
Zakharova RN, Mikhailova AE, Krivoschapkin VG

Development of a population-based study protocol of life quality of the Republic Sakha (Yakutia) population

UDC: 614.1. (571.56)

The article deals with planning and organizing the process of population-based study of the life quality of the adult population of the Republic Sakha (Yakutia). Described in detail the logical structure developed the study protocol and determines the amount of the minimum representative sample.

Keywords: quality of life, the population study, the development of the study protocol.

Introduction. The study of life quality (QOL) - a reliable method of assessing health and general well-being, which allows to quantify the characteristics of multi-component of human life - physical, psychological and social functioning [1, 4, 5].

For the various institutions of society are more valuable data on the results of population studies, QOL, the so-called normal population QOL. The norm in this case are the values of QoL mean of the population of a country and a region. Note that the standard values are found in all countries [2, 3, 6, 7, 8, 9, 10, 11, 12, 13, 14].

According to the methodology of the study of quality of life first and fundamental step in conducting population-based study is to develop a research protocol QOL. The study protocol QL - a document that develop before the start of the study, and which do not change during the study. At the stage of development of the study protocol tasks such as evaluation of the sample size, the definition of research tools, verification of inclusion criteria, etc. [4, 5].

This article presents the main stages of development of a protocol population-based study of quality of life of the adult population of the Republic of Sakha (Yakutia).

Development of a research protocol.

Protocol population study QOL was developed in accordance with the recommendations of the International Project study of quality of life - ICO. In accordance with the principles of the construction protocol population-based study made the following provisions:

1. Defining goals and objectives of population research, design and entry criteria.

The purpose of the study:

To study the regional quality of life of the adult population on the model of a representative sample of the population of the Republic of Sakha (Yakutia).

Research objectives:

- Determine the volume of a representative sample of the population for the study of the quality of life of the adult population of the Republic of Sakha (Yakutia), taking into account age and gender characteristics of the population;



- Identify indicators of the quality of the adult population of the Republic of Sakha (Yakutia), depending on sex, age and area of residence of respondents using a standard questionnaire SF-36;

- Conduct a standardization of the data for each of the scales of the questionnaire to determine the standardized population-based indicators of quality of life according to sex, age and area of residence of the respondents;

Criteria for inclusion in the study. The study will include individuals of both sexes aged 15 and older, living in the industrial, agricultural and arctic zones of the Republic of Sakha (Yakutia), of different social groups, regardless of the presence or absence of any medical condition. The study will not include persons who have not attained 15 years of age and persons with any disability group.

Study Design

A population study on the quality of life of the adult population, health-related planned by the three medical and economic zones of the Republic of Sakha (Yakutia) - industrial, agricultural and Arctic. In the industrial area by the quota and random sampling selected Yakutsk and Tomponsky area in the Arctic - Even-Bytantai and Oleneksky in the agricultural zone - Nyurbinsk and Namsky region. In Yakutsk will be selected two typical areas: the center and the outskirts of the city. In rural areas, out of the total population by the list of random numbers will be selected respondents corresponding sex and age.

Data will be collected by questionnaire respondents direct interview.

2. Description of the research tools

The study will use a questionnaire assessment of QoL SF-36 and the socio-demographic map, developed in this work, and are tested in a pilot study.

The questionnaire SF-36 includes eight health concepts that are most often measured in population studies and who are most affected by the disease. SF-36 questionnaire for self-completion by the respondent to the survey computer or to fill it with a trained interviewer in person or by phone. It is applicable at the age of 14 years and older. The model underlying the construction of scales and measurements of total SF-36 questionnaire has three levels:

- 36 questions;
- 8 scales formed from 2-10 issues;
- 2 total measurement, which together span.

35 questions were used to calculate the scores on scales of 8, 1 - for the assessment of the state of patients for the past 4 weeks.

Analysis of QOL held on the following scales:

1. Physical functioning (PF) - Physical Functioning (PF) - the scale that assesses physical activity, including self-care, walking, climbing stairs, carrying heavy loads, and the performance of significant physical activity. The indicator reflects the scale of the amount of daily exercise, which is not limited to health: the higher, the more physical activity, according to the study, it can be done. Low scores on this scale indicate that physical activity is considerably limited health.

2. Role-physical functioning (RFF) - Role Physical (RP) - a scale which shows the role of physical problems in limiting life, reflects the degree to which health limits the performance of normal activities, ie characterizes the degree of restriction of work or daily activities the problems that are associated with health: the higher the score, the less, according to the respondent's health problems limit their daily activities. Low scores on this scale indicate that the daily activities significantly restricted physical state of health.

3. The scale of pain (B) - Bodily Pain - assesses the intensity of pain and its



impact on the ability to engage in normal activities, including work on the house and outside in the past month: the higher the score, the less, according to the respondent, pain they experienced. Low values of the scale indicates that the pain significantly limits the physical activity of the test.

4. General health (NEOs) - General Health (GH) - assesses the state of health at the moment, the prospects of treatment and disease resistance: the higher the score, the better the health status of the respondent or the patient.

5. The scale of viability (F) - Vitality (V) - involves assessment by the respondent or by the patient feel full of strength and energy. Lower scores indicate a fatigue study, reduced vitality.

6. The scale of social functioning (SF) - Social Functioning (SF) - assesses satisfaction with the level of social activity (socializing, spending time with friends, family, neighbors, collective) and reflects the extent to which physical or emotional state of the respondent or their patient's limits: the higher the score, the higher the social activity for the last 4 weeks. Low scores correspond to significant restriction of social contact, reducing the level of communication due to the deterioration of health.

7. Role-emotional functioning (RAF) - Role Emocional (RE) - involves the assessment of the extent to which emotional state interfere with work or other regular daily activities, including a large amount of time for their execution, reducing the amount of work done, reduction in water quality: the higher the the less emotional state limits daily activity of the respondent.

8. Psychological health (PZ) - Mental Health (MH) - characterizes the mood, the presence of depression, anxiety, assesses overall positive emotions: the higher the score, the more time respondents felt calm, at peace during the last month. Low scores indicate the presence of depression, anxiety, psychological troubles.

4. Description of socio-demographic map

In accordance with the recommendations of the International Quality of Life Assessment Project has developed a special socio-demographic map that takes into account cultural and social characteristics of the Republic of Sakha (Yakutia). Socio-demographic map consists of 14 questions and includes demographic characteristics (gender, age, occupation, education, marital status) and the substantive nature of the questions that provide information about the level of income and living conditions.

5. Informed consent

Texts invitations to study and informed consent of the respondent presented below.

Dear yakutyanin!

You know that health is one of the most important values of the person and the need to take care of him. According to the World Health Organization, "health - is the complete physical, mental and social well-being and not merely the absence of disease.

"We invite you to participate in a study of quality of life related to health of the population of the Republic of Sakha (Yakutia). The results of the study you will learn from the media. We guarantee complete anonymity of the information received.

Thanks for agreeing to fill out a questionnaire!

The text of informed consent is given below:

I understand that this study is conducted to determine the quality of life of the adult population of the Republic of Sakha (Yakutia). I provided the following

information on the ongoing investigation:

- conducted a population-based study, and does not disclose confidential information about each of the respondents;
- As a result of the study will identify indicators of quality of life of the adult population of the Republic of Sakha (Yakutia), depending on age and sex using a standard questionnaire SF-36;
- will be held standardization of the data to determine the population of standardized indicators of quality of life according to sex, age and residence area of the adult population of the Sakha Republic (Yakutia)
- Based on the data obtained will be developed recommendations for the use of research results in the medical and social fields. I understand the information provided.

I had the opportunity to ask me questions and I got (a) answers to my satisfaction. I voluntarily agree to participate in this study.

6. Methods of statistical analysis

The total sample size for the study population, as well as for individual medical and economic zone of the Republic of Sakha (Yakutia) is defined for a given power of 80% and the level of statistical significance of $p < 0.05$.

Test samples for the presence or absence of a normal distribution performed by constructing a histogram of the frequency and test Kolmogorov - Smirnov. If the distribution of the sample is different from the normal, to test hypotheses about the significance of differences between the means of the sample will be used nonparametric methods Mann - Whitney (Mann-Whitney U-test) and the Kruskal - Wallis test (Kruskal - Wallis ANOVA). Analysis of the relationships between the groups sampling will be conducted using the Spearman correlation coefficient.

Conclusion

Population-based study QoL adult population of the Republic of Sakha (Yakutia) is a well-designed study, the relevant recommendations ICOLA. Conducting population-based study in accordance with the developed protocol will develop standardized QOL indicators, to create referent base of populational QOL values, which can be used to compare the QOL of patients with various diseases in accordance with the age and sex of patients, assessing the effectiveness of therapy in scientific research, further development integrated approach to the assessment of QoL of the population, taking into account the objective characteristics, conditions and processes of life.

References

1. V.N.Amirdzhanova, D.V.Gorjachev, N.I. Korshunov, A.P.Rebrov, V.N.Sorockaja. Populjacionnye pokazateli kachestva zhizni po oprosniku SF-Z6 [Population-based indicators of quality of life by questionnaire SF-36] Nauchno-prakticheskaja revmatologija [Scientific and practical rheumatology]. 2008; 1: 30-47 (in Russian).
2. Kozhokeeva V.A. Razrabotka protokola populjacionnogo issledovanija kachestva zhizni vzroslogo naselenija g. Bishkek s ispol'zovaniem obshhego oprosnika SF-Z6 [Development of a protocol population-based study of quality of life of the adult population of Bishkek using a common questionnaire SF-36]. Vestnik Mezhnacional'nogo centra issledovanija kachestva zhizni [Bulletin of Research Center of Transnational quality of life], 2010; 15-16: 91-96 (in Russian).
3. Kriulenko I.P., Ionova T.I., Nikitina T.P., Kurbatova K.A. Populjacionnoe issledovanie kachestva zhizni naselenija Kostromy i Kostromskoj oblasti [Population study of the quality of life of Kostroma and Kostroma region]. Vestnik Mezhnacional'nogo centra issledovanija kachestva zhizni [Bulletin of Research Center of Transnational quality of life], 2009, 13-14: 41-50 (in Russian).
4. Novik A.A., Ionova T.I. Rukovodstvo po issledovaniju kachestva zhizni v medicine [Guide to the study of quality of life in medicine] / - SPb.: Izdatel'skij Dom «Neva»; M.: «OLMA-PRESS Zvezdnyj mir» [St. Petersburg.: Publishing House "Neva", M.: "Olma-Press Star World"], 2002 (in Russian)
5. Suhonos Ju.A. Populjacionnye issledovanija kachestva zhizni [Population-based studies of quality of life]. Avtoref. diss... kand. med. nauk [Author. diss ... Candidate. honey. Science]. Sankt-Peterburg: 2003 (in Russian)
6. Brenner M.H. Health costs and benefits of health policy // International journal of Health servicies.-1977. - Vol. 7. - P. 581-623;
7. Briancon S. Norms of SF-36 in a French adult population. Ecole de Sante Publique. UPRES EA 1124. Nancy. France / Briancon S., Empereur F., Guillemin F., Presiozi P., Hercberg S. // J. Quality of life research. - 1998. - Vol. 7;
8. Brook R.H. Overview of adult health status measures fielded in RAND's Health Insurance Study / Brook RH, Ware JE, Davies-Avery A., et al. // Med Care. - 1979. - Vol. 17 (Suppl. 7). - P. 1-131;
9. Bullinger M. Translating Health Status Questionnaires and Evaluating Their Quality: The IQOLA Project Approach / Bullinger M., Alonso J., Apolone G., et al. // J. Clin. Epidemiol.-1998.-Vol. 51.-No11.-P. 913-923;
10. Campbell D.T. Convergent and discriminant validation by thee multitrait - multimethod matrix / Campbell DT, Fiske DW // Psychological Bulletin. - 1959.-Vol. 56.-P.81-105;
11. Sella D.F. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure / Cella DF, Tulsky DS, Gray G. et al. // J. Of Oncol. - 1993. - Vol. 11. - P. 570-579;
12. Cella D.F. Quality of life outcomes: measurement and validation // Oncology. - 1996.-Vol. 11.-P. 233-246;
13. Cella D.F. Quality of life: the concept // Journal of Palliative Care. - 1992. - Vol.8, No3.,-P.8-13;
14. Cindy L.K. Lam. Tests of scaling assumptions and construct



validity of the Chinese (HK) version of the SF-36 health survey /
Cindy LK Lam, Barbara Gandek et al. // J. Clin. Epidem.-1998. - Vol.
51. - Vol. 11. - P. 1137-1147;

Information about authors

Zakharova Raisa Nikolaevna

Place of work: Research Institute for Health North-Eastern Federal University named after MK Ammosov, Laboratory of Medical and Social Studies of quality of life of the population of the North, MD, PhD, Head of the Laboratory 677010, Republic Sakha (Yakutia), Yakutsk, Sergelyakhskoe Highway 4 body-2Comte. Phone: +7 (411.2) 35-32-75, 79142223002 e-mail: prn.inst @ mail.ru

Mikhailova Anna Efremovna

Place of work: Research Institute for Health North-Eastern Federal University named after MK Ammosov, Laboratory of Medical and Social Studies of quality of life of the population of the North, Ph.D., Senior Researcher 677010, Republic Sakha (Yakutia), Yakutsk, Sergelyakhskoe Highway 4 body-2Comte. Phone: +7 (411.2) 35-32-75, 79841008152 e-mail: nsvnsr.66 @ mail.ru

Krivoshapkin Vadim Grigor'evich

Place of work: Research Institute for Health North-Eastern Federal University named after MK Ammosov, director of the Institute, Professor, MD, 677010, Republic Sakha (Yakutia), Yakutsk, Sergelyakhskoe Highway 4 body-2Comte. phone: +7 (411.2) 35-32-75