**Press Release**

**STUDY HIGHLIGHTS No. 2/2022**

Homeopathy works beyond the placebo effect – numerous high-quality scientific studies demonstrate this. In our ‘Study Highlights’ series we present examples of research which show the effectiveness of homeopathy beyond the placebo effect.

In this second issue, we describe a 2020 study which investigates the effect of homeopathy in reducing seromas after mastectomy and immediate breast reconstruction. Seromas are collections of fluid that can form after surgery.

**Topic and Main Author**

Homeopathic treatment to reduce seroma after mastectomy and immediate breast reconstruction, by Dr Adi Maisel Lotan, Department of Plastic and Reconstructive Surgery, Hebrew University of Israel, Jerusalem, Israel.

**What is the study about and what is the added benefit of homeopathic treatment?**

Breast cancer is the most common type of tumour in women and in most cases treatment involves a mastectomy followed by breast reconstruction. Post-operative seroma (an accumulation of fluid in the wound area) is common after breast reconstruction. It causes discomfort to patients and can lead to other medical problems, such as slower wound healing and/or delays in further oncology treatment. This can subsequently lead to a longer hospital stay and higher medical costs. The common practice to prevent excessive fluid accumulation is the insertion of surgical drains. Despite extensive research, no completely effective method for preventing seroma has been found. This prompted the authors to investigate new methods to reduce drainage.

The current study included 55 women (78 breasts) aged 18 years or older who had undergone mastectomy and immediate breast reconstruction. It was designed as a randomised, placebo-controlled, double-blind study and investigated the effect of the homeopathic remedies *Arnica montana* and *Bellis perennis* on seroma formation.

**Worum geht es in der Studie und welchen Mehrwert hat die homöopathische Behandlung dabei?**Brustkrebs ist die häufigste Tumorart bei Frauen, und in den meisten Fällen umfasst die Behandlung eine Mastektomie, gefolgt von einer Brustrekonstruktion. Ein postoperatives Serom (eine Flüssigkeitsansammlung im Wundbereich) ist nach einer Brustrekonstruktion häufig. Es verursacht Beschwerden bei den Patientinnen und kann zu weiteren medizinischen Problemen führen, z. B. zu einer langsameren Wundheilung und/oder zu Verzögerungen bei der weiteren onkologischen Behandlung. Dies kann in der Folge zu einem längeren Krankenhausaufenthalt und höheren medizinischen Kosten führen. Die gängige Praxis zur Vermeidung übermäßiger Flüssigkeitsansammlungen ist das Einlegen chirurgischer Drainagen. Trotz umfangreicher Forschungsarbeiten konnte bisher keine vollständig wirksame Methode zur Vermeidung von Seromen gefunden werden. Dies veranlasste die Autoren, neue Methoden zur Verringerung der Drainage zu untersuchen.

Die aktuelle Studie umfasst 55 Frauen (78 Brüste) im Alter von 18 Jahren oder älter, die sich einer Mastektomie und einer sofortigen Brustrekonstruktion unterzogen haben. Sie

**What are the scientific results?**

Two groups were compared, receiving either *Arnica montana* and *Bellis perennis* or a placebo. The primary measure of treatment effectiveness was the time that elapsed before the surgical drains could be removed ("time to drain removal"). Other monitored criteria included use of painkillers and complications.

- Homeopathic treatment reduced the average drainage time by 2.4 days, from 13.5 days in the placebo group to 11.1 days in the homeopathy group, and this result was statistically significant (p< 0.05).

- The use of opioids (painkillers) was lower in the homeopathy group than in the placebo group, although the difference missed the threshold for statistical significance (p=0.057).

- No side effects of the homeopathic treatment were observed.

**Was sind die wissenschaftlichen Ergebnisse?**Es wurden zwei Gruppen verglichen, die entweder eine individuelle homöopathische Behandlung oder ein Placebo erhielten. Die Wirksamkeit wurde durch Messung der PMS-Symptome (prämenstrueller Score), der Einnahme konventioneller Medikamente und der

Zeit, die verging, bis die chirurgischen Drainagen entfernt werden konnten ("Zeit bis

**How was the study conducted?**

* It was a prospective, randomised, placebo-controlled, double-blind study.
* 55 women (78 operated breasts) who had undergone mastectomy and immediate breast reconstruction were enrolled in the study. 29 women (42 breasts) were randomly assigned to receive two homeopathic remedies - *Arnica montana* C 30 and *Bellis perennis* C 30 - according to a fixed dosing schedule from the day of surgery until the drainage was removed. 26 women (36 breasts) received a placebo according to the same regimen.
* The mastectomies and reconstructive surgeries were performed by experienced breast or plastic surgeons.
* Drains were removed when fluid outflow fell below 30 ml/24 h.
* Postoperative variables were assessed by a study coordinator on days 3 and 7 after surgery.
* Time to drain removal and complications were analysed per breast. Medication use after surgery was evaluated per patient.

**How do the authors classify the results?**Seroma formation is a common problem after mastectomy and breast reconstruction in women with breast cancer. A reduction in seroma formation means that patients experience less discomfort after surgery, i.e. fewer complications and they need less pain medication. This in turn can help to shorten the hospital stay and reduce hospital costs. The positive effect of *Arnica montana* and *Bellis perennis* on reducing seromas - measured here by time to drainage removal - is therefore a promising outcome of this study, both for patients and healthcare providers.

**What is the added value of the study?**

* This is the first prospective randomised trial in a clinical setting of the use of homeopathy in the postoperative management of breast reconstruction.
* Homeopathy as a low-cost and low-risk treatment option should be further investigated as a medically valuable and cost-effective adjunctive treatment after surgery.
* As seromas are not limited to surgery related to breast cancer, this study offers promising perspectives for considering this homeopathic treatment protocol in other similar clinical settings.

**Study title / Source**Lotan, A.M., Gronovich, Y., Lysy, I. et al. Arnica montana and Bellis perennis for seroma reduction following mastectomy and immediate breast reconstruction: randomized, double-blind, placebo- controlled trial. Eur J Plast Surg 43, 285–294 (2020). <https://doi.org/10.1007/s00238-019-01618-7>

 **About HRI**

HRI was founded in London in 2007 by physicist and cancer researcher Dr Alexander Tournier. The Institute promotes new, high-quality scientific research on homeopathy and organises international research conferences and expert meetings.

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**Published so far:**

* HRI Study Monitor No. 1/2022: Homeopathy in women with premenstrual symptoms - <https://www.hri-research.org/2022/04/hri-study-highlights-no-1-2022/>