Summary. Introduction. Nowadays there are a number of questionnaires with a score assessment of mental disorders. However, they are not adapted to the specific manifestations of DRP and require additional correction.

Aim. To determine the criteria of necessity of psychological help for the patient with DRP.

Materials and methods. 96 patients with DRP. The methods of the study were as follows: functional diagnostic examinations (visometry without correction and with optimal correction, direct and indirect ophthalmoscopy, optical coherent tomography of the retina and the optic disc); the assessment of mental state of patients using original and adapted tests.

Results. The criteria of necessity of specialized psychological help for the patient with DRP are: level of fatigue manifestations in points is higher than 33 for patients with NPDRP, 49 with PPDRP and 56 with PDRP (according to the mean values of the total score of MFI at the corresponding stage of DRP); veracity of at least 2 statements from the additional questions and/or high values (>12) of at least 2 MFI subscales; changes in cognitive function, classified as severe or moderate.

Conclusions. The integrated, modified questionnaire for patient's mental condition assessment, based on MFI for fatigue manifestations, MMSE for cognitive impairment and the additional questions provides a reliable way to determine the criteria for specialized psychological help necessity.

Key words: diabetic retinopathy, psychological help.

Introduction. Diabetic retinopathy (DRP) is a widespread and threatening problem. Of all registered cases of diabetes mellitus (DM) (366 million in 2011 with an estimated growth to 552 million in 2030 [1]) it develops in 30-60% [2]. After 10 years of the disease, most patients with DM have manifestations of DRP [3, 4]. DRP is a disruption of the retina functions, which leads to blindness and simultaneously to severe psychological complications in the patient due to progressive reduction of vision with a combination of diabetic encephalopathy signs. The clinical picture of diabetic encephalopathy is manifold, it is a pattern of cognitive impairments such as reduced memory and attention, worsening of orientation in time and space, decreased mental and physical capacity, sleep disturbance, emotional lability or depression, autonomic neurological disorders [5]. Similarly, any
disruption of the visual function can be associated with a number of social and emotional complications [6, 7]. Up to 1/3 of people with various visual impairments have significant depressive manifestations [7]. Working adult population with vision impairments of any genesis often report general decrease in mental health, socialization and a lower quality of life compared to their healthy peers [8]. With DRP, this reduction in vision is progressive and more pronounced. Mental discomfort is also caused by the specificity of DRP treatment: vitrectomy, intravitreal administration of drugs, a large amount of laser coagulation. The patient is afraid of the procedures and their complications, often doubts their effectiveness and is significantly frustrated after the smallest treatment failures. Also, the financial burden is a considerable problem due to the high cost of ophthalmic interventions. The combination of such mental complications with the progression of DRP and, consequently, steady loss of vision, contributes to the formation of a vicious circle, reducing the motivation to treatment and its effectiveness through all of the above mentioned problems [9]. Today professional psychological examination of patients in ophthalmology departments and hospitals is not provided, therefore it is important for ophthalmologists be able to singly and quickly assess the emotional and cognitive disturbances to determine whether a psychotherapist is required. With a timely detection of such manifestations and adequate elimination of them, it is possible to significantly improve the quality of life of the patient with DRP, to motivate for the necessary medical procedures, which will positively affect the outcome of treatment.

Nowadays there are a number of questionnaires with a score assessment of mental disorders. However, they are not adapted to the specific manifestations of DRP and require additional correction. All this determines the relevance of the problem of timely diagnosis of psychological disorders in patients with DRP.

Aim. To determine the criteria of necessity of psychological help for the patient with DRP.

Materials and methods. On the basis of the Department of Otorhinolaryngology with Ophthalmology of the Ukrainian Medical Stomatological Academy and the Ophthalmology Department of the Poltava Regional Clinical Hospital named after M.V. Sklifosovsky 96 patients with DRP at different stages of development were examined, and were divided into three groups of observation. The study was conducted in compliance with ethical norms, and the norms of the Helsinki Declaration. All respondents filled out an informed consent to participate in the study. The age of patients was from 43 to 67 years (56±0.7 years on average), there were 57 men and 39 women. The methods of the study were as follows: functional diagnostic examinations (visometry without correction and with optimal
correction, direct and indirect ophthalmoscopy, optical coherent tomography of the retina and the optic disc); the assessment of mental state of patients using original and adapted tests.

The assessment of visual acuity was conducted in a well-lit room, from a distance of 5 meters, using the EDTRS tables with Ukrainian optotypes (patent for utility model №117908 dated 10.07.2017) according to modified ETDRS tables №1, №2 (copyrights №73733, №73742 respectively). Indirect ophthalmoscopy was performed in a darkened room using the ophthalmoscope OZ-5. The examiner was at a distance of 40-50 cm from the patient, in the right arm took an ophthalmoscopic mirror, and in the left – a 13 D lens. The mirror was placed to the patient’s eye, directing the reflected beams from the light source located behind and somewhat to the left from the patient, to the pupil of the examined eye, viewing it through the hole of the ophthalmoscopic mirror. After an even glow of the pupil is recievied, the examiner placed a magnifying glass at a distance of 7-8 cm from the eye (ophthalmoscope opening, center of loupe and the pupil should have been on one axis). Accommodating to the frontal plane, which is located in 5-8 cm from the loupe, the investigator could see as if in the air a true reverse and enlarged image of the fundus (in order to improve the observation, the pupil of the examined eye was dilated with mydriatics). For a detailed examination of the eye fundus, a direct ophthalmoscopy with an electric hand-held ophthalmoscope HEINE mini 3000 was performed, also in a darkened room. The researcher pressed the device tightly to their eye and approached the eye of the patient (to a distance of 2-3 cm), directing a beam of light through the dilated pupil. After the image of the fundus appeared, a lens was adjusted by turning a large refractive disc, correcting the ametropia of the investidator and the patient to obtain a clear image. For ophthalmoscopy in a red-free light, a blue-green filter was introduced into the optical system by rotating the disk. Optical coherent tomography (OCT) of the retina and the optic nerve disk (Fig.1) was performed on the TOPCON 3D OCT-2000 Series device, mapping in the «Macula: 3D Scan» mode of 512x128, 6x6 mm. To analyse and measure the structure of the retina, the following reflections of the retina layers were used:

- the vitreoretinal interface,
- the nerve fibres layer,
- the ganglionic layer,
- the inner and the outer nuclear layers,
- the inner and outer plexiform layers,
- membrana limitans externa,
- the layer of rods and cones;
- the neuroepithelium,
- the pigmented layer and the layer of choriocapillaries.

For the assessment of mental disorders we used the Multidimensional Fatigue Inventory (MFI, E.M. Smets et al., 1995) and the Mini-Mental State Examination (MMSE, M.F. Folstein et al., 1975). The Multidimensional Fatigue Inventory (MFI) by E.M. Smets, B. Garssen, B. Bonke, J. De Haes, 1995 includes 20 questions.

A patient evaluates their condition and grades each statement according to its truthfulness with a 5-point scale.

1. I feel fit.
   Yes, that is true 1 2 3 4 5 No, that is not true

2. Physically I feel only able to do a little.
   Yes, that is true 5 4 3 2 1 No, that is not true

3. I feel very active.
   Yes, that is true 1 2 3 4 5 No, that is not true

4. I feel like doing all sorts of nice things.
   Yes, that is true 1 2 3 4 5 No, that is not true

5. I feel tired.
   Yes, that is true 5 4 3 2 1 No, that is not true

6. I think I do a lot in a day.
   Yes, that is true 1 2 3 4 5 No, that is not true

7. When I am doing something, I can keep my thoughts on it.
   Yes, that is true 1 2 3 4 5 No, that is not true

8. Physically I can take on a lot.
   Yes, that is true 1 2 3 4 5 No, that is not true

9. I dread having to do things.
   Yes, that is true 5 4 3 2 1 No, that is not true

10. I think I do very little in a day.
    Yes, that is true 5 4 3 2 1 No, that is not true

11. I can concentrate well.
    Yes, that is true 1 2 3 4 5 No, that is not true

12. I am rested.
    Yes, that is true 5 4 3 2 1 No, that is not true

13. It takes a lot of effort to concentrate on things.
    Yes, that is true 5 4 3 2 1 No, that is not true

14. Physically I feel I am in a bad condition.
Yes, that is true 5 4 3 2 1 No, that is not true
15. I have a lot of plans.
Yes, that is true 1 2 3 4 5 No, that is not true
16. I tire easily.
Yes, that is true 5 4 3 2 1 No, that is not true
17. I get little done.
Yes, that is true 5 4 3 2 1 No, that is not true
18. I don’t feel like doing anything.
Yes, that is true 5 4 3 2 1 No, that is not true
19. My thoughts easily wander.
Yes, that is true 5 4 3 2 1 No, that is not true
20. Physically I feel I am in an excellent condition.
Yes, that is true 1 2 3 4 5 No, that is not true (Table I)

Mini-Mental State Examination (MMSE), M.F. Folstein, S.E. Folstein, P.R. McHugh, 1975.
The patient must complete the task or answer the questions.
1. “What is the year (1 point)? Season (1)? Month (1)? Date (1)? Day of the week (1)?”
2. “Where are we now: Region (1)? County (1)? Town/city (1)? Hospital (1)? Floor (1)?”
3. The examiner names three unrelated objects clearly and slowly, then asks the patient to
   name all three of them (like ball, man, car; flower, dog, table etc). 3 points.
4. “Spell WORLD backwards.” 5 points.
5. “Earlier I told you the names of three things. Can you tell me what those were?” 3 points.
6. Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient
to name them. 2 points.
7. “Repeat the phrase: ‘No ifs, ands, or buts.’”. 1 point.
8. “Take the paper in your right hand, fold it in half, and put it on the floor.” (The examiner
gives the patient a piece of blank paper.) 3 points.
9. “Please read this and do what it says.” (Written instruction is “Close your eyes.”) 1 point.
10. “Make up and write a sentence about anything.” (This sentence must contain a noun and a
verb.) 1 point.
11. “Please copy this picture.” (The examiner gives the patient a blank piece of paper and asks
him/her to draw the symbol below. All 10 angles must be present and two must intersect (Fig.
1)).

Results:
24-30 points – No cognitive impairment;
22-23 – Minor cognitive impairment (conditionally absent if the individual has only a general secondary education);
18-21 – Mild or moderate cognitive impairment;
0-17 – Severe cognitive impairment.

The tests were combined during the patients’ examination. We conducted the MFI orally because of the decrease in visual acuity in most patients. Furthermore, to increase the sensitivity of the study, the following additional questions were used (randomly asked during the examination), or similar phrases were tracked in patients’ statements:

My doctor does not pay enough attention to my suffering.
Yes, that is true   I do not know   No, that is not true
My treatment is too complicated and uncomfortable.
Yes, that is true   I do not know   No, that is not true
My vision can not be saved
Yes, that is true   I do not know   No, that is not true
I do not have to worry about my health at all
Yes, that is true   I do not know   No, that is not true
I am sure that treatment will not be beneficial
Yes, that is true   I do not know   No, that is not true
I do not trust my doctor
Yes, that is true   I do not know   No, that is not true
My finances are not enough for minimal treatment
Yes, that is true   I do not know   No, that is not true

We have also modified several MMSE questions:
№ 6: Show the patient one simple object, such as a wristwatch, a pencil, a paper, or a pen, and ask the patient to name it. 1 point.
№ 9: If a patient has problem with reading, the examiner closes their eyes and asks to repeat after them.
№ 10: If a patient has problem with writing, the sentence could be spoken aloud.
№ 11: We asked a patient to divide a large square, which is already depicted on paper (or imaginary, if necessary, but then without a point in the centre), on nine small identical squares by drawing four straight lines and to put a dot in the centre. 2 points.

Modified question number 11 evaluates simultaneously the presence of metamorphopsia in a patient with DRP and the ability to estimate the geometry of the figure only by the examiner’s instructions.
Statistical analysis of the results is done using descriptive statistics of the EXEL software. The arithmetic mean value (M), standard error of mean (mM), the probability value (p), the determination coefficient (R2), the Pearson correlation coefficient (r) were calculated. The probability value in the work is taken as p<0.05.

**Results.** In our country the most up-to-date DRP classification is the one proposed by Pasechnikova N.V. and Naumenko V.O., which was approved at the XII Congress of Ophthalmologists of Ukraine (Odessa, 2010) (Table II). We used this classification to analyse the changes in the eye fundus of the examined patients.

**Nonproliferative DRP (NPDRP) – group I (Fig.2, a)**
Patients with this stage did not have complaints on vision. However, on ophthalmoscopy, the following changes were observed: burciform protuberances of the capillaries (microaneurysms) – 30 patients (60 eyes, 100%), intraretinal punctate or dashed haemorrhages – 23 patients (39 eyes, 65%), intraretinal microvascular anomalies (shunts between arterioles and venules) – 12 patients (18 eyes, 30%), solid exudates – 18 patients (30 eyes, 50%).

**Pre-proliferative DRP (PPDRP) – group II (Fig.2, b)**
For 31 patients (62 eyes) this stage was characterized by: accumulated haemorrhages in 28 patients (56 eyes, 90.3%), diffuse retinal oedema in 13 patients (20 eyes, 32.3%), venous loop formation in 25 patients (43 eyes, 69.4%), as well as ischemic areas of the retina – 8 patients (16 eyes, 25.8%). The veins of the retina were beaded, unevenly enlarged in 31 patients (62 eyes, 100%).

**Proliferative DRP (PDRP) – group III (Fig.2, c)**
On the eye fundus 35 patients (70 eyes, 100%) had zones of ischemia with neovascularization, oedema of the retina, fibrous changes of the posterior hyaloid membrane; preretinal haemorrhages were observed in 15 patients (28 eyes, 40%), hemophthalmus in 11 patients (11 eyes, 15.7%), tractional detachment of retina in 7 patients (9 eyes, 12.9%).

The results of visometry by ETDRS tables were as follows: in patients of the group I – 0.72±0.14, of the group II – 0.34 ± 0.02, in the group III – 0.09 ± 0.005.

Patients were interviewed using a modified mental test. Duration of mental state examination of one person was 15-17 minutes. Due to the combined application of the tests and their modifications, we were able to adapt them to the characteristics of patients with DRP.

A correlation analysis was performed with the severity of fatigue and cognitive manifestations compared to the stages of DRP.
We studied the dependence of the aggravation of fatigue manifestations, which we evaluated in points (Y) from the stage of DRP, which was determined clinically (X). To test the hypothesis, all the obtained data was processed statistically. On the basis of these findings, correlation fields (Fig.3) were constructed and the regression equation was chosen to estimate the relationships between the above described parameters. Thus, there is a direct strong correlation between the increase in fatigue manifestation (total score) and the stage of DRP. The determination coefficient (R2) is 0.73; the correlation coefficient (r) is 0.66 (p<0.05).

We also noted the increase in mean values of the MFI subscales by the stages of DRP (Fig.4). Furthermore, the answers “yes, this is true” to additional questions or the presence of similar personal phrases in the amount of at least 2 coincide with no less than 2 values of the MFI subscales above 12 points.

At the same time, we studied the dependence of cognitive impairment severity, which was evaluated in points (Y) from the stage of DRP, which was determined clinically (X). To test the hypothesis, all the obtained data was processed statistically, the sampling is indicated in Table III. On the basis of these findings, correlation fields (Fig.5) were constructed and the regression equation was chosen to estimate the relationships between the above described investigated parameters. Thus, there is a tendency, but a low correlation between the decrease of cognitive function and the DRP stage. The determination coefficient (R2) is 0.23; the correlation coefficient (r) is -0.17.

Based on the obtained data we have formulated the criteria of necessity of specialized psychological help for the patient with DRP.

At least one of the following may be a criterion:
- The level of fatigue manifestations in points is higher than 33 for patients with NPDRP, 49 with PPDPRP and 56 with PDRP (according to the mean values of the total score of MFI at the corresponding stage of DRP).
- Veracity of at least 2 statements from the additional questions and/or high values (>12) of at least 2 MFI subscales.
- Changes in cognitive function, classified as severe or moderate.

Conclusions.
1. The integrated, modified questionnaire for patient's mental condition assessment, based on MFI for fatigue manifestations, MMSE for cognitive impairment and the additional questions provides a reliable way to determine the criteria for specialized psychological help necessity.

2. A modified test is adapted to the features of patients with diabetic retinopathy.
3. A strong correlation was found between the severity of fatigue manifestations and the stage of diabetic retinopathy, the result is reliable (the determination coefficient is 0,73; the correlation coefficient is 0,66, p<0,05). A tendency with a low correlation between the decrease in cognitive function and the stage of DRP was found (the determination coefficient is 0,23; the correlation coefficient is -0,17).

References:
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Fig. 1. 1 point
Fig. 2. Nonproliferative (a), Pre-proliferative (b) and Proliferative (c), DRP on OCT.
Fig. 3. Dependence of increase in fatigue manifestations (total score) from the stage of DRP.
Fig. 4. Evaluation of fatigue manifestations in patients with different stages of DRP by mean values of MFI subscales.
Fig. 5. Dependence of decrease in cognitive function from the stage of DRP.

Table I. Results

Table II. The DRP classification, approved at the XII Congress of Ophthalmologists of Ukraine.

Table III. Evaluation of cognitive impairment in patients with different stages of DRP.