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Tese

Impacto da reabilitação oral protética na qualidade de vida, índices nutricionais e no controle glicêmico de pacientes idosos com diabetes mellitus tipo 2

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Orientador: Prof. Dr. Rafael Guerra Lund

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Resumo

BRÍGIDO, Jandenilson Alves. Impacto da reabilitação oral protética na qualidade de vida, índices nutricionais e no controle glicêmico de pacientes idosos com diabetes mellitus tipo 2. 2021. 120f. Tese de Doutorado em Odontologia – Programa de Pós Graduação em Odontologia. Universidade Federal de Pelotas, Pelotas, 2021.

Estudos têm demonstrado melhor controle glicêmico de indivíduos diagnosticados com diabetes mellitus tipo 2 quando ocorre maior adesão a um padrão alimentar saudável. A reabilitação oral protética pode melhorar a eficiência mastigatória e corrigir problemas nutricionais, além de melhorar requisitos estéticos e funcionais, mas não está claro se consegue influenciar no controle glicêmico de indivíduos idosos com diabetes mellitus tipo 2. Assim, a presente tese foi dividida em três artigos. O primeiro artigo foi uma revisão sistemática de estudos clínicos randomizados, que investigou a influência da reabilitação oral protética combinada ou não com orientação de dieta no perfil nutricional de pacientes idosos. Foram selecionados 12 estudos e foi possível observar que embora os pacientes que receberam tratamento protético tivessem melhora significativa na capacidade mastigatória, não foi encontrado um padrão consistente de melhora no estado nutricional. Entretanto, quando os indivíduos receberam simultaneamente tratamento protético e simples aconselhamento dietético, melhorou a ingestão de nutrientes e perfil nutricional em pacientes idosos desdentados. O segundo artigo foi uma revisão sistemática de estudos clínicos randomizados e prospectivos, que analisou o efeito da reabilitação protética na qualidade de vida relacionada à saúde oral em pacientes idosos. Dos 11 estudos selecionado, quatro são estudos clínicos randomizados e sete estudos clínicos prospectivos. Constatou-se que os tratamentos com as próteses dentárias analisadas apresentaram melhora na maioria dos domínios de qualidade de vida, principalmente na limitação funcional, incapacidade física e psicológica. Verificou-se que os indivíduos idosos reabilitados com overdentures sobre implantes ou próteses fixas adesivas apresentaram média significativamente melhor dos escores de qualidade de vida relacionada à saúde oral, em comparação ao tratamento com prótese total ou próteses parciais removíveis. E o terceiro artigo foi um estudo clínico prospectivo, que avaliou a influência da reabilitação oral protética associada ao aconselhamento dietético simplificado no controle glicêmico, estado nutricional e qualidade de vida de idosos com diabetes mellitus tipo 2. Foram avaliados 39 pacientes e houve melhora significativa no estado nutricional e na qualidade de vida relacionada à saúde bucal após 12 meses da terapia protética combinada com aconselhamento dietético simples, mas não houve melhora significativa no controle glicêmico dos indivíduos, durante o período da investigação. Com base nos estudos apresentados, foi possível concluir que a reabilitação oral protética tem um impacto positivo na qualidade de vida relacionada à saúde oral, mas precisa ser associada ao aconselhamento dietético para ter efeito consistente no estado nutricional de indivíduos idosos. A hipótese de que o tratamento com próteses removíveis combinadas com aconselhamento dietético simplificado poderia influenciar no controle glicêmico de idosos com diabetes mellitus 2 não foi confirmada. Outras investigações com seguimento mais longo são necessárias para estabelecer se a melhora do estado nutricional persiste ao longo dos anos.

Palavras-chave: Prótese Dentária. Diabetes mellitus. Avaliação nutricional. Qualidade de vida relacionada à saúde bucal. Controle glicêmico.

Abstract

BRÍGIDO, Jandenilson Alves. Impact of oral prosthetic rehabilitation on quality of life, nutritional status and glycemic control in elderly individuals with type 2 diabetes mellitus. 2021. 120p. Thesis PhD in Dentistry. Graduate Program in Dentistry. Federal University of Pelotas, Pelotas, 2021.

Studies have shown an improvement in glycemic control in individuals diagnosed with type 2 diabetes mellitus when there is greater adherence to a healthy eating pattern. Prosthetic oral rehabilitation can improve masticatory efficiency and correct nutritional problems, in addition to improving aesthetic and functional requirements, but it is unclear whether it can influence the glycemic control of elderly individuals with type 2 diabetes mellitus. Thus, this thesis was divided into three articles. The first article was a systematic review of randomized clinical trials, which investigated the influence of prosthodontic rehabilitation combinates or not with dietary advice on nutritional status in elderly patients. Twelve studies were selected and it was possible to observe that although patients who received prosthetic treatment had a significant improvement in chewing capacity, a consistent pattern of improvement in nutritional status was not found. However, when subjects received simultaneously prosthetic treatment and simple dietary advice, it improved nutrient intake and nutritional status in edentulous elderly patients. The second article was a systematic review of randomized clinical trials and prospective studies that analyzed the effect of prosthetic rehabilitation on oral health related quality of life in elderly patients. Of the 11 studies selected, four are randomized clinical trials and seven are prospective clinical studies. It was found that treatments with dental prostheses analyzed showed improvement in most of the domains of quality of life, mainly in functional limitation, physical and psychological disabilities. It was found that elderly individuals rehabilitated with implant overdentures or fixed adhesive prosthesis resulted in significantly better mean of oral health related quality of life scores compared to treatment with complete dentures or removable partial dentures. And the third article was a prospective clinical study, which evaluated the influence of oral prosthetic rehabilitation and simplified dietary advice on the glycemic control, nutritional status, and quality of life of elderly individuals with type 2 diabetes mellitus. Thirty-nine patients were evaluated and there was a significant improvement in nutritional status and oral health related quality of life after 12 months of prosthetic therapy combined with simple dietary counseling, but there was no significant improvement in the individuals' glycemic control during the investigation period. Based on the studies presented, it was possible to conclude that oral prosthetic rehabilitation has a positive impact on oral health related quality of life, but it needs to be combined with dietary counseling to have a consistent effect on the nutritional status of elderly individuals. The hypothesis that treatment with removable dentures combined with simplified dietary advice could influence the glycemic control of elderly people with diabetes mellitus 2 was not confirmed. Further investigations with longer follow-up are needed to establish whether the improvement in nutritional status persists over the years.

Key words: Dental Prosthesis. Diabetes mellitus. Nutritional status. Oral health related quality of life. Glycemic control.

Sumário

1 Introdução

O diabetes mellitus (DM) tipo 2 apresenta etiologia complexa e multifatorial, envolvendo fatores genéticos e ambientais, correspondendo a aproximadamente 95% de todos os casos de DM (SKYLER et al., 2017; ADA, 2021). Costuma acometer principalmente adultos a partir dos 40 anos de idade, sendo mais prevalente em idosos. A herança familiar ainda não está totalmente esclarecida, mas pode ser significativamente afetada por hábitos nutricionais e de atividade física (SBD, 2019).

Na rotina clínica dos atendimentos odontológicos, é comum receber pacientes, principalmente idosos, que relatam não apresentar uma função mastigatória eficiente, geralmente ocasionada por ausência de dentes ou por próteses dentárias desadaptadas. Estudos têm mostrado que não só a presença, mas também a qualidade das próteses, podem ser associadas com ingestão alimentar e variedade dietética, podendo corrigir problemas nutricionais, além de melhorar requisitos estéticos e funcionais (GUNJI et al., 2009; BORGES et al., 2011; IWASAKI et al., 2014). Além disso, Kossioni et al. (2018) relataram que a reabilitação oral protética associada ao aconselhamento nutricional personalizado, pode melhorar o estado nutricional dos pacientes. Próteses desadaptadas e necessitando de ajustes provocam incômodos na hora de se alimentar, estimulando alguns pacientes a rejeitar determinados alimentos, o que pode vir a ocasionar um déficit nutricional (GUNJI et al., 2009).

Quando esses indivíduos idosos são diagnosticados com diabetes, especialmente DM tipo 2, faz parte da rotina médica realizar orientações em terapia nutricional, que se concentra no equilíbrio dos macronutrientes para a manutenção do bom controle metabólico (NEUENSCHWANDER et al., 2019; ADA, 2021**).** DM tipo 2 pode ser retardado ou prevenido, por meio de modificações de estilo de vida e a educação nutricional é parte do plano alimentar como ferramenta para otimizar a aderência à terapia nutricional (SBD, 2019). Estudos têm observado uma diminuição da incidência de DM tipo 2 quando ocorre maior adesão a um padrão alimentar saudável, que inclui maior consumo de grãos inteiros e fibra alimentar, além da redução de ingestão de carne vermelha total e processada, alimentos com alta carga glicêmica e bebidas adoçadas com açúcar (SCHWINGSHACKL et al., 2017; MICHA et al., 2017; BELLOU et al., 2018).

Diante desse contexto, questiona-se: “As reabilitações orais protéticas podem impactar no perfil nutricional e na qualidade de vida relacionada à saúde oral de forma a influenciar no controle glicêmico de indivíduos idosos com DM tipo 2?”

Não há evidências científicas sobre a influência da reabilitação oral, por meio da instalação de próteses dentárias em pacientes desdentados ou substituição de próteses inadequadas no controle glicêmico de indivíduos idosos, especialmente nos que apresentam DM tipo 2. As revisões sistemáticas publicadas enfatizam a relação da perda de dentes com perfil nutricional, qualidade de vida e satisfação dos pacientes (NASCIMENTO et al., 2016; GAEWKHIEW et al., 2017; HAAG et al., 2017), mas existe uma escassez de estudos na literatura recente, avaliando o efeito das reabilitações orais protéticas na nutrição e na qualidade de vida relacionada à saúde oral de pacientes idosos.

Estudos demonstraram que o tratamento periodontal pode ser benéfico para o controle glicêmico do DM tipo 2 (SIMPSON et al., 2015; D'AIUTO et al., 2018), constando nas recomendações da Sociedade Brasileira de Diabetes (SBD, 2019) o acompanhamento periodontal desses indivíduos. Dessa forma, caso confirmada uma possível influência da reabilitação oral no tratamento de pacientes com DM tipo 2, essa terapia também poderia ser incorporada ao manejo desses indivíduos. Assim, os objetivos desta tese, desenvolvida em três artigos, foram: 1) investigar, por meio de uma revisão sistemática de estudos clínicos randomizados, a influência da reabilitação oral protética combinada ou não com orientação de dieta no perfil nutricional de pacientes idosos; 2) analisar, por meio de uma revisão sistemática de estudos clínicos randomizados e prospectivos, o efeito da reabilitação protética na qualidade de vida relacionada à saúde oral em pacientes idosos; e 3) avaliar clinicamente a influência da reabilitação oral protética associada ao aconselhamento dietético simplificado no controle glicêmico, estado nutricional e qualidade de vida de idosos com DM tipo 2.

2 Revisão de literatura

2.1 Diabetes mellitus

O termo DM é utilizado para descrever um grupo de distúrbios metabólicos associados à intolerância à glicose, de etiologia múltipla e heterogênea, caracterizado pela deficiência na secreção de insulina e/ou em sua ação. A hiperglicemia, causada por defeitos de secreção deste hormônio, desempenha um papel importante nas complicações da DM (IDF, 2019). Tem sido classificado, baseado em sua etiologia, em tipo DM 1, tipo 2 e gestacional, além de outras formas menos comuns que incluem diabetes monogênicos e secundários (SKYLER et al., 2017; ADA, 2021).

DM tipo 1 é causada pela destruição de células produtoras de insulina (β pancreáticas), enquanto DM tipo 2 resulta de defeitos na molécula de insulina ou da alteração de seus receptores celulares, ocasionando resistência insulínica. DM gestacional consiste de uma intolerância aos carboidratos, que se inicia na gestação, também por resistência insulínica, devido à produção de hormônios hiperglicemiantes pela placenta, que pode persistir após o parto (INSEL et al., 2015; SKYLER et al., 2017).

Estimativas globais do ano de 2019 indicam que 463 milhões de adultos viviam com DM (9,3%), e esse número poderá chegar a 700 milhões (10,9%) em 2045 (IDF, 2019). No Brasil, um estudo transversal estimou que cerca de 7,5% da população teria DM (FLOR e CAMPOS, 2017), enquanto no estudo de Muzy et al. (2021), foi estimado uma prevalência de 9,4%. Um estudo multicêntrico demonstrou que, no Brasil, 15% da população com DM apresentava o tipo 1 e 85% tipo 2 (MENDES et al., 2010).

DM tipo 2 pode ser diagnosticado com base em critérios de glicose plasmática e são utilizados no rastreamento: Hemoglobina glicada (HbA1c) $\geqslant$ 6,5%; Glicemia de jejum (mínimo de 8 horas) $\geqslant$ 126 mg/dL e Glicemia plasmática no teste oral de tolerância à glicose de 2 horas $\geqslant$ 200 mg/dL (ADA, 2021). A pré-diabetes (glicemia de jejum entre 100 e 125 mg/dL, glicemia de 2 horas pós-sobrecarga entre 140 e 200 mg/dL ou HbA1c entre 5,7 e 6,5%) não caracteriza uma patologia em si, mas uma condição de alto risco para o desenvolvimento de DM tipo 2. A determinação da

HbA1c possibilita estimar quão elevadas as glicemias estiveram nos últimos 3 a 4 meses (ARMSTRONG et al., 2017; ADA, 2021).

O DM tipo 2 é uma doença multifatorial, poligênica, ainda não completamente esclarecida, associada à riscos comportamentais e ambientais, causado por uma resistência à insulina, combinada a uma incapacidade de produção de uma quantidade de insulina adicional, para compensar esta resistência (DEFRONZO et al., 2004; SKYLER et al., 2017). Incentivada por um aumento da população, do envelhecimento, da urbanização, da obesidade e da falta de prática de atividade física, tornou-se uma epidemia mundial (IDF, 2019; ADA, 2021). Tem como principal fator de risco ambiental a obesidade, que contribui para a resistência periférica à ação da insulina, através dos níveis elevados de ácidos graxos livres, os quais inibem a utilização de glicose, com o consequente aumento na produção deste hormônio, caracterizando a hiperinsulinemia (DEFRONZO et al., 2004; FERNANDEZ-REAL e PICKUP, 2008).

2.2 Avaliação Nutricional

A avaliação do estado nutricional mede a influência da nutrição na saúde do indivíduo, podendo ser realizada por meio de exame físico, métodos antropométricos, provas bioquímicas, escalas geriátricas, avaliações subjetivas e inquéritos alimentares. Não há padrão ouro para determinar o estado nutricional, porém, há critérios universalmente aceitos para definir desnutrição (IDF, 2019). A European Society of Parenteral and Enteral Nutrition (ESPEN), define desnutrição como um estado resultante da deficiente absorção ou ingestão alimentar, que leva a uma alteração da composição corporal (diminuição da massa magra e da massa celular), levando à diminuição das funções física e mental, dificultando a recuperação frente à doença (SOBOTKA; ALLISON, 2011).

No caso dos idosos, a alimentação ideal deve ser balanceada, ingerindo pequenas porções, fracionadas ao longo do dia. A desnutrição nesse grupo etário é frequentemente associada a problemas físicos, sociais e psicológicos, que justificam a busca de condutas e diagnósticos nutricionais, que podem melhorar a qualidade da dieta dessa população (WORLD HEALTH ORGANIZATION, WHO, 2003; ADA, 2021). Uma orientação nutricional associada à diminuição do sedentarismo, são consideradas terapias de primeira escolha, promovendo melhora da sensibilidade à

insulina, podendo reduzir os níveis de glicemia, a circunferência abdominal e a gordura visceral. Ademais, podem melhorar o perfil lipídio e os níveis de pressão arterial, tendo maior consciência sobre a doença, modificando escolhas alimentares e atitudes inadequadas (ADA, 2021).

A terapia nutricional no manejo do DM é importante por seu papel na prevenção, no gerenciamento da doença e para reduzir o desenvolvimento das complicações decorrentes da doença (WHO, 2003). A melhor estratégia nutricional para a promoção da saúde e redução do risco de doença crônica é a obtenção de nutrientes adequados a partir de uma alimentação variada, moderada e equilibrada **(**NEUENSCHWANDER et al., 2019**).** A dieta indicada para pacientes com diabetes deve ser moderada em carboidratos e proteínas, baixo teor lipídico, gordura saturada, sal e açúcares simples e rica em fibras solúveis, que favorecem o controle de dislipidemias e da glicemia, por reduzir a absorção de colesterol e carboidratos (TRITISARI et al., 2018; VOLKERT et al., 2018).

O questionário Mini Avaliação Nutricional (MAN) foi desenvolvido por Guigoz et al. (1994) com o propósito de identificar a presença de desnutrição ou risco do seu desenvolvimento em idosos, validada em grandes e representativas amostras. É uma ferramenta apropriada para a avaliação nutricional, quando comparada a outros questionários, por identificar melhor os pacientes gravemente malnutridos (CAMINA-MARTIN et al., 2015). É um instrumento validado no Brasil para rastreio nutricional, sendo não invasivo, altamente sensível, específico, confiável e rápido (KAISER et al., 2009), em que o estado nutricional é analisado incluindo vários parâmetros como a história clínica, o exame físico, os dados antropométricos e a ingestão alimentar (GUIGOZ et al., 1994).

O diagnóstico de desnutrição pode ser identificado se o Índice de Massa Corporal (IMC) for <18,5 kg/m^2 ou se houver uma perda de peso não intencional combinada com IMC <20 kg/m^2 ou ainda com o Índice de Massa Livre de Gordura, variável consoante idade e sexo (SOETERS et al., 2017). Testes laboratoriais como parâmetros bioquímicos e sanguíneos, também têm um importante papel na avaliação do estado nutricional, podendo ser úteis para se detectar deficiências nutricionais de forma precoce, antes mesmo que as medidas antropométricas demonstrem alguma alteração (BARONE et al., 2003). No entanto, esses testes podem estar alterados na presença de processos infecciosos/inflamatórios e

doenças degenerativas e, em idosos, estarem alterados na presença de desequilíbrios hídricos e permeabilidade vascular (ADA, 2021).

Evidências científicas demonstram que a intervenção nutricional tem impacto significativo na redução da HbA1c no DM (WHO, 2003; LEY et al., 2014; SCHWINGSHACKL et al., 2017; ZHANG et al., 2017). Além disso, quando associado a outros componentes do cuidado em DM, o acompanhamento nutricional pode favorecer ainda mais os parâmetros clínicos e metabólicos, decorrentes de uma melhor adesão ao plano alimentar prescrito (VOLKERT et al., 2018). Segundo as diretrizes da SBD 2019-2020, a perda de peso é a principal forma de reduzir o risco de diabetes, e o DM2 pode ser evitado por meio de mudanças no estilo de vida e intervenção não farmacológica (LEY et al., 2014; SBD, 2019).

2.3 Reabilitação Protética e Nutrição

Vários estudos demonstraram que a perda de dentes compromete a fonação, mastigação, deglutição, estética e vida social, impactando na qualidade de vida dos indivíduos (GERRITSEN et al., 2010; HAAG et al., 2017; HAAG; PERES; BRENNAN, 2017). Ademais, tem sido associada com condições sistêmicas de saúde, como hipertensão e DM (KASSEBAUM et al., 2014; KOSSIONI et al., 2018). Além do edentulismo, que é a completa perda de dentes em ambas as arcadas, há outras formas como a perda severa de dentes, descrita como a presença de pelo menos nove dentes permanentes, e perda com dentição funcional, que pode ser definida como a presença de pelo menos 21 dentes, necessários para uma capacidade mastigatória adequada (RIBEIRO et al., 2016).

Perda dentária e consequentes alterações na função oral podem acarretar limitações na escolha da dieta. Assim, alimentos macios, facilmente mastigáveis, pobre em fibras, vitaminas e minerais, nem sempre com qualidade nutricional adequada, são mais consumidos nesses casos (LIMA et al., 2007; GAEWKHIEW et al., 2017), comprometendo a saúde geral e agravando doenças crônicas, comuns do envelhecimento (MOYNIHAN et al., 2007). Como a perda de dentes é geralmente associada a adultos mais velhos, a conscientização crescente da importância da saúde bucal, no campo da nutrição geriátrica, tem sido evidenciada.

Alguns pesquisadores sugerem que é possível o indivíduo apresentar uma dentição funcional, quando têm mais de 20 dentes naturais presentes, necessários

para uma função dentária adequada, sem o auxílio de próteses substitutas (ERVIN; DYE, 2012). Enquanto alguns estudos verificaram melhor desempenho mastigatório após a reabilitação protética, com melhora do estado nutricional e diminuição do número de pacientes com risco de desnutrição (BORGES et al., 2011; MADHURI et al., 2014), outros não observaram diferença (AWAD et al., 2012; PERUCHI et al., 2016). Há ainda os estudos que não encontraram diferenças no perfil nutricional, entre reabilitar com prótese convencionais removíveis ou sobre implantes, como no caso das overdentures (GJENGEDAL et al., 2012; HAMDAN et al., 2013).

2.4 Qualidade de Vida Relacionada à Saúde Bucal

A saúde bucal é reconhecida como um componente essencial e integral do estado geral de saúde e bem-estar dos idosos e altas prevalências de edentulismo são encontradas nessa faixa etária. Em pacientes parcial e totalmente desdentados, o tratamento com próteses dentárias pode melhorar eficiência mastigatória, estética, fonação e benefícios psicológicos, melhorando sua capacidade de aceitação social, com reflexos diretos sobre a sua qualidade de vida (CHANG et al., 2016).

Embora não haja nenhum padrão ouro para medir a qualidade de vida, tem sido estabelecido uma série de instrumentos capazes de realizar avaliações objetivas do impacto da saúde bucal. Diversos estudos avaliaram a qualidade de vida de pacientes edêntulos, mediante diferentes metodologias e questionários, formulados nas dimensões que estão baseadas no modelo teórico de saúde oral, uma vez que este propõe uma sequência hierárquica de eventos associados com as doenças bucais (FILLION et al., 2013; MADHURI et al., 2014; FERNANDEZ-ESTEVAN, 2015).

O questionário Oral Health Impact Profile, também referido na literatura como OHIP-49, por possuir esta quantidade de questões, é um dos mais utilizados (SLADE e SPENCER, 1994). É um instrumento confiável e com validade comprovada, sendo aplicado para determinar a eficácia do tratamento, a satisfação do paciente, a estética dentária e a reabilitação protética, traduzido e adotado em muitos países (CHANG et al., 2016). Um instrumento de coleta de dados deve ser prático, de baixo custo e com uma quantidade de perguntas que não seja demasiadamente longa, o que pode inviabilizar estudos epidemiológicos (SLADE, 1997). Desta forma, houve uma redução no número de perguntas e o

estabelecimento de novos questionários, como o OHIP-14 (SLADE, 1997) e o OHIPEDENT, que é o OHIP para pacientes edêntulos (ALLEN e LOCKER, 2000). O questionário pode ser aplicado tanto na forma de entrevista pessoal, entrevista via telefone ou auto aplicado e apresenta a mesma estrutura do anterior, com os mesmos 7 domínios, com duas questões em cada um deles, totalizando 14 questões, tendo sido validado no Brasil por Oliveira e Nadanovsky (2005).

Estudos que utilizaram o questionário OHIP observaram um impacto positivo da reabilitação oral protética sobre a qualidade da vida dos pacientes, bem como a redução de limitações e dores físicas, psicológica e desconforto social (SARGOLZAIE et al., 2017; BUGONE et al., 2019). Para muitos pacientes, a reabilitação oral significa um retorno a um estilo de vida normal, já que estão mais expostos a distúrbios emocionais devido à insegurança e a baixa autoestima, interferindo na sua capacidade de inclusão social (SHEIHAM et al., 2001; NORDENRAM et al., 2013). A percepção de uma alimentação insatisfatória pode produzir maiores impactos sobre a qualidade de vida, pois remete à análise sobre qual o impacto da ausência de dentes e de próteses, provocam no estado nutricional dos pacientes (MOYNIHAN, 2007).

3 Projeto de Pesquisa

3.1 Introdução

O envelhecimento é um processo dinâmico no qual ocorrem alterações progressivas no organismo, tornando-o mais susceptível a agressões intrínsecas, que podem ser classificadas como inerentes ao funcionamento do próprio corpo, e extrínsecas, que são definidas como influências ambientais, aumentando de forma exponencial o aparecimento de doenças crônicas (HAN et al., 2014; ALVARENGA et al., 2019). O diabetes mellitus (DM), uma doença que está afetando a população de forma crescente, associado à maior obesidade, deficiências nutricionais e estilo de vida sedentário, tem se tornado um sério problema de Saúde Pública, associado a custos elevados em saúde (FLOR e CAMPOS, 2017; NEUENSCHWANDER et al., 2019).

DM é uma doença metabólica complexa, caracterizada pela elevação anormal dos níveis de glicose plasmática, seja pela resistência e/ou falta de produção da insulina, geralmente relacionada a modificações do metabolismo dos carboidratos, lipídios e proteínas, apresentando desordens heterogêneas e risco aumentado para outras condições sistêmicas (NEUENSCHWANDER et al., 2019). DM tipo 2 é responsável por 90% de todos os casos de diabetes, sendo mais comumente encontrado em idosos (INTERNATIONAL DIABETES FEDERATION - IDF, 2017) e fatores modificadores, como dieta, podem contribuir para o aparecimento ou influenciar na progressão do distúrbio (DYSON et al., 2018).

A perda de dentes está relacionada principalmente com a cronicidade e os efeitos cumulativos da cárie dentária e doença periodontal (CHESTNUTT et al., 2000; RIBEIRO et al., 2016), doenças altamente prevalentes na população. Embora a odontologia moderna esteja voltada para prevenção, ainda se observa uma crescente demanda de perdas dentárias, gerando desdentados parciais ou totais, com a necessidade de reabilitação protética (GAEWKHIEW et al., 2017; KOSSIONI et al., 2018). O edentulismo tem sido associado a diversos fatores como idade, sexo, renda salarial, grau de instrução, doenças cardiovasculares e hipertensão. Evidência limitada, mas emergente, sugere relação entre DM e perda dentária (LUO et al., 2015; GREENBLATT et al., 2016).

Durante o envelhecimento, a função mastigatória pode ser prejudicada por modificações fisiológicas e redução do número de dentes (MADHURI et al., 2014; KOSSIONI et al., 2018). As altas taxas de prevalência de perdas dentárias, indicam

uma grande necessidade de reabilitação protética em idosos (RIBEIRO et al., 2016). Os danos à saúde bucal interferem na ingestão de nutrientes e a ineficiência mastigatória leva a uma redução na ingestão de alimentos, principalmente fibrosos (LUO et al., 2015; KOMAGAMINE et al., 2016), o que pode estar relacionado à ocorrência de vários distúrbios gastrointestinais, sistêmicos, desnutrição e doenças crônicas em idosos (MOYNIHAN et al., 2009, IOANNIDOU et al., 2014), ademais, escolhas alimentares alternativas subsequentes podem levar à obesidade (NASCIMENTO et al., 2016). Estudos têm demonstrado que a terapia nutricional é fundamental na prevenção, tratamento e gerenciamento do DM, favorecendo o controle glicêmico através da redução dos níveis de hemoglobina glicada (HbA1c), mostrando-se eficaz em reduzir a incidência de DM tipo 2 (LEY et al., 2014; PEREIRA et al., 2016).

A dieta pobre em nutrientes e as mudanças na alimentação, com alto consumo de alimentos ultraprocessados, que possuem elevado teor calórico e de gorduras, estão associadas com o declínio do número de dentes e com o aumento da idade (MOYNIHAN, 2007), pois a presença dos dentes proporciona grandes benefícios como a possibilidade de mastigar uma série de alimentos de diferentes texturas e valores nutricionais. Sendo assim, o número e a distribuição de dentes naturais, além da presença de próteses dentárias, influenciam na facilidade e no conforto em mastigar (HUTTON et al., 2002; WALLS e STEELE, 2004), indicando uma possível associação bidirecional entre perda dentária e obesidade (NASCIMENTO et al., 2016).

Alguns estudos relacionaram o edentulismo com desnutrição em idosos, em função de prejuízos no processo de mastigação, dificultando a digestão de alimentos e levando à restrição alimentar (ALTENHOEVEL et al., 2012; TANNEN et al., 2012). Demonstrou-se também que indivíduos com perda de dentes e que não utilizavam próteses dentárias, eram mais propensos a estarem sob risco nutricional, sugerindo que nos casos de edentulismo, o uso de próteses totais representaria um benefício para o restabelecimento de um estado nutricional adequado (DE MARCHI et al., 2008; IWASAKI et al., 2014).

A avaliação nutricional é um processo sistemático, tendo como objetivo obter informações importantes, que podem identificar precocemente problemas relacionados à nutrição, inclusive desnutrição em idosos, que é considerada mais complexa nessa população, devido ao processo fisiológico de envelhecimento.

Devem ser utilizados métodos com questões simples e rápidas, que facilitem destacar sinais de alerta do estado nutricional (LACEY; PRITCHETT, 2003). Vários métodos são empregados para a avaliação do risco nutricional, um exemplo é o Mini Avaliação Nutricional - MAN (GUIGOZ et al., 1994), que é um instrumento de avaliação clínica, usado para identificar risco nutricional ou desnutrição instalada em pacientes idosos, sem a ajuda de um profissional especializado (ABD et al., 2017; MALAFARINA et al., 2018).

Os impactos da perda dentária, podem ser demonstrados pela diminuição das capacidades funcionais de mastigação e fonação, prejuízos nos requisitos estéticos, instabilidade emocional e psicológica e interferência nutricional, afetando a qualidade de vida e o bem-estar do paciente (MUSACCHIO et al., 2007; BUGONE et al., 2019). Para mensurar a qualidade de vida relacionada à saúde bucal, é utilizado o instrumento *Oral Health Impact Profile* (Perfil do Impacto da Saúde Bucal – OHIP) na sua versão reduzida (OHIP-14), descrita por Slade (1997), com o objetivo de avaliar o impacto das doenças bucais no bem-estar físico, psicológico e social dos pacientes, além de sua capacidade de realizar atividades corriqueiras (HAAG et al., 2017, BUGONE et al., 2019).

O uso prolongado de próteses inadequadas ou a ausência de prótese dentárias, pode acarretar em problemas estéticos, fonéticos, funcionais e nutricionais, afetando os aspectos motores e sensoriais do processo mastigatório (NORDENRAM et al., 2013), além da qualidade de vida (TSAKOS et al., 2004). A preocupação em entender melhor as mudanças que ocorrem no organismo com o envelhecimento, tem se tornado cada vez mais frequente, principalmente com o aumento do número de idosos e maior expectativa de vida da população (GUPTA et al., 2018).

Apesar de estudos indicarem a associação entre doença periodontal e DM (LALLA, PAPAPANOU, 2011; PRESHAW et al., 2012; ZHOU et al., 2015), ainda existe uma literatura escassa sobre a influência da reabilitação oral, através da instalação de próteses dentárias em pacientes desdentados ou através de substituição de próteses inadequadas, na qualidade de vida, perfil nutricional e controle glicêmico de indivíduos idosos, especialmente nos que apresentam DM tipo 2. O delineamento da possível influência da reabilitação oral no tratamento de pacientes com DM, pode constituir uma estratégia importante a ser incorporada ao manejo holístico desses indivíduos, já que as intervenções odontológicas protéticas

geralmente não estão inseridas nas diretrizes de tratamento e acompanhamento dessa doença, podendo ser uma contribuição futura tanto para o tratamento como para a prevenção e evolução da DM.

3.2. Objetivos

3.2.1 Gerais

- Determinar a influência da reabilitação oral protética no estado nutricional, controle glicêmico e na qualidade de vida de indivíduos idosos com diabetes mellitus tipo 2.

3.2.2 Específicos

- Revisar sistematicamente os estudos que avaliaram a associação da reabilitação oral protética e perfil nutricional.
- Analisar sistematicamente a literatura que avaliou a associação entre reabilitação oral com próteses removíveis e melhor qualidade de vida.
- Determinar a possível associação entre a reabilitação oral protética e a qualidade de vida em indivíduos idosos com diabetes mellitus tipo 2, por meio do questionário Oral Health Impact Profile (OHIP-14).
- Avaliar a associação entre a reabilitação oral protética e estado nutricional em indivíduos idosos com diabetes mellitus tipo 2, através do questionário Mini Avaliação Nutricional (MAN).
- Avaliar a associação entre a reabilitação oral protética e controle glicêmico em indivíduos idosos com diabetes mellitus tipo 2, por meio de exames de Hemoglobina Glicada e Glicemia em jejum.

3.3. Metodologia

3.3.1 Revisão Sistemática

Foram elaboradas duas perguntas de pesquisa usando a estratégia P.I.C.O. A primeira revisão sistemática tem como pergunta de pesquisa: A reabilitação oral influencia no perfil nutricional de pacientes idosos? e utilizará a sequência de busca que inclui termos da Medical Subject Headings (MeSH), além de outros termos sinônimos como: (*dentures OR prosthodontic rehabilitation OR dental prosthesis OR dental prostheses) AND (nutrition OR desnutricion OR obesity OR nutritional OR "nutritient intake") AND ("clinical trial*").

A segunda revisão sistemática terá como pergunta de pesquisa: A reabilitação com próteses removíveis está associada à qualidade de vida relacionada à saúde bucal de pacientes edêntulos? e usará a estratégia de busca: (*dentures OR prosthodontic rehabilitation OR dental prosthesis OR dental prostheses) AND (quality of life OR quality OR OHRQoL AND ("Clinical Trial"*).

Em relação aos critérios de elegibilidade, nas duas revisões serão incluídos artigos originais, com desenho de estudo clínico, sem restrição de idioma e nem de data. Na primeira serão incluídos estudos com pacientes acima de 60 anos, sem problemas de saúde geral e que relacionaram uso de prótese dentária fixa ou removível ao estado nutricional. Na segunda serão incluídos estudos com pacientes adultos acima de 25 anos, sem problemas de saúde geral e que associaram uso de prótese dentária fixa ou removível com qualidade de vida relacionada à saúde bucal.

As revisões sistemáticas serão realizadas de acordo com as normas PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-Analyses (MOHER et al., 2009). A busca de artigos será feita por três examinadores previamente treinados e calibrados (JAB, RGL e MSS), independentemente, nas bases de dados: PubMed, Lilacs, Web of Science, Scielo e The Cochrane Library. A seleção dos artigos será realizada inicialmente por dois examinadores que usem a mesma estratégia de busca e os critérios de inclusão, através da leitura dos títulos e resumos, posteriormente os artigos pré-selecionados serão lidos na íntegra para finalizar elegibilidade. Caso exista alguma diferença na seleção dos artigos, um terceiro examinador será consultado para entrar em consenso. Todo o processo seguirá conforme Fluxograma PRISMA. Os dados relevantes serão extraídos de todos os estudos que atenderem aos critérios: (1) O primeiro autor e ano de publicação; (2) Objetivos do estudo; (3) População estudada; (4) Tipo de Estudo e (5) Principais achados.

3.3.2 Estudo Clínico

3.3.2.1 Tipo de Estudo

Este estudo será do tipo observacional prospectivo.

3.3.2.2 População Alvo e Seleção da Amostra

A amostra será de conveniência e formada por indivíduos adultos idosos com diagnóstico de DM tipo 2, que compareçam à clínica de ensino do Curso de Graduação em Odontologia da Unifametro (Centro Universitário Fametro), na cidade de Fortaleza, Ceará, independente de etnia ou sexo, os quais serão convidados a participar do estudo e divididos em 6 grupos, de acordo com a perda e reposição de dentes (adaptado de ERVIN; DYE, 2012):

- Grupo DFN (dentição funcional natural) = presença de pelo menos 21 dentes naturais - sem dentes substituídos presentes;
- Grupo DFP (dentição funcional com prótese) = presença de pelo menos 21 dentes naturais e substituídos adequadamente;
- Grupo DIN (dentição incompleta natural) = presença de 1 a 20 dentes naturais - sem dentes substituídos;
- Grupo DIP (dentição incompleta com prótese) = presença de 1 a 20 dentes naturais e substituídos;
- Grupo ADP (ausência de dentes com prótese) = totalmente edêntulo com prótese total adequada; e
- Grupo AD (ausência de dentes) = totalmente edêntulo sem prótese ou prótese inadequada.

Os dentes substituídos incluirão próteses removíveis e fixas, inclusive sobre implantes dentários. As próteses serão consideradas adequadas quando não apresentarem problemas de retenção e estabilidade (testes de travamento e assentamento), sem queixas dos pacientes de deslocamento da prótese durante mastigação, fala, deglutição, sorriso ou mesmo repouso.

Os pacientes serão selecionados pelo pesquisador responsável, que também providenciará a confecção das novas próteses dentárias, para posterior análise e comparação.

3.3.2.3 Critérios de inclusão

Serão incluídos no estudo os indivíduos com 60 anos ou mais, que apresentarem DM2 e exames de HbA1c ≥ 6,5% e/ou glicose em jejum (com tempo acima de 8h) > 126 mg/dL (ADA, 2019).

Os pacientes desdentados totais deverão apresentar tecidos e rebordos remanescentes íntegros e devidamente cicatrizados, com tempo mínimo de 4 (quatro) meses da última exodontia dentária.

3.3.2.4 Critérios de Exclusão

Serão excluídos do estudo aqueles que estiverem em uso de insulina, sem condições de equilíbrio para aferição do peso ou alguma outra medida, os portadores de doença renal crônica, doença hepática, SIDA e outras patologias que alteram significativamente a composição corporal.

3.3.2.5 Procedimentos Clínicos

Os indivíduos participantes desta pesquisa, inicialmente serão submetidos a uma anamnese e exame clínico, com preenchimento de Ficha Clínica (Apêndice A) para identificação dos pacientes, perfil sociodemográfico, história médica (confirmando o diagnóstico de DM2), história clínica bucal e odontograma.

Após exame clínico os pacientes serão entrevistados através de questionários específicos sobre qualidade de vida relacionada à saúde bucal (OHIP-14) e Avaliação Nutricional (MAN). Os questionários serão previamente aplicados em um grupo de pacientes com faixa etária similar e se necessário, mudanças serão realizadas para garantir o entendimento do instrumento.

Será solicitado exame de sangue em Laboratório de Análises Clínicas de Referência, para avaliar níveis de Hemoglobina Glicada e Glicemia em jejum. Todos os pacientes receberão orientações nutricionais adequadas.

Nos pacientes dos grupos DIN, DIP e AD (edêntulos parciais < 21 dentes e edêntulos totais sem prótese ou utilizando próteses inadequadas), serão confeccionadas novas próteses dentárias removíveis convencionais por especialista

em Prótese Dentária, e após fase de adaptação (6 e 12 meses), serão aplicados novos questionários e exames laboratoriais, para fins de comparação.

3.3.2.6 Avaliação Nutricional e Controle Glicêmico

O questionário MAN (Anexo A) será aplicado por um pesquisador calibrado, diferente daquele que realizou o exame clínico e anamnese dos pacientes.

Serão utilizados balança portátil e estadiômetro calibrados, para aferição de peso e altura, com cálculo do IMC, e fita métrica, para medir circunferência de braço e panturrilha, que constituem a avaliação antropométrica. Em seguida serão realizadas as avaliações globais, dietéticas e subjetivas, que constam no instrumento de avaliação. Todos os dados serão devidamente anotados pelo examinador e as perguntas serão lidas juntamente com o participante, que escolherá livremente a resposta de cada questão.

Cada item tem um valor que correspondente às aferições realizadas e às respostas do voluntário, somando-se os resultados obtidos em cada quesito, chegando a um número final, o Escore total do MAN, dividindo os seguintes grupos de pacientes:

a) Estado nutricional adequado: MAN>24 pontos;

b) Risco de depleção nutricional, porém com bom prognóstico para intervenção: MAN entre 17 e 23,5 pontos;

c) Os que apresentam subnutrição energético-proteica declarada, ou desnutrido: MAN<17 pontos.

Assim, serão anotados e tabulados os Escores Totais de cada participante, antes (baseline) e depois da confecção das novas próteses dentárias (6 e 12 meses pós tratamento).

Os exames sanguíneos providenciados antes (baseline) e após confecção das próteses dentárias (6 e 12 meses), serão realizados nos mesmos padrões, coletados e analisados no mesmo laboratório, e no mesmo horário, no início da manhã. Os dados obtidos em cada indicador serão anotados em uma planilha específica e analisados se estarão dentro do padrão de normalidade.

Os diabéticos do tipo 2 serão classificados, de acordo com os níveis séricos de hemoglobina glicada (HbA1c): Grupo Controle Glicêmico adequado (HbA1c < 7,0%) e Grupo Controle Glicêmico Inadequado (HbA1c ≥ 7%).

3.3.2.7 Índice de qualidade de vida

O questionário OHIP-14 (Anexo B) também será aplicado por um pesquisador calibrado, diferente daquele que realizou o exame clínico e anamnese dos pacientes. O examinador procederá à leitura de cada pergunta juntamente com o participante, que escolherá livremente a resposta de cada questão, entre cinco opções, conforme a Escala Ordinal de pontuação (sempre: 4 pontos; frequentemente: 3 pontos; às vezes: 2 pontos; raramente: 1 ponto e nunca: 0 ponto), conforme estabelecido pelo autor do questionário (SLADE e SPENCER, 1994).

Posteriormente, os dados serão ordenados e calculado do valor final, em pontos para cada paciente entrevistado. Os valores serão multiplicados pelo peso de cada pergunta conforme tabela 1.

Tabela 1 – Pesos das perguntas do questionário OHIP-14

Pergunta 1: peso = 0,51	**Pergunta 8: peso = 0,48**
Pergunta 2: peso = 0,49	**Pergunta 9: peso = 0,60**
Pergunta 3: peso = 0,34	**Pergunta 10: peso = 0,40**
Pergunta 4: peso = 0,66	**Pergunta 11: peso = 0,62**
Pergunta 5: peso = 0,45	**Pergunta 12: peso = 0,38**
Pergunta 6: peso = 0,55	**Pergunta 13: peso = 0,59**
Pergunta 7: peso = 0,52	**Pergunta 14: peso = 0,41**

Dessa forma, ao somar a pontuação final de todas as perguntas, serão obtidos os valores variando entre 0 e 28 pontos. Quanto mais alto for o total, pior é o impacto da saúde bucal na qualidade de vida, significando que é menos percebida. Os questionários, antes (baseline) e depois da confecção das novas próteses dentárias (6 e 12 meses), serão aplicados e analisados no mesmo padrão e pelo mesmo pesquisador.

3.3.2.8 Treinamento e Calibração

A calibração será realizada para as condições clínicas em avaliação. Antes do início do estudo, o pesquisador será submetido a treinamentos e calibrações e o valor de concordância será calculado através de coeficientes Kappa.

3.3.2.9 Aspectos Éticos, Riscos e Benefícios

Conforme as exigências da resolução 466/2012 do Conselho Nacional de Saúde, o Projeto de Pesquisa foi submetido ao Comitê de Ética em Pesquisa associado ao local de realização do estudo (Unifametro Fortaleza) e aprovado sob parecer nº 3.461.743 (Anexo C). Todos os participantes serão informados sobre os propósitos do estudo e assinarão um Termo de Consentimento Livre e Esclarecido (Apêndice B), quando serão devidamente elucidados com relação aos procedimentos a serem realizados, bem como, seus riscos, benefícios e sigilo de suas identidades.

A realização da pesquisa envolve riscos de aspecto não físico, uma vez que poderá causar constrangimento e/ou desconforto gerado pela aplicação dos questionários, que serão minimizados através do anonimato de sua participação, bem como a sua desistência em qualquer fase da pesquisa. O exame sanguíneo para avaliação de índices glicêmicos pode trazer algum desconforto, mas com o objetivo de garantir uma maior segurança, esta coleta de pequena quantidade de sangue será realizada dentro de um laboratório de análises clínicas de referência, utilizando-se de instrumentais estéreis para a coleta e será realizada por uma equipe especializada e capacitada. O exame odontológico e caso seja necessário, a confecção de próteses dentárias, não implicarão em riscos diretos à saúde dos participantes, pois o exame clínico e o tratamento a que será submetido é um procedimento odontológico de rotina e bem estabelecido, realizado com instrumentais devidamente esterilizados.

O estudo apresenta como benefícios a detecção de doenças bucais e alterações periodontais existentes, e quando necessário, o paciente receberá orientações sobre as doenças e o tratamento, além do encaminhamento para confecção de próteses dentárias. A pesquisa também contribuirá para um estudo

científico que poderá evidenciar a necessidade de avanços no planejamento dos serviços de saúde bucal, concentrando esforços na prevenção da perda dentária.

3.3.2.10 Análise Estatística

Será realizada análise descritiva dos dados com as estimativas de média e desvio padrão para as variáveis quantitativas. As comparações entre as estimativas de médias entre os grupos serão realizadas por Análise de Variância (ANOVA), para identificar se a distribuição de pelo menos um dos grupos se difere dos demais, e para determinar entre quais grupos a diferença é significativa, será utilizado o Teste de Tukey. Para o desfecho avaliação nutricional será utilizado uma regressão linear múltipla. Em todos os testes será adotado um nível de significância de 95% ($p<0,05$).

3.4 Orçamento

Especificação do material	Quantidade/unidade	Valor R$
Folha A4	02 resmas	50,00
Caneta esferográfica	05	25,00
Cartuchos de Tinta	10	800,00
Balança portátil	01	80,00
Estadiômetro	01	300,00
Fita métrica	01	20,00
Kit Exame clínico	10	1000,00
Total	-	**2.275,00**

Financiado com recursos dos próprios pesquisadores.

3.5 Cronograma de Atividades

Atividades	MÊS/ANO																								
	JUN/2019	JUL/2019	AGO/2019	SET/2019	OUT/2019	NOV/2019	DEZ/2019	JAN/2020	FEV/2020	MAR/2020	ABR/2020	MAIO/2020	JUN/2020	JUL/2020	AGO/2020	SET/2020	OUT/2020	NOV/2020	DEZ/2020	JAN/2021	FEV/2021	MAR/2021	ABR/2021	MAIO/2021	JUN/2021	JUL/2021
Levantamento Bibliográfico	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Submissão ao Comitê de Ética em Pesquisa (CEP)	X																									
Qualificação do Projeto					X																					
Revisão Sistemática 1					X	X	X	X																		
Revisão Sistemática 2									X	X	X	X														
Calibração do examinador	X	X																								
Triagem, seleção, exame dos pacientes e aplicação dos questionários		X	X	X	X	X	X	X	X	X	X	X	X													
Reabilitação oral dos pacientes com próteses dentárias		X	X	X	X	X	X	X	X	X	X	X	X													
Qualificação do Projeto de Tese					X																					
Análise e avaliação dos resultados						X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Reavaliação dos pacientes								X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Redação do trabalho							X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Apresentação de resultados parciais em encontros e congressos										X	X	X	X	X	X	X	X	X	X	X						
Preparação da Tese e de artigos para publicação															X	X	X	X	X	X	X	X	X	X	X	
Defesa da Tese, Relatório de retorno à instituição de pesquisa e ao CEP																										X

4 Relatório do trabalho de campo

O estudo clínico foi aprovado pelo Comitê de Ética em Pesquisa do Centro Universitário Fametro – UNIFAMERO, sob o parecer nº 3.461.743 (Anexo C).

O projeto de pesquisa foi devidamente qualificado em 17 de outubro de 2019, perante Banca Examinadora composta pelos seguintes membros: Prof. Dr. Rafael Guerra Lund, Profa. Dra. Fernanda Faot e Prof. Dr. Mateus Bertolini Fernandes dos Santos. Após a qualificação e diante das contribuições dos professores da banca, foi sugerido avaliar um único grupo de pacientes, uma vez que a divisão em vários grupos, conforme descrito no projeto inicial, dificultaria obter uma amostra adequada, no tempo estabelecido.

Com a pandemia de COVID-19, além de acatarmos a realização do estudo em um único grupo de pacientes, foi necessário modificar o período de reavaliação dos pacientes para 12 meses após instalação e ajuste das próteses dentárias, que antes estava programado para 6 e 12 meses.

Três estudos foram realizados, segundo consta no projeto da presente tese, sendo duas revisões sistemáticas e um estudo clínico prospectivo. A primeira etapa foi providenciar avaliação e tratamento dos pacientes selecionados para o estudo clínico. O principal obstáculo encontrado foi confirmar o diagnóstico de DM2, pois alguns pacientes relatavam ter diagnóstico de diabetes, mas não portavam os resultados dos exames, o que foi solucionado solicitando o último exame sanguíneo realizado ou, quando necessário, foi pedido novos exames. Outra dificuldade foi convencer os pacientes, idosos e com diabetes, a retornarem para a reavaliação após 1 ano, pois faziam parte do grupo de risco à infecção do COVID-19. Com início da vacinação e a necessidade de também retornarem para acompanhamento médico, aos poucos foi possível examinar a maioria dos pacientes selecionados no estudo.

As revisões sistemáticas foram realizadas ao longo de 2021, paralelamente às análises do estudo clínico.

O presente trabalho está apresentado de acordo com o nível de descrição em artigos, previsto no Manual de normas UFPel para trabalhos acadêmicos da Universidade Federal de Pelotas (2019), disponível no seguinte endereço eletrônico: https://wp.ufpel.edu.br/sisbi/files/2019/06/Manual.pdf

5 Artigo 1

The effect of prosthetic rehabilitation with or without dietary advice on nutritional status: a systematic review

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CONFLICT OF INTEREST
The authors have no conflicts of interest to declare.

Este artigo foi redigido seguindo as normas do periódico Gerodontology.

Abstract

Objective: To investigate the influence of prosthodontic rehabilitation combinates or not with dietary advice on nutritional status in elderly patients.

Background: Elderly people frequently report tooth loss, affecting their nutritional status. There is a gap in the scientific evidence about the influence of prosthodontic rehabilitation on nutritional status.

Methods: An electronic search was conducted in Pubmed/MEDLINE, Web of Science, and Cochrane databases to identify randomized clinical trials that evaluated the effect of prosthetic rehabilitation with and without providing dietary advice on nutritional status in subjects aged 60 years or older, with a follow-up of at least 1 month after prosthesis rehabilitation.

Results: Of the 1,098 articles identified in the initial search, 12 were selected for the final review. No significant difference between the types of prosthesis were found regarding the chewing by the elderly population. Although patients who received prosthetic treatment had significant improvement in chewing ability, a consistent pattern of improvement in nutritional status was not observed when they did not receive dietary advice. In addition, the association between the condition of the dentition, the masticatory performance and nutritional change of elderly patients has been found, especially when the MNA questionnaire was used as an assessment tool. Studies that evaluated simultaneous complete denture treatment and simple dietary advice in pamphlet form showed an improvement of nutrient intake in edentulous elderly patients.

Conclusions: Isolated prosthetic rehabilitation may not have the effect of exerting a change in nutritional status of edentulous elderly patients. In general, simultaneous dietary consulting and prosthetic treatment in combination may improve dietary habits, since masticatory capacity and efficiency are not the only factors that influence the nutritional status of a patient.

Key words: Elderly, Prosthetic Dentistry, Nutritional Status, systematic review

Introduction

Aging is a dynamic process in which progressive changes occur in the body, making it more susceptible to intrinsic aggressions, which can be classified as inherent to the functioning of the body itself, and extrinsic, which are defined as environmental influences, increasing exponentially the appearance of chronic diseases.[1,2] In this process, masticatory function can be impaired by reduced number of teeth[3,4] and the high prevalence rates of tooth loss, indicate a great need for prosthetic rehabilitation in elderly.[5]

Partial or total edentulism can affect nutritional status, especially protein intake. Nutrient consumption tends to decrease with ageing, and one of the causes could be poor oral health status.[6,7] Tooth loss is associated with chewing impairment, and edentulous individuals consume significantly lower amounts of nutrient-rich foods such as vegetables, fruits, meat, and whole grains.[8] Elderly people frequently report tooth loss, which can lead to avoid consumption of a number of food types that require rigorous mastication, affecting their dietary intake and nutritional status, and consequently affecting general health and the quality of life.[3,9,10] Thus, the edentulous have high intakes of saturated fat and cholesterol compared with similar dentate individuals.[11] The concern to understand the changes that occur in the organism with ageing, as well as in the stomatognathic system, comes to be more and more frequent, as the significant increase in life expectancy of the human population becomes evident.[12]

Previous research has shown that, in many cases, isolated prosthodontic rehabilitation, such as complete dentures, implant overdentures, removable partial dentures, does not result in a positive dietary change.[11] The evaluation of patients' nutritional status should be considered as a part of an overall plan for oral health

care.[13,14] The absence of tailored dietary counseling may be inadequate to attain a significant improvement on nutritional status in elderly patients.[15] Kossioni[4] reported that prosthetic oral rehabilitation associated with personalized nutritional counseling could improve the nutritional status of patients.

There is a gap in the scientific evidence about the influence of prosthodontic rehabilitation on nutritional status in elderly people. Thus, this systematic review aimed to investigate the influence of prosthodontic rehabilitation with or without dietary advice on nutritional status in elderly patients.

Material and methods

Eligibility criteria and Information sources

The present study is reported according to the guidelines of the PRISMA statement for conducting a systematic review.[16] The review protocol was prospectively submitted to PROSPERO International Prospective Register of Systematic Reviews for registration (CRD42020200475).

Table 1 reports inclusion criteria for participants, interventions, comparisons, outcomes and study design (PICOS). The focused question according to the PICO schema is: “Does prosthodontic rehabilitation with or without dietary advice improve nutritional status in elderly patients?”

Before starting the study, inclusion and exclusion criteria were established. The following inclusion criteria were applied: (1) randomized clinical trials, that evaluated the effect of prosthetic rehabilitation with and without providing dietary advice on nutritional status; (2) patients aged 60 years and older; (3) treatment involving prosthetic rehabilitation with complete dentures, implant overdentures, removable or fixed partial dentures and dietary advice; and (4) follow-up of at least 1

month after prosthesis rehabilitation. The following were exclusion criteria: (1) case series or case reports, editorial letters, reviews, and unpublished data; (2) experimental laboratory studies; and (3) animal studies.

Search Strategy and Selection process

The PubMed/MEDLINE, Web of Science, and Cochrane Library databases were electronically used to identify articles published until August 2021 utilizing the keywords of different combinations (Table 2). In addition, a hand search of reference lists of relevant articles from the electronic searches was made.

The titles and abstracts of all reports identified through the electronic searches were read independently by 2 authors (JAB and WLOR). Initially, all titles were screened to eliminate nonrelated publications and reviews. Then, all selected abstracts were analyzed and the full-text articles were consequently retrieved, and selected articles were analyzed. In case of a disagreement, a third reviewer (RGL) was consulted to resolve any doubt about whether an article should be included or not.

Data collection process and Data items

A standardized data extraction form was developed in Microsoft Excel to tabulate data relevant to the research focus. The following information was independently extracted from each study by the two authors: primary author, publication year, publication country, objective, patients' age, sample size, follow-up/observation period, type of prosthetic rehabilitation, nutritional outcomes, and synopsis of clinical outcomes.

The primary outcome was the influence of prosthodontic rehabilitation on nutritional status in elderly patients. Secondary outcome was to explore the combined effect of prosthetic treatment and simple dietary advice on nutritional status.

Study risk of bias assessment

Risk of bias assessment was performed using Revised Cochrane risk of bias tool for randomized trials (RoB 2), considering the judgment of the bias arising from the randomization process, bias due to deviations from intended intervention, bias due to missing outcome data, bias in measurement of the outcome, and bias in selection of the reported result.[17]

Results

Initially, the search queries identified a total of 1,098 studies from the three electronic databases of PubMed/MEDLINE, Web of Science, and Cochrane Library. After excluding 41 articles because of duplication, the remaining (1,057) articles were screened based on the pre-set eligibility criteria. Then, after reviewing the titles and abstracts, 994 articles were found irrelevant for this review in terms of outcome of interest, thus leaving 63 articles for eligibility assessment. A final total of 12 relevant articles were included in the systematic review for data extraction. The flow diagram of the entire searching processes of the original studies for this review is shown in Figure 1.

The characteristics of the included studies are presented in Table 3. These studies were performed between 2003 and 2019. All of the patients included in the studies received prosthetic rehabilitation of complete dentures, removable partial

dentures, resin bonded bridgework, or implant overdenture. The number of patients in the sample of the included studies ranged from 22 to 128, and their mean age ranged from 65 to 85 years.

Regarding the nutritional status, four studies used complete MNA, one applied MNA-SF, three used brief-type self-administered diet history questionnaire, one applied 24-hour dietary recalls, and three evaluated some biochemical markers of nutritional status.

Four RCTs studies[25,26,28,29]investigated changes in nutrient intake and/or markers of nutritional status after intervention with mandibular implant supported by overdenture treatment or complete dentures. Although patients who received prosthetic treatment had significant improvement in chewing ability, a consistent pattern of improvement in nutritional status was not observed. Four RCTs studies[21,23,24,27] investigated changes in nutrient intake and/or markers of nutritional status after intervention with a prosthetic treatment with cobalt-chromium removable partial prostheses or shortened dental arch using adhesive bridgework. There was no significant difference in the increase in masticatory function for both treatment groups. Enhanced masticatory performance does not signify improved nutritional status. Four RCTs studies[18-20,22] investigated the combined effect of complete denture renewal and simple dietary advice on food intake among elderly edentulous patients who requested new complete dentures (Table 4). Simple dietary advice using a uniform pamphlet in addition to new complete dentures fabrication increased the nutrient intake of edentulous elderly. Most of the included studies showed a high risk of bias (Figure 2).

Discussion

This systematic review aimed to investigate the influence of prosthetic rehabilitation with or without dietary advice on nutritional status in elderly patients. Our review supports that isolated prosthetic rehabilitation may not have the effect of exerting a change in nutritional status of edentulous elderly patients. In general, studies found that simultaneous dietary consulting and prosthetic treatment in combination may improve dietary habits, since masticatory capacity and efficiency are not the only factors that influence the nutritional status of a patient.

The oldest studies related to the theme sought to investigate whether there was a difference between removable prostheses, especially complete dentures, and overdentures, in the quality of masticatory capacity and, consequently, in the improvement of the nutritional profile. The four selected studies that investigated the influence of complete dentures and overdentures on the nutrient intake by elderly patients[25,26,28,29]showed that there is no significant difference between the types of prosthesis in chewing ability by the elderly population. Then, implant overdentures do not have a more positive effect on the nutritional state of elderly edentate individuals than complete dentures, when evaluated before and after treatment, although overdentures can improve the intake of some types of food and promote greater quality of life and overall satisfaction.

In some studies,[23,27,29] the association between use or need of prostheses, the masticatory performance and nutritional change of elderly patients has been found, especially when the MNA questionnaire was used as an assessment tool. Other studies[25,26,28] have found no association, especially when hematological biochemical markers were used. One study[21] observed that masticatory performance may only have minor associations with nutritional status, and other study[24] found that the only

measure which illustrated consistent significant improvements in nutritional status for either group were Vitamin D levels. There are two possible reasons which explain the inconsistent findings in the association between prosthetic treatment and nutritional status. One is that nutritional intake is complex and not solely determined by dental status.[13] Another is that the effect of prosthetic treatments may have been reduced by the fact that the participants are over 60 years old, and the biological and physiological factors have had a more significant impact on the diet of this population, that is, factors related to aging may overlap with prosthetic rehabilitation benefits.[18]

It is possible that the types of prostheses have an influence on the nutritional profile in a short period of time and that a nutritional orientation associated with the recommendations of posterior control of the prosthesis could prolong this benefit. Then, the focus of the selected studies, which previously was to compare the types of prosthetic rehabilitation and check which would be more effective in interfering with changes in nutritional habits, changed to investigate whether the manufacture of dental prosthesis associated with basic nutritional guidance would present more promising results.

The study of Amagai et al.[22] was a pioneer in observing that a nutritional guidance associated with oral prosthetic rehabilitation could improve the food intake of edentulous patients. A protocol for a randomized clinical trial was proposed to investigate the effect of a simultaneous combination of simple dietary advice provided by dentists and the provision of new complete dentures on the food intake of edentulous individuals.[15] Based on the protocol, several studies were carried out and it was possible to observe that the production of a new prosthesis with simple dietary advice can improve nutrient intake in edentulous elderly patients, but the

effect is likely to be short-term, requiring these patients to be constantly stimulated to continue following the nutritional guidelines and use of dental prostheses.

The main limitation of this study was that a small number of randomized clinical trials was found, mainly associating dental prostheses and dietary advice. Second, the data were derived from studies that used different screening tools. There was no standardization of data collection instruments. Some studies carried out research the assessment of the nutritional status using the Mini Nutritional Assessment short-form (MNA-SF), others used a brieftype self-administered diet history questionnaire (BDHQ), and other studies used haematological samples which were screened for biochemical markers of nutritional status, and 24-hour dietary recalls. Third, the studies used different follow-up periods, ranging from 1 to 12 months. Finally, many studies were conducted in different countries, preventing generalization of the results, since the chewing process and choice of diet can be influenced by cultural issues. The quality of the included studies varied. Random sequence generation was adequately conducted in majority RCTs but four of the studies did not report or conduct allocation concealment appropriately.

The simple dietary advice that can be implemented by a dentist is more practical and facilitates that guidance is provided when installing the dental prosthesis. It is necessary that dentists know these basic guidelines and understand the importance of motivating the elderly in return visits. More intervention studies are necessary to elucidate the association between prosthodontic rehabilitation in nutrient intake in elderly patients. It is important to have studies with a longer follow-up period, so that the patient has a better adaptation of the prosthetic rehabilitation, especially for those patients who have never used dental prosthesis. It is also necessary to evaluate the effect of isolated simple dietary advice in the absence of

provision of complete dentures. Also, a longer follow-up may help to establish whether the improvement in nutritional status persists over the years, and what would be the necessary frequency of return of elderly people so that the stimulus to maintain the guidelines continues to promote benefit. Finally, the follow-up of a nutritionist, with more in-depth guidance, is important for elderly patients who have lost their teeth, as they are at greater risk of malnutrition.

Conclusion

Isolated prosthetic rehabilitation may not have the effect of exerting a change in nutritional status of edentulous elderly patients. In general, simultaneous dietary consulting and prosthetic treatment in combination may improve dietary habits, since masticatory capacity and efficiency are not the only factors that influence the nutritional status of a patient.

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Table 1. Participants, interventions, comparisons, outcomes and study design (PICOS) used to systematically review randomized controlled trials for prosthetic rehabilitation with or without dietary advice on nutritional status of elderly people.

Participants	Elderly people (60 years and older)
Interventions	Intervention with prosthetic rehabilitation and dietary advice
Comparisons	Complete dentures with or without dietary advice; removable partial dental prostheses or resin Bonded Bridgework; complete dentures or implant overdenture
Outcomes	Nutritional status
Study design	Randomized controlled trials

Table 2. Electronic search strategies.

PubMed
#1: (Elderly) OR (Aged) OR (Dental Care for Aged) OR (Dentistry for Aged) OR (Aged, Dentistry for) OR (Dental Care for Elderly) #2: (Denture) OR (Denture, Partial, Removable) OR (Removable Partial Denture) OR (Denture, Removable Partial) OR (Dentures, Removable Partial) OR (Partial Denture, Removable) OR (Partial Dentures, Removable) OR (Removable Partial Dentures) OR (Denture, Partial, Fixed) OR (Fixed Bridge) OR (Bridge, Fixed) OR (Bridges, Fixed) OR (Fixed Bridges) OR (Fixed Partial Denture) OR (Denture, Fixed Partial) OR (Dentures, Fixed Partial) OR (Fixed Partial Dentures) OR (Partial Denture, Fixed) OR (Partial Dentures, Fixed Pontic) OR (Pontics) OR (Denture, Complete) OR (Complete Denture) OR (Complete Dentures) OR (Dentures, Complete) OR (Dental Prosthesis) OR (Prosthesis, Dental) OR (Dental Prostheses) OR (Prostheses, Dental) OR (Dental Prosthesis, Implant-Supported) OR (Dental Prosthesis, Implant Supported) OR (Implant-Supported Dental Prosthesis) OR (Dental Prostheses, Implant-Supported) OR (Implant Supported Dental Prosthesis) OR (Implant-Supported Dental Prostheses) OR (Prostheses, Implant-Supported Dental) OR (Prosthesis, Implant-Supported Dental) OR (Denture, Implant-Supported) OR (Denture, Implant Supported) OR (Implant-Supported Denture) OR (Dentures, Implant-Supported) OR (Implant Supported Denture) OR (Implant-Supported Dentures) OR (Prosthesis Dental, Implant-Supported) OR (Dental, Implant-Supported Prosthesis) OR (Dentals, Implant-Supported Prosthesis) OR (Implant-Supported Prosthesis Dental) OR (Implant-Supported Prosthesis Dentals) OR (Prosthesis Dental, Implant Supported) OR (Prosthesis Dentals, Implant-Supported) OR (Prosthodontics) OR (Dentistry, Prosthetic) OR (Prosthetic Dentistry) #3: (Nutrition) OR (Nutritional Status) OR (Status, Nutritional) OR (Nutrition Status) OR (Status, Nutrition) OR (Malnutrition) OR (Nutritional Deficiency) OR (Nutritional Deficiencies) OR (Undernutrition) OR (Malnourishment) OR (Malnourishments) OR (Obesity) OR (nutrient intake) OR (Food Intake) OR (Intake, Food) OR (Ingestion) #4: (Randomized Controlled Trials as Topic) OR (Randomized Controlled Trials as Topic) OR (Controlled Clinical Trials, Randomized) OR (Clinical Trials, Randomized) OR (Trials, Randomized Clinical) OR (Randomized Controlled Trial) OR (Randomized clinical trial) **OR (**((clinical[Title/Abstract] AND trial[Title/Abstract]) OR clinical trials as topic[MeSH Terms] OR clinical trial[Publication Type] OR random*[Title/Abstract] OR random allocation[MeSH Terms] OR therapeutic use[MeSH Subheading])) OR ((randomized controlled trial[Publication Type] OR (randomized[Title/Abstract] AND controlled[Title/Abstract] AND trial[Title/Abstract]))) #1 AND #2 AND #3 AND #4
Web of Science
#1: TS=((Elderly) OR (Aged) OR (Dental Care for Aged) OR (Dentistry for Aged) OR (Aged, Dentistry for) OR (Dental Care for Elderly)) #2:TS=((Denture) OR (Denture, Partial, Removable) OR (Removable Partial Denture) OR (Denture, Removable Partial) OR (Dentures, Removable Partial) OR (Partial Denture, Removable) OR (Partial Dentures, Removable) OR (Removable Partial Dentures) OR (Denture, Partial, Fixed) OR (Fixed Bridge) OR (Bridge, Fixed) OR (Bridges, Fixed) OR (Fixed Bridges) OR (Fixed Partial Denture) OR (Denture, Fixed Partial) OR (Dentures, Fixed Partial) OR (Fixed Partial Dentures) OR (Partial Denture, Fixed) OR (Partial Dentures, Fixed Pontic) OR (Pontics) OR (Denture, Complete) OR (Complete Denture) OR (Complete Dentures) OR (Dentures, Complete) OR (Dental Prosthesis) OR (Prosthesis, Dental) OR (Dental Prostheses) OR (Prostheses, Dental) OR (Dental Prosthesis, Implant-Supported) OR (Dental Prosthesis, Implant Supported)) #3:TS=((Nutrition) OR (Nutritional Status) OR (Status, Nutritional) OR (Nutrition Status) OR (Status, Nutrition) OR (Malnutrition) OR (Nutritional Deficiency) OR (Nutritional Deficiencies) OR (Undernutrition) OR (Malnourishment) OR (Malnourishments) OR (Obesity) OR (nutrient intake) OR (Food Intake) OR (Intake, Food) OR (Ingestion)) #4: TS=((Randomized Controlled Trials as Topic) OR (Randomized Controlled Trials as Topic) OR (Controlled Clinical Trials, Randomized) OR (Clinical Trials, Randomized) OR (Trials, Randomized Clinical) OR (Randomized Controlled Trial) OR (Randomized clinical trial)) #1 AND #2 AND #3 AND #4
Cochrane Library
#1: (Elderly) OR (Aged) OR (Dental Care for Aged) OR (Dentistry for Aged) OR (Aged, Dentistry for) OR (Dental Care for Elderly) #2:(Denture) OR (Denture, Partial, Removable) OR (Removable Partial Denture) OR (Denture, Removable Partial) OR (Dentures, Removable Partial) OR (Partial Denture, Removable) OR (Partial Dentures, Removable) OR (Removable Partial Dentures) OR (Denture, Partial, Fixed) OR (Fixed Bridge) OR (Bridge, Fixed) OR (Bridges, Fixed) OR (Fixed Bridges) OR (Fixed Partial Denture) OR (Denture, Fixed Partial) OR (Dentures, Fixed Partial) OR (Fixed Partial Dentures) OR (Partial Denture, Fixed) OR (Partial Dentures, Fixed Pontic) OR (Pontics) OR (Denture, Complete) OR (Complete Denture) OR (Complete Dentures) OR (Dentures, Complete) OR (Dental Prosthesis) OR (Prosthesis, Dental) OR (Dental Prostheses) OR (Prostheses, Dental) OR (Dental Prosthesis, Implant-Supported) OR (Dental Prosthesis, Implant Supported) #3: (Nutrition) OR (Nutritional Status) OR (Status, Nutritional) OR (Nutrition Status) OR (Status, Nutrition) OR (Malnutrition) OR (Nutritional Deficiency) OR (Nutritional Deficiencies) OR (Undernutrition) OR (Malnourishment) OR (Malnourishments) OR (Obesity) OR (nutrient intake) OR (Food Intake) OR (Intake, Food) OR (Ingestion) #1 AND #2 AND #3

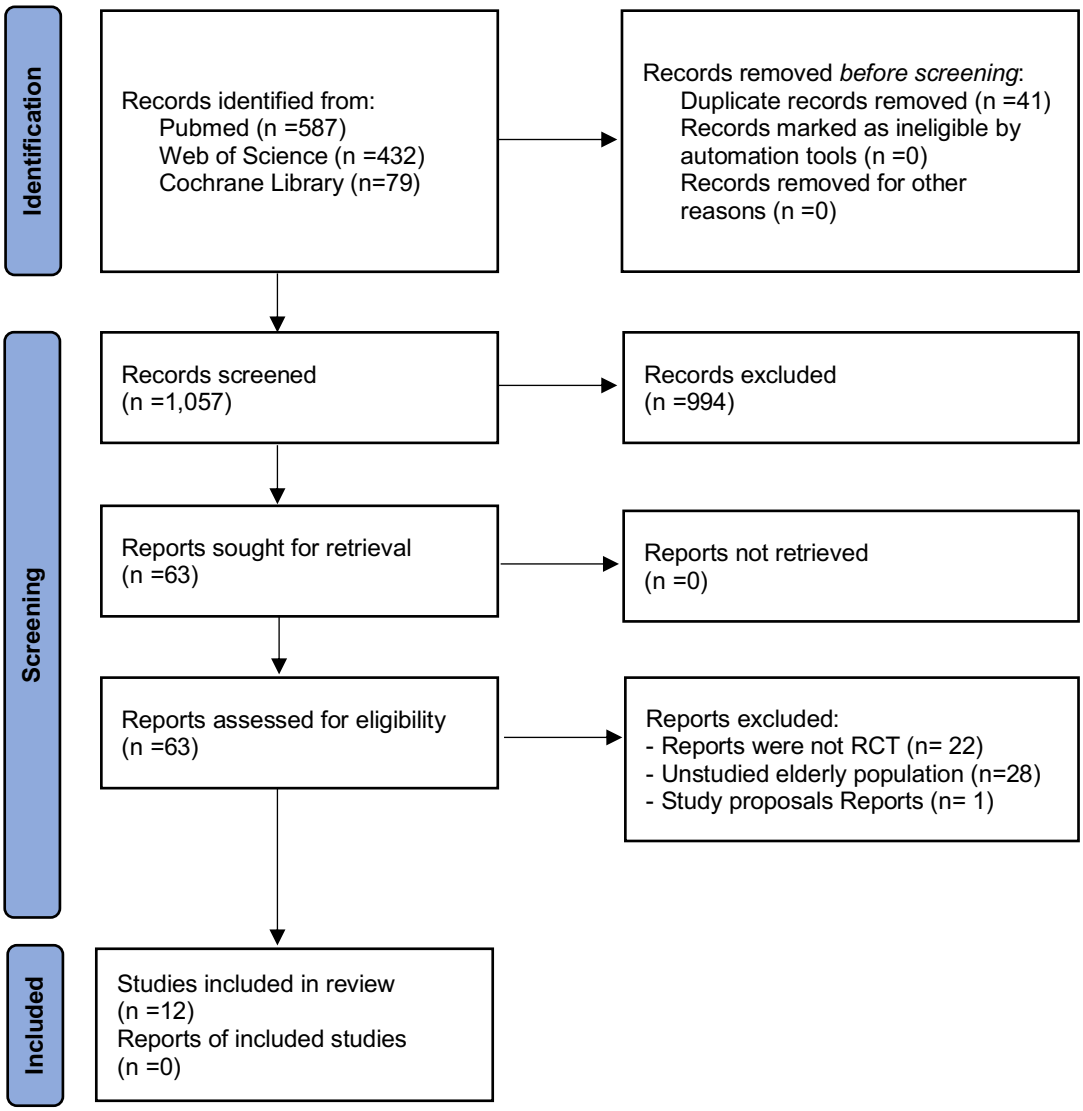

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram for prosthetic rehabilitation with or without dietary advice in randomized controlled trials regarding nutritional status.

Table 3. Description of the randomized clinical trials included in the systematic review.

Study	**Publication Country**	**Aim of study**	**Number of Patients (Available for follow up)** **Intervention group** **Control group**	**Age (Years)**	**Follow-up**	**Inclusion criteria for the study subjects**
Suzuki et al., 2019[18]	Japan	To clarify the combined effect on the nutritional statuses of edentulous elderly patients, of dentists providing new CD with simple dietary advice.	35 (29) 35(30)	Mean age 76.7	3 and 6 months after treatment	At least 1 year after becoming edentulous, regardless of the existence of a stump, able to attend the hospital unaided; able to understand Japanese; and able to understand and respond to questionnaires.
Kanazawa et al., 2019[19]	Japan	To evaluate the combined effects of a new CD fabrication and simple dietary advice provided by dentists using unique pamphlets on nutrient intake in edentulous elderly patients.	35 (29) 35 (30)	Mean age 76.7	Pretreatment and 3- and 6-months post-treatment	More than 1 year of being edentulous, regardless of the presence of a tooth stump, visit the institution by themselves, those who could understand, write, and speak Japanese; and those who could understand and respond to questionnaires.
Suzuki et al., 2018[20]	Japan	To clarify the combined effect of new CD fabrication and simple dietary advice using a uniform pamphlet on the nutrient intake and masticatory function of elderly edentulous.	35 (31) 35 (31)	Mean age 77.0	3 months post-treatment	More than 1 year of being edentulous, regardless of the presence of a stump, visit the institution by themselves, who could understand written and spoken Japanese, understand and respond to questionnaires.
Wallace et al., 2018[21]	Ireland	To compare the impact of two tooth replacement strategies for partially dentate older patients on masticatory performance and nutritional status.	65 (44) 67 (45)	65 years and older	Baseline (pre-treatment) and 12 months post-treatment intervention	Aged 65 years and older, minimum of six remaining sound natural teeth in either arch, seeking replacement for missing natural teeth, ability to accept routine dental care in a dental chair; no medical conditions which could prevent routine dental treatment.

Amagai et al., 2017[22]	Japan	To investigate the combined effect of CD renewal and simple dietary advice on food intake.	35 (31) 35 (31)	Mean age 77.0	Baseline and 3 months after the final denture adjustment.	Edentulous, sought replacement of their dentures due to dental issues, able to visit the hospital unassisted, able to understand written and spoken Japanese, and respond to a questionnaire.
McKenna et al., 2015[23]	Ireland	To compare the impact of two different tooth replacement strategies on the nutritional status of partially dentate older patients.	64 (44) 66 (45)	Mean age 70.1	Baseline and 1, 6 and 12 months after treatment intervention	Seeking replacement of missing natural teeth, had a minimum of eight remaining natural teeth in either arch of good prognosis, accept routine dental care in a dental chair, could communicate in English and no medical conditions which precluded routine dental treatment.
McKenna et al., 2014[24]	Ireland	To conduct a randomized controlled clinical trial of partially dentate older adults comparing functionally orientated treatment based on the SDA concept with conventional treatment using RPDP to replace missing natural teeth.	64 (44) 66 (45)	Mean age 70.1	Baseline (pre-treatment), 1 month, 6 months and 12 months after treatment intervention	Seeking replacement of missing natural teeth, accept routine dental care in a dental chair, communicate in English, no medical conditions which precluded routine dental treatment, a minimum of 6 sound remaining natural teeth in either arch in any position.
Hamdan et al., 2013[25]	Canada	To assess the effects of mandibular two-IOD on the nutritional status of edentate elders.	127 (103) 128 (114)	Mean age 69.7	Baseline and 12 months after prosthesis delivery	Men and women (≥ 65 years) who had been edentate for a minimum of 5 years, adequate understanding of written and spoken English or French, as well as willingness and ability to understand the protocol and to give informed consent.
Müller et al., 2013[26]	Switzerland	To investigate denture satisfaction following the conversion of existing mandibular CD to IOD in very old edentulous patients who depend on help for activities of	23 (16) 22 (18)	Mean age 85.0	Baseline, 3 and 12 months follow-up	Inclusion criteria comprised an age of 75 years or older and living institutionalized or receiving help for activities of daily living as assessed with the Instrumental Activities of

		daily living.				Daily Living Scale dress and feed oneself, edentulous and wear CD.
McKenna et al. 2012[27]	Ireland	To investigate the impact of tooth replacement on the nutritional status for conventional treatment using RPDP and functionally orientated treatment based on the SDA.	21 (21) 23 (23)	Mean age 68.2	Baseline and 1 month after treatment	Aged 65 years and older, had a minimum of six remaining natural teeth in one arch, no evidence of dementia, were able to have routine treatment in a dental chair and could communicate in the English language.
Awad et al., 2012[28]	Canada	To determine whether providing simple mandibular IOD to elderly individuals would give them a significantly better nutritional profile than those who receive CD.	127 (110) 128 (109)	65 years and older	Baseline, 6 and 12 months follow-up	Males and females, 65+ years of age, edentate for a minimum of 5 years, wish to replace their existing CD, adequate understanding of written and spoken English or French, and willing and able to understand the protocol and give informed consent.
Morais et al., 2003[29]	Canada	To teste for post-treatment differences in nutritional status between patients with mandibular two IOD and those with CD.	30 (29) 30 (27)	Ages 65-75	Before and after 6 months of treatment	Males and females, age 65-75 years, complete edentulism for > 5 years, patient wants replacement of existing CD, ability to understand and respond to the scales used, willingness to accept and give informed consent.

CD (complete denture); RPDP (removable partial dental prostheses); SDA (shortened dental arch); IOD (implant overdenture).

Table 4. Intervention, markers of nutritional status, follow-up/observational period and synopsis of clinical results for the selected studies.

Study	Intervention group	Control group	Markers of nutritional status	Synopsis of Results
Suzuki et al., 2019[18]	New CD + simple dietary advice	New CD + denture care advice	MNA-SF	At 6 months after treatment, the MNA-SF score in the intervention group was significantly higher than that in the control group. Comparing the within-group changes in the MNA-SF score revealed that the score increased significantly from 3 to 6 months in the intervention group.
Kanazawa et al., 2019[19]	New CD + dietary advice	New CD + denture care advice	BDHQ + intake of energy, lipids, carbohydrates, minerals, and vitamins	At 3 months post-treatment, the intake of several nutrients was significantly higher in the intervention group than the control group, whereas at 6 months post-treatment, plant protein intake was significantly higher in the intervention group, and animal protein and vitamin B12 intakes were significantly higher in the control group.
Suzuki et al., 2018[20]	New CD + dietary advice	New CD + denture care advice	BDHQ	The new CD fabrication enabled the recover some degree of masticatory function of independent edentulous elderly. To improve nutrient intake of the edentulous elderly, new CD fabrication alone was not enough and may need one-on-one simple dietary advice given by the dentist who orally explained the contents of the uniform pamphlet.
Wallace et al., 2018[21]	RPDP	SDA group - RBB	MNA	Although the number of occluding antagonist pairs of teeth was significantly higher in patients with RPDP, there was no significant difference in the increase in masticatory function compared to patients restored to a SDA. The study results illustrate that nutritional status is not consistently associated with masticatory function based on linear regression models.
Amagai et al., 2017[22]	New CD + simple dietary advice	New CD + denture care advice	BDHQ	At baseline, there was no significant difference in the food intake between the two groups. At the 3-month assessment, the intervention group showed significantly greater intake of chicken, fish with bones, and carrots and pumpkins compared to the control group.
McKenna et al., 2015[23]	RPDP	SDA group - RBB	MNA + MNA-SF	For MNA, there was a mean increase of 0.15 points at 6 months and a further increase of 0.19 points at 12 months. These increases were similar within the treatment groups. For MNA-SF, the analysis showed that there were no significant differences recorded over the data collection points after

				treatment intervention.
McKenna et al., 2014[24]	RPDP	SDA group - RBB	Biochemical markers of nutritional status	For Vitamin D there was a significant difference between levels recorded at post-operative timepoints after treatment intervention (increase of 7% at 6 months compared to baseline). There was no further change in recorded levels at 12 months and these increases were similar within the two treatment groups.
Hamdan et al., 2013[25]	Maxillary CD + mandibular IOD	Maxillary CD + mandibular CD	Three 24-hour dietary were collected through telephone interviews	No significant between-group differences were found. No evidence of nutritional advantages for independently living medically healthy edentate elders wearing two implant mandibular overdentures over those wearing CD in their dietary intake at one year following prosthesis delivery.
Müller et al., 2013[26]	Mandibular IOD	Conventional reline of lower CD	Body mass index (kg/m^2) + MNA + Blood markers (hemoglobin, albumin, folic acid, vitamin B12, and C-reactive protein)	Body mass index decreased in both groups, but the decline tended to be smaller in the intervention group; blood markers and the MNA did not confirm this tendency.
McKenna et al. 2012[27]	RPDP	RBB	MNA + Haematological biomarkers	As the number of contacts increased, MNA scores, in addition to vitamin B12, serum folate and total lymphocyte count, also increased. After treatment intervention, the only measure of nutritional status that showed a statistically significant improvement for both treatment groups were MNA score.
Awad et al., 2012[28]	Maxillary CD and mandibular IOD	Maxillary and mandibular CD	Blood serum concentration of homocysteine, folate, vitamin B6, vitamin B12, C-reactive protein, and albumin	A decline of folate from baseline values in both study groups, as well as those of vitamins B6 and B12 and albumin, was observed. Significant between-group differences were detected in food preparation and in the individuals' ability to chew a variety of foods.
Morais et al., 2003[29]	Mandibular IOD	Mandibular CD	Anthropometric Data, Blood Nutrient Concentrations, and Dietary Assessment	Significant improvements in anthropometric parameters were detected in the IOD but not in the CD group. Significant increases were seen in concentrations of serum albumin, hemoglobin, and B12. No significant between group differences were found.

CD (complete denture); RPDP (removable partial dental prostheses); SDA-group (shortened dental arch); IOD (implant overdenture); RBB (Resin Bonded Bridgework); MNA (Mini Nutritional Assessment); MNA-SF (Mini Nutritional Assessment short-form); BDHQ (Brieftype self-administered diet history questionnaire).

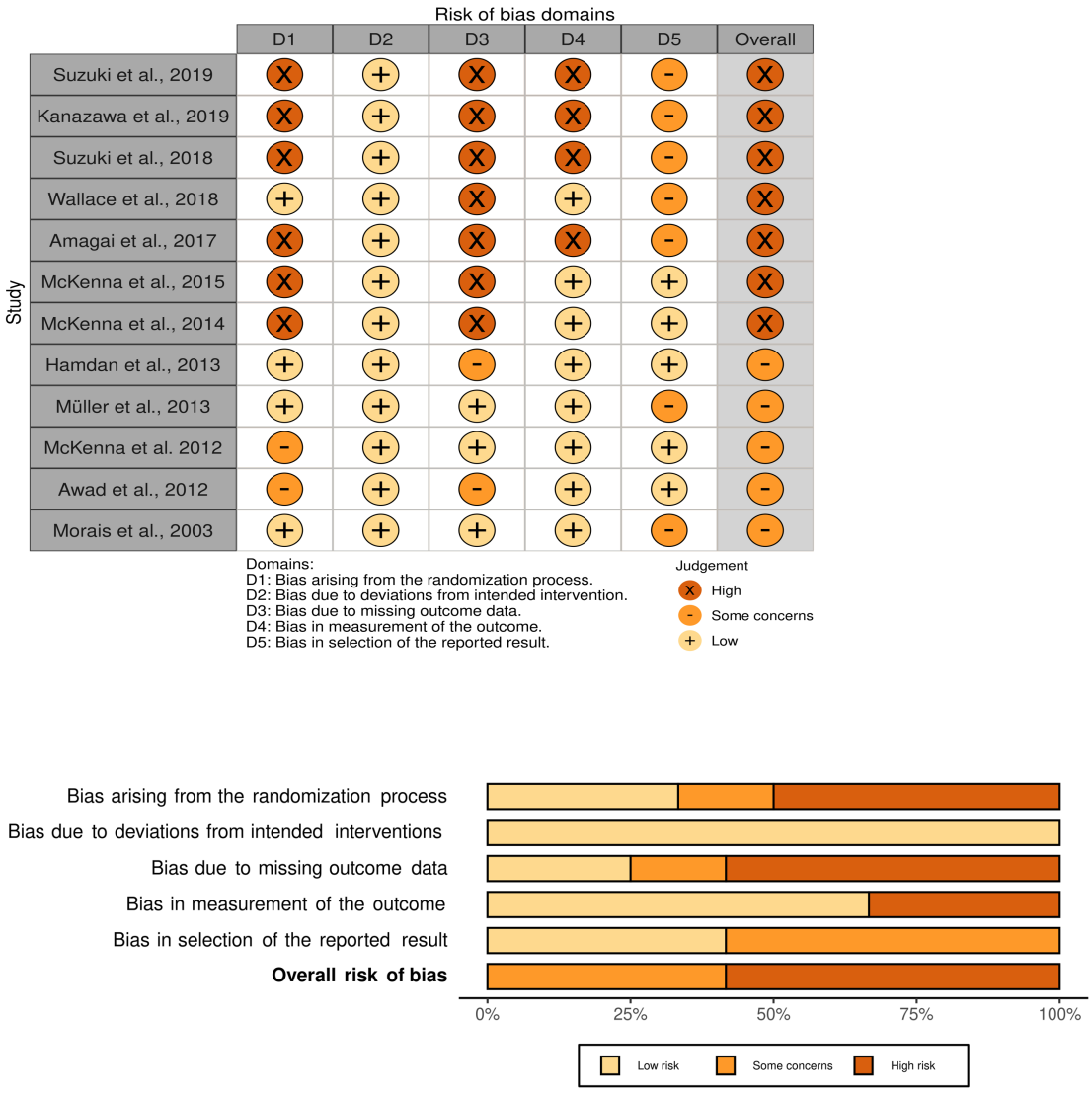

Figure 2. A, Risk of bias graph. B, Risk of bias summary for RCTs based on Revised Cochrane risk of bias tool for randomized trials (RoB 2).

6 Artigo 2

Effect of prosthetic rehabilitation on oral health related quality of life in elderly patients: a systematic review

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CONFLICT OF INTEREST
The authors have no conflicts of interest to declare.

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Abstract

Purpose: To analyze the effect of prosthetic rehabilitation on oral health related quality of life (OHRQoL) in elderly patients. **Materials and Methods:** An electronic search was conducted in Pubmed/MEDLINE, Web of Science, and Cochrane databases to identify randomized clinical trials and prospective clinical studies that evaluated the effect of prosthetic rehabilitation on OHRQoL in individuals mean age over 60 years. These studies also needed to describe intervention involving complete dentures, implant retained overdentures, removable partial prostheses or fixed partial prostheses, and follow-up of at least 1 month after prosthetic rehabilitation. **Results:** Of the 589 articles identified in the initial search, 8 were selected for the review, and 3 additional articles were included after hand searching, resulting in total 11 articles in systematic review. As result, it was found that complete dentures, implant overdentures and removable or fixed partial dentures improved in most of the domains of OHRQoL, mainly in functional limitation, physical and psychological disabilities. It was found that retention, stability, comfort, speech and chewing efficiency improved drastically with implant overdentures, with enhanced patient's satisfaction and a better oral health-related quality of life, when compared with complete dentures. Functional treatment with fixed adhesive prosthesis resulted in significantly better mean of OHRQoL scores compared to treatment with removable partial dentures. **Conclusion:** This review suggests that prosthetic rehabilitation has a positive impact on oral health related quality of life in elderly patients.

Introduction

Tooth loss is a problem which can lead to different functional limitations, affect it psychologically and has significant side effects that influence the perception of satisfaction of individuals.[1,2] There has been an increase in mean age of the population worldwide and the mutilating dental practices of the last decades have resulted a large number of elderly edentulous people.[3] Edentulous conditions have negative effects on oral health related quality of life (OHRQoL),[4,5] and there is a need to perform oral rehabilitation treatments to reestablish the population's masticatory, aesthetic and phonetic condition.[6,7]

Prevalence rates for use of and need for dental prostheses among Brazilian elderly (65-74 years of age) were 78.2% and 68.7%, respectively, in a study that evaluated elderly participants in the National Oral Health Survey in 2010.[8] It has been demonstrated that the tooth loss has negative effects on OHRQoL.[9,10] Problems include restrictions on chewing capacity and interference with the diet, reducing the possibility of eating certain foods, phonetic limitations, loss of support for facial musculature, decreased vertical dimension and aesthetic impairment.[11] However, it is not yet clear whether oral prosthetic would mitigate this reduction and which type of dental prosthesis would be most significantly associated with a possible improvement in quality of life.

Different treatment options have been proposed in order to replace the lost tooth and restore function and aesthetics parameters in partial or total edentulous patients.[9] The most traditional prosthetic oral rehabilitation and the most commonly performed in edentulous patients is the conventional complete dentures supported by the mucosa, followed by removable or fixed partial prostheses and, more recently, osseointegrated implants and the subsequent installation of overdentures.[12,13]

Patients ask for solutions to compensate for tooth loss and restore their self-esteem. Thus, the improving quality of life is one of the main goals of treatment for prosthetic oral rehabilitation and patient satisfaction must be considered as a central feature for treatment quality and the success of the most appropriate therapy for each clinical situation.[14]

OHRQoL is a complex patient-centered measurement system that focuses on the impact of oral problems and pathologies on the well-being of individuals and assesses whether professional dental interventions really deliver satisfactory results to the patients.[9] Oral health impact profile (OHIP) is one of the most used tools for the evaluation of OHRQoL, with a variable number of subjective questions (OHIP-12 to OHIP-53), are considered multidimensional, of quick administration and quotation, allowing to assess the severity, extent and prevalence of negative impacts in a single application or at different times.[15] Thus, it has been translated to many languages and its validity and internal consistency have already been proven for use in several countries worldwide.[16] Geriatric Oral Health Assessment Index (GOHAI) is one of the most commonly used scales in assessment of oral related quality of life in geriatric population.[17]

So, is essential to assess the extent to which oral rehabilitation of patients with tooth loss is effective not only in improving masticatory capacity, aesthetic and phonetic requirements, but also to determining if the rehabilitation had the intended patient reported effect.[1] Previous systematic reviews have evaluated differences in patients' OHRQoL and patient satisfaction between prosthetic types after treatments.[18–20] However, it is not clear whether the placement of dental prostheses (complete dentures, implant overdentures and removable or fixed partial dentures) influences the quality of life of elderly patients. Therefore, the aim of this systematic

review was to evaluate the effect of prosthetic rehabilitation on OHRQoL in elderly patients.

Material and methods

Eligibility criteria and Information sources

The question addressed was the following: “Does prosthetic rehabilitation improve quality of life in elderly patients?”. The research question was set according to the PICOS format for clinical questions: Population: Elderly people; Intervention: Prosthetic rehabilitation (complete dentures, removable or fixed partial dentures and overdentures); Comparison: Before and after prosthetic treatment; Outcome: oral health-related quality of life (OHRQoL); Study design: Randomized controlled trials (RCT) and prospective clinical studies.

Inclusion criteria were determined by the authors before the beginning of the study: clinical studies (RCT and prospective clinical studies), a follow-up time of ≥ 1 month after prosthetic rehabilitation, clinical trials that evaluated the effect of prosthetic rehabilitation on OHRQoL in elderly people (mean age over 60 years), intervention involving complete dentures, implant overdentures, and removable or fixed partial dentures. Studies were excluded if they were animal or in vitro studies, case series or case reports letters, reviews, and experimental laboratory studies.

The study was reported following the PRISMA Statement (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines.[21] The review protocol was prospectively submitted on the Prospective International Registry of Systematic Reviews - PROSPERO, under the registration number: CRD 42020209175.

Search Strategy and Selection process

The PubMed/MEDLINE, Web of Science, and Cochrane Library databases were performed to identify potential articles published up until May 2020 utilizing the keywords of different combinations (Table 1). In addition, an extensive hand search was also performed through the references listed in the included papers.

A 3-stage screening was performed. All stages (titles, abstract, full-text) were carried out in duplicate and independently by 2 reviewers. Initially, all titles were screened to eliminate nonrelated publications and reviews. Then, all selected abstracts were analyzed and the full-text articles were consequently retrieved, based on a specifically designed data extraction form for each article to confirm the eligibility of the study and collect relevant data. In case of disagreement regarding eligibility, a third reviewer's opinion was sought for further discussion, and a decision was made by consensus.

Data collection process and Data items

Data were entered directly into a pre-formatted database, using Microsoft Excel. The data required of our final selection were extracted and tabulated based on the following items: author, year of publication, purpose of study, study design, patients' age, number of subjects, follow-up time of each study, type of prosthetic rehabilitation, OHRQoL selected questionnaire, and synopsis of results.

The primary outcome was patient-reported outcome measure: OHRQoL. Secondary outcome was to compare the effect of different prosthetic types in OHRQoL. All results that were compatible with each outcome domain in each study were sought.

Study risk of bias assessment

The risk of bias was assessed according to Cochrane risk of bias tool for RCT (RoB 2)[22,23] and prospective clinical studies (ROBINS-I).[24,25]

Results

Out of total 705 initial records obtained through electronic, only 58 were selected for complete text review by two independent reviewers. Out of 50 rejected articles, 20 were not RCT and prospective studies, 28 unstudied elderly population, 2 were study proposals, and 3 additional articles included after hand searching, resulting in total 11 articles in systematic review. The flowchart of the entire search and the article identification process is shown in Figure 1.

The studies selected were performed between 2003 and 2020. All of the patients included in the studies received prosthetic rehabilitation and answered a questionnaire used to investigate the impact of oral conditions on the quality of life of patients rehabilitated with prostheses. The characteristics of the included studies are presented in Table 2 and 3. The number of patients included in the sample ranged from twenty-five to 102 and their mean age ranged from 62 to 74.2 years. Ten studies had a sample size of <100 participants and only one study included over 100 participants.[31] Every article included in the analysis was carefully assessed and the relevant data were extracted and tabulated. Four studies were RCT, and the rest were prospective clinical studies. They differed widely with respect to methodology, study designs and outcomes, so the possibility of attempting a meta-analysis was eliminated.

In two studies, patients were divided into a fixed restoration group based on shortened dental arch concept and another removable group.[28,29] Three studies used

a complete denture group and another overdenture group.[31,34,35] One study evaluated OHRQoL in patients rehabilitated with implant-retained mandibular overdentures.[30] The rest examined oral health-related impacts on the quality of life of patients before and after prosthetic treatment with complete dentures.[17,26,27,32,33] In the majority of studies, the questionnaire used to investigate the impact of oral conditions on the quality of life was the OHIP, and follow up done in studies after prostheses insertion were for minimum of 4 weeks to maximum follow up of 2 years.

As result, it was found that dental prostheses improved in most of the domains of OHRQoL,[17,26-31,32-35] mainly in functional limitation, physical and psychological disabilities. It was found that implant overdentures are more likely than complete dentures to improve OHRQL for edentulous patients.[31,34,35] Functional treatment with fixed adhesive prosthesis resulted in significantly better mean of OHRQoL scores compared to treatment with removable partial dentures.[28,29]

Mandibular 2-implant overdentures are more likely than CD to improve OHRQoL for edentulous patients.

Risk of bias across studies and within studies is shown in Figure 2 (RCTs) and Figure 3 (prospective clinical studies). Risk of bias to RCTs revealed a high risk of bias in 1 of 4 studies evaluated. Risk of bias to prospective clinical studies revealed that two of the trials included were unbiased for all domains.

Discussion

The present systematic review investigated the impact of prosthetic rehabilitation on OHRQoL in elderly patients. OHRQoL has been used as evaluation criteria for dental prosthesis which could improve mastication, comfort, self-esteem and satisfaction on their own appearances.[36] Several clinical studies were done assessing patient satisfaction regarding speech, mastication, chewing efficiency, post

insertion appointments required with complete dentures, removable or fixed partial prostheses, implant overdentures, and their role in improving OHRQoL.[17,26-31,32-35]

In the five studies that examined OHRQoL in patients who underwent prosthetic oral rehabilitation with complete dentures, it was possible to observe improvement in most of the domains evaluated, mainly in functional limitation, physical and psychological disabilities.[17,26,27,32,33] Factors such as difficulty in chewing, limiting social contact, satisfaction with appearance, feeling nervous or embarrassed, showed significant improvement in the selected studies. Dable et al.[17] reported that there was a significant difference between men and women, indicating a better rate for women, probably motivated by the greater acceptance of prosthetic treatment. In these selected studies, the domains of physical pain and social disability were the least positively impacted, probably due to the greater difficulty of adaptation with the complete dentures used as prosthetic rehabilitation.

Three studies used a complete denture restauration group and another overdenture group.[31,34,35] These studies compared OHRQoL of elderly people who received implants and subsequent mandibular overdentures or received complete dentures. All studies observed a significant increase in OHRQoL in individuals who received implant overdentures, including in the psychological and social domains, probably due to the increase in masticatory efficiency promoted by prostheses retained by implants.[31,34,35] This result was also found in a cross-sectional study[16] and also in a systematic review carried out with adult patients, in which it was observed that retention, stability, comfort, speech and chewing efficiency improved drastically with overdentures, with enhanced patient's satisfaction and a better OHRQoL, when compared with complete dentures.[18]

In the multicenter study carried out by Awad et al.[31] it was observed that the cultural difference can affect the results of OHRQoL, which would explain the difficulty of comparing the different studies carried out in different places in the world, in which the valuation of the aspects of quality of life is different. In this study, it was also possible to observe that the complete dentures group worsened in OHRQoL, indicating that expectations with this type of prosthesis were not fully met and also because they generally have less stability, retention and masticatory capacity.[18]

Two studies used a fixed rehabilitation group and another removable group.[28,29] The objective was to compare two different dental replacement strategies for partially edentulous elderly patients, one with functionally oriented treatment according to the principles of the shortened dental arch and the other with conventional treatment using removable partial dentures. The results of these studies demonstrate that functional treatment with fixed adhesive prosthesis resulted in significantly better mean OHRQoL scores compared to treatment with removable partial dentures. One explanation would be for the closer approximation of fixed dentures to natural teeth, since the patient does not need to remove dental prostheses and can simulate something closer to the time that still had teeth in that region. A recent study has shown different results. It was observed that restorations presented an improvement in oral health-related quality of life, but removable dental prostheses showed better improvement than fixed ones in various dimensions.[15]

Of the 11 studies selected for this review, 9 used one of the versions of the OHIP, which is meant to provide information about perceptions of oral health. The complete 49 item version is not always applicable in a clinical study because its time consuming and was used in only one of the studies. Three studies used the OHIP-20 version, two used the simplified version OHIP-14 and three studies used the OHIP-

EDENT, specialized to edentulous patients. Another 2 studies used GOHAI to assess quality of life and satisfaction.

Despite the benefits presented by prostheses retained by implants, such as preservation of residual alveolar bone, improvement in masticatory efficiency, increase in retention and stability of overdentures, many patients showed little interest in implant treatment. The reason for this may be due to fear of surgical intervention and the cost factor related to implants. A systematic review of the cost-effectiveness of implant prostheses concluded that two-implant-retained overdentures are more expensive but cost-effective than the complete dentures, and single-implant overdentures are less expensive than the two-implant-retained.[37]

The majority of the studies take place in clinics specialized in the field of dental prosthesis, but it would be important to investigate whether similar results would be achieved in treatments performed in primary care, where generally the majority of the population is served.[8] Another difficulty in comparing studies is the different instruments used to assess OHRQoL, using different versions of OHIP. Cultural and international differences may usually affect the different aspects of OHRQoL in performance of dental prosthesis.[31]

The limitations of the studies included in this review are the short follow-up time and the small sample of participants. A longer follow-up period would be necessary to investigate the impact of the survival of different prostheses on OHRQoL. The sample size used in the studies was relatively small, therefore, the data should be interpreted with caution and should serve as an incentive for further studies.

Conclusion

The collective evidence from the selected studies confirms that prosthetic rehabilitation has a positive effect on oral health related quality of life in elderly patients.

Despite the favorable results, it was observed that patients with complete dentures have a poorer OHRQoL than groups of patients with overdentures, and functional treatment with fixed adhesive prosthesis resulted in significantly better mean OHRQoL scores compared to treatment with removable partial dentures.

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Table 1. Electronic search strategies.

PubMed
#1: (Elderly) OR (Aged) OR (Dental Care for Aged) OR (Dentistry for Aged) OR (Aged, Dentistry for) OR (Dental Care for Elderly)
#2: (Denture) OR (Denture, Partial, Removable) OR (Removable Partial Denture) OR (Denture, Removable Partial) OR (Dentures, Removable Partial) OR (Partial Denture, Removable) OR (Partial Dentures, Removable) OR (Removable Partial Dentures) OR (Denture, Partial, Fixed) OR (Fixed Bridge) OR (Bridge, Fixed) OR (Bridges, Fixed) OR (Fixed Bridges) OR (Fixed Partial Denture) OR (Denture, Fixed Partial) OR (Dentures, Fixed Partial) OR (Fixed Partial Dentures) OR (Partial Denture, Fixed) OR (Partial Dentures, Fixed Pontic) OR (Pontics) OR (Denture, Complete) OR (Complete Denture) OR (Complete Dentures) OR (Dentures, Complete) OR (Dental Prosthesis) OR (Prosthesis, Dental) OR (Dental Prostheses) OR (Prostheses, Dental) OR (Dental Prosthesis, Implant-Supported) OR (Dental Prosthesis, Implant Supported) OR (Implant-Supported Dental Prosthesis) OR (Dental Prostheses, Implant-Supported) OR (Implant Supported Dental Prosthesis) OR (Implant-Supported Dental Prostheses) OR (Prostheses, Implant-Supported Dental) OR (Prosthesis, Implant-Supported Dental) OR (Denture, Implant-Supported) OR (Denture, Implant Supported) OR (Implant-Supported Denture) OR (Dentures, Implant-Supported) OR (Implant Supported Denture) OR (Implant-Supported Dentures) OR (Prosthesis Dental, Implant-Supported) OR (Dental, Implant-Supported Prosthesis) OR (Dentals, Implant-Supported Prosthesis) OR (Implant-Supported Prosthesis Dental) OR (Implant-Supported Prosthesis Dentals) OR (Prosthesis Dental, Implant Supported) OR (Prosthesis Dentals, Implant-Supported) OR (Prosthodontics) OR (Dentistry, Prosthetic) OR (Prosthetic Dentistry)
#3:(quality of life) OR (quality) OR (OHRQoL) OR (Life Quality) OR (Health-Related Quality Of Life) OR (Health Related Quality Of Life) OR (HRQOL)
#4: (Randomized Controlled Trials as Topic) OR (Randomized Controlled Trials as Topic) OR (Controlled Clinical Trials, Randomized) OR (Clinical Trials, Randomized) OR (Trials, Randomized Clinical) OR (Randomized Controlled Trial) OR (Randomized clinical trial) OR (((clinical[Title/Abstract] AND trial[Title/Abstract]) OR clinical trials as topic[MeSH Terms] OR clinical trial[Publication Type] OR random*[Title/Abstract] OR random allocation[MeSH Terms] OR therapeutic use[MeSH Subheading])) OR ((randomized controlled trial[Publication Type] OR (randomized[Title/Abstract] AND controlled[Title/Abstract] AND trial[Title/Abstract]))))
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Cochrane Library
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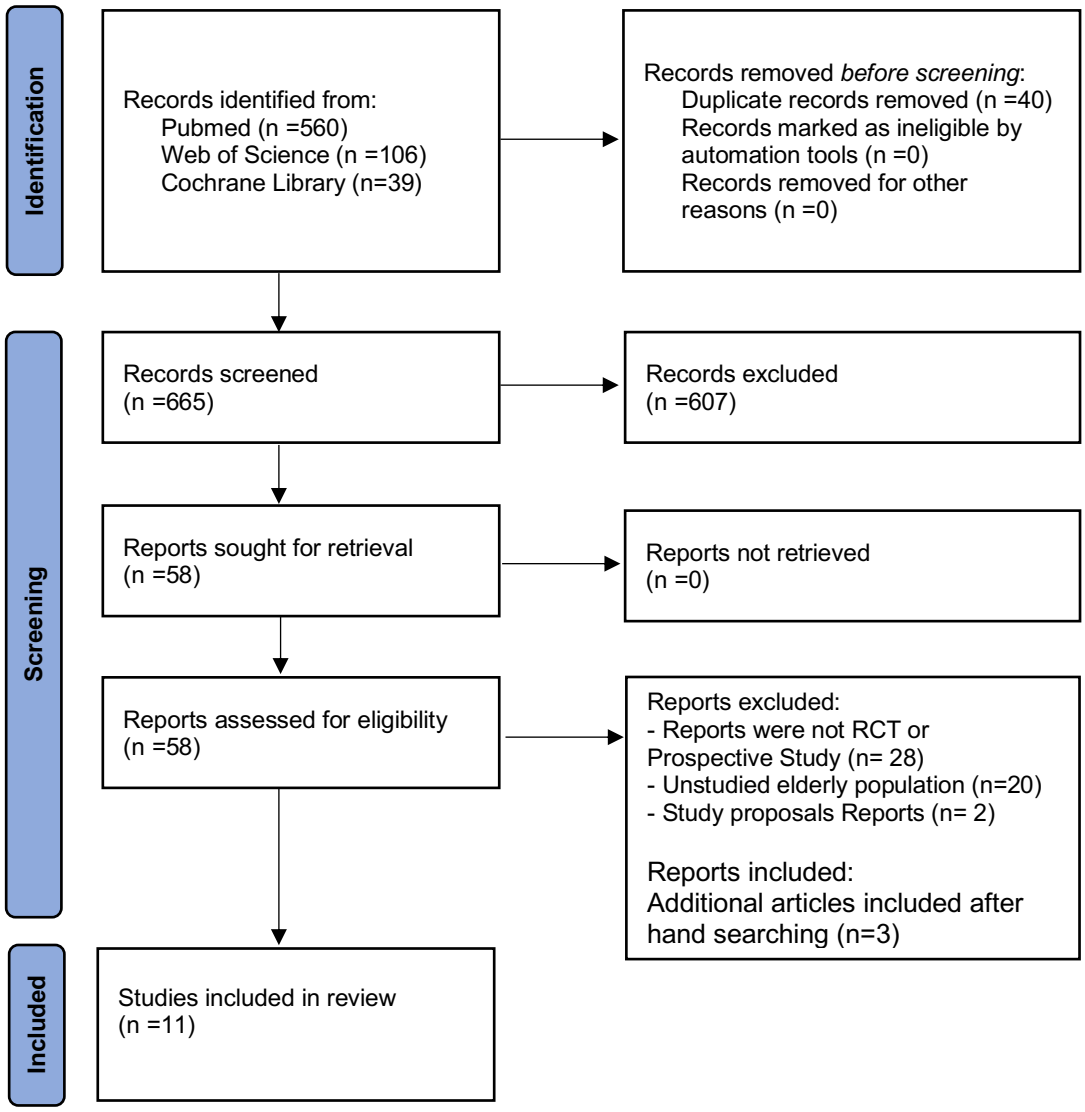

Figure 1. Preferred Reports Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram for prosthetic rehabilitation on oral health related quality of life in elderly patients.

Table 2. Description of the studies included in the systematic review – author (citation); type of study, number of patients; age; outcomes evaluated; follow-up.

Author's/Year Type of study	Number of Patients (Available for follow up)	Age (Years)	Outcomes evaluated	Follow-up
Shrestha et al., 2020[26] Prospective	100 (88)	mean age 67 years (range 53-91 years)	OHRQoL of edentulous patients, and to assess any associations related to age, gender, and OHRQoL.	Once pretreatment (at the first visit) and once post treatment (8 weeks post insertion of dentures).
Figueredo et al., 2020[27] Prospective	20 (20)	65 years and older (mean age of 77.6)	Self-perceived masticatory ability and oral OHRQoL in frail and nonfrail elders.	The assessments were carried out before and 2 months after the prosthetic treatment.
McKenna et al., 2018[28] RCT	65 (44) 67 (45)	74.1 (RPD) and 73.9 (SDA) aged 65 years and older	OHRQoL of two different tooth replacement strategies for partially dentate older patients.	Baseline, 1, 6, 12 and 24 months after treatment.
McKenna et al., 2015[29] RCT	65 (44) 67 (45)	aged 65 years and older	Impact on OHRQoL measured using the short form of the OHIP-14.	Baseline, 1 month, 6 months and 12 months after treatment.
Sun et al., 2014[30] Prospective	50 (50)	55 -74 years (mean 62 years)	Masticatory efficiency and OHRQoL in patients rehabilitated with implant-retained mandibular overdentures.	One month before the mandibular complete denture was anchored to the osseointegrated implants, and 6 months after anchoring.
Awad et al., 2014[31] Prospective	203 (102)	mean age 68.8 years	OHRQoL in patients who received mandibular 2-implant overdentures and complete dentures.	Baseline and at 6 months post-treatment.
Dable et al., 2013[17] Prospective	114 (63)	mean age 69.41 (aged between 60-82 years)	The problems of completely edentulous patients and their relationship to the Quality of Life.	Before and after 6 months of their treatment.
Shigli et al., 2010[32] Prospective	35 (27)	mean age 67.65 (aged 60–84 years)	OHRQoL among patients with complete denture.	Before and 1 month after insertion of dentures in completely edentulous patients.
Ellis et al., 2007[33] Prospective	49 (40)	mean age 74.2 (aged 55 to 85 years)	Patient satisfaction and OHRQoL of patients restored with complete conventional or duplicate dentures.	Before treatment and 1 month after delivery of their new dentures.
Awad et al., 2003[34] RCT	30 30	mean age 69.3 years (aged 65 to 75)	Elderly patients' satisfaction and OHRQoL with mandibular two-implant overdentures and complete dentures.	Prior to treatment and 2 months postdelivery.

Heydecke et al., 2003[35] RCT	30 (25) 30 (30)	mean age 69.4 years (aged 65–75 years)	OHRQoL of seniors who received either mandibular implant overdentures or cmplete dentures.	Before treatment, then at two and 6 months after delivery of the dentures (OHIP-20). The Short Form (SF-36) health survey was completed at baseline and 6 months only.

Randomized controlled trials (RCT); OHRQoL (Oral health related quality of life); Removable partial dentures (RPD); Shortened dental arch (SDA); OHIP (Oral health impact profile).

Table 3. Description of the studies included in the systematic review – author (citation); interventions; OHRQoL questionnaire; synopsis of results related to OHRQoL.

Author's/Year	Interventions	OHRQoL questionnaire	Synopsis of results related to OHRQoL
Shrestha et al., 2020[26]	CD	OHIP-EDENT	CD improved the OHRQoL of edentulous patients.
Figueredo et al., 2020[27]	CD	OHIP-EDENT	CD insertion may play an important role in improving mastication and OHRQoL in elderly people, especially those with the frail elders.
McKenna et al., 2018[28]	RPD and functionally orientated treatment based on SDA concept.	OHIP-14	Both treatment groups reported improvements in OHIP-14 scores at 24 months. Patients in the SDA group maintained their improvements in OHRQoL scores throughout the 24-month study period. For the RPD group the initial improvement in OHRQoL score began to diminish after 6 months.
McKenna et al., 2015[29]	RPD group and the SDA group (resin bonded bridgework)	OHIP-14	In terms of impact on OHRQoL, treatment based on the SDA concept achieved significantly better results than that based on RPD 12 months after treatment intervention.
Sun et al., 2014[30]	IOD treatments	OHIP-49	Implant-retained mandibular overdentures can significantly improve patients' masticatory efficiency and OHRQoL.
Awad et al., 2014[31]	Mandibular CD or IOD and opposed by CD	OHIP-20	Mandibular 2-implant overdentures are more likely than CD to improve OHRQoL for edentulous patients.
Dable et al., 2013[17]	CD	GOHAI	There was a significant change in the quality of life in elderly after their prosthodontic rehabilitation, though the self-rated general health did not show any significant improvement.
Shigli et al., 2010[32]	CD	GOHAI	Patients reported improvement in functional changes after placement of CD.
Ellis et al., 2007[33]	CD	OHIP-20	The provision of new CD resulted in an overall improvement in OHRQoL and satisfaction.
Awad et al., 2003[34]	Mandibular two-IOD and CD	OHIP-49 OHIP-EDENT	Mandibular two-IOD combined with maxillary CD provide better function and oral health–related quality of life than CD.
Heydecke et al., 2003[35]	Mandibular IOD or CD	OHIP-20 and SF-36 general health questionnaire	Senior patients in this trial who received mandibular implant overdentures 6 months before had significantly better oral health status than patients given CD.

OHIP (Oral Health Impact Profile); OHIP-EDENT (OHIP specialized to edentulous patients); GOHAI (Geriatric Oral Health Assessment Index); SF-36 (Short Form health survey); OHRQoL (Oral health related quality of life); CD (complete denture); RPD (removable partial denture); SDA (shortened dental arch); IOD (implant overdenture).

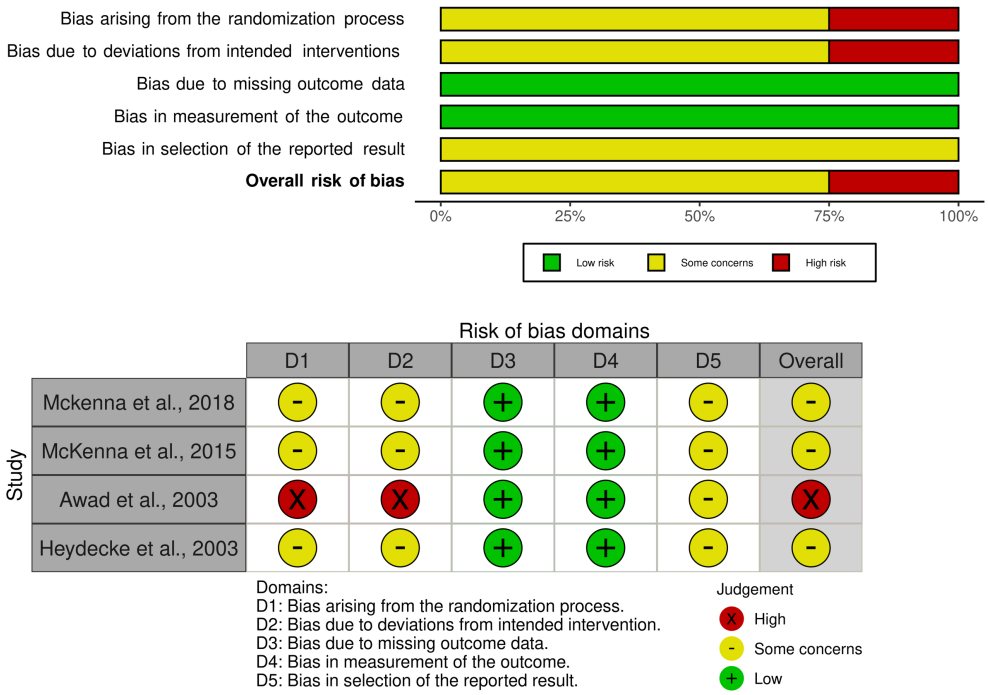

Figure 2. A, Risk of bias graph. B, Risk of bias summary for RCTs based on Revised Cochrane risk of bias tool for randomized trials (RoB 2).

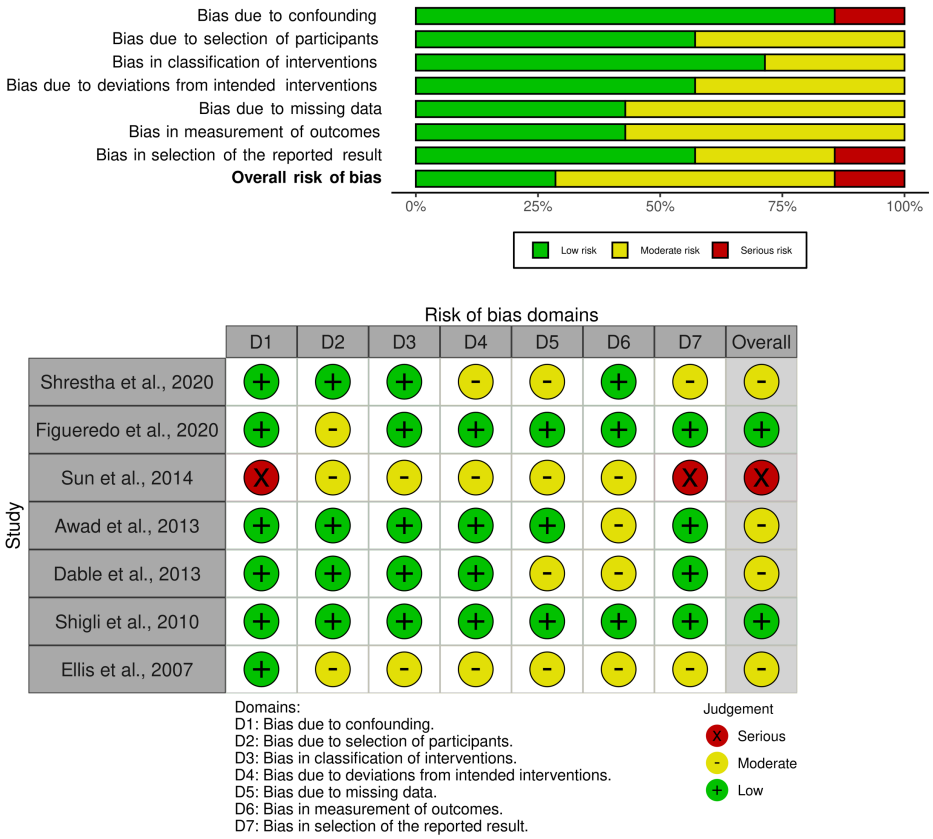

Figure 3. A, Risk of bias graph. B, Risk of bias summary for prospective clinical studies based on ROBINS-I tool.

7 Artigo 3

Influence of prosthetic rehabilitation and simple dietary advice on glycemic control, nutritional status and oral health-related quality of life in elderly individuals with type 2 diabetes: 1 year of a prospective study

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ABSTRACT

Statement of problem

Type 2 diabetes is the most common type of diabetes mellitus, being diagnosed most often in the elderly. Nutritional therapy is essential in the prevention, treatment and management of diabetes, favoring glycemic control. The inadequate use or need for dental prostheses can affect the masticatory process, which can lead to aesthetic, functional and nutritional problems, as well as can impair quality of life.

Purpose

The aim of the study was to determine the influence of oral prosthetic rehabilitation and simplified dietary advice on the glycemic control, nutritional status, and oral heath related quality of life (OHRQoL) of elderly individuals with type 2 diabetes.

Material and methods

Elderly persons who are diagnosed with type 2 diabetes mellitus and aged 60 years or older, needing oral rehabilitation with complete or partial removable dentures, were eligible for this study. The primary outcome measure for this prospective study was glycemic control, which was measured by glycosylated hemoglobin (HbA1c) levels. The Oral Health Impact Profile (OHIP-14) questionnaire and the Mini Nutritional Assessment short form (MNA-SF) were included as secondary outcomes measures. Assessments of outcome measures were performed at baseline and at 12 months follow-up after prosthesis delivery combined with a simple dietary advice in pamphlet form. Data were analyzed using the Wilcoxon matched-pairs test.

Results

Thirty-nine patients were assessed for eligibility. No laboratory parameter (HbA1c levels) changed significantly during the investigation period. Both nutritional status and OHRQoL were significantly improved after prosthetic therapy combined with

dietary advice ($p<0.001$). The median MNA-SF increased from 12.0 (8.0-13.0) (baseline) to 13.0 (11.0-14.0) at the 12-month follow-up ($p<0.001$).

Conclusions

The results showed that prosthodontic treatment with complete and partial dentures combined with a simple dietary advice did not influence glycemic control. However, our results provide strong indications of a direct impact on nutritional status and OHRQoL among patients rehabilitated with complete and partial dentures, which confirms the functional advantages of prosthetic rehabilitation.

Clinical implications

Prosthodontic treatment with complete and partial dentures combined with simple dietary advice improved nutritional status in elderly individuals.

INTRODUCTION

Diabetes mellitus (DM) is a global health problem and the patients with this disease are at increased risk for many other health problems, including microvascular and macrovascular complications, owing to hyperglycemia and individual components of the insulin resistance syndrome.[1,2] According to the International Diabetes Federation - IDF,[3] type 2 diabetes is the most common type of diabetes mellitus and accounts for 90% of all cases of diabetes, being more commonly found in the elderly, and modifiable factors such as diet contribute to the onset or influence the progression of the disorder.[4]

Global estimates for the year 2019 indicate that 35.6 million (19.3%) of people aged 65–99 years were living with diabetes, and this number could reach 195.2 million by 2030 and 276.2 million by 2045.[3] Brazil is considered one of the epicenters of diabetes in the last decade. A cross-sectional study estimated that about 7.5% of the population has DM.[5] It is projected that the number of Brazilian people older than 65 years with diabetes will reach 9.6 million by 2030 and 14.9 million by 2045.[6]

Moreover, nutritional deficiency is one of the several consequences of edentulism, as it negatively interferes on the masticatory function, which in turn can limit food choices and diet variety, making it difficult to ingest nutritious foods.[7,8] Some studies have related edentulism with malnutrition in the elderly, due to damage to the chewing process, leading to food restriction,[9,10] and alternative food choices can lead to obesity.[11]

The high prevalence rates of tooth loss indicated a great need of dental prostheses in elders.[12] Studies have shown that individuals with tooth loss and who did not wear complete or partial dentures were more likely to be at nutritional risk, which may be related to the occurrence of various gastrointestinal and systemic disorders, malnutrition and chronic diseases in the elderly,[13,14] suggesting that the

use of dental prostheses would represent a benefit for the reestablishment of an adequate nutritional status.[15] In previous studies, prosthetic rehabilitation combined with simple dietary advice in pamphlet form provided in the clinical setting resulted in significant increases in the intake of some foods.[16,17]

Uncontrolled diabetes was associated with increased risk of future tooth loss compared with normal glycemic status,[18] and Kaur et al.[19] reported an overall positive association between type 2 diabetes and number of missing teeth, which was stronger in women than in men. Other Studies have also shown that nutritional therapy is essential in the prevention, treatment and management of diabetes, favoring glycemic control through the reduction of glycated hemoglobin (HbA1c) levels, being effective in reducing the incidence of type 2 DM.[20,21]

The assessment of nutritional status measures the influence of nutrition on the individual's health can be performed through physical examination, anthropometric methods, biochemical tests, geriatric scales, subjective assessments and dietary surveys.[3] The Mini Nutritional Assessment Short Form (MNA-SF) is a fast, simple, and sensitive method for screening malnutrition, designed to facilitate the application in elderly.[22]

The inadequate use or need for dental prostheses can affect the masticatory process, which can lead to aesthetic, functional and nutritional problems,[23] as well as interfere with quality of life.[24] To measure the oral heath related quality of life (OHRQoL), the Oral Health Impact Profile short form instrument (OHIP-14), described by Slade,[25] is used to assess the impact of oral problems on well-being physical, psychological and social aspects of patients, in addition to their ability to perform everyday activities.[26,27]

Although studies indicate the association between tooth loss and diabetes, the literature provides little evidence on the contribution of oral rehabilitation, through the installation of dental prostheses, in the improvement of diabetes control, nutritional profile and satisfaction of elderly individuals, especially who have type 2 diabetes. Thus, the aim of the study was to determine the influence of oral prosthetic rehabilitation and simplified dietary advice on the glycemic control, nutritional status, and quality of life of elderly individuals with type 2 DM. The null hypothesis was that glycemic control would not differ in the follow-up at 12 months, after prosthetic rehabilitation combined with nutritional counseling.

MATERIAL AND METHODS

Experimental design and patients

This prospective clinical study was approved by the Ethics Committee at Fametro University Center, Fortaleza, Brazil (CAAE number: 6188719.9.0000.5618). Study participation was voluntary, with participants providing written informed consent prior to enrolment. This study was conducted according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Guidelines (Appendix File 1).[28]

Elderly persons of all races and ethnicities who lived in the community of Fortaleza city and seeking oral rehabilitation by complete and removable partial dentures at the Unifametro Dental School clinic were eligible for this study. The participants were recruited from November 2019 until April 2020. One year follow up data was collected from the last patient in June 2021. Patients had to meet several inclusion criteria: (a) aged of 60 years or older; (b) previous use of complete or partial dentures for at least 6 months or non-use of complete or partial dentures; (c) diagnosis of type 2 DM for at least 2 years; and (d) willing and able to understand the

protocol and give informed consent. Elderly persons with physical disabilities, taking insulin, out of balance conditions for weight measurement or some other measure, chronic kidney disease, liver disease, AIDS or other conditions which significantly change body composition were excluded.

The presence of diabetes was determined by a self-reported response to the question “Have you ever been told by a doctor or health care professional that you have type 2 diabetes?” Responses included yes, no, or borderline. The participants with borderline diabetes were classified as not having diabetes.[29] The diagnosis was confirmed by blood tests (HbA1c) percentages ≥ 6.5% and/or fasting blood glucose levels (time >8 h) >126 mg/dL.[30] The edentulous patients had to have tissues and entire remaining edges and properly healed, with a minimum of four months from the last tooth extraction.

The patients had complete arch restoration with missing teeth replaced using cobalt-chromium frameworks or complete dentures, constructed by the same dental laboratory and all operative treatment was conducted by clinician with postgraduate training in prosthodontics. Clinicians delivering the treatments used standard practice methods.

The participants received their new dental prostheses and 20 min of simple dietary advice. All advice was conducted by a dentist with the aid of pamphlets. The pamphlet was based on the nutrition guide of the Brazilian Society of Diabetes (SBD).[31] The participants also received advice as to how to care for their new dental prostheses, in accordance with the guidelines published by the American College of Prosthodontists.[32]

Outcome Measures

Assessments of outcome measures were performed at baseline and at 12 months follow-up after the prosthesis delivery combined with a simple dietary advice in pamphlet form.

The primary outcome measure for this prospective study was glycemic control, which was measured by blood test (HbA1c levels). OHRQoL, which was measured using OHIP-14,[33] and nutritional status, using the MNA-SF,[34] were included as secondary outcomes measures. In addition, it was used that HbA1c < 7% to indicate controlled diabetes and HbA1c ≥ 7% to indicate uncontrolled diabetes.[30]The questionnaires were completed by the examiner who interviewed the patients on two different occasions. Blood test (HbA1c levels) and the questionnaires were recorded before dental prostheses insertion. When no further adjustment was required or indicated, patients were asked to return for a further review 1 year later and OHIP-14 and MNA-SF were recorded by a single recorder. Blood tests were performed using the same technique, collected and analyzed in reference laboratory.

Statistical analysis

The estimated sample size needed to detect a difference with the primary outcome of the study was 30 participants (power 80%, alpha 0.05, two tailed). An additional 30% were recruited to compensate for loss to follow-up. This sample size is also sufficient to detect the minimally important difference in the secondary outcomes. This calculation was done using the OpenEpi calculator Version 3.01 (Open Source Epidemiologic Statistics for Public Health, www.openepi.com).

Descriptive statistics were used to evaluate outcomes. Data normality was tested using Shapiro–Wilk test. Blood parameters (HbA1c) and ordinal data (MNA

and OHIP-14) were compared with Wilcoxon matched-pairs test. All data analyses were performed with a significance level of 5% using the software JASP Version 0.14.1 (JASP Team, 2020).

RESULTS

Thirty-nine patients in the trial completed the 12-month follow-up (Figure 1). During the follow-up, five participants declined to participate because they moved to another city.

Table 1 summarizes the baseline demographic and prosthetic clinical characteristics for 39 elderly subjects (16 men and 23 women, aged between 60 and 83 years; mean 65.8 years) enrolled in the study. The mean of baseline teeth number was 7.8 ± 5.5 (maxillary), and 9.3 ± 4.2 (mandibular). Thirty individuals were treated with removable partial dentures and nine with complete dentures.

No laboratory parameter (HbA1c levels) changed significantly during the investigation period (Table 2). No differences in the levels of glycemic control from the 12-month follow-up were observed ($p=0.180$). Table 2 shows the nutritional status at baseline and at 12 months follow-up after prosthesis delivery. At baseline, 26 participants were considered well nourished, and 13 were at risk of malnutrition; at 12 months after treatment, 33 were well nourished, and 6 were at risk of malnutrition. All patients had MNA-SF scores above 8, so no patient was malnourished. The median MNA-SF score at each assessment time is shown in Table 2. A significant improvement in nutritional status was observed 12 months after prosthetic therapy combined with dietary advice ($p<0.001$). The median MNA-SF increased from 12.0 (8.0-13.0) (baseline) to 13.0 (11.0-14.0) at the 12-month follow-up.

Table 3 shows improvement in OHRQoL 12 months after installation of the prosthetic rehabilitation, in terms of general OHIP-14 results and the evaluation of

seven dimensions, showing a statistically significant positive impact of prosthetic treatment on OHRQoL ($p<0.001$).

DISCUSSION

Type 2 DM is a multifactorial disease, not yet completely understood, which are associated with behavioral and environmental risks.[35,36] Encouraged by an increase in population, aging, urbanization, obesity and lack of physical activity, it has become a global epidemic.[3,30] Considering the findings of this study, the null hypothesis was accepted because there were no significant differences after one year in the levels of glycemic control analyzed. In addition, this study was a pioneer in evaluating the possibility of oral prosthetic rehabilitation associated with nutritional guidance impairing the nutritional profile and quality of life, and consequently the glycemic control of elderly patients with type 2 DM. Malnutrition in this age group is often associated with physical, social and psychological problems,[30] which justify the search for behaviors that can improve the nutritional quality of this population.

Nutritional guidance associated with a decrease in sedentary lifestyles are considered first-choice therapies, promoting improved insulin sensitivity and may reduce blood glucose levels.[2] Suzuki et al.[37] reported that the dietary advice offered by a dentist with the aid of a pamphlet might be important to improving nutritional statuses in the elderly, because complete dentures users may have difficulty chewing and avoiding certain foods. Other studies have shown that not only the presence of dental prostheses, but also the quality of prosthetic treatments and their adjustments, can be associated with nutrients, food intake and dietary variety, which can correct nutritional problems, in addition to improving aesthetic and phonation requirements.[15,38,39] Kossioni et al.[40] reported that oral prosthetic rehabilitation

associated with personalized nutritional counseling can improve the nutritional status of patients.

Although some studies have verified better masticatory performance after prosthetic rehabilitation, with an improvement in the nutritional profile and a decrease in the number of patients at risk of malnutrition,[39,41] other studies did not observe any difference,[42,43] probably due to non-modification of eating habits. Thus, it is important to establish educational programs with a view to influencing eating habits, along with dental treatments.[44]

MNA-SF questionnaire is an appropriate instrument for nutritional assessment in the current literature, when compared to other questionnaires, as it better identifies severely malnourished patients.[45] Although scientific evidence demonstrates that nutritional intervention has a significant impact on reducing HbA1c in DM,[20,46,47] in the present study there was no significant change in HbA1c levels. Probably, to have beneficial effects, the simple dietary advice offered by a dentist with the aid of a pamphlet contained information about food requirements and balanced diet, need to be combined with individualized medical nutrition therapy.[31]Previous research has shown that prosthetic oral rehabilitation associated with personalized nutritional counseling could improve the nutritional status of patients.[40]

In partially and totally edentulous patients, treatment with dental prostheses can improve masticatory efficiency, aesthetics, phonation and psychological benefits, improving their capacity for social acceptance, with direct effects on their quality of life.[48] Our findings show that a significantly higher proportion of patients who received prosthodontic treatment reported improvement in their OHRQoL. The majority of patients who received prosthetic rehabilitation reported improvements in all domains of the OHIP-14. These findings are in accordance with studies that used the OHIP

questionnaire and observed a positive impact of prosthetic oral rehabilitation on the quality of life of patients, as well as the reduction of limitations and physical, psychological pain and social discomfort.[27,49] For many patients, oral rehabilitation means a return to a normal lifestyle, as they are more exposed to emotional disturbances due to insecurity and low self-esteem, interfering with their capacity for social inclusion.[23,50]

This trial consisted of some limitations. MNA is a popular instrument for determining potential malnutrition in elderly people.[51] It is the most widely accepted questionnaire and it is used worldwide, being able to identify nutrition-related problems early,[45] without the help of a specialized professional.[52] However, using only the MNA-SF as a screening tool, it means that the nutritional status has not been assessed in detail. Several methods are used to assess nutritional risk, such as anthropometric data, blood nutrient concentrations, and dietary assessment. In addition, more long-term follow-up is recommended because changing dietary habits takes a long time. Finally, the limitation of this trial includes homogeneity of the sample. The study could have been carried out with two groups to verify differences between complete and removable partial dentures.

The influence of oral prosthetic rehabilitation associated with nutritional counseling in the treatment of patients with type 2 DM may constitute an important strategy to be incorporated into the management of these individuals, since prosthetic dental interventions are generally not included in the guidelines for monitoring this disease, and may be a future contribution to both the treatment and prevention and evolution of diabetes, especially in the elderly.

This trial indicated that prosthodontic treatment with complete and partial dentures combined with simple dietary advice improved nutritional status in studied

population. Further studies are required to examine whether the simple dietary advice combined with an individualized food plan will have a long-term effect on improving nutrient intake in these patients.

CONCLUSION

Under the conditions of this 12-month follow-up the results suggest that prosthodontic treatment with complete and partial dentures combined with a simple dietary advice do not influence glycemic control. However, these findings provide strong indications of a direct impact on nutritional status and OHRQoL among patients rehabilitated with complete and partial dentures, which confirms the functional advantages of prosthetic rehabilitation.

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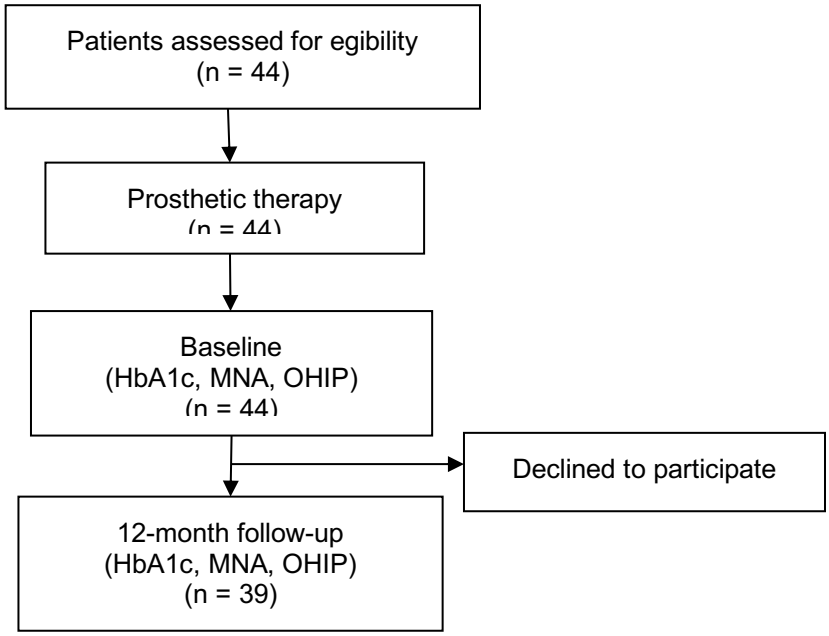

Figure 1. Flowchart of participants.

Table 1. Socio-demographic and prosthetic clinical characteristics of patients.

Variables	**Absolute (relative) frequency**
Gender (n)	
Men	16 (41%)
Women	23 (59%)
Education level (n)	
Elementary	22 (56.4%)
High school / College	17 (43.6%)
Physical activity (n)	
Inactive	22 (56.4%)
Active	17 (43.6%)
Previous nutritional monitoring (n)	
No	10 (25.6%)
Yes	29 (74.4%)
Reason to seek oral rehabilitation	
Loss of CD/RPD retention	18 (46.2%)
Loss of prosthesis itself	2 (5.1%)
Prosthesis fracture	4 (10.2%)
Aesthetic	15 (38.5%)
Prosthesis type performed (n)	
CD in both jaws	2 (5.1%)
Maxillary CD and mandibular RPD	7 (18.0%)
RPD in both jaws	25 (64.1%)
Maxillary or mandibular RPD	5 (12.8%)

CD: complete dentures; RPD: removable partial dentures

Table 2. Glycosylated hemoglobin level (HbA1c), number of elderly people with controlled diabetes, nutritional status, and MNA-SF score at each assessment time.

	Pre-treatment	12 months post-treatment	p Value[b]
HbA1c[a]	6.9 (5.4-13.1)	6.9 (5.3-13.1)	0.180
Glycosylate hemoglobin level[c]			1.000
HbA1c < 7%	23 (59%)	24 (62%)	
HbA1c ≥ 7%	16 (41%)	15 (38%)	
Nutritional status[c]			0.011
Well nourished (MNA-SF score >12)	26 (66.7%)	33 (84.6%)	
At risk (MNA-SF score: 8–11)	13 (33.3%)	6 (15.4%)	
Malnutrition (MNA-SF score <7)	0 (0.0%)	0 (0.0%)	
MNA-SF score[a]	12.0 (8.0-13.0)	13.0 (11.0-14.0)	< 0.001

[a]Data were presented as median (interquartile range).
[b]Wilcoxon test
[c]Data were presented as number of participants.
HbA1c < 7% - controlled diabetes; HbA1c ≥ 7% - uncontrolled diabetes
MNA-SF = Mini Nutritional Assessment short-form.

Table 3. OHIP-14 score at each assessment time.

Domain	Pre-treatment	12 months post-treatment	p Value [a]
Functional limitation	1.0 (0-3.1)	0.5 (0-1.5)	< 0.001
Physical pain	1.0 (0-3.0)	0.7 (0-2.0)	< 0.001
Psychological discomfort	1.0 (0-3.0)	0.5 (0-2.0)	< 0.001
Physical disability	1.0 (0-3.0)	0.5 (0-2.0)	< 0.001
Psychological disability	1.2 (0-3.0)	0.0 (0-2.0)	< 0.001
Social disability	1.0 (0-3.0)	0.0 (0-1.0)	< 0.001
Handicap	0.6 (0-3.0)	0.0 (0-1.0)	< 0.001
Overall	6.3 (0-18.5)	2.7 (0-9.1)	< 0.001

Data were presented as median (interquartile range).
[a]Wilcoxon test

Appendix File 1. STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Reported on page
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4,5
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	6, 7
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	NA
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	7
Bias	9	Describe any efforts to address potential sources of bias	6, 7
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	8
		(*b*) Describe any methods used to examine subgroups and interactions	8
		(*c*) Explain how missing data were addressed	8

		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	8
		(*e*) Describe any sensitivity analyses	NA
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	8
		(c) Consider use of a flow diagram	20
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8, 9, 21
		(b) Indicate number of participants with missing data for each variable of interest	NA
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	8, 20
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	8, 9
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	NA
		Cross-sectional study—Report numbers of outcome events or summary measures	NA
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8, 9, 22, 23
		(*b*) Report category boundaries when continuous variables were categorized	8, 9, 22, 23
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	10-12
Generalisability	21	Discuss the generalisability (external validity) of the study results	12, 13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

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

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

8 Considerações Finais

Baseado nos resultados obtidos, a reabilitação oral protética combinada com orientação nutricional básica pode influenciar positivamente no perfil nutricional e na qualidade de vida relacionada à saúde oral de indivíduos idosos com DM tipo 2. Não foi observado efeito significativo na melhora do controle glicêmico desses pacientes após instalação das próteses dentárias, no acompanhamento por 12 meses, provavelmente devido a não modificação dos hábitos alimentares dentro desse prazo.

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Apêndices

Apêndice A – Ficha de Exame Clínico

Número: _____

CARACTERIZAÇÃO DEMOGRÁFICA E SOCIOECONÔMICA

Nome:_____
Cor: _____ Sexo: M □ F □
Data de nascimento: _____ Idade: _____Profissão: _____
Residência:_____
Cidade:_____
Telefones:_____
E-mail: _____Data do exame: _____
Responsável:_____

1. Qual o seu estado civil?
1 ( ) Casado (a)
2 ( ) Solteiro (a)
3 ( ) Viúvo (a)
4 ( ) Divorciado (a)

2. Qual o seu grau de escolaridade?
1 ( ) Não alfabetizado
2 ( ) Ensino fundamental incompleto
3 ( ) Ensino fundamental completo
4 ( ) Ensino médio incompleto
5 ( ) Ensino médio completo
6 ( ) Ensino superior incompleto
7 ( ) Ensino superior completo
8 ( ) Pós-graduação.
9 ( ) Não sei

3. Qual a renda da sua família, em reais?
1 ( ) Até 1 salário mínimo
2 ( ) De 1 a 2 salários mínimos
3 ( ) De 2 a 3 salários mínimos
4 ( ) De 3 a 5 salários mínimos
5 ( ) De 5 a 10 salários mínimos
6 ( ) Mais de10 salários mínimos
7 ( ) Sem rendimento

4. Tem praticado atividade física?
1( ) Sim 2( ) Não 3 ( ) Não sei. Qual?
_____

5. Tem realizado acompanhamento nutricional?
1( ) Sim 2( ) Não 3 ( ) Não sei. Qual?
_____

HISTÓRICO GERAL

Quanto tempo de diagnóstico de Diabetes mellitus tipo 2? _____

Hemoglobina Glicada: _____ Data: _____

Glicemia em jejum: _____ Data: _____

Está em tratamento médico? □ SIM □ NÃO Motivo:_____

Outras Doenças sistêmicas:_____

Usa ou usou medicamentos recentemente? □ SIM □ NÃO

Quais?_____

Fuma? □ SIM □ NÃO □ EX-FUMANTE

HISTÓRICO BUCAL

1- Presença de dentes:
( ) sim ( ) não
Quantos?
Maxila: dentes
Mandíbula: dentes

2- Usuário de prótese:
( ) sim ( ) não
Maxila:
Mandíbula:

3- Tempo de uso da última prótese:
Maxila:
( ) 1 a 6 anos ( ) 7 anos ou mais: anos
Mandíbula:
( ) 1 a 6 anos ( ) 7 anos ou mais: anos

4- Estado de conservação da prótese:
Maxila:
( ) satisfatório ( ) insatisfatório
Mandíbula:
( ) satisfatório ( ) insatisfatório

5- Dorme com a prótese:
( ) sim ( ) não

6- Higienização da prótese:
Maxila: ( ) com placa ( ) sem placa
Mandíbula: ( ) com placa ( ) sem placa

7- Higienização da boca:
( ) sim. Como? ( ) escova
( ) bochecho
( ) outros
( ) não

8- Avaliação dos tecidos moles: Lesão traumática presente
( ) sim: ( )localizada ( ) difusa
( ) não

9- Oclusão:
( ) satisfatória
( ) insatisfatória
Desvio de linha média ( )sim ( )não

10- Satisfação com a prótese:
-Retenção e estabilidade
( ) satisfatória
( ) insatisfatória
- Pronuncia bem as palavras:
( ) sim ( ) não
- Está satisfeito com a estética:
( ) sim ( ) não

11- Possui sintomatologia dolorosa muscular, óssea ou na ATM?
( ) sim ( ) não
Local:

12- Capacidade mastigatória:
- Consegue mastigar tudo o que gosta de comer?
( ) sim ( ) não
- Consegue alimentar-se bem com a prótese?
( ) sim ( ) não
- Consegue comer cenoura crua, amendoim ou carne?
( ) sim ( ) não
- O que mais gosta de comer?
_____

GRUPO DO ESTUDO:

( ) Grupo DFN (dentição funcional natural)

( ) Grupo DFP (dentição funcional com prótese)

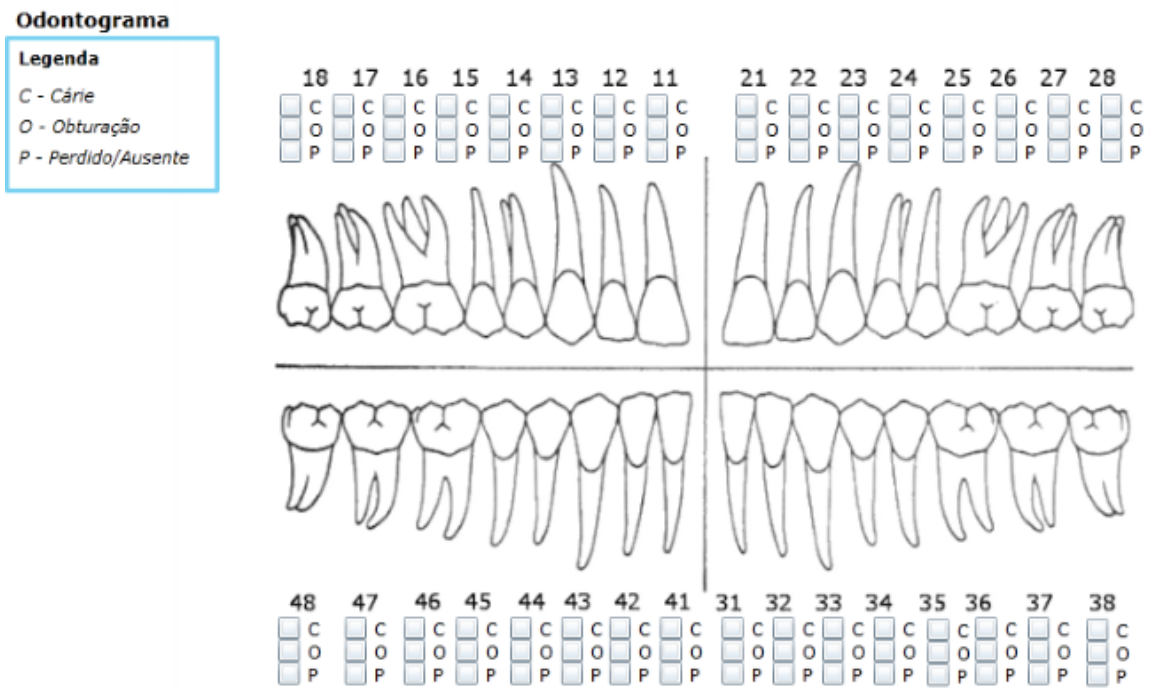
( ) Grupo DIN (dentição incompleta natural)

( ) Grupo DIP (dentição incompleta com prótese)

( ) Grupo ADP (ausência de dentes com prótese)

( ) Grupo AD (ausência de dentes)

OBSERVAÇÕES:



APÊNDICE B - TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Por esse instrumento particular declaro, para os devidos fins éticos e legais, que eu _____, brasileiro (a), nascido em ___/____/____, portador do RG nº _____ residente à _____ _____na cidade de _____ - Ceará, fui convidado (a) e concordo com a participação voluntária na pesquisa **"Impacto da reabilitação oral protética na qualidade de vida, índices nutricionais e no controle glicêmico de pacientes idosos com diabetes mellitus tipo 2"** e declaro que fui esclarecido (a) de maneira a não restarem dúvidas sobre a minha participação no estudo, de acordo com os termos abaixo relacionados:

1- A referida pesquisa tem como objetivo determinar a influência da perda de dentes no estado nutricional, controle glicêmico e na qualidade de vida de indivíduos idosos portadores de diabetes mellitus tipo 2.

2- A minha participação se daria da seguinte forma: os pacientes serão submetidos a exame clínico odontológico (exame dos dentes e gengiva), avaliação nutricional e avaliação de qualidade de vida com a aplicação de questionários, encaminhados para exame de hemoglobina glicada e glicemia em jejum (exame de sangue) em Laboratório de Análises Clínicas de Referência e quando indicado será confeccionada prótese dentária que poderá melhorar capacidade de mastigação.

3- A realização da pesquisa envolve riscos de aspecto não físico, uma vez que poderá causar constrangimento e/ou desconforto gerado pela aplicação dos questionários, que serão minimizados através do anonimato de sua participação, bem como a sua desistência em qualquer fase da pesquisa. O exame sanguíneo poderá trazer algum desconforto, mas com o objetivo de garantir uma maior segurança, esta coleta de pequena quantidade de sangue será realizada dentro de um laboratório de análises clínicas de referência, utilizando-se de instrumentais estéreis para a coleta e será realizada por uma equipe especializada e capacitada. O exame odontológico e caso seja necessário, a confecção de próteses dentárias, não implicarão em riscos diretos à saúde dos participantes, pois é um procedimento odontológico de rotina e bem estabelecido, realizado com instrumentais devidamente esterilizados, e os pacientes serão atendidos pelo responsável dessa pesquisa, que é especialista em Prótese Dentária, mas se houver algum problema ou desconforto, estes serão acompanhados pelo pesquisador que dará todo o apoio e encaminhamentos necessários para minimizá-los.

4- O estudo apresenta como benefícios a detecção de doenças bucais e alterações na gengiva existentes, e quando necessário, o paciente receberá orientações sobre as doenças e o tratamento,

além do encaminhamento para confecção de próteses dentárias. A pesquisa também contribuirá para um estudo científico que poderá evidenciar a necessidade de avanços no planejamento dos serviços de saúde bucal, concentrando esforços na prevenção da perda dentária.

5- Estou ciente de que serei esclarecido durante todo o decorrer da pesquisa sobre quaisquer dúvidas relacionadas a esta e que possuo plena liberdade para desistir, retirando o meu consentimento a qualquer momento, sem sofrer nenhuma penalização.

6- Estou ciente que os dados e resultados obtidos na pesquisa serão utilizados para fins didáticos e de divulgação em revistas científicas brasileiras ou estrangeiras; porém será garantido o sigilo de minha identidade, assegurando a minha privacidade.

7- Estou ciente que a participação na pesquisa não acarretará em nenhum gasto e caso tenha algum prejuízo material ou imaterial em decorrência da pesquisa poderá solicitar indenização, de acordo com a legislação vigente.

8- O pesquisador responsável, que rubrica e assina duas vias desse documento, compromete-se a conduzir a pesquisa de acordo com o que preconiza a Resolução 466/12 de 12/06/2012, que trata dos preceitos éticos e da proteção aos participantes da pesquisa.

Endereço do responsável pela pesquisa:
Nome: Jandenilson Alves Brígido **Instituição**: Centro Universitário Fametro
Endereço: Av. Filomeno Gomes Nº 184 – Jacarecanga - Telefone: (85) 3022-7068

ATENÇÃO:
Se você tiver alguma dúvida sobre a sua participação na pesquisa entre em contato com o Comitê de Ética em Pesquisa da UNIFAMETRO – Rua Conselheiro Estelita Nº 500 – Centro, Fortaleza-CE, Telefone (85) 3206-6417 - e-mail: cep@unifametro.com.br.

Desta forma, uma vez tendo lido e entendido tais esclarecimentos, dato, rubrico e assino duas vias desse termo de consentimento, por estar de pleno acordo com o teor do mesmo e declaro que recebi uma das vias.

Fortaleza, ____ de _____ de _____.

_____

Consentimento do Paciente

_____

Jandenilson Alves Brígido

Pesquisador Responsável

Anexos

Anexo A – Mini Avaliação Nutricional

Mini Nutritional Assessment
MNA®

Nestlé Nutrition Institute

Apelido: Nome:

Sexo: Idade: Peso, kg: Altura, cm: Data:

Responda à secção "triagem", preenchendo as caixas com os números adequados. Some os números da secção "triagem".
Se a pontuação obtida for igual ou menor que 11, continue o preenchimento do questionário para obter a pontuação indicadora de desnutrição.

Triagem

A Nos últimos três meses houve diminuição da ingesta alimentar devido a perda de apetite, problemas digestivos ou dificuldade para mastigar ou deglutir?
0 = diminuição grave da ingesta
1 = diminuição moderada da ingesta
2 = sem diminuição da ingesta ☐

B Perda de peso nos últimos 3 meses
0 = superior a três quilos
1 = não sabe informar
2 = entre um e três quilos
3 = sem perda de peso ☐

C Mobilidade
0 = restrito ao leito ou à cadeira de rodas
1 = deambula mas não é capaz de sair de casa
2 = normal ☐

D Passou por algum *stress* psicológico ou doença aguda nos últimos três meses?
0 = sim 2 = não ☐

E Problemas neuropsicológicos
0 = demência ou depressão graves
1 = demência ligeira
2 = sem problemas psicológicos ☐

F Índice de Massa Corporal (IMC = peso[kg] / estatura [m²])
0 = IMC < 19
1 = 19 ≤ IMC < 21
2 = 21 ≤ IMC < 23
3 = IMC ≥ 23 ☐

Pontuação da Triagem (subtotal, máximo de 14 pontos) ☐☐
12-14 pontos: estado nutricional normal
8-11 pontos: sob risco de desnutrição
0-7 pontos: desnutrido
Para uma avaliação mas detalhada,continue com as perguntas G-R

Avaliação global

G O doente vive na sua própria casa (não em instituição geriátrica ou hospital)
1 = sim 0 = não ☐

H Utiliza mais de três medicamentos diferentes por dia?
0 = sim 1 = não ☐

I Lesões de pele ou escaras?
0 = sim 1 = não ☐

J Quantas refeições faz por dia?
0 = uma refeição
1 = duas refeições
2 = três refeições ☐

K O doente consome:
- pelo menos uma porção diária de leite ou derivados (leite, queijo, iogurte)? sim ☐ não ☐
- duas ou mais porções semanais de leguminosas ou ovos? sim ☐ não ☐
- carne, peixe ou aves todos os dias? sim ☐ não ☐

0.0 = nenhuma ou uma resposta «sim»
0.5 = duas respostas «sim»
1.0 = três respostas «sim» ☐.☐

L O doente consome duas ou mais porções diárias de fruta ou produtos hortícolas?
0 = não 1 = sim ☐

M Quantos copos de líquidos (água, sumo, café, chá, leite) o doente consome por dia?
0.0 = menos de três copos
0.5 = três a cinco copos
1.0 = mais de cinco copos ☐.☐

N Modo de se alimentar
0 = não é capaz de se alimentar sozinho
1 = alimenta-se sozinho, porém com dificuldade
2 = alimenta-se sozinho sem dificuldade ☐

O O doente acredita ter algum problema nutricional?
0 = acredita estar desnutrido
1 = não sabe dizer
2 = acredita não ter um problema nutricional ☐

P Em comparação com outras pessoas da mesma idade, como considera o doente a sua própria saúde?
0.0 = pior
0.5 = não sabe
1.0 = igual
2.0 = melhor ☐.☐

Q Perímetro braquial (PB) em cm
0.0 = PB < 21
0.5 = 21 ≤ PB ≤ 22
1.0 = PB > 22 ☐.☐

R Perímetro da perna (PP) em cm
0 = PP < 31
1 = PP ≥ 31 ☐

Avaliação global (máximo 16 pontos) ☐☐.☐
Pontuação da triagem ☐☐.☐
Pontuação total (máximo 30 pontos) ☐☐.☐

Avaliação do Estado Nutricional

de 24 a 30 pontos ☐	estado nutricional normal
de 17 a 23,5 pontos ☐	sob risco de desnutrição
menos de 17 pontos ☐	desnutrido

References
1. Vellas B, Villars H, Abellan G, *et al.* Overview of the MNA® - Its History and Challenges. *J Nutr Health Aging.* 2006; **10**:456-465.
2. Rubenstein LZ, Harker JO, Salva A, Guigoz Y, Vellas B. Screening for Undernutrition in Geriatric Practice: Developing the Short-Form Mini Nutritional Assessment (MNA-SF). *J. Geront.* 2001; **56A**: M366-377
3. Guigoz Y. The Mini-Nutritional Assessment (MNA®) Review of the Literature - What does it tell us? *J Nutr Health Aging.* 2006; **10**:466-487.

Anexo B – Questionário OHIP -14

1.Você teve problemas para falar alguma palavra por causa de problemas com sua(s) prótese(s)?
( ) nunca ( ) quase nunca ( ) às vezes ( ) quase sempre ( ) sempre
2.Você sentiu que o sabor dos alimentos ficou pior por causa de problemas com sua(s) prótese(s)?
( ) nunca ( ) quase nunca ( ) às vezes ( ) quase sempre ( ) sempre
3.Você já sentiu dores fortes em sua boca?
( ) nunca ( ) quase nunca ( ) às vezes ( ) quase sempre ( ) sempre
4.Você se sentiu incomodado ao comer algum alimento por causa de problemas com sua(s) prótese(s)?
( ) nunca ( ) quase nunca ( ) às vezes ( ) quase sempre ( ) sempre
5. Você ficou constrangido por causa de problemas com sua(s) prótese(s)?
( ) nunca ( ) quase nunca ( ) às vezes ( ) quase sempre ( ) sempre
6. Você se sentiu estressado por causa de problemas com sua(s) prótese(s)?
( ) nunca ( ) quase nunca ( ) às vezes ( ) quase sempre ( ) sempre
7. Sua alimentação ficou prejudicada por causa de problemas com sua(s) prótese(s)?
( ) nunca ( ) quase nunca ( ) às vezes ( ) quase sempre ( ) sempre
8. Você teve que parar suas refeições por causa de problemas com sua(s) prótese(s)?
( ) nunca ( ) quase nunca ( ) às vezes ( ) quase sempre ( ) sempre
9.Você encontrou dificuldade para relaxar por causa de problemas com sua(s) prótese(s)?
( ) nunca ( ) quase nunca ( ) às vezes ( ) quase sempre ( ) sempre
10. Você sentiu-se envergonhado por causa de problemas com sua(s) prótese(s)?
( ) nunca ( ) quase nunca ( ) às vezes ( ) quase sempre ( ) sempre
11. Você ficou irritado com outras pessoas por causa de problemas com sua(s) prótese(s)?
( ) nunca ( ) quase nunca ( ) às vezes ( ) quase sempre ( ) sempre
12. Você teve dificuldades em realizar suas atividades diárias por causa de problemas com sua(s) prótese(s)?
( ) nunca ( ) quase nunca ( ) às vezes ( ) quase sempre ( ) sempre
13. Você sentiu que a vida, em geral, ficou pior por causa de problemas com sua(s) prótese(s)?
( ) nunca ( ) quase nunca ( ) às vezes ( ) quase sempre ( ) sempre
14. Você ficou totalmente incapaz de fazer suas atividades diárias por causa de problemas com sua(s) prótese(s)?
( ) nunca ( ) quase nunca ( ) às vezes ( ) quase sempre ( ) sempre

Anexo C – APROVAÇÃO CEP

FACULDADE METROPOLITANA DA GRANDE FORTALEZA - FAMETRO

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: IMPACTO DA REABILITAÇÃO ORAL PROTÉTICA NA QUALIDADE DE VIDA, ÍNDICES NUTRICIONAIS E NO CONTROLE GLICÊMICO DE PACIENTES IDOSOS PORTADORES DE DIABETES MELLITUS TIPO 2

Pesquisador: JANDENILSON ALVES BRÍGIDO

Área Temática:

Versão: 2

CAAE: 16188719.9.0000.5618

Instituição Proponente: EMPREENDIMENTO EDUCACIONAL MARACANAÚ

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.461.743

Apresentação do Projeto:

Os autores manifestam que a terapia nutricional é fundamental na prevenção, tratamento e gerenciamento do diabetes mellitus (DM). O edentulismo é considerado um agravo à saúde bucal, que pode impactar na função mastigatória, fonética, prejuízos de ordem nutricional, comprometimento estético, com efeitos diretos sobre a condição psicológica e, a qualidade de vida dos indivíduos. Nesse entender o presente trabalho avaliará a influência da reabilitação protética na qualidade de vida, estado nutricional e índices glicêmicos. O estudo é de tipo qualitativo, quantitativo, observacional. Para isso serão selecionados indivíduos com 60 anos ou mais com diagnóstico de DM tipo 2, divididos em 6 grupos da seguinte forma: grupo 0 = presença de 21 a 32 dentes naturais - sem dentes substituídos; grupo 1 = presença de 21 a 32 dentes naturais e substituídos; grupo 2 = presença de 1 a 20 dentes naturais - sem dentes substituídos; grupo 3 = presença de 1 a 20 dentes naturais e substituídos; grupo 4 = totalmente edêntulo com prótese total bem adaptada; e grupo 5 = totalmente edêntulo sem prótese ou prótese desadaptada. Serão aplicados os questionários Oral Health Impact Profile - short form (OHIP-14) para avaliar o impacto da condição oral na qualidade de vida, e a Mini Avaliação Nutricional (MAN) associado a exames laboratoriais, para investigar o estado nutricional e o controle glicêmico. Nos pacientes com necessidade de reabilitação oral protética (grupos 2, 3 e 5), serão confeccionadas próteses dentárias, e após fase de adaptação (6 e 12 meses), serão

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UF: CE **Município:** FORTALEZA
Telefone: (85)3206-6417 **Fax:** (85)3206-6417 **E-mail:** cep@unifametro.edu.br

aplicados novos questionários e exames laboratoriais para fins de comparação.
Após a obtenção dos dados, será realizada análise descritiva dos dados com as estimativas de média e desvio padrão para as variáveis quantitativas. As comparações entre os grupos, serão realizadas a partir do teste t de Student para comparações de amostras independentes e o teste t de Student pareado para as condições antes x depois (amostras dependentes). Em todos os testes será adotado um nível de significância de 95%($p<0,05$).

Objetivo da Pesquisa:

Objetivo geral:

• Determinar a influência da reabilitação oral no estado nutricional, controle glicêmico e na qualidade de vida de indivíduos idosos portadores de diabetes mellitus tipo 2. Objetivos Específicos:

• Revisar sistemáticamente os estudos que avaliaram a associação do edentulismo e diabetes mellitus tipo 2.

• Avaliar a associação entre a reabilitação oral e a qualidade de vida em indivíduos idosos com diabetes mellitus tipo 2, por meio do Oral Health Impact Profile (OHIP14).

• Avaliar a associação entre a reabilitação oral e avaliação nutricional em indivíduos idosos com diabetes mellitus tipo 2, através da Mini Avaliação Nutricional (MAN).

• Avaliar a associação entre a reabilitação oral e controle glicêmico em indivíduos idosos com diabetes mellitus tipo 2, por meio de exames de Hemoglobina Glicada e Glicemia em jejum.

Avaliação dos Riscos e Benefícios:

Os pesquisador manifestam que a realização da pesquisa envolve riscos de aspecto não físico, uma vez que poderá causar constrangimento e/ou desconforto gerado pela aplicação dos questionários, que serão minimizados através do anonimato de sua participação, bem como a sua desistência em qualquer fase da pesquisa. O exame sanguíneo para avaliação de índices glicêmicos pode trazer algum desconforto, mas com o objetivo de garantir uma maior segurança, esta coleta de pequena quantidade de sangue será realizada dentro de um laboratório de análises clínicas de referência, utilizando-se de instrumentais estéreis para a coleta e será realizada por uma equipe especializada e capacitada. O exame odontológico e caso seja necessário, a confecção de próteses dentárias, não implicarão em riscos diretos à saúde dos participantes, pois o exame clínico e o tratamento a que será submetido é um procedimento odontológico de rotina e bem estabelecido, realizado com instrumentais devidamente esterilizados, e os pacientes serão atendidos pelo responsável dessa pesquisa, que é especialista

em Prótese Dentária.

O estudo apresenta como benefícios a detecção de doenças bucais e alterações periodontais existentes, e quando necessário, o paciente receberá orientações sobre as doenças e o tratamento, além do encaminhamento para confecção de próteses dentárias. A pesquisa também contribuirá para um estudo científico que poderá evidenciar a necessidade de avanços no planejamento dos serviços de saúde bucal, concentrando esforços na prevenção da perda dentária.

Comentários e Considerações sobre a Pesquisa:

Sem comentários adicionais.

Considerações sobre os Termos de apresentação obrigatória:

O trabalho apresenta os termos obrigatórios devidamente preenchidos

- Termo de anuência assinado pela Reitora da instituição;
- Folha de rosto assinada pela Reitora da instituição;
- Projeto da pesquisa;
- Termo de consentimento livre esclarecido.

Recomendações:

Sem comentários adicionais.

Conclusões ou Pendências e Lista de Inadequações:

Considerando que o projeto atende as recomendações da resolução N° 466/12 o mesmo esta aprovado pelo CEP UNIFAMETRO.

Considerações Finais a critério do CEP:

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1379396.pdf	29/06/2019 10:09:45		Aceito
Cronograma	Cronograma_de_Atividades_Corrigido.pdf	29/06/2019 10:08:14	JANDENILSON ALVES BRÍGIDO	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_Jandenilson_CEP_corrigido.pdf	29/06/2019 10:07:24	JANDENILSON ALVES BRÍGIDO	Aceito
Declaração de Instituição e Infraestrutura	Anuencia_Jandenilson.pdf	19/06/2019 11:31:07	JANDENILSON ALVES BRÍGIDO	Aceito
Folha de Rosto	Folha_de_rosto_Jandenilson.pdf	19/06/2019	JANDENILSON	Aceito

FACULDADE METROPOLITANA DA GRANDE FORTALEZA - FAMETRO

Continuação do Parecer: 3.461.743

Folha de Rosto	Folha_de_rosto_Jandenilson.pdf	11:27:00	ALVES BRÍGIDO	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Projeto_Jandenilson.pdf	16/06/2019 21:42:38	JANDENILSON ALVES BRÍGIDO	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

FORTALEZA, 19 de Julho de 2019

Assinado por:
Germana Costa Paixão
(Coordenador(a))

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