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Synopsis

Duration of external neck stabilisation in the management of older and frail patients with a new odontoid fracture: the DENS RCT

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Abstract

Background: Fractures of the cervical spine's odontoid process can result from low-impact falls in frail or older adults, and are usually managed in hard collars to immobilise the fracture and promote bony healing. However, bony healing often does not occur in older/frail adults and is not necessary for good outcomes. Further, hard collars can cause complications, such as skin pressure ulcers, and difficulties with swallowing or personal care.

Objective: To examine whether management of odontoid process fractures without hard collar immobilisation is associated with improved quality of life in older/frail patients.

Design and methods: The Duration of External Neck Stabilisation trial was a non-blinded randomised controlled trial with a nested qualitative study.

Setting and participants: Aimed to recruit 887 participants from 25 United Kingdom hospitals, over 2 years. Eligible patients were aged ≥ 65 years, or with Rockwood Clinical Frailty Scale of ≥ 5.

Interventions: Comparing early hard collar removal (intervention) with standard management in a hard collar for 12 weeks.

Main outcome measures: Primary outcome measure: quality of life 12 weeks following randomisation. EuroQol-5 Dimensions, five-level version.

Randomisation: Web-based randomisation system based on age, fracture type and frailty.

Blinding: Participants not blinded. Outcome event adjudication committee blinded to treatment allocation.

Results: The study was terminated prematurely because of slow recruitment. One hundred and thirty-eight patients were randomised with. 83.3% aged > 75 years old and. 72.5% of fractures being odontoid type 2. Mean number of days in collar 0.2 (standard deviation 1.4) for early removal of collar participants, and 55.5 days (standard deviation 38.0) for standard management participants; 15.6% of standard management participants crossed over, 3.0% of early removal of collar participants. Twenty-eight days after randomisation, 80 patients (61.5%) were not wearing a collar.

This synopsis should be referenced as follows:
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Primary end-point assessment (EuroQol 5 dimension instrument five-level version at 12 weeks), based on intention-to-treat analysis, mean score 0.650 (standard error 0.039, 0.490 to 0.86) in early removal of collar group and 0.0667 (standard error 0.040, 0.51 to 0.89) in standard management group. Pre-specified subgroup analysis by fracture type (p = 0.3645), Rockwood score (p = 0.6593) and age (p = 0.4088) were non-significant. Qualitative study participants reported decreased autonomy following the fracture. Standard management patients reported additional negative impacts. There was need for better information about the injury, 'normal' recovery and return to activities.
Seventeen patients died; 10 (17.2%) early removal of collar group, 7 (9.8%) standard management group [odds ratio = 1.92 (95% confidence interval 0.61 to 6.04), p = 0.266]. No deaths directly related to fracture or trial allocation.
Limitations: The study opened in 2021, during the COVID-19 pandemic. The recruited population is underpowered considering the planned sample size. The qualitative analysis revealed several obstacles to trial recruitment, including loss of equipoise.
Conclusions: Clinicians should consider prioritising independence and comfort of older/frail patients with odontoid fracture by early collar removal. This study supports that this can be achieved without a clear detriment to the patient.
Future work: There is not likely equipoise for a further randomised trial, even if measures could be considered to enhance recruitment. Instead, future prospective observational studies would be well placed to confirm and extend our findings.
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A plain language summary of this synopsis is available on the NIHR Journals Library Website https://doi.org/10.3310/GJPB0728.

Background

Older or frail patients are prone to falls. The incidence of falls increased 70% from 2010 to 2017, with 220,160 hospital admissions for falls in patients over 65 years old, and an estimated annual cost of £4.4B for related fragility fractures.[2] As the population ages, falls will increase, and associated fractures become more prevalent. Fractures of the odontoid process [Duration of External Neck Stabilisation (DENS)] of the second vertebrae in the cervical spine (C-spine) can occur following low-impact falls in frail or older people.[1] The Trauma Audit and Research Network database identified at least 1700 odontoid fractures each year in England and Wales, 85% in people over 65 years.

One-year mortality following an odontoid fracture is 20–50%, similar to, or higher than, following a hip fracture, likely reflecting the underlying frailty and health status of those at risk of low-impact falls.[3] In the UK, when comparing cervical fractures to hip fractures in patients over 60 years old, there is a greater incidence of delirium and pressure sores, a longer duration of hospital stay and an increased chance of discharge to a care facility rather than home. Surprisingly then, there is a lack of research aimed at improving outcomes for older or frail patients with odontoid fractures.

Options for odontoid fracture management include surgical fixation or external immobilisation. In older or frail adults, surgical fixation may improve rates of radiological bone fusion but is not associated with improved functional outcomes, irrespective of odontoid fracture type.[4] Complication rates following odontoid fixation surgery are high in the older and frail population, and so, in the UK, 85–90% of patients are managed non-operatively,[1] most with a hard cervical collar for 6–12 weeks, 24 hours a day. The hard collar aims to promote bony fusion and to prevent neurological deterioration or instability pain, but bony fusion occurs in only 20–80% of patients, compared to stable fibrous non-union in 60–80%.[5–7] Fibrous union is an acceptable outcome. Pain control, quality of life (QoL), mortality and functional outcomes are comparable for patients with fibrous union compared to bony fusion. Late neurological deterioration is very rare in either group.[8]

Not only do hard collars not add value in terms of fracture and functional outcomes for these older and frail patients, but also they can cause harm, including skin pressure ulcers and difficulties with swallowing, breathing and personal care, all of which can affect QoL.[9] In older or frail patients, short- to medium-term QoL is important. The DENS trial aimed to address the question whether collars are needed at all in this population by exploring the hypothesis that management of odontoid process fractures without immobilisation is associated with improved QoL compared with management in a hard collar for 12 weeks.

Methods

The DENS trial was a non-blinded randomised controlled trial (RCT) with a nested qualitative study comparing early removal of a hard collar (ERC) (intervention) with treatment in a hard collar for 12 weeks [standard management (SM)] in older or frail adults with a new odontoid process fracture. The detailed trial protocol has been published.[1] The trial received a favourable ethical opinion from Scotland A Research Ethics Committee (REC) on the 10 June 2021 (21/SS/0036) and the Leeds West REC (on behalf of England and Wales) on the 29 July 2021 (21/YH/0141). Patients and the public played an active role in developing the project protocol.

The primary outcome measure was QoL assessed using the EuroQol-5 Dimensions, five-level version (EQ-5D-5L)[10] at 12 weeks following randomisation. Secondary outcome measures included 2- and 6-week EQ-5D-5L, and Neck Disability Index (NDI)[11] measurements. Compliance with hard collar use and discharge destination were determined. Adverse events (AEs) were recorded up to 12 weeks. Expected AEs relating to hard collar use or odontoid process fractures included skin pressure ulcers, dysphagia and recurrent falls. The final study protocol amendment was approved (v7.0) on the 17 November 2023.

The original overarching aims of the embedded qualitative study were:

1. To understand and explore trial recruitment experiences from the perspectives of patients, carers (if the patient was unable to give informed consent) and healthcare professionals (HCPs).
2. To explore whether, and why, patients do/do not adhere to the intervention (ERC) or (SM in a hard collar for 12 weeks).

We also used patient/carer interviews to understand how treatment allocations affected patients' QoL. This is reflected in our decision to include an additional aim:

3. To understand and explore how using/not using hard collar management affected older/frail people's everyday QoL.

The objectives of the qualitative study were to:

a, inform refinements to the recruitment/consent pathway used in the trial (if required)
b. help inform decision-making about using hard collar/no collar management in older/frail people who have dens fractures
c. aid interpretation of trial results.[12]

Towards the end of data analysis and write-up, the trial team was approached by a group of clinicians wishing to develop specific guidance on patient care and hard collar management in older/frail adults. Our analysis, which included emergent findings, had already indicated a clear need for this type of guidance, particularly from a patient/carer perspective. A decision was made to support this initiative and further analyse the interview data to address an additional study aim:

4. To understand what information and support is needed to support the care and recovery of older/frail adults following a dens fracture.

A health economics analysis was planned with the following aim:

To assess differences between trial arm in NHS costs, quality-adjusted life-years (QALYs) and cost–utility from an NHS and personal social services perspective up to 6 months. This was scaled back due to restrictions on cost side data, and refocused on QALYs and family care and paid carer time with wider healthcare resource use (HCRU) and associated incremental cost per QALY calculations limited to descriptive and explorative analysis only.

Eligibility for main study (Figure 1)

Inclusion criteria:

- Aged ≥ 65 years, or Rockwood Clinical Frailty Scale (CFS) of ≥ 5 [at least mildly frail: help needed in high-order instrumental activities of daily living (ADL)].
- Recent odontoid process fracture of any type, secondary to low-impact trauma (any degree of fracture angulation, displacement or canal narrowing). History of recent trauma (within 3 weeks).
- Recruited within 3 weeks of injury.
- Determined by consultant spinal surgeon as suitable for standard treatment in hard collar or treatment without a collar.

Exclusion criteria:

- Fracture sustained in a high-impact injury.
- New neurological deficit attributable to the fracture.
- Unable to tolerate a hard collar.
- Additional (non-odontoid process) C-spine fracture not suitable for management without a hard collar.

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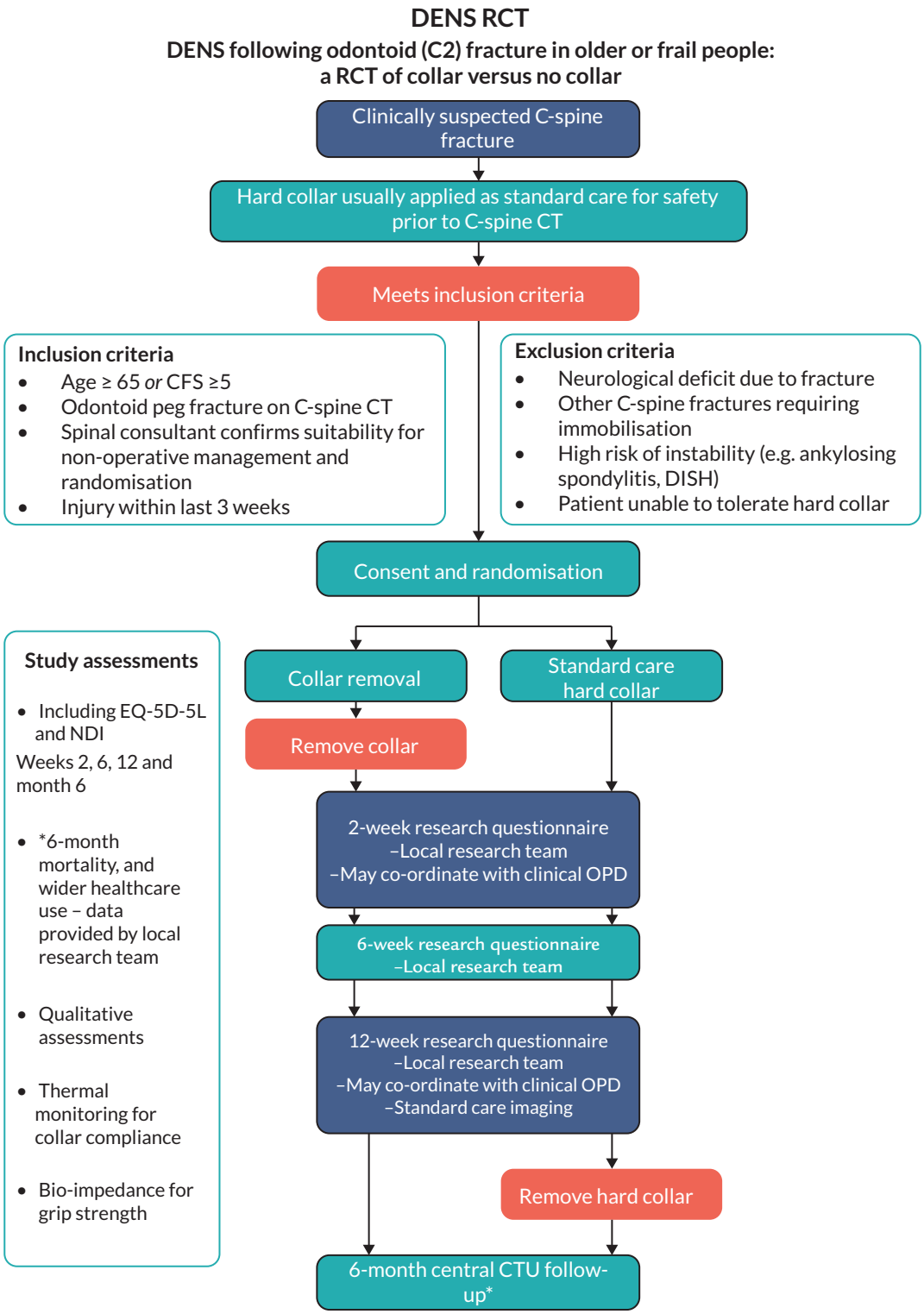

FIGURE 1 The DENS trial flow chart. CT, computerised tomography; CTU, Clinical Trials Unit; DISH, diffuse idiopathic skeletal hyperostosis; OPD, outpatient department. Material in this figure is reproduced with permission from Woodfield *et al.*[1] This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) licence, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: https://creativecommons.org/licenses/by/4.0/. The figure includes minor additions and formatting changes to the original text.

- Underlying condition with risk of spinal instability (e.g. ankylosing spondylitis).
- Fracture suspected to be older than 3 weeks at the time of assessment.
- Not expected to survive to hospital discharge.

A consultant radiologist report of an odontoid process fracture on computerised tomography (CT), and confirmation of eligibility by a consultant spinal surgeon (orthopaedic or neurosurgical), was required. The type of odontoid fracture, for example, per the Anderson and D'Alonzo classification,[13] did not affect eligibility. Patients with additional C-spine fractures were eligible if suitable for management without a hard collar. There were no exclusions for other injuries (e.g. fractured femur). Any neck stabilisation could be applied as part of standard care prior to randomisation, including trauma collar, blocks, spinal board, padded hard collar or soft collar.

Eligibility assessment and randomisation took place as soon as possible after injury (target within 48 hours) to maximise the impact of study intervention. Recruitment was permitted for up to 3 weeks after the injury to provide flexibility for those presenting late, or who were acutely unwell. Patients or their representative gave consent.

Web-based randomisation occurred with a minimisation algorithm based on:

- age at randomisation (< 75 vs. ≥ 75 years)
- odontoid fracture type (I–III)[14]
- frailty (CFS ≥ 4 vs. < 4).[15]

Following randomisation to standard care, the choice of hard collar, and arrangements for collar care, was based on a site's usual practice. For those allocated to the intervention (collar removal), the collar was directed to be removed as soon as possible, with the option of weaning over several days if required for optimising pain management. A protocol amendment was introduced to permit soft collars to be used as part of a weaning regimen, but not in lieu of a hard collar. Removal of a collar prior to 12 weeks in the hard collar arm or wearing of a collar in the no-collar arm was recorded as a failure of adherence.

Sample size

The intention was to recruit 887 participants from 25 UK sites over 2 years, based on 90% power and a 5% significance level, for an effect size of 1/6 on the EQ-5D-5L at 12 weeks, with a reduction accounting for correlation between baseline covariates (age, frailty score) and 12 weeks EQ-5D-5L. The resulting sample size was inflated to 887 in order to allow for approximately 20% missing data.

Trial assessments

Local clinical follow-up was as per standard care. Research assessments were carried out at 2, 6 and 12 weeks by the local research team, and by a blinded member of the central research team at 6 and 12 months. Assessments were via telephone interviews, postal or online questionnaires, or during standard care appointments. A proxy could provide information when required. No study-specific follow-up imaging was mandated. Participants followed local clinical protocols for imaging.

Statistical analyses

Statistical analyses were based on an intention to treat (ITT), with a 5% two-sided significance level used throughout. A detailed statistical analysis plan was developed by the study statisticians and finalised prior to locking of the trial database (see *Report Supplementary Material 1*). The primary analysis of the primary outcome used a repeated measures mixed-effects analysis of covariance, including terms for treatment, time, study site (fitted as a random effect) and the randomisation minimisation variables (as fixed effects). The model also included a time by treatment interaction. Secondary outcomes measured at multiple time points were analysed using the repeated-measures approach described for the primary outcome. Where outcomes were not measured repeatedly, analyses were undertaken using the appropriate version of the generalised linear model (e.g. linear for continuous outcomes, logistic for binary outcomes or Poisson for count data). Exploratory subgroup analyses of the primary outcome were undertaken for the randomisation minimisation variables, repeating the primary analysis and including an interaction term between intervention and subgroup.

Health economic analyses

The health economic analysis proposed in the original study plan was also amended based on the revised recruitment target. Further, initial HCRU data collection by patient diary proved to have poor response rates and was changed to questionnaires. While the questionnaires had completeness in line with that typical in RCTs,[16] early trial closure meant that total combined data from the diaries and questionnaires remained below 40% completeness. Hence, further revision limited HCRU analysis focused on descriptive statistics only among complete data returned (see *Report Supplementary Material 2*).

Such matters did not affect estimation of QALYs, changes in family assistance need or paid carer time. Self-reported need for increased family assistance post fracture was assessed at 2, 6 and 12 weeks, and 6-month time points on a complete-case analysis (CCA) basis with comparisons between trial arms undertaken by simple logistic regression. QALYs and total paid carer time were

estimated by an area under the curve approach based on EQ-5D-5L data {Hernandez algorithm[17] to match current policy [National Institute for Health and Care Excellence (NICE)]}[16,18] and reported number of hours paid care on week surveyed, respectively. In each, multiple imputation by chained equations were used to address missing data with a sensitivity analysis of complete case by time point also undertaken. Differences in trial arms for QALYs and paid carer time were estimated by non-parametric bootstrapped differences in means to account for skew.

Qualitative study

Following the tragic death of Mary Godfrey shortly after the NIHR agreed to fund the trial, Julia Lawton and Helen Eborall at the Usher Institute, University of Edinburgh stepped in to lead on the qualitative sub-study. Prior to this study commencing, they developed a revised protocol which was approved by the funder and Mia Closs was appointed to conduct data collection and analysis. This section reports the work arising from the revised qualitative study design.

For further methodological details, see related publication.[19] Interviews were conducted with HCPs involved in trial recruitment, individuals who declined trial participation (Aim 1), and trial participants (patients) and/or their carers (Aims 1–4). HCPs were recruited from eight centres open by June 2022. Purposive sampling was undertaken to ensure participants from a range of professional backgrounds and geographical locations were included. We selected seven sites across England and Scotland for recruitment of trial participants. These served diverse patient populations (in terms of demographic factors, such as the socioeconomic and ethnic diversity) and included major trauma centres, neurosurgery units and smaller, rural-based hospitals. Recruitment was from both trial arms.

Data collection

In-depth interviews, informed by topic guides, were conducted with all participants. HCPs and decliners were interviewed once, while patients/carers were interviewed twice – shortly after trial recruitment and 12–16 weeks later (i.e. at the end of the fracture management period). This longitudinal approach allowed us to capture participants' perceptions and experiences before the fracture, to better understand and explore how these were affected by trial allocation. HCPs and decliner interviews took place between December 2021 and July 2022, and patient/carer interviews between December 2021 and April 2023. Rapid data collection and analysis were undertaken to feedback findings and recommendations to support trial recruitment.

Analysis

Given the volume and complexity of the data collected, the need to expedite data analysis to address Aim 1, analysis was primarily conducted using the framework approach.[20,21] Additional analyses exploring adherence to trial allocation and participants' information and support needs when using the trial allocation were undertaken using thematic approaches.[22] To maximise rigor, three experienced qualitative researchers (Mia Closs, Julia Lawton and Helen Eborall) were involved in the analysis.

Results

Patients were randomised between November 2021 and November 2023. Follow-up was completed by 10 June 2024, because a protocol amendment reduced follow-up to 6 months. One thousand one hundred and eighty-five patients were screened (*Figure 2*). Of those, 1040 patients were not randomised. Reasons included that the patient did not have a recent odontoid fracture (192), the patient was determined as unsuitable by the assessing spinal surgeon for management without a collar (102), and consent refused by patient (101) or representative (36). Of 145 patients assessed for eligibility, 139 were determined eligible; only 1 of these patients did not consent.

The 138 patients recruited into the trial represent 15.6% of the planned sample size (887). Randomisation was equal between arms. Ten centres recruited 71.7% of patients. Thirty centres were opened, and patients were recruited from 27 centres. The two highest recruiting centres were King's College London (11.6%) and the Royal Infirmary in Edinburgh (9.4%) (*Table 1*).

Patient baseline covariates

Patient characteristics were broadly matched between the two study arms (*Table 2*). About 59.9% of patients were female. Mean age was 82.3 years; 83.3% of patients randomised were aged > 75 years old. Most patients had a Rockwood CFS > 4 (vulnerable). Prior to admission with a new odontoid fracture, 91.2% of all patients were domiciled at home and approximately half were mobile unaided, and 21% mobile with 1 stick. The mean Charlson Comorbidity Index (CCI) was 4.8. The ethnicity of recruited patients was 'White any background' for 94.2%.

Admission assessments

Of the fractures, 72.5% were odontoid type II (see *Table 2*) Most patients sustained their neck injury in a fall from a standing height (54.7%), or downstairs (25.5%) (*Table 3*). Prior to assessment of eligibility, 83.6% of patients were first managed in hard collar or a Laerdal stiff neck collar.

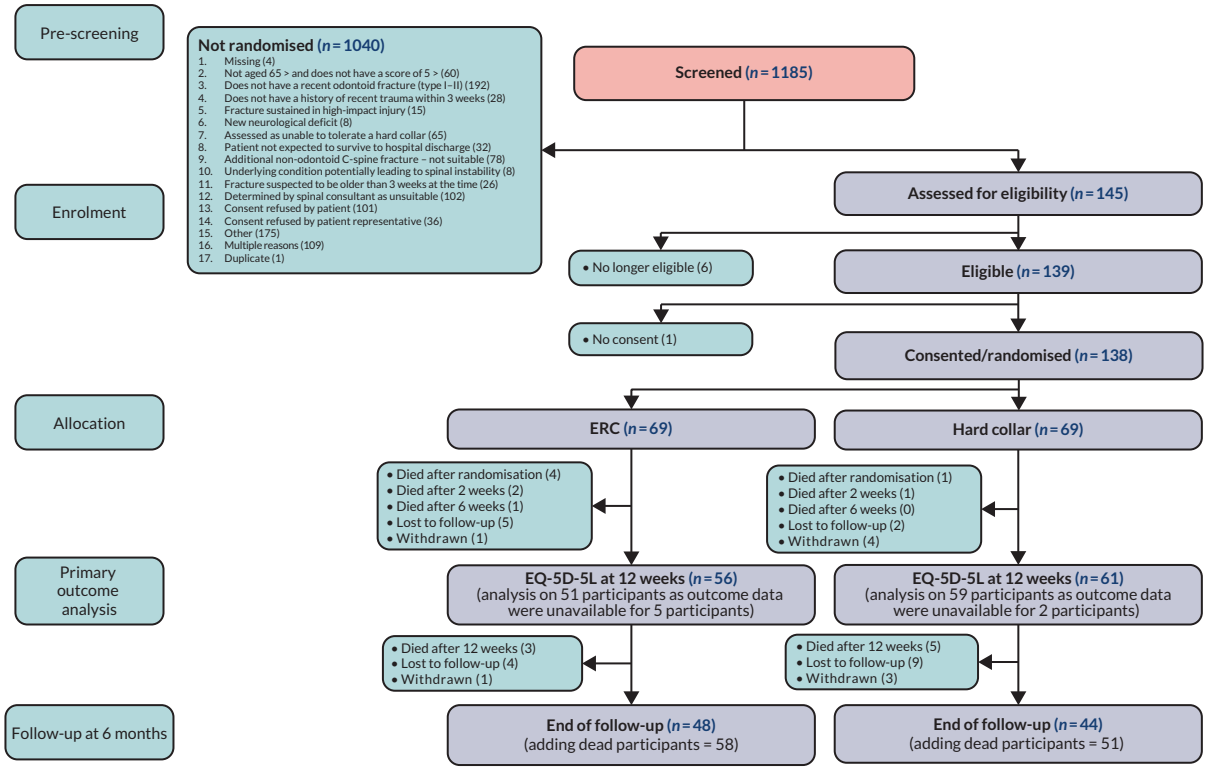

FIGURE 2 Study CONSORT flow chart of patient screening, reasons for non-randomisation and randomisation allocation.

TABLE 1 Patient recruitment by centre

Parameter	Categories	ERC, *N* = 69	Hard collar, *N* = 69	All groups, *N* = 138
Centre size, *n* (%)	Edinburgh Royal Infirmary	5 (7.2)	8 (11.6)	13 (9.4)
	Northumbria (NSECH)	4 (5.8)	3 (4.3)	7 (5.1)
	St Mary's, Imperial	6 (8.7)	4 (5.8)	10 (7.2)
	King's College London	8 (11.6)	8 (11.6)	16 (11.6)
	Derriford Hospital, Plymouth	3 (4.3)	3 (4.3)	6 (4.3)
	The Walton Centre, Liverpool	5 (7.2)	7 (10.1)	12 (8.7)
	Leeds General Infirmary	7 (10.1)	5 (7.2)	12 (8.7)
	Sheffield Northern General	7 (10.1)	3 (4.3)	10 (7.2)
	St George's	3 (4.3)	4 (5.8)	7 (5.1)
	Gloucester	4 (5.8)	2 (2.9)	6 (4.3)
	All other centres[a]	17 (24.6)	22 (31.9)	39 (28.3)

a Centres with fewer than six participants.

Treatment adherence

Mean number of days in a collar was 0.2 [standard deviation (SD 1.4)] for patients allocated to ERC and 55.5 days (SD 38.0) for participants in the hard collar group (*Table 4*). A protocol deviation was reported for 40.6% of participants randomised to hard collar. Protocol deviations were not necessarily treatment deviations. Of 15.6% hard collar participants switched intervention, compared to 3.0% of early collar removal participants. The collar was replaced in four patients allocated to ERC, two within 14 days. Forty-seven (68.1%) of patients allocated to hard collar retained it for at least 28 days. Ten patients had the collar removed within 14 days of randomisation.

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TABLE 2 Patient baseline characteristics

Parameter	Categories	ERC, *N* = 69	Hard collar, *N* = 69	All groups, *N* = 138
Age mean (SD)	N/A	82.0 (7.4)	82.7 (8.0)	82.3 (7.7)
Female, *n* (%)	N/A	40 (58.0)	42 (61.8)	82 (59.9)
Any White background, *n* (%)	N/A	64 (92.8)	65 (95.6)	129 (94.2)
Domicile at home at admission, *n* (%)	N/A	60 (87.0)	65 (95.6)	125 (91.2)
Mobility admission, *n* (%)	Wheelchair[a]	4 (5.8)	6 (8.8)	10 (7.3)
	Walking frame	16 (23.2)	10 (14.7)	26 (19.0)
	Two sticks	2 (2.9)	1 (1.5)	3 (2.2)
	One stick	12 (17.4)	18 (26.5)	30 (21.9)
	Unaided	35 (50.7)	33 (48.5)	68 (49.6)
CCI mean (SD)	N/A	4.9 (1.6)	4.8 (1.7)	4.8 (1.6)
Age at randomisation, *n* (%)	< 75	11 (15.9)	12 (17.4)	23 (16.7)
	≥ 75	58 (84.1)	57 (82.6)	115 (83.3)
Odontoid fracture type grouped, *n* (%)	Type I or III	1 (1.4)	1 (1.4)	2 (1.4)
	Type II	50 (72.5)	50 (72.5)	100 (72.5)
	Type III	18 (26.1)	18 (26.1)	36 (26.1)
Rockwood CFS, *n* (%)	> 4	42 (60.9)	44 (63.8)	86 (62.3)
	≤ 4	27 (39.1)	25 (36.2)	52 (37.7)

N/A, not applicable.
a Full body hoist/stand aid or equivalent, including wheelchair.

TABLE 3 Characteristics of mechanism of injury and first neck care

Parameter	Categories	ERC, *N* = 69	Hard collar, *N* = 69	All groups, *N* = 138
Mechanism of injury *n* (%)	Trip/fall/TLOC-from standing height	34 (49.3)	41 (60.3)	75 (54.7)
	Trip/fall/TLOC- >standing height but < 3 m	2 (2.9)	0	2 (1.5)
	Trip/fall/TLOC-downstairs	21 (30.4)	14 (20.6)	35 (25.5)
	RTA/pedestrian/cycle etc	1 (1.4)	5 (7.4)	6 (4.4)
	Other (please give details)	11 (15.9)	7 (10.3)	18 (13.1)
	Unknown	0	1 (1.5)	1 (0.7)
First neck stabilisation *n* (%)	Blocks and tape	7 (10.1)	11 (16.7)	18 (13.3)
	CHC (laerdal stiff neck)	7 (10.1)	7 (10.6)	14 (10.4)
	CHC (Aspen)	27 (39.1)	34 (51.5)	61 (45.2)
	CHC (Miami-J)	21 (30.4)	11 (16.7)	32 (23.7)
	CHC (Philadelphia)	0	S1 (1.5)	1 (0.7)
	CHC (other)	4 (5.8)	1 (1.5)	5 (3.7)
	No collar	3 (4.3)	1 (1.5)	4 (3.0)

CHC, cervical hard collar; RTA, road traffic accident; TLOC, transient loss of consciousness.

TABLE 4 Adherence to study allocation

	Categories	ERC, *N* = 69	Hard collar, *N* = 69	All groups, *N* = 138
Collar-use days mean (SD)	N/A	0.2 (1.4)	55.5 (38.0)	27.9 (38.6)
Intervention crossover *n* (%)	Yes	2 (3.0)	10 (15.6)	12 (9.2)

Twenty-eight days after randomisation, 80 patients (61.5%) were not wearing a collar, compared to 50 who were.

Outcome assessment

For primary end-point assessment (EQ-5D-5L at 12 weeks), data was available for 51 ERC patients, and 59 hard collar patients. Seven ERC patients had died by this point, and two hard collar patients (see *Figure 1*). Based on an ITT analysis, model-adjusted mean EQ-5D-5L score was 0.650 [standard error (SE) 0.039] in the ERC group and 0.667 (SE 0.040) in the hard collar group. There was no evidence of a difference between the groups {adjusted mean difference −0.017 [95% confidence interval (CI) −0.103 to 0.068]; $p = 0.836$} (*Table 5*, *Figure 3*). Pre-specified subgroup analyses by fracture type[2] ($p_{interaction} = 0.365$), Rockwood score ($p_{interaction} = 0.659$) and age ($p_{interaction} = 0.409$) also showed no evidence of a difference between groups (*Figure 4*).

Secondary outcome assessment included NDI. At 12 weeks post randomisation, there was no evidence of a difference between treatment allocations [adjusted mean difference 0.899 (95% CI −5.875 to 7.672); $p = 0.762$] (*Table 6*).

At discharge (*Table 7*), 55.6% of patients were discharged home without a package of care, compared to 91.2% who had been living at home prior to admission. Additionally, 27.7% of patients were mobile without assistance at discharge, down from 49.6% at admission. The proportion of patients using a walking frame increased from 19.0% prior to admission to 36.0% at discharge. Finally, a statistical comparison of discharge destination showed no significant differences between the intervention groups.

Mortality and adverse events

Fifteen patients had died by 6 months, 10 (17.2%) in the ERC group compared to 5 (9.8%) in the hard collar group. [Two patients were recorded as alive during the official 6-month mortality check, but both died shortly afterward, such that they were still within the programmatic 6-month period. This explains the discrepancy in the number of deaths in the hard collar group ($n = 5$) with that stated in the consort flow chart ($n = 7$).]

Formal statistical assessment for risk of mortality ERC versus hard collar demonstrated no evidence of a difference between groups {odds ratio [OR = 1.92 (95% CI 0.61 to 6.04); $p = 0.266$]}. Where the cause of death was available, in no patients was it directly related to their cervical fracture or trial allocation. AEs affected approximately one-third of patients, and the majority were mild (*Table 8*).

Patients experiencing serious adverse events (SAEs) were more common in the ERC group ($n = 10$, 13.3%) than the hard collar group ($n = 3$, 5.4%). SAEs in the ERC group included stroke, infection (5), fall (3), confusion (2) and subdural haematoma. There was one episode of fracture displacement, classed as 'moderate' severity and 'possibly related'. Hard collar SAEs included opioid overdose, fall, difficulty swallowing, pneumonia, 'speech deficit and unilateral upper limb discomfort'.

Health economic analysis

While some analyses were inhibited by missing cost data, there does not appear to be evidence to support differences in cost, QALYs, or cost-effectiveness between trial arms. (see *Report Supplementary Material 3*) Due to the trial ending early it is not possible to rule out underpowering. Of the variables, we can report on, there may be an indication that hard collar patients needed more support from family members. At all time points, in the hard collar arm a statistically significant number of participants reported increased need for family assistance at the 5% level (*Table 9*). This does not appear to have led to a similar increase in paid care time; hence it may reflect the encumbrance of the collars themselves.

There was a lower rate of paid carer time at home in the ERC group compared to the hard collar group, at each time point, and totalled over all time points (*Table 10*). Week 2 of the imputed data was significantly lower. This analysis excludes participants in each arm reporting 24 hours a day, 7 days a week care which is thought to be a misinterpretation of the question. Including such entries changes little with a difference of −8.005 (95% CI −37.355 to 15.801) total hours paid care [ERC minus standard of care (SC)].

Completeness of EQ-5D-5L data was within normal bounds for economic evaluations of clinical trials allowing univariate assessment of QALYs as per the original

TABLE 5 Primary outcome assessment of EQ-5D-5L

Time post randomisation	Adjusted mean (SE)		Difference in means (95% CI)
	ERC	Hard collar	
Week 2	0.534 (0.0458)	0.509 (0.0459)	0.025 (−0.082 to 0.132)
Week 6	0.627 (0.0397)	0.576 (0.0403)	0.051 (−0.036 to 0.139)
Week 12	0.650 (0.0389)	0.667 (0.0397)	−0.017 (−0.103 to 0.066)
6 months' follow-up	0.616 (0.0408)	0.643 (0.0427)	−0.028 (−0.121 to 0.066)
Overall	0.607 (0.0361)	0.599 (0.0375)	0.008 (−0.067 to 0.083)

Note
Model-adjusted mean estimates and differences.

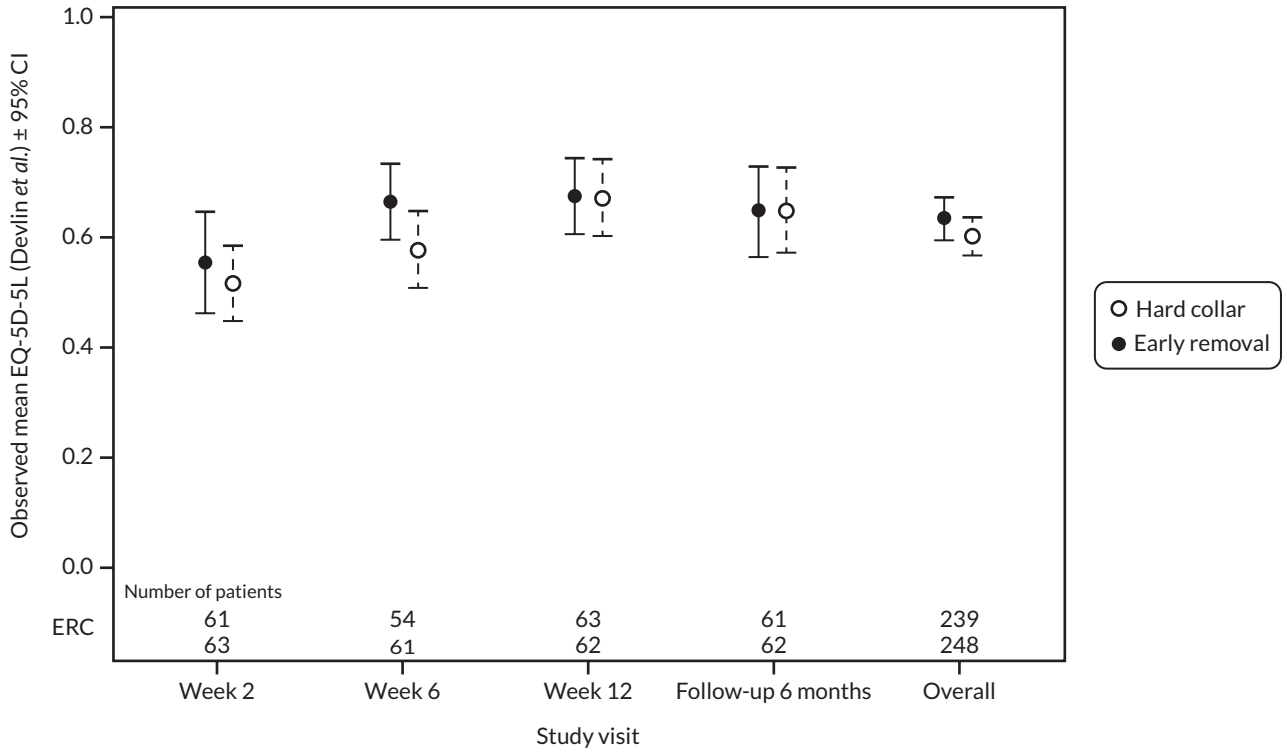

FIGURE 3 EQ-5D-5L (1) utility model-adjusted means (& 95% CI) by time point post randomisation. Population = ITT. Calculated using the methodology by Devlin *et al.*[23] 1 = 'best possible health', 0 = 'dead'.

health economic analysis plan (see *Report Supplementary Material 2*). This demonstrated no significant differences between trial arms, with very small point estimates suggestive of no change (see *Appendix 3*, *Table 12*). Mean SE QALYs 0.244 (0.019) versus 0.229 (0.02) for SC versus ERC, respectively, Difference in means (ERC minus SC): −0.0147 (95% CI −0.067 to 0.036). A result which is consistent with the main trial's primary outcomes, which use the same variables albeit without combining into QALYs. The QALYs additionally utilise multiple imputation by chained equations due to their nature as a composite variable.

Qualitative study

Participants

Thirty-two individuals (patients and carers) were interviewed, regarding the experiences of 27 trial

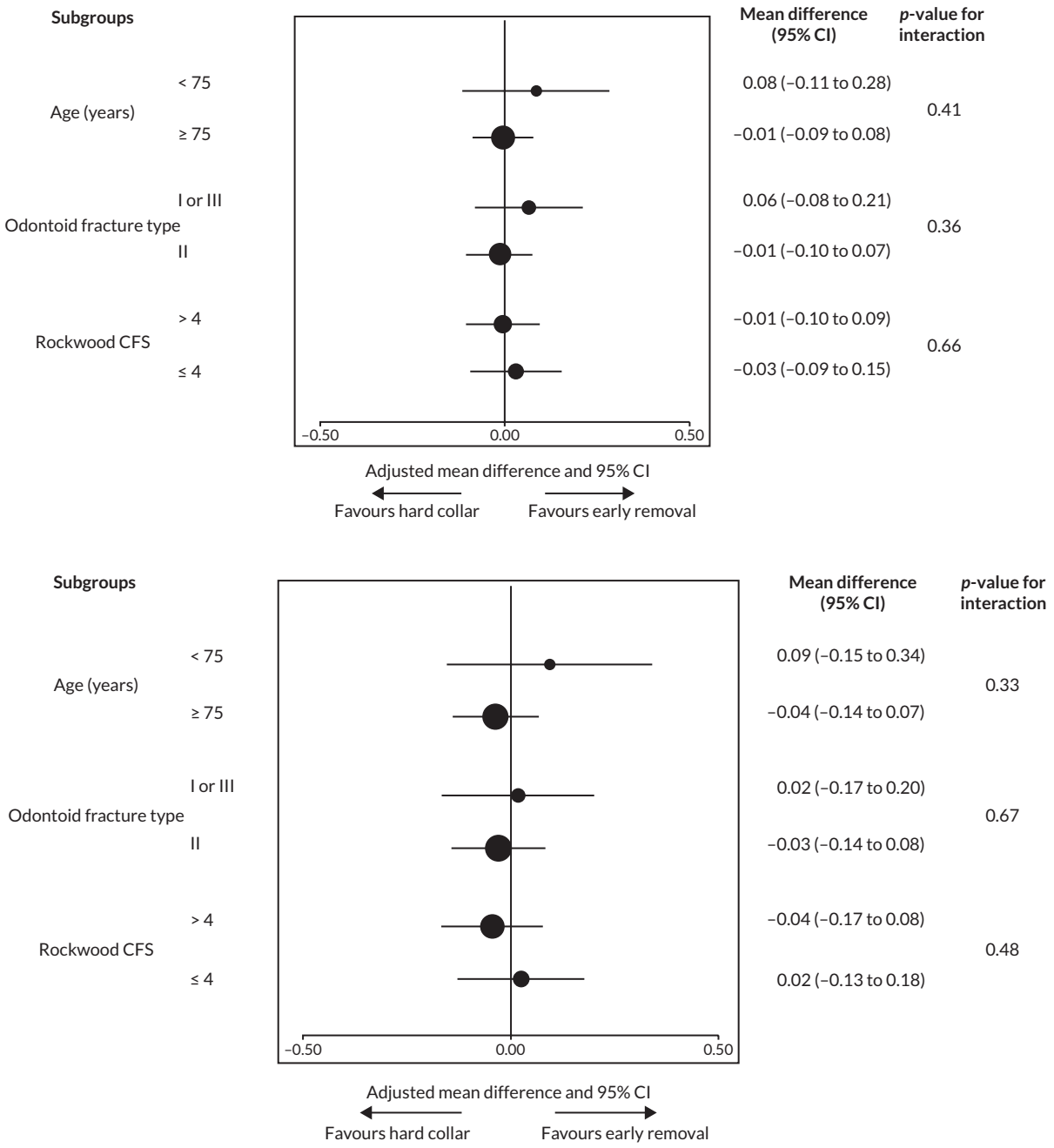

FIGURE 4 Primary outcome (EQ-5D-5L) by subgroup analysis. Using Devlin *et al.* (top) and Hernandez *et al.* (bottom). Outcome analysed using an adjusted mixed linear repeated measures regression model. Covariates: age at consent ≥ 75 or < 75 years, odontoid fracture type II vs. type I–III, and Rockwood clinical frailty score ≤ 4 or > 4. Centre fitted as a random parameter (large vs. small). An interaction term between intervention and the subgroup variable was included in the model.

participants. Fourteen had been randomised to the hard collar arm and 13 to early collar removal. One decliner and 12 HCPs were interviewed. No information was available about how many decliner recruitment packs were sent out. Participant characteristics are presented in (see *Appendix 4*). Five patient/carer participants did not take part in follow-up interviews: one withdrew from the trial, one died, one non-contactable, and two declined further interviews for health-related reasons.

Understanding trial recruitment experiences

In June 2022, a decision was made to conduct a rapid analysis of all interviews undertaken to date to help elucidate barriers to trial recruitment and how they could be overcome. This involved interviews with 1 decliner, 12 HCPs and 12 patients/carers. After this analysis, we continued to analyse new patient/carer interviews, but no new insights arose related to trial recruitment (see *Appendix 5* and *Appendix 6*).

TABLE 6 Neck Disability Index assessments

Time post randomisation	Adjusted mean (SE)		Difference in means (95% CI)
	ERC	Hard collar	
Week 2	42.210 (2.8654)	43.340 (2.7964)	−1.130 (−7.908 to 5.648)
Week 6	34.264 (2.8383)	35.208 (2.8045)	−0.944 (−7.743 to 5.855)
Week 12	29.495 (2.8259)	28.596 (2.7851)	0.899 (−5.875 to 7.672)
6 months' follow-up	23.474 (2.9153)	25.689 (2.9178)	−2.215 (−9.443 to 5.012)
Overall	32.360 (2.4273)	33.208 (2.4356)	−0.848 (6.386 to 4.691)

TABLE 7 Discharge destination and mobility

Parameter	Categories	ERC, *N* = 69	Hard collar, *N* = 69	All groups, *N* = 138
Hospital stay mean (SD)	N/A	12.9 (14.2)	13.8 (18.6)	13.3 (16.5)
Mobility discharge *n* (%)	Wheelchair	6 (10.3)	9 (14.8)	15 (12.6)
	Walking frame	22 (37.9)	21 (34.4)	43 (36.1)
	Two sticks	4 (6.9)	0	4 (3.4)
	One stick	9 (15.5)	15 (24.6)	24 (20.2)
	Unaided	17 (29.3)	16 (26.2)	33 (27.7)
	Missing	11	8	19
Destination at discharge *n* (%)	Home – no package of care	36 (58.1)	33 (53.2)	69 (55.6)
	Sheltered accommodation	3 (4.8)	1 (1.6)	4 (3.2)
	Carers at home without nursing	9 (14.5)	13 (21.0)	22 (17.7)
	Care home with nursing	9 (14.5)	5 (8.1)	14 (11.3)
	Other hospital	5 (8.1)	10 (16.1)	15 (12.1)
	Missing	7	7	14

TABLE 8 Summary of AE episodes

	ERC (*n* = 75)	Hard collar (*n* = 56)
Proportion of patients having at least one AE *n* (%)	21 (28.0)	17 (30.4)
Mild	39 (70.9)	18 (60.0)
Moderate	14 (25.5)	10 (33.3)
Severe	2 (3.6)	2 (6.7)
Number of patients with at least one SAE	10 (13.3)	3 (5.4%)
Total number of SAEs	13	5
Gastrointestinal disorders	3 (5.5)	8 (25.8)
Infections and infestations	12 (21.8)	4 (12.9)

TABLE 8 Summary of adverse event episodes (*continued*)

	ERC (*n* = 75)	Hard collar (*n* = 56)
Musculoskeletal and connective tissue disorders	4 (7.3)	4 (12.9)
Skin and subcutaneous tissue disorders	3 (5.5)	8 (25.8)
Respiratory, thoracic and mediastinal disorders	8 (14.5)	1 (3.2)
Proportion of patients having at least one SAE	10 (13.3%)	3 (5.4%)
AE causality – probably related	17 (30.9)	17 (54.8)

TABLE 9 Hypothetical incremental cost-effectiveness ratios (ERC minus SC)

Cost methodology	QALY methodology	Difference in cost (ERC–SC) (£)	Difference in QALYs (ERC–SC)	ICER (incremental cost per QALY)
Base case				
CCA, including 24/7 care	Imputed	−1940.45	−0.015	£132,133.48 per QALY
Sensitivity analyses				
CCA, including 24/7 care	CCA	−1940.45	0.005	ERC dominant
CCA, excluding 24/7 care	Imputed	−377.63	−0.015	£25,714.11 per QALY
CCA, excluding 24/7 care	CCA	−377.63	0.005	ERC dominant

24/7, 24 hours per day, 7 days per week; dominant, trial arm has both reduced costs and improved QALYs relative to comparator, rendering ICER moot; ICER, incremental cost-effectiveness ratio (difference in costs divided by differences in QALYs); SC, standard of care.

Note
Point estimates of ICERs under different combinations of analysis methods for total costs and QALYs.

TABLE 10 Comparison of rates of reported hours per week of paid care by trial arm

	SC (A), *n* = 62		ERC (B), *n* = 67		Difference in means (B) minus (A)	
Time point	Mean	(SE)	Mean	(SE)	Difference	(95% CI)
Week 2	1.837	(0.663)	0.773	(0.301)	−1.064	(−2.394 to −0.004)
Week 6	1.208	(0.483)	0.855	(0.348)	−0.353	(−1.365 to 0.558)
Week 12	2.189	(0.915)	0.974	(0.572)	−1.215	(−2.963 to 0.418)
Month 6	1.350	(0.622)	0.807	(0.381)	−0.543	(−1.782 to 0.480)
Total[a]	44.722	(14.500)	22.757	(7.643)	−21.965	(0.126 to −50.071)

a Total hours of home care packages estimated via area under the curve between time points (4*week 2 + 5*week 6 + 10*week 12 + 7*month 6).

The analysis revealed several obstacles to trial recruitment.

Equipoise

Most HCPs noted that standard hospital practice could have influenced patients' willingness to wear/not wear a hard collar and, consequently, trial recruitment. HCPs observed that hard collars were still commonplace in hospitals and ward (i.e. non-trial) staff emphasised the importance of a hard collar in restricting head/neck movement. By the time a recruitment approach was made, potential participants were often wary about possibility of randomisation to ERC. This perception was supported by some patients/caregiver interviewees who discussed wanting clear information and reassurance from a trustworthy source that both arms of the trial were safe. In other sites, interviewees described how management

without a hard collar, or with a much-reduced period, had already become more commonplace with non-trial staff rapidly identifying some patients as being unable to tolerate a hard collar. In such cases, trial staff did not believe they could persuade patients to consider trial participation and the possibility of wearing the collar again and, hence, did not approach them.

Some HCPs raised concerns that participants, especially those with advanced dementia or other cognitive or memory issues, could find wearing a hard collar distressing, so should not be randomised. ERC raised different concerns. After discharge, many patients with a hard collar receive weekly check-ups (pad changes, skin integrity check), which HCPs noted provided incidental benefits for patients, additional reassurance and contact at a time when particularly vulnerable due to their recent trauma. Some HCPs expressed discomfort about ERC as provisioning of these weekly checks would be lost.

Remote recruitment

Trial recruitment started during the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic, during national and local lockdowns. Consequently, limited face-to-face interactions were possible in healthcare settings. HCPs noted that the initial approach, and sometimes the entire recruitment process, was undertaken remotely. Many HCPs expressed an active dislike of remote recruitment or a strong preference for face-to-face communication with potential trial recruits as this made it easier to build trust, pick up non-verbal cues, and identify when potential participants might be struggling to grasp concepts such as randomisation and equipoise. There could also be challenges of making contact with potential participants if the patient was still on a ward without their own phone, or had been discharged to somewhere other than their own home.

Healthcare professionals noted that carer proxies often seemed reluctant to agree to trial participation when they were approached separately from the patient, because these individuals still wanted to try to actively include the patient in decision-making. Interviews with carers supported this assumption and highlighted the importance of trying to include all parties, even when patients lacked capacity to give informed consent. This was challenging during the pandemic restrictions.

Burden of trial paperwork

Some HCPs were apprehensive about making recruitment approaches due to the terminology and depth of information provided in the patient information sheet (PIS) which, they suggested, some frail/older people might struggle to understand. Some voiced concerns about the participant diaries and questionnaires being too arduous for a frail/older patient group to complete. Patient and carers, in comparison, described the PIS relatively straightforward to understand. Participants reported finding the diary quick and easy to complete and none described the questionnaire as being problematic to fill in, albeit many reported completing this paperwork erratically (e.g. once a week rather than daily, or when they remembered to do so).

Wider issues

Although not specific to the trial, the SARS-CoV-2 pandemic and other recent events (e.g. exit from the European Union) were reported as having left hospitals short-staffed and remaining staff exhausted. HCPs suggested that, consequently, asking anything more of hospital staff, such as helping to facilitate trial recruitment, was problematic.

Generating recommendations to improve trial recruitment

To determine appropriate courses of action, the research team undertook a collaborative process with members of the Trial Management Group (TMG), patient and public involvement (PPI) contributors, and HCPs involved in active participant recruitment. The report of this activity, along with a summary of the recommendations and subsequent actions is provided in *Report Supplementary Material 4*.

Exploring how using/not using hard collar management affected older/frail people's everyday quality of life

Findings from this component of the qualitative study have been comprehensively reported,[19] so we only provide a brief overview here. Both patient groups reported substantial, negative QoL experiences with the fall itself. Lack of access to care services and information were major contributory factors. While many negative experiences cut across both patient groups, we identified some ways in which the hard collar or ERC reinforced or alleviated (negative) QoL impacts, with the perceived benefits/burdens to using hard collar or ERC varying between individuals.

Autonomy, role and activity

All participants reported experiencing decreased autonomy following the fracture, including needing some/increased help with bathing and dressing, shopping, cooking and laundry. All participants also reported being unable to undertake a variety of day-to-day activities they/the patient had enjoyed prior to the facture, because

of localised and general fatigue, pain, loss of confidence and anxiety. However, patients randomised to a hard collar reported additional negative impacts, such as having to have food cut up and/or fed to them; difficulties going downstairs as the upright positioning of their head made it difficult to look down; and problems with personal hygiene/grooming. Hard collar patients also reported difficulties wearing hearing aids while wearing the collar, which led to feelings of disconnection and difficulties communicating.

Experiences of healthcare

Across treatment groups, many reported a paucity of help, support, guidance and advice from health or social care services which led to upset, anguish and sometimes anger. This was often experienced in heighted ways by hard collar participants who described having been advised in hospital that the collar pads would be changed weekly by their district nurse or physiotherapist and, hence, feeling let down when no-one came to help, and no appointments could be made to have this done.

Emotional impacts

Many participants across both groups described worrying about whether the fracture would heal and being (even more) dependent on others for care/assistance. For some hard collar participants, the collar itself also contributed to their emotional distress, describing the indignity of being unable to shave or wash their hair, or the tight fit of the collar, and restriction of head movement that had caused them to feel frightened and trapped. However, for others, wearing the collar was described as having made them feel '*safe*' or '*cosy*'.

Health perception

There were few apparent differences in the health perceptions of ERC and hard collar participants, with the role of the collar in pain management appearing to vary between individuals. Important health-related QoL considerations emerged with regards to experiences of pressure sores and rashes. Participants who used a hard collar often reported problems affecting their shoulders, upper chest, chin and ears – all areas where the edge of the collar rested. These wounds were described as painful and as adding to participants' overall discomfort.

Exploring whether, and why, patients do/do not adhere to their management allocation

There is currently no national standardised guidance on collar management following dens fractures in older/frail patients, or on management without a collar. The trial protocol allowed for variation in recommendations given to patients in line with local practice. Together, this means there is no standard understanding of what would constitute (non)adherence within this setting. Therefore, we use the term (non)adherence in its broadest sense – to reflect episodes after management allocation when hard collar patients removed their collar or ERC patients put their collar back on. Several themes were identified and are reported below. See *Appendix 5* (*Table 13*) for illustrative quotations.

Strict adherence

Strict adherence was reported by some hard collar participants, but was particularly commonplace in those randomised to ERC, where patients often indicated having no interest in using the collar again, despite experiencing localised pain and fatigue. A few also commented that, as they were participating in a trial, they did not want to risk influencing the results by using a collar. This belief was also noted by one hard collar participant who, despite being told that the fracture had healed, continued to use the collar to fulfil their perceived obligation as a trial participant. Other hard collar participants expressed the belief that adhering strictly to their hard collar management would give them the best chance of recovery, while others still described sticking firmly to hard collar use because of the pain and discomfort they experienced when they tried to take it off.

Episodes of non-collar use in patients randomised to hard collar arm

While only one ERC participant reported an episode of collar use, many hard collar participants discussed a range of situations when they had regularly or occasionally chosen to temporarily remove the collar. This included to undertake self-care activities such as washing, dressing, or eating. Several commented that they considered removal of the collar in such situations to be a low-risk activity, and noted that they would put the collar back on before walking around, which they considered to be more hazardous. Some hard collar participants described taking their collars off when resting in a chair or lying down during the day. Again, this was presented as a low-risk activity. Patients/carers described their decisions to temporarily remove the collar as sticking to the principle of their management allocation, while allowing respite from negative experiences arising from the collar, such as itching, sweating and feeling trapped. Sleeping at night was a time when hard collar participants claimed to have followed the management advice they had been given. However, this advice appeared to differ between individuals with some reporting having been advised to keep the collar on overnight and others to remove it.

Crossovers (permanent change)

A small number of patients crossed over from their allocated management approach. Some crossovers occurred following discussion with a clinician, others without their awareness. Crossovers involving hard collar patients included individuals with significant comorbidities, such as advanced dementia and emphysema. These individuals and/or their carers described how wearing the collar had exacerbated symptoms, such as shortness of breath or confusion/agitation. An additional hard collar patient had their collar removed after developing pressure sores.

In comparison, a patient allocated to ERC explained their crossover took place after they had begun exercising their neck to regain strength and prevent stiffness. After experiencing increasing pain as a result, they had returned to hospital where, apparently, staff identified that the bones had now become displaced. This led to a decision that the collar be reinstated.

Crossover cases where there appeared to be no clinical involvement or discussion with the trial team only occurred with ERC patients. This included one individual who appeared unaware that ERC was an option and still had their collar in place at the time of the follow-up interview, and a second who said that someone had phoned them about removing the collar but, as it was more comfortable, they had decided to keep it on. In both situations, these individuals appeared to understand they were participating in a research study.

Understanding information and support needs

Our analysis identified five core themes, detailed below. An additional theme, specific to hard collar participants was also identified: time without the collar. A table of illustrative data are provided in *Appendix 6* (*Table 14*).

General (condition-specific) information

Patients/carers often discussed wanting to understand the(ir) injury better. While they recalled that HCPs had discussed the injury and its implications at the time of diagnosis, many described having felt quite traumatised/unwell at the time and, hence, had found it difficult to fully understand or recall the information provided. Both patients and carers described later searching the internet or trying to contact their HCPs to get further information or clarification on specific details, often with little success. Their unmet information needs cohered around: understanding bony-fusion/stable fibrous non-union and what happens if it does not occur, the benefits and risks associated with the different management options; and, the longer-term outcomes following a dens fracture (in terms of general and localised functioning and pain). Many also described wanting information about the likelihood of achieving a full recovery.

Signs of normal and abnormal recovery

Many patients and caregivers in both management groups highlighted a need for information about what a 'normal' recovery should look like. Such participants suggested that having insight into the kinds of symptoms (e.g. pain levels, neck stiffness) that could or should be expected and usual time frames for recovery would help them develop realistic expectations, plan better for the medium-term, and, crucially, know if their experiences were unusual and/or potentially problematic.

Safe and hazardous activities

Many highlighted a need for information about the kinds of activities (e.g. household chores, hobbies) which could be conducted without compromising their recovery.

How to actively support recovery

Relatedly, many patients emphasised the importance of staying fit and active to maintain functional abilities and prevent deterioration. These individuals expressed a desire for information about exercises and activities they could undertake to support their recovery. They also described wanting guidance on how to actively prevent any deterioration in their general health and fitness while recovering from the fracture, and to minimise risk of side effects and complications arising from the fracture, such as muscle weakness or stiffness.

Direct access to information and further support

To address the above unmet needs, participants highlighted benefits to being given clear and comprehensive written information about their fracture and how it should be managed, which they could refer to when needed.

Participants described how navigating the healthcare system had been extremely difficult, particularly navigating between the acute/specialist healthcare services and community healthcare services, and between health and social care sectors. Establishing who, where and how to access information, care and other practical help was experienced as profoundly problematic and emotionally and physically draining. Hence, to support their recovery and help them adapt to living with increasing acute or chronic care needs, participants described needing someone or someway to (facilitate) access to appropriate resources, including information, care provisioning and/or or practical support.

Time without the collar

Many hard collar patients described choosing to remove their collar at particular times and/or for particular activities. Patients/carers appeared to believe that removing the collar in such situations would present minimal risks to their healing and recovery. However, their accounts suggested that they had not been given clear and consistent advice from HCPs about when and for how long they could remove the collar for.

Discussion

It matters to both older and frail patients, and to their family and carers, how to best manage odontoid fractures. We investigated how to optimise care through a trial of early collar removal versus standard care for hard collar management. We hypothesised that ERC would have a positive impact on QoL and would be associated with a more rapid return to baseline level of function and independence, while avoiding treatment-related complications.

We recruited 138 patients (mean age 82.3 years, 60.9% CFS > 4, mostly living at home and walking unaided or with a stick, who fractured following a fall from standing height or down stairs). This was only 15.6% of the planned sample size, despite exceeding the planned number of sites opened to recruitment. The study was terminated because of slow recruitment.

The study opened in 2021, against the challenges of the ongoing COVID-19 pandemic. Qualitative interviews, in particular, identified the challenges for staff and patients of remote recruitment. COVID-19 restrictions also affected trial set-up, site opening and intermittently paused recruitment. Recruitment was greatly affected by absences of research nurse staff, who were frequently pulled into more acute roles. Protocol changes were made to minimise any burden of data collection on patients and their carers and on nurses. We also simplified eligibility requirements with the intention of capturing a greater proportion of patients across sites. The changes did not accelerate recruitment sufficiently.

Of necessity during the COVID-19 pandemic, the DENS trial was at the forefront of surgical trials promoting remote recruitment. Despite the experiences we are reporting, remote recruitment is increasingly deployed in trials. Specialist surgical advice, such as fracture management, can be delivered from a central hub to peripheral hospitals, and standard care follow-up delivered remotely as well. So, patients are not required to be seen in person in the specialist hospital, which is better for patients. Recruiting these patients to trials requires that we investigate how to improve remote recruitment. The HCPs reported being uncomfortable with it, which attention to study design and training may be able to resolve, but how to do this effectively requires investigation. PPI will be critical to understanding how to enhance the remote recruitment experience.

One thousand and forty patients screened were not randomised, mostly because they were not actually eligible for the study, or did not consent. For example, 65 screened patients were determined not to be able to tolerate a collar, and 32 not to be able to survive to discharge. Inconsistent advice about hard collars may have contributed to the 101 patients and 36 representatives who refused consent. There were also 102 patients determined as unsuitable by the assessing spinal surgeon. The reason(s) for a patient being unsuitable were not required to be documented in the screening log, but most likely related to features of the fracture that the surgeon deemed made it unsafe for management without a collar. There are, however, no evidenced-based guidelines to inform decisions as to which odontoid fracture types can be safely managed without a collar. That is why in the DENS trial we did not impose criteria regarding fracture features in assessment of eligibility. Surgeon decision-making was, therefore, subjective, informed by experience. In theory, it might have been possible to recruit patients without requiring the opinion of a spinal surgeon, avoiding the influence of surgeons on patient enrolment. However, at the time of study development, inclusion of the surgeon assessment was considered a necessary safety step.

Based on our pre-study sample size estimates, the population that we recruited is underpowered to assess whether there is a difference in how duration of collar use affects patient QoL (measured by EQ-5D-5L), the primary study end point. We did not observe a difference in EQ-5D-5L between treatment allocation groups, in an ITT analysis, calculated using the methodology by Devlin (as specified in design); we observed the same result with the Hernandez methodology[24] (now preferred by NICE following change in policy). The reported outcomes may have also been affected by the large proportion of patients in the hard collar group who removed their collar earlier than planned, for at least some of the time.

Hard collar participants reported a greater number of unique impacts on their QoL, but this does not necessarily translate into a substantively 'worse' overall QoL compared to ERC participants. The study nevertheless presents data

that can inform consideration of management without a hard collar for older or frail patients diagnosed with a new odontoid fracture.

Early collar removal was safe for the recruited population. There were numerically slightly more deaths in the ERC arm of the study compared to the hard collar arm (10 vs. 5). This was not statistically significant, and the deaths, at least where data were available, were not directly related to the facture or to its treatment. We cannot determine whether functional impairment or immobility consequent to a hard collar contributed to mortality. SAEs were more common in the ERC cohort but were largely unrelated to the study intervention.

The trial data evidences that the study population prefers early collar removal. Few patients returned to a hard collar after ERC for comfort. By contrast, only 28 days after randomisation, 80 patients (61.5%) were not wearing a collar, compared to 50 who were, despite equal allocation to the study arms. Other patients reported removing their collar intermittently. The qualitative study findings provided insight into the circumstances and rationales participants had to justify collar removal. For example, some patients allocated to a hard collar considered that they were adhering to that treatment strategy while still removing the collar at such time as sleeping or for self-care. Some patients reported having been advised to keep the collar on overnight and others to remove it.

Other than the DENS study, there are no previous or ongoing trials of odontoid fracture management without neck immobilisation in older or frail patients, but some patients were already being managed without a collar prior to the study. In our earlier survey, UK spinal surgeons reported they would currently manage such fractures without external immobilisation if the patient was unable to tolerate the collar or was distressed by it (90%), had a short life expectancy (65%), or if complications such as skin breakdown or cardiorespiratory disease occurred (77–80%).[1]

Clinicians may consider, based on the data presented here, developing recommendations that older or frail patients with a new odontoid fracture are managed without a hard collar by default. Our embedded qualitative study highlighted the need for clear, consistent guidance to be put in place, to support patient recovery, independence and rehabilitation. Spinal surgeons need to lead on providing a consensus approach to underpin this. Patients and their carers should be supported with information about the fracture, its healing and return to activities. Qualitative analysis was undertaken to support development of a national position statement regarding the information and support which should be given to this population after an odontoid fracture.

In a revision to the study protocol, we included the option of a soft collar for patients weaning from a hard collar, with the aim of capturing an aspect of standard practice for some patients. We would not, though, suggest that a soft collar is incorporated into a standard care pathway. Soft collars are used by fewer than 10% of UK spinal surgeons for odontoid fractures,[15] but provide minimal restriction of neck movements, and are not useful in managing neck pain. Soft collars can also be associated with collar-related complications, such as dysphagia or skin breakdown.

In our health economic analysis, there was an indication that patients with a hard collar needed more support from family members, which may reflect an encumbrance of the collar itself. There was a lower rate of paid carer time in the ERC group compared to the hard collar group, at each time point, and totalled over all time points, but this does not necessarily mean that there was a lower burden of need. Our data and qualitative analysis evidence that consideration should be given to the additional health and social care input required to assist patients with ADL, even if managed with no hard collar. Across the recruited patients, at hospital discharge (comparing to hospital admission), almost 50% fewer patients walked unaided, and the use of a walking frame doubled (19.0–36.0%).

In conclusion, we challenge clinicians to consider prioritising the functional independence and comfort of older and frail patients with odontoid fracture by early collar removal. This can be achieved without a clear detriment to the patient. Our experience with trial recruitment, and insights from the qualitative study, suggest that there is a steer among clinicians and patients and their carers towards ERC as being better for patients. Some uncertainties remain. There is not likely equipoise for a further randomised trial, even if measures could be considered to enhance recruitment. Instead, future prospective observational studies would be well placed to confirm and extend our findings, for example, via a registry initiated at the point of CT trauma scanning.

Implications for decision-makers

We challenge clinicians to consider prioritising the functional independence and comfort of older and frail patients with odontoid fracture by early collar removal. This study supports that this can be achieved without a clear detriment to the patient. Our experience with trial recruitment, and insights from the qualitative study, suggest that there is a steer among clinicians and patients

and their carers towards ERC as being better for patients. There is not likely equipoise for a further randomised trial, even if other measures could be considered to enhance recruitment. Instead, future prospective observational studies would be well placed to further confirm and extend our findings.

Research inclusion

This study was open in 30 UK centres, across diverse geographical locations, serving socioeconomic and ethnically diverse populations. About 59.9% of participants were female. The ethnicity of recruited patients was 'White any background' for 94.2%.

Both the principal study and embedded qualitative study were developed to serve diverse patient populations, including demographic, socioeconomic and ethnic diversity. Patients were recruited from major trauma centres, neurosurgery units and smaller, rural-based hospitals. The results are generalisable in the UK.

Climate health and sustainability

Early removal of collars can enhance patient independence, reducing the need for additional support, both from family and HCPs. This could reduce travel and length of hospital stay, which would have a positive effect.

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Patient and public involvement

Anne Moss and May Smith are people with personal experience volunteering with people who have experienced traumatic injury or of an odontoid fracture. They were involved from the funding of the project in protocol development, and preparation of patient/carer information, and consent forms. They participated in the project management and governance though the project management group and TSC.

Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

The trial received a favourable ethical opinion from Scotland A Research Ethics Committee (REC) on 10 June 2021 (21/SS/0036) and the Leeds West REC (on behalf of England and Wales) on 29 July 2021 (21/YH/0141).

Information governance statement

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Primary conflicts of interest: Julia Lawton was member of HTA General Committee 1 March 2018–30 November 2019. John Norrie was member of HTA CTU Standing advisory committee 1 May 2018–1 May 2023, HTA and EME Editorial Board 1 November 2015–31 March 2019, EME Funding committee 1 August 2019–1 August 2022.

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This synopsis was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

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For more information about this research, please view the award page (www.fundingawards.nihr.ac.uk/award/NIHR131118).

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List of supplementary material

Report Supplementary Material 1
Statistical analysis plan

Report Supplementary Material 2
Health economic analysis plan

Report Supplementary Material 3
Health economic evaluation tables

Report Supplementary Material 4
Recruitment analysis report

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/GJPB0728).

Supplementary material has been provided by the authors to support the report, and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

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List of abbreviations

ADL	activities of daily living
AE	adverse event
CCA	complete-case analysis (complete cases by time point)
CCI	Charlson Comorbidity Index
CFS	Clinical Frailty Scale
C-spine	cervical spine
CT	computerised tomography
DENS	Duration of External Neck Stabilisation
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
ERC	early removal of a hard collar
HCP	healthcare professional
HCRU	healthcare resource use
ITT	intention to treat
NDI	Neck Disability Index
NICE	National Institute for Health and Care Excellence
PIS	patient information sheet
PPI	patient and public involvement
QALY	quality-adjusted life-year
QoL	quality of life
RCT	randomised controlled trial

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SAE	serious adverse event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SC	standard of care
SM	standard management
TMG	Trial Management Group

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Appendix 2

TABLE 11 Participant group characteristics

HCP participants	
Profession background	Doctor 5 Nurse 4 Other (e.g. research specialist, physiotherapist and so on) 3
Specialty	Research 4 Neurosciences, spinal/neurosurgery 5 Emergency (accident and emergency) 2 Generalist/multiple specialties 1
Patient/carer participants	
Age (patient)	64–94 years. Median: 82 years. Mode: 78 years
Frailty (patient)	Median score: 4. Mode: 6
Trial allocation	13 patients allocated to ERC, 14 patients allocated to SM
Place of residence pre accident	26 patients lived at home, 6 of whom lived alone, 19 with their spouse/partner and 1 with their adult offspring 1 lived in a nursing home
Capacity	2 patients were adults with incapacity (AWI)
Support needs pre-fracture	17 patients were in independent with ADL 5 required support with a few ADL 5 required support with many or most ADL
Interviewee	16 interviews with patient alone 6 with proxy alone, including 3 spouses/partners, and 3 adult offspring 5 with both patient and their proxy
Reasons for proxy interview	Dysphasia, hearing difficulties, ongoing short-term memory loss, ongoing pain or fatigue related to dens fracture, advanced dementia (AWI)

Appendix 3

TABLE 12 Recruitment analysis – additional quotes/illustrative data

Theme	Subtheme	Quote/illustrative data
Equipoise and eligibility	Intervention equipoise – ERC SM traditional and safe management option – ERC experimental and unproven	**D7.**HCP: *I mean, it just sort of came up in the discussions that we had when we were setting up the trial, … and he said, yeah, we know it's safe to take the collar off, I was like, sitting there, I was like, mmm, is it? … But obviously I'm a [grade] so, you know, this is way above my pay grade and experience, so if everyone thinks it's safe then I just tend to go along with it, but obviously traditional management is in the collar, so yeah … I hope it's okay to take the collar off, we'll see in three months*
	Intervention equipoise – SM HCPs are uncomfortable witnessing the participants' distress in collar	**D5.**HCP: *No, I don't really understand that, so basically the last two patients with me have just been really distressed, so I've not influenced their decision, but I wanted to take it off, do you know what I mean … So, did I want to leave the collar on, no because it's causing them so much distress*
	Intervention equipoise – standard practices Standard hospital practice impacting recruitment to the trial	**D7.**HCP: *I find the whole trust building very difficult, because usually what happens in these local hospitals, I think they're told they've got a C2 fracture, they need to wear this collar 24/7 otherwise they're going to be quadriplegic, and those are the words that the patients have told me. They're like, oh, how do you know this is safe to take the collar off? You know, it's literally a random person calling them and telling them, oh it would be fine to take it off, after they've been told they would be paralysed if they do that*
	Subgroup equipoise Subgroup equipoise concerns involving adults with incapacity (AWI)	**D8.**HCP: *And a lot of the patients who we're looking at are … lack capacity, who have dementia, and I think it's … it's quite difficult recruiting patients who lack capacity. Em, because it … it would be fine if it's no collar. Em, but if there's a patient who lacks capacity who's randomised to a hard collar, it's … it's quite worrying. […] So sometimes a collar might not be the right answer for a patient [with dementia] with a fracture*

TABLE 12 Recruitment analysis – additional quotes/illustrative data (*continued*)

Theme	Subtheme	Quote/illustrative data
	ERC/frail participants returning home without additional care or support	**D3.**HCP: *If it's on [the collar], then I know they're going to get seen by other people. If they take it off, then that stops, and then … So it's more about additional care and people actually getting that contact over the 12 weeks. […] So that's just a bit nerve-wracking, and not just because of the fracture in her neck but because of all the other things. You're just denying someone contact with … who, by the very nature of the inclusion criteria, is frail and has had a fall or an accident*
Approach – process, information, motivation and decision-making	**Approaching remotely** Active dislike of remote recruitment/strong preference for face-to-face	**D3.**HCP: *The second lady that I spoke to was actually over the phone and again I was really nervous about doing that over the phone and there's so much you don't get. Again, all of those things about them feeling confident in you, it's harder over the phone*
	The difficulties of establishing own credentials	**D7.**HCP: *I find the whole trust building very difficult […] They're like, oh, how do you know this is safe to take the collar off? You know, it's literally a random person calling them and telling them, oh it would be fine to take it off, after they've been told they would be paralysed if they do that*
	Actually making contact often problematic	**D7.**HCP: *Some of them don't have a mobile phone, so they only have, you know, once they get referred, they only get referred with their home phone, and sometimes they're still in hospital … you need to then contact the hospital, and have you ever try to call a ward and try to speak to a patient?*
	Approaching proxies Proxies appear reluctant to opt in when approached separately from patient	**D8.**HCP: *I think it's sort of when they're not sitting with their- the relative or they're their friend, when we're discussing their care, it's, em, I think they get a little bit sort of hesitant to say anything. Whereas if they're sat with the patient, they can kind of you know, feel like the patient's involved*
	Including the patient in the conversation, consider respectful and preferable by HCPs	**D5.**HCP: *She was there the whole time but she will probably have no recollection of what went on. I explained everything respectfully, the way I would with anybody elderly in the same room, just because she's confused, I'm not going to treat her any differently*
	Views on participant information and paperwork – HCPs HCPs believed elderly participants struggle to understand the study and the PISs	**D7.**HCP: *The elderly patient, you know, for them to even read that information sheet and the consent form, it's like you mentioned, with these long sentences, very tiring and, you know, they don't really understand what we're talking about. If you have an 80-year-old patient, and you're like, someone's going to look at your records. The way it's worded is very difficult for them to understand*
	Patient diaries and questionnaires were perceived by HCPs as too arduous for this patient group	**D8.**HCP: *So it's sort of when we say: ah, you know, there's a two week follow-up, there's a six week, and then you've got your six month, and then you've got your patient diary as well, where it's a daily- a daily thing, where you've gotta write down how your pain is, and have you took any medication that day, and what medication you've took. I think to them it's a lot. [right] Em, especially when you know, these patients are elderly, they've come into hospital and most- well if they've come into ED they're not really allowed anybody to stay with them*
	Concerns about completion and continuity of the diary and questionnaire	**D8.**HCP: *Luckily we've only got one patient in, and the diary hasn't gone missing. But that's one of my concerns if, you know, if they are from a care home. And I've got experience of that cause my father was in a care home as well. And- and things can go missing and like you know, they- you can, with them being very busy, they might not have time to put the information down*
	Views on participant information and paperwork – decliner Belief that paperwork would be too demanding – not actually seen any of the paperwork	**Decliner D13:** *Well the reason I then said: no, was because I realised there was something to be filled in every day [right]. […] as I say, if it had been a couple of questions like a couple of tick-boxes, they [care home carers] would have done it. But I wouldn't have asked them to do the amount of em, questions that the girl told me it would be. So [yeah] that was … that was the only reason. Cause I was quite willing to participate* **M:** *yeah, no, sure. And did you get to see the questionnaire sheets at all?* **Decliner D13:** *No, I didn't see it*

continued

TABLE 12 Recruitment analysis – additional quotes/illustrative data (*continued*)

Theme	Subtheme	Quote/illustrative data
	Views on participant information and paperwork – participants Only a few participants recalled the PIS or details of the discussions with HCPs. Found it relatively straightforward/no particular comments or concerns	**D2.ERC:** *Well, he probably … a little bit of it's coming back to me. He told me that there was research going on, comparing recovery of people who wore the collar, and who didn't wear the collar* **D6.ERC:** *Yeah, I thought the notes were really good. We both read them. And yeah, we could understand what was going on, et cetera. And the filling in of the forms is easy enough to do*
	Diary quick and easy to complete/not a burden. Questionnaire not problematic	**D2.ERC:** *No, that's fine. I've been through it [questionnaire] a few times and I've started the diary, and it's mainly about how much pain I'm in, and so that's fine*
	Motivation and decision-making – HCPs Perception ERC *the* selling point of the trial and motivational factor	**D5.**HCP**:** *That's as simple as it is, they both wanted the collar off and so did the family and so did the staff looking after them but that was really it, they wanted the collar off*
	Motivation and decision-making – participants' motivation Most participants discussed altruistic motives for participation	**D21.ERC:** *Em, I think, just to help anybody else if it was in any way gonna be helpful for someone else that had done the same thing I had done, you know, like I've got this habit of falling over and tripping up, and things you know (laughs). So I don't know, I think it was just that at the time, I just thought: oh well, if it's gonna help somebody else, I'll just get- you know, if they can get any, em, any help from it, you know, [… yeah] I would help, you know*
	Other motivations presented alongside altruism, for example, receiving better care and more attention (due to being in a trial)/possibility of removing the collar	**D11.ERC:** *One of the reasons why I was quite sort of happy to do the research, is two reasons really, one is just being a good person, you know … good citizen type thing. But the other, the main reason to be honest was, em, was just for my own care and attention, because eh, as I said in the … in the Zoom meeting, I've never … I had never seen the consultant before (laughs) And I've had a Zoom call with the consultant because I was doing the r … agreed to do the research (laughing)*
	All motivations tempered by need for safety	**D2.ERC:** *My main thought was, because I knew then that the computer would either say yes, you take it off, or no, you don't. My main concern was, you know, this is research, I don't want to damage my health any more than it's already damaged. And envisaging myself with a broken bone in my neck without support was a little scary, you know, at first. So I think I was reassured that it wasn't going to damage me, or they wouldn't be doing it*
	Motivation and decision-making – participant decision-making Time to discuss the trial with other people and consider pros and cons	**D14.ERC:** *They gave me time to- he asked me to think about it. And he'll phone me back … he gave me quite a while to he phoned me back, and I spoke to my grand-daughter about it … And it was unanimous to take it, cause they'd seen me in this cage thing, my wife, aye, yeah. [yeah] And my family. [right] I asked (laughs) I went to them all. They says: well, you're sorta nothing to lose. And the cage thing [yeah] it was horrendous really, you know [right. Right] Whether this works or not, it might have to go back, I don't know*
	Searching the internet for more information, discussing with partners/spouses, and adult children	**D29.**SM**:** *My daughter looked up in research from abroad, cause there's been more research apparently done abroad, with these collars. And, so what she has read from the research there, it seemed to say that there hasn't been a significant difference if you had or hadn't a collar*
Randomisation	HCP – **enacting allocation** HCPs disappointed for participants/not getting preferred allocation	**D5.**HCP**:** *No, I mean the hardest thing is when you … as I said before, when you see people that really want it off and then you're going to be potentially not doing that*
	Perceived need to backtrack on original reassurance and encouragement with SM allocation	**D3.HP:** *Yeah, they already have it on and you're suggesting to take it off, where everybody else has told them that they've got to keep it on. So I feel like you have to make sure that they understand that both options are safe. But by doing that you are saying that you don't have to wear this. So it must be very tempting. … We send them off for 12 weeks and we've got no idea what they're doing at home*

TABLE 12 Recruitment analysis – additional quotes/illustrative data (*continued*)

Theme	Subtheme	Quote/illustrative data
	Outlying cases delays in enacting the allocation (ERC)	**D7.**HCP**:** *I was even struggling with a patient that I wanted to include in the study and that was happy to participate in the study and she has carers that come home to her to help with her daily care, but also to change the collar. And the carer's refused to take the collar off, after she had been randomised to no collar*
	Participant preference SM preference – direct and indirect pain relief	**D1.**SM**:** *I felt at the time that I would rather he wear the collar, they did explain that the neck would heal normally without the collar but I wanted him to keep the collar on because he said it did give ease to him, it eased the pain because it stopped him from moving his head. So, I was quite pleased when the random thing came up, that they wanted him to wear the collar for 12 weeks*
	ERC preference – discomfort of the collar, loss of independence, or difficulties in undertaking their day-to-day activities	**M:** *Right, okay. So did you, at the time when you were thinking about maybe wearing the collar or not wearing the collar, did you have a preference?* **D2.ERC:** *Oh, I absolutely did. I mean, by that time, I was absolutely just appalled at how horrible the collar was. And it was almost a feeling of claustrophobia. A couple of nights and I was trying to go to sleep, and I was just feeling, I can't stand this thing any more. You know, I hope I don't get to the point where I just want to tear it off. … but I mean, for an active person to suddenly be 12 weeks in that thing, you know, where you can't move your head and you can't, you know, do your normal things, that was pretty devastating. To go from being very active, to being almost non-active at all, in one fell swoop, I suppose was having an effect on me, yes*
	Different preferences between the patient and their spouse/underlying indifference	**M:** *So can I check- so you were allocated to keep the collar on, were you? Were you hoping to be allocated to take the collar off?* **D20.**SM**:** *Well it didn't matter, I just said I would participate, and I'm participating, yeah … I wasn't forced into anything, I just volunteered, yeah*
Wider issues	COVID/hospitals short staffed/remaining staff exhausted	**D12.**HCP**:** *If you're somewhere where you're really reliant on: no, actually, I need to get this on other people's radar, because I don't have a mechanism of finding these patients myself [yeah] very easily, that's gonna be tricky at the moment, cause no matter how well you publicise this, how hard you chase the communication, there are a lot of people in healthcare right now, who kind of very much, 'if I get out of bed and go to work, and do what is absolutely required of me that day to a reasonable standard, and make it home again, that's like a good day at work'. [yeah] And anything over and above might be, some days, a step too far, for them, because it's been a pretty harsh couple of years [yeah] And probably for many people, maybe the hardest couple of years they will ever have in their career*

Appendix 4

Recruitment recommendations and subsequent actions

Process of translation into recommendations to improve recruitment

Analysis of the data revealed a number of issues that may have had a detrimental impact on trial recruitment. In order to interpret the results in full, and determine an appropriate course of action, the research team undertook a collaborative process with members of the TMG, PPI contributors, and HCPs involved in active participant recruitment. This process took the form of a *What? So what? Now what?* procedure[10] – an established approach used in healthcare and other settings to bring research findings together with other stakeholder perspectives and experiences to help develop tangible, practical and implementable recommendations. In this case, the following structure was used:

What? *(understanding the event)* Summaries of key themes from the qualitative findings were circulated to members of the TMG, PPI contributors and HCPs involved recruitment in advance of an online meeting.

So what? *(making sense of the findings and their implications)* During the online meeting (held on 5 July 2022), the group came together to discuss the issues and consider their impact on trial recruitment. Attendees were encouraged to reflect on the study findings and draw on their own experiences and expertise to interpret the information provided. Thoughts, opinions and suggestions were openly discussed. The meeting was recorded to aid an accurate write-up. Individuals who were not able to attend the meeting were encouraged to send their comments to the qualitative research team.

Now what? *(identifying a course of action)* Throughout the meeting, after discussion of each main ('So what') issue, attendees were asked generate consensus-based recommendations ('Now what'). While in many cases this could (and did) involve a specific course of action, in others, the group recommended that more information needed to be gathered or specialist advice sought before finalising a decision.

Following the meeting, the recommendations were written up and circulated to the attendees for ratification. Once confirmed, the recommendations were circulated to the TMG for implementation.

Below, we detail the agreed recommendations arising from the meeting, and summarise the actions that subsequently followed.

Agreed recommendations

The following recommendations were agreed:

- Development and sharing of low-cost resources and strategies to promote equipoise among recruitment staff and support the explanation of 'randomisation' and the trial rationale for the trial population (older/frail adults).
- The Chief Investigator/TMG to meet with DENS Statisticians to discuss the practicalities and consequences of reducing the number/frequency of participant questionnaires.
- The Chief Investigator/TMG and health economist to meet to discuss the feasibility of removing the requirement for participants to complete daily paper diaries.
- Face-to-face recruitment to be encouraged where possible, for example, seeing patients in person at fracture clinics. Tips and strategies to support remote recruitment will be cascaded to recruitment staff.
- Specific district general hospitals seeing high rates of potential participants to be approached about opening as a recruitment centre in their own right when practical and financially viable.
- Recruitment sites which do not have existing and entrenched cultures (of removing/not removing collars) to be prioritised.

Subsequent actions

Following circulation of the agreed recommendations, the following actions occurred:

- Following discussion with the health economists, the requirement for data collection via the daily patient diary has been removed. This changed was confirmed with the funders in early 2023. Specific elements of the diary, relevant to health economics analysis, were added to the questionnaires instead and the diary was then withdrawn.
- Similarly, following consultation with the DENS statisticians, the final (12 months) questionnaire has been withdrawn from data collection. The final follow-up with direct patient involvement is now the 6-month questionnaire with additional longer-term data obtained via the Safe Haven.
- Monthly online informal meeting are being run by the trail managers. These are being used to provide a regular opportunity to share resources, strategies and tips to support recruitment, and challenge assumptions and preconceptions.
- New recruitment sites are continuing to open, including satellite hospitals now opening as recruitment centres in their own right. Other centres, with focused issues preventing recruitment (e.g. lack of staff), have been closed to allow TMG resources to focus on supporting sites with better recruitment potential.

Appendix 5

TABLE 13 Adherence analysis – additional quotes/illustrative data

Theme	Code	Quote/illustrative data
Strict adherence	(ERC) no interest/no need to use the collar again	**D2.ERC:** *No, never. I don't want to see the thing, it's out in the garage now. I thought my husband had binned it, I forgot to do it. I just think it's a shame that it can't be reused. It can't be sanitised and reused, that's my only desire for the collar*
	Fulfilling perceived obligation as a trial participant (ERC)	**M:** *Was there any point when you might have wanted to have the collar during that time, that it might have been helpful?* **D14.ERC:** *No. [no] No, I mean I'd- because they were trying it out, so there was no use to say no to it, because it was only a trial anyway. Eh, so it was unfair to moan and say: I'm no wanting it now, you know. If you take a job on, you have to finish the job, you know*
	Fulfilling perceived obligation as a trial participant (SM)	**D1.**SM: *Not in the early days, no, but I think I would have taken it off a couple of weeks ago. And particularly last week, when I got the information from orthopaedics to say that they'd x-rayed him and the neck had healed quite well. … But I knew, because of the research that we'd agreed, that we would keep it on for 12 weeks*
	Best chance of recovery (SM)	**D1.**SM: *Well, my understanding was that if he didn't wear the collar, then the healing would take longer, and he was in pain with his neck before the collar went on. So I didn't want him to be in pain, and I didn't want the healing to cause his neck to be … his head to be bent in any way, you know. Because I know sometimes when bones heal themselves, they don't necessarily heal in the right way. So I was quite happy that it was, the collar, on*
	Pain and discomfort when they tried to take it off	**D33.**SM: *I mean she actually took it off the other day, when- when she shouldn't have done. It fell off. And she did say that when she moved her neck it was crunching. … they put the collar straight back on again. So she desperately needs to wear it. So it is doing what it should be doing*
	Just to change the pads	**D9.**SM: *I just had to come in once a week to get physiotherapy at (names hospital) in (names town), and have the pads that they're called, you know the pads inside [yeah, yeah] change the pads*
	Too scared to change pads alone/ take it off to wash – not able to get any help	**D10.**SM: *No, she needs- she'd like to be able to wash after all this time. But she's just- too- too frightened to, because of the warning. […] I mean she's washed her face in the little- at the beginning. But there's no shower or anything like that. She wasn't allowed to take it off. We asked the local surgery to come and put a new liner in it- we were given a- but they didn't come. They didn't come. […] it didn't come off at all. The doctor told her to keep it on, so she kept it on*
Episodes of non-collar use (SM patients)	ERC participant – sent collars by relatives who were concerned about ERC as a form of fracture management	**D21.ERC:** *My son ordered three collars, three supports. And she's not happy with them. And they- they're too painful to wear. And the hospital did say: don't wear a collar. They- they refused to give her a collar. And they said it's better if she doesn't wear anything. [yeah] So she's no been wearing anything. She's been eh, collar free*
	For self-care activities, such as washing, dressing or eating (SM)/ collar back on before standing up or walking around (higher risk)	**D20.**SM: *It gives you a feeling of em, security, [right] the- I wouldn't, em, okay, I- I was rigorous keeping it on the first fortnight. [yeah] And I found it very hard to eat and drink [yes] So I now take it off for washing and eating. […] okay] and if I'm going out I put it on again*
	when resting in a chair or lying down during the day	**D29.**SM: *I did if I was- if I was reclining in my bed, or in my recliner upstairs, I did, honestly. But I honestly didn't walk about with my collar off. You know, when I- that kind- that- that's how it was*
	Respite from negative experiences (itching, sweating and feeling trapped)	**D31.**SM: *well, actually I do take it off for a little while, and I don't- I don't do any moving, if I'm sitting in a chair [right, okay] I will take it off for a quarter of an hour or so, to get- to get some relief*
	Sleeping at night – differing advice about the collar on overnight	**D23.**SM: *She don't have the collar on at night. The doctor told me up the hospital, that she can leave it off* **D20.**SM: *They [the doctors] like you to lie on your back in bed with a collar on, and I couldn't do that, that made it even worse*

continued

TABLE 13 Adherence analysis – additional quotes/illustrative data (*continued*)

Theme	Code	Quote/illustrative data
Crossovers (permanent change)	Clinical involvement (SM) – comorbidities – dementia/confusion/agitation	**D4.**SM**:** *And she said, look, she said, we're going to have a word with the home, and there'll be a nurse coming to see her, and if she gets distressed and it's just not working, just take it off. So, I think, she went to the home that night at about seven o'clock, and I think it didn't last long, 'cause she'd been very distressed with it on, so they'd taken it off. They phoned somebody up, and then took it off*
	Clinical involvement (SM) – comorbidities – emphysema, exacerbated symptoms and shortness of breath	**D40.**SM**:** *We've been discussing my emphysema. [yes] And because of it, and the distress it's causing me with the collar [yeah] they've agreed I can stop wearing the collar completely […] I wore it for 26 days […] It was absolute agony. I was- there w- two or three nights when I had- I couldn't breathe, I was at my wit's end, and I ended up standing at the front of the house in my pyjamas, and- just gulping in fresh air. It was absolutely appalling, it was dreadful, one of the worst fortnights in my – if months – in my life*
	Clinical involvement (SM) – after developing pressures sores	**D36.** SM**:** *I did have the collar taken off, in em- I wore it for about six weeks I think [right, okay] But then, em, I developed em, a very bad wound from the collar. You know, it rubbed my neck … and so the consultant at (names hospital) decided to take the collar off, and give the wound a chance to heal [right okay] So that's what he did. … I'm still em, I'm still actually have got a dressing on it* **M:** *So when it came off [mmm] did you- did you keep it at all? Did you use the collar at any point since then?* **D36.** SM**:** *No, I've got the collar, but I haven't used it. Em, I don't know what to do with it really*
	Clinical involvement (ERC) – 'exercising' neck, returning to active life	**D6.ERC:** *We went back yesterday. So she's put the collar back on and told him to wear it all the time because some of the bones had become misplaced. … He was in a lot of pain and he also, I think he was overdoing it, he was trying to make his neck move and I don't think he should have. He'd keep turning it make sure he could do it and things like that. He wasn't keeping it still. But he is that type of man that he wants to get better so he'll push it to the end*
	No clinical involvement – choosing to keep the collar on despite allocation	**First interview ERC participant D28** **D28.ERC:** *But as I say they didn't give me anything except this [the collar] and 'don't take it off' … Mustn't take it off. … but I never heard another thing until the end of last week when a doctor, from this place [local trial clinician], I don't know, phoned me up and explained, you know, all this [taking part in the trial] … about he didn't think it- obviously as bad as they thought it was in the beginning. … But I mean if I'm told to do anything serious, then I do it, like keep this thing on my head, so I kept it on my head* **Follow-up interview 14 weeks later** **M:** *How things have been over the last few months?* **D28.ERC:** *Well, em, when I went up to (names hospital) I said about the, you know, cause I'd been wearing the collar all the time, and he did say that I could take it off. But em, I do- I leave the collar still on, but it's em, a bit difficult doing it myself. And, but course if I haven't got the collar on, I'm likely to turn my neck a bit quick, and I do feel it then* **M:** *So did you keep the collar on all the time?* **D28.ERC:** *I did have it on all the time until I went to, yes, to see (names hospital) yeah* **M:** *And how long ago did you go to (names hospital)?* **D28.ERC:** *Eh. A fortnight, three weeks [approx. 11 weeks after injury]*

Appendix 6

TABLE 14 Information needs analysis – additional quotes/illustrative data

Theme	Code	Quote/illustrative data
General (condition-specific) information	Wanting to understand the(ir) injury better	**D2.ERC:** *My doctor's been very helpful. But I was curious, I suppose, in wanting information about what had happened to me, the damage that had been done, the kind of fracture and what was likely to happen at the end of 12 weeks, how much would it have healed and how much of my mobility and going back to my normal life would have been restored*
	Problems fully understand or recall the information provided	**D29.SM:** *I mean I was away in, och I was in cuckoo land with all the painkillers I was on. I said: look, speak to- my husband was there – look speak to my daughter, she'll- she'll be able tell me what I should be doing*
	Searching for more info – little success (internet/ own doctors)	**D30.ERC:** *I mean I've got access- you know, I tried reading things on the internet, but even on the internet it tells you what it is, but it doesn't tell you what to expect for the future with it*
	Likelihood of recovery	**D30.ERC:** *Well the only worry is I just don't know- I don't know what's going on, I don't know what to expect. Em, (sighs) it's just- it's just all- the unknown- I haven't managed to talk to a doctor. … How bad is it? What- what are the ch- what, you know, when he does come out, what- what is gonna be his life? I mean is he gonna be able to be like he was before? Is he gonna be in a wheelchair, I- I- all these things, I just- it- it's the unknown, cause I just don't know, because nobody's talking to me*
Signs of normal and abnormal recovery	Is it normal or potentially problematic (pain levels, analgesic use, neck stiffness)	**D11.ERC:** *The one thing I- regardless of collar, what- what I find odd is that em, I don't know h- but I don't know what's appropriate … you sort of expect you know, I mean perhaps the pains I'm getting now are normal, but what if they weren't? (laughs). … I'm getting certain pain, different pains as it develops. And I don't know whether that means something's (laughing) getting worse. Or whether it's just part of the progression [yeah] for getting better*
	Lack of information/ limited contact with HCPs – feeling frustrated, anxious and isolated during the recovery period	**D2.ERC:** *So I was left with a great void there. Initially I was very frustrated and felt very alone, if you'd like to put it that way*
Safe and hazardous activities	Frustration and distress	**D14.ERC:** *He is- he gets frustrated that I won't let him do things, that you know, still thinks he should do things*
	limiting general household activities and hobbies because of uncertainty	**D14.ERC:** *Well, I'm just worried if he hasn't got this collar for protection, and when I was watering the garden, he was out there, and he wanted to water the garden, you know. And I- I felt if he swung about- I don't know how- nobody's told me how to- if- what he can do, and what he can't do. They told me anything. Nobody's told us anything*
	At odds with identity/ feeling a sense of self-worth	**D21.ERC:** *Just- what they- they did say was rest. You know, they said rest a lot [yeah] em, but I'm not the type that can just sort of sit about and do nothing all day*
How to actively support recovery	Information about exercises and activities to directly support recovery	**D29.SM:** *And I need- I would like to know from the physio what to – what to push, and what to just let, you know, go with. If I need to push my neck one way or the other* --- **D14.ERC:** *They've no given me any exercises. She [wife] says she mollycoddles me* **M:** *Is that something that kind of, that would have been useful? [aye.] Yeah* **D14.ERC:** *Aye. Don't- don't do this. Definitely not, sortae, or: you can do this, and it helps. Or eh, if you know what I mean: do that, you know (speaking in background) Aye, she- she's maybe stopping me doing things that are- that would be good for it or*
	Uncertain but trying things anyway	**D21.ERC:** *But what I do, at tea-time every night, after tea, I'd sit and I look from side to side. I don't know if I'm doing that, if I should be doing that. But I do exercises. I nod up and down, and side to side* **M:** *And how is that?* **D21.ERC:** *It's okay. I think it probably helps to keep it- cause sometimes I feel as though my neck is almost in a- a lock, you know. And just to keep it supple, I do this every night* **M:** *I mean did you read any information anywhere about doing that?* **D21.ERC:** *No, it's just something I thought I would do, you know, to try and exercise it a little bit. No, I never read- yeah, is it alright to do that?*

continued

TABLE 14 Information needs analysis – additional quotes/illustrative data (*continued*)

Theme	Code	Quote/illustrative data
	How to actively prevent any deterioration in their general health and fitness/minimise risk of side effects and complications	**D2.ERC:** *Something else, I just have a note here, the frustration is, right now I would like to know if I should be doing exercises or getting any physiotherapy, but I don't, I can't get that information. I feel that some exercises now, you know, even if I had a sheet telling me what it's safe to do, I could start doing a little bit myself* --- **D20.**SM**:** *I haven't had any physio [right] There was a question I was going to ask you [yeah] Can I do neck exercises, for to strengthen the neck?*
Direct access to information and further support	Wanting comprehensive written info	**D28.ERC:** *I got no instructions, nothing (laughs) you just have to use your instinct, don't you? I mean my- my daughter had come up to the hospital by then. And we decided that em, you know, at least between the two of us. But I did feel that em, you should have some sort of booklet or something*
	Navigating health/social care system difficult and emotionally draining	**D6.ERC:** *I mean, it was quite difficult. The Monday after he did it I went to our GPs and asked them …'cause he needed a frame 'cause the stick wasn't strong enough, so he needed a frame. And I must admit, I broke down there because all they said to me was, go to social services. I'phoned social services and they said to me, you're on a list. And that was it. … they just palmed me off again, or social services did. They just didn't listen that I needed something urgently*
Time without the collar (SM)	SM patients do take collar off at certain times	**D29.**SM**:** *I did if I was- if I was reclining in my bed, or in my recliner upstairs, I did, honestly. But I honestly didn't walk about with my collar off. You know, when I- that kind- that- that's how it was*
	Perceived minimal risk activities only	**D31.**SM**:** *Well, actually I do take it off for a little while, and I don't- I don't do any moving, if I'm sitting in a chair [right, okay] I will take it off for a quarter of an hour or so, to get- to get some relief*
	Lack of information	**D20.**SM**:** *Well, this is the funny thing about it all, what do you call it, that I got no information about anything really. All I got was the collar, and I wasn't told to do this, or do that, or do the other. You know, you're eh, it was up to yourself, it was a learning curve … it would have been handy like you know in the beginning to be given a bit of paper to say what was possible and what wasn't* --- **D10.**SM**:** *I didn't receive any instruction or help with what to do about the- no, coupled with the fact that there was no advice or anything coming from her own- her own doctor, they- they just fitted the neck-brace and just said to expect it to be there for a few weeks*