PURPOSE: To date, only a few studies have evaluated the health-related quality of life (HRQOL) of patients with chronic lymphocytic leukemia (CLL) receiving chemotherapy. Therefore, the German CLL Study Group assessed HRQOL in younger patients with advanced CLL receiving first-line chemotherapy with fludarabine or fludarabine plus cyclophosphamide (FC). PATIENTS AND METHODS: Three hundred seventy-five patients younger than 66 years with advanced CLL were randomly assigned to receive either fludarabine alone (fludarabine 25 mg/m²/d for 5 days intravenously [IV], repeated every 28 days) or FC (fludarabine 30 mg/m²/d for 3 days IV plus cyclophosphamide 250 mg/m²/d for 3 days, repeated every 28 days). Six courses of treatment were planned to be administered. The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30 was sent to all patients at baseline and after 6, 12, and 24 months. RESULTS: Eighty-nine percent of 362 included patients completed at least one questionnaire (163 fludarabine- and 158 FC-treated patients). Comparing the baseline levels of 249 CLL patients with the general German population, significant differences in nearly all HRQOL scales were assessed between the two groups.

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multivariate analysis showed no significant differences in all HRQOL scales between both arms. In both treatment arms, symptoms such as fatigue, insomnia, and appetite loss improved to lower levels after the end chemotherapy. Except for lower physical status, no significant difference in HRQOL between male and female patients was evaluated. CONCLUSION: Fludarabine-based treatment seems to improve HRQOL little to moderately in younger patients with advanced CLL. No significant difference between fludarabine- and FC-treated patients was observed.