

University of Stavanger

STATISTICAL ANALYSIS PLAN (SAP)
Project: Nurse Assisted eHealth Service
from Hospital to Home: Ameliorating Burden
of Treatment among Patients with Non-
Communicable Diseases (eHealth@H2H)
NCT05750953

Deviations from SAP

DEVIATIONS FROM SAP of April 6th. 2026

	Description and reason for deviation
Analysis of the eHealth@Hospital-2-Home data followed the Statistical Analysis plan (SAP) version 1.0 (https://register.clinicaltrials.gov/prs/beta/records) with a few exceptions. The deviations were decided upon during blinded analysis of the data and detailed in the following table.	
SAP section number	
4.2.6	Due to participants receiving different versions of the scales of the CollaboRATE items, we changed from using the “means score” approach to the “top score” approach, which gives a binary score indicating if the participant selected the top score for all three items or not.
5.2.4	Covariate selection was performed in R v. 4.5.0 based on an automated forward selection procedure using likelihood ratio tests (LRT) at $\alpha = 0.05$. For continuous variables, both linear and nonlinear (restricted cubic spline with different degrees of freedom 3-6) terms were considered, with the LRT choosing the best representation. Random slopes were disregarded at this point.
5.2.4	Due to low numbers, the dropout categories were simplified into 1) death or dropout due to serious health issues at any time, 2) drop-out due to other reasons (e.g. disinterest) at any time, 3) complete follow-up. Predictors were assessed in a multinomial model (not ordinal as planned).

5.2.6	The heteroskedasticity assessment was performed as part of the sensitivity analyses.
5.2.7	Sensitivity analyses: 1) Convergence problems prevented the presentation of results from Inverse Probability Weighting (IPW) analysis. The IPW weights were relatively stable even without stabilization or truncation (1-3.5). Very few predictors of dropout were identified (strata, living alone, age), similar to what we found in the variable selection in 5.2.4. 2) Turns out the dates of each follow-up were not systematically registered in the data set, so not able to do this. 3) Not justified, as the primary outcome was nicely distributed. 4) Due to convergence issues, these analyses were limited to checking simple residual dependencies separately.
5.2.8	Subgroup analyses: Since there was no evidence of subgroup differences in the treatment effect on the primary outcome, separate effect estimates were not presented.
5.3	Methods for continuous secondary outcomes: although Days alive and out of hospital (DAOH) may be considered a continuous outcome, it differs from the other in that we only have one value for each participant (no baseline, no post-1/post-2 assessments). Thus, for this variable we did not use mixed