

## **TITLE PAGE**

### **Title:**

To treat or not to treat: comparison of different criteria used to determine whether weight loss is to be recommended

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1 **Abstract:**

2 *Background*

3 Excess body fat is a major risk factor for disease primarily due to its endocrine activity. In  
4 recent years several criteria have been introduced to evaluate this factor. Nevertheless,  
5 treatment need is currently assessed only on the basis of an individual's Body Mass Index  
6 (BMI), calculated as body weight (in kg) divided by height in m<sup>2</sup>. The aim of our study was to  
7 determine whether application of the BMI, compared to adiposity-based criteria, results in  
8 underestimation of the number of subjects needing lifestyle intervention.

9 *Methods*

10 We compared treatment need based on BMI classification with four adiposity-based criteria:  
11 percentage body fat (%BF), considered both alone and in relation to metabolic syndrome risk  
12 (MS), waist circumference (WC), as an index of abdominal fat, and Body Fat Mass Index  
13 (BFMI, calculated as fat mass in kg divided by height in m<sup>2</sup>) in 63 volunteers (23 men and 40  
14 women, aged 20 – 65 years).

15 *Results*

16 According to the classification based on BMI, 6.3% of subjects were underweight, 52.4%  
17 were normal weight, 30.2% were overweight, and 11.1% were obese. Agreement between the  
18 BMI categories and the other classification criteria categories varied; the most notable  
19 discrepancy emerged in the underweight and overweight categories. BMI compared to almost  
20 all of the other adiposity-based criteria, identified a lower percentage of subjects for whom  
21 treatment would be recommended. In particular, the proportion of subjects for whom  
22 clinicians would strongly recommend weight loss on the basis of their BMI (11.1 %) was  
23 significantly lower than those identified according to WC (25.4%, p = 0.004), %BF (28.6%,  
24 p=0.003), and MS (33.9%, p=0.002).

25 *Conclusions*

- 1 The use of the BMI alone, as opposed to an assessment based on body composition, to
- 2 identify individuals needing lifestyle intervention may lead to unfortunate misclassifications.
- 3 Population-specific data on the relationships between body composition, morbidity, and
- 4 mortality are needed to improve the diagnosis and treatment of at-risk individuals.

## 1 **Background**

2           It is generally accepted that several major diseases are related to overweight and  
3 obesity. These include metabolic syndrome and type 2 diabetes mellitus, cardiovascular  
4 diseases, some tumours, gallbladder diseases, nonalcoholic steatohepatitis, sleep apnoea and  
5 osteoarthritis [1-6]. The endocrine activity of adipose tissue is strongly implicated in most of  
6 these diseases [7,8]. Therefore, excess body fat rather than excess body weight is detrimental  
7 to health; hence, paradoxically, metabolically obese, normal weight individuals, not deemed  
8 obese on the basis of height and weight parameters, were found to be hyperinsulinaemic,  
9 insulin-resistant, predisposed to type 2 diabetes mellitus, hypertriglyceridaemic, or to have  
10 premature coronary heart disease; these individuals responded favourably to caloric restriction  
11 [9-11].

12           Health professionals should assess patients on the basis of their body composition  
13 rather than their body weight [12]. Thus, new clinical criteria have been introduced to  
14 evaluate body adiposity, such as percentage body fat (%BF), considered both alone [13] and  
15 in relation to metabolic syndrome risk [14], and waist circumference, as an index of  
16 abdominal fat [1,15]. Recently, the Body Fat Mass Index (BFMI, calculated as fat mass in kg  
17 divided by height in m<sup>2</sup>) was introduced, in nutritional assessment, as an additional element  
18 for assessing adiposity [16-18].

19           Nevertheless, treatment need is currently assessed on the basis of an individual's Body  
20 Mass Index (BMI), calculated as their body weight (in kg) divided by their height in m<sup>2</sup> [1].

21           The aim of our study was to determine whether application of the BMI, compared to  
22 adiposity-based criteria, results in underestimation of the number of subjects needing a  
23 lifestyle intervention.

## 1 **Methods**

### 2 *Sample*

3 A sample of 63 volunteers (all white, 23 men and 40 women, aged 20-65 years), was  
4 recruited. To be included in the study they had to have a good health status, a sedentary  
5 lifestyle, and could not be on a low-calorie diet or on drug therapy for acute or chronic  
6 illnesses. All the recruited subjects attended the Human Nutrition and Eating Disorders  
7 Research Centre, University of Pavia, between January 2004 and January 2005 to undergo a  
8 nutritional assessment and body composition analysis; the diagnostic radiology examinations  
9 were carried out at the IRCCS Salvatore Maugeri Foundation, Pavia.

### 10 *Study design*

11 The subjects attended the dietology outpatient clinic early in the morning after an  
12 overnight fast. On arrival, they emptied their bladders. Anthropometric measurements were  
13 taken. Body composition was assessed by means of bioimpedance analysis (BIA) and then  
14 dual-energy X-ray absorptiometry (DXA). Later in the morning, when the examinations were  
15 complete, the subjects were allowed to eat.

### 16 *Anthropometric measurements*

17 The subjects, wearing minimal clothing, were weighed to the nearest 0.1 kg using a  
18 balance beam scale equipped with a stadiometer. Their height, standing barefoot, was  
19 measured to the nearest 0.5 cm. Their BMI was calculated in the standard way: weight in kg  
20 divided by height in m<sup>2</sup>. The subjects were then classified into four groups according to the  
21 WHO BMI cutoffs [1] :

22 A) BMI: “underweight” : BMI < 18.5 kg/m<sup>2</sup>

23 “normal weight”: BMI = 18.5 - 24.9 kg/m<sup>2</sup>

24 “overweight” : BMI = 25 - 29.9 kg/m<sup>2</sup>

25 “obese” : BMI ≥ 30 kg/m<sup>2</sup>

1           Waist circumference was measured to the nearest 0.1 cm with a measuring tape placed  
2 at the midpoint between the lower border of the ribs and the upper border of the pelvis. The  
3 subjects were then divided, according to gender-specific waist circumference values, into  
4 three categories denoting risk of metabolic complications [1] :

5 B) waist circumference as an index of abdominal fat:

6       “not increased”               : < 80 cm females, < 94 cm males

7       “increased”                   : 80-87.9 cm females, 94-101.9 cm males

8       “substantially increased” :  $\geq$  88 cm females,  $\geq$  102 cm males

9 *Body composition assessment*

10           To reduce methodological biases when classifying subjects according to adiposity-  
11 based criteria, we used the same methods reported by the appropriate reference studies: DXA  
12 to measure %BF (C) [13] ; and BIA to assess both metabolic syndrome risk (D) [14] and  
13 BFMI (E) [16].

14           DXA was performed using a Norland RX-26 scanner (Norland Corp., W, USA),  
15 which automatically gave a %BF reading. BIA was performed using a Human Im Scan device  
16 (Dietosystem, Milan, Italy); %BF was calculated using Deurenberg’s formula [19]. The  
17 subjects were then classified according to different criteria (see Appendices):

18 C) %BF: the subjects were classified according to %BF cutoffs calculated by Gallagher et al.  
19 for the white subgroup of their study population [13].

20 D) Metabolic syndrome risk: the subjects were classified on the basis of %BF cutoffs  
21 calculated by Zhu in the white subgroup of the American population that took part in  
22 NHANES III [14].

23 E) Body Fat Mass Index: the subjects were classified according to the BFMI cutoffs  
24 calculated by Kyle on the basis of a very large sample of white men and women living in  
25 Switzerland [16].

1 To classify the subjects for whom weight loss would be recommended or strongly  
2 recommended (for each criterion), we applied the following cutoffs (also see Appendices).

3 Weight loss recommended:

4 (A) BMI  $\geq 25 \text{ kg/m}^2$ , in both women and men;

5 (B) waist circumference  $\geq 80 \text{ cm}$  in women and  $\geq 94 \text{ cm}$  in men;

6 (C) total body fat, expressed as percentage body fat: %BF  $\geq 33\%$  in women and  $\geq 21\%$  in  
7 men in the 20-39 years age group, %BF  $\geq 35\%$  in women and  $\geq 23\%$  in men aged 40-59  
8 years, %BF  $\geq 38\%$  in women and  $\geq 25\%$  in men aged 60-79 years;

9 (D) metabolic syndrome risk: %BF  $\geq 30.8\%$  in women and  $\geq 21.2\%$  in men;

10 (E) BFMI  $\geq 8.2 \text{ kg/m}^2$  in women and  $\geq 5.2 \text{ kg/m}^2$  in men (“overfat”).

11 Weight loss strongly recommended:

12 (A) BMI  $\geq 30 \text{ kg/m}^2$  in women and men;

13 (B) waist circumference  $\geq 88 \text{ cm}$  in women and  $\geq 102 \text{ cm}$  in men;

14 (C) total body fat, expressed as percentage body fat: %BF  $\geq 39\%$  in women and  $\geq 26\%$  in  
15 men in the 20-39 years age group, %BF  $\geq 41\%$  in women and  $\geq 29\%$  in men aged 40-59  
16 years, %BF  $\geq 43\%$  in women and  $\geq 31\%$  in men aged 60-79 years;

17 (D) metabolic syndrome risk: %BF  $\geq 37.2\%$  in women and  $\geq 29.1\%$  in men;

18 (E) BFMI  $\geq 11.8 \text{ kg/m}^2$  in women and  $\geq 8.3 \text{ kg/m}^2$  in men (severely “overfat”).

19 *Statistical analysis*

20 Sex-related differences in anthropometric measurements and body fat indices were  
21 tested using unpaired t-tests or  $\chi^2$ - tests. Statistical significance was defined as  $p < 0.05$ .

22 Agreement between BMI and abdominal fat, %BF, metabolic syndrome risk, and BFMI was  
23 evaluated using Kendall’s Tau-b test. McNemar’s test was applied to evaluate whether the  
24 percentage of subjects in whom weight loss was deemed necessary on the basis of BMI was

1 equal to the percentages identified on the basis of the other body composition assessments;  
2 similarly, the percentage of subjects whose BMI would prompt a strong recommendation to  
3 lose weight was compared to the percentages of subjects in whom application of each of the  
4 other adiposity classification criteria also revealed a definite need to lose weight. All analyses  
5 were carried out with the statistical software program SPSS, version 13.0.

6 *Statement of ethics*

7         We certify that this research complied fully with all applicable institutional and  
8 governmental regulations concerning the ethical use of human volunteers and with the terms  
9 of the Helsinki Declaration. The University of Pavia ethics committee approved the study  
10 protocol, and all the recruited subjects gave their written informed consent to take part.

11

## 1 **Results**

2           The women enrolled in the study were slightly younger than the men ( $38.5 \pm 14$  years  
3 vs  $39.2 \pm 13.3$  years), but this difference was not statistically significant ( $t=0.201$ ,  $p=0.841$ ).

4           On average, the men recorded higher body weight, waist circumference and BFMI values  
5 than the women, while the women had a higher %BF and metabolic syndrome risk (Table 1).  
6           Body fat percentage measured by DXA was significantly linearly related to that measured by  
7 BIA ( $r_{\text{Pearson}}=0.827$ ,  $p<0.0001$ ).

8           According to the classification based on BMI, 6.3% of subjects were underweight,  
9 52.4% were normal weight, 30.2% were overweight, and 11.1% were obese. Abdominal  
10 adiposity was not increased in 63.5% of subjects, increased in 11.1%, and substantially  
11 increased in 25.4%. Total body fat, considered alone, was low in 3.2% of subjects, normal in  
12 49.2%, increased in 19.0%, and high in 28.6%. Metabolic syndrome risk related to %BF was  
13 low in 7.1% of subjects, normal in 37.5%, increased in 21.4%, and high in 33.9%. BFMI was  
14 low in 3.6% of subjects, normal in 42.9%, increased in 32.1%, and high in 21.4%.

15           Metabolic syndrome risk was the only criterion to show significant gender-related  
16 differences ( $\chi^2=9.430$ ;  $p=0.024$ ): greater percentages of the women compared to the men  
17 showed a high metabolic syndrome risk (37.1% vs 28.6%), and a low and normal metabolic  
18 syndrome risk (8.6% vs 4.8% and 45.7% vs 23.8%, respectively); conversely, a greater  
19 proportion of the men had an increased metabolic syndrome risk (42.9% vs 8.6%).

20           Agreement between the BMI categories and the other classification criteria categories  
21 varied (Table 2). The most notable discrepancy emerged in the underweight and overweight  
22 categories. Of the subjects classed as underweight on the basis of BMI, 75% had normal  
23 %BF and metabolic syndrome risk values, and none had an increased waist circumference. In  
24 the BMI normal weight subjects, increased abdominal fat was found in 9.1%, increased %BF  
25 in 15.2%, and increased metabolic syndrome risk in 20%; a high %BF was found in 6.1% of

1 the normal weight subjects and a high metabolic syndrome risk in 16.7%. In the overweight  
2 subjects, a marked discrepancy emerged between the BMI and the adiposity indices: more  
3 than 50% of the subjects had a high %BF and metabolic syndrome risk and just under 50%  
4 high abdominal fat. In the subjects rated as obese on the basis of their BMI, there was good  
5 agreement between all the criteria.

6 Comparing the BMI with the BFMI categories, 75% of the underweight subjects had  
7 a normal fat status. In the BMI normal weight category, 30% of the subjects were “overfat”  
8 according to the BFMI, while in the overweight category only 6.7% of subjects had a normal  
9 fat status and 40% had a severely “overfat” status. There was good agreement between BMI  
10 and BFMI in the obese subjects. Overall, the BMI showed good agreement with BFMI (tau-b  
11 Kendall=0.722,  $p<0.001$ ) and waist circumference (abdominal fat) (tau-b Kendall=0.704,  
12  $p<0.001$ ). The level of agreement between the various BMI categories and the %BF and  
13 metabolic syndrome risk categories was moderate (tau-b Kendall=0.672,  $p<0.001$  and tau-b  
14 Kendall=0.563,  $p<0.001$  respectively).

15 The percentages of subjects for whom weight loss treatment would be recommended  
16 and strongly recommended, on the basis of each criterion, are summarised in figure 1. The  
17 proportion of subjects for whom clinicians would recommend weight loss on the basis of their  
18 BMI (41.3%) was not significantly different from the proportions in whom it would be  
19 recommended on the basis of %BF ( $p=0.344$ ) and abdominal fat ( $p=0.508$ ). Conversely, a  
20 significant difference emerged in relation to the criteria metabolic syndrome risk ( $p=0.022$ )  
21 and BFMI ( $p=0.021$ ). The picture changes when analysing the proportion of subjects for  
22 whom weight loss would be strongly recommended, with the proportion identified on the  
23 basis of BMI (11.1%) differing significantly from the proportion identified by abdominal fat  
24 ( $p=0.004$ ), %BF ( $p=0.003$ ), and metabolic syndrome risk ( $p=0.002$ ). Instead, no significant

- 1 difference was found between the proportions of subjects whom clinicians, on the basis of
- 2 BMI versus BFMI, would be strongly urged to lose weight ( $p=0.125$ ).

## 1 **Discussion**

2           Obesity is a metabolic disorder characterised by excess body fat, which is an important  
3 risk factor for disease, not only because it is a volume-filling organ, but primarily due to the  
4 endocrine activity of adipose tissue [7,8,20].

5           Although the BMI is easily calculated and can be readily used in population studies, it  
6 does not discriminate between fat mass and fat-free mass, or reflect the fat mass distribution  
7 in the body [21,25]. In our study, the BMI compared to almost all of the other criteria, based  
8 on adiposity, identified a lower percentage of subjects for whom treatment would be  
9 recommended and strongly recommended. In particular, the difference was statistically  
10 significant when the BMI was compared to metabolic syndrome risk. These findings suggest  
11 that a certain proportion of subjects classified as normal weight on the basis of their BMI  
12 would not be recommended for treatment even though they harbour excess body fat which  
13 could have clinical and metabolic consequences. This is also true if we compare the BMI to  
14 the BFMI, the latter an index that denotes the amount of body fat in relation to stature. Indeed,  
15 the BFMI, which can be considered a qualitative evaluation of BMI, can result in a better  
16 clinical assessment of subjects. From a clinical point of view, basing an individual's treatment  
17 needs on their BMI can place at risk those subjects who, on the basis of their metabolic  
18 syndrome risk, %BF, and waist circumference, would be strongly advised to undergo weight-  
19 loss treatment.

20           As regards the underweight subjects, a large proportion of them had normal (not low)  
21 %BF, waist circumference, metabolic syndrome risk, and BFMI values. However, in these  
22 subjects, the misclassification does not have important clinical consequences, since treatment  
23 would not, on the basis of any of the criteria, be recommended for any of them.

24           Thus, our data confirm that indirect estimates of body composition (i.e. BMI) are  
25 useful for groups but unreliable in individuals [26]. Furthermore, our data also underline the

1 importance of discriminating between lean mass and fat mass, and of relating these  
2 parameters to body height, in order to obtain a better nutritional assessment. In addition, the  
3 clinical consequences of an altered body composition should be taken into account. The use  
4 of the BMI alone to evaluate overweight and obese individuals leads to undesirable  
5 misclassifications. Of note, our study sample consisted of people with a sedentary lifestyle,  
6 which may predispose them to increased adiposity even before an increase in body weight  
7 becomes evident; this implies that normal weight subjects can be at risk of excessive  
8 adiposity.

9         Thus, there is a need to replace the BMI or to supplement it with other diagnostic  
10 criteria, in particular, ones that focus on body adiposity, considered both alone and with  
11 regard to its distribution. If confirmed by data from larger studies, our results highlight the  
12 need to investigate the clinical consequences of excess body fat in normal weight subjects.  
13 Several studies have focused on the relationship between the BMI and morbidity and  
14 mortality [2,3,27]. Unfortunately, to date, few studies have focused on the relationship  
15 between %BF and morbidity and mortality, and those that have been conducted were  
16 restricted to specific ethnic groups [14,16,28-31]. Thus, precise %BF cutoffs that can be used  
17 in clinical settings to evaluate an individual's health remain to be determined.

18         Since %BF has important clinical consequences, and treatment costs and drop-out  
19 rates among "overfat" subjects are high, there is clearly a pressing need for precise and  
20 unambiguous guidelines. In particular, %BF cutoffs should be defined that can be used in  
21 addition to the BMI and waist circumference values already published for the diagnosis and  
22 treatment of at-risk subjects [1].

## 1 **Conclusions**

2           The use of the BMI alone, as opposed to an assessment based on body composition, to  
3 identify individuals needing lifestyle intervention may lead to unfortunate misclassifications.  
4 Population-specific data on the relationships between body composition, morbidity, and  
5 mortality are needed to improve the diagnosis and treatment of at-risk individuals.

**Declaration of competing interests**

The authors declare that they have no competing interests.

### **Authors' contributions**

OC: conception and design of the study; generation, collection and assembly of data; interpretation of data; drafting of the manuscript

SV: analysis and interpretation of data

GP: conception and design of the study; generation, collection and assembly of data

CT: conception and design of the study

MT: collection, assembly and interpretation of data

OT: collection, assembly and interpretation of data

AT: conception and design of the study; generation, collection and assembly of data; interpretation of data; drafting of the manuscript

All the authors have read and approved the final manuscript.

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## Appendices

*Appendix 1:* Percentage body fat cutoffs for white people, proposed by Gallagher et al. [13]:

Age and BMI	% body fat		
	Men	Women	
20-39 y	18.5 kg/m <sup>2</sup>	8	21
	25 kg/m <sup>2</sup>	21	33
	30 kg/m <sup>2</sup>	26	39
40-59 y	18.5 kg/m <sup>2</sup>	11	23
	25 kg/m <sup>2</sup>	23	35
	30 kg/m <sup>2</sup>	29	41
60-79 y	18.5 kg/m <sup>2</sup>	13	25
	25 kg/m <sup>2</sup>	25	38
	30 kg/m <sup>2</sup>	31	43

*Appendix 2:* Percentage body fat thresholds related to metabolic syndrome risk proposed by Zhu et al. for white people [14]:

BMI (kg/m <sup>2</sup> )	% body fat	
	Men	Women
18.5	11.0	22.5
25.0	21.2	30.8
30.0	29.1	37.2

*Appendix 3:* Body Fat Mass Index cutoffs for healthy white adults, proposed by Kyle et al. [16]:

BMI (kg/m <sup>2</sup> )	BFMI (kg/m <sup>2</sup> )	
	Men	Women
18.5	1.8	3.9
25.0	5.2	8.2
30.0	8.3	11.8

## Figure legends

*Figure 1: Weight loss treatment recommendations for each criterion.*

Percentage of subjects for whom weight loss would be recommended, including those for whom it would be strongly recommended, on the basis of the different criteria: BMI (Body Mass Index), WC (waist circumference, as an index of abdominal fat), %BF (total body fat, expressed as percentage body fat), MS (metabolic syndrome risk: %BF related to the risk of developing metabolic syndrome), BFMI (Body Fat Mass Index)

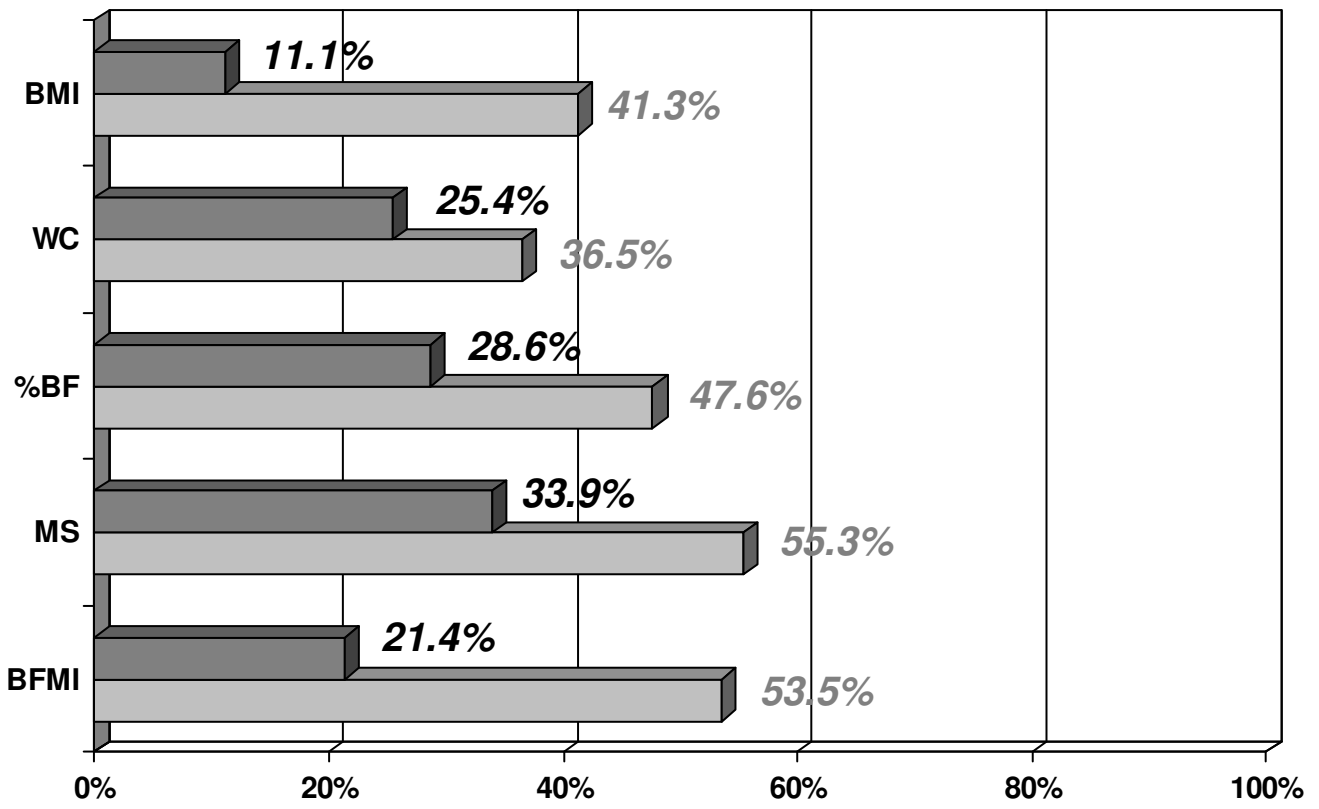
*Table 1 – Summary of statistics by sex (mean values and standard deviations in square brackets).*

<b>Criteria</b>	n	Weight (kg)	BMI (kg/m <sup>2</sup> )	%BF	MS	WC (cm)	BFMI (kg/m <sup>2</sup> )
Males	23	75.3 [11.2]	24.7 [3.9]	21.5 [8.6]	24.2 [7.6]	89.5 [10.8]	6.2 [2.8]
Females	40	62.0 [11.0]	23.8 [4.2]	34.8 [8.4]	32.6 [9.1]	80.8 [12.2]	8.0 [3.3]
<b>Test and p-value</b>		t=4.59 p<0.0001	t=0.78 p=0.438	t=-6.00 p<0.0001	t=-3.52 p<0.001	t=2.83 p=0.006	t=-2.01 p=0.049

Table 2: Agreement between the BMI categories and the other classification criteria categories expressed as percentage values. The grey areas represent the main diagonal of the agreement matrix.

Other classification criteria categories	Body Mass Index			
	underweight	normal weight	overweight	obese
<b>low</b>				
%BF	25.0	3.0	-	-
MS	25.0	10.0	-	-
BFMI	25.0	3.3	-	-
<b>normal</b>				
%BF	75.0	75.8	15.8	-
MS	75.0	53.3	6.7	14.3
WC	100.0	90.9	31.6	-
BFMI	75.0	66.7	6.7	-
<b>Increased</b>				
%BF	-	15.2	31.6	14.3
MS	-	20.0	40.0	-
WC	-	9.1	21.1	-
BFMI	-	30.0	53.3	14.3
<b>High</b>				
%BF	-	6.1	52.6	85.7
MS	-	16.7	53.3	85.7
WC	-	-	47.4	100.0
BFMI	-	-	40.0	85.7

%BF = total body fat, expressed as percentage body fat; MS = metabolic syndrome risk; WC = waist circumference, as an index of abdominal fat; BFMI = Body Fat Mass Index



■ Weight loss recommended    ■ Weight loss strongly recommended

Figure 1