

ORIGINAL

Health-related quality of life in individuals with metabolic syndrome: A cross-sectional study



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Abbreviations: BMI, body-mass index; CVD, cardiovascular disease; HRQoL, Health-Related Quality of Life; MetS, Metabolic Syndrome; SF-36, Health-Related Quality of Life questionnaire.

Abreviaturas: CVRS, Calidad de vida relacionada con la salud; ECV, Enfermedad cardiovascular; IMC, Índice de masa corporal; SF-36, Cuestionario de calidad de vida relacionado con la salud; SM, Síndrome metabólico.

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◇ Please see a list of the members of the PREDIMED-Plus study investigators in [Appendix A](#).

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KEYWORDS

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Weight-loss;
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Abstract

Introduction and objectives: Metabolic syndrome (MetS) is a combination of various cardiovascular risk factors with a major impact on morbidity and premature mortality. However, the impact of MetS on self-reported health-related quality of life (HRQoL) is unknown.

This study evaluated the HRQoL in a Spanish adult population aged 55 years and older with MetS.

Method: A cross-sectional analysis was performed with baseline data from the PREDIMED-Plus multicentre randomized trial. The participants were 6430 men and women aged 55–75 years with overweight/obesity (body mass index ≥ 27 and ≤ 40 kg/m²) and MetS. The SF-36 questionnaire was used as a tool to measure HRQoL. Scores were calculated on each scale of the SF-36 by gender and age.

PALABRAS CLAVE

Bienestar;
Calidad de vida
relacionada con la
salud;
Obesidad;
Pérdida de peso;
PREDIMED-Plus

Results: Participants showed higher scores in the social function (mean 85.9, 95% CI; 85.4–86.4) and emotional role scales (mean 86.8, 95% CI; 86.0–87.5). By contrast, the worst scores were obtained in the aggregated physical dimensions. In addition, men obtained higher scores than women on all scales. Among men, the worst score was obtained in general health (mean 65.6, 95% CI; 65.0–66.2), and among women, in body pain (mean 54.3, 95%CI; 53.4–55.2). A significant decrease was found in the aggregated physical dimensions score among participants 70–75 years old, but an increased one in the aggregated mental dimensions, compared to younger participants.

Conclusions: Our results reflect that the MetS may negatively affect HRQoL in the aggregated physical dimensions, body pain in women, and general health in men. However, this adverse association was absent for the psychological dimensions of HRQoL, which were less affected.

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Calidad de vida relacionada con la salud en individuos con síndrome metabólico: un estudio descriptivo

Resumen

Introducción y objetivos: El síndrome metabólico (SM) es la combinación de diversos factores de riesgo cardiovascular que pueden derivar en un mayor impacto en la morbimortalidad prematura. Sin embargo, el impacto del SM en la calidad de vida relacionada con la salud (CVRS) es desconocido. El objetivo de este estudio es evaluar la CVRS en la población adulta española de 55 años o más con SM.

Métodos: Se realizó un análisis transversal con los datos del ensayo PREDIMED-Plus. Seis mil cuatrocientos treinta varones y mujeres entre 55-75 años con sobrepeso/obesidad y SM. El instrumento de medida de la CVRS fue el cuestionario SF-36. Cada escala del SF-36 fue descrita y estratificada por sexo.

Resultados: Los participantes mostraron valores más altos en las escalas función social (media: 85,9; IC 95%: 85,4-86,4) y rol emocional (media: 86,8; IC 95%: 86,0-87,5). En los varones, la peor puntuación fue en la dimensión salud general (media: 65,6; IC 95%: 65,0-66,2) y en las mujeres el dolor corporal (media: 54,3; IC 95%: 53,4-55,2). Además, los varones obtuvieron puntuaciones más altas en todas las escalas. En la escala función física en varones se encontró una disminución significativa de la CVRS en los participantes entre 70 y 75 años en comparación con los más jóvenes. Las peores puntuaciones se obtuvieron en las dimensiones físicas agregadas.

Conclusiones: El SM afecta de manera negativa a la CVRS en las dimensiones agregadas físicas, haciendo especial hincapié en la esfera dolor corporal en mujeres y salud general en varones. Sin embargo, las esferas psicológicas se encuentran menos afectadas por el SM.

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Introduction

Metabolic syndrome (MetS) is a cluster of various cardiovascular risk factors such as abdominal obesity, high blood pressure, insulin resistance, and impaired serum lipid profiles that, when combined, can lead to cardiovascular disease (CVD)¹ and increase the risk of mortality.²

The prevalence of MetS in the adult population, using standardized measurements in a representative sample of the Spanish population³ was 22.7% (26.0% women vs. 19.4% men). This prevalence increases with age and is higher in women aged 65 years or older.

It is important to highlight that MetS may lead to alterations in self-perceived well-being, which, for many people, may be more important than the comorbidities

associated with MetS.⁴ MetS and an increased body-mass index (BMI) > 27 kg/m², have been linked to a decrease in health-related quality of life (HRQoL).^{5,6}

In turn, weight loss and an increase in physical activity may enhance HRQoL.⁶

Self-perceived HRQoL is relevant because it could be a strong predictor of chronic disease and long-term mortality.^{7,8} One of the most widely used tools to measure the HRQoL is the short-form SF-36 questionnaire, which has been used by over 400 articles up to date.⁹ It has been shown to be useful for the general population, specific subgroups, and in studies comparing the burden of different illness.¹⁰ In the content review, metric properties and development of the Spanish version of SF-36 done by Vilagut et al.,¹¹ the authors concluded that the SF-36 questionnaire

Table 1 Descriptive characteristics at baseline of the studied sample.

	Total (n = 6430)		Men (n = 3350)		Women (n = 3080)	
	N	%	N	%	N	%
<i>Age (years)</i>						
55–59	884	13.8	884	26.4		
60–64	2129	33.1	981	29.3	1148	37.3
65–69	2149	33.4	944	28.2	1205	39.1
70–75	1268	19.7	541	16.1	727	23.6
<i>Marital status</i>						
Single	325	5.1	143	4.3	179	5.8
Married	4917	76.5	2840	84.8	2080	67.6
Divorced/separated	782	12.2	252	7.5	260	8.4
Widow	662	10.3	106	3.2	556	18.1
<i>Educational level</i>						
No studies	25	0.4	5	0.2	20	0.7
Primary	3056	47.5	1259	37.6	1797	58.4
Secondary	1859	28.9	1105	34.3	754	24.5
University or higher	1431	22.3	965	28.8	466	15.1
Insufficient data	56	0.9	15	0.4	41	1.3
<i>Employment situation</i>						
Active	1336	20.8	991	29.6	345	11.2
Housewife	936	14.6	6	0.2	930	30.3
Retired	3582	55.7	2001	59.7	1581	51.5
Other	576	9.0	352	10.5	213	7.0

is a particularly well-suited tool to use in investigations and clinical practice with high validity and reproducibility. The primary aim of our study was to assess the HRQoL for the adult Spanish population aged 60 years or older with MetS. This result is of great interest, since it would allow us to assess if being overweight/obese and having MetS may be associated to a poorer quality of life. Moreover, it would permit the design of global strategies in nursing care in order to be able to increase the quality of life in this vulnerable population.

Methods

Study design and participants

We carried out a cross-sectional evaluation of baseline data within the framework of the PREDIMED-Plus trial, which design has been extensively described elsewhere^{12,13} and which study protocol can be found on the PREDIMED-Plus website (<https://www.predimedplus.com/>).¹⁴ Briefly, PREDIMED-Plus study is an ongoing, 6-year, multi-center, parallel group, randomized clinical trial conducted in 23 Spanish recruitment centers to assess the effectiveness of an intensive weight-loss intervention program based on an intensive weight-loss intervention program (based on an energy restricted Mediterranean diet, physical activity promotion and behavioral support) on severe cardiovascular events in comparison with a control group receiving normal care.

The trial was approved by the *Institutional Review Board* of all recruitment centers where the study was conducted.¹²

The trial was registered in 2014 at the International Standard Randomized Controlled Trial (ISRCTN8988870).

Eligible participants were community-dwelling men (aged 55–75 years) and women (aged 60–75 years) with overweight or obesity (BMI ≥ 27 kg/m² and < 40 kg/m²), meeting at least 3 criteria of the MetS definition,¹⁵ and CVD free. Detailed inclusion and exclusion criteria have been extensively described elsewhere^{12,13} and are available at <http://predimedplus.com/>.¹⁴ We recruited 6874 participants from October 2013 to December 2016 who were randomly assigned in a 1:1 ratio to the intensive diet and lifestyle intervention group or to the usual care group. All participants provided written informed consent.

For the current analysis, we excluded 338 participants who did not complete half of the items that make up the scale and 106 participants with missing information on the baseline HRQoL questionnaire (SF-36-items). From the remaining 6430 participants, 5078 had completed the 36-items at baseline and 1352 participants answered more than half of the items that make up the scale. To preserve the sample size, the imputation of the mean was used to replace missing data. A total of 6430 participants were included for evaluation in the current study. The data were analyzed using the available, complete PREDIMED-Plus database, dated 10/08/2017.

Health-related quality of life assessment

HRQoL was measured using a Spanish version of SF-36, the questionnaire that was validated for the Spanish

Table 2 Average scores of the scales evaluated in the SF-36 in the full sample and by sex.

	PREDIMED-Plus		
	Mean	SD	95% CI
<i>Total (n = 6430)</i>			
Physical Function	76.1	16.4	75.7–76.6
Physical Role	76.1	35.6	75.2–77.0
Bodily Pain	62.2	26.6	61.6–62.9
General Health	62.3	18.7	61.9–62.8
Vitality	63.5	21.6	63.0–64.0
Social Function	85.9	20.9	85.4–86.4
Emotional Role	86.8	30.5	86.0–87.5
Mental Health	74.4	19.4	73.9–74.9
Aggregated Physical dimensions	44.9	8.9	44.7–45.2
Aggregated Mental dimensions	51.2	10.5	51.0–51.5
<i>Men (n = 3350)</i>			
Physical Function	81.7	16.4	81.1–82.2
Physical Role	84.3	29.7	83.2–85.3
Bodily Pain	69.5	24.9	68.6–70.3
General Health	65.6	17.4	65.0–66.2
Vitality	69.3	19.2	68.7–70.0
Social Function	89.7	17.9	89.1–90.3
Emotional Role	92.0	23.9	91.2–92.8
Mental Health	79.2	17.0	78.7–79.8
Aggregated Physical dimensions	47.2	7.7	46.9–47.4
Aggregated Mental dimensions	53.1	9.0	52.8–53.4
<i>Women (N = 3080)</i>			
Physical Function	70.1	20.6	69.4–70.8
Physical Role	67.2	39.1	65.9–68.6
Bodily Pain	54.3	26.0	53.4–55.2
General Health	58.8	19.4	58.1–59.5
Vitality	57.2	22.2	56.4–58.0
Social Function	81.8	23.1	81.0–82.6
Emotional Role	81.0	35.4	79.8–82.3
Mental Health	69.1	20.5	68.4–69.8
Aggregated Physical dimensions	42.5	9.5	42.2–42.9
Aggregated Mental dimensions	49.1	11.6	48.7–49.5

CI: Confidence Interval; SD: Standard deviation.

population, and is widely used as a precise way to measure self-perceived HRQoL.^{11,16}

SF-36 has 36 items that assess eight dimensions or scales: physical functioning, physical role functioning, bodily pain, general health, vitality, social role functioning, emotional role functioning, and mental health. These dimensions are grouped into two components: the physical component of health (physical functioning, physical role functioning, bodily pain and general health) and the mental component or psychosocial aspects (vitality, social role functioning, emotional role functioning, and mental health). The reliability of the scale, measured with Cronbach's α from the SF-36 questionnaire, used to determine the values of the Spanish population of ≥ 60 years was higher than the proposed standard of 0.7.¹⁷

Each item was scored with a numeric value, then all values corresponding to the same domain were added up and adjusted to a scale from 0 to 100. A higher punctuation means better health. The HQRoL was completed during the baseline visit.

Other covariates

Socio-demographic variables such as sex, age, birthplace, level of education, and current job were collected using a general questionnaire at baseline.

Statistical analysis

Measures of central tendency and spread were calculated with their 95% confidence intervals for the scores in each of the dimensions of the SF-36. The distribution of participants by sociodemographic characteristics was presented with proportions. We used the stratified values for quinquennials of age (men: 55–59, 60–64, 65–69 and 70–74 years; women: 60–64, 65–69 and 70–74 years) and sex. All analyses were performed with the statistical package StataCorp. 2015. Stata Statistical Software: Release 14. College Station, TX: StataCorp LP.

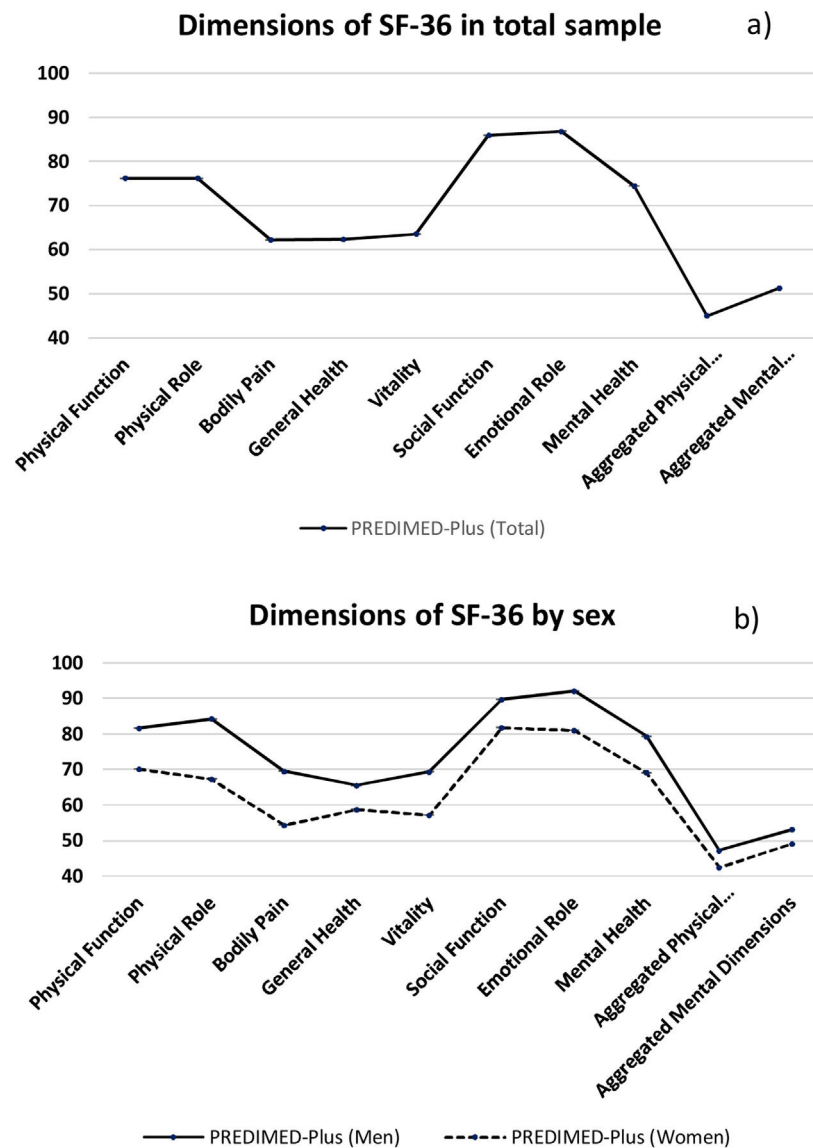


Figure 1 Average scores of the SF-36 dimensions in PREDIMED-Plus study. (a) Scores in the full sample. (b) Scores by sex.

Results

Table 1 shows the descriptive characteristics of the sample at baseline. A total of 6430 participants, 52.1% of whom were men and 47.9% women, were included. The average age was 64.9 (4.9) years. Most of them were married (76.5%) and had only elementary studies (47.5%). The proportion of participants who were retired was 55.7%.

Table 2 shows the SF-36 scale scores, applied both to the general form and stratified by sex in the PREDIMED-Plus study. Participants showed higher values in social function and emotional role scales in total sample and both sexes. In men, the worst score was the dimension of general health and the women was the bodily pain scale. In addition, men obtained higher scores on all scales than women (**Fig. 1**).

Table 3 shows the scores obtained in SF-36 in men and women stratified for quinquennials of age groups (55–59

years/60–64 years/65–69 years/70–75 years). In men, it can be seen that as age increases, HRQoL decreases significantly on the physical function scale. Participants aged 70–75 have a worse HRQoL than those aged 55–59 to 60–65. There is also a nonsignificant decrease in HRQoL on the physical role scale in older participants. In all other dimensions the score is similar in all three age ranges. In the case of women, we also found significant differences in the scales of physical function and physical role between the different age ranges, with a decrease in HRQoL in people between 70 and 75 years old compared to those between 60 and 65 years old. In the rest of the scales there is a slight increase, without significant differences, in the mean scores as age advances (**Fig. 2**).

Both in the overall sample and in the sample stratified by age and sex, we can verify that the worst scores were obtained in the aggregated physical dimensions.

Table 3 Average scores of SF-36's dimensions in PREDIMED-Plus by sex and age.

	n	PREDIMED-Plus (Men)			n	PREDIMED-PLUS (Women)		
		Mean	SD	95% CI		Mean	SD	95% CI
<i>Physical function</i>								
55–59 years	884	83.2	16.2	82.1–84.3				
60–64 years	981	82.8	15.6	81.8–83.7	1148	72.1	20.0	70.9–73.2
65–69 years	944	81.3	16.4	80.2–82.3	1205	70.4	20.7	69.2–71.6
70–75 years	541	78.0	17.3	76.5–79.4	727	66.6	21.2	65.0–68.1
<i>Physical role</i>								
55–59 years	884	83.8	30.2	81.8–85.8				
60–64 years	981	85.6	28.8	83.8–87.4	1148	67.6	39.1	65.4–69.9
65–69 years	944	84.4	29.6	82.5–86.3	1205	68.3	38.7	66.1–70.5
70–75 years	541	82.4	30.5	79.8–84.9	727	64.9	39.8	62.0–67.8
<i>Bodily pain</i>								
55–59 years	884	66.6	26.2	64.9–68.3				
60–64 years	981	69.9	24.5	68.3–71.4	1148	54.0	26.1	54.5–55.6
65–69 years	944	71.6	23.8	70.1–73.1	1205	54.3	25.9	52.9–55.8
70–75 years	541	69.8	25.2	67.7–71.9	727	54.7	26.1	52.8–56.6
<i>General health</i>								
55–59 years	884	62.8	18.2	61.6–64.0				
60–64 years	981	66.3	17.5	65.2–67.4	1148	57.6	19.5	56.5–58.7
65–69 years	944	66.8	16.5	65.8–67.9	1205	59.5	19.3	58.4–60.6
70–75 years	541	66.5	17.0	65.0–67.9	727	59.4	19.6	58.0–60.9
<i>Vitality</i>								
55–59 years	884	64.6	19.5	63.3–65.9				
60–64 years	981	70.2	19.2	70.0–71.4	1148	56.0	22.0	54.8–57.3
65–69 years	944	72.0	18.5	70.8–73.1	1205	57.9	22.4	56.6–59.1
70–75 years	541	70.8	18.5	69.2–72.3	727	57.9	22.2	56.3–59.5
<i>Social function</i>								
55–59 years	884	86.8	20.2	85.5–88.2				
60–64 years	981	90.8	17.0	89.8–91.9	1148	80.6	23.2	79.2–81.9
65–69 years	944	91.0	16.9	89.9–92.1	1205	82.2	23.2	80.9–83.5
70–75 years	541	90.2	16.8	88.8–91.6	727	83.0	23.9	81.3–84.6
<i>Emotional role</i>								
55–59 years	884	88.8	28.1	87.0–90.7				
60–64 years	981	92.6	23.3	91.1–94.1	1148	79.9	36.4	77.8–82.0
65–69 years	944	93.9	20.8	92.6–95.3	1205	81.6	34.9	79.6–83.5
70–75 years	541	93.0	22.3	91.1–94.9	727	81.9	34.7	79.4–84.4
<i>Mental health</i>								
55–59 years	884	75.5	17.3	74.3–76.6				
60–64 years	981	80.0	17.1	79.0–81.1	1148	68.4	20.2	67.2–69.5
65–69 years	944	81.2	16.3	80.2–82.3	1205	69.2	20.9	68.1–70.4
70–75 years	541	80.6	16.4	79.2–82.0	727	70.1	20.3	68.6–71.6
<i>Aggregated physical dimensions</i>								
55–59 years	884	47.2	8.0	46.7–47.8				
60–64 years	981	47.5	7.3	47.1–48.0	1148	42.8	9.4	42.3–43.4
65–69 years	944	47.2	7.5	46.7–47.7	1205	42.7	9.5	42.2–43.3
70–75 years	541	46.3	7.9	45.6–47.0	727	41.7	9.5	41.0–42.4
<i>Aggregated mental dimensions</i>								
55–59 years	884	50.8	9.8	50.2–51.5				
60–64 years	981	53.5	8.8	52.9–54.0	1148	48.3	11.7	47.6–49.0
65–69 years	944	54.3	8.4	53.8–54.8	1205	49.3	11.7	48.6–49.9
70–75 years	541	54.3	8.2	53.6–54.9	727	50.1	11.1	49.3–50.9

CI: Confidence Interval; SD: Standard deviation.

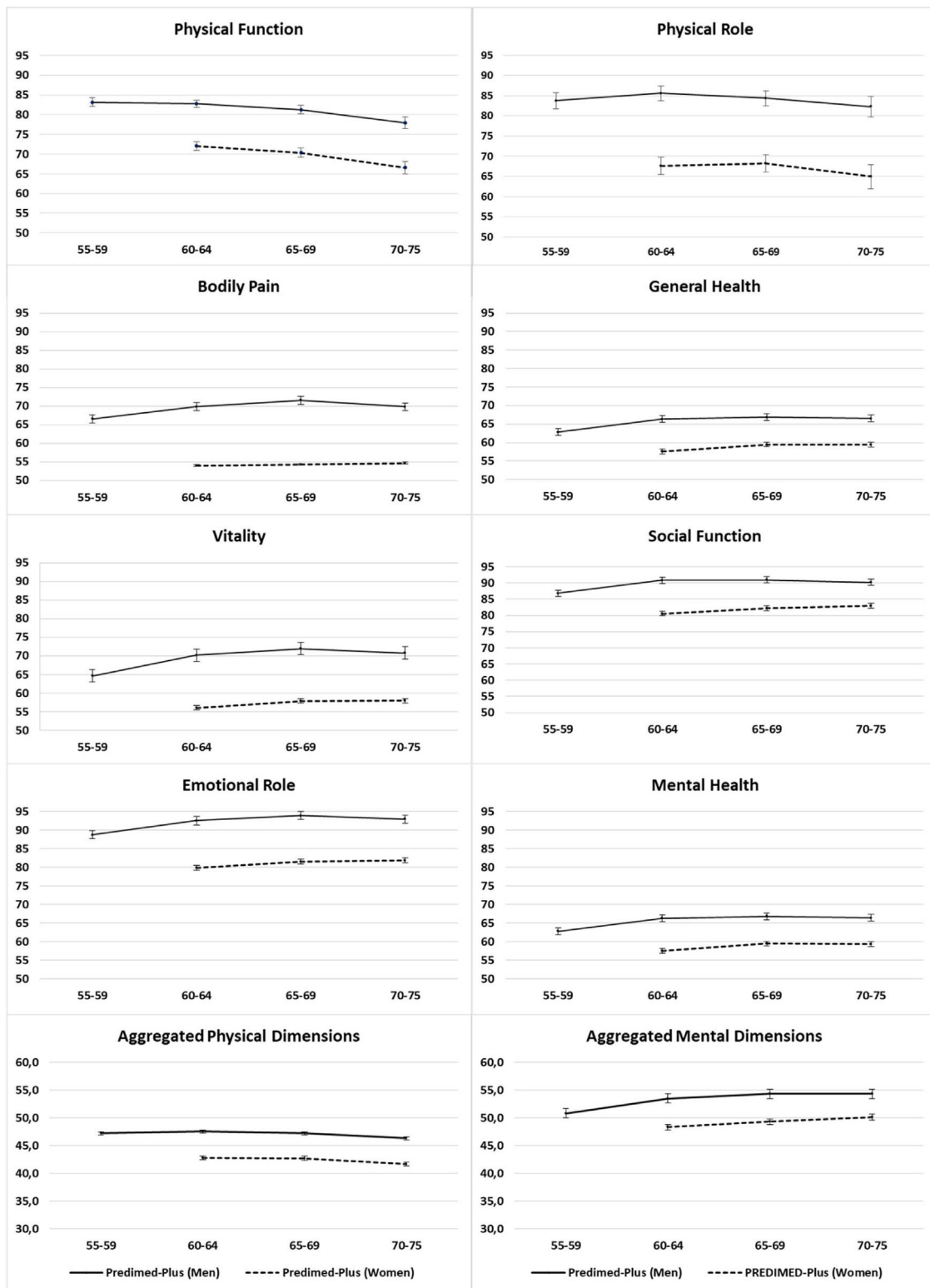


Figure 2 Average scores of SF-36's dimensions in PREDIMED-Plus by sex and age.

Discussion

The main findings of the present cross-sectional study conducted in individuals with MetS suggest that better average scores were obtained in the emotional role

functioning and social functioning scales. The lower values in our study for the areas of bodily pain, general health and vitality, were probably due to the participants' MetS which may have led to a negative impact on their HRQoL.

In all our sample, the minimum scores documented for men were for general health, bodily pain and vitality scales, while for women the minimum scores were also in the physical role scale, like other studies.^{5,18–21} This could be due to all participants in our study being overweight/obese and at least three criteria of MetS, as well as an age between 55 and 75 years. Obesity is a problem that has been on the rise as is the normalization of overweight in the elderly,^{22,23} so its impact on HRQoL can be expected to be more pronounced in the physical dimension and more moderate in the psychosocial dimension. The dimensions of the SF-36 questionnaire that measure the physical burden are the perception of general health, physical functioning, vitality and bodily pain.²¹ Obesity means an excessive body fat storage, in addition, participants are aged between 55 and 75 years and at this age there is a decrease in muscle mass and abdominal and perivisceral body fat redistribution. This is associated with increased abdominal circumference, which means increased difficulties in mobility, daily activities and bodily pain. There is also decreased functional ability and an increased disability rate, which occurs during aging and are exacerbated by obesity.^{24,25}

A comparison with the reference values of HRQoL in the Spanish population ≥ 60 years published by López-García et al.,¹⁷ in 2003 (Figs. 1S and 2S, supplementary data) shows that the data follow the same distribution as in our study, the scales with the highest mean scores in both males and females are emotional role and social function, while the lowest scores can be found in the dimensions general health and vitality. In addition, we also found a decrease in HRQoL in the physical dimensions. Similarly, the scores obtained in women are lower than in men. We obtained results similar to previous studies.^{26–29} However, if we compare each of the scales, we observe that the scores in the PREDIMED-Plus study are higher than the reference values for the Spanish population ≥ 60 years on all scales except bodily pain. A possible explanation to the observed differences could be explained due to the 15 years that have elapsed between the studies. Because the HRQoL is a reflection of the knowledge, experiences and values of individuals and collectivities, which are conditioned by a particular moment, quality of life criteria have evolved through the years.³⁰ PREDIMED-Plus is a primary cardiovascular prevention trial. Consequently, although participants have MetS, they have not yet had a cardiovascular event and therefore consider themselves healthy people, while the participants in the study by López-García et al.¹⁷ were selected from a sample of the general population where participants with and without pathologies and several chronic conditions were also included. Therefore, it is expected that the HRQoL in our study might be higher.³¹

In the Karlsson et al. study³² the results were the other way around, meaning people with obesity scored lower in their mood compared to healthy reference people. However, in our study an association with better mental health was similar to the Barcones-Molero et al. study.²¹

There, they checked the obesity and weight gain influence over quality of life, according to SF-36 for the dynamic cohort Seguimiento Universidad de Navarra (SUN) and the average values for mental health increased with BMI and became statistically significant in unadjusted models.

Men showed higher scores than women in all scales, which is the same in other studies in abdominal obesity and type 2 diabetes, in the population over 65 years old and in the general population, both in national studies and in international studies.^{19,29,32,33}

In physical components (physical functioning and physical role functioning), scales can be also observed that when the age increases the quality of life is decreased. Perhaps due to aging a loss of functional capacity is involved and is consistent with the rates of the Spanish population between 70 and 75 years old with disabilities or limitations, which represents 21.8% of total.²⁵

This study has some limitations. First, it is an observational cross-sectional descriptive study, so it does not imply causality. Also, the participants in our study are not representative of the general population as they all have MetS. However, the high number of participants and that after 15 years the scores obtained in the HRQoL questionnaire follow the same concordance as the reference values for the Spanish population ≥ 60 years is a strength, as well as the correct validity and reproducibility to measure the quality of life related to the health of the SF-36 questionnaire.

In conclusion, we can say that our results may reflect that the MetS might have a negative influence dimensions of HRQoL, general health, bodily pain and vitality the same cannot be said about psychological dimensions, which are less affected. Furthermore, we observed that HRQoL in women was poorer than in men for several dimensions, particularly, in the bodily pain dimension and the physical role and vitality dimensions. Therefore, the approach from Primary Care consultations on the impact generated by the MetS on HRQoL together with their potential causes is fundamental, paying special attention to the differences between men and women in this associationsexes.

Registration of clinical trials

The trial was registered in 2014 at the International Standard Randomized Controlled Trial (ISRCTN89898870).

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Conflict of interest

The authors have declared that there are no competing interests.

Appendix A.

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Appendix B. Supplementary data

Supplementary data associated with this article can be found, in the online version, at [doi:10.1016/j.semrg.2020.03.003](https://doi.org/10.1016/j.semrg.2020.03.003).

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