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PRÓ-REITORIA DE PÓS-GRADUAÇÃO EM ODONTOLOGIA  
MESTRADO EM ODONTOLOGIA**

**JÉSSICA GOMES ALCOFORADO DE MELO**

**EFICÁCIA DO CHÁ VERDE (*Camellia sinensis* (L.) Kuntze) NO TRATAMENTO  
DA PERIODONTITE: REVISÃO SISTEMÁTICA E META-ANÁLISE**

**CAMPINA GRANDE - PB**

**2019**

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DA PERIODONTITE: REVISÃO SISTEMÁTICA E META-ANÁLISE**

Dissertação apresentada ao Programa de Pós-Graduação em Odontologia da Universidade Estadual da Paraíba como parte dos requisitos para obtenção do título de Mestre em Odontologia.

Linha de Pesquisa: Estudo das Terapias Complementares em Odontologia

Orientadora: Profa. Dra. Edja Maria Melo de Brito Costa

**CAMPINA GRANDE - PB**

**2019**

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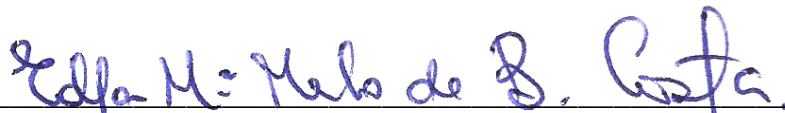
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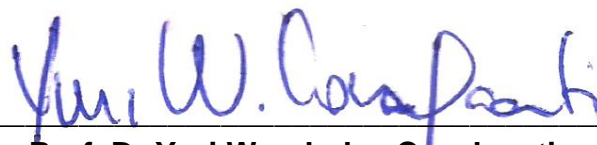
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Aprovado em 04/07/2019

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*Dedico este trabalho a **Deus** e a  
**Nossa Senhora da Conceição**,  
a minha mãe **Maria Lúcia** e meus  
avós **Maria** e **Geraldo**.*

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*“Nada é tão nosso quanto os nossos sonhos.”*

**Nietzsche**

*“O que é feito com amor, é bem feito.”*

**Van Gogh**

## EFICÁCIA DO CHÁ VERDE (*Camellia sinensis* (L.) Kuntze) NO TRATAMENTO DA PERIODONTITE: REVISÃO SISTEMÁTICA E META-ANÁLISE

### RESUMO

Este trabalho teve o objetivo de analisar a evidência científica quanto à eficácia do chá verde (*Camellia sinensis*), em suas diferentes formas e aplicações, no tratamento da periodontite. Foram realizadas buscas nas bases de dados PubMed/MEDLINE, Scopus, Web of Science, Cochrane, Scielo, Lilacs, Science Direct, na literatura cinzenta, além de uma busca manual, até abril de 2019. Foram incluídos ensaios clínicos randomizados que avaliaram o chá verde como agente terapêutico adjuvante no tratamento da periodontite. Dois revisores independentes selecionaram os estudos, extraíram os dados e analisaram o risco de viés dos estudos utilizando o instrumento RoB 2.0 da Cochrane, assim como a qualidade da certeza utilizando o GRADE. Inicialmente, 3.025 estudos foram encontrados, dos quais nove foram incluídos nas análises qualitativa e quantitativa. O risco de viés foi baixo em apenas quatro estudos, alto em outros quatro e apenas um, dos nove estudos, foi considerado como com alguns problemas. Foram identificadas quatro formas de apresentação do chá verde: sachês, tiras de hidroxipropilcelulose, gel e dentifrício. O chá verde, em todos os estudos, foi administrado em associação com a raspagem e o alisamento radicular. O tempo de tratamento variou de 21 dias a 6 meses. Constatou-se a partir da meta-análise, que a utilização do chá verde, especificamente na forma de sachê, reduziu significativamente o sangramento à sondagem (SMD = -0,71 [-1,39, -0,03]  $p = 0,04$ ,  $I^2 = 82\%$ ) e o índice gengival (SMD = -0,78 [-1,33, -0,23]  $p = 0,006$ ,  $I^2 = 80\%$ ). As formas de apresentação em sachê e dentifrício reduziram o índice de placa (SMD = -0,63 [-1,18, -0,08]  $p = 0,02$ ,  $I^2 = 77\%$ ). Para a redução da profundidade de sondagem, não houve diferença significativa entre utilizar o chá verde ou apenas a raspagem e o alisamento radicular (SMD = -0,27 [-0,97, 0,42]  $p = 0,44$ ,  $I^2 = 89\%$ ). A certeza da evidência para a profundidade de sondagem foi muito baixa. A evidência científica que sugere a eficácia do uso do chá verde adjunto à terapia periodontal é fraca. Se faz necessário a realização de estudos adicionais com melhor qualidade metodológica para confirmar a evidência.

**Palavras-chave:** chá verde; *camellia sinensis*; doença periodontal; revisão sistemática.

# EFFECTIVENESS OF THE GREEN TEA (*Camellia sinensis* (L.) Kuntze) IN THE TREATMENT OF PERIODONTITIS: SYSTEMATIC REVIEW AND META-ANALYSIS

## ABSTRACT

This study had the goal to analyze the scientific evidence regarding the efficiency of green tea (*Camellia sinensis*) in its different forms and applications for the treatment of periodontitis. It was searched in the electronic databases PubMed/MEDLINE, Scopus, Web of Science, Cochrane, Scielo, Lilacs, Science Direct, in the gray literature, as well as manual search, until April 2019. Then, it was randomized clinical trials evaluating the green tea as an adjuvant therapeutic agent in the treatment of periodontitis. Two independent reviewers selected the studies, extracted the data and analyzed the risk of bias of the studies using the Cochrane RoB 2.0 instrument and the analysis of the quality of certainty using GRADE. Initially, 3,025 studies were found, of which nine were included in the qualitative and quantitative analysis. The risk of bias was low in only four studies, high in four, and only one of the nine studies was considered to have some problems. Four ways of presenting green tea were identified: sachets, hydroxypropylcellulose strips, gel and dentifrice. Green tea, in all studies, was given in combination with scraping and root straightening. The treatment time ranged from 21 days to 6 months. It was verified from the meta-analysis that the use of green tea, specifically as a sachet, significantly reduced probing bleeding (SMD = -0,71 [-1,39, -0,03]  $p = 0,04$ ,  $I^2 = 82\%$ ) and the gingival index (SMD = -0,78 [-1,33, -0,23]  $p = 0,006$ ,  $I^2 = 80\%$ ). The presentation forms as sachet and dentifrice reduced plaque index (SMD = -0,63 [-1,18, -0,08]  $p = 0,02$ ,  $I^2 = 77\%$ ). To reduce the probing depth, there was no significant difference between using green tea or just scraping and root straightening (SMD = -0,27 [-0,97, 0,42]  $p = 0,44$ ,  $I^2 = 89\%$ ). The certainty of the evidence for the depth of probing was very low. The scientific evidence that suggest the efficiency of the usage of green tea adjunct to periodontal therapy is weak. Thus, it is necessary to perform additional studies with better methodological quality to confirm the evidence.

**Keywords:** green tea; *camellia sinensis*; periodontal diseases; systematic review.

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## 1 INTRODUÇÃO

A doença periodontal é uma condição prevalente na população brasileira e de outros países da América Latina (DRISKO, 2001; ARAÚJO; SUKEKAVA, 2007; HOLTFRETER *et al.*, 2015). Afeta cerca de 20 a 50% da população mundial (ALBANDAR; RAMS, 2002), com alta prevalência em adolescentes, adultos e idosos, cujos danos podem ser irreversíveis aos tecidos periodontais, culminando em perda dentária (FERREIRA *et al.*, 2014; SHABBIR; RASHID; TIPU, 2016), caracterizando um problema de saúde pública (BRASIL, 2012; NAZIR, 2017).

A raspagem e o alisamento radicular constituem a base do tratamento periodontal não-cirúrgico e é considerado o padrão ouro (PETERSILKA; EHMKE; FLEMMING, 2002; FLEMMING; WINGENDER, 2010, DABIJA-WOLTER *et al.*, 2018). No entanto, em alguns casos, a anatomia da raiz e o contorno da bolsa periodontal podem dificultar o tratamento, impedir a redução da carga bacteriana, produzindo-se em alguns pacientes repetidas sessões da terapia periodontal, sem sucesso. Além disso, o debridamento mecânico convencional geralmente não erradica, e sim, reduz a média dos patógenos periodontais (HAGENFELD *et al.*, 2018), o que tem justificado o tratamento associado com antimicrobianos (FREITAS *et al.*, 2016).

O objetivo do tratamento periodontal é reduzir o número dos microrganismos patogênicos em contato com os tecidos periodontais, bem como, dos seus produtos biológicos, como as endotoxinas, antígenos, enzimas e outras substâncias irritantes ao tecido. Este tem sido o princípio para o desenvolvimento de novas terapias para doença periodontal, as quais baseiam-se no controle desses fatores, especialmente, no controle das bactérias anaeróbias gram-negativas, presentes no ambiente subgingival das bolsas periodontais (AGARWAL; VEMANARADHYA; MEHTA, 2012; HAGENFELD *et al.*, 2018).

Nesta perspectiva, observa-se na literatura uma tendência para o uso de produtos naturais, como recurso coadjuvante, no tratamento da doença periodontal (LAZAR; SAVIUC; CHIFRIUNE, 2016; MARTÍNEZ; GÓMEZ; OH, 2017), dentre eles, destaca-se o chá verde (*Camellia Sinensis*) (HIRASAWA *et al.*, 2002; FUNOSAS *et al.*, 2005; KUDVA; TABASUM; SHEKWAT, 2011; CHAVA; VEDULA, 2013; GADAGI; CHAVA; REDDY, 2013; HATTARKI; BHAT, 2013; RATTANASUWAN *et al.*, 2014; YUVARAJA *et al.*, 2016; FERIAI *et al.*, 2018).



O consumo do chá verde pode reduzir o risco de doença periodontal (Kushiyama *et al.*, 2009, Ferial *et al.*, 2018), favorecendo o tratamento periodontal, em função de sua atividade anti-colagenase e por inibir a aderência de *Porphyromonas gingivalis* nas células epiteliais bucais (MAKIMURA *et al.*, 1993, SAKANAKA *et al.*, 1996).

O chá verde é utilizado de diferentes formas no tratamento da doença periodontal. Recentemente, foi publicado um estudo de revisão sistemática sobre o uso do chá verde adjunto ao tratamento mecânico da periodontite (GARTENMANN *et al.*, 2019), cujo cadastro no PROSPERO não foi identificado e sua análise limitou-se a avaliar o uso do chá verde como aplicação tópica subgingival. Não foi encontrado nas bases de pesquisa PubMed, Lilacs, Scopus, Scielo, Web of Science, Cochrane e Prospero, nenhum estudo de revisão sistemática com o objetivo de analisar as evidências científicas da eficácia do chá verde, em suas diferentes formas e aplicações, adjunto ao tratamento da periodontite, sendo, portanto, objeto deste trabalho, cadastrado no PROSPERO, sob o nº CRD42018115953. Esta revisão se diferencia da revisão sistemática publicada, pela inclusão de diferentes formas de apresentação do chá verde e a busca em um maior número de bases eletrônicas.

## 2 REFERENCIAL TEÓRICO

### 2.1 Doença Periodontal: Periodontite

A doença periodontal é uma infecção polimicrobiana progressiva, sua manifestação clínica refere-se à inflamação que ocorre nos tecidos periodontais em resposta ao crescimento de biofilme ao longo da margem gengival (TORRES *et al.*, 2018). Socransky *et al.* (1998) observaram, por meio da técnica de checkerboard DNA-DNA hybridization, a presença de 5 complexos bacterianos principais neste ambiente subgengival: o complexo vermelho, o laranja, o verde, o amarelo e o roxo. Tais complexos estão intimamente ligados com a instalação e progressão da doença periodontal e, cada um desses grupos apresenta diferentes graus de patogenicidade.

No Workshop de 1999 da Academia Americana de Periodontia, a doença periodontal foi classificada em periodontite crônica e agressiva (ARMITAGE, 1999). A periodontite crônica foi caracterizada pela abundância de biofilme e cálculo, combinando com o padrão generalizado de destruição óssea, além de estar relacionada com algumas condições sistêmicas, como a artrite reumatoide (LEECH; BARTOLD, 2015). A periodontite agressiva possui uma rápida taxa de destruição periodontal, cujo acúmulo de biofilme e cálculo não é compatível (ALBANDAR, 2014), e o paciente não apresenta qualquer envolvimento sistêmico que justifique a progressão rápida da doença (ARMITAGE, CULLINAN, 2010). A periodontite agressiva, na classificação de 1999 (ARMITAGE, 1999), é subdividida em localizada e generalizada, com base na extensão da destruição (RAMACHANDRA, 2017). No Workshop de 2017 foi proposta uma nova classificação das periodontites, agora agrupadas em uma única categoria, “periodontite”, sendo caracterizadas com base em um sistema multidimensional de estadiamento e gradação (CATON *et al.*, 2018).

A periodontite é uma doença multifatorial, tendo como fator etiológico primário o biofilme dentário multiespécie, formado especialmente em nível subgengival, com participação de diferentes espécies de bactérias (PASTER *et al.*, 2006; BAKER *et al.*, 2017; KOMMEREIN *et al.*, 2018), fungos e até vírus (BAKER *et al.*, 2017). Esse biofilme induz uma resposta inflamatória, que pode causar danos irreversíveis aos tecidos periodontais, acarretando na perda de dentes, caso não seja removido ou controlado (FERREIRA *et al.*, 2014; SHABBIR; RASHID; TIPU, 2016).

Sabe-se que o biofilme subgengival presente nos sítios saudáveis é diferente daqueles dos sítios com a doença (XIMENEZ-FYVIE; HAFFAJEE; SOCRANSKY, 2000; LOURENÇO *et al.*, 2014). O microbioma de indivíduos saudáveis abrange mais de 500 bactérias conhecidas que vivem simbioticamente (LIPSKY *et al.*, 2017). Os diversos microrganismos presentes no biofilme estabelecem relações ecológicas entre si e podem oferecer vantagens às cepas das bactérias periodontais presentes para que estas, possam estabelecer infecções crônicas no hospedeiro (BARBOSA *et al.*, 2015).

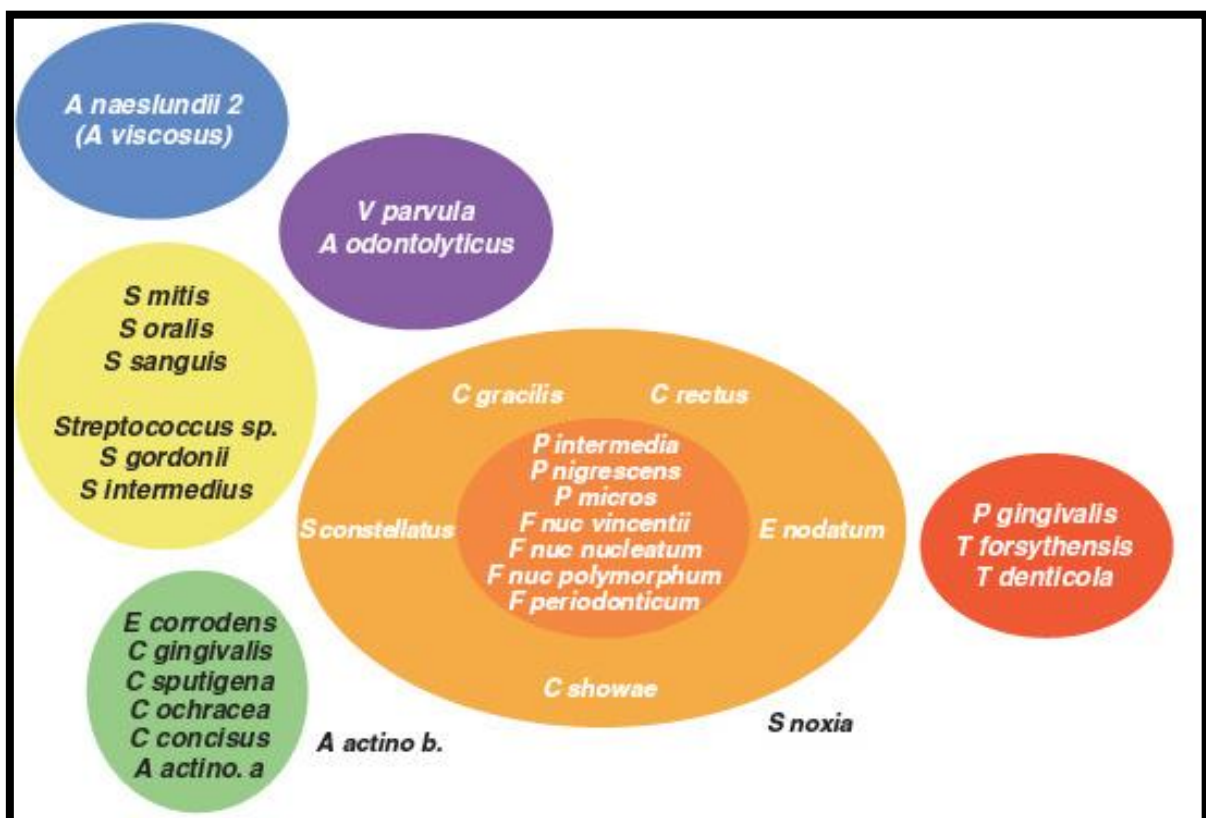


Figura 1. Diagrama representando a relação entre as espécies com os complexos e entre os complexos. Adaptado de Socransky *et al.* (1998).

O biofilme associado à doença periodontal é caracterizado pela presença de bactérias, como: a *Actinobacillus actinomycetemcomitans*, bactéria Gram-negativa associada à periodontite agressiva; as espécies de *Fusobacterium*, por aumentarem em número nas bolsas gengivais à medida que a doença periodontal progride e *Porphyromonas gingivalis* e *Prevotella intermedia*, geralmente, isoladas do sulco gengival de pacientes com periodontite crônica (SANTOS *et al.*, 2002; SANTOS *et al.*, 2003; AGARWAL; VEMANARADHYA; MEHTA, 2012). O desenvolvimento de

novas terapias para o tratamento da doença periodontal baseia-se, especialmente, no controle dessas bactérias (AGARWAL; VEMANARADHYA; MEHTA, 2012).

### 2.1.1 Tratamento da periodontite

O tratamento da doença periodontal é direcionado para a eliminação/supressão da microbiota subgengival. O debridamento da raiz por meio mecânico da raspagem e alisamento é a abordagem considerada o padrão ouro (SANGHANI; SHIVAPRASAD; SAVITA, 2014; DABIJA-WOLTER *et al.*, 2018). Resulta na redução da inflamação, da profundidade de sondagem e leva à estabilidade do nível de inserção (MLACHKOVA; POPOVA, 2014), promovendo a remoção mecânica do cálculo e o rompimento de colônias bacterianas presentes no dente e na superfície radicular (KRISHNA; DE STEFANO, 2016). Após a raspagem e alisamento radicular, a cicatrização do tecido periodontal pode reduzir as indicações para a terapia cirúrgica periodontal (MLACHKOVA; POPOVA, 2014).

A recolonização microbiana subgengival após o debridamento pode ocorrer lentamente em vários meses, particularmente quando combinada com o controle do biofilme supragengival (MAGNUSSON *et al.*, 1984; SEGELNICK; WEINBERG, 2006; MOMBELLI, 2017). Se a higiene bucal for defeituosa, a microbiota subgengival patogênica pode se reestabelecer com 42-60 dias após uma sessão da raspagem e alisamento radicular (MOUSQUES; LISTGARTEN; PHILLIPS, 1980; SBORDONE *et al.*, 1990; QUIRYNEN *et al.*, 2002). Muitas espécies excederam os valores basais no dia 2 após o debridamento mecânico quando não realizada uma boa higiene bucal (UZEL *et al.*, 2011). Estudos *in vitro* mostram que o número total de unidades formadoras de colônias diminui apenas durante os primeiros 2 meses, portanto, passado esse período as bactérias já repovoaram a bolsa periodontal (QUIRYNEN *et al.*, 2002; SEGELNICK; WEINBERG, 2006). Algumas bolsas periodontais são recolonizadas em 120-240 dias, apesar das múltiplas sessões de debridamento e controle do biofilme dentário (MAGNUSSON *et al.*, 1984; QUIRYNEN *et al.*, 2002).

O debridamento mecânico convencional geralmente não erradica, mas reduz a média dos patógenos periodontais (HAGENFELD *et al.*, 2018). Em vista do ecossistema complexo da bolsa periodontal, o uso adjuvante dos agentes antimicrobianos tem sido defendido juntamente com a instrumentação mecânica. A terapia antimicrobiana local tem a vantagem de proporcionar uma concentração eficaz do fármaco no local da infecção com carga sistêmica mínima e baixo risco

para a emergência de resistência bacteriana (SANGHANI; SHIVAPRASAD; SAVITA, 2014; JOSHI *et al.*, 2014).

### **2.1.1.1 Terapia antimicrobiana local**

A terapia antimicrobiana local na periodontite envolve a colocação direta de um agente antimicrobiano na bolsa periodontal, minimizando o impacto sistêmico. Os agentes antimicrobianos locais podem ser aplicados como parte dos regimes de higiene bucal doméstica ou como parte dos procedimentos de tratamento no consultório odontológico (JOSHI *et al.*, 2014; SINDHURA; HARSHA; SHILPA, 2017).

O iodo-povidine, hipoclorito de sódio diluído e digluconato de clorexidina podem ser utilizados para irrigação da bolsa periodontal durante ou após o procedimento de debridamento da raiz (KRISHNA; DE STEFANO, 2016). A utilização do iodo-povidine promoveu uma redução significativa da profundidade de sondagem e no sangramento gengival (SINDHURA; HARSHA; SHILPA, 2017), além de promover uma melhora na cicatrização de feridas (ROSLING *et al.*, 1986; CHRISTERSSON *et al.*, 1988; SELVAGI *et al.*, 2003). Um estudo realizado em cães mostrou que a irrigação com hipoclorito de sódio resultou em sinais histológicos de aumento da atividade osteoblástica, embora a redução em profundidade de sondagem fosse igual à obtida na raspagem e alisamento radicular sozinho (VIEIRA; O'LEARY; KAFRAWY, 1982).

A clorexidina é considerada o padrão ouro dos agentes químicos para o controle da inflamação gengival, devido ao seu eficaz efeito antiplaca (RADAFSHAR *et al.*, 2017; SHALINI; RAMESH, 2018). Estudos que avaliaram o efeito da irrigação subgengival com clorexidina, diariamente por 1 mês, constataram que o estado periodontal é melhorado e mantido por mais de 2 meses, sendo, portanto, útil como auxiliar no tratamento periodontal não-cirúrgico (WIEDER; NEWMAN; STRAHAN, 1983). Sua utilização como chip adjunto à raspagem e alisamento radicular mostrou uma redução da carga microbiana dos periodontopatógenos desde o início até 3 meses, porém, não houve efeito superior ao debridamento mecânico sozinho (KUMAR *et al.*, 2014; MEDAIAH *et al.*, 2014). Algumas bactérias presentes na placa bacteriana estão resistentes a múltiplas drogas, inclusive à clorexidina (SALEEM *et al.*, 2016).

Outra substância é o bicarbonato de sódio, quando utilizado em associação com a raspagem e alisamento radicular pode ocasionar uma melhora na condição

periodontal do paciente (CHRISTERSSON *et al.*, 1988). Porém, por ser um material abrasivo pode promover escoriações na gengiva, sendo seu efeito tão eficaz quanto o debridamento mecânico sozinho (SIMON; LAKSHMAIAH; CHICKANNA, 2015).

Foi comprovado o uso de antibióticos na irrigação subgengival que promove uma melhora clínica quando utilizado adjunto à raspagem e alisamento radicular, a aplicação na forma de dispositivos de entrega local sustentada, ou seja, que permanece no local por um longo período, promove uma redução de 0,4mm de profundidade de sondagem (JEPSEN; JEPSEN, 2016). Os veículos testados para a administração local de forma sustentada incluem soluções, pastas, fibras ocas, tiras acrílicas, fibras monolíticas, celulose reabsorvível, colágeno, nanopartículas, chips, micropartículas, nanofibras e gel biodegradável (RAMS; SLOTS, 1996; JOSHI *et al.*, 2014; LEE *et al.*, 2016).

Porém, nem todos os pacientes apresentam resultados satisfatórios com a utilização de antibióticos (sistêmico e de aplicação local) no tratamento (SILVA-SENE *et al.*, 2013), além da resistência microbiana de alguns periodontopatógenos, como o *Fusobacterium nucleatum*, *P. gingivalis* e *P. intermedia* após a administração subgengival do metronidazol, como visto no estudo de Larsen, Fihen (1997). No estudo de Shabbir; Rashid; Tipu (2016) constatou-se a resistência completa à tetraciclina pelos isolados de *P. gingivalis* e *P. intermedia*, enquanto a resistência intermediária à tetraciclina foi indicada pelos isolados *P. asaccharolytica* e *P. melaninogenica*.

Dessa forma, os fitoquímicos se mostram como uma alternativa aos fármacos, com propriedades desejáveis e menores efeitos colaterais (RAMESH *et al.*, 2016), visto que drogas a base de plantas são utilizadas desde a antiguidade no tratamento de diversas doenças, incluindo a doença periodontal (CRAG; NEWMAN, 2013; ABULLAIS *et al.*, 2015; SHABBIR; RASHID; TIPU, 2016).

Neste cenário, destaca-se o chá verde (*Camellia sinensis* (L.) Kuntze), em função das suas propriedades terapêuticas. O chá verde tem sido analisado como agente coadjuvante no tratamento periodontal, na sua utilização por via sistêmica em forma de sachê para infusão (FERIAL *et al.*, 2018). No entanto, ainda não existe evidência científica em relação a sua eficácia nas diferentes formas de aplicação existentes.

## 2.2 Chá verde (*Camellia sinensis* (L.) Kuntze)

O chá verde é uma bebida popular mundialmente - a mais consumida depois da água (NAMITA; MUKESH; VIJAY, 2012), obtido da folha fresca do arbusto *Camellia sinensis* (L.) Kuntze (BANCIROVA, 2010), pertencente à família Theaceae (NAMITA; MUKESH; VIJAY, 2012; KHURSHID *et al.*, 2016). O termo chá verde refere-se a forma como é fabricado, evitando a oxidação dos componentes polifenólicos (GRAHAM, 1992).



Figura 2. *Camellia sinensis*, 1: folhas; 2: fruto. Fonte: Namita; Mukesh; Vijay, 2012.

O perfil fitoquímico da planta pode variar de acordo com o clima, a época do ano, idade da folha e as práticas hortícolas (LUNDER, 1989). Podem ser identificados aminoácidos, polissacarídeos, alcaloides, vitaminas e polifenóis, principalmente flavonoides (CHOPADE *et al.*, 2008). Os componentes que mais se destacam são os polifenóis, em especial as catequinas dos flavonoides (GRAHAM, 1992), como a catequina (C), epicatequina (EC), galocatequina (CG), epigalocatequina (EGC), galato de epicatequina (ECG) e galato de epigalocatequina (EGCG) (MAKIMURA *et al.*, 1993; NAMITA; MUKESH; VIJAY, 2012).

A *C. sinensis* também contém ácido gálico e outros ácidos fenólicos em sua composição, como o ácido clorogênico e ácido cafeico, além dos flavonoides, como o kaempferol, myricetin e quercetina (CABRERA; ARTACHO; GIMENEZ, 2006; AWADALLA *et al.*, 2011a).

As catequinas são solúveis em água, incolores e adstringentes. São oxidáveis, com potenciais de oxidação variáveis (TANIZAWA *et al.*, 1984). A eficácia antioxidante das catequinas é exercida através de dois mecanismos, um deles é o

mecanismo direto: pela eliminação de radicais livres, íons metálicos e quelantes (CABRERA; ARTACHO; GIMENEZ, 2006). Isso ocorre devido ao grupo hidroxila presente na sua estrutura, que possui a capacidade de estabilizar os radicais livres (FRAGA *et al.*, 2010).

As folhas da *C. sinensis* contêm moléculas bioativas que podem promover saúde periodontal (KOYAMA *et al.*, 2010). Um estudo recente sugere que o EGCG induz, de modo dose-dependente, a secreção de betadefensina humana 1 (hBD1) e 2 (hBD2) pelas células epiteliais, após um tratamento por 24h (LOMBARDO BEDRAN *et al.*, 2014). Sabe-se que as hBDs são ativas contra os principais periodontopatógenos (DALE; FREDERICKS, 2006), podendo contribuir para a redução dos microrganismos presentes nos sítios subgengivais e da invasão dos tecidos periodontais por esses patógenos (LOMBARDO BEDRAN *et al.*, 2014). Além disso, elas atenuam, principalmente a hBD2, a secreção de citocinas por células epiteliais estimuladas por lipopolissacarídeos e macrófagos, reduzindo a inflamação gengival (SEMPLE *et al.*, 2011; DONNARUMMA *et al.*, 2007).

Diversos estudos foram realizados avaliando a eficácia no controle químico do biofilme e da inflamação gengival das catequinas da *C. sinensis*, devido ao seu papel no controle da inflamação gengival (KUSHIYAMA *et al.*, 2009) e a sua propriedade antibiofilme (CABRERA; ARTACHO; GIMENEZ, 2006). Em um estudo recente, os autores avaliaram a eficácia do bochecho do chá verde (*C. sinensis*) no controle do biofilme e da inflamação gengival, utilizando a clorexidina como comparação. Obteve-se que os dois foram eficazes, sendo o *C. sinensis* uma opção como coadjuvante na manutenção da higiene bucal, devido às suas propriedades antibacterianas e antioxidantes (PRIYA *et al.*, 2015).

Sua ação anti-inflamatória deve-se provavelmente ao efeito inibitório sobre as enzimas colagenolíticas e sobre os patógenos periodontais (MAKIMURA *et al.*, 1993; PRIYA *et al.*, 2015). Esta propriedade tem impacto direto na progressão da doença, considerando que o aumento da atividade colagenolítica é uma característica da doença periodontal, resultando na destruição progressiva do periodonto (GENCO, 1981; TRINDADE *et al.*, 2015).

A utilização do chá verde como um sistema de liberação local e lenta, um gel, como um mecanismo para melhorar a periodontite foi feito por Hirasawa *et al.* (2002). Constatou-se que possui efeito antimicrobiano contra a *Porphyromonas*



*gingivalis* e que o debridamento mecânico associado ao sistema de liberação local contendo chá verde é eficaz na modulação da doença periodontal.

Além de colutórios e sistemas de liberação local e lenta (tiras e gel), o chá verde (*Camellia sinensis*) vem sendo estudado na composição de dentifrício, associando o seu uso ao tratamento não-cirúrgico da periodontite, resultando em uma melhora no quadro clínico dos pacientes (HRISHI *et al.*, 2016).

Recentemente, foi realizada uma revisão sistemática com meta-análise avaliando a eficácia de produtos de liberação local (gel e tiras) adjunto à raspagem e o alisamento em pacientes com periodontite crônica. Observou-se que tais estudos mostravam o chá verde, nestas formulações, como um promissor fitoquímico para auxiliar no tratamento da doença periodontal, devido a redução da profundidade de sondagem (GARTENMANN *et al.*, 2019).

### **3 OBJETIVOS**

#### **3.1 Objetivo geral**

- Avaliar as evidências científicas da eficácia do chá verde adjunto ao tratamento da periodontite e na remissão dos parâmetros clínicos de inflamação.

#### **3.2 Objetivos específicos**

- Analisar as diferentes formas farmacêuticas à base de chá verde, utilizadas no tratamento periodontal;
- Verificar os protocolos de uso do chá verde no tratamento da periodontite.

## 4 METODOLOGIA

### 4.1 Estratégia de busca

Esta revisão sistemática foi registrada junto ao *International prospective register of systematic reviews* (PROSPERO) com o número de registro CRD42018115953 (Anexo 1). Os procedimentos metodológicos seguiram os critérios do *checklist* Prisma (MOHER et al., 2009), tendo como pergunta norteadora: O chá verde (*Camellia sinensis*) no tratamento da doença periodontal se mostra eficaz? A estratégia utilizada para definir os critérios de elegibilidade foi a População, Intervenção, Comparação e Desfecho: pacientes com doença periodontal (P), utilização do chá verde (*Camellia sinensis*) no tratamento da doença periodontal (I); tratamento convencional da doença periodontal (C) e remissão dos parâmetros clínicos da periodontite (O).

Os critérios de inclusão foram ensaios clínicos controlados randomizados que avaliaram a eficácia do chá verde (*Camellia sinensis*), em suas diferentes formas e aplicações, como agente terapêutico adjunto ao tratamento da periodontite e pacientes sem doença sistêmica. Os critérios de exclusão foram ensaios clínicos registrados, mas sem resultados parciais, estudos *in vitro*, *in situ*, caso-controle, coorte, transversais, relatos de caso, série de casos, opiniões de especialistas, cartas ao editor, editoriais e revisões de literatura.

A pesquisa eletrônica foi realizada em 7 bases de dados (PubMed/MEDLINE, Web of Science, Lilacs, Scielo, Cochrane Central Register of Controlled Trials, Scopus e EMBASE - Science Direct) de agosto de 2018 a abril de 2019 (tabela 1). Realizou-se a busca na literatura cinzenta no OpenGrey, OpenThesis e no Catálogo de Teses e Dissertações da CAPES, assim como uma busca manual na lista de referência dos estudos incluídos após leitura do texto completo e de revisões sistemáticas relacionadas ao tema. Não houve restrição com a data de publicação e idioma.

Tabela 1. Estratégia de busca utilizada nas bases de dados eletrônicas.

DATABASE	SEARCH STRATEGY
<b>PubMed</b> ( <a href="http://www.ncbi.nlm.nih.gov/pubmed">http://www.ncbi.nlm.nih.gov/pubmed</a> ), <b>OpenGrey</b> ( <a href="http://www.opengrey.eu/">http://www.opengrey.eu/</a> ), <b>OpenThesis</b> ( <a href="http://www.openthesis.org/">http://www.openthesis.org/</a> ), <b>Science Direct</b> ( <a href="https://www.sciencedirect.com/">https://www.sciencedirect.com/</a> )	(green tea OR green tea extract OR green tea catechins OR camellia sinensis OR catechins) AND (periodontitis OR periodontal diseases OR periodontal pocket OR chronic periodontitis OR adult periodontitides OR adult periodontitis OR chronic periodontitides OR aggressive periodontitis OR juvenile periodontitis OR prepubertal periodontitis OR circumpubertal periodontitis)
<b>Scopus</b> ( <a href="http://www.scopus.com/">http://www.scopus.com/</a> )	( TITLE-ABS-KEY ( green AND tea ) OR TITLE-ABS-KEY ( green AND tea AND extract ) OR TITLE-ABS-KEY ( green AND tea AND catechins ) OR TITLE-ABS-KEY ( camellia AND sinensis ) OR TITLE-ABS-KEY ( catechins ) AND TITLE-ABS-KEY ( periodontitis ) OR TITLE-ABS-KEY ( periodontal AND diseases ) OR TITLE-ABS-KEY ( periodontal AND pocket ) OR TITLE-ABS-KEY ( chronic AND periodontitis ) OR TITLE-ABS-KEY ( adult AND periodontitides ) OR TITLE-ABS-KEY ( adult AND periodontitis ) OR TITLE-ABS-KEY ( chronic AND periodontitides ) OR TITLE-ABS-KEY ( aggressive AND periodontitis ) OR TITLE-ABS-KEY ( juvenile AND periodontitis ) OR TITLE-ABS-KEY ( prepubertal AND periodontitis ) OR TITLE-ABS-KEY ( circumpubertal AND periodontitis )
<b>Web of Science</b> ( <a href="http://webofknowledge.com/">http://webofknowledge.com/</a> )	TÓPICO: (((((green tea OR green tea extract) OR green tea catechins) OR camellia sinensis) OR catechins) AND (((((((((((periodontitis OR periodontal diseases) OR periodontal pocket) OR chronic periodontitis) OR adult periodontitides) OR adult periodontitis) OR chronic periodontitides) OR aggressive periodontitis) OR juvenile periodontitis) OR prepubertal periodontitis) OR circumpubertal periodontitis))
<b>Scielo</b> ( <a href="http://www.scielo.org/">www.scielo.org/</a> )	(green tea) OR (green tea extract ) OR (green tea catechins) OR (camellia sinensis) OR (catechins) AND (periodontitis) OR (periodontal diseases) OR (periodontal pocket) OR (chronic periodontitis) OR (adult periodontitides ) OR (adult periodontitis) OR (chronic periodontitides) OR (aggressive periodontitis) OR (juvenile periodontitis) OR (prepubertal periodontitis) OR (circumpubertal periodontitis)
<b>Cochrane</b> ( <a href="https://www.cochranelibrary.com/">https://www.cochranelibrary.com/</a> )	(green tea OR green tea extract OR green tea catechins OR camellia sinensis OR catechins OR catechin [MeSH] OR tea [MeSH]) AND (periodontitis OR periodontitis [MeSH] OR periodontal diseases OR periodontal diseases [MeSH] OR periodontal pocket OR chronic periodontitis OR chronic periodontitis [MeSH] OR adult periodontitides OR adult periodontitis OR chronic periodontitides OR aggressive periodontitis OR aggressive periodontitis [MeSH] OR juvenile periodontitis OR prepubertal periodontitis OR circumpubertal periodontitis [MeSH])
<b>Lilacs</b> ( <a href="http://lilacs.bvsalud.org/">http://lilacs.bvsalud.org/</a> )	(green tea OR green tea extract OR green tea catechins OR camellia sinensis OR catechins) [Palavras] and (periodontitis OR periodontal diseases OR periodontal pocket OR chronic periodontitis OR adult periodontitides OR adult periodontitis OR chronic periodontitides OR aggressive periodontitis OR juvenile periodontitis OR prepubertal periodontitis OR circumpubertal) [Palavras]
<b>Catálogo de Teses e Dissertações CAPES</b> ( <a href="https://catalogodeteses.capes.gov.br/catalogo-teses/#/">https://catalogodeteses.capes.gov.br/catalogo-teses/#/</a> )	green tea AND periodontal diseases

MeSH – Medical Subject Heading.

Dois revisores independentes (J.G.A.M., J.P.S.) avaliaram os títulos e resumos a partir dos critérios de elegibilidade, que estavam organizados em uma

tabela de Excel. Primeiramente foi realizada a calibração com 20% dos estudos identificados, cuja concordância interobservador foi satisfatória ( $k = 0.862$ ), e os revisores foram considerados capazes de analisar os títulos e resumos remanescentes para a pré-seleção dos artigos. Foram analisados os textos completos dos estudos pré-selecionados e após a leitura, os documentos que preencheram os critérios de elegibilidade foram incluídos na revisão. Os casos discordantes entre os dois revisores foram resolvidos por meio de consenso e uma discussão com um terceiro revisor (E.M.M.B.C.).

Extraímos o ano de publicação, país, idioma, local de realização do estudo, idade/faixa etária, tamanho da amostra, parâmetros utilizados para diagnóstico da periodontite, protocolo de extração, parte da planta utilizada, forma farmacêutica, aplicação, tipos de tratamento utilizado, tratamento controle, placebo, intervenção, desfecho, análise estatística e medidas de efeito utilizadas.

#### **4.2 Avaliação da Qualidade Metodológica**

Os revisores avaliaram a qualidade metodológica dos estudos utilizando o instrumento Risk of Bias 2.0 (RoB) (Anexo 2) da Cochrane (HIGGINS *et al.*, 2011), que consiste em uma ferramenta para avaliar o risco de viés em ensaios clínicos randomizados. Esta ferramenta avalia a ocorrência de vieses nos seguintes aspectos: processo de randomização, desvios nas intervenções pretendidas, dados faltantes, medição dos desfechos, seleção dos resultados relatados e a tendência geral de viés.

#### **4.3 Síntese dos Dados e Análise Estatística**

Foi realizada a análise qualitativa dos resultados e utilizado o *software* Review Manager, versão 5.3, da Cochrane, para a metanálise. Foi realizada uma análise por subgrupos, utilizando o efeito randômico, a diferença de média padronizada e a heterogeneidade foi quantificada pelo teste  $I^2$ .

#### **4.4 Certeza da Evidência**

Avaliamos a força das evidências dos estudos selecionados para a metanálise utilizando um sistema de Avaliação, Desenvolvimento e Avaliação (GRADE – Assessment, Development and Evaluation), através da plataforma GRADEpro

(GUYATT *et al.*, 2008). Para ensaios clínicos randomizados, a certeza se inicia alta e vai sendo reduzida a sua confiança quando apresenta algum problema nos seguintes domínios: risco de viés, inconsistência, evidência indireta, imprecisão e viés de publicação. A cada problema se reduz um nível nessa confiança. As diretrizes do GRADE classificam a evidência como muito baixa, baixa, moderada ou alta.

## 5 RESULTADOS

### 5.1 Seleção dos estudos

A busca eletrônica inicialmente identificou 3.024 estudos, em que 243 estavam duplicados. Após a leitura dos títulos e resumos, 2.757 estudos foram excluídos por não preencherem os critérios de elegibilidade, e 24 foram selecionados para a leitura do texto completo. Após a leitura do texto completo, 16 artigos foram excluídos. Um por não se tratar de um ensaio clínico randomizado (FUNOSAS *et al.*, 2005), outro estudo por comparar pacientes saudáveis com diabéticos (GADAGI; CHAVA; REDDY, 2013), onze estudos avaliavam pacientes com gengivite (BEHFARNIA *et al.*, 2016; SHALINI; RAMESH, 2018; RADAFSHAR *et al.*, 2017; PRIYA *et al.*, 2015; SARIN *et al.*, 2015; BALAPPANAVAR; SARDANA; SINGH, 2013; RASSAMEEMASMAUNG; PHUSUDSAWANG; SANGALUNGKARN, 2013; JENABIAN *et al.*, 2012; KRAHWINKEL; WILLERSHAUSEN, 2000; KRAHWINKEL; STANNARIOUS; WILLERSHAUSEN, 2000; CARDOSO *et al.*, 2016). Um estudo avaliou as propriedades antibacteriana e anticariogênica do chá verde (AWADALLA *et al.*, 2011b), outro avaliou o seu efeito na mucosa oral de pacientes entubados (HSU *et al.*, 2010) e um terceiro avaliou apenas o seu efeito antiplaca (KAUR; JAIN; KAUR, 2014). Nove estudos foram incluídos nesta revisão sistemática, sendo um deles selecionado a partir da busca manual nas referências dos trabalhos selecionados (Figura 3).

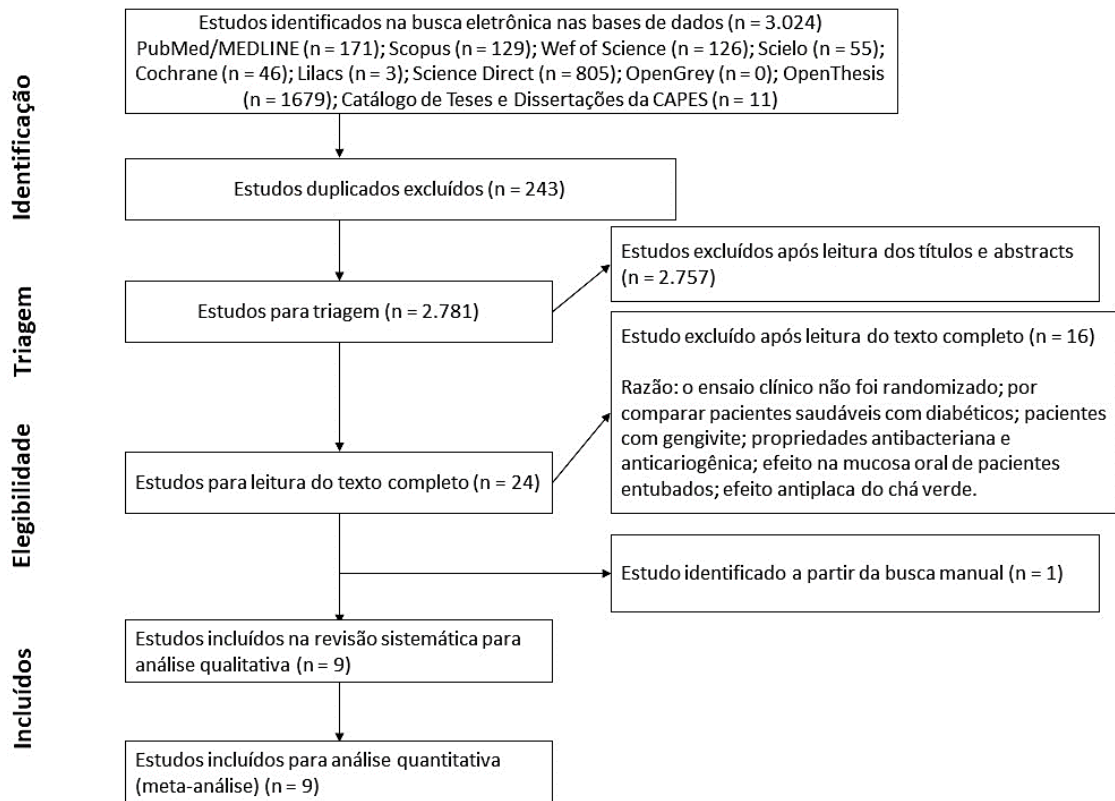


Figura 3. Fluxograma da seleção dos artigos.

## 5.2 Característica dos estudos incluídos

O tamanho da amostra dos estudos variou de 6 a 120 pacientes, entre 18 a 74 anos de idade. Todos os pacientes possuíam periodontite crônica, com profundidade de sondagem maior que 4 mm. Foram identificadas quatro formas de apresentação do chá verde: sachês, tiras de hidroxipropilcelulose (HCP), gel e dentífrico. O chá verde, em todos os estudos, foi administrado em associação com a raspagem e o alisamento radicular e o tempo de tratamento variou de 21 dias a 6 meses (Tabela 2).



Tabela 2. Características dos estudos incluídos na revisão sistemática.

Autor, ano	Características da população	n	Desenho do estudo, intervenção	Tempo de duração	Características da droga teste/posologia	Parâmetros analisados
Chava (2013)	Idade não informada. 15 mulheres e 15 homens.  Critérios de inclusão: periodontite crônica com base na presença de fatores locais, achados clínicos associados e PPD de 4 a 6 mm em > 30% dos locais.  Critérios de exclusão: doenças sistêmicas decorrentes dos efeitos nocivos da cafeína do chá verde, que podem causar acúmulo de alumínio e diminuir a biodisponibilidade da dieta; que receberam tratamento periodontal e/ou tratamento antimicrobiano tópico ou sistêmico nos últimos 6 meses, incluindo o uso de enxaguatório bucal; gestantes e lactantes porque a cafeína pode aumentar a frequência cardíaca; fumantes.	30 (60 sítios)	RCT, boca dividida.  Tratamento: RAR + Gel termorreversível com chá verde.  Controle: RAR + Gel termorreversível placebo.  Medições: inicial e 4 semanas.	4 semanas	10mg/ml de extrato de chá verde, água destilada, carbômero e poloxâmero.  O gel foi introduzido subgingivalmente no primeiro dia da consulta.	PPD, CAL e GI (Loe e Silness, 1963).
Chopra (2016)	20-50 anos.  Critérios de inclusão: periodontite crônica leve a moderada (perda de inserção clínica ≤ 5mm).  Critérios de exclusão: doença sistêmica; grávida e lactantes; receberam tratamento periodontal nos 6 meses anteriores; fumantes e consumidores de bebidas alcoólicas ou qualquer hábito prejudicial à saúde; aparelho ortodôntico ou prótese dentária; consumidores de chá verde.	120	RCT.  Tratamento: RAR + Infusão do sachê com chá verde.  Controle: RAR + Infusão do sachê com placebo.  Medições: inicial, 1 e 3 meses.	12 semanas	Sachês com chá verde.  2 sachês por dia, em 240ml de água fervida por 1-2min.	PI (Silness e Loe, 1967), GI (Loe e Silness, 1963), BOP (Ainamo e Bay, 1975), PPD e CAL (sonda Carolina do Norte nº15).

## Continuação da tabela 2

Deshpande (2012)	21-43 anos. Sexo não especificado.  Critérios de inclusão: sistemicamente saudáveis; periodontite crônica e um mínimo de 20 dentes.  Critérios de exclusão: gestantes e lactantes; fumantes no último ano; que tenham realizado tratamento periodontal nos últimos 12 meses.	30	RCT.  Tratamento: Grupo 1: RAR + Infusão do chá verde. Grupo2: apenas a infusão do chá verde.  Controle: RAR.	6 meses	Sachês de 1,75g de chá verde.  4 xícaras por dia.	PI (Silness e Loe, 1963), BOP (Muhlemann e Son, 1971), Índice Periodontal (Russell, 1956).
Ferial (2018)	45 anos.  Critérios de inclusão: pelo menos 2 dentes com PPD≥5 mm em cada quadrante; SS≥5 mm; perda de inserção clínica≥3 mm.  Critérios de exclusão: doença sistêmica; grávidas lactantes; tratamento periodontal ou utilização de antibiótico e AINEs nos últimos 6 meses; fumantes e consumidores bebidas alcoólicas; consumidores de chá verde de mais de um copo por semana; aparelho ortodôntico fixo.	30	Medições: inicial, 3 e 6 meses. RCT.  Tratamento: RAR + Infusão do sachê de chá verde.  Controle: RAR.  Medições: inicial e 6 semanas.	6 semanas	Sachê com chá verde.  Tomar o chá 2x ao dia.	PPD, BOP (Ainamo e Bay, 1975) e PI (O'Leary, 1972).
Hattarki (2013)	Idade não informada. Sexo não especificado.  Critérios de inclusão: idade >35 anos; PPD≥5 mm, arcada dentária com > 20 dentes naturais.  Critérios de exclusão: comprometimento médico; que receberam antibióticos nos últimos 6 meses; fumantes; grávidas e lactantes.	20	RCT, boca dividida.  Tratamento: RAR + tiras de HCP com catequinas de chá verde.  Controle: RAR.  Medições: inicial, 1 e 5 semanas.	5 semanas	Tiras de HCP contendo catequinas do chá verde.  As tiras foram inseridas subgingivalmente.	PI (Silness e Loe, 1967), GI (Loe e Silness, 1963), PPD (sonda milimetrada William's).

## Continuação da tabela 2

Hirasawa (2002)	41-64 anos. 3 mulheres e 3 homens.  Critérios de inclusão: periodontite avançada; PPD $\geq$ 5m.  Critérios de exclusão: comprometimento sistêmico.	6	RCT, boca dividida - Estudo piloto.  Tratamento: Grupo 1: RAR + tira de HCP com chá verde. Grupo 2: apenas tira de HCP com chá verde.  Controle: RAR + tira de HCP placebo.  Medições: inicial e 8 semanas.	8 semanas	Tiras de HCP contendo 5% de catequinas do chá verde.  As tiras foram inseridas subgingivalmente semanalmente.	PPD (sonda periodontal padrão), teste microbiológico e determinação da atividade da peptidase
Hrishi (2016)	18-60 anos.  Critérios de inclusão: pelo menos seis locais com PPD>4 mm; perda de inserção clínica de 1-2 mm (periodontite leve) ou de 3-4 mm (periodontite moderada).  Critérios de exclusão: que haviam sido submetidos à terapia periodontal cirúrgica ou não cirúrgica nos últimos 6 meses; pacientes com diabetes mellitus, artrite reumatoide, osteoporose e distúrbios hemorrágicos; mulheres grávidas e lactantes; fumantes; <20 dentes; história de uso de antibióticos, agentes anti-inflamatórios e qualquer quimioterápico nos últimos 3 meses.	30	RCT – Estudo piloto.  Tratamento: RAR + Dentrifício com chá verde.  Controle: RAR + Dentrifício com triclosan e flúor.  Medições: inicial e 4 semanas.	4 semanas	57% de carbonato de cálcio, 1% de lauril sulfato de sódio, 1.4% de extrato de chá verde, 21% de glicerina, 1,5% de goma adragante, 0.1% de agente aromatizante, 2% de metilparabeno, 2% de sacarina sódica e 100g de água.  Escovação 2x ao dia por no mín. 2 min e no máx. 5 min	PI (Silness e Loe, 1967), GI (Loe e Silness, 1963), BOP (Ainamo e Bay, 1975), PPD e CAL (sonda milimetrada William's).
Kudva (2011)	30-55 anos. Sexo não especificado.  Critérios de inclusão: periodontite crônica; PPD de 5-8 mm bilateralmente, que não foram submetidas a qualquer forma de terapia periodontal ou tratamento antimicrobiano tópico ou sistêmico nos últimos 6 meses.  Critérios de exclusão: comprometimento sistêmico; gestantes; lactantes; fumantes; <20 dentes.	14	Ensaio clínico controlado randomizado, boca dividida.  Tratamento: RAR + tiras de HCP com catequinas do chá.  Controle: RAR.  Medições: inicial e 21 dias.	21 dias	Tiras de HCP contendo catequinas do chá verde.  As tiras foram inseridas subgingivalmente, de modo que permanecesse na base da bolsa, e não exposta.	PI (Silness e Loe, 1967), GI (Loe e Silness, 1963), PPD (sonda Carolina do Norte nº15) e amostras microbiológicas: <i>P. gingivalis</i> , <i>P. intermedia</i> , <i>A.a.</i> , <i>Fusibacterium species</i> e <i>Capnocytophaga species</i> .

### Continuação da tabela 2

Rattanasuwan (2014)	34-70 anos e 37-74 anos.	42	RCT.	6 meses	12% w/w de extrato de chá verde com 80% do total de catequinas, água desionizada, álcool, álcoois de açúcar, parabenos e derivados de celulose.	PPD e CAL, GI (Loe e Silness, 1963), BOP (Ainamo e Bay, 1975) e PI (O'Leary, 1972).
	<p>Critérios de inclusão: periodontite crônica; PPD de 5-10mm sem comprometimento de furca, cárie ou restauração; não alérgicos ao chá verde ou produto do chá verde.</p> <p>Critérios de exclusão: doenças sistêmicas; fumantes; gestantes e lactantes; tratamento periodontal ou antibioticoterapia nos últimos 6 meses.</p>		<p>Tratamento: RAR + Gel subgengival de chá verde.</p> <p>Controle: RAR + Gel subgengival placebo.</p> <p>Medições: inicial, 1, 3 e 6 meses.</p>		<p>O gel foi introduzido subgengivalmente após a RAR.</p>	

RAR – raspagem e alisamento radicular, RCT – ensaio clínico randomizado, HCP – hidroxipropilcelulose, PPD – profundidade de sondagem, BOP – sangramento à sondagem, CAL – nível de inserção clínica, PI – índice de placa, GI – índice gengival.

A Tabela 2 evidencia heterogeneidade clínica nos estudos a respeito da profundidade de sondagem considerada para o diagnóstico da periodontite crônica. Os estudos compararam os resultados intra-grupo, a partir das várias medições realizadas, e inter-grupos, e de forma geral observa-se que o chá verde é eficaz como coadjuvante no tratamento da periodontite crônica (Tabela 3). Os índices profundidade de sondagem, sangramento à sondagem e índice gengival melhoraram significativamente na metade dos estudos ( $p < 0,05$ ), diferente do índice de placa que não apresentou melhora estatisticamente significativa.

Formas farmacêuticas	Autor, ano	Parâmetros clínicos				
		PPD	CAL	BOP	PI	GI
Sachê para infusão	Chopra (2016)	++	++	++ <sup>d</sup>	++ <sup>a</sup>	++ <sup>c</sup>
	Deshpande (2012)	NR	NR	++ <sup>e</sup>	+ <sup>a</sup>	NR
	Ferial (2018)	++	NR	++ <sup>d</sup>	+ <sup>b</sup>	NR
Tiras de HCP	Hattarki (2013)	+	NR	NR	+ <sup>a</sup>	+ <sup>c</sup>
	Hirasawa (2002)	+	NR	NR	NR	NR
	Kudva (2011)	++	NR	NR	+ <sup>a</sup>	+ <sup>c</sup>
Gel	Chava (2013)	++	++	NR	NR	++ <sup>c</sup>
	Rattanasuwan (2014)	+	+	+ <sup>d</sup>	+ <sup>b</sup>	+ <sup>c</sup>
Dentífrício	Hrishi (2016)	+	++	++ <sup>d</sup>	+ <sup>a</sup>	++ <sup>c</sup>

Tabela 3. Eficácia do chá verde para cada parâmetro clínico analisado.

PPD – profundidade de sondagem, CAL – nível de inserção, BOP – sangramento à sondagem, PI – índice de placa, GI – índice gengival Índice utilizado: <sup>a</sup>Silness e Loe, 1967; <sup>b</sup>O’Leary, 1972; <sup>c</sup>Loe e Silness, 1963; <sup>d</sup>Ainamo e Bay, 1975; <sup>e</sup>Muhlemann e Son, 1971. +: houve melhora, mas o valor de  $p$  na comparação inter-grupo não foi significativo. ++: houve melhora e o valor de  $p$  na comparação inter-grupo foi significativo ( $< 0,05$ ). NR: não reportado.

### 5.3 Risco de viés dos estudos incluídos

A avaliação do risco de viés para os estudos incluídos está apresentada na figura 4. Todos os estudos não apresentaram nenhum possível viés nas categorias dos dados de resultados ausentes e reportados. Uma grande parte dos estudos não

apresentou dados suficientes sobre a sequência de randomização e alocação dos participantes, assim como os desvios das intervenções pretendidas. Apenas um estudo apresentou alto risco de viés devido à falta de informação sobre o cegamento dos participantes e pesquisadores. O julgamento final do risco de viés evidencia que quatro estudos apresentam alto risco, devido à grande quantidade de problemas.



Figura 4. Avaliação do risco de viés de cada estudo incluído a partir do instrumento Risk of Bias 2.0 da Cochrane.

#### 5.4 Meta-análise

Foram realizadas as meta-análises dos subgrupos por índice de diagnóstico (profundidade de sondagem, sangramento à sondagem, índice de placa e índice gengival). Dos nove estudos, oito foram incluídos para a análise da profundidade de sondagem (CHOPRA *et al.*, 2016; FERIAL *et al.*, 2018; HATTARKI; PUSHPA; BHAT, 2013; HIRASAWA *et al.*, 2002; KUDVA; TABASUM; SHEKHAWAT, 2011; CHAVA; VEDULA, 2013; RATTANASUWAN *et al.*, 2014; HRISHI *et al.*, 2016), três para o sangramento à sondagem (CHOPRA *et al.*, 2016; FERIAL *et al.*, 2018; RATTANASUWAN *et al.*, 2014), cinco para o índice de placa (CHOPRA *et al.*, 2016; DESHPANDE; DESHPANDE; MAFOUD, 2012; HATTARKI; PUSHPA; BHAT, 2013; KUDVA; TABASUM; SHEKHAWAT, 2011; HRISHI *et al.*, 2016) e seis para o índice gengival (CHOPRA *et al.*, 2016; HATTARKI; PUSHPA; BHAT, 2013; KUDVA; TABASUM; SHEKHAWAT, 2011; CHAVA; VEDULA, 2013; RATTANASUWAN *et al.*, 2014; HRISHI *et al.*, 2016), por utilizarem o mesmo índice para avaliação.

A figura 5 mostra que não houve diferença significativa entre uso do chá verde e o controle na redução da profundidade de sondagem. Dessa forma, não existe evidência de que o chá verde, em qualquer forma de apresentação, é mais efetivo do que apenas a raspagem e o alisamento radicular na redução da profundidade de sondagem (SMD = -0,27 [-0,97, 0,42]  $p < 0,44$ ,  $I^2 = 89\%$ ).

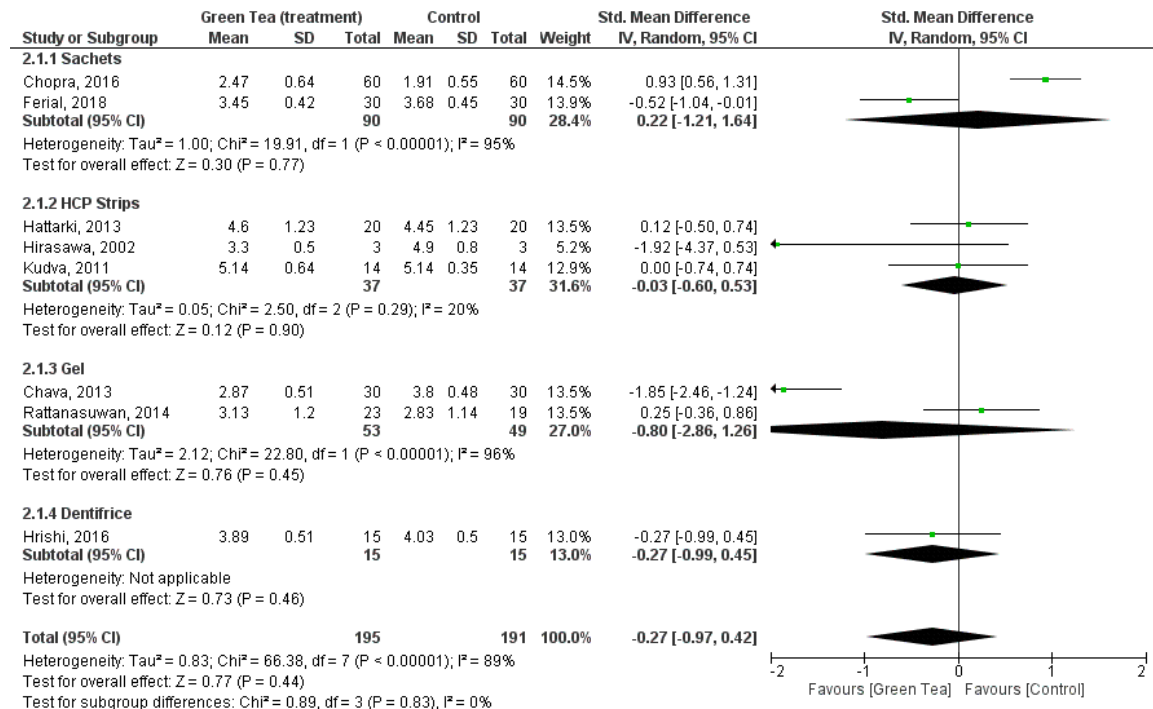


Figura 5. Forest plot da meta-análise comparando o efeito do chá verde versus controle na profundidade de sondagem analisado por subgrupos.

Para a segunda meta-análise (figura 6), dos três estudos incluídos apenas dois foram favoráveis à utilização do chá verde, na forma de sachê para infusão, na redução do sangramento à sondagem. O estudo que utilizou o chá verde na forma de gel não se mostrou eficaz para este desfecho. De uma forma geral, o chá verde foi mais eficaz do que apenas a raspagem e alisamento radicular na redução do sangramento à sondagem (SMD = -0,71 [-1,39, -0,01]  $p = 0,04$ ,  $I^2 = 82\%$ ).

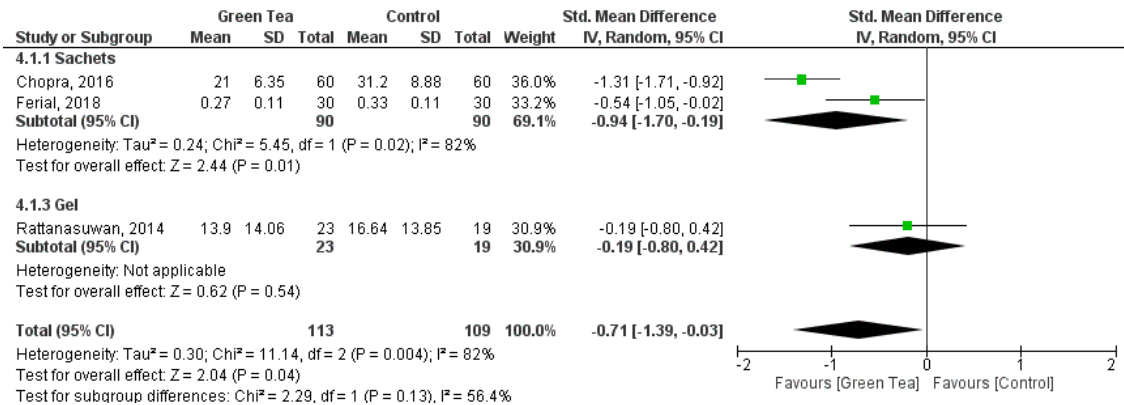


Figura 6. Forest plot da meta-análise comparando o efeito do chá verde versus controle no sangramento à sondagem analisado por subgrupos.

Os indivíduos que utilizaram o chá verde na forma de dentífrico e sachê para infusão obtiveram uma maior redução na formação de placa, quando comparados aqueles que receberam apenas a raspagem e o alisamento radicular, como visto na figura 7. Portanto, a utilização do chá verde se mostra um importante aliado na redução do índice de placa (SMD = -0,63 [-1,18, -0,08]  $p = 0,02$ ,  $I^2 = 77\%$ ).

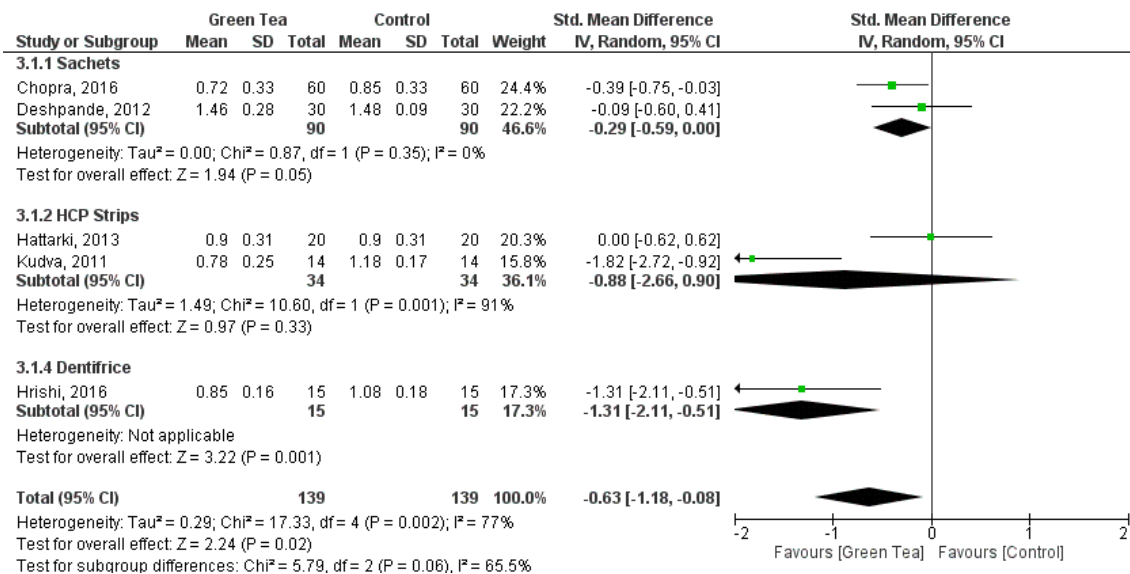


Figura 7. Forest plot da meta-análise comparando o efeito do chá verde versus controle no índice de placa analisado por subgrupos.

A figura 8 ilustra a meta-análise realizada com todas as formas de apresentação em relação a redução do índice gengival, favorecendo o chá verde (SMD = -0,78 [-1,33, -0,23]  $p = 0,006$ ,  $I^2 = 80\%$ ). Os indivíduos que consumiram o



sachê contendo chá verde obtiveram uma maior redução neste índice, diferente das outras formas de apresentação.

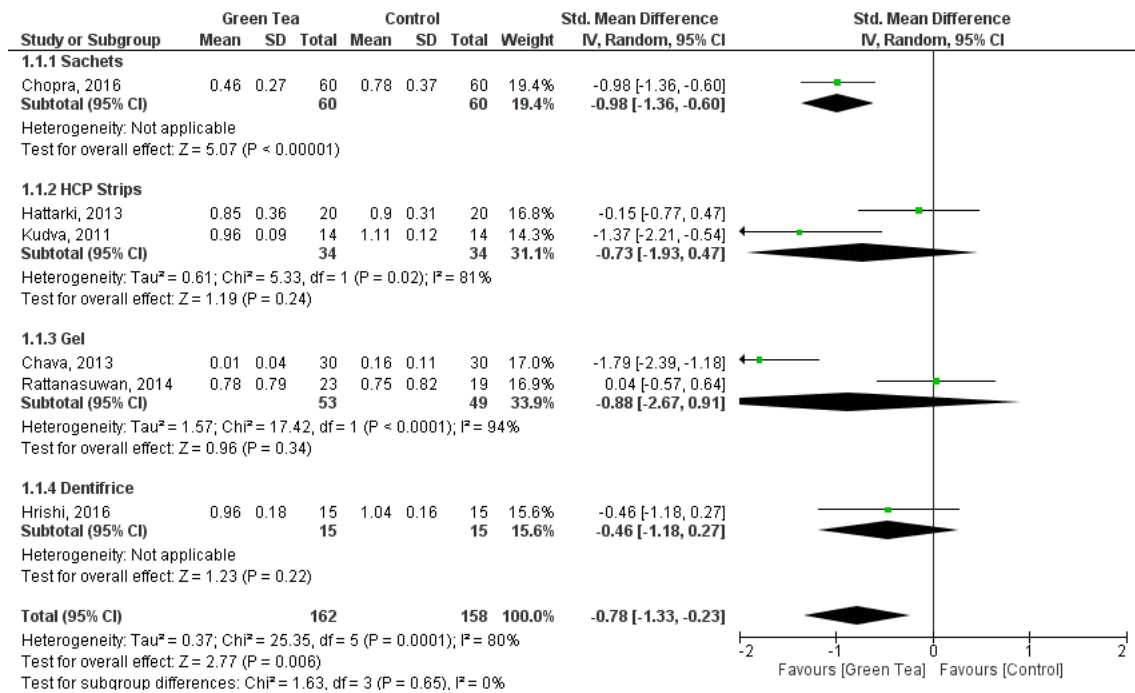


Figura 8. Forest plot da meta-análise comparando o efeito do chá verde versus controle no índice gengival analisado por subgrupos.

## 5.5 Certeza da evidência

A certeza da evidência para a profundidade de sondagem é muito baixa, devido aos parâmetros do risco de viés, inconsistência e imprecisão terem sido baixados um nível. Para o sangramento à sondagem, os parâmetros baixados um nível foram a inconsistência e imprecisão, no índice de placa foram os parâmetros do risco de viés e imprecisão, sendo, portanto, uma certeza da evidência baixa. No índice gengival, diminuiu um nível do parâmetro imprecisão, sendo considerada uma certeza moderada (Tabela 4).

Tabela 4. GRADE

Nº dos estudos	Delineamento do estudo	Avaliação da certeza					Nº de pacientes		Efeito		Certeza	Importância
		Risco de viés	Inconsistência	Evidência indireta	Imprecisão	Outras considerações	Chá verde	Controle	Relativo (95% CI)	Absoluto (95% CI)		
Profundidade de Sondagem												
8	RCT	Grave <sup>a</sup>	Grave <sup>b</sup>	Não grave	Grave <sup>c</sup>	Nenhum	195	191	-	SMD <b>0.27 menor</b> (0.97 menor para 0.42 mais alto)	⊕○○○ MUITO BAIXA	Importante
Sangramento à Sondagem												
3	RCT	Não grave	Grave <sup>b</sup>	Não grave	Grave <sup>c</sup>	Nenhum	113	109	-	SMD <b>0.71 menor</b> (1.39 menor para 0.03 menor)	⊕⊕○○ BAIXA	Importante
Índice de Placa												
5	RCT	Grave <sup>a</sup>	Não grave	Não grave	Grave <sup>c</sup>	Nenhum	139	139	-	SMD <b>0.63 menor</b> (1.18 menor para 0.08 menor)	⊕⊕○○ BAIXA	Importante
Índice Gengival												
6	RCT	Não grave	Não grave	Não grave	Grave <sup>c</sup>	Nenhum	162	158	-	SMD <b>0.78 menor</b> (1.33 menor para 0.23 menor)	⊕⊕⊕○ MODERADA	Importante

**CI:** intervalo de confiança; **SMD:** diferença de média padronizada, **RCT:** ensaio clínico randomizado

#### Explicações

- Os estudos apresentam alguns problemas no processo de randomização.
- I<sup>2</sup> elevado, acima de 80%.
- Pequeno tamanho amostral (< 200).

## 6 DISCUSSÃO

O chá verde apresentou-se como um importante auxiliar na redução dos sinais clínicos de inflamação, sendo amplamente pesquisado na região asiática, em especial na Índia. Foram identificadas quatro formas de apresentação: sachê para infusão, tiras de HCP, gel e dentifrício. Apresentaram uma certeza da evidência científica moderada para a redução do índice gengival, baixa para redução do sangramento à sondagem e índice de placa, e uma evidência muito baixa para a redução da profundidade de sondagem.

Esses efeitos na redução dos sinais clínicos da periodontite podem ser resultantes da ação das catequinas do chá verde, que apresentam uma forte ação na redução da inflamação gengival (CHOPRA *et al.*, 2016). Na análise descritiva dos estudos, observou-se que o chá verde em forma de sachê (CHOPRA *et al.*, 2016), gel (CHAVA; VEDULA, 2013) e dentifrício (HRISHI *et al.*, 2016) promovem uma melhora na redução do índice gengival. Por outro lado, apesar da meta-análise favorecer a utilização do chá verde, considerando o conjunto das diferentes apresentações, apenas o sachê para infusão reduziu este índice. Esta certeza é moderada por apresentar um número amostral pequeno, baixando, portanto, um nível por imprecisão. Também foi observado que o sachê para infusão contendo chá verde é um bom agente na redução do sangramento à sondagem, apresentando uma baixa certeza da evidência da eficácia do chá verde.

O chá verde nas formas de sachê para infusão e dentifrício apresentaram eficácia na redução do índice de placa, com baixa certeza de evidência, em função dos estudos apresentarem alguns problemas no processo de randomização, o que ocasionou a redução em um nível na avaliação do risco de viés no GRADE. Este achado suporta a propriedade antiplaca do chá verde (HAMILTON-MILLER, 2001; HRISHI *et al.*, 2016). No estudo de HRISHI *et al.*, (2016) o grupo controle utilizou dentifrício com triclosan, que possui propriedade antiplaca, e mesmo assim, a redução do índice de placa foi favorável para o chá verde.

Uma meta-análise realizada por Gartenmann *et al.* (2019) analisou os estudos que utilizaram o chá verde nas formas de tiras de HCP e gel, mostrando que houve uma redução na profundidade de sondagem de 0,57 mm a favor das catequinas do chá verde administradas localmente como adjuvante à raspagem e alisamento radicular. Porém, nesta revisão sistemática, apenas um estudo, dos quatro inseridos

na revisão de Gartenmann *et al.* (2019), não foi incluído, por não ser um ensaio clínico randomizado, e se analisou todas as formas de apresentação do chá verde existentes. O tratamento com o chá verde não foi favorável para reduzir a profundidade de sondagem em nenhuma das formas. Tal evidência possui uma certeza muito baixa por apresentar um alto risco de viés, além de uma alta heterogeneidade.

Grande parte dos estudos não informou a concentração do chá verde utilizada para cada forma de apresentação, assim como não houve a utilização de um antimicrobiano padrão-ouro como controle. A falta de padronização dos parâmetros clínicos de diagnóstico, como a profundidade de sondagem e o nível de inserção clínica, pode levar a uma diferença inter-grupos estatisticamente não significativa, como visto nos estudos de Hattarki; Pushpa; Bhat (2013), Rattanasuwan *et al.* (2014) e Hrishii *et al.* (2016).

Apesar da melhora dentro de cada grupo, em cada estudo individualmente, ao longo do tempo de tratamento ser significativa, essa falta de padronização no diagnóstico pode ser o motivo do uso do chá verde não ser favorável para melhora dos parâmetros de remissão da periodontite, como demonstrado nesta revisão sistemática.

A maioria dos estudos desta revisão apresentou problemas no processo de randomização, chegando a ser considerado como um alto risco de viés, visto que os estudos padrão-ouro são os ensaios clínicos randomizados duplo-cego. Adicionalmente, a alta heterogeneidade dos estudos pode ter prejudicado no resultado da meta-análise e na certeza da evidência, especialmente, do parâmetro da profundidade de sondagem. O tempo de duração dos estudos variou bastante, o que impediu que se fosse realizada a análise intra-grupo para cada forma de apresentação do chá verde.

O tempo de duração dos estudos e a amostra variaram consideravelmente, o que podem ter afetado diretamente os resultados. Sugere-se, então, novos estudos com amostras maiores, com padronização da duração do tratamento e da profundidade de sondagem para diagnóstico da periodontite crônica, visto que os estudos utilizaram a classificação de 1999 das doenças periodontais (ARMITAGE, 1999), a fim de que se diminua a heterogeneidade dos indivíduos. O chá verde por apresentar a forma de utilização em sachê para infusão, pode ser uma ótima

alternativa para o tratamento adjunto fora do consultório, o que pode ser de grande importância clínica para a motivação por parte do paciente para o tratamento.

## 7 CONSIDERAÇÕES FINAIS

A partir desta revisão sistemática com meta-análise pode-se concluir que há fraca evidência científica que sugere a eficácia do chá verde (*Camellia sinensis* (L.) Kuntze) como adjunto ao tratamento da periodontite crônica. Os estudos que investigam a utilização do chá verde como adjuvante ao tratamento periodontal não-cirúrgico são heterogêneos, dificultando, portanto, que se tenha uma forte evidência. Mais estudos específicos com cada forma farmacêutica citada nesta revisão são necessários, assim como uma padronização no diagnóstico clínico e no tempo de tratamento.

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## **APÊNDICES**

## APÊNDICE

## Registro bibliográfico que não atenderam aos critérios de elegibilidade

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## **ANEXOS**

## Anexo 1

**PROSPERO**  
International prospective register of systematic reviews



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### Systematic review

Please complete all mandatory fields below (marked with an asterisk \*) and as many of the non-mandatory fields as you can then click *Submit* to submit your registration. You don't need to complete everything in one go, this record will appear in your *My PROSPERO* section of the web site and you can continue to edit it until you are ready to submit. Click *Show help* below or click on the icon to see guidance on completing each section.

This record cannot be edited because it has been rejected

#### 1. \* Review title.

Give the working title of the review, for example the one used for obtaining funding. Ideally the title should state succinctly the interventions or exposures being reviewed and the associated health or social problems. Where appropriate, the title should use the PI(E)COS structure to contain information on the Participants, Intervention (or Exposure) and Comparison groups, the Outcomes to be measured and Study designs to be included.

Efficacy of Green Tea (*Camellia sinensis* (L.) Kuntze) in the Treatment of Periodontal Disease: Systematic Review

#### 2. Original language title.

For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

Eficácia do Chá Verde (*Camellia sinensis* (L.) Kuntze) no Tratamento da Doença Periodontal: Revisão Sistemática

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

Give the date when the systematic review commenced, or is expected to commence.  
17/09/2018

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

Give the date by which the review is expected to be completed.  
01/06/2019

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

Indicate the stage of progress of the review by ticking the relevant Started and Completed boxes. Additional information may be added in the free text box provided.

Please note: Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. Should evidence of incorrect status and/or completion date being supplied at the time of submission come to light, the content of the PROSPERO record will be removed leaving only the title and named contact details and a statement that inaccuracies in the stage of the review date had been identified.

This field should be updated when any amendments are made to a published record and on completion and publication of the review. If this field was pre-populated from the initial screening questions then you are not able to edit it until the record is published.

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The review has not yet started: No

Review stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
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 (e.g. Funded proposal, protocol not yet finalised).

**6. \* Named contact.**

The named contact acts as the guarantor for the accuracy of the information presented in the register record.  
Jéssica Melo

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

Miss Melo

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

Give the electronic mail address of the named contact.

gameloj@gmail.com

**8. Named contact address**

Give the full postal address for the named contact.

Programa de Pós Graduação em Odontologia. Rua Baraúnas, 351 - Bairro Universitário - Campina Grande-PB, CEP 58429-500

**9. Named contact phone number.**

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

+55 (81) 998169443

**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 da Paraíba

**Organisation web address:**

<http://pos-graduacao.uepb.edu.br/ppgo/>

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

Give the title, first name, last name and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong.

Miss Jessica Melo. Postgraduate Program in Dentistry, Universidade Estadual da Paraíba, Campina Grande-PB, Brazil.

Dr Jossaria Sousa. Department of Dentistry, Universidade Estadual da Paraíba, Campina Grande-PB, Brazil.  
Professor Ramon Fimino. Postgraduate Program in Dentistry, Universidade Federal de Minas Gerais, Belo Horizonte-MG, Brazil.

Dr Ana Granville-Garcia. Postgraduate Program in Dentistry, Universidade Estadual da Paraíba, Campina Grande-PB, Brazil.

Dr Cassiano Nonaka. Postgraduate Program in Dentistry, Universidade Estadual da Paraíba, Campina Grande-PB, Brazil.

Dr Edja Costa. Postgraduate Program in Dentistry, Universidade Estadual da Paraíba, Campina Grande-PB, Brazil.

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

Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Include any unique identification numbers assigned to the review by the individuals or bodies listed.

None.

### 13. \* Conflicts of interest.

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

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.

### 15. \* Review question.

State the question(s) to be addressed by the review, clearly and precisely. Review questions may be specific or broad. 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 PI(E)COS where relevant.

Is green tea (*Camellia sinensis*) effective in treating periodontal disease?

### 16. \* Searches.

Give details of the sources to be searched, search dates (from and to), and any restrictions (e.g. language or publication period). The full search strategy is not required, but may be supplied as a link or attachment.

The research will be conducted in the databases:

PubMed/MEDLINE;

Web of Science;

LILACS;

SciELO;

Cochrane Central Register of Controlled Trials;



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Scopus;  
ScienceDirect;  
OpenGrey;  
OpenThesis;  
Catálogo de Teses e Dissertações da CAPES.

A manual search will also be performed on the reference list of included studies.

**17. URL to search strategy.**

Give a link to a published pdf/word document detailing either the search strategy or an example of a search strategy for a specific database if available (including the keywords that will be used in the search strategies), or upload your search 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.

Do not 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. This could include health and wellbeing outcomes.

Periodontal disease is a progressive polymicrobial infection, its clinical manifestation refers to the inflammation that occurs in periodontal tissues in response to biofilm growth along the gingival margin (TORRES et al., 2018). The goal of periodontal therapy is to reduce the number of pathogenic microorganisms in contact with periodontal tissues, as well as their biological products, such as endotoxins, antigens, enzymes and other tissue irritants. Therefore, scaling and root planing are the basis of non-surgical periodontal treatment (PETERSILKA; EHMKE; FLEMMING, 2002; FLEMMING; WINGENDER, 2010). It is observed a tendency in the literature for the use of natural products as a coadjuvant resource in the treatment of periodontal disease (LAZAR; SAVIUC; CHIFRIUNE, 2016; MARTÍNEZ; GÓMEZ; OH, 2017). Among these products, we can highlight the presence of green tea (*Camellia Sinensis*) (HIRASAWA et al., 2002). It has anti-inflammatory, antibacterial, anticary, antioxidant, antifungal, antiviral, anti-diabetic, antimutagenic and anti-tumor functions.

This systematic review of the literature aims to analyze the scientific evidence of the efficacy of green tea in the treatment of periodontal disease.

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

Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

Inclusion: Patients with periodontal disease.

Exclusion: Patients without periodontal disease.

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



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Give full and clear descriptions or definitions of the nature of the interventions or the exposures to be reviewed.

**Inclusion:** Use of green tea (*Camellia sinensis*) in the treatment of periodontal disease.

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

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

**Inclusion:** Conventional treatment in the treatment of periodontal disease.

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

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

**Inclusion:** We will include randomized clinical trials to assess the beneficial effects of the intervention.

**23. Context.**

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

**Studies include the intervention we want to evaluate for effectiveness and gold standard.**

**There will be no restrictions regarding language or date of publication.**

**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.

**The depth of probing (probing of 6 areas).**

**Gingival index (determined using appropriate indexes, such as Gingival Index and Modified Gingival Index).**

**The plate index (determined using appropriate indices as Quigley and Hein Plaque Index, Turesky modification of the Quigley and Hein Plaque Index, Silness and Loe Plaque Index and Navy Plaque Index).**

**Gingival bleeding (determined using appropriate indices as Sulcus Bleeding Index and Gingival Bleeding Index).**

**Timing and effect measures**

**Changes in plaque and gingival scores from baseline to the last available follow-up, measured using means, standard deviations and percentage reductions.**

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

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

**Determine the effectiveness of green tea and if it causes any adverse effect.**

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Timing and effect measures

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

Give the procedure for selecting studies for the review and extracting data, including the number of researchers involved and how discrepancies will be resolved. List the data to be extracted.

The selection of the studies will be carried out by two researchers (JGAM and JPS) independently and duly calibrated. Initially, the articles will be pre-selected, whose titles and abstracts correspond to the objectives of the research. Papers that appear to meet the eligibility criteria will be selected for full text analysis. After reading the full texts, documents that meet the eligibility criteria will be included in the review. Discordant cases between the two researchers will be reevaluated to verify the possibility of inclusion in the study and evaluated by a third party researcher (EMMBC) if necessary. The information on the articles excluded from the study will be recorded in a supplementary table. In a flowchart the process of selecting the articles will be compiled, following the criteria of the Prisma checklist (Main Items for Reporting Systematic Review of Meta-analyses) (MOHER et al., 2009). Data extraction will include information on year of publication, type of study, country, language, data collection period, place of study, age / age range, sample size, exposure, type of extraction, part of the plant used, pharmaceutical form, control treatment, intervention, outcome, adverse effects, statistical analysis and measures of effect used.

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

State whether and how risk of bias will be assessed (including the number of researchers involved and how discrepancies will be resolved), how the quality of individual studies will be assessed, and whether and how this will influence the planned synthesis.

The Cochrane Risk of Bias 2.0 (RoB) instrument will be used (HIGGINS et al., 2011), a tool to assess risk of bias in randomized clinical trials. This tool evaluates the occurrence of bias in the following aspects: randomization process, deviations in interventions, missing data, measurement of outcomes, selection of reported results, and overall bias trend.

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

Give the planned general approach to synthesis, e.g. whether aggregate or individual participant data will be used and whether a quantitative or narrative (descriptive) synthesis is planned. It is acceptable to state that a quantitative synthesis will be used if the included studies are sufficiently homogenous.

A qualitative synthesis is planned, and if appropriate, a quantitative synthesis will also be conducted.

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

Give details of any plans for the separate presentation, exploration or analysis of different types of participants (e.g. by age, disease status, ethnicity, socioeconomic status, presence or absence or co-morbidities); different types of intervention (e.g. drug dose, presence or absence of particular components of intervention); different settings (e.g. country, acute or primary care sector, professional or family care); or different types of study (e.g. randomised or non-randomised).

None.

**30. \* Type and method of review.**

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Select the type of review and the review method from the lists below. Select the health area(s) of interest for your review.

**Type of review**

Cost effectiveness

No

Diagnostic

No

Epidemiologic

No

Individual patient data (IPD) meta-analysis

No

Intervention

No

Meta-analysis

No

Methodology

No

Narrative synthesis

No

Network meta-analysis

No

Pre-clinical

No

Prevention

No

Prognostic

No

Prospective meta-analysis (PMA)

No

Review of reviews

No

Service delivery

No

Synthesis of qualitative studies

No

Systematic review

Yes

Other

No

**Health area of the review**

Alcohol/substance misuse/abuse

No

Blood and immune system

No

Cancer

No

Cardiovascular

No

Care of the elderly

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No

Child health  
No

Complementary therapies  
No

Crime and justice  
No

Dental  
Yes

Digestive system  
No

Ear, nose and throat  
No

Education  
No

Endocrine and metabolic disorders  
No

Eye disorders  
No

General interest  
No

Genetics  
No

Health inequalities/health equity  
No

Infections and infestations  
No

International development  
No

Mental health and behavioural conditions  
No

Musculoskeletal  
No

Neurological  
No

Nursing  
No

Obstetrics and gynaecology  
No

Oral health  
No

Palliative care  
No

Perioperative care  
No

Physiotherapy  
No

Pregnancy and childbirth  
No

Public health (including social determinants of health)  
No

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Rehabilitation  
No

Respiratory disorders  
No

Service delivery  
No

Skin disorders  
No

Social care  
No

Surgery  
No

Tropical Medicine  
No

Urological  
No

Wounds, injuries and accidents  
No

Violence and abuse  
No

### 31. Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error.

English  
Portuguese-Brazil

There is not an English language summary

### 32. Country.

Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved.

Brazil

### 33. Other registration details.

Give the name of any organisation where the systematic review title or protocol is registered (such as with The Campbell Collaboration, or The Joanna Briggs Institute) together with any unique identification number assigned. (N.B. Registration details for Cochrane protocols will be automatically entered). If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

### 34. Reference and/or URL for published protocol.

Give the citation and link for the published protocol, if there is one

Give the link to the published protocol.

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

**No I do not make this file publicly available until the review is complete**

Please note that the information required in the PROSPERO registration form must be completed in full even if access to a protocol is given.

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**35. Dissemination plans.**

Give brief details of plans for communicating essential messages from the review to the appropriate audiences.

**Do you intend to publish the review on completion?**

No

**36. Keywords.**

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords will help users find the review in the Register (the words do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

Green tea; Periodontal Disease; Periodontitis; Gingivitis.

**37. Details of any existing review of the same topic by the same authors.**

Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

**38. \* Current review status.**

Review status should be updated when the review is completed and when it is published. For newregistrations the review must be Ongoing. Please provide anticipated publication date

Review\_Ongoing

**39. Any additional information.**

Provide any other information the review team feel is relevant to the registration of the review.

**40. Details of final report/publication(s).**

This field should be left empty until details of the completed review are available.  
Give the link to the published review.



## Anexo 2 – ROB 2.0 da Cochrane

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The RoB 2.0 tool (individually randomized, parallel group trials)

### Study design

- Randomized parallel group trial
- Cluster-randomized trial
- Randomized cross-over or other matched design

Specify which outcome is being assessed for risk of bias

Specify the numerical result being assessed. In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Is your aim for this study...?

- to assess the effect of *assignment to intervention*
- to assess the effect of *starting and adhering to intervention*

Which of the following sources have you obtained to help inform your risk of bias judgements (tick as many as apply)?

- Journal article(s) with results of the trial
- Trial protocol
- Statistical analysis plan (SAP)
- Non-commercial trial registry record (e.g. ClinicalTrials.gov record)
- Company-owned trial registry record (e.g. GSK Clinical Study Register record)
- "Grey literature" (e.g. unpublished thesis)
- Conference abstract(s) about the trial
- Regulatory document (e.g. Clinical Study Report, Drug Approval Package)
- Research ethics application
- Grant database summary (e.g. NIH RePORTER, Research Councils UK Gateway to Research)
- Personal communication with trialist
- Personal communication with the sponsor

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## Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in **red** are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

Bias domain	Signalling questions	Elaboration	Response options
Bias arising from the randomization process	1.1 Was the allocation sequence random?	<p>"Yes" if a random component was used in the sequence generation process such as using a computer generated random numbers, referring to a random number table, minimization, coin tossing; shuffling cards or envelopes; throwing dice; or drawing of lots. Minimization may be implemented without a random element, and this is considered to be equivalent to being random.</p> <p>"No" if the sequence is non-random, such that it is either likely to introduce confounding, or is predictable or difficult to conceal, e.g. alternation, methods based on dates (of birth or admission) or patient record numbers, allocation decision made by clinicians or participants, based on the availability of the intervention, or any other systematic or haphazard method.</p> <p>If the only information about randomization methods is to state that the study is randomized, then this signalling question should generally be answered as "No information". There may be situations in which a judgement is made to answer "Probably No" or "Probably yes". For example, if the study was large, conducted by an independent trials unit or carried out for regulatory purposes, then it may be reasonable to assume that the sequence was random. Alternatively, if other (contemporary) trials by the same investigator team have clearly used non-random sequences, it might be reasonable to assume that the current study was done using similar methods. Similarly, if participants and personnel are all unaware of intervention assignments throughout/during the trial (blinding or masking), this may be an indicator that the allocation process was also concealed, but this will not necessarily always be the case.</p> <p>If the allocation sequence was clearly concealed but there is no information about how the sequence was generated, it will often be reasonable to assume that the sequence was random (although this will not necessarily always be the case).</p>	<u>Y / PY</u> / <u>PN / N</u> / NI
	1.2 Was the allocation sequence concealed until participants were recruited and assigned to interventions?	"Yes" if any form of remote or centrally administered randomization, where the process of allocation is controlled by an outsourced unit or organization, independent of the enrolment personnel (e.g. independent central pharmacy, telephone or internet-based randomization service providers).	<u>Y / PY</u> / <u>PN / N</u> / NI

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	1.3 Were there baseline imbalances that suggest a problem with the randomization process?	<p>"Yes" if envelopes or drug containers were used appropriately. Envelopes should be sequentially numbered, sealed with a tamper proof seal and opaque. Drug containers should be sequentially numbered and of identical appearance. This level of detail is rarely provided in reports, and a judgement may be required (e.g. "Probably yes" or "Probably no").</p> <p>"No" if there is reason to suspect the enrolling investigator or the participant had knowledge of the forthcoming allocation.</p> <p><i>NB Imbalances that are small and compatible with chance should not be highlighted using the RoB 2.0 tool; chance imbalances are not bias.</i></p> <p>Answer "No" if no imbalances are apparent or if any observed imbalances are compatible with chance</p> <p>Answer "Yes" if there are imbalances that indicate problems with the randomization process, including:</p> <ol style="list-style-type: none"> <li>(1) unusually large differences between intervention group sizes; or</li> <li>(2) a substantial excess in statistically significant differences in baseline characteristics than would be expected by chance alone; or</li> <li>(3) imbalance in key prognostic factors (or baseline measures of outcome variables) that are unlikely to be due to chance.</li> </ol> <p>An answer of "Yes/Probably yes" may exceptionally be given if the groups are surprisingly balanced in a way that appears incompatible with chance and the randomization methods, thus raising suspicion about the methods used.</p> <p>In some circumstances, it may be reasonable to answer "Yes/Probably yes" (rather than "No information") when there is a surprising lack of information on baseline characteristics when such information could reasonably be expected to be available/reported.</p> <p>Answer "No information" when there is no <i>useful</i> baseline information available (e.g. abstracts, or studies that reported only baseline characteristics of participants in the final analysis).</p> <p>The answer to this question should not be used to influence answers to questions 1.1 or 1.2. For example, if the trial has large baseline imbalances, but authors report adequate randomization methods, questions 1.1 and 1.2 should still be answered on the basis of the reported adequate methods, and any concerns about the imbalance</p>	<u>Y / PY</u> / <u>PN / N</u> / NI
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	<b>Risk of bias judgement</b>	should be raised in the answer to the question 1.3 and reflected in the domain-level risk of bias judgement). See Figure 1.	Low / High / Some concerns
	Optional: What is the predicted direction of bias arising from the randomization process?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable

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Bias domain	Signalling questions	Elaboration	Response options
Bias due to deviations from intended interventions	<b>If your aim for this study is to assess the effect of assignment to intervention, answer the following questions</b>		
	2.1. Were participants aware of their assigned intervention during the trial?	If participants are aware of their group assignment, it is more likely that additional health-related behaviours will differ between the assigned intervention groups, so risk of bias will be higher. Masking participants, which is most commonly achieved through use of a placebo or sham intervention, may prevent such differences.	Y / PY / <u>PN</u> / <u>N</u> / NI
	2.2. Were carers and trial personnel aware of participants' assigned intervention during the trial?	If those involved in caring for participants or making decisions about their health care are aware of the assigned intervention, then implementation of the intended intervention, or administration of additional co-interventions, may differ between the assigned intervention groups. Masking carers and trial personnel, which is most commonly achieved through use of a placebo, may prevent such differences.	Y / PY / <u>PN</u> / <u>N</u> / NI
	2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention beyond what would be expected in usual practice?	When interest focusses on the effect of assignment to intervention, it is important to distinguish between: (a) deviations that happen in usual practice following the intervention and so are part of the intended intervention (for example, cessation of a drug intervention because of acute toxicity); and (b) deviations from intended intervention that arise due to expectations of a difference between intervention and comparator (for example because participants feel "unlucky" to have been assigned to the comparator group and therefore seek the active intervention, or components of it, or other interventions). We use the term "usual practice" to refer to the usual course of events in a non-trial context. Because deviations that arise due to expectations of a difference between intervention and comparator are not part of usual practice, they may lead to biased effect estimates that do not reflect what would happen to participants assigned to the interventions in practice. Trialists do not always report (and do not necessarily know) whether deviations that are not part of usual practice actually occurred. Therefore the answer "No information" may be appropriate. However, if such deviations <i>probably</i> occurred you should answer "Probably yes".	NA / Y / PY / <u>PN</u> / <u>N</u> / NI
2.4. If Y/PY to 2.3: Were these deviations from intended intervention unbalanced between groups and likely to have affected the outcome?	Deviations from intended interventions that do not reflect usual practice will be important if they affect the outcome, but not otherwise. Furthermore, bias will arise only if there is imbalance in the deviations across the two groups.	NA / Y / PY / <u>PN</u> / <u>N</u> / NI	

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			20/10/2016
2.5 Were any participants analysed in a group different from the one to which they were assigned?	This question addresses one of the fundamental aspects of an "intention-to-treat" approach to the trial analysis: that participants are analysed in the groups to which they were assigned through randomization. If some participants did not receive their assigned intervention, and such participants were analysed according to intervention received, then the balance between intervention groups created by randomization is lost.		Y / PY / <u>PN</u> / N / NI
2.6 If Y/PY/NI to 2.5: Was there potential for a substantial impact (on the estimated effect of intervention) of analysing participants in the wrong group?	Risk of bias will be high in a randomized trial in which sufficiently many participants were analysed in the wrong intervention group that there could have been a substantial impact on the results. There is potential for a substantial impact if more than 5% of participants were analysed in the wrong group, but for rare events there could be an impact for a smaller proportion.		NA / Y / PY / <u>PN</u> / N / NI
<b>If your aim for this study is to assess the effect of starting and adhering to intervention, answer the following questions</b>			
2.1. Were participants aware of their assigned intervention during the trial?	If participants are aware of their group assignment, it is more likely that additional health-related behaviours will differ between the intervention groups, so risk of bias will be higher. Masking participants, which is most commonly achieved through use of a placebo, may prevent such differences.		Y / PY / <u>PN</u> / N / NI
2.2. Were carers and trial personnel aware of participants' assigned intervention during the trial?	If those involved in caring for participants and those otherwise involved in the trial are aware of group assignment, then it is more likely that implementation of the intended intervention, or the administration of additional co-interventions, will differ between the intervention groups. Masking carers and trial personnel, which is most commonly achieved through use of a placebo, may prevent such differences.		Y / PY / <u>PN</u> / N / NI
2.3. If Y/PY/NI to 2.1 or 2.2: Were important co-interventions balanced across intervention groups?	Risk of bias will be higher if unplanned co-interventions were implemented in a way that would bias the estimated effect of intervention. Co-interventions will be important if they affect the outcome, but not otherwise. Bias will arise only if there is imbalance in such co-interventions between the intervention groups. Consider the co-interventions, including any pre-specified co-interventions, that are likely to affect the outcome and to have been administered in this study. Consider whether these co-interventions are balanced between intervention groups.		NA / Y / PY / <u>PN</u> / N / NI
2.4. Was the intervention implemented successfully?	Risk of bias will be higher if the intervention was not implemented as intended by, for example, the health care professionals delivering care during the trial. Consider whether implementation of the intervention was successful for most participants.		Y / PY / <u>PN</u> / N / NI
2.5. Did study participants adhere to the assigned intervention regimen?	Risk of bias will be higher if participants did not adhere to the intervention as intended. Lack of adherence includes imperfect compliance, cessation of intervention, crossovers to the comparator intervention and switches to another active intervention. Consider available information on the proportion of study participants who continued with their		Y / PY / <u>PN</u> / N / NI

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2.6. If N/PN/NI to 2.3, 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of starting and adhering to the intervention?	assigned intervention throughout follow up, and answer "No" or "Probably No" if this proportion is high enough to raise concerns. Answer "Yes" for studies of interventions that are administered once, so that imperfect adherence is not possible. It is possible to conduct an analysis that corrects for some types of deviation from the intended intervention. Examples of appropriate analysis strategies include inverse probability weighting or instrumental variable estimation. It is possible that a paper reports such an analysis without reporting information on the deviations from intended intervention, but it would be hard to judge such an analysis to be appropriate in the absence of such information. If everyone in one group received a co-intervention, adjustments cannot be made to overcome this. Some examples of analysis strategies that would not be appropriate to estimate the effect of intended intervention are (i) "ITT analysis", (ii) "per protocol analysis", and (iii) "analysis by treatment received".		NA / Y / PY / <u>PN</u> / N / NI
<b>Risk of bias judgement</b>	See Figure 2 and Figure 3.		Low / High / Some concerns
Optional: What is the predicted direction of bias due to deviations from intended interventions?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.		Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

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Bias domain	Signalling questions	Elaboration	Response options
Bias due to missing outcome data	3.1 Were outcome data available for all, or nearly all, participants randomized?	The appropriate study population for an analysis of the intention to treat effect is all randomized patients. Note that imputed data should be regarded as missing data, and not considered as "outcome data" in the context of this question. "Nearly all" (equivalently, a low or modest amount of missing data) should be interpreted as "enough to be confident of the findings", and a suitable proportion depends on the context. For continuous outcomes, availability of data from 95% (or possibly 90%) of the participants would often be sufficient. For dichotomous outcomes, the proportion required is directly linked to the risk of the event. If the observed number of events is much greater than the number of participants with missing outcome data, the bias would necessarily be small.	Y / PY / PN / N / NI
	3.2 If N/PN/NI to 3.1: Are the proportions of missing outcome data and reasons for missing outcome data similar across intervention groups?	"Similar" (with regard to proportion and reasons for missing outcome data) includes some minor degree of discrepancy across intervention groups as expected by chance. Assessment of comparability of reasons for missingness requires the reasons to be reported.	NA / Y / PY / PN / N / NI
	3.3 If N/PN/NI to 3.1: Is there evidence that results were robust to the presence of missing outcome data?	Evidence for robustness may come from how missing data were handled in the analysis and whether sensitivity analyses were performed by the trial investigators, or from additional analyses performed by the systematic reviewers. See Figure 4	NA / Y / PY / PN / N / NI
	<b>Risk of bias judgement</b>		Low / High / Some concerns
	Optional: What is the predicted direction of bias due to missing outcome data?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

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Bias domain	Signalling questions	Elaboration	Response options
Bias in measurement of the outcome	4.1 Were outcome assessors aware of the intervention received by study participants?	"No" if outcome assessors were blinded to intervention status. In studies where participants report their outcomes themselves (i.e., participant-reported outcome), the outcome assessor is the study participant.	Y / PY / PN / N / NI
	4.2 If Y/PY/NI to 4.1: Was the assessment of the outcome likely to be influenced by knowledge of intervention received?	Knowledge of the assigned intervention may impact on participant-reported outcomes (such as level of pain), observer-reported outcomes involving some judgement, and intervention provider decision outcomes, while not impacting on other outcomes such as observer reported outcomes not involving judgement such as all-cause mortality. In many circumstances the assessment of <i>observer reported outcomes not involving judgement</i> such as all-cause mortality might be considered to be unbiased, even if outcome assessors were aware of intervention assignments.	NA / Y / PY / PN / N / NI
	<b>Risk of bias judgement</b>	See Figure 5.	Low / High / Some concerns
	Optional: What is the predicted direction of bias due to measurement of the outcome?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

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Bias domain	Signalling questions	Elaboration	Response options
Bias in selection of the reported result	<p>Are the reported outcome data likely to have been selected, on the basis of the results, from...</p> <p>5.1. ... multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain?</p>	<p>A particular outcome domain (i.e. a true state or endpoint of interest) may be <b>measured</b> in multiple ways. For example, the domain pain may be measured using multiple scales (e.g. a visual analogue scale and the McGill Pain Questionnaire), each at multiple time points (e.g. 3, 6 and 12 weeks post-treatment). If multiple measurements were made, but only one or a subset is reported on the basis of the results (e.g. statistical significance), there is a high risk of bias in the fully reported result.</p> <p><b>A response of "Yes/Probably yes" is reasonable if:</b></p> <p>There is clear evidence (usually through examination of a trial protocol or statistical analysis plan) that a domain was measured in multiple ways, but data for only one or a subset of measures is fully reported (without justification), and the fully reported result is likely to have been selected on the basis of the results. Selection on the basis of the results arises from a desire for findings to be newsworthy, sufficiently noteworthy to merit publication, or to confirm a prior hypothesis. For example, trialists who have a preconception or vested interest in showing that an experimental intervention is beneficial may be inclined to selectively report outcome measurements that are favourable to the experimental intervention.</p> <p><b>A response of "No/Probably no" is reasonable if:</b></p> <p>There is clear evidence (usually through examination of a trial protocol or statistical analysis plan) that all reported results for the outcome domain correspond to all intended outcome measurements.</p> <p>or</p> <p>There is only one possible way in which the outcome domain can be measured (hence there is no opportunity to select from multiple measures).</p> <p>or</p> <p>Outcome measurements are inconsistent across different reports on the same trial, but the trialists have provided the reason for the inconsistency and it is not related to the nature of the results.</p> <p><b>A response of "No information" is reasonable if:</b></p>	<p>Y / PY / PN / N / NI</p>

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	<p>5.2 ... multiple analyses of the data?</p>	<p>Analysis intentions are not available, or the analysis intentions are not reported in sufficient detail to enable an assessment, and there is more than one way in which the outcome domain could have been measured.</p> <p>A particular outcome domain may be <b>analysed</b> in multiple ways. Examples include: unadjusted and adjusted models; final value vs change from baseline vs analysis of covariance; transformations of variables; conversion of continuously scaled outcome to categorical data with different cut-points; different sets of covariates for adjustment; different strategies for dealing with missing data. Application of multiple methods generates multiple effect estimates for a specific outcome domain. If multiple estimates are generated but only one or a subset is reported on the basis of the results (e.g. statistical significance), there is a high risk of bias in the fully reported result.</p> <p><b>A response of "Yes/Probably yes" is reasonable if:</b></p> <p>There is clear evidence (usually through examination of a trial protocol or statistical analysis plan) that a domain was analysed in multiple ways, but data for only one or a subset of analyses is fully reported (without justification), and the fully reported result is likely to have been selected on the basis of the results. Selection on the basis of the results arises from a desire for findings to be newsworthy, sufficiently noteworthy to merit publication, or to confirm a prior hypothesis. For example, trialists who have a preconception or vested interest in showing that an experimental intervention is beneficial may be inclined to selectively report analyses that are favourable to the experimental intervention.</p> <p><b>A response of "No/Probably no" is reasonable if:</b></p> <p>There is clear evidence (usually through examination of a trial protocol or statistical analysis plan) that all reported results for the outcome domain correspond to all intended analyses.</p> <p>or</p> <p>There is only one possible way in which the outcome domain can be analysed (hence there is no opportunity to select from multiple analyses).</p> <p>or</p> <p>Analyses are inconsistent across different reports on the same trial, but the trialists have provided the reason for the inconsistency and it is not related to the nature of the results.</p>	<p>Y / PY / PN / N / NI</p>
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		<p><b>A response of "No information" is reasonable if:</b>                  Analysis intentions are not available, or the analysis intentions are not reported in sufficient detail to enable an assessment, and there is more than one way in which the outcome domain could have been analysed.</p>	
	<b>Risk of bias judgement</b>	See Figure 6.	Low / High / Some concerns
	Optional: What is the predicted direction of bias due to selection of the reported result?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable

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Bias domain	Signalling questions	Elaboration	Response options
Overall bias	<b>Risk of bias judgement</b>	See Table 1	Low / High / Some concerns
	Optional: What is the overall predicted direction of bias for this outcome?	If the likely direction of bias can be predicted, it is helpful to state this. The direction might be characterized either as being towards (or away from) the null, or as being in favour of one of the interventions.	Favours experimental / Favours comparator / Towards null / Away from null / Unpredictable



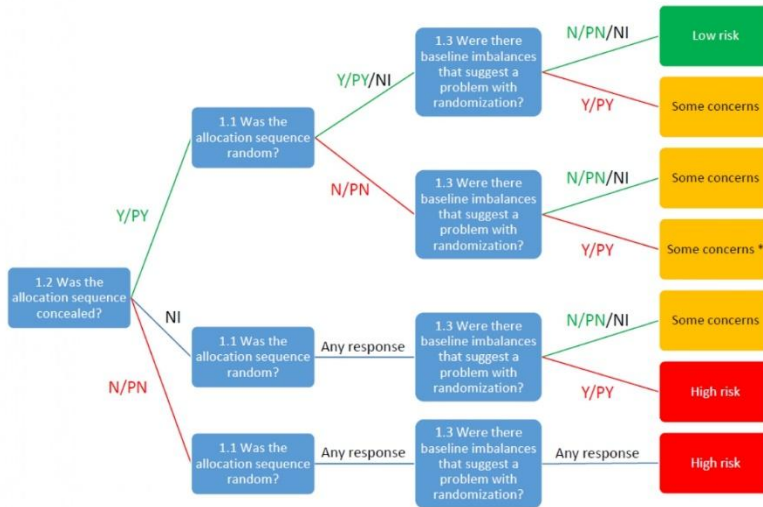
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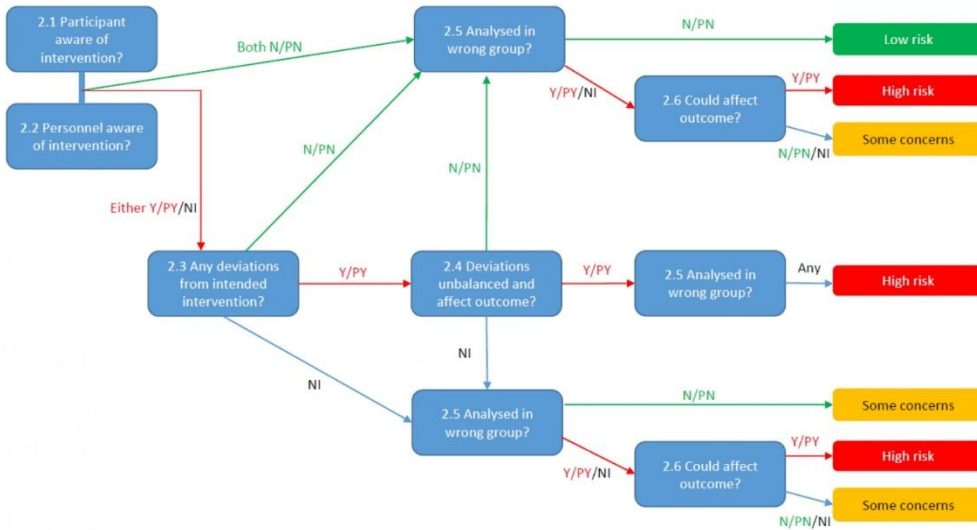
Figure 1. Suggested algorithm for reaching risk of bias judgements for bias arising from the randomization process. (\*In some cases a judgement of "High risk" would be appropriate.). This is only a suggested decision tree: all default judgements can be overridden by assessors.



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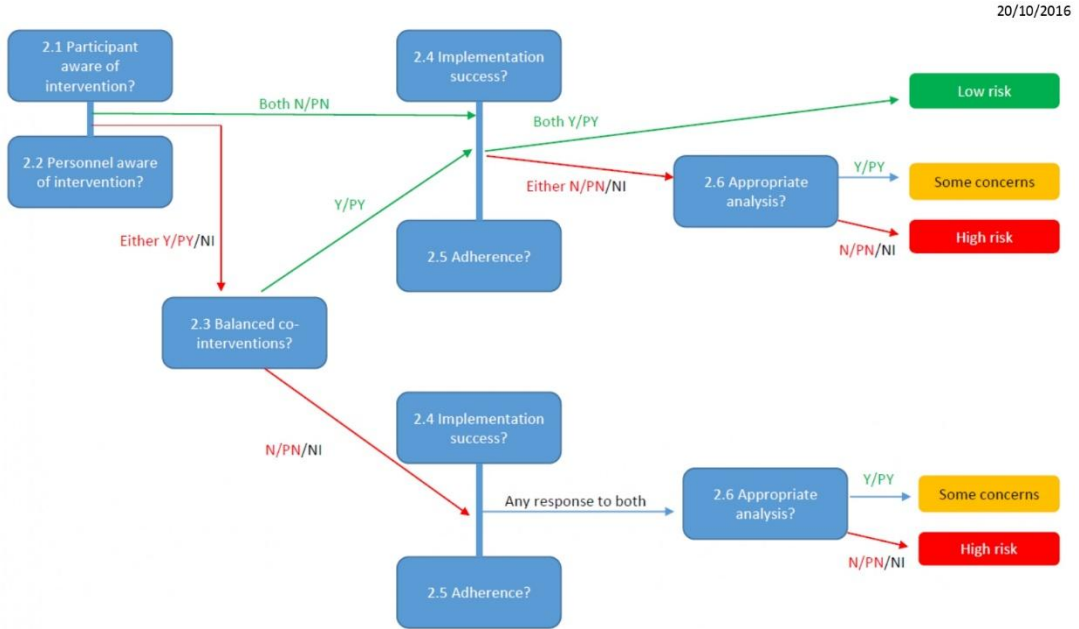
Figure 2. Suggested algorithm for reaching risk of bias judgements for bias due to deviations from intended interventions (effect of assignment to intervention). This is only a suggested decision tree: all default judgements can be overridden by assessors.



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Figure 3. Suggested algorithm for reaching risk of bias judgements for bias due to deviations from intended interventions (effect starting and adhering to intervention). This is only a suggested decision tree: all default judgements can be overridden by assessors.

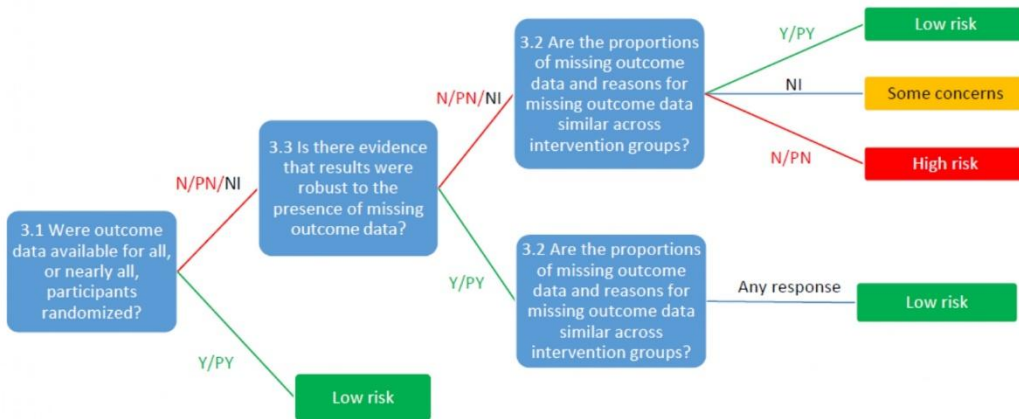


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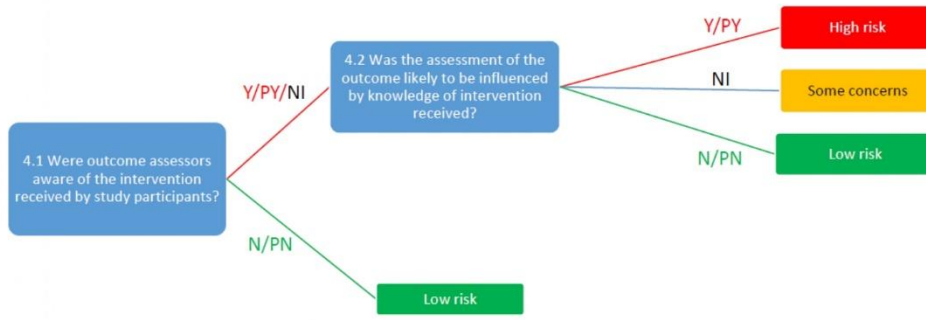
Figure 4. Suggested algorithm for reaching risk of bias judgements for bias due to missing outcome data. This is only a suggested decision tree: all default judgements can be overridden by assessors



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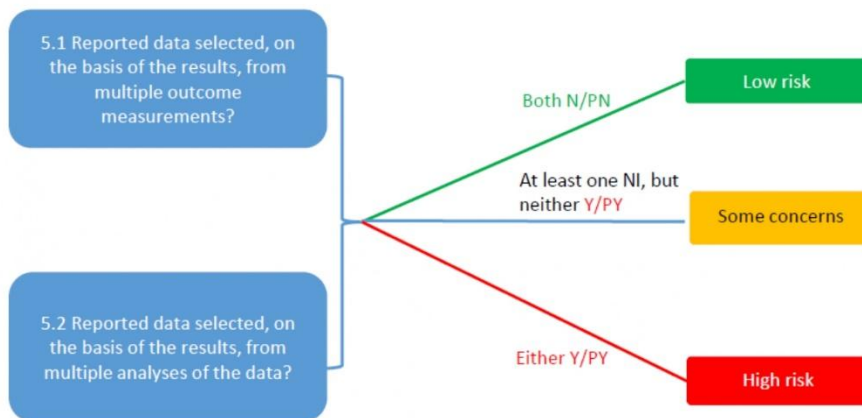
Figure 5. Suggested algorithm for reaching risk of bias judgements for bias in measurement of the outcome. This is only a suggested decision tree: all default judgements can be overridden by assessors.



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Figure 6. Suggested algorithm for reaching risk of bias judgements for bias in selection of the reported result. This is only a suggested decision tree: all default judgements can be overridden by assessors



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**Table 1. Reaching an overall risk of bias judgement for a specific outcome.**

<b>Overall risk of bias judgement</b>	<b>Criteria</b>
Low risk of bias	The study is judged to be at <b>low risk of bias</b> for all domains for this result.
Some concerns	The study is judged to be at <b>some concerns</b> in at least one domain for this result.
High risk of bias	The study is judged to be at <b>high risk of bias</b> in at least one domain for this result. Or The study is judged to have <b>some concerns for multiple domains</b> in a way that substantially lowers confidence in the result.