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## STUDY PROTOCOL

# Effect of the Pilates method on women with temporomandibular disorders: A study protocol for a randomized controlled trial



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Received 20 March 2015; received in revised form 19 June 2015; accepted 24 June 2015

### KEYWORDS

Temporomandibular joint disorders;  
Posture;  
Pain;  
Clinical trial;  
Pilates

**Summary** *Background:* There is no consensus regarding the influence of temporomandibular disorders (TMD) on postural changes, but it is believed that an imbalance in one may influence the other. The aim of this study is to evaluate changes in the level of pain, the severity of TMD, the EMG activity of masticatory muscles and posture of young women undergoing training in Pilates, as well as correlating postural changes, pain level, severity of TMD and EMG activity of masticatory muscles.

*Methods/Design:* A randomized clinical trial with blinded assessors will be held. 40 patients divided randomly into two groups will be assessed. The control group will receive conventional treatment with occlusal splint while the intervention group, in addition to conventional treatment will participate in Pilates sessions. Both groups will consist of women aged 18–35 years with TMD and pain. The research follow-up period will be 15 weeks.

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*Abbreviations:* TMJ, Temporomandibular Joint; TMD, Temporomandibular Disorder; RDC/TMD, Research Diagnostic Criteria for Temporomandibular Disorders; BMI, Body Mass Index; IG, Intervention Group; CG, Control Group; VAS, Visual Analogue Scale; MFIQ, Mandibular Function Impairment Questionnaire; EMG, Electromyography.

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<http://dx.doi.org/10.1016/j.jbmt.2015.06.011>

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## Background

The temporomandibular joint (TMJ) is a very specialized structure of the stomatognathic system that is subject to impairment of neurological, orthopedic and/or musculoskeletal origin, resulting in temporomandibular disorders (TMD) (Matta and Honorato, 2003). TMD occurs in both sexes and all age groups, affecting about 7–15% of the population, but its incidence is higher in adult women of working age (Felício et al., 2012), with a ratio of five women for every man (Biasotto-Gonzalez, 2005).

The etiology of TMD is multifactorial (Chaves et al., 2008), but some factors can be highlighted, such as malocclusion, jaw or TMJ trauma, muscle disorders, parafunctional habits (Guidelines, 2003) and emotional or postural problems (Oliveira et al., 2006).

Data on the influence of changes in the stomatognathic system related to postural changes are still quite controversial, but it is believed that diseases of this system can induce pain and/or dysfunction in other systems through the central command or by reflex connectivity between the two anatomical regions (Browne et al., 1998).

In this sense, some studies claim that the position of the head and cervical spine affects the positioning of the jaw and the hyoid bone, and that consequently these changes may be associated with craniomandibular pain (Andrade et al., 2007; Rocabado, 1983; Visscher et al., 2002). While one study has suggested that treating TMD leads to a significant reduction in cervical symptoms in these patients (Von Piekartz and Lütke, 2011), other studies reported no such relationship (Armijo-Olivo et al., 2011; Iunes et al., 2009; Matheus et al., 2009). Several techniques, among them the use of splints, have been used to treat TMD and its associated problems (Maluf et al., 2008), however, few randomized clinical trials have attempted to evaluate the effect of global treatments in order to alleviate the signs and symptoms of TMD.

It is known that treatments using exercise based on Pilates principles have been widely used as a means of assistance to patients with pain, especially in the spinal column (Airaksinen et al., 2006; Delitto et al., 2012; La Touche et al., 2008; Ozer Kaya et al., 2012), but, to the best of our knowledge, there are no studies relating to Pilates-based treatments in patients with TMD.

Pilates can be performed on the ground, called “Mat Pilates”, or using specific devices (Muscolino and Cipriani, 2004). For the method to be considered complete, six essential principles must be taken into account: breath control, concentration, centering, precision and fluid motion (Da Silva and Mannrich, 2009).

Thus, whereas the Pilates Method is presented as a good tool for the treatment of discomfort in the spine, which may be related to the TMD, the objective of this project is to evaluate whether the Pilates Method is capable of modifying the level of pain, the severity of TMD, the electromyographic (EMG) activity of the masticatory muscles and posture of women with TMD and, if there are changes, to identify the correlation between them.

## Methods/design

### Study design and ethical approval

This will be a randomized controlled trial with blinded evaluators.

This study is registered in Plataforma Brasil, and was approved by the Research Ethics Committee of the Federal University of Rio Grande do Sul under number: 817 321 on 02/10/2014, and has been approved for publication in clinicalTrials under the number ID: NCT 02292355, on 06/11/2014.

All patients will sign the informed consent term, prepared in compliance with Resolution 466/2012 of the Brazilian Health Council.

### Participants

Request for participants will be published in major newspapers and through social media. All respondents will be informed of all the study procedures, and those that are interested, will be provided with a brief introduction about the selection process. Detailed information about participants will be given in the eligibility criteria.

### Inclusion criteria

Considering the comparatively higher incidence of TMD in adult women of working age, women between 18 and 35 years old, diagnosed with temporomandibular disorder according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) (Kosminsky et al., 2004), complaining of pain in the TMJ region, classified as greater than 2.5 (moderate to high) by the Visual Analogue Scale.

### Exclusion criteria

The exclusion criteria consist of: body mass index (BMI) greater than 35 kg/m<sup>2</sup>; diagnosis of other disorders of the stomatognathic system; a history of any surgical procedure on the face, teeth and spine in the last six months; severe pathologies of the spine (fractures, inflammatory diseases or tumors); intellectual disability or inability to give consistent information; ongoing treatment for TMD, whether physical, medical or dental therapy throughout the study period; practicing Pilates in the last six months; pregnancy; the use of dental prosthesis or appliance; a history of trauma to the face and/or temporomandibular joint in the last six months; temporomandibular joint dislocation in the last six months; dental flaws between canines and molars; cross bite, overbite or open bite; undershot or overshot jaw; vestibular disorders that may interfere with the balance; the use of continuous medication for pain or inflammation.

### Benefits and risks

This study provides no additional risks to those involving the usual practice of the Pilates exercises. Any discomfort associated with practice of physical activity, including the

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