**UNIVERSIDADE FEDERAL DO CEARÁ**
**FACULDADE DE FARMÁCIA, ODONTOLOGIA E ENFERMAGEM**
**CURSO DE ODONTOLOGIA**

**GABRIELA BEZERRA WALRAVEN**

# EFEITOS DE UMA DIETA LIVRE DE GLÚTEN NA QUALIDADE DE VIDA E DE SONO DE MULHERES COM DISFUNÇÃO TEMPOROMANDIBULAR: UM ESTUDO PILOTO.

# EFFECTS OF A GLUTEN-FREE DIET ON QUALITY OF LIFE AND SLEEP OF WOMEN WITH TEMPOROMANDIBULAR DISORDER: A PILOT STUDY.

**FORTALEZA**
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Orientadora: Profª. Drª. Lívia Maria Sales Pinto Fiamengui

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À Deus.

Aos meus pais, Diva e Ricardo.

Aos meus irmãos Guilherme e Ricardo

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# APRESENTAÇÃO

Este Trabalho de Conclusão de Curso (TCC) está de acordo com o formato alternativo para TCCs e encontra-se sob o formato de artigo científico, seguindo as normas da revista “Archives of Oral Biology” (attachment C).

## RESUMO

Objetivo: O objetivo deste estudo piloto foi avaliar a influência de dieta livre de glúten (DLG) na qualidade de vida e qualidade do sono de mulheres com disfunção temporomandibular (DTM). Material e métodos: 13 mulheres com idade entre 18 e 55 anos diagnósticadas com dor miofascial de acordo com o *Research Diagnostic Criteria for Temporomandibular Disorders* foram incluídas no estudo e submetidas a 1 mês de DLG. Os desfechos avaliados foram qualidade de vida e qualidade de sono, mensuradas, respectivamente, através dos questionários *Short-Form* 36 e Índice de qualidade de sono de Pittsburg na suas versões validadas e traduzidas para a língua portuguesa. Voluntárias também foram solicitadas a informar a intensidade de dor antes e após a DLG através de escala numérica verbal. Os dados foram submetidos à análise estatística com nível de significância de 5% (Teste "T" pareado, Wilcoxon, teste exato de Fisher). Resultados: Após 1 mês de DLG, as voluntárias apresentaram redução na intensidade da dor (T1 = 7,69 ± 1,49; T2 = 4,00 ± 2,6; p = 0,001), melhora na qualidade do sono (T1 = 8,23 ± 4,02; T2 = 6,15 ± 2,85; p = 0,031) e melhora significativa nos escores do SF-36 relacionados à função física, dor corporal e vitalidade. Conclusão: DLG parece impactar positivamente a qualidade de vida e qualidade de sono em mulheres com DTM, mas mais estudos são necessários para avaliar sua real eficácia como tratamento coadjuvante para DTM.

**Palavras-chave**: Transtornos da articulação temporomandibular, Dieta Livre de Glúten, Qualidade de Vida, Sono.

## ABSTRACT

Objective: The aim of this pilot study was to evaluate the influence of a gluten-free diet (GFD) on quality of life and sleep in women with Temporomandibular Disorder.

Design: 13 women aged between 18 and 55 years diagnosed with myofascial pain according to the Research Diagnostic Criteria for Temporomandibular Disorders (TMD) were included in the study and underwent 1 month of GFD. The evaluated outcomes were quality of life and quality of sleep, measured, respectively, through the Short-Form 36 and Pittsburg Sleep Quality Index questionnaires in their validated versions and translated into Portuguese. Volunteers were also asked to report pain intensity before and after GFD using a verbal numeric scale. The data were submitted to statistical analysis with a significance level of 5% (paired "T" test, Wilcoxon, Fisher's exact test). Results: After 1 month of GFD, the volunteers showed a reduction in pain intensity ($T1 = 7.69 \pm 1.49$; $T2 = 4.00 \pm 2.6$; $p = 0.001$), improvement in sleep quality ($T1 = 8.23 \pm 4.02$; $T2 = 6.15 \pm 2.85$; $p = 0.031$) and significant improvement in SF-36 scores related to physical function, bodily pain and vitality.

Conclusion: GFD appears to positively impact quality of life and sleep quality in women with TMD, but further studies are needed to assess its real effectiveness as an adjunctive treatment for TMD.


**Key-words:** Temporomandibular Joint Disorders, Gluten-free diet, Quality of life, Sleep.

# LISTA DE TABELAS

## LISTA DE ABREVIATURAS E SIGLAS

| | |
|---|---|
| BMI | Body Mass Index |
| CPM | Conditioned Pain Modulation |
| GFD | Gluten Free Diet |
| NRS | Numeric Rating Scale |
| PSQI | Pittsburg Sleep Quality Index |
| RDC/DTM | Research Diagnostic Criteria for Temporomandibular Disorders |
| ReBEC | Brazilian Registry of Clinical Trials |
| SF-36 | Short Form Health Survey-36 |
| SPSS | Statistical Package for the Social Science |
| TMD | Temporomandibular Disorders |
| TMJ | Temporomandibular Joint |

**SUMÁRIO**

## INTRODUCTION

Several studies have investigated the efficacy of dietary interventions in reducing pain severity in individuals with chronic painful conditions,[25] mainly for their anti-inflammatory potential, such as hypocaloric[36], gluten-free[28] and even vegan gluten-free[13,18] diets. The effects of those interventions on quality of life[33] and sleep quality[28,33] have also been assessed. Gluten-Free Diet (GFD) has become popular in the recent past few years, and emerging studies suggests it may be beneficial for chronic pain-related disorders such as fibromyalgia[36], rheumatoid arthritis[13,18], migraine[29] and irritable bowel syndrome[28,35].

Gluten is a protein complex found in grains such as wheat, rye and barley[37] and is described as a substance with pro-inflammatory activity.[4,15,20,29,30,37] Due to its high content of proline and glutamine, gluten is not completely digested in the gastrointestinal tract,[30] and those peptides may exacerbate intestinal permeability, trigger immune response[22] and cause inflamattion[14] that may reach other tissues.[24] Those events are more severe in individuals presenting gluten-related disorders, however, evidences suggest its occurrence even in non-celiac patients.[7,17,34]

Temporomandibular Disorders (TMD) encompasses a group of musculoskeletal and neuromuscular conditions that involve the Temporomandibular Joints (TMJ), the masticatory muscles and all associated tissues[35]. TMD pain-related is often poorly localized to the masticatory structures[5], and some patients may also present widespread pain.[35] Besides pain complaint, TMD patients often present affective disturbance, such as depression[28,32], anxiety[10,26] and distress[19], impaired quality of life[3,26] and altered sleep patterns[26]. Those comorbidities are also frequent among individuals with a variety of pain-related disorders.[12,31]

Conservative treatment modalities for TMD management are several and include self-management strategies, manual therapies, exercises, occlusal splint, pharmacotherapy, counseling and others[13,14]. Diet habits modifications may also play an important role as an additional conservative treatment modality, not only regarding food hardness, but also its composition. In 2016, when establishing self-management programmes for individuals with TMD, an international Delphi process emphasized the lack of studies in the field of TMD and nutrition. Besides, it has been suggested that clinical trials for chronic pain should assess not only pain, but the patient itself and several aspects of daily life experienced by those individuals.[39]

Thus, the aim of this pilot study was to evaluate the influence of a 1-month GFD on quality of life and sleep quality of women with TMD.

## MATERIALS AND METHODS

### Ethics

This pilot study, registered in the Brazilian Registry of Clinical Trials (ReBEC) with the identification RBR-4GZJ9M, was developed at the Federal University of Ceará and approved by the local Human Research Committee (CEP/UFC/PROPESQ) under protocol number 2.439.297. All participants read and signed the Informed Consent Form before entering the study.

### Study design and participants

Subjects were recruited by means of social media, leaflets and advertisement at the Federal University of Ceará, from March to December 2018, in the city of Fortaleza – Brazil. Inclusion criteria were women volunteers, aged between 18 and 55 years old, diagnosed with myofascial pain according to Research Diagnostic Criteria for Temporomandibular Disorders, and presenting pain complain graded as 5 at minimum in a Numeric Rating Scale (NRS) ranging from 0 (no pain) to 10 (worst pain ever possible). Volunteers should present no history of TMD treatment for, at least, the last three months. Exclusion criteria were volunteers presenting toothache, fibromyalgia, frequent or chronic primary headache, history of facial trauma, systemic conditions such as uncontrolled diabetes and hypertension, systemic erythematosus lupus, Hansen's disease, multiple sclerosis, hypothyroidism, carpal tunnel syndrome, intracranial hypertension, pregnancy, previously diagnosed disabling psychological and neurological disorders, history of chikungunya fever, and those that made frequent use or abuse of licit or illicit drugs. Volunteers following a restrictive diet and/or with history of signs and symptoms of gluten intolerance and sensitivity or wheat allergy[40] were also excluded.

Subjects who fulfilled the eligibility criteria were invited to perform an individualized 1-month GFD.

### Outcome variables

### Reported pain intensity

Subjects were asked to inform their pain intensity in a NRS of 11 points before and after 1-month GFD. For statistical analysis, pain intensity was categorized into mild/ moderate (1 to 6 on NRS) and severe (7 to 10 on NRS) pain.

**The 36-Item Short Form Health Survey**

To evaluate quality of life, a validated, standardized and translated to Portuguese questionnaire, consisting of 11 closed questions to emphasize self-perception about your own health in the last four weeks. The Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) item, was applied,[6] to assess positive and negative aspects of 8 domains, that are divided into 2 groups – physical health (Physical Functioning, Role Physical, Bodily Pain and General Health) and mental health (Vitality, Social Functioning, Role Emotional and Mental Health)–, scores for each domain ranges from 0 (worst health) to 100 (best health) .[6]

**The Pittsburgh Sleep Quality Index**

The Pittsburg Sleep Quality Index (PSQI) is a 19-items self-report, validated, standardized and translated to Portuguese questionnaire that encompasses 7 components score: subjective sleep quality, sleep duration, sleep disturbance, sleep latency, habitual sleep efficiency, use of sleep medication and wake time dysfunction. The components are scored and summed leading to a final score that ranges from 0 to 21, where values higher than 5 indicate a poor sleep quality.[2]

**Intervention**

**Nutritional protocol**

Clinical and dietary data were obtained through a structured questionnaire. Anthropometric measurements of weight, using a stand-on anthropometric scale (Filizola®, Filizola SA, Brazil), and height were assessed. Body Mass Index (BMI) was calculated using the formula BMI = weight (kg)/ height ($m^2$). In spite of anthropometric assessment, it was emphasized that the aim of the study was to prescribe a GFD, not a calorie-restricted one.[5]

A 24-hour dietary recall was applied to analyze food intake, where the volunteer was instructed to report her diet during the day before and a habitual consumption recall about her eating routine. From the results obtained, dietary changes were planned together with the volunteer and according to her individualities, replacing foods that were a source of gluten by those lacking this protein in their nutritional composition, respecting sociocultural preferences and establishing equivalent portions in terms of calories and macronutrients.

In addition to the diet, each participant received a list of foods that could be eaten or should be excluded,[5,8] and then the volunteer was instructed to complete a food diary for 7 consecutive days. During the GFD, participants could contact the nutritionist and were contacted weekly to answer some question. After 1 month, another 24-hour dietary recall and also a habitual consumption recall was performed by the nutritionist, who also analyzed participant's food diary. Those who did not complete the food diary and/or had consumed gluten-containing foods during the study period were excluded.

**Statistical analysis**

Data were expressed as quantitative and qualitative variables. The Kolmogorov-Smirnov test was applied to evaluate normal distribution. Paired "T" - test was used to evaluate pain intensity, sleep quality and quality of life domains between T1 and T2. Wilcoxon test was used to analyze domains presenting non-normal distribution. In addition, absolute risk, relative risk and odds ratio were used to evaluate the association between the diet (with or gluten free), sleep quality (good or poor) and pain intensity (mild/moderate or severe). For those purpose, Fisher's exact test was used. The significance level was set at 5% ($p= 0.05$) and statistical analysis were performed using Statistical Package for the Social Science (SPSS).

# RESULTS

## General Description

182 volunteers were evaluated, 17 included and 13 completed the study (lost to follow-up = 1; discontinued the intervention = 3). Sociodemographic data from the final sample are presented on table 1.

Table 1. Sample characterization.

| | | **(N=13)** |
|---|---|---|
| **Race/ Ethnicity** | **Black** | 4 |
| | **White** | 1 |
| | **Brown** | 7 |
| | **Asian** | 1 |
| **Education level** | **High school complete** | 6 |
| | **Junior high school complete** | 1 |
| | **Postgraduate** | 0 |
| | **Higher education incomplete** | 3 |
| | **Higher education complete** | 3 |
| **Marital status** | **Single** | 6 |
| | **Married** | 6 |
| | **Widow** | 1 |
| **Employed** | **Yes** | 12 |
| | **No** | 1 |
| **BMI (mean ± standard deviation)** | | 24,83 ± 4,66 |
| **Age (mean ± standard deviation)** | | 30 ± 7,64 |

BMI: body mass index.

## Outcome variables

After 1-month GFD, participants presented a reduction on pain intensity (T1 = 7.69 ± 1.49; T2 = 4.00 ± 2.6; p = 0.001) and improvement on sleep quality (T1 = 8.23 ± 4.02; T2 = 6.15 ± 2.85; p = 0.031) (Table 2). Odds ratio of severe pain were elevated 66-fold when participants consumed gluten and it was also associated to a heightened risk of poor sleep (Table 3).

Table 2. Association between quality of sleep and pain.

| **Variável** | **Dieta** | **n** | **Média** | **DP** | **t†** | **p** |
|---|---|---|---|---|---|---|
| Qualidade do sono | Antes | 13 | 8,23 | 4,02 | 2,441 | 0,031* |

| | | | | | | |
|---|---|---|---|---|---|---|
| (Pittsburgh) | Após | 13 | 6,15 | 2,85 | | |
| Dor (EAV) | Antes | 13 | 7,69 | 1,49 | 4,104 | 0,001* |
| | Após | 13 | 4,00 | 2,60 | | |

† Teste t-pareado,

* Diferença estatisticamente significante (p<0.05).

Table 3. Association between diet (with or gluten free), sleep quality and pain intensity.

| **Diet** | **Sleep quality** | | **Pain** | |
|---|---|---|---|---|
| | **Poor** | **Good** | **Severe** | **Mild/Moderate** |
| **With Gluten (T1)** | 10 (58,8) | 3 (33,3) | 11 (91,7) | 2 (14,3) |
| **Gluten-free (T2)** | 7 (41,2) | 6 (66,7) | 1 (8,3) | 12 (85,7) |
| **Relative Risk (IC 95%)** | 1,429 (0,796 – 2,564) | | 11,000 (1,650 – 73,345) | |
| **Odds Ratio (IC 95%)** | 2,857 (0,528 – 15,473) | | 66,000 (5,226 – 833,557) | |
| **p§** | 0,205 | | <0,001 | |

§ Fisher's exact test.

Data regarding quality of life are shown on table 4. Participants presented improvement on SF-36 domains related to physical functioning, bodily pain and vitality.

Table 4. SF-36 scores before and after a 1-month GFD.

| **SF-36** | **Diet** | **n** | **Average** | **SD** | **t† ou Z&** | **p** |
|---|---|---|---|---|---|---|
| **Physical functioning** | Before | 13 | 67,69 | 7,48 | 2,339† | 0,037* |
| | After | 13 | 81,15 | 5,25 | | |
| **Role physical** | Before | 13 | 51,92 | 10,76 | 1,508& | 0,132 |
| | After | 13 | 63,46 | 12,54 | | |
| **Bodily Pain** | Before | 13 | 39,00 | 5,27 | 2,303† | 0,040* |
| | After | 13 | 52,62 | 5,08 | | |
| **General health** | Before | 13 | 45,54 | 4,73 | 0,867† | 0,403 |
| | After | 13 | 50,15 | 5,18 | | |
| **Vitality** | Before | 13 | 41,15 | 6,08 | 3,717† | 0,003* |
| | After | 13 | 56,54 | 6,56 | | |
| **Social functioning** | Before | 13 | 62,54 | 6,17 | 2,097† | 0,058 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | After | 13 | 75,08 | 6,30 | | |
| **Role emotional** | Before | 13 | 56,46 | 10,95 | 0,979[&] | 0,327 |
| | After | 13 | 69,23 | 12,21 | | |
| **Mental health** | Before | 13 | 59,69 | 5,86 | 0,626[†] | 0,543 |
| | After | 13 | 62,46 | 6,77 | | |

[†] Paired-t test, [&]Wilcoxon test

[*] Statistically significant difference ($p<0.05$).

Standard Deviation (SD)

## DISCUSSION

This pilot study aiming to evaluate the influence of a GFD on pain, quality of life and sleep quality of women with TMD. After 1-month GFD, participants presented a reduction on pain intensity, improvement on sleep quality and quality of life. When consuming gluten, participants were at higher risk of presenting severe pain and poor sleep, therefore, GFD may be beneficial for individuals with TMD and future clinical trials on this field is suggested.

The Initiative on Methods, Measurement and Pain Assessment in Clinical Trials (IMMPACT) was formed in 2002 to develop recommendations for the design and interpretation of clinical trials of treatment for patients with pain.[11] In 2007, efforts were performed in order to identify relevant outcome domains for clinical trials from the perspective of people who experience chronic pain. Authors identified several different aspects of daily life that people being treated for chronic pain conditions consider important when evaluating the effectiveness of treatments. Besides pain reduction, the most relevant aspects were enjoyment of life, emotional well-being, fatigue, weakness and sleep-related problems. The study indicated that patients with chronic pain consider functioning and well-being as appropriate targets of treatments.[39]

It is already established that a huge part of patients presenting pain-related TMD present poor sleep quality[12] and reduced quality of life[19,21,23,26,33,38], and those conditions may influence pain perception and management.[16] Therefore, the effect of TMD treatments on these conditions, among others, should also be assessed.

Slim et al. 2017,[36] aiming to evaluate the influence of a 6-month GFD on gluten sensitivity-like symptoms in adults with fibromyalgia and also its influence on fibromyalgia severity, quality and quantity of sleep, intensity and interference of pain in daily activities, severity of depressive symptoms, severity of state and trait anxiety, quality of life and patients perception of the disease severity, found the intervention improved the number of experienced gluten sensitivity symptoms and the severity of fibromyalgia symptoms, but did not influence any other outcome. Another study,[33] found 1-year of a GFD improved physical and mental scores in patients with FM associated to celiac disease.[33] In the present study, participants' improved SF-36 domains related to physical functioning, bodily pain and vitality after 1-month GFD, however, since this outcome has not been previously evaluated in patients with TMD, it precludes us from comparing our findings with other published data.

The findings presented here suggest a 1-month GFD improves sleep quality in women with TMD. Both poor sleep quality and pain seems to be part of a complex and bidirectional interaction though the mechanism is still not well understood.[9] When analyzing our findings, it seems consuming gluten heighten the risk of presenting a poor sleep quality, however, future studies are needed to elucidate the role of GFD on sleep pattern.

There are several limitations in the present study with the most relevant being the absence of a control group, the small sample size and short treatment duration. However, it consisted of a pilot study and one should keep in mind that the primary purpose of a pilot study is to prevent waste of researchers from launching a large-scale study costly in time and money. Also, only women participants were included and findings presented here should not be generalized. Still, the present study is of relevance to better design future studies and we suggest future double-blinded randomized placebo-controlled trial with a longer intervention duration.

Considering the recommended core outcome measures for chronic pain clinical trials (IMPMPACT recommendations)[11] and also considering that gluten ingestion has been associated with anxiety[1] and depression[27], we also suggest future clinical trials aiming to evaluate the influence of a GFD on other parameters, such as anxiety, depression and mood state. Symptoms and adverse events secondary to intervention and participants satisfaction with treatment[11] should also be addressed.

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**ANEXO A – TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO (TCLE)**

Você está sendo convidada para participar, como voluntária, da pesquisa intitulada "INFLUÊNCIA DA INGESTÃO DE GLÚTEN NOS MECANISMOS SOMATOSSENSORIAIS MECÂNICOS DE MULHERES COM DOR MIOFASCIAL DA MUSCULATURA MASTIGATÓRIA". Leia atentamente as informações abaixo e faça qualquer pergunta que desejar, para que todos os procedimentos desta pesquisa sejam esclarecidos.

O objetivo da pesquisa é avaliar a influência da ingestão de glúten na dor e sensibilidade na região da face em mulheres com dor nos músculos da mastigação, bem como comparar índices de qualidade de vida e qualidade do sono em mulheres que aderiram a uma dieta sem glúten. O glúten é uma substância encontrada em cereais como trigo, centeio e cevada, e está presente em alimentos como pão, macarrão, bolo, bolacha, etc.

A pesquisa terá duração de **1 mês** e as voluntárias selecionadas serão divididas em três grupos, conforme segue abaixo. Ao participar, você se compromete em seguir as instruções do grupo em que foi alocada.

**Grupo 1:** Voluntárias com DTM que irão seguir uma dieta livre de glúten.

Se você apresenta dor na face, poderá ser alocada nesse grupo por meio de sorteio pré-determinado. Sua condição dolorosa será confirmada através do questionário validado para diagnóstico de DTM. Você deverá comparecer as consultas agendadas, seguir a dieta prescrita pela nutricionista e as orientações dadas pela equipe. Após finalizar a sua participação na pesquisa, a equipe continuará o seu tratamento o associando técnicas convencionais reconhecidas para controle da dor em indivíduos com Disfunção Temporomandibular.

**Grupo 2:** Voluntárias com DTM que irão seguir uma dieta livre de glúten **após um mês** da avaliação inicial

Se você apresenta dor na face, poderá ser alocada neste grupo por meio de sorteio pré-determinado, e deverá apenas comparecer as consultas agendadas. Sua condição dolorosa será confirmada através de um questionário validado para o diagnóstico de DTM. Passando-se 1 mês da primeira avaliação, você será reavaliada e terá consulta com nutricionista para prescrição da dieta livre de glúten. Além disso, a equipe dará continuidade ao seu tratamento associando a dieta a outras técnicas convencionais reconhecidas para controle da dor em indivíduos com Disfunção

Temporomandibular.

**Grupo 3:** Voluntárias sem DTM que **não** irão seguir uma dieta livre de glúten.

Se você não possui dor na face, será alocada neste grupo. A confirmação de que você não apresenta DTM será realizada através de um questionário da Academia Americana de Dor Orofacial. Você deverá comparecer a uma única consulta agendada para a realização dos procedimentos que serão explicados a seguir.

**Todos os grupos** deverão permitir que a pesquisadora aplique dois questionários de triagem para confirmar os critérios necessários para participar da pesquisa na primeira consulta. Também serão aplicados dois questionários na primeira consulta e no retorno de 1 mês (com excessão do grupo 3 que não terá retorno), um relacionado a sua saúde geral e outro relacionado a qualidade do seu sono.

O acompanhamento nutricional, durante o mês da pesquisa, tem por objetivo orientar substituições, quando necessárias, por alimentos sem glúten, respeitando sua cultura e hábitos alimentares, com o intuito de não alterar sua ingestão calórica. No primeiro momento, em ambiente reservado, será realizada uma avaliação antropométrica e nutricional, o que significa que iremos aferir seu peso e altura para o cálculo do índice de massa corporal (IMC), da circunferência da cintura (CC) e de dobras cutâneas para o cálculo do percentual de gordura corporal, além de alguns questionamentos sobre seus hábitos alimentares. Você receberá uma lista com uma relação de alimentos que contém ou não glúten, para que possa auxiliar na sua escolha alimentar durante a pesquisa, bem como um diário alimentar, onde irá relatar seu consumo durante esse período. No segundo momento, após 30 dias, você será reavaliada quanto aos mesmos parâmetros.

No acompanhamento odontológico, alguns exames serão executados nas consultas inicial e final da sua participação. O grupo 3 fará os mesmos exames, porém em consulta única. Os primeiros serão feitos utilizando-se uns filamentos de nylon, onde você deverá responder várias vezes sobre a sensibilidade sentida no momento do exame de acordo com as instruções da pesquisadora. Também será utilizado um aparelho capaz de medir a pressão exercida nos músculos (algômetro), o qual possui uma ponta circular que fica em contato com determinadas áreas do seu rosto. Esta ponta funcionará como a ponta de um dedo fazendo pressão em

determinados músculos e não machuca de forma alguma. Esse aparelho será utilizado no exame até que a voluntária relate um leve desconforto, sem que haja dor, e o valor registrado será anotado. Também será necessário que esse teste seja repetido, dessa vez com a sua mão direita imersa em um recipiente contendo água gelada, o que causará desconforto, porém isso durará menos de 2 minutos. Caso você apresente dor na face, essa dor pode aumentar levemente após os exames.

Os exames não produzirão qualquer tipo de dano físico, moral ou material, e, além disso, poderão trazer benefícios, pois, caso alguma relação entre dor na face e ingestão de glúten seja encontrada, um novo tipo de tratamento poderá ser utilizado.

Suas informações fornecidas serão mantidas confidenciais, respeitando sua privacidade. Você tem a garantia de receber respostas a qualquer pergunta ou esclarecimento a qualquer dúvida sobre os assuntos relacionados com a pesquisa, através do telefone da pesquisadora do projeto e, se necessário, através do telefone do Comitê de Ética em Pesquisa.

Você não terá nenhum tipo de despesa para participar desta pesquisa, bem como nada será pago por sua participação. Você não deve participar contra a sua vontade e, em caso de recusa, não será penalizado de forma alguma. Além disso, você tem a liberdade de deixar de participar do estudo a qualquer momento, sem que isso traga prejuízo a continuidade de quaisquer tratamentos que você esteja fazendo nessa instituição.

Um possível risco nutricional envolvido está em uma redução de fontes de proteínas, porém, essas fontes retiradas serão substituídas por outras adequadamente pela nutricionista da equipe. Se você apresenta dor na face, essa dor pode aumentar levemente após os testes odontológicos. A consulta pode tornar-se cansativa devido a quantidade de questionários e testes que serão realizados. Além disso você estará suscetível aos riscos inerentes ao seu descolamento até a Universidade. A participação nesta pesquisa não traz complicações legais e nenhum dos procedimentos usados oferece riscos à dignidade dos participantes.

Após estes esclarecimentos, solicitamos o seu consentimento de forma livre para participar desta pesquisa. Portanto preencha, por favor, os itens que se seguem.

Contato da responsável pela pesquisa:

Nome: Juliana Araújo Oliveira

Instituição: Universidade Federal do Ceará

Endereço: Rua Monsenhor Furtado s/n, Rodolfo Teófilo

Telefone: (85) 981707905

ATENÇÃO: Se você tiver alguma consideração ou dúvida, sobre a sua participação na pesquisa, entre em contato com o Comitê de Ética em Pesquisa da UFC/PROPESQ – Rua Coronel Nunes de Melo, 1000 - Rodolfo Teófilo, fone: 3366-8344. (Horário: 08:00-12:00 horas de segunda a sexta-feira).O CEP/UFC/PROPESQ é a instância da Universidade Federal do Ceará responsável pela avaliação e acompanhamento dos aspectos éticos de todas as pesquisas envolvendo seres humanos.

O abaixo assinado_____, _____anos, RG:_____, declara que é de livre e espontânea vontade que está como participante de uma pesquisa.

Eu declaro que li cuidadosamente este Termo de Consentimento Livre e Esclarecido e que, após sua leitura, tive a oportunidade de fazer perguntas sobre o seu conteúdo, como também sobre a pesquisa, e recebi explicações que responderam por completo minhas dúvidas. E declaro, ainda, estar recebendo uma via assinada deste termo.

Fortaleza,_____/_____/____

_____ | _____

Nome da voluntária Assinatura

_____ | _____

Nome da testemunha (se a voluntária não souber assinar) Assinatura

_____ | _____

Nome da pesquisadora principal Assinatura

_____ | _____

Nome do pesquisador que aplicou o TCLE Assinatura

# ANEXO B – PARECER DO CÔMITE DE ÉTICA EM PESQUISA

UFC - UNIVERSIDADE FEDERAL DO CEARÁ /

## PARECER CONSUBSTANCIADO DO CEP

**DADOS DO PROJETO DE PESQUISA**

**Título da Pesquisa:** INFLUÊNCIA DA INGESTÃO DE GLÚTEN NOS MECANISMOS SOMATOSSENSORIAIS MECÂNICOS DE MULHERES COM DOR MIOFASCIAL DA MUSCULATURA MASTIGATÓRIA

**Pesquisador:** JULIANA ARAUJO OLIVEIRA

**Área Temática:**

**Versão:** 2

**CAAE:** 78108217.8.0000.5054

**Instituição Proponente:** Departamento de Odontologia Restauradora

**Patrocinador Principal:** Financiamento Próprio

**DADOS DO PARECER**

**Número do Parecer:** 2.439.297

**Apresentação do Projeto:**

A dor crônica é frequentemente associada ao sofrimento psicológico e comprometimento social, com redução na qualidade de vida, na capacidade de trabalho e despende elevados gastos para a saúde pública. As Disfunções Temporomandibulares representam um conjunto de distúrbios músculoesqueléticos associados ao sistema mastigatório e uma série de sintomas, sendo a dor o sintoma mais comum geralmente concentrado em músculos mastigatórios e/ou Articulações Temporomandibulares, exacerbada pelo movimento mandibular e funções estomatognáticas. A ligação entre hábitos alimentares e doenças crônicas tem se tornado cada vez mais forte nos últimos anos. Estudos têm demonstrado o impacto destes hábitos em desordens como a fibromialgia, artrite reumatoide e cefaleias. O glúten é um complexo de proteínas que podem estar presentes em vários cereais, tais como trigo, centeio e cevada. Tem sido apontado como uma substância com atividade pró-inflamatória e uma dieta livre de glúten tem sido alvo de estudo não só em pacientes portadores de doença celíaca, mas também em outras condições crônicas. Pacientes com dor crônica constantemente têm seu sistema imunológico ligado com níveis mais altos de mediadores inflamatórios levando a sensibilização periférica, o que pode impulsionar processos de sensibilização central e dor. Este estudo tem como objetivo avaliar a influência da ingestão de glúten nos mecanismos somatossensoriais mecânicos de mulheres com dor miofascial da musculatura mastigatória. Adicionalmente, comparar índices de qualidade de vida e qualidade

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do sono em mulheres que aderiram a uma dieta livre de glúten, com e sem o diagnóstico de DTM. Trata-se de um estudo quali-quantitativo do tipo ensaio clínico não-randomizado controlado cego, onde 50 mulheres de 20 a 45 anos serão divididas nos seguintes grupos: Grupo 1 (mulheres saudáveis), Grupo 2 (mulheres com dor miofascial da musculatura mastigatória), segundo critérios de inclusão e exclusão bem estabelecidos. As voluntárias serão submetidas aos Testes Quantitativos Sensoriais (TQS) mecânicos (Limiar de Detecção Mecânica, Limiar Doloroso Mecânico, Somação Temporal, Controle de Modulação de Dor, Limiar de Dor à Pressão) e responderão os questionários para avaliação da qualidade de vida e qualidade do sono (questionário genérico de qualidade de vida SF-36 e o Índice da Qualidade do Sono de Pittsburgh) antes e após um mês da adesão a uma dieta livre de glúten. As voluntárias serão acompanhadas por uma nutricionista tendo sua qualidade alimentar e medidas antropométricas registradas antes e após a dieta. Para a análise estatística dos TQS intergrupos, será utilizado o teste "T" de Student. Para as análises intragrupos, o teste "t" pareado será utilizado para comparar os TQS antes e após a alteração da dieta. O teste qui-quadrado será utilizado para verificar associação entre os grupos estudados e qualidade de vida e do sono. Qualidade de vida e qualidade do sono também serão analisados empregando-se estatística descritiva, enfatizando as distribuições das variáveis estudadas. Um nível de significância de 5% será adotado para todos os testes.

**Objetivo da Pesquisa:**

Objetivo Primário: Este estudo tem como objetivo avaliar a influência da ingestão de glúten nos mecanismos somatossensoriais mecânicos de mulheres com dor miofascial da musculatura mastigatória.

Objetivo Secundário:

1.Avaliar alterações somatossensoriais mecânicas em mulheres com dor miofascial (RDC/TMD) da musculatura mastigatória antes e 1 mês após prescrição de dieta livre de glúten, e comparar com grupo controle.

2.Avaliar influência da dieta livre de glúten na qualidade de vida e qualidade de sono de mulheres com dor miofascial (RDC/TMD) da musculatura mastigatória, e comparar com grupo controle.

3.Analisar o padrão alimentar das mulheres com dor miofascial (RDC/TMD) da musculatura mastigatória.

**Avaliação dos Riscos e Benefícios:**

Riscos:

Os efeitos adversos da exclusão do glúten parecem estar principalmente associados à menor ingestão de fibras (podendo acarretar em alterações no perfil da flora intestinal) e ao aumento da




ingestão calórica. Entretanto, a adequada prescrição alimentar por nutricionista auxilia os pacientes a aderirem dieta isenta de glúten de forma equilibrada, sendo feita a escolha de alimentos densos em nutrientes, naturalmente isentos de glúten, e balanceados em macro e micronutrientes. Se a voluntária apresenta dor na face, essa dor pode aumentar levemente após o teste realizado com o algometro. A consulta pode tornar-se cansativa devido a quantidade de questionários e testes que serão realizados. A voluntária estará suscetível aos riscos inerentes ao seu descolamento até a Universidade. A participação nesta pesquisa não traz complicações legais e nenhum dos procedimentos usados oferece riscos à dignidade dos participantes.

Benefícios:

Ao participar desta pesquisa o participante dos grupos sem dor miofascial da musculatura mastigatória não terá nenhum benefício direto. Os voluntários que possuem essa condição podem ter uma melhora do quadro segundo a hipóteses do estudo e, após a finalização do estudo, receberão tratamento reconhecido para a sua disfunção temporomandibular no ambulatório de dor orofacial e distúrbios da ATM da UFC. Nada será pago aos voluntários por sua participação. Esperamos que este estudo traga informações importantes sobre a importância de abordagens multidisciplinares na prática clínica, de forma que o conhecimento que será construído a partir desta pesquisa possa analisar se procedimentos clínicos sem associações multidisciplinares estão sendo assertivos e resolutivos ou não. Ademais, espera-se que o estudo forneça informações importantes sobre a ingestão de glúten e a intensidade da dor de pacientes com dor miofascial crônica e se a redução do mesmo seria significativamente benéfica.

**Comentários e Considerações sobre a Pesquisa:**

Pesquisa de muita relevância, pois espera-se que, após um mês de dieta livre de glúten, as mulheres com dor miofascial apresentem melhora na qualidade de vida e de sono.

**Considerações sobre os Termos de apresentação obrigatória:**

Apresentou os termos obrigatórios. Conforme solicitado, a pesquisadora esclareceu no orçamento quem assumirá as despesas.

**Recomendações:**

Não se aplica.

**Conclusões ou Pendências e Lista de Inadequações:**

Não se aplica.

**Considerações Finais a critério do CEP:**

UFC - UNIVERSIDADE FEDERAL DO CEARÁ /


Continuação do Parecer: 2.439.297

**Este parecer foi elaborado baseado nos documentos abaixo relacionados:**

| Tipo Documento | Arquivo | Postagem | Autor | Situação |
|---|---|---|---|---|
| Informações Básicas do Projeto | PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_976532.pdf | 29/11/2017 19:18:16 | | Aceito |
| Orçamento | ORCAMENTO.pdf | 29/11/2017 19:17:50 | JULIANA ARAUJO OLIVEIRA | Aceito |
| Projeto Detalhado / Brochura Investigador | PROJETO_PLATAFORMA_BRASIL_F.pdf | 14/11/2017 19:27:03 | JULIANA ARAUJO OLIVEIRA | Aceito |
| TCLE / Termos de Assentimento / Justificativa de Ausência | TCLE.pdf | 14/11/2017 19:26:47 | JULIANA ARAUJO OLIVEIRA | Aceito |
| Outros | TERMO_DE_COMPROMISSO.pdf | 25/08/2017 00:06:41 | JULIANA ARAUJO OLIVEIRA | Aceito |
| Outros | CARTA_DE_APRECIACAO.pdf | 25/08/2017 00:06:11 | JULIANA ARAUJO OLIVEIRA | Aceito |
| Declaração de Instituição e Infraestrutura | AUTORIZACAO_INSTITUCIONAL.pdf | 25/08/2017 00:04:14 | JULIANA ARAUJO OLIVEIRA | Aceito |
| Declaração de Pesquisadores | DECLARACAO_DE_CONCORDANCIA.pdf | 25/08/2017 00:03:50 | JULIANA ARAUJO OLIVEIRA | Aceito |
| Cronograma | CRONOGRAMA.pdf | 25/08/2017 00:02:53 | JULIANA ARAUJO OLIVEIRA | Aceito |
| Folha de Rosto | FOLHA_DE_ROSTO.pdf | 25/08/2017 00:02:07 | JULIANA ARAUJO OLIVEIRA | Aceito |

**Situação do Parecer:**
Aprovado

**Necessita Apreciação da CONEP:**
Não

FORTALEZA, 14 de Dezembro de 2017

**Assinado por:**
**FERNANDO ANTONIO FROTA BEZERRA**
**(Coordenador)**

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# ANEXO C – MAGAZINE STANDARDS ARCHIVES OF ORAL BIOLOGY

## GUIDE FOR AUTHORS

Editors-in-Chief:

**Professor S W Cadden, Dundee, Scotland**
**Dr Fionnuala T. Lundy, Northern Ireland, UK**

Archives of Oral Biology is an international journal which aims to publish papers of the highest scientific quality reporting new knowledge from the orofacial region including:
- developmental biology
- cell and molecular biology
- molecular genetics
- immunology
- pathogenesis
- microbiology
- biology of dental caries and periodontal disease
- forensic dentistry
- neuroscience
- salivary biology
- mastication and swallowing
- comparative anatomy
- paeleodontology

Archives of Oral Biology will also publish expert reviews and articles concerned with advancement in relevant methodologies. The journal will consider clinical papers only where they make a significant contribution to the understanding of a disease process.

These guidelines generally follow the Uniform Requirements for Manuscripts Submitted to Biomedical Journals

### *Types of Contribution*

Original papers and review articles are welcomed. There will be no differentiation on the basis of length into full or short communications. Editorial commentaries will also be considered but only by invitation. All submissions will be refereed.

*Page charges*
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### *Submission checklist*

You should use this list to carry out a final check of your submission before you send it to the journal for review. Please check all relevant sections in this Guide for Authors for more details.

**Ensure that the following items are present:**

One author has been designated as the corresponding author with contact details:
- E-mail address
- Full postal address

All necessary files have been uploaded:
*Manuscript*:
- Include keywords
- All figures (include relevant captions)
- All tables (including titles, description, footnotes)
- Ensure all figure and table citations in the text match the files provided
- Indicate clearly if color should be used for any figures in print

*Graphical Abstracts* (where applicable)
*Highlights* (where applicable)
*Supplemental files* (where applicable)

Further considerations
- Manuscript has been 'spell checked' and 'grammar checked'
- All references mentioned in the Reference List are cited in the text, and vice versa

- Permission has been obtained for use of copyrighted material from other sources (including the Internet)
- Relevant declarations of interest have been made
- Declarations of authors' contributions have been made if there are four or more authors
- Journal policies detailed in this guide have been reviewed
- Referee suggestions and contact details provided, based on journal requirements

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## BEFORE YOU BEGIN

### *Ethics in publishing*

Please see our information pages on Ethics in publishing and Ethical guidelines for journal publication.

### *Studies in humans and animals*

If the work involves the use of human subjects, the author should ensure that the work described has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. The manuscript should be in line with the Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals and aim for the inclusion of representative human populations (sex, age and ethnicity) as per those recommendations. The terms sex and gender should be used correctly.

Authors should include a statement in the manuscript that informed consent was obtained for experimentation with human subjects. The privacy rights of human subjects must always be observed.

All animal experiments should comply with the ARRIVE guidelines and should be carried out in accordance with the U.K. Animals (Scientific Procedures) Act, 1986 and associated guidelines, EU Directive 2010/63/EU for animal experiments, or the National Institutes of Health guide for the care and use of Laboratory animals (NIH Publications No. 8023, revised 1978) and the authors should clearly indicate in the manuscript that such guidelines have been followed. The sex of animals must be indicated, and where appropriate, the influence (or association) of sex on the results of the study.

### *Declaration of interest*

All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential competing interests include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. Authors must disclose any interests in two places: 1. A summary declaration of interest statement in the title page file (if double-blind) or the manuscript file (if single-blind). If there are no interests to declare then please state this: 'Declarations of interest: none'. This summary statement will be ultimately published if the article is accepted. 2. Detailed disclosures as part of a separate Declaration of Interest form, which forms part of the journal's official records. It is important for potential interests to be declared in both places and that the information matches. More information.

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Submission of an article implies that the work described has not been published previously (except in the form of an abstract or as part of a published lecture or academic thesis or as an electronic preprint, see 'Multiple, redundant or concurrent publication' section of our ethics policy for more information), that it is not under consideration for publication elsewhere, that its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically, without the written consent of the copyright-holder. To verify originality, your article is likely to be checked by the originality detection service CrossCheck.

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### Author contributions

For transparency, we encourage authors to submit an author statement file outlining their individual contributions to the paper using the relevant CRediT roles: Conceptualization; Data curation; Formal analysis; Funding acquisition; Investigation; Methodology; Project administration; Resources; Software; Supervision; Validation; Visualization; Roles/Writing - original draft; Writing - review & editing. Authorship statements should be formatted with the names of authors first and CRediT role(s) following. More details and an example

### Authorship

All authors should have made substantial contributions to all of the following: (1) the conception and design of the study, or acquisition of data, or analysis and interpretation of data, (2) drafting the article or revising it critically for important intellectual content, (3) final approval of the version to be submitted.

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## PREPARATION

### Peer review

This journal operates a single anonymized review process. All contributions will be initially assessed by the editor for suitability for the journal. Papers deemed suitable are then typically sent to a minimum of two independent expert reviewers to assess the scientific quality of the paper. The Editor is responsible for the final decision regarding acceptance or rejection of articles. The Editor's decision is final. Editors are not involved in decisions about papers which they have written themselves or have been written by family members or colleagues or which relate to products or services in which the editor has an interest. Any such submission is subject to all of the journal's usual procedures, with peer review handled independently of the relevant editor and their research groups. More information on types of peer review.

### REVISED SUBMISSIONS

When submitting the revised manuscript, please make sure that you upload the final version of the paper with the changes highlighted. Please remove the old version(s) of the manuscript before submitting the revised version.

*Use of word processing software*

It is important that the file be saved in the native format of the word processor used. The text should be in single-column format. Keep the layout of the text as simple as possible. Most formatting codes will be removed and replaced on processing the article. In particular, do not use the word processor's options to justify text or to hyphenate words. However, do use bold face, italics, subscripts, superscripts etc. When preparing tables, if you are using a table grid, use only one grid for each individual table and not a grid for each row. If no grid is used, use tabs, not spaces, to align columns. The electronic text should be prepared in a way very similar to that of conventional manuscripts (see also the Guide to Publishing with Elsevier). Note that source files of figures, tables and text graphics will be required whether or not you embed your figures in the text. See also the section on Electronic artwork.

To minimize unnecessary errors you are strongly advised to use the 'spell-check' and 'grammar-check' functions of your word processor.

## Article structure

*Manuscript Structure*

Follow this order when typing manuscripts: Title, Authors, Affiliations, Abstract, Keywords, Main text (Introduction, Materials & Methods, Results, Discussion for an original paper), Acknowledgments, Appendix, References, Figure Captions and then Tables. Do not import the Figures or Tables into your text. The corresponding author should be identified with an asterisk and footnote. All other footnotes (except for table footnotes) should be identified with superscript Arabic numbers.

*Introduction*

This should be a succinct statement of the problem investigated within the context of a brief review of the relevant literature. Literature directly relevant to any inferences or argument presented in the Discussion should in general be reserved for that section. The introduction may conclude with the reason for doing the work but should not state what was done nor the findings.

*Materials and Methods*

Enough detail must be given here so that another worker can repeat the procedures exactly. Where the materials and methods were exactly as in a previous paper, it is not necessary to repeat all the details but sufficient information must be given for the reader to comprehend what was done without having to consult the earlier work.

Authors are requested to make plain that the conditions of animal and human experimentation are as outlined in the "Ethics" and "Studies on Animals" sections above

*Results or Findings*

These should be given clearly and concisely. Care should be taken to avoid drawing inferences that belong to the Discussion. Data may be presented in various forms such as histograms or tables but, in view of pressure on space, presentation of the same data in more than one form is unacceptable.

*Discussion*

This should explore the significance of the results of the work, not repeat them. A combined Results and Discussion section is occasionally appropriate. Avoid extensive citations and discussion of published literature.

*Conclusions*

The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion section.

## Essential title page information

- ***Title.*** Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.
- ***Author names and affiliations.*** Please clearly indicate the given name(s) and family name(s) of each author and check that all names are accurately spelled. You can add your name between parentheses in your own script behind the English transliteration. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lower-case superscript letter immediately after the author's name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name and, if available, the e-mail address of each author.
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- ***Present/permanent address.*** If an author has moved since the work described in the article was done, or was visiting at the time, a 'Present address' (or 'Permanent address') may be indicated as a footnote to that author's name. The address at which the author actually did the work must be retained as the main, affiliation address. Superscript Arabic numerals are used for such footnotes.

As titles frequently stand alone in indexes, bibliographic journals etc., and indexing of papers is, to an increasing extent, becoming computerized from key words in the titles, it is important that titles should be as concise and informative as possible. Thus the animal species to which the observations refer should always be given and it is desirable to indicate the type of method on which the observations

are based, e.g. chemical, bacteriological, electron-microscopic, histochemical, etc. A "running title" of not more than 40 letters and spaces must also be supplied. A keyword index must be supplied for each paper.

### Highlights

Highlights are mandatory for this journal as they help increase the discoverability of your article via search engines. They consist of a short collection of bullet points that capture the novel results of your research as well as new methods that were used during the study (if any). Please have a look at the examples here: example Highlights.

Highlights should be submitted in a separate editable file in the online submission system. Please use 'Highlights' in the file name and include 3 to 5 bullet points (maximum 85 characters, including spaces, per bullet point).

### Structured abstract

The paper should be prefaced by an abstract aimed at giving the entire paper in miniature. Abstracts should be no longer than 250 words and should be structured as per the guidelines published in the Journal of the American Medical Association (JAMA 1995; 273: 27-34). In brief, the abstract should be divided into the following sections: (1) Objective; (2) Design - if clinical, to include setting, selection of patients, details on the intervention, outcome measures, etc.; if laboratory research, to include details on methods; (3) Results; (4) Conclusions.

### Keywords

Immediately after the abstract, provide a maximum of 6 keywords, using British spelling and avoiding general and plural terms and multiple concepts (avoid, for example, 'and', 'of'). Be sparing with abbreviations: only abbreviations firmly established in the field may be eligible. These keywords will be used for indexing purposes.

### Abbreviations

As Archives of Oral Biology is a journal with a multidisciplinary readership, abbreviations, except those universally understood such as mm, g, min. u.v., w/v and those listed below, should be avoided if possible. Examples of abbreviations which may be used without definition are: ADP, AMP, ATP, DEAE-cellulose, DNA, RNA, EDTA, EMG, tris.
Other abbreviations used to improve legibility should be listed as a footnote on the title page as well as being defined in both the abstract and the main text on first usage. Chemical symbols may be used for elements, groups and simple compounds, but excessive use should be avoided. Abbreviations other than the above should not be used in titles and even these should be avoided if possible.

*Acknowledgements*
Collate acknowledgements in a separate section at the end of the article before the references and do not, therefore, include them on the title page, as a footnote to the title or otherwise. List here those individuals who provided help during the research (e.g., providing language help, writing assistance or proof reading the article, etc.) but who did not meet all the criteria for authorship (see Authorship section above).

*Formatting of funding sources*
List funding sources in this standard way to facilitate compliance to funder's requirements:

Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

It is not necessary to include detailed descriptions on the program or type of grants and awards. When funding is from a block grant or other resources available to a university, college, or other research institution, submit the name of the institute or organization that provided the funding.

If no funding has been provided for the research, please include the following sentence:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

## Bacterial nomenclature

Organisms should be referred to by their scientific names according to the binomial system. When first mentioned the name should be spelt in full and in italics. Afterwards the genus should be abbreviated to its initial letter, e.g. 'S. aureus' not 'Staph. aureus'. If abbreviation is likely to cause confusion or render the intended meaning unclear, the names of microbes should be spelt in full. Only those names which were included in the Approved List of Bacterial Names, Int J Syst Bacteriol 1980; 30: 225-420 and those which have been validly published in the Int J Syst Bacteriol since 1 January 1980 have standing in nomenclature. If there is good reason to use a name that does not have standing in nomenclature, the names should be enclosed in quotation marks and an appropriate statement concerning the nomenclatural status of the name should be made in the text (for an example see Int J Syst Bacteriol 1980; 30: 547-556). When the genus alone is used as a noun or adjective, use lower case Roman not italic, e.g.'organisms were staphylococci' and 'streptococcal infection'. If the genus is specifically referred to use italics e.g. 'organisms of the genus Staphylococcus'. For genus in plural, use lower case roman e.g. 'salmonellae'; plurals may be anglicized e.g.'salmonellas'. For trivial names, use lower case Roman e.g. 'meningococcus'

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Whilst it is accepted that authors sometimes need to manipulate images for clarity, manipulation for purposes of deception or fraud will be seen as scientific ethical abuse and will be dealt with accordingly. For graphical images, this journal is applying the following policy: no specific feature within an image may be enhanced, obscured, moved, removed, or introduced. Adjustments of brightness, contrast, or color balance are acceptable if and as long as they do not obscure or eliminate any information present in the original. Nonlinear adjustments (e.g. changes to gamma settings) must be disclosed in the figure legend.

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*General points*

- Make sure you use uniform lettering and sizing of your original artwork.
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- Number the illustrations according to their sequence in the text.
- Use a logical naming convention for your artwork files.
- Provide captions to illustrations separately.
- Size the illustrations close to the desired dimensions of the published version.
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Regardless of the application used other than Microsoft Office, when your electronic artwork is finalized, please "Save as" or convert the images to one of the following formats (note the resolution requirements for line drawings, halftones, and line/halftone combinations given below):

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TIFF (or JPEG): Color or grayscale photographs (halftones), keep to a minimum of 300 dpi.

TIFF (or JPEG): Bitmapped (pure black & white pixels) line drawings, keep to a minimum of 1000 dpi.

TIFF (or JPEG): Combinations bitmapped line/half-tone (color or grayscale), keep to a minimum of 500 dpi.

**Please do not:**

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- Submit graphics that are disproportionately large for the content.

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## Tables

Please submit tables as editable text and not as images. Tables can be placed either next to the relevant text in the article, or on separate page(s) at the end. Number tables consecutively in accordance with their appearance in the text and place any table notes below the table body. Be sparing in the use of tables and ensure that the data presented in them do not duplicate results described elsewhere in the article. Please avoid using vertical rules and shading in table cells.

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*List:* references should be arranged first alphabetically and then further sorted chronologically if necessary. More than one reference from the same author(s) in the same year must be identified by the letters 'a', 'b', 'c', etc., placed after the year of publication.
*Examples:*
Reference to a journal publication:
Van der Geer, J., Hanraads, J. A. J., & Lupton, R. A. (2010). The art of writing a scientific article. *Journal of Scientific Communications, 163*, 51–59. https://doi.org/10.1016/j.Sc.2010.00372.
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Van der Geer, J., Hanraads, J. A. J., & Lupton, R. A. (2018). The art of writing a scientific article. *Heliyon, 19*, e00205. https://doi.org/10.1016/j.heliyon.2018.e00205.
Reference to a book:
Strunk, W., Jr., & White, E. B. (2000). *The elements of style*. (4th ed.). New York: Longman, (Chapter 4).
Reference to a chapter in an edited book:
Mettam, G. R., & Adams, L. B. (2009). How to prepare an electronic version of your article. In B. S. Jones, & R. Z. Smith (Eds.), *Introduction to the electronic age* (pp. 281–304). New York: E-Publishing Inc.
Reference to a website:
Cancer Research UK. Cancer statistics reports for the UK. (2003). http://www.cancerresearchuk.org/aboutcancer/statistics/cancerstatsreport/ Accessed 13 March 2003.
Reference to a dataset:
[dataset] Oguro, M., Imahiro, S., Saito, S., Nakashizuka, T. (2015). *Mortality data for Japanese oak wilt disease and surrounding forest compositions*. Mendeley Data, v1. https://doi.org/10.17632/xwj98nb39r.1.
Reference to a conference paper or poster presentation:

Engle, E.K., Cash, T.F., & Jarry, J.L. (2009, November). The Body Image Behaviours Inventory-3: Development and validation of the Body Image Compulsive Actions and Body Image Avoidance Scales. Poster session presentation at the meeting of the Association for Behavioural and Cognitive Therapies, New York, NY.

### *Data visualization*

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### Statistical analysis

Authors should ensure that the presentation and statistical testing of data are appropriate and should seek the advice of a statistician if necessary. A number of common errors should be avoided, e.g.: -

• Use of parametric tests when non-parametric tests are required

• Inconsistencies between summary statistics and statistical tests such as giving means and standard deviations for data which were analysed with non-parametric tests.

• Multiple comparisons undertaken with multiple t tests or non-parametric equivalents rather than with analysis of variance (ANOVA) or non-parametric equivalents.

• Post hoc tests being used following an ANOVA which has yielded a non-significant result.

• Incomplete names for tests (e.g. stating "Student's t test" without qualifying it by stating "single sample", "paired" or "independent sample")

• n values being given in a way which obscures how many independent samples there were (e.g. stating simply n=50 when 10 samples/measurements were obtained from each of 5 animals/human subjects).

• Stating that P=0.000 (a figure which is generated by some computer packages). The correct statement (in this case) is P<0.0005.

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