

Correction to: Homeopathic Treatment as an Add-On Therapy May Improve Quality of Life and Prolong Survival in Patients with Non-Small Cell Lung Cancer: A Prospective, Randomized, Placebo-Controlled, Double-Blind, Three-Arm, Multicenter Study

The Oncologist, Volume 25, Issue 12, December 2020, Pages e1930–e1955, <https://doi.org/10.1002/onco.13548>

This is a second correction to Michael Frass, et al. “Homeopathic Treatment as an Add-On Therapy May Improve Quality of Life and Prolong Survival in Patients with Non-Small Cell Lung Cancer: A Prospective, Randomized, Placebo-Controlled, Double-Blind, Three-Arm, Multicenter Study,” <https://doi.org/10.1002/onco.13548>. The journal published the article in 2020 and a correction in 2021, and the editors issued an Expression of Concern in 2022 after new concerns were raised about the data contained in the article. Additional details not included in the original publication have since been provided by the authors and reviewed by the editors to clarify these concerns. These omissions do not affect the results of this study.

The following details regarding the study design augment the Trial Information:

- The study was registered as a double-blind randomized two-arm controlled trial on ClinicalTrials.gov in January 2012. Its title then was “Prospective, Randomized, Placebo-controlled, Double-blind, Multicenter Study Evaluating Quality of Life in Patients with Advanced Malignant Tumors With or Without ‘Add-on’ Homeopathy.” A third arm included patients who did not consent to randomization but agreed to observation of their disease course without homeopathy.
- Per the original protocol, the investigators planned to enroll patients with advanced glioblastoma and advanced sarcoma in the same trial and to analyze them separately. The target sample size across the treatment arms was 600 patients. After it became apparent that a sufficient number of these patients could not be recruited alongside patients with non-small cell lung cancer (NSCLC), recruitment of the sarcoma and glioblastoma patient groups was terminated as part of the amended protocol in 2015.
- The study title also was changed then to reflect that amendment.
- All eligible patients recruited into the study were entered into the computerized randomization program “Randomizer” and were recorded in the automatically running log (“Audit Trail”). The blinding codes were held by the randomizing statistician, within the randomization platform.
- Data were analyzed by an external statistician, independent of the randomizing statistician, at the end of the study.

In the Materials and Methods section, the authors wish to clarify the following points:

- Exclusion criteria were standard for treatment trials; only patients who were candidates for chemotherapy were enrolled.
- Double-blinding was upheld throughout the study; data were unblinded only after the statistical analysis.
- In 2018, after 140 patients with NSCLC had been accrued, a planned interim analysis was performed. The study was closed early due to slow accrual.
- Except for the baseline questionnaire, patients completed questionnaires prior to their next appointment. The date of the next appointment was noted on the questionnaire itself. If an appointment had to be postponed, and the questionnaire was returned late, then the date was changed by hand, accordingly. The completed questionnaires were then given to the study nurses.

Finally, in Table 1, Baseline characteristics and treatment, the authors wish to clarify the following points:

- “HR” is a typographical error and should have been “RR” for relative risk.
- One-sided p values were only reported for the exact Fisher test, except for baseline comparisons, where

p-values are regularly used as ‘flags’ to highlight potential bias. One-sided p-values higher than 0.3 suggest that the randomization was balanced.