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In-office tooth bleaching and quality of life: systematic review and meta-analysis

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Clareamento dental de consultório e qualidade de vida: revisão sistemática e  
metanálise

Dissertação apresentada ao Programa de Pós-Graduação em Odontologia, Centro de Ciências Biológicas e da Saúde, Universidade Estadual do Oeste do Paraná, como requisito parcial para obtenção do título de Mestre em Odontologia

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Clareamento dental de consultório e qualidade de vida: revisão sistemática e metanálise

Dissertação apresentada ao Programa de Pós-Graduação em Odontologia em cumprimento parcial aos requisitos para obtenção do título de Mestra em Odontologia, área de concentração Odontologia, linha de pesquisa Materiais Dentários Aplicados à Clínica Odontológica, APROVADO(A) pela seguinte banca examinadora:



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## RESUMO

**Introdução:** O clareamento dental em consultório é um método eficaz, seguro e popular entre os pacientes que buscam um sorriso mais bonito. **Objetivo:** Avaliar por meio da revisão sistemática e meta-análise se o clareamento dental em consultório melhora a qualidade de vida dos pacientes submetidos ao tratamento. **Materiais e Método:** Utilizando as bases de dados eletrônicas MEDLINE (via PubMed), Biblioteca Cochrane, Biblioteca Odontológica Brasileira, Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS) e bases de citações (Scopus e Web of Science) foram selecionados artigos que avaliaram a qualidade de vida de pacientes submetidos a clareamento dental em consultório, incluindo apenas ensaios clínicos randomizados e boca dividida em humanos com base em seus títulos e sem restrição de data de publicação ou idioma. A data de início dos estudos de pesquisa foi 15 de abril de 2021 e recebeu uma atualização em 14 de julho de 2021. Dois revisores selecionaram os estudos que atenderam aos critérios de inclusão. Informações relevantes sobre o desenho do estudo, as intervenções dos participantes e os resultados foram extraídas independentemente usando formulários de extração personalizados. Os mesmos revisores avaliaram a qualidade dos estudos usando a ferramenta Cochrane Collaboration para detectar o risco de viés. **Análise estatística:** Os dados foram analisados usando o software estatístico Rstudio, foram realizadas metanálises em estudos elegíveis e resumidas pelo cálculo da diferença média padronizada para dados contínuos e a razão de risco, e os resultados foram expressos em gráficos. **Resultados:** Dois revisores selecionaram os estudos que atendiam aos critérios de inclusão. Dos 68 artigos em texto completo avaliados, 17 artigos permaneceram e foram analisados. Destes, um artigo teve alto risco de viés, três tiveram baixo risco e os outros 13 tiveram risco incerto. A meta-análise mostrou que dos estudos elegíveis tivemos 50% de satisfação após o clareamento em consultório. **Conclusão:** Houve melhora da qualidade de vida dos pacientes que realizaram clareamento dental de consultório.

**PROSPERO:** CRD42020221805

**Palavras-chave:** Qualidade de Vida. Clareamento Dental. Descoloração do Dente.

## ABSTRACT

**Introduction:** In-office tooth bleaching is an effective, safe and popular method among patients looking for a more beautiful smile. **Objectives:** To evaluate through a systematic review and meta-analysis whether in-office tooth bleaching improves the quality of life of patients undergoing treatment. **Materials and Method:** Using electronic databases MEDLINE (via PubMed), Cochrane Library, Brazilian Dental Library, Latin American and Caribbean Health Sciences Literature (LILACS) and citation databases (Scopus and Web of Science) were selected. articles that evaluated the quality of life of patients undergoing in-office tooth bleaching, including only randomized clinical trials and split mouth in humans based on their titles and without restriction of publication date or language. The start date of the research studies was April 15, 2021 and received an update on July 14, 2021. Two review authors selected studies that met the inclusion criteria. Relevant information about study design, participant interventions, and outcomes was independently extracted using custom extraction forms. The same reviewers assessed the quality of studies using the Cochrane Collaboration tool to detect risk of bias. **Statistical analysis:** Data were analyzed using Rstudio statistical software, meta-analyses were performed on eligible studies and summarized by calculating the standardized mean difference for continuous data and the hazard ratio, and the results were expressed in graphs. **Results:** Two reviewers selected studies that met the inclusion criteria. Of the 68 full-text articles evaluated, 17 articles remained and were analyzed. Of these, one article was at high risk of bias, three were at low risk, and the other 13 were at uncertain risk. The meta-analysis showed that of the eligible studies we had 50% satisfaction after in-office tooth bleaching. **Conclusion:** There was an improvement in the quality of life of patients who underwent in-office tooth bleaching.

**PROSPERO:** CRD42020221805

**Keywords:** Quality of Life. Tooth bleaching. Tooth discoloration.

## ABBREVIATION LIST

BA	Bleaching Agent
HR	High Risk
LR	Low Risk
AH	At-Home Bleaching
IN	In-Office Bleaching
OHIP	Oral Health Impact Profile for Dental Aesthetics
PIDAQ	Psychosocial Impact of the Dental Aesthetics Questionnaire
OES	Oralfacial Esthetic Scale
EEO	Escala de Estética Oral
WD	Whitening Dentifrices
SMD	Standardized Mean Difference
SD	Standard Deviation
NRS	Numerical Rating Scale
RCT	Randomized Clinical Study
AVS	Analog Visual Scale
CI	Confidence Interval
ID	Identification
GI	Gingival Irritation
n.r.	Not Reported in the Study
CP	Carbamide Peroxide
HP	Hydrogen Peroxide
IR	Uncertain risk
RoB	Risk of Bias
PS	Patient Satisfaction
Vs.	<i>Versus</i>

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# **CAPÍTULO I**

In-office tooth bleaching and quality of life: systematic review and meta-analysis

## Introduction

Self-esteem – directly linked to the individual's mental health and quality of life, is how people see and project their expectations. The growing patients' demand to improve their teeth appearance highlights the aesthetic need. (Maran et al., 2018). For the most, a beautiful smile is straight, harmoniously, shaped, and whiter teeth (Moreira et al., 2016). The last explains the wide seek for dental bleaching. Treatment effectiveness, safety, conservativeness, low-cost and fast result as well (Rezende et al., 2013; Pirolo et al., 2014).

Recently, studies showed improved quality of life for those who underwent dental bleaching (Bersezio et al., 2019a, 2018a; Kovacevic Pavicic et al., 2020) using instruments, as questionnaires. The most used is the Oral Health Impact Profile for Dental Aesthetics (OHIP, also called OHIP-14). It analyzes four essential dimensions: oral function, orofacial pain, orofacial appearance, and psychosocial impact (John et al., 2016; Robinson et al., 2003; Meireles et al., 2014). OHIP-14 comprehends 14 questions regarding the impact on quality of life-related to oral conditions with two items each to the three dimensions (social, psychological, and physical) (Nascimento et al., 2018). Answers are scored (from 0 to 56) by the Likert scale: 4 (very often), 3 (often), 2 (occasionally), 1 (almost never) and 0 (never) (Bersezio et al., 2019a; Estay et al., 2020). Literature also reports the Psychosocial Impact of the Dental Aesthetics Questionnaire (PIDAQ). PIDAQ comprises 23 items into four subscales (3 negative and one positive). Dental self-confidence (6 questions), social impact (8 negative questions), psychological impact (6 questions), and aesthetics (3 questions) are the dimensions. Answers are scored (from 0 to 72) by the Likert scale (Bersezio et al., 2018a; Bersezio et al., 2019a).

However, many subjective points that must be noteworthy to this quality-dental bleaching interplay assessment: socio-dental elements (Skaret, 2004), psychosocial impact (Angel et al., 2018; Bonafé, 2016), and that dentistry specifically. The treatment approach (that should meet the patient's expectations) (Bonafé et al., 2021) disregarding or minimizing may hamper the assessment since the influence on individual satisfaction. In this sense, instrument accuracy should consider: the baseline tooth color (Rezende et al., 2016), the benefit of combined methods (Cardenas et al., 2019;

Dourado Pinto et al., 2019; Kothari et al., 2020), the in-between sessions days (de Paula et al., 2015), the PH concentration versus change color effectiveness and tooth sensitiveness (Lima et al., 2018; Ferraz et al., 2019; Maran et al., 2020; Pontes et al., 2020), gel time application (Kose et al., 2016; Martins et al., 2018), gel agent type (Abrantes et al., 2021), the use of LED/laser irradiation (Mondelli et al., 2018; Kury et al., 2021), and so long.

Given instruments must be simple, reliable, accurate, and validated (Meireles, 2014), and the different methodologies of clinical studies to evaluate the in-office bleaching and psychosocial aspects relationship, this systematic review aimed to answer the research question: “Does in-office bleaching improve the quality of life of adult patients?”

## **Data & sources**

### ***Protocol***

This study was in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA)<sup>22, 23</sup> and registered with the International Prospective Register of Systematic Reviews (PROSPERO) (Registration: CRD42020221805).

### ***Search Strategy***

The search strategy was on 15 April 2021 updated on 14 July 2021. It was first defined for the MEDLINE database via PubMed based using a controlled vocabulary (MeSH terms) and free keywords for each concept of the PICO question in the end of the introduction section. The quality of life of patients undergoing in-office tooth whitening using specific questionnaires was the evaluated outcome<sup>5, 6, 7, 14, 42</sup>.

The MEDLINE search strategy was adapted to other electronic databases (Cochrane Library, Brazilian Library in Dentistry, Latin American and Caribbean Health Sciences Literature database (LILACS), and citation databases (Scopus, Embase, and Web of Science) (Table 1). Grey literature (SIGLE) was investigated by searching the abstracts of the annual conference of the International Association for Dental Research (IADR) and its regional divisions (2001-2019), the database System for Information on Grey Literature in Europe and dissertations (SIGLE) and theses using the ProQuest Dissertations and Theses full-text database, and the Periódicos Capes Theses database. Ongoing studies were searched in the following clinical trial registries: Current Controlled Trials, International Clinical trials registry platform, ClinicalTrials.gov, Rebec, and EU Clinical Trials Register.

Additionally, the reference lists of all primary and eligible studies of this systematic review were hand-searched for additional relevant publications. The first two pages of the related articles link to each primary study in the PubMed database were also reviewed to search eligible studies. In the whole search process, studies were not restricted based on publication date, number of patients and language.

### ***Eligibility criteria***

Parallel and split-mouth RCTs that assessed the quality of life of patients undergoing in-office tooth whitening were included.

### ***Study Selection and Data Collection Process***

The articles retrieved by the literature search were revised in three phases. All studies were analyzed using the Endnote X6 program, and initially scanned for relevance by title followed by the evaluation of the abstract, and finally, the full-text retrieval. In case of doubts in any of these phases, the study was kept to the next phase. The full texts were read by three reviewers to check if they met the inclusion criteria.

Each eligible article received a study identification (ID), combining the first author and year of publication. Two reviewers (LP/ANCM) summarized and categorized data, such as study design, number of patients, interventions, and outcomes, independently. A decision was reached by consulting a third reviewer in cases of disagreement. When multiple reports of the same study (i.e., reports with different follow-ups) were found, data of all reports were extracted directly into a single data-collection form to avoid multiple data entry.

Data were collected on the improvement of quality of life after the end of the bleaching treatment (7 to 30 days after bleaching). This variation was due to differences in the evaluation periods reported in the primary studies. If the study did several assessment times, this review chose the seventh day after bleaching (the most reported period).

### ***Data extraction and conversion to desired format***

Patient satisfaction data were extracted as primary studies reported.

### ***Risk of Bias in Individual Studies***

Quality assessments of the selected trials carried out by two independent reviewers using the Cochrane Collaboration tool for assessing the risk of bias (RoB version 1) for RCTs<sup>24</sup>. The assessment criteria contain six items: selection bias (adequate sequence generation and allocation concealment), performance bias (patient and operator blinding), detection bias (evaluator blinding), attrition bias (incomplete outcome data), reporting bias (selective outcome reporting), and other bias. There was no other type of bias inclusion in the latter domain. Discussion and consulting the third one (B.M.M.) (if needed) solved disagreements among the reviewers.

Reviewers judged each domain level as low, high, or unclear risk of bias. Low means all five domains were low risk of bias. Unclear means one or more domains were an unclear risk. High means at least one item was high risk.



### ***Summary measures and synthesis of results***

Data analysis (RStudio statistical program Version 1.3.959 © 2009-2020 RStudio, PBC) and meta-analyses were for all eligible studies. Using (or not) different instruments and scales guided the choice of continuous outcomes effect measure. All meta-analyses were a random-effects model, but only when patient's life quality after in-office bleaching assessment. Cochran Q test, I<sup>2</sup> statistic, and the prediction interval assessed heterogeneity.

## Results

### *Study selection*

The search strategy was on 2021 April 14th. After database screening and removal of duplicates identified 15.312 studies and, 146 studies remained when title and abstract screening. After full-text evaluation, there were 129 RCTs excluded because: other techniques than bleaching inclusion, in-office bleaching versus at-home bleaching comparisons, at-home or non-vital bleaching, patient satisfaction no evaluating, clinical study, full article not found. (Figure 1).

### *Characteristics of included articles*

Table 2 lists the twenty-nine eligible studies' characteristics which were parallel or split-mouth designs. Patients' ages ranged from 18 to 70 years (Table 2).

### *Quality of life*

The methods were: Psychosocial Impact of Dental Aesthetics Questionnaire (PIDAQ) plus Oral Health Impact Profile (OHIP-14) (seven studies)<sup>5, 14, 42, 6, 12, 37, 41</sup> Oral Impact on Daily Performance (OIDP) (one study)<sup>23</sup>; IPS 0-100 (evaluation of possibility of success) (one study)<sup>36</sup>; 0-2 scale (one study)<sup>33</sup>; the both SERQoL and 5-point Likert scale (one study)<sup>38</sup>; the three PIDAQ, Oral facial Esthetic Scale (OES), OHIP and Rosenberg Self Esteem Scale (verbal rating ranging from strongly agree to strongly disagree) (one study)<sup>7</sup>. PIDAQ questionnaire plus EEO (Escala de Estética Oral), which is an OES Portuguese-language version was on only study<sup>43</sup>. There were unspecified questionnaires (three studies)<sup>35, 22, 40</sup> or scale<sup>39</sup> (Table 2) (Table 3).

### *Bleaching protocol*

*In-office bleaching.* The comparisons were: 35% and 6% PH (with and without light activation) (four studies)<sup>34, 12, 37, 40</sup>; 35% PH with and without light activation (two studies)<sup>33, 39</sup>; bleaching with 35% PC (one study)<sup>35</sup>; 38% PH photoactivated and a placebo (three studies)<sup>7, 38, 41</sup>; 37.5% PH and 6% PH (three studies)<sup>5, 14, 12</sup>, 35%, 10%, 15% PH systems with light activation (one study)<sup>36</sup>; 35% PH and 37% PC bleaches (one study)<sup>42</sup>; 35% PH with a placebo (one study)<sup>43</sup>; 6% and 15% PH (one study)<sup>23</sup>; 15% and 35% PH gels in-office bleaching (one study)<sup>22</sup> (Table 2).

### ***Assessment of the risk of bias (RoB)***

Figure 2 presents eligible studies' risk of bias. Some adequately reported the assessment criteria, although the allocation concealment and blinding<sup>33, 14, 35, 36, 39, 7, 38, 41, 43</sup>. From the 17 studies, one was high<sup>36</sup>, thirteen was unclear<sup>14, 33, 5, 35, 12, 37, 23, 39, 7, 38, 40, 41, 43</sup>, and three were low risk of bias<sup>6, 22, 42</sup>.

### ***Meta-analysis***

There was no meta-analysis for twelve studies: lack of data reporting, inserting five studies<sup>35, 22, 23, 42, 43</sup> that reported patient satisfaction, through dichotomous data, evaluating the relationship of in-office tooth bleaching with quality of life.

The evidence of improvement in this interaction was 50% (95% CI:  $I^2 = 83\%$ ,  $\tau^2 = 0.0327$ ). The lowest evidence (22.6%) was for Ferraz et al. (2019). The highest (76%) was for Soares (2018) (Figure 3).

## Discussion

Physical appearance has become increasingly important for human beings. Physical attractiveness significantly influences the social consequences<sup>44</sup>. Psychological suffering might be negative body image-related and sociocultural factors (such as an ideal beauty standard through the media)<sup>45</sup>. So, more demand for aesthetic treatments significantly increases, including dental bleaching, is a reflect.

Among the smile harmony aspects, dental color (easily perceived) might concern the people more than the shape and tooth alignment<sup>46, 16</sup>. Indeed, color changes can improve smile overall patient satisfaction, even without other changes<sup>16</sup>.

Despite the effect of dental bleaching on the quality of life is a controversial issue<sup>15, 34, 47</sup>, the present meta-analysis showed an improvement for 50% of patients who underwent in-office bleaching. Thus, this treatment higher patients' self-esteem, with no strong correlation. While one study reveals the aesthetic value for the patient's self-perception<sup>34</sup>, the other two<sup>15, 47</sup> reported no improvement. Disagreements rely mainly on the different questionnaires applied on the evaluation but bleaching procedure can influence too<sup>15</sup>. Results should consider the gel (type, concentration), number of applications, and possible side effects.

Patients may develop tooth sensitivity with discomfort and pain<sup>10</sup>. This side effect rate (under evaluation in the literature) depends on the place (if in-office or at-home) and peroxide carbamide gel concentration (20% or 38%), but not only. Sensitivity was higher for in-office dental bleaching<sup>48</sup>, although another study showed similar levels of tooth sensitivity when comparing the techniques<sup>49</sup>. Comparing CP 20% at-home with 38% HP in-office, a higher percentage of patients experienced tooth sensitivity in the first (71.4% and 15%, respectively)<sup>50</sup>. The duration contact between tooth and gel (greater than at-home bleaching agents) may also interfere with the tooth sensitivity<sup>50</sup>.

The patient's expectations (desires, hopes, and anticipations) should meet the treatment performed because they expect a more positive response - not coming true can frustrate they<sup>51</sup>. Brugnera et al. (2020)<sup>35</sup> showed better satisfaction results for the 35% CP violet LED bleaching group than that for CP 35% only. In this case, the faster the color change, the more the satisfaction with the treatment.

Determining the success or failure of aesthetic treatment demands dentists use indicators to assess subjective characteristics through objective and quantifiable measures<sup>52, 16</sup>. In this context, measuring the quality of life requires validated, translated, and adapted for different cultures questionnaires<sup>43</sup>. As far as possible, a dentistry-for-specific instrument would more properly conduct the evaluation<sup>43</sup>.

Quality of life assessment in dentistry is relatively new. Literature shows the use of instruments is increasing<sup>34, 10</sup>. Questionnaires are notably unique, but some do not consider dental related questions. For example, the PIDAQ does not include the “tooth color” (topic seen on the EEO) despite covering many relevant quality of life factors<sup>15</sup>. Given that, researchers should align the dental characteristics of the questionnaire to the study aim. Moreover, a new one that focuses dentistry field would make the studies more trustworthy.

The included studies in the present review and meta-analysis used different questionnaires (PIDAQ<sup>14, 5, 34, 12, 37, 7, 41, 43</sup>, OHIP<sup>14, 5, 34, 12, 37, 7, 41</sup>, and OES<sup>7, 43</sup>) that encompass psychosocial assessment questions. Authors' numerical scales and questions used possibly generated answers that did not enroll all the complexity of quality of life measures. It hinders a more accurate assessment. Thus, one should cautiously analyze the weak relationship between in-office dental bleaching and quality improvement due to the studies' lack of standardization. In addition, a low risk of bias with the same bleaching method and the same questionnaire clinical trial would faithfully answer whether and how in-office dental bleaching improves the individual quality of life.

**Conclusion**

In-office dental bleaching improved the patients' quality of life with a weak relationship.

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**Table 1.** Electronic database and search strategy conducted initially in 14<sup>h</sup> April 2021 updated July 14

<b>Pubmed (15/04/21)</b>		
<b>#1</b> ((((((((((((((((((Tooth discoloration[MeSH Terms]) OR ("Tooth discoloration"[Title/Abstract])) OR (Color[MeSH Terms])) OR ("tooth discolouration"[Title/Abstract])) OR ("teeth discoloration"[Title/Abstract])) OR ("teeth discolouration"[Title/Abstract])) OR ("discolored tooth"[Title/Abstract])) OR ("discoloured tooth"[Title/Abstract])) OR ("discolored teeth"[Title/Abstract])) OR ("discoloured teeth"[Title/Abstract])) OR ("dental discoloration"[Title/Abstract])) OR ("dental discolouration"[Title/Abstract])) OR ("tooth staining"[Title/Abstract])) OR ("teeth staining"[Title/Abstract])) OR ("stained tooth"[Title/Abstract])) OR ("stained teeth"[Title/Abstract])) OR ("dental staining"[Title/Abstract])) OR (colour[Title/Abstract]))	<b>#2</b> ((((((((((((((((((Quality of Life[MeSH Terms]) OR ("Quality of Life"[Title/Abstract])) OR ("Oral Health"[Title/Abstract])) OR (Oral Health[MeSH Terms])) OR (Quality of Health Care[MeSH Terms])) OR ("Quality of Health Care"[Title/Abstract])) OR ("Life Quality"[Title/Abstract])) OR (Tooth Bleaching[MeSH Terms])) OR (Tooth Bleaching Agents[MeSH Terms])) OR (Hydrogen Peroxide[MeSH Terms])) OR ("Hydrogen Peroxide"[Title/Abstract])) OR ("Carbamide Peroxide"[Title/Abstract])) OR (Carbamide Peroxide[MeSH Terms])) OR (dental offices[MeSH Terms])) OR ("Dental Offices"[Title/Abstract])) OR ("At-home"[Title/Abstract])) OR ("In-office"[Title/Abstract])) OR (Bleaching[Title/Abstract])) OR (Whitening[Title/Abstract])) OR ("dentist-supervised"[Title/Abstract]))	<b>#3</b> (randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized controlled trials[mh] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR clinical trial[pt] OR clinical trials[mh] OR ("clinical trial"[tw]) OR ((singl*[tw] OR doubl*[tw] OR trebl*[tw] OR tripl*[tw]) AND (mask*[tw] OR blind*[tw])) OR (placebos[mh] OR placebo*[tw] OR random*[tw] OR research design[mh:noexp] OR comparative study[pt] OR evaluation studies as topic[mh] OR follow-up studies[mh] OR prospective studies[mh] OR control*[tw] OR prospective*[tw] OR volunteer*[tw]) NOT (animals[mh] NOT humans[mh]))
<b>#1 AND #2 AND #3</b>		
<b>Cochrane (22/05/21)</b>		
<b>#1</b> Mesh Descriptor: [Tooth Discoloration] explode all trees	<b>#6</b> Mesh Descriptor: [Quality of Life] explode all trees	
<b>#2</b> Mesh Descriptor: [Color] explode all trees	<b>#7</b> Mesh Descriptor: [Oral Health] explode all trees	
<b>#3</b> (discolored next t*th): ti,ab,kw OR (color): ti,ab,kw OR (discolored next t*th): ti,ab,kw OR (dental next discoloration): ti,ab,kw OR (t*th next staining): ti,ab,kw	<b>#8</b> Mesh Descriptor: [Quality of Health Care] explode all trees	
<b>#4</b> (stained t*th): ti,ab,kw OR (dental next staining): ti,ab,kw	<b>#9</b> Mesh Descriptor: [Tooth Bleaching] explode all trees	
<b>#5</b> #1 or #2 or #3 or #4	<b>#10</b> Mesh Descriptor: [Tooth Bleaching Agents] explode all trees	
	<b>#11</b> Mesh Descriptor: [Hydrogen Peroxide] explode all trees	
	<b>#12</b> Mesh Descriptor: [Carbamide Peroxide] explode all trees	
	<b>#13</b> Mesh Descriptor: [Dental offices] explode all trees	
	<b>#14</b> ("quality of life"): ti,ab,kw OR ("oral health"): ti,ab,kw OR ("quality of health care") ti,ab,kw OR (t*th next bleaching): ti,ab,kw OR ("life quality"): ti,ab,kw	
	<b>#15</b> ("hydrogen peroxide"): ti,ab,kw OR ("carbamide peroxide") ti,ab,kw OR ("dental offices") ti,ab,kw OR ("at-home"): ti,ab,kw OR ("in-office"): ti,ab,kw	
	<b>#16</b> (bleaching): ti,ab,kw OR (whitening) ti,ab,kw OR ("dentist-supervised") ti,ab,kw	
	<b>#17</b> #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16	
<b>#18 #5 AND #17</b>		

**Lilacs/BBO (12/05/21)**

**#1** (MH: "Tooth discoloration" OR MH: color OR "Tooth discoloration" OR color OR "tooth discolouration" OR "teeth discoloration" OR "teeth discolouration" OR "discolored tooth" OR "discoloured tooth" OR "discolored teeth" OR "discoloured teeth" OR "dental discoloration" OR "dental discolouration" OR "dental discolouration" OR "tooth staining" OR "teeth staining" OR "stained tooth" OR "stained teeth" OR "dental staining" OR colour OR "descoloração dos dentes" OR "descoloração do dente" OR "dente descolorido" OR "dentes descoloridos" OR "descoloração dentária" OR "manchas nos dentes" OR "dente manchado" OR "dentes manchados" OR "coloração dentária" OR cor OR "decoloración del diente" OR "diente descolorido" OR "mancha del diente" OR "diente manchado" OR "manchado del diente" OR color)

**#2** (MH: "Quality of Life" OR MH: "Oral Health" OR MH: "Quality of Health Care" OR MH: "Tooth Bleaching" OR MH: "Tooth Bleaching Agents" OR MH: "Hydrogen Peroxide" OR MH: "Carbamide Peroxide" OR MH: "dental offices" OR "Quality of Life" OR "Oral Health" OR "Quality of Health Care" OR "Life Quality" OR "Tooth Bleaching" OR "Tooth Bleaching Agents" OR "Hydrogen Peroxide" OR "Carbamide Peroxide" OR "Dental Offices" OR "At-home" OR "In-office" OR Bleaching OR Whitening OR "dentist-supervised" OR "Qualidade de vida" OR "Saúde bucal" OR "Qualidade dos cuidados de saúde" OR "Clareamento dentário" OR "Agentes clareadores dentais" OR "Peróxido de hidrogênio" OR "Peróxido de carbamida" OR "Consultórios odontológicos" OR "Em casa" OR "No consultório" OR Clareamento OR "supervisionado por dentista" OR "Calidad de vida" OR "Salud bucal" OR "Calidad de la atención médica" OR "Blanqueamiento dental" OR "Agentes blanqueadores de hidrógeno" OR "Peróxido de hidrógeno" OR "Consultorios dentales" OR "En casa" OR "En el consultorio" OR Blanqueamiento OR "supervisado por un dentista")

**#1 AND #2****Scopus (15/06/21)**

**#1** ( TITLE-ABS-KEY ( "t??th discoloration" ) OR TITLE-ABS-KEY ( Colo?r ) OR TITLE-ABS-KEY ( "t??th discolouration" ) OR TITLE-ABS-KEY ( "discolored t??th" ) OR TITLE-ABS-KEY ( "discoloured t??th" ) OR TITLE-ABS-KEY ( "dental discoloration" ) OR TITLE-ABS-KEY ( "t??th staining" ) OR TITLE-ABS-KEY ( "stained t??th" ) OR TITLE-ABS-KEY ( "dental staining" ) )

**#2** ( TITLE-ABS-KEY ( "Quality of Life" ) OR TITLE-ABS-KEY ( "Oral Health" ) OR TITLE-ABS-KEY ( "Quality of Health Care" ) OR TITLE-ABS-KEY ( "Life Quality" ) OR TITLE-ABS-KEY ( "Hydrogen Peroxide" ) OR TITLE-ABS-KEY ( "Carbamide Peroxide" ) OR TITLE-ABS-KEY ( "Dental Offices" ) OR TITLE-ABS-KEY ( "At-home" ) OR TITLE-ABS-KEY ( "In-office" ) OR TITLE-ABS-KEY ( Bleaching ) OR TITLE-ABS-KEY ( Whitening ) OR TITLE-ABS-KEY ( "dentist-supervised" ) )

**#1 AND #2****Web of science (02/06/21)**

**#1** TÓPICO:( "t\*th discoloration" ) OR TÓPICO:( color ) OR TÓPICO:( "discolored t\*th" ) OR TÓPICO:( "dental discoloration" ) OR TÓPICO:( "discoloured t\*th" ) OR TÓPICO:( "dental staining" ) OR TÓPICO:( "stained t\*th" ) OR TÓPICO:( "dental staining" )

**#2** TÓPICO:( "quality of life" ) OR TÓPICO:( "oral health" ) OR TÓPICO:( "quality of health care" ) OR TÓPICO:( "t\*th bleaching" ) OR TÓPICO:( "life quality" ) OR TÓPICO:( "hydrogen peroxide" ) OR TÓPICO:( "carbamide peroxide" ) OR TÓPICO:( "dental offices" ) OR TÓPICO:( "at-home" ) OR TÓPICO:( "in-office" ) OR TÓPICO:( bleaching ) OR TÓPICO:( whitening ) OR TÓPICO:( "dentist-supervised" )

**#1 AND #2****Embase (28/06/21)**

**#1** 'tooth discoloration'/exp OR 'color'/exp OR color: ab, ti OR 'tooth discoloration': ab, ti OR 'teeth discoloration': ab, ti OR 'teeth discolouration': ab, ti OR 'discolored tooth': ab, ti OR 'discoloured tooth': ab, ti OR 'discoloured teeth': ab, ti OR 'discolored teeth': ab, ti OR 'tooth staining': ab, ti OR 'teeth staining': ab, ti OR 'stained tooth': ab, ti OR 'stained teeth': ab, ti OR 'dental staining' ab, ti

**#2** 'quality of life'/exp OR 'health'/exp OR 'health care quality'/exp OR 'quality of life': ab, ti OR 'dental procedure'/exp OR 'tooth bleaching agent'/exp OR 'hydrogen peroxide'/exp OR 'carbamide peroxide'/exp OR 'dental facility'/exp OR 'at home': ab, ti OR 'in-office ': ab, ti OR bleaching: ab, ti OR whitening: ab, ti OR 'dentist supervised': ab, ti

**Table 2.** Summary of the primary studies included in the systematic review

2010	Alomari	Par allel [n.r.]	0	4	27.8 [18-40]	1 2 [30%]	A3/Up per central incisors	A: 35% HP / 10 B: 35% HP + blue light/10 C: 35% HP + LED light/10 D: 35% HP + metal halide curing light/10	1 X 20	Sc ale 0 -2	41
2018	Angel	Spli t-mouth [University]	5	3	27.36 ± 9.28 [20-53]	1 7 [51.5%]	A <sub>3</sub> or less/Upper lateral incisors	H: 37.5% HP <sup>a</sup> /35 L: 6% HP <sup>a</sup> /35	3 x 12 [2] (7)	PI DAQ OHIP- 14	0 pb [35] 7 pb [35] 30 pb [35] 90 pb [33]
, Stay 2019.1a	Bersezio	Spli t-mouth [University]	3	3	27.4 ± 9.28 [20-53]	1 7 [51.5%]	A <sub>3</sub> /Upp er central incisors	H: 37.5% HP <sup>a</sup> /33 L: 6% HP <sup>a</sup> /33	3 x 12 [3] (7)	PIDAQ e OHIP	0 pb [33] 7 pb [33] 30 pb [33] 90 pb [33]
, Martin 2019.2	Bersezio	Spli t-mouth [University]	1	3	24.1 ± 3.87 [18-25]	1 2 [63,1%]	A2/Up per central incisors	L: 6% HP <sup>d</sup> + light/31 H: 35% Hpe + light/31	3 X 12 [2] (7)	PI DAQ e OHIP	0 pb [31] 30 pb [30] 360 pb [27] 720 pb [19]
2020	Brugnera	Par allel [University]	0	5	27.6 ± 4.7 [20-39]	1 1 [22.0%]	A2/Up per central incisor and canine	G1 35% CP/25 G2 35% CP <sup>f</sup> + violet LED light/25	G1: 2 x 30 (7) G2: 2 x 30 + 60s light x20 (7)	Q uestionnaire	0 sb [50] 0 pb [50] 14 pb [50]
2015	Delafiori	Par allel [University]	8	4	[18-30]	n .r. [n.r.]	A3/Ant erior teeth	M: 10%HP+light/12 H: 35%HP+light/12 H: 35%HP/12	5x7'30" [1] 5x7'30" [1] 3x15 [1]	IP S	7pb [11] 30pb[12] 180pb[12] 360pb[11]
ic Pavicic 2018	Kovacev	Par allel [University]	0	6	22 [19-28]	1 5 [25%]	n.r./ma xillary central incisor	L: placebo/30 H: 38% HP photoactivated/30	n.r. (de acordo com a instrução do fabricante)	SE RQoL e 5- point Likert scale	0 sb [60] n.r.

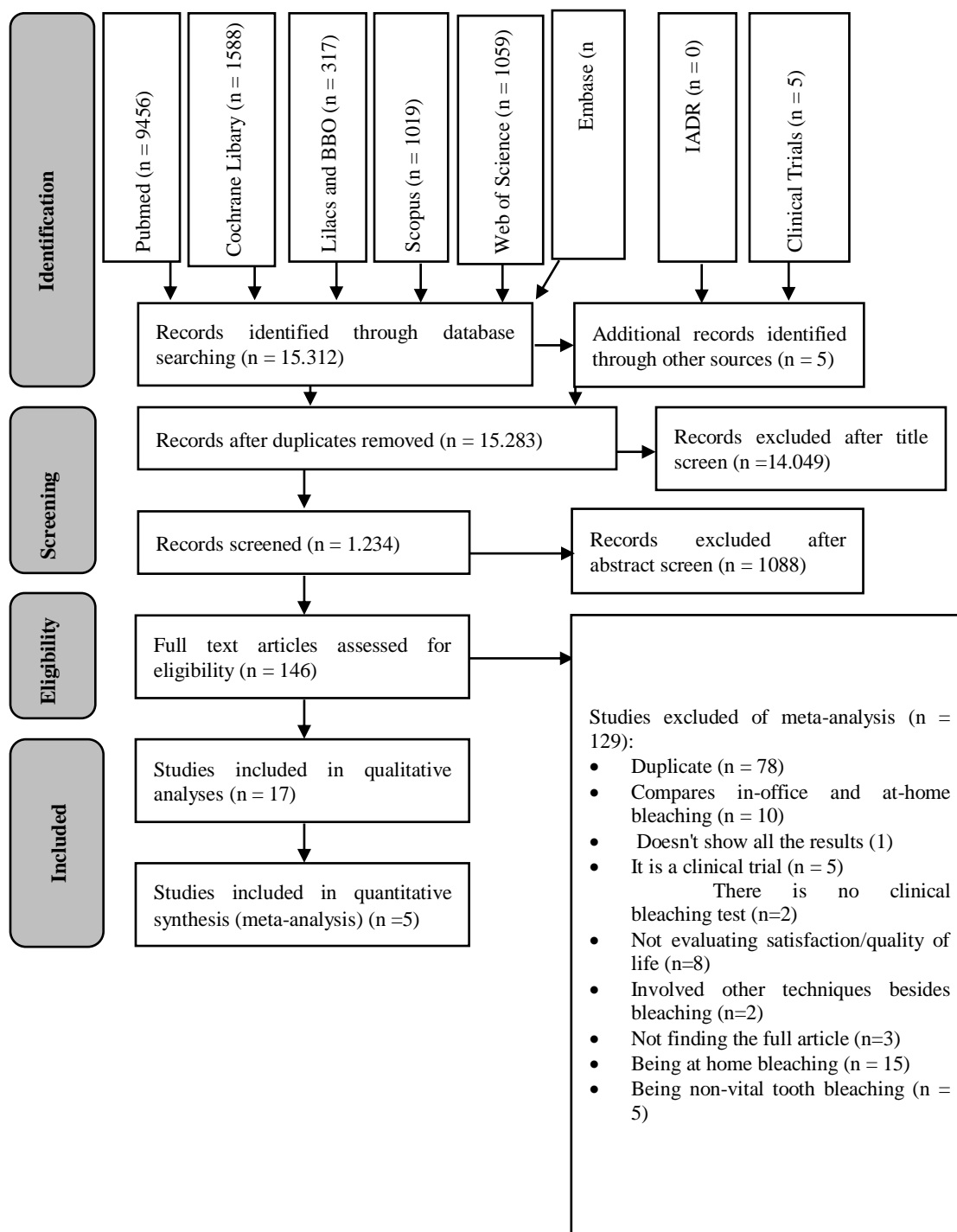


2020	Estay	Split-mouth [University]	5	2	27 ± 7.5 [20-54]	3 [52%]	1 A3 or darker/upper central incisors	L: 6% HP/25 H: 35% HP/25	3 x 12 [2] (7)	PI DAQ OHIP- 14	7 pb [25] 30 pb [25] 180 pb [25] 360 pb [25]
2016; 2017	Fernandez Vildosola	Split-mouth [University]	1	3	24.1 ± 4.95 [n.r.-n.r.]	7 [54.8%]	1 A2/Upp er central incisors	L: 6% HP <sup>e</sup> + light/31 H: 35% HP <sup>e</sup> + light/31	2 x 12 [3] (7)	PI DAQ e OHIP	0 pb [31] 7 pb [29] 30 pb [29] 270 pb [27] 360 pb [27]
2019	Ferraz	Parallel	4	5	26.38 [18 - 40]	1 [39%]	2 A1/Up per right central incisor	L: 6% HP <sup>b</sup> /27 H: 15% HP <sup>b</sup> /27	3 x 10 [3] (7)	DP OI	0 pb 54 7 pb 54 14 pb 52 30 pb 52 180 pb 38
2008	Gomes	Split-mouth	4	2	[20-30]	n.r. [n.r.]	n n.r./15- 25	H: 35%HP + LIGHT led - halógena H: 35%HP + LIGHT led-laser- sem ativação física	3x2'30" cada hemiarcada 3x3' [2] [7]	sc ales	0pb [n.r.] 7pb[n.r.] 360pb [n.r.]
dic 2020	Kovacev	Parallel	0	6	20.0 ± 23.0 [19-28]	5 [25.0%]	1 n.r./rig ht maxillary central incisor	H: 38% HP <sup>b</sup> + light/30 L: Placebo	3x10 [1]	PI DAQ OES OHIP Rosenberg Self Esteem Scale verbal rating scale scale ranging	7 sb [70] 7 pb [60]
2018	Lima	Split-mouth [University]	5	2	24 ± n.r. [18-28.]	8 [73.0%]	1 A3/ Anterior teeth	L: 15%HP/25 H: 35%HP/25	3X15 [2] (7)	Q uestionnaire	7sb [22] 14sb[22] 30pb[22]

2015	Martín	Splint-mouth [University]	1	3	24.5 ± 6.33 [n.r.-n.r.]	9 [63.3%]	1	A2/Upper central incisors	L: 6% HPn.r. + light/31 H: 35% HPn.r. + light/31	2 x 12 [3] (7)	Questionnaire	0 sb [31] 7 sb [30] 14 sb [30] 7 pb [30] 30 pb [30]
2018	Pavicic	Parallel [n.r.]	0	6	22 [19-28]	5 [25%]	1	n.r./right maxillary central incisor	H: 38% HP <sup>b</sup> + L: Placebo/30	3 x 10 [1]	PI DAQ e OHIP	7 Sb [60] 7 pb [60]
2018	Peixoto	Parallel [University]	0	4	23.6 ± 3.98 [n.r.-n.r.]	7 [42.5%]	1	2.5M <sub>2</sub> /Upper canines	H: 35% HP <sup>i</sup> /20 L: 37% CP <sup>u</sup> /20	H: 3 x 15 [2] (7) L: 1 x 40 [2] (7)	5 questions	7 sb [20] 7 pb [20] 30 pb [20]
2018	Soares	Parallel [University]	0	5	25.8 ± n.r. [18-n.r.]	7[34%]	1	equal to or darker than 2.5 M2/upper anterior teeth	H: 35%HP/25 PLACEBO/25	1X45 [2][7]	EO PDAQ <sup>E</sup>	0pb[50] 7pb[46]

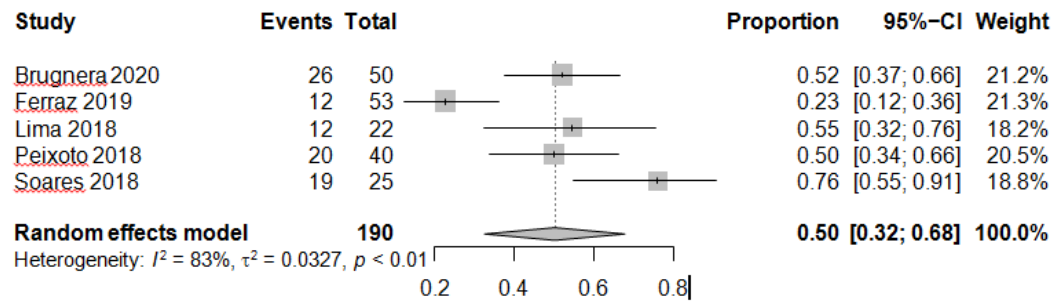
**Table 3.** Studies and questionnaire used

<b>Study ID</b>	<b>Questionnaire Quality of Life</b>
Alomari 2010	Scale 0 - 2
Angel 2018	PIDAQ e OHIP-14
Bersezio, Estay 2019.1	PIDAQ e OHIP
Bersezio, Martin 2019.2	PIDAQ e OHIP
Brugnera 2020	Questionnaire
Delafiore 2015	IPS
Estay 2020	PIDAQ e OHIP-14
Fernandez 2016; Vildosola 2017	PIDAQ e OHIP
Ferraz 2019	OIDP
Gomes 2008	Scales
Kovacevic Pavicic 2018	SERQoL e 5-point Likert scale
Kovacevic 2020	PIDAQ, OES, OHIP, Rosenberg Self Esteem Scale
Lima 2018	Questionnaire
Martín 2015	Questionnaire
Pavicic 2018	PIDAQ e OHIP
Peixoto 2018	5 questions
Soares 2018	EEO e PIDAQ

**Figure 1.** Flow diagram of study identification

**Figure 2.** Summary of the risk of bias assessment according to the Cochrane Collaboration tool

	Adequate sequence generation?	Allocation concealment?	Patient blinding?	Operator blinding?	Evaluator blinding?	Incomplete outcome data addressed?	Free of selective reporting?
Alomari 2010							
Angel 2018							
Bersezio, Estay 2019.1							
Bersezio, Martin 2019.2							
Brugnera 2020							
Delafiore 2015							
Estay 2020							
Fernandez 2016; Vildosola 2017							
Ferraz 2019							
Gomes 2008							
Kovacevic Pavicic 2018							
Kovacevic 2020							
Lima 2018							
Martín 2015							
Pavicic 2018							
Peixoto 2018							
Soares 2018							

**Figure 3.** Results of meta-analysis

## ATTACHMENT - PROJECT REGISTRATION BY THE INTERNATIONAL REGISTRY OF PROSPECTIVE SYSTEMATIC REVIEWS (PROSPERO)

**PROSPERO**  
International prospective register of systematic reviews

  
National Institute for  
Health Research

**UNIVERSITY of York**  
Centre for Reviews and Dissemination

### Systematic review

Fields that have an **asterisk (\*)** next to them means that they **must be answered**. **Word limits** are provided for each section. You will be unable to submit the form if the word limits are exceeded for any section. **Registrant** means the person filling out the form.

#### 1. \* Review title.

Give the title of the review in English

Patients with dental discoloration submitted to in office dental bleaching can you improve the quality of life?

#### 2. Original language title.

For reviews in languages other than English, give the title in the original language. This will be displayed with the English language title.

Pacientes com descoloração dental submetidos ao clareamento dental de consultório podem ter melhora na qualidade de vida?

#### 3. \* Anticipated or actual start date.

Give the date the systematic review started or is expected to start.

28/09/2020

#### 4. \* Anticipated completion date.

Give the date by which the review is expected to be completed.

31/08/2021

#### 5. \* Stage of review at time of this submission.

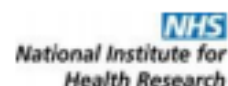
Tick the boxes to show which review tasks have been started and which have been completed. Update this field each time any amendments are made to a published record.

Reviews that have started data extraction (at the time of initial submission) are not eligible for inclusion in PROSPERO. If there is later evidence that incorrect status and/or completion date has been supplied, the published PROSPERO record will be marked as retracted.

This field uses answers to initial screening questions. It cannot be edited until after registration.

The review has not yet started: No

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Review stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Provide any other relevant information about the stage of the review here.

**6. \* Named contact.**

The named contact is the guarantor for the accuracy of the information in the register record. This may be any member of the review team.

LARISSA POZZOBON

**Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:**

Miss POZZOBON

**7. \* Named contact email.**

Give the electronic email address of the named contact.

larissa\_pozzobon@hotmail.com

**8. Named contact address**

Give the full institutional/organisational postal address for the named contact.

AVENIDA CARLOS GOMES 904, APTO 35, CEP 85819-350

**9. Named contact phone number.**

Give the telephone number for the named contact, including international dialling code.

55 (45) 99802-6036

**10. \* Organisational affiliation of the review.**

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

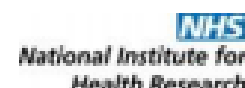
UNIVERSIDADE ESTADUAL DO OESTE DO PARANÁ (UNIOESTE)

**Organisation web address:**

larissa\_pozzobon@hotmail.com



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**11. \* Review team members and their organisational affiliations.**

Give the personal details and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong. **NOTE: email and country now MUST be entered for each person, unless you are amending a published record.**

Miss LARISSA POZZOBON. UNIVERSIDADE ESTADUAL DO OESTE DO PARANÁ  
Dr Fabiana Scarparo Naufel. UNIVERSIDADE ESTADUAL DO OESTE DO PARANÁ  
Dr Bianca Medeiros Maranh. UNIVERSIDADE ESTADUAL DO OESTE DO PARANÁ  
Dr. Maria Daniela Basso de Souza. UNIVERSIDADE ESTADUAL DO OESTE DO PARANÁ

**12. \* Funding sources/sponsors.**

Details of the individuals, organizations, groups, companies or other legal entities who have funded or sponsored the review.

None

**Grant number(s)**

State the funder, grant or award number and the date of award

None

**13. \* Conflicts of interest.**

List actual or perceived conflicts of interest (financial or academic).

None

**14. Collaborators.**

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members. **NOTE: email and country must be completed for each person, unless you are amending a published record.**

**15. \* Review question.**

State the review question(s) clearly and precisely. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PICO or similar where relevant.

Does in-office dental bleaching really improve the quality of life of patients with tooth discoloration?

**16. \* Searches.**

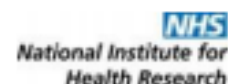
State the sources that will be searched (e.g. Medline). Give the search dates, and any restrictions (e.g. language or publication date). Do NOT enter the full search strategy (it may be provided as a link or attachment below.)

To identify trial investigations that must be included for this review, we shall search on the electronic databases MEDLINE via PubMed, Scopus, Web of Science, Latin American and Caribbean Health Sciences Literature database (LILACS), Brazilian Library in Dentistry (BBO) and Cochrane Library.

We will also hand-search the reference lists of all primary studies for additional relevant publications and the related articles link of each primary study in the PubMed database without restrictions to publication date or languages.

No restrictions will be placed on the publication date or languages, and all relevant studies will be translated and reviewed. We will search the abstracts of the annual conference of the International Association for Dental Research (IADR) and their regional divisions (2001-2019).

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We are also going to explore the grey literature using the database System for Information on Grey literature in Europe (SIGLE), and dissertations and theses using the ProQuest Dissertations and Theses Fulltext database, and Periódicos Capes Theses database as well.

To locate unpublished and ongoing trials related to the review question, we will search the following clinical trials registries: Current Controlled Trials ([www.controlledtrials.com](http://www.controlledtrials.com)), International Clinical trials registry plataforma (<http://apps.who.int/trialssearch/>), The ClinicalTrials.gov ([www.ClinicalTrials.gov](http://www.ClinicalTrials.gov)), Rebec ([www.rebec.gov.br](http://www.rebec.gov.br)), EU Clinical Trials Register (<https://www.clinicaltrialsregister.eu>).

The search strategy will be appropriately modified for each database and executed by two reviewers to identify eligible studies. The full text versions of the papers that appear to meet the inclusion criteria will be retrieved for further assessment and data extraction.

**17. URL to search strategy.**

Upload a file with your search strategy, or an example of a search strategy for a specific database, (including the keywords) in pdf or word format. In doing so you are consenting to the file being made publicly accessible. Or provide a URL or link to the strategy. Do NOT provide links to your search results.

Alternatively, upload your search strategy to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

**Don't make this file publicly available until the review is complete**

**18. \* Condition or domain being studied.**

Give a short description of the disease, condition or healthcare domain being studied in your systematic review.

Improve in quality of life.

**19. \* Participants/population.**

Specify the participants or populations being studied in the review. The preferred format includes details of both inclusion and exclusion criteria.

**Inclusion criteria:** Patients with permanent dentition with discolored teeth.

**Exclusion criteria:** patients not eligible for cosmetic treatments due to the presence of other important pathological conditions such as dental caries, need for endodontics, orthodontics and periodontal treatment.

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**20. \* Intervention(s), exposure(s).**

Give full and clear descriptions or definitions of the interventions or the exposures to be reviewed. The preferred format includes details of both inclusion and exclusion criteria.

**In office tooth bleaching.**

**21. \* Comparator(s)/control.**

Where relevant, give details of the alternatives against which the intervention/exposure will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

**In office tooth bleaching.**

**22. \* Types of study to be included.**

Give details of the study designs (e.g. RCT) that are eligible for inclusion in the review. The preferred format includes both inclusion and exclusion criteria. If there are no restrictions on the types of study, this should be stated.

**Inclusion criteria: randomized controlled trials that evaluated the quality of life of patients submitted to dental bleaching. We will include only parallel, split-mouth clinical trials in humans.**

**Exclusion criteria: non-controlled clinical trials, editorial letters, case reports and case series will be excluded.**

**23. Context.**

Give summary details of the setting or other relevant characteristics, which help define the inclusion or exclusion criteria.

**Inclusion criteria: patients with discolored teeth.**

**Excluded criteria: patients not eligible for cosmetic treatments due to the presence of other important pathological conditions such as dental caries, need for endodontics and periodontal treatment.**

**24. \* Main outcome(s).**

Give the pre-specified main (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurement are made, if these are part of the review inclusion criteria.

**Quality of life assessment (assessed with different questionnaires, e.g: OHIP-14, PIDAC, OES, among others, as noted in the studies).**

**\* Measures of effect**

Please specify the effect measure(s) for you main outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

**The effects will be evaluated after the end of treatment (mean difference or standardized mean difference or risk ratio).**

**25. \* Additional outcome(s).**

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List the pre-specified additional outcomes of the review, with a similar level of detail to that required for main outcomes. Where there are no additional outcomes please state 'None' or 'Not applicable' as appropriate to the review

None.

**\* Measures of effect**

Please specify the effect measure(s) for you additional outcome(s) e.g. relative risks, odds ratios, risk difference, and/or 'number needed to treat.

None.

**26. \* Data extraction (selection and coding).**

Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded.

Articles will be selected by title and abstracts according to the previously described search strategy.

Duplicated articles published in more than one database will be considered only once. Full-text articles will also be obtained when the title and abstract have sufficient information to make a clear decision.

Subsequently, two reviewers will classify those which met the inclusion criteria. To handle with such a large number of studies, we will use a study ID for each eligible study, combining first author and year of publication. Any disagreements between the reviewers over the eligibility of particular studies will be resolved through discussion with a third reviewer.

**27. \* Risk of bias (quality) assessment.**

State which characteristics of the studies will be assessed and/or any formal risk of bias/quality assessment tools that will be used.

The assessment criteria include six items: performance bias (patient and operator blinding), detection bias (evaluator blinding), attrition bias (incomplete outcome data), reporting bias (selective outcome reporting), selection bias (adequate sequence generation and allocation concealment) and other bias. Any other type of bias in the latter domain in this systematic review will not included.

Disagreements among the reviewers will solved through discussion, and if needed, by consulting a fourth reviewer. Each domain level will be judged to be low, high, or unclear. The study will have the low risk of bias if all five domains of the risk of bias tool are low risk. If one or more domains has an unclear risk, the study will be considered as an unclear risk; if at least one item has a high risk of bias, the study has a high risk of bias.

**28 \* Strategy for data synthesis.**

Describe the methods you plan to use to synthesise data. This must not be generic text but should be specific to your review and describe how the proposed approach will be applied to your data. If meta-analysis is planned, describe the models to be used, methods to explore statistical heterogeneity, and software package to be used.

Data will analyzed using the software RStudio statistical program (Version1.3.1093 2009-2020 RStudio, PBC). Meta-analyses were performed in all eligible studies.

**29\* Analysis of subgroups or subsets.**

State any planned investigation of 'subgroups'. Be clear and specific about which type of study or