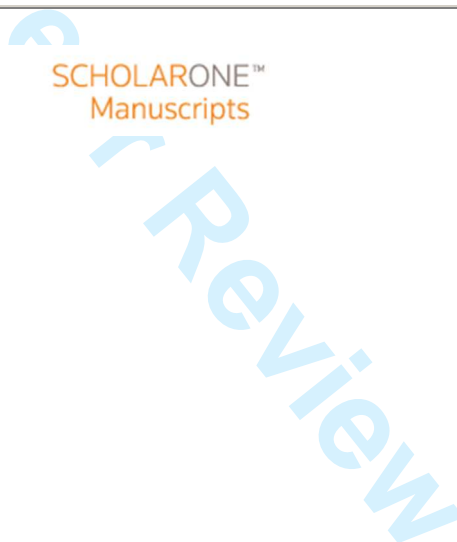


Using a mixed-method research to study the quality of life of coeliac women

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Using mixed-method research to study the quality of life of coeliac women

Abstract

Aims

To research the quality of life of Spanish women with coeliac disease

Background

Coeliac women express lower quality of life than male coeliacs.

Design

Explanatory sequential approach using mixed methods and with a gender perspective.

Methods

The research was carried out between May and July 2015. In its quantitative stage it aims to determine the health-related quality of life (HRQoL) in a representative sample (n=1097) of Spanish adult women with coeliac disease using a specific questionnaire named CD-QOL. In its qualitative phase it aims to describe the life experiences of a woman with coeliac disease in a qualitative manner by means of interviews (n=19) with a semi-structured script. Quantitative data were analysed using SPSS 20 and presented in descriptive statistics. Qualitative data were analysed using directed content analysis.

Results

The quantitative process gave us values on the four aspects studied: dysphoria, disease limitations, health problems, and inadequate treatment. These aspects allowed us to create a qualitative process, based on which we generated an interview, from which four larger categories emerged. These categories were: feelings at diagnosis, limitations in day-to-day life, social perceptions of the disease, and personal meanings of coeliac disease. Thus both phases of our project are totally connected. There was a high level of congruence between quantitative scores and narratives.

Conclusion

This study shows us the strong points of mixed methods in health sciences. The mixed-method strategy gave us a wider view of the experience of women living with coeliac disease. In our case, a strength and not a limitation is having performed the quality of life study in coeliac women using a mixed methodology, approaching the experience of being a coeliac woman in Spain in two different but complementary ways. The quantitative and qualitative data allowed us to interpret the experiences of our participants.

Keywords: Coeliac Disease; Coeliac Disease-Quality of Life (CD-QOL); Quality of life related to health; Spain; nursing; Mixed Methods

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'What does this paper contribute to the wider global clinical community?'

- Coeliac women express lower quality of life than male coeliacs. It is necessary to express life experience from the point of view of a coeliac woman. There are few studies that talk about the quality of life of coeliac women, and there are even less which also talk about the qualitative experience of coeliac women.
- The health related quality of life of coeliac women is average compared to previous studies. In their responses, coeliac women expressed a lack of support from society and the health system in particular. Coeliac women express fears in relation to their social life in general and their future in particular.
- The results of our study show that the health system in general and nurses in particular could help women with coeliac disease by giving them support on an emotional level. Nursing plays an important role in educating the population, and in the case of our study, nurses could educate the population about what coeliac disease is and what a gluten-free diet is, thereby preventing the social exclusion experienced by women with coeliac disease.

Use of Mixed-Method Research to study the quality of life of women with coeliac disease.

Introduction

Coeliac disease (CD) is a systemic autoimmune disorder primarily affecting the digestive system, which is characterised by chronic inflammation of the small intestine triggered by an immune response and maintained through exposure to gluten in the diet (Schuppan *et al.* 2009). CD affects genetically predisposed children and adults (Ludvigsson *et al.* 2013), and is more common in women than in men with a ratio of 2:1 (Maki & Collin 1997).

Global prevalence of CD is estimated at 1%, with variations depending on the age and country of origin of the populations concerned (Mustalahti *et al.* 2010; WGO 2013). This was confirmed in a recent multi-centre study in Europe, which showed a prevalence of 2% in Finland and 0.3% in Germany (Mustalahti *et al.* 2010), as well as percentages of 1-2% in the adult population of Western Europe (West *et al.* 2003). Recent studies have shown that in North America and Europe the number of new cases of CD found in a determined period in a given population is increasing (Catassi *et al.* 2010). What's more, CD represents a growing entity, as current prevalence of the condition is significantly higher than it was 20 years ago (Catassi *et al.* 2010). Despite this, various authors recognise that the real frequency of CD may be underestimated due to high rates of misdiagnosis in coeliac patients, in particular adults.

The prevalence of CD in Spain was determined in a population study based on determining positive serology: The global prevalence of CD in all ages was 1:204 subjects, being higher in children (1:71) than in adults (1:357) (Mariné *et al.* 2011)

Theoretical Background

When an individual is diagnosed with CD, he or she must face significant changes to his or her life. On the one hand, the development of symptoms related to the disease has a biological effect. On the other hand, the feeling of being afflicted with a chronic illness, the need to follow a restrictive, demanding and permanent diet, together with periodic medical checks or the possibility of other family members being diagnosed mean that the illness has a significant psychosocial impact. In adults, a diagnosis of CD entails changes to living habits, due to the appearance of emotional changes resulting from feeling different from the rest, and shame or fear of being contaminated by contact with gluten, as well as the additional difficulties in following a gluten-free diet (GFD) away from the home, especially at work or while travelling (Lee & Newman 2003).

As a general rule and following the establishment of a gluten-free diet (GFD), a coeliac individual will maintain it, and will undergo a significant improvement in symptoms in a matter of days or weeks (Autodore *et al.* 2012). However, the change to dietary habits for life in an adult entails many problems (Sverker *et al.* 2005)

Prior research (Ring Jacobsson *et al.* 2012) shows that the various disadvantages of having CD and following a GFD are more pronounced in women than in men. This suggests that the signs of general malaise should not be attributed to CD, but instead to complications in adjusting to the nature of the illness (Roos *et al.* 2009)

Other prior studies exist which confirm that women diagnosed with CD report a lower quality of life than men diagnosed with the same illness (Zarkadas *et al.* 2006; Ring Jacobsson *et al.* 2012) due to restrictions in their day-to-day lives (Hallert *et al.* 2003) and social lives (Hallert *et al.* 2002).

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4 Recent studies have shown gender differences (Sverker *et al.* 2009) by studying the day-to-day
5 predicaments of men and women with coeliac disease. Both men and women reported different
6 social situations in relation to the purchasing and preparation of foods (Sverker *et al.* 2009).
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12 It seems reasonable that in light of all of the prior studies, the use of mixed methods is needed in
13 order to try to explain the phenomenon of women with coeliac disease, as well as to be able to study
14 the quality of life of these women and the causes of their problems, and the restrictions they must
15 make in their day-to-day lives.
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22 At this point it seems logical to come up with a way to approach this series of problems. To do this
23 we need a methodology which enables us to explain the various situations from a new perspective
24 capable of tackling all the problems with their own methodologies, and this methodology is mixed
25 methods.
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37 **Methodology**

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39 Mixed methods provide us the opportunity to integrate a variety of theoretical perspectives into one,
40 in the interests of improving the understanding of the study to be carried out. On the one hand we
41 encounter a quantitative methodology, with a deductive approach, the aim of which is to test our
42 hypothesis, gather descriptive information, and examine the relationship between the variables;
43 these data provide us with measurable proof. Moreover, based on the results of the quantitative
44 methodology, we will extract a series of questions with a qualitative methodology with an inductive
45 approach based on the context and significance of human experience. In this case they will be semi-
46 structured interviews, which will help us provide detailed information directly from the participants.
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57 The qualitative approach used will be phenomenology.
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4 There are different possibilities for the design which do not aim to be exhaustive as there are
5 various possible approaches in health sciences research (Öhlen 2010; Creswell *et al.* 2011), of the
6 different types, we will use a sequential explanatory design (Creswell & Plano Clark 2007; Johnson
7 *et al.* 2007; Teddlie & Yu 2007) as it is a popular approach in health sciences, it is normally used in
8 the quantitative results of a quality of life scale, to which we will add the qualitative data to better
9 understand the responses, meaning the qualitative data aim to explain in greater detail the
10 mechanisms which underlie the quantitative results (Creswell & Plano Clark 2007)
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21 Our study will therefore be a mixed-methods explanatory sequential study with a gender
22 perspective, in which we will set out 2 phases. The quantitative phase aims to determine the health-
23 related quality of life (HRQoL) in a representative sample of Spanish adult women with coeliac
24 disease, as well as its determining factors by means of a specific questionnaire named CD-QOL. In
25 the second phase, it should be noted that few studies have focused on describing the life experiences
26 of women with coeliac disease, therefore it seems important to explore and delve deeper into these
27 experiences in a qualitative manner by means of interviews with a semi-structured script.
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39 *Research ethics*

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41 Regarding research ethics, in all the phases, participants were informed that they had no obligation
42 to participate and were free to refuse or stop the interview at any stage (Rea & Parker 2012).
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48 **Quantitative Phase**

49 **Design and scope of the study**

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51 This observational, descriptive and transversal study on an intentional non-probabilistic sample of
52 Spanish adults women with coeliac disease, representative of the adult coeliac population of Spain
53 (aged between 16 to 75 years), was carried out between May and July 2015.
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1 The criterion defining a coeliac patient was the giving of a diagnosis by a medical specialist, and the
2 subject being a member of a regional association of coeliac patients included in Federation of
3 Coeliac Associations in Spain (FACE). The need to document the diagnosis and pay regular
4 instalments was interpreted as a low risk of selection bias. All of the patients who correctly filled
5 out the self-assessment questionnaire supporting this study were included. Subjects aged less than
6 16 years and older than 75 years were excluded.
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17 Part of these analytical results, belonging to a larger study, has been published (Rodriguez-Almagro
18 et al. 2016). In this new study, our qualitative results relating to the quality of life of women with
19 coeliac disease are studied using a mixed methodology. To these results a methodological
20 qualitative part is added, and all of the data are analysed together.
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28 Rigour in quantitative research is determined by examining the quality of the research (Muijs 2011).
29 To do this, a checklist appropriate to each type of study was used. In our case, the checklist used
30 was a Strobe statement. Taking into account empirical evidence and theoretical considerations, a
31 group of methodologists, researchers, and editors developed the Strengthening the Reporting of
32 Observational Studies in Epidemiology (STROBE) recommendations to improve the quality of
33 reporting of observational studies. The STROBE Statement consists of a checklist of 22 items,
34 which relate to the title, abstract, introduction, methods, results and discussion sections of articles.
35 (Vandenbroucke et al., 2009)
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48 Variables of the study

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50 A data gathering log was designed which included an explanation of the aims and purposes of the
51 study and ensured anonymity, confidentiality and the remaining ethical guarantees. This
52 questionnaire was sent to an accountable person at each of the Coeliac Associations of Spain's 17
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Autonomous Communities, and at the same time was sent to the different coeliac associations over social networks, which published this study to be filled in by its members voluntarily.

The anonymous questionnaire gathered demographic information on the sample: age (years), gender, time since CD diagnosis (years), self-declared correct compliance with a GFD (yes/no), time with gluten (years).

In 2010 Drossman *et al* validated the specific questionnaire CD-QOL to measure the HRQoL in coeliac patients (Dorn *et al.* 2010), which was later adapted and validated to be used in Spanish by Casellas *et al* in 2013 (Casellas *et al.* 2013).

The HRQoL was evaluated by means of the specific questionnaire CD-QOL, a validated translation into Spanish (14) for adult patients. The CD-QOL consists of 20 items which explore 4 aspects: dysphoria, limitations, health concerns, and inadequate treatment, which were scored by the patient using a Likert scale, from 1 (strongly disagree) to 5 (strongly agree). The CD-QOL produces a global score from 0 (worst quality of life) to 100 (best quality of life) points. Each one of the four aspects is expressed on the same scale of 0-100.

Calculation of the sample size

The number of patients necessary to estimate an adequate representation of the Spanish population was calculated on the basis of the population of Spain on 1 January 2015 aged between 16 and 75 years (“Instituto Nacional de Estadística,” 2015) (17,526,476 subjects), an estimated coeliac disease prevalence of 1%, a level of confidence of 95% and an absolute error of 0.6%. A minimum number of 1022 was needed in order to accurately carry out the study.

Statistical analysis

For the descriptive statistics, absolute and relative frequencies were used for the qualitative variables; mean frequencies (standard deviation) for the quantitative data if they showed a normal distribution, and a median (interquartile range) if not. For the bivariate analysis, Pearson's chi-squared test was used when the independent and dependent variables were qualitative, and the Student-Fisher t-test and Analysis of Variance (ANOVA) when the variable response was quantitative. Finally a multivariate analysis was done using multiple linear regression to control confounding, where the dependent variable was the overall quality score and the score for the four aspects that make it up, while the independent variables were the sex and age of the patient, the diagnosis time and the treatment time. For the statistical analysis, the program SPSS v 20.0. was used, which is valid on any platform (Windows 7, Mac).

Ethical aspects

This observational study carried out using anonymous data was designed in accordance with the Declaration of Helsinki enacted by the World Medical Association (WMA).

Qualitative Phase

A study was carried out using qualitative methodology, applying the perspective of gender, by means of interviews with a semi-structured script with women with coeliac disease. Qualitative methodology is especially useful to understand a phenomenon from the perspective of those involved, exploring their beliefs, expectations, feelings, and explanations for their behaviour and attitudes. The perspective of gender allows unequal situations to be observed, as well as different needs associated with traditional roles, in relation to the care of these women.

The sampling was intentional (Polit & Hungler 2000), conducting interviews with those adult women with coeliac disease who contacted the research team after having seen the appeals on social

1 networks during the period between May and July 2015, and although the size of the theoretical
2 sample was insufficient to guarantee external validity in terms of other investigation models (Jeon
3 2004), it was sufficient to saturate all of the categories by including participants of varying
4 sociodemographic characteristics.
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12 The data gathered in the interviews was recorded in password-protected audio files to which only
13 the authors have access (Bryant & Charmaz 2007).
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19 The only criteria for inclusion were to be a woman with coeliac disease, independent of the time
20 since diagnosis, and to be aged between 16 and 75 years.
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26 In total, in an initial phase 19 semi-structured interviews were conducted, gathering a series of
27 sociodemographic characteristics such as age, sex and the time since diagnosis with Coeliac Disease
28 (Table 1) with a semi-structured script followed to modulate the interviews (Table 2). The
29 interviews lasted between 45 and 60 minutes, and were transcribed fully. All of the participants
30 took part in a voluntary and informed manner. Furthermore, it should be noted that the anonymity
31 of the person and the confidentiality of the information was kept throughout the whole study as well
32 as in future public presentations of results, following all of the requirements established in the
33 Helsinki declaration, thereby guaranteeing against any future ethical problem which could arise in
34 relation to the investigation. The women were identified with codes to respect their anonymity, and
35 the interviews were identified with the letter I (for Interview) followed by a sequential number from
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52 All of the interviews began with an open question (Giorgi 1997) to invite the participants to narrate
53 their experiences of living with coeliac disease and to focus the issue: 'Tell me your experience of
54 living with Coeliac Disease?'. The participants were encouraged to freely narrate their experience
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1 of the disease, and the interviewer followed the script in a free manner to encourage the
2 participants.
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8 The analysis of the information was done using Amadeo Giorgi's phenomenological method, which
9 aims to discover the meanings through essential themes; this method showed results about the
10 experiences of women living with coeliac disease through the categorisation of all of the findings
11 into units of meaning, based on the philosophy of Edmund Husserl and Merleau-Ponty, and is
12 sufficiently generic to be applied to any science (Giorgi 2009)
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15 The text of the interviews was therefore analysed in the following manner (Giorgi, 1997; Jacobsson
16 et al., 2012):
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Transcription: The interviews were read while the tapes were listened to, in order to obtain an initial superficial interpretation. This step gave ideas on the meaning of the whole and how to proceed with a deeper analysis.

Elaboration of Units of general meaning: the interviews were read once again, but this time with the aim of identifying the smallest parts, the units of meaning, within the perspective of the phenomenon of being a woman living with CD.

To avoid theoretical explanations, the data were kept to the most specific level possible. One unit of meaning may be part of a sentence or a paragraph.

Elaboration of Units of meaning relevant to the theme of the investigation: taking as a reference the Units of general meaning identified in the previous step, it was sought to select from among the units of meaning those relevant to the research theme. When themes are repeated in the units of meaning, the investigator aimed to find convergences and divergences between them, and construct the theme categories based on these. The repetition of themes indicates that it was possible to get to the essence or meaning of the phenomenon studied.

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4 Verification of the relevant units of meaning: once the units of meaning relevant to the investigation
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6 were obtained, we looked for criteria allowing us to group some of the units of meaning into
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8 categories which reflect common aspects or characteristics. These categories constitute a new
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10 element which allows us to name a set of relevant units of meaning under one epigraph, theme,
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12 issue, etc.
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17 The selection was carried out by grouping the units by common meanings, forming groups of
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19 meaning. From these groups, themes which show the meaning of experiencing or living determined
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21 phenomena will be identified and interpreted. The general structure, that is, a new group, was
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23 synthesised in a representation of the phenomenon of being a woman living with CD.
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30 During the process, the criteria for methodological rigour of credibility, dependability,
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32 confirmability and transferability were observed (Lincoln & Guba, 1985; Cornejo Cancino & Salas
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34 Guzmán, 2011).
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37 Credibility was accomplished by the purposeful selection of participants to assure maximum
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39 variation, as well as by carefully following the research design step by step. Dependability was
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41 ensured by the first author performing and transcribing all interviews and also through transparent
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43 description of the research steps taken, that is, inquiry audit. Confirmability was ensured by
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45 providing quotes from the interviews as examples of explicated meanings, and to show
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47 transferability, a rich description of the context of participants is provided (Ring Jacobsson,
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49 Milberg, Hjelm & Friedrichsen, 2016). All authors were involved in the validation of the results,
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51 questioning each step of the analysis to check for possible alternative interpretations. The analysis
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53 was discussed until agreement was reached.
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Results: Quantitative Phase

The aim of this phase was to measure the quality of life of Spanish women with CD, as well as to find out HRQoL by means of the questionnaire CD-QOL. However, we wanted to go one step further and combine these results with the qualitative phase by using a mixed method. Therefore, using these quantitative results a script was developed with open questions which are laid out in the results of the qualitative phase, and which consolidate and reinforce the results of the CD-QOL.

Participants

A total of 1097 women with coeliac disease correctly completed the questionnaire, with a mean age of 32.7 (10.5) years (ranging from 16 to 75). **Table 1** summarises the main demographic features of the population.

"Insert Table 1 about here."

HRQoL level in coeliac patients

The mean HRQoL of the sample, evaluated using the questionnaire CD-QOL, was 56.1 (SD=18.25) points.

Of the aspects composing the CD-QOL index, *dysphoria* was the aspect with the highest mean score of 81.0 (SD=19.86) points, followed by *disease limitations* with 52.3 (SD=23.39) points, *health problems* with 50.8 (SD=25.94) points, and finally *inadequate treatment* showed the lowest mean score with 36.7 (SD=21.16) points. **Figure 1** graphically shows the distribution of each aspect.

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"Insert Figure 1 about here."

In relation with the foregoing, items 6, 8, and 9 of the CD-QOL questionnaire, the latter two related with the perception of *inadequate treatment*, obtained the worst mean scores, as shown in **Table 2**.

"Insert Table 2 about here."

Factors determining HRQoL in coeliac patients

The time since diagnosis and the time spent following a gluten-free diet proved to be independent factors which determine HRQoL in adult women with CD, in accordance with the univariate and multivariate analyses. However, each one of these factors showed a differential influence on the various aspects which the questionnaire CD-QOL evaluates (**Table 3**):

"Insert Table 3 about here."

Age determined a lower score in the aspect *health problems*, which is significantly lower in the 31-40 years group in the univariate analysis (**Table 3**). The multivariate analysis documented a relationship between an older age of the patient and a worse score for this aspect (**Table 4**), although it was not statistically significant ($p=0.056$).

The time since diagnosis with CD significantly affected the scores in all of the aspects which make up the CD-QOL index (**Table 3**); the multivariate analysis only showed a significant association in the aspect *inadequate treatment*, in the sense that the greater the time passed since CD diagnosis, the worse the scores given to this aspect (**Table 4**).

"Insert Table 4 about here."

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4 Finally, a significant association was observed between the time spent on a GFD and the mean
5
6 HRQoL score on the global CD-QOL scale in each of its aspects (**Table 2**). This significant
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8 association was maintained throughout the multivariate analysis, both for the global index as well as
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10 in three of its aspects (**Table 4**). The greater the time spent following a GFD, the better the global
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12 mean score on the CD-QOL scale, as well as in the *dysphoria* and *limitations* aspects. The aspect
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14 *inadequate treatment* showed a significant inverse relationship.
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Results: Qualitative Phase

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21 The aim of this phase was to add more in-depth results and obtain a more detailed understanding of
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23 how women with coeliac disease feel in their day-to-day, what their quality of life is, and to try to
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25 explain their experience of life with coeliac disease in their own words. We must highlight that the
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27 interview with open questions came in part from the results obtained in the quantitative phase of the
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29 questionnaire CD-QOL. All of the interviews started with the question ‘Tell me how it is for you,
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31 living with coeliac disease?’. This was then followed by asking a series of open questions which are
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33 listed below:
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40 Some questions were asked in relation to the dysphoria category of the quantitative phase in order
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42 to clarify the results and add greater complexity to the data:
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46 -What did you feel when you were diagnosed with coeliac disease? Do you feel ill? How did they
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48 tell you? How would you have liked to be told?
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53 -Fears
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57 -Is there loneliness in having coeliac disease?
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4 Some questions were asked in relation to the disease limitations category of the quantitative phase
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6 in order to add greater depth to the results:
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11 -Avoiding eating out
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15 -Avoiding travelling
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19 -Living with the disease day-to-day
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26 Some questions were asked in relation to the health problems category of the quantitative phase
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28 which will add value to the results:
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33 -Chronicity and treatment of coeliac disease
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37 -Is social support needed?
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41 - Social Conscience
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48 Some questions were asked in relation to the inadequate treatment category of the quantitative
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50 phase in order to add consistency to the results:
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55 -Difficult situations experienced as a coeliac sufferer
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1 - Unawareness of the illness, family, friends, restaurants, etc.

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4 To finish, a series of open questions were asked to provide additional data to our interviews.

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8 Experience of the illness, positive or negative

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12 Emotional relationships with family members

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17 Emotional relationships with friends

18 19 20 21 Participants

22 A total of 19 women with CD were interviewed, with a mean age of 32.94 years, which is closely
23 related to the mean age of the quantitative sample, 32.7 years. **Table 5** summarises the main
24 demographical features of the population, and all of them are undergoing treatment with a GFD.
25 Rigorous study of the interviews carried out brought up four categories representative of the life
26 experience of those woman, which were named as follows: feelings at diagnosis, limitations in day-
27 to-day life, social perceptions of the illness, and personal definitions of coeliac disease.
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40 **"Insert Table 5 about here."**

41 42 43 *Feelings at diagnosis*

44 The women in the study show in their responses that there is a lack of information when giving a
45 diagnosis. They feel afraid, anger at the unknown, and really feel the disease at this stage. At the
46 same time they feel relief, relief at knowing what they have and that with plenty of training they can
47 come to terms with living with their illness day-to-day:
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54 "I felt a mixture of anger at what I had and at the lack of information they gave me at the time, and
55 that I could no longer live a normal life because of food" (I2)
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4 “When they tell you, at first you’re surprised and don’t know if that’s what you really have. He told
5
6 us of the risks and told my mother that I could die, and that’s not easy, a mother being told her
7
8 daughter could die, but that’s unlikely if you’re aware of the illness, thank God, and my mother and
9
10 I have felt much more reassured since then” (I12)

11 12 13 14 15 *Limitations in day-to-day life*

16
17 From our interviews regarding women following a GFD, implications emerge in their social life.
18
19 Some of these women are excluded from eating out due to uncertainty about content of the food,
20
21 and uncertainty about cross contamination.
22
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24
25 These women feel isolated. Social isolation is common in coeliac sufferers. They feel a lack of
26
27 companionship, affection and support which is made worse by the lack of quality social
28
29 relationships. Among the possible causes are the various circumstances coeliac sufferers must face
30
31 in their lives: difficulty finding restaurants, and the existence of a certain rejection in society,
32
33 especially by hotels and restaurants. All of this leads to a deprivation of emotional, physical and
34
35 financial support which coeliac sufferers are less able to respond to.
36
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41 One of the interviewees told us “I don’t usually go to restaurants, in this town there’s not much to
42
43 choose from and when for once we decided to go out for dinner to celebrate our anniversary we
44
45 almost ended up arguing with the waiter... I mean, you try and explain it but people have no reason
46
47 to understand... that night, first we ordered grilled vegetables and when it came it turned out they
48
49 were battered, we explained that I couldn’t eat it because it contained flour, then we tried with
50
51 grilled fish (they assured us it wasn’t battered) but the fish turned up swimming in a rather thick
52
53 sauce (thickened with flour, of course) so eventually my husband ate there and I at home, as
54
55 always.” (I7)
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4 Socializing out with friends and family is not as enjoyable when it centres on eating; eating at home
5
6 with family is less problematic. Coeliac disease has an impact not only on women but on their
7
8 social network too.
9

10 11 12 13 *Social perceptions of the disease*

14
15 In the reduction of data a social unawareness emerges. All of the women have made up their minds
16
17 that we must raise awareness in nurseries, schools and on television to gain a better understanding
18
19 of coeliac disease.
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23
24 Moreover, almost all of the participants allude in one way or another to the existence of
25
26 associations, and the support they provide to coeliac women.
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29
30 “At university I met a friend who also had coeliac disease, and through her I signed up to the
31
32 association. It was an incredible discovery for me because they helped me a lot; they gave me a
33
34 book with gluten-free brands and products and explained a lot of things I didn’t know” (I18)
35
36

37 38 39 *Personal meanings of coeliac disease*

40
41 In all of the interviews there are concerns about the future in relation to life, work, the results show
42
43 that all of the feelings the women have may be a characteristic feature of coeliac disease in them
44
45 specifically.
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50 As treatment continues, and they correctly manage their gluten-free diet, patients show a reduction
51
52 in anxiety, fears, and so on. At the same time they generate valid coping strategies which
53
54 correspond to an increase in well-being and a valid sense of release for the effective operation of
55
56 their day-to-day lives.
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4 “Living with coeliac disease worries me, I think about the future, I think about whether my children
5 will have coeliac disease, maybe it’s silly but all that together with my fears about developing other
6 related illnesses make me rethink my future and everything that goes with that” (I14)
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12 “Really, coeliac disease is just not eating gluten, don’t you think? Once you’ve got over that, at
13 least in my case all of the fears and concerns vanished, and this has helped me want to eat out, relate
14 with people again and take on all of the difficult situations which I couldn’t before” (I3)
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20 21 **Discussion**

22
23 In this study the HRQoL of a representative sample of adult Spanish women with CD was
24 evaluated, both in an overall manner as well as based on the aspects that form part of HRQoL, and
25 the determining factors or factors associated with it were determined. Our methodological approach,
26 a combined qualitative and quantitative process, allowed us to capture the real experiences of
27 coeliac women. The quantitative process gave us values on the four aspects studied, dysphoria,
28 disease limitations, health problems, and inadequate treatment. These aspects allowed us to create a
29 qualitative process, based on which we generated an interview, from which four larger categories
30 emerged. These categories were: feelings at diagnosis, limitations in day-to-day life, social
31 perceptions of the disease, and personal meanings of coeliac disease. Thus both phases of our
32 project are totally connected.
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48 Our results suggest that the use of an educational program could improve the categories described
49 in the qualitative interviews, so one of the future lines of research could be to re-interview women
50 after completing an educational program on coeliac disease. (Ring Jacobsson, Milberg, Hjelm &
51 Friedrichsen, 2016)
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4 Our results suggest that the HRQoL level in the general adult coeliac population of the community
5 could be less than in hospital-recruited populations (Casellas et al. 2013), giving rise to the
6 hypothesis that periodic medical checks improve quality of life by encouraging better adherence to
7 a GFD (Casellas et al. 2015); in fact, correct adherence to a GFD has repeatedly been shown to be
8 an independent factor associated with a better quality of life among coeliac patients. Our study
9 explores for the first time the HRQoL in a wide sample of coeliac women from the general
10 population, recruited from throughout Spain and therefore representing the general coeliac
11 population. Overall, the perceived HRQoL level was shown to be average, and influenced by the
12 age of the patients, the time since diagnosis, and the time on treatment with a GFD. Remarkably,
13 HRQoL significantly increased the longer a gluten-free diet was followed, data reflected both in the
14 quantitative questionnaire as well as in the qualitative interviews.
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30 The quantitative data alone would not have been enough to come to the final conclusions of this
31 study; the qualitative interviews support these data and reinforce the strong character of mixed-
32 methods research.
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40 **Limitations and Future Research**

41 The study has various limitations, firstly, the instrument to measure quality of life reflects only the
42 aspects studied, it is for this reason that we used mixed methods, using the interviews and
43 experiences to try and provide a solid anchor and give consistency to our quantitative results.
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50 We must also recognize limitations in our study derived from the absence of a non-random
51 sampling procedure. The attitudes towards CD of the women who voluntarily responded to the
52 appeal may have been more favourable than those who did not respond, with it being possible that
53 participation in this study reflects a greater involvement of the patient in CD (with the subsequent
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1 better adherence to a GFD), or on the contrary, it may reflect greater involvement of those most
2 affected.
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8 Another of the limitations is the age of the participants, any future line of research should take on
9 the ages not included in our study, in this case a study with adolescents or even girls would be
10 welcomed, and which would make us rethink the possible future situations which may occur due to
11 having coeliac disease from a young age.
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15 **Conclusions**

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17 However, we believe that the quality of life of women with coeliac disease was average and it is
18 conditioned by the sex and age of the patient, time since diagnosis, and the treatment time with
19 GFD. It is also associated with a greater degree of control of their disease, a greater amount of time
20 spent following the diet, and a significantly increased HRQoL. The qualitative part shows aspects
21 not included in the CD-QOL questionnaire such as fear of the future, work and social
22 misunderstanding due to coeliac disease.
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35 This study shows us the strong points of mixed methods in health sciences. The mixed-method
36 strategy gave us a wider view of the experience of women living with coeliac disease. In our case, a
37 strength and not a limitation is having performed the quality of life study in coeliac women using a
38 mixed methodology, approaching the experience of being a coeliac woman in Spain in two different
39 but complementary ways. The quantitative and qualitative data allowed us to interpret the
40 experiences of our participants.
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51
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53 shared their experiences of daily life with the illness with us, without them this work would not
54 have been possible. Acknowledgments also go to all of the coeliac associations and groups in Spain.
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Relevance to clinical practice

- Why is this research or review needed? Coeliac women express lower quality of life than male coeliacs.
- It is necessary to express life experience from the point of view of a coeliac woman.
- There are few studies that talk about the quality of life of coeliac women, and there are even less which also talk about the qualitative experience of coeliac women.

What are the key findings?

- The HRQoL of coeliac women is average compared to previous studies. In their responses, coeliac women expressed a lack of support from society and the health system in particular.
- Coeliac women express fears in relation to their social life in general and their future in particular.

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

- The results of our study show that the health system in general and nurses in particular could help women with celiac disease by giving them support on an emotional level.

- Nursing plays an important role in educating the population, and in the case of our study, nursing could educate the population about what coeliac disease is and what a gluten-free diet is, thereby preventing the social exclusion experienced by women with coeliac disease.

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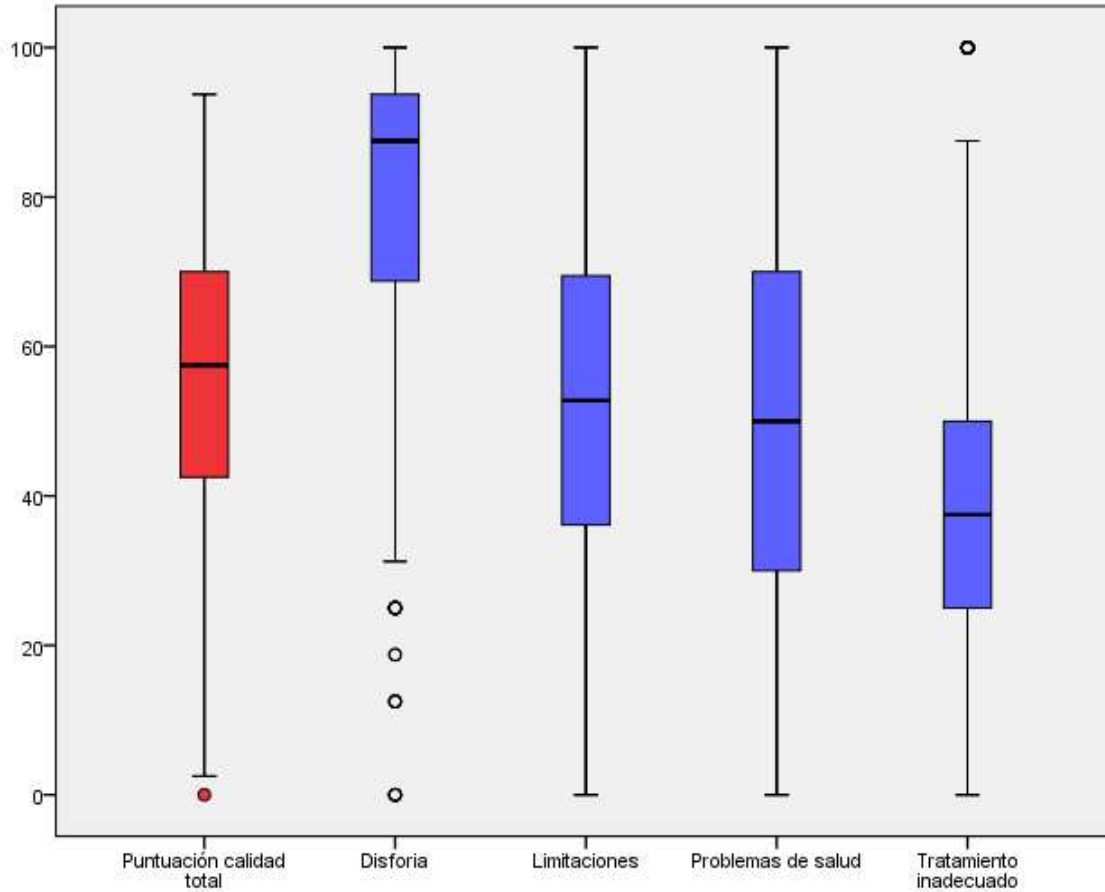
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Table 1. Characteristics of the population studied (Quantitative Phase)

Population	
n=1097	
Age (years)	
Mean [SD]	32.7 [10.45]
Categorised	[n/%]
16-20 years	112 [10.2]
21-30 years	401 [36.6]
31-40 years	348 [31.7]
41-50 years	165 [15.0]
51-60 years	58 [5.3]
>60 years	13 [1.2]
Time since diagnosis (years)	
Mean [SD]	9.0 [9.17]
	[n/%]
<1 year	199 [18.1]
>1 -5 years	366 [33.4]
6-10 years	184 [16.8]
11-15 years	114 [10.4]
>15 years	234 [21.3]
Treatment time (years)	
Mean [SD]	8.7 [8.83]
	[n/%]
< 1 year	211 [19.2]
>1 -5 years	370 [33.7]
6-10 years	180 [16.4]
11-15 years	115 [10.5]
>15 years	221 [20.1]

Fig 1. Box diagram of the overall score for the CD-QOL questionnaire and the aspects that form part of it. (Quantitative Phase)



[Total overall score, Dysphoria, Limitations, Health problems, Inadequate treatment]

Table 2. Description of the scores for the items which make up the CD-QOL questionnaire. (Quantitative Phase)

Number	Description	Median [p25-p75]
Item 1	I feel limited by this disease	3 [2-3]
Item 2	I feel worried that I will suffer from this disease	3 [2-4]
Item 3	I feel concerned that this disease will cause other health problems	3 [2-4]
Item 4	I feel worried about my increased risk of cancer from this disease	3 [2-4]
Item 5	I feel socially stigmatized for having this disease.	3 [2-4]
Item 6	I feel like I'm limited in eating meals with coworkers	2 [1-3]
Item 7	I feel like I am not able to have special foods like birthday cake and pizza	3 [2-4]
Item 8	I feel that the diet is sufficient treatment for my disease	2 [1-3]
Item 9	I feel that there are not enough choices for treatment	2 [1-4]
Item 10	I feel depressed because of my disease	5 [4-5]
Item 11	I feel frightened by having this disease	5 [4-5]
Item 12	I feel like I don't know enough about the disease	4 [3-5]
Item 13	I feel overwhelmed about having this disease	5 [4-5]
Item 14	I have trouble socializing because of my disease	4 [3-5]
Item 15	I find it difficult to travel or take long trips because of my disease	3 [2-4]
Item 16	I feel like I cannot live a normal life because of my disease	4 [3-5]
Item 17	I feel afraid to eat out because my food may be contaminated	3 [1-4]
Item 18	I feel worried about the increased risk of one of my family members having coeliac disease	3 [2-4]
Item 19	I feel like I think about food all the time	3 [2-5]
Item 20	I feel concerned that my long-term health will be affected	3 [2-4]

Table 3. (Univariate results of the factors associated with the quality of life of the coeliac patient and the aspects which form part of it. (Quantitative Phase)

	Overall Score	Dysphoria	Limitations	Health problems	Inadequate treatment
	Mean Score (SD)	Mean Score (SD)	Mean Score (SD)	Mean Score (SD)	Mean Score (SD)
Age					
16-20 years	59.7 [19.85]	83.0 [18.35]	54.2 [24.39]	60.0 [28.47]	32.3 [21.68]
21-30 years	55.9 [17.50]	81.3 [18.53]	51.5 [22.71]	51.0 [26.16]	36.7 [21.01]
31-40 years	54.7 [17.91]	81.1 [20.49]	51.3 [23.55]	47.3 [24.67]	36.0 [19.63]
41-50 years	56.2 [17.76]	80.1 [20.54]	53.7 [22.20]	49.9 [23.93]	35.9 [22.86]
51-60 years	57.1 [21.91]	76.6 [25.40]	53.8 [27.01]	53.3 [27.92]	42.2 [25.09]
>60 years	64.4 [20.94]	83.7 [18.84]	63.9 [27.62]	61.15 [26.47]	36.5 [19.41]
p-value*	0.100	0.457	0.330	<0.001	0.451
Time since diagnosis					
<1 year	51.7 [18.94]	72.2 [22.44]	46.0 [23.23]	50.0 [25.63]	40.4 [19.81]
>1 -5 years	52.6 [17.13]	77.7 [20.43]	48.2 [22.05]	47.38 [24.25]	34.6 [21.46]
6-10 years	56.2 [16.59]	84.0 [17.08]	50.9 [22.49]	50.9 [24.61]	38.1 [20.34]
11-15 years	60.0 [18.61]	89.0 [18.55]	58.7 [22.49]	53.03 [27.50]	31.4 [22.57]
>15 years	63.5 [17.88]	89.0 [14.53]	62.0 [23.00]	55.8 [25.94]	38.4 [21.02]
P-value*	<0.001	<0.001	<0.001	0.003	0.001
Time since treatment					
<1 year	51.0 [18.81]	71.3 [23.09]	45.8 [23.05]	48.4 [25.80]	40.0 [19.59]
>1 -5 years	53.0 [16.90]	78.3 [19.71]	48.5 [21.79]	47.8 [24.16]	35.7 [22.20]
6-10 years	56.3 [16.97]	84.0 [17.18]	50.8 [22.78]	51.44 [24.62]	37.5 [19.99]
11-15 years	60.0 [18.55]	88.8 [18.52]	58.5 [22.63]	53.6 [27.47]	30.9 [21.61]
>15 years	64.1 [17.78]	89.9 [13.63]	62.8 [23.39]	56.2 [28.25]	37.6 [20.97]
P-value*	<0.001	<0.001	<0.001	0.001	0.004

*P-value obtained from Analysis of Variance test.

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Table 4. Multivariate analysis by means of multiple linear regression between quality of life and the aspects that form part of it in relation to age, time since diagnosis, and time since treatment (Qualitative Phase)

	Overall Score		Dysphoria		Limitations		Health problems		Inadequate treatment	
	B-coef [CI 95%]	P-value	B-coef [CI 95%]	P-value	B-coef [CI 95%]	P-value	B-coef [CI 95%]	P-value	B-coef [CI 95%]	P-value
Age	-0.23 [-0.12 - 0.08]	0.652	-0.08 [-0.19 - 0.03]	0.130	0.06 [-0.07 - 0.19]	0.343	-0.14 [-0.29 - 0.04]	0.056	-0.02 [-0.11 - 0.14]	0.812
Time since Diagnosis	0.21 [-0.07-0.49]	0.142	0.12 [-0.18 - 0.42]	0.420	0.23 [-0.14 - 0.57]	0.226	0.18 [-0.23 - 0.58]	0.393	0.41 [0.01 - 0.74]	0.016
Time since Treatment	0.32 [0.03-0.61]	0.030	0.52 [0.21 - 0.83]	0.001	0.50 [0.13 - 0.87]	0.007	0.11 [-0.31 - 0.53]	0.601	-0.39 [-0.71 - -0.03]	0.035

* The value of the coefficients and their confidence intervals are per year of age.
B-coef: Beta Coefficient; CI: Confidence Interval

Table 5. Sociodemographic characteristics of the coeliac women (Qualitative Phase)

Interview	Age	Time with CD
N=19 Women		
1	21 YEARS	8 MONTHS
2	19 YEARS	3 YEARS
3	34 YEARS	3 YEARS
4	37 YEARS	5 YEARS
5	22 YEARS	3 MONTHS
6	28 YEARS	9 MONTHS
7	41 YEARS	7 YEARS
8	47 YEARS	10 MONTHS
9	33 YEARS	15 YEARS
10	44 YEARS	2 YEARS
11	17 YEARS	10 YEARS
12	29 YEARS	3 YEARS
13	36 YEARS	7 YEARS
14	24 YEARS	5 YEARS
15	31 YEARS	1 YEAR
16	63 YEARS	26 YEARS
17	33 YEARS	3 YEARS
18	43 YEARS	5 YEARS
19	24 YEARS	4 YEARS