Report on progress – Christien Klein-Laansma

A pragmatic, randomized controlled pilot study comparing individualized homeopathic treatment add-on and usual care only in women with premenstrual disorders (PMD)

State of affairs per March 2015

The Netherlands
Ethical approval was obtained in May 2012.
Recruitment of women for the screening phase started in October 2012. 134 women were interested, 72 started the screening phase with diaries during two months. In January 2015, recruitment was completed, with 38 women included and randomised for the treatment phase.
Present situation: 3 women dropped out before the start of the treatment, because they were not randomised to their preferred treatment (homeopathy or usual care), 3 women dropped out during the treatment phase (reasons: pregnancy or too busy), 30 women completed the study, 2 women have recently started the treatment phase.
End of study: expected August 2015.

Sweden
Ethical approval was obtained in December 2012.
Recruitment of women for the screening phase started April 2013. Recruitment was paused shortly after the start, because of an upheaval in the Swedish media and at the Mid-Sweden University concerning controversies towards homeopathy. Recruitment was resumed in June 2013 and will continue through 2015.
Present situation: 85 women were interested, 65 actually started the screening phase with diaries during two months, 17 women were included and randomised for the treatment phase, of whom 13 finished the study and 4 dropped out for various reasons (pregnancy, life events). At present, 3 women are in the screening phase.
End of study: expected mid 2016.

Germany
Ethical approval: the study protocol was submitted for approval in July 2012. In March 2013, the local ethical committee decided that the proposed RCT study would be treated as a drug trial. It was decided to transform it to an observational study with homeopathic treatment only, with 19 women to recruit. In May 2014 the adjusted protocol was submitted to the ethical committee, largely delayed, among others because of legal discussions. In November 2014 the ethical committee consented that the research would be organised as an observational study. An amendment was submitted to the ethical committee in February 2015.
Recruitment: recruitment for the screening phase started per January 2015. Active recruitment from an existing waiting list was postponed till the contracts for partial supply of medication were approved by the clinics administration.
Present situation: 3 women were interested, received information, signed informed consent and started the screening phase. At present, 1 women started the treatment phase.
End of study: expected mid-end 2016.

Future activities

Recruitment will continue in Sweden and Germany through 2015.
Data analysis of the research in 3 countries and reports about first findings could be expected end of 2016 or start of 2017, depending on the speed of further recruitment in Germany and Sweden.