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- 1 Explanatory factors and levels of health-related quality of life among healthy pregnant women
- 2 at midpregnancy: A cross-sectional study of The PregnActive Project
- 3

4 **Abstract**

5 **Aims:** To identify potential explanatory factors and establish health-related quality of life
6 levels of healthy pregnant women at midpregnancy.

7 **Background:** The health-related quality of life levels perceived by pregnant women are lower
8 than those perceived by women of similar age and decline during the course of pregnancy.

9 **Design:** An exploratory cross-sectional design was used.

10 **Methods:** One hundred thirty-four healthy women from antenatal clinics completed
11 questionnaires were administered a cardiorespiratory fitness test and wore a multi-sensor
12 body monitor for 7 days at midpregnancy. Data were collected from September 2015 -
13 December 2016.

14 **Results:** Cardiorespiratory fitness, musculoskeletal symptoms and age were identified as
15 explanatory factors of the physical component summary of health-related quality of life.
16 Explanatory factors of the mental component summary included musculoskeletal and
17 psychological symptoms and light activity. Significant differences in health-related quality of
18 life levels were identified among groups of pregnant women stratified by age, occupational
19 status, pregnancy symptoms and cardiorespiratory fitness.

20 **Conclusions:** Modifiable factors of HRQoL, such as cardiorespiratory fitness and active
21 lifestyle may be important areas to target in interventions aimed at promoting HRQoL in
22 healthy women at midpregnancy. The identification of the groups of pregnant women with
23 lower levels of HRQoL may help midwives and health professional to focus their advice and
24 conduct interventions on these groups of pregnant women. These modifiable factors should be
25 considered in future longitudinal studies to determine causal effects, will likely help improve
26 multidisciplinary treatments.

27 **Keywords**

28 health-related quality of life, pregnancy, cardiorespiratory fitness, nursing, midwives,

29 symptoms, physical activity

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32 **Summary statement**

33 Why is this research or review needed?

- 34 ▪ The identification of the main explanatory factors of HRQoL at midpregnancy is needed to
35 improve the knowledge on this topic and support the prenatal care.
- 36 ▪ Knowledge related to pregnant women’s groups with low HRQoL levels enables the
37 development of specific treatments and interventions by midwives who focus on these
38 groups of pregnant women.

39 What are the key findings?

- 40 ▪ The physical component of HRQoL at midpregnancy is associated with a younger age, a
41 low level of musculoskeletal symptoms and a high level of cardiorespiratory fitness.
- 42 ▪ The mental component of HRQoL is associated with low levels of psychological and
43 musculoskeletal symptoms and a high level of light-intensity physical activities.
- 44 ▪ Pregnant women who are older, non-workers and have low CRF levels present low levels
45 on the physical component of HRQoL. Pregnant women who have high numbers of
46 pregnancy symptoms exhibit low levels on the mental component of HRQoL.

47 How should the findings be used to influence policy/practice/research/education?

- 48 ▪ Modifiable factors of HRQoL, such as cardiorespiratory fitness and active lifestyle, should
49 be considered in the prenatal care and when designing interventions regarding HRQoL at
50 midpregnancy.
- 51 ▪ The identification of pregnant women’s groups with low levels of HRQoL may help
52 midwives and health professional to better tailor their advice and conduct interventions on
53 these groups of pregnant women.

54 **Keywords**

55 health-related quality of life, pregnancy, cardiorespiratory fitness, nursing, midwives,
56 symptoms, physical activity.

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72 **INTRODUCTION**

73 Health-related quality of life (HRQoL) is considered a broad measure of perceived health
74 related to both self-reported chronic diseases and their risk factors (Centers for Disease
75 Control and Prevention, 2000). The study of HRQoL is an increasing interest in public health,
76 particularly during gestation because of the established decline in HRQoL levels during the
77 course of pregnancy (Álvarez Silvaes, de Diego Suárez, Almazán Ortega, González
78 González, & Rodríguez Núñez, 2008; Chang et al., 2014; Förger, Østensen, Schumacher, &
79 Villiger, 2005). The lower HRQoL levels among pregnant women compared with non-
80 pregnant women of similar age highlight the need to identify the aspects that affect HRQoL
81 during pregnancy, specifically in physical functioning, which is the main aspect of HRQoL
82 affected by the discomfort and distress produced by pregnancy (Álvarez Silvaes et al., 2008;
83 Förger et al., 2005; Gartland, Brown, Donath, & Perlen, 2010).

84 **Background**

85 One potential explanation for the lower levels of HRQoL perceived by pregnant women
86 compared with non-pregnant women may be related to the anatomical, physiological and
87 psychological changes that occur during the course of pregnancy and their related symptoms
88 (Tan & Tan, 2013). The appearance of pregnancy-related symptoms produces discomfort and
89 distress in pregnant women's health and are associated with low HRQoL levels (Lacasse,
90 Rey, Ferreira, Morin, & Bérard, 2008; Nicholson et al., 2006; Olsson & Nilsson-Wikmar,
91 2004; Setse et al., 2009). The majority of the literature focuses on the investigation of specific
92 symptoms and studies that assess the wide range of pregnancy-related symptoms are required
93 (Nazik & Eryilmaz, 2014).

94 In terms of physiological changes, pregnancy is characterized by an increase in heart rate at
95 rest, an increase in cardiac output and diminished peripheral vascular resistance to meet the

complex demands of fetal development (Dallmann et al., 2017). Cardiorespiratory fitness (CRF) has been established as a determinant of individual physical work capacity and better physical health (Ehrman et al., 2017). However, the CRF declines during pregnancy as a result of a limitation in the work capacity, but not the absolute capacity, of the aerobic system, which is caused by an increase in the ventilatory response related to the elevated metabolic costs of exercise (Davenport, Steinback, & Mottola, 2009). Physical inactivity aggravates this limitation in work capacity and aerobic exercise programs have consequently been proposed to prevent the decline in CRF during pregnancy (Ramirez-Velez et al., 2011). Although physical functioning is considered the main aspect of HRQoL affected by pregnancy and CRF shows a consistently positive association with HRQoL in the general adult and clinical populations (Engberg et al., 2017; Munguía-Izquierdo, Santalla, & Lucia, 2015), the associations between CRF levels and HRQoL during pregnancy remain unexplored.

The available knowledge regarding the associations between physical activity levels and HRQoL perceived by pregnant women is scarce. Previous studies did not identify associations between self-reported physical activity and HRQoL (Bahadoran & Mohamadirizi, 2015; Tendais, Figueiredo, Mota, & Conde, 2011). In the scientific literature, the current use of self-reported measures of physical activity (Downs, Chasan-Taber, Evenson, Leiferman, & Yeo, 2012), which have several limitations, such as the influence of recall bias and social desirability, highlights the need to objectively measure physical activity in future studies to improve our understanding of the association between physical activity levels and HRQoL in pregnant women.

THE STUDY

Aims

The aims of this study were to: 1) assess the associations of CRF, pregnancy symptoms and objectively measured physical activity levels with HRQoL in pregnant women at midpregnancy; and 2) establish and compare HRQoL levels at midpregnancy, as measured by the SF-36 and stratified by sociodemographic, physical and clinical variables.

Our working hypotheses were that high CRF and physical activity levels would be positively associated with high HRQoL levels and that pregnancy-related symptoms would be negatively associated with HRQoL.

Design

This investigation comprised an exploratory cross-sectional study of pregnant women recruited from antenatal clinics at midpregnancy.

Sample and settings

At the 12th gestational week visit to the antenatal clinics at Utrera Hospital, potential participants (N=200), aged 18-45 years, were individually informed of the study aims and protocol. Women with physical illnesses or disabilities that affected their normal daily routine and women with high-risk pregnancies (i.e., diabetes or hypertension) were excluded. Written informed consent was obtained from participants prior to study enrollment. The study sample was composed of 150 pregnant women and 16 pregnant women were excluded because of incomplete data collection.

Ethical consideration

The study protocol obtained ethical approval from the Medical Research Ethics Committee of the University Hospital Virgen del Rocío (Seville, Spain) in accordance with the Declaration of Helsinki, approval number 2014PI-066. The STROBE guideline items were fulfilled during the course of the study (von Elm et al., 2008).

Data collection

Coinciding with the second visit to the antenatal clinics (approximately the 20th week of gestation), the sociodemographic (age, marital status, educational level and occupational status) and clinical (pre-pregnancy body mass index (BMI), trimester of gestation and parity) characteristics were assessed using a self-reported questionnaire and data from medical records, respectively. Anthropometrical characteristics were evaluated by the same trained researcher following standard procedures using a calibrated digital scale (Tanita Corporation, Tokyo, Japan) and a stadiometer (Seca 780, Hamburg, Germany) and the BMI was calculated (kg/m^2). In this session, the HRQoL and pregnancy-related symptoms were assessed using standardized questionnaires (the Medical Outcome Study 36-item short form and the Pregnancy Symptoms Inventory, respectively). CRF was examined through a field-based test and a body monitoring device was placed on the left arm of the pregnant women. The body monitoring device measured the energy expenditure and physical activity behaviors of pregnant women over the following 8 days, during which the pregnant women were asked not to change their habitual lifestyle. At the end of this period, the pregnant women returned to the hospital to remove the body monitoring device. Data were collected from September 2015 to December 2016 by trained researchers.

Instruments

The Medical Outcome Study 36-item short form (SF-36) is a HRQoL questionnaire that provides a basic understanding of the functional health and wellbeing status. This tool contains eight domains which are summarized in a physical component summary (PCS) and mental component summary (MCS). The scores of the SF-36 are transformed to a 0-to-100 scale, where a low score represents a worse HRQoL. These two summary scales explain 80 to 85% of the variance in the eight domains for the general population (Vilagut et al., 2008; Ware et al., 1995). The mean score for the general Spanish population is 50, with a standard deviation of 10 points (Vilagut et al., 2008). A difference of half a SD or a five-points

168 difference (domain scores) and two to three points difference (summary scores) are
169 considered clinically relevant (Norman, Sloan, & Wywich, 2003; Ware, Kosinski, & Keller,
170 1994).

171 The pregnancy Symptoms Inventory is a 41-item Likert inventory that assesses the frequency
172 of symptom occurrence and their effects (Foxcroft, Callaway, Byrne, & Webster, 2013). The
173 Spanish version of this tool (Oviedo-Caro, Bueno-Antequera, & Munguía-Izquierdo, 2017)
174 was employed. For each symptom, pregnant women must choose between four options of
175 prevalence (never/rarely/sometimes/often). We created summary scores to quantify the
176 number of symptoms perceived sometimes and above by pregnant women for each category
177 of pregnancy-related symptoms: musculoskeletal, dermatological, urogenital, gastrointestinal,
178 cardiovascular and respiratory, neurological and psychological symptoms (Nazik & Eryilmaz,
179 2014).

180 The distance covered in the 6-minute walk test, which has previously been used with pregnant
181 women (Ramirez-Velez et al., 2011), was employed to assess the CRF. We used a 45.7-meter
182 rectangular course delimited by cones, with a 90-degree turn to minimize changes in rhythm
183 compared with a straight corridor space with a 180-degree turn. Pregnant women were
184 encouraged to walk as far as possible without running or jogging. The same trained instructor
185 explained the protocol, provided a demonstration prior to the start, supervised the test and
186 recorded the distance covered to the nearest 0.1 m. The heart rate was monitored beat-to-beat
187 during the test and 2-min recovery period using a heart rate monitor (Polar Electro Oy,
188 Kempele, Finland).

189 A body monitoring device, Sensewear Mini Armband (BodyMedia Inc., Pittsburgh, PA,
190 USA) was used to objectively assess energy expenditure, physical activity and sedentary
191 behavior. This device, which has been validated in pregnant women (Smith, Lanningham-
192 Foster, Welk, & Campbell, 2012), includes sensors to measure energy expenditure by

monitoring the heat flow from the body, skin temperature, galvanic skin response and 3-axis accelerometer for motion detection. The physiologic information gathered by the sensor array together with simple body measurements were processed using Sensewear algorithms to obtain accurate estimations of energy expenditure for all types of activities (Sensewear professional software version 8.1. BodyMedia Inc., Pittsburgh, PA, USA). The monitor was worn for 8 completed days, including five weekdays and two weekend days, with the exception of during water-based activities such as swimming or bathing. For the day to be considered completed, the monitor was required to be carried for more than 95% of the entire day (1368 min). To avoid any type of immediate reactivity, we removed the first completed day of monitoring from the analysis (Corder, Ekelund, Steele, Wareham, & Brage, 2008).

Validity and reliability

Both the original and Spanish versions of the SF-36 are reliable and valid instruments for evaluating HRQoL (Vilagut et al., 2008; Ware et al., 1995) and their psychometric properties have been satisfactorily analyzed among pregnant women (Jomeen & Martin, 2005). The two summary measures, PCS and MCS have demonstrated good internal reliability (Cronbach's $\alpha = 0.92$ & 0.91), accounting for 82 and 84% of the total variance (Ware et al., 1995).

In addition, both the original and Spanish versions of the Pregnancy Symptoms Inventory (Foxcroft et al., 2013; Oviedo-Caro et al., 2017) are reliable and valid tools for evaluating a wide range of pregnancy-related symptoms. The weighted kappa values range from 0.589 to 0.889, which indicates good reliability (Oviedo-Caro et al., 2017).

Statistical analysis

Statistical tests were performed using the Statistical Package for the Social Sciences version 20 (IBM Corp., Armonk, NY, USA), with the significance set to $p < 0.050$.

A multiple stepwise linear regression analysis was performed to determine the relative contributions of the study variables to the summary scales of HRQoL (dependent variables). Variance inflation factor values greater than 3 were used to indicate multicollinearity problems in the model. Graphic and statistical analyses of residuals were used to verify the normality, linearity and homoscedasticity of the regression analysis. To prevent overfitting, significant correlates from the bivariate test were included in the model. To quantify bivariate associations between HRQoL and the study variables, Pearson or Spearman correlation coefficients were used, depending on whether the data showed normal or skewed distributions. Variables with skewed distributions were transformed to reach a normal distribution when possible, using a square root transformation for moderate activity and moderate-to-vigorous physical activity (MVPA) and a reciprocal transformation ($1/x$) for pre-pregnancy and current BMI. The correlation values were interpreted as follows: <0.25 , weak or null; $0.25-0.50$, fair; $0.50-0.75$, moderate to good; and >0.75 , good to excellent.

Differences in the HRQoL scores according to sociodemographic variables with an influence on pregnancy (Baron et al., 2017), fulfillment of MVPA recommendations (World Health Organization, 2010), light activity, CRF and number of pregnancy-related symptom levels were calculated using Student's t-tests or Mann-Whitney U tests depending on whether the data showed normal or skewed distributions, respectively. Adjustment for multiple comparisons was performed using the Bonferroni method by dividing the significance level of 0.05 by the number of comparisons, in this case, $0.05/10 = 0.005$. To determine groups of light activity, CRF and pregnancy-related symptoms we employed the median split procedure, which group individuals according to whether they are over or under the median.

RESULTS

One hundred thirty-four healthy pregnant women, who had a mean age of 32.5 years and a mean BMI of 26.5 kg/m², fulfilled the inclusion criteria, provided written consent and completed the study protocol. The characteristics of the sample are presented in Table 1.

Study variables with significant simple correlation with HRQoL summary scores were included in the regression models as independent variables (Table S1). The model for the PCS of HRQoL included age, parity, vigorous activity, days meeting MVPA recommendations, CRF and musculoskeletal, cardiovascular, gastrointestinal and psychological symptoms. The model of the MCS of HRQoL included light activity, light-to-vigorous activity summary and psychological, musculoskeletal, cardiovascular, gastrointestinal, urogenital and dermatological symptoms.

The multiple regression analysis indicated that the CRF ($\beta=0.35$; $p<0.001$), age ($\beta=-0.26$; $p=0.001$) and musculoskeletal symptoms ($\beta=-0.26$; $p=0.001$) were explanatory factors of the PCS of HRQoL and the model explained 15% ($p<0.001$) of the variability (Table 2). There was no multicollinearity among the variables in the final model. Musculoskeletal symptoms ($\beta=-0.24$; $p=0.005$), psychological symptoms ($\beta=-0.21$; $p=0.014$) and light activity ($\beta=0.17$; $p=0.048$) were identified as explanatory factors of the MCS of HRQoL and the model explained 16% ($p<0.001$) of the variability (Table 3). There was no multicollinearity among the variables in the final model.

Table 4 provides the HRQoL scores for the healthy pregnant women at midpregnancy, stratified by sociodemographic, physical and clinical variables. The average scores for the domains ranged from 52.8 points in the vitality domain to 91.4 points in the emotional role domain. The PCS score was significantly lower than the MCS score ($p<0.001$). The pregnant women who were older, non-workers and had a low level of CRF presented significantly lower PCS scores than their counterparts ($p<0.005$). The pregnant women who perceived a high number of pregnancy symptoms presented significantly lower MCS scores than their

counterparts ($p<0.005$). The pregnant women with a high number of pregnancy symptoms scored lower in all summaries and domains of HRQoL than the pregnant women with a low number of pregnancy symptoms and most differences were significant ($p<0.005$).

DISCUSSION

This study constitutes the first investigation to assess the associations of objectively measured physical activity, CRF and pregnancy-related symptoms with HRQoL at midpregnancy. The findings of this study corroborate that the physical component of HRQoL is more affected by pregnancy than the mental component; moreover, the results highlight the importance of CRF, musculoskeletal and psychological symptoms, light activity and age as explanatory factors of HRQoL. In addition, this study presents and compares the scores of the Medical Outcome Study 36-item short form of healthy pregnant women at midpregnancy, stratified by sociodemographic, physical and clinical variables.

Consistent with previous studies in clinical populations (Engberg et al., 2017; Munguía-Izquierdo et al., 2015), our study identified an association between CRF and the physical component of HRQoL, whereas no association was identified between CRF and the mental component of HRQoL. Our results indicate that high CRF during pregnancy is associated with the PCS of HRQoL. Although expected, this finding has not previously been demonstrated and further studies are required to confirm it. This finding could be explained by the fact that CRF is an essential and integral biological indicator of human health that represents the capacity for daily living activities. The reduction in the work capacity of the aerobic system during pregnancy as a result of maternal demand (Davenport et al., 2009) and the protective effect of CRF on established pregnancies (Thorell, Goldsmith, Weiss, & Kristiansson, 2015) emphasize the importance of future studies investigating existing methods to improve or maintain CRF in pregnant women to enhance HRQoL.

288 Pregnancy symptoms presented a negative association with both the PCS and MCS of
289 HRQoL, musculoskeletal symptoms were identified as an explanatory factor of both summary
290 components and psychological symptoms were only associated with the MCS of HRQoL.
291 Consistent with our findings, several studies have indicated the negative association of
292 individual musculoskeletal symptoms with both the PCS and MCS (Ghanei-Gheshlagh,
293 Toloeipoor-Lanjavani, Lazari, & Moslemi, 2014; Olsson & Nilsson-Wikmar, 2004), which
294 could be explained by the impaired physical abilities and functional limitations produced by
295 musculoskeletal symptoms in pregnant women's activities of daily life. This limitation in
296 daily life activities affects not only physical functioning but also the social and mental
297 activities of pregnant women's lives, thus explaining the negative impact on both summary
298 components of HRQoL. The negative association of psychological symptoms with the MCS
299 of HRQoL is consistent with findings from previous studies in pregnant women (Nicholson et
300 al., 2006; Setse et al., 2009). This consistency across studies could be explained by the fact
301 that pregnancy is a vulnerable period of mental health in women's lives because of the intense
302 psychological and biological changes that occur during this period, which are translated into
303 impairments in social interactions and changes in social status related to gender role
304 socialization (Marcus, 2009). Future studies and interventions should aim to include the wide
305 range of pregnancy symptoms and not only focus on specific symptoms to reduce the impact
306 of pregnancy-related symptoms on pregnant women's HRQoL.

307 Age was identified as an explanatory factor of the PCS of HRQoL; in addition, significantly
308 lower PCS scores were identified in an older group of pregnant women compared with a
309 younger group. These results are consistent with previous studies (Li et al., 2012; Vilagut et
310 al., 2008) and could be explained by the fact that physical discomforts are more likely to
311 occur in older than younger pregnant women (Li et al., 2012) as a result of the established
312 high frequency of health problems, such as gestational diabetes, chronic hypertension,

placenta previa or miscarriage (Khalil, Syngelaki, Maiz, Zinevich, & Nicolaides, 2013). Although age was not identified as an explanatory factor of the MCS of HRQoL, younger pregnant women presented lower, although not significant, MCS scores than older pregnant women, consistent with findings from previous studies (Li et al., 2012). This finding may be a result of the high stress levels perceived by younger pregnant women, given the changes produced in their lives by expecting a child and emotional immaturity and economic dependency may more often be characteristic of younger pregnant women than older pregnant women (Kelly, Fitzsimons, & Baker, 2016). In this sense, older pregnant women have had more life experiences, which may have helped them develop better coping methods that they can use to address emotional problems (Li et al., 2012).

With regard to physical activity, time spent in light-intensity activities was identified as an explanatory factor of the MCS of HRQoL; however, we did not identify associations with MVPA, which is consistent with findings from previous studies in pregnant women (Bahadoran & Mohamadirizi, 2015) and female adults (Shibata, Oka, Nakamura, & Muraoka, 2007). The positive association between light physical activity and HRQoL could be explained by the potential action of physical activity on both health and wellness, which improves HRQoL (Vuillemin et al., 2005). This finding may indicate the need to take into account light-intensity activities in the assessment of the physical activity levels and patterns of pregnant women and this finding is supported by the high prevalence of light-intensity physical activities in pregnant women's daily lives, which could be explained by pregnant women's selection of less-demanding activities during pregnancy to compensate for the increase in basal energy expenditure (Melzer, Schutz, Boulvain, & Kayser, 2009). The lack of an association between the MVPA levels and HRQoL is consistent with findings from previous studies in pregnant women (Bahadoran & Mohamadirizi, 2015) and female adults (Shibata et al., 2007). This result highlights that meeting the recommended physical activity

338 volume recommendations is not sufficient for women to perceive significantly better HRQoL.
339 A dose-response of the number of days for which the physical activity recommendation is
340 fulfilled may be related to a better physical component of HRQoL; however, further studies
341 that assess this association and confirm these statements are required.

342 Our results indicate that the mean scores of all SF-36 domains were lower than the values
343 identified in healthy pregnant women at the second trimester (Förger et al., 2005), with the
344 exception of the emotional role. These discrepancies may have occurred because the previous
345 study (Förger et al., 2005) included a higher percentage of nulliparous than parous pregnant
346 women, whereas in our study, the percentages of each group were similar. It has been
347 established that nulliparous pregnant women report higher scores of HRQoL than parous
348 pregnant women (Li et al., 2012). Consistent with a previous study (Li et al., 2012), our
349 participants reported the lowest scores on the physical role and vitality domains, which
350 indicates the highest impairment at the second trimester of pregnancy and suggests the need to
351 focus health care interventions on these specific domains. Compared with normative data for
352 age-matched healthy adult Spanish women (Vilagut et al., 2008), we identified lower scores
353 for the PCS in pregnant women than in healthy adult Spanish women. However, the MCS did
354 not present differences. In contrast to the scores obtained in healthy age-matched adult
355 Spanish women (Vilagut et al., 2008), pregnant women presented higher scores on the mental
356 than the physical component of HRQoL. These statements highlight the substantial
357 discomfort and distress on physical health caused by pregnancy (Álvarez Silvestre et al., 2008)
358 and the importance of the development of multi-dimensional interventions in routine health
359 care during pregnancy focused on the amelioration of this discomfort and distress.

360 According to the differences between the stratified groups, the significantly low PCS scores
361 identified in the group of pregnant women who were non-workers are consistent with a
362 previous study (Rezaei et al., 2016). This finding should be explained cautiously because

pregnant women on sick leave from work were included in our group of non-workers. Both healthy pregnant women unable to work because of a job that could be risky for pregnancy and pregnant women with medical or obstetrics problems are included in this group. Pregnant women with medical or obstetrics problems have impaired physical health, which may have worsened their PCS scores.

Strengths and limitations

A strength of this study is the objective measurement of physical activity using a validated device in pregnant women (Smith et al., 2012). The preferential use of objective measures is important for improving our understanding of the associations between physical activity and HRQoL in healthy pregnant women, thus enhancing the precision of the self-reported physical activity measurements used in previous studies (Kolu, Raitanen, & Luoto, 2014). The strict analysis of Sensewear data, which included only pregnant women who wore the monitor during seven complete days (for more than 95% of each day), strengthens the objective measurement of daily activity. Another strength of this study is the comparison of the SF-36 scores of healthy pregnant women at midpregnancy stratified by sociodemographic, physical and clinical variables, thus enabling the detection of lower level groups, which may help midwives and health professional to focus this advice on these groups of pregnant women.

The present study is not without limitations. The cross-sectional design precludes the description of the evolution of the main outcomes during the course of pregnancy and avoids the identification of relationships between outcomes at different stages of pregnancy. Future studies should analyze the explanatory factors of HRQoL among pregnant women at later stages of pregnancy and conduct a longitudinal analysis over the course of the pregnancy. Another limitation is the exclusion of high-risk pregnant women and only the inclusion of pregnant women who met the eligibility criteria and voluntarily participated, which could

result in self-selection bias. Future epidemiological and multi-center studies with larger sample sizes are also required to explore these associations.

HRQoL is considered a broad measure of perceived health. Studies that investigate the association of the explanatory factors identified in this study with obstetrics and medical outcome measures will improve the knowledge regarding the influence of the explanatory factors on pregnancy. In addition, the SF-36 provides a basic understanding of the functional health and wellbeing status. Future studies with a larger and random sample are needed to establish normative values for the SF-36. The combined use of this tool with other HRQoL questionnaires, such as the WHOQOL-BREF or the EuroQol-5D, will improve the knowledge of this topic during pregnancy.

In the stratified group analysis, the age and occupational status groups did not present similar percentages of pregnant women, which may have limited statistical power. However, the low percentage of younger pregnant women in the present study could be explained by the fact that the median age of pregnant women in Spain was 32.4 years old (Instituto Nacional de Estadística del Gobierno de España, 2015). In addition, the inclusion of pregnant women on sick leave from work in the group of non-workers may have worsened the PCS scores of this group.

CONCLUSION

The identification of the main explanatory factors of HRQoL may help midwives and health professionals better tailor their advice and focus the prenatal care. Modifiable factors of HRQoL, such as cardiorespiratory fitness and active lifestyle, may be important areas to target in interventions aimed at promoting HRQoL in healthy women at midpregnancy. In addition, the results of this study suggest that older age, not working, perceiving a higher level of musculoskeletal symptoms and having a low level of cardiorespiratory fitness are

412 associated with a lower level of the physical component of HRQoL in healthy pregnant
413 women at midpregnancy. Similarly, perceiving a high level of psychological and
414 musculoskeletal symptoms and having a low level of light-intensity physical activities are
415 associated with a lower level of the mental component of HRQoL in healthy pregnant women
416 at midpregnancy. More in-depth knowledge, such as knowledge gained from longitudinal
417 research aiming to determine causal effects, will likely help improve multidisciplinary
418 treatment and, consequently, the HRQoL of healthy women at midpregnancy.

419

420 AUTHOR CONTRIBUTIONS

421 All authors have agreed on the final version and meet at least one of the following criteria

422 [recommended by the ICMJE (<http://www.icmje.org/recommendations/>)]:

- 423 • substantial contributions to conception and design, acquisition of data or analysis and
424 interpretation of data;
- 425 • draughting the article or revising it critically for important intellectual content.

426

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Table 1. Demographic characteristics of the sample (n=134).

Variables	Mean (SD) or Median (IQR)
Age (years old)	32.5 (4.2)
Pre-pregnancy BMI ($\text{kg} \cdot \text{m}^{-2}$)	24.9 (4.4)
Current BMI ($\text{kg} \cdot \text{m}^{-2}$)	26.5 (4.5)
Number of daughters	0.5 (0.6)
Light activity ($\text{h} \cdot \text{d}^{-1}$)	5.2 (1.4)
Moderate activity ($\text{min} \cdot \text{wk}^{-1}$)	546.0 (401.0-838.0)
Vigorous activity ($\text{min} \cdot \text{wk}^{-1}$)	0.0 (0.0-1.0)
Light to vigorous activity ($\text{min} \cdot \text{d}^{-1}$)	398.1 (106.7)
MVPA in ≥ 10 -min bouts ($\text{min} \cdot \text{wk}^{-1}$)	222.5 (107.0-358.0)
Days meeting ≥ 30 min if MVPA in ≥ 10 -min bout ($\text{d} \cdot \text{wk}^{-1}$)	3.0 (2.1)
N (%)	
Ethnicity	
Caucasian	134 (100)
Age	
18-30 years old	33 (24.6)
31-44 years old	101 (75.4)
Pre-pregnancy BMI	
$< 25 \text{ kg/m}^2$	77 (57.5)
$> 25 \text{ kg/m}^2$	57 (42.5)
Current BMI	
$< 25 \text{ kg/m}^2$	65 (48.5)
$> 25 \text{ kg/m}^2$	69 (51.5)
Marital status	
Single without partner	2 (1.5)
Single with partner	39 (29.1)
Married	91 (67.9)
Divorced or separated	2 (1.5)
Parity	
0	72 (53.7)
≥ 1	62 (46.3)
Highest level of education	
Non-Tertiary	72 (53.7)
Tertiary	62 (46.3)
Occupational status*	
Workers	85 (63.4)
Non-workers	
Unemployed	28 (20.9)
Sick leave from work	19 (14.2)
MVPA recommendations	
Inactive	99 (73.9)
Active	35 (26.1)

*Two student excluded of occupational status.

Abbreviations. BMI: Body Mass Index, MVPA: Moderate to vigorous physical activity.

Table 2. Final model of the stepwise regression analysis with the physical component of HRQOL as the **outcome** variable (n=134)

Variables ^a	<i>B</i>	95% C.I.	SE	β	<i>t</i>	VIF	<i>p</i> value
(Constant)	37.12	22.96, 51.28	7.16		5.19		
CRF	0.05	0.03, 0.07	0.01	0.35	4.61	1.01	< 0.001
Age	-0.48	-0.75, -0.21	0.14	-0.26	-3.48	1.00	0.001
Musculoskeletal symptoms	-1.41	-2.21, -0.61	0.41	-0.26	-3.48	1.01	0.001

B: unstandardized coefficient; β : standardized coefficient; SE: standard error; VIF: variance inflation.

^aOnly significant correlates in the bivariate tests were included in the model (CRF, age and musculoskeletal symptoms).

*Significant when *P* < 0.050.

Table 3. Final model of the stepwise regression analysis with the mental component of HRQOL as the **outcome** variable (n=134)

Variables ^a	<i>B</i>	95% C.I.	SE	β	<i>t</i>	VIF	<i>p</i> value
(Constant)	51.61	45.73, 57.49	2.97				
Musculoskeletal symptoms	- 1.40	-2.36, -0.44	0.48	- 0.24	- 2.89	1.10	0.005
Psychological symptoms	- 0.91	-0.64, -0.19	0.37	- 0.21	- 2.49	1.11	0.014
Light activity	0.96	0.01, 1.91	0.48	0.17	1.99	1.08	0.048

B: unstandardized coefficient; β : standardized coefficient; SE: standard error; VIF: variance inflation.

^aOnly significant correlates in the bivariate tests were included in the model (CRF, age and musculoskeletal symptoms).

*Significant when $P < 0.050$.

Table 4. HRQOL scores in pregnant women at midpregnancy and classified by stratified variables.

	n	Physical function (0-100)	Physical Role (0-100)	Pain (0-100)	General Health (0-100)	Vitality (0-100)	Social Function (0-100)	Emotional Role (0-100)	Mental Health (0-100)	PCS (0-100)	MCS (0-100)
All	134	73.7 (16.7)	65.2 (26.2)	67.5 (21.7)	74.7 (15.8)	52.8 (14.7)	80.1 (20.5)	91.4 (16.6)	75.3 (16.1)	45.4 (7.7)	51.7 (8.2)
Age											
≤30 years old	33	76.5 (17.5)	74.8 (27.6)	70.9 (21.4)	77.4 (17.7)	53.8 (17.7)	79.5 (21.2)	88.6 (21.0)	71.1 (20.3)	48.8 (8.0)	49.1 (9.8)
>30 years old	101	72.8 (16.4)	62.1 (25.1)	66.4 (21.8)	73.9 (15.1)	52.5 (13.7)	80.3 (20.3)	92.3 (14.9)	76.7 (14.3)	44.3 (7.4)	52.5 (7.5)
<i>p value</i>		0.264	0.015	0.301	0.266	0.674	0.851	0.269	0.079	0.003	0.037
Parity											
Nulliparous	72	75.1 (14.9)	68.8 (26.5)	71.1 (21.3)	77.0 (15.5)	55.3 (15.6)	80.6 (21.7)	91.4 (16.4)	74.7 (16.8)	47.0 (7.2)	51.4 (8.8)
Parous	62	72.1 (18.5)	61.1 (25.4)	63.2 (21.6)	72.0 (15.8)	50.0 (13.1)	79.6 (19.1)	91.4 (16.9)	76.1 (15.4)	43.5 (8.0)	52.0 (7.6)
<i>p value</i>		0.305	0.091	0.035	0.067	0.037	0.797	0.990	0.599	0.009	0.633
Pre-pregnancy BMI											
<25 kg/m ²	77	74.9 (18.1)	65.0 (27.7)	65.6 (20.6)	77.5 (13.3)	52.8 (15.6)	83.6 (18.7)	90.5 (17.9)	75.5 (16.8)	45.7 (8.2)	51.9 (8.7)
≥25 kg/m ²	57	72.1 (14.5)	65.5 (24.3)	70.0 (23.1)	71.0 (18.1)	52.9 (13.5)	75.4 (21.9)	92.7 (14.7)	75.1 (15.3)	45.0 (7.1)	51.4 (7.7)
<i>p value</i>		0.344	0.923	0.241	0.019	0.997	0.022	0.447	0.879	0.598	0.723
Current BMI											
<25 kg/m ²	65	78.3 (15.7)	68.6 (28.1)	68.0 (20.1)	78.2 (12.8)	53.9 (16.1)	86.2 (18.0)	91.7 (17.0)	75.5 (17.2)	47.1 (7.9)	51.9 (8.8)
≥25 kg/m ²	69	69.3 (18.4)	62.0 (24.0)	66.9 (23.3)	71.5 (17.6)	51.8 (13.3)	74.5 (21.2)	91.2 (16.4)	75.2 (15.1)	43.8 (7.2)	51.4 (7.8)
<i>p value</i>		0.002	0.151	0.767	0.014	0.404	0.001	0.867	0.931	0.012	0.723
Occupational status*											
Workers	83	75.1 (15.8)	72.5 (23.1)	69.8 (19.7)	76.4 (14.8)	53.3 (15.0)	83.3 (18.0)	93.8 (13.6)	77.5 (14.5)	46.7 (6.7)	52.6 (6.8)
Non-workers	49	70.8 (18.0)	52.0 (26.3)	62.8 (24.3)	73.0 (16.6)	52.6 (14.1)	76.3 (22.7)	88.9 (18.9)	73.2 (16.7)	42.7 (8.6)	51.2 (8.7)
<i>p value</i>		0.154	<0.001	0.077	0.227	0.773	0.053	0.091	0.122	0.004	0.321
Educational level											
Non-tertiary	72	71.5 (18.2)	61.6 (27.0)	63.7 (22.5)	73.0 (16.7)	51.3 (15.3)	79.2 (20.7)	90.6 (17.5)	73.2 (15.8)	44.1 (8.3)	51.2 (8.0)
Tertiary	62	76.3 (14.4)	69.4 (24.8)	71.9 (20.1)	76.7 (14.5)	54.6 (13.9)	81.3 (20.3)	92.3 (15.6)	77.8 (16.3)	46.9 (6.8)	52.2 (8.6)
<i>p value</i>		0.094	0.089	0.030	0.172	0.192	0.559	0.553	0.098	0.038	0.467
Light activities											
<5 h/d	64	72.8 (14.7)	61.4 (26.1)	64.5 (22.1)	71.7 (17.3)	51.8 (13.6)	75.8 (21.8)	90.2 (17.4)	72.4 (17.9)	44.4 (7.5)	50.4 (9.3)
≥5 h/d	70	74.5 (18.4)	68.7 (25.9)	70.2 (21.1)	77.5 (13.7)	53.8 (15.7)	84.1 (18.4)	92.5 (15.9)	78.0 (13.9)	46.3 (7.9)	52.8 (7.1)
<i>p value</i>		0.560	0.110	0.129	0.032	0.415	0.018	0.432	0.045	0.165	0.091
MVPA recommendations											
<5 d/wk with at least 30 min/d	99	72.8 (16.5)	66.3 (24.7)	68.4 (22.0)	73.5 (16.3)	52.5 (14.2)	80.6 (20.0)	92.0 (16.1)	76.2 (14.9)	45.2 (7.0)	52.0 (7.3)
≥5 d/wk with at least 30 min/d	35	76.1 (17.1)	62.1 (30.0)	64.8 (21.0)	78.2 (13.9)	53.8 (16.2)	78.9 (22.0)	89.8 (18.2)	72.9 (19.2)	45.9 (9.6)	50.6 (10.5)
<i>p value</i>		0.313	0.423	0.395	0.127	0.674	0.688	0.494	0.292	0.631	0.382
Cardiorespiratory Fitness**											
<555 m	66	69.1 (16.9)	59.5 (28.1)	63.9 (23.0)	71.5 (15.9)	50.7 (13.1)	77.5 (20.7)	90.5 (18.0)	75.0 (13.9)	43.0 (7.7)	51.7 (7.2)
≥555 m	67	77.9 (15.2)	70.6 (23.1)	70.5 (19.8)	77.7 (15.2)	54.7 (15.9)	82.5 (20.1)	92.2 (15.3)	75.4 (18.2)	47.6 (7.1)	51.5 (9.2)
<i>p value</i>		0.002	0.014	0.079	0.022	0.115	0.160	0.573	0.874	0.001	0.889
Number of pregnancy symptoms											
<11 symptoms	68	76.5 (16.9)	72.1 (24.3)	71.9 (21.6)	77.9 (14.0)	58.5 (14.5)	86.2 (16.6)	96.3 (11.3)	80.4 (13.7)	46.8 (7.7)	54.6 (6.2)
≥11 symptoms	66	70.8 (16.0)	58.1 (26.4)	62.9 (21.0)	71.5 (16.9)	47.1 (12.7)	73.9 (22.2)	86.4 (19.5)	70.2 (16.8)	43.9 (7.5)	48.7 (9.0)
<i>p value</i>		0.044	0.002	0.015	0.019	<0.001	<0.001	<0.001	<0.001	0.031	<0.001

Correlation values are either Pearson or Spearman correlation.

* Two student excluded of occupational status.

** One pregnant women excluded due to incomplete data.

* Significant when *p value* < 0.005

Table S1. Associations between HRQL scores and the rest of variables in pregnant women at midpregnancy (n=134).

	Physical Function (0-100)	Physical Role (0-100)	Pain (0-100)	General Health (0-100)	Vitality (0-100)	Social Function (0-100)	Emotional Role (0-100)	Mental Health (0-100)	Physical Component Summary (0-100)	Mental Component Summary (0-100)
Sociodemographic										
Age (yr)	-0.19 *	-0.17	-0.09	-0.10	-0.12	-0.04	-0.04	0.05	-0.21 *	0.06
Parity	-0.05	-0.17 *	-0.23 **	-0.16	-0.22 *	-0.06	0.01	0.01	-0.22 *	0.01
Pre-pregnancy BMI (kg m ⁻²)	-0.22 *	-0.03	0.05	-0.22 *	-0.05	-0.20 *	-0.00	-0.07	-0.11	-0.08
Current BMI (kg m ⁻²)	-0.28 ***	-0.09	0.01	-0.20 *	-0.06	-0.18 *	-0.08	-0.05	-0.16	-0.07
Physical activity categories										
Light activity (h d ⁻¹)	0.14	0.22 *	0.09	0.13	0.07	0.23 **	0.18 *	0.14	0.14	0.16 *
Moderate activity (min d ⁻¹)	0.13	0.08	0.04	0.16	0.09	0.16	0.07	0.07	0.09	0.11
Vigorous activity (h d ⁻¹)	0.24 **	0.20 *	-0.02	0.22 *	-0.01	0.10	-0.08	0.05	0.26 **	-0.02
Physical activity summaries										
Light to vigorous activity (min d ⁻¹)	0.19 *	0.20 *	0.08	0.17 *	0.09	0.27 **	0.17 *	0.13	0.15	0.17 *
Moderate to vigorous activity in ≥10-min bouts (min d ⁻¹)	0.16	0.05	0.06	0.16	0.07	0.11	0.02	0.05	0.14	0.03
Meeting ≥ 30 minutes of MVPA in ≥10-min bouts (d wk ⁻¹)	0.20 *	0.07	0.06	0.16	0.12	0.07	0.03	0.06	0.17 *	0.03
Pregnancy-related symptoms										
Total Symptoms	-0.32 ***	-0.31 ***	-0.33 ***	-0.16	-0.42 ***	-0.31 ***	-0.31 ***	-0.35 ***	-0.30 ***	-0.38 ***
Musculoskeletal symptoms	-0.27 ***	-0.24 **	-0.41 ***	-0.18 *	-0.35 ***	-0.14	-0.28 ***	-0.23 **	-0.30 ***	-0.23 **
Dermatological symptoms	-0.20 *	-0.12	-0.15	-0.09	-0.18 *	-0.15	-0.21 *	-0.17 *	-0.14	-0.19 *
Urogenital symptoms	-0.17	-0.22 ***	-0.11	-0.07	-0.30 ***	-0.15	-0.15	-0.14	-0.16	-0.20 *
Gastrointestinal symptoms	-0.27 ***	-0.15	-0.11	-0.10	-0.20 *	-0.26 **	-0.10	-0.28 ***	-0.17 *	-0.24 **
Cardiovascular and Respiratory symptoms	-0.19 *	-0.25 **	-0.17 *	-0.08	-0.26 **	-0.21 *	-0.13	-0.23 **	-0.20 *	-0.24 **
Neurological symptoms	-0.03	-0.11	-0.22 **	0.03	-0.12	-0.01	-0.03	0.05	-0.17	0.00
Psychological symptoms	-0.19 *	-0.22 **	-0.22 **	-0.08	-0.32 ***	-0.24 **	-0.25 **	-0.31 ***	-0.18 *	-0.33 ***
Cardiorespiratory fitness										
6MWT distance covered (m) ^a	0.34 ***	0.24 **	0.23 **	0.24 **	0.16	0.23 **	-0.02	0.10	0.37 ***	0.03

Correlation values are either Pearson or Spearman correlation.

* $p < 0.050$.** $p < 0.010$.*** $p < 0.001$.^a One pregnant women excluded due to incomplete data.