

# BMJ Open Quality and reporting of patient-reported outcomes in elderly patients with hip fracture: a systematic review

Puck van der Vet <sup>1</sup>, Sandra Wilson,<sup>2</sup> R Marijn Houwert,<sup>1</sup> Egbert-Jan Verleisdonk,<sup>3</sup> Marilyn Heng <sup>2</sup>

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<sup>1</sup>Department of Trauma Surgery, University Medical Centre Utrecht, Utrecht, Netherlands

<sup>2</sup>Department of Orthopaedic Surgery, Massachusetts General Hospital, Boston, Massachusetts, USA

<sup>3</sup>Department of Surgery, Diaconessenhuis, Zeist, Netherlands

## Correspondence to

Puck van der Vet;  
puck\_vandervet94@hotmail.com

## ABSTRACT

**Objective** To assess how patient-reported outcomes (PROs) are reported and to assess the quality of reporting PROs for elderly patients with a hip fracture in both randomised controlled trials (RCTs) and observational studies.

**Design** Systematic review.

**Data sources** Medline, Embase and CENTRAL were searched on 1 March 2013 to 25 May 2021.

**Eligibility criteria** RCTs and observational studies on geriatric (≥65 years of age) patients, with one or more PRO as outcome were included.

**Data extraction and synthesis** Primary outcome was type of PRO; secondary outcome and quality assessment was measured by adherence to the Consolidated Standards of Reporting Trials (CONSORT) extension for patient-reported outcomes (CONSORT-PRO). Because of heterogeneity in study population and outcomes, data pooling was not possible.

**Results** 3659 studies were found in the initial search. Of those, 67 were included in the final analysis. 83.6% of studies did not adequately mention missing data, 52.3% did not correctly report how PROs were collected and 61.2% did not report adequate effect size. PRO limitations were adequately reported in 20.9% of studies and interpretation of PROs was adequately reported in 19.4% of studies. Most Quality of Life (QoL) outcomes were measured by the EuroQol 5-Dimension 3-Levels, and pain as well as patient satisfaction by Visual Analogue Scale.

**Conclusion** This study found that a high variety of PRO measures are used to evaluate geriatric hip fracture care. In addition, 47.8% of studies examining PROs in elderly patients with hip fracture do not satisfy at least 50% of the CONSORT-PRO criteria. This enables poorly conducted research to be published and used in evidence-based medicine and, consequently, shared decision-making. More efforts should be undertaken to improve adequate reporting. We believe extending the CONSORT-PRO extension to Strengthening the Reporting of Observational Studies in Epidemiology for observational studies would be a valuable addition to current guidelines.

## INTRODUCTION

Hip fractures are a major health problem, affecting approximately 18% of women and 6% of men.<sup>1</sup> Mortality and morbidity rates after hip fractures are high and often cause

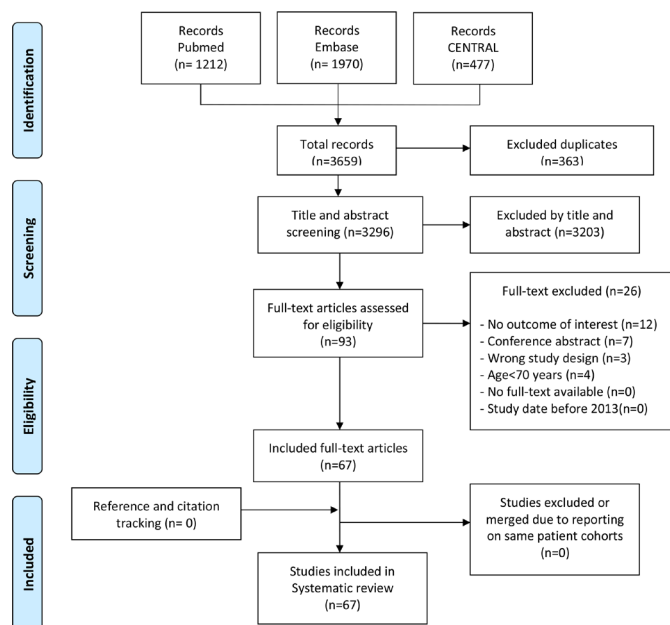
## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ To our knowledge, this is the first systematic review on the reporting quality of patient-reported outcomes in geriatric hip fracture care.
- ⇒ This systematic review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.
- ⇒ A limitation is that we did not perform a meta-analysis because we could not pool data.
- ⇒ Another limitation is that we did not include study protocols or non-English studies, which may have caused bias.

loss of independence in elderly patients. The estimated cost of hip fractures in the USA was 17 billion in 2002.<sup>2</sup> In addition, due to the ageing population, the incidence of hip fractures continues to increase and is estimated to be 4.5 million in 2050.<sup>3</sup> Consequently, hip fractures are considered one of the biggest challenges of future healthcare.

Traditionally, research on patients with geriatric hip fracture tended to focus on objective, clinician-reported outcomes measures, such as mortality, complication rate and hospital length of stay. However, recent literature stresses the importance of patient-reported outcomes (PROs) to evaluate treatment, estimate cost-effectiveness and improve clinical decision-making and patient-centred care.<sup>4</sup>

A PRO is generally defined as an outcome of a patient's health condition or health behaviour that is reported directly by the patient, without interpretation of the patient's response by a clinician or anyone else.<sup>5 6</sup> Patient-reported outcomes measures (PROMs) are instruments to measure these outcomes. Earlier literature on PROs in elderly patients with a hip fracture shows that a hip fracture negatively affects PROs such as Quality of Life (QoL), and that Fear of Falling is increased after a hip fracture, thereby increasing the risk of a secondary fracture.<sup>7</sup> PROs are frequently used in recent hip fracture studies researching different types of treatment,



**Figure 1** Preferred Reporting Items for Systematic Reviews and Meta-Analysis flow diagram presenting the search and selection of studies evaluating PRO(M) in elderly patients with hip fracture.

or studies investigating the potential benefit of comanaged care pathways (ie, orthogeriatric care pathways).<sup>8,9</sup>

While there are already many instruments and questionnaires to measure PROs, and though more measures are currently being developed, there is little to no guidance as to which measure should be used and how PROs should be analysed and interpreted.<sup>10</sup> Earlier studies showed that the quality of reporting PROs in randomised controlled trials (RCTs) was low and that PROs are prone to risk of bias.<sup>11</sup> Therefore, in 2013, the Consolidated Standards of Reporting Trials (CONSORT) extension for patient-reported outcomes (CONSORT-PRO) was published for RCTs to improve quality of reporting.<sup>12</sup> So far, no such measurement exists for harbouring the quality of reporting PROs in observational studies. The objective of this study was to assess how PROs are reported and to assess the quality of reporting PROs for elderly patients with a hip fracture in RCTs and observational studies. We hypothesised that most RCTs would not adhere to the CONSORT-PRO extension and observational studies would have low quality of reporting PROs for elderly patients with a hip fracture.

## METHODS

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis statement.<sup>13</sup> There is no published protocol for this review.

### Search strategy and study selection

We conducted a literature search in PubMed/Medline, CENTRAL and Embase for PRO(M) studies on elderly

patients (above 65 years of age) with a hip fracture, published after 27 February 2013 (date of the publication of the CONSORT-PRO extension). The last search was conducted on 25 May 2021. Online supplemental table A shows the search syntax. After removing duplicates, two independent reviewers (SW and PV) screened titles and abstracts for eligible studies. Eligible studies were RCTs or observational studies on elderly patients with a hip fracture, with at least one PRO as an outcome measure. Outcome measures such as the Charnley score, which can be measured by both clinician and patient, were included only if reported by the patient and if it was described in the article as PRO.

Hereafter, full texts were screened by the same two reviewers. Inclusion criteria were studies on patients over 65 years of age, who were treated (non)-surgically for a hip fracture, and the study had to report one or more PRO. Exclusion criteria were non-English studies, no available full text, letters, case reports, reviews, conference papers and study protocols. Disagreements on eligibility and inclusion were resolved through discussion and, if needed, consultation of a third researcher. References of the included studies were screened for studies that were not found in the original literature search.

### Data extraction

Data were extracted by two independent reviewers (SW and PV). Methodological quality was assessed using the Methodological Index for Non-Randomized Studies (MINORS) criteria for observational studies and the CONSORT 2010 PRO extension tool for randomised trials. MINORS is a 12-item list that corresponds with a scale ranging from 0 to 24 for comparative studies and 0–16 for non-comparative studies (the last 4 criteria are not applicable to non-comparative studies).<sup>14</sup> Disagreements were resolved through discussion and consensus. Online supplemental table B shows details of the critical appraisal.

### Patient and public involvement

No patients and/or public were involved in the design and conduct of this research.

### Primary and secondary outcomes

Primary outcomes included the type of PROM reported and whether it was a primary or a secondary endpoint in the study. Secondary outcome was adherence to the CONSORT-PRO extension. The CONSORT-PRO extension adds five PRO extension items to the CONSORT-2010 Statement and provides PRO elaborations to nine CONSORT criteria, which results in 14 criteria. We based this scoring list on an earlier conducted study on the uptake of CONSORT-PRO in all types of studies.<sup>15</sup> Two independent reviewers (PV and SW) scored the adherence to the CONSORT-PRO criteria. For the purpose of this analysis, we scored the criteria ‘2’ if it was adequately described (by which was meant that a criterium (for instance missing data) was mentioned in the article and that the article involved an explanation of how the criterium was assessed), ‘1’ when it was inadequately

**Table 1** Characteristics of journals with the highest number of included studies and highest impact factors

| Journal                                                        | Impact factor 2020 | No. of included studies | CONSORT/STROBE endorsement | CONSORT-PRO score mean (range) |
|----------------------------------------------------------------|--------------------|-------------------------|----------------------------|--------------------------------|
| <i>Age and Ageing</i>                                          | 10.668             | 2                       | Yes                        | 26                             |
| <i>The Journals of Gerontology: Series A: Biol Sci Med Sci</i> | 6.053              | 2                       | Yes                        | 22.5 (22–23)                   |
| <i>Journal of American Geriatric Society</i>                   | 5.562              | 1                       | Yes                        | 18                             |
| <i>The Journal of Bone and Joint Surgery</i>                   | 5.284              | 2                       | Yes                        | 23.5 (23–24)                   |
| <i>Anaesthesia and Analgesia</i>                               | 5.108              | 1                       | Yes                        | 10                             |
| <i>The Bone &amp; Joint Journal</i>                            | 5.082              | 5                       | Yes                        | 20 (19–21)                     |
| <i>Journal of the American Medical Directors Association</i>   | 4.669              | 2                       | No                         | 16.5 (11–22)                   |
| <i>Osteoporosis International</i>                              | 4.507              | 2                       | No                         | 14.5 (11–18)                   |
| <i>CORR</i>                                                    | 4.176              | 2                       | Yes                        | 24                             |
| <i>Quality of Life Research</i>                                | 4.147              | 1                       | Yes                        | 22                             |
| <i>Archives of Physical Medicine and Rehabilitation</i>        | 3.966              | 1                       | Yes                        | 25                             |
| <i>BMC Geriatrics</i>                                          | 3.921              | 2                       | Yes                        | 22                             |
| <i>Acta Orthopaedica</i>                                       | 3.717              | 2                       | Yes                        | 17 (16–18)                     |
| <i>European Journal of Trauma and Emergency Surgery</i>        | 3.693              | 1                       | Yes                        | 13                             |
| <i>Clinical Rehabilitation</i>                                 | 3.477              | 3                       | Yes                        | 23                             |
| <i>PLoS One</i>                                                | 3.240              | 1                       | Yes                        | 26                             |
| <i>International Orthopaedics</i>                              | 3.075              | 1                       | Yes                        | 24                             |
| <i>Archives of Orthopaedic and Trauma Surgery</i>              | 3.067              | 1                       | Yes                        | 18                             |
| <i>BMJ Open</i>                                                | 2.692              | 1                       | Yes                        | 20                             |
| <i>Injury</i>                                                  | 2.586              | 8                       | Yes                        | 15 (9–21)                      |
| <i>Journal of Orthopaedic Trauma</i>                           | 2.512              | 1                       | Yes                        | 19                             |
| <i>BMC Musculoskeletal Disorders</i>                           | 2.362              | 4                       | Yes                        | 15.5 (12–19)                   |

Impact factor retracted from *Journal of Citation Reports*.  
 CONSORT, Consolidated Standards of Reporting Trials; STROBE, Strengthening the Reporting of Observational Studies in Epidemiology; .

described (by which is meant that a criterium (for instance missing data) was mentioned, but an explanation of how missing data was handled was missing), and ‘0’ when it was not reported/missing, thus resulting in a score ranging from 0 to 28. Disagreements were resolved through discussion and consensus with a third reviewer. In accordance with the previously mentioned article, adherence was deemed ‘good’ when >80% of criteria were met, ‘moderate’ when 50%–79% of criteria were met, and ‘poor’ when <49% of criteria were met. Before scoring, the reviewers discussed the CONSORT-PRO extension to ensure uniformity. A preformed data sheet was used for data extraction, including basic study characteristics: first author, date of publication, journal of publication, country of study, intervention, sample size and follow-up period. Journals were screened on their websites and their ‘instruction for authors’ page on CONSORT/STROBE endorsement. Journals’ impact factor was recorded through the 2020 Web of Science Journal Citation Report.

### Statistical analysis

Statistical analyses were carried out using SPSS Statistics V.27 (IBM Corporation). Results were evaluated descriptively, using total numbers and percentages for categorical variables. Mean values (M) along with the standard deviation (SD) were used for numeric, normally distributed data. The Shapiro-Wilks test was used to assess normal distribution. We

used the  $\chi^2$ -test to assess differences in categorical values. Since this systematic review contained little missing data (<5%), and the data were missing completely at random, we performed complete case analysis. Multivariable logistic regression analysis was used to observe the relation between (in)adequate reporting of CONSORT-PRO criteria and the study characteristics. To correct for possible overfitting, we included only those variables that were notable at an alpha level of 0.10 in the bivariate analyses. The models standardly included study design and journal. P values with a significance level of 0.05 were considered statistically significant. A subgroup analysis was performed according to study design to assess differences between experimental and observational research.

### RESULTS Search

A flow chart of the literature search and study inclusion is shown in [figure 1](#). After title and abstract screening, 93 studies were assessed for eligibility, of which 67 studies were included in the final analysis. Forty-two were RCTs and 25 were observational cohort studies. A total of 44 journals were included, with impact factors ranging from 0.471 to 10.668 ([table 1](#)).

**Table 2** Characteristics of included studies

|                                               | Number of studies (n=67), n (%) |
|-----------------------------------------------|---------------------------------|
| Type of study                                 |                                 |
| RCT                                           | 35 (52.2)                       |
| Follow-up RCT                                 | 5 (7.5)                         |
| Prospective observational cohort              | 7 (10.4)                        |
| Retrospective observational cohort            | 19 (28.4)                       |
| Follow-up observational                       | 1 (1.5)                         |
| Mentioned PRO as                              |                                 |
| Primary outcome                               | 33 (50.0)                       |
| Secondary outcome                             | 33 (50.0)                       |
| Mean follow-up                                |                                 |
| 1–6 months                                    | 15 (25.0)                       |
| 7–12 months                                   | 23 (38.3)                       |
| 1–2 years                                     | 12 (20.1)                       |
| 2–12 years                                    | 10 (16.8)                       |
| Number of centres                             |                                 |
| Single centre                                 | 40 (65.6)                       |
| Multicentre                                   | 21 (34.4)                       |
| Mentioned CONSORT/STROBE adherence in article | 10 (15.4)                       |
| Funding                                       |                                 |
| No influence of funding on results            | 43 (68.3)                       |
| Possible influence of funding on results      | 20 (31.7)                       |

Missing values were excluded from analysis. CONSORT, Consolidated Standards of Reporting Trials; RCT, randomised controlled trial; STROBE, Strengthening the Reporting of Observational Studies in Epidemiology.

### Study characteristics

The 67 included studies analysed a total of 53 931 patients, of which 15 124 were men. Weighted mean age was  $83.90 \pm 1.98$  (range 71.0–99). Follow-up ranged from 0 to 144 months. Study characteristics are displayed in

table 2 and detailed study characteristics are shown in online supplemental table C. Most studies originated from Scandinavia, Europe and China. Figure 2 displays demographic distribution.

### PRO reporting

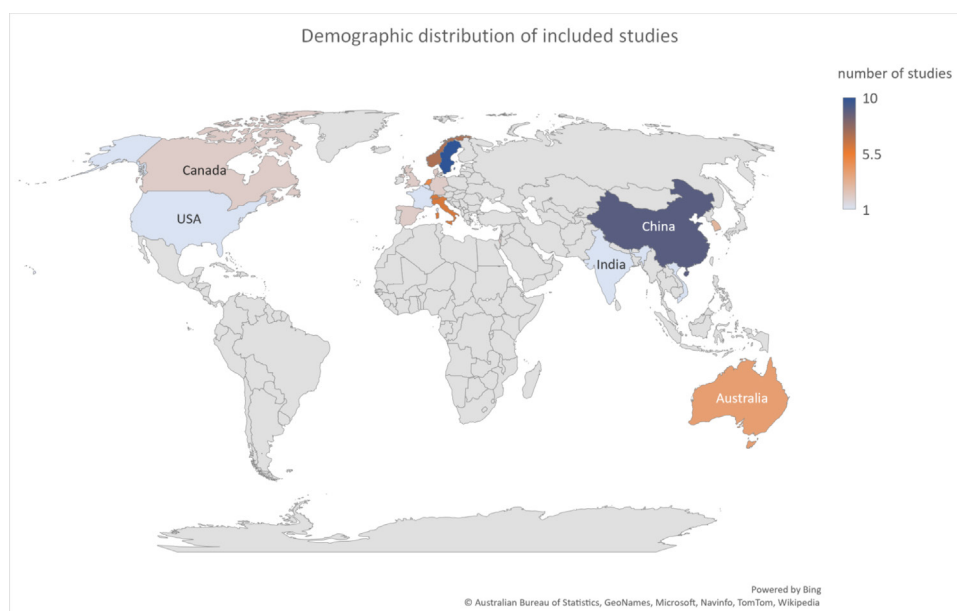
In total, 48 studies reported QoL. Of those, 32 (66.7%) used the EQ-5D-3L as measurement. Twenty-one studies included pain as an outcome measurement. Of those 21 studies, 13 (61.9%) used a VAS as measurement and only one study used a validated pain scale (the PAINAD). Patient-reported functional outcomes were measured using different outcome measurements, most of which were not PROs (ie, Harris Hip score). ADLs were most commonly measured using the Barthel index (45.8%). Details on PROM reporting are shown in table 3.

### Consolidated Standards of Reporting Trials extension for Patient-Reported Outcomes

A total of 10 articles (15.4%) mentioned adherence to the CONSORT/STROBE statement. There were no studies that mentioned the CONSORT-PRO, or any other PRO-reporting guideline. Figure 3, table 4 and online supplemental table D show the adherence to the CONSORT-PRO criteria. Overall reporting mean was  $16.6 \pm 5.8$  (range 1–26).

Thirty (44.8%) studies adequately described the PRO in their abstract and validity and reliability were cited in 76.1% of studies. Adequate reporting was also noted on criteria C15 (baseline outcomes, 76.1%) and C16 (denominator, 83.6%).

Inadequate reporting on PRO hypothesis was noted in 85.1% of studies (n=57). Statistical approaches to missing data were not adequately reported in 83.6% of studies (n=56). 61.2% of studies did not adequately report an effect size or a precision measure, 80.6% did



**Figure 2** Demographic distribution of the included studies. Count: number of studies from each country. Light blue=1, orange=4, 5, dark blue=8.



**Table 3** PRO(M) outcomes

| Type of PRO(M)                                      | No. of studies |
|-----------------------------------------------------|----------------|
| Quality of life measurement (n=48)                  |                |
| EuroQoL 5-Dimension 3-Level (EQ-5D-3L)              | 32             |
| Short Form-36 (SF-36)                               | 7              |
| Short Form-12 (SF-12)                               | 4              |
| Barthel index                                       | 1              |
| DEMqoL                                              | 1              |
| Depression list                                     | 1              |
| AQoL-8D                                             | 1              |
| Qualeffo 41                                         | 1              |
| Pain (n=21)                                         |                |
| Visual Analogue Scale (VAS)                         | 13             |
| Numeric Rating Scale (NRS)                          | 6              |
| Ordinal scale (4-point)                             | 1              |
| PAINAD                                              | 1              |
| Functional outcomes (n=5)                           |                |
| Oxford hip score                                    | 1              |
| Charnley score                                      | 1              |
| Falls Efficacy Scale-International (FES-I)          | 1              |
| SF-36                                               | 1              |
| WOMAC                                               | 1              |
| Patient satisfaction (n=9)                          |                |
| VAS                                                 | 4              |
| Binary                                              | 2              |
| Ordinal scale (3-point, 4-point, 5-point, 10-point) | 3              |
| Activities of daily living, ADL (n=24)              |                |
| KATZ                                                | 6              |
| Barthel index                                       | 11             |
| Nottingham                                          | 2              |
| Ordinal scale (3-point)                             | 1              |
| NHLSD                                               | 1              |
| FIM                                                 | 2              |
| Instrumental ADL                                    | 4              |
| Canadian Occupational Performance Measure           | 1              |

Numbers are noted in total numbers of studies that reported on a certain PRO, some studies used multiple measurement for 1 PRO (ie, both KATZ and Nottingham for ADL).

AQoL 8D, Assessment of Quality of Life 8 Dimensions; DEMQOL, Dementia Quality of Life Measure Qualeffo 41: Quality of Life questionnaire; NHLSD, nursing home life-space diameter; PAINAD, pain assessment in advanced dementia; WOMAC, The Western Ontario and McMaster Universities Osteoarthritis Index.

not adequately report interpretation of the PRO results and 79.1% did not adequately report on any PRO-related limitations.

### Subgroup analyses

#### RCT versus observational

Overall, CONSORT-PRO criteria were reported more adequately in RCTs than in observational cohort studies

( $p=0.026$ ). A significant difference between RCTs and observational research was found in adequate reporting of sample size calculations ( $p=0.002$ ).

#### Predictors of higher CONSORT-PRO score

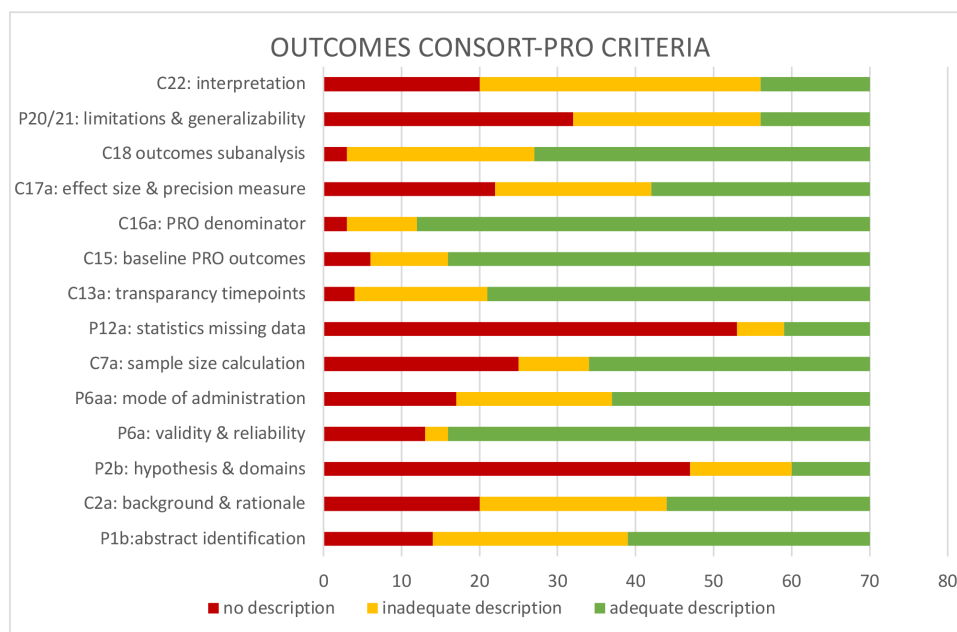
A significant predictor of higher adherence to the CONSORT-PRO score was the study design (coefficient: 1.240, 95% CI 0.165 to 2.333,  $p=0.026$ , adjusted  $R^2=0.279$ ). The second significant predictor for higher CONSORT-PRO scores was if CONSORT-adherence was stated in the methods of an article (coefficient: 1.925, 95% CI 0.422 to 3.429,  $p=0.012$ , adjusted  $R^2=0.279$ ). Journal, country and whether PRO was reported as a primary or secondary outcome did not significantly predict CONSORT-PRO adherence.

### DISCUSSION

To our knowledge, this is the first systematic review that analyses (the quality of) reporting PROs in studies on geriatric patients with a hip fracture. Though PROs are often reported in hip fracture studies, the quality of reporting PROs is not monitored. We found high variability in outcome measures. EQ-5D-3L was most commonly used for measuring QoL, VAS for pain and patient satisfaction, KATZ for ADL. Second, we found that while the overall quality of reporting seems to improve compared with previous literature, the reporting of missing data, PRO limitations and PRO interpretation continues to be suboptimal.

Earlier studies have also reported high variation in outcome measures. A recent scoping review from the National Trauma Research Action Plan group also found high heterogeneity in outcome measures.<sup>16</sup> Standardisation of PROMs should be pursued to adequately analyse and fully comprehend health outcomes in the trauma population. A promising initiative to make PRO reporting more uniform is the PRO measurement information system (PROMIS), a reporting system that was developed in 2007 with the support of the National Institute of Health. This study, however, finds that PROMIS is still infrequently used in research on elderly patients with a hip fracture.

Compared with previous literature, this study generally found higher CONSORT-PRO adherence. In 2015, Bylicki *et al* investigated CONSORT-PRO adherence in randomised clinical trials evaluating cancer therapy. They used a modified version of the CONSORT-PRO questionnaire and found lower adherence scores in 8 out of 13 criteria.<sup>17</sup> Stevens *et al* conducted a systematic review on PRO reporting in RCTs of unplanned general surgeries and also found lower adherence scores in 7 of the 11 CONSORT-PRO criteria that they reported.<sup>18</sup> Mercieca-Bebber *et al* also studied uptake of the CONSORT-PRO in studies of high-impact journals in 2017 for the International Society for Quality of Life Research (ISOQOL) and they found similar reporting rates (67.6% in their study vs 67.3% in this study; in studies who did not report



**Figure 3** Number of studies adhering to the Consolidated Standards of Reporting Trials extension for Patient-Reported Outcomes (CONSORT-PRO) criteria. Red: no description, yellow: inadequate description, green: adequate description.

CONSORT adherence) and (77.7% vs 80.0% in studies who reported CONSORT adherence).<sup>15</sup>

A possible explanation for the difference in reporting rates could be that our study was conducted at least 4 years later than the earlier systematic reviews on PRO reporting. Knowledge of the CONSORT-PRO extension may be more prominent now, eight years after publication of the CONSORT-PRO extension, which may also improve reporting of PROs in general over time. It

could also mean that reporting guidelines (CONSORT, CONSORT-PRO, STROBE) are effective in improving reporting quality. Still, it remains notable since we also include observational studies, for which no PRO guideline exists.

Nonetheless, adherence to several important CONSORT-PRO criteria remained poor. Most included articles in this study did not adequately state their statistical approaches for dealing with missing data. Missing data

**Table 4** Modified Consolidated Standards of Reporting Trials extension for Patient-Reported Outcomes (CONSORT-PRO) extension

| Item | Description                                                                                                                                                                                                  | No description n (%) | Inadequate description n (%) | Adequate description n (%) |
|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|------------------------------|----------------------------|
| 1    | P1b: the PRO should be identified in the abstract as a primary or secondary outcome                                                                                                                          | 13 (19.4)            | 24 (35.8)                    | 30 (44.8)                  |
| 2    | C2a: Background and rationale for PRO assessment                                                                                                                                                             | 19 (28.4)            | 24 (35.8)                    | 24 (35.8)                  |
| 3    | P2b: hypothesis should be stated and relevant domains identified, if applicable                                                                                                                              | 44 (65.7)            | 13 (19.4)                    | 10 (14.9)                  |
| 4    | P6a: Evidence of PRO-instrument validity and reliability should be provided or cited if available                                                                                                            | 13 (19.4)            | 3 (4.5)                      | 51 (76.1)                  |
| 5    | P6aa: Mode of administration, including the person completing the PRO and methods of data collection                                                                                                         | 16 (23.9)            | 19 (28.4)                    | 32 (47.8)                  |
| 6    | C7a: How sample size was determined: only if PRO was a primary study outcome                                                                                                                                 | 23 (34.3)            | 9 (13.4)                     | 35 (52.2)                  |
| 7    | P12a Statistical approaches for dealing with missing data are explicitly stated                                                                                                                              | 50 (74.6)            | 6 (9.0)                      | 11 (16.4)                  |
| 8    | C13a: Results: the number of PRO outcome data at baseline and at subsequent time points should be made transparent                                                                                           | 3 (4.5)              | 15 (22.4)                    | 49 (73.1)                  |
| 9    | C15: Baseline table/outcomes showing PRO data when collected                                                                                                                                                 | 6 (9.0)              | 10 (14.9)                    | 51 (76.1)                  |
| 10   | C16a: For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups, required for PRO results                                      | 3 (4.5)              | 8 (11.9)                     | 56 (83.6)                  |
| 11   | C17a: For each primary and secondary outcome, results for each group, the estimated effect size and its precision measure (such as 95% CI). For multidimensional PRO results from each domain and time point | 22 (32.8)            | 19 (28.4)                    | 26 (38.8)                  |
| 12   | C18: Results of any other analysis and adjusted analysis distinguishing prespecified from explanatory, including PRO analysis where relevant                                                                 | 3 (4.5)              | 24 (35.8)                    | 40 (59.7)                  |
| 13   | P20/21: PRO-specific limitations and implications for generalisability and clinical practice                                                                                                                 | 31 (46.3)            | 22 (32.8)                    | 14 (20.9)                  |
| 14   | C22: PRO data should be interpreted in relation to clinical outcomes including survival data, where relevant                                                                                                 | 19 (28.4)            | 35 (52.2)                    | 13 (19.4)                  |

are common, and sometimes unavoidable in PRO-related research.<sup>19</sup> Yet, it is commonly known that missing data can potentially lead to biased estimates and loss of information, study power and interpretability.<sup>19</sup> A number of approaches for dealing with missing data are known, and they have been published by ISOQOL to assist researchers in dealing with missing data. It is worrying that so few studies reported their (methods for dealing with) missing data and that so few journals, regardless of their impact factors, corrected it during peer review. Another finding was that 61.2% of studies did not report appropriate effect size and precision measurement. Most studies only reported p values. Though a p value expresses statistical significance; it provides no information about the magnitude of a possible effect. Reporting p values by themselves can easily lead to misinterpretation of the results and should therefore be avoided.<sup>20 21</sup> An effect size (ie, OR, relative risk, Pearson correlation) shows the *magnitude of the difference between groups* and is therefore more helpful in interpreting results. Along with a precision measure, they are now required in most reporting standards.

Other important PRO criteria that were rarely met were ‘interpretation of PRO findings’ and ‘PRO limitations’ (both were met in only ~20% of cases). Failure to report limitations and failure to adequately interpret results can lead to unwarranted conclusions. Since outcomes of PRO studies are used as important arguments in shared-decision making, high reporting quality is important. Nonetheless, this study shows that not only authors, but also journals still fail in adequate reporting. This limits the objectiveness of medical research and more efforts should be made to improve quality of reporting.

Observational studies in this systematic review had significantly lower reporting rates than RCTs, as hypothesised. Moreover, the study design (RCT vs observational study) was a significant predictor for CONSORT adherence. No reporting guidelines for PROs currently exist for observational studies. Hence, when interpreting the results, it should be kept in mind that the observational studies were scored with a scoring system that was not specifically designed for that study design. This could be a reason for the lower adherence scores. RCTs are often favoured over observational studies due to the possible unmeasured bias or confounding that can occur in observational research. However, surgical RCTs are difficult to conduct and, as shown in this article, can lead to misleading results in case of inadequate reporting. Recent literature thus stresses the usefulness of observational studies in trauma surgery.<sup>22</sup> We therefore believe that extending the CONSORT-PRO extension to STROBE (an example of which is found in online supplemental table E) would be valuable for future research.

This study has several limitations. Though we made a thorough search strategy along with an experienced librarian, a publication bias could have occurred along with potential bias due to the exclusion of non-English studies and studies with patients <65 years of age. However, since we included a relatively large amount of studies

from different databases, we do not think additional studies would have significantly changed our conclusion. Another limitation is that we included studies from April 2013 and the protocols of these studies may have been written before CONSORT-PRO publication. This may have caused adherence to be low. Third, we reviewed published articles and online supplemental material of included studies but not study protocols. Some of the CONSORT-PRO criteria may have been addressed in the study protocol. However, CONSORT-PRO advises that the information should be noted in the final report as well. Despite these limitations, this study adds to the existing literature as it is the first to provide a broad overview of quality of reporting PRO in this study population and shows current shortcomings of PRO research. It also serves as a benchmark to monitor quality of PRO reporting in future orthopaedic trauma studies.

## CONCLUSION

This systematic review shows that a wide variety of PRO measures are used to evaluate care in geriatric patients with a hip fracture. To better understand health outcomes, we encourage attempts at standardisation of PRO measures, linking of PRO measures, and creation of standard outcome sets. In addition, while we found slightly higher CONSORT-PRO adherence than previous literature, the reporting of missing data, reporting PRO limitations, and—interpretation remains poor, which impedes adequate interpretation by clinicians and the use of PROs in clinical practice. We therefore advise researchers, reviewers and journal editors to ensure proper PRO reporting. To improve quality of PRO reporting in observational studies, we recommend extending the CONSORT-PRO studies to the STROBE guidelines for observational studies.

**Twitter** Marilyn Heng @marilyn\_heng

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**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.



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**Data availability statement** All data relevant to the study are included in the article or uploaded as supplementary information.

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#### ORCID iDs

Puck van der Vet <http://orcid.org/0000-0003-1577-1660>

Marilyn Heng <http://orcid.org/0000-0002-4047-6818>

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## Supplementary materials

## Supplementary table A: search syntax

**Pubmed (n=1212)** <https://pubmed.ncbi.nlm.nih.gov/>

((("patient outcome assessment"[MeSH]) OR ("quality of life"[MeSH]) OR (quality of life[Title/Abstract]) OR ("patient satisfaction"[MeSH] OR patient satisfaction[Title/Abstract]) OR HR-PRO[tiab] OR HRPRO[tiab] OR HRQL[tiab] OR HRQoL[tiab] OR QL[tiab] OR QoL[tiab] ("Health Status"[Mesh]) OR (Patient\*[Title/Abstract] AND report\*[Title/Abstract] AND outcome\*[Title/Abstract]) OR (Patient\*[Title/Abstract] AND report\*[Title/Abstract] AND outcome\*[Title/Abstract] AND measure\*) AND ("Hip Fractures"[Mesh] OR (hip[Title/Abstract] OR femoral[Title/Abstract] OR femur[Title/Abstract] OR (upper[Title/Abstract] AND leg[Title/Abstract])) AND ("Fractures, Bone"[Mesh] OR fractu\*[Title/Abstract]))) AND (("Aged"[Mesh] OR aged[Title/Abstract] OR elderly[Title/Abstract] OR geriatric[Title/Abstract] OR octogenarian[Title/Abstract] OR nonagenarian[Title/Abstract] OR old[Title/Abstract])) AND (2013/1/1:2021/5/24[pdat])) NOT (("addresses"[Publication Type] OR "biography"[Publication Type] OR "case reports"[Publication Type] OR "comment"[Publication Type] OR "directory"[Publication Type] OR "editorial"[Publication Type] OR "festschrift"[Publication Type] OR "interview"[Publication Type] OR "lectures"[Publication Type] OR "legal cases"[Publication Type] OR "legislation"[Publication Type] OR "letter"[Publication Type] OR "news"[Publication Type] OR "newspaper article"[Publication Type] OR "patient education handout"[Publication Type] OR "popular works"[Publication Type] OR "congresses"[Publication Type] OR "consensus development conference"[Publication Type] OR "consensus development conference, nih"[Publication Type] OR "practice guideline"[Publication Type]) NOT ("animals"[MeSH Terms] NOT "humans"[MeSH Terms]) AND (2013/1/1:2021/5/24[pdat]))

**CENTRAL (n=477)** <https://www.cochranlibrary.com/advanced-search>

Hip Fractures in Title Abstract Keyword AND (elderly OR aged OR geriatric OR octogenarian OR nonagenarian OR old\*) in Title Abstract Keyword AND ((Patient AND reported AND outcome\*) OR ("patient reported outcomes") OR (patient near/3 outcome) OR ("patient reported outcome\* measure\*") OR (Patient\* next satisfaction) OR ("patient\* satisfaction") ("Quality of Life")\* OR (PRO)) in Title Abstract Keyword - (Word variations have been searched) → limit year 2013-Current

**Embase (n=1970)** <https://www-embase-com.vu-nl.idm.oclc.org/search/quick?phase=continueToApp>

('patient-reported outcome'/exp OR 'patient-reported outcome':ti,ab OR 'patient reported outcomes'/exp OR 'patient reported outcomes':ti,ab OR 'patient reported outcome measure'/exp OR 'patient reported outcome measure':ti,ab OR 'patient reported outcome measurement'/exp OR 'patient reported outcome measurement':ti,ab OR 'patient reported outcome measurement information system'/exp OR 'patient reported outcome measurement information system':ti,ab OR 'quality of life'/exp OR 'quality of life':ti,ab OR 'quality of life assessment'/exp OR 'quality of life assessment':ti,ab OR 'patient satisfaction'/exp OR 'patient satisfaction':ti,ab OR ((patient NEAR/3 outcome):ti,ab) OR hrqol:ti,ab) AND ('proximal femur fracture'/exp OR femur:ti,ab OR femoral:ti,ab OR hip:ti,ab OR 'upper leg bone':ti,ab) AND ('fracture'/exp OR fractu\*:ti,ab) AND ('aged'/exp OR aged OR elderly OR nonagenarian\* OR octogenarian\* OR geriatric OR old OR 'frail elderly':ti,ab) AND (2013:py OR 2014:py OR 2015:py OR 2016:py OR 2017:py OR 2018:py OR 2019:py OR 2020:py OR 2021:py) AND [humans]/lim AND [abstracts]/lim

Supplement table B: Critical appraisal MINORS

| MINOR criteria               | Clearly stated aim | Inclusion of consecutive patients | Prospective collection of data | Appropriate endpoints | Unbiased assessment endpoints | Appropriate Follow-up | Loss to follow-up <5% | Prospective calculation study size | Adequate control group | Contemporary groups | Baseline equivalence of groups | Adequate statistical analysis | Total MINORS score |
|------------------------------|--------------------|-----------------------------------|--------------------------------|-----------------------|-------------------------------|-----------------------|-----------------------|------------------------------------|------------------------|---------------------|--------------------------------|-------------------------------|--------------------|
| <b>RCTs</b>                  |                    |                                   |                                |                       |                               |                       |                       |                                    |                        |                     |                                |                               |                    |
| Ma et al 2018                | 2                  | 0                                 | 2                              | 2                     | 2                             | 0                     | 2                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 20/24              |
| Lilot et al 2013             | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 2                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 22/24              |
| Prestmo et al 2016           | 2                  | 2                                 | 2                              | 2                     | 2                             | 2                     | 2                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 24/24              |
| Jianbo et al 2019            | 1                  | 2                                 | 2                              | 2                     | 0                             | 2                     | 2                     | 0                                  | 2                      | 2                   | 2                              | 1                             | 18/24              |
| Karlsson et al 2002          | 2                  | 2                                 | 2                              | 2                     | 2                             | 2                     | 2                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 24/24              |
| Lu et al 2017                | 2                  | 2                                 | 2                              | 2                     | 1                             | 2                     | 2                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 23/24              |
| Cadossi et al 2013           | 2                  | 2                                 | 2                              | 2                     | 2                             | 2                     | 1                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 23/24              |
| Wei et al 2020               | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 1                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 21/24              |
| Beaupre 2020                 | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 0                     | 1                                  | 2                      | 2                   | 2                              | 2                             | 19/24              |
| Taraldsen et al 2019         | 2                  | 2                                 | 2                              | 2                     | 2                             | 2                     | 1                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 23/24              |
| Liu et al 2019               | 1                  | 1                                 | 2                              | 2                     | 1                             | 1                     | 1                     | 1                                  | 2                      | 2                   | 2                              | 2                             | 18/24              |
| Kammerlander et al 2018      | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 1                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 21/24              |
| Moerman et al 2017           | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 1                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 21/24              |
| Inngul et al 2013            | 2                  | 0                                 | 2                              | 2                     | 0                             | 2                     | 2                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 20/24              |
| Hedbeck et al 2013           | 2                  | 0                                 | 2                              | 2                     | 1                             | 2                     | 1                     | 2                                  | 2                      | 1                   | 2                              | 2                             | 19/24              |
| Gambatesa et al 2013         | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 2                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 22/24              |
| Dolatwoski et al 2019        | 2                  | 0                                 | 2                              | 2                     | 1                             | 2                     | 2                     | 2                                  | 2                      | 2                   | 1                              | 2                             | 20/24              |
| Monticone et al 2018         | 2                  | 2                                 | 2                              | 2                     | 2                             | 2                     | 1                     | 1                                  | 2                      | 2                   | 2                              | 2                             | 22/24              |
| Bartha et al 2019            | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 1                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 21/24              |
| Crotty et al 2019            | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 2                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 22/24              |
| Tol et al 2017               | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 1                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 21/24              |
| Chammout et al 2019          | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 2                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 22/24              |
| Figved et al 2021            | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 1                     | 2                                  | 2                      | 2                   | 1                              | 2                             | 20/24              |
| Langslet et al 2018          | 2                  | 1                                 | 2                              | 2                     | 2                             | 2                     | 2                     | 2                                  | 2                      | 2                   | 1                              | 2                             | 22/24              |
| Ugland et al 2017            | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 0                     | 2                                  | 2                      | 2                   | 1                              | 2                             | 19/24              |
| Martín-Martín et al 2014     | 2                  | 2                                 | 2                              | 2                     | 2                             | 2                     | 2                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 24/24              |
| Gregersen et al 2015         | 2                  | 2                                 | 2                              | 2                     | 2                             | 2                     | 2                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 23/24              |
| Schmal et al 2018            | 2                  | 2                                 | 2                              | 2                     | 2                             | 1                     | 0                     | 0                                  | 2                      | 2                   | 0                              | 1                             | 16/24              |
| Mak et al 2016               | 2                  | 0                                 | 2                              | 2                     | 1                             | 1                     | 1                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 19/24              |
| Song et al 2020              | 2                  | 2                                 | 2                              | 2                     | 2                             | 2                     | 2                     | 0                                  | 2                      | 2                   | 2                              | 2                             | 22/24              |
| Barenus et al 2018           | 2                  | 2                                 | 2                              | 2                     | 2                             | 2                     | 2                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 24/24              |
| Solarino et al 2020          | 2                  | 2                                 | 2                              | 2                     | 2                             | 2                     | 1                     | 0                                  | 2                      | 2                   | 2                              | 2                             | 21/24              |
| Nardi et al 2018             | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 0                     | 0                                  | 2                      | 2                   | 2                              | 2                             | 18/24              |
| Pompeo et al 2019            | 1                  | 1                                 | 2                              | 2                     | 2                             | 2                     | 0                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 20/24              |
| O'Halloran et al 2016        | 2                  | 2                                 | 2                              | 2                     | 2                             | 1                     | 1                     | 2                                  | 2                      | 2                   | 0                              | 1                             | 19/24              |
| Segev-Jacubovski et al 2019  | 2                  | 2                                 | 2                              | 2                     | 2                             | 2                     | 1                     | 0                                  | 2                      | 2                   | 2                              | 2                             | 21/24              |
| Panella et al 2018           | 2                  | 2                                 | 2                              | 2                     | 2                             | 1                     | 1                     | 1                                  | 2                      | 2                   | 2                              | 2                             | 21/24              |
| Masters et al 2021           | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 2                     | 1                                  | 2                      | 2                   | 2                              | 2                             | 21/24              |
| Caiaffa et al 2016           | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 1                     | 0                                  | 2                      | 2                   | 2                              | 1                             | 18/24              |
| Orive et al 2015             | 2                  | 1                                 | 2                              | 2                     | 1                             | 2                     | 1                     | 1                                  | 2                      | 2                   | 2                              | 1                             | 19/24              |
| Renerts et al 2019           | 2                  | 2                                 | 2                              | 2                     | 2                             | 2                     | 1                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 23/24              |
| Pol et al 2019               | 2                  | 0                                 | 2                              | 2                     | 2                             | 2                     | 1                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 21/24              |
| <b>Observational studies</b> |                    |                                   |                                |                       |                               |                       |                       |                                    |                        |                     |                                |                               |                    |
| Blauth et al 2021            | 2                  | 2                                 | 2                              | 2                     | 1                             | 2                     | 1                     | 2                                  | 2                      | 2                   | 1                              | 2                             | 21/24              |
| Van der Sijp et al 2020      | 2                  | 0                                 | 1                              | 2                     | 1                             | 2                     | 2                     | 2                                  | 2                      | 2                   | 2                              | 2                             | 20/24              |

|                        |   |   |   |   |   |   |   |   |   |   |   |   |       |
|------------------------|---|---|---|---|---|---|---|---|---|---|---|---|-------|
| Dung et al 2019        | 2 | 0 | 2 | 2 | 1 | 2 | 2 | 0 | 2 | 2 | 1 | 0 | 16/24 |
| Jolly et al 2019       | 1 | 1 | 2 | 2 | 1 | 2 | 1 | 2 | 2 | 2 | 0 | 0 | 16/24 |
| Hommel et al 2016      | 2 | 2 | 0 | 2 | 0 | 2 | 0 | 2 | - | - | - | - | 10/16 |
| Jonas et al 2015       | 2 | 0 | 0 | 2 | 0 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 17/24 |
| Sköldenberg et al 2014 | 2 | 1 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 22/24 |
| Kristensen et al 2020  | 2 | 0 | 1 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 19/24 |
| Beaupre et al 2019     | 2 | 0 | 2 | 2 | 2 | 2 | 0 | 0 | 2 | 2 | 2 | 2 | 18/24 |
| Leonardsson et al 2016 | 2 | 0 | 1 | 2 | 0 | 2 | 0 | 0 | - | - | - | - | 7/16  |
| Chen et al 2014        | 2 | 1 | 1 | 2 | 1 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 20/24 |
| Liu et al 2020         | 2 | 1 | 1 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 21/24 |
| Werner et al 2017      | 2 | 1 | 1 | 2 | 1 | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 20/24 |
| Pass et al 2020        | 2 | 2 | 0 | 2 | 0 | 2 | 0 | 2 | 2 | 2 | 2 | 2 | 18/24 |
| Jo et al 2021          | 2 | 1 | 1 | 1 | 1 | 2 | 2 | 0 | - | - | - | - | 10/16 |
| Flury et al 2020       | 2 | 1 | 1 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 21/24 |
| Löfgren et al 2015     | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 2 | 21/24 |
| Yoon et al 2021        | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 2 | 21/24 |
| Kalmet et al 2019      | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 2 | 21/24 |
| Ju et al 2019          | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 2 | 21/24 |
| Thürig et al 2016      | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 2 | 21/24 |
| Kim et al 2019         | 2 | 2 | 1 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 2 | 21/24 |
| Todd et al 2015        | 2 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 2 | 1 | 2 | 1 | 10/24 |
| Soleimani et al 2020   | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 0 | 2 | 2 | 2 | 2 | 21/24 |
| Jorissen et al 2020    | 2 | 0 | 1 | 2 | 1 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 20/24 |

Supplementary table C: detailed study information

| First author | Journal                                          | Year | Country         | Study period | Design  | N patients | Male | Female | Mean age | Mean FU | Prim/sec PRO | No. of centers | MINORS total |
|--------------|--------------------------------------------------|------|-----------------|--------------|---------|------------|------|--------|----------|---------|--------------|----------------|--------------|
| Ma           | Experimental and Therapeutic Medicine            | 2018 | China           | 1,17         | RCT     | 88         | 30   | 58     | 83,89    | 0       | Primary      | 1              | 20           |
| Lilot        | Anesthesia and Analgesia                         | 2013 | France          | 2,25         | RCT     | 68         | 15   | 53     | 84,5     | 0       | Secondary    | 1              | 22           |
| Prestmo      | BMC Geriatrics                                   | 2016 | Norway          | 3,67         | RCT-FU  | 397        | 104  | 293    | 83,3     | 42      | Primary      | 1              | 24           |
| Jianbo       | Injury                                           | 2019 | China           | 17           | RCT     | 100        | 60   | 40     | 78,8     | 24      | Secondary    | 1              | 18           |
| Karlsson     | Archives of physical medicine and rehabilitation | 2020 | Sweden          | 26           | RCT     | 205        | 58   | 147    | 82,9     | 12      | Primary      | 1              | 24           |
| Lu           | AOTS                                             | 2017 | China           | 23           | RCT-FU  | 78         | 20   | 58     | 86,04    | 38,68   | .            | 2              | 23           |
| Cadossi      | The Bone & Joint journal                         | 2013 | Italy           | 25           | RCT     | 83         | 21   | 62     | 83,3     | 30,1    | Primary      | 1              | 23           |
| Blauth       | BMJ Open                                         | 2021 | Switzerland     | 18           | OPCS    | 281        | 74   | 207    | 82,9     | 12      | Secondary    | 12             | 21           |
| van der Sijp | Injury                                           | 2020 | The Netherlands | 25           | OPCS    | 114        | 30   | 84     | 83,9     | 12      | Secondary    | 1              | 20           |
| Wei          | J Am Geriatr Soc                                 | 2020 | China           | 82           | RCT     | 154        | 42   | 112    | 82,7     | 36      | Primary      | 1              | 21           |
| Beaupre      | J Gerontol A Biol Sci Med Sci                    | 2020 | Canada          | 52           | RCT     | 77         | 23   | 54     | 87,9     | 12      | Primary      | 3              | 19           |
| Dung         | Open Access Maced J Med Sci                      | 2019 | Vietnam         | 23           | OPCS    | 35         | 9    | 26     | 84,29    | 6       | Secondary    | 2              | 16           |
| Taraldsen    | PLoS ONE                                         | 2019 | Norway          | 37           | RCT     | 143        | 33   | 110    | 83,4     | 12      | Secondary    | 1              | 23           |
| Jolly        | J Multidiscip Health                             | 2019 | India           | 36           | OPCS    | 100        | .    | .      | 80,0     | 12      | Primary      | 1              | 16           |
| Liu          | J Clin Orthop Traum                              | 2019 | China           | 24           | RCT     | 83         | 48   | 35     | 82,7     | .       | Primary      | 1              | 18           |
| Kammerlander | Int J Clin Exp Med                               | 2018 | Switzerland     | 40           | RCT     | 223        | 37   | 186    | 85,8     | 12      | Secondary    | 9              | 21           |
| Moerman      | Injury                                           | 2017 | The Netherlands | 24           | RCT     | 201        | 58   | 143    | 83,5     | 12      | Primary      | 4              | 21           |
| Hommel       | BMC Musculoskelet Disord                         | 2016 | Sweden          | 36           | ORCS    | 1023       | 274  | 749    | 87,8     | 4       | Secondary    | 1              | 14           |
| Jonas        | Int J Older People Nurs                          | 2015 | United Kingdom  | 32           | ORCS    | 110        | 22   | 88     | 78,5     | 24      | Secondary    | >15            | 17           |
| Sköldenberg  | Injury                                           | 2014 | Sweden          | 29           | OPCS-FU | 50         | 14   | 36     | 81,0     | 24      | Secondary    | 1              | 22           |
| Inngul       | Acta Orthop                                      | 2013 | Sweden          | 38           | RCT-FU  | 120        | 29   | 91     | 86,1     | 48      | Primary      | 1              | 20           |
| Hedbeck      | Int Orthop                                       | 2013 | Sweden          | 83           | RCT     | 60         | 11   | 49     | 84,6     | 24      | Secondary    | 1              | 19           |
| Gambatesa    | J Orthop Trauma                                  | 2013 | Italy           | 18           | RCT     | 40         | 3    | 37     | 80,8     | 1       | Primary      | 1              | 22           |
| Dolatwoski   | JBJS                                             | 2019 | Norway          | 36           | RCT     | 219        | 62   | 157    | 83,2     | 24      | Primary      | 3              | 20           |
| Kristensen   | Clinical orthopaedics and related research       | 2020 | Norway          | 144          | ORCS    | 30178      | 8752 | 21426  | 84,0     | 36      | Secondary    | >15            | 19           |



|               |                                                                  |      |                 |     |        |      |      |      |       |      |           |     |    |
|---------------|------------------------------------------------------------------|------|-----------------|-----|--------|------|------|------|-------|------|-----------|-----|----|
| Monticone     | Clinical rehabilitation                                          | 2018 | Italy           | 41  | RCT    | 30   | 9    | 37   | 77,45 | 12   | Secondary | 1   | 22 |
| Bartha        | Acta Anaesthesiologica Scandinavia                               | 2019 | Sweden          | 48  | RCT-FU | 149  | 54   | 146  | 85,5  | 12   | Secondary | 1   | 21 |
| Beaupre       | Journal of Gerontology                                           | 2019 | Canada          | 48  | OPCS   | 77   | 22   | 55   | 88,6  | 12   | Primary   | 3   | 18 |
| Crotty        | Age and Ageing                                                   | 2019 | Australia       | 30  | RCT    | 240  | 62   | 178  | 88,6  | 12   | Primary   | 3   | 22 |
| Tol           | The Bone & Joint journal                                         | 2017 | The Netherlands | 264 | RCT-FU | 50   | 3    | 47   | 81,2  | 144  | Primary   | 8   | 21 |
| Chammout      | JBJS                                                             | 2019 | Sweden          | 55  | RCT    | 120  | 30   | 90   | 86,0  | 24   | Primary   | 2   | 22 |
| Leonardsson   | The Bone & Joint journal                                         | 2016 | Sweden          | 12  | ORCS   | 2118 | 549  | 1569 | 85,0  | 12   | Primary   | >15 | 18 |
| Figved        | Acta Orthop                                                      | 2021 | Norway          | 18  | RCT    | 28   | 6    | 22   | 80,5  | 24   | Secondary | 1   | 20 |
| Langslet      | Clinical orthopaedics and related research                       | 2018 | Norway          | 23  | RCT-FU | 223  | 56   | 167  | 83,2  | 60   | Primary   | 2   | 22 |
| Chen          | Injury                                                           | 2014 | China           | 72  | ORCS   | 130  | 49   | 81   | 76,7  | .    | Secondary | 1   | 20 |
| Liu           | Osteoporosis international                                       | 2020 | China           | 144 | ORCS   | 327  | 35   | 292  | 93,7  | .    | Primary   | 6   | 21 |
| Morice        | Orthopaedics & Traumatology, Surgery & Research                  | 2015 | France          | 36  | ORCS   | 39   | 6    | 33   | 101,3 | 23   | Primary   | 1   | 16 |
| Ugland        | Osteoporosis international                                       | 2017 | Norway          | 41  | RCT    | 150  | 41   | 109  | 81,3  | 3    | Primary   | 1   | 19 |
| Reina         | Orthopaedics & Traumatology, Surgery & Research                  | 2018 | France          | 12  | OPCS   | 542  | 124  | 418  | 87,0  | 6    | Secondary | .   | 16 |
| Werner        | BMC Musculoskeletal Disord                                       | 2017 | Germany         | 17  | ORCS   | 143  | 43   | 100  | 84,5  | .    | Secondary | 1   | 20 |
| Pass          | EJOT                                                             | 2020 | Germany         | 24  | ORCS   | 5554 | 1674 | 3862 | 82,0  | 4    | Secondary | >15 | 18 |
| Jo            | Hip & Pelvis                                                     | 2021 | Korea           | .   | ORCS   | 82   | 35   | 47   | 84,1  | 12   | Secondary | 1   | 13 |
| Flury         | Journal of Orthopaedics                                          | 2020 | Switzerland     | 68  | ORCS   | 90   | 21   | 69   | 83,5  | 34   | Secondary | 1   | 21 |
| Löfgren       | The International journal of health planning and management      | 2015 | Sweden          | 12  | ORCS   | 503  | 159  | 344  | 83,3  | 12   | primary   | 1   | 21 |
| Martín-Martín | Clinical rehabilitation                                          | 2014 | Spain           | 6   | RCT    | 116  | 28   | 88   | 82    | 6    | secondary | 1   | 24 |
| Yoon          | BMC geriatrics                                                   | 2021 | Korea           | 24  | ORCS   | 211  | 50   | 161  | 81,6  | 6    | secondary | 3   | 21 |
| Kalmet        | Geriatric orthopaedic surgery & rehabilitation                   | 2019 | NL              | 24  | ORCS   | 398  | 116  | 282  | 82,7  | 24   | primary   | 1   | 21 |
| Ju            | Orthopaedic surgery                                              | 2019 | China           | 24  | ORCS   | 168  | 56   | 112  | 80,1  | 15,7 | primary   | 1   | 21 |
| Gregersen     | Journal: Journal of the American Medical Directors Association - | 2015 | Denmark         | 42  | RCT    | 157  | 35   | 122  | 86,3  | 12   | primary   | 1   | 23 |

|                  |                                                                                                    |      |             |     |        |      |      |      |      |      |           |    |    |
|------------------|----------------------------------------------------------------------------------------------------|------|-------------|-----|--------|------|------|------|------|------|-----------|----|----|
|                  | Volume 16, Issue 9, pp. 762-6 - published 2015-09-01                                               |      |             |     |        |      |      |      |      |      |           |    |    |
| Schmal           | Rehabilitation Research and Practice                                                               | 2018 | Denmark     | .   | OPCS   | 22   | 11   | 11   | 81   | 0.2  | primary   | .  | 16 |
| Mak JC           | BMC Musculoskelet                                                                                  | 2016 | Australia   | .   | RCT    | 218  | 50   | 168  | 83.9 | 6    | secondary | 5  | 19 |
| Song             | BMC musculoskeletal disorders                                                                      | 2020 | China       | 48  | RCT    | 94   | 24   | 70   | 71.8 | 12   | primary   | 1  | 22 |
| Thürig           | Patient Saf. Surg.                                                                                 | 2016 | Switzerland | 60  | ORCS   | 86   | 24   | 62   | 75   | 12   | secondary | 1  | 21 |
| Barenius         | The bone & joint journal                                                                           | 2018 | Sweden      | 48  | RCT-FU | 141  | 42   | 99   | 81.3 | 48   | secondary | 1  | 24 |
| Solarino         | Hip international : the journal of clinical and experimental research on hip pathology and therapy | 2020 | Italy       | 18  | OPCS   | 118  | 50   | 68   | 74.3 | 24   | primary   | 1  | 21 |
| Nardi            | J Am Med Dir Assoc                                                                                 | 2018 | Switzerland | 36  | OPCS   | 107  | 17   | 90   | 83   | 12   | secondary | 1  | 18 |
| Pompeo           | Journal of orthopaedic surgery and research                                                        | 2019 | Italy       | 24  | OPCS   | 323  | 51   | 104  | 85.4 | 12   | secondary | 2  | 20 |
| Kim              | Injury                                                                                             | 2019 | Korea       | 36  | ORCS   | 112  | 42   | 70   | 80.8 | 19   | primary   | 1  | 21 |
| Todd             | International journal of orthopaedic and trauma nursing                                            | 2015 | USA         | 6   | ORCS   | 56   | 21   | 35   | .    | .    | secondary | 1  | 10 |
| Nishioka         | Journal of the Academy of Nutrition and Dietetic                                                   | 2018 | Japan       | 24  | ORCS   | 110  | 24   | 86   | 85.4 | .    | secondary | 15 | 21 |
| O'Halloran       | Clinical rehabilitation                                                                            | 2016 | Australia   | 9   | RCT    | 25   | 4    | 21   | 82.6 | 2    | secondary | 1  | 19 |
| Segev-Jacobovski | OTJR (Thorofare N J)                                                                               | 2019 | Israel      | .   | OPCS   | 55   | 16   | 39   | 80.8 | 6    | primary   | 1  | 21 |
| Panella          | Injury                                                                                             | 2018 | Belgium     | .   | RCT    | 514  | 119  | 395  | 81.3 | 6    | secondary | 26 | 21 |
| Masters          | The Bone & Joint journal                                                                           | 2021 | UK          | .   | RCT    | 432  | 134  | 228  | .    | .    | secondary | 5  | 21 |
| Soleimani        | Clinical Gerontologist                                                                             | 2020 | Israel      | 11  | RCT    | 88   | 22   | 22   | 71.0 | 14.5 | primary   | 1  | 21 |
| Caiaffa          | Injury                                                                                             | 2016 | Italy       | 30  | ORCS   | 266  | 93   | 173  | 78.9 | .    | secondary | 6  | 18 |
| Orive            | Int. J. Clin. Pract.                                                                               | 2015 | Spain       | 15  | OPCS   | 891  | 193  | 698  | 83.2 | 12   | primary   | 7  | 19 |
| Renerts          | Quality of life research                                                                           | 2019 | Switzerland | 12  | RCT    | 173  | 36   | 137  | 84.2 | 12   | primary   | 1  | 23 |
| Pol              | Age and ageing                                                                                     | 2019 | NL          | 17  | RCT    | 240  | 49   | 191  | 83.8 | 6    | primary   | 6  | 21 |
| Jorissen         | Bone                                                                                               | 2020 | Australia   | 150 | ORCS   | 2771 | 1164 | 3607 | 85.8 | 12   | secondary | .  | 20 |

RCT: randomized controlled trial. ORCS: observational retrospective cohort study. OPRS: Observational prospective cohort study. FU: Follow-up. PRO: patient-reported outcome.

Supplement table D: differences in reporting CONSORT-PRO between RCTs/observational studies and PRO as primary/secondary outcome

| Description                                                                                                                                                                                                                   | Adequate description n(%) | Adequate reporting in |                     |              | Adequate reporting when PRO outcome is |           |              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------|-----------------------|---------------------|--------------|----------------------------------------|-----------|--------------|
|                                                                                                                                                                                                                               |                           | RCT                   | Observational study | P-value      | Primary                                | Secondary | P-value      |
| P1b: the PRO should be identified in the abstract as a primary or secondary outcome                                                                                                                                           | 30(44.8)                  | 21(50.0)              | 9(36.0)             | 0.332        | 22(66.7)                               | 8(24.2)   | <b>0.002</b> |
| C2a: Background and rationale for PRO assessment                                                                                                                                                                              | 24(35.8)                  | 17(40.5)              | 7(28.0)             | 0.490        | 15(45.5)                               | 9(27.3)   | 0.174        |
| P2b: hypothesis should be stated and relevant domains identified, if applicable                                                                                                                                               | 10(14.9)                  | 8(19.0)               | 2(8.0)              | 0.338        | 6(18.2)                                | 4(12.1)   | 0.177        |
| P6a: Evidence of PRO-instrument validity and reliability should be provided or cited if available                                                                                                                             | 51(76.1)                  | 36(85.7)              | 15(60.0)            | 0.057        | 28(84.4)                               | 22(66.7)  | 0.090        |
| P6aa: Mode of administration, including the person completing the PRO and methods of data collection                                                                                                                          | 32(47.8)                  | 22(52.4)              | 10(40.0)            | 0.200        | 18(54.5)                               | 13(39.4)  | 0.211        |
| C7a: How sample size was determined: only if PRO was a primary study outcome                                                                                                                                                  | 35(52.2)                  | 26(61.9)              | 9(36.0)             | <b>0.002</b> | 17(51.1)                               | 17(51.1)  | 0.499        |
| P12a: Statistical approaches for dealing with missing data are explicitly stated                                                                                                                                              | 11(16.4)                  | 8(19.0)               | 3(12.0)             | 0.716        | 4(12.1)                                | 7(21.2)   | 0.471        |
| C13a: Results: the number of PRO outcome data at baseline and at subsequent time points should be made transparent                                                                                                            | 49(73.1)                  | 31(73.8)              | 18(72.0)            | 0.964        | 28(84.4)                               | 20(60.6)  | 0.085        |
| C15: Baseline table/outcomes showing PRO data when collected                                                                                                                                                                  | 51(76.1)                  | 33(78.6)              | 18(72.0)            | 0.283        | 28(84.8)                               | 22(66.7)  | 0.151        |
| C16a: For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups, required for PRO results                                                       | 56(83.6)                  | 34(81.0)              | 22(88.0)            | 0.729        | 28(84.8)                               | 27(81.8)  | 0.653        |
| C17a: For each primary and secondary outcome, results for each group, the estimated effect size and its precision measure (such as 95% confidence interval). For multidimensional PRO results from each domain and time point | 26(38.8)                  | 16(38.1)              | 10(40.0)            | 0.037        | 17(51.5)                               | 9(27.3)   | 0.130        |
| C18: Results of any other analysis and adjusted analysis distinguishing prespecified from explanatory, including PRO analysis where relevant                                                                                  | 40(59.7)                  | 29(69.0)              | 11(44.0)            | 0.111        | 24(72.7)                               | 15(45.5)  | 0.079        |
| P20/21: PRO-specific limitations and implications for generalizability and clinical practice                                                                                                                                  | 14(20.9)                  | 9(21.4)               | 5(20.0)             | 0.162        | 9(27.3)                                | 5(15.2)   | 0.207        |
| C22: PRO data should be interpreted in relation to clinical outcomes including survival data, where relevant                                                                                                                  | 13(19.4)                  | 10(23.8)              | 3(12.0)             | 0.378        | 9(27.3)                                | 4(12.1)   | 0.294        |

Supplementary table E CONCEPT STROBE -PRO Extension—checklist of items that should be included in reports of observational studies reporting patient-reported outcomes

|                           | Item No | Recommendation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Page No |
|---------------------------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| <b>Title and abstract</b> | 1       | (a) Indicate the study's design with a commonly used term in the title or the abstract<br>(b) Provide in the abstract an informative and balanced summary of what was done and what was found<br><i>PRO should be named in the abstract and identified as primary/secondary outcome</i>                                                                                                                                                                                                                                                                                                                                                                                                          |         |
| <b>Introduction</b>       |         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |         |
| Background/rationale      | 2       | Explain the scientific background and rationale for the investigation being reported<br><i>Explain the background and rationale for PRO assessment</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |         |
| Objectives                | 3       | State specific objectives, including any prespecified hypotheses<br><i>State PRO hypothesis and identify relevant domains, where relevant</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |         |
| <b>Methods</b>            |         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |         |
| Study design              | 4       | Present key elements of study design early in the paper                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |         |
| Setting                   | 5       | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |         |
| Participants              | 6       | (a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up<br><i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls<br><i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants<br>(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed<br><i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case |         |
| Variables                 | 7       | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable<br><i>Evidence of PRO measurement validity should be provided or cited if available including the person completing the PRO and methods of data collection (paper, telephone, electronic, other)</i>                                                                                                                                                                                                                                                                                                                                                    |         |
| Data sources/measurement  | 8*      | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |         |
| Bias                      | 9       | Describe any efforts to address potential sources of bias <i>including biases posed by PRO</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |         |
| Study size                | 10      | Explain how the study size was arrived at                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |         |
| Quantitative variables    | 11      | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |         |
| Statistical methods       | 12      | (a) Describe all statistical methods, including those used to control for confounding<br>(b) Describe any methods used to examine subgroups and interactions<br>(c) Explain how missing data were addressed <i>statistical approached for dealing with missing PRO data should be explicitly stated</i><br>(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed<br><i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed<br><i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy<br>(e) Describe any sensitivity analyses                                    |         |

Continued on next page



| <b>Results</b>    |     |                                                                                                                                                                                                              |
|-------------------|-----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Participants      | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed            |
|                   |     | (b) Give reasons for non-participation at each stage                                                                                                                                                         |
|                   |     | (c) Consider use of a flow diagram                                                                                                                                                                           |
|                   |     | (d) Number of PRO outcome data at baseline and at subsequent time points should be made transparent                                                                                                          |
| Descriptive data  | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders                                                                     |
|                   |     | (b) Indicate number of participants with missing data for each variable of interest                                                                                                                          |
|                   |     | (c) Cohort study—Summarise follow-up time (eg, average and total amount)                                                                                                                                     |
|                   |     | (d) include baseline PRO data, when collected                                                                                                                                                                |
| Outcome data      | 15* | Cohort study—Report numbers of outcome events or summary measures over time                                                                                                                                  |
|                   |     | Case-control study—Report numbers in each exposure category, or summary measures of exposure                                                                                                                 |
|                   |     | Cross-sectional study—Report numbers of outcome events or summary measures                                                                                                                                   |
| Main results      | 16  | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included |
|                   |     | (b) Report category boundaries when continuous variables were categorized                                                                                                                                    |
|                   |     | (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period                                                                                             |
| Other analyses    | 17  | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses                                                                                                               |
|                   |     | Including PRO analysis, where relevant                                                                                                                                                                       |
| <b>Discussion</b> |     |                                                                                                                                                                                                              |
| Key results       | 18  | Summarise key results with reference to study objectives                                                                                                                                                     |
| Limitations       | 19  | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias                                                   |

|                                                                                                          |    |                                                                                                                                                                            |  |
|----------------------------------------------------------------------------------------------------------|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Interpretation                                                                                           | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence |  |
|                                                                                                          |    |                                                                                                                                                                            |  |
| PRO-specific limitations and implications for generalizability and clinical practice should be addressed |    |                                                                                                                                                                            |  |
| Generalisability                                                                                         | 21 | Discuss the generalisability (external validity) of the study results                                                                                                      |  |
|                                                                                                          |    |                                                                                                                                                                            |  |
| PRO data should be interpreted in relation to clinical outcomes, including survival data, where relevant |    |                                                                                                                                                                            |  |
| <b>Other information</b>                                                                                 |    |                                                                                                                                                                            |  |
| Funding                                                                                                  | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based              |  |

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.