Life quality in patients with diabetes mellitus treated by use of fetal stem cells

Demchuk M.P.¹, Ivankova O.V.¹, Klunnyk M.O.¹, Matiyashchuk I.G.¹, Novytska A.V.¹, Sych N.S.¹, Sinelnyk A.A.¹, Karaiev T.V.¹, Shulak M.M.¹, Skalozub M.V.² and Sorochynska K.I.²

¹Clinical Department, Cell Therapy Center EmCell, Kyiv, Ukraine
²Laboratory and Biotechnology Department, Cell Therapy Center EmCell, Kyiv, Ukraine

*Corresponding author: Dr. M.P. Demchuk, MD, PhD Internal Medicine, Clinical Department, Cell Therapy Center EmCell, apt. 18, 7a Bratyslavska str., 02166, Kyiv City, Ukraine; cell: +38-068-889-8989; E-mail: mdmmaryap2017@gmail.com

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Abstract
Clinical assessment of life quality in the patients with diabetes mellitus (DM) had been made after treatment conducted using fetal stem cells (FSCs). The study results confirmed signs of complications related to the disease course among all patients of the main group (MG) and the control group (CG). Higher life quality was recorded among the patients suffering from DM when, alongside the standard medicinal therapy, they had been administered suspended FSCs. The main features of life quality improvement among the patients were less marked lesions over the skin, decreased complaints at the site of digestive systems as well as their concerns related to cardiovascular functions; blood circulation in the lower extremities improved and sensitivity through peripheral regions was somewhat enhanced too. FSCs preparations also revealed positive effects on sleep and psychological state among the treated patients. In addition, better sexual function in males suffering from DM was remarkable as well. Improvement of life quality in the MG patients contributed to proofs with conclusions on particularly high efficiency of FSCs suspensions in complex treatment of the patients suffering from DM.

Keywords
Fetal stem cells; Diabetes mellitus; Life quality; Sexual function

Abbreviation
FSC: Fetal Stem Cell; MG: Main Group; CG: Control Group; DM: Diabetes Mellitus; WHO: World Health Organization; CV: Cardio-Vascular; GI: Gastrointestinal; CFU: Colony Forming Unit; HIV: Human Immunodeficiency Virus; HBV: Hepatitis B Virus; HCV: Hepatitis C Virus; HGV: Hepatitis G Virus; CMV: Cytomegalovirus; HPV: Human Papilloma Virus; HHV6: Human Herpesvirus 6 Infection; HSV: Herpes Simplex Virus; EBV: Epstein-Barr Virus.
Introduction

Diabetes mellitus (DM), in accordance with definition of the WHO, is regarded as chronic disease that can happen in circumstances when pancreatic glands cannot produce enough of insulin, or when the organism is not able to accumulate insulin produced. Such occurrence can result in high blood glucose ranges (hyperglycemia), as well as disturbances of carbohydrates, lipids and proteins metabolism. Sequelae of DM consist in persistent affection, disturbances of functions as well as deficiency in various organs. DM can usually progress with unexpected fast disease course. Therefore, the problem of life quality in the patients suffering from DM is regarded essential and not enough investigated.

Life quality, as some WHO experts believe, can resemble perception of life position by suffering individuals in regard to the context of their culture, the system of values they are living with; and it can remain in conformity with their personal goals, expectations, own standards and tasks. Life quality can be dependent on the physical, social and emotional factors of human life by influencing the humans and can remain of vital significance for the person. Quality of life is a definite degree of comfort of the patient; both with respect to his/her inner body and within the frameworks of surrounding society, this same person is living with.

Life quality assessment can illustrate us not the degree of all disturbances, but in the way, how the human has been taught for stamina under a particular disease course. In onset of type 1 DM, there are lots of inconveniences promoted by a strict demand in diet, or the other requirements – control of blood glucose range – in the same manner and, simultaneously, to a need of administration of insulin on repeated occasions and every day etc. Overtime, all mentioned actions can become a mainstay of the patient’s routine life and he/she cannot feel inconveniences because of existing restrictions. Subjective estimation of well-being by the patient himself is essential for the future definition of all attributed therapy effects in the individual.

Objective of this study is assessment of life quality in the patients suffering from DM after complex administration of FSCs along with conventional treatment tactics for the patients.

Material and Methods

This research involved the main group (MG) of the patients suffering from verified DM disease who were administered FSCs as a complex treatment, whereas control group (CG) included the patients who did not undergo FSCs therapy.

Verification of diagnosis among the patients of both groups we conducted based on the clinical signs of DM, disease anamnesis with available results of physical, laboratory and instrumental investigations. The principal criterion for selection of the patients and inclusion of them to the MG was: duration of the disease over 10 years and the level of glycated hemoglobin (HbA1c) which constituted ≥ 7, 5% (RR - 4, 8-6, 1%) (Risk factor for presented complications against the background of DM disease course).

HbA1c – is the marker of retrospective assessment of carbohydrates metabolism; it remains the biochemistry index of blood showing the average glucose level in blood for a period of 3 months; which results from non-enzyme glucose binding to hemoglobin of the erythrocytes (life span of cells constitutes 100-120 days). [1]

This study constituted 43 patients where 23 of them enrolled to the MG under study: 13 male patients and 10 females, whereas CG included 20 patients – 10 men and 10 women respectively. Age range in both groups made up 35-60 years. At the baseline of the study, patients of both groups continued medical therapy in accordance with preliminarily defined scheme.

All patients of the MG had a single therapy course by use of FSCs [2]. In order to prepare suspensions, we used human embryo of 5 to 12 weeks gestation [3]. The embryo was received after maternal pregnancy interruption at the premises of health care establishments and owing to social indications in healthy women who were earlier examined for presence of viral and the other hemic infections. All works with fetal material were carried out with the strict adherence to all legislative and ethical norms acting on the territory of Ukraine [4, 5, 6].

Before use of FSCs, all patients got information about the plan of medical and diagnostic measures; received information on the results of clinical-laboratory and
instrumental investigations; comprehensive information about FSCs, methods of their use as well as the modes of administration were announced to the patients under study. After clarifying all patients signed informed consent to proceed with treatment.

FSCs were selected from the cryobank where cryopreserved suspensions were stored in liquid nitrogen at very low temperature (-196°C); choice was individually made for each patient under study. All FSCs suspensions cryopreserved for clinical application were exposed to bacteriological and virology control (HIV1, HIV2, HBV, HCV, HGV, CMV, EBV, HHV6, HSV 1,2, HPV, Rubella, Parvovirus B19, Treponema pallidum, Toxoplasma gondii, Chlamidia trachomatis, Mycoplasma hominis, Mycoplasma genitalium, Ureaplasma Parvum, Urealytcum). All FSCs preparations contain the predetermined number of nucleated cells and CD34+, the number of CFU, including clearly defined viability of cells prior to cryopreservation.

Defrost of suspensions was performed in accordance with the standard protocols. The containers with FSCs prior to administration were evacuated from liquid nitrogen, sunk to the heated bath at temperature of (+37°C); then the suspended preparations were soaked until appearance of liquid phase. The next manipulations were carried out at indoor temperature with a strict adherence to the rules of aseptic. Additional controls of suspension quality were performed precisely before administration; in particular, microscopy testing was conducted and viability of cells was calculated using fluorescence-based flow cytometer.

All patients of the MG were administered FSCs treatment including intravenous drip-feed infusion of cell suspensions which were extracted from human fetal liver. Preparations were injected intravenously using the system for drip-feed blood transfusion with 200 mL 0.9% physiological sodium chloride solution following preliminary jet I.V. premedication with 10 mg dimedroli and 30 mg prednisolone. Speed of administration made up 20-40 drops per minute. Suspensions were injected in the volume from 2.0 mL to 8.0 mL per the course of treatment and the number of nucleated cells constituted from 5 to 35 x 10⁶/mL, with percentage of viable cells not less than 70%. Besides intravenous stem cells administration, all patients in the MG were additionally performed implantation of pre-neuronal stem cells using a depot within adipocellular tissue of the anterior abdominal wall. Each course of treatment was composed of suspended FSCs preparation in a quantity of 2.0 to 7.5 mL.

In order to define effects of FSCs on life quality of the patients suffering from DM with different degree of expression of the main clinical symptoms of the disease, the corresponding questionnaire form was applied [7] (see table 1.)

**Table 1:** Questionnaire form to assess life quality in patients with DM.

<table>
<thead>
<tr>
<th>Condition of skin covers</th>
<th>1. Are you concerned about redness, skin inflammation, or appearance of purulent vesicles over your skin?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>a) No, I’m not / very rarely</td>
</tr>
<tr>
<td></td>
<td>b) It occasionally can cause inconvenience doing my routine activity</td>
</tr>
<tr>
<td></td>
<td>c) Interferes with daily chores at home and professional duties</td>
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<tr>
<td></td>
<td>2. Are you concerned about intense skin dryness, formation of incurable fissures on the feet, which can persist for a long time?</td>
</tr>
<tr>
<td></td>
<td>a) No, I’m not / very rarely</td>
</tr>
<tr>
<td></td>
<td>b) It occasionally can cause inconvenience while doing routine activity</td>
</tr>
<tr>
<td></td>
<td>c) Interferes with daily chores at home and professional duties</td>
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<tr>
<td></td>
<td>3. Are you concerned about formation of skin ulcers, or lesions on the skin?</td>
</tr>
<tr>
<td></td>
<td>a) No, I’m not / very rarely</td>
</tr>
<tr>
<td></td>
<td>b) They can occasionally cause certain inconvenience at home and at the working place</td>
</tr>
<tr>
<td></td>
<td>c) This becomes a cause of inability to carry out professional duties</td>
</tr>
</tbody>
</table>
### Status of GI tract

4. Are you concerned about appearance of the small tender wounds, ulcers in the mouth cavity?
   - a) No, I’m not
   - b) Yes, I am. It occasionally can cause pain at mastication of food; this somewhat disturbs taste sensations
   - c) Yes, I am. Such problems interfere with daily activity at home and professional duties

5. Are you suffering from disturbances of defecation (constipations)?
   - a) No, I’m not
   - b) Yes, I am, occasionally
   - c) Yes, I am

6. Do you record any body weight gain?
   - a) Practically no
   - b) Body mass gaining can cause certain inconvenience in daily activity at home and professional duties
   - c) Excessive body mass interferes with common everyday duties and professional activity

7. Are you keeping on a diet?
   - a) Yes, diet became a norm of my everyday mode of living / No, as I am not suffering from diabetes
   - b) Not much change in my usual nutrition; excluding only products with high sugar intake
   - c) I need to radically change my common dietary regimen, select products or buy special meals

8. Are you concerned about occasional pains in stomach?
   - a) No, I’m not
   - b) Yes, I am. Occasionally, I can feel pains in it, especially, if nutrition irregularity
   - c) Yes, I am. I can often feel pain causing decrease of workability

### Peripheral blood circulation

15. Are you concerned about pains in the shins, which can appear or become much intense while walking; such pains may disappear or diminish at stopping; when at rest etc.?
   - a) No, I am not / they are less marked
   - b) Yes, I am. Pains can result in reduced volume of performed everyday exercising and interfere with rational rest (e.g. In the out-f-doors)
   - c) Yes, I am. They can result in inability to perform professional duties and make me dependent on the relatives in activity of daily living

16. Are you suffering from ulcerative lesions of the feet?
   - a) No, I am not
   - b) Yes, I am – but the ones not requiring operative treatment
   - c) Yes, I am (amputation was done)

17. Are you suffering from gnawing “cramping” pains in the calves at night?
   - a) No, I am not
   - b) Yes, I am. They occasionally can happen, but cramps do not interfere with sleep
c) Yes, I am. My cramps can become a cause of insomnia

18. Do you suffer from painful cramps in the calf muscles (at night time; if at rest)?
   a) No, I do not
   b) Yes, I do. They occasionally can interfere with rest and sleep at night
   c) Yes, I do. Painful cramps can become the major cause of my insomnia

19. Do you feel like losing your strength in the legs?
   a) No, I do not
   b) Yes, I do. This can result in decrease of volume of everyday loads, interfere with effective rest (in the out-of-doors)
   c) Yes, I do. It can become the main cause of inability to carry out professional duties and makes me dependent on the relatives in activities of daily living

**Condition of organs of sensations**

20. Do you have dull, spreading or drawing pains in the symmetric areas of the arms and legs at night?
   a) No, I do not
   b) Yes, I do. Pains can somewhat interfere with my sleep
   c) Yes, I do. Pains can become the principal cause of night time insomnia

21. Is decrease of vision acuity characteristic for you?
   a) No, it is not / not much
   b) Yes, it is. My eyesight acuity is reduced, but this does not interfere with my everyday job
   c) Yes, it is. Eyesight acuity can sharply decrease that creates problems with carrying out my professional duties

22. Do you record any sort of hearing deterioration?
   a) No, I do not
   b) Yes, I do. I can have some extent of decreased hearing, but no need using special hearing aid for that
   c) Yes, I do. I suffer from marked hearing loss and this interferes with elementary communication at work, or at home

23. Do you feel any decreased pain sensitivity over the region of hands and/or feet?
   a) No, I do not
   b) Yes, I do. Some extent of sensitivity decrease in the limbs was observed
   c) Yes, I do. Sensitivity is much affected

24. Do you feel decreasing of warmth and sensitivity to cold in the region of your hands and feet?
   a) No, I do not
   b) Yes, I do. Some sort of sensitivity decreasing is observed
   c) Yes, I do

25. Do you find it difficult to differentiate various objects after touching them?
   a) No, I do not
   b) Yes, I do. Some sort of reduced sensitivity in the fingers is characteristic
   c) Yes, I do
### Sexual function

26. Are you suffering from deteriorated sexual health?
   - a) No, I am not
   - b) Yes, I am. Likely concern may happen from time to time
   - c) Yes, I am. This really makes me feel inferior; it can even cause tension with my family relations etc.

### Psychological features of personality

27. Are you suffering from feelings of loneliness, or sort of worthlessness?
   - a) No, I am not
   - b) Yes, I am. It can occasionally occur
   - c) Yes, I am. It can happen and makes me embarrassed

28. Are you suffering from any sort of mood irregularity (increased tearfulness, irritability etc.)?
   - a) No, I am not
   - b) Yes, I am. Sometimes it can be recorded
   - c) Yes, I am. This happens and can become the cause of complicated relations with the surrounding people

29. How often do you develop sensation of anxiety for your life, or any sort of apprehension?
   - a) Almost never
   - b) In cases of exacerbation of the disease symptoms
   - c) Regularly

30. Do you have any fear of death?
   - a) No, I do not
   - b) Yes, I do. But just when disease exacerbation is much severe
   - c) Yes, I do. Such feeling can become my frequent concern

31. Are you suffering from memory deterioration?
   - a) No, I am not
   - b) Yes, I am. I can record certain worsening of memory, problems with attention while doing some work
   - c) Yes, I am. My memory and attention are much deteriorated; I can have difficulty with fine motions and doings work connected with calculations

### Sleep

32. Do you wake up at night having problems with dropping off to sleep again?
   - a) No, I do not
   - b) Yes, I do. Sometimes
   - c) Yes, I do. I can often feel diseased or feel unrested

33. Does pain interfere with quality of your sleep?
   - a) No, it does not
   - b) Yes, it does. Occasionally
   - c) Yes, it does. It can be the major factor of insomnia

34. Do you need awakening at night because of urgency to urination?

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35. Do you wake up at night with sensations of thirst and need drinking some water?
   a) No, I do not
   b) Yes, I do, sometimes need
   c) Yes, this can seriously disturb my night time rest

Social aspects of adaptation and satisfaction with overall health care

36. Do you often need changing the medicines for treatment of diabetes mellitus?
   a) No, I constantly take one and the same medicine, because I feel fine after using them
   b) Yes, I do. Principal medical drugs must be changed 2-3 times per year (mainly because of price)
   c) Yes, I do; the main drugs must be changed 2 and more times per 6 months as my condition can deteriorate

37. Does your administered treatment influence your life quality (preparations in tablets, injections etc.)?
   a) No, I do not. I do not see any deterioration in my life quality
   b) Yes, I do. This can interfere with my working day
   c) Yes, I do. My daily routine is fully adjusted to the use of medicines; doing my work activity is almost impossible

38. Are you quite satisfied with the results of therapy performed?
   a) Yes, I am
   b) No, I am not in full extent
   c) No, I am not satisfied

39. Are you a sort of overburdened with your work or housing duties?
   a) No, I am not
   b) Yes, I am. If disease exacerbation happens
   c) Yes, I am. Constantly

40. Do you believe that your DM disease interferes with your realization at work, or professional growth?
   a) No, I don’t / No, as I do not have occupation
   b) Yes, I do, this is the cause of misfortune at work
   c) Yes, I do, I believe my career failed because of that

41. Do you consider yourself as a burden for people surrounding you?
   a) No, I do not
   b) Yes, I do. Sometimes, but just when disease is at the stage of exacerbation
   c) Yes, I do.
The questions in the form were directed at finding out the principal symptoms of the disease according to the poly-systemic character of disturbances, being remarkable for the course of DM in the patients. They were split into the groups based on systemic characteristic features: condition of skin, status of gastrointestinal (GI) tract, status of cardiovascular (CV) system, peripheral blood circulation, organs of sensations, genital functions, psychological characteristics in human and sleep. There were 3 options with possible answers to each question: option 1 (0 score) – symptoms are practically absent and/or they cannot influence the mode of living in the patient; option 2 (1 score) – moderate (occasional) manifestations of the symptoms in a combination with decreased life activity of the patient (every day, professional); option 3 (2 scores) – marked symptomatic manifestations and related inability to perform the main working activity and daily duties.

Results and Discussion

Life quality assessment was performed in accordance with the list of questions indicated in the table 1 at the initial point prior to treatment and after administration of FSCs – over 1 month, 3, 6, 9 and 12 months. The main results of observation had been depicted in the figure according to the graphs.

The figure suggests the complex of symptoms with the main clinical signs of DM. At the baseline of the study problems with skin were revealed in 83.3% of individuals in the MG and similar concerns were recorded by 73.3% of patients under study in the CG. Over 1 month after FSCs administration, appearance of problems with skin decreased in the MG under study by 7.2% and by 3.4% among the patients of the CG. Condition of skin covers over 3 months revealed improvement by 73.2% in the MG patients, whereas it was better only by 30% in the patients of the CG. Maximal improvement of skin condition in both groups is observed over 9 months – it is recorded in 80.5% of patients in the MG versus 53.4% of patients in the CG.

Figure 1: Psychological characteristics of the patients.

Figure 2: Sleep quality.
At the beginning of the study, GI tract problems had been recorded in 95.3% of individuals in the MG versus 90% of the patients under study in the CG. Over 1 month following FSCs administration, the number of patients who had complaints related to GI tract decreased; making up 75.3% of patients in the MG and it was 84% - for the CG patients respectively. In addition, the maximal lowering in the symptoms reflecting GI functions was recorded over 9 months under observation and such ranges were decreased by 32.9 % (MG) versus 9.3 % (CG) of the patients.

All MG patients presented the complaints related to the characteristics of cardiovascular (CV) system at the baseline of the study and the same concerns were remarkable for the CG (93.3%) too. As early as over 1 month after FSCs transplantation, the number of patients with CV problems reduced and it constituted 76.9% (MG) versus 80% (CG) respectively. Within a period under observation both groups revealed a gradual decrease in complaints related to CV system. Over 12 months under study CV system state improved by 58.6% in the MG patients whereas CG patients recorded improvement by 53.4%.

Peripheral circulation problems in the legs were detected in 84.6% of the interviewed within the group under study, whereas the same problems were characteristic just for 70% of CG patients. For over 1 month after stem cells therapy, all symptoms related to features of peripheral blood circulation in the lower limbs became less marked in the patients of the MG (reported by 60% of the patients under study); whereas the same symptom complex in the patients of the CG remained unchanged and its signs were remarkable for 70% of the interviewed (CG). Maximal improvement of circulation state was recorded in the patients of both groups over 9 months under study and the similar advantages were preserved until the end of the whole period of supervision. Thus, in the MG status of blood circulation in the legs improved by 65.6%, whereas the patients of the CG recorded the same advantages only by 26.4%.

Disturbances of sensitivity at the baseline were revealed in 79.6% of the MG patients and the number of similar concerns in the CG patients made up 50% among the interviewed patients. Over 1 month after FSCs therapy and at the beginning of observation signs of sensitivity concerns were recorded in 64.1% of the MG patients under the study; whereas CG patients recorded likely problems in 50% of the interviewed individuals. No significant improvement in sensitivity of the CG patients was attested during the whole period of observation. The MG patients under study reported a gradual restoration of sensitivity and at the endpoint of the study such characteristic features improved by 62.4%.

Sexual health was mostly disturbing issue for the men both in the MG and in the CG; most of women ignored such a question. Thus, at the baseline of the study, absolutely all males in both groups were concerned about reduced sexual functions. Before treatment, 61.5% of the men in the MG and 25% of men of the CG considered erectile dysfunction as the cause for them feel inferior; in particular, the factor causing tension with family relations in the male patients.

Decrease in sexual functions intermittently caused complaints in 38.5% of the men of the MG, whereas CG constituted 75% of men with the same problems. Within the total period of observation in patients of the CG, no evidence of any sort of sexual dysfunction was recorded. Over 1 month after use of FSCs, 23% of males in the MG did not reveal any sexual dysfunction; whereas decreased erections might intermittently cause apprehension in around 61.5% of males with DM; and just 15.5% of male diabetics believed that decreased sexual function becomes the cause of their personal deficit, resulting in problems with family relations. Already over 3 months after stem cell treatment, no one of the men in the MG supported his argue, so that reduced erections really can become the cause of them feel inferior making their family interrelations tense. In this respect, maximum increase in life quality by the values of male health was observed over 6 months after use of FSCs and in percentage, it remained at the same level until the end of the study. Over 12 months 53.8% of males did not record any problems with their sexual function and 46.2% of the men under study might occasionally notice some sort of apprehension. Any disease can change personality to some extent and this allows us speaking about changes in psychological status of the patient, if compared with that recorded prior to disease diagnosis. A diseased human perceives surrounding world through the prism of the disease. Diabetes mellitus is tightly connected with emotional strain. Improvement of psychological well-being of the patient suffering from DM may have a direct influence on successful management of person’s own disease, and, subsequently, a likely advantage results in better life quality among the patients. During the first 3 days after use of FSCs, all patients in the MG revealed a better emotional background – as their mood was fine; they built-up the plans for the future. Over 1 month after conducted treatment, 32.3% of patients in the MG did not record any psychological problems (due to their answers to such questions). Simultaneously, no single patient recorded improvement of psychological well-being in the CG and it remained at the previous level. Maximum improvement of psychological status was observed over 9 months after use of FSCs. Around 60% of patients in the MG revealed lack of psychology concerns; and over 12 months the same percentage of the patients also remained unchanged at the endpoint of the study. Over 6 months from the beginning of the study, 34% of patients in the CG recorded absence of psychological problems and, subsequently, such a percentage of the patients remained until the end of the study.

Sleep is ultimately necessary for the human, because it maintains a range of various body functions that can support human life. Dissatisfaction with sleep and lack of vigor after sleeping etc., can significantly reduce the quality of living. At the moment of life quality estimation in the patients with DM at baseline of the study – sleep deterioration of different extent was determined practically in all patients. Over 1 month after use of FSCs, a quality of sleep in patients of the MG increased almost by 38%. Simultaneously, in patients who were administered conventional treatment, improvements in sleep formula became higher only by 4.8% and such a percentage did not reveal much increasing until the end of observational period. Over 3 months, sleep quality in the patients of the CG increased by 7.2%, over 6 months it was higher by 11.1% in comparison with baseline period. The same percentage somewhat decreased and constituted 7.2% over 12 months after treatment administered. Among the patients of the MG, a sleep quality was gradually becoming higher during the whole period of observation. Over 3 months values for improvement of sleep elevated by 45.7%, in comparison with the baseline score and the same value was higher by 56.7% over 6 months after treatment administered. Within the next observational period, such an improvement remained stable: it was by 57.9% over 9 months and by 59.7% over 12 months respectively.

Conclusions

DM is the disease where human organism cells experience problems with blood glucose uptake and capacity of transforming it to the energy. As a result, sugar accumulated in blood is not utilized as a nutritious substance in such patients. Persistent hyperglycemia becomes the principal cause of DM-related complications. Multi-system abnormality characteristic for DM can negatively affect the life quality in such groups of patients. The above results of the study proved the evidence that FSCs can have a posi-
tive effect on life quality in the patients suffering from DM. If the results received in the MG are correlated with the corresponding values in patients of the CG within the whole process of observation, then much remarkable therapy effects were recorded in the patients of the MG. In addition, one shall conclude that application of generally accepted medicinal therapy in CG patients did not much affect quality of sleep, sexual function, or the complex of psychological symptoms in the patients under study. Simultaneously, use of FSCs had much significant and faster positive effect on the above-mentioned parameters. Advantages of increased life quality among such groups of patients contribute to the best results of therapy for DM sufferers and its principal task is preserving and strengthening of overall health in human with respect to psycho-emotional and social advantages in the patients suffering from DM.

References


4. Law of Ukraine about organ transplantation and other anatomic materials to the person.

