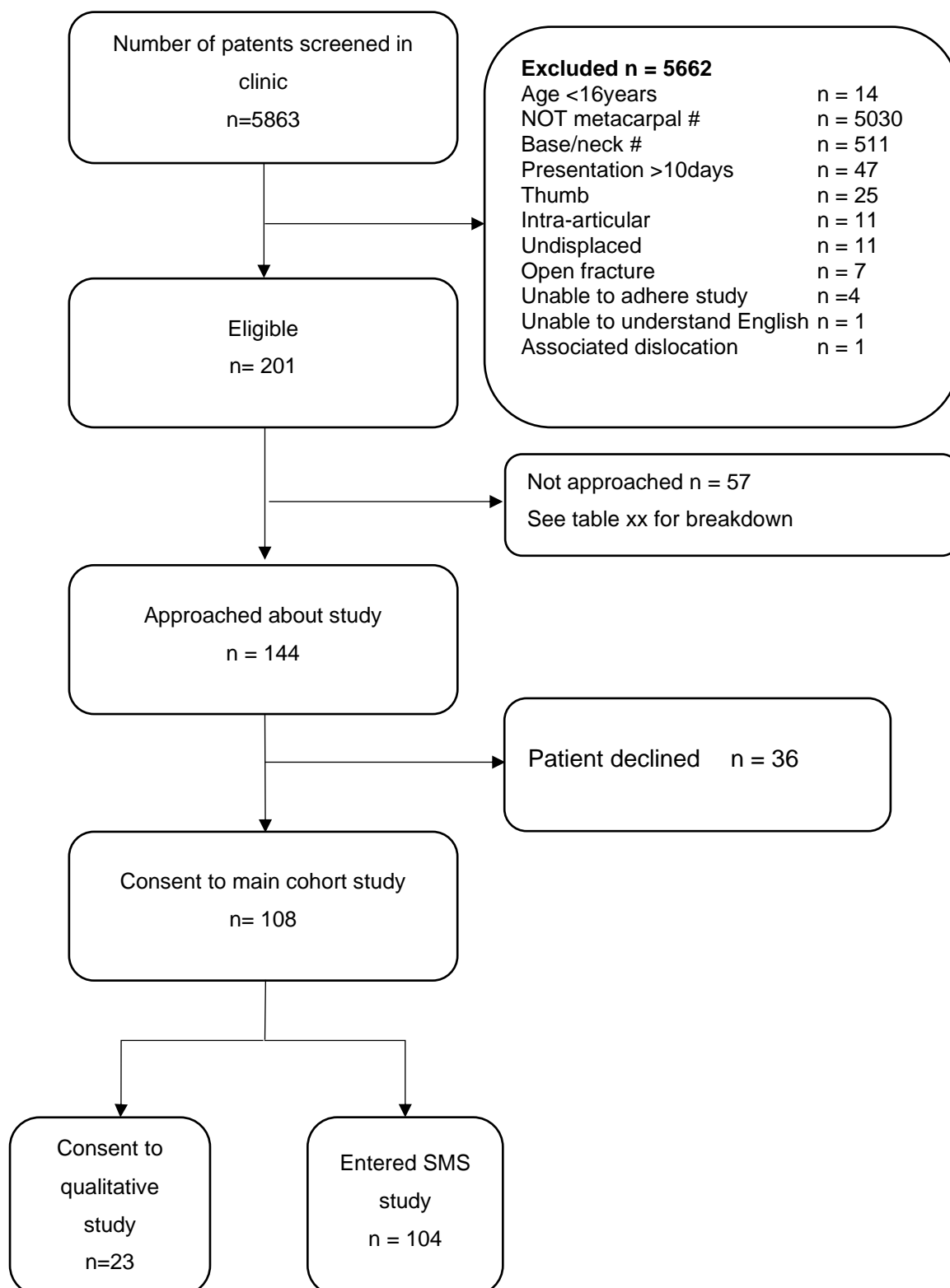


## Basic Results FACTS study (ISRCTN13922779)

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### Participant flow



## Baseline characteristics

	Non-surgical n = 65	Surgical n = 12	Treatment unknown n = 31
<b>Age</b>			
Mean[sd]	40 [18.2]	31 [11.1]	33 [15.4]
Median [25 <sup>th</sup> , 75 <sup>th</sup> ]	34 [24, 52]	29 [23, 36]	31 [18, 40]
Min, max	18, 85	19, 53	16, 69
<b>Gender, n (%)</b>			
Male	41 (63)	9 (75)	23 (74)
Female	24 (37)	3 (25)	8 (25)
<b>Ethnicity, n (%)</b>			
White	54 (85)	11 (92)	25 (81)
Indian	3 (5)	0	0
Pakistani	2 (3)	1 (8)	2 (6)
Black Caribbean	1 (2)	0	1 (3)
Chinese	1 (2)	0	0
Mixed Race	3 (5)	0	1 (3)
Other Asian (Non-Chinese)	0	0	1 (3)
Other	1 (2)	0	1 (3)
<b>Employment status, n (%)</b>			
Full-time employed	31 (48)	5 (42)	16 (52)
Part-time employed	5 (8)	0	2 (6)
Self-employed	8 (12)	2 (17)	5 (16)
Student	10 (15)	3 (25)	5 (16)
Retired	6 (9)	0	0
Unemployed	4 (6)	2 (17)	3 (10)
Other	1 (2)	0	0
<b>Laterality of fracture, n (%)</b>			
Left	27 (42)	3 (25)	
Right	38 (58)	9 (75)	
Missing			31
<b>Dominant hand affected, n (%)</b>			
Yes	43 (66)	10 (83)	
No	22 (34)	2 (17)	
Missing			31

<b>Source of referral, n (%)</b>				
	ED	45 (69)	11 (92)	24 (77)
	MIU/Walk-in Centre	15 (23)	1 (8)	6 (19)
	Other	5 (8)	0	1 (3)
<b>Time from injury to presentation (days)</b>				
	Mean[sd]	1 [1.9]	<1 [0.2]	1.1 [1.8]
	Median [25th, 75th centile]	1 [<1, 1]	<1 [<1, <1]	1 [0, 1]
	Min, max	<1, 9	<1, 1	0, 7
<b>Baseline PROMs, mean [SD]</b>				
	PEM	48.6 [10.9]	56.1 [8.4]	47.8 [8.2]
	Quick-DASH	37.6 [8.2]	41.7 [7]	38.6 [7.4]
	PROMIS-UE	27.3 [8.6]	28.9 [11]	27.8 [10.6]
	EQ-5D-5L Index	0.600 [0.200]	0.600 [0.200]	0.600 [0.199]
	EQ-5D-5L VAS*	75.0 [15.4]	72.0 [20.2]	81.6 [14.7]
	Missing VAS score	2	0	1

## Outcome measures

Full completion of study by site. Data are n (%)

Site	Baseline n = 108	6 weeks n = 77	3months n = 57	6 months n = 49
A	16 (100)	11 (61)	8 (50)	7 (44)
B	25 (100)	18 (72)	12 (48)	11 (44)
C	1 (100)	1 (100)	1 (100)	1 (100)
D	10 (100)	5 (50)	3 (30)	3 (30)
E	56 (100)	42 (75)	34 (61)	27 (48)

Adherence to follow-up by treatment modality and reminders required to prompt response.  
Percentages may not sum to 100 due to rounding. SMS: Short Message Service.

	Non-surgical treatment n = 65	Surgical treatment n = 12	Treatment unknown n = 31	Total n = 108
<b>6 weeks</b>				
<b>Research clinic, n (%)</b>				
Invited				108
Responded to invite				90 (83)
Attended	65 (84)	12 (16)	0	77 (71)
Virtual	60 (85)	11 (15)	0	71 (92)
In-person clinic	5 (83)	1 (17)	0	6 (8)
Did not attend clinic			31	31 (29)
<b>3 months</b>				
<b>Questionnaires, n (%)</b>				
Delivered				104
Fully completed	50 (72)	8 (12)	11 (16)	69 (66)
Partially completed	2 (67)	1 (33)	0	3 (3)
Did not complete questionnaire				32 (31)
<b>Days until response</b>				
Mean [sd]	7 [8]	18 [28]	18 [16.7]	10 [14]
Median [25 <sup>th</sup> , 75 <sup>th</sup> centile]	6 [0, 12]	6 [5, 11]	14 [3, 32]	6 [1, 16]
Min, max	0, 33	0, 88	0, 53	0, 88
<b>Number of reminders required, n (%)</b>				
No reminder required	37 (80)	5 (11)	4 (11)	46 (64)
One SMS	4 (50)	3 (38)	1 (13)	8 (11)
Two SMS	4 (67)	1 (17)	1 (17)	6 (8)
SMS + phone call	7 (58)	0	5 (42)	12 (17)
<b>6 months</b>				
<b>Questionnaires, n (%)</b>				
Delivered				104
Fully completed	46 (82)	7 (13)	3 (5)	56 (54)
Partially completed	3 (75)		1 (25)	4 (4)
Did not complete questionnaire				44 (42)
<b>Days until response</b>				
Mean [sd]	9 [9]	6 [6]	2 [3]	9 [9]
Median [25 <sup>th</sup> , 75 <sup>th</sup> centile]	8 [1, 13]	4 [1, 13]	1 [0, 6]	7 [1, 13]
Min, max	0, 36	0, 15	0, 7	0, 36
<b>Number of reminders required, n (%)</b>				
No reminder required	25 (51)	6 (86)	2 (50)	31 (55)
One SMS	9 (18)	1 (14)	0	10 (18)
Two SMS	5 (10)	0	0	5 (9)
SMS + phone call	10 (20)	0	2 (50)	10 (18)

Summary of change in patient reported outcome measures from baseline at 6 weeks, 3 months and 6 months

	Change from baseline		
	6 weeks	3 months	6 months
<b>PEM</b>			
Mean [SD]	-22.4 [11.3]	-27.2 [11.9]	-29.7 [12.8]
Median [25 <sup>th</sup> , 75 <sup>th</sup> centile]	-22 [-30, -16]	-28 [-36, -22]	-31 [-40, -22]
N	77	72	49
Missing	31	36	59
<b>Quick-DASH</b>			
Mean [SD]	-17.2 [8.8]	-21.5 [9.8]	-23.8 [8.0]
Median [25 <sup>th</sup> , 75 <sup>th</sup> centile]	-18 [-24, -11]	-23 [-28, -16]	-23 [-29, -18]
N	77	71	50
Missing	31	37	58
<b>PROMIS-UE</b>			
Mean [SD]	14.1 [12.1]	21.1 [10.5]	24.1 [10.1]
Median [25 <sup>th</sup> , 75 <sup>th</sup> centile]	12.2 [7.6, 2.3]	21.0 [14.7, 28.9]	24.5 [17.5, 30.6]
N	77	69	59
Missing	31	39	59
<b>EQ-5D-5L index</b>			
Mean [SD]	0.16 [0.27]	0.24 [0.24]	0.33 [0.22]
Median [25 <sup>th</sup> , 75 <sup>th</sup> centile]	0.16 [0.00, 0.33]	0.23 [0.06, 0.39]	0.30 [0.18, 0.48]
N	77	71	59
Missing	31	37	49
<b>EQ-5D-5L VAS</b>			
Mean [SD]	8.8 [16.0]	9.3 [20.86]	9.6 [21.3]
Median [25 <sup>th</sup> , 75 <sup>th</sup> centile]	5 [0, 15]	9.5 [-2.5, 20]	10 [-5, 21]
N	74	68	56
Missing	34	40	52

Minimal clinically important difference (MCID) and minimum detectable change (MDC) for patient reported outcome measures using different methods. ROC: Receiver operating characteristic

PROM	n	MDC	MCID		
			Distribution methods	Anchor methods	ROC curve method
PEM	56	25.4	1.9 – 17.8	9.4 – 26.6	29 - 35
Quick-DASH	55	18.7	3.5 – 13.3	4.6 – 21.2	20 - 21
PROMIS	55	19.1	1.5 – 13.5	5.2 – 20.4	19.1 - 19.3
EQ-5D-5L index	55	0.5	0.04 – 0.4	0.1 - 0.2	NA
EQ-5D-5L VAS	53	42.1	3.4 – 29.8	NA	NA

### Adverse Events

There were no adverse events associated with this study.