Review Article

The effect of complete dentures on edentulous patients’ oral health-related quality of life in long-term: A systematic review and meta-analysis

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ABSTRACT

Background: To evaluate whether the long-term use of complete dentures (CD) into promotes significant changes in the oral health-related quality of life (OHRQoL) in edentulous patients.

Methods: A systematic review and meta-analysis was conducted. A broad search in Pubmed, Web of Science, Scopus, Cochrane Library, Grey Literature, clinical trials registers and manual search was done. The eligibility criteria were based on population, intervention, comparisons and outcome: (P) edentulous patients, (I) CDs rehabilitation, (C) OHRQoL after CD, (O) change in scores of OHRQoL. Two independent reviewers applied the eligibility criteria, collected qualitative data, performed methodological quality and evaluated the certainty of the evidence (grading of recommendations assessment, development and evaluation). The meta-analysis was analyzed in RevMan 5.4 with 95% confidence intervals (CIs) and \( P < 0.05 \).

Results: A total of 2452 records were identified. Twenty-four articles were included in qualitative synthesis. Nineteen studies were qualified as good, 3 as fair and 2 as poor quality. Twelve studies were included in quantitative analysis (meta-analysis). The use of CD did not improved OHRQoL in a period of 3 months through the assessment of the Geriatric Oral Health Assessment Index (GOHAI) instrument (\( P = 0.55; CI; 6.86 [-15.60, 29.31] \)), and Oral Health Impact Profile-14 (OHIP-14) (\( P = 0.05; CI; -14.91 [-29.87, 0.04] \)), with very low certainty of evidence. In a long term, 6 months, GOHAI instrument (\( P < 0.00001; CI; 16.22 [10.70, 21.74] \)), OHIP 20 (\( P = 0.02; CI; -11.09 [-20.54, -1.64] \)) and OHIP-EDENT (\( P = 0.0004; CI; -8.59 [-13.32, -3.86] \)) showed improvement on OHRQoL, with very low and low evidence of certainty, respectively.

Conclusion: CD has the strong potential to contribute to oral health-related quality of life in long-term.

Key Words: Complete denture, edentulous mouth, quality of life

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Website: www.drj.ir
www.drijournal.net
ncbi.nlm.nih.gov/pmc/journals/1480

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INTRODUCTION

Tooth loss is still an unfortunate reality for many patients, especially for the elderly.[1] Edentulism has consequences such as reduction of the lower third of the face, decrease of vertical dimension, loss or reduction of masticatory movement, poor esthetics and phonetic problems.[2] Dietary restrictions and difficulty to eat certain foods are also mentioned by edentulous patients.[3-5] Typically, preference is given to foods that are easier to crush, which can compromise the nutritional needs of the individual, and thus affect general health.[6,7] Those alterations can impact oral health-related quality of life (OHRQoL) and compromise the psychosocial behavior of the individual.[8]

Osseointegrated implants have been used as a treatment for dental loss with high success rates. However, this treatment modality is not available for all patients due to general health, cost, and/or anatomical problems.[9] In spite of removable complete dentures (CDs) being a viable treatment option for the edentulous, they require an adequate bone ridge height to allow the retention and stability, thus efficiently recovering masticatory function.[3]

It is possible to notice a positive change in the behavior of these individuals after CDs oral rehabilitation with fully adapted, comfortable and aesthetic removable CDs. Patients regain self-esteem and general well-being, fit satisfactorily back into social esthetic standards and recover lost nutritional capacity.[10,11]

Thus, the objective of this systematic review and meta-analysis was to evaluate whether the scientific evidence of the long-term use of CD into promotes significant changes in the OHRQoL in edentulous patients.

MATERIALS AND METHODS

This systematic review was recorded on the systematic reviews database PROSPERO (CRD: 42016038907). The written was performed according to Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines (http://www.prisma-statement.org)[12] [Appendix 1] and checked according to a Measurement Tool to Assess Systematic Reviews 2 (AMSTAR-2)[13] [Appendix 2]. The following focused question was outlined according to the population, intervention, comparisons and outcomes (PICO): Do CDs influence the edentulous patients’ OHRQoL in long-term?

Search strategy

The process to search primary studies was done up to June 28, 2020. The following electronic databases were assessed: Pubmed, Web of Science, Scopus and Cochrane Library. The search strategy included appropriate MeSH terms, keywords, and other free terms followed the syntax rules of each database. It was used Boolean operators (OR, AND) to combine searches [Table 1]. The grey literature was consulted through SIGLE (System of Information on Grey Literature) (http://www.opengrey.eu). To find additional studies, a hand search was performed on the reference lists of the retrieved studies.

Inclusion and exclusion criteria

The selection of studies was made by analysis of titles and abstracts that met the inclusion criteria. There was no restriction on language or year of publication. The inclusion criteria outlines articles according to the PICO and study design as follows:

- Population (P): Edentulous patients (both arches)
- Intervention (I): CDs rehabilitation
- Comparison (C): OHRQoL evaluation before and after CDs rehabilitation
- Outcome (O): Change in scores of OHRQoL evaluated in a follow up period of at least 3 months
- Study design (S): Clinical trial, controlled clinical trials, randomized-controlled trials, cohort studies.

The following the exclusion criteria were considered: (i) case reports, review articles, book chapters; (ii) studies in patients with medical conditions such as systemic diseases, syndromes and craniofacial anomalies, or who have special needs or were hospitalized; (iii) studies that used nonvalidated questionnaires; (iv) absence of a baseline evaluation or a baseline was not used to compare with the follow up; (v) absence of follow up; (vii) without results per groups; (vii) studies out theme proposed records.

Study selection

Two independent reviewers analyzed all articles (LAAA and LSG). To assess the agreement between authors, 10% of the publications were random selected in this literature research, and their classification was compared. Kappa statistic was employed and demonstrated good inter-examiner agreement ($K = 0.90$). Duplicate studies were excluded. If the title and abstract were not clear, the
article was read in full. If doubt remained, authors were contacted. If disagreements occurred, a third author (LSA) was called, aiming for a consensus.

**Data extraction (qualitative data)**

Two independent reviewers (LSG and AMCM) extracted relevant data presented in the articles. To characterize and demonstrate the methodological design, we presented the following in detail: Author/year of publication, country where the research was carried out, age of subjects, sample size, social dental index (questionnaire) used to assess the OHRQoL, form of application, type of study, groups compared and the time of follow up.

Another data extracted from the elected articles was average impact for the total scale and subscales before (baseline) and after the CD installation and its association with OHRQoL.

**Evaluation criteria of study risk of bias**

Methodological quality and risk of bias control were evaluated in accordance to the guidelines “Quality Assessment Tool for Before-After (Pre-Post) Studies with No Control Group” described by the National Institutes of Health.[14] This quality assessment tool allows classifying before-after studies with no control group and provides a standardized approach for evaluating the quality. The tools were designed to assist reviewers in focusing on concepts that are key for critical appraisal of the internal validity of a study.

Two reviewers (LSG and LAAA) independently assessed the quality of the included studies, which quality reviewers could select “yes,” “no,” or “cannot determine/not reported/not applicable” in response to each item on the tool. For each item in which “no” was selected, reviewers were instructed to consider the potential risk of bias that could be introduced by that flaw in the study design or implementation.

“Cannot determine” and “not reported” were also noted as representing potential flaws. In general terms, a “good” study has the least risk of bias, and results are considered to be valid. A “fair” study is susceptible to some bias deemed not sufficient to invalidate its results. The fair quality category is likely to be broad, so studies with this rating will vary in their strengths and weaknesses. A “poor” rating indicates significant risk of bias. So, we established as
“good” studies those that presented up to 3 answers “no”; “fair” studies that presented from 3 to 5 answers of “no”; and “poor” studies that presented more than 5 answers of “no.”

Meta-analysis (quantitative data)
For the meta-analysis, we pooled and extracted the mean and the standard deviation (continuous data) from the included studies. Subgroups were established prior to the overall analysis of the outcome, according to the time of follow-up of OHRQoL questionnaire. Each study was included in the analysis only once.

RevMan 5.4 software (Cochrane Central Executive Team, St Albans House, 57-59 Haymarket, London, United Kingdom) was used to analyze the data for heterogeneity and produce a graphical display of results. For forest plots, 95% confidence intervals (CIs) and P values were calculated. Heterogeneity among the results of studies and the quantification of inconsistency were evaluated using the I² test. Values of I² <25%, I² 25%-50% and I² >50% were considered high, moderate and low, respectively. In the Forest plot, P < 0.05 was used to test for overall effect.

Co-variables that influence in the stability of the main outcomes of meta-analysis will be treated with sensibility analysis or meta-regression. Meta-regression consists of a form of sensitivity analysis in covariable meta-analysis. In meta-regression, the number of covariates to be included is limited to the number of studies considered in the meta-analysis. Ideally, one covariate should be used for every ten studies. If the sum of included studies of an outcome exceeded 10, funnel plots can also be generated to analyze the publication bias test.

Grading of recommendations assessment, development and evaluation
Two reviewers (LSG and LAAA) independently analyzed the quality of the evidence (certainty in the estimates of effect) using the grading of recommendations assessment, development and evaluation (GRADE) approach. The domains evaluated in clinical studies are risk of bias, inconsistency, indirectness, imprecision and publication bias. The GRADE defines the quality of scientific evidence more clearly and objectively and can be classified as high, moderate, low or very low.

RESULTS
Flowchart recommended by PRISMA guidelines [Figure 1] describes the number of articles identified in each step of the study. A total of 2452 articles were found, of which 928 were duplicate articles and were removed. Of the 1524 remaining articles, 1460 were excluded after the application of eligibility criteria. Sixty-four articles were accessed in full and of these, 24 were selected for evaluation of methodological. No studies were found through the manual search in the references of the articles.

The characterization and methodological design extracted from the articles are presented in Table 2. The publications from 2003 and 2020 were assessed. The countries with most studies were Brazil, India and England. The population age ranged from 36 to 93 years old. The smallest sample was 15 volunteers and the biggest was 224. Three studies used Geriatric Oral Health Assessment Index (GOHAI), six studies used Oral Health Impact Profile (OHIP) and twelve studies used OHIP for Edentulous (OHIP-EDENT) as the questionnaire tool. It was observed that in the last 5 years from 9 studies, 8 papers used OHIP for Edentulous (OHIP-EDENT) as the questionnaire tool. The most common study design was RCT comparing the CD group with another type of oral rehabilitation. The longest time of follow-up was 5 years followed by 1 study that followed up for 2 years and 4 studies that followed up for 12 months.

From 24 studies, only two presented no significant changes on OHRQoL after new CD treatment. For GOHAI instrument, higher score is associated with a more positive oral health related quality of life, while in the other OHRQoL questionnaires, such as OHIP-14, OHIP-20, OHIP-49 and OHIP-EDENT, lower score is associated with a more positive oral health related quality of life. Based on the checklist to assess the risk of bias, 19 studies were qualified as good, 3 studies as fair and 2 as poor [Table 4]. The mainly problems were detected on questions 3, 5 and 7.

A meta-analysis was performed to evaluate the studies having comparable results. Some studies were not included in this meta-analysis due the authors reported the data in frequency. Some studies had a mean impact of baseline or follow-up. A random-effect model was used when substantial high heterogeneity (I² >50%) was found in

Table 1

| Study | Population | Intervention | Duration | Country | Study Design | Outcome | Quality | Publication bias | Methodological design |
|-------|------------|--------------|----------|---------|--------------|---------|---------|----------------|---------------------|
| Study 1 | Brazil | New CD | 1 year | Brazil | RCT | OHRQoL | Good | Low | Methodological |
| Study 2 | India | New CD | 2 years | India | RCT | OHRQoL | Good | Low | Methodological |
| Study 3 | England | New CD | 5 years | England | RCT | OHRQoL | Good | Low | Methodological |

Figure 1

Flowchart recommended by PRISMA guidelines.
meta-analysis.\textsuperscript{[15]} Forest plots were created according to the instruments: GOHAI at 3\textsuperscript{[26,29]} and 6\textsuperscript{[25,26]} months [Figure 2]; OHIP-14\textsuperscript{[36,38]} at 3 months [Figure 3]; OHIP-20\textsuperscript{[30-32]} [Figure 4] and OHIP-EDENT\textsuperscript{[21,24,27,28]} at 6 months [Figure 5]. The meta-analysis showed no favorable outcome for the use of CD on improving OHRQoL in a period of 3 months through the assessment of the GOHAI instrument ($P = 0.55$; CI: $6.86 [-15.60, 29.31]$), and OHIP-14 ($P = 0.05$; CI: $-14.91 [-29.87, 0.04]$). In a long term, 6 months, GOHAI instrument ($P < 0.00001$; CI: $16.22 [10.70, 21.74]$), OHIP 20 ($P = 0.02$; CI: $-11.09 [-20.54, -1.64]$) and OHIP-EDENT ($P = 0.0004$; CI: $-8.59 [-13.32, -3.86]$) showed improvement on OHRQoL, with very low and low evidence of certainty, respectively.

This study did not have as many co-variables to perform the meta-regression or sensitivity analysis. Publication bias cannot be assessed once there were no subgroup analyses with at least 10 studies included in the meta-analysis.

The certainty of the evidence is shown in Table 5. It was considered very low when the GOHAI and OHIP-14 instruments were applied in 3 months after patients rehabilitated with new CDs. At 6 months, the certainty of the evidence was very low in the GOHAI and OHIP-20 questionnaires. In the subgroup analysis for the GOHAI instrument and in OHIP-EDENT, also at 6 months, the certainty of the evidence was considered very low and low respectively. Serious or very serious problems regarding the risk of bias, inconsistency and imprecision were detected in the studies included in this meta-analysis.
Table 2: Data characterization and methodological design from included articles (n=24)

| Author/year      | Country    | Age       | Total sample and CD group | Instrument/ application form | Type of studies | Comparison group | Follow up                           |
|------------------|------------|-----------|---------------------------|------------------------------|----------------|-----------------|-------------------------------------|
| Heydecke et al.  | Canada     | 65 to 75  | Total: 55 CD: 30          | OHIP-20: Self-applied        | RCT            | Overdenture and CD | Baseline/6 months                  |
| Veyrune et al.   | France     | 40 to 81  | Total: 25 CD: 25          | GOHAI Interview              | RCT            | Before and after CD | Baseline and delivery/6 weeks and 12 weeks (3 months) |
| Forgie et al.    | Scotland   | Mean age | Total: 58 CD: 58          | OHIP-14: Self-applied        | CT             | Before and after CD | Baseline/3 months                  |
| Scott et al.     | WD         | Mean age 71 years | Total: 65 CD: 65 | OHIP-14: Self-applied | CT             | CD using two different confection methods | Baseline/3 months                  |
| Ellis et al.     | United Kingdom | 40 to 80 | Total: 54 CD: 26          | OHIP-20: WD                 | Cohort         | Mandibular overdentures and CD | Baseline/6 months                  |
| Michaud et al.   | Canada     | 64 to 85  | Total: 255 CD: 128        | OHIP-20: WD                 | RCT            | Overdenture and CD | Baseline/6 months/12 months        |
| Goiato et al.    | Brazil     | WD        | Total: 60 CD: 60          | OHIP-EDENT: WD              | CT             | Before and after CD | Baseline/3 months                  |
| Ha et al.        | Korea      | 65 to 93  | Total: 439 CD: 178        | OHIP-14K: Self-reported      | CT             | PRP and CD        | Baseline/3 months                  |
| Harris et al.    | Ireland    | WD        | Total: 122 CD: 65         | OHIP-49: WD                 | RCT            | Overdenture and CD | Baseline/3 months/6 months         |
| Dable et al.     | India      | 60 to 82  | Total: 63 CD: 63          | GOHAI: WD                   | RCT            | Before and after CD | Baseline/6 months                  |
| Viola et al.     | Brazil     | 37 to 86  | Total: 70 CD: 70          | OHIP-EDENT: Interview        | CT             | Before and after CD | Baseline/3 months                  |
| Regis et al.     | Brazil     | 47 to 80  | Total: 39 CD: 39          | OHIP-EDENT: Interview        | RCT            | CD using two different confection methods | Baseline/3 months/6 months         |
| Kuo et al.       | Taiwan     | 65 and over | Total: 224 CD: 224   | OHIP-49: OHIP-14S: OHIP-14T: OHIP-EDENT: 36-item Short-Form (SF-36): Interview | CT             | Before and after CD | Baseline/6 months                  |
| Cakir et al.     | Turkey     | 36 to 81  | Total: 116 CD: 29         | OHIP-14: Self-applied        | RCT            | Overdenture, FPP, PRP and CD | Baseline/12 months                 |
| Madhuri et al.   | India      | Up to 50  | Total: 42 CD: 42          | GOHAI Interview              | CT             | Before and after CD | Baseline/3 months/6 months/12 months |
| Nuñez et al.     | Brazil     | 65 to 74  | Total: 50 CD: 50          | OHIP-EDENT: WD              | RCT            | CD using two different confection methods | Baseline/1 month/6 months         |
| Sivakumar et al. | India      | 55 to 81  | Total: 66 CD: 66          | OHIP-EDENT: Interview        | CT             | Before and after CD | Baseline/1 month/6 months         |
| Cardoso et al.   | Brazil     | 49 to 75  | Total: 50 CD: 25          | OHIP-EDENT: WD              | CT             | Before and after CD | Baseline/3 months                  |
| Degrandi et al.  | Uruguay    | 40 to 85  | Total: 91 CD: 91          | OHIP-14: Self-applied        | CT             | Before and after CD | Baseline/3 months                  |
| Marra et al.     | WD         | WD        | Total: 60 CD: 30          | OHIP-EDENT: WD              | CT             | Overdenture and CD | Baseline/5 years                   |
| Amagai et al.    | Japan      | WD        | Total: 62 CD: 62          | OHIP-EDENT-J: WD            | RCT            | CD-Simple dietary advice and CD+Denture care advice | Baseline/3 months                 |
| Alves et al.     | Brazil     | 50 to 82  | Total: 15 CD: 15          | OHIP-EDENT: WD              | CT             | Before and after CD | Baseline/3 months/2 years          |

Contd...
DISCUSSION

Tooth loss is a major problem for people worldwide because tooth replacement does not always meet the basic needs of these patients. The consequences of edentulism can impact OHRQoL\textsuperscript{[41]} and to compromise social life.\textsuperscript{[6,7]} Also, there is a preference for soft foods, which compromises the overall health of these patients through inadequate ingestion of nutrients.
Table 3: Mean before and after complete dentures in edentulous patients and association with oral health-related quality of life (n=24)

| Author/year          | Questionnaire | Total scale Mean impact (SD) | Subscale Mean impact (SD) | Association of new CD and improvement on OHRQoL |
|----------------------|---------------|------------------------------|---------------------------|-----------------------------------------------|
| Heydecke et al. (2003)<sup>[30]</sup> | OHIP-20       | Baseline=56.32 (19.85) 6 months=47.84 (22.16) | Baseline FL=11.56 (3.54) PP=15.48 (5.70) PD1=5.95 (3.01) PD2=10.88 (4.65) PD3=5.00 (2.53) SD=4.20 (1.55) HP=3.24 (1.64) 6 months FL=10.36 (4.44) PP=12.36 (6.10) PD1=4.60 (3.03) PD2=9.48 (5.60) PD3=4.40 (2.71) SD=3.88 (1.59) HP=2.76 (1.64) | Yes. Using OHIP-20, there were association of CD and OHRQoL in Physical Pain and Psychological discomfort subscale |
| Veyrune et al. (2005)<sup>[29]</sup> | GOHAI         | Baseline=48.23 (7.68) 6 weeks (1 month)=49.58 (7.16) 12 weeks (3 months)=43.46 (12.05) |            | WD |
| Forgie et al. (2005)<sup>[34]</sup> | OHIP-14       | WD                           |            | WD |
| Scott et al. (2006)<sup>[35]</sup> | OHIP-14       | WD                           |            | WD |
| Ellis et al. (2010)<sup>[31]</sup> | OHIP-20       | Baseline=30.70 (18.30) 6 months=27.40 (24.06) |            | WD |
| Michaud et al. (2012)<sup>[32]</sup> | OHIP-20       | Baseline=55.00 (20.00) 6 months=37.00 (19.00) 12 months=35.00 (17.00) |            | WD |
| Goiato et al. (2012)<sup>[18]</sup> | OHIP-EDENT    | WD                           |            | WD |

Contd...
| Author/year (year) | Questionnaire | Total scale | Subscale | Association of new CD and improvement on OHRQoL |
|--------------------|---------------|-------------|----------|-----------------------------------------------|
| Martins et al. (2012) | OHIP-14 | Baseline 31.78 (10.58) | 3 Months FL=2.5 (2.16) | Yes. This study showed considerable improvement in the OHRQoL among the poor elderly population. |
| Ha et al. (2012) | OHIP-14 | Baseline FL=5.65 (2.16) | 3 Months FL=2.25 (2.16) | Yes. This study showed considerable improvement in the OHRQoL among the poor elderly population. |
| Harris et al. (2013) | OHIP-49 | Baseline FL=35.57 (12.17) | 3 Months FL=20.39 (12.66) | Yes. OHIP-49 demonstrated association 3 months after receiving CD. No further improvements on OHRQoL were found in 6 months on any of the measures. |
| Dable et al. (2013) | GOHAI | Baseline 28.90 (7.28) | 6 Months HP=4.96 (9.10) | Yes. An improvement in GOHAI score was observed 6 months after the participants received their new CD. |
| Viola et al. (2013) | OHIP-EDENT | Baseline FL=8.11 (3.18) | 3 Months FL=5.14 (1.96) | Yes. This study indicated that in all domains there were significant improvements in the OHRIP scores with the new CD. |
| Regis et al. (2013) | OHIP-EDENT | Baseline 11.70 (7.90) | 3 Months FL+PD3=2.50 (4.8) | Yes. Considering total sample, new dentures improved OHRQoL at three and at 6 months (comparing to baseline). |
| Kuo et al. (2013) | OHIP-49 | Baseline 60.30 (35.09) | 6 Months FL=12.45 (7.38) | Yes. This study suggests that denture treatments are associated with improvements of OHRQoL. |
Table 3: Contd...

| Author/year       | Questionnaire | Total scale Mean impact (SD) | Subscale Mean impact (SD) | Association of new CD and improvement on OHRQoL |
|-------------------|---------------|-----------------------------|---------------------------|-----------------------------------------------|
| **OHIP-14S**      |               | Baseline=16.40 (10.63)      | FL=2.70 (2.27)            | 6 Months                                      |
|                   |               | 6 months=14.60 (10.61)      | PP=2.20 (1.97)            |                                               |
|                   |               |                             | PD1=2.70 (2.00)           |                                               |
|                   |               |                             | PD2=2.50 (2.04)           |                                               |
|                   |               |                             | PD3=2.10 (1.94)           |                                               |
|                   |               |                             | SD=1.90 (1.77)            |                                               |
|                   |               |                             | HP=2.20 (2.16)            |                                               |
| **OHIP-14T**      |               | Baseline=17.40 (10.76)      | FL=2.70 (2.27)            | 6 Months                                      |
|                   |               | 6 months=15.10 (10.75)      | PP=2.20 (1.86)            |                                               |
|                   |               |                             | PD1=3.30 (2.49)           |                                               |
|                   |               |                             | PD2=2.90 (2.18)           |                                               |
|                   |               |                             | PD3=2.10 (1.91)           |                                               |
|                   |               |                             | SD=1.90 (1.77)            |                                               |
|                   |               |                             | HP=2.40 (2.22)            |                                               |
| **OHIP-EDENT**    |               | Baseline=23.70 (13.46)      | FL=5.90 (2.87)            | 6 Months                                      |
|                   |               | 6 months=21.60 (14.73)      | PP=4.10 (3.39)            |                                               |
|                   |               |                             | PD1=3.30 (2.49)           |                                               |
|                   |               |                             | PD2=3.70 (2.88)           |                                               |
|                   |               |                             | PD3=2.00 (1.94)           |                                               |
|                   |               |                             | SD=2.50 (2.49)            |                                               |
|                   |               |                             | HP=2.20 (2.01)            |                                               |
| Cakir et al. (2014) | OHIP-14      | Baseline=21.24 (2.82)       | FL=16.02 (1.20)           | 12 months                                     |
|                   |               | 12 months=12.24 (2.80)      | PP=18.22 (2.89)           | Yes. A positive influence on OHRQoL was observed, mainly on FL, PD2 and HP. |
|                   |               |                             | PD1=11.78 (3.07)          |                                               |
|                   |               |                             | PD2=23.67 (2.04)          |                                               |
|                   |               |                             | PD3=24.29 (8.96)          |                                               |
|                   |               |                             | SD=6.60 (2.54)            |                                               |
|                   |               |                             | HP=15.67 (6.70)           |                                               |
| Madhuri et al. (2014) | GOHAI       | Baseline=21.11 (4.47)       | WD                        | Yes. The insertion of CD was effective in increasing OHRQoL. |
|                   |               | 3 months=39.26 (2.20)       |                           |                                               |
|                   |               | 6 months=40.04 (1.16)       |                           |                                               |
|                   |               | 12 months=40.19 (1.15)      |                           |                                               |
| Nuñez et al. (2015) | OHIP-EDENT   | Baseline=16.90 (8.00)       | FL+PD2=4.50 (2.20)        | 1 Month                                       |
|                   |               | 1 month=3.90 (4.50)         | FL+PD2=1.70 (1.70)        |                                               |
|                   |               | 6 months=4.80 (6.30)        | PD1+PD3=5.10 (2.80)       |                                               |
|                   |               |                             | PD1+PD3=1.00 (1.90)       |                                               |
|                   |               |                             | SD=2.30 (2.60)            |                                               |
|                   |               |                             | SD=0.40 (1.20)            |                                               |
|                   |               |                             | PP+PD1=1.10 (1.50)        |                                               |

Contd...
Table 3: Contd...

| Author/year            | Questionnaire | Total scale | Subscale | Association of new CD and improvement on OHRQoL |
|------------------------|---------------|-------------|----------|-----------------------------------------------|
|                        |               | Mean impact (SD) | Mean impact (SD) |                                             |
|                        |               | Baseline | 1 month | 6 Months |                                             |
|                        |               | FL=2.59 (1.97) | FL=1.20 (1.46) | FL=0.50 (1.30) |                                             |
|                        |               | PP=2.48 (2.07) | PP=1.64 (2.06) | PP=0.50 (0.99) |                                             |
|                        |               | PD1=1.89 (2.06) | PD1=0.43 (0.89) | PD1=8.29 (0.76) |                                             |
|                        |               | PD2=3.43 (2.66) | PD2=1.52 (1.68) | PD2=0.79 (1.60) |                                             |
|                        |               | PD3=2.20 (2.36) | PD3=0.41 (0.87) | PD3=0.25 (0.77) |                                             |
|                        |               | SD=1.68 (1.93) | SD=0.30 (0.99) | SD=0.27 (0.70) |                                             |
|                        |               | HP=1.29 (1.74) | HP=0.21 (0.80) | HP=0.02 (0.02) |                                             |
| Sivakumar et al. (2015) | OHIP-EDENT   | Baseline | 1 month | 6 Months | Yes. Elderly edentulous patients had an improved overall OHRQoL after CD therapy. |
|                        |               | 5 years | 3 years | 5 years |                                             |
|                        |               | FL=8.93 (3.57) | FL=5.36 (3.57) | FL=5.36 (3.57) |                                             |
|                        |               | PP=8.93 (3.57) | PP=5.36 (3.57) | PP=5.36 (3.57) |                                             |
|                        |               | PD1=7.14 (3.57) | PD1=3.57 (1.79) | PD1=3.57 (1.79) |                                             |
|                        |               | PD2=8.93 (3.57) | PD2=4.46 (3.57) | PD2=4.46 (3.57) |                                             |
|                        |               | PD3=8.93 (3.57) | PD3=3.57 (1.79) | PD3=3.57 (1.79) |                                             |
|                        |               | SD=8.93 (3.57) | SD=3.57 (3.57) | SD=3.57 (3.57) |                                             |
|                        |               | HP=7.14 (3.57) | HP=3.57 (3.57) | HP=3.57 (3.57) |                                             |
| Cardoso et al. (2016) | OHIP-EDENT   | WD        | WD       | WD       | Yes. Elderly edentulous patients had an improved overall OHRQoL after CD therapy. |
| Degrandi et al. (2017) | OHIP-14       | Baseline | 5 years | 3 months | Yes. There was a significant statistical improvement of the OHRQL as perceived by the surveyed patients. |
| Marra et al. (2017)   | OHIP-EDENT   | Baseline | 5 years | 3 months | Yes. The results indicated that OHRQoL was significantly improved after treatment with new CD |
| Amagai et al. (2017)  | OHIP-EDENT-J | WD        | WD       | WD       | Yes. There were more significant improved dimensions of OHIP-EDENT-J in the intervention group than in the control group at the 3-month assessment. |
Table 3: Contd...

| Author/year          | Questionnaire | Total scale Mean impact (SD) | Subscale Mean impact (SD) | Association of new CD and improvement on OHRQoL |
|----------------------|---------------|-----------------------------|---------------------------|------------------------------------------------|
| Alves et al. (2018)  | OHIP-EDENT    | WD                          | WD                        | Yes. Differences in discomfort and chewing inability between the initial evaluation and 2 years into wearing the dentures were confirmed, demonstrating an improvement in patient OHRQoL |
| Tôrres et al. (2019) | OHIP-EDENT    | WD                          | WD                        | Yes. new complete dentures significantly improved the OHRQoL |
| Albuquerque et al. (2020) | OHIP-EDENT | Baseline=12.40 (6.30) 3 months=6.70 (5.60) 6 months=5.00 (5.20) | 3 months FL+PD2=3.50 (2.20) 3 PD1+PD3=2.80 (2.00) 4 SD=1.40 (1.50) 1 PP+PD1=4.70 (2.70) | Yes. Regardless of the technique, participants reported better OHRQoL in both follow-up periods (3 and 6 months after denture delivery) |

WD: Without data; FL: Functional limitation; PP: Physical Pain; PD1: Psychological Discomfort; PD2: Physical Disability; PD3: Psychological Disability; SD: Social Disability; HP: Handicap; OHIP: Oral Health Impact Profile; OHIP-EDENT: Oral Health Impact Profile for assessing edentulous subjects; GOHAI: Geriatric Oral Health Assessment Index; OIDP: The Oral Impacts on Daily Performance; OHRQoL: Oral health-related quality of life; CD: Complete dentures
Table 4: Quality assessment (n=24)

| Author/year          | Question 1 | Question 2 | Question 3 | Question 4 | Question 5 | Question 6 | Question 7 | Question 8 | Question 9 | Question 10 | Question 11 | Question 12 | Quality Rating |
|----------------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|----------------|
| Heydecke et al. (2003) [30] | Yes        | Yes        | Yes        | Yes        | Yes        | No         | Na         | No         | Na         | Yes         | Yes         | Yes         | G              |
| Veyrune et al. (2005) [29]  | Yes        | Yes        | Yes        | No         | No         | Yes        | Na         | Yes        | Yes        | Yes         | No         | Na          | G              |
| Forgie et al. (2005) [34]  | Yes        | No         | Yes        | No         | No         | Yes        | No         | Na         | Yes        | Yes         | No         | Na          | P              |
| Scott et al. (2006) [35]   | Yes        | No         | No         | Yes        | No         | No         | No         | Na         | No         | Na         | No         | Na          | G              |
| Ellis et al. (2010) [31]   | Yes        | Yes        | No         | Yes        | No         | Yes        | Na         | Yes        | Yes        | Yes         | No         | Na          | G              |
| Michaud et al. (2012) [32] | Yes        | Yes        | Yes        | No         | Yes        | Yes        | Na         | Yes        | Yes        | Yes         | Na         | No          | G              |
| Goiato et al. (2012) [33]  | Yes        | Yes        | Yes        | Nr         | No         | Yes        | Yes        | Na         | Nr         | Yes         | No         | Na          | F              |
| Ha et al. (2012) [36]      | Yes        | No         | Yes        | No         | No         | No         | Yes        | No         | Yes        | Yes         | No         | Na          | F              |
| Harris et al. (2013) [37]  | Yes        | Yes        | Yes        | Nr         | Yes        | Yes        | No         | Na         | Yes        | Yes         | Na         | No          | F              |
| Dable et al. (2013) [20]   | Yes        | Yes        | Yes        | No         | No         | Yes        | No         | Na         | Yes        | Yes         | No         | Na          | F              |
| Viola et al. (2013) [38]   | Yes        | Yes        | Yes        | Nr         | No         | Yes        | No         | Na         | No         | Na         | Yes         | No          | G              |
| Regis et al. (2013) [39]   | Yes        | Yes        | Yes        | Yes        | No         | Yes        | No         | Na         | Yes        | Yes         | Yes        | Na          | G              |
| Kuo et al. (2013) [40]     | Yes        | No         | Yes        | No         | Yes        | Yes        | Na         | Yes        | Yes        | Yes         | Yes        | Na          | G              |
| Cakir et al. (2014) [41]   | Yes        | Yes        | Yes        | Yes        | No         | Na         | Yes        | Yes        | No         | Na         | No          | Na          | G              |
| Madhuri et al. (2014) [42] | Yes        | No         | Yes        | Yes        | Yes        | Yes        | Na         | Yes        | Yes        | Yes         | Na         | No          | G              |
| Nuñez et al. (2015) [43]   | Yes        | Yes        | Yes        | Yes        | Yes        | Yes        | Na         | Yes        | Yes        | Yes         | Na         | No          | G              |
| Sivakumar et al. (2015) [44] | Yes      | Yes        | Yes        | Yes        | Yes        | No         | Na         | Yes        | Yes        | Yes         | Na         | No          | G              |
| Cardoso et al. (2016) [45] | Yes        | Yes        | Yes        | Yes        | Yes        | Yes        | Na         | Yes        | Yes        | Yes         | Na         | No          | G              |
| Degrandi et al. (2017) [46] | Yes        | Yes        | Yes        | Yes        | Yes        | No         | Na         | Yes        | Yes        | Yes         | Na         | No          | G              |
| Marra et al. (2017) [47]   | Yes        | Yes        | Yes        | No         | Yes        | No         | Na         | Yes        | Yes        | Yes         | Na         | No          | G              |
| Amagai et al. (2017) [48]  | Yes        | Yes        | Yes        | Yes        | Yes        | Yes        | Na         | Yes        | Yes        | Yes         | Na         | No          | G              |
| Alves et al. (2018) [49]   | Yes        | Yes        | No         | Yes        | No         | Na         | Yes        | Yes        | Yes        | Yes         | Na         | No          | G              |
| Tôrres et al. (2019) [50]  | Yes        | Yes        | Yes        | No         | Yes        | No         | Na         | Yes        | Yes        | Yes         | Na         | No          | G              |
| Albuquerque et al. (2020) [51] | Yes      | Yes        | Yes        | Yes        | Yes        | No         | Na         | Yes        | Yes        | Yes         | Na         | No          | G              |

Questions: 1. Was the study question or objective clearly stated?; 2. Were eligibility/selection criteria for the study population prespecified and clearly described?; 3. Were the participants in the study representative of those who would be eligible for the test/service/intervention in the general or clinical population of interest?; 4. Were all eligible participants that met the prespecified entry criteria enrolled?; 5. Was the sample size sufficiently large to provide confidence in the findings?; 6. Was the test/service/intervention clearly described and delivered consistently across the study population?; 7. Were the outcome measures prespecified, clearly defined, valid, reliable, and assessed consistently across all study participants?; 8. Were the people assessing the outcomes blinded to the participants’ exposures/interventions?; 9. Was the loss to follow-up after baseline 20% or less? Were those lost to follow-up accounted for in the analysis?; 10. Did the statistical methods examine changes in outcome measures from before to after the intervention? Were statistical tests done that provided P values for the pre-to-post changes?; 11. Were outcome measures of interest taken multiple times before the intervention and multiple times after the intervention (i.e., did they use an interrupted time-series design)?; 12. If the intervention was conducted at a group level (e.g., a whole hospital, a community, etc.) did the statistical analysis take into account the use of individual-level data to determine effects at the group level?; CD: Cannot determine; Na: Not applicable; Nr: Not reported; Quality Rating: G: Good; F: Fair (acceptable); P: Poor.
Table 5: Evidence profile

| Study design | Risk of bias | Inconsistency | Indirectness | Imprecision | Other considerations | Number of patients | Effect | Certainty | Importance |
|--------------|--------------|---------------|--------------|-------------|---------------------|-------------------|--------|-----------|------------|
| GOHAI (3 months) | 2 Randomised trials | Not serious | Very serious<sup>a</sup> | Not serious | Very serious<sup>b</sup> | none | 67 | 67 | MD 6.86 (−15.629-31) | ☐☐☐☐ | Very low | Important |
| GOHAI (6 months) | 2 Randomised trials | Serious<sup>c</sup> | Serious<sup>d</sup> | Not serious | Serious<sup>d</sup> | None | 105 | 105 | MD 16.22 (10.7-21.74) | ☐☐☐☐ | Very low | Important |
| GOHAI measurements | 4 Randomised trials | Serious<sup>c</sup> | Not serious | Not serious | Serious<sup>e</sup> | None | 172 | 172 | MD 12.33 (7.06-7.6) | ☐☐☐ | Low | Important |
| OHIP-14 (3 months) | 2 Randomised trials | Serious<sup>f</sup> | Very serious<sup>e</sup> | Not serious | Very serious<sup>b</sup> | None | 269 | 269 | MD -14.91 (−29.87-0.04) | ☐☐☐☐ | Very low | Important |
| OHIP-20 (6 months) | 3 Randomised trials | Not serious | Serious<sup>d</sup> | Not serious | Very serious<sup>b</sup> | None | 184 | 184 | MD -11.09 (−20.54−1.64) | ☐☐☐☐ | Very low | Important |
| OHIP-EDENT (6 months) | 4 Randomised trials | Not serious | Serious<sup>d</sup> | Not serious | Serious<sup>d</sup> | None | 390 | 390 | MD -8.59 (−13.32−3.86) | ☐☐☐ | Low | Important |

Explanations: <sup>a</sup>Considerable heterogeneity across studies and there is no overlap of confidence intervals. <sup>b</sup>Small sample for continuous data and wide confidence interval. <sup>c</sup>Dable et al. (2013) was classified as fair quality. <sup>d</sup>Considerable heterogeneity across studies. <sup>e</sup>Small sample. <sup>f</sup>Ha et al. (2012) was classified as fair quality. CI: Confidence interval; MD: Mean difference; OHIP: Oral health impact profile; OHIP-EDENT: Oral health impact profile for assessing edentulous subjects; GOHAI: Geriatric oral health assessment index.
Even though osseous implants present a great success rate, many patients are not able to be subjected to this type of treatment for many reasons.\textsuperscript{[9]} Thus, CDs are a viable option of treatment for these cases. These prostheses recover the main functions of the stomatognathic system,\textsuperscript{[10]} but it is necessary to present good retention and stability.\textsuperscript{[1]} Evidence-based dentistry is important to provide a basis of solid evidence for all professionals who are committed to offering the best treatment option for their patients.

In this systematic review, the articles selected used different instruments to detect if new CDs were able to improve patients’ OHRQoL. On qualitative analysis, excepting two articles,\textsuperscript{[31,35]} 22 papers\textsuperscript{[8,18‑30,32‑34,36‑40]} concluded that the use CD improved the OHRQoL. CDs have been studied for many years, so a significant number of articles involving total prostheses and quality of life were found. A previous systematic\textsuperscript{[11]} review selected 6 articles to evaluate whether treatment with new CDs improves OHRQoL in elderly patients. The present systematic review selected 24 articles. So, based on increased number of publications on this important clinical evaluation, an update a systematic review needs to be done.\textsuperscript{[42]} This fact makes us realize the importance that this therapeutic option still presents in the dentistry scenario.

The addition of new synthesis methods, such as GRADE, improved the quality of the analysis and the clarity of the findings to answer the question if the new CD improves OHRQoL. Added to it, this research was carried out in the most important databases, in the grey literature and manually in the bibliographic references of the selected articles. We also used common MeSH terms and keywords from articles published in the same field in order to minimize the possibility of not finding potentially eligible studies. Thus, the likelihood of risk of bias from this systematic review is low as also observed by AMSTAR-2 checklist.

The meta-analysis detected that greater follow-up (6 months) improved impact on OHRQoL in the long-term. These findings emphasizes that studies with greater follow-up are necessary to obtain an improvement in the long-term impact of OHRQoL. The study with longest time of follow-up was 5 years\textsuperscript{[39]} followed by 1 study that follow-up for 2 years\textsuperscript{[22]} and 4 studies\textsuperscript{[23,26,32,37]} that follow-up for 12 months. The methodological design from the majority of the excluded papers presented no evaluation of the baseline or presented short or unspecified follow-up periods. The lack of baseline in many studies probably occurred due to the lack of use of total prosthesis by the volunteers at the initial time of the study. Early evaluation of the use of new prostheses may compromise the outcome, due to patient’s neuromuscular adaptation.\textsuperscript{[43]} Therefore, studies with a follow-up of <3 months were excluded.

The aim of this study was to search all available literature reporting the impact of new CD on OHRQoL. The possibility of combining patients’ needs and desires with the professional’s personal expertise in oral rehabilitation treatment planning should always be carried out based on the best scientific evidence available. Thus, it is important to evaluate the quality of evidence demonstrated by articles that propose to detect changes in OHRQoL after oral interventions.

Studies that met the eligibility criteria were submitted to a risk of bias analysis with a qualifier (“Quality Assessment Tool for Before-After (Pre-Post) Studies with No Control Group”).\textsuperscript{[14]} The qualifier items most frequently missing in the selected articles were sample size calculation (question 3 and 5) and the evaluation of the instruments’ psychometric properties (question 7).

Sample size calculation in clinical trials is of great importance to ensure that the number of participants is large enough to have a high probability of detecting
true and clinically significant differences between groups or treatments. In this systematic review, ten studies performed the sample size calculation, which indicates the need for greater care in future, research in relation to this important question.

In addition to the methodological problems found in articles, some studies presented their results in a nonreproducible way considering the evaluation of psychometric properties of instruments for evaluation of OHRQoL. Psychometric properties are essential requirements for measuring instruments. The main psychometric properties of a measuring instrument are validity, reliability and in the studies analyzing before and after a treatment, the responsiveness. Seven studies realized some of these evaluations. Validity of an instrument can be defined as its ability to actually measure what it proposes to measure. The validity as mentioned above was guaranteed in all selected studies since all of them used validated instruments, including validation for the languages of their respective populations. Reliability is the first characteristic that an instrument must present. This refers to the degree to which the repeated application of an instrument on the same subject produces equal results, that is, indicates the reproducibility of a measure. Reliability should be contextualized in terms of stability and internal consistency.

Only four studies realized test-retest of the OHRQoL instruments applied in their population. In this procedure, the same measuring instrument is applied at two times to the same group of people after a period of time to confirm the reliability of the instrument.

Internal consistency is perhaps the most widely used approach. It is understood as the degree of homogeneity in which the items designated to measure the same concept are interrelated. The most commonly used measurement for internal consistency is Cronbach’s Alpha Coefficient. Three articles performed this measurement and the results were satisfactory.

Responsiveness is the psychometric property that assesses the instrument’s ability to detect changes and is used primarily in clinical work to test QoL changes during or after treatment. Responsiveness is an important characteristic of OHRQoL instruments, which are used as evaluative measures to assess the change pre-and post-treatment. This property is not well established in many studies that have measured OHRQoL, which is a significant omission given the increasing tendency to use OHRQoL measurements as outcomes in clinical trials and evaluation studies. The absence of evaluation of this property is a worrying fact. In the present systematic review, only four articles applied this measurement. This fact corroborates with Antunes et al. in their systematic review evaluating changes in the OHRQoL of children and adolescents under 14 years old after oral health interventions, a moderate level of evidence was observed. One factor responsible for this level of evidence was that there were no evaluations of psychometric properties such as responsiveness.

To perform the meta-analysis was a challenge in this study. Results expressed as graphs and frequency, absence of information examiners calibration, made the comparison of the data of some articles impossible. It is important to emphasize that we tried to contact the authors, but we did not receive an answer. The difficulty to perform the meta-analysis was also especially high for the included studies that did not use the same quality-of-life assessment instrument. So, we chose to analyze in subgroups when it is possible to compile results from the same instrument at different follow-up times, as commonly performed in quality of life systematic review studies. Despite these difficulties, the meta-analysis compiled the results of 12 included studies related to the OHIP-14, OHIP-20, OHIP-EDENT and GOHAI instrument.

There was a diversity of instruments used in the articles included in this systematic review. However, there is a specific instrument validated for elderly patients (OHIP-EDENT), which, if standardized for this type of study, would allow a comparison between the results obtained by several studies. This study observed twelve studies (50%) using OHIP-EDENT (50%) as the questionnaire tool. We also observed an increasing tendency on use of this instrument once in the last 5 years from 9 studies, 8 papers used the OHIP-EDENT. Despite, the meta-analysis confirmation of an improve on OHRQoL using different instruments, we can perceive that the lack of standardization of the instrument hinders a more objective and efficient analysis of the results.

The meta-analysis of this study to affirm a favorable outcome for the use of CD on improving OHRQoL
in long-term; however very low certainty of evidence was observed in the GOHAI and OHIP-20 questionnaire analysis, and low certainty of evidence in the subgroup analysis for the GOHAI instrument and in OHIP-EDENT. It can be explained by the heterogeneity presented by some studies: Small follow-up periods, applied the instrument by mail, did not explain how the questionnaire was applied or did not use an expressive sample size for this type of therapeutic option. The results of this review suggest that the exchange of unsatisfactory CDs for new ones has the strong potential to contribute to OHRQoL. However, based on the heterogeneity, risk of bias and low certainty of the evidence that some studies presented, well-designed studies are necessary due to the importance that CD still present in the contemporary dentistry.

CONCLUSION

CD has the strong potential to contribute to oral health-related quality of life in long-term.

Financial support and sponsorship

This study was supported by grant (process E-26/010.002501/2016) from Fundação Carlos Chagas Filho de Amparo à Pesquisa do Estado do Rio de Janeiro (FAPERJ).

Conflicts of interest

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or nonfinancial in this article.

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## Appendix 1: PRISMA checklist

| Section/topic                          | # | Checklist item                                                                 | Reported on page |
|----------------------------------------|---|-------------------------------------------------------------------------------|-----------------|
| Title                                  | 1 | Identify the report as a systematic review, meta-analysis, or both             | 1               |
| Abstract                               | 2 | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number | 1               |
| Introduction                           | 3 | Describe the rationale for the review in the context of what is already known | 2               |
| Rationale                              | 4 | Provide an explicit statement of questions being addressed with reference to PICOS | 3               |
| Methods                                | 5 | Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number | 2               |
| Eligibility criteria                   | 6 | Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale | 2               |
| Information sources                    | 7 | Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched | 2               |
| Search                                 | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated | 2, 3            |
| Study selection                        | 9 | State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis) | 2               |
| Data collection process                | 10| Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators | 3               |
| Data items                             | 11| List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made | 3               |
| Risk of bias in individual studies     | 12| Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis | 3               |
| Summary measures                       | 13| State the principal summary measures (e.g., risk ratio, difference in means)     | 4               |
| Synthesis of results                   | 14| Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I²) for each meta-analysis | 4               |
| Risk of bias across studies            | 15| Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies) | 4               |
| Additional analyses                    | 16| Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified | 4               |
| Results                                | 17| Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram | 4, 5            |
| Study characteristics                  | 18| For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations | 4, 6, 7, 8, 9, 10, 11, 12 |
| Risk of bias within studies            | 19| Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12) | 4, 13           |
| Results of individual studies          | 20| For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot | 5, 7, 15        |
| Synthesis of results                   | 21| Present results of each meta-analysis done, including confidence intervals and measures of consistency | 5, 7, 15        |
| Risk of bias across studies            | 22| Present results of any assessment of risk of bias across studies (see item 15) | 5, 14           |
| Additional analysis                    | 23| Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression) [see item 16] | 5               |
| Discussion                             | 24| Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers) | 7, 15           |
| Limitations                            | 25| Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias) | 15, 16          |

Contd...
Appendix 1: Contd...

| Section/topic | # | Checklist item                                                                 | Reported on page |
|---------------|---|--------------------------------------------------------------------------------|-----------------|
| Conclusions   | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research | 17              |
| Funding       | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review | 17              |

PICOS: Participants, interventions, comparisons, outcomes, and study design

Appendix 2: Quality assessment of the systematic review based on A Measurement Tool to Assess Systematic Reviews 2-checklist

| Question                                                                 | Answer possibilities                                                                                                                                                                                                 | Classification |
|--------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| 1. Did the research questions and inclusion criteria for the review include the components of PICO? | Yes: The 4 elements of PICO are described somewhere in the report or the criteria of studies inclusion was clear. No: Any element of PICO was not described or the criteria of studies inclusion was not clear | Yes             |
| 2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol? | Partial yes: The authors state they had written protocol or guide that included all the following items: review question, a search strategy, inclusion/exclusion criteria, a risk of bias assessment. Yes: Partial yes plus should be specified meta-analysis/synthesis plan (if appropriate); a plan for investigating causes of heterogeneity, justification for any deviation from the protocol. No: Did not report about previous registered protocol. | Yes             |
| 3. Did the review authors explain their selection of the study designs for inclusion in the review? | Yes: The study report the type of studies included. No: The study did not report the type of study included. | Yes             |
| 4. Did the review authors use a comprehensive literature search strategy? | Partial yes: search in at least 2 databases, provide keyword/search strategy and justified publication restrictions. Yes: Partial yes plus search in reference list of included studies, search in register studies, consulted experts, search in grey literature and conducted search in 24 months of competition review. No: Did not achieve the items in partial yes. | Yes             |
| 5. Did the review authors perform study selection in duplicate? | Yes: At least two reviewers independently agreed on selection of eligible studies and achieved consensus on which studies to include, or two reviewers selected a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder selected by one reviewer. No: Did not answer this question. | Yes             |
| 6. Did the review authors perform data extraction in duplicate? | Yes: At least two reviewers achieved consensus on which data to extract from included studies or two reviewers extracted data from a sample of eligible studies and achieved good agreement (at least 80 percent), with the remainder extracted by one reviewer. No: Did not answer this question. | Yes             |
| 7. Did the review authors provide a list of excluded studies and justify the exclusions? | Partial yes: Provided a list of all potentially relevant studies that were read in full-text form but excluded from the review. Yes: Justified the exclusion from the review of each potentially relevant study. No: Did not report any detail about full-text assessed studies and excluded. | Yes             |
| 8. Did the review authors describe the included studies adequate detail? | Partial yes: Described not in detail populations, interventions, comparators, outcomes and research design. Yes: Described the items of parities in detail plus timeframe for follow-up. No: Did not describe populations, interventions, comparators, outcomes or research design. | Yes             |
| 9. Did the review authors use a satisfactory technique for assessing the RoB in individual studies that were included in the review? | Partial yes: Use a nonstandard instrument but capable of detecting serious methodological flaw. YES: Use a standard instrument for RoB. No: Use a non-standard instrument not capable of detecting serious methodological flaws. | Yes             |
| 10. Did the review authors report on the sources of funding for the studies included in the review? | Yes: Reported the sources of funding for individual studies included in the review or report that the reviewers looked for this information but it was not reported by study authors also qualifies. No: Did not report sources of funding for individual studies included in the review and didn’t looked for this information. | Yes             |

Contd...
### Appendix 2: Contd...

| Question                                                                 | Answer possibilities                                                                                                                                                                                                 | Classification |
|--------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| 11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results? | Yes: The authors justified combining the data in a meta-analysis; AND used an appropriate weighted technique to combine study results adjusting for heterogeneity if present; AND investigated the causes of any heterogeneity if present. No: Did not perform one or more criteria described above. No: No meta-analysis was conducted. | Yes             |
| 12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis? | Yes: Included only low risk of bias studies (according each risk of bias scale used in systematic reviews)* or if the authors performed analyses to investigate possible impact of RoB on summary estimates of effect. No: Did not perform one or more criteria described above. No: No meta-analysis was conducted. | Yes             |
| 13. Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review? | Yes: Included only the low risk of bias studies or a discussion of the likely impact of RoB was discussed. No: Did not perform one or more criteria described above. | Yes             |
| 14. Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review? | Yes: There was no significant heterogeneity or if present, the authors performed an investigation of sources of any heterogeneity in the results and discussed the impact of this on the results of the review. No: Did not perform one or more criteria described above. | Yes             |
| 15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review? | Yes: Performed graphical or statistical tests for publication bias and discussed the likelihood and magnitude of impact of publication bias. No: Did not perform a statistical evaluation about publication bias. No: No meta-analysis was conducted. | Not applicable |
| 16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review? | Yes: The authors reported no competing interests or the authors described their funding sources and how they managed potential conflicts of interest. No: The authors did not report anything about conflict of interest. | Yes             |

RoB: Risk of bias; PICO: Population, intervention, comparisons and outcomes