Participant flow

Assessed for eligibility for
MONITOR (n= 926)

Excluded (n= 480)
☐ Not PSA (n=52)
☐ CASPAR criteria not met (n=90)
☐ Previous treatment with DMARDs/ TNFi
  (n=209)
☐ Patient declined (n=64)
☐ No time available (n=3)
☐ Patient unsuitable/ unwilling to consent
  (n=39)
☐ No room at clinic/staff unavailable (n=6)
☐ Awaiting outcome of investigations (n=2)
☐ Previous reaction to biologics (n=1)
☐ referred to biologics (n=1)
☐ Other (n=1)
☐ Planning children (n=1)
☐ Moved area/Difficulty to travel (n=4)
☐ Discharged from hospital care n=1
☐ Discharged continued treatment at another
  hospital (n=1)
☐ No comment (n=3)

Enrolment

SPEED not open to
recruitment (n= 136*)

Included in MONITOR (n=446)

Not Eligible for SPEED (n=118)
Neither poly nor oligo with poor prognostic
factors (n=41)
☐ Didn't consent to future studies in MONITOR
  (n=11)
☐ Patient has significant axial disease (n=10)
☐ Safety issue preventing use of some of
  DMARDs included in study (n=20)
☐ Paused due to Covid (n= 9)
☐ Planning pregnancy (n= 1)
☐ Declined (n=11)
☐ Surgery (n= 1)
☐ No reason (n= 6)
☐ Already on biologics (n=2)
☐ Fear of needles (n=1)
☐ Loss to follow up (n=4)
☐ Blood bottles shortage (n=1)

Screened for SPEED
(n= 310)

Randomized into SPEED
(n=192)

Allocation

Allocated to standard step-up care (n= 64)
Received Step-up care (n= 63)
Declined treatment offered (n=1)

Allocated to Combo DMARD (n= 63)
Received Combo DMARD (n= 58)
Declined treatment offered (n=5)

Allocated to TNFi (n= 65)
Received TNFi (n= 61)
Declined treatment offered (n=4)

Follow-Up

Primary outcome available at 24-weeks
(ITT): (n = 39)
Missing primary outcome (n=25):
  • n= 19 had at least one PASDAS
    score component missing,
  • n=6 withdrew before week 24

Primary outcome available at 24-weeks
(ITT): (n= 47)
Missing primary outcome (n=16):
  • n= 13 had at least one PASDAS
    score component missing,
  • n=3 withdrew before week 24

Primary outcome available at 24-weeks
(ITT): (n = 53)
Missing primary outcome (n=12):
  • n= 9 had at least one PASDAS
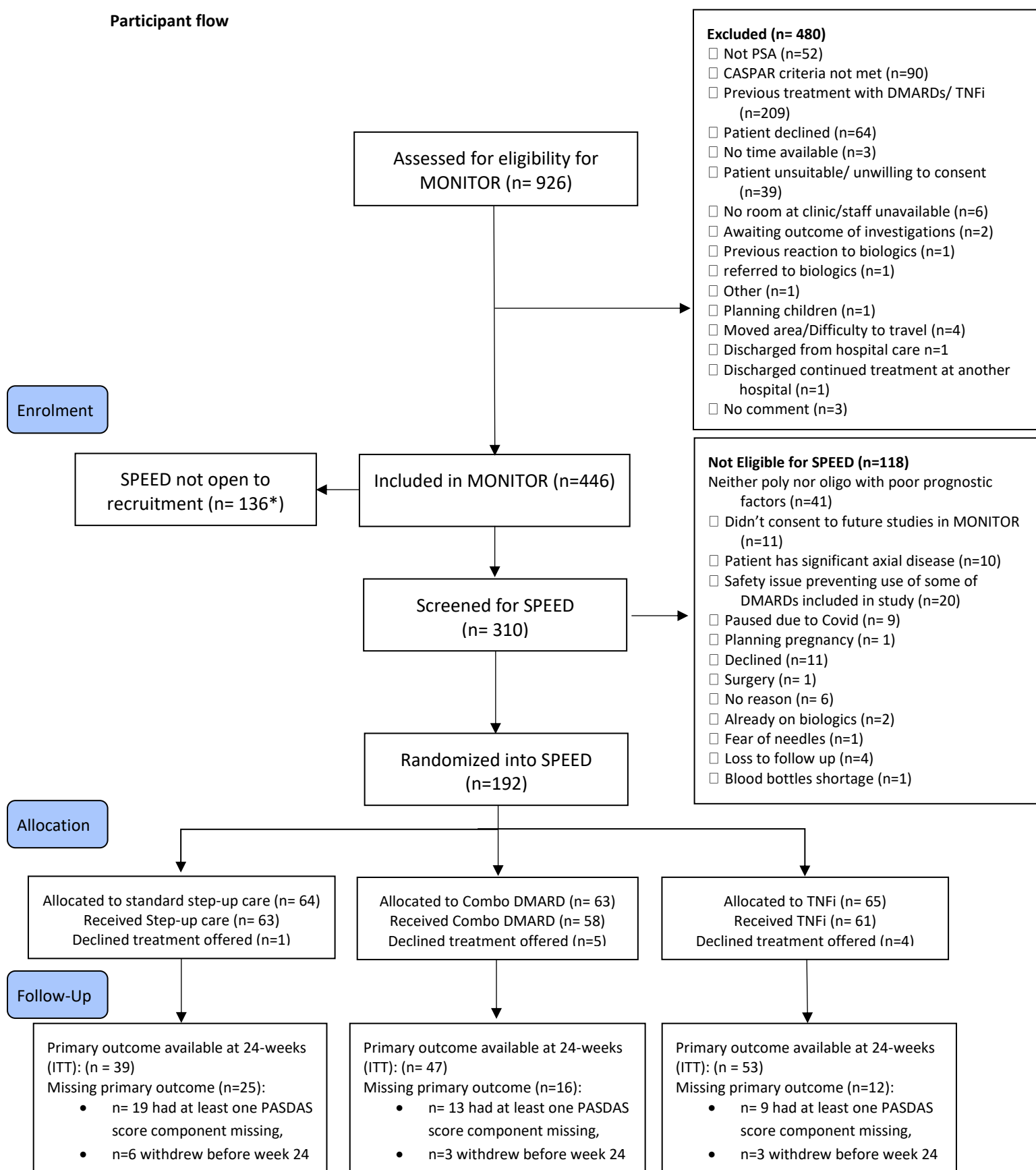   score component missing,
  • n=3 withdrew before week 24

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Baseline Characteristics – Baseline characteristics of participants included in the SPEED Trial (first four columns) and baseline characteristics of participants in the MONITOR cohort who were not enrolled in SPEED (last column).

	Standard step-up care N=64	Combo DMARD N=63	TNFi N=65	Total SPEED N=192	Total MONITOR excluding SPEED N = 254
Age (years), n, median [IQR]	64, 50·0 [34·0, 57·0]	63, 51·0 [37·0, 60·0]	65, 48·0 [34·0, 57·0]	192, 49·0 [34·0,58·0]	254, 42·5 [34·0, 54·0]
Sex, n (%)					
Female	31/64 (48·4%)	33/63 (52·4%)	28/65 (43·1%)	92/192 (47·9%)	122/254 (48·0%)
Male	33/64 (51·6%)	30/63 (47·6%)	37/65 (56·9%)	100/192 (52·1%)	132/254 (52·0%)
BMI (kg/m2), n (%)					
Underweight-normal	13/64 (20·3%)	9/62 (14·5%)	15/63 (23·8%)	37/189 (19·6%)	66/238 (27·7%)
Overweight	21/64 (32·8%)	28/62 (45·2%)	22/63 (34·9%)	71/189 (37·6%)	85/238 (35·7%)
Obese	30/64 (46·9%)	25/62 (40·3%)	26/63 (41·3%)	81/189 (42·8%)	87/238 (36·6%)
TJC, n, median [IQR]	64, 9·0 [5·0, 21·5]	63, 10·0 [5·0, 17·0]	63, 10·0 [6·0, 18·0]	190, 10·0 [5·0, 18·0]	250, 5·0 [2·0,12·0]
SJC, n, median [IQR]	64, 5·0 [2·0, 8·5]	63, 5·0 [3·0, 9·0]	63, 5·0 [3·0, 9·0]	190, 5·0 [3·0, 9·0]	250, 2·0 [1·0, 5·0]
Presence of psoriasis, n (%)	58/63 (92·1%)	58/62 (93·5%)	57/62 (91·9%)	173/187 (92·5%)	217/237 (91·6%)
PASI score, n, mean (SD)	63, 3·3 (4·7)	61, 2·8 (3·9)	62, 3·4 (3·6),	186, 3·2 (4·1)	228, 4·1 (6·2)
median [IQR]	1·9 [0·3, 3·8]	1·4 [0·6, 3·4]	1·9 [0·7, 5·4]	1·8 [0·6, 3·8]	2·1 [0·4, 4·5]
Presence of enthesitis, n (%)	33/64 (51·6%)	30/63 (47·6%)	33/63 (52·4%)	96/190 (50·5%)	132/227 (58·1%)
LEI, n, mean (SD),	25, 2·0 (1·0)	22, 2·1 (1·3)	23, 1·7 (1·1)	70, 1·9 (1·1)	89, 2·2 (1·3),
median [IQR]	2·0 [1·0, 2·0]	2·0 [1·0, 3·0]	1·0 [1·0, 2·0]	2·0 [1·0, 2·0]	2·0 [1·0, 3·0]
Presence of dactylitis, n (%)	23/64 (35·9%)	21/63 (33·3%)	20/63 (31·7%)	64/190 (33·7%)	48/222 (21·6%)
Dactylitis count, n, mean (SD)	23, 2·1 (1·3)	21, 2·2 (2·1)	20, 2·6 (2·1)	64, 2·3 (1·9)	48, 1·9 (1·1),
median [IQR]	2·0 [1·0, 3·0]	1·0 [1·0, 2·0]	2·0 [1·5, 3·0]	2·0 [1·0, 3·0]	2·0 [1·0, 2·0]
PASDAS, n, mean (SD**)**	64, 5·6 (1·2),	61, 5·5 (1·3)	61, 5·7 (1·1)	186, 5·6 (1·2)	168, 4·8 (1·4),
median [IQR]	5·5 [5·0, 6·3]	5·6 [4·6, 6·3]	5·8 [5·1, 6·3]	5·6 [4·9, 6·3]	4·9 [3·9, 5·8]
DAPSA, n, mean (SD)	64, 35·0 (18·6)	61, 34·0 (17·5)	63, 34·5 (15·4)	188, 34·5 (17·1)	177, 24·6(17·6)
median [IQR]	28·5 [21·3, 48·3]	29·6 [22·4, 40·1]	31·1 [24·9, 39·9]	29·5 [22·8, 42·0]	20·2 [13·5, 31·4]
PsAID, n, mean (SD)	64, 5·4 (2·1)	63, 5·3 (2·2)	63, 5·5 (2·0)	190, 5·4 (2·1)	234, 4·7 (2·3)
median [IQR]	6·1 [3·8, 7·0]	5·3 [3·5, 7·2]	6·2 [3·5, 7·2]	5·6 [3·5, 7·1]	4·7 [2·8, 6·6]
HAQ, n, mean (SD)	64, 1·2 (0·7)	63, 1·2 (0·6)	63, 1·2 (0·6)	190, 1·2 (0·6)	236, 0·8 (0·7)
median [IQR]	1·2 [0·8, 1·7]	1·2 [0·8, 1·6]	1·1 [0·8, 1·6]	1·2 [0·8, 1·6]	0·8 [0·2, 1·2]
SF-36, n, mean (SD)	64, 32·6 (9·9)	63, 34·2 (10·6)	63, 30·8 (9·8)	190, 32·5 (10·2)	210, 36·6 (10·6)
median [IQR]	31·8 [25·0, 41·2]	32·5 [26·7, 45·2]	30·3 [23·5, 39·0]	31·3 [24·8, 39·6]	36·9 [28·1, 45·1]
CRP, n, mean (SD)	64, 17·7 (31·6)	62, 20·2 (28·3)	63, 11·5 (16·6)	189, 16·4 (26·4) 6·0	181, 12·1 (22·6)
median [IQR]	6·8 [2·8, 18·9]	9·1 [3·6, 22·3]	5·3 [2·0, 14·0]	[2·9, 18·8]	4·0 [2·0, 11·0]
RF negative, n (%)	49/54 (90·7%)	49/53 (92·5%)	49/50 (98·0%)	147/157 (93·6%)	180/191 (94·2%)

DMARD: disease-modifying anti-rheumatic drug; **BMI:** Body Mass Index**; TJC:** Tender Joint Count; **SJC:** Swollen Joint Count; **PASI:** Psoriasis Area and Severity Index; **LEI:** Leeds enthesitis index**; PASDAS:** Psoriatic Arthritis Disease Activity Score; **DAPSA:** Disease Activity index in Psoriatic Arthritis; **PsAID:** Psoriatic Arthritis Impact of Disease; **HAQ:** Health Assessment Questionnaire; **SF-36:** Short Form Health Survey; **CRP:** C-reactive protein; **RF:** Rheumatoid Factor

Outcome measures – Primary outcome and key secondary outcomes at 24 and 48 weeks

Outcome	Time point (weeks)	Standard step-up care N= 64	Combo DMARD N= 63	TNFi N= 65	Comparison[1]	Adjusted mean differences (95% CI)	P-value
PASDAS (Primary outcome) n, mean (SD), median [IQR]	24	39, 4·7 (1·5), 4·4 [3·9, 5·6]	47, 4·0 (1·5), 4·4 [2·6, 5·2]	53, 3·6 (1·9), 3·5 [2·1, 4·7]	Combo DMARD vs· Step-up care	-0·80 (-1·40, -0·19)	0·0096
					TNFi vs· Step-up care	-1·13 (-1·78, -0·49)	0·0006
					TNFi vs· Combo DMARD	-0·44 (-1·10, 0·22)	0·1952
PASDAS, n, mean (SD)	48	45, 4·1 (1·8)	45, 3·8 (1·5)	49, 3·5 (1·7)	Combo DMARD vs· Step-up care	-0·48 (-1·11, 0·16)	0·1444
					TNFi vs· Step-up care	-0·69 (-1·31, -0·07)	0·0298
PSAID, n, mean (SD)	24	43, 3·8 (2·1)	51, 3·5 (2·4)	54, 3·1 (2·5)	Combo DMARD vs· Step-up care	-0·27 (-1·07, 0·54)	0·5187
					TNFi vs· Step-up care	-0·72 (-1·53, 0·09)	0·0795
	48	45, 3·4 (2·5)	46, 3·3 (2·6)	51, 3·0 (2·5)	Combo DMARD vs· Step-up care	-0·33 (-1·15, 0·48)	0·4229
					TNFi vs· Step-up care	-0·52 (-1·33, 0·29)	0·2058

Outcome	Time point (weeks)	Step-up care N= 64	Combo DMARD N= 63	TNFi N= 65	Comparison[1]	Odds Ratio (CI 95%)	P-value
PASDAS (Good vs rest), n (%)	24	3/39 (7·7%)	15/46 (32·6%)	24/52 (46·2%)	Combo DMARD vs· Step-up care	6·22 (1·63, 23·67)	0·0074
					TNFi vs· Step-up care	11·05 (2·98, 40·97)	0·0003
					TNFi vs· Combo DMARD	1·83 (0·79, 4·21)	0·1579
	48	11/45 (24·4%)	15/43 (34·9%)	20/49 (40·8%)	Combo DMARD vs· Step-up care	1·78 (0·70, 4·53)	0·2271
					TNFi vs· Step-up care	2·10 (0·85, 5·18)	0·107
PASDAS (Good and Moderate vs Poor), n (%)	24	20/39 (51·3%)	29/46 (43·0%)	39/52 (75·0%)	Combo DMARD vs· Step-up care	1·81 (0·71, 4·59)	0·2137
					TNFi vs· Step-up care	3·16 (1·18, 8·45)	0·0217
	48	25/45 (55·5%)	31/43 (72·1%)	37/49 (75·5%)	Combo DMARD vs· Step-up care	2·09 (0·81, 5·38)	0·1281
					TNFi vs· Step-up care	2·22 (0·85, 5·80)	0·105
MDA[2], n (%)	24	4/42 (9·5%)	15/51 (29·4%)	18/54 (33·3%)	-	-	-
	48	11/44 (25·0%)	12/45 (26·7%)	16/51 (31·4%)	-	-	-
PsAID acceptable symptom state (<4)[2], n (%)	24	24/43 (55·8%)	28/51 (54·9%)	33/54 (61·1%)	-	-	-
	48	26/45 (57·8%)	29/46 (63·0%)	32/51 (62·7%)	-	-	-

[1] Treatment "B" is the reference group in comparison of "A" vs· "B".

[2] No analytical or comparative evaluation was conducted; the report presents only descriptive findings.

DMARD: disease-modifying anti-rheumatic drug; **PASDAS**: Psoriatic Arthritis Disease Activity Score; **PsAID**: Psoriatic Arthritis Impact of Disease; **MDA**: Minimum Disease Activity

Adverse events: Safety outcomes for all randomised participants and treatment satisfaction for medication (at 24 and 48 weeks)

Outcome	Time point (weeks)	Standard step-up care N = 64	Combo DMARD N = 63	TNFi N = 65
Serious adverse events[1]	0-48	2/64 (3·1%)	0 (0%)	1/65 (1·5%)
Serious adverse reactions[1]	0-48	1/64 (1·6%)	0 (0%)	1/65 (1·5%)
Medication side effects[1]				
Headache	0-24	9/54 (16·7%)	11/55 (20·0%)	5/57 (8·8%)
Nausea	0-24	19/54 (35·2%)	20/55 (36·4%)	15/57 (26·3%)
Diarrhea	0-24	6/54 (11·1%)	8/55 (14·5%)	6/57 (10·5%)
Liver abnormalities	0-24	11/54 (20·4%)	19/55 (34·5%)	18/57 (31·6%)
Infections	0-24	3/54 (5·6%)	3/55 (5·5%)	6/57 (10·5%)
Treatment Satisfaction[2]				
Effectiveness	24	41, 58·7 (20·1)	49, 61·1 (25·1)	53, 70·1 (24·7)
	48	43, 55·9 (20·9)	46, 64·7 (27·3)	49, 67·5 (25·5)
Side Effects	24	41, 70·6 (27·8)	48, 73·6 (28·5)	53, 87·9 (20·4)
	48	43, 75·3 (29·7)	46, 81·8 (23·3)	49, 83·9 (25·5)
Convenience	24	41, 80·2 (17·0)	49, 79·9 (17·2)	53, 79·7 (16·1)
	48	43, 77·3 (20·4)	46, 79·0 (18·1)	49, 85·0 (15·3)
Global Satisfaction	24	41, 58·7 (23·4)	49, 65·9 (29·0)	53, 74·9 (25·1)
	48	43, 56·3 (25·8)	46, 71·4 (24·7)	49, 72·0 (25·9)

[1] Reported as n (%)

[2] Reported as n, mean (SD)