

Bulpitt and Fletcher's Specific Questionnaire for Quality of Life Assessment of hypertensive patients

INSTRUMENTO DE AVALIAÇÃO DA QUALIDADE DE VIDA PARA HIPERTENSOS DE BULPITT E FLETCHER

INSTRUMENTO DE EVALUACIÓN DE LA CALIDAD DE VIDA PARA HIPERTENSOS DE BULPITT Y FLETCHER

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ABSTRACT

This study translated and validated Bulpitt and Fletcher's Specific Questionnaire for Quality of Life Assessment of hypertensive patients. The translation and the back-translation were performed by four English teachers, and the final version was submitted to a board of referees. Questions with a Content Validity Index lower than 80% were modified and re-evaluated. The questionnaire was applied in 110 hypertensive outpatients (52 ± 8 years old, 65 % female, blood pressure 128 ± 17 / 75 ± 13 mmHg), which also answered the SF-36, and also in 20 normotensive people, whose characteristics were similar to those of the hypertensive subjects. The domains of SF-36 and Bulpitt and Fletcher's instrument correlated to each other ($p < 0.05$), except for the social aspects ($r = 0.07$, $p = 0.04$) and the general state of health ($r = 0.04$, $p = 0.61$). Hypertensive patients showed more positive responses to the symptoms (40%) than the normotensives (15%). The instrument was validated and is now ready to be used in our midst.

KEY WORDS

Quality of life.
Hypertension.
Reproducibility of results.
Validation studies.

RESUMO

Este estudo realizou a tradução para o português e a validação do questionário específico para avaliação da qualidade de vida em hipertensos de Bulpitt e Fletcher. A tradução e o back-translation foram realizados por 4 professores de inglês e a versão final submetida a um corpo de juizes. Questões com Índice de Validade de Conteúdo menor que 80% foram modificadas e reavaliadas. O questionário foi aplicado em 110 hipertensos ambulatoriais (52 ± 8 anos, 65% mulheres, pressão arterial 128 ± 17/ 75 ± 13 mmHg), que também responderam ao SF-36, e em 20 normotensos, com características semelhantes às dos hipertensos. Os domínios do SF-36 e do instrumento de Bulpitt e Fletcher se correlacionaram ($p < 0,05$), exceto em relação a aspectos sociais ($r=0,07$, $p=0,44$) e a estado geral de saúde ($r=0,04$, $p=0,61$). Os hipertensos apresentaram mais respostas positivas a sintomas (40%) do que os normotensos (15%). O instrumento foi validado e está apto para ser usado em nosso meio.

DESCRIPTORIOS

Qualidade de vida.
Hipertensão.
Reprodutibilidade dos testes.
Estudos de validação.

RESUMEN

Este estudio ha realizado la traducción para el portugués y la validación del cuestionario específico para evaluación de la calidad de vida en hipertensos de Bulpitt y Fletcher. La traducción y el back-translation fueron realizados por 4 profesores de inglés y la versión final sometida a un cuerpo de jueces. Cuestiones con Índice de Validad de Contenido menor que 80% fueron modificadas y reevaluadas. El cuestionario fue aplicado en 110 hipertensos en seguimiento ambulatorial (52 ± 8 años, 65% mujeres, presión arterial 128 ± 17/ 75 ± 13 mmHg), que también respondieron al instrumento de evaluación de calidad de vida SF-36, y en 20 normotensos, con características semejantes a de los hipertensos. Los dominios del SF-36 y del instrumento de Bulpitt y Fletcher se correlacionaron ($p < 0,05$), excepto en relación a aspectos sociales ($r=0,07$, $p=0,44$) e al estado general de salud ($r=0,04$, $p=0,61$). Los hipertensos presentaron mas respuestas positivas a síntomas (40%) de que los normotensos (15%). El instrumento fue validado y está apto la utilización en la lengua portuguesa.

DESCRIPTORIOS

Calidad de vida.
Hipertensión.
Reproducibilidad de resultados.
Estudios de validación.

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INTRODUCTION

Hypertension is a highly-prevalent disease in our midst. The V Brazilian Guidelines in Arterial Hypertension show that population studies performed in some Brazilian cities show that the prevalence of the disease ranges from 22.3% to 43.9%⁽¹⁾. Hypertension is one of the main factors of risk for cardiovascular diseases and has high costs, not only in the healthcare area, but also in the socioeconomic sphere. These costs usually originate in complications that include cerebrovascular diseases, coronary diseases, heart failure, chronic kidney failure and vascular disease of the extremities. In Brazil, cardiovascular diseases are the foremost cause of morbimortality, as 27.4% of the deaths in 2003 were due to those diseases, with strokes being the main cause of death in all regions of the country, victimizing mainly women⁽¹⁾. In addition to being responsible for 40% of the deaths due to strokes, it also accounts for 25% of those caused by coronary diseases⁽²⁾.

Hypertension is a chronic disease that requires drug and non-drug treatment for life, and its chronicity may interfere directly in several spheres of the patients' life. The hypertensive patient's self-esteem may be threatened due to the possibility of aggravations, and, consequently, the emotional sphere as well, with the onset of negative emotions such as depression and anxiety⁽¹⁾. In addition to this psychological aspect, physical changes may emerge due to side effects of hypertensive drugs and cardiovascular changes caused by hypertension itself.

Therefore, the quality of life of patients undergoing treatment, either drug-based or not, may be affected by the side effects of the drugs, the diseases that may be associated to the hypertension, the necessity of changes in the lifestyle and also by the diagnosis of the disease, which apparently causes the loss of the body silence and the presence of the disease as a factor of death, thus changing quality of life⁽¹⁾.

An important consideration regarding the monitoring of hypertensive patients is that the method used to reduce their blood pressure should not interfere in their quality of life⁽⁵⁾. Due to this perception, in the past decades, the interest for evaluating the hypertensive patients' quality of life increased significantly.

QUALITY OF LIFE AND HYPERTENSION

One of the greatest challenges in the diagnosis and control of hypertension is related to knowing the impact of the disease and its treatment on the patient's life. The asymptomatic course of the disease, until it is discovered or until the targeted organs are damaged are important factors that make this aspect even more difficult.

Studies have shown that the knowledge of a hypertension diagnostic reflects on the report of symptoms, on absenteeism at the workplace and on quality of life⁽¹⁻¹⁰⁾. A study performed in the 1970s shows that the lack of balance, dizziness and nocturia were consequences of hypertension, and that they could significantly deteriorate the patient's quality of life⁽⁵⁾. Hypertensive patients have their quality of life significantly reduced when compared to normotensive people, especially women, with more damage to the target organs, higher heart rate and weight excess⁽²⁾. Therefore, evaluating the quality of life in hypertensive people became an important part in the proposal of treatment.

The instruments used to evaluate the hypertensive patient's quality of life must be sensitive to the evaluation of the adverse events of each anti-hypertensive drug, among other topics. These authors suggest that the dimensions chosen in studies about quality of life should reflect the potential of adverse events of the treatment, as well as the deficit in the performance at work, problems with sexual functions and mood swings⁽¹⁾.

One of the greatest challenges in the diagnosis and control of hypertension is related to knowing the impact of the disease and its treatment on the patient's life.

BULPITT AND FLETCHER'S SPECIFIC QUESTIONNAIRE FOR HEALTH-RELATED QUALITY OF LIFE ASSESSMENT OF HYPERTENSIVE PATIENTS

Bulpitt and Fletcher's Specific Questionnaire for Health-Related Quality of Life assessment of hypertensive patients⁽⁴⁾ was designed in order to be used in studies lasting up to one year. As it focuses on the evaluation of the impact of hypertension, itself an asymptomatic disease, it only detects psychological and mood alterations due to the diagnostic and adverse effects of the treatment in hypertensive patients undergoing outpatient treatment. This questionnaire does not allow for the detection of long-term changes due to conditions that may affect the independence of the individuals, such as strokes. In these cases, the use of questionnaires that evaluate the health profile and describe the limitations in the lifestyle due to the disease, such as the Nottingham Health Profile (NHP), is indicated.

Bulpitt and Fletcher's questionnaire (attached) is self-applicable, and deals with aspects of physical and psychological well-being and the patient's perception of the anti-hypertensive treatment on their lifestyle. It has questions regarding the clinical situations, the side effects of the treatment and the social, professional, emotional and sexual aspects that are possibly related to the disease or the treatment. It is straightforward, clear, simple, and, especially, it focuses on the main aspects involved with hypertension. The questions were elaborated so as to be answered with *yes* or *no*, and there is the option of an open-ended an-

swer. When added together, the answers yield a score. A score of 0 was attributed for death, and 1 was the maximum possible score. The values attributed to calculate the score of each questionnaire are distributed as follows:

- zero: death;
- 0.125: restrained to the bed;
- 0.375: restrained to the household, but not to the bed;
- 0.500: asleep, or in a constant state of resting;
- 0.625: unemployed for medical reasons;
- 0.750: unable to work for a period over three days, or unable to perform household chores;
- 0.800: hypertension, or its treatment, interferes in leisure or social activities;
- 0.875: none of the aforementioned situations, however, the patient has 30% of the symptoms, according to questions 1 to 30 in the questionnaire;
- 0.975: none of the aforementioned situations, however, the patient has less than 30% of positive answers in questions 1 to 30 in the questionnaire;
- 1.000: none of the aforementioned situations and no positive answer in questions 1 to 30.

Open-ended questions have only a descriptive, complementary function.

VALIDATING BULPITT AND FLETCHER'S QUALITY OF LIFE ASSESSMENT INSTRUMENT FOR HYPERTENSIVE PATIENTS

The questionnaire was translated to Portuguese by two English teachers, who were native to the country of origin of the instrument. This first version in Portuguese was back-translated into English by two Brazilian teachers of English, who had not taken part in the previous stage. Later, the original instrument and the translated versions were compared: the divergences were analyzed by the group, rewritten when necessary, and finally a consensus was reached, which yielded the final version of the instrument.

The final version of the instrument was submitted to a board of referees composed by three physicians and three nurses, all of them bilingual and aware of the disease in question, as well as the goals of the questionnaire and the concepts being analyzed. This process aimed to guaranteeing the reproductibility of the instrument in another language. The board of referees was allowed to suggest the replication of instructions on how to fill the form in order to minimize errors in its comprehension, as well as suggesting changes or the elimination of items that were considered irrelevant, inadequate and/or ambiguous, and present

others that are more culturally adequate and understandable for the general population, if that were the case.

After the analysis, the changes suggested by the referees were implemented, with the items that were agreed upon by at least 80% of the evaluators. To obtain the index of agreement regarding the conceptual equivalence, the evaluations of each referee were compared with the evaluations of all the others, with the CVI being calculated for each pair (referee A × referee B; referee A × referee C; referee B × referee C; and so on). The CVI was calculated for each item, which indicated the percentage of answers with satisfactory translations among the referees, on an item-by-item basis. This index was useful in the identification of items that needed to be changed.

$$\text{CVI} = \frac{\text{number of items evaluated as equivalent by two referees}}{\text{Total number of items of the scale}}$$

CVI = Content Validation Index

Out of the 46 questions that comprise Bulpitt and Fletcher's Quality of Life assessment instrument, only questions 1, 3, 21, 23 and 31 needed to be modified due to low CVI. These questions were not agreed upon by 80% of the referees in some of their equivalences, and, as such, needed to be changed in order to become equivalent.

Afterwards, the instrument was pre-tested, which is the stage of the translation process where the equivalence between the original and the final version of the instrument, analyzing the comprehension of its items by the target population. For that, the instrument was applied on a group of 10 patients. A *not applicable* answer was added to each question of the instrument, with the purpose of identifying which items could present cultural incompatibilities, which were not usual or even not understood by our population. Questions with more than 10% of *not applicable* answers were carefully re-evaluated and rewritten, in order to maintain the properties and structure of the question. This stage was performed with 10 hypertensive patients with characteristics that were similar to those patients evaluated in the criterion validity stage.

The modified instrument was re-applied on a new group of 10 patients. The instructions, as well as each of the items, were discussed with the patients regarding its clarity and comprehension, which resulted in the instrument presented in the appendix.

For the next validation stage, which corresponded to the estimates of criterion validity, 110 hypertensive people undergoing outpatient treatment were studied, aged 52 ± 8 years old, female (65%), white (60%), with full elementary education (63%), married (68%), with a body mass index of 30 ± 4 Kg/m² and average blood pressure $128 \pm 17 / 75 \pm 13$ mmHg. This stage refers to the degree of correlation of the scores of an instrument to a reliable external criterion, designated as the *gold standard*. The Medical Outcomes Study 36-Item Short-Form Health Survey - SF-36 - was used as the gold standard for this analysis. In spite of

being a generic questionnaire, it has dimensions that could be correlated with the specific questionnaire about hypertension, in addition to being an instrument that has been used in several studies, showing good measurement properties such as reproductibility, validity and susceptibility to alterations. The SF-36 has also been used by other investigators in several diseases, including hypertension. It was translated and validated for the Portuguese language in 1997⁽¹⁾. Therefore, the instrument undergoing evaluation had its components grouped according to the dimensions that existed in the SF-36 by the Brazilian authors (social

aspects, general state of health, physical aspects, vitality, functional capacity, mental health, emotional aspects and pain). The comparison between both instruments revealed a significant statistical correlation among all domains, with two exceptions: social aspects and general state of health (Table 1). Vitality was the item with the lowest score, both in SF-36 (56 ± 22) and in Bulpitt and Fletcher's specific questionnaire (1.5 ± 0.5). In both questionnaires, functional capacity (SF-36 = 75 ± 22 and Bulpitt = 6 ± 1) and social aspects (SF-36 = 77 ± 30 e Bulpitt = 5 ± 1) were the highest-scoring domains (Table 1).

Table 1 - Correlation between the domains of the SF-36 and Bulpitt and Fletcher's questionnaire for quality of life assessment

Domains	Instrument		R value	P value
	Bulpitt (average \pm SD)	SF-36 (average \pm SD)		
Social Aspects	5 ± 1	77 ± 30	0.07	0.44
Functional Capacity	6 ± 1	75 ± 22	0.35	0.0002
General Health State	2 ± 0.5	73 ± 19	0.04	0.61
Physical Aspects	3.1 ± 3	72 ± 37	0.36	0.0001
Pain	2 ± 0.5	65 ± 23	0.20	0.03
Mental Health	2 ± 0.6	62 ± 24	-0.22	0.02
Emotional Aspects	2 ± 0.4	61 ± 44	0.27	0.003
Vitality	1.5 ± 0.5	56 ± 22	0.32	0.0006

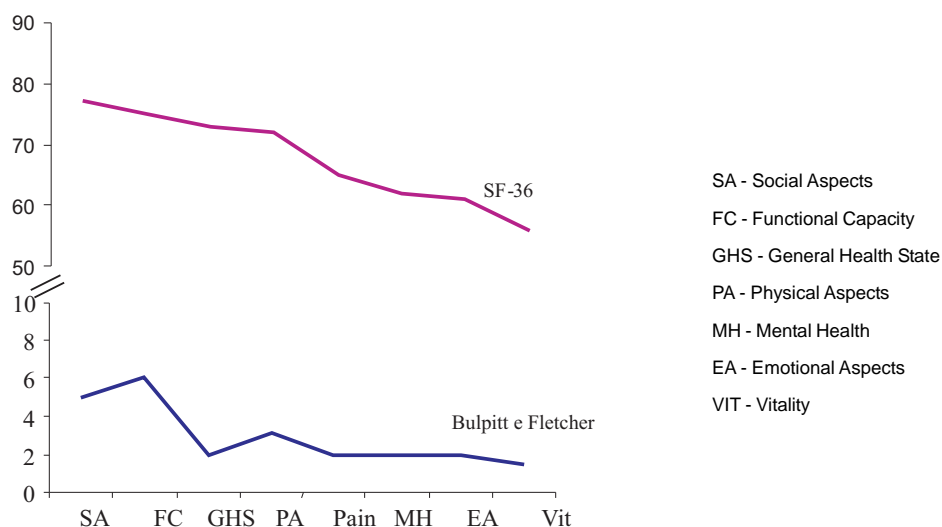


Figure 1 - Comparison between the scores of the SF-36 domains and Bulpitt and Fletcher's Specific Questionnaire for Health-Related Quality of Life assessment of hypertensive patients

In the *social aspects* and *general state of health*, the correlation coefficients were not significant (Table 1), showing that there is no correlation between those two measurements in these domains. The *mental health* domain had

a negative correlation, which, although very low, suggests that the instruments do not have the same purpose in this dimension.

Figure 2 shows that the outline of Bulpitt and Fletcher's questionnaire is very similar to the SF-36, with the exception of the social aspects and the general state of health domains, which did not have a good correlation, and the mental health domain, which had an inverse correlation,

as described before. These aspects are probably due to the characteristics of the evaluated instrument, whose focus is not the isolated evaluation of these domains, focusing instead on the adverse effects of the treatment.

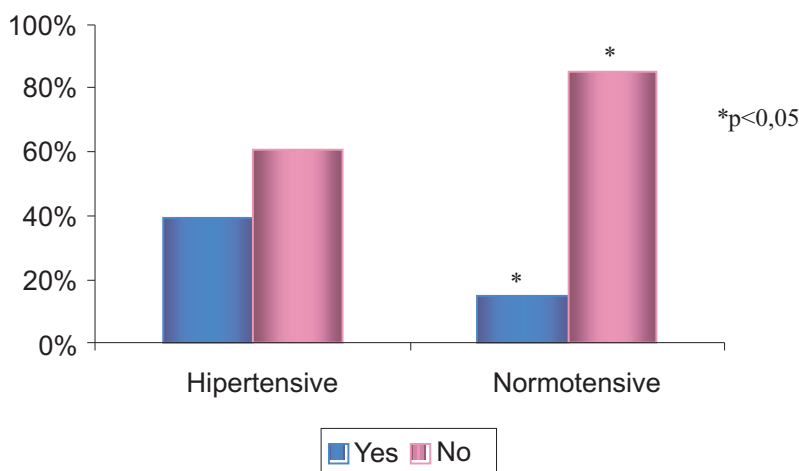


Figura 2 - Percentage of "Yes" and "No" answers in the hypertensive and normotensive groups.

The next stage consisted of the application of the instrument to a group of normotensive people to verify the capacity of discrimination among groups expected to have differences among each other. For this validation, a group of normotensive people (blood pressure < 140/90 mm Hg) was correlated with a group of hypertensive patients (blood pressure \geq 140/90 mm Hg, with or without drug treatment, or blood pressure < 140/90 mm Hg with drug treatment), previously evaluated. Figure 2 shows that the number of yes answers to changes or symptoms mentioned in the instrument used with the normotensive group was significant lower (15%) than the same answer in the hypertensive group (40%). These data suggest that the hypertensive group had a higher deficit in quality of life when compared

with the normotensive group. The difference ($p < 0.05$, chi-square test) detected by the instrument shows its ability of discriminating among different groups.

CONCLUSION

Bulpitt and Fletcher's questionnaire is the first specific instrument about quality of life for hypertensive patients, in Brazil, that has undergone the whole process of translation and transcultural adaptation proposed by literature. As its validity is thus proven for the anti-hypertensive treatment, it can be used in the clinical practice and investigation.

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APPENDIX

Scoring of Health Index

Seção 1

Por favor, assinale a alternativa correspondente à sua resposta ou coloque um número no local apropriado.
Ex.: HORAS DE SONO (8).

1. No último mês você sentiu tontura ou teve algum desmaio?

() SIM () NÃO

Se NÃO, por favor pule para a questão 4.

2. Se SIM, a tontura ou desmaio ocorreram enquanto você estava em pé?

() SIM () NÃO

3. Por quantas horas no dia você sentiu tontura ou desmaio?

() Menos do que uma

() 1 a 2 horas

() mais do que duas horas

4. No último mês, você se sentiu freqüentemente sonolento durante o dia?

() SIM () NÃO

5. Quantas horas, em média, você dorme por dia?

_____ horas

6. No último mês você sentiu fraqueza nas pernas?

() SIM () NÃO

7. Você sentiu a vista turva ou embaçada no último mês?

() SIM () NÃO

8. Você tem falta de ar quando caminha no chão plano em comparação a pessoas de sua idade?

() SIM () NÃO

9. Seus tornozelos incham no final do dia?

() SIM () NÃO

10. Comparando-se a outros homens e mulheres de sua idade, você tende a caminhar:

() mais lentamente

() mais rapidamente

() no mesmo passo

11. Com que freqüência normalmente seus intestinos funcionam?

Coloque o número de vezes por dia () ou

Número de vezes por semana ()

12. Você apresenta intestino solto ou fezes líquidas com frequência?

() SIM () NÃO

13. No último mês, você ficou com o intestino preso muitas vezes?

() SIM () NÃO

14. Quantas vezes, em média, você levanta durante a noite para urinar?

() 0

() 1

() 2

() + que 2

15. No último mês você tem sentido a boca seca?

() SIM () NÃO

Se NÃO, por favor passe para a questão 17

16. Se SIM, a boca seca atrapalha você para falar ou comer?

() SIM () NÃO

17. No último mês você tem sido incomodado por um gosto ruim na boca?

() SIM () NÃO

18. No último mês você tem sido incomodado por nariz entupido ou escorrendo?

() SIM () NÃO

19. Comparando-se a outras pessoas de sua idade, sua capacidade de concentração é:

() melhor que a média

() mesma que a média

() pior que a média

20. No último mês você sentiu vermelhidão no seu rosto ou pescoço?

() SIM () NÃO

21. Durante o último mês, você foi freqüentemente incomodado por sonhos agitados que pareciam reais ou por pesadelos?

() SIM () NÃO

22. Durante o último mês, você sentiu enjôo ou vomitou com freqüência?

() SIM () NÃO

23. Você teve alguma lesão na pele no último mês?

() SIM () NÃO

24. Você tem apresentado coceira no último mês?

() SIM () NÃO

25. Seus dedos ficam pálidos quando está frio?

() SIM () NÃO

Se NÃO, por favor passe para a questão 27

26. Se SIM, eles ficam doloridos?

SIM NÃO

27. Você tem sofrido de dor de cabeça no último mês?

SIM NÃO

Se NÃO, passe para a questão 30

Se SIM, por favor passe para a questão 28 e 29

28. Com que freqüência suas dores de cabeça ocorrem?

1 ou mais vezes por dia

1 até 6 vezes por semana

menos que uma vez por semana

29. Em que hora do dia sua dor de cabeça ocorre?

ao acordar pela manhã

durante o dia, sem estar presente quando você acorda

durante à noite

30. Você tem tido tosse seca no último mês?

SIM NÃO

31. As próximas questões se referem a sua vida sexual. Sabemos que estas questões são de natureza muito pessoal, mas são importantes, pois estamos interessados em todos os aspectos do seu bem estar e gostaríamos que você as respondesse. Gostaríamos de enfatizar, novamente, que essa informação é confidencial.

Seu interesse em sexo está:

menor

o mesmo ou maior

32. Você tem relação sexual?

SIM NÃO

Se NÃO, por favor pule para a questão 33

Se SIM, por favor pule para a questão 34

33. Suas razões para não ter relações sexuais são (assinale quantas alternativas forem necessárias)

Falta de interesse

Outra razão relacionada com sua saúde (por favor especifique)

Outra razão relacionada com sua saúde (por favor especifique)

Outra razão não relacionada com sua saúde (por favor especifique)

34. Com que freqüência você tem relações sexuais? Por favor, escreva no espaço o número de:

vezes por semana

vezes por mês ou

vezes por ano

35.

Somente para homens

Durante a relação sexual você é incomodado por não conseguir manter uma ereção?

() SIM () NÃO

Somente para mulheres

Durante a relação sexual você tem sentido dificuldade para se excitar (ficar molhada/ lubrificada)?

() SIM () NÃO

Seção 2

36. Por favor assinale a alternativa que melhor representa a sua situação

() emprego remunerado

() emprego não remunerado, mas trabalhando em casa ou com parentes

() desempregado, mas procurando por um trabalho

() desempregado, afastado por motivos de doença

() aposentado

37. Se você assinalou em “emprego remunerado”, no último mês, quantos dias você faltou devido à sua doença? (por favor escreva o número de dias no espaço, ou assinale nenhum se você não teve falta devido à doença)

() dias

38. Se você faltou ao trabalho por motivos de doença, escreva qual foi a razão

39. Durante o último mês, você tem se sentido incapaz de realizar atividades domésticas habituais devido à sua doença?

() SIM () NÃO

40. Se SIM, por quantos dias você esteve incapacitado de realizar suas atividades habituais devido à doença?

Por favor, escreva o número de dias ()

41. Quais foram as razões pelas quais você esteve incapaz de realizar suas atividades habituais?

42. Você tem alguma atividade de lazer ou divertimento?

() SIM () NÃO

43. Se SIM, por favor escreva quais são as suas atividades de lazer ou divertimento

44. Seu estado de saúde tem interferido nas suas atividades de lazer ou divertimento?

() SIM () NÃO

45. Se SIM, de que maneira?

46. O seu estado de saúde tem interferido de alguma outra maneira na sua vida recentemente?

() SIM () NÃO

Se SIM, de que maneira?

Pontuação do Questionário de Bulpitt e Fletcher

Questões	Respostas	Pontuação
1, 2, 4, 6, 7, 8, 9, 12, 13, 15, 16, 17, 18, 20, 21, 22, 23, 24, 25, 26, 27, 30, 35, 39, 42, 44, 46	<ul style="list-style-type: none"> • sim • não 	0 1
14	<ul style="list-style-type: none"> • 0 a 1 • 2 e >2 	1 0
19	<ul style="list-style-type: none"> • melhor ou mesma que a média • pior que a média 	1 0
28	<ul style="list-style-type: none"> • 1 ou mais vezes por dia • 1 até 6 vezes por semana • menos que uma vez por semana 	0 0 1
31	<ul style="list-style-type: none"> • menor • o mesmo ou maior 	0 1
32 (depende da 33)	<ul style="list-style-type: none"> • sim • não e questão 33 outra razão relacionada à saúde • não e questão 33 falta de interesse ou outra razão • não relacionada à saúde 	1 0 1
35	<ul style="list-style-type: none"> • sim • não 	0 1
36	<ul style="list-style-type: none"> • Se emprego remunerado ou emprego não remunerado ou aposentado • Desempregado 	1 0
37	<ul style="list-style-type: none"> • Se $\geq 0 \leq 1$ • Se > 1 	1 0
3, 5, 10, 11, 19, 29, 33, 34, 38, 40, 41, 43, 45	DESCRITIV AS	

Score = soma de todos os pontos x 100

35