

Randomized and controlled study on the efficacy of naturopathy in migraine prophylaxis.



migraine

An innovative study

What is the aim of the study?

The project aims to evaluate, with scientific rigor, the effectiveness of naturopathy as a complementary method in the prevention and treatment of primary headache (migraine), through a randomized, controlled, open-label study.

Who is it for?

The study intends to enroll 84 people, aged between 18 and 65, diagnosed with migraine, with or without aura, according to the diagnostic criteria of the International Headache Society (ICHD-3 beta), in both episodic form (from 4 to 14 episodes per month), and chronic (> 15 episodes per month).

Where will the activities take place?

The study will take place in northern Italy. The neurological examinations will be carried out at the Hospital of Novi Ligure (AL). The naturopathic

interventions will be carried out at the LUMEN center in San Pietro in Cerro (PC) and, where possible and appropriate, online activities will be proposed.

How long will it last?

The RCT study will last six months. Another six months will be dedicated to administering the naturopathic intervention also to patients initially and consciously allocated to the control arm to reward their adherence to the research.

Has it already obtained approval from the Ethics Committee?

YES. In 2020, the study obtained a favorable opinion from the Intercompany Ethics Committee of the Alessandria Hospital.

Why is it important?



+ SUSTAINABILITY
- POLLUTION



+ HEALTH
- MEAT
CONSUMPTION



+ ETHICS
- SOCIAL SPENDING

Because headache is the second disabling disease in the world

Primary, episodic and chronic headaches are diseases characterized by a high prevalence in the general population; in particular, migraine affects about 25% of women of childbearing age, in which it is classified according to the WHO in 2nd place among the disabling diseases.

Because it is a study of high ethical value

The naturopathic intervention acts on lifestyles and, as evidenced by the scientific evidence currently available, by this nature involves a lower environmental impact, lower consumption of animal proteins, greater prevention on chronic degenerative diseases and a reduction in social costs compared to conventional interventions, in particular pharmacological. The study also has another intrinsic ethical aspect to the research design: the naturopathic intervention will also be offered to the control arm at the end of the first six months of monitoring.

Because acting on lifestyles is a protective factor in general for health, even for infections

The lack of a pervasive and effective health promotion strategy has made the Italian population, especially the elderly, more fragile and vulnerable, even to infections. This study, focusing on health promotion through lifestyles, acts as a pivotal example of preventive medicine.

Because it has highly scientific and internationally relevance

The study is a Randomized Controlled Trial (RCT), so it has the highest level of scientificity possible for an intervention study. Furthermore, at an international level, there is a lack of studies based on evidence of efficacy (EBM) on interventions related to Traditional and Complementary Medicine (T&CM), despite an increasing number of people who turn to this sector: therefore it represents a rarity worldwide.



Why support it?



It collects scientific evidence to change paradigm

To promote a paradigm shift that places health promotion and environmental sustainability at the center, there is also a need to collect scientific evidence that demonstrates the concrete impact and tangible effects of a new model of primary care that collaborates with care.

Advantages offered to sponsors

Those who decide to sponsor the study will have the opportunity to define with LUMEN APS a **communication plan** that can give the company the visibility it deserves.

The sponsors will also have the opportunity to offer, at advantageous conditions, some corporate welfare proposals based on the SALUS principles to their employees. The proposals, managed by Vis Naturae scarl, are visible on the website:

www.naturopatia.org/welfare-aziendale

Advantages offered to those who donate

Those who support the study with a donation will receive valuable information on promoting their health through small and healthy daily habits and, based on the size of the donation, will also have the opportunity to personally experience some of the proposals contained in the experimental protocol, staying for a few days at the LUMEN center.

Donations are deductible or deductible in the annual income tax return by the natural and legal persons who have made the donation, within the limits and in the manner established by Italian law. LUMEN APS certifies that it possesses all the subjective and objective requirements required by Italian Legislative Decree n. 117/2017.



What is the **fundraising goal**?

The project has an estimated cost of € 163,300. Of these € 52,800 are already covered as a co-financing share (32%). The remaining 68%, equal to **€ 110,500**, must be found through the forms of non-repayable financing, donation or sponsorship.



Who will lead it?

Coordinating Center



Ospedale S. Giacomo
Novi Ligure (AL) - reparto Neurologia

Organization that promotes the study



LUMEN APS - San Pietro in Cerro (PC)

Professional partner



Vis Naturae scarl - Piacenza

Team



dr. Eugenia Rota

Scientific supervision (principal investigator)

Doctor surgeon, specialist in Neurology, Director of the Complex Structure of Neurology Novi Ligure / Tortona, ASL AL (Italy). She is the author of about one hundred scientific articles in international journals (including some reviews and clinical studies) and of some chapters of neurology texts; she is also a member of numerous national and international scientific societies.



Nat. Milena Simeoni

Naturopath responsible

Naturopath, teacher and founder of LUMEN APS. She was scientific director for LUMEN APS as a collaborating center of a study conducted by the IRCCS Istituto dei Tumori di Milano on lifestyles and breast cancer relapses. She is co-author of some scientific articles related to this study, in which part of the methods envisaged in the migraine study were applied.

Who is in charge of fundraising?

LUMEN APS is a social promotion association aimed at promoting Healthy Lifestyles, through a transversal approach that combines the philosophical principles of Traditional Medicine with the most recent scientific knowledge.

The association was founded in 1992 starting from a small village in a countryside of northern Italy, and established itself, within a few years, at a national level, reaching a European dimension in 2019. LUMEN has followed a coherent growth path strongly anchored to the founding values, made possible thanks to the precious contribution of the hundreds of members and volunteers who support the association's activities every year.

www.naturopatia.org/associazione

LUMEN APS is the leader of the European SALUS Network with the aim of placing the promotion of health and environmental sustainability at the center of European policies.

www.salusnetwork.eu/