The Fibromyalgia Impact Questionnaire: A validated Spanish version to assess the health status in women with fibromyalgia

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Abstract

Objective

To translate, adapt, validate and assess the sensitivity to change of a Spanish version of the Fibromyalgia Impact Questionnaire (FIQ-S).

Methods

The FIQ-S was adapted following the translation and back-translation methodology. Female patients with fibromyalgia (FM) were invited to participate. Reliability was analyzed by the Spearman correlation coefficient between test and retest. Internal consistency was checked by the Cronbach's alpha coefficient. Construct validity was analyzed comparing FIQ-S with: HAQ, FHAQ, SF-36, SCL90-R, and the visual analogue scale for pain. Sensitivity to change was assessed in an 8-week randomized trial of exercise therapy. Feasibility was analyzed by the time taken in completing the FIQ-S and the proportion of patients able to complete the questionnaire.

Results

Translation was concordant. Adaptation affected at 4 sub-items of physical function. One-hundred and two FM patients completed the protocol. Mean age was 48.7 years with a mean of 9.2 years of evolution. Test-retest correlations were between 0.61-0.85 ($p < 0.0001$). Internal consistency showed alpha = 0.82 for all items and alpha = 0.86 for the sub-items of physical function. Significant correlations ($p < 0.0001$) were found between the FIQ-S items and HAQ, FHAQ, SF-36 and SCL90-R. For patients treated with the exercise program, the pre-treatment FIQ-S score was 52.0 ± 11.5 and the post-treatment score was 40.8 ± 13.7 ($p < 0.003$). Mean time for completing FIQ-S was 3.3 minutes. In 4% of the patients external help was needed.

Conclusion

The FIQ-S is a reliable, valid and responsive to changes questionnaire for measuring health status and physical function in Spanish speaking FM patients.

Key words

Fibromyalgia, fibromyalgia impact questionnaire, validation, health assessment, Spanish version.

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Received on February 19, 2004; accepted in revised form on June 16, 2004.

Introduction

Fibromyalgia (FM) syndrome is a very common entity in clinical practice with a 20% of rheumatology consultations and up to 6% in those of non-specialized medical clinics (1). Moreover, diverse therapeutic modalities have not shown long-term satisfactory results contributing to perpetuate these patients in the clinic. During the last years more attention has been focused on the search for adequate tools to evaluate outcome measures in FM patients. The Fibromyalgia Impact Questionnaire (FIQ), developed and validated by Burckhardt *et al*. (2) in 1991, is a specific health questionnaire which evaluates current health status in patients with FM.

The FIQ has been translated into Swedish (3), Hebrew (4), Spanish (5), German (6), Turkish (7), Korean (8), French (9) and Italian (10), and validated in several populations, showing in all these translated versions psychometric properties similar to the original version. Today, FIQ is one of the most commonly used tools for clinical investigators in patients with FM. The aim of this study is to translate, adapt, validate and assess the responsiveness to change of a Spanish version of FIQ to be used in a Spanish speaking population.

Patients and methods

Patients

Patients who were attending the rheumatology clinic of a tertiary care teaching hospital fulfilling America College of Rheumatology (ACR) classification criteria for FM (11) were invited to participate in the study. Excluded were: patients younger than 18 years and older than 65 years of age, males, those with chronic diseases and poor general health (musculoskeletal inflammatory diseases, physically handicapped, severe heart and lung diseases, morbid obesity, limitating drug treatments), those with severe psychiatric or psychological alterations and those involved in a litigation or compensation process.

Translation and cultural adaptation

The Spanish version of the FIQ (FIQ-S) was adapted from the original version (2) following the translation and back-translation rules (12). Briefly, two bilingual linguists of Spanish origin translated into Spanish the original version; after that, a consensus about the equivalence of terms used in the translation was reached between linguists and clinical investigators thus obtaining the initial Spanish translated version. Two other bilingual linguists, this time of Anglo-Saxon origin and without previous knowledge of the questionnaire, back-translated this version into English. Finally, the quality of this back-translated version and the accuracy with the original version was analysed.

The initial Spanish translated version was administered to a pilot group of FM patients to evaluate the comprehension difficulty. After some minimal modifications and adaptations, a definitive FIQ-S version was obtained (see Appendix). Cultural adaptation affected some sub-items of physical function. Modifications were done considering the habits of our people after asking patients of the pilot group. In the question about the number of days feeling good, we included the possibility of zero.

Questionnaires and tools

Fibromyalgia Impact Questionnaire (FIQ) (2). This measures physical function, work, well being, and it contains visual analogue scales (VAS) for pain, sleep, fatigue, stiffness, anxiety and depression. A total score may be obtained after normalization of some items (between 0-10) and summing with all VAS. Total score ranges between 0-80 (without job items), where a higher score indicates a negative impact.

Health Assessment Questionnaire (HAQ) (13). Initially developed for assessing functional capacity in patients with rheumatoid arthritis (RA), it consists of 20 questions scored between 0-3, with higher scores indicating worse functional capacity. In this study we used the Spanish version of HAQ (14).

Fibromyalgia Health Assessment Questionnaire (FHAQ) (15). This is a subset of the HAQ obtained by means of Rasch analysis to be used in patients with FM. It contains 8 questions and the scoring

method is similar to HAQ with a final score between 0-3. In this study we extracted the 8 questions from the Spanish version of HAQ.

Medical Outcomes Survey Short Form-36 (SF-36) (16). This is a health-related quality of life questionnaire. It contains 36 questions grouped in 8 dimensions: physical function, role physical, bodily pain, general health, vitality, social function, role emotional and mental health. Every dimension may reach a score between 0-100, with higher scores indicating better status. There is also one question about health change during the past year scored in a Likert scale. In this study we used the Spanish version (12).

Symptom Checklist-90-Revised (SCL-90R) (17). Developed and validated for measuring psychological distress in general population, it contains 90 questions grouped in 9 different domains: somatization, obsessive/compulsive, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid ideation and psychoticism. Every dimension is scored in a Likert scale between 0-4, with higher scores indicating worse status. In this study we used a Spanish translated version (18).

VAS-pain scale consists of a 10-cm line along which patients are asked to mark their recent pain. Scores range from 0-10, with higher scores indicating more pain. In this study we used a translated Spanish version (19).

Tender Point Score (TPS). Tender points were evaluated by digital palpation at 18 sites, following ACR recommendations (11). The range of the score lies between 0-18.

Procedures

All patients were evaluated to confirm the presence of FM criteria and rule out any of the exclusion criteria. After adequate information regarding objectives of the study, patients gave written consent before their inclusion in the study protocol.

At the first visit, demographic data were obtained and FIQ-S was given to be completed in the clinic room and the time consumed was computed. The remaining questionnaires and tools were assigned to be completed at home. After one week, patients came back to the clinic for a second visit and completed another FIQ-S in the same conditions. During that week, there were no modifications in the treatment.

Some of the patients were included in an 8-week randomized clinical trial of exercise-based therapy. In this clinical trial, 19 patients were treated in our center following a daily physical exercise program monitored by a physiotherapist and compared with 21 patients treated with a cognitive behavioural therapy program (20). The results showed in this study correspond with the end of the 8-week program.

Statistical analysis

Assessment of test-retest reliability was measured by the Spearman correlation coefficient (r) of the items between the test and retest performed one week later. The internal consistency was measured by means of the Cronbach's coefficient alpha for the 10 items of the FIQ-S. Alpha coefficients were also obtained for the 9 sub-items of the physical function and for the 6 VAS. The construct validity was measured by the Spearman correlation coefficient (r) between the items of FIQ-S and some of the components of HAQ, FHAQ, SCL 90-R, SF-36, VAS-pain and TPS which try to measure similar concepts.

The assessment of sensitivity to change was calculated by means of the paired t-test between the pre-treatment and post-treatment evaluations in those patients included in the physical exercise program. Differences among patients who improved, remained unchanged and worsened were tested by an analysis of variance (ANOVA). A Spearman's correlation coefficient between change in total score of FIQ-S (pre-treatment FIQ-S score minus post-treatment FIQ-S score) and the Likert scale of health change during the past year owing to the SF-36, was also calculated.

The operational qualities or feasibility of FIQ-S were assessed by the percentage of patients who were able to complete the questionnaire by themselves and by the time employed in filling it out.

Results

A total of 170 patients fulfilling ACR criteria for FM attended the rheumatology clinic. Of these, 68 patients were excluded due to: age, 24; severe psychiatric alterations, 16; other important diseases, 13; male sex, 5; uncompleted protocol, 5; litigation, 3, and no acceptance of the study, 2 patients. Demographic characteristics of 102 female patients who completed the study protocol can be seen in Table I. Of the 50 full-time employed patients, only 42 had the possibility to be pensioned by the social security system of our country. Of these, 26 (62%) were still working while 16 (32%) were partially pensioned by FM.

Analysis of translation was concordant and satisfactory for most of the questions. None of the questions back-translated was considered as doubtful by the translators. Cultural adaptation affected 4 sub-items of physical function:

In the second sub-item, the term "dryer" was removed (only 12% had a dryer) leaving the definitive item as: Hacer la colada con lavadora (Do laundry with a washer).

In the fifth sub-item, other utensils such as "mopa" (mop) and "fregona" (mop to be soaked in water) were added. Although 72% of patients had a vacuum at home, it is more common to use a "fregona" or a "mopa" since floor rugs are not as frequent as in other countries. The final sub-item was described as: Pasar la fregona, la mopa o la

Table I. Demographic characteristics of 102 female patients with FM included in the study.

Age (yrs.)	48.7 ± 9.8
Tender points score	15.1 ± 2.5
Evolution time	9.2 ± 7.2 yr
Education	
Illiterates	4 (3.9%)
Elementary studies	64 (62.7%)
Middle level	30 (29.4%)
Superior university studies	4 (3.9%)
Work status	
Homemaker	46 (45.1%)
Working full time	50 (49.0%)
Pensioned	3 (2.9%)
Unemployed	3 (2.9%)

aspiradora (which could be translated as: "Clean the floors with a mop or a vacuum").
The ninth sub-item was directly removed (only 5% of patients had a yard).
The tenth sub-item was also removed (only 12% drove a car regularly). In this case the sub-item was substituted by: Utilizar transporte público (Use public transportation), which is the most common form of transportation in our city. With these adaptations, the item of physical function contained 9 sub-items instead of the original 10.
In the analysis of reliability as stability, correlation coefficients between the test and retest were between 0.58 for VAS-anxiety to 0.83 for work missed days (Table II). Internal consistency showed an alpha coefficient of 0.82 for the total items of the FIQ-S; alpha = 0.79 for the 8 items, without the 2 items concerning work, and alpha = 0.86 for the 9 sub-items of the physical function.
Correlation coefficients between FIQ-S items and components of other questionnaires can be seen in Table III. The most important correlations were as follows. Physical function correlated with HAQ ($r = 0.58$, $p < 0.0001$), FHAQ ($r = 0.63$, $p < 0.0001$), physical functioning of SF-36 ($r = -0.36$, $p < 0.0001$) and vitality of SF-36 ($r = -0.40$ ($p < 0.0001$). The most important correlations of the question about the number of days feeling good were with physical function of SF-36 ($r = -0.38$, $p < 0.0001$) and with the dimension of depression of SCL 90R ($r = -0.38$, $p < 0.0001$). VAS pain of FIQ-S correlated with VAS-pain ($r = 0.62$, $p < 0.0001$) and bodily pain of SF-36 ($r = -0.62$, $p < 0.0001$). VAS fatigue correlated with vitality of SF-36 ($r = -0.42$, $p < 0.0001$) as well as pain components of other questionnaires. VAS morning tiredness correlated with vitality in the SF-36 ($r = -0.43$, $p < 0.0001$). VAS anxiety correlated with the component of mental health of SF-36 ($r = -0.54$, $p < 0.0001$) and with anxiety ($r = 0.47$, $p < 0.0001$) and depression components ($r = 0.49$, $p < 0.0001$) of SCL 90R. VAS depression also showed a good correlation with mental health of SF-36 ($r = -0.65$, $p < 0.0001$), as well with depression ($r = 0.58$, $p < 0.0001$) and anxiety components ($r = 0.49$, $p < 0.0001$) of SCL90R. FIQ-S total score correlated with HAQ ($r = 0.41$, $p < 0.0001$) and FHAQ ($r = 0.48$, $p < 0.0001$). The most important correlations of job ability were also with total score of HAQ ($r = 0.67$, $p < 0.0001$) and FHAQ ($r = 0.70$, $p < 0.0001$). Correlation coefficients between FIQ-S and FHAQ were higher than with HAQ. TPS correlations with the items of FIQ-S were low and most of them did not reach statistical significance, with the exception of VAS depression ($r = -0.38$, $p < 0.0001$). For all the patients treated with the exercise program, the pre-treatment FIQ-S total score was 52.0 ± 11.5 and the post-treatment FIQ-S total score was 40.8 ± 13.7 ($p < 0.003$). The number of days in the past week feeling good, VAS fatigue, VAS stiffness and VAS anxiety showed statistical significant differences.
After completing treatment protocol, patients were divided following health change perception requested by SF-36 questionnaire in: improved, 5 patients; remained unchanged, 5 patients, and worsened, 9 patients. ANOVA showed a statistical significant difference ($p < 0.05$) between groups in post-treatment scores. Pre-treatment FIQ-S scores did not show statistical differences. The FIQ-S total scores before and after treatment are shown in Table IV. For the 5 patients who reported clinical improvement after treatment, items of post-treatment FIQ-S also improved showing statistical significant differences with the exception of stiffness, anxiety and depression. The correlation coefficient between patient assessment of health change and the difference between the pre-treatment and post-treatment FIQ-S total scores was 0.72 ($p < 0.0001$), suggesting that FIQ-S was sensible to perceived health status change.
The mean time required to complete the FIQ-S by patients was 3.28 ± 1.37 minutes (range 1.5 – 9.3). Only 4 (3.9%) patients needed external help to complete the questionnaire.

Table II. Test and retest reliability. Spearman correlation coefficients between items of FIQ-S performed with a difference of one week. All coefficients reached statistical significance for a $p < 0.01$.

	Correlation coefficient
Physical function	0.79
Days feel good	0.68
VAS pain	0.75
VAS fatigue	0.66
VAS morning tiredness	0.61
VAS stiffness	0.60
VAS anxiety	0.58
VAS depression	0.67
TOTALFIQ	0.85
Work missed days	0.83
Job ability	0.76

Discussion

Clinical investigation in FM has always had the difficulty that no objective outcomes are available to assess these patients. Recently, the FIQ questionnaire has been translated into different languages and has shown to be a valid and reliable instrument in many populations of FM patients. In this study we validated FIQ-S in our FM patients and we found that it is a valid and reliable instrument in our population.
Scores of the different items of FIQ-S, as well as the total score, have been slightly higher than in other studies (2-4, 6-10). The strict exclusion criteria applied to our population, which were responsible of a rejection of one third of the patients with FM, may explain these differences. In our opinion, the patients included in the study were much more homogeneous and are a good representation of FM female patients.
Due to the relative similarity between English and Spanish, translation was performed in a satisfactory manner without any difficulty. Cultural adaptation affected some sub-items of physical function and were necessary because only a minority of patients in our population performed some of the tasks described in the original version (e.g. 95% of patients do not usually drive a car).
A criticism received by the original FIQ is that it systematically underesti-

Table III. Construct validity. Spearman correlation coefficients between items of FIQ-S and other tools and questionnaires.

	Physical function	Days feel good	VAS pain	VAS fatigue	VAS morning tiredness	VAS stiffness	VAS anxiety	VAS depression	Total FIQ-S	Work missed days	Job ability
TPS	0.14	0.25*	0.18	0.29**	0.11	0.27**	0.22*	0.38**	0.34**	0.17	0.25
VAS-pain scale (^)	0.19	0.33**	0.62**	0.43**	0.28**	0.30**	0.34**	0.27**	0.51**	-0.18	0.42*
HAQ	0.58**	0.18	0.31**	0.30**	0.25*	0.28**	0.10	0.12	0.41**	0.25	0.67**
FHAQ	0.63**	0.25*	0.37**	0.34**	0.29**	0.33**	0.13	0.14	0.48**	0.22	0.70**
SF-36 (#)											
Physical functionning	-0.36**	-0.38**	-0.33**	-0.31**	-0.32**	-0.27**	-0.07	-0.17	-0.41**	-0.02	-0.55**
Role physical	-0.34**	-0.15	-0.19**	-0.19	-0.21*	-0.16	-0.12	-0.25*	-0.33**	-0.24	-0.52**
Bodily pain	-0.37**	-0.35**	-0.62**	-0.49**	-0.25*	-0.34**	-0.27**	-0.29**	-0.56**	-0.09	-0.58**
General health	-0.28**	-0.25*	-0.31**	-0.23*	-0.31**	-0.32**	-0.18	-0.21*	-0.37**	-0.05	-0.52**
Vitality	-0.40**	-0.37**	-0.39**	-0.42**	-0.43**	-0.41**	-0.32**	-0.30**	-0.57**	-0.28	-0.52**
Social functionning	-0.45**	-0.22*	-0.40**	-0.30**	-0.27**	-0.36**	-0.34**	-0.40**	-0.56**	-0.27	-0.44*
Role emotional	-0.07	-0.00	-0.22*	-0.28**	-0.12	-0.24*	-0.29**	-0.44**	-0.33**	-0.14	-0.22
Mental health	-0.23*	-0.36**	-0.44**	-0.46**	-0.32**	-0.44**	-0.54**	-0.65**	-0.67**	-0.06	-0.19
SCL90-R											
Somatization	0.39**	0.25*	0.50**	0.43**	0.27**	0.45**	0.40**	0.41**	0.60**	0.22	0.56**
Obsessive/compulsive	0.36**	0.39**	0.32**	0.42**	0.28**	0.43**	0.36**	0.47**	0.60**	0.28	0.25
Interpersonal sensitivity	0.19	0.11	0.18	0.10	0.14	0.29**	0.28**	0.41**	0.37**	0.28	0.12
Depression	0.36**	0.38**	0.37**	0.38**	0.32**	0.47**	0.49**	0.58**	0.68**	0.13	0.20
Anxiety	0.26**	0.20	0.35**	0.33**	0.20*	0.44**	0.47**	0.49**	0.54**	0.04	0.20
Hostility	0.20*	0.22*	0.18	0.19	0.07	0.26*	0.28**	0.39**	0.37**	0.22	0.02
Phobic anxiety	0.25*	0.09	0.14	0.12	0.16	0.34**	0.21*	0.36**	0.36**	0.20	0.10
Paranoid ideation	0.12	0.20*	0.23*	0.11	0.11	0.28**	0.26**	0.36**	0.34**	0.16	0.16
Psychoticism	0.32**	0.14	0.18	0.18	0.18	0.40**	0.25*	0.45**	0.43**	0.13	0.22

(^) VAS-pain scale taken from a translated Spanish version (19).
(#) Correlation coefficients with SF-36 are negative because higher scores represent healthier patients as opposite with the remaining questionnaires and tools.
* $p < 0.05$; ** $p < 0.01$

Table IV. FIQ-S total scores of patients before and after exercise treatment.

	No. of pts. (¶)	Pre-treatment FIQ-S	Post-treatment FIQ-S*
Improved	5	58.2 (9.7)	32.4 (12.1)
Remain unchanged	5	47.2 (13.7)	34.8 (11.7)
Worsened	9	51.1 (10.7)	48.8 (11.8)

(¶) The stratification of patients was performed in accordance with the answers of patients in the Likert scale of health change during the past year owing to the SF-36.
Standard deviation shown between parentheses.
* $p < 0.05$ for differences between groups in post-treatment FIQ-S.

mates functional impairment by asking questions that are not usually performed by patients (15). In FIQ-S adaptation, the introduced changes clearly improve the item of physical function by incorporating activities that are usually performed by patients. Similar adaptations have been performed in other studies (3,4,8).

In FIQ-S, all items showed a high reliability with a significant correlation between test and retest. Also, a good internal consistency has been shown with an alpha Cronbach coefficient of 0.82 for all items and 0.86 for the nine subitems of physical function.

There is no gold standard for patients with FM and a study of validity should be performed comparing FIQ-S items with similar scales of other questionnaires. Psychometric characteristics have been previously determined in other validation studies by correlations with AIMS (2, 9), HAQ (3, 6-8, 10), SF-36 (6, 9, 10), SCL 90R (8) and McGill pain questionnaire (9), showing moderate although significant correlations. In FIQ-S validation, we also found similar significant correlations.

HAQ has been one of the most commonly used questionnaires in other validation studies (3, 6-8, 10), and in some of them, it has been considered as a gold standard (6, 8). Although HAQ was initially developed and validated in patients with RA, it has also been used in patients with FM. Recently, Wolfe *et al*. (15) have developed a FM specific questionnaire extracted from HAQ, the FHAQ, which has shown very good psychometric properties. In this validation study we used FHAQ and we also found that correlations between FIQ-S and FHAQ were always better than with HAQ.

Although there are no normative data of FIQ in the general population, Hedin *et al.* (3) showed that FIQ has a good discriminant capacity when used in pa-

tients with RA or healthy controls. In that study, they found that FIQ was able to discriminate between FM patients and healthy controls in most items, as well as between FM and RA patients. Interestingly, the score of physical function of FIQ showed a significant discrimination between RA and FM patients, while the HAQ did not (3).

In our study, we also assessed the sensitivity of FIQ-S to change in a randomized clinical trial of exercise-based therapy (20) and we found that this questionnaire is quite sensible to changes. The significant differences found between pre and post treatment suggest that it is responsive to change. Similar results concerning sensitivity to change have been previously found in the original version of FIQ (21) with another non pharmacological therapy. These authors showed that FIQ was able to detect clinically meaningful changes in the direction of improvement as well as in clinical decline (21).

Feasibility of FIQ-S showed good properties. It took a mean of 3 and a half minutes to complete the questionnaire by patients, similar to the mean time found in other studies (9), and patients did not find it difficult to complete the questionnaire. If we take into account that scoring time by investigator is also reduced, we may say that FIQ-S is a very useful tool in the clinic. There is a previous validation study of the FIQ into Spanish (5) published in an abstract form. The test-retest reliability correlations and the Cronbach's alpha coefficient were close similar to our results. Authors also found the FIQ a valid instrument to be used in FM women in Spain.

In summary, the Spanish version of FIQ is a reliable, valid and responsive to changes questionnaire for measuring health status and assessing physical function in female patients with FM. It takes about 3 minutes and it is easy to complete for the majority of the patients of our population.

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Appendix. The Spanish version of FIQ

INSTRUCCIONES: En las preguntas que van de la a a la i, por favor rodee con un círculo el número que mejor describa cómo se encontró en general durante la última semana. Si no tiene costumbre de realizar alguna de las siguientes actividades, tache la pregunta.

1. Ha sido usted capaz de:

		Siempre	La mayoría de las veces	En ocasiones	Nunca
a.	Hacer la compra	0	1	2	3
b.	Hacer la colada con lavadora	0	1	2	3
c.	Preparar la comida	0	1	2	3
d.	Lavar los platos y los cacharros de la cocina a mano	0	1	2	3
e.	Pasar la fregona, la mopa o la aspiradora	0	1	2	3
f.	Hacer las camas	0	1	2	3
g.	Caminar varias manzanas	0	1	2	3
h.	Visitar a amigos / parientes	0	1	2	3
i.	Utilizar transporte público	0	1	2	3

2. ¿Cuántos días de la última semana se sintió bien?

0 1 2 3 4 5 6 7

3. ¿Cuántos días de la última semana faltó usted al trabajo por causa de su fibromialgia? (Si no trabaja usted fuera de casa, deje esta pregunta en blanco)

0 1 2 3 4 5

(En las siguientes preguntas, ponga una marca como esta | en el punto de la línea que mejor indique cómo se sintió en general durante la última semana)

4. Cuando fue a trabajar, ¿cuánta dificultad le causaron el dolor u otros síntomas de su fibromialgia en el desempeño de su trabajo?

Sin problema ..... Mucha dificultad

5. ¿Cómo ha sido de fuerte el dolor?

Sin dolor ..... Dolor muy fuerte

6. ¿Cómo se ha encontrado de cansada?

Nada cansada ..... Muy cansada

7. ¿Cómo se ha sentido al levantarse por las mañanas?

Bien..... Muy cansada

8. ¿Cómo se ha notado de rígida o agarrotada?

Nada rígida ..... Muy rígida

9. ¿Cómo se ha notado de nerviosa, tensa o angustiada?

Nada nerviosa ..... Muy nerviosa

10. ¿Cómo se ha sentido de deprimida o triste?

Nada deprimida ..... Muy deprimida