BIANCA APARECIDA DE SOUSA

EFEITOS DE UMA INTERVENÇÃO COM TEMPO RESTRITO DE ALIMENTAÇÃO EM INDIVÍDUOS COM EXCESSO DE PESO

LAVRAS - MG

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Profa. Dra. Camila Maria de Melo

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EFEITOS DE UMA INTERVENÇÃO COM TEMPO RESTRITO DE ALIMENTAÇÃO EM INDIVÍDUOS COM EXCESSO DE PESO

EFFECTS OF AN INTERVENTION WITH TIME RESTRICTED EATING IN OVERWEIGHT INDIVIDUALS

Dissertação apresentada à Universidade Federal de Lavras, como parte das exigências do Programa de Pós Graduação em Nutrição e Saúde, área de concentração Nutrição e Saúde, para a obtenção do título de Mestre.

APROVADA EM 08 DE MAIO DE 2025.

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LAVRAS – MG

2025

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RESUMO

O tempo restrito de alimentação (TRA) consiste em restringir o tempo de alimentação durante o dia e prolongar o tempo de jejum. Estudos têm demonstrado que esta pode ser uma estratégia mais sustentável a longo prazo para a redução da massa corporal. Além disso, parece viável para melhora na qualidade do sono em indivíduos com excesso de peso. O objetivo desta dissertação foi avaliar os efeitos do TRA sobre parâmetros de sono e composição corporal em adultos com obesidade e com apneia obstrutiva do sono (AOS). Para ambos os ensaios clínicos realizados com TRA de 8h por 12 semanas, foram incluídos indivíduos com obesidade (IMC> 30Kg/m²) e janela alimentar superior a 11 horas, e no ensaio clínico *crossover,* foram incluídos indivíduos com AOS. Todos os participantes foram submetidos a medidas antropométricas, de composição corporal por bioimpedância elétrica, avaliação do sono por meio de monitor portátil de sono e questionários, avaliação do consumo alimentar por registro alimentar de três dias antes e depois da intervenção. No ensaio randomizado, foram incluídos 35 participantes e no estudo do tipo *crossover* 12 participantes. Em ambos os estudos, a idade da amostra foi superior a 40 anos e de ambos os sexos. A adesão à intervenção dos dois estudos foi superior a 4 dias por semana. No estudo randomizado, foi observada redução do peso corporal e do IMC apenas entre os participantes que completaram a intervenção TRA, com redução da massa muscular esquelética, massa livre de gordura e de água corporal total, exclusivamente no grupo TRA pela intenção de tratamento (IT). Não foram observadas alterações no sono. No estudo *crossover*, houve redução significativa da massa corporal, IMC, circunferência da cintura e da massa muscular apendicular apenas no grupo TRA avaliado após a intervenção. O grupo TRA apresentou uma redução significativa no tempo de ronco e na carga hipóxica e aumento significativo na saturação mínima de oxigênio. Dessa forma, a presente dissertação demonstrou que uma intervenção com TRA não foi efetiva em reduzir o peso e melhorar parâmetros de sono em indivíduos obesos, porém pode ser benéfica na melhora de parâmetros de sono em indivíduos com distúrbio de sono como a AOS.

Palavras-chave: Obesidade; Sono; Jejum intermitente; Crononutrição.

ABSTRACT

Time-restricted eating (TRE) involves limiting the daily eating window and extending the fasting period. Studies have indicated that this approach may represent a more sustainable long-term strategy for body mass reduction. Additionally, it appears to be a feasible method for improving sleep quality in individuals with excess weight. The objective of this dissertation was to evaluate the effects of TRE on sleep parameters and body composition in adults with obesity and obstructive sleep apnea (OSA). For both clinical trials implementing an 8-hour TRE regimen over 12 weeks, individuals with obesity (BMI > 30 kg/m²) and a habitual eating window greater than 11 hours were included. In the crossover trial, participants with OSA were specifically recruited. All participants underwent anthropometric assessments, body composition analysis via bioelectrical impedance, sleep evaluation using portable sleep monitors and questionnaires, and dietary intake assessment through three-day food records before and after the intervention.The randomized trial included 35 participants, while the crossover study included 12 participants. In both studies, the sample comprised individuals over 40 years of age and of both sexes. Adherence to the intervention exceeded four days per week in both trials. In the randomized study, reductions in body weight and BMI were observed only among participants who completed the TRE intervention. In the intention-to-treat analysis (ITT), reductions in skeletal muscle mass, fat-free mass, and total body water were observed exclusively in the TRE group. No significant changes in sleep parameters were detected. In the crossover study, significant reductions in body mass, BMI, waist circumference, and appendicular skeletal muscle mass were found only in the TRE group following the intervention. This group also exhibited significant reductions in snoring duration and hypoxic burden, as well as a significant increase in minimum oxygen saturation. Therefore, this dissertation demonstrated that while a TRE intervention was not effective in reducing weight or improving sleep parameters in individuals with obesity, it may offer benefits for improving sleep-related parameters in individuals with sleep disorders such as OSA.

Key-words: Obesity; Sleep; Intermittent fasting; Crononutrition.

INDICADORES DE IMPACTO

O projeto intitulado Efeitos do Tempo Restrito de Alimentação sobre peso, composição corporal e sono de indivíduos com excesso de peso investigou os efeitos de uma intervenção nutricional durante 12 semanas sobre o peso, composição corporal e sono de indivíduos com excesso de peso no município de Lavras e região. Considerando seu caráter extensionista, o projeto incluiu estudantes e servidores da comunidade acadêmica e participantes fora do ambiente acadêmico que se disponibilizaram a participar do projeto, o que contabilizou por volta de 40 participantes. Além de beneficiar diferentes indivíduos, contou com o envolvimento de alunos de iniciação científica e parcerias com outros professores dentro e fora da Universidade. Seu principal impacto envolve a saúde dos participantes, mas também o impacto social, em que destaca-se o acesso gratuito, voluntário e seguro a um programa voltado a redução do peso corporal, realizado por profissional capacitado e que contribui para resultados benéficos à qualidade de vida dessa população, como redução do peso corporal, melhora de parâmetros de sono e redução do risco de desenvolvimento de doenças associadas como diabetes e hipertensão. Além disso, o projeto possibilitou uma avaliação do sono dos participantes com um dispositivo portátil de alta tecnologia, acessível, de fácil uso e validado para diagnóstico de Apneia obstrutiva do sono (AOS), uma doença muito comum em indivíduos obesos, associada a diferentes desfechos negativos, porém com diagnóstico dificultado pelo valor e acesso ao método padrão ouro no diagnóstico de AOS.

IMPACT INDICATORS

The project titled "Effects of Time-Restricted Feeding on Weight, Body Composition, and Sleep in Overweight Individuals" investigated the effects of a 12-week nutritional intervention on the weight, body composition, and sleep of overweight individuals in the municipality of Lavras and surrounding areas. Given its extension-oriented nature, the project included students and staff from the academic community as well as participants from outside the academic environment who volunteered to take part, totaling approximately 40 participants. In addition to benefiting a diverse group of individuals, the project involved undergraduate research students and fostered collaborations with professors both within and outside the university. Its primary impact lies in improving participants' health, but it also has a significant social impact by providing free, voluntary, and safe access to a weight reduction program led by a qualified professional. This initiative contributed to beneficial outcomes for participants' quality of life, such as weight loss, improved sleep parameters, and a reduced risk of developing associated conditions like diabetes and hypertension. Furthermore, the project enabled sleep assessments using a high-tech, portable, user-friendly, and validated device for diagnosing obstructive sleep apnea (OSA), a highly prevalent condition among obese individuals that is linked to various adverse health outcomes. The use of this device helped address the challenges of diagnosing OSA, which is often hindered by the high cost and limited accessibility of the gold-standard diagnostic method.

SUMÁRIO

1 INTRODUÇÃO

A obesidade é uma doença crônica não transmissível que afeta uma em cada oito pessoas no planeta e por isso é considerada um importante problema de saúde pública (NCD-RisC, 2024). A etiologia da doença é complexa e multifatorial, resultante da influência do ambiente, do estilo de vida, condições genéticas, psicológicas e culturais (Abeso, 2022 e 2016). Sua principal consequência envolve alterações metabólicas que implicam no surgimento de doenças como diabetes, doenças cardiovasculares e redução na qualidade e tempo de vida (Zokaei et al., 2020; Seravalle & Grassi, 2017; Dikaiou et al., 2021).

A má qualidade e o tempo reduzido de sono têm sido associados ao desenvolvimento de obesidade (Chaput, J. P., 2023; Fátima, Doi e Mamun, 2016). Estudos sugerem que alterações no balanço energético, bem como um comportamento alimentar inadequado induzidos pela restrição aguda do sono são responsáveis pelo ganho de peso (Broussard e Klein, 2022). Outra explicação é que a redução do tempo de sono aliada às mudanças drásticas no estilo de vida da população, implica no desequilíbrio do ritmo circadiano e aumenta as chances de desenvolver obesidade e condições associadas (Challet 2019; Chaput et al., 2022; Marhefkova et al., 2024).

A via de mão dupla entre sono e obesidade, é também consolidada pela alta prevalência de distúrbios do sono como a apneia obstrutiva do sono (AOS) em pacientes com obesidade (Bonsinore, 2022). As consequências da AOS, como a fragmentação do sono e hipóxia intermitente, quando não tratadas, estão associadas ao surgimento de doenças cardiovasculares, ganho de peso e alterações metabólicas (Drager et al., 2018; Melo et al., 2017). Isso reforça a necessidade de um tratamento mais efetivo para a obesidade, que envolve alterações no estilo de vida, com destaque para a melhora dos hábitos alimentares (Abeso, 2022).

Existem várias estratégias nutricionais que desempenham um importante papel na regulação do peso corporal. Dietas com restrição calórica, controle de macronutrientes e mudanças na qualidade da alimentação são aliadas na perda de peso corporal (Napoleão et al., 2021; Dobrosielski et al., 2017; Kechribari et al., 2022). No entanto, a adesão a essas estratégias é considerada baixa (Cienfuegos et al., 2022), dando espaço a novas estratégias que visem o controle da obesidade.

O tempo restrito de alimentação (TRA) é um tipo de jejum intermitente que contribui para a redução do peso corporal, tornando-se uma alternativa de tratamento para a obesidade. A limitação do tempo de alimentação durante o dia promove a redução da fome e do desejo de comer, a redução do consumo calórico e ainda contribui para a perda de peso corporal mais

sustentável do que em outros tipos de intervenções dietéticas (Cienfuegos et al., 2022; Adafer et al., 2020). Além disso, parece contribuir para melhora da qualidade do sono, resistência insulínica e promove melhora na oxidação de gorduras (Allison et al., 2021).

Estudos recentes, têm buscado compreender os efeitos do TRA na qualidade do sono, insônia e risco para AOS (Cienfuegos et al., 2022; Adafer et al., 2020), mas ainda falta consenso na literatura dos efeitos do TRA sobre o sono de indivíduos com obesidade, principalmente devido a falta de dados objetivos de avaliação do sono. Além disso, até o momento nenhum ensaio clínico testou os efeitos do TRA sobre os desfechos sono e composição corporal em indivíduos com AOS

2 OBJETIVOS

2.1 Objetivo geral

O objetivo deste estudo foi avaliar os efeitos de uma intervenção com TRA sobre sono e composição corporal em indivíduos com excesso de peso e com AOS.

2.2 Objetivos específicos

Avaliar os efeitos de uma intervenção com TRA de 8h durante 12 semanas sobre o peso e composição corporal.

Avaliar os efeitos de uma intervenção com TRA de 8h durante 12 semanas sobre o perfil de sono de indivíduos com obesidade e indivíduos com AOS

3 JUSTIFICATIVA

A obesidade é um importante problema de saúde pública que predispõe doenças como diabetes, doenças cardiovasculares e distúrbios do sono, como a AOS. Ao mesmo tempo, o sono é um processo biológico que quando reduzido ou em má qualidade tem sido associado à obesidade. É evidente a via de mão dupla entre sono e obesidade, o que reforça a necessidade de maior atenção sobre distúrbios de sono e o próprio sono. Grande parcela da população não reconhece a importância do sono, considerado um componente essencial para a manutenção da saúde e qualidade de vida. Na literatura, o estudo do sono ainda vem crescendo e existem muitas lacunas a serem preenchidas.

Considerando que o tratamento da obesidade e de distúrbios do sono envolvem a redução do peso corporal, são necessárias intervenções nutricionais viáveis. Estudos demonstram que o TRA contribui para uma perda de peso mais sustentável que outros tipos de intervenção nutricional, ainda contribui para a redução de gordura corporal e melhora dos parâmetros de sono. No entanto, estudos demonstram que os efeitos da TRA na melhora dos parâmetros de sono vão além da perda de peso, associando-o com o alinhamento do ritmo circadiano. Reduzir o período alimentar durante o dia tende a prolongar o intervalo entre a última refeição do dia e o horário de dormir, o que também está associado a regulação do relógio biológico e consequente melhora dos parâmetros metabólicos e do sono.

Dessa forma, ao avaliar os efeitos de uma intervenção nutricional com TRA sobre diferentes desfechos em indivíduos obesos e com distúrbios de sono, o presente trabalho contribui para o desenvolvimento de alternativa viável para a redução do peso corporal e melhora de diferentes componentes da saúde.

4 HIPÓTESE

A obesidade é uma doença crônica não transmissível, associada a outras doenças metabólicas, a pior qualidade do sono e a distúrbios do sono. O tratamento da obesidade, por sua vez, implica em melhora nos parâmetros de sono e condições metabólicas. Atualmente, o TRA tem ganhado espaço ao demonstrar importantes efeitos na perda de peso e uma boa adesão, além da melhora do quadro de resistência insulínica e melhora na qualidade do sono.

Dessa forma, acredita-se que restringir o tempo de alimentação tenha efeitos sobre o sono e a composição corporal de indivíduos com excesso de peso e em indivíduos com AOS. Temos como hipótese nula (H0) que indivíduos com excesso de peso submetidos ao TRA não apresentem mudanças nos parâmetros de sono e perda de peso. Como hipótese alternativa (H1) a intervenção nutricional com TRA pode contribuir para a perda de peso, melhora da composição corporal e qualidade do sono destes pacientes.

5 REFERENCIAL TEÓRICO

5.1 Obesidade

A obesidade é considerada um importante problema de saúde pública, pois afeta 159 milhões de crianças e adolescentes e 879 milhões de adultos, o que contabiliza 1 bilhão de pessoas no mundo, ou seja, uma em cada oito pessoas no mundo convivem com a obesidade (NCD-RisC, 2024). No Brasil, segundo os dados da Pesquisa de Vigilância de Fatores de Risco e Proteção para Doenças Crônicas por Inquérito (VIGITEL) (Brasil, 2020), no conjunto das 27 cidades brasileiras, a frequência de excesso de peso foi de 55,4% em 2019, sendo ligeiramente maior entre homens (57,1%) do que entre mulheres (53,9%).

Trata-se de uma doença crônica não transmissível, definida pelo acúmulo anormal e excessivo de depósitos de gordura corporal, consequência do desequilíbrio entre ingestão e gasto de energia (Schneeberger, Gomis, Claret 2014). O excesso de gordura corporal tem sido associado a maior prevalência de alterações no metabolismo de lipídios e glicemia em indivíduos adultos (Zokaei et al., 2020). Consequentemente isso implica no surgimento de doenças como hipertensão arterial, diabetes mellitus e Doenças Cardiovasculares (DCV), tendo a última doença um alto grau de mortalidade (Seravalle, Grassi, 2017; Dikaiou et al., 2021).

A etiologia da obesidade é complexa e multifatorial, resultante da influência do ambiente, do estilo de vida, além de condições genéticas, psicológicas, culturais e étnicas (Abeso, 2016; Abeso, 2022). Distúrbios nos mecanismos de controle da fome e saciedade, como os hormônios leptina e grelina, também são considerados importantes causadores do excesso de peso (Obradovic et al., 2021; Espinoza García, Martinez Moreno, Reyes Castillo, 2021). Recentemente, a má qualidade e o tempo reduzido de sono também têm sido associados ao desenvolvimento de obesidade (Chaput et al, 2023; Fátima, Doi, Mamun, 2016).

5.2 Obesidade e sono

O sono é um processo biológico associado à diminuição da responsividade ao ambiente externo e corresponde ao período diário de jejum e de mobilização dos estoques de energia (Challet, 2019; Ogilvie e Patel, 2017). Evidências demonstram sua importância no processo de memória, aprendizagem, regulação do sistema imunológico, além de outros benefícios para a manutenção da saúde (Ogilvie e Patel, 2017; Drager et al., 2018).

De modo geral, a população tem apresentado um tempo de sono inferior ao recomendado pela Fundação Nacional de Sono (Hirshkowitz et al., 2015), que recomenda de 7 a 9 horas de sono para o público jovem e adulto. Tanto uma curta duração, quanto uma duração

muito prolongada do sono tem sido associada a um maior risco de obesidade (Chaput et al., 2023; Keramat et al., 2023). Uma explicação plausível de acordo com os estudos é que alterações no balanço energético, hormônios de fome e saciedade, bem como o comportamento alimentar inadequado induzidos pela restrição aguda do sono são responsáveis pela regulação do peso (Broussard e Klein, 2022). Outra explicação é que a redução do tempo de sono aliada às mudanças drásticas no estilo de vida da população, como a realização de atividades quando o organismo está promovendo o sono, implica na redefinição dos relógios circadianos, também chamada cronoruptura (Challet, 2019; Chaput et al., 2023).

O desalinhamento circadiano tem ganhado destaque entre os pesquisadores principalmente pelo seu papel em regular a liberação de hormônios que afetam a tolerância à glicose, como cortisol, hormônio do crescimento e melatonina, que são componentes associados ao sono e a obesidade (Marhefkova et al. 2024). Dessa forma, o desequilíbrio no ritmo circadiano aumenta as chances de desenvolver obesidade e condições associadas, como diabetes e síndrome metabólica (Marhefkova et al. 2024; Sheikh-Ali, Maharaj J., 2014).

5.3 Apneia Obstrutiva do Sono

A existência de uma via de mão dupla entre sono e obesidade, pode ser também explicada pela alta prevalência de distúrbios do sono como a AOS em pacientes com obesidade (Bonsignore, 2022). Estima-se que quase 1 bilhão de pessoas no mundo possam ter o diagnóstico de AOS, e o Brasil encontra-se entre os 10 países com maior número de indivíduos com AOS (Benjafield et al., 2019). Além disso, a prevalência da doença tende a aumentar com a idade, consequente de alterações promovidas pelo envelhecimento, sendo mais comum entre os homens, pelo fato de que a anatomia das vias aéreas superiores (VAS) dos homens são mais colapsáveis do que as das mulheres (Duarte et al., 2022).

A AOS é um distúrbio respiratório do sono caracterizado por repetidas obstruções da via aérea superior durante o sono, nomeadas como apneias, quando ocorrem obstruções totais da via aérea e hipopneias quando as obstruções são parciais (Levi et al., 2015; Kapur et al., 2017). A fisiopatologia da AOS é complexa e pode ser associada ao comprometimento anatômico ou ineficiência dos músculos dilatadores das VAS, baixo limiar de despertares ou mesmo do controle ventilatório instável (Duarte et al., 2022). Seus principais sintomas incluem ronco alto, sono não reparador e sonolência diurna excessiva e consequências como a fragmentação do sono e hipóxia intermitentes, que quando não tratadas, estão associadas ao

surgimento de doenças cardiovasculares, ganho de peso e alterações metabólicas (Drager et al., 2018; Melo et al., 2017).

O método padrão ouro para o diagnóstico da AOS é a polissonografia do tipo I, completa e supervisionada em laboratório, cujo o diagnóstico de AOS é estabelecido baseado no Índice de Apneia hipopneia (IAH) superior ou igual a 5 eventos por hora (Duarte et al., 2022). No entanto, devido a limitações da polissonografia do tipo I, muitos estudos têm utilizado dispositivos domésticos pela maior viabilidade, o que aumenta o acesso ao diagnóstico e consequentemente ao tratamento (Pinheiro et al., 2020; Domingues et al., 2024). Uma das principais formas de tratamento da AOS envolve a terapia com pressão positiva contínua noturna nas vias aéreas (CPAP), que por sua parte apresenta dificuldades na adesão (Mohammadieh et al., 2017). Embora exista outras formas de tratamento da AOS, como cirurgia e outros dispositivos, a perda de peso de forma isolada promove melhorias aos pacientes com AOS e quando combinada ao CPAP, podem promover benefícios ainda mais significativos pela fato de contribuir para melhora do estilo de vida (Carneiro-Barrera et al., 2022).

5.4 Estratégias nutricionais para perda de peso

O tratamento mais efetivo para a obesidade envolve principalmente a redução do peso corporal. Alterações no estilo de vida, como a prática de atividade física, melhora dos hábitos alimentares e tratamento psicológico são fatores essenciais para o alcance da redução do peso corporal (Abeso, 2022). Dessa forma, o tratamento adequado da obesidade torna-se necessário para o controle de comorbidades associadas, redução da mortalidade e manutenção da qualidade de vida da população (Abeso, 2016; Abeso, 2022).

Um dos pontos chave para o tratamento da obesidade envolve a modificação da alimentação, que pode ser alcançada por diferentes estratégias nutricionais. Dietas com restrição calórica, por exemplo, envolvem a redução de 25 a 30% da ingestão de energia e podem prevenir e/ou reverter os efeitos nocivos do acúmulo excessivo de gordura corporal e da obesidade (Napoleão et al., 2021). Dietas com baixo teor de carboidrato, de acordo com a revisão de Dobrosielski et al (2017), geram maior perda de peso em adultos obesos, quando comparados a dieta com baixo teor de gordura e restrição calórica.

No que se refere às estratégias voltadas a mudanças na qualidade da dieta, Beulen et al (2018) demonstra que a substituição de ácidos graxos saturados por ácidos graxos poliinsaturados contribui para a reversão da obesidade. Além disso, um estudo transversal

demonstrou que a maior adesão à dieta mediterrânea e o envolvimento em atividade física, por tempo superior ou igual a 30 min/dia, foram associados a uma menor probabilidade de ter insônia entre 269 adultos apneicos (Kechibari et al., 2022). Apesar dos inúmeros benefícios das diferentes estratégias nutricionais para a redução do peso corporal, sabe-se que a adesão a essas estratégias é baixa. Um estudo avaliando a adesão à dieta mediterrânea em estudantes universitários espanhóis, demonstrou que metade da amostra avaliada tinha uma aderência baixa ou muito baixa (Del Rio et al., 2016).

Dessa forma, uma nova estratégia para redução do peso tem ganhado destaque na literatura. Atualmente, há evidências de que a restrição energética intermitente, também conhecida como jejum intermitente, produz perda de peso e redução de gordura corporal equivalente a restrição energética contínua (Ryndres, et al., 2019). Além disso, acredita-se que a desregulação do ritmo circadiano tenha possíveis efeitos sobre o controle do peso corporal e estudá-los pode ajudar no processo de desenvolvimento de estratégias para perda de peso (Basolo et al., 2021).

5.5 Tempo Restrito de Alimentação, perda de peso e sono

O TRA é um tipo de jejum intermitente que consiste em confinar o tempo de alimentação entre 4 a 10 horas e manter o restante do tempo em jejum (Cienfuegos et al., 2022). O TRA promove a redução da fome e do desejo de comer, redução do consumo calórico e contribui para perda de peso corporal (Cienfuegos et al., 2022; Adafer et al., 2022). Torna-se assim, uma alternativa viável para o tratamento da obesidade, com o diferencial de promover uma maior adesão pelo fato de não controlar a qualidade ou quantidade de alimentos consumidos (Cienfuegos et al., 2022).

Grande parte de ensaios clínicos que avaliaram os efeitos do TRA observaram redução no peso corporal (Steger et al., 2023;Wilkinson et al., 2020; Jamshed et al., 2020; Park et al., 2021). Dois estudos clínicos de intervenção demonstraram redução não só no peso corporal, mas também no percentual de gordura corporal total e gordura visceral em intervenções com TRA de 10 h e 8 h durante 12 e 14 semanas, respectivamente (Steger et al., 2023;Wilkinson et al., 2020). No estudo de Bao et al (2022) com 12 voluntários saudáveis, a restrição do tempo de alimentação inferior a 6 horas demonstrou um balanço energético negativo depois de acompanhado por 3 dias em câmara metabólica, o que representa uma perda de peso próxima a 0,4 Kg.

Além dos seus efeitos na perda de peso, acredita-se que um dos benefícios do TRA também esteja relacionado a melhora dos parâmetros de sono. No estudo de Wilkinson et al

(2020) composto por 19 adultos com síndrome metabólica, foi observado um aumento significativo do sono reparador, avaliado subjetivamente, pelo percentual de dias em que houve relato de sensação de descanso após dormir. No estudo de Simon et al. (2022), uma maior restrição da janela alimentar foi associada a maior duração do sono no final de uma intervenção TRA de 8 horas com duração de 12 semanas.

O mecanismo que explica o efeito benéfico do TRA sobre a perda de peso e o sono parte do alinhamento do ritmo biológico e seus principais marcadores, a melatonina e o cortisol (Ryndres et al., 2019). Para promover o sono, as concentrações de melatonina, hormônio responsável pela indução do sono, aumenta à medida que a luz desaparece, atingem o pico durante a escuridão e caem quando expostas à luz para promover a vigília (Vasey 2021). Enquanto isso, o cortisol apresenta um pico no início da manhã, seguido de níveis decrescentes durante o dia, com níveis mais baixos logo após adormecer (Chawla et al., 2021). O desalinhamento circadiano promovido por alterações no estilo de vida da população, como trabalho noturno e uso excessivo de telas, contribuem para o aumento da exposição à luz, consequente diminuição da melatonina circulante no plasma sanguíneo e aumento do cortisol, responsáveis por alterações metabólicas e prejuízos no sono (Vasey et al., 2021; Odriozola et al., 2024; Chawla et al., 2021).

Ao promover a redução do período diário de alimentação, o TRA pode contribuir para a regulação do ritmo circadiano e assim reduzir os sinais da síndrome metabólica e melhorar a qualidade do sono (Raji et al., 2024; Wilkinson et al., 2020). Além disso, a redução do período alimentar tende a diminuir o consumo alimentar próximo à hora de dormir, o que no estudo de Xiao et al., 2019 esteve associado a menores chances de sobrepeso ou obesidade e consequentemente, melhora do sono. No entanto, a literatura ainda é bastante escassa no que se refere ao tema crononutrição.

De modo geral, o TRA pode promover a melhora da qualidade do sono e melhora na oxidação de gorduras principalmente em indivíduos obesos sem distúrbios do sono (Allison et al., 2021). Em indivíduos obesos com risco para o desenvolvimento de distúrbios do sono como a AOS, a literatura dispõe de apenas um estudo que avalia os efeitos do TRA de 4h e 6h nos parâmetros de sono (Cienfuegos et al., 2022). Além disso, grande parte dos estudos avaliando o efeito do TRA sobre o sono utilizam, na maioria das vezes, métodos subjetivos para avaliação do sono, como por exemplo, o Índice de Qualidade do Sono de Pittsburgh (PSQI) (Bao et al., 2022; Cienfuegos et al., 2022; Manoogian et al., 2022).

5.6 Outros benefícios do Tempo Restrito de Alimentação

Ao referir-se a obesidade, é evidente sua associação a alterações no perfil metabólico, liberação de citocinas inflamatórias, estresse oxidativo e a alteração da microbiota intestinal. Essa relação complexa pode apresentar benefícios com o TRA, o que tem sido observado em alguns estudos. Uma metanálise de 17 ensaios clínicos, por exemplo, observou a diminuição de triglicérides, colesterol total e colesterol LDL (lipoproteína de baixa densidade) utilizando o TRA (Lili Liu et al., 2022). Quanto ao perfil glicídico, um estudo controlado e randomizado com 153 participantes observou a redução da hemoglobina glicada e da glicemia de jejum após uma intervenção TRA 10h aliada a dieta mediterrânea (Manoogian et al., 2022). Outro estudo utilizando apenas a intervenção TRA 6 horas por 5 semanas demonstrou melhoras na tolerância à glicose e sensibilidade à insulina, mesmo sem redução do peso corporal, em adultos do sexo masculino com pré-diabetes (Sutton et al., 2018).

O mesmo autor, Sutton et al., 2018 encontra efeitos do TRA na redução do estresse oxidativo, o que também é observado em uma intervenção TRA de 4 e 6 horas em adultos com obesidade, porém, com duração de 8 semanas (Cienfuegos et al., 2020). Sabe-se que o estresse oxidativo é também associado ao desenvolvimento de doenças inflamatórias, logo, sua redução pode contribuir para a melhora da inflamação. No estudo de Zeb et al (2020), essa melhora no perfil inflamatório pode ser observada com a redução da produção de citocinas pró-inflamatórias, por exemplo, a redução na IL-1 β (interleucina - 1 β) e no TNF - β (fator de necrose tumoral - α) após intervenção com TRA.

A microbiota intestinal é um dos pontos que têm sido atualmente estudados. Em estudos com animais, o TRA gerou modificações na microbiota intestinal após 12 semanas de intervenção (Rust et al., 2023). Em humanos, um estudo utilizando jejum intermitente revelou modificações da composição da microbiota intestinal de pacientes com síndrome metabólica antes e após a intervenção, com aumento dos filos *Bacteroidetes e Firmicutes* (Guo et al., 2021). No que se refere a uma amostra submetida a intervenção TRA, o estudo de Zeb et al., 2020 demonstrou além do aumento na diversidade microbiana, a melhora dos níveis de saturação de oxigênio.

Todos os benefícios associados aos efeitos do TRA podem contribuir para a prevenção e tratamento da obesidade e doenças associadas, como doenças cardiovasculares, síndrome metabólica e outros distúrbios que prejudicam a qualidade de vida dessa população. Entretanto, são necessários mais estudos para comprovar os diversos benefícios do TRA em humanos e

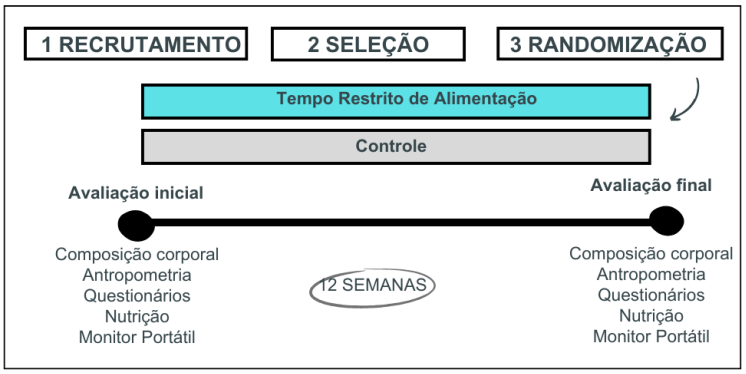
para compreender qual a duração do TRA e o tempo de intervenção são mais viáveis para a obtenção desses benefícios.

6 METODOLOGIA

6.1 Desenho do estudo

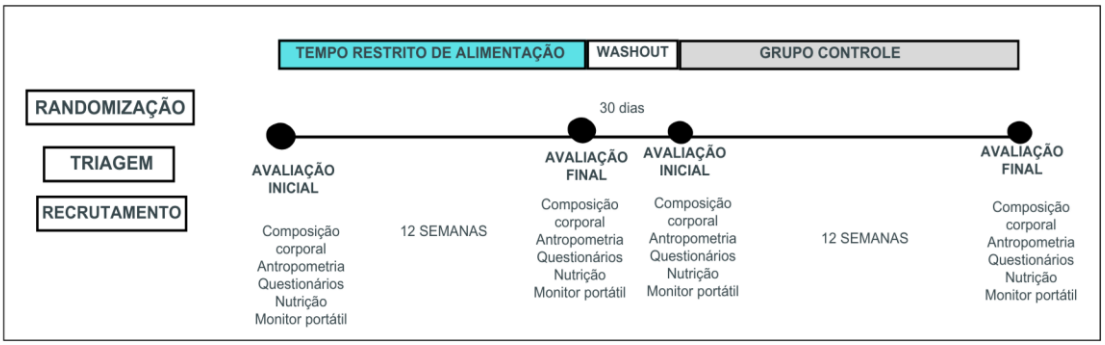
O primeiro ensaio clínico foi randomizado e controlado conforme demonstrado na figura 1, com duração total de 12 semanas. O segundo ensaio clínico foi do tipo crossover, controlado com duração de 12 semanas de intervenção, com período de *washout* de 4 semanas (Figura 2). Em ambos os estudos os participantes foram randomizados de acordo com idade e sexo, em seguida, randomizados ao acaso por meio do programa Excel para compor o grupo intervenção ou o grupo controle. O grupo intervenção consistiu em seguir um protocolo com TRA de 8h por dia. O grupo controle consistiu em manter o tempo de alimentação superior a 10h por dia e recebeu orientação nutricional baseada nas recomendações do Guia Alimentar para a população brasileira (Brasil, 2014). O presente estudo passou pelo Comitê de Ética em Pesquisa da Universidade Federal de Lavras e foi aprovado sob o parecer nº 6.207.765 e registrado no Registro Brasileiro de Ensaios Clínicos (REBEC) sob o protocolo RBR-9rh56ph. O estudo iniciou em dezembro de 2023 e finalizou em dezembro de 2024, quando foi alcançado um número um pouco acima do proposto no cálculo amostral.

Figura 1. Desenho do estudo de 12 semanas com TRA 8 horas.



Fonte: Do autor (2025).

Figura 2. Desenho do estudo *crossover* de 12 semanas com TRA 8 horas.



Fonte: Do autor (2025).

6.2 Seleção, recrutamento e avaliação dos participantes

A amostragem foi realizada por conveniência no município de Lavras e região e o recrutamento ocorreu por meio de divulgação em redes sociais e de cartazes ou abordagem pessoal no município de Lavras. Os participantes deveriam satisfazer os critérios de inclusão que constam das seguintes características: adultos com idade entre 30 anos e 60 anos, com IMC igual ou superior a 30Kg/m², de ambos os sexos e com janela alimentar entre 11 e 14 horas. Somente para o ensaio clínico *crossover* foi incluído o critério de inclusão referente ao diagnóstico de AOS (Índice de Dessaturação de Oxigênio - IDO >5).

Não foram incluídos no estudo indivíduos que apresentassem alguma doença grave como câncer, doenças hepáticas ou renais, mulheres gestantes ou com crianças até dois anos de idade, idosos institucionalizados, indivíduos que estejam engajados em algum tipo de tratamento para perda de peso ou acompanhamento nutricional, que tomem medicamentos que interfiram na taxa metabólica (ex: inibidores de apetite), pessoas que apresentam alguma incapacidade física ou intelectual comprovadas por diagnóstico médico e que não tenha condições de participar das avaliações propostas, pessoas que se recusem a participar das avaliações ou intervenções propostas, trabalhadores em turnos e noturnos.

Todos os critérios foram avaliados subjetivamente ou por meio de questões presentes na entrevista inicial (Apêndice A), que além de avaliar os critérios de elegibilidade constava de questões sobre condição socioeconômica e escolaridade. No entanto, essas informações somente foram utilizadas após o consentimento do participante na pesquisa. Após a triagem, os participantes em potencial recebiam informações detalhadas sobre o estudo e eram convidados a assinar o termo de consentimento livre e esclarecido (Apêndice B).

As avaliações dos participantes foram realizadas no Departamento de Nutrição da Universidade Federal de Lavras. Os participantes elegíveis com base na triagem, recebiam um

oxímetro de dedo para uso durante a noite e eram instruídos a comparecer no local de avaliação para dar prosseguimento ao estudo. A instrução do preparo para os exames foi enviado por meio de redes sociais alguns dias antes da coleta para a pessoa se programar. Foram coletados dados antropométricos e de composição corporal, dados de consumo alimentar e de sono, antes e após a intervenção de 12 semanas. Todos os dados foram armazenados em local adequado e as informações asseguradas.

6.3 Avaliação do sono

A avaliação do perfil de sono e o diagnóstico de AOS foram obtidos por meio de um monitor portátil digital de dedo da marca Biologix de alta resolução, validado para o diagnóstico de AOS (Pinheiro et al., 2020). O dispositivo é composto por um oxímetro sem fio de alta resolução, um acelerômetro embutido conectado a um aplicativo de smartphone e o algoritmo de nuvem automatizado para a detecção de dessaturação de oxigênio. O oxímetro disponibilizado deveria ser colocado no dedo no momento em que o paciente pretendesse dormir e retirado na manhã do dia seguinte, assim que o paciente despertasse, conforme recomendações da empresa responsável. Os dados foram obtidos por meio da média de dois relatórios e incluíam tempo total de sono (minutos), tempo acordado após o sono (minutos), latência do sono (minutos), eficiência do sono (percentual), tempo de ronco (minutos e percentual), índice de dessaturação de oxigênio (IDO) (eventos por hora), índice de dessaturação de oxigênio sono (IDOs) (eventos por hora), carga hipóxica (%.min /hora), saturação de oxigênio (SpO2) mínima, média e máxima (%). No que se refere ao diagnóstico de AOS, a classificação do grau da apneia foi obtido pelo IDO que variava entre <5 eventos por hora o que indica qualidade do sono normal, 5 a 15 eventos por hora compatível com apneia do sono leve, 15 a 30 eventos por hora compatível com apneia do sono moderada e maior que 30 eventos por hora compatível com apneia do sono acentuada.

A avaliação subjetiva da qualidade do sono foi obtida por meio da versão traduzida do Índice de Qualidade do Sono de Pittsburgh (PSQI) (Bertolazi et al., 2011). Trata-se de uma escala no qual a somatória dos seus sete componentes conferem uma pontuação global que varia de 0 a 21, que classifica a qualidade do sono de 0 a 4 como boa, 5 a 10 como ruim e maior que 10 como presença de distúrbios do sono. Outra avaliação também obtida foi a autopercepção dos indivíduos sobre sonolência diurna avaliada por meio da versão brasileira da Escala de Sonolência de Epworth (Bertolazi et al., 2009), composta por oito questões com pontuação que varia de 0 a 24 pontos e quando igual ou superior a 9 pontos indica sonolência anormal.

6.4 Antropometria e composição corporal

Todas as medidas antropométricas e a avaliação da composição corporal foram realizadas no período da manhã, entre 7h e 9h para evitar possíveis interferências. Foram coletados dados antropométricos como massa corporal (Kg) e estatura (cm), por meio de balança digital e estadiômetro, respectivamente, para que posteriormente fosse realizado o cálculo do IMC. A aferição da circunferência da cintura foi realizada adotando-se a metodologia de Taylor et al (2000), sendo a medida realizada no ponto mínimo do tronco entre o rebordo costal e a crista ilíaca. A circunferência do pescoço foi obtida com o participante sentado, com a coluna ereta e cabeça para o horizonte (plano de Frankfurt) e a fita posicionada na menor circunferência do pescoço logo acima da proeminência laríngea (pomo de Adão). Para a avaliação da composição corporal, os participantes foram submetidos a bioimpedância elétrica (BIA), combinada a instrução adequada, enviada por meio de redes sociais. A análise da BIA foi realizada com o equipamento Biodynamics InBody 230®, com os voluntários em posição ortostática. Os participantes foram instruídos a manter jejum de 8 horas antes e a usar roupas leves, não portar objetos como relógio, anel, aliança, pulseira, colar, brinco e piercing durante o exame. Também não deveriam praticar exercícios físicos intensos e não ingerir café, chás, álcool, bebidas efervescentes, bebidas energéticas ou diuréticos no dia da avaliação e no dia anterior. Além disso, deveriam estar normalmente hidratados e urinar antes do exame. A avaliação em mulheres em idade reprodutiva foi realizada nos mesmos períodos do ciclo menstrual a fim de evitar possíveis vieses decorrentes de alterações corporais nesses períodos.

6.5 Consumo alimentar e nível de atividade física

O consumo alimentar foi obtido por meio de dois recordatórios 24 horas e complementados por registros alimentares, aplicados ou autopreenchidos em 3 dias não consecutivos, incluindo um dia de final de semana, antes do início da intervenção e durante a intervenção. Os participantes recebiam instruções para o preenchimento dos registros e ao finalizar o preenchimento, era marcado um encontro presencial ou online para repassar e complementar as informações faltantes com profissional treinado. Com as informações em mãos, foi realizada a crítica dos inquéritos alimentares por meio do Manual de Crítica de Inquéritos Alimentares (de Castro et al., 2014) e o auxílio da Tabela para Avaliação do consumo alimentar em medidas caseiras (Pinheiro et al., 2005). Os dados de energia e macronutrientes (carboidrato, proteína e lipídeos) foram obtidos por meio do software de nutrição DietSmart e a cafeína foi obtida por meio da Tabela Brasileira de teor de cafeína

(Rocha et al., 2022). Em seguida, os dados foram corrigidos pela variabilidade individual por meio do software Multiple Source Method (MSM), para melhor representação da ingestão habitual dessas pessoas.

O nível de atividade física foi obtido pelo International Physical Questionnaire (IPAQ), versão curta (Pardini et al, 2001). Os participantes foram classificados conforme pontuação total do escore e de acordo com a recomendação mínima de 75 min de atividade vigorosa e 150 min de atividade física moderada, de acordo com o Guia de Atividade física para a população brasileira (BRASIL, 2021) nas categorias: ativos (quando alcançarem valores maior ou igual a recomendação) ou inativos (quando alcançarem valores inferiores a recomendação).

6.6 Intervenção e adesão TRA

A intervenção TRA consiste em restringir o tempo de alimentação, reduzindo o intervalo entre a primeira e a última refeição do dia. No grupo TRA 8h, os participantes foram solicitados a restringir a ingestão alimentar diária em 8 horas totais, com tempo de jejum de 16 horas. O horário de alimentação deveria ter início às 11 horas da manhã e o fim da janela alimentar às 19h. Durante o período de alimentação foi instruído o consumo alimentar até alcançar a saciedade, sem restrição em relação a quantidade ou conteúdo calórico da alimentação dos sujeitos. Durante o período de jejum, foi liberado o consumo de bebidas que contenham cafeína como café e chás, porém sem o consumo de açúcar ou adoçantes artificiais para evitar possíveis interferências na tolerância à glicose. Além disso, foram estimulados a consumir muita água e instruídos a manter o nível de atividade física habitual durante todo o ensaio. Para a avaliação da adesão ao TRA de 8 horas foi utilizado um registro diário de adesão, que registra os horários em que cada indivíduo começa e termina de comer a cada dia. O registro diário de adesão foi disponibilizado por meio de um bloco de anotações considerando se tratar de uma população que não possuía muita facilidade com o uso de tecnologia e possíveis ocorrências com os aparelhos no decorrer da pesquisa. As instruções de preenchimento do diário de adesão foram fornecidas pelo pesquisador e exemplificadas na própria capa do diário. Se o registro indicasse um consumo alimentar dentro da janela apropriada de 8 horas, conforme estabelecido entre os grupos, o dia era rotulado como 'aderente'. Se o registro indicasse o consumo alimentar fora da janela de alimentação de 8 horas, esse dia seria rotulado como 'não aderente'. No final das contas, a adesão à dieta TRA foi avaliada como o número de dias aderentes por semana multiplicado por 100 e dividido por 7 dias, sendo a adesão total das 12 semanas, obtida pela média do percentual obtido em cada

semana (Zhang et al., 2022; Jamshed et al., 2022;Steger et al., 2022).

6.7 Análise estatística

A avaliação da distribuição dos dados foi realizada por meio do teste de Shapiro Wilk. Caso os dados não apresentassem distribuição normal, os mesmos eram transformados em logaritmo ou eram direcionados para os testes não paramétricos. Os dados de caracterização da amostra, adesão e janela alimentar são apresentados por meio de estatística descritiva em média ± desvio padrão ou número amostral (porcentagem). Inicialmente foi realizado um teste T independente para verificar a diferença entre os dados basais dos grupos. Para o desfecho primário e secundário (sono e composição corporal) antes e durante a pesquisa, foi realizada a Análise de Variância (ANOVA) de medidas repetidas, seguido do Post Hoc no qual foi considerado o teste de Bonferroni. Também foi calculada a diferença entre os dados finais e basais (delta) e testada a diferença entre os grupos pelo Teste T independente. Os demais dados são apresentados em média e desvio padrão, por meio de tabelas e figuras. Foi utilizado um nível de significância 0,05 e intervalo de confiança de 95%. Todas as análises foram realizadas no software SPSS 15.0.

7 RESULTADOS

Os resultados da presente dissertação serão apresentados em formato de artigos científicos. Foram elaborados dois artigos a fim de responder aos objetivos propostos: o primeiro trata-se de um ensaio clínico randomizado e o terceiro, um ensaio clínico *crossover*, que serão detalhados a seguir. Além disso, como produto desta dissertação destaca-se também o artigo intitulado 'Efeitos do tempo restrito de alimentação na qualidade do sono e composição corporal: uma revisão sistemática' (Apêndice C).

Artigo 1

Artigo submetido à revista Obesity.

TITLE: Effects of a Time-Restricted Eating Intervention on Sleep and Body Composition in Adults with Obesity: A Pilot Study

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SUMMARY

The aim of this study was to evaluate the effects of an 8-hour TRE intervention over 12 weeks on weight loss, body composition, and sleep in obese adults. Participants aged 30 to 65 years with a Body Mass Index (BMI) > 30 kg/m², both sexes, and with eating windows from 11 and 14 hours were included. Thirty-five participants were randomized to either an 8-hour TRE intervention group for 12 weeks (TRE - meals between 11:00 AM and 7:00 PM) or a control group (CON; eating window > 10 hours with nutritional guidance). Body weight, height, waist and neck circumference, and body composition (bioelectrical impedance) were assessed. Sleep parameters were evaluated using a Biologix® portable sleep monitor, the *Pittsburgh* Sleep Quality Index (PSQI), and daytime sleepiness was assessed using the *Epworth* Sleepiness Scale (ESS). A reduction in body weight (p=0.08) was observed only among those who completed the intervention inTRE group. No significant effects of TRE intervention on sleep were found.

A clinical reduction in the hypoxic burden and snoring time was observed in the TRE group, suggesting potential effects of TRE on sleep and paving the way for further research.

Key words: Time restricted eating, intermittent fasting, sleep, body composition, obesity.

INTRODUCTION

Obesity is a chronic non-communicable disease that affects one in every eight individuals globally, thus representing a significant public health issue (Phelps et al., 2024). Excess body fat in the adult population has been associated with sleep quality and duration, such as sleep duration of less than 7 hours and circadian misalignment (Marhefkova et al., 2024; Sheikh-Ali & Maharaj, 2014). Furthermore, in obese adults, sleep duration has been found to have an inverse relationship with body weight and fat (Li Q, 2021; Chen et al., 2019).

Time-Restricted Eating (TRE) has emerged as a promising dietary intervention for weight loss. It is a form of intermittent fasting that involves limiting food intake during the day and extending the fasting period overnight, thereby maintaining a robust daily eating cycle (Templeman et al., 2020). Studies have shown that adults who adhere to TRE typically experience a weight loss ranging from 1% to 4% of their body weight and may exhibit improvements in metabolic markers (Verhoef et al., 2013; Jamshed et al., 2022; Chaput et al., 2005).

This type of intervention may also benefit sleep quality, as even a slight reduction in body weight could contribute to improvements in sleep parameters and a reduction in the risk of sleep disorders, such as Obstructive Sleep Apnea (OSA) (Simon, 2023; Martin et al., 2016). Furthermore, the reduced duration of the daily eating window, by increasing the gap between the last meal and bedtime, represents another mechanism through which TRE could help mitigate symptoms of metabolic syndrome and improve sleep quality (Raji et al., 2024; Wilkinson et al., 2020).

Given the role of weight loss in sleep, recent studies have sought to understand the effects of TRE (time-restricted eating) on sleep parameters (Cienfuegos et al., 2022; Adafer et al., 2020). A significant portion of these studies, which fail to observe the effects of TRE on sleep, rely on subjective measures, further emphasizing the lack of consensus in the literature (Bao et al., 2022; Steger et al., 2023; Gabel et al., 2019; Park et al., 2021). On the other hand, studies that objectively monitored sleep using actigraphy have observed changes in sleep parameters among participants undergoing a TRE intervention (Manoogian et al., 2022; Kirkhan et al., 2023).Nevertheless, the studies that investigate sleep objectively are limited to actigraphy and no studies have been done with polysomnography or other new technology devices for sleep measurements. This highlights the need for further research aimed at understanding the most appropriate timing and duration of the intervention to improve sleep with a better accurate sleep measurement.

We hypothesize that TRE may have effects on objective measures obtained during sleep, and, to the best of our knowledge, no clinical trial has explored these variables, such as hypoxic load and oxygen saturation. Therefore, the objective of this study was to assess the effects of an 8-hour TRE intervention over 12 weeks on weight loss, body composition, and sleep parameters in obese adult individuals.

METHODOLOGY

Study Design

A randomized, controlled, non-blinded clinical trial was conducted, as demonstrated in Figure 1. Initially, participants were stratified by age and sex, and then randomly assigned to the intervention or control group using an Excel spreadsheet. The intervention group followed a protocol of 8 hours a day of time-restricted feeding (TRE) for 12 weeks. The control group maintained a feeding window of more than 10 hours per day and received

nutritional guidance based on the recommendations of the Brazilian Dietary Guidelines (Brazil, 2014). This study was approved by the Ethics Committee for Human Research of the Federal University of Lavras under approval number 6.207.765 and registered in the Brazilian Registry of Clinical Trials (REBEC) under protocol RBR-9rh56ph. The study began in February 2024 and concluded in August 2024, when the sample size slightly exceeded the initial target calculated in the sample size estimation.

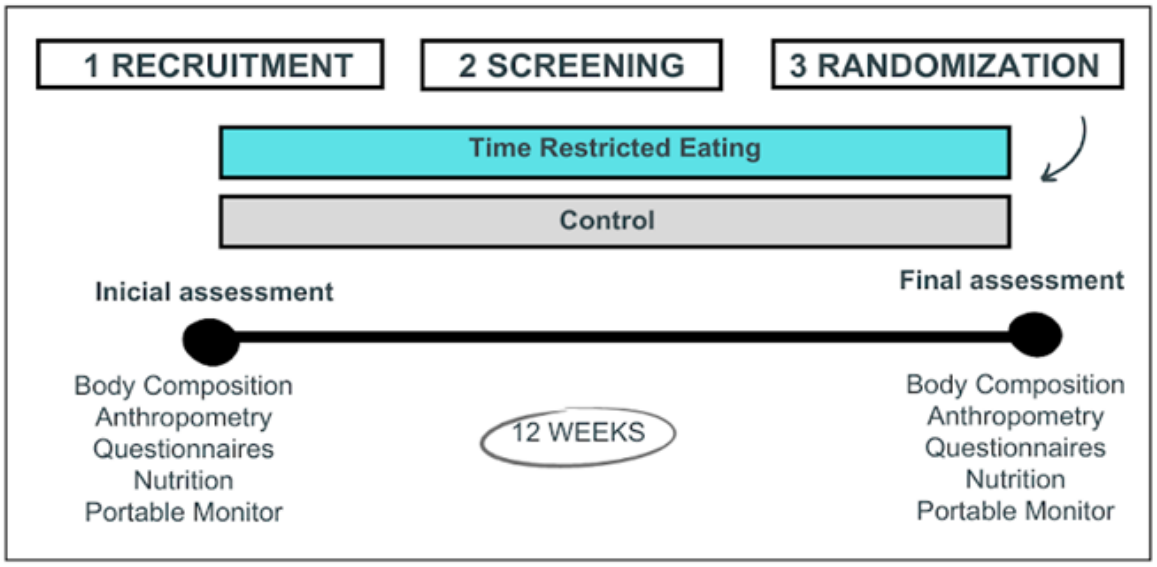

Figure 1. Study Design of 12 Weeks with 8-Hour Time-Restricted Eating (TRE).

Sample Selection and Recruitment

Sampling was performed using a convenience method in the municipality of Lavras and surrounding areas, and recruitment occurred through social media advertising, posters, and personal approaches within the municipality of Lavras. Participants had to meet the inclusion criteria, which included the following characteristics: adults aged between 30 and 60 years, with a body mass index (BMI) equal to or greater than 30 kg/m², of both sexes, and with eating windows from 11 to 14 hours.

Individuals were excluded from the study if they had any serious illness such as cancer, liver or kidney diseases, pregnant women, women with children under two years of age, institutionalized elderly individuals, individuals undergoing any weight loss treatment or nutritional follow-up, individuals using medications that interfere with metabolic rate (e.g., appetite suppressants), individuals with physical or intellectual disabilities confirmed by medical diagnosis and unable to participate in the proposed evaluations, individuals refusing to participate in the assessments or interventions, and shift or night workers.

All criteria were assessed subjectively or through questions in the initial interview, which, in addition to evaluating eligibility criteria, included questions about socioeconomic status and education. However, this information was only used after obtaining the participant's consent to participate in the research. Following the screening, eligible participants received detailed information about the study and were invited to sign the informed consent form.

Participant Assessment

The participant assessments were conducted at the Department of Nutrition of the Federal University of Lavras. Eligible participants, based on the screening process, were provided with a finger oximeter for overnight use and were instructed to attend the assessment site to proceed with the study. Preparation instructions for the exams were sent via social media a few days prior to the data collection, allowing participants to plan accordingly. Anthropometric and body composition data, as well as dietary and sleep data, were collected before and after the 12-week intervention. All data was stored in an appropriate location, ensuring the confidentiality and security of the information.

Sleep Assessment

The sleep assessment and diagnosis of OSA were obtained using a high-resolution, portable digital finger oximeter (Biologix), validated for OSA diagnosis (Pinheiro et al., 2020).

The device consists of a wireless high-resolution oximeter, a built-in accelerometer connected to a smartphone application, and an automated cloud algorithm for detecting oxygen desaturation. The provided oximeter was to be placed on the participant's finger when they intended to sleep and removed the following morning upon waking, according to the manufacturer's recommendations. Data were collected by averaging two reports and included total sleep time (minutes), wake time after sleep (minutes), sleep latency (minutes), sleep efficiency (percentage), snoring time (minutes and percentage), oxygen desaturation index (ODI) (events per hour), sleep oxygen desaturation index (S-ODI) (events per hour), hypoxic load (%·min/hour), and minimum, mean, and maximum oxygen saturation (SpO2) (%). Regarding the diagnosis of OSA, the severity of the apnea was classified based on the ODI, where <5 events per hour indicates normal sleep quality, 5-15 events per hour is consistent with mild sleep apnea, 15-30 events per hour is consistent with moderate sleep apnea, and >30 events per hour is consistent with severe sleep apnea.

The subjective assessment of sleep quality was obtained using the portuguese version of *Pittsburgh* Sleep Quality Index (PSQI) (Bertolazi et al., 2011). This scale consists of seven components, the sum of which provides a global score ranging from 0 to 21, classifying sleep quality as follows: 0 to 4 as good, 5 to 10 as poor, and greater than 10 indicates the presence of sleep disturbances. Participants' self-perception of daytime sleepiness was evaluated using the Portuguese version of *Epworth* Sleepiness Scale (Bertolazi et al., 2009), which consists of eight questions with scores ranging from 0 to 24. A score of 9 or higher indicates abnormal daytime sleepiness.

Anthropometry and Body Composition

All anthropometric measurements and body composition assessments were performed in the morning, between 7:00 AM and 9:00 AM, to avoid potential interferences. Anthropometric data such as body weight (kg) and height (cm) were collected using a digital

scale and stadiometer, respectively, for subsequent calculation of Body Mass Index (BMI). Waist circumference was measured using the methodology of Taylor et al. (2000), with the measurement taken at the minimal point of the trunk between the costal margin and the iliac crest. Neck circumference was measured with the participant seated, with the spine erect and the head aligned with the horizontal plane (Frankfurt plane), and the tape placed at the smallest circumference of the neck just above the laryngeal prominence (Adam's apple). For body composition assessment, participants underwent bioelectrical impedance analysis (BIA) using the Biodynamics InBody 230® equipment, with participants in an orthostatic position. The assessment in women of reproductive age was conducted during the same phases of the menstrual cycle to avoid potential biases resulting from body changes during different phases.

Physical Activity Level

Physical activity level was assessed using the International Physical Activity Questionnaire (IPAQ), short version (Pardini et al., 2001). Participants were classified according to their total score and based on the minimum recommendation of 75 minutes of vigorous activity and 150 minutes of moderate physical activity, as outlined in the Brazilian Physical Activity Guidelines (BRASIL, 2021), into the following categories: active (when meeting or exceeding the recommended values) or inactive (when not meeting the recommended values).

Time-Restricted Eating (TRE) Intervention

The TRE intervention consists of restricting the feeding window, reducing the time between the first and last meal of the day. In the 8-hour TRE group, participants were instructed to restrict their daily food intake to a total of 8 hours, with a 16-hour fasting period. The feeding window begins at 11:00 AM and ends at 7:00 PM. During the feeding period, participants were instructed to consume food until they reached satiety, without restrictions regarding the quantity or caloric content of their meals. During the fasting period, the

consumption of beverages containing caffeine was allowed, but without sugar or artificial sweeteners to avoid potential interference with glucose tolerance. Additionally, participants were encouraged to drink plenty of water and were instructed to maintain their usual level of physical activity throughout the study.

Adherence to TRE

To assess adherence to the 8-hour TRE, a daily adherence log was used to record the times when each participant began and ended eating each day. The adherence log was provided in the form of a notebook, considering the population's limited familiarity with technology and potential issues with devices during the study. The instructions for completing the adherence log were provided by the researcher and exemplified on the cover of the log itself. If the log indicated food consumption within the appropriate 8-hour window, as established for the groups, the day was labeled as 'adherent.' If the log indicated food consumption outside the 8-hour feeding window, the day was labeled as 'non-adherent.' Adherence to the TRE diet was then calculated as the number of adherent days per week, multiplied by 100 and divided by 7 days, with total adherence over the 12 weeks being obtained by averaging the percentage of adherence each week. In this study, all participants were included, including those with low adherence.

Statistical Analysis

Based on the study design and the tests of interest, a sample size calculation was performed. To achieve a statistical power of 80%, an effect size of 0.4, and a significance level of 5%, a minimum of 30 participants was required. The data distribution was assessed using the Shapiro-Wilk test. If the data did not follow a normal distribution, they were log-transformed or analyzed using non-parametric tests. Descriptive statistics for sample characteristics, adherence, feeding window, and physical activity are presented as mean ± standard deviation

or sample size (percentage). An independent t-test was initially conducted to verify differences between baseline data of the groups. For the primary and secondary outcomes (sleep and body composition) before and during the study, generalized estimating equations (GEE) was performed, followed by a Post Hoc analysis, where the Bonferroni test was applied. The difference between final and baseline data (delta) was also calculated and the difference between groups was tested using the independent t-test, including for the feeding window data. Other data are presented as mean and standard deviation in tables and figures. The analyses described were conducted separately for the ITT group and the group that completed the 12-week intervention. A significance level of 0.05 and a 95% confidence interval were used. All analyses were performed using SPSS 15.0 software. Body composition data are presented for all participants, except for one who had a metal pin in one of their arms and could not undergo bioimpedance analysis.

Results

Initial Selection and Recruitment

After the study announcement, 70 individuals expressed interest in participating. Forty-two of these were selected based on initial eligibility criteria, and 37 adults with obesity were included in the clinical investigation and randomized into two groups (19 in the intervention group and 18 in the control group). However, 2 individuals were excluded due to missing baseline data before the intervention, resulting in a total of 35 participants in the current Intention-to-Treat (ITT) analisis (Figure 1).

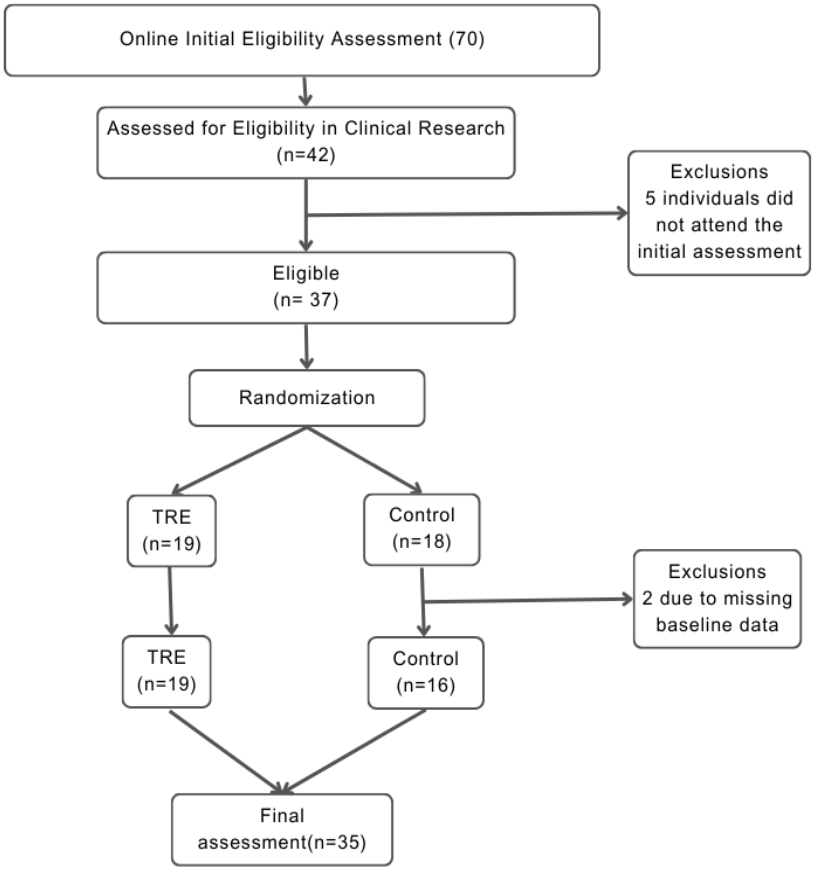

Figure 2. CONSORT Flowchart of Recruitment and Inclusion of Participants in the Study Crossover.

General Characteristics of the Sample

The average age of the sample was 41.8 ± 9.2 years, with a predominance of female participants. There was no significant difference in the sex distribution between the control and time-restricted eating (TRE) groups ($p = 0.5$). A predominance of participants with higher educational levels and an income of up to two minimum wages was observed. The majority of participants had obstructive sleep apnea (OSA) and hypertension (HTN) as the predominant condition, assessed using the digital oximeter (Biologix) and questionnaires, respectively. Participants also exhibited a baseline eating window considered prolonged (12.42 ± 1.06 hours). All participants had a total score on the Pittsburgh Sleep Quality Index (PSQI) greater than 5,

indicating poor sleep quality, and a total sleep time (TST) of less than 7 hours. The general characteristics of the participants are presented in Table 1. No significant differences were found between groups regarding baseline data on eating window ($p = 0.201$), body mass index (BMI), and age ($p > 0.05$).

Adherence to TRE, Meal Timing and Dietary Intake

Adherence to the 8-hour TRE intervention in the Intent-to-Treat (ITT) analysis was 45.9 ± 33.6%, equivalent to an adherence of 3.2 days per week of 8-hour TRE. No participants reported adverse effects such as nausea, discomfort, or dizziness. The feeding window of the intervention group was reduced by approximately 3 hours compared to the baseline eating window (12.54 ± 1.10 vs. 9.44 ± 1.25, $p<0.001$), whereas in the control group, the reduction was not significant (12.30 ± 1.01 vs. 11.42 ± 1.19, $p=0.785$). The timing of the first meal of the day was significantly different ($p=0.035$) between the groups, with the TRE group starting their meals much later. As for the last meal of the day, the control group ate about 40 minutes later than the TRE group, without a significant difference ($p=0.254$) (TABLE 2).

Physical Activity Level

No significant differences were found in the physical activity level assessed by the IPAQ, before and after the intervention in the TRE groups (57.9% active and 42.1% inactive to 52.6% active and 47.36% inactive) and the control group (75% active and 25% inactive to 62.5% active and 37.5% inactive).

Anthropometry and Body Composition

Table 4 presents anthropometric and body composition data at baseline and after 12 weeks for both groups of the 35 participants included in the Intention-to-Treat (ITT) analysis. No significant changes in body weight, BMI, body fat and other anthropometric measurements between baseline and 12 weeks were observed. Although no changes in body and fat mass

between groups, a significant difference between delta value was observed for Skeletal Muscle Mass (CONTROL=0,150 Kg; TRE=-0,497 Kg; P=0,037; cohen's d = 0.737), Fat Free Mass (CONTROL=0,100Kg; TRE=-0,868Kg; P=0,012; cohen's d = 0.501) and, Total Body Water (CONTROL=0,003Kg; TRE=-0,868Kg; P=0,024; cohen's = 0.542). However, among the participants who completed the 12-week intervention (Table 5), a significant reduction in weight (p= 0.008) and a trend toward a decrease in BMI (p= 0.006) were observed in the TRE group. In addition to a significant difference in the delta of neck circumference (CONTROL=-0,369cm; TRE=-0,679cm; P=0,020; cohen's d = 1.14).

Sleep Outcomes

Table 6 presents the effects of the intervention on the sleep parameters. No significant differences were observed between the groups. The analysis of the participants who completed the 12-week study is presented in Table 7. Although not significant, the hypoxic load (delta cohen´s d = 0,763) and the time spent snoring (delta minutes cohen´s d = 0,810; % cohen´s d = 0,504) increased in the control group and decreased in the TRE group. No significant differences were found between the TRE and control groups for any of the sleep variables analyzed.

Table 1. Baseline sociodemographic, clinical, anthropometric, and sleep characteristics.

Features	All participants (n=35)	CONTROL (n=16)	TRE (n=19)
Age (years)	41.8 ± 9.22	41.5 ± 10	42.4 ± 8.93
Sex			
Female	20(57.1%)	10(62.5%)	10 (52.6%)
Education			
Master's or doctorate	7 (20.6%)	3(18.75%)	4(21.05%)
Complete university degree	9 (26.5%)	3(18.75%)	6(31.57%)
High school complete	17 (50%)	10(62.5%)	7(36.84%)
Incomplete elementary school	1 (2.9%)	0	1 (6.25%)
Income			
More than 3 minimum wages	8 (23.5%)	4(25%)	4(21.05%)
2 to 3 minimum wages	9 (26.5%)	3(18.75%)	6 (31.6%)
Up to 2 minimum wages	17 (50%)	9(56.25%)	8(42.1%)
Disease			
OSA	28 (80%)	13 (81.25%)	15 (79%)
Diabetes Mellitus	2(5.71%)	2(12.5%)	0
SAH	11(31.43%)	6(37.5)	5(26.3%)
Gastroesophageal reflux	2(5.71%)	1(6.25%)	1(5.3%)
Liver disease	4(11.44%)	1(6.25%)	3(15.8%)
PCOS	1(2.85%)	1(6.25%)	0
Fibromyalgia	2(5.71%)	1(6.25%)	1(5.3%)
Sleep			
PSQI	7.2 ± 2.77	6.63 ± 2.83	7.68 ± 2.71
ESS	9.26 ± 4.42	8.44 ± 3.76	9.95 ± 4.90
TST (min)	345 ± 53.8	344 ± 46.2	347 ± 60.6
Eating window (hours)	12:42 ± 1:06	12:30± 1:01	12:54± 1:10

TRE: Time Restricted Eating; OSA: Obstructive Sleep Apnea; SAH: Systemic arterial Hypertension; PCOS: Polycystic Ovary Syndrome; PSQI: Pittsburgh Sleep Quality Index; ESS: Epworth Sleepiness Scale; TST: Total Sleep Time.

Table 2. Adherence to the TRE intervention, meal timing and eating window.

Variables	CONTROL (n=16)	TRE (n=19)	p-value; Cohen´s d
First meal (h)	8:08± 1:13	9:26± 1:39	0.035; 0.421
Last meal (h)	19:54± 1:25	19:16 ± 1:50	0.254; 0.390
Eating window (h)	11:42 ± 1:19	9:44± 2:25	0.006; 0.992
Delta eating window (h)	00:47± 1:08	3:13± 2:45	0.007; 0.539
Meals per day (n)	4.32± 1.22	3.75 ± 0.79	0.114; 0.293

TRE: Time restricted Eating; Eating window: interval between the first meal and the last meal of the day.

Table 3. Anthropometry and Body Composition of Obese Individuals Before and After a Time-Restricted Eating (TRE) Intervention (ITT).

	CONTROL (16)			TRE (19)						
Variables	**Baseline**	**12 weeks**	**Delta**	**Baseline**	**12 weeks**	**Delta**	**Time (p-value;)**	**Group (p-value;)**	**Time x Group (p-value;)**	**Delta (p-value;Cohen's d)**
WC (cm)	108 ±7.63	106 ± 8.31	-2.20 ± 4.52	113 ± 10.2	110 ± 9.82	-3.35 ± 3.27	0.000	0.180	0.383	0.390; 0.295
NC (cm)	40.4 ± 2.97	40 ± 2.97	-0.369 ± 0.761	42 ± 4.87	41.3 ± 4.59	-0.679 ± 0.90	0.000	0.241	0.257	0.287; 0.367
Weight (Kg)	96.2 ± 11.8	95.6 ± 11.6	-0.637 ± 2.41	100 ±13.3	98.3 ± 12.5	-1.91 ± 2.97	0.004	0.399	0.149	0.178; 0.467
BMI (Kg/m²)	34.5 ± 4.66	34.2 ± 4.76	-0.287 ± 0.79	35.2 ± 2.93	34.5 ± 2.67	-0.668 ± 0.98	0.001	0.690	0.192	0.222; 0.421
Body fat (%)	40.5 ± 8.88	39.9 ± 9.69	-0.594 ± 2.02	39.3 ± 6.0	39 ± 6.43	-0.274 ± 1.21	0.122	0.698	0.540	0.567; -0.196
Body fat (Kg)	39.1 ± 10.5	38.1 ± 11.11	-0.973 ± 2.57	39.2 ± 7.12	38.2 ± 6.93	-1.00 ± 2.10	0.013	0.978	0.973	0.974; 0.011
SMM (Kg)	32.5 ± 7.24	32.6 ± 7.59	0.150 ± 0.93	34.6 ± 6.73	34.1± 6.76*	-0.479 ± 0.78	0.283	0.456	0.032	0.037; 0.737
Ap MM (Kg)	24 ± 5.12	24 ± 5.13	0.006 ± 0.60	25.4 ± 4.84	25.1 ± 4.73	-0.316 ± 0.53	0.116	0.458	0.101	0.104; 0.567
FFM (Kg)	57.5 ± 11.7	57.6 ± 12.3	0.100 ± 1.83	61.0 ± 11.0	60.2 ± 11.1	-0.868 ± 1.29	0.154	0.429	0.072	0.012; 0.501
TBW (Kg)	42.1 ± 8.55	42.1 ± 8.96	0.003 ± 1.31	44.7 ± 8.04	44.1 ± 8.05	-0.663 ± 0.93	0.088	0.420	0.088	0.024; 0.542

TRE: Time restricted Eating; BMI: Body mass index; WC: Waist circumference; NC: Neck circumference; SMM: Skeletal Muscle mass; Ap MM: Appendicular muscle mass; FFM: Fat-free mass; TBW: Total body water; CM: centimeters; Kg: Kilograms. Data presented as mean ± SD; p-values for Generalized estimating equations and Student t test for delta analysis; Cohen's d = effect size for t Student.

Table 4. Anthropometry and Body Composition of Obese Individuals Before and After a Time-Restricted Eating (TRE) Intervention.

	CONTROL (11)			TRE (9)						
Variables	**Baseline**	**12 weeks**	**Delta**	**Baseline**	**12 weeks**	**Delta**	**Time (p-value;)**	**Group (p-value;)**	**Time x Group (p-value;)**	**Delta (p-value;Cohen's d)**
WC (cm)	106.6 ±6.63	104.2±8.32	-2.20 ± 4.52	117.4±11.9	112.2 ±11.7	-3.35 ± 3.27	0.000	0.026	0.079	0.136; 0.070
NC (cm)	39.9±3.09	40.9±2.86	-0.95±2.07	45.1±3.85	43.6±3.67	-1.48±2.19	0.565	0.005	0.007	0.020; 1.14
Weight (Kg)	92.86±3.34	92.07 ± 3.24	-0.791±2.90	105.2±4.38	101.65±4.0*	-3.54 ±3.52	0.002	0.039	0.047	0.071; 0.863
BMI (Kg/m²)	33.9 ± 5.02	33.6 ±5.16	-0.291±1.03	35.7 ±3.25	34.5 ± 2.74*	-0.20±1.16	0.001	0.446	0.052	0.079; 0.837
Body fat (%)	40.8 ± 6.88	40.1 ± 8.55	-0.773 ± 2.41	37.8 ±5.14	37.1 ±5.84	-0.276±2.44	0.080	0.288	0.918	0.986; -0.008
Body fat (Kg)	38.2 ± 9.66	37 ± 10.9	-0.491±6.01	39.9± 7.96	37.8 ± 7.38	-2.10±6.01	0.007	0.750	0.506	0.861;- 0.079
SMM (Kg)	30.6 ± 5.75	31.0±6.32	0.609±1.30	37.08±5.59	36.3±5.73	-0.730±0.90	0.243	0.022	0.101	0.131; 0.711
Ap MM (Kg)	23.06±1.23	22.9±1.29	-0.127±0.608	27.2±1.26	26.7±1.25	-0.478±0.616	0.023	0.024	0.215	0.219; 0.579
FFM (Kg)	54.8±2.72	54.9±3.89	0.009±2.18	65.2±2.79	64.12±2.96	-1.13±1.58	0.187	0.016	0.179	0.204; 0.592
TBW (Kg)	40.24±1.96	40.16±2.22	-0.072±1.56	47.8±2.04	46.94±2.12	-0.90±1.15	0.110	0.015	0.181	0.204; 0.593

TRE: Time restricted Eating; BMI: Body mass index; WC: Waist circumference; NC: Neck circumference; SMM: Skeletal Muscle mass; Ap MM: Appendicular muscle mass; FFM: Fat-free mass; TBW: Total body water; CM: centimeters; Kg: Kilogram. Data presented as mean ± SD; p-values for Generalized estimating equations and Student t test for delta analysis; Cohen's d = effect size for t Student.

Table 5. Sleep Parameters of Obese Individuals Before and After 12-Week Time-Restricted Eating (TRE) Intervention (ITT).

	CONTROL (16)			TRE (19)						
Variables	**Baseline**	**12 weeks**	**Delta**	**Baseline**	**12 weeks**	**Delta**	**Time (p-value)**	**Group (p-value)**	**Time x Group (p-value)**	**Delta (p-value;Cohen's d)**
ESS (score)	8.44 ± 3.76	8.06 ± 4.06	-0.375 ± 2.50	9.95 ± 4.90	8.95 ± 4.82	-1.00 ± 2.38	0.094	0.620	0.473	0.457;0.256
PSQI (score)	6.63 ± 2.83	6.38 ± 3.48	-0.250 ± 1.91	7.68 ± 2.71	6.95 ± 3.10	-0.737 ±2.40	0.164	0.386	0.492	0.509;0.224
ODI (E/h)	14 ± 11.6	13.6 ± 9.68	-0.376 ± 5.06	16.4 ± 18.2	18.1 ± 23.8	1.710 ± 8.21	0.544	0.515	0.344	0.365;0.306
ODI sleep (E/h)	13.9 ± 12.6	13.8 ± 10.9	-0.025 ± 4.83	17.3 ± 20.8	18.6 ± 25.6	1.300 ± 8.45	0.565	0.482	0.550	0.582;-0.188
TST (min)	344 ± 46.2	332 ± 57.1	-11.300 ± 58.1	347 ± 60.6	315 ± 81.6	-31.300 ± 59.2	0.028	0.695	0.300	0.322;0.340
Sleep latency (mim)	29.3 ± 24.6	21.4 ± 10.4	-8.150 ± 20.10	23.4 ± 10.9	23.7 ± 12.7	0.326 ± 5.80	0.121	0.664	0.093	0.089;-0.595
Sleep efficiency (%)	81.4 ± 7.36	82.9 ± 7.34	1.470 ± 8.19	82.9 ± 7.65	81.9 ± 8.33	-1.000 ± 4.95	0.836	0.921	0.277	0.280;0.372
TA after sleep (min)	42 ± 26.2	39 ± 19.9	-2.970 ± 24.5	41.7 ± 26.8	36.2 ± 20.7	-5.490 ± 19.4	0.250	0.825	0.731	0.735;0.115
Desaturations (N)	95.5 ± 72.6	84.3 ± 56	-11.300 ± 45.9	98.7 ± 89.6	97.4 ± 107	-1.260 ± 34.5	0.353	0.755	0.459	0.466;-0.250
Snoring time (min)	153 ± 118	151 ± 112	-1.970 ± 114	145 ± 128	127 ± 112	-18.100 ± 54.0	0.173	0.366	0.51	0.588;0.185
Snoring time (%)	36.5 ± 28.3	30.9 ± 28.6	1.140 ± 29	30.9 ± 28.6	33.1 ± 25.5	2.130 ± 8.23	0.719	0.278	0.852	0.888;-0.048
Hypoxic load(%.min/h)	49.8±31.5	58.3 ± 38.9	8.490 ± 24.7	66 ± 78.4	71.8 ± 108	5.790 ± 36.2	0.244	0.554	0.947	0.803;0.085
Minimum SpO2 (%)	83 ± 5.53	82.4 ± 6.60	-0.625 ± 2.52	83 ± 9.09	83.4 ± 9.38	0.447 ± 3.32	0.853	0.829	0.264	0.297;-0.359
Average SpO2 (%)	93.8 ± 3.55	94.6 ± 1.35	0.813 ± 3.13	93 ± 5.23	94.2 ± 2.77	1.180 ± 4.18	0.124	0.528	0.775	0.785;-0.093
Maximum SpO2 (%)	99.6 ± 0.52	99.5 ± 0.70	-0.093 ± 0.37	99.6 ± 0.60	99.4 ± 0.71	-0.158 ± 0.501	0.081	0.813	0.656	0.676;0.143

TRE: Time restricted Eating; ESS: Epworth Sleepiness Scale; PSQI: Pittsburgh Sleep Quality Index; ODI: Oxygen desaturation index; TST: Total Sleep Time; TA: Time awake after sleep; E\h: events per hour. Data presented as mean ± SD. *Statistically significant difference revealed between baseline and after 12 weeks according to analysis of Generalized estimating equations (GEE) and Bonferroni's post hoc test. Student t test for delta analysis; Cohen's d = effect size for t Student.

Table 6. Sleep parameters of Obese Individuals Before and After a 12-Week Time-Restricted Eating (TRE) intervention.

	CONTROL (11)			TRE (9)						
Variables	**Baseline**	**12 weeks**	**Delta**	**Baseline**	**12 weeks**	**Delta**	**Time (p-value)**	**Group (p-value)**	**Time x Group (p-value)**	**Delta (p-value;Cohen's d)**
ESS (score)	7.82±4.23	7.64±4.67	-0.182 ± 2.82	9.33 ± 4.97	8.11 ± 4.54	-1.22± 3.11	0.283	0.900	0.440	0.444;0.352
PSQI (score)	6.73±3.25	6.27±4.19	-0.455 ± 2.30	7.22 ± 3.23	6.22 ± 3.49	-1.00±3.39	0.246	0.871	0.663	0.674;0.921
ODI (E/h)	10.64±4.88	11.38±7.50	0.976 ± 3.08	13.06 ± 12.14	12.01 ± 10.89	-0.767±5.04	0.871	0.699	0.330	0.353; 0.428
ODI sleep (E/h)	10.01±5.68	11.4±8.11	1.30 ± 3.39	12.6 ± 13.6	11.3 ± 10.9	-1.29±6.38	0.998	0.764	0.245	0.183;0.837
TST (min)	352.6±47.8	350.3±43.0	-2.34± 53.6	357.4 ± 41.9	304.91 ± 85.8	-52.50±79.3	0.610	0.314	0.087	0.109; 0.757
Sleep latency (mim)	34.91±27.9	21.95±12.3	-12.60±23.1	24.88 ± 7.75	22.76 ± 8.15	-1.860±5.25	0.026	0.424	0.109	0.536;-0.610
Sleep efficiency (%)	80.18±7.32	84.5±4.69*	4.320 ± 5.11	82.33 ± 7.52	81.55 ± 9.10	-0.778±6.89	0.176	0.891	0.051	0.073; 0.854
TA after sleep (min)	50.53±24.6	38.5±18.57	-9.040 ±23.6	52.11 ± 28.73	35.86 ± 20.17	-12.60±27.1	0.008	0.945	0.691	0.760; 0.140
Desaturations (N)	77.22±40.4	76.0±51.98	-1.230 ± 23.9	84.88 ± 68.93	70.27 ± 65.66	-14.60±28.2	0.058	0.968	0.233	0.265; 0.517
Snoring time (min)	144±116.2	172.4±111.5	28.500 ± 82.1	150 ± 144.5	120.22±116.6	-29.80±57.0	0.498	0.557	0.057	0.088; 0.810
Snoring time (%)	33±25.5	42.4 ± 27.1	9.620 ± 19.9	34.4 ± 33	32.1 ± 28.9	1.30±10.8	0.452	0.616	0.086	0.308; 0.504
Hypoxic load(%.min/h)	44.75±27.2	58.32±40.7	13.700 ± 28.4	51.2 ± 40.6	46.11 ± 37.08	-5.09±18.7	0.640	0.731	0.102	0.107; 0.763
Minimum SpO2 (%)	81.2±7.52	67.6 ± 33.9	-13.700±28.4	85.2 ± 4.54	90.3 ± 19.8	5.09±18.70	0.395	0.046	0.062	0.107;-0.763
Average SpO2 (%)	94.5±1.57	94.3±1.42	-0.136±0.924	91.7 ± 7.04	94.4 ± 1.65	2.67±5.81	0.171	0.336	0.129	0.685;-0.712
Maximum SpO2 (%)	99.5±0.568	99.4 ± 0.78	-0.182±0.405	99.6±0.682	99.2±0.791	-0.389±0.55	0.006	0.743	0.318	0.318; 0.438

TRE: Time restricted Eating; ESS: Epworth Sleepiness Scale; PSQI: Pittsburgh Sleep Quality Index; ODI: Oxygen desaturation index; TST: Total Sleep Time; TA: Time awake after sleep; E\h: events per hour. Data presented as mean ± SD. *Statistically significant difference revealed between baseline and after 12 weeks according to analysis of Generalized estimating equations (GEE) and Bonferroni's post hoc test. Student t test for delta analysis; Cohen's d = effect size for t Student.

DISCUSSION

In a sample of adults living with obesity undergoing an 8-hour TRE intervention for 12 weeks, a reduction in body weight was observed only among those who completed the intervention, with no decrease in body fat or anthropometric measurements in the ITT analysis. The delta analysis showed a significant reduction in skeletal muscle mass, fat free mass, and total body water in the ITT group, but no changes in individuals who completed the intervention. Regarding sleep parameters, the ITT analysis did not reveal significant effects of the TRE intervention on sleep.

TRE might be regarded as a supportive strategy for weight loss, as it employs a less restrictive approach compared to traditional calorie-restricted diets (14). However, despite the generally good adherence observed with TRE, the literature suggests that its effects on weight loss are not as significant as those achieved through continuous daily caloric restriction (29). Among individuals who adhered to the TRE for five or more days per week (71%), positive outcomes were observed, including weight loss, reductions in body fat, and improved metabolic health (17). In the present study, despite being instructed to eat *ad libitum* to remain as close as possible to their habitual consumption patterns, participant adherence to the intervention was only 49%. These findings raise questions about the cost-effectiveness of TRE as a weight loss intervention, especially when compared to more established dietary strategies that yield more substantial outcomes.

Reduction in body weight is one of the main outcomes achieved with TRE. In the present study, we did observe a significant reduction in body weight and BMI only in the analysis of those who finished the intervention, as seen in most studies with the 8-hour TRE (1,19,21,30). In those studies in which weight loss was observed, a reduction in body fat and maintenance of muscle mass were also noted, which are positive aspects of the weight loss process. However, in the studies conducted by Park et al. (19) and Chow et al. (31), a significant

reduction in muscle mass was observed following an 8-hour TRE intervention over 4 and 12 weeks, respectively. Interestingly, despite the lack of weight loss, in ITT analysis this study observed a reduction in skeletal muscle mass without changes in body fat, which may be a consequence of low adherence to the intervention or compensation through caloric restriction at the final days of intervention.

Excess body fat, typical in individuals with obesity, is associated with poorer sleep quality (4,5). In this study, we observed that even though participants were randomly selected, the majority of individuals with obesity (80%) were classified with OSA of varying degrees, showing poor sleep quality according to the PSQI and a sleep duration of less than 7 hours, which is considered below the recommended amount for adults (32). Thus, reducing weight and improving body composition may contribute to the improvement of sleep parameters.

In the present study, sleep quality and daytime sleepiness assessed by subjective methods remained unchanged in both groups by the end of the study. This finding is similar to several studies that also used subjective methods for sleep assessment (33). Cienfuegos et al.(14), for example, found no changes in sleep parameters in obese women subjected to 4-hour and 6-hour TRE over 6 weeks. Pavlou et al.(34) also demonstrated that 8-hour TRE over 6 months did not result in any changes in sleep quality, duration, insomnia severity, or OSA risk in individuals with type 2 diabetes assessed through questionnaires, despite significant weight loss.

Furthermore, even in studies that used objective sleep measures, no significant changes were found in these parameters measured by actigraphy, such as in the study by Kirkhan et al.(21) and Simon et al.(10), which tested 8-hour TRE for 12 and 8 weeks, respectively. Despite the lack of significant changes in sleep parameters, it's important to note some interesting clinical changes as the reduction in hypoxic burden (delta cohen´s d = 0,763), snoring time (delta minutes cohen´s d = 0,810; % cohen´s d = 0,504) observed in the TRE group. The

visualization of these results may stem from the use of new technologies for sleep assessment, which present variables not captured by conventional methods. The nocturnal digital monitoring device used in the present study (ODM-biologix) consist of a high-resolution wireless oximeter, an integrated accelerometer connected to a smartphone application, and an automated cloud algorithm for detecting oxygen desaturation (35).This technique is more comfortable, easily used at home, and has the potential to address night-to-night variability in OSA severity. Moreover, it has been validated for the diagnosis of OSA and its severity (23).

The reduction in snoring time is an important positive outcome, considering the correlation between snoring duration and poorer sleep quality (36). In a cross-sectional study, individuals who snored reported shorter total sleep time and more days with sleep deprivation compared to individuals who did not snore (37).

Recent literature has introduced a new variable called hypoxic burden, which, in addition to the frequency of respiratory events, also captures the depth and duration of hypoxemia (38). This data may provide useful and more precise information for identifying and managing OSA, considering hypoxic burden as an important predictor of cardiovascular risk in OSA (39). According to Karhu et al. and Hietakoste et al. (40,41), deeper apneas and hypopneas are associated with worsening OSA and trigger a greater cardiovascular response compared to shorter and milder events. In the present study, the substantial yet nonsignificant reduction in hypoxic burden observed in the TRE group, compared to the substantial increase in the control group, suggests that TRE intervention may contribute to reducing the risk of CVD in patients with OSA.

TRE contributes to improvements in anthropometric parameters and may indirectly promote better sleep outcomes. However, the timing of the eating window can influence the effectiveness of the intervention. In the present study, participants followed a delayed TRE protocol, beginning their first meal of the day at 11:00 a.m., thereby skipping breakfast — a

meal often considered nutritionally important. Megson et al.(42) demonstrated that increased breakfast consumption during weight loss treatment was significantly associated with greater weight reduction among individuals with obesity. Conversely, among individuals who do not habitually consume breakfast, introducing this meal was linked to increased caloric intake and subsequent weight gain (43). Furthermore, the efficacy of TRE may also depend on the timing of the eating window, as earlier time-restricted feeding (e.g., between 8:00 a.m. and 7:00 p.m.) appears to yield more favorable outcomes in terms of body fat reduction and cardiometabolic health when compared to delayed eating windows (e.g., between 12:00 p.m. and 11:00 p.m.) (44,45).

However, as previously mentioned, TRE acts as a secondary strategy for weight control. Therefore, combining TRE with other strategies may lead to more significant improvements in sleep. The study by Manoogian (20) demonstrated a reduction in sleep disturbances and daytime sleepiness in individuals who underwent a 10-hour TRE intervention combined with a Mediterranean diet. Similarly to our study, integrating TRE with nutritional guidance could potentially enhance outcomes.

Limitations and strengths

The present study had several limitations. First, although it was a randomized study, the participants could not be blinded to the intervention, which is common in studies with dietary interventions. Second, individuals who enrolled to participate in the study may have already been interested in TRE or may have wished to improve their health by making a change in their diet. Third, in the TRE group, the start and end times of the eating window were established without considering the chronotype of each participant, which could impact adherence. Forth, other objective sleep measures would increase the quality of sleep data, however the use of multiple devices for sleep measurements might have difficult adherence to the study. Nevertheless, this study has important strengths as a rigorous control of eating window, an

inclusion of an objective sleep monitoring with a reduced cost and made in a domestic environment, which contribute to a more realistic sleep measurement.

CONCLUSION

In this study, restricting the eating window to 8 hours over a 12-week period resulted in reductions in body weight and BMI among individuals who completed the intervention. However, no reductions in fat mass or improvements in sleep parameters were observed in individuals with obesity. Nevertheless, numerical changes with moderate to large effect sizes were noted in hypoxic burden and snoring following the TRE intervention. Further research is needed to clarify the effects of TRE on sleep, including clinical trials that incorporate multiple objective sleep assessment parameters and combine TRE with other therapeutic strategies.

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7.2 Artigo 2

Artigo na sua versão preliminar apresentado conforme as normas de submissão da revista Clinical Nutrition.

TÍTULO: Effects of a Time-Restricted Eating Intervention on Sleep and Body Composition in Adults with Obstructive Sleep Apnea: A Randomized Cross-over Clinical Trial.

ABSTRACT

Objectives: This study aimed to evaluate the effects of an 8-hour Time-Restricted Eating (TRE) intervention over 12 weeks on weight loss, body composition, and sleep in adults with Obstructive Sleep Apnea (OSA).

Methods: A randomized crossover clinical trial was conducted. Participants aged 30 to 65 years with a Body Mass Index (BMI) ≥30 kg/m², diagnosed with OSA, of both sexes, with eating windows from 11 to 14 hours were included. The participants were randomized into an 8-hour TRE intervention (meals between 11 a.m. and 7 p.m.) or control group (eating window >10 hours and nutritional guidance). Twelve participants completed the intervention. Measurements included body weight, height, waist and neck circumference, and body composition (bioelectrical impedance). Sleep parameters were assessed using a Biologix® portable sleep monitor and questionnaires.

Results: The average age of the sample was 44.6 ± 7.84 years, 50% female. Adherence to the TRE intervention was 4.2 days per week. A reduction in body weight ($p = 0.002$), BMI ($p = 0.002$), waist circumference ($p = 0.001$) and Appendicular Muscle Mass ($p = 0.044$) was observed in the TRE group. In terms of sleep parameters, a reduction in snoring time ($p= 0.025$), hypoxic burden ($p= 0.008$) and an increase in minimum oxygen saturation ($p= 0.009$) were noted in the TRE group.

Conclusion: The findings of this study suggest that an 8-hour TRE protocol may be an adjuvant treatment for weight loss and improvement of sleep parameters in individuals with OSA.

Brazilian Registry of Clinical Trials (REBEC) - protocol RBR-9rh56ph

Key words: Time restricted eating, intermittent fasting, obstructive sleep apnea, body composition, sleep, hypoxic burden.

INTRODUCTION

Obstructive sleep apnea (OSA) is a sleep-related breathing disorder characterized by repeated obstructions of the upper airway during sleep, resulting in pauses or reductions in respiratory flow (LÉVI et al., 2015). It is estimated that the disorder affects nearly 1 billion people worldwide, with Brazil being the tenth country with the highest number of individuals with OSA (Duarte et al., 2022). Its symptoms directly impact the quality of life and, when left untreated, increase the risk of developing cardiovascular diseases, which imposes a burden on the universal health system (Kapur et al., 2017).

The high prevalence of OSA in patients with obesity reinforces the bidirectional relationship between those (Bonsignore, 2022). This relationship is mainly justified by the deposition of adipose tissue in the upper airway, such as the neck, tongue, and pharynx, leading to lumen reduction and increased chances of airway collapse (Duarte et al., 2022). On the other hand, OSA can also predispose individuals to alterations in energy balance, as well as changes in food consumption caused by acute sleep restriction resulting from shorter sleep duration or sleep fragmentation (Broussard and Klein, 2022).

The dysregulation of circadian rhythm has also been investigated as one of the probable contributors to weight gain. Late-night eating and prolonged eating windows, exceeding 11 hours a day, lead to increased caloric intake and consequent weight gain (Challet, 2019; Chaput et al., 2022; Marhefkova et al., 2024). Studies demonstrate that reducing the daily eating

window and consuming food earlier in the day have health benefits, such as promoting weight loss and reducing the risk of inflammatory and metabolic diseases (Oliveira et al., 2016; Marinac et al., 2015).

Thus, Time-Restricted Eating (TRE) emerges as a promising coadjuvant alternative for weight reduction. TRE is considered a type of intermittent fasting that involves maintaining a reduced eating window during the day and prolonging the fasting period at night without monitoring food intake, which provides good adherence of 80 to 90% per week (Cienfuegos, 2020; Gabel, 2018; Lin, 2023; Zhang, 2022; Manoogian, 2022; Chow, 2020; Lowe, 2020). Additionally, TRE results in an unintentional reduction in energy intake of 300-500 kcal per day and weight loss between 3-5% over 2-12 months in adults with obesity, with a reduction in body fat and maintenance of muscle mass, in most of studies (Ezpeleta et al., 2024; de Sousa et al, 2025).

This type of intervention can also benefit sleep quality, as even a slight reduction in body weight can contribute to improvements in sleep parameters (Simon, 2023; Martin et al., 2016). Moreover, reducing the duration of the daily eating window, thereby increasing the interval between the last meal and bedtime, might represent a mechanism through which TRE could enhance sleep quality (Raji et al., 2024; Wilkinson et al., 2020). The review by Lopez-Minguez (2019) reveals that earlier meal timing increases resting energy expenditure and improves glucose tolerance, promoting weight loss in individuals with overweight and obesity. Others also corroborate these findings by demonstrating the effects of TRE on improving sleep parameters, particularly in individuals with obesity (Manoogian et al., 2023; Wilkinson, 2020; and Steger et al., 2023). However, to date, no studies have been found that investigate the effects of TRE interventions on sleep parameters in obese individuals diagnosed with OSA.

Therefore, the aim of this study was to evaluate the effects of a 12-week TRE intervention on anthropometry, body composition, and sleep in individuals living with obesity and OSA.

METHODS

Study Design

A randomized, controlled, crossover clinical trial was developed, as demonstrated in Figure 1. Initially, participants were stratified by age and sex, and then randomly assigned to the intervention or control group using the Excel program. The intervention group followed a protocol with 8-hour Time-Restricted Eating (TRE) per day. The control group maintained a feeding window of more than 10 hours per day and received nutritional guidance based on the recommendations of the Brazilian Dietary Guidelines (Brazil, 2014). Each group lasted 12 weeks, with a washout period of 30 days. This study was approved by the Ethics Committee for Human Research of the Federal University of Lavras under approval number 6.207.765 and registered in the Brazilian Registry of Clinical Trials (REBEC) under protocol RBR-9rh56ph. The study began in February 2024 and concluded in August 2024, when the sample size slightly exceeded the initial target calculated in the sample size estimation.

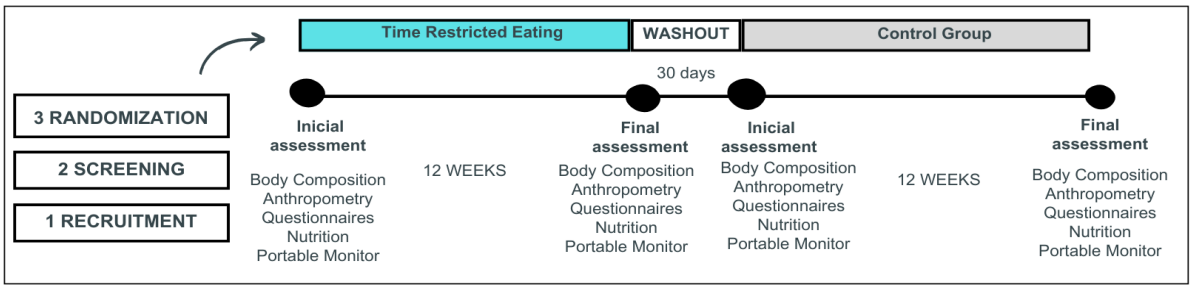

Figure 1. Study Design of 12 Weeks with 8-Hour Time-Restricted Eating (TRE).

Sample Selection and Recruitment

Sampling was performed using a convenience method in the municipality of Lavras and

surrounding areas, and recruitment occurred through social media advertising, posters, and personal approaches within the municipality of Lavras. Participants had to meet the inclusion criteria, which included the following characteristics: adults aged between 30 and 60 years, with a Body Mass Index (BMI) equal to or greater than 30 kg/m², of both sexes, and with a feeding window between 11:00 and 14:00 hours.

Individuals were excluded from the study if they had any serious illness such as cancer, liver or kidney diseases, pregnant women, women with children under two years of age, institutionalized elderly individuals, individuals undergoing any weight loss treatment or nutritional follow-up, individuals using medications that interfere with metabolic rate (e.g., appetite suppressants), individuals with physical or intellectual disabilities confirmed by medical diagnosis and unable to participate in the proposed evaluations, individuals refusing to participate in the assessments or interventions, and shift or night workers.

All criteria were assessed subjectively or through questions in the initial interview, which, in addition to evaluating eligibility criteria, included questions about socioeconomic status and education. However, this information was only used after obtaining the participant's consent to participate in the research. Following the screening, eligible participants received detailed information about the study and were invited to sign the informed consent form.

Participant Assessment

The participant assessments were conducted at the Department of Nutrition of the Federal University of Lavras. Eligible participants, based on the screening process, were provided with a finger oximeter for overnight use and were instructed to attend the assessment site to proceed with the study. Preparation instructions for the exams were sent throught social media a few days prior to the data collection, allowing participants to plan accordingly. Anthropometric and body composition data, as well as dietary and sleep data, were collected before and after the 12-week intervention. All data was stored in an appropriate location,

ensuring the confidentiality and security of the information.

Sleep Assessment

The sleep profile assessment and diagnosis of OSA were obtained using a high-resolution, portable digital finger oximeter (Biologix brand), validated for OSA diagnosis (Pinheiro et al., 2020). The device consists of a wireless high-resolution oximeter, a built-in accelerometer connected to a smartphone application, and an automated cloud algorithm for detecting oxygen desaturation. The provided oximeter was to be placed on the participant's finger when they intended to sleep and removed the following morning upon waking, according to the manufacturer's recommendations. Data were collected by averaging two reports and included total sleep time (minutes), wake time after sleep (minutes), sleep latency (minutes), sleep efficiency (percentage), snoring time (minutes and percentage), oxygen desaturation index (ODI) (events per hour), sleep oxygen desaturation index (ODI-s) (events per hour), hypoxic load (%·min/hour), and minimum, mean, and maximum oxygen saturation (SpO2) (%). Regarding the diagnosis of OSA, the severity of the apnea was classified based on the ODI, where <5 events per hour indicates normal sleep quality, 5-15 events per hour is consistent with mild sleep apnea, 15-30 events per hour is consistent with moderate sleep apnea, and >30 events per hour is consistent with severe sleep apnea.

The subjective assessment of sleep quality was obtained using the Portuguese version of the Pittsburgh Sleep Quality Index (PSQI) (Bertolazi et al., 2011). This scale consists of seven components, the sum of which provides a global score ranging from 0 to 21, classifying sleep quality as follows: 0 to 4 as good, 5 to 10 as poor, and greater than 10 indicates the presence of sleep disturbances. Another assessment obtained was the participants' self-perception of daytime sleepiness, evaluated using the Portuguese version of the Epworth Sleepiness Scale (Bertolazi et al., 2009), which consists of eight questions with scores ranging from 0 to 24. A score of 9 or higher indicates abnormal daytime sleepiness.

Anthropometry and Body Composition

All anthropometric measurements and body composition assessments were performed in the morning, between 7:00 AM and 9:00 AM, to avoid potential interference. Anthropometric data such as body weight (kg) and height (cm) were collected using a digital scale and stadiometer, respectively, for subsequent calculation of Body Mass Index (BMI). Waist circumference was measured using the methodology of Taylor et al. (2000), with the measurement taken at the minimal point of the trunk between the costal margin and the iliac crest. Neck circumference was measured with the participant seated, with the spine erect and the head aligned with the horizontal plane (Frankfurt plane), and the tape placed at the smallest circumference of the neck just above the laryngeal prominence (Adam's apple). For body composition assessment, participants underwent bioelectrical impedance analysis (BIA) using the Biodynamics InBody 230® equipment, with participants in an orthostatic position. The assessment in women of reproductive age was conducted during the same phases of the menstrual cycle to avoid potential biases resulting from body changes during different phases.

Dietary Intake

Dietary intake was assessed using two 24-hour dietary recalls, supplemented by food diaries completed or self-reported on three non-consecutive days, including one weekend day, both before and during the intervention. Participants received instructions for completing the food diaries, and once completed, an in-person or online meeting was scheduled to review and supplement any missing information with a trained professional. After gathering the information, the dietary recalls were critically evaluated using the Dietary Recall Critique Manual (de Castro et al., 2014) and with the help of the Household Measurement Table for Dietary Intake Assessment (Pinheiro et al., 2005). Data on energy and macronutrients (carbohydrates, proteins, and lipids) were obtained using the DietSmart nutrition software, and caffeine intake was assessed using the Brazilian Caffeine Content Table (Rocha et al., 2022).

Subsequently, the data were adjusted for individual variability using the Multiple Source Method (MSM) software to better represent the participants' habitual intake.

Physical Activity Level

Physical activity level was assessed using the International Physical Activity Questionnaire (IPAQ), short version (Pardini et al., 2001). Participants were classified according to their total score and based on the minimum recommendation of 75 minutes of vigorous activity and 150 minutes of moderate physical activity, as outlined in the Brazilian Physical Activity Guidelines (BRASIL, 2021), into the following categories: active (when meeting or exceeding the recommended values) or inactive (when not meeting the recommended values).

Time-Restricted Eating (TRE) Intervention

The TRE intervention consists of restricting the feeding window, reducing the time between the first and last meal of the day. In the 8-hour TRE group, participants were instructed to restrict their daily food intake to a total of 8 hours, with a 16-hour fasting period. The feeding window was to begin at 11:00 AM and end at 7:00 PM. During the feeding period, participants were instructed to consume food until they reached satiety, without restrictions regarding the quantity or caloric content of their meals. During the fasting period, the consumption of beverages containing caffeine was allowed, but without sugar or artificial sweeteners to avoid potential interference with glucose tolerance. Additionally, participants were encouraged to drink plenty of water and were instructed to maintain their usual level of physical activity throughout the study.

Adherence to TRE

To assess adherence to the 8-hour TRE, a daily adherence log was used to record the times when each participant began and ended eating each day. The adherence log was provided in the form of a notebook, considering the population's limited familiarity with technology and potential issues with devices during the study. The instructions for completing the adherence log were provided by the researcher and exemplified on the cover of the log itself. If the log indicated food consumption within the appropriate 8-hour window, as established for the groups, the day was labeled as 'adherent.' If the log indicated food consumption outside the 8-hour feeding window, the day was labeled as 'non-adherent.' Adherence to the TRE protocol was then calculated as the number of adherent days per week, multiplied by 100 and divided by 7 days, with total adherence over the 12 weeks being obtained by averaging the percentage of adherence each week.

Statistical Analysis

Based on the study design and the tests of interest, a sample size calculation was performed. To achieve a statistical power of 80%, an effect size of 0.4, and a significance level of 5%, a minimum of 12 participants was required. The data distribution was assessed using the Shapiro-Wilk test. If the data did not follow a normal distribution, they were log-transformed or analyzed using non-parametric tests. Descriptive statistics for sample characteristics, adherence, feeding window, and physical activity are presented as mean ± standard deviation or sample size (percentage). An independent t-test was initially conducted to verify differences between baseline data of the groups. For the primary and secondary outcomes (sleep and body composition) before and during the study, Generalized Estimation Equation (GEE) was performed, followed by a Post Hoc analysis, where the Bonferroni test was applied. The difference between final and baseline data (delta) was also calculated and

the difference between groups was tested using the independent t-test, including for the feeding window data. In addition to these analyses, differences were also tested between those who demonstrated adherence to the intervention greater than 4 days (approximately 60%) and those with adherence less than or equal to 4 days, within the TRE group only. Other data are presented as mean and standard deviation in tables and figures. A significance level of 0.05 and a 95% confidence interval were used. All analyses were performed using SPSS 15.0 software.

RESULTS

Initial Selection and Recruitment

After the study announcement, 70 individuals expressed interest in participating, and forty-two were selected based on the initial eligibility criteria. Twenty-nine adults with obesity met all the inclusion criteria, however seven were excluded for not having a diagnosis of OSA. Thus, twenty-two volunteers were included in the clinical investigation and randomly assigned to two groups (twelve in the intervention group and ten in the control group). After completing the twelve weeks and following the washout period, the participants switched groups, totaling twelve participants with complete crossover (Figure 1).

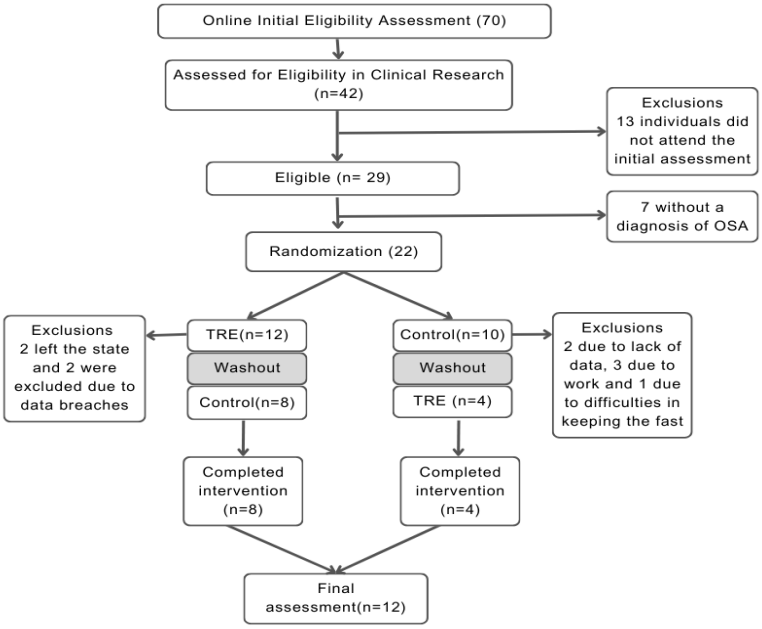

Figure 2. CONSORT Flowchart of Recruitment and Inclusion of Participants in the Study.

General Characteristics of the Sample

The average age of the sample in this study was 44.6 ± 7.84 years, with 50% female participants. There was no significant difference in gender distribution between the control and time-restricted eating (TRE) groups ($p = 0.5$). There was a predominance of participants with complete high school education and an income of up to two minimum wages. Most participants were classified as having mild obstructive sleep apnea (OSA) and presented with systemic arterial hypertension (SAH) and liver disease as predominant comorbidities, as reported by participants. The participants also had a basal feeding window that was considered prolonged (12.36 ± 0.52 hours). All participants had a total score on the Pittsburgh Sleep Quality Index (PSQI) higher than 5, indicating poor sleep quality, and a total sleep time (TST) of less than 7 hours. The general characteristics of the participants are shown in Table 1. No significant differences were found between the groups regarding baseline data on eating window ($p = 0.201$), body mass index (BMI) and age ($p > 0.05$).

Table 1. Baseline Characteristics of Participants.

Features	All participants (n=12)
Age (years)	44.6 ± 7.84
Sex	
Female	6 (50%)
Education	
Master's or doctorate	3 (25%)
Complete university degree	3 (25%)
High school complete	6 (50%)
Income	
More than 3 minimum wages	6 (25%)
2 to 3 minimum wages	2 (16.7%)
Up to 2 minimum wages	7 (58.3%)
Classification of degree of OSA	
Mild OSA	7 (58.3%)
Moderate OSA	5 (41.7%)
Disease	
Diabetes Mellitus	1 (5.71%)
SAH	3 (31.43%)
Gastroesophageal reflux	1 (5.71%)
Liver disease	3 (11.44%)
Artrose	1 (2.85%)
Fibromyalgia	1 (5.71%)
Sleep	
PSQI (score)	7.47 ± 3.43
ESS (score)	8.40 ± 4.77
TST (min)	355 ± 38.7
Eating window (hours)	12:36 ± 0:52
BMI (Kg/m²)	35.5 ± 4.85

OSA: Obstructive Sleep Apnea; SAH: Systemic arterial Hypertension; PCOS: Polycystic Ovary Syndrome; PSQI: Pittsburgh Sleep Quality Index; ESS: Epworth Sleepiness Scale; TST: Total Sleep Time; BMI: Body Mass Index.

Adherence to TRE, Meal Timing and Dietary Intake

Adherence to the 8-hour TRE intervention was 59.8 ± 20.8 %, which is equivalent to adherence to 4.2 days per week of 8-hour TRE. No participants reported adverse effects such as nausea, discomfort or dizziness, however, one person withdrew due to difficulties in maintaining the intervention.The intervention group's eating window was reduced by approximately 4 hours compared to the baseline eating window (-3:54 ± 1:44 hours, $p<0.001$,

Cohen's d= 0.951). The TRE group started their meals significantly later (10:12) and finished their last meal of the day significantly earlier (19:00), when compared to the control group (Table 2). Regarding food consumption, a significant increase in carbohydrate intake (%) was observed in the control group, significant difference in delta protein (CONTROL=-2.35%; TRE= 2.28%; P=0,017; Cohen's d = -1.051) and delta carbohydrate (CONTROL=7.55%; TRE= -5.25%; P=0,027; Cohen's d = 0.964), as shown in Table 3.

Table 2. Adherence to the TRE Intervention, Meal Timing, and Duration.

Variables	CONTROL (n=12)	TRE (n=12)	p-value;Cohen's d
First meal (h)	7:48 ± 1:12	10:12 ± 1:24	0.002;0.743
Last meal (h)	20:20 ± 1:34	19:00 ± 1:16	0.008;0.639
Eating window before (h)	11:06 ± 1:58	12:30 ± 1:07	0.046;-0.877
Eating window after (h)	12:18 ± 0:58	8:36 ± 1:03	0.001;3.676
Delta eating window (h)	1:11 ± 2:40	3:54 ± 1:44	0.001;0.951
Meals per day (n)	4.25 ± 0.809	3.46 ± 0.423	0.005;0.688

TRE: Time restricted Eating; Delta eating window: Eating window after - eating window before

Table 3. Effects of TRE intervention on energy, macronutrient, and caffeine consumption in obese individuals.

Variables	CONTROL (12)			TRE (12)			Time (p-value)	Group (p-value)	Time x Group (p-value)	Delta (p-value;d de Cohen)
	Baseline	12 weeks	Delta	Baseline	12 weeks	Delta				
Energy (Kcal)	2176± 560	2057±723	-119.0±665	2133 ± 886	1929±413	-204.00±1032	0.341	0.668	0.801	0.811;0.098
Carbohydrates (g)	242± 69.4	265±85	23.10±121	270 ± 92.4	249±54.5	-21.00±115	0.964	0.773	0.340	0.371;0.373
Carbohydrate (%)	44.9 ± 8.60	52.5±4.45*	7.55±9.28	52 ± 6.77	51.5±5.35	-0.525±7.36	0.032	0.179	0.014	0.027;0.964
Proteins (g)	99.8 ± 8.41	79.9±22.6	-19.9±28.9	82.7 ± 26.3	86.4±25.8	3.74±27.4	0.142	0.604	0.032	0.052;-0.839
Protein (%)	18.3 ±5.76	16±2.93	-2.35±4.30	15.9±2.44	18.2±4.95	2.28±4.51	0.975	0.930	0.007	0.017;-1.051
Lipids (g)	82.9 ± 22.3	70.9 ± 27.7	-12.10±22.7	73.5 ± 34.1	65.6±18.6	-7.84±39.4	0.113	0.365	0.737	0.751;-0.131
Lipid (%)	34.9 ± 6.16	30.7±6.88	-4.19±10.9	30.7±8.23	30.3±4.15	-0.451±8.36	0.223	0.176	0.326	0.357;-0.383
Caffeine (mg)	48.1 ± 43.7	55.7±51.9	7.64±48.1	54.7±34.8	62.1±60.3	7.36±50.5	0.101	0.703	0.789	0.989;0.005

TRE: Time restricted Eating; Kcal: kilocalories; g: gram; %: percentage; mg: milligrams; Data presented as mean ± SD; p-values for Repeated measures ANOVA and Student t test for delta analysis; n^2p = effect size for ANOVA; Cohen's d = effect size for t Student

Physical Activity Level

No significant differences were found in the level of physical activity assessed by the IPAQ before and after the intervention in the TRE groups (66.6% active and 33.3% inactive to 41.6% active and 58.3% inactive) and in the control group (66.6% active and 33.3% inactive to 50% active and 50% inactive).

Anthropometry and Body Composition

Table 3 presents anthropometric and body composition data at baseline and after 12 weeks for the control and TRE intervention groups. A significant reduction was observed for weight (p=0.002), BMI (p=0.997), WC (p=0.001) and appendicular MM (p=0.044) between baseline and 12 weeks only in the TRE group. These results are confirmed by the significant difference in delta, which, in turn, was also significant in delta SMM (P=0.028, Cohen's d=0.959).

Sleep Outcomes

The sleep parameters evaluated are presented in Table 4. "The TRE group showed a trend toward increased minimum oxygen saturation (Bonferroni p-value 0.057). Also, a significant difference was observed between the deltas of snoring time (CONTROL=4.08%; TRE=-07.31%; P=0,025; Cohen's d = 0.980), hypoxic burden (CONTROL=13.5%.min/h; TRE=-17.9%.min/h; P=0,008; Cohen's d = 1.188) and minimum oxygen saturation (CONTROL=-1.130%; TRE= 3.96%; P=0,009; Cohen's d = 1.163), demonstrating a greater reduction in hypoxic load and snoring time (%), the improved minimum oxygen saturation in the TRE group.

Adherence in intervention: anthropometry, body composition and sleep outcomes

Table 6 presents anthropometric and body composition data at baseline and after 12 weeks for the adherence > 4 days and adherence < 4 days and TRE intervention groups. A significant reduction was observed for BMI (p=0.038) between baseline and 12 weeks only in the TRE group with adherence < 4 days, in significant reduction in WC (p= <0.001) in the group with adherence > 4 days and group with adherence < 4 days. No significant differences in sleep parameters were observed between the groups with adherence greater than or less than 4 days, however, an improvement in subjective sleep quality was observed in the higher adherence group (p = 0.018) as shown in Table 7.

Table 4. Anthropometry and Body Composition of Obese Individuals with OSA before and after a 12-week TRE intervention.

	CONTROL (12)			TRE (12)						
Variables	**Baseline**	**12 weeks**	**Delta**	**Baseline**	**12 weeks**	**Delta**	**Time (p-value)**	**Group (p-value)**	**Time x Group (p-value)**	**Delta (p-value;d de Cohen)**
WC (cm)	110 ±10.50	109.0±10.0	-0.650 ± 3.53	114±12.0	109 ± 12.30*	-5.250±2.41	0.000	0.682	0.000	0.001;1.524
NC (cm)	42.5±4.50	41.8 ± 4.99	-0.633 ± 1.19	43±5.06	42.2 ± 4.67	-0.975± 0.90	0.000	0.781	0.407	0.436;0.324
Weight (Kg)	101±15.70	101± 15.70	-0.225 ± 1.85	103±15.9	99.8 ± 15.40*	-3.340±3.33	0.001	0.917	0.003	0.010;1.156
BMI (Kg/m²)	35.4 ± 4.93	35.2 ± 5.10	-0.217 ± 0.81	36.2±4.93	35 ± 4.50*	-1.19±1.12	0.000	0.886	0.011	0.023;0.997
Body fat (%)	39.1 ± 7.80	38.6 ± 8.46	-0.525 ± 2.11	40 ± 7.76	39.1 ± 7.82	-0.875±1.44	0.047	0.834	0.620	0.640;0.194
Body fat (Kg)	39.6 ± 10.30	39.0±10.60	-0.642 ± 2.26	41.2±10.3	39 ± 9.64	-2.240±2.39	0.001	0.835	0.078	0.106;0.689
SMM (Kg)	34.8 ± 7.44	35.1± 7.84	0.292 ± 0.90	35.1±7.71	34.5 ± 7.73	-0.617±0.90	0.380	0.970	0.014	0.028;0.959
Ap MM (Kg)	25.6 ± 5.08	25.7 ± 5.25	0.108 ± 0.62	25.9±5.30	25.4 ± 5.70*	-0.508±0.57	0.086	1.000	0.008	0.019;1.036
FFM (Kg)	61.3 ± 12.00	61.8 ± 12.7	0.425 ± 1.89	61.9±12.6	61 ± 12.00	-0.917±1.69	0.482	0.982	0.055	0.080;0.750
TBW (Kg)	45 ± 8.73	45.2 ± 9.29	0.283 ± 1.38	45.4±9.22	44.7 ± 9.20	-0.733±1.22	0.376	0.985	0.046	0.069;0.781

TRE: Time restricted Eating; BMI: Body mass index; WC: Waist circumference; NC: Neck circumference; SMM: Skeletal Muscle mass; Ap MM: Appendicular muscle mass; FFM: Fat-free mass; TBW: Total body water; cm: centimeters; Kg: kilogramars. Data presented as mean ± SD; p-values for Repeated measures ANOVA and Student t test for delta analysis; n^2p = effect size for ANOVA; Cohen's d = effect size for t Student.

Table 5. Sleep parameters of obese individuals with OSA before and after a 12-week TRE intervention.

	CONTROL (12)			TRE (12)						
Variables	**Baseline**	**12 weeks**	**Delta**	**Baseline**	**12 weeks**	**Delta**	**Time (p-value)**	**Group (p-value)**	**Time x Group (p value)**	**Delta (p-value;d de Cohen)**
ESS (score)	8.92±4.80	8.67 ± 4.96	-0.250 ± 2.14	9.58 ± 4.44	8.67 ±5.09	-0.917 ± 1.88	0.722	0.973	0.122	0.426;0.331
PSQI(score)	7.75±3.67	7.42 ± 4.17	-0.333 ± 2.02	8.33 ± 3.58	6.33 ± 3.31	-2.000 ± 3.41	0.033	0.852	0.128	0.159;0.595
ODI (E/h)	14.6±10.20	15.6 ±13.50	1.090 ± 6.23	14.3 ± 8.29	11.6 ± 11.80	-2.730 ± 7.50	0.541	0.598	0.156	0.188;0.554
ODI sleep (E/h)	13.6±12.10	16 ±15.40	2.380 ± 4.05	13.7 ± 8.62	11.6 ± 12.90	-2.050 ± 8.28	0.899	0.650	0.082	0.110;0.681
TST (min)	356±26.40	300 ± 46.90	-56.50±50.10	361 ± 37.50	348 ± 63.30	-13.800± 68.50	0.003	0.049	0.068	0.095;-0.71
Sleep latency (mim)	36.7±25.20	29.1±16.40	-7.56±27.60	25.5 ± 10.80	26.3 ± 9.66	0.775 ± 4.62	0.380	0.181	0.280	0.313;-0.42
Sleep efficiency (%)	80.8±7.14	82.8 ± 4.66	1.960±5.89	83.8 ± 6.13	84.6 ± 4.87	0.750 ± 5.45	0.222	0.216	0.586	0.607;0.21
TA after sleep (min)	47.5±24.10	33.2 ±12.20	-14.40±16.20	40.1 ± 25.20	34.6 ± 23.00	-5.500 ± 21.80	0.008	0.696	0.238	0.271;-0.46
Desaturations (N)	95.3±85.90	87.9 ±69.80	-7.420±42.60	101 ± 70.30	80.4 ± 90.40	-21.100±63.60	0.177	0.981	0.518	0.542;0.253
Snoring time (min)	174±123.0	161±122.0	-13.70±43.70	218 ± 130.00	168 ± 124.00	-50.200±60.80	0.002	0.592	0.078	0.106;0.688
Snoring time (%)	39.6±28.10	43.7±32.90	4.080 ± 8.45	48.1 ± 30.20	40.8 ± 27.20	-7.310 ± 14.00	0.474	0.807	0.012	0.025;0.986
Hypoxic load(%.min/h)	46.9±35.30	60.4±40.20	13.500 ± 21.8	58.6 ± 30.50	40.6 ± 31.60	-17.900±30.40	0.352	0.624	0.004	0.008;1.188
Minimum SpO2 (%)	83.4±5.41	82.3 ± 5.92	-1.130 ±2.79	81.4 ± 5.56	85.3 ± 3.88	3.960 ± 5.52	0.097	0.789	0.003	0.009;1.163
Average SpO2 (%)	94.6±1.24	94.7 ± 1.11	0.083 ± 0.70	94.5 ± 1.16	94.8 ± 1.47	0.375 ± 0.77	0.112	0.964	0.312	0.343;-0.39
Maximum SpO2 (%)	99.6±0.53	99.5± 0.62	-0.083 ± 0.29	99.6 ± 0.59	99.5 ± 0.70	-0.083 ± 0.55	0.337	0.853	1.000	1.00;0.000

TRE: Time restricted Eating; ESS: Epworth Sleepiness Scale; PSQI: Pittsburgh Sleep Quality Index; ODI: Oxygen desaturation index; TST: Total Sleep Time; TA: Time awake after sleep; E\h: events per hour. Data presented as mean ± SD. *Statistically significant difference revealed between baseline and after 12 weeks according to analysis of variance (ANOVA) of repeated measures and Bonferroni's post hoc test. p-values for Repeated measures ANOVA and Student t test for delta analysis; n^2p = effect size for ANOVA; Cohen's d = effect size for t Student.

Table 6. Anthropometric and body composition parameters of individuals with obesity and obstructive sleep apnea (OSA) undergoing a 12-week, 8-hour time-restricted eating (TRE) intervention, stratified by adherence above or below 4 days per week.

	Adherence > 4 days (7)			Adherence < and = 4 dias (5)						
Variables	**Baseline**	**12 weeks**	**Delta**	**Baseline**	**12 weeks**	**Delta**	**Time (p-value)**	**Group (p-value)**	**Time x Group (p-value)**	**Delta (p-value;d de Cohen)**
WC (cm)	113.17±4.7	108±4.35*	-5.63±2.41	114.3±4.7	109.5±5.17*	-4.87±2.56	0.000	0.697	0.000	0.605;-0.308
NC (cm)	42.7±1.39	42.1±1.26	-0.667±0.896	43.5±2.42	42.2±2.24	-1.28±0.866	0.000	0.598	0.283	0.308;0.628
Weight (Kg)	105.7±5.96	102.4±4.97	-3.29±3.72	100.5±6.6	97.0±6.74	-3.42±3.13	0.000	0.991	0.010	0.871;0.097
BMI (Kg/m²)	37.7±2.25	36.58±1.94	-1.17±1.40	34.65±1.2	33.4±1.26*	-1.22±0.889	0.000	0.743	0.032	0.897;0.077
Body fat (%)	40.6±3.95	39.45±4.0	-1.17±1.49	39.3±1.60	38.7±1.57	-0.583±1.46	0.029	0.867	0.524	0.767;0.178
Body fat (Kg)	43.13±4.98	40.6±4.73	-2.47±2.62	39.3±2.46	37.28±2.23	-2.02±2.36	0.001	0.917	0.184	0.733;0.205
SMM (Kg)	35.75±3.04	35.3±2.89	-0.417±1.12	34.5±2.9	33.7±3.11	-0.817±0.884	0.086	0.949	0.030	0.830;0.128
Ap MM (Kg)	26.3±1.98	25.8±1.89	-0.483±0.697	25.5±2.13	24.9±2.19	-0.533±0.472	0.009	0.940	0.025	0.569;-0.34
FFM (Kg)	62.5±5.02	61.8±4.72	-0.750±1.97	61.2±4.82	60.1±5.13	-1.08±1.52	0.165	0.907	0.136	0.561;-0.35
TBW (Kg)	45.9±3.65	45.28±3.43	-0.650±1.47	44.8±3.53	44.03±3.74	-0.817±1.04	0.107	0.912	0.110	0.583;0.331

TRE: Time restricted Eating; ESS: Epworth Sleepiness Scale; PSQI: Pittsburgh Sleep Quality Index; ODI: Oxygen desaturation index; TST: Total Sleep Time; TA: Time awake after sleep; E\h: events per hour. Data presented as mean ± SD. *Statistically significant difference revealed between baseline and after 12 weeks according to analysis of variance (ANOVA) of repeated measures and Bonferroni's post hoc test. p-values for Repeated measures ANOVA and Student t test for delta analysis; n^2p = effect size for ANOVA; Cohen's d = effect size for t Student.

Table 7. Sleep parameters of individuals with obesity and obstructive sleep apnea (OSA) undergoing a 12-week, 8-hour time-restricted eating (TRE) intervention, stratified by adherence above or below 4 days per week.

	Adherence > 4 days (7)			Adherence < and = 4 days (5)						
Variables	**Baseline**	**12 weeks**	**Delta**	**Baseline**	**12 weeks**	**Delta**	**Time (p-value)**	**Group (p-value)**	**Time x Group (p value)**	**Delta (p-value;d de Cohen)**
ESS (score)	9.83±1.80	8.33±2.23	-1.29±2.14	9.33±1.66	9.0±1.69	-0.400±1.52	0.391	0.750	0.305	0.937;-0.04
PSQI(score)	7.5±0.90	5.33±0.84	-2.71 ± 2.06	9.16±1.69	7.33±1.52*	-1.83±4.85	0.047	0.966	0.046	0.875;-0.93
ODI (E/h)	14.8±2.90	12.3±4.99	-2.50±9.17	13.7±3.53	10.77±4.2	-2.97±6.28	0.338	0.847	0.351	0.447;0.463
ODI sleep (E/h)	13.7±3.04	12.7±5.66	-1.09±8.74	13.61± 3.66	10.47±4.310	-3.40±8.38	0.759	0.862	0.176	0.473;0.434
TST (min)	360±19.10	328±20.7	-31.90±72.9	362.7±7.80	367±25.89	4.29±64.9	0.043	0.133	0.156	0.739;0.201
Sleep latency (mim)	24.3±3.20	25.6±3.80	1.25±4.61	26.7±4.96	27±3.72	0.300±5.01	0.475	0.389	0.387	0.157;-0.89
Sleep efficiency (%)	83.5±2.32	84.4±2.45	0.917±3.17	84.16±2.45	84.75±1.48	0.583±7.44	0.336	0.409	0.809	0.117;1.006
TA after sleep (min)	40.3±9.97	34.45±10.9	-5.81±11.6	39.99±9.75	34.8±6.42	-5.20±30.2	0.065	0.918	0.200	0.114;-1.01
Desaturations (N)	96.2±25.47	88.6±41.78	-7.50±63.0	106.8±29.17	72.08±27.03	-34.7±66.9	0.158	0.907	0.767	0.875;0.094
Snoring time (min)	227.9±46.3	163.7±47.4	-64.2±61.9	208.4±54.3	172.2±49.4	-36.2±61.9	0.002	0.654	0.096	0.361;-0.56
Snoring time (%)	53.16±10.4	40.4±9.87	-12.8±15.7	43.03±12.7	41.16±11.34	-1.87±10.6	0.189	0.645	0.006	0.190;-0.81
Hypoxic load(%.min/h)	60.7±9.96	41.0±10.55	-19.6±36.1	56.44±13.55	40.22±13.9	-16.2±26.8	0.111	0.804	0.006	0.891;-0.82
Minimum SpO2 (%)	81.16±1.75	84.58±1.33	3.42±6.76	81.58±2.51	86.08±1.62	4.50±4.53	0.024	0.685	0.006	0.536;0.375
Average SpO2 (%)	94.58±0.36	94.75±0.52	0.167±0.931	94.33±0.52	94.9±0.617	0.583±0.585	0.028	0.763	0.100	0.134;-0.95
Maximum SpO2 (%)	99.6±0.962	99.5±0.311	-0.167±0.753	99.5±0.311	99.5±0.235	0.00±0.316	0.368	0.466	0.988	0.785;-0.16

TRE: Time restricted Eating; ESS: Epworth Sleepiness Scale; PSQI: Pittsburgh Sleep Quality Index; ODI: Oxygen desaturation index; TST: Total Sleep Time; TA: Time awake after sleep; E\h: events per hour. Data presented as mean ± SD. *Statistically significant difference revealed between baseline and after 12 weeks according to analysis of variance (ANOVA) of repeated measures and Bonferroni's post hoc test. p-values for Repeated measures ANOVA and Student t test for delta analysis; n^2p = effect size for ANOVA; Cohen's d = effect size for t Student.

DISCUSSION

In individuals with OSA who underwent an intervention with 8 hours of TRE over 12 weeks, a reduction in weight, BMI, waist circumference, appendicular muscle mass and skeletal muscle mass was observed. In terms of sleep parameters, there was a reduction in snoring time and hypoxic load, as well as an increase in minimum oxygen saturation in the TRE group. Among individuals who completed the 8-hour TRE intervention, adherence greater than 4 days per week led to an improvement in subjective sleep quality.

TRE has emerged as an adjunct nutritional intervention for the treatment of obesity, contributing effectively to body weight reduction, as demonstrated in several studies with varying intervention durations (Cienfuegos et al., 2022; Kirkham et al., 2022; Kin and Song, 2023; Su Jeong et al., 2022; Damazewski et al., 2023). However, according to Liu et al. (2022), TRE does not appear to be more beneficial than daily caloric restriction in terms of reducing body weight and fat mass in individuals with obesity. By promoting involuntary body weight reduction, TRE facilitates better adherence to treatment, considered excellent when ranging between 80–90% (O'Connor et al., 2022). In this study, although adherence to TRE was lower than the threshold of excellence established in the literature, reductions in body mass and sleep were observed. Unlike other studies in which adherence exceeded 80% and resulted in weight reduction but showed no effects on sleep (Jamshed et al., 2022; Kirkham et al., 2023), this study presented additional benefits. Moreover, even with overall adherence considered low, achieving at least 4 days of adherence per week was associated with greater benefits compared to adherence below 4 days, as evidenced by the improvement in subjective sleep quality observed in this study.

Studies have shown that TRE can lead to a 3–5% reduction in body weight over 1 to 3 months in adults with obesity (Cienfuegos et al., 2020; Gabel et al., 2018; Zhang et al., 2022; Chow et al., 2020). According to the review study by Ezpeleta et al., 2024, the weight loss induced by TRE is primarily attributed to reductions in fat mass rather than lean mass. In the present study, the primary contributor to body weight reduction was a 5% decrease in body fat mass, although not significant, while appendicular muscle mass decreased by only 1.93%, and Total Body Water decreased by 1.61% relative to baseline values, despite the increased protein intake in the TRE group. In Park et al., 2021 study, for example, individuals who underwent an 8-hour TRE intervention and experienced weight loss also showed a reduction in both fat mass and muscle mass. However, this reduction in muscle mass may be a consequence of low adherence to the intervention, even compensation through caloric restriction in the final days of the intervention and also in relation to the reduction in physical activity levels observed in both groups.

Regardless of body composition, TRE has been associated with positive effects on sleep. The majority of studies evaluating the effects of TRE on sleep, even with reductions in body fat, did not find significant changes in sleep parameters (Cienfuegos et al., 2022; Gabel et al., 2019; Park et al., 2021; Kim and Song, 2023; Zhang et al., 2022; Lin et al., 2023 and Kirkham et al., 2023). Manoogian et al. (2022), for example, observed improvements in sleep parameters but found no changes in body composition—only in body weight. The challenge in observing results related to sleep primarily stems from the fact that these studies included participants with good sleep quality and adequate sleep duration (exceeding 7 hours per night) (Hirshkowitz et al., 2015) and no sleep disorders. However, when individuals with mild to moderate sleep disorders and altered baseline sleep metrics are evaluated, it becomes easier to identify significant changes in sleep parameters following TRE interventions, as demonstrated in the present study.One of the sleep parameters widely assessed and modified in our sample was total

sleep time (TST), which was already below the recommended level and showed a substantial reduction in the control group, albeit not significant. This further highlights the positive effects of TRE on sleep.

The present study is the first to demonstrate the significant effects of TRE on sleep parameters not previously evaluated in other clinical trials, such as the reduction of snoring time and hypoxic burden, and the increase in minimum oxygen saturation in individuals with OSA. Snoring is one of the main nocturnal symptoms of OSA and, when reduced in patients with OSA, provides benefits not only for the patient's health but also for bed partners (Yaremchuk K., 2020). An interventional study demonstrated a significant reduction in the ESS score reported by both the patient with OSA and their bed partners after a three-month therapy with CPAP (Continuous Positive Airway Pressure) (Chaidas et al., 2022). The hypoxic burden, in turn, is a variable recently studied in the literature, and when reduced, it indicates not only a decrease in frequency but also a shorter duration and lesser depth of respiratory events (Martinez-Garcia et al., 2023; Pinnila et al., 2023). The reduction in respiratory events leads to an increase in oxygen saturation, also observed in this study, and a reduction in the production of reactive oxygen species and systemic inflammation, thereby lowering the risk of cardiovascular morbidities (Iannella et al., 2022). Thus, reducing the hypoxic burden may decrease the risk of developing cardiovascular diseases and contribute to the proper management of OSA (Coso et al., 2024). According to Karhu et al., 2021 and Hietakoste et al., 2020, these findings can be corroborated by showing that deeper respiratory events are associated with the worsening of OSA and trigger a greater cardiovascular response compared to shorter and milder events.

The beneficial effects of TRE on body mass and improvements in sleep parameters involve various mechanisms, with the circadian rhythm being a prominent factor. Circadian misalignment caused by lifestyle changes, such as night shifts and excessive screen time,

contributes to increased light exposure, reduced circulating melatonin levels in the blood plasma, and elevated cortisol during the onset of sleep, which are associated with metabolic disruptions and impaired sleep quality (Vasey et al., 2021; Odriozola et al., 2024). By reducing the daily feeding window, TRE may help regulate the circadian rhythm, thereby mitigating metabolic syndrome symptoms and improving sleep quality (Raji et al., 2024; Wilkinson et al., 2020). Additionally, shortening the feeding window during the day tends to reduce food consumption close to bedtime, which, according to Xiao et al., 2019, was linked to decreased likelihood of overweight or obesity and improved sleep quality. In the present study, participants in the TRE group reduced their eating window by approximately 4 hours and advanced dinner time by over 1 hour, thereby increasing the interval between their last meal and bedtime. This adjustment may have contributed to the positive outcomes observed with TRE.

This study has several limitations. Firstly, although it was a randomized study, participants could not be blinded to the intervention, which is common in studies involving dietary interventions. Secondly, individuals who volunteered to participate in the study may have already been interested in TRE or sought to improve their health through dietary changes. Thirdly, in the TRE group, the start and end times of the eating window were established without considering each participant's chronotype, which could influence adherence. However, this study also has significant strengths. Notably, it is the first to test a TRE intervention in individuals with OSA, featuring strict control of the eating window and the inclusion of objective sleep monitoring. This monitoring was conducted at a low cost in a home setting, providing a more realistic measurement of sleep compared to polysomnography.

CONCLUSION

In this study, restricting the eating window to 8 hours per day for 12 weeks resulted in reductions in weight, BMI, waist circumference and appendicular muscle mass in individuals with OSA. Regarding sleep parameters, reductions in snoring time and hypoxic burden, as well as an increase in minimum oxygen saturation, were observed in the TRE group. However, further studies are necessary to evaluate the effects of TRE interventions on other sleep disorders and in participants with altered baseline sleep metrics. Additionally, more advanced methods for sleep assessment, such as polysomnography, should be employed to deepen the understanding of these effects.

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8 CONSIDERAÇÕES FINAIS

Este estudo avaliou os efeitos da intervenção nutricional com TRA de 8h por 12 semanas na redução do peso corporal, composição corporal e parâmetros de sono de indivíduos obesos com e sem distúrbios de sono. No que se refere ao sono, a falta de medidas objetivas e o foco apenas na duração do sono limita a observação de resultados relativos ao desfecho. Mesmo quando o sono foi avaliado por meio de métodos objetivos e por meio de novos parâmetros, o TRA de 8 horas durante 12 semanas não revelou alterações significativas no desfecho em indivíduos obesos, consequência da dificuldade em estabelecer conclusões sólidas em participantes com uma duração de sono saudável. No entanto, quando avaliados somente o grupo com diagnóstico de AOS, nosso estudo demonstrou contribuição significativa do TRA, como redução do tempo de ronco, redução da carga hipóxica e aumento da saturação de oxigênio. Dessa forma, nossos achados revelam que restringir o tempo de alimentação tem contribuição positiva para os distúrbios do sono como a AOS. No entanto, são necessários mais estudos para avaliar os efeitos das intervenções de TRE em outros distúrbios do sono e em participantes com parâmetros de sono alterados. Além disso, métodos mais avançados de avaliação do sono, como a polissonografia, devem ser utilizados para aprofundar a compreensão desses efeitos.

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APÊNDICE A – ENTREVISTA INIICAL

Nome:_____ Idade: ____

Renda:_____ Grau de escolaridade: _____

Possui alguma doença?

Possui distúrbios do sono como insônia, síndrome das pernas inquietas, narcolepsia e trabalhadores em turnos ou noturnos?

Faz uso de algum medicamento? Quais?

Peso atual:_____ Altura:_____

Qual horário habitualmente vai para cama?

Qual horário habitualmente se levanta?

Possui hábito de levantar depois de dormir para comer?

Está engajado com algum tratamento para perda de peso ou acompanhamento nutricional?

Horário em que realiza a primeira refeição do dia?

Horário em que realiza a última refeição do dia?

APÊNDICE B - Termo de Consentimento Livre e Esclarecido (TCLE)

Prezado(a) Senhor(a), você está sendo convidado(a) a participar da pesquisa de forma totalmente voluntária da Universidade Federal de Lavras. Antes de concordar, é importante que você compreenda as informações e instruções contidas neste documento. Será garantida, durante todas as fases da pesquisa: sigilo; privacidade; e acesso aos resultados.

I - Intervenção nutricional com Tempo Restrito de Alimentação em indivíduos com apneia obstrutiva do sono.

Aprovado pelo Comitê de Ética em Pesquisa sob o parecer 6.084.402
Pesquisador(es) responsável(is): Camila Maria de Melo
Cargo/Função: Professora
Instituição/Departamento: UFLA/DNU
Telefone para contato: (35) 3829-9781
Local da coleta de dados: Universidade Federal de Lavras

II – OBJETIVOS
Avaliar os efeitos de uma intervenção nutricional com tempo restrito de alimentação na apneia obstrutiva do sono. Testaremos a hipótese de que restringir o tempo da alimentação resulte em melhora dos parâmetros de sono e reduza a gravidade da apneia obstrutiva do sono, além de contribuir para a melhoria dos parâmetros bioquímicos, antropométricos e de composição corporal, e de alterações na microbiota oral.

III – JUSTIFICATIVA
Considerando o exposto, o presente estudo visa explorar os efeitos de uma intervenção nutricional com tempo restrito de alimentação na apneia obstrutiva do sono, a fim de contribuir com o desenvolvimento de estratégia viável e mais sustentável para a perda de peso e consequente melhora da gravidade da apneia do sono e melhora da qualidade de vida da população.

IV - PROCEDIMENTOS DO EXPERIMENTO
AMOSTRA
Adultos entre 18 e 65 anos diagnosticados com apneia obstrutiva do sono e janela alimentar entre 11 e 14 horas.

EXAMES
Os participantes serão avaliados, por meio de aplicação de questionários de hábitos alimentares e qualidade do sono. Também serão submetidos a avaliação da composição corporal por meio de um aparelho que conduz um tipo fraco de corrente elétrica pelo corpo e vai fornecer informações sobre a quantidade de água, massa de gordura, massa magra e massa óssea dos indivíduos. Na antropometria, serão obtidos dados como estatura, peso obtido por balança e a circunferência da cintura obtida por fita métrica. Além disso, será realizada coleta de sangue por profissional de enfermagem, oximetria (que utiliza um dispositivo no dedo que emite uma luz capaz de interagir com o corpo e medir a quantidade de oxigênio no sangue) e técnica de actigrafia (um relógio de pulso fornecido pelos pesquisadores para avaliação do sono e ciclo circadiano). Por fim, também será realizada a coleta de material biológico da cavidade oral para a análise da microbiota oral, escovando a face interna das bochechas com a escova citológica

esterilizada, considerado um método rápido, seguro e barato. As avaliações serão realizadas em dois momentos distintos: antes e após a intervenção de 12 semanas. Os dados serão coletados por Bianca Aparecida de Sousa de forma presencial e após o término da pesquisa os dados serão arquivados

V - RISCOS ESPERADOS

O maior risco presente na pesquisa está relacionado a coleta de sangue para a avaliação bioquímica como glicemia de jejum, colesterol total e frações, hemoglobina glicada (HbG) e proteína C reativa (PCR). Trata-se de um procedimento invasivo que pode causar dor e risco de contaminação, mas que terá o risco minimizado pois será realizada por profissionais de enfermagem capacitados com materiais adequados e devidamente esterilizados. Em relação aos demais riscos, os participantes podem ficar desconfortáveis ao preparo para a avaliação da composição corporal e coleta de sangue, pois é necessário seguir algumas recomendações como fazer jejum de 8 horas, que pode gerar algum mal estar. Além disso, podem sentir-se desconfortáveis durante a avaliação antropométrica, no qual, será necessário expor regiões do corpo como a barriga para a obtenção da circunferência de cintura. Além de poder gerar algum desconforto com o escovado bucal, que pode gerar pequenas lesões na cavidade oral, mas terá os desconfortos minimizados pois será realizado o treinamento adequado dos pesquisadores por profissional capacitado. Contudo, podem surgir desconfortos ao responder algumas perguntas dos questionários, visto que se trata de respostas relacionadas à vida pessoal dos mesmos, apesar dos questionários abordarem questões gerais relacionadas à alimentação e sono. O tempo elevado para resposta aos questionários também pode causar desconfortos, mas pode ser solucionado ao propor aos participantes a opção de levar os questionários para que possam ser preenchidos em outros momentos e devolvidos aos participantes em outro momento. Para redução de todos os riscos, os participantes poderão desistir da pesquisa a qualquer momento.

VI – BENEFÍCIOS

Os benefícios para os participantes da pesquisa incluem provável perda de peso, mudança de composição corporal, melhora de índices bioquímicos, na gravidade da AOS e nos demais parâmetros de sono, assim como alterações na microbiota oral que são resultados esperados na presente pesquisa. Todos os participantes poderão ter acesso aos dados bioquímicos e de composição corporal. Além disso, a pesquisa tem como intuito testar uma intervenção nutricional que pode ser ampliada para o tratamento de Doenças Crônicas Não Transmissíveis e contribuir para a melhora da qualidade de vida da população.

VII – CRITÉRIOS PARA SUSPENDER OU ENCERRAR A PESQUISA

A pesquisa será encerrada quando o número de participantes necessário for atingido.

VIII - CONSENTIMENTO PÓS-INFORMAÇÃO

Após convenientemente esclarecido pelo pesquisador e ter entendido o que me foi explicado, consinto em participar do presente Projeto de Pesquisa.

Lavras, _____ de _____ de 20___.

_____ _____

_____

Nome (legível) / RG Assinatura

ATENÇÃO! Por sua participação, você: não terá nenhum custo, nem receberá qualquer vantagem financeira; será ressarcido de despesas que eventualmente ocorrerem; será indenizado em caso de eventuais danos decorrentes da pesquisa; e terá o direito de desistir a qualquer

momento, retirando o consentimento sem nenhuma penalidade e sem perder quaisquer benefícios. Em caso de dúvida quanto aos seus direitos, escreva para o Comitê de Ética em Pesquisa em seres humanos da UFLA. Endereço – Campus Universitário da UFLA, Pró-reitoria de pesquisa, COEP, caixa postal 3037. Telefone: 3829-5182.
Este termo de consentimento encontra-se impresso em duas vias, sendo que uma cópia será arquivada com o pesquisador responsável e a outra será fornecida a você.

No caso de qualquer emergência entrar em contato com o pesquisador responsável no Departamento de NUTRIÇÃO. Telefones de contato: (35) 3829-9781.

APÊNDICE C- Revisão Sistemática

Effect of time-restricted eating on sleep quality and body composition: A systematic review

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Abstract

Context: Time restricted eating (TRE) is a dietary approach that consolidates energy intake in a restricted period during the day. Is an alternative approach to weight loss and might be important to sleep quality.

Objective: The present study aims to review the current literature related to the effects of time restricted eating (TRE) on sleep quality and body composition in adults.

Data Sources: A literature search in Pubmed, Scopus, Web of Science (Clarivate) and BVS/Bireme databases was carried out until May 2024.

Data extraction: June 2024.

Data analysis: Eleven studies were included in the present systematic review. Study samples varied between 19 and 137 participants, with predominance of female sex in ten studies. Seven (58,3%) of the studies tested an intervention of 8h of TRE, with an intervention range between four weeks and twelve months. All studies observed weight loss. Nine studies showed reductions in fat mass, including two studies that observed reductions in visceral fat mass. No studies, independently of weight loss or body composition changes, objectively observed changes in sleep duration after TRE interventions. However, in the subjective evaluation, one study found a reduction in sleep duration of 30 ± 13 min, an increase in latency of 7 ± 3 min

and a reduction in sleep efficiency of 2% ± 1% in the group treated with ERT compared to the control group.

Conclusion: TRE seems to be effective in weight loss and fat mass reduction but most studies found no effect in sleep parameters. There is a lack of standardized methods for sleep measurements in reviewed studies. However, these results could provide valuable data for the design and formulation of new well-founded studies assessing sleep using objective methods and including different sleep parameters.

Key words: Time restricted eating, intermittent fasting, sleep, body composition.

INTRODUCTION

Modern lifestyle choices have been associated with behaviors that disrupt circadian rhythms. Inconsistent time of meals and late eating, with meals close to rest time, seems to influence weight gain.[1] The study by Gil and Panda[2] shows that more than half of adults eat during a window of 15 hours or more every day and restricting this time would contribute to reducing body weight and improving sleep.

Time restricted eating (TRE) is a type of intermittent fasting based on the circadian rhythm, that consists of restricting food intake to a reduced daily hours and extending fasting at beginning of the night and in the first hours in the morning.[3] TRE contributes to a reduction in body weight without a significant modification in energy intake or diet composition, making it a viable alternative weight management and obesity treatment.[4] The current literature also shows other benefits such as improving insulin levels, blood pressure, lipid profile and oxidative stress.[5,6]

A recent systematic review demonstrated that intermittent fasting is effective in reducing body weight, total body fat and visceral fat mass[7] and TRE alone or in combination to caloric restriction with an eating window of 6 to 8h contributes to weight and fat loss and, might contribute to a reduction in fat-free mass.[8]

Weight loss and improvements in body composition is associated with sleep quality.[9] Even a slight reduction in body weight contributes to improvements in sleep quality.[10] Recent studies show that interventions with TRE lead to a reduction of at least four percent of total body weight.[11,12] Bohlman et al.[13] in a recent systematic review suggest that TRE does not worsen sleep quality, although controversial results. Nevertheless, the link between the effect

of TRE on body composition and sleep parameters are unclear in the literature, as well as the most appropriate time of food restriction and duration of the intervention to drive these effects.

Therefore, the aim of this systematic review is to investigate the effects of time restricted eating on body composition and sleep parameters in adult individuals.

METHODS

Study type

A systematic review of the literature was performed following The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[14] and methodological recommendations of Cochrane Collaboration[15] and registered in PROSPERO(CRD42024524598).

Review question

The PICOS formulation detailed in Table 1 was adopted, from which the research question was created and refined: Does restricting eating time have an effect on sleep parameters and body composition in adults?

Search strategies

Databases searched were MEDLINE/Pubmed, SCOPUS, Web of Science (Clarivate) and BVS/Bireme. From MEDLINE/PubMed we seek descriptors indicated by Medical Subject Headings (Mesh) and Boolean operators “OR” and “AND”, as follows: (((((((Intermittent Fasting) OR (fasting)) OR (Time Restricted Eating)) OR (Eating)) OR (Time Restricted)) OR (Time Restricted Fasting OR Fasting, Time Restricted OR Restricted Fastings, Time OR Time Restricted Feeding OR Feeding, Time Restricted OR Time Restricted Feedings)) AND ("Sleep" OR Sleeping Habits OR Sleep Habits OR Habits, Sleep OR Sleep Habit OR Sleeping Habit OR Habit, Sleeping OR Habits, Sleeping)). The same search was carried out in the four databases from February to May 2024.

Eligibility criteria

The studies had to be clinical, intervention, controlled or uncontrolled, over the age of 18, with no gender restriction. The interventions had to control feeding time, with any time and duration of the intervention, with or without a control group. Body composition could be

assessed by any validated method such as bioelectrical impedance (BIA), dual-energy X-ray absorptiometry (DXA) and magnetic resonance imaging (MRI). Sleep could be assessed by polysomnography, actigraphy and validated sleep assessment questionnaires. The languages of publication were not delimited. The exclusion criteria were: (I) regarding the study design: with non-human models or literature reviews; (II) regarding the participants: pregnant women, children and adolescents; (III) regarding the intervention: not controlling or restricting feeding time.

Procedures for developing the systematic review

This systematic review was developed according to the following steps:

1st step. Reading the titles and abstracts, excluding the ones not related to the research question and the duplicates. Two authors (BAS and ACQ) performed this step independently and checked by the third author (CMM); inconsistencies were solved in a consensus meeting.

2nd step. Obtainment of the selected articles in full and reading to identify in detail the inclusion and exclusion criteria. Two authors performed this step independently (BAS and ACQ), and the divergences were solved in a consensus meeting with the third author (CMM).

3rd step. Data extraction of the studies by the first author (BAS), checked by the second author (ACQ), and organized in commercially available spreadsheet software. The data extracted were: location and time of the study, study objectives, study design, sample characteristics, type of intervention, control group (if any), duration of the intervention, adherence and side effects of the intervention, methods for assessing sleep, body composition and compliance to the intervention or diet, main results and synthesis of findings. The results are summarized descriptively or in percentages (%). Sleep and body composition results are presented as mean, mean standard deviation, confidence interval in some cases, p-value and percentage.

Quality assessment (risk of bias)

The risks of bias were assessed independently by two researchers (BAS and CMM), and the divergences were solved from a consensus meeting including the third author (JPLO). The Cochrane risk of bias tool v. 2 was adopted, and the software RoB2[16] was used to assess the randomized clinical trials, while ROBINS I[17] was used to assess the non-randomized clinical trials.

According to ROB 2[16]cluster-randomized trials, the risk of bias is assessed by considering the randomization process, deviations from the interventions intended interventions, missing outcome data, outcome measurement and the selection of reported results. According to ROBINS I[17], the risk of bias is assessed by considering the factors confounding, classification of interventions, selection of participants, deviations from intended interventions, missing data, measurements outcome and selection of reported result. The overall risk of bias evaluation is subjective and decided among the research team. The risk of bias was defined based on the majority of decisions from the five items of Rob 2[16] and of seven items decisions Robins I[17] (high risk, some concerns, or low risk).

RESULTS

Searches

The initial search resulted in 1690 publications. After initial screening by title and abstract, 9 studies were in duplicate, and 1645 studies were excluded for not meeting the eligibility criteria, resulting in 36 studies selected for a full reading. This step led to the exclusion of 25 studies, 14 did not test TRE and did not show the control of the eating window, 8 studies did not evaluate or describe sleep and body composition outcomes and 2 have not been finalized. After double-checking for exclusion and inclusion criteria, 11 studies were included on the present systematic review. Figure 1 shows the flowchart of the article selection process.

Summary of findings

Studies characteristics

Tables 2 and 3 show the data extracted from the included studies. Samples varied between 19 and 137 participants, aged between 18 and 71 years old, with a predominance of female sex in ten studies. Seven studies were performed in the United States of America (USA), two in Korea, one in Canada and one in China. Seven were randomized controlled trials and four were one arm clinical trials. Seven (58.3%) of the studies tested interventions of 8h of TRE. The duration of interventions was between four weeks and twelve months, with two studies lasting 4 weeks, three (27%) studies of 8 weeks, three during 12 weeks, two studies with 14 weeks duration and, one of long-term intervention of 12 months.

Regarding body composition assessments, five studies (45.4%) used DXA (Dual-energy X-ray absorptiometry) and five by BIA (Bioelectrical Impedance), while one study used MRI (Magnetic Resonance Imaging). For sleep evaluation, eight studies (72.7%) used questionnaires including Pittsburgh Sleep Quality Index (PSQI), Insomnia Severity Index (ISI), Munich Chronotype Questionnaire (MCTQ) and, Berlin Questionnaire. Two studies used questionnaires plus actigraphy, and one used only actigraphy.

Most of the studies monitored *ad libitum* food consumption using apps, daily adherence records and daily food records. The study by Kim and Song[18] provided bars with 20g of protein in order to avoid muscle loss, despite not providing meals.

All studies observed reductions in body weight. From the 11 studies, nine observed reductions in total body fat, two showed reductions in visceral fat mass.[19,20] It is noteworthy that the body composition data from the study conducted by Kirkham et al.[21] are presented in Kirkham et al.[20]. Ten studies showed baseline sleep data except for Jamshed et al[22] and all showed an average sleep duration close to or greater than seven hours, considered the minimum recommended amount per night.[23] All studies focused on the sleep duration, in addition to other subjective sleep variables.

Effects of TRE on body composition and sleep

All included studies evaluated both body composition and sleep parameters. It's important to highlight the difference in intervention duration between studies, with most interventions varying between 4 and 14 weeks and on study lasting 12 months.

Figure 2 shows a summary of the sleep and body composition results. All of the studies observed a weight loss after intervention that varied between 0.94 to 7.6 kg. Regarding body composition, nine studies (83%) showed reductions in body weight and body fat.[18–20,24–29]The reductions in body fat showed a range of 0.5 to 2.8kg. Wilkinson et al.[19] and Zhang et al.[28] also found reductions in visceral fat mass analyzed by bioelectrical impedance. Only two studies didn't show any differences in body composition after TRE intervention.[22,30]

Regarding sleep, most studies evaluated sleep by questionnaires and only three studies had actigraphy measurements; these studies did not observe changes in sleep duration after TRE.[19,21,30] Both Wilkinson et al.[19] and Kirkham et al.[20] showed reductions in fat mass and

only Manoogian et al.[30] did not show any body composition changes, besides weight loss. Regarding study design, although similar TRE intervention (8 - 10h TRE; 8-12 weeks duration) the studied samples differed greatly, Wilkinson et al.[19] and Kirkham et al.[20] samples were reduced and composed by obese individuals (n=19 and n=22) and both were non-controlled studies. Instead, Manoogian et al.[30] studied a larger sample of 137 men and women (70% obese; 40% male sex) 24-h shift workers. In addition to a larger sample, this study had a control group that received nutritional advice for a mediterranean diet. This is the only included study that analyzed sleep duration objectively and was controlled. Nevertheless, the results failed to show body composition changes in association to sleep changes after TRE intervention. It's important to note that the study of Manoogian et al.[30] included shift workers, a population that usually are not included in TRE interventions, due to circadian misalignment. Taken together, no studies, independently of weight loss or body composition changes, objectively observed changes in sleep duration after TRE interventions.

The majority of the studies evaluated sleep subjectively using different questionnaires as PSQI, ESS, ISI, Berlin, MCTQ questionnaires, including the ones that used both questionnaires and actigraphy. From the studies that showed weight and fat loss after TRE, only two showed changes in sleep parameters subjectively. Wilkinson et al.[19] showed an increase in the perception of restful sleep from 69.88% ± 25.61% of days at the start of the study, to 88.16% ± 21.89% ($p = 0.019$) at the end of the intervention and 35% reduction in the variance of waking time in the intervention group (3.42 hours to 2.21 hours). Steger et al.[29], found reductions in sleep duration of 30 ± 13 min ($p= 0.03$), an increase in latency of 7 ± 3 min ($p = 0.04$) and a reduction in sleep efficiency of 2% ± 1% ($p = 0.04$) compared to the control group. No changes in sleep quality, sleep time including sleep onset, sleep compensation, sleep inertia or chronotype were found.

Six studies (55%) were not able to find changes in subjective sleep parameters even after weigh and body composition changes.[18,24–28]

Finally, two studies that participants presented weight loss without changes in body composition showed divergent results regarding sleep parameters (evaluated subjectively). Manoogian et al.[30] showed reductions in sleep disturbances at the end of the intervention (-0.16, 95% CI -0.30 to -0.02, $p = 0.027$) and reduced daytime sleepiness of SOC (-0.87, IC 95% -1.49 a -0.25, $p = 0.007$) and TRE (-1.10, IC 95% -2.00 a -0.19, $p = 0.019$) compared to baseline, although no significant differences between groups. Jamshed et al.[22] in a study conducted with

90 predominantly female, obese adults participating in a Weight Loss Program, an 8-hour TRE for 14 weeks plus energy restriction found no significant differences in sleep duration, bedtime, wake time and sleep latency, assessed by PSQI, between the groups.

The addition of calorie restriction to TRE would accelerate weight loss and body composition improvements. Steger et al.[29] evaluated the effects of TRE on metabolic health, sleep and mood in 36 volunteers with obesity who actually complied with the intervention (5 out of 7 days). An intervention with 8-hour TRE and energy restriction (eTRE+ER) of 500 kcal below energy expenditure was carried out to the experimental group and a control group of eating time greater than or equal to 12 hours, lasting 14 weeks. Assessments of body composition revealed that the eTRE+ER group lost 7.6 ± 1.0 kg (7.0% ± 0.9%, $p < 0.001$), which means an additional 3.7 ± 1.2 kg compared to the control group. It also decreased body fat by 2.8 ± 1.3 kg and trunk fat by an additional 1.6 ± 0.7 kg compared to the control group. There were no differences in fat-free mass (-1.2 ± 0.3 vs. -1.8 ± 0.6 kg; -0.7 ± 0.6 kg; $p = 0.25$), appendicular lean mass (-0.3 ± 0.4 kg; $p = 0.42$) and visceral fat (-0.1 ± 0.1; $p = 0.37$). There were no changes in sleep quality (0.2 ± 0.7; $p = 0.79$), sleep onset (8 ± 13 minutes; $p = 0.51$), sleep compensation (-22 ± 14 minutes; $p = 0.16$), sleep inertia (1 ± 3 minutes; $p = 0.78$) or chronotype (1 ± 16 minutes; $p = 0.94$) assessed by questionnaires. However, there was a reduction in sleep duration of 30 ± 13 min, an increase in latency of 7 ± 3 min and a reduction in sleep efficiency of 2% ± 1% in the TRE compared to the control group.

In a study conducted with 90 obese adults (predominantly female) participating in a Weight Loss Program, Jamshed et al.[22] performed an 8-hour TRE for 14 weeks. The participants were divided into two groups; the eTRE+ER group with an 8-hour eating window and energy restriction, and the CON+ER group with a 12-hour eating window and energy restriction. The eTRE+ER group lost an additional 2.3 kg of body weight (95% CI, -3.7 to -0.9 kg; $p = 0.002$) compared to the CON+ER group. However, there were no significant differences in absolute fat loss (-1.4 kg; 95% CI, -2.9 to 0.2 kg; $p = 0.09$), fat-free mass (-0.1 kg; -0.9 to 0.7 kg; $p = 0.75$), trunk fat (-0.9Kg; -1.8 to 0.1Kg; $p = 0.07$), visceral fat (-0.1Kg; -0.2 to 0.1Kg; $p = 0.37$) or appendicular lean mass (-0.1Kg; -0.6 to 0.5Kg; $p = 0.78$). No differences were found in sleep duration, bedtime, wake time and sleep latency, assessed by PSQI, between the groups.

Risk of bias and quality assessment

Figure 3 shows the individual risk of bias In Non-randomized Studies – of Interventions (ROBINS-I). Two studies were classified as 'moderate risk'[18,21] and three as 'serious risk'.[19,24,25] The Figure4 shows the individual risk of bias cluster-randomized trials (RoB 2 CRT). Four studies were classified as 'some concerns'[22,27,28,30] and two studies as 'High risk'.[26,29]

DISCUSSION

This Systematic Review investigated the interrelationship of TRE on body composition and sleep parameters in adults. Twelve clinical trials were included and most of the studies tested 8-hour TRE interventions lasting 8 weeks or more except for one of 4 weeks and one of an year of intervention. The sample was composed predominantly of overweight, female adults. Nine studies, although methodological differences showed that TRE are capable of contributing to reduction in total body fat, perhaps in visceral fat mass, without changes in fat-free mass. No sleep improvements were found when this outcome was objectively measured, however, improvements in sleep perception were found in 66% of the studies. Several potential confounders were identified among the study designs that could explain the lack of intervention effects on sleep parameters: (I) Adherence and duration of the intervention; (II) Age of the voluntaries; (III) Food control; (IV) Sleep characteristics of the voluntaries and lack of standardized methods to measure sleep; (V) Absence of data. The discussion will be conducted based on these possible confounders, and the risk of bias will be addressed.

Adherence and duration of the intervention

It would seem logical that prolonged fasting would be associated with lower adherence to the TRE intervention. In this review, the majority of studies had an intervention of 8-hour of TRE or more (10h maximum) and the duration of the intervention were predominantly of 8 or 12 weeks or more. According to the authors, adherence to the intervention was considered excellent, ranging from 80 to 98%, i.e. an average adherence of 6 days each week. Furthermore, longer fasting period interventions (16h and 18h) also showed high adherence rates, 80% in the Cienfuegos et al.[26] study for exemple. Otherwise, Jefcoate et al.[31] in a study with 16 participants, had demonstrated a low adherence (63%) even with a short intervention duration (5 weeks) and lower fasting period (14h).

The shorter duration of the interventions, on the other hand, did not prove to be a facilitating factor for adherence. Moreover, it may have hindered better outcomes, such as greater weight loss and more significant changes in body composition. Termannsen et al[32] studied the feasibility of TRE and found, in a systematic review that included 28 studies, an adherence rate of 95% in studies during less than 12 weeks and 89% in studies of higher or equal to 12 weeks duration. Thus, it's possible to say that TRE was well implemented in the analysed studies and it is feasible to reduce weight and fat mass, however, this body composition achieved by TRE was not always enough to contribute to sleep improvements. This might be due to the fact that the observed changes in body weight and composition did not reach the minimum threshold of effect in weight loss (5 to 10%) considered in the literature, that might be necessary for observe benefits in sleep parameters.[33,34]

Still, even when controlling for other barriers to treatment adherence such as social events, work commitments, night time leisure activities, living conditions, and family life[31], the main bias regarding adherence to TRE relates to its assessment. A significant portion of studies applies a TRE intervention but does not assess its adherence[24,35,36] or the evaluation method used is often quite subjective. This assessment, in most cases, occurs through apps, reports, or notes prone to forgetfulness and requiring a great deal of honesty and commitment from the participant. This fact makes it difficult to understand whether the results were not achieved due to the lack of patient adherence or the effect of the intervention itself.

Age of the volunteers

In this review, the age range of the studie´s participants varied from 18 to 71 years old, which could serve as a confounding factor when evaluating the proposed outcomes. With aging, one of the primary changes that occurs is the body composition, characterized by an increase in body fat, particularly in the abdominal region and visceral organs, alongside a gradual decline in muscle mass after the age of 30.[37] In Li et al.[38] review study, they describe sleep changes in healthy aging characterized by reduction in sleep duration, difficulties in sleep maintenance and lower deep sleep. Therefore, the physiological differences between younger and older adults may impact the comparison of body composition and sleep outcomes throughout the analysed studies. Additionally, younger adults may have a slightly reduced forgetfulness factor in adherence assessment.

Food control

The isolated TRE provides autonomy to participants, allowing them to eat to satiety without any restrictions related to quality or quantity of food consumption. Cienfuegos et al.[26] and Manoogian et al.[30] demonstrate that regardless of dietary control, there was a reduction in energy intake among the TRE groups of 6 hours, 8 hours, and 10 hours compared to the control group. Similar results are found in the systematic review conducted by Adafer et al.[4], in which TRE led to a 20% reduction in caloric intake on average, without changing the macronutrients distribution. Interestingly, in this study, caloric restriction was described as unintentional by the participants, which might serve as a protection against cognitive restriction.

However, it might be possible that changes in caloric intake have been hindered by the fact that few studies focus on assessing food consumption. Furthermore, studies on TRE have placed greater emphasis on metabolic outcomes, but there is a gap in current research evaluating its effects on food behavioral and dietary quality.

Caffeine consumption is another component of significant relevance in studies involving TRE intervention, particularly concerning sleep outcomes. Some reviewed studies[21,25,26,28,30] caffeine consumption, from non-energy drinks such as coffee, black tea and soda, was allowed during the fasting period. The elevated consumption of caffeine might promote weight loss and increase fat oxidation.[39] However, the majority of studies do not control the consumption of this component, with the exception of Lin's study[27], which limited the intake to 2 non-energy drinks a day, and Kirkhan's study[21], which allowed consumption from 8am to 12pm, without quantity restriction. Indeed, when consumed in higher doses or close to bedtime, caffeine leads to reduced total sleep time and efficiency, and increased sleep latency.[40] All these factors probably impairs sleep quality and thus, compromise the observed effects of TRE on sleep parameters.

Sleep assessment and characteristics

The majority of studies included in this review employed subjective methods to assess sleep, such as questionnaires, with only three with actigraphy. While subjective sleep assessment is a practical and suitable tool for clinical screening and large-scale studies, it lacks

the precision of objective tools like polysomnography (PSG).[41] Actigraphy is a method to assess sleep quality and quantity through movement assessment, it reflects sleep quality and duration from algorithms applied to raw motor activity data. It has been used to study nocturnal sleep and circadian rest/activity rhythm in different situations.[42] A study comparing three different sleep assessment methods in patients with insomnia and fibromyalgia showed that actigraphy had more concordant values with Polysomnography (PSG) than the sleep diary, which is a subjective method.[43]

In addition, there was a greater focus only on the sleep duration variable in some studies. Improvements in sleep perception such as the felling of restorative sleep and sleep latency (the time spend between time of lie down and sleep), were not explored in some studies other than sleep duration. McStay et al.[44] study, for example, showed that sleep duration remained unchanged but effects of intermittent fasting on sleep latency and efficiency were observed. This lack of standard of sleep variables between studies contributes to the different results found in the analysed literature.

In studies where baseline data was provided, the duration of sleep in the samples was typically within the recommended range, approximately close to 7 hours. It is argued that there may be little utility in detecting improvements in sleep parameters among individuals who already exhibit good sleep quality, especially when assessing the same variable, such as sleep duration. In addition, sleep was not the main outcome in the studies.

Absence of data

The absence of baseline and post-intervention data difficulties the analysis of the effects of the TRE intervention. Two studies did not present baseline data such as sleep duration, only the difference between studied groups.

Risk of bias

The risk of bias was assessed by the adequate Cochrane instruments according to the study design, being five Randomized Control Trial studies assessed by Rob 2[18,19,21,24,25] and the remaining studies risk of bias was assessed by Robins I tool, specifically developed for non

randomized trials. Three non randomized studies were considered as high risk[19,24,25] and two of moderate risk[18,21] while the randomized control trials, two of them were considered at serious risk of bias[26,29] and four were considered of moderate risk.[22,27,28,30] The main justification for reaching the high risk classification stems from the difficulty in blinding participants and researchers, which is a common issue in dietary intervention studies. In the studie by Steger et al.[29] the lack of data in the results on the intervention group and the true value of the outcome was a significant risk of bias. Crossover trials in which only data from the first period are available should be considered at risk of bias, especially when investigators explicitly used a two-phase strategy.

Intermittent fasting versus TRE

Overall, intermittent fasting is a more intense approach compared to TRE strategy. Intermittent fasting strategies most commonly include alternate-day fasting, which involves fasting for 24 hours every other day, and the 5:2 method, with 24-hour fasting twice a week and a very low-calorie diet consumed on 2 other days of the week.[45]

Otherwise, TRE implies fasting only during the day, moving the last meal away from bed time when glucose metabolism is impaired.[46–48] Typically TRE interventions are designed to reduce eating window to 8 hours per day or less. The literature shows evidence regarding the adverse effects of eating late and higher amounts of food on sleep.[49,50] Lopes et al.[51] showed that individuals diagnosed with obstructive sleep apnea who ate late had longer sleep latency, a higher Apnea Hypopnea Index (AHI) and a higher risk of poor sleep quality compared to early eaters. In a clinical trial, healthy individuals experienced a deterioration in sleep parameters on the night they consumed a high-fat, slow-digesting meal compared to an easier-to-digest meal.[52] In this sense, the alignment of meals to the biological clock in association with a limited eating window should contribute to weight maintenance and might be a complementary strategy for long term weight loss, taking turns with moderate energy restricted diets.

CONCLUSION

Besides the theoretical implication of TRE effects on sleep quality, the lack of objective measures of sleep in response to a TRE intervention limits the results regarding this outcome.This systematic literature review suggests that TRE produces weight loss and changes

in body composition, but its effects on sleep remain unclear, independently of body composition changes. Usually regardless of body composition changes, studies did not show changes in sleep measured by actigraphy, while the perception of sleep might change after the intervention.

It is difficult to establish solid conclusions in participants with a healthy sleep duration and with sleep assessment focused only on duration, without analyses on other sleep quality parameters. However, these findings can provide valuable data for designing and formulating new well-founded studies. Clinical trials with sleep assessment using objective methods and including different sleep parameters are needed to elucidate the effect of TRE on sleep.

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system in healthy young males. *Stress and Health*. 2021;37(4):640-649. doi:10.1002/smi.3025

Table 1. PICOS criteria for inclusion of studies

Parameter	Description
Participants	Adults
Intervention	Time-restricted eating
Comparison	Free food
Outcome	Improved sleep parameters and body composition
Study design	Experimental (randomized clinical or not)

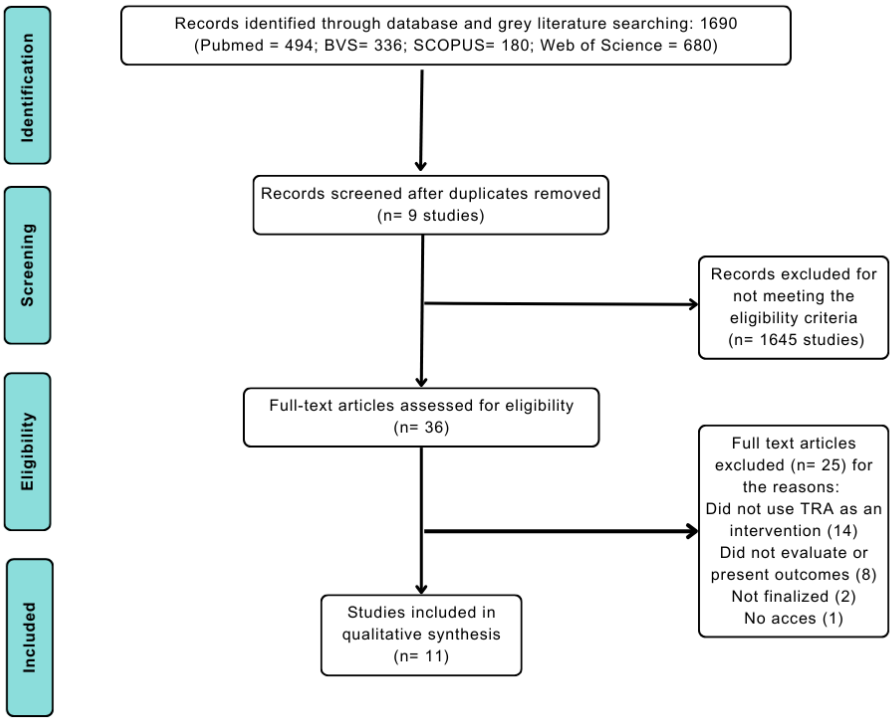

Fig. 1. Flow chart of the systematic review.

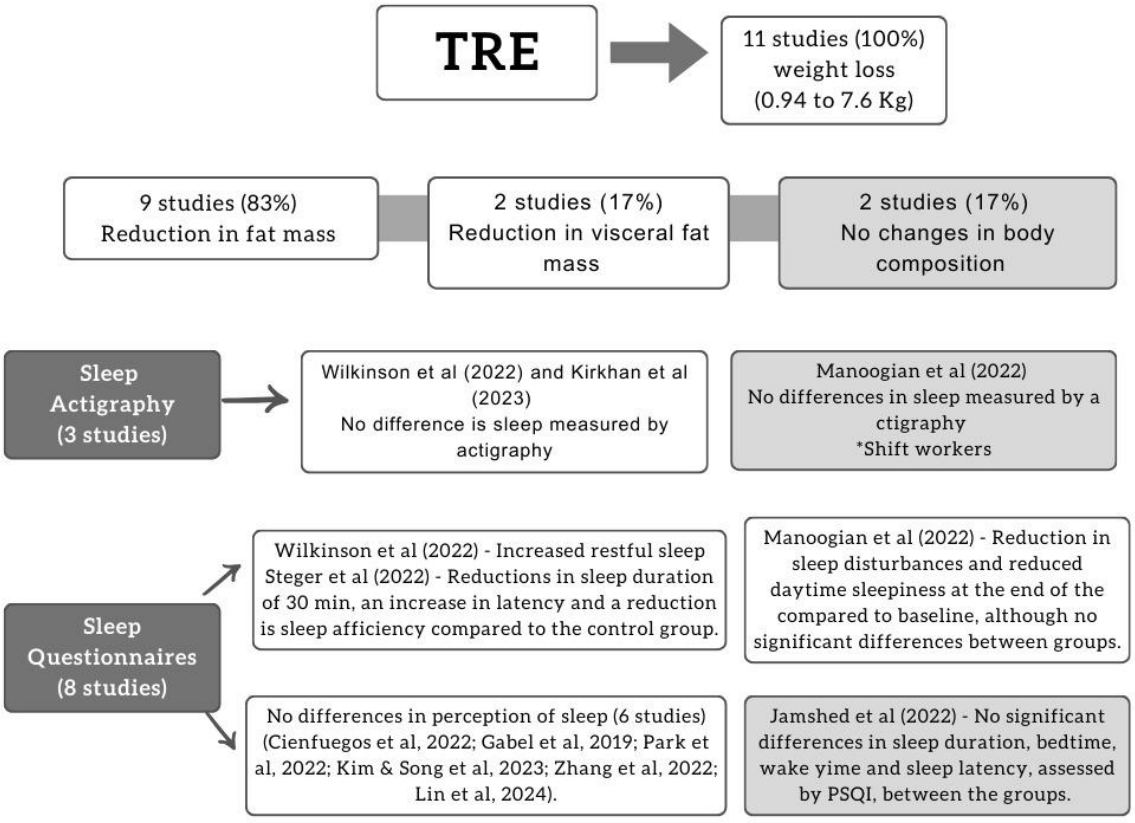

Fig. 2. Summary of the sleep and body composition results

Table 2. Main features of the studies included in the systematic review.

Author (year) [ref]	Location of the study	Design	Sample
Wilkinson et al. (2020) [41]	USA;	SAS	Obese adults with metabolic syndrome; mean age 59 ± 11.14 years; 13 men and 6 women.
Manoogian et al.(2022) [41]	USA;	RCT	Workers on 24-hour shifts; mean age 40,36 ± 9.04, 91% male.
Cienfuegos et al. (2022) [41]	USA;	RCT	Obese adults, mean age 45 to 49 years old, 15 men and 34 women
Steger et al. (2022) [41]	USA;	RCT	Obese adults (BMI >30kg/m²), average age 44 ± 12; 72% female.
Gabel et al. (2019) [41]	USA;	RCT	Obese adults (BMI 30-45 kg/m²), predominantly female, mean age 45-49 years;
Park et al. (2021) [41]	Korea;	SAS	Healthy young adults, mainly active at night, average age 22.5± 2.8 years, 25 women and 8 men.
Kin e Song (2023) [41]	Korea;	SAS	Healthy young adults; mean age 23.4 ± 2.9 years, 64.7% women
Jamshed et al. (2022) [41]	USA;	RCT	Obese adults; participants in a Weight Loss Program; average age 43±11; 80% women
Kirkham et al. (2023) [41]	Canada;	SAS	Breast cancer survivors; BMI of 31.8 ± 4.8 kg/m², mean age 66 ± 5 years old
Zhang et al (2022)	China	RCT	Healthy adults aged 18 to 30 and BMI greater than 24 Kg/m²
Lin et al (2024)	Chicago	RCT	Adults 18 to 65 with a BMI between 30 and 50 kg/m2

RCT: Randomized Controlled Trial. SAS: Single Arm Studies.

Table 3. Main information about the interventions and results of the studies included in the systematic review

Author (year) ref	Intervention	Control or placebo group	Duration	Food time assessment	Sleep assessment	BC assessment	Main sleeps results	Main BC results
Wilkinson et al (2020)[22]	TRE 10 hours	-	12 weeks	App MCC	PSQI, App mCC, Actigraphy	BIA	Increase in restful sleep from 69.88% ± 25.61% of days at the start of the study, to 88.16% ± 21.89% (p = 0.019); 35% reduction in the variance of waking time in the intervention group (3.42 hours to 2.21 hours)	Significant reductions in body weight from the start (-3.30 ± 3.20 kg), body fat percentage (-1.01% ± 0.91%) and a reduction in visceral fat (-0.58 ± 0.77 (-3%), p = 0.004).
Manoogian et al (2022)[24]	TRE 10 hours + mediterranean diet	Nutritional advice + mediterranean diet	12 weeks	Rec 24h	Actigraphy; ESS; PSQI	BIA	Reductions in sleep disturbances at the end of the intervention (-0.16, 95% CI -0.30 to -0.02, p = 0.027) and reduced daytime sleepiness SOC (-0,87, IC 95% -1,49 a -0,25, p = 0,007) e TRE (-1,10, IC 95% -2,00 a -0,19, p = 0,019) compared to baseline. No significant differences between groups	Significant reduction in body weight was found in the TRE group of -0.94 kg, p 0.0006.

Cienfuegos et al (2022)[25]	TRE 4 hours and 6 hours	No food restrictions	8 weeks	7 day food record; Daily adherence record	PSQI; ISI; Berlin Questionnaire	DXA	No changes were observed between baseline and week 8 in sleep duration (TRE 4h 0.2±0.2; TRE 6h 0.2±0.2; control 0.2±0.3), latency (TRE 4h 0.12 ± 0.18; TRE 6h 0 ± 0.13; control -0.23 ± 0.17), insomnia (TRE 4h 0.3 ± 0.9; TRE 6h -2.8 ± 1.0; control 0.4 ± 1.2) or risk of OSA.	Reduction in fat mass (TRE 4h -2.8 ± 0.4; TRE 6h -1.4 ± 0.3) and body weight (TRE 4h -3.9 ± 0.4; TRE 6h -3.4 ± 0.4) was observed in both groups. Lean mass and visceral fat mass remained unchanged.
Bao et al (2022)[18]	TRE 5,5h	Eating time 11 hours	3 days confined in metabolic chamber	Meals provided by the research	VAS	BIA	Reduction in subjective sleepiness assessed by the visual sleep scale was observed in both groups, but with no significant differences between the groups.	-

Steger et al (2022)[23]	TRE 8 hours + energy restriction (ER)	Eating time ≥ 12 hours	14 weeks	3 day digital food record	PSQI, MCTQ	DXA	Reduction in sleep duration of 30 ± 13 min, an increase in latency of 7 ± 3 min and a reduction in sleep efficiency of 2% ± 1% compared to the control group. No changes in sleep quality, sleep time, including sleep onset, sleep compensation, sleep inertia or chronotype.	TRE+ER group lost 7.6 ± 1.0 kg (7.0% ± 0.9%, $p < 0.001$) and decreased body fat by 2.8 ± 1.3 kg and trunk fat by an additional 1.6 ± 0.7 kg compared to the control group. No differences in fat free mass, appendicular lean mass and visceral fat.
Simon et al (2022)[20]	TRE 8 hours	No TRE	12 weeks	App MCC	Actigraphy	DXA	A greater restriction of the food window was associated with longer sleep duration at the end of the intervention ($\beta = -0.46$ [95% CI -9.2, $p = 0.03$). No significant changes in sleep duration and actigraphy variables between the groups.	Data was not presented.

Gabel et al (2019)[26]	TRE 8 hours (Good sleepers)	TRE 8 hours (Bad sleepers)	12 weeks	Daily adherence record	ISI, PSQI, Berlin Questionnaire	DXA	The PSQI score (week 1: 4.7±0.5 and week 12: 4.8±0.7) and insomnia (week 1: 5.2±0.9 and week 12: 5.3±0.9) did not change significantly after 12 weeks of TRE in both groups. No differences in sleep cycle and sleep duration between the groups	Body weight (week 1: 95±3 Kg and week 12: 92±3) and fat mass (week 1: 42±2Kg and week 12: 40±2Kg) decreased after 12 weeks of intervention. No difference in muscle mass and visceral fat mass.
Park et al (2021)[27]	TRE 8 hours	-	4 weeks	Food recording by App	PSQI (adapted)	BIA	No significant changes in the duration ($p= 0.2172$) and pattern of sleep between the groups assessed by the adapted PSQI.	Significant individual changes in body weight (-1.0 ± 1.4 kg) and body fat percentage (-0.4 ± 1.9%). Greater loss of muscle mass and fat was observed in individuals in the weight loss group
Kesztyüs et al (2020)[28]	TRE 8 to 9 hours	-	3 months	-	VAS	-	Sleep quality changed significantly by 9.6 ± 13.9 ($p < 0.001$) with no significant difference between the groups TRE.	There was a reduction in body weight, but no body composition data was presented.
Kim and Song (2023)[19]	eTRE 8 hours (fasting before noon)	I-TRE 8 hours (fasting after noon)	4 weeks	Food recording by App	PSQI	BIA	No significant difference in sleep duration (7.4 ± 1.4 and 7.5 ± 0.8 h), wake-up	eTRE group, body weight showed significant reductions of -0.9, to -1.4 kg in weeks 1-4

						time (09:16 ± 01:26h and 09:13 ± 01:06h) and bedtime (01:51 ± 01:39h and 01:40 ± 01:09h) between the pre-intervention and intervention periods.	compared to baseline and fat mass also decreased significantly by -0.7, -0.9 kg at weeks 3 and muscle mass was 0.3 kg lower than at baseline. l-TRE group showed no significant changes in any measure of body composition.
Jamshed et al (2022)[21]	TRE 8 hours + energy restriction	Eating time ≥ 12 hours + energy restriction	14 weeks	PSQI	DXA	No differences were found in sleep duration, bedtime, wake time and sleep latency, assessed by PSQI, between the groups	eTRE+ER group lost an additional 2.3 kg of body weight (95% CI, -3.7 to -0.9 kg; P = 0.002) compared to the CON+ER group. No significant differences in absolute fat loss (-1.4 kg; 95% CI, -2.9 to 0.2 kg; P = 0.09), fat-free mass (-0.1 kg; -0.9 to 0.7 kg; P=0.75), trunk fat (-0.9Kg; -1.8 to 0.1Kg; P=0.07), visceral fat (-0.1Kg; -0.2 to 0.1Kg; P=0.37) or appendicular lean mass (-0.1Kg; -0.6 to 0.5Kg; P= 0.78).

Kirkham et al (2023)[29]	TRE ad libitum 8 hours	-	8 weeks	Actigraphy	MRI	No significant changes in sleep duration (0.1 ± 0.8; P=0.99) assessed by actigraphy	With regard to weight and body composition, body mass decreased by an average of 1.0 kg (interquartile range -2.3 to 0.2 kg), total body fat mass and visceral TA volume were significantly reduced by this intervention.

VAS: Visual Analog Scale; ISI: Insomnia Severity Index; MCTQ: Munich Chronotype Questionnaire; ESS: Epworth Sleep Scale; TA: Adipose tissue; MRI: magnetic resonance imaging

Author (year)[ref]	Bias due to confounding	Bias in classification of interventions	Bias in selection of participants into the study or analysis	Bias due to deviations from intended interventions	Bias due to missing data	Bias arising from measurement of the outcome	Bias in selection of the reported result	Overall risk of bias	
Wilkinson et al. (2020)[19]	−	+	+	+	!	!	+	−	Serious
Gabel et al. (2019)[25]	−	+	+	+	!	!	!	−	Serious
Park et al. (2021)[24]	−	+	+	+	+	!	!	−	Serious
Kin e Song (2023)[18]	!	+	+	+	+	!	+	!	Moderate
Kirkhan et al. (2023)[21]	!	+	+	+	+	!	+	!	Moderate

Fig. 3. Assessment of risk of bias of individual articles (ROBINS I).

Author (year)[ref]	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	Bias in selection of the reported result	Overall risk of bias	
		Effect of assignment	Effect of adhering					
Mannogian et al. (2022)[30]	+	!	!	+	!	+	!	Some concerns
Cienfuegos et al. (2022) [26]	+	!	!	+	−	+	−	High risk
Steger et al. (2023)[29]	+	!	!	−	−	+	−	High risk
Jamshed et al. (2022)[22]	+	!	!	+	!	+	!	Some concerns
Zhang et al. (2022)[28]	+	!	!	+	!	+	!	Some concerns
Lin et al. (2024)[27]	+	!	!	+	!	+	!	Some concerns

Fig. 4. Assessment of risk of bias of individual articles (RoB 2 cluster-randomized trials and crossover).* Doman S: Risk of bias arising from period and carryover effects in a crossover trial: Low risk.