

ProbioCOPETM

Bacillus coagulans NU-10, the innovative probiotic strain for mood improvement and mental well-being with scientific evidence.





What is ProbioCope™ ?

Bacillus coagulans NU-10 branded as ProbioCope™ is the first probiotic strain clinically tested and proven for mood improvement and mental well-being.

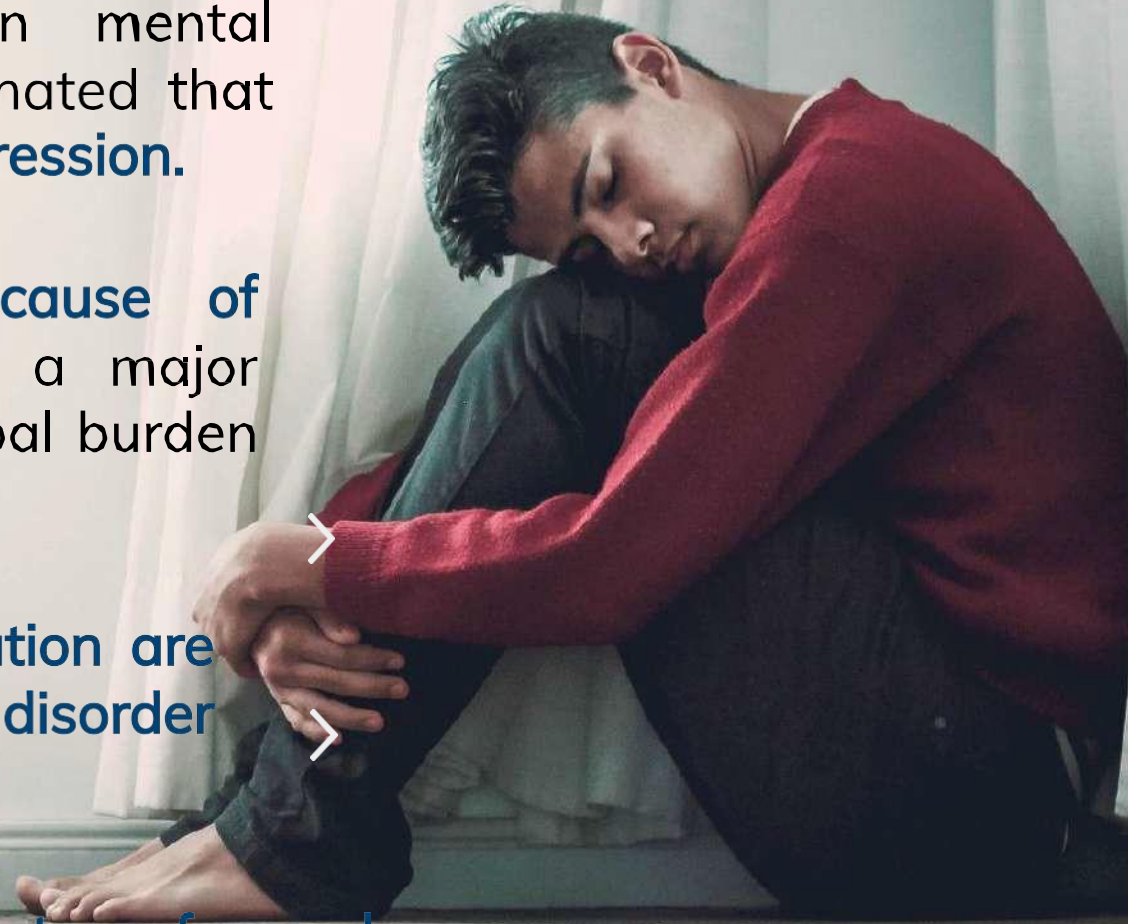
**Probiotics With Scientific Evidence
For Effective Formulations**

Clinically researched probiotic strain

- Lactose free.
- Gluten free.
- GMO free.
- Vegan.
- Stable at room temperature, no freezing conditions are required.
- Heat & low pH resistance.
- High survival.

Key facts

- **1 in every 8 people** in the world live with a **mental disorder**.
- Depression is a common mental disorder. Globally, it is estimated that **5% of adults suffer from depression**.
- **Depression is a leading cause of disability worldwide** and is a major contributor to the overall global burden of disease.
- **Up to 33.7% of the population are affected by an anxiety disorder during their lifetime**.
- **Women have higher rates of mood and anxiety disorders**.



The pandemic has a negative impact on mental health



72% of the global population **felt stressed** at least some of the time in 2021.

+21% since 2018

46% of global consumers indicate to have cognitive or **mental health problems.**

+12% since 2019

Consumers are looking for products which can balance their mood

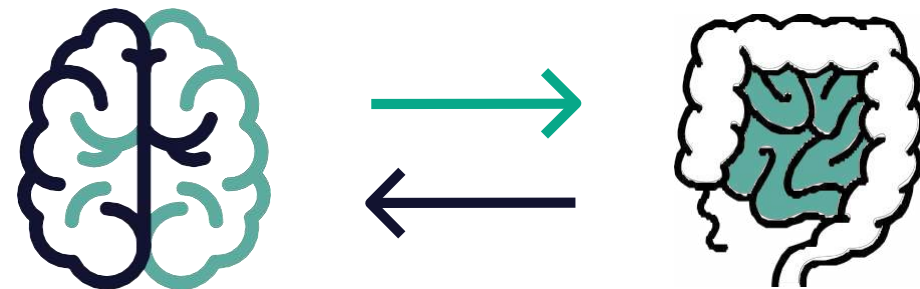
280 million people worldwide could benefit from **ProbioCope™** to maintain a positive mood, improve mental health well-being, and enhance their vitality.



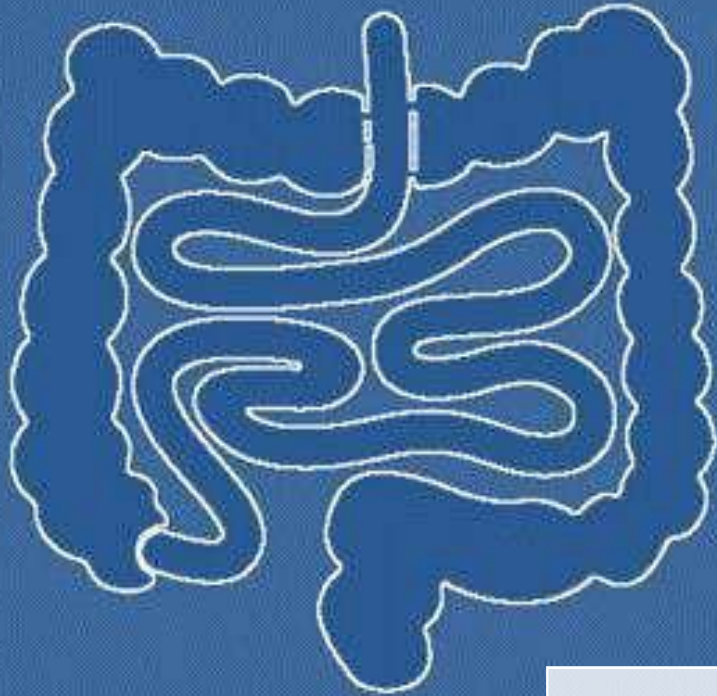


What is the Gut-Brain Axis (GBA)?

The **Gut-Brain Axis (GBA)** consists of bidirectional communication between the central and the enteric nervous system, linking emotional and cognitive centers of the brain with peripheral intestinal functions. **Recent advances in research have described the importance of gut microbiota in influencing these interactions.**



Gut-Brain Axis (GBA)



GUT TO BRAIN

Enteric nervous system in the gut produces neurotransmitters such as serotonin and metabolites which impact mental health conditions such as stress, anxiety, and depression.



Gut-Brain connection



BRAIN TO GUT

Stress, anxiety, and other mental health conditions have physiological consequences, such as disrupting gut motility and functionality, which results in symptoms such as constipation and stomach pain.

Clinical study

Preliminary results

Study features

Product: *Bacillus coagulans* NU-10 (50mg/day for 90 days), branded as ProbioCope™.

Description: Single-center, double-blind, randomized, prospective pilot clinical study, compared to placebo.

Methods: Blood test to assess levels of IgA, IgG, INF- γ and leukocytes. Quality of life test (SF36) to assess general mental health.

Primary objective: Evaluate the efficacy of a probiotic product based on *Bacillus coagulans* NU-10 on immunomodulation in healthy volunteers.

Secondary objective: Evaluate the improvement of quality of life and the non-occurrence of adverse events.

Subjects: 60 healthy people (50% experimental group – 50% placebo group).

Duration: 90 days, 2 visits during the experimental phase.

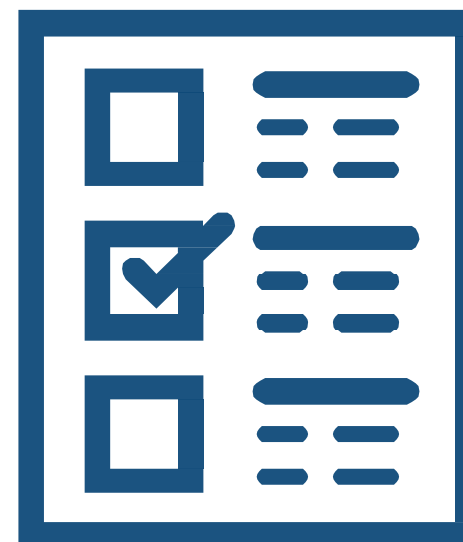
Current status: On-going (preliminary results of 51 people out of 60).

What is SF36 health survey?

The **Short Form-36 Health Survey (SF-36)** is one of the most widely used and evaluated generic health-related quality of life (HRQL) questionnaires.

It comprises 36 questions which cover eight dimensions of health:

- Vitality
- Physical functioning
- Bodily pain
- General health perceptions
- Physical role functioning
- Emotional role functioning
- Social role functioning
- Mental health



The statistical summaries for the variables of the "SF-36" quality of life questionnaire have been performed for baseline time (T0) and end time (T90) by group (placebo and product) for the different dimensions.

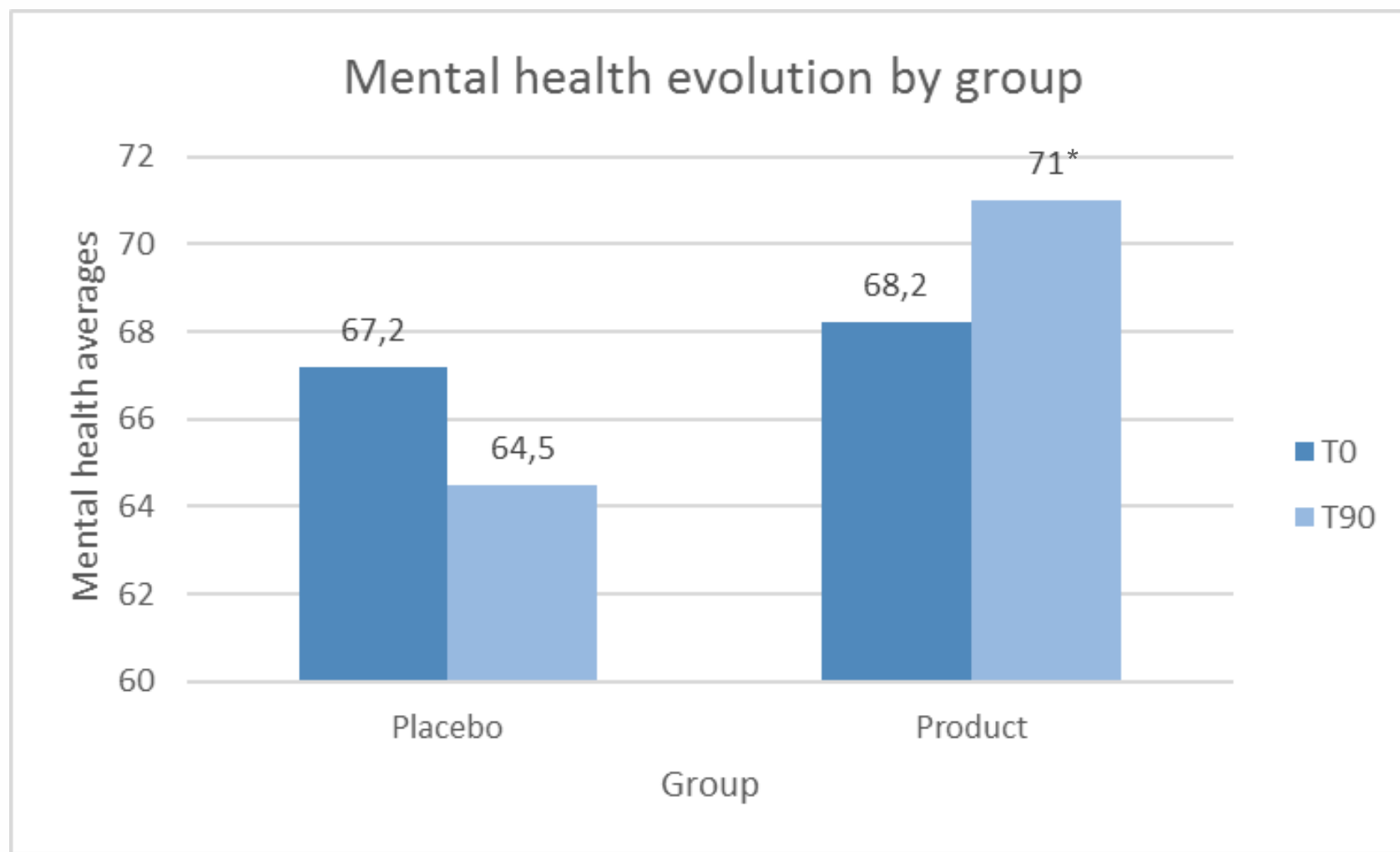
ProbioCOPE™ : SF36 dimensions evolution by group

	Placebo	Product	p-value interaction
Physical function	-0.2% ↓	1.2% ↑	0.0749
Physical role	1.0% ↑	1.0% ↑	0.3966
Pain	3.9% ↑	4.6% ↑	0.4133
General health	-1.0% ↓	1.7% ↑	0.3921
Vitality	-2.1% ↓	3.0% ↑	0.1061
Social function	7.1% ↑	9.3% ↑	0.4793
Emotional role	3.1% ↑	4.8% ↑	0.2886
Mental health	-4.0% ↓	4.1% ↑	0.0228*

A summary of changes for each dimension is presented in the following table. **Product improves its average better than placebo group in all cases** (except physical role that are equal). Furthermore, in product case, in average, all items improve.

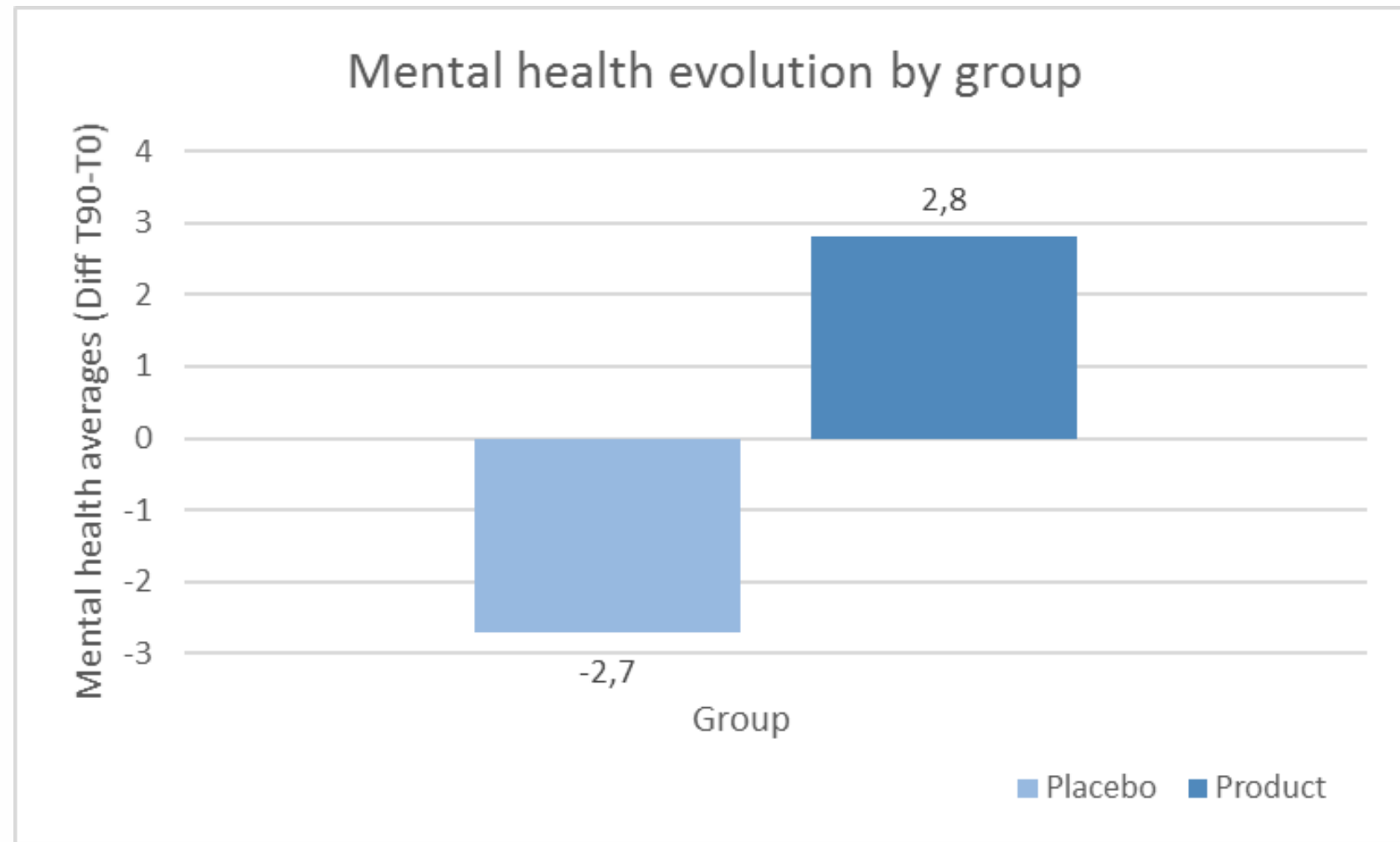
There are significant changes in the case of "mental health" in what the difference between the changes (T90-T0) in placebo (-4.0%,) and product (+4.1%, improvement) is significant (**p-value=0.02***).

Mental health dimension averages by time and treatment group



ProbioCope™ significantly improves mental health ($p=0.02^*$).

Mental health mean differences (T90-T0) by treatment group



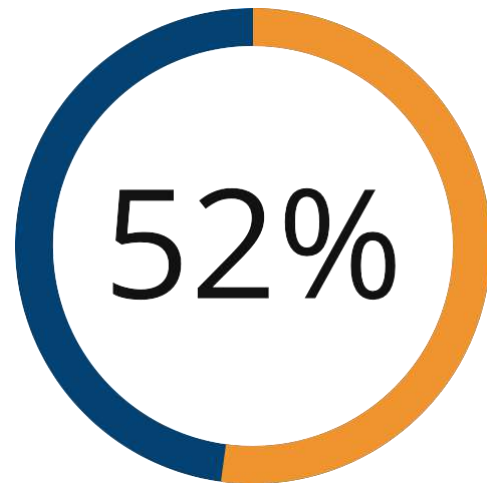
Mental health dimension improves in product and decreases in placebo.



ProbioCope™ improves mental health

Mental health dimension evaluates general mental health, including:

- Depression.
- Anxiety.
- Control of behavioral and emotional control.
- Overall positive effect.



Mental health

**52% of product group
participants increased
their mental health**



ProbioCope™ promotes positive mood and supports mental health well-being

40% of product group participants were less nervous.

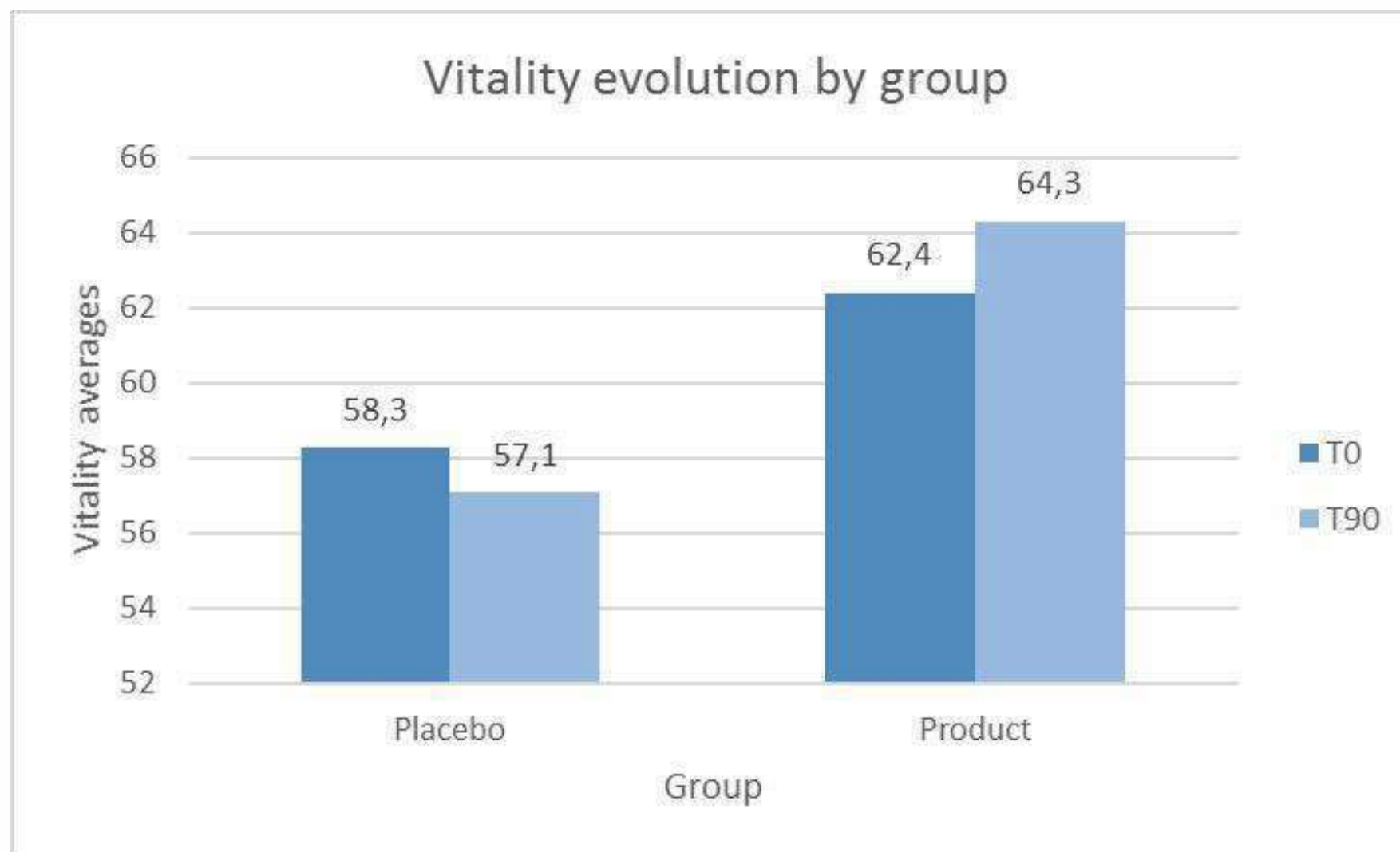
32% of product group participants felt calm and peaceful.

20% of product group participants felt less discouraged and happier.





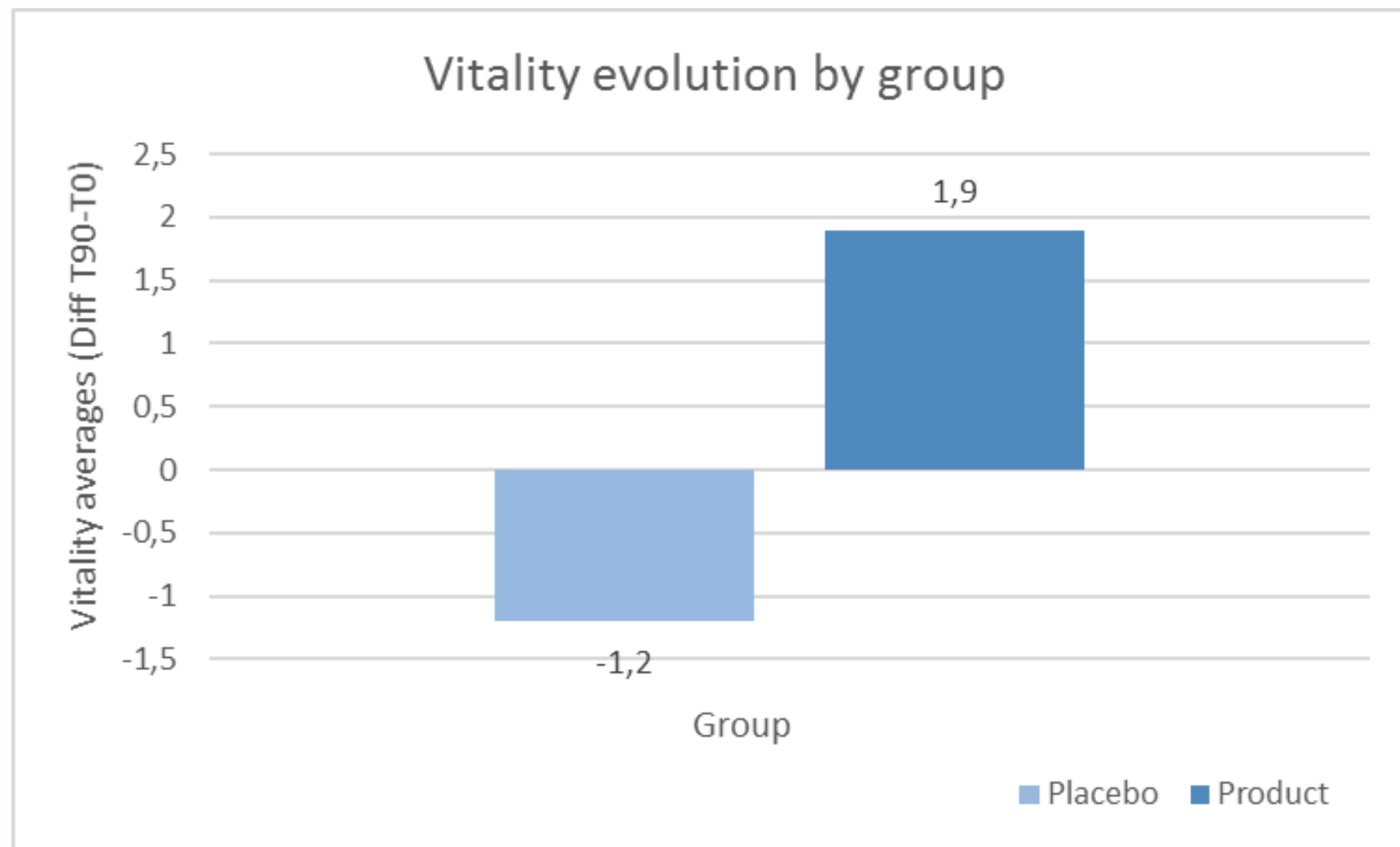
Vitality dimension averages by time and treatment group



ProbioCope™ improves vitality.



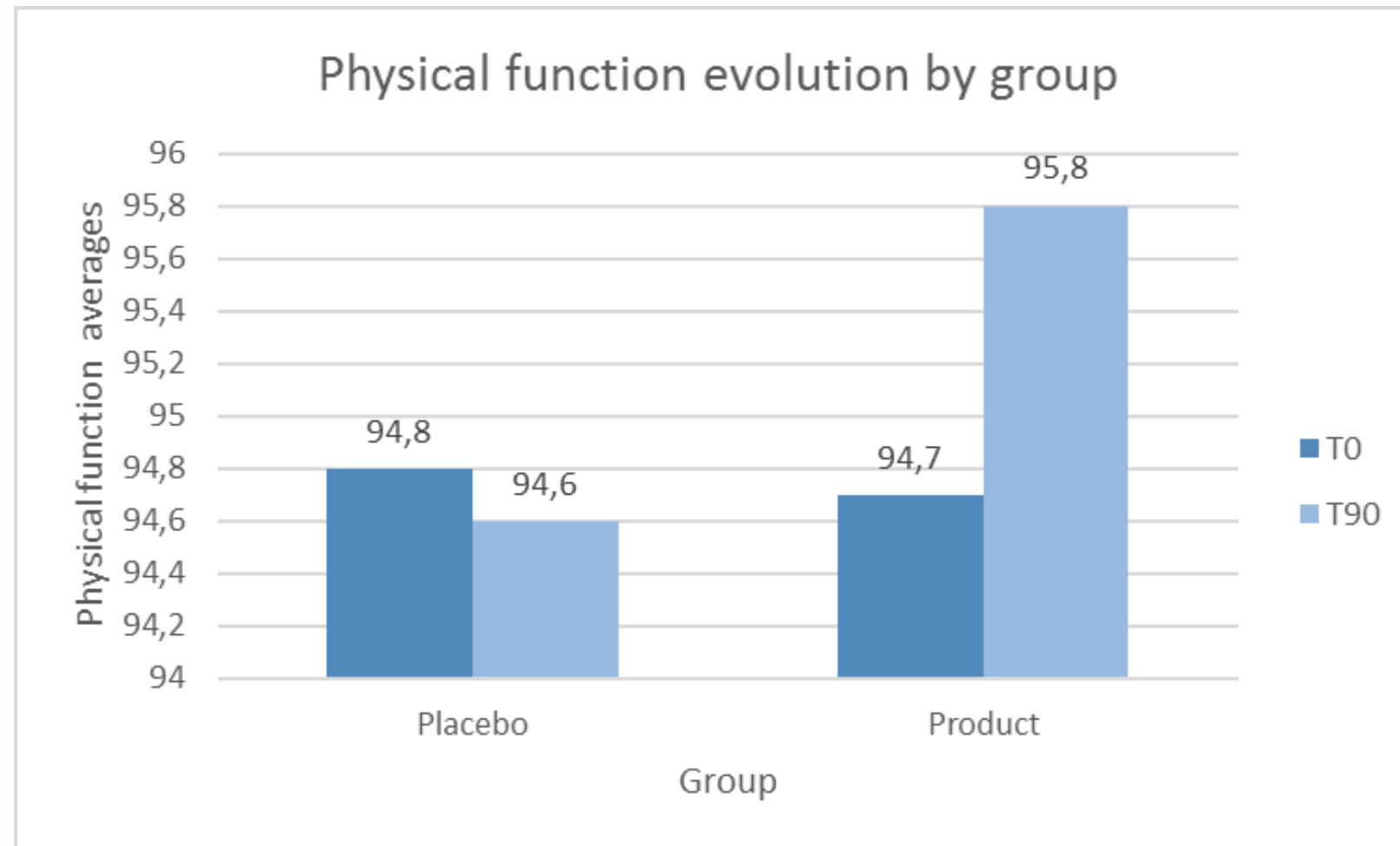
Vitality mean differences (T90-T0) by treatment group



Vitality improves in product and decreases in placebo.

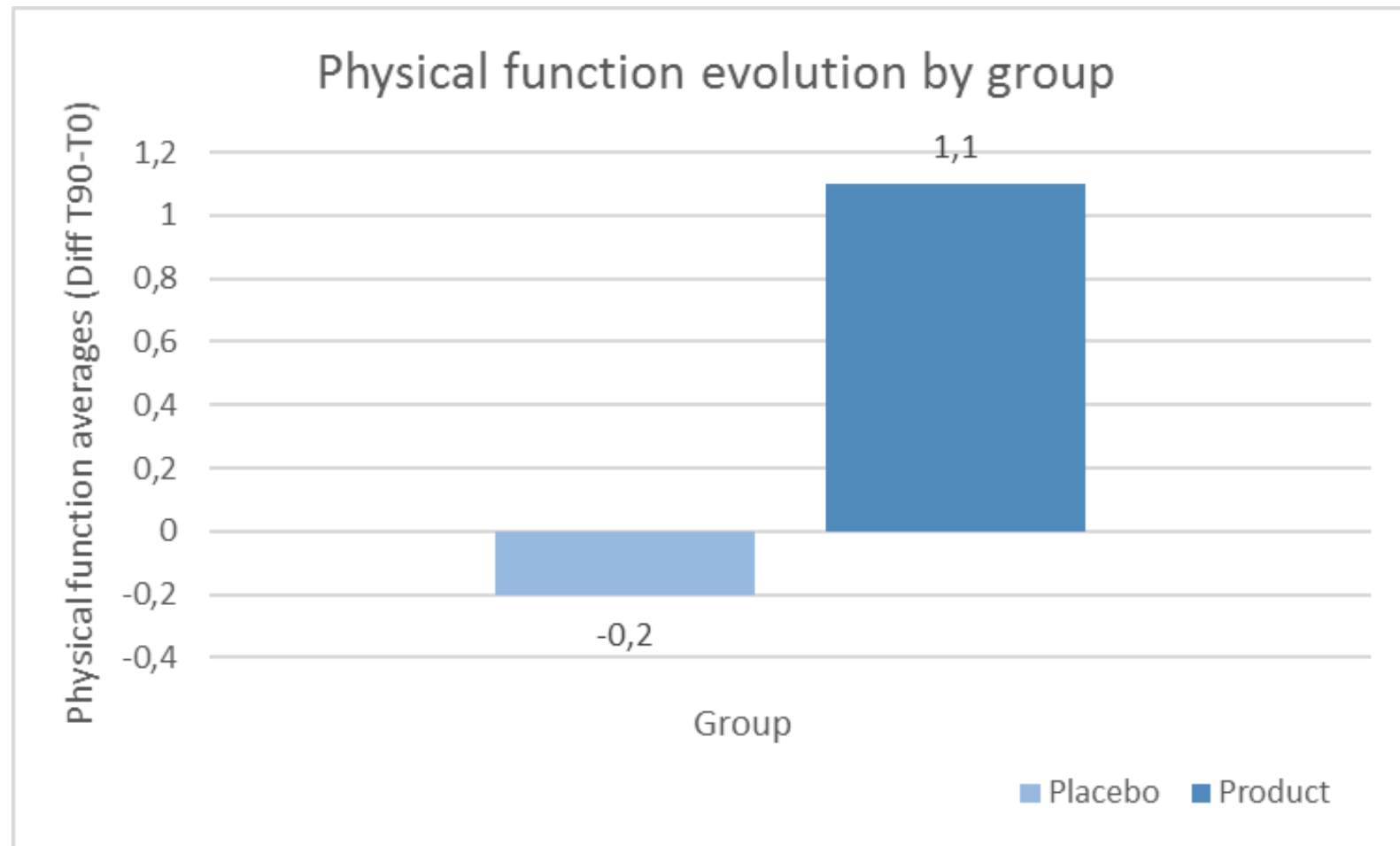


Physical function dimension averages by time and treatment group



ProbioCope™ improves physical function.

Physical function mean differences (T90-T0) by treatment group



Physical function improves in product and decreases in placebo.



ProbioCope™ enhances vitality

32% of product group participants felt less exhausted.



28% of product group participants felt less tired.

20% of product group participants felt full of vitality.

Efficacy conclusions

Bacillus coagulans NU-10, branded as ProbioCopeTM has been clinically demonstrated through a randomized, double-blind study and compared with placebo its modulation activity on mood and mental well-being, when dosed at 50mg/serving.

Participants in the probiotic group showed **improvement in all 8 health concepts** of the survey.

In concept "**Mental Health**" the difference between changes in T90 and baseline in the participants of product group and placebo group showed **significant differences**.

The results reinforce the validity of the brain-gut axis concept and warrant the **influence of probiotics on psychological well-being**.

"The exclusive probiotic strain for mood improvement and mental well-being"



**SCIENTIFICALLY
PROVEN**



Food applications

- Among lactic acid bacteria, *Lactobacillus* and *Bifidobacterium* are the most commonly used bacteria in probiotic foods, but they are not resistant to heat treatment.
- *Bacillus coagulans* has recently attracted the attention of researchers and food manufacturers, as it exhibits characteristics of both the *Bacillus* and *Lactobacillus* genera. ***B. coagulans* is a spore-forming bacterium which is resistant to high temperatures with its probiotic activity.**
- Fermentation conditions, freezing, thawing, drying, cell protection additives, rehydration of dried probiotics, and microencapsulation applications are factors that affect the survival of probiotic microorganisms during probiotic food production.
- The survival and stability of *B. coagulans* has considerably improved compared to others through its spore-forming abilities. **It is identified as an ideal choice for the development of functional foods by protecting their vitality in high-temperature applications.**

It is an **ideal probiotic strain** which can be used in foods, food supplements and beverages to add functionality. It can be used in a wide range of products due to its stability (pH, temperature and water content).

- **Finished products:** protein bars, chocolate, granola and breakfast cereals.
- **Baked foods:** cookies, cakes and cookie dry powders, cake and soup mixes.
- **Dairy products:** milk products, cheese, yogurts and ice cream.
- **Beverages:** tea, coffee, soda, juices, sport drinks and vegetable drinks.
- **Dietary supplements:** gummies, strips, capsules, tablets, vials, powders, oils, and liquids.



Thank you for you attention

ProbioCOPE ™

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