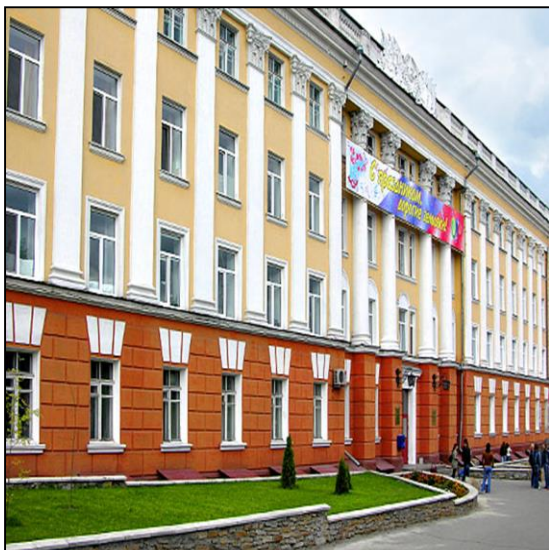


**Efficacy and safety study of functional juice
beverages FITOGURU TONUS**

in conditions of Altai State Medical University,
Federal Agency for Healthcare and Social
Development



Altai State Medical University



- ✓ Included in the List of Medical Institutions authorized to conduct clinical trials of medicinal products
- ✓ Today ASMU is one of the leading higher medical education establishments in Western Siberia

**Principal investigator – *B.I. Kozlov* , Doctor of medical sciences,
professor, Department of Faculty Therapy**

Study objectives, type and design

Purposes and objectives:

- ✓ To study the dynamics of guiding clinical symptoms, parameters of laboratory and functional examinations in almost healthy persons with specific diseases.
- ✓ To evaluate efficacy of Fitoguru drinks in almost healthy persons with signs of specific diseases.
- ✓ To substantiate possibility and safety of drink usage as an adjunct in correction of clinical manifestations of diseases.

Type:

- ✓ Prospective single-site comparative open-label study.
- ✓ Period: August-December 2010

Design:

- ✓ Fitoguru drinks were used in almost healthy people with clinical manifestations of certain diseases as an adjunct source of bioactive substances in order to study their influence on clinical laboratory and functional parameters as well as quality of life.
- ✓ Number of patients – 40 persons.

Extent of examinations

Clinical examination (30 days)

- Complete blood count (haemoglobin, erythrocytes, leukocytes, erythrocyte sedimentation rate)
- Antioxidant state (in plasma – total antioxidant activity and thiobarbiturate-reactive products, in red blood cells – total antioxidant activity, superoxide dismutase, catalase, glutathione peroxidase)
- Assessment of involuntary nervous system tonus by Kareem index

Urine analysis

- colour, transparency, specific density, reaction, protein, glucose, epithelia, leukocytes, erythrocytes, cylinders, mucus

Bicycle exercises (functional tests)

- exercise capacity, chronotropic reserve and isotropic reserve, double product index, threshold power, index of metabolic cost

Quality of life

- WAM scale (Wellbeing, Activity, Mood)
- MFI 20 questionnaire (simplified modification)
- Chronic prostatitis symptom index (NIH-CPSI)
- International index of Erectile Function (IIEF)

Inclusion and exclusion criteria

Inclusion criteria

- Patients older than 18 and younger than 64 years of age
- Almost healthy volunteers
- Willingness to comply with protocol procedures
- Written informed consent

Exclusion criteria

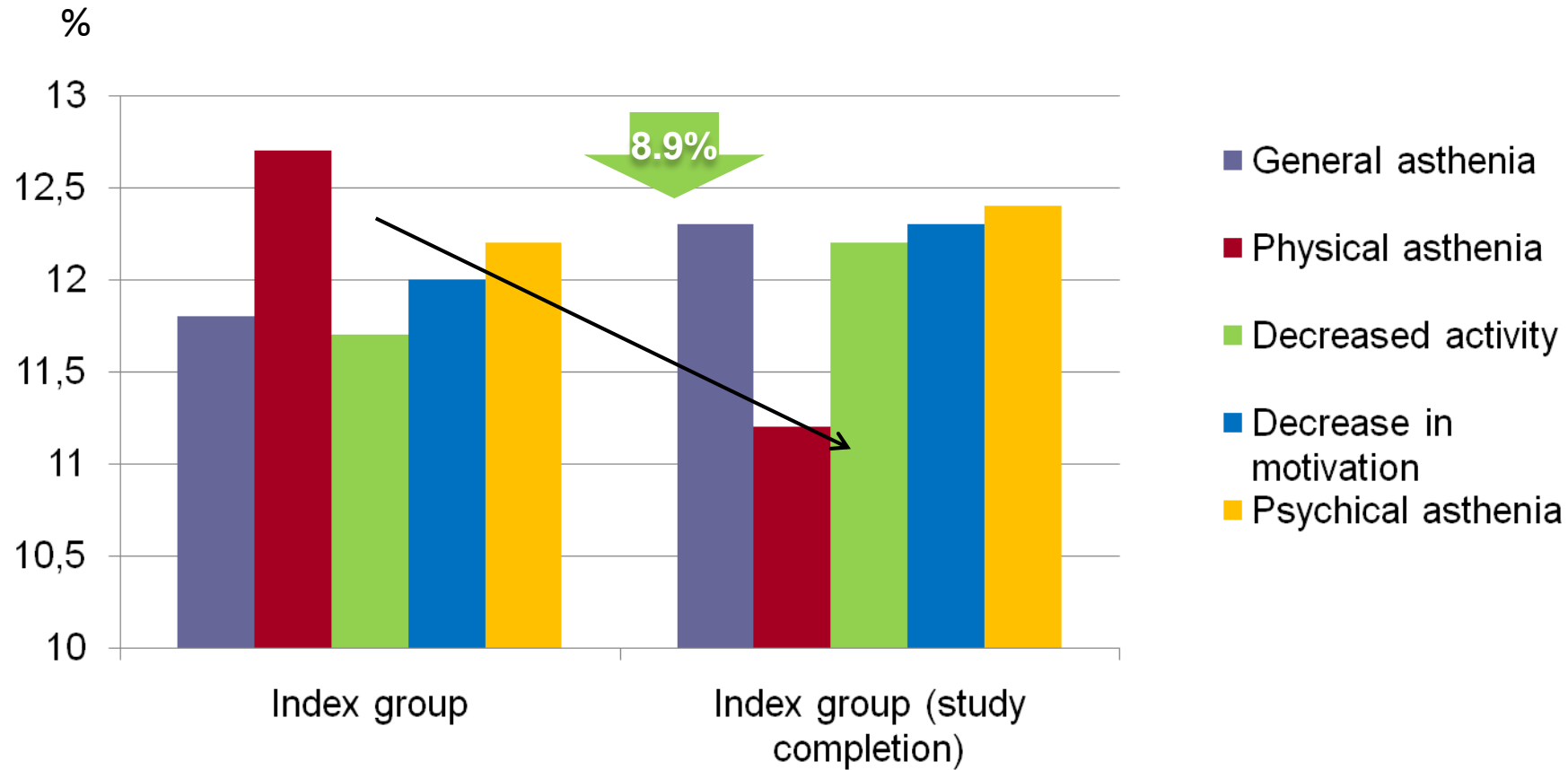
- Idiosyncrasy of product components
- Diabetes
- Phenylketonuria
- Contraindications to bicycle exercises
- Advanced general diseases
- Oncological diseases of any localization, HIV, tuberculosis, alcohol or drug abuse, mental illnesses
- Simultaneous participation in any other clinical study, as well as in the past 30 days
- Pregnancy, lactation



“Efficacy and safety study of enriched juice drink “Fitoguru Tonus Grape-Fruit-Orange (Fitoguru Tonus)” in almost healthy people with signs of asthenovegetative syndrome

Evaluation of asthenovegetative syndrome severity

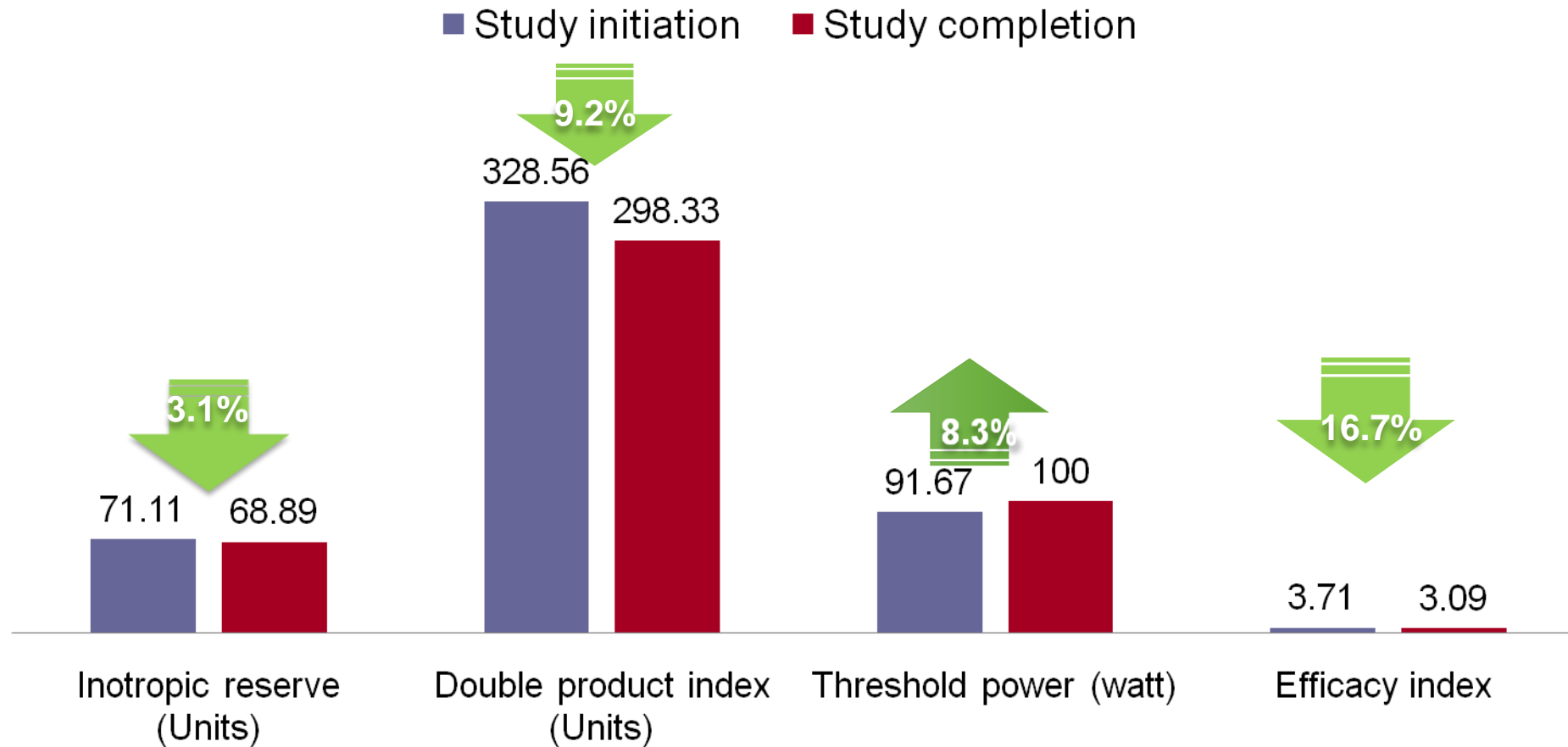
On MFI 20 scale



Decrease of physical asthenia by **8.9%**.

*- statistically significant differences at the beginning and at the end of the study ($p < 0.05$)

Dynamics of bicycle exercise parameters in women

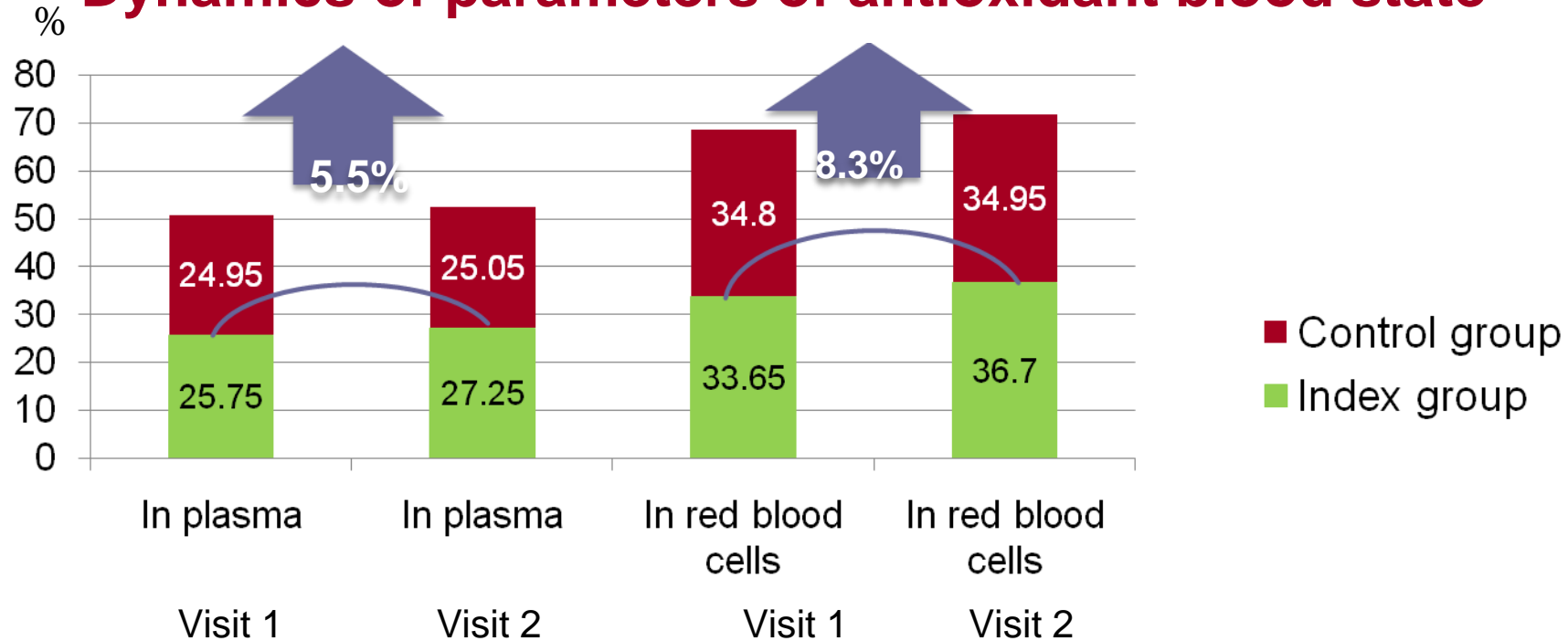


Decrease in parameters: inotropic reserve by **3.1%**, double product index by **9.2%**, metabolic cost index by **8.3%**, as well as increase in threshold power by **16.7%** in **women** proves stabilization of cardiovascular system function

* - statistically significant differences at the beginning and at the end of the study($p < 0.05$)

Efficacy

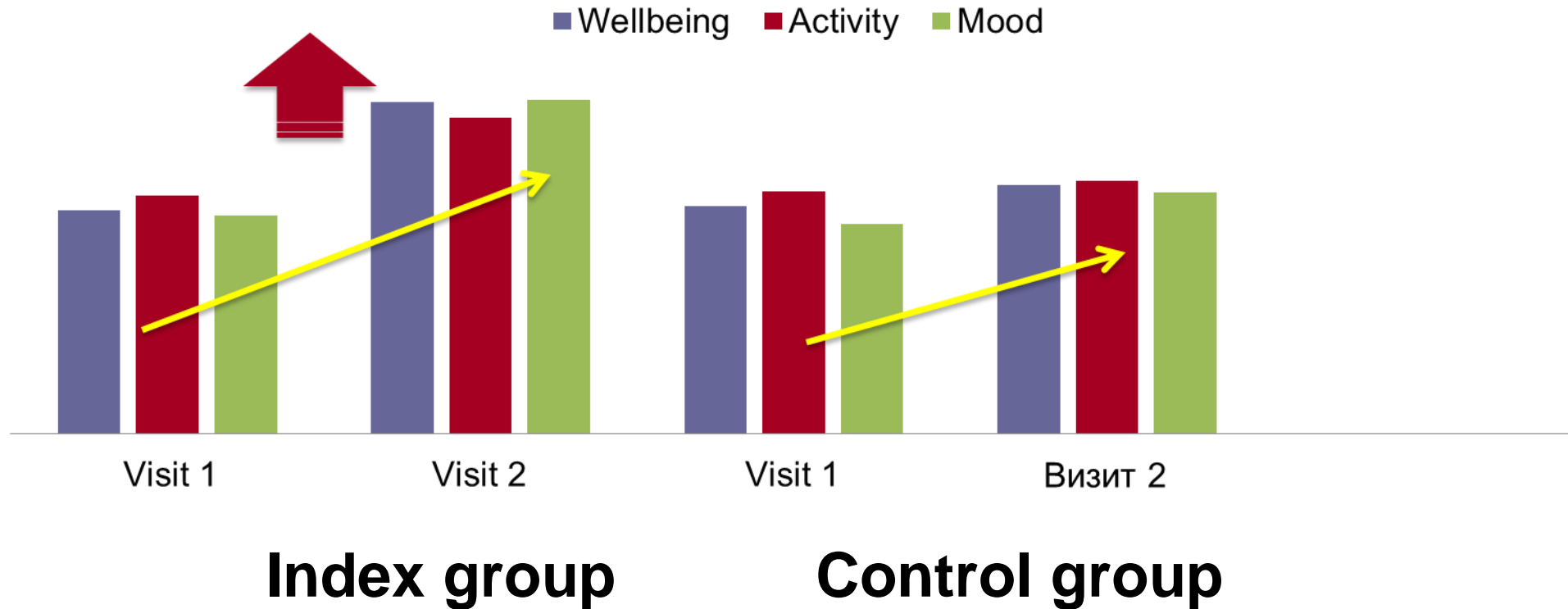
Dynamics of parameters of antioxidant blood state



Increase of total antioxidant activity in red blood cells by **8.3%** and in plasma by **5.5%**.

* - statistically significant differences at the beginning and at the end of the study ($p < 0.05$)

Parameters of WAM scale



Improvement of testing results for wellbeing, activity, mood according to WAM scale in **90%** of cases.

* - statistically significant differences at the beginning and at the end of the study ($p < 0.05$)

Conclusion

- ✓ Specific studies on safety assessment based on the clinical and laboratory data showed no significant deviations from the normal and initial parameters after a course of drink intake.
- ✓ Drink intake leads to increase in overall antioxidant activity in plasma by **5.5%** and in red blood cells by **8.3%**; content of superoxide dismutase by **6.5%**, glutathione peroxidase by **1%** in red blood cells of subjects; to decrease in thiobarbiturate-reactive products in blood plasma by **8%**.
- ✓ Decrease of number of patients with clinical signs of physical asthenia has been noted in the group of subjects who received the drink. In particular, when assessing the level of asthenia on MFI 20 scale, the intensity of physical asthenia has decreased by **8.9%** .
- ✓ Drink intake leads to decrease in such parameters as inotropic reserve by **3.1%**, double product index by **9.2%**, metabolic cost index by **8.3%**, as well as to increase in threshold activity by **16.7%** which proved stabilization of cardiovascular system function in assessing bicycle exercise data in women.

Altay State Medical University, The Federal Agency for Healthcare and Social Development in Russia, Russian Ministry of Healthcare

**Principal Researcher, Doctor of Medical Sciences,
Professor Boris Ivanovich Kozlov**



“Based on conducted clinical studies, it is proven the ability of Fitoguru Tonus to influence the certain body functions. The drink is recommended to improve the functionality of the central nervous system, improve the adaptive capacity of the body and physical endurance.