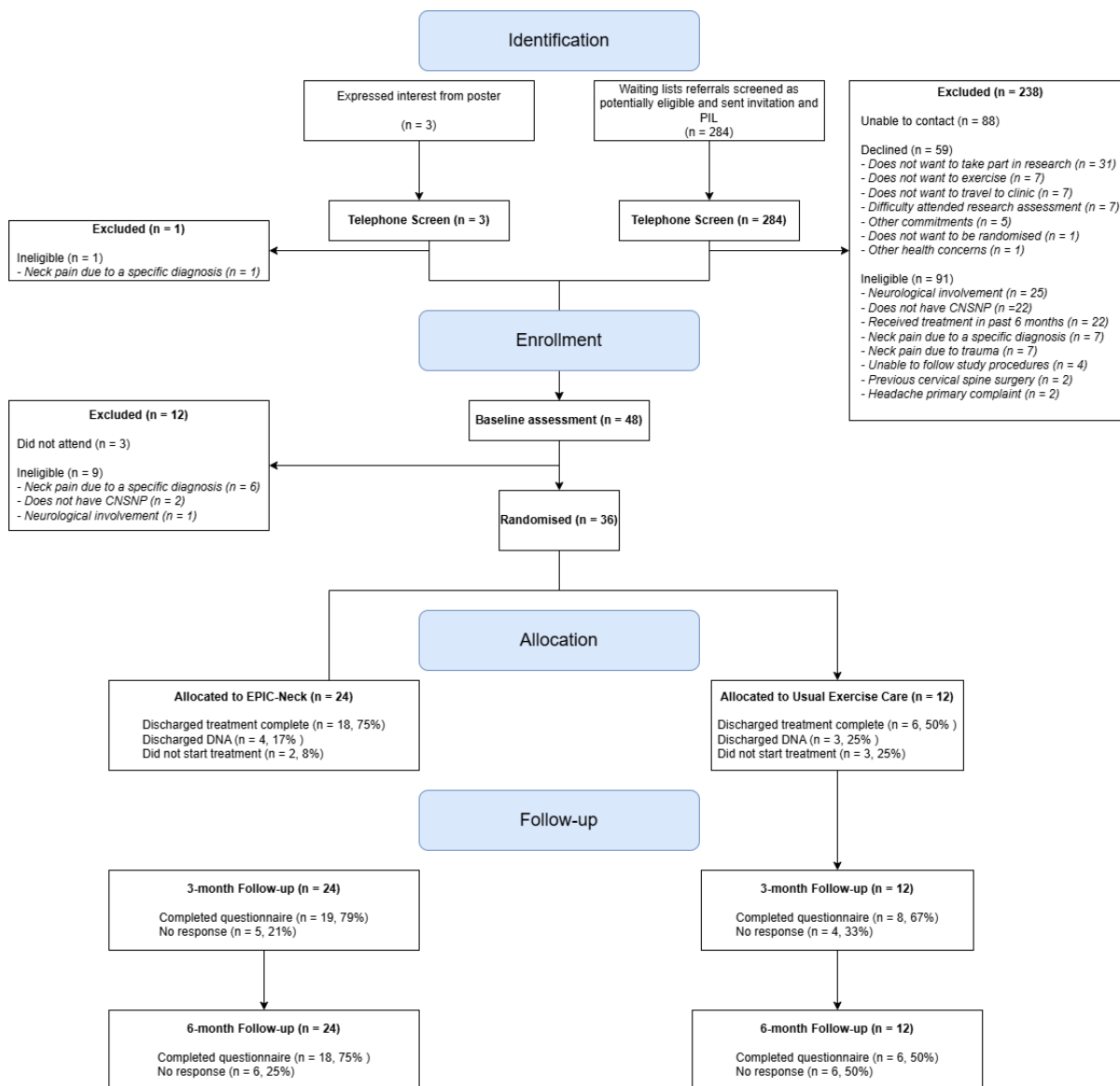


# ISRCTN Basic results summary

## Participant flow

Figure 1 – CONSORT Flow diagram



Abbreviation: DNA – Did not attend; PIL – Patient information leaflet; CNSNP – Chronic non-specific neck pain

## Baseline characteristics

Table 1 – Patient participant baseline characteristics

Demographic characteristic	EPIC-Neck n=24		Usual Exercise Care n=12		Full sample n=36	
	n	%	n	%	n	%

<b>Gender</b>						
Female	11	45.8%	5	41.7%	16	44.4%
Male	13	54.2%	7	58.3%	20	55.6%
<b>Age</b>						
18-30	3	12.5%	3	25.0%	6	16.7%
31-40	7	29.2%	1	8.3%	8	22.2%
41-50	3	12.5%	3	25.0%	6	16.7%
51-60	7	29.2%	3	25.0%	10	27.8%
61+	4	16.7%	2	16.7%	6	16.7%
<b>Ethnicity</b>						
<b>Asian or Asian British</b>	9	37.5%	6	50.0%	15	41.7%
Indian	2	8.3%	1	8.3%	3	8.3%
Pakistani	7	29.2%	5	41.7%	12	33.3%
<b>Black or Black British</b>	3	12.5%	2	16.7%	5	13.9%
African	1	4.2%	1	8.3%	2	5.6%
Caribbean	1	4.2%	0	0.0%	1	2.8%
Other	1	4.2%	1	8.3%	2	5.6%
<b>Mixed</b>	1	4.2%	1	8.3%	2	5.6%
White & Black Caribbean	1	4.2%	1	8.3%	2	5.6%
<b>White</b>	10	41.7%	3	25.0%	13	36.1%
British	9	37.5%	3	25.0%	12	33.3%
Irish	1	4.2%	0	0.0%	1	2.8%
<b>Other</b>	1	4.2%	0	0.0%	1	2.8%
Arab	1	4.2%	0	0.0%	1	2.8%
<b>IMD decile</b>						
Most deprived (deciles 1-3)	19	79.2%	7	58.3%	26	72.2%
Middle (deciles 4-7)	4	16.7%	5	41.7%	9	25.0%
Least deprived (deciles 8-10)	1	4.2%	0	0.0%	1	2.8%
<b>Marital status</b>						
Living with partner	6	25.0%	1	8.3%	7	19.4%
Married/civil union	13	54.2%	5	41.7%	18	50.0%
Separated/divorced	1	4.2%	1	8.3%	2	5.6%
Unmarried (never married)	4	16.7%	5	41.7%	9	25.0%
<b>Cohabiting status</b>						
Cohabiting	24	100.0%	10	83.3%	34	94.4%
Living alone	0	0.0%	2	16.7%	2	5.6%
<b>Neck pain location</b>						
Left	11	45.8%	9	75.0%	20	55.6%
Right	11	45.8%	6	50.0%	17	47.2%
Middle	7	29.2%	7	58.3%	14	38.9%
Base of skull	2	8.3%	1	8.3%	3	8.3%

Abbreviations: IMD - Index of multiple deprivation;

## Outcome measures

The primary outcome aim of this study was to determine whether to continue to a large-scale definitive trial using pre-specified criteria. The researchers are primarily interested in whether

1. The EPIC-Neck intervention is delivered as intended (delivery fidelity), measured by EPIC-Neck appointment audio recordings and observations scored against a fidelity checklist at the study end
2. The EPIC-Neck programme and usual care exercise are sufficiently different (contamination), measured by usual exercise care appointment audio recordings and observations scored against a fidelity checklist and physiotherapist at the study end
3. The degree to which people delivering and receiving the EPIC-Neck programme consider it to be appropriate (acceptability), measured using an acceptability questionnaire at 3 and 6 months and EPIC-Neck participant interviews at 4 months, and interviews with physiotherapists delivering the EPIC-Neck programme after the majority of treatment has been completed.
4. The mean rate of recruitment per month (mean recruitment rate), measured using study monitoring data at treatment completion.

The results were:

**Table 2 Primary feasibility outcomes**

	<b>Feasibility outcomes</b>
<b>Mean recruitment rate</b>	4.5 participants per month, 95%CI [3.0, 6.1]
<b>Retention rate</b>	67% at 6 months, 95% CI [49, 81]
<b>Delivery fidelity</b>	Overall mean score 2.4 (SD 1.3, 95% CI: 1.7, 3.1); 53% of components scored 1.5–3
<b>Contamination</b>	Mean checklist score 1.1/5 (SD 1.0, 95%CI: 0.6, 1.6); 1/17 components observed
<b>Acceptability</b>	Mean 3.9 (SD 1.0, 95%CI: 3.7, 4.1); concerns were identified

Secondary feasibility outcomes were:

**Table 3: Secondary feasibility outcomes**

<b>Secondary feasibility outcome</b>	<b>Method of assessment</b>	<b>Results</b>
<b>1. Safety of the intervention</b>	Adverse event case report forms completed throughout the study period	No exercise-related serious adverse events were reported. One participant experienced a temporary worsening of neck pain (non-serious, related adverse event). One participant experienced a transient episode of syncope at work (serious adverse event, unrelated to the intervention).
<b>2. Inclusivity of recruitment procedures</b>	Participant Screening and Recruitment log analysed at study end	No statistically significant differences were observed between randomised and non-randomised individuals by age, sex,

		ethnicity, first language, interpreter need, or Index of Multiple Deprivation. Participants represented a wide age range (19–82 years), multiple ethnic groups, and predominantly high socioeconomic deprivation (IMD deciles 1–3).
<b>3. Definition of usual exercise care</b>	Audio-recordings of usual care physiotherapy appointments and semi-structured interviews with physiotherapists delivering usual exercise care	Usual exercise care consisted primarily of physiotherapist-prescribed home exercises delivered according to routine NHS practice. Behaviour change strategies and structured self-management components central to EPIC-Neck were observed infrequently. Contamination was low, with a mean fidelity checklist score of 1.1 out of 5, and only 1 of 17 EPIC-Neck components observed in usual care.
<b>4. Completeness of planned definitive-trial outcome measures at 6 months</b>	Questionnaire return rates and item-level completeness assessed at baseline, 3 months, and 6 months	Baseline questionnaire completion was 100%. Follow-up questionnaire return rates were 75% at 3 months and 67% at 6 months. Among participants who completed treatment, retention at 6 months was 91%. Item-level completeness was high across all returned questionnaires for all planned outcome measures.

## Adverse Events

No exercise-related serious adverse events were reported. One participant experienced a temporary worsening of neck pain (non-serious, related adverse event). One participant experienced a transient episode of syncope at work (serious adverse event, unrelated to the intervention).