticular N =	Oligoarticular N =	Total N =
Average hand erosion score			
Missing			
Average feet erosion score			
Missing			
Total erosion score			
Missing			
Average hand JSN score			
Missing			
Average feet JSN score			
Missing			
Total JSN score			
Missing			
Proportion of patients with hand erosion			
Missing			
Proportion of patients with feet erosion			
Missing			
Proportion of patients with any erosion			
Missing			
Sharp-van der Heijde hand score			
Missing			
Sharp-van der Heijde feet score			
Missing			
Sharp-van der Heijde total score			
Missing			

*Categorical variables summarised with n (%)

*Continuous variables summarised with mean (SD), median (IQR)

Notes: Inflammatory Back Pain (IBP) is calculated by five components: Age at onset <40 years, Insidious onset, Improvement with exercise, No improvement with rest, Pain at night (with improvement upon getting up); if any four of them would be positive.

Table 10: Clinical characteristics by sex

	Female N =	Male N =	Total N =
PASDA			
Missing			
TJC			
Missing			
SJC			
Missing			
Joints involved			
Polyarticular			
Oligoarticular			
Missing			
Current psoriasis			
No			
Yes			
Missing			
PASI			
Missing			
Proportion with any enthesitis			
Missing			
Total enthesitis count			
Missing			
Proportion with any Dactylitis			
Missing			
Dactylitis count			
Missing			
Proportion with Axial Disease			
BASMI*			
Missing			
BASDAI*			
Missing			
PsAID			
Missing			
WPAI score			
1) Percent work time missed due to health			
Missing			
2) Percent impairment while working due to health			
Missing			
3) Percent overall work impairment due to health			
Missing			
4) Percent activity impairment due to health			
Missing			
Duration of PsA (month)			
Missing			
Sharp-van der Heijde total score			
Missing			
Total erosion score			
Missing			
Total JSN score			
Missing			

* Calculated just for patients who have Axial disease (these are the patients that filled in the BASMI n=90, BASDAI n =74)

Categorical variables summarised with n (%)

Continuous variables summarised with mean (SD), median (IQR)

4.2 Treatment compliance & details of the interventions

Compliance with the relevant treatment is defined by the treating clinician's assessment of whether participants have taken their drugs as prescribed (yes/ no).

Possible treatment options including conventional systemic disease-modifying anti-rheumatic drugs (csDMARDs), biologic DMARDs (bDMARDs) and targeted synthetic DMARDs (tsDMARDs) but still allows physician discretion dependent on individual patient circumstances and wishes.

Table 6: Compliance with standard care

	Total n (%)
Compliant with drugs 0-12 weeks	
Compliant with drugs 12-24 weeks	
Compliant with drugs 24-36 weeks	
Compliant with drugs 36-48 weeks	

4.3 Cohort Results

The primary analysis will report the outcomes together with 95% confidence intervals. The estimates for the participants receiving the standard treatment (pragmatic 'step-up' 'treat to target' treatment) in MONITOR will be compared informally to the outcomes for the relevant trial arms of the TICOPA trial (i.e. no formal statistical tests will be performed). Supplementary analysis will be undertaken to explore the many baseline prognostic factors to examine which patients most benefit from this treatment and whether important subgroups can be defined.

The nature and mechanism for missing variables and outcomes will be investigated.

Primary outcome

The primary outcome will be the proportion of patients achieving a good response level (reduction from baseline of ≥ 1.6 and final score of ≤ 3.2) measured by the PsA Disease Activity Score (PASDAS) at 48 weeks. The PASDAS is a weighted index comprising assessments of joints, function, acute-phase response, quality of life (QOL), and patient and physician MD by VAS. It is represented by the formula:

$$\text{PASDAS} = (((0.18 \times \sqrt{\text{Physician global VAS}}) + (0.159 \times \sqrt{\text{Patient global VAS}}) - (0.253 \times \sqrt{\text{SF36} - \text{PCS}}) + (0.101 \times \text{LN}(\text{Swollen joint count} + 1)) + (0.048 \times \text{LN}(\text{Tender joint count} + 1)) + (0.23 \times \text{LN}(\text{Leeds Enthesitis Count} + 1)) + (0.377 \times \text{LN}(\text{Dactylitis count} + 1)) + (0.102 \times \text{LN}(\text{CRP} + 1)) + 2) \times 1.5$$

where LN = natural logarithm, PCS = physical component summary scale of SF36, CRP = C-reactive protein in mg/l, SF36 = Medical Outcomes Study Short Form-36. All VAS scores are 0–100 mm. Swollen joint count is 66 joints, and tender joint count 68. The score range of the PASDAS is 0–10, with worse disease activity represented by higher scores. The primary outcome will be reported according to Table 7. Each cell will report the numbers and proportions of individuals meeting the specified constraints across the final PASDAS score and improvement.

Table 7: Primary outcome

	Improvement		
Final PASDAS score	>1.6	≤ 1.6 but >0.8	≤ 0.8
≤ 3.2	Good	Moderate	Poor
>3.2 but <5.4	Moderate	Moderate	Poor
≥ 5.4	Moderate	Poor	Poor

Secondary outcomes

The secondary outcomes in MONITOR are listed below and will be reported with mean and standard deviations (median and IQR) for continuous outcomes and frequency and percentages for categorical outcomes.

- Time from baseline to first achieving minimal disease activity (MDA) and PASDAS good response.
- Proportion achieving PASDAS good response at 24, 48 and 96 weeks.
- Proportion achieving PASDAS moderate response at 24, 48 and 96 weeks.
- Change in PsA impact of disease (PSAID) score from baseline to follow up.
- Proportion achieving PSAID patient acceptable symptom state (<2 very low, <3 low, <5 moderate, ≥5 high) at follow up.
- Change in work productivity (absenteeism, presenteeism and productivity loss)
- Side effects reported at each time point, combined with the Treatment satisfaction questionnaire for medication (TSQM). There are three existing versions of the TSQM: Version 1.4, Version II, and Version 9. Version 1.4 of TSQM was designed as a general measure of treatment satisfaction with medication, it has 14 items with 4 domains: Effectiveness, Side Effects, Convenience, Global Satisfaction.

4.4 Safety

Only SAEs occurring to a participant where in the opinion of the CI the event was 'related' (resulted from administration of any of the research procedures) and 'unexpected' in relation to those procedures will be reported, i.e. SUSARs are reported.

Table 8: Summary of SUSARs

	Total n
Number of participants with relevant SUSARs	
Number of SUSARs	
Numbers of deaths	

Table 9: Listing of SUSARs

Event log number	Event description	Classification of event (SAE, SAR,SUSAR)	Date of study entry	Date of event	System Organ Class
n/a	n/a	n/a	n/a	n/a	n/a

5. OTHER

6. REFERENCES

7. GLOSSARY OF ABBREVIATIONS

ACPA	Anti-citrullinated peptide antibodies
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ALT	alanine aminotransferase
ANA	Antinuclear antibodies
BASDAI	Bath Ankylosing Spondylitis Disease Activity Index
BASMI	Bath ankylosing spondylitis metrology index
BASFI	Bath Ankylosing Spondylitis Functional Index
BSA	Body surface area
BSR	British Society for Rheumatology
CASPAR	CIASsification criteria for Psoriatic Arthritis
CI	Chief Investigator
CRF/eCRF	Case Report Form / electronic Case Report Form
CRP	C-reactive protein
DMARDs/csDMARD/tsDMARD	Disease Modifying Anti-Rheumatic Drugs / Conventional systemic disease-modifying anti-rheumatic drugs / targeted synthetic DMARDs
DSMC	Data & Safety Monitoring Committee
eGFR	Estimated Glomerular Filtration Rate
EMS	Early morning stiffness
EuroQol	European Quality of Life
EULAR	EUropean League Against Rheumatism
FBC	full blood count
FCS/DMSO	Fetal calf serum/ dimethyl sulfoxide
GCP	Good Clinical Practice
GP	General Practitioner
HAQ	Health assessment questionnaire
HRA	Health Research Authority
HRQoL	Health-related quality of life
IBP	Inflammatory back pain
ICER	Incremental cost-effectiveness ratio
ICF	Informed Consent Form
IPAQ	International physical activity questionnaire
LEI	Leeds enthesitis index
LFTs	Liver function tests
MDA	Minimal disease activity