Background Two years after implementation, a regional advance care planning (ACP) programme has led to a rate of meaningful and valid advance directives of 36% in nursing homes that adopted the programme (control: 0.4%). Effects on clinical endpoints, however, were not compared yet.

Aim To evaluate whether a regional ACP programme leads to improved end-of-life outcomes, judged from the patients’ perspective, and saves resources at the same time.

Methods Endpoints: Reduction of hospital days during the last 3 months of life (primary), increase of nursing home as place of death, improvement of quality of life during end-of-life period (as judged by bereaved relatives), and congruence of factual medical treatment in the last year of life with documented advance care plans.

Sample: All long-term care residents dying within 2 years study period PLUS all long-term residents deceased within 3 years before the study period in in the two post-intervention nursing homes, compared with a corresponding sample in two structurally similar control homes. 250 deceased residents per group are sufficient to demonstrate a reduction of the average number of hospital days from 5 to 3 days with a power of 80%.

Analysis: Two-sided permutation tests for each endpoint, extended by statistical modelling.

Discussion Demonstrating relevant effects of regional ACP programmes on clinical outcomes is methodologically challenging, but possible and necessary. This study protocol has been proposed to the German ministry of education and research in 11/2012, the funding decision is pending.