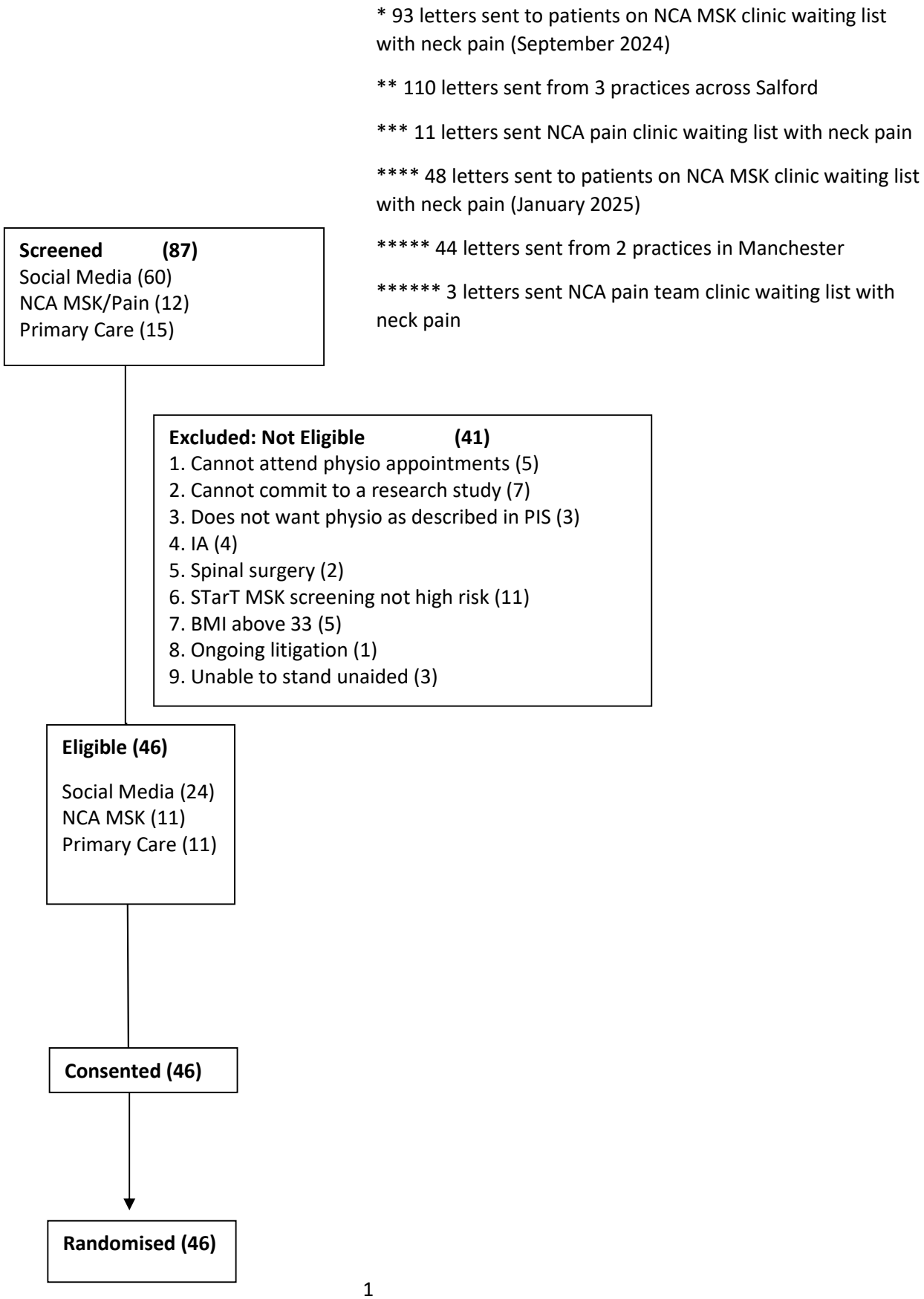
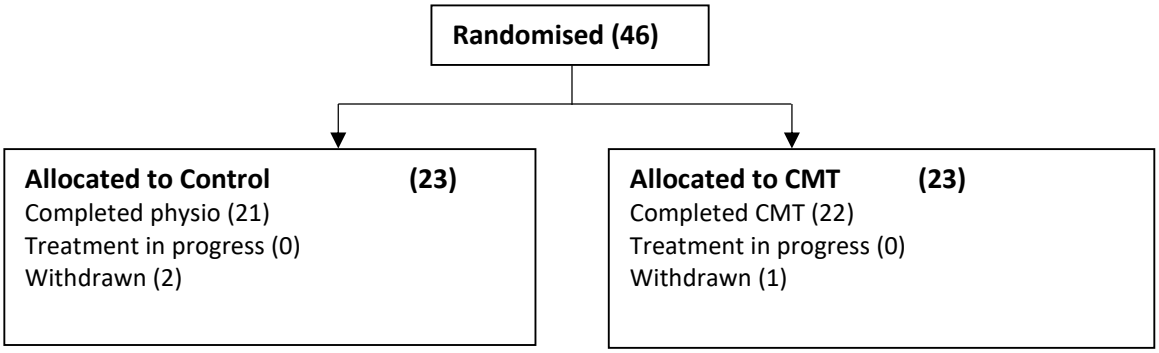
CONSORT flow diagram – Screening and Recruitment

Figure 1a- COMPIN Study CONSORT diagram - Screening and Recruitment



1b. CONSORT flow diagram – Randomisation

Figure 1b - Study CONSORT diagram – Randomisation and treatment progress



Formal Withdrawals

The following table shows all the data regarding withdrawals at different stages during the trial.

	Number	Percentage (%)
Number of Participants consented	46	N/A
Number of Participants randomised	46	N/A
Total number of withdrawals (% consented) **Reason for withdrawal** Did not attend first two appointments and was not contactable (1) Moved out of area before treatment started (1) No reason given (1)	3	6.5
Number of withdrawals after Consenting (% of consented)	/	/
Number of withdrawals after Randomisation (% of randomised) Control Intervention	3 2 1	6.5 4.3 2.2

Table 1: Diversity characteristics

Category	Domain	Intervention (n=23)	Control (n=23)	Overall (n=46)
Disability	Yes – some/small barriers or limitations	3	2	5
	No	19	18	37
	Prefer not to say	1	3	4
Ethnicity	Indian	0	1	1
	Pakistani	1	2	3
	Any other Asian background	1	0	1
	African	1	1	2
	Caribbean	0	1	1
	English / Welsh / Scottish / Northern Irish	17	12	29
	Irish	1	1	2
	Any other white background	0	2	2
	Latina/Latino/Latinx	0	1	1
	Judiasm	1	0	1
	White south European	0	1	1
	Malaysian	1	0	1
	Cypriot	0	1	1
Religion	No religion	8	4	12
	Bhuddist	1	0	1
	Christian	8	15	23
	Hindu	1	0	1
	Jewish	1	0	1
	Muslim	1	4	5
	Spiritual	1	0	1
	Prefer not to say	2	0	2
Socioeconomic	Modern professional	9	4	13
	Senior, middle or junior managers	3	1	4
	Clerical and intermediate occupations	1	1	2
	Technical and craft occupations	4	4	8
	Routine, semi-routine and manual	3	10	13
	Long-term unemployed	1	0	1
	Small business owners	1	2	3
	Other	1	1	2

Table 2: Baseline demographic characteristics and baseline health outcomes. Mean (SD) are given unless stated otherwise.

Baseline characteristics	CMT (n= 23)	PiP (n=23)	Total (n=46)
Age (years)	55 (11.5)	60 (10)	57.5 (10.75)
Gender: Females, n (%)	14/23 (56%)	11/23 (48%)	25/46 (54%)
BMI (Kg/m^2)	25.4 (3.4)	25.45 (3.0)	28.0 (2.8)
Neck Disability Index (NDI)	17.6 (6.2)	16.8 (10.5)	17.2 (8.35)
Pain Catastrophising Scale (PCS)	18.1 (10.5)	16.4 (13.3)	17.25 (11.9)
Tampa Scale of Kinesiophobia	33.2 (5.1)	29.7 (6.5)	31.45 (5.8)
Numerical Rating Scale (NRS)	5.1 (2.0)	5.5 (2.3)	5.3 (2.15)
STarT MSK Tool	11.8 (3.6)	11.4 (3.9)	11.6 (3.75)
EQ-5D-5L	10.7 (2.8)	10.9 (4.6)	10.8 (3.7)

Table 3: Mean (SD) for each outcome at 14 weeks post-randomisation for the two groups

Outcome	14 weeks	
	CMT (n=20)	**PiP (n=17)**
Neck Disability Index	12.2 (7.3)	12.1 (10.2)
Pain catastrophizing scale	9.1 (12.3)	12.5 (15.5)
Numerical Rating Scale	2.3 (2.2)	3.1 (2.3)
Tampa scale of kinesiophobia	22.5 (9.8)	22.8 (10.4)
EQ-5D-5L	8.0 (1.9)	9.4 (4.0)

Table 3: Mean (SD) for each outcome at 26 weeks post-randomisation for the two groups *Neck Disability Index and EQ-5D-5L taken as minimum data set at 26 weeks

Outcome	26 weeks	
	CMT (n=16)	**PiP (n=19)**
Neck Disability Index	10.5 (5.4)	12.6 (11.7)
Pain catastrophizing scale	4.2 (2.3)	13.3 (12.0)
	26 weeks	
	CMT (n=12)	**PiP (n=14)**
Numerical Rating Scale	2.6 (2.0)	4.0 (2.5)
Tampa scale of kinesiophobia	24.2 (4.6)	25.0 (7.4)
EQ-5D-5L	8.1 (2.0)	9.3 (4.8)

Table 4: Mean (SD) for each outcome at 26 weeks post-randomisation for the two groups *Neck Disability Index and EQ-5D-5L taken as minimum data set at 26 weeks

Outcome	26 weeks	
	CMT (n=16)	**PiP (n=19)**
Neck Disability Index	10.5 (5.4)	12.6 (11.7)
Pain catastrophizing scale	4.2 (2.3)	13.3 (12.0)
	26 weeks	
	CMT (n=12)	**PiP (n=14)**
Numerical Rating Scale	2.6 (2.0)	4.0 (2.5)
Tampa scale of kinesiophobia	24.2 (4.6)	25.0 (7.4)
EQ-5D-5L	8.1 (2.0)	9.3 (4.8)

Table 5: Within-group change in outcome measures from baseline to 14 weeks with effect sizes and 95% confidence intervals (CI).

Outcome	CMT (n=20)			PIP (n=17)		
	Change	Effect size	95% CI	Change	Effect size	95% CI
Neck Disability Index	-6.4	-0.89	-8.48, -4.22	-5.0	-0.48	-7.61, -2.39
Pain catastrophizing scale	-9.1	-0.79	-14.21, -3.85	-3.9	-0.27	-9.40, 1.73
Numerical Rating Scale	-2.8	-1.33	-3.95, -1.55	-2.4	-1.03	-3.69, -1.02
Tampa scale of Kinesiophobia	-10.7	-1.37	-16.20, -5.20	-6.9	-0.80	-12.86, -1.02
EQ-5D-5L	-2.7	-1.12	-3.16, -2.24	-1.5	-0.36	-2.05, -1.01

Table 6: Within-group change in outcome measures from baseline to 26 weeks with effect sizes and 95% confidence intervals (CI) *Neck Disability Index and EQ-5D-5L taken as minimum data set at 26 weeks

Outcome	CMT			PIP		
	Change	Effect size	95% CI	Change	Effect size	95% CI
Neck Disability Index CMT CMT (n=16), PIP (n=19)	-7.1	-1.23	-10.08, -4.17	-4.2	-0.38	-7.28, -1.14
Pain catastrophizing scale CMT (n=12), PIP (n=14)	-9.8	-2.13	-13.69, -5.81	-3.4	-0.26	-8.22, 1.51
Numerical Rating Scale CMT (n=12), PIP (n=14)	-1.8	-0.91	-3.43, -0.23	-1.2	-0.54	-2.56, 0.13
Tampa scale of Kinesiophobia CMT (n=12), PIP (n=14)	-9.4	-2.01	-12.87, -5.96	-5.1	-0.82	-8.43, -1.72
EQ-5D-5L CMT (n=16), PIP (n=19)	-2.1	-1.06	-2.55, -1.58	-1.6	-0.35	-2.45, -0.82

Adverse events

There were no serious adverse events reported in this study.