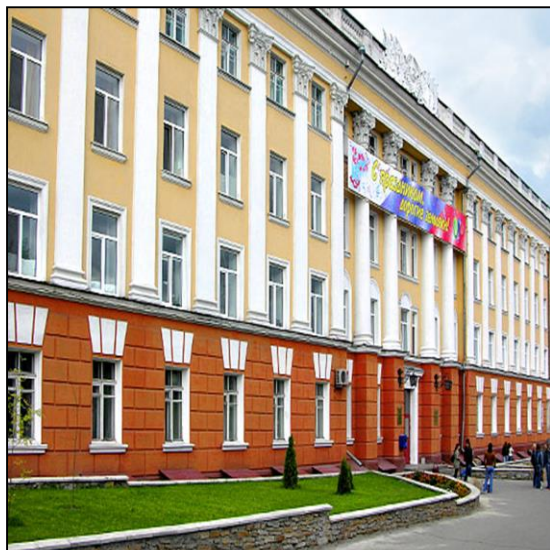


**Efficacy and safety study of functional juice
beverages FITOGURU IMMUNO**
in conditions of Altai State Medical University,
Federal Agency for Healthcare and Social
Development



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

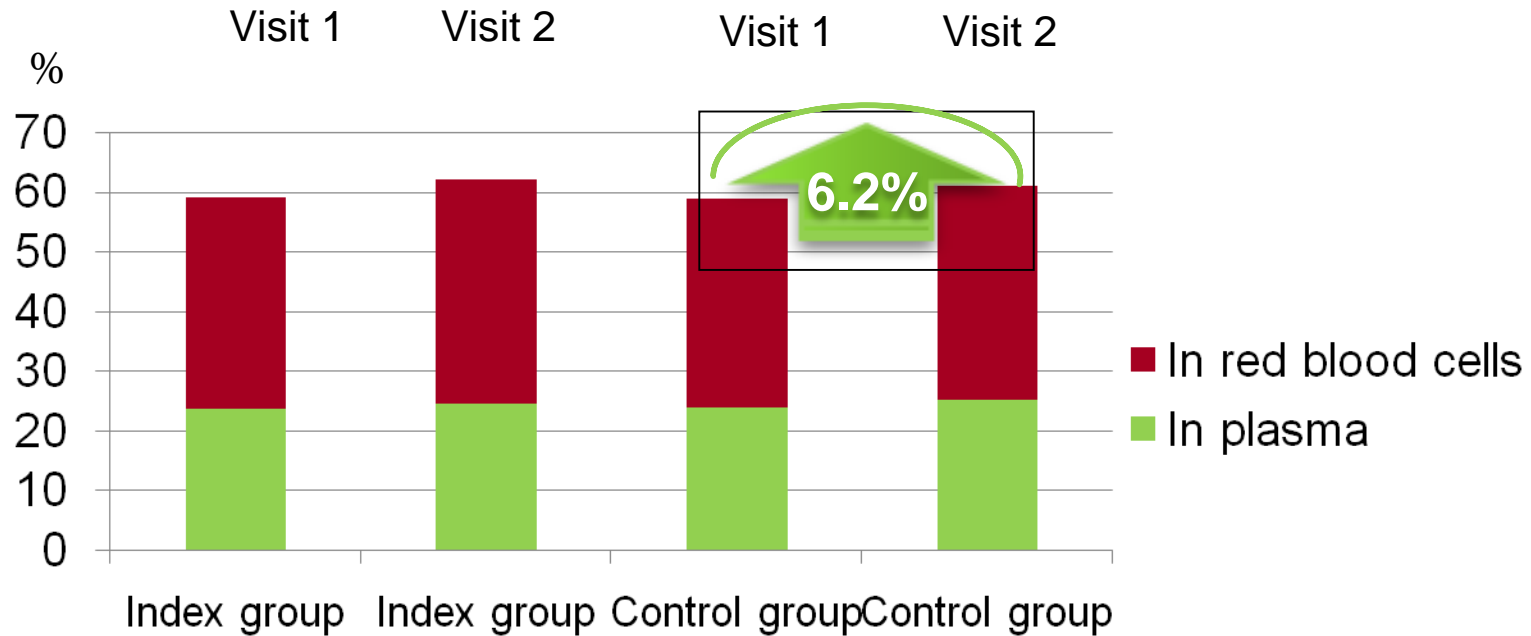
- Idiosyncrasy of product components
- Diabetes
- Phenylketonuria
- Contraindications to bicycle exercises
- Advanced general diseases
- Oncological diseases of any localization, HIV, tuberculosis, alcohol or drug abuse, mental illnesses
- Simultaneous participation in any other clinical study, as well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



“Efficacy and safety study of enriched juice drink “Fitoguru Cranberry – Black current – Propolis (FITOGURU Immuno)” in people recovering after aggravation of chronic non-communicable diseases”

Efficacy

Dynamics of antioxidant blood state parameters

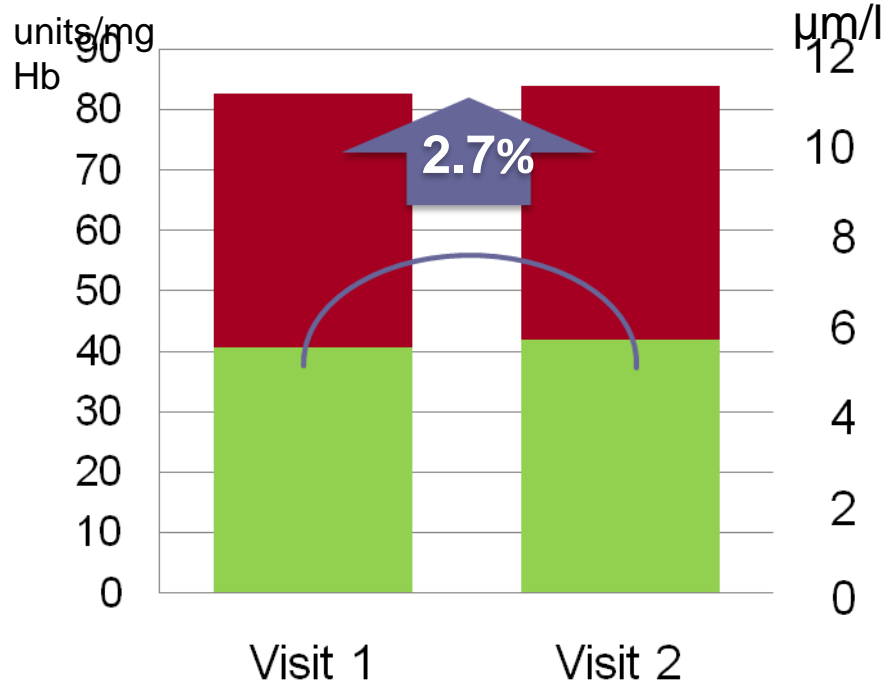


Increase of total antioxidant activity parameters in red blood cells by **6.2%**

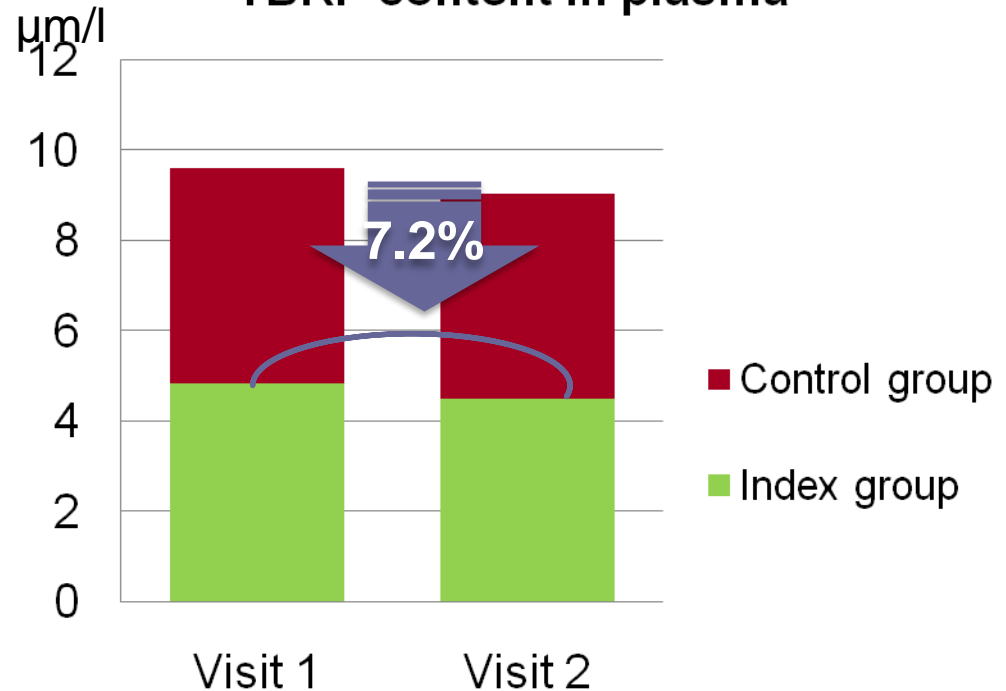
* - statistically significant differences at the beginning and at the end of the study ($p < 0.05$)

Content of superoxide dismutase in red blood cells and thiobarbiturate-reactive products in plasma

SOD content in red blood cells



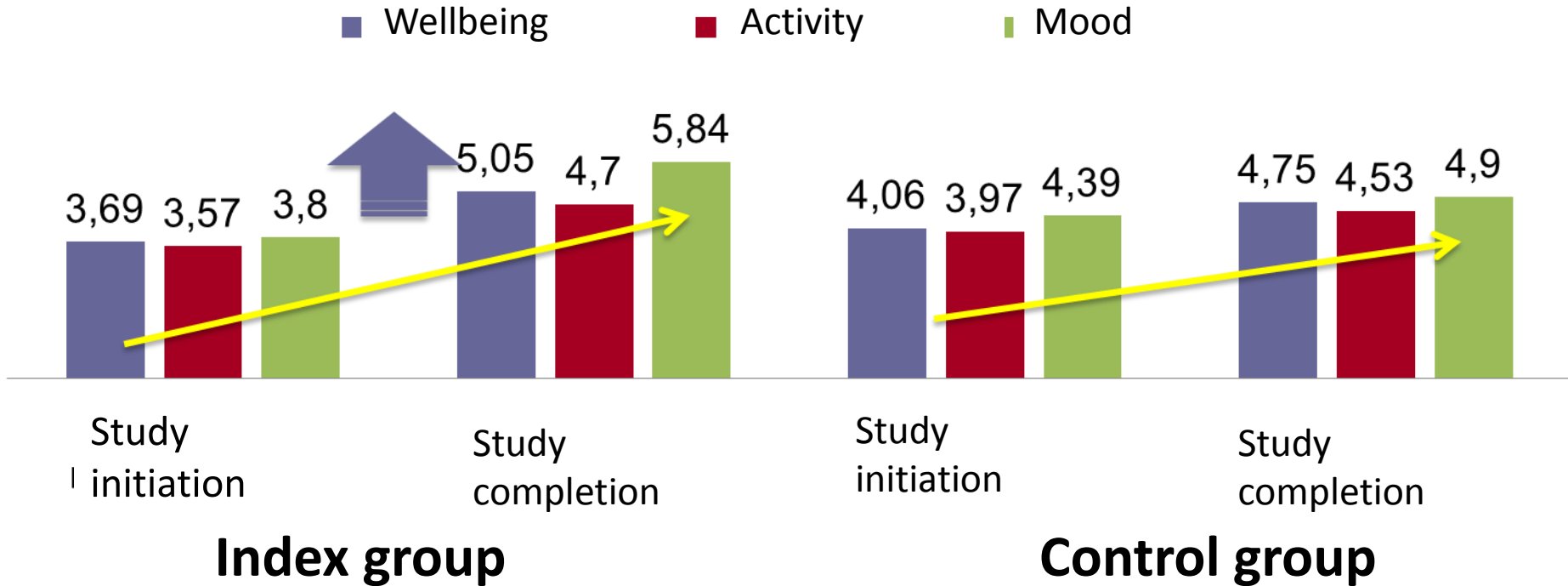
TBRP content in plasma



Increase in superoxide dismutase content in red blood cells by **2.7%** and decrease in thiobarbiturate-reactive products in plasma by **7.2%**.

* - 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

- ✓ Study product intake lead to positive dynamics of such parameters as total antioxidant activity in red blood cells to **6.2%**,
- ✓ to significant increase in content of superoxide dismutase in red blood cells by **2.7%** and
- ✓ to decrease in content of thiobarbiturate-reactive products in plasma by **7.2%** in index group.
- ✓ **100%** compliance* of the subjects has been noted.

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 that consumption of Fitoguru Immuno led to a positive (statistically significant) dynamics of the indicators in the system of lipid peroxidation - antioxidant protection. In patients undergoing convalescence after suffering exacerbations of chronic non-infectious diseases who took Fitoguru Immuno drink has seen significant improvement in subjectively determined quality of life was observed during the observation period.