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# The Comparison of Musculoskeletal Variables in Females With and Without Functional Abdominal Bloating: A Protocol Study

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## Introduction

Functional abdominal bloating (FAB), one of the common functional gastrointestinal disorders (FGIDs), is a subjective sensation of increased abdominal pressure or trapped gas. Bloating may or may not be associated with an objective increase in abdominal girth (abdominal distension) [1]. According to the Rome IV criteria, an international diagnostic algorithm of FGIDs, FAB is defined as a single entity and is not part of any other FGIDs [2]. Also, the onset of symptoms should be at least

# ABSTRACT

Background: Functional abdominal bloating (FAB) is a subjective sensation of increased abdominal pressure. Musculoskeletal factors may be related to functional abdominal bloating, but this association has not been investigated. The present study compares trunk-related musculoskeletal factors (spinal alignment and abdominal muscle function) in females with and without FAB. Methods: This is a protocol study of a case-control study that will be conducted in females with (n=45) and without FAB (n=45), aged 18-60 years. A specially designed load cell setup and a flexicurve ruler will be used for the measurements of static abdominal muscle force and endurance, thoracic kyphosis, and lumbar lordosis, respectively. Additionally, skeletal muscle mass will be measured using body composition analysis. Depending on data distribution, an independent t-test or Mann-Whitney test will be used to determine differences in variables between the two groups. A multiple logistic regression will be used to investigate the adjusted associations of the trunk-related musculoskeletal variables and associations of the trunk-related musculoskeletal variables with functional abdominal bloating.

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six months before diagnosis, and the recurrent feeling of bloating must have been present in the last three months [1, 2]. While bloating affects up to 30% of adults, the prevalence of FAB is unknown, and the condition is more common and severe in females than males [1]. Known physical and psychological complications of FAB include stomach pain, discomfort, stress, anxiety, and depressive disorders, all of which have a negative impact on daily activities and quality of life in adults [3, 4]. The etiology of FAB has not been fully established; however, studies have identified several risk factors, including excessive intestinal gas, increased intra-abdominal fat, weight gain, and psychological problems [5].

One contributing variable to FAB may be the weakness of abdominal muscles [6]. In a healthy person postprandial,

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the diaphragm relaxes, the abdominal muscles contract, and the capacity of the abdominal cavity increases without abdominal protrusion [7]. However, adults with FAB show diaphragm-abdominal dyssynergia. Abdominal muscles, especially the anti-gravity internal obliques, relax, and the diaphragm contracts. This leads to a disruption in the distribution of abdominal contents and abdominal protrusion and may result in weakness of the abdominal muscles [5]. Although this dyssynergia has been reported in several studies [8, 9], no studies have examined the association between abdominal muscle function and bloating symptoms in a population affected by FAB. Sullivan et al. reported that bloating patients had weaker abdominal muscles (unable to do sit-up tests) than the control group [6], but the affected group was not diagnosed with FAB. Also, valid and accurate muscle measurements are needed to quantify and determine abdominal muscle force in a population affected by FAB.

Sagittal spinal curvatures may affect the distribution of abdominal contents and relate to gut function [10-12]. It is hypothesized that thoracic hyperkyphosis (excessive thoracic kyphosis) decreases the vertical abdominal cavity [5], and exaggerated lumbar lordosis redistributes abdominal contents, causing abdominal wall protrusions [13]. Alvarez et al. reported that examining patients with bloating in a supine position with extended hips and knees led to distension and bloating symptoms. However, when participants flexed their knees, the symptoms disappeared. Voluntary hyperlordosis was associated with an exaggeration of bloating/distension [13]. Decreased muscle mass can affect sagittal spinal alignment and, consequently, may affect gastrointestinal (GI) function. However, no study has evaluated the associations between spinal-related factors (skeletal muscle mass and spinal alignments) and FAB. Several studies have reported associations between spinalrelated musculoskeletal factors and gastroesophageal reflux disease (GERD). It is hypothesized that a flexed posture can increase intra-abdominal pressure, which induces pressure on the esophagus and predisposes patients to GERD. In 2009, Miyakoshi et al. examined the associations between spinal factors (thoracic and lumbar kyphosis, vertebral fracture) and GERD in 112 people with osteoporosis. They reported that GERD had significant associations with decreased lumbar lordosis (r=0.57, P<0.001) and the number of thoracic (r=0.21, P<0.001)P=0.02) and lumbar (r=0.47, P<0.001) vertebral fractures [14]. This result has been reported in other cross-sectional and longitudinal studies [15, 16].

Given the confirmed role of trunk muscle force in spinal integrity and the fact that increased kyphosis of the spine and decreased skeletal muscle mass are well-established impairments for GERD, it appears that these modifiable factors can affect the digestive system. However, no study has found a link between spinal-related factors and FAB. Because these factors are modifiable by exercise, further studies exploring spinal factors and abdominal muscles in FAB can help prioritize prevention strategies and enhance current interventions that target only drug or diet regimes. Therefore, the present study aims to investigate and compare spinal-related factors (thoracic kyphosis, lumbar lordosis, abdominal muscle strength and endurance, and skeletal muscle mass) in females with and without FAB. We hypothesize that the mentioned factors are significantly different between groups.

# Methods

This study is the protocol of a case-control design. After approval by the Ethical Committee of Isfahan University of Medical Sciences (IR.MUI.MED.REC.1400.067), the study will be conducted in 2023 at the Institute of Primary Prevention of Non-Communicable Diseases of Isfahan University of Medical Sciences, Isfahan, Iran. Participants will be recruited from the Isfahan Functional Disorders (ISFUN), a population-based longitudinal study conducted on a sample of adults aged 18-60 years in the Kerdabad area of Isfahan over four years (2017-2022) [17]. From the original population of 1930 participants, 194 were identified as having FAB based on Rome IV criteria. From this list of 194 people with FAB, a random sample will be selected (using a table of random numbers) to form the case group. Similarly, a random sample will be selected as the control group from the list of people without any gastrointestinal disorder. Thus, the case group will comprise females aged 18-60 living in the Kerdabad area of Isfahan who have had symptoms for at least six months before diagnosis and have experienced recurrent bloating at least one day a week during the last three months [2]. The control group will consist of females aged 18-60 years living in the Kerdabad area of Isfahan who do not have any gastrointestinal disorders.

The inclusion criteria are females aged 18-60 with a body mass index (BMI) less than 30 kg/m<sup>2</sup>. After receiving a complete explanation of the study's purpose and methods and signing a written consent, each participant will be assessed by an internal specialist, a physical therapist, and a nutritionist. Participants with a deformity, fracture, or dislocation of the spine, spinal malignancy, chemotherapy, rheumatology conditions, neurological disorders, or any cognitive impairments will be excluded. Participants with a history of current back pain, back pain requiring medical attention, or a history of stomach operation in the past year will also be excluded. Other exclusion criteria include current pregnancy, use of medications over the prior 12 months that could affect muscle performance, central nervous system or equilibrium, use of various antibiotics, bismuth, probiotic drugs during the last three months, current use of Mebeverine, Dimethicone, Dicyclomine, Hyoscine, Belladonna, adherence to special diets such as a ketogenic diet, vegetarianism, Fermentable Oligosaccharides, Disaccharides, Monosaccharides AND Polyols (FODMAP), and smoking and alcohol consumption.

A gastroenterologist will then assess each participant to confirm the presence of FAB in the case group and the absence of any FGIDs in the control group based on Rome IV criteria. This specialist will be blinded to the results of the ISFUN study. We will perform individual matching to control for confounding factors such as age and BMI. Each case will be matched to a control based

## on age and BMI.

# Sample Size Calculation

The sample size was calculated using G\*Power software based on the logistic regression model. Under the assumptions H0: P=0.5 and H1: P=0.7, the odds ratio (OR) was calculated as

$$OR = \frac{\frac{0.7}{0.3}}{\frac{0.5}{0.5}} = 2.33$$

With a significance level ( $\alpha$ ) of 0.05 and a power of 90 percent, the required sample size was determined to be 90 (45 for each group) [18].

# Measurements

# Sagittal Curvatures of Spine

A flexicurve ruler will be used to measure thoracic kyphosis and lumbar lordosis. Initially, participants will be asked to stand in their usual relaxed posture. The spinous process of C7 and the superior aspect of the sacrum (S1) will be marked, and the flexicurve ruler will be placed over the spinous processes of the thoracic and lumbar regions to fit the contours of the thoracic and lumbar curves (Figure 1a). The molded ruler will then be carefully removed and traced over a piece of graphic paper, and the two ends of the trace (C7, S1) will be connected with a vertical line. Subsequently, the deepest distance between the curve and the vertical line will be measured as thoracic and lumbar width (Figure 1b) [19]. The Kyphosis Index (KI) and Lordosis Index (LI) will be calculated using the following formulae: KI=thoracic width/thoracic length×100

# LI=lumbar width/lumbar length×100 [19].

This procedure will be repeated three times, and the mean of KI and LI will be analyzed. A very high reliability and a moderate level of validity have been reported for the Flexicurve Index [20].

#### Anterior Abdominal Muscle Function

For quantifying force, as a measure of isometric

strength, and endurance, an "S" shape load cell will be used in a sitting position. The designed setup includes a stool, a fixed vertical bar, an "S" shape load cell, and a vest with four inflexible ropes for connecting the participant to the load cell (Figure 2a). After a 5-minute walking warm-up, the participants will be instructed to sit on the stool in a neutral, upright position with their back to the load cell, their hips and knees flexed to 90 degrees, and their arms crossed over the chest [21]. Thigh and anterior superior iliac spine (ASIS) restraints will be secured to the legs and back support of the stool, respectively [22]. The load cell will be aligned with the scapula, and the participants will be connected to the load cell through the four inflexible ropes of the vest. The participants will be instructed to pull their trunk forward maximally and maintain this maximum force for three to five seconds (Figure 2b). The maximum force, separated by 60-second rest periods, will be documented as anterior abdominal muscle strength (kg) [23, 24].

For endurance measurement, participants are instructed to perform a sustained contraction at 50% of the maximum force as their target. The test will be stopped when the force can no longer be maintained above 90% of the target level [25].

The setup demonstrated high to very high reliability for isometric trunk strength measurements (ICC>0.86 for flexors, ICC>0.95 for extensors) [24, 26] and high reliability (ICC>0.80) for back endurance measurements in females [26]. Furthermore, the validity of the instrument was confirmed by a high correlation between the load cell measurements and calibrated external forces (r=0.99, P<0.001) [26].

#### Skeletal Muscle Mass Measurement

Bioelectrical impedance analysis (BIA) will be used to measure skeletal muscle mass. The reliability and validity of this device have been reported as ICC>0.95 and r>0.79, respectively [27]. Participants should stand with extended arms and hang down in a natural standing position. The index fingers should be in contact with the hand electrodes, and the soles of the feet should be in



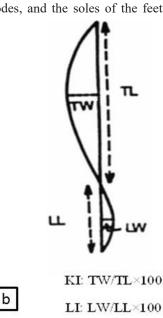


Figure 1: a. Modeled ruler to the spine; b. Flexicurve calculation: KI=thoracic width (TW)/thoracic length (TL)×100; LI=lumbar width (LW)/lumbar length (LL)×100

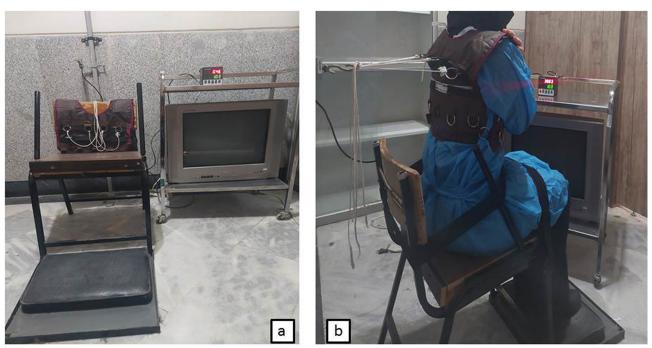


Figure 2: a. The designed setup for anterior abdominal wall muscles: Vertical bar, An" S" shape load cell, vest & rope to the load cell, monitor; b. static measurement of abdominal muscle function in sitting position. The load cell is aligned with the midline and with the scapula, then participant pulls trunk front maximally.

contact with the foot electrodes [28]. The data output of Inbody 270 (Inbody Co., Seoul, Korea) includes total skeletal muscle mass (SMM) and lean mass of the four limbs normalized to height (SMI) [28, 29].

# Statistical Analysis

The analyses will be performed using PSS statistical software (version 24.0, IBM, Armonk, USA) with an  $\alpha$  error of 0.05. An independent sample t-test will be used to compare variables between groups. Additionally, a logistic regression model will be employed to determine the main predictor of FAB.

## Discussion

Due to the anatomical proximity of abdominal muscles and spinal curvatures to the gastrointestinal tract, these musculoskeletal factors may play a significant role in the normal function of the gastrointestinal tract. Some evidence has reported associations between certain FGIDs or other gastrointestinal disorders and musculoskeletal factors. However, the associations between spinal curvatures, abdominal muscles, and FAB remain questionable. The present study is the first to identify the role of these musculoskeletal factors in FAB. We expect our results will help identify the influence of these musculoskeletal variables on FAB, further illuminating understanding and treatment options for this disorder.

This study, like others, has its limitations and challenges. We initially planned to design a populationbased case-control study. However, due to the absence of a comprehensive system for registering information about gastrointestinal patients in the city, we encountered numerous complexities and difficulties in designing a community-based case-control study with incident cases. Given the opportunity to use the baseline data from the ISFUN study (the first cohort study in the Middle Eastern region) aimed at investigating functional somatic syndromes (such as functional gastrointestinal disorders) and considering that musculoskeletal changes are more likely to be observed in chronic cases, we decided to use prevalent cases, which are valuable in their own right.

# Conclusion

Understanding knowledge of the influence of spinal curvatures and abdominal muscle function on FAB will improve our understanding of the role of these musculoskeletal variables in the development of FAB, and may lead to new methods for treating this type of FGIDs.

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## Conflict of Interest: None declared.

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