



Influence of adjunctive classical homeopathy on global health status and subjective wellbeing in cancer patients – A pragmatic randomized controlled trial[☆]

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KEYWORDS

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Summary

Objectives: The use of complementary and alternative medicine has increased over the past decade. The aim of this study was to evaluate whether homeopathy influenced global health status and subjective wellbeing when used as an adjunct to conventional cancer therapy.

Design: In this pragmatic randomized controlled trial, 410 patients, who were treated by standard anti-neoplastic therapy, were randomized to receive or not receive classical homeopathic adjunctive therapy in addition to standard therapy. The study took place at the Medical University Vienna, Department of Medicine I, Clinical Division of Oncology.

[☆] Trial Registration: ClinicalTrials.gov: NCT00861432.

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Main outcome measures: The main outcome measures were global health status and subjective wellbeing as assessed by the patients. At each of three visits (one baseline, two follow-up visits), patients filled in two different questionnaires.

Results: 373 patients yielded at least one of three measurements. The improvement of global health status between visits 1 and 3 was significantly stronger in the homeopathy group by 7.7 (95% CI 2.3–13.0, $p = 0.005$) when compared with the control group. A significant group difference was also observed with respect to subjective wellbeing by 14.7 (95% CI 8.5–21.0, $p < 0.001$) in favor of the homeopathic as compared with the control group. Control patients showed a significant improvement only in subjective wellbeing between their first and third visits.

Conclusion: Results suggest that the global health status and subjective wellbeing of cancer patients improve significantly when adjunct classical homeopathic treatment is administered in addition to conventional therapy.

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The use of complementary and alternative medicine (CAM), such as herbal, vitamin and nutritional supplements, has increased over the past decade.¹ Various CAM techniques are used by a substantial percentage of patients attempting to ameliorate treatment outcome achieved by conventional therapies. 20–60% of patients in the United States use some form of CAM in various practice settings, with an estimated 16–20% using CAM along with prescribed medication.^{2–4} In Austria, 27% of cancer patients (33% female vs. 20% male) use interventions from the broad CAM category.⁵ Their administration is widely proposed by general practitioners (44%) or at the patients' own initiative (39%), but very rarely (4%) recommended by the oncologist. Using a detailed interview, the authors show that understanding of CAM methods varies widely.⁵ This is not surprising, as complementary medicine includes a broad range of options, from intake of herbal preparations, vitamins and extracts from various natural sources to various religious and spiritual practices. Similar to allopathic medicine, further study is needed to prove that CAM therapies are effective. This is a major concern because patients do not routinely report use of CAM when providing a medication history.^{6,7} This observation is complicated by the fact that many oncology patients use several complementary techniques together with their conventional treatment. One example: in a phase I clinical study of 309 patients, 162 (52%) used one or more CAM methods.⁸ This rising interest in CAM has been acknowledged by the medical community,⁹ with homeopathy, in particular, increasingly used by cancer patients.^{10,11}

The aim of this prospective, controlled study was to evaluate whether adjunctive homeopathic treatment has any influence on global health status and subjective wellbeing in patients with various types of cancer. Homeopathy, one of the most popular CAM forms, is based on the 'Law of Similars', which determines that substances causing symptoms in healthy individuals can be used to stimulate healing in patients who have similar symptoms due to their illness.¹² The remedies are produced by serial dilution and vigorous shaking (called succussion) between every dilution. In classical homeopathy, treatment consists of two main elements: taking the individual case history and prescribing individually selected homeopathic medicines, which correspond to the sum of symptoms presented by the patient. The purpose of the homeopathic case history is to ascertain the totality

of signs and symptoms of the patient, enabling the selection of an individualized homeopathic medicine based on the broad themes and idiosyncratic characteristics elicited from the totality of presenting symptoms physical, mental and emotional.¹² Classical homeopaths generally use one remedy at a time, usually highly diluted and agitated and in rare repetitions only rarely combining two or more remedies.

In this study, we focused on the homeopathic method. We used standardized questionnaires to assess global health status as well as subjective wellbeing. The study was not designed to evaluate the effect of specific homeopathic remedies used for specific symptoms, such as vomiting and nausea.

Patients and methods

Study design

The study was approved by the Ethical Committee of the Medical University of Vienna on November 4, 2008; # 513/2008. Included were all patients over 18 years of age prior to their first conventional treatment (chemotherapy, radiation therapy, surgical therapy) who signed an informed consent form. The only exclusion criteria were inability to comply with the study protocol, and the mental inability to fill out the questionnaires. On their first visit, patients were told by an administrative staff member about the availability of a study exploring the effect of additive homeopathy on global health status and subjective wellbeing, and were given a patient's information sheet. Once written informed consent was given, eligible patients were randomized to receive standard anti-cancer care (control group), or standard anti-cancer care together with adjunctive homeopathic therapy (homeopathy group).

The random allocation was made by a computer-generated code using sequentially numbered containers. The random allocation sequence (Microsoft Excel) was generated by an individual uninvolved in the study, and study participants were assigned to the groups according to the randomization list. The homeopathy group received individually tailored homeopathic treatment daily, according to the guidelines described by Hahnemann,¹² using the Complete Repertory,¹³ Kent's Materia Medica¹⁴ and the Pocket Manual

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