

# Effects of Auricular Acupuncture on Hot Flashes Under Adjuvant Endocrine Therapy of Women with Breast Cancer

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## Background:

Breast cancer is the most common cancer affecting women in Germany. In 70%, the cancer cells are hormone-receptor positive [1], for which an adjuvant endocrine therapy is suggested to prevent breast cancer recurrence [2]. Side effects of antihormonal therapies can be hot flashes, which affect the wellbeing, decrease sleep quality and can promote fatigue, causing treatment non-adherence [3-5] and thus potentially risking breast cancer recurrence.

## Necessity of this study:

Conventional therapies for hot flashes during menopause are either contraindicated (hormonal replacement therapy) for breast cancer patients or cause relevant side effects, like gabapentin does [6]. This suggests a necessity for complementary therapies having fewer side effects to promote better treatment adherence and thereby potentially preventing cancer recurrence.

## Why auricular acupuncture?

Empirical studies indicated body acupuncture to be effective for hot flashes [7]. Compared to drug treatments, acupuncture is considered to have very few side effects [8]. Auricular acupuncture offers several advantages over body acupuncture:

- Acquiring the skill is easier and quicker
- possible to implement in group settings
- low-costs
- less time consuming

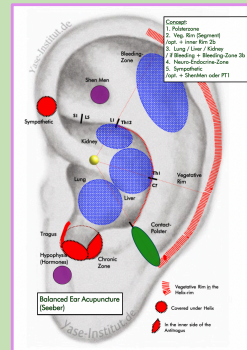
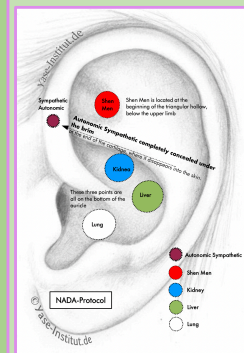
With this clinical trial we want to analyze the effects of auricular acupuncture on hot flashes during adjuvant endocrine therapy

## Methods:

- three armed, single-centered, randomized, confirmatory, prospective, clinical trial
- including 99 patients comparing:
  - balanced auricular acupuncture with
  - the NADA – protocol and a
  - waitlist-control group

## The interventions:

Balanced auricular acupuncture is a semi-standardized method according to Jan Seeber which is established at the Clinic for Integrative Oncology & Supportive Care at the Evang. Kliniken Essen-Mitte for more than ten years.



NADA acupuncture (National Acupuncture Detoxification Association) is a standardized protocol developed in the USA to treat stress, trauma and psychiatric disorders.



## Inclusion criteria:

- histologically confirmed diagnosis of non-metastatic hormone-receptor positive breast cancer under adjuvant endocrine therapy
- hot flashes
- willingness to participate in the study and signed informed consent

## Exclusion criteria:

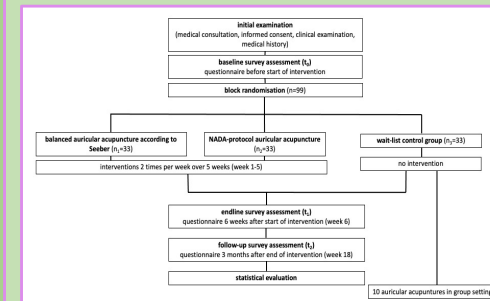
- ongoing or planned chemotherapy, radiotherapy, follow-up treatment or reconstructive plastic surgery during the study period
- severe physical or psychopharmacologically treated psychiatric comorbidities, due to which a patient is unable to participate in the study
- pregnancy
- participation in other clinical trials with behavioral, psychological or complementary medical interventions
- regular use of barbiturate or antidepressants
- abuse of drugs or alcohol
- ongoing acupuncture treatment
- lack of ability to complete questionnaire independently
- operations or infection in the area to be acupunctured

## Study design:

Observation period of five months with three questionnaire assessments:

- T0 – baseline assessment prior to the start of the trial
- T1 – endline assessment six weeks after intervention start
- T2 – follow-up assessment three months after end of the last treatment

Intervention group 1: two times per week over 5 weeks: balanced auricular acupuncture  
 Intervention group 2: two times per week over 5 weeks: NADA auricular acupuncture  
 Wait list control group: no interventions during the study period, at the end of 3 months follow-up: 10 auricular acupuncture treatments



## Measurements:

Hot flashes are the primary outcome measure, evaluated with the somato-vegetative symptoms subscale of the Menopause Rating Scale (MRS). Secondly additional symptoms induced by adjuvant endocrine therapy, such as perceived stress, wellbeing, psychological and urogenital symptoms as well as insomnia are examined with standardized questionnaires.

## Outlook:

Hot flashes are part of a complex of menopausal-like vasovagal symptoms caused by adjuvant endocrine therapy, which also includes insomnia. Based on positive study results concerning auricular acupuncture to treat insomnia patients, we expect potentially beneficial outcomes for patients with hot flashes as well.

## References:

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