



Effect of High-Intensity Focused Ultrasound on Sleep Quality Measures in Obese Doubled Chin Women: a Randomized Controlled Trial

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ABSTRACT

INTRODUCTION. The double chin is an excessive accumulation of fat in the pre- and post-platysma that can manifest in various forms and sizes. Thin individuals might manifest a double chin, similar to those who are afflicted by obesity. It may result in a reduction in the definition of the mandible and give the perception of obesity or aging.

AIM. To evaluate any effect of High-Intensity Focused Ultrasound (HIFU) on sleep quality measures in obese women with a double chin.

MATERIALS AND METHODS. Typically, 60 women aged 35–50 years were selected from AL Qasr-Alaini Hospital and were equally divided at random into groups A and B ($n = 30$). Group A (HIFU with exercise) received 3 HIFU sessions, a session/month/three months with adouble chin exercise (daily). Group B (Exercise group) received daily double chin exercises for only three months. Pre- and post-intervention, we assessed body mass index (BMI), hormonal changes (cortisol level), submental fat, and sleep apnea Apnea-Hypopnea Index.

RESULTS AND DISCUSSION. The results revealed no significant effect in age, weight, and height in both groups ($p > 0.05$). Post-three-month intervention, group A demonstrated a statistically significant decrease in the predetermined assessed outcomes compared to group B ($p < 0.001$).

CONCLUSION. There was established a significant impact of HIFU on measurements of sleep quality in obese doubled chin women.

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KEYWORDS: doubled chin, focused ultrasound, sleep quality, obesity, body mass index

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Влияние высокоинтенсивного фокусированного ультразвука на показатели качества сна у женщин с локальным жировым отложением в области подбородка: рандомизированное контролируемое исследование

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РЕЗЮМЕ

ВВЕДЕНИЕ. Второй подбородок — это избыточное накопление жира в пред- и постплатизменной области, которое может проявляться в различных формах и размерах. У худых людей двойной подбородок может проявляться так же, как и у тех, кто страдает от ожирения. Он может привести к уменьшению рельефа нижней челюсти и создать впечатление ожирения или старения. **ЦЕЛЬ.** Оценить влияние высокоинтенсивного фокусированного ультразвука (HIFU) на показатели качества сна у женщин с локальным жировым отложением в области подбородка.

МАТЕРИАЛЫ И МЕТОДЫ. Для исследования были отобраны 60 женщин в возрасте 35–50 лет на базе больницы Аль-Каср-Алайни, которые были разделены в произвольном порядке на группы А и В ($n = 30$). Группа А посещала 3 сеанса высокоинтенсивного фокусированного ультразвука (HIFU с упражнениями), один сеанс в месяц/три месяца с упражнениями для двойного подбородка (ежедневно). Группа В (группа упражнений) получала ежедневные упражнения для двойного подбородка в течение трех месяцев. До и после вмешательства оценивались индекс массы тела, гормональные изменения (уровень кортизола), количество субментального жира и индекс апноэ-гипопноэ во сне.

РЕЗУЛЬТАТЫ И ОБСУЖДЕНИЕ. Результаты не выявили значительного влияния возраста, веса и роста в обеих группах ($p > 0,05$). После трехмесячного вмешательства в группе А наблюдалось статистически значимое снижение заранее определенных результатов по сравнению с группой В ($p < 0,001$).

ЗАКЛЮЧЕНИЕ. Установлено значительное влияние высокоинтенсивного фокусированного ультразвука (HIFU) на показатели качества сна у женщин с локальным жировым отложением в области подбородка.

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INTRODUCTION

Obesity, a multifaceted medical disorder, constitutes a major public health issue in the United States as it has become an engraving epidemic [1]. Obesity is determined by the body mass index (BMI) ≥ 25 kg/m² (Misinterpretation of obesity, or describe in more detail) which is evaluated by dividing weight (kg) by the square of height (m²) [2]. Obesity is widespread in Egypt, with evaluated prevalence representing 61–70 % of the entire population aged more than 20 years [3]. Studies have revealed that 65 % (of men) and 76 % (of women), respectively, aged more than 15 years, are overweight or obese. In terms of obesity alone, the obesity prevalence is higher among females, with 39–48 % of females being obese, compared to 18–22 % of males [4].

Currently, obesity is widely acknowledged as a worldwide epidemic, and the American Medical Association and World Obesity Federation have classified it as a chronic progressive disease, separate from its role as a risk factor for other diseases [5]. The significant obese comorbidities include reduced life expectancy of 5–20 years, metabolic diseases (type 2 diabetes mellitus [T2DM] and fatty liver disease), cardiovascular diseases (hypertension, Myocardial Infarction, and stroke), musculoskeletal disease

(osteoarthritis), sleep apnea, depression, Alzheimer's, various cancers (colon, rectal, prostate, endometrium, breast, kidney, liver, ovarian), endocrine abnormalities including irregular menstrual cycles, amenorrhea, and infertility in overweight women. In addition, obesity is a major factor participating in the increasing T2DM occurrence [6].

High-Intensity Focused Ultrasound (HIFU) therapy utilizes the physical properties of ultrasound waves, such as good penetration, focalization, and directionality, to focus multiple low-energy ultrasound beams from outside the body onto the target lesion within the body [7]. This generates high-energy effects, including thermal, mechanical, and acoustic cavitation effects. A study on HIFU for facial and neck rejuvenation found significant improvements in such areas as the nasolabial folds, jawline, submental, and neck, with over 80 % improvement rates, according to physicians, and over 78 % of patient satisfaction. Common side effects were pain during the procedure and transient erythema, both resolving spontaneously. One case of transient numbness in the mandibular region was reported. Overall, HIFU was effective and safe for noninvasive facial and neck rejuvenation [8].

Obesity is related to significant reductions in expiratory reserve volume and functional residual capacity. The obesity impact on total lung capacity, residual volume, and spirometry is minimal and often falls within the normal range unless the obesity is exceptionally severe [9]. The primary cause of reduced total respiratory system compliance in obesity is a reduction in lung compliance, with a moderate impact on chest wall compliance [10]. Obesity is linked to reduced gas exchange and oxygenation and varied but often moderate impacts on carbon monoxide diffusing ability, often resulting in an elevated carbon monoxide transfer coefficient [11]. Cervical and chin subcutaneous adipose tissue (SAT) accumulation is a recognized characteristic of obesity [12].

Therefore, we hypothesized that utilizing HIFU with double chin exercises, which involves the application of direct ultrasound energy transmitted to the target area in short pulses, decreases double chin and improves sleep quality measures. Consequently, it has become a new therapeutic method for the treatment of many disorders. The objective was to investigate the fat storage sensitivity to long-term weight-loss targeted lifestyle interventions and determine their correlations with body adiposity, insulin resistance, and cardiometabolic risk.

AIM

To evaluate any effect of HIFU on sleep quality measures in obese women with a double chin.

MATERIALS AND METHODS

Randomization Methodology

Participants were randomly assigned to Group A (HIFU + exercises) or Group B (exercises only) using a computer-

generated random number sequence. The allocation was conducted by an independent researcher who was not involved in the recruitment, intervention, or data analysis processes to ensure allocation concealment. Sealed, opaque envelopes were used to assign participants to their respective groups to maintain blinding during the allocation process. Both participants and outcome assessors were blinded to the group assignments to minimize bias.

The inclusion criteria included: This double-blinded, randomized controlled trial recruited 60 patients aged 35–50 years, who were clinically stable, from Al Qasr-Alaini, from January 2024 to April 2024. The study was authorized by the Faculty of Physical Therapy Cairo University's Ethical Committee (P.T.REC/012/004481), registered at clinicaltrials.gov (NCT06217445), and followed the Helsinki Declaration. Participants were supplied with a detailed description of the study's objectives, possible hazards, and anticipated benefits and then signed an informed consent form. They had a comprehensive checkup before the research commenced and were referred by a chest specialist. Participants were equally assigned at random into groups A and B ($n = 30$). Group A received 3 HIFU sessions, a session/month/three months, with double chin exercise (daily). Group B received double chin exercises only daily for three months.

The exclusion criteria included the following: Presence of neurological disorders (stroke history or Parkinson's disease), renal or hepatic problems, acute disease, exposure to chemotherapy, recent surgery, any contraindications for utilizing HIFU including pregnancy, metal prosthesis or implants, epilepsy, DM, autoimmune disorders, heart diseases including the pacemaker, thrombosis, BMI < 30 and > 39.9, age < 35 and > 50 years, or male subjects (Fig. 1).

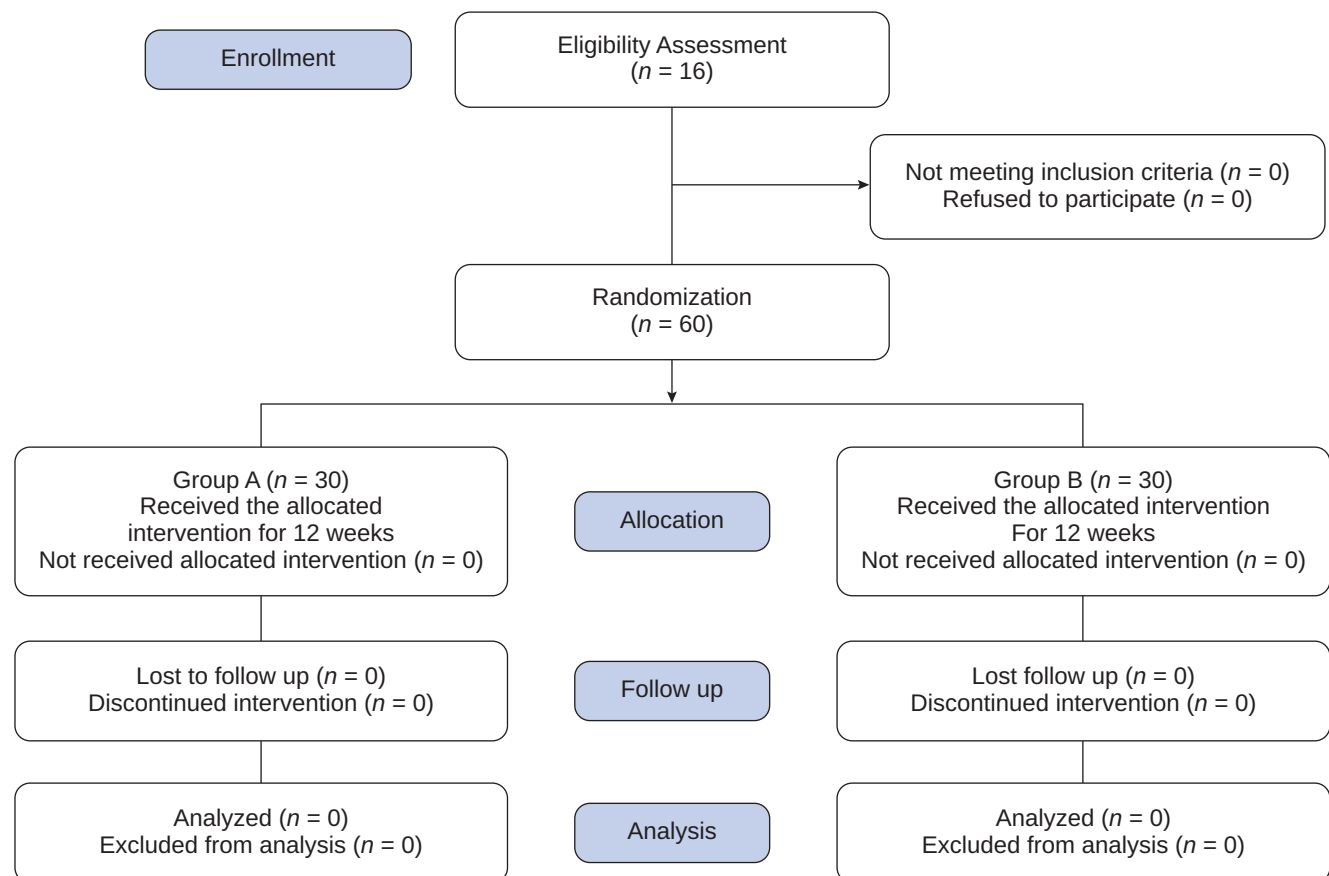


Fig. 1. Study flowchart

Outcome measurement

Using the initial body weight and height measurements, we determined BMI in the following manner:

$$\text{BMI} = \text{Weight (kg)} / \text{Height (m}^2\text{)}$$

InLaboratory measurements

Cortisol levels were assessed using venous blood sample tests at 9 AM and 9 PM pre- and post-intervention at TAG LAB laboratories. The reference ranges were 4.3–22.4 µg/dL (in the morning), and 3.0–16.6 µg/dL (in the evening).

Intervention procedures

HIFU

The HIFU employs focused ultrasound energy to target the skin layers located immediately beneath the surface. The ultrasound energy induces a fast heating of the tissue. Upon reaching a specific temperature, the cells are damaged. Meanwhile, this may seem counterintuitive; the damage actually triggers the cellular production of collagen, a protein that supplies the skin with structural integrity. As collagen levels rise, the skin becomes more tight and firm, resulting in fewer wrinkles. The high-frequency ultrasound beams target a specific tissue spot under the skin's surface to ensure that the upper layers of the skin and adjacent regions are unaffected. The personal suitability of HIFU may vary among individuals. The procedure is most effective for individuals aged > 30 years who have mild-to-moderate skin laxity. Individuals with photodamaged skin or a significant level of skin laxity may need many therapies prior to showing any visible findings.

First, a physician or technician cleansed the specific area and might use a topical anesthetic cream prior to the procedure, followed by the application of an ultrasound gel. The HIFU apparatus was positioned in direct contact with the skin. The physician or technician adjusted the apparatus to the suitable configuration utilizing an ultrasound viewer. The target area was then subjected to short pulses of ultrasound energy for 30–90 min, next the device was removed. During the application of ultrasound energy, patients might experience heat and tingling. They consumed painkillers if it was necessary. They immediately returned home and continued their regular daily routines following the session. Full outcomes are often seen three months following the completion of the last treatment [13].

Double chin exercises

Straight jaw jut

Patients angled their heads backward and looked upwards at the ceiling. They protruded their jaws forward to perceive a stretch beneath the chin, retaining for 10 s. Finally, they relaxed their jaws and repositioned the head to a neutral position.

Ball exercise

Patients positioned a 9–10 inch ball beneath their chin and pressed their chin down against the ball and repeated this many times daily.

Pucker up

Patients looked at the ceiling with their heads inclined slightly backward, contracting their lips as if they were kissing the ceiling to stretch the region below their chin.

Finally, they stopped the puckering and returned their heads to the original position.

Tongue stretch

Patients looked straight ahead, sticking their tongues out as far as they could. They lifted their tongues upward and toward their nose and held for 10 s, then released.

Neck stretch

Participants sloped their heads backward and looked at the ceiling. They applied pressure with their tongues against the mouthroof, holding for 5–10 s, and then released.

Bottom jaw jut

Participants sloped their heads backward and looked at the ceiling, then turned their heads to the right. They slid their bottom jaws forward, held for 5–10 s and released. This process was repeated with the head facing left [14].

Statistical analysis

Data analysis was conducted utilizing SPSS, version 23.0 (SPSS Inc., Chicago, Illinois, USA). The quantitative data are presented as mean ± standard deviation and ranges when their distribution was parametric (normal), while non-normally distributed variables (non-parametric data) are presented as median with an interquartile range (IQR). Furthermore, qualitative variables are presented as numbers and percentages. Data normality was assessed via the Kolmogorov — Smirnov and Shapiro — Wilk Tests.

Independent-sample *t*-test of significance was deployed to compare between two means. A paired sample *t*-test of significance was utilized for the comparison of related samples. The mean difference was employed to calculate the mean improvement post-intervention, which equals the variance between the second and the first readings. Percentage change was deployed to determine the percentage of improvement post-intervention, which equals the variation between second — first reading/first reading × 100. The confidence interval was adjusted to 95 %, and the margin of error accepted was adjusted to 5 %. $p \leq 0.05$, $p \leq 0.001$, and $p > 0.05$ indicated significance, high significance, and no significance.

RESULTS AND DISCUSSION

Subject characteristics

The findings manifested no significant variances between groups in age, BMI, and sex distribution ($p > 0.05$) (Table 1).

Between-group comparison

Statistically significant lower mean values of BMI, hormonal changes (cortisol level), submental fat, and sleep apnea Apnea-Hypopnea Index (AHI) were observed at post-intervention in group A than in group B ($p < 0.001$) (Tables 2–5). A statistically significant higher mean value of the weight impact on quality of life was found at post-intervention in group A than in group B ($p < 0.001$) (Table 6).

This study suggests that receiving 36 sessions of HIFU (3 sessions/week/12 weeks), integrated with double chin exercises, significantly impacts sleep quality measurements in obese double-chin women. This finding was consistent with Bove T. et al. [15], revealing that HIFU transducers distribute ultrasound waves evenly throughout several

Table 1. Subject characteristics

	Group A (n = 30)	Group B (n = 30)	Test value	p-value	Significant
Age (years)					
Mean ± SD	43.33 ± 4.22	41.80 ± 4.82	1.310	0.195	NS
Range	35–50	35–50			
Weight (kg)					
Mean ± SD	92.13 ± 5.76	93.32 ± 7.40	0.027	0.762	NS
Range	85–105	81–106			
Height (cm)					
Mean ± SD	165.47 ± 5.75	166.23 ± 5.85	0.262	0.611	NS
Range	155–175	158–179			

Note: NS — non significant; SD — standard deviation; p — value, probability value.

Table 2. Body mass index comparison between groups

BMI	Group A	Group B	Unpaired t-test	p-value	Significant
Pre-intervention					
Mean ± SD	33.71 ± 2.32	33.34 ± 1.79	0.462	0.500	NS
Range	30.04–37.2	30.12–37.66			
Post-intervention					
Mean ± SD	28.95 ± 1.58	31.42 ± 1.54	7.537	0.001	HS
Range	26.33–31.64	28.34–34.37			

Note: SD — standard deviation; NS — non-significant.

Table 3. Hormonal changes (cortisol level) comparison between groups

Hormonal	Group A	Group B	Unpaired t-test	p-value	Significant
Pre-intervention					
Mean ± SD	39.29 ± 3.87	39.97 ± 7.08	0.457	0.649	NS
Range	29.6–47.9	30–50			
Post-intervention					
Mean ± SD	15.36 ± 3.71	37.83 ± 7.01	15.51	0.001	HS
Range	7.9–21.1	28–50			

Note: SD — standard deviation; NS — non-significant.

Table 4. Submental fat scale comparison between groups

Submental fat scale	Group A	Group B	Unpaired t-test	p-value	Significant
Pre-intervention					
Mean ± SD	3.10 ± 0.84	3.40 ± 0.50	-1.675	0.099	NS
Range	1–4	3–4			
Post-intervention					
Mean ± SD	0.60 ± 0.62	2.63 ± 0.72	-11.724	0.001	HS
Range	0–2	21–4			

Note: SD — standard deviation; NS — non-significant.

Table 5. Sleep apnea Apnea-Hypopnea Index comparison between groups

Assessment of sleep apnea AHI	Group A	Group B	Unpaired t-test	p-value	Significant
Pre-intervention					
Mean ± SD	20.93 ± 8.49	22.03 ± 4.62	-0.624	0.535	NS
Range	51–30	15–30			
Post-intervention					
Mean ± SD	7.90 ± 5.25	19.87 ± 5.78	-8.394	0.001	HS
Range	0–15	10–29			

Note: SD — standard deviation; NS — non-significant.

Table 6. Impact of weight on quality of life comparison between groups

Impact of weight on quality of life	Group A	Group B	Unpaired t-test	p-value	Significant
Pre-intervention					
Mean ± SD	59.50 ± 12.58	53.03 ± 13.64	1.081	0.315	NS
Range	45–75	41–69			
Post-intervention					
Mean ± SD	91.50 ± 6.32	52.87 ± 11.58	16.037	0.001	HS
Range	75–100	30–70			

Note: SD — standard deviation; NS — non-significant.

АХМЕД Н.Т.М. И ДР. | ОРИГИНАЛЬНАЯ СТАТЬЯ

layers of skin and bodily tissues without making direct contact with the epidermis. Ultraformer III features several thermal energy-generating cartridges, which maintain consistent temperatures of 65–75 °C to stimulate coagulation for collagen regeneration in the face and tighten body tissues for shaping waistlines, thighs, and other body parts [16]. Our results corroborate the findings of Arora G. and Shirolikar M. [17], which have revealed that the examination of the micro-focused ultrasound apparatus impacts the lower face area of 103 adults. Among 93 patients who participated in this trial, 65.6 % expressed satisfaction with the outcomes evaluated by blinder viewers, and 58.1 % of patients demonstrated improvement. Ultrasound devices preserve the integrity of the epidermis while delivering thermal energy to the dermis. The epidermis mitigating damage reduces negative consequences such as bruising, pain, and blisters. Heat-induced dermis injury triggers novel collagen production, resulting in skin tightening [18].

Additionally, preliminary results indicate that HIFU can effectively reduce the frequency and intensity of snoring. Studies suggest that patients experience significant improvements in sleep quality and a reduction in snoring episodes post-treatment [19]. The study of Azuelos A. et al. [20] described a prospective study including 20 patients who received a series of HIFU treatments. The HIFU outcomes were assessed employing the adjusted FACE-Objective Assessment Scale and the subjective Investigator Global Improvement Assessment Scale (IGIAS — 1 to 3). A group of five blind evaluators examined the results of the procedure by analyzing images captured prior to and post the procedure. They documented side

impacts and assessed the pain utilizing a visual analog scale ranging from 0–10. Significant clinical improvements, including enhanced cervicomental angle definition, were identified in the treated regions. Four out of five evaluators found that the pre-and post-therapy assessment ratings for double chin and skin laxity showed considerable improvement. Within the IGIAS score range, two patients scored 1–5, seven patients scored 6–10, and 11 patients scored 11–15. Moreover, no patients had a score ranging from 5 to 0, and no significant issues were documented.

Weight loss with a balanced diet and regular exercise can assist in lowering overall body fat, including fat stored under the chin [21]. For some individuals with mild submental fullness, this may be sufficient to achieve the desired improvement [22]. The HIFU is extensively utilized for skin regeneration and tightening, so our objective was to determine the HIFU’s safety and effectiveness in rejuvenating the face and neck [23]. The study of Berg E. [24] has revealed that a double chin is typically linked to weight gain and develops when extra fat accumulates around the chin area; they discovered how you can lose chin fat with six simple double chin exercises and learned how a low-carb diet helps get rid of excess fat and saggy skin.

HIFU is alternatively referred to as focused ultrasound surgery (FUS), which is designed to manage neuropathic pain, uterine fibroids, and malignancies of the prostate, bone, breast, liver, kidney, and testes [25]. This approach attempts to maintain a high quality of life for the patient [26]. The study of Salsi B. et al. [27] suggested that at the 12-week follow-up after the final therapy, the mean submental fat and laxity scores showed a significant reduction from baseline ($p < 0.01$).

Contini M. et al. [28] reported that among the 693 studies that were found, only 16 were eligible, and all of them had exclusively female participants. Brow lifts (0.47–1.7 mm) and submental lifts (defined as a 26–45 mm² decrease in the submental area on lateral photos) measurements have shown that MFU could tighten the skin. Faetani L. et al. [29] suggested that while exercise can strengthen muscles around the neck and jaw, it does not specifically target fat in these areas. Understanding the unique nature of subcutaneous fat distribution in the neck and chin underscores the challenges in spot reduction.

Among adults, obesity is considered a risk factor for snoring and OSA and a major determinant for treatment choices in snoring with or without OSA [30]. Therefore, it is important to study obesity as part of the general characteristics of snoring patients in particular. The prevalence of obesity is a well-studied subject in the general communities [31].

The current research has some limitations that must be observed. First, since only females were involved

in this study, the results cannot be generalized to all populations. Second, the current study only looked at people between 35 and 50 years old. It needs to be found out if similar results can be found in younger and older groups. Third, the current study only included people with a BMI between 30–39.9 kg/m². It needs to include people with BMI < 30 kg/m² and > 40 kg/m². Fourth, the extended follow-up period and know the paucity of trustworthy research on the impact of HIFU on sleep quality measurements.

CONCLUSION

HIFU improves sleep quality measures. Additionally, HIFU can be an alternate therapy to be employed in integration with exercises. More studies with bigger sample sizes must evaluate the long-term consequences of HIFU on sleep quality measurements in obese doubledchin women. Further studies are recommended to measure thyroid function tests. Other studies include subjects with severe obesity BMI > 40 kg/m².

ADDITIONAL INFORMATION

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Informed Consent for Publication. Written consent was obtained from the patient for publication of relevant medical information.

Data Access Statement. The data that support the findings of this study are available on reasonable request from the corresponding author.

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