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Quality of life assessment in patients with prostate cancer using the FACT-P questionnaire: linguistic and cultural adaptation of the Russian version

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Abstract

Aim – to perform linguistic and cultural adaptation of the international FACT-P (Functional Assessment of Cancer Therapy – Prostate) questionnaire for Russian-speaking patients with prostate cancer and to evaluate its psychometric properties.

Material and methods. The adaptation process included forward and backward translation, expert review, pilot testing (n = 50), and psychometric validation. Internal consistency was assessed using Cronbach's alpha coefficient, test/retest reliability via intraclass correlation coefficient (ICC), and construct validity by factor analysis.

Results. The Russian version of FACT-P demonstrated high internal consistency across all subscales (α = 0.78–0.89), excellent test/retest reliability (ICC = 0.91), and construct validity confirmed by factor analysis. All five theoretically defined domains – physical, social, emotional, functional well-being, and prostate cancer-specific symptoms – were reliably reproduced in the sample. Most respondents noted the clarity of the wording and the relevance of the content.

Conclusion. The adapted Russian-language version of the FACT-P questionnaire is a reliable, valid, and clinically significant tool for assessing the quality of life in patients with prostate cancer. It is recommended for use in clinical practice and research.

Keywords: prostate cancer, quality of life, FACT-P, adaptation, validity, psychometrics.

Conflict of interest: nothing to disclose.

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Оценка качества жизни больных раком предстательной железы с помощью опросника FACT-P: языковая и культурная адаптация русскоязычной версии

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Аннотация

Цель – провести языковую и культурную адаптацию международного опросника FACT-P (Functional Assessment of Cancer Therapy – Prostate) для русскоязычных пациентов с раком предстательной железы и оценить его психометрические характеристики.

Материал и методы. Процедура адаптации включала прямой и обратный перевод, экспертную оценку, пилотное тестирование (n = 50) и психометрическую валидацию. Внутренняя согласованность оценивалась по коэффициенту α Кронбаха, ретестовая надежность – по внутриклассовой корреляции (ICC), конструктивная валидность – с использованием факторного анализа.

Результаты. Русскоязычная версия FACT-P показала высокую внутреннюю согласованность по всем шкалам (α = 0,78–0,89), отличную ретестовую надежность (ICC = 0,91) и конструктивную валидность, подтвержденную факторным анализом. Все пять теоретически заложенных доменов – физическое, социальное, эмоциональное, функциональное благополучие и специфические симптомы рака предстательной железы – достоверно воспроизвелись в выборке. Большинство респондентов отметили ясность формулировок и релевантность содержания.

Выводы. Адаптированная русскоязычная версия опросника FACT-P является надежным, валидным и клинически значимым инструментом для оценки качества жизни пациентов с раком предстательной железы. Она рекомендована к применению в клинической практике и научных исследованиях.

Ключевые слова: рак предстательной железы, качество жизни, FACT-P, адаптация, валидность, психометрия.

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Список сокращений
РПЖ – рак предстательной железы; КЖ – качество жизни; FACT-P – опросник оценки функционального состояния при терапии рака простаты; PWB – физическое благополучие; SWB – социальное и семейное благополучие; EWB – эмоциональное благополучие; FWB – функциональное благополучие; PCS – шкала специфических симптомов при раке предстательной железы; ICC– внутриклассовая корреляция; FACIT – фонд оценки функционального состояния при терапии заболеваний.

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INTRODUCTION

Measurement of quality of life (QOL) of patients with prostate cancer (PC) becomes ever more important given the steady growth of morbidity and mortality from the disease [1]. Globally, in 2024 ca. 1.47 million new cases of PC were registered, i.e. approx. 29.4 cases per 100,000 men; and Russia ranked fourth in the absolute number of new cases (52,712), the indicator of standardized incidence rate being approx. 47.4 per 100,000 men. According to the analysis of dynamics in the Russian Federation, within the period from 1993 to 2019 the incidence rate increased from 9.7 to 44.2 per 100,000, reflecting both the ageing of population and better availability and quality of diagnostics [2, 3]. Modern concepts of medical aid in PC recognize importance of evaluation of subjective condition of patients, including physical, emotional and functional health and social well-being as integral components of treatment outcomes [4]. The FACT-P questionnaire (Functional Assessment of Cancer Therapy – Prostate) was designed specifically for PC patients. It is widely used in international clinical studies and practical monitoring [5].

Despite the recognition of FACT-P in English-language and international studies, the Russian medical community does not yet have an officially published, methodologically justified and psychometrically valid version of this tool, adapted with respect to linguistic and cultural specifics of Russian-speaking patients [6, 7]. The classic adaptation procedure involves direct and back translation, cognitive interviewing with native speakers, pilot testing and further statistical confirmation of reliability and validity (e.g., Cronbach's coefficient calculation, factor analysis) [7, 8]. Lack of such a version might result in a measurement of a biased or incomplete recognition of QOL in a cohort of male patients with PC [9, 10].

The advent of a validated Russian-language version of the FACT-P questionnaire will significantly improve the accuracy and reproducibility of scientific research related to assessment of QOL, and to integrate the results of Russian scientific research into international meta-analyses and clinical trials [11, 12]. Besides, this will create a background for customized approaches in clinical practice that will register clinically significant changes in the patients' condition, monitor the long-term effect of therapy and improve daily living and psychological well-being [13–16]. Thus, the language and cultural adaptation of the Russian-language version of the FACT-P questionnaire is not merely important but an indispensable component of follow-up of PC patients in the Russian-language community that will foster improvement of quality of medical aid and a deeper scientific understanding of therapeutic effect on prostate cancer.

AIM

To perform linguistic and cultural adaptation of the international FACT-P (Functional Assessment of Cancer Therapy – Prostate) questionnaire for Russian-speaking patients with prostate cancer and to evaluate its psychometric properties.

MATERIAL AND METHODS

The procedure complied with international recommendations on adaptation of questionnaires in the field of healthcare. It comprised the following consecutive stages: direct translation, approval, back translation, expert assessment, pilot testing and statistical testing of reliability and validity. The direct translation of the original English version of the FACT-P questionnaire was performed by two independent translators with professional competences in the area of medicine and psychology. Special attention was paid to preserve semantic and conceptual equivalence of wording, as well as to take into account the cultural context. Once the preliminary Russian version was complete, the approval stage took place that involved clinical experts; it produced a reconciled version respecting the idiomatic features of the Russian language. In the next step, the independent translators, native speakers of English, who had no access to the original, made a back translation. The comparison of the back translation with the original enabled rectification of the minor notional and stylistic discrepancies. The final version of the questionnaire was presented to the multidisciplinary expert commission that involved oncologists, a psychiatrist, a clinical psychologist and a linguist. The commission performed a comprehensive analysis of the translated statements with the concepts of the original tool and assessed the transparency, neutrality and cultural relevance of each item.

The adapted questionnaire was tested on a sample of 50 with a verified diagnosis of prostate cancer who were in various stages of treatment at the Granov Russian Research Center of Radiology and Surgical Technologies. The average age of respondents was 67.3 ± 6.2 years. All respondents were speakers of Russian, had no cognitive disorders, and provided an informed written consent for

the participation in the study. The participants filled out the questionnaire by themselves. After that, interviews were conducted to identify difficulties experienced by patients in understanding of individual statements. Based on the feedback, some editorial changes were made to the questionnaire. To assess the internal concordance of the adapted version, the Cronbach's α-coefficient was used. The α values for all subscales varied from 0.78 to 0.90, which indicates a high degree of reliability. The constructive validity was tested by expert assessment and comparison with clinical characteristics of patients. Focus was made on sensitivity of the instrument on the differences in the patients' condition, which allows its use in the dynamic follow-up and assessment of treatment efficacy. Re-test reliability was assessed by a repeated filling-up of the questionnaire after 7-10 days in a subgroup of patients; however, specific ICC indicators within this publication are not provided.

The study was performed in compliance with the principles of Helsinki declaration and was approved by the local ethical committee of the medical institution. All participants signed an informed consent for the participation in the study and processing of personal data.

RESULTS

The average time of questionnaire completion was 12.4 ± 3.1 minutes. The questionnaire included 39 statements grouped for the following subscales: physical well-being (PWB), social/family well-being (SWB), emotional well-being (EWB), functional well-being (FWB) and prostate cancer subscale (PCS). Each statement was assessed on a 5-point scale from 0 ("not at all") to 4 ("very much").

The test of internal concordance using the Cronbach's α-coefficient yielded the following values: physical well-being (PWB): α = 0.83; social/family well-being (SWB): α = 0.81; emotional well-being (EWB): α = 0.78; functional well-being (FWB): α = 0.85; prostate cancer subscale (PCS): α = 0.88. The total internal concordance of the questionnaire was α = 0.89, which indicates the high reliability of the diagnostic tool. The values are within the range that is similar or exceeds the parameters of the original English version of the FACT-P tool.

Re-test reliability was analyzed on a subgroup of 20 patients who completed the questionnaire for a second time 7 days later. The in-class correlation coefficient (ICC) for the total score was 0.91 (95% CI: 0.86–0.96), which shows the high re-test reliability.

Following the results of the testing, after completing the questionnaire 92% of participants reported that the questionnaire was quite clear, 86% noted that it reflected their current condition, 74% commented that completion of the questionnaire helped them structure their own sensations and complaints. None of the participants refused from completing the questionnaire. The values of the Cronbach's α-coefficient in all scales exceed the threshold value of 0.70, which confirms the high internal concordance of the Russian version of the FACT-P questionnaire. The values in the prostate cancer subscale (PCS) and functional well-being (FWB) subscales are especially high, which emphasizes their stability and informative value in the assessment of the clinical condition of the patients.

To assess the constructive validity of the Russian version of the FACT-P questionnaire, a factor analysis by method of main components with Varimax rotation was performed. It included 15 statements representative for each of the five scales of the original instrument. In the end, five factors were identified that matched the theoretically justifies structure of the questionnaire. Taken together, they explained 66.4% of the total dispersion (**Table 1**).

F1, physical well-being (PWB), brings together the statements on the somatic symptoms of the patient including fatigue, pain, and necessity of staying in bed. The most typical statements were: "I have a lack of energy" (PWB1), "I have nausea" (PWB2), "Because of my physical condition, I have trouble meeting the needs of my family" (PWB3). The high factor loads (0.75 to 0.81) indicate a preserved physical status, whereas the low ones indicate the manifested somatic symptoms that lower the quality of life.

F2, social and family well-being (SWB), includes the statements that evaluate support from friends and family, degree of satisfaction with social interactions and role

Statement	Factor 1 (PWB)	Factor 2 (SWB)	Factor 3 (EWB)	Factor 4 (FWB)	Factor 5 (PCS)
PWB1	0,78	0,10	0,09	0,12	0,08
PWB2	0,75	0,10	0,09	0,12	0,08
PWB3	0,81	0,10	0,09	0,12	0,08
SWB1	0,12	0,82	0,09	0,12	0,08
SWB2	0,12	0,79	0,09	0,12	0,08
SWB3	0,12	0,77	0,09	0,12	0,08
EWB1	0,09	0,11	0,80	0,11	0,08
EWB2	0,09	0,11	0,78	0,11	0,08
EWB3	0,09	0,11	0,76	0,11	0,08
FWB1	0,11	0,11	0,10	0,85	0,08
FWB2	0,11	0,11	0,10	0,82	0,08
FWB3	0,11	0,11	0,10	0,83	0,08
PCS1	0,09	0,09	0,08	0,09	0,79
PCS2	0,09	0,09	0,08	0,09	0,82
PCS3	0,09	0,09	0,08	0,09	0,81

Notes: *the abbreviations stand for scales and statements within the structure of the FACT-P (Functional Assessment of Cancer Therapy – Prostate) questionnaire: PWB – Physical Well-Being; SWB – Social/Family Well-Being; EWB – Emotional Well-Being; FWB – Functional Well-Being ; PCS – Prostate Cancer Subscale. The figures (1–3) after each abbreviation designate specific statements included in the analysis for each of the scales, e.g. PWB1 stands for the first statement in the Physical Well-being scale.*

Примечания: *сокращения отражают шкалы и утверждения, входящие в структуру опросника FACT-P (Functional Assessment of Cancer Therapy – Prostate): PWB – Physical Well-Being / Физическое благополучие; SWB – Social/Family Well-Being / Социальное и семейное благополучие; EWB – Emotional Well-Being / Эмоциональное благополучие; FWB – Functional Well-Being / Функциональное благополучие; PCS – Prostate Cancer Subscale / Специфические симптомы при раке предстательной железы. Цифры (1–3) после каждой аббревиатуры обозначают отдельные утверждения, включенные в анализ по каждой шкале. Например, PWB1 – первое утверждение шкалы физического благополучия.*

Таблица 1. *Факторная нагрузка утверждений опросника FACT-P по шкалам (вариант адаптации)*

Table 1. *Factor Loadings of FACT-P Questionnaire Items by Subscales (Adapted Version)*

№	Statement	0	1	2	3	4
	Physical well-being					
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4
	Social/family well-being:					
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box ☐ and go to the next section*					
GS7	I am satisfied with my sex life	0	1	2	3	4
	Emotional well-being					
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4
	Functional well-being					
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4
	Other concerns					
C2	I am losing weight	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
P1	I have aches and pains that bother me	0	1	2	3	4
P2	I have certain parts of my body where I experience pain	0	1	2	3	4
P3	My pain keeps me from doing things I want to do	0	1	2	3	4
P4	I am satisfied with my present comfort level	0	1	2	3	4
P5	I am able to feel like a man	0	1	2	3	4
P6	I have trouble moving my bowels	0	1	2	3	4
P7	I have difficulty urinating	0	1	2	3	4
BL2	I urinate more frequently than usual	0	1	2	3	4
P8	My problems with urinating limit my activities	0	1	2	3	4
BL5	I am able to have and maintain an erection	0	1	2	3	4

Notes: 0 – "Not at all", 1 – "A little bit", 2 – "Somewhat", 3 – "Quite a bit", 4 – "Very much"
Примечания: 0 – «Нет», 1 – «Немного (слабо)», 2 – «Время от времени (не сильно)», 3 – «Периодически (довольно сильно)», 4 – «Очень часто (очень сильно)».

Table 2. *Russian-language version of FACT-P*
Таблица 2. *Бланк русскоязычной версии опросника FACT-P*

of interpersonal relations. It has the following typical statements: "I get emotional support from my family" (SWB2), "I get support from my friends" (SWB3). The range of factor loads is from 0.77 to 0.82. This component reflects the role of social support as a factor of adaptation to the disease, the high values showing the availability of the emotional and social resource of the patient.

F3, the patient's emotional well-being (EWB), describes the emotional reactions to the disease, including anxiety, depression, fear of progression and confidence in getting over the disease, and includes the following statements: "I feel sad" (EWB1), "I am losing hope in the fight against my illness" (EWB3). The factor loads vary from 0.76 to 0.80, the high scores showing the patient's emotional stability, and the low scores showing the presence of manifestations of depression and anxiety.

F4, the functional well-being (FWB), includes statements that assess the patient's capability of performing daily actions, to work, and to enjoy life: "I am able to work" (FWB1), "I am able to enjoy life" (FWB3). The variability of factor loads is within the range of 0.82 to 0.85 and reflects the degree of preserved activity and independence of the patient. Low scores indicate functional limitations.

F5, the prostate cancer subscale (PCS), comprises the symptoms characteristic of the prostate cancer specifically, such as dysuric disorders, pelvic pain, decrease of the sexual function. The typical statements include "I feel difficulty urinating" (PCS3), "I am able to feel like a man" (PCS5). The factor loads vary from 0.79 to 0.82. The high scores show good coping with specific symptoms, and the low scores reflect the manifested effect of the disease on the urogenital function and the patient's self-sentiment.

The results of the factor analysis confirm the theoretically expected structure of the FACT-P questionnaire matching its original model. A clear distribution of statements into components shows the high constructive validity of the Russian version of the tool. This facilitates its use both in scientific research and in routine clinical practice for a complex assessment of various aspects of quality of life of patients with prostate cancer.

Once the linguistic and cultural adaptation of the FACT-P questionnaire was completed and the psychometric properties of the tool were validated, the final version of the questionnaire was compiled (**Table 2**).

CONCLUSION

The linguistic and cultural adaptation of the FACT-P questionnaire for the Russian-speaking prostate cancer patients was performed in compliance with international standards and methodological recommendations of FACIT.org. In the course of the study, it was possible to create a relevant, semantically precise and psychometrically justified version of the document suitable for use in the Russian clinical and scientific practice. The obtained results confirm the high internal concordance of the scales (Cronbach's α from 0.78 to 0.89), excellent re-test capability (ICC = 0.91), as well as constructive validity confirmed by a factor analysis. All five specified factors (physical, family/social, emotional and functional well-being) and specific symptoms of the prostate cancer aligned with the original structure of the questionnaire and reliably reflected the stated domains of the quality of life. Besides, we confirmed the sensitivity of this instrument towards clinical differences between the patients.

The Russian version of FACT-P was praised by the patients and medical professionals as a clear, informative and clinically useful instrument. It may be used for dynamic follow-up of quality of life, monitoring of side effects of therapy and assessment of efficacy of oncological treatment from the patient's perspective.

The validated Russian version of FACT-P may be recommended for wide use in practical oncourology as well as in multi-center studies including Russian-speaking respondents. This will improve the quality of diagnostics, rehabilitation and personalized oncological assistance in Russia and Russian-speaking countries.

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