

# 8

## Of maca and men: Peru



### GENERAL INFORMATION

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#### ◆ **Implementation period**

December 2000 to August 2001

#### ◆ **Costs**

Total cost from Laboratorios Hersil S.A. (Peru): US\$26,000 and total cost from Universidad Peruana Cayetano Heredia: US\$30,000, including US\$10,000 (salary of principal investigator, equipment, seminal analysis) and US\$20,000 (funds from the vice-rectorate of investigation).

## SUMMARY

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For centuries, people living at high altitudes in Peru have cultivated maca (*Lepidium meyenii*). The root of this plant has traditionally been used as a food source. It is also reputed to have energizing, aphrodisiac and fertility-enhancing properties.

Aware of the traditional uses of maca, a Peruvian pharmaceutical company, Laboratorios Hersil, contacted the Universidad Peruana Cayetano Heredia to carry out independent studies on the clinical effects of Gelatinized Maca, one of its commercially available products derived from dried maca roots, in healthy men.

These studies — the first scientific tests to be performed on human volunteers using a pharmaceutical product derived from maca — were divided into two parts:

- a 12-week double-blind, placebo-controlled, randomized trial in which different doses of Gelatinized Maca were compared with a placebo, the aim being to demonstrate any effect of the Gelatinized Maca capsules on anthropometrical, haematological, mood, energy, sexual desire and hormone parameters in apparently healthy adult men; and
- a 4-month oral treatment designed to determine the effect of Gelatinized Maca on sperm and semen production in healthy adult men.

At the prescribed doses, Gelatinized Maca improved mood, decreased anxiety, decreased stress, increased serum adrenal androgens, increased self-report of sexual desire, increased self-report of energy levels, and increased sperm count and sperm motility. These effects were observed in the absence of any changes in serum hormone levels.

## BACKGROUND AND JUSTIFICATION

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*Lepidium meyenii* (maca) belongs to the cabbage family (Brassicaceae). It is a perennial plant that is cultivated exclusively between 4,000 and 4,500 metres above sea level in the central Peruvian Andes. Traditionally, maca roots, which look like large radishes, have been used by Peruvians living at high altitudes as a source of nutrition as well as for its reputed energizing, aphrodisiac and fertility-enhancing properties.

Evidence for the historic cultivation of maca dates back to around 1600 B.C. Bernabe Cobo, in his seventeenth century chronicle, "History of the New World", described how, in Chinchaycocha (Junin) in the central Peruvian Andes, he found a plant named maca that improved fertility in men. During the Spanish conquest, these observations led to maca being used to improve the fertility of mares, counteracting problems induced by exposure to high altitudes.

In 1961, the fertility-enhancing properties of maca were demonstrated in

experiments using rats. However, the results were never published in a peer-review journal.

In 1989, the United States National Research Council labelled maca one of the "lost crops of the Incas", and it was declared in danger of extinction as a domesticated plant in Peru.

More recently, there has been something of a "maca boom" caused by an interest in its pharmaceutical properties and a growing demand for maca products in Europe, Japan and the United States.

In Peru, dried maca roots are ground to a powder and commonly sold in drug-stores as a medicine and food supplement to increase stamina and fertility. It is also used as a juice taken during breakfast or mixed with hard liquor. This increased demand for maca has created new markets and a new source of income for Peruvian farmers. However, there is a danger that patents granted to pharmaceutical companies in the United States, if enforced, may prevent Peruvian farmers, the true innovators of the crop, from taking advantage of the increasing worldwide interest in maca.

Today's maca crops represent centuries of repeated selection by Andean farmers, but it is only in the last 20 years that scientific researchers and Peruvian government officials have been actively testing and conserving maca seeds and varieties (fig. 1).

Owing to the increasing demand for maca for both local use and export, the area planted with maca in Peru has

expanded from less than 50 hectares in 1994 to 1,200 hectares in 1999. Current estimates put the area of maca being cultivated at approximately 2,000 hectares. Historically, maca cultivation was limited to the Carhuamayo-Junin and Cerro de Pasco areas, but now production has been expanded to several other parts of Peru as well as neighbouring areas of Bolivia and, further afield, in northwest Argentina.

Most of the research carried out on maca in Peru has appeared in popular local publications and relates to the plant's fertility-enhancing properties in guinea pigs, rats and sheep. Despite the fact that maca was originally described as a nutritional supplement and fertility-enhancing product, there are claims that it also has many other properties, including effects as an aphrodisiac and a tonic, and that it can help to counter anaemia, fatigue and goitre. It is also reputed to boost the immune system, restore the body's homeostasis, and increase the level



**Figure 1** | Black, red and yellow ecotypes of maca crop varieties.

of such serum hormones as gonadotrophin, oestrogen and testosterone. In the United States, maca is often advertised as increasing energy, stamina and endurance in athletes, promoting mental clarity, treating male impotence, and helping with menstrual problems, female hormone imbalances, menopause and chronic fatigue syndrome. Several retailers use the terms "Peruvian Ginseng" or "Andean Viagra".

However, before this research programme, none of these claimed properties had been scientifically demonstrated in humans. Given the increased demand for maca in Europe, Japan and the United States, it was therefore necessary to carry out well-designed trials to demonstrate the effects of the plant. If such claims can be validated, the demand for maca is likely to increase, providing benefits for Peru, and especially the farmers in the Andean region.



**Figure 2** | Commercially available Gelatinized Maca, marketed by Laboratorios Hersil as *La Molina*.

## DESCRIPTION

Before the current case study began, a private Peruvian pharmaceutical laboratory (Laboratorios Hersil) collaborated with a public institution (the National Agrarian University) to develop a product from maca that is now marketed as a food supplement under the brand name of *Maca La Molina* or "Gelatinized Maca" (fig. 2). To create Gelatinized Maca, the roots are dried and then processed to remove the starch and leave behind the other naturally occurring chemicals and nutrients.

Around the same time, research at the Universidad Peruana Cayetano Heredia demonstrated that an aqueous extract of dried maca roots improved spermatogenesis (the production of sperm) in male rats. Laboratorios Hersil therefore entered into a collaborative agreement with the Universidad Peruana Cayetano Heredia to carry out a clinical study using Gelatinized Maca on human subjects.

### EFFECTS OF MACA: 12-WEEK TRIAL

The main study included a 12-week, double-blind, placebo-controlled, randomized trial in which treatment with Gelatinized Maca was compared with a placebo. The study involved 60 men between 21 and 56 years of age and in apparent good health. The clinical parameters recorded included:

- nutritional and metabolic measurements;
- sexual desire;

- erection;
- urine iodine levels;
- energizing effects;
- effects on mood, anxiety and stress;
- haematological measurements;
- semen analysis; and
- serum hormone levels.

For 12 weeks, one group of 15 men received three tablets of Gelatinized Maca a day (each tablet contains 500 milligrammes of dried maca root = 1.5 grammes in total), one tablet being taken every 8 hours. In the second group, 15 men received six tablets a day of Gelatinized Maca (3.0 grammes in total), two tablets being taken every 8 hours. The third group of 15 men took three Gelatinized Maca tablets each morning (1.5 grammes in total). The other three groups (four men in each group) received daily placebo tablets during the 12-week study following the same schedules as the maca-treated groups. During the study, all men maintained their usual eating regimen.

### **EFFECTS OF MACA ON HORMONE LEVELS**

Blood samples were taken before the trial began and again after 2, 4, 8 and 12 weeks of treatment with either maca or the placebo. Measurements of serum cortisol, dehydroepiandrosterone (DHEA), dehydroepiandrosterone-sulphate (DHEAS), 17-hydroxyprogesterone (17-OHP), oestradiol and testosterone concentrations were determined by using commercially available radioimmunoas-

say kits. Serum follicle stimulating hormone (FSH), luteinizing hormone (LH) and prolactin levels were measured by solid phase immunoradiometric assays also using commercial kits.

Results showed that serum cortisol was unaffected after treatment with either a placebo or maca, except at 2 and 12 weeks of treatment with 3 grammes of maca per day, when increased levels were observed. Serum DHEAS levels increased significantly at 4 and 12 weeks of treatment with maca, while no changes were observed in the placebo group (see table). Serum DHEA levels decreased significantly throughout the trial in groups treated with placebo or maca at 1.5 grammes per day. The group treated with 3 grammes of maca showed no reduction in serum DHEA at 2 and 8 weeks of treatment and a lower reduction than the placebo group at 4 weeks of treatment.

When considering the reproductive hormones present in the serum, the data showed that taking maca had no effect on any of the hormones studied (LH, FSH, 17-OHP, oestradiol, prolactin or testosterone).

### **EFFECTS OF MACA ON MOOD AND ANXIETY**

The effects of maca on appetite, energy level and mood were carried out by self-assessment. Effects on mood, anxiety and stress were also assessed using standard psychological tests: the Hamilton Depression Rating Scale (HAM-D) and Beck test for depression; the Hamilton Anxiety Rating Scale (HAMA) and the Zung test for anxiety; and an auto-evalu-

ation questionnaire for stress. HAM-D and HAMA scores were assessed after 4, 8 and 12 weeks of treatment, together with serum levels of adrenal hormones.

Self-reports of mood indicated improvements after 4, 8 and 12 weeks of treatment with maca, whereas the mood of the placebo group did not alter during the trial. Scores for depression using the HAM-D assessment were reduced after 4 weeks of treatment with maca, whereas the HAM-D scores of the placebo group did not change. Anxiety levels, measured on the HAMA scale, were reduced at 4, 8 and 12 weeks of treatment with maca, and in the placebo group after 8 and 12 weeks of treatment. In general, more significant effects were observed with a dose of 3 grammes of maca per day compared to 1.5 grammes.

In conclusion, treatment with maca improved mood, as measured by reduced scores in tests for depression and anxiety. This effect could be due to an increased

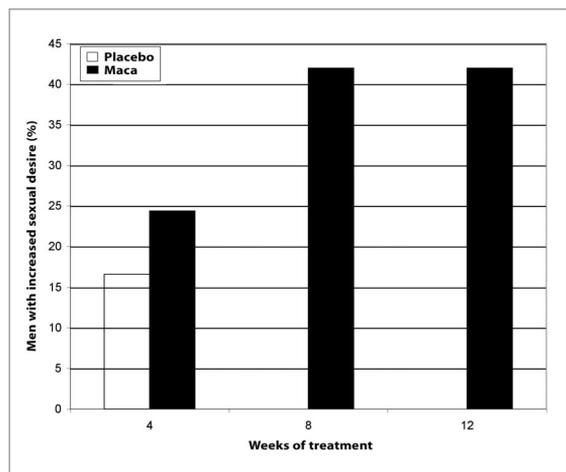
concentration of DHEAS hormone in blood serum.

### EFFECT OF MACA ON SEXUAL DESIRE

Sexual desire was assessed using a subjective (self-report) response after 4, 8 and 12 weeks of treatment. The base value (before treatment) was considered as having a score of 1, and each subject was asked if his sexual desire diminished during the treatment (score 0), did not change (score 1), increased slightly (score 3), or increased moderately to greatly (score 5).

Subjects taking maca reported an increase in sexual desire after 8 and 12 weeks of treatment (fig. 3). Statistical analyses showed that this effect was not due to changes in either Hamilton scores for depression or anxiety, or to serum testosterone and oestradiol levels, which remained unchanged compared to the placebo group (see table).

**Figure 3** | Increase of self-reported sexual desire in men taking either a placebo or Gelatinized Maca. (Results for the placebo at 8 and 12 weeks were 0 per cent).



Logistic regression analysis of the probability that maca (at two different dose rates), the Hamilton anxiety score, the Hamilton depression score, serum testosterone and serum oestradiol levels affect the self-perception of increased sexual desire after 12 weeks of treatment.

VARIABLE	COEFFICIENT OF REGRESSION	STANDARD ERROR	SIGNIFICANCE
Maca, 1.5g/day	21.37	1.01	HS*
Maca, 3g/day	19.85	1.06	HS
Anxiety score	-0.03	0.17	NS
Depression score	0.22	0.15	NS
Serum testosterone	-0.49	0.35	NS
Serum oestradiol	0.02	0.03	NS
Constant	-19.70	1.83	HS

\*HS = highly significant (probability < 0.0001); NS = not significant.  
Maca (1.5 or 3g) was analysed with respect to the placebo.

#### EFFECTS OF MACA ON SEMEN PRODUCTION: 4-MONTH STUDY

Nine apparently healthy adult male volunteers, between 24 and 44 years of age, gave their written informed consent before participating in this study.

Each participant received either 1.5 or 3.0 grammes of Gelatinized Maca a day during the 4-month period of the trial. Semen analysis was performed according to guidelines of the World Health Organization. In addition, blood serum levels of the reproductive hormones FSH, LH, oestradiol, prolactin and testosterone were measured before and after the experiment.

Treatment with Gelatinized Maca resulted in increased semen volume, sperm count per ejaculate, motile sperm count and sperm motility. The increased sperm count was not related to dose of maca. Serum hormone levels did not change significantly after treatment with maca. In conclusion, maca improved sperm production and sperm motility via mechanisms not related to LH, FSH, prolactin, testosterone and oestradiol.

#### PATENTING AND COMMERCIALIZATION

Tablets of Gelatinized Maca (*Maca La Molina*) produced by Laboratorios Hersil

are sold in pharmacies in Peru as a nutrient supplement.

Two United States companies also hold patents on maca — or maca-derived products — although these are being fought in the relevant courts by civil rights groups, which contend that any patents on maca should benefit the Peruvian farmers who originally identified the crop's beneficial properties and developed the modern-day varieties through centuries of repeated selection.

## PARTNERSHIPS

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In November 2002, a workshop, "Towards a National Strategy for Maca", was organized to define the latest advances with respect to crop management, pharmaceutical investigations, the commercial situation and the legal status of maca. It was organized by Maca-Chain and PROMPEX. Maca-Chain includes different interest groups such as farmers; dealers; owners of enterprises; government representatives, including members from the agricultural ministry; and scientists from such institutions as universities and the Peruvian Institute of Medicinal Plants. PROMPEX, on the other hand, is the government institution that aims to develop Peruvian exports and that collaborates with industry and other government agencies involved in foreign trade.

The workshop concluded that:

- owing to current market tendencies and the search for natural and

organic products, maca has the potential to be a major export product from the highlands of Peru. This will result in an increase in employment opportunities, help to fight poverty and maintain sustainability;

- owing to the proven properties of maca — and others currently being investigated — maca should be successful in export markets;
- commercial success will depend of identifying target consumers and satisfying their needs;
- despite the preoccupation of different sectors interested in maca, there is no integration between them; and
- the lack of a defined target public is due to the lack of knowledge of all the beneficial properties of maca. This, in turn, is a consequence of poor investment in scientific research by both the Government and the private sector.

## REPLICABILITY

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Nearly all companies selling maca-based products internationally refer to the clinical studies on the effects of maca extract on humans carried out at the Universidad Peruana Cayetano Heredia. To date, no other research group has published any work on the effects of maca on humans.

A pharmaceutical company in Peru has been assessing the effect of maca as an energizer with a local football team. The

team did win an international competition, but there is no scientific data to relate this achievement to the intake of maca.

It is also important to note that the results of the study refer only to the product assessed (Gelatinized Maca). In Peru, there are several kinds of maca products on the market. It is therefore necessary to demonstrate that the effects of maca reported here can be achieved with other maca preparations.

## POLICY IMPLICATIONS

Recently, the Government of Peru passed a law prohibiting the exportation of maca seeds, allowing only processed products to be exported. Research into the effects of maca on humans carried out at the Universidad Peruana Cayetano Heredia is thought to be among the factors leading to this decision.

## LESSONS LEARNED

Among the difficulties faced during the 12-week study was the problem of trying to obtain an adequate number of volunteers. This was solved by motivating the participants, explaining to them the importance of the research and its potential implications.

A combination of factors made the experience possible. These included the existence of a critical mass of the necessary research expertise in human reproduction, the existence of a modern labo-

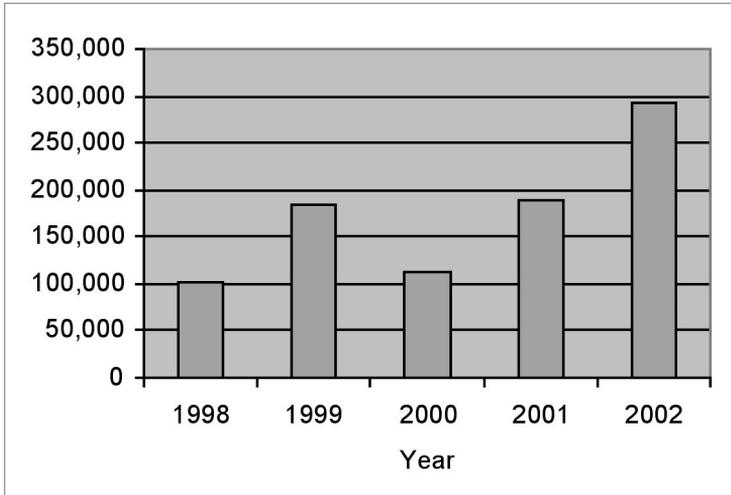
ratory at the Laboratories of Investigation and Development in the Faculty of Sciences and Philosophy at the Universidad Peruana Cayetano Heredia, and the need for scientific data to support properties claimed for maca.

## IMPACT

Publication of the research carried out at the Universidad Peruana Cayetano Heredia in international scientific peer-review journals has allowed the broad diffusion of the results. These papers are also frequently cited by other scientists working with maca.

In addition, the studies have been reported widely in the national and international mass media, including newspapers, radio and television. The principal investigator was interviewed by journalists from Colombia, Mexico and Spain; a news report appeared on the internationally broadcast television channel, CNN; and the research featured in a documentary by the Discovery Channel, United States. Following on from this, Laboratorios Hersil and PROMPEX have reported an increase in exports of Gelatinized Maca (fig. 4). Many other manufacturers that sell their maca products abroad also use Universidad Peruana Cayetano Heredia research results in their promotional literature.

Other scientists are now interested in testing the effect of Gelatinized Maca on male infertility. Among these is Georges-Antoine de Boccard, a certified urologist



**Figure 4** | Amount of maca (kg) exported from Peru, 1998 to 2003.

working at the Endocrinology and Fertility Clinic, Department of Gynaecology and Obstetrics, University Hospital of Geneva, Switzerland.

In an initiative to perform collaborative research between Peru and France, Peru's National Council of Science and Technology (CONCYTEC), a government institution devoted to the promotion of research and development of technology, organized a meeting on the clinical and pharmacological effects of maca, which was attended by the principal investigator along with experts from France and Denmark.

At the national level, the study has also created increased interest in the consumption of maca and produced a need to increase maca production. To assist in this endeavour, Laboratorios Hersil has begun a joint venture with the National Agrarian University to improve the culti-

vation and selection of maca varieties.

In economic terms, as production increases, farmer income will increase. However, as much of the increase in export value is added during the processing phase, farmers will receive only a small proportion of these benefits.

There is no problem with product sustainability since maca is a cultivated plant. Indeed, as farmers increase their income through the cultivation of maca, they are reducing their informal mining activities, practices that often lead to severe environmental degradation.

## FUTURE PLANS

Maca occurs in different ecotypes defined by their skin colours, including black, red and yellow, with the yellow form being the most common and popu-

lar (fig. 1). These colours are due to the concentration of anthocyanins in the external layers. It is still unknown if the medicinal properties of maca vary according to the colour ecotype. It is also important to determine the active ingredients present in maca for each of the properties identified by Universidad Peruana Cayetano Heredia scientists.

It is also necessary to determine the effective dose. In this report, two doses (1.5 and 3 grammes per day) were assessed. However, when people living at high altitudes in Peru drink maca as a juice, as is the tradition, they tend to take about 10 to 20 grammes or more daily.

There are also plans, through CONCYTEC, to influence government policy on medicinal plants and research subsidies. Until such support is finalized, funds for research on maca in Peru are limited.

## PUBLICATIONS

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*Diana Garayar:* Urine iodine determination.

*Carmen Góñez:* Radioimmunoanalysis of serum hormone levels.

*Carla Gonzales:* Semen analysis.

*Sharon Castillo, Arturo Chung, Amanda Córdova, Manuel Gasco, Julio Rubio and Karla Vega:* Field work.