Designing a randomized double-blind controlled clinical trial for add-on homeopathy in cancer patients: challenges and suggestions

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Background: Clinical studies are mandatory to investigate the influence of homeopathy on cancer patients. A retrospective evaluation of a study on the effect of additive homeopathy on life quality and subjective well-being of cancer patients suggested a better survival in patients with advanced tumor stages. Therefore, we planned a prospective, randomized, placebo-controlled, double-blind, multicenter study evaluating survival and quality of life in patients with advanced malignant tumors with or without add-on homeopathy.

Methods: A study has been planned to include 300 patients suffering from advanced tumor stages (glioblastoma IV, metastasized sarcoma, non-small cell lung cancer IV). Survival, starting from diagnosis, and quality of life, measured by the QLQ-C30, the SF-36 and a subjective well-being questionnaire, are the study endpoints. Methodological challenges encompass the planning stage and specific for trials including homeopathic treatment have been documented. After the start of the trial these challenges are now classified and discussed.

Results:

Randomization

- Difficulty to recruit patients: Patients amenable to homeopathic treatment might be unwilling to participate due to the chance of being randomized to a placebo.

Placebo treatment

- Difficulty to gauge the treatment effect: It is difficult for the blinded homeopath to gauge the effect of homeopathic treatment as opposed to possible placebo effects. This might even affect the therapist’s own belief in his “therapeutic model” (Fisher et al., 2011).

Blinding

- Center specific traditions: Ways of prescribing the homeopathic medication are not standardized across centers. However, the list of possible homeopathic drugs is not limited.

Multiple centers

- Objective vs. subjective endpoints: Placebo controlled clinical trials are well established in oncology, but the end points' acceptance is controversial. If “softer” subjective endpoints are chosen such as quality of life, the effect of the non-CAM community a placebo control is mandatory.

Further study design issues

- Criticism of Randomized Controlled Trials: Trial-related ethical questions, i.e., the ethical framework for the conduct of double-blind placebo-controlled randomized clinical trials as the highest source of evidence (see Kaplitt, 2001; Walsh et al., 2004).

General aspects

- Efficacy vs. effectiveness: Essential discrepancies between the goals and instruments of efficacy studies and studies of effectiveness have been pointed out (see Ketelslegers, 2003; Katz et al., 2005).

Conclusions:

Our findings highlight that additive homeopathic treatment evokes specific challenges for investigators planning a cancer trial. Homeopathic studies differ essentially from conventional studies, the methodological specifics of two different medical approaches have to be covered. Therefore a homeopathic study embedded in a traditional medical environment demands additional staff, financial and spatial resources. Hopefully our reflections are helpful for the design of future studies in this field.

References: