

*Protocolo con recomendaciones para aplicar el  
WHOQOL-BREF en población con cáncer de mama*

*Protocol with recommendations for applying the  
WHOQOL-BREF in breast cancer population*

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### **Abstract**

**Objective:** To determine the content validity of a protocol with recommendations for the application of the WHOQOL-BREF instrument in the assessment of quality of life in women with breast cancer.

**Materials and methods:** This is a descriptive, observational, instrument-validation type study. The process was developed in 3 phases, including content validation with the participation of experts in the areas of oncology,

psychology, social work, and nursing, who assessed the clarity, coherence, relevance, and sufficiency of the protocol. The degree of agreement among the evaluators was determined using the rWG index.

**Results:** The protocol obtained average scores higher than 9.0 in all items, most of them with rWG indices higher than 0.5. Meanwhile, the evaluators added key recommendations such as permanent support during the application of the survey and the inclusion of active pauses, due to the length of the instrument.

**Conclusions:** A protocol to improve the application of the WHOQOL-BREF instrument in the breast cancer population is presented.

**Keywords:** Quality of life, neoplasm, instrument validation, women's health.

## Resumen

**Objetivo:** Determinar la validez de contenido de un protocolo con recomendaciones para la aplicación del instrumento WHOQOL-BREF, en la evaluación de la calidad de vida en mujeres con cáncer de mama.

**Materiales y métodos:** Estudio descriptivo, observacional, tipo validación de instrumentos. El proceso se desarrolló en 3 fases, incluyendo validación de contenido con la participación de expertos en las áreas de oncología, psicología, trabajo social, y enfermería; valorando la claridad, coherencia, pertinencia, y suficiencia del protocolo. Se determinó el grado de acuerdo entre los evaluadores con el índice RwG.

**Resultados:** El protocolo obtuvo puntajes promedios superiores a 9,0 en todos los ítems, la mayoría con índices RwG mayor a 0,5. Por su parte, los evaluadores adicionaron recomendaciones claves como acompañamiento permanente durante la aplicación de la encuesta e incluir pausas activas, por la extensión del instrumento.

**Conclusiones:** Se presenta un protocolo para mejorar la aplicación del instrumento WHOQOL-BREF en población con cáncer de mama.

**Palabras clave:** Calidad de vida, neoplasia, validación de instrumentos, salud de la mujer.

## Introduction

Worldwide, breast cancer represents approximately 25% of all neoplasms. It occurs most frequently in low- and middle-income countries (1,2). In 2020, a total of 2,261,419 million women were diagnosed with breast cancer worldwide. It represents approximately 14.1% of cancers for Latin America and the Caribbean (3). It has been reported that mortality

due to this pathology in developed countries is approximately 7% and in developing countries 14% (4).

In Colombia, for the year 2020, a prevalence of 282.94 cases per 100,000 inhabitants was estimated, which increased by almost 50 cases per 100,000 inhabitants compared to 2019. On the other hand, mortality from this disease for 2020 was 11.91 deaths per 100,000 population, increasing by 2.18 points compared to 2019. In 2020, the highest values in morbidity and mortality measures since 2017 were estimated for this cancer (4).

Breast cancer can be classified into several types, the most frequent being ductal and infiltrating lobular carcinomas. The first type originates in the lactiferous ducts, which allow the milk flow from the breast to the nipple and represents approximately 80% of the cases. The second begins in the lobules that produce breast milk and occurs in 10 to 12% of cases. The remaining types of breast cancer together do not exceed 10% of cases, among them are those that originate in the connective tissue and stroma (5-7).

Although the treatment of the pathology will depend, among others, on the histopathological type reported, most interventions include surgery, hormonal therapy, radiotherapy, chemotherapy, immunotherapy, and monoclonal antibodies (6,7). Early diagnosis is key to increase the survival rate in this population (7).

Breast cancer, both in the diagnostic phase and in its evolution, induces physical and psychological stress responses; most patients suffer from depression, anxiety, and alexithymia. In young women, additionally, breast changes, alterations in body weight and possible scars affect more frequently the perception of their bodies. These conditions added to the changes induced by chemotherapy, hormonal therapy, and ovarian ablation, facilitate the presence of sexual dysfunction and affect fertility (8).

The range of responses described above negatively impacts the quality of life (QOL) of women with breast cancer and the dynamics of their socio-affective interactions (9,10). According to the World Health Organization (WHO), QOL is "the individual's perception of one's position in life within



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the context of the cultural and value system in which one lives, in relation to one's goals, hopes, norms and concerns". This concept addresses different aspects such as physical health, psychological state, social relationships, personal beliefs, level of dependence and relationship with the environment (11,12). It has been reported that the perception of the disease acts as a possible modulating variable of great interest in the assessment of QOL, since its spectrum includes signs, symptoms of the pathology, causes, consequences, time of duration, evolution and treatments received (13).

The assessment of the impact of cancer on people's living conditions, including quality in all its components, should be part of the follow-up processes (14). These assessments are useful to guide intervention models that address the individual in a comprehensive manner (15).

Among the instruments that have been used to assess QOL in the breast cancer population is the WHOQOL-BREF (reduced version of the WHOQOL-100 questionnaire), which consists of two global items: global QOL, general health, and 26 questions on some specific aspects. Each item has 5 Likert-type response options and generates a profile of four areas: physical health, psychological, social relations, and environment. According to the recommendations for the application of the instrument, it should be self-administered, allowing up to 2 weeks between the time of delivery of the survey and the return of the responses. However, when the person is not able to read or write for reasons of education, culture, or health, it can be administered by an interview (16-18).

One of the validation processes performed on this instrument in Taiwan highlights its strength in measuring the QOL of cancer patients and notes that it allows the detection of changes associated with adverse treatment events. However, they suggest that it should be used with caution when the aim is to compare different types of cancer survivors. In addition, they highlight the need for studies exploring how best to use the WHOQOL-BREF for cancer survivors of different organs and systems (19).

The WHOQOL-BREF has already been validated for its use in the Colombian population (20) and has been used to measure QOL in the breast cancer population (21-23). However, the results of a pilot test conducted under the project "Quality of life in women with breast cancer receiving chemotherapy treatment. Popayán, Cauca - Colombia, year 2019"; suggested that, a) the application of the instrument through a directed survey is appropriate, given the difficult health conditions and

the advanced age of most of the participants, in addition, some patients expressed difficulties in interpreting some of the items; b) behaviors such as crying, anxiety and indisposition of the patient, can block the mind and affect the full understanding of the questions and therefore the reliability of the answers; c) the interviewer must be trained in the application of the instrument; having clarity in the objective of each question and knowing how to approach different situations or questions from the participant.

The scenario presented above justified the need to develop a WHOQOL-BREF application protocol that would reduce the risks of variability in the interpretation of the questions, improve the reliability of the measurement, and promote a more objective assessment of QOL. Therefore, the present study proposes the design and validation of a protocol containing recommendations for the best application of the questionnaire in the breast cancer population. It is hoped that these findings will contribute to the construction of strategies that promote comprehensive care of the oncologic patient that transcends the functional component (24).

### **Materials and methods**

Under the quantitative approach, a descriptive, observational, validation-type instrument study was carried out. Eleven thematic and methodological experts participated in the validation process.

The construction of the protocol to improve the application of the WHOQOL-BREF in the breast cancer population was carried out in 3 phases: in the first phase, a scientific literature search related to breast cancer and some studies in which this instrument has been used as a tool to evaluate the QOL of people with breast cancer was carried out in order to learn about the structure and application of the instrument. In this phase the interdisciplinary team was also formed by three nursing students, two medical students, two Masters in Epidemiology in health services, with experience in health research and university teaching, and a clinical psychologist with experience in research and university teaching.

The second phase consisted in the construction of the protocol for the application of the WHOQOL-BREF, taking as main reference the findings of a pilot test carried out at the Teaching Hospital of San José de Popayán with 25 women with breast cancer who were receiving chemotherapy. Periodical meetings of the researchers' group were held, where the first version of the protocol was generated and answers to possible questions from the participants were proposed.

In the third and final phase, the content of the instrument was validated. For this procedure, a group of experts in the areas of oncology, psychology, social work, and nursing were contacted via e-mail and sent the WHOQOL-BREF and the protocol constructed for its application. They were consulted on the clarity, coherence, relevance, and adequacy of the instrument. They were also asked to assign a score between 0 and 10 for each item, where 0 was the lowest score and 10 the highest score. They were also asked to add comments they considered relevant to take into account when applying the questionnaire (25).

Once the results were obtained, the average, median and range of scores for each item were calculated. The level of agreement among the evaluators was assessed using the rWG index, with a score above 0.5 being considered appropriate. It was established that if the evaluators considered major changes, the protocol would be adjusted and sent to the entire evaluation group to obtain the definitive version (26). The analyses were performed with the free-access software RStudio version 4.0.2.

It is important to point out that this research is part of the project called "Quality of life in women with breast cancer receiving chemotherapy treatment. Popayán, Cauca - Colombia, year 2019", which has the endorsement of the ethics committee of the Teaching Hospital of San José and is registered in the Vice-rectorate of Research of the Universidad del Cauca (id 4761).

## **Results**

### **a. Protocol construction**

A protocol was structured in three parts: presentation, characterization, and measurement of quality of life. In the first part, it is suggested to introduce the interviewer and the research group to which they belong, as well as the research project and the institution to which they are linked. It is also suggested to collect the informed consent form at this stage. The second part suggests the collection of some sociodemographic and clinical variables that allow an approximation to the characteristics of the population to be evaluated. The third part contains the WHOQOL-BREF in its Spanish

*«In this phase the interdisciplinary team was also formed by three nursing students, two medical students, two Masters in Epidemiology in health services.»*



version and the details of how to ask each question to the participant.

The process was complemented with several discussion sessions in the research group, which allowed to review each of the questions, their intention, and the best way to ask them. In addition, role-playing sessions were held to adjust the preparation and adaptation of the surveys.

### **b. Protocol validation**

The group of expert evaluators of the survey protocol was integrated by professionals with extensive experience in the care of the breast cancer population in its different stages, from screening to rehabilitation, in the clinical, educational, research, health promotion and disease prevention fields. Their profiles are described in Table 1.

**Table 1.** Profile of the evaluators who participated in the content validation process.

<b>Evaluator</b>	<b>Professional background and relevant experience for the research</b>
1	Epidemiologist with research on oncology patients.
2	Specialist nurse candidate for a Master's degree. Palliative care leader in a Health Services Provider Company (EPS) in the department of Cauca.
3	Nurse with a master's degree in management of health organizations. Work experience with oncology population, managing psychological support, strict follow-up at least every 6 months by oncology if the patient is in remission, follow-up by nursing, pain and palliative care, education on warning signs.
4	Occupational therapist. Specialist in health auditing. Master's in public health. Doctoral candidate in public health with mention in health systems and services. Research in oncology patients.
5	Specialist in family medicine. National coordinator of a cancer program in a Colombian EPS. Family member of a breast cancer patient.
6	Nurse. Master's in public health. Experience in oncologic patient care at home.
7	Specialist in family medicine. Experience in ontological patient care in private practice.
8	Psychologist Specialist in family. Undergraduate thesis on psychological support to spouses of cancer patients. One year experience in the Colombian National Cancer Institute, in support to breast patients and family. Experience in psychological support through private consultation.
9	Surgeon. Radiotherapy Oncologist. Founder and coordinator of a department of Oncology in Colombia. Breast pathology researcher.
10	Nurse. Master's in Epidemiology. Experience in breast cancer research.
11	Nurse. Specialist in pain management and palliative care.

Source: Own elaboration of the research group.

Among the main suggestions for adjustments to the initial protocol mentioned by the evaluators, the following stand out: a) Permanent support of the interviewer to complete the questionnaire; b) Include ethnicity in the initial data; c) Mention whether the protocol applies to people with hearing, visual and physical limitations; d) Provide an additional support route, at the end of the survey, in case the user needs access to psychosocial support, or wishes to continue with the support she already had in progress; e) Create a guide route, which supports the protocol and serves for applicability in future research and accompanies the research. f) Make it clear that the protocol is designed for the interviewer and not for the participant. g) Incorporate active pauses in the application of the instrument, given the length of the questionnaire.

The averages assigned by the evaluators to the characteristics of clarity, coherence, sufficiency and relevance are presented in Table 2. For all items, average scores above 9.0 were obtained and most of the items with an rWG index greater than 0.5, which is considered adequate. The clarity item obtained an rWG index of 0.15, making it necessary to apply the wording recommendations provided by the evaluators.

**Table 2.** Scores assigned by the evaluators and level of agreement

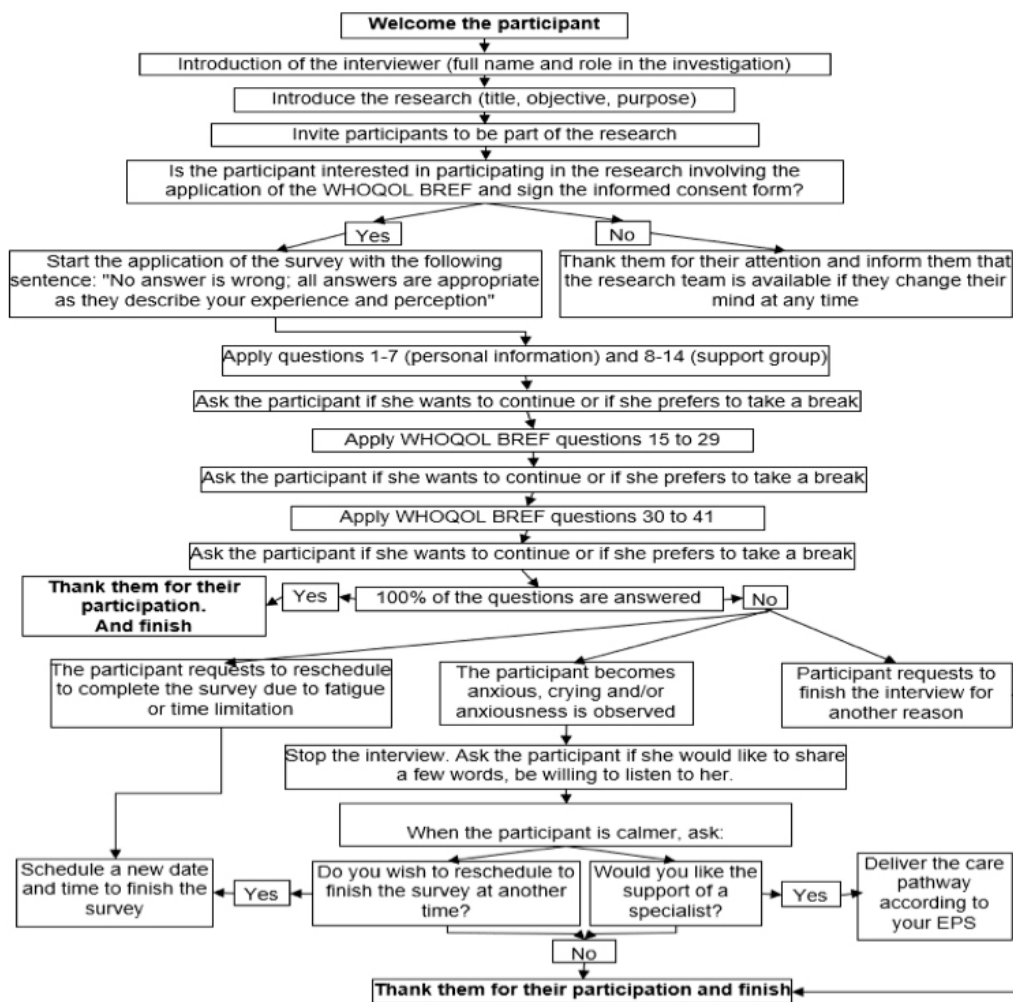
Ítem	Average	Median (range)	Level of agreement
Clarity	9.5	10 (7-10)	0,15
Coherence	9.4	10 (8-10)	0,60
Relevance	9.7	9 (8-10)	0,67
Sufficiency	9.2	9 (8-10)	0,51

Source: Own elaboration of the research group.

The final version of the protocol was reviewed for style by an external expert, a Hispanic philologist, who suggested adjustments in the use of punctuation marks, writing and presentation. A decision flow chart was also incorporated into the final version to show how to proceed in the event of different decisions by the participant (see Figure 1).



**Figure 1.** Flow chart of the WHOQOL- BREF application protocol



Fuente: Elaboración propia del grupo investigador.

In this link you can download the complete Spanish version of the protocol: <https://drive.google.com/uc?export=download&id=108xDIQFpDMfQ9NY2XMKyVYadRydt7h6v>



*The protocol designed in this research is intended to be applied by an interviewer, in order to be able to capture in a better way what breast cancer patients feel and think, especially considering that the change in lifestyle generated by the diagnosis causes physical, emotional, spiritual, social, and occupational ...»*

## Discussion

Breast cancer is the number one cause of female death and a public health problem that not only affects the physical and emotional health of patients, but also affects their QOL. This QOL, in turn, constitutes a clinical indicator that makes it possible to evaluate both well-being and the progression of the disease and the efficacy of treatments (27), and can indirectly be an indicator of the quality of health care received by these patients.

The proposal to build a protocol that optimizes the best way to apply the WHOQOL-BREF in the breast cancer population can avoid, among others, information biases related to problems in the reading or interpretation of the questions and allow a closer approximation to the reality of the analyzed item.

The protocol designed in this research is intended to be applied by an interviewer, in order to be able to capture in a better way what breast cancer patients feel and think, especially considering that the change in lifestyle generated by the diagnosis causes physical, emotional, spiritual, social, and occupational repercussions in this type of patients (24). In this sense, the General Council of the Official Colleges of Psychologists in Spain, promulgated two major strategies to strengthen the appropriate use of the tests: a) restrictive, meaning that it should limit the use of certain instruments to qualified professionals; and b) informative, extending education to interviewers, patients, and family members. In addition, it is suggested that the more knowledgeable the team is, the more it can prevent possible biases in the collection of information. It is also important to “formulate agreements on the basic principles of the evaluation process among the different professionals involved and, sometimes, among the different interested parties.” (28).

It is possible that the questions asked by the WHOQOL-BREF evoke a traumatic memory in people, indirectly generating in them a re-experiencing of the traumatic moment experienced in the diagnosis and recalling intrusive thoughts with their emotional impact (29), which is manifested through silence or crying. Therefore, one of the contributions to highlight in this work is the incorporation of a decision flow chart and guidelines that allow dealing assertively with possible emotional expressions, such as tiredness or crying. In addition, it considers extreme situations in which referral to a health service may be necessary.

It is necessary to clarify that during the application of the survey there is no therapeutic process; however, in the protocol some elements of the active forgetfulness strategy were incorporated in such a way as to avoid the emotional re-experiencing of the participant. These skills together with some assertive communication strategies, developed by the trained interviewer for the application of the instrument, will facilitate an accompaniment to the participant, who will calmly appropriate the expressed emotions, will value with certainty the achievements in her life (indirectly), minimizing the impact of paralyzing nostalgia and catastrophic thoughts (30).

The application of the WHOQOL-BREF by the interviewer may have some negative implications such as difficulties for people to answer questions related to their sexual activity, which some authors call “bias due to sensitive questions” (31); therefore, it will also be important to find a quiet, comfortable space and build trust with the participant. In addition, in the case of participants with no limitations in reading, writing, or clinical condition that prevents them from answering the questionnaire independently, it should be self-administered, being important the availability of the team to address any questions or requirements.

As for the time required for the application of the survey under the guidance of an interviewer, according to the results of the pilot test, prior to this study, it could take up to 40 minutes, which may prevent the questionnaire from being filled out in its entirety, either due to lack of time or the need to carry out other occupations such as medical appointments. The longer the questionnaire is, the more tired and less concentrated the participant is. One of the recommendations arising from this research is the incorporation of active breaks, given that, as it has been widely described, fatigue is a common symptom in women with breast cancer (32) and the ideal is not to subject them to stressful and exhausting situations.

There are still many challenges to be faced in relation to the application of this type of instruments like the WHOQOL-BREF, it will be necessary to continue exploring the best methodologies for its application, considering cultural, educational, and clinical variables. In addition to involving breast cancer patients in subsequent validation exercises, both WHOQOL-BREF and the present protocol for its application.

This protocol focuses on women with breast cancer, but it can also be applied to men with this pathology. In this case, it should be taken into account that the impact of cancer on aspects such as body image varies

between men and women, given that there exists biological, diagnostic and treatment differences (33). Under particular considerations, this same protocol can also be used in populations with other pathologies.

### **Conclusions**

This study found that the built protocol to improve the application of the WHOQOL-BREF in the measurement of QOL in women with breast cancer is valid in its content. In addition, it is clear, sufficient, relevant, and current, and it considers relevant aspects such as fatigue due to the length of the instrument and the emotional susceptibility that the questions may provoke, which in many cases tend to evoke the before and after of the disease.

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