

Comprehensive approach to menopausal symptomatology with a food supplement: Interim analysis of the LIBIRTY study

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CONTEXT

Menopausal hormone therapy (MHT) is, according to the WHO, the most effective treatment of vasomotor symptoms in menopause. However, many women have contraindications to this treatment or prefer a non-hormonal approach to manage these symptoms.

Libicare Meno[®] is a food supplement that contains dry extracts of several plants (olive leaves [hydroxytyrosol], *Humulus lupulus* [Luprenol[®]], *Cimicifuga racemosa* L, *Trigonella foenum-graecum*, *Turnera diffusa*, *Tribulus terrestris* and *Ginkgo biloba*), B-group vitamins, vitamin D, melatonin, selenium and zinc, indicated to help women to cope, through a comprehensive way, with the symptoms of menopause.

OBJECTIVE

The objective of the study is to evaluate the effectiveness and tolerability of **Libicare Meno**[®] on the quality of life of women with menopausal symptoms.

MATERIAL AND METHODS

Observational, single-center, prospective, open-label, single-cohort study (**LIBIRTY study**). Currently recruiting 40 postmenopausal women between 45 and 65 years old with menopausal symptoms of requiring therapy. **Libicare Meno**[®] treatment: 1 capsule DAY in the morning and 1 capsule NIGHT at night, for 12 weeks. The intermediate results of the primary endpoint are presented: changes in the score of the 16-item abridged version of the Cervantes Health-Related Quality of Life scale for menopause¹ at 4 and 12 weeks. The Short-Form Scale contains four main dimensions (Menopause and Health, Psychological, Sexuality, and Couple Relations), with the first dimension composed of three subdimensions (Vasomotor Symptoms, Health, and Aging).

RESULTS

The first 20 patients included have been analyzed. The mean total scale score decreased from 39.20 at baseline to 32.08 and 25.09 at 4 and 12 weeks, respectively ($p < 0.001$ at baseline vs 4 and 12 weeks). The mean scores of all the domains have improved, especially those of menopause and health and psychic (**Fig.1**).

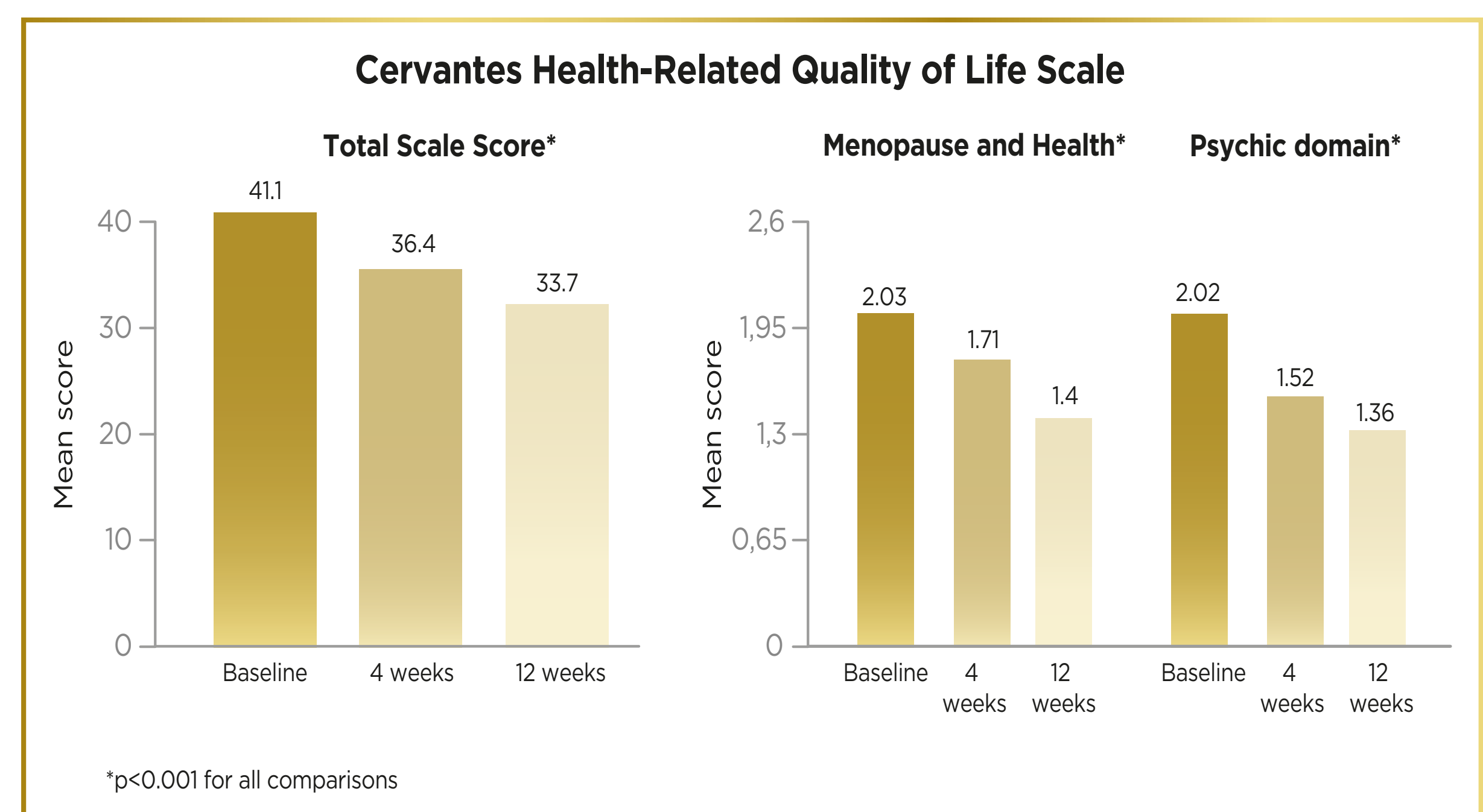


Figure 1. Total Score evolution and evolution of some of the domains of Cervantes Scale.

It is worth highlighting the clear clinical benefit regarding the vasomotor symptoms (**Fig.2**).

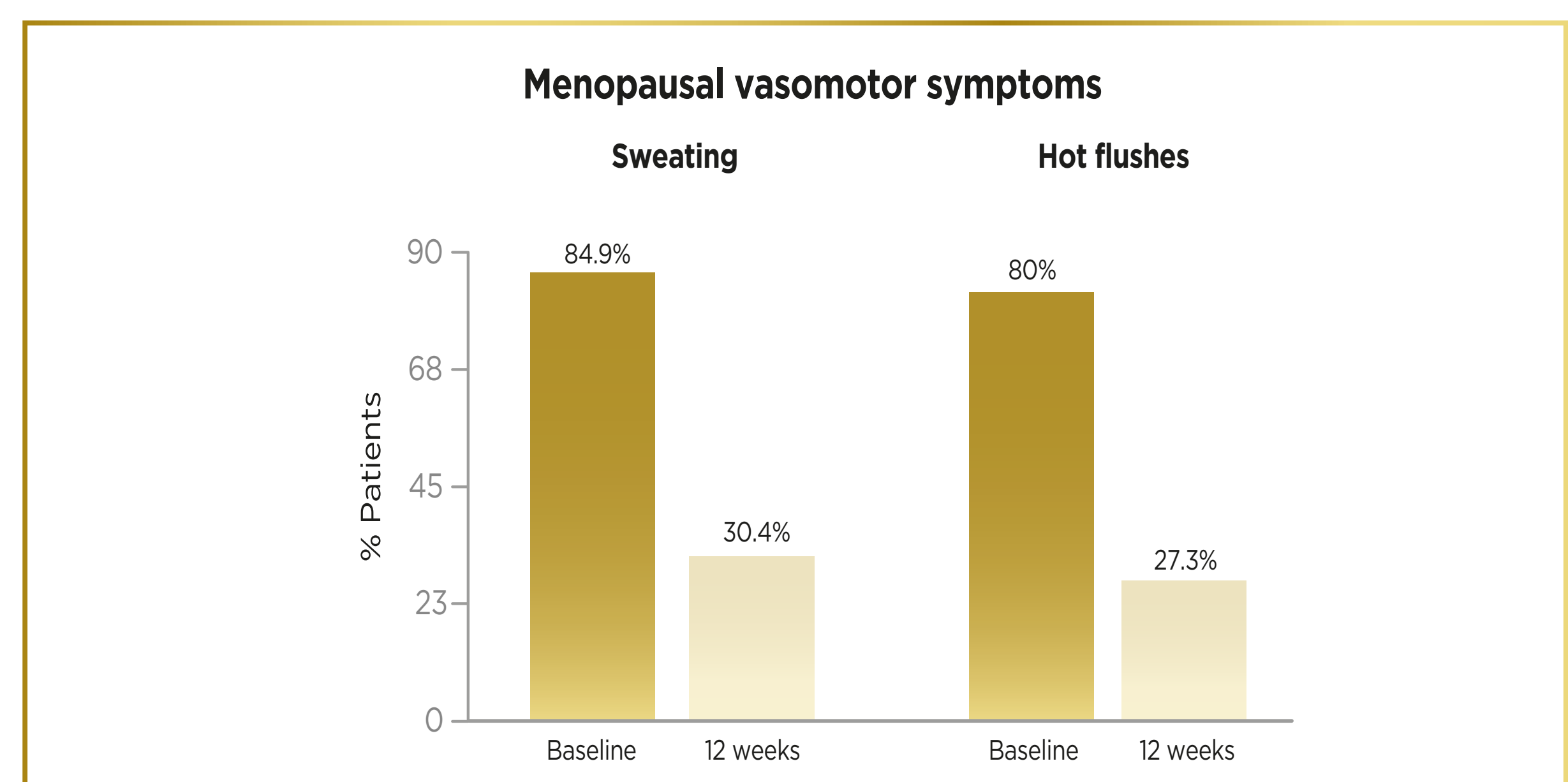


Figure 2. Percentage of patients indicating scores of 4 or 5 out of 5 (worst situation) regarding menopausal vasomotor symptoms.

CONCLUSIONS

This interim analysis tends to indicate that the administration of **Libicare Meno**[®] in postmenopausal women improves quality of life, especially thanks to the reduction of menopausal vasomotor symptoms, statistically significant at 4 and 12 weeks. These preliminary findings need to be confirmed at the end of the study.

¹ Coronado P et al. Menopause. 2015 Mar; 22(3): 325-36.