Table G.3. Association of Randomization Group With Study Outcomes, Comparing Patients With and Without Heart Disease[a]

Outcome	Patients With Heart Disease					Patients Without Heart Disease					Interaction[d]	
	No. of Patients/ No. of Clinicians[b]	Descriptive by Group[c]		β	p	Valid n_b	Descriptive by Group[c]		β	p	β	p
		Control	Inter-vention				Control	Inter-vention				
Aim 1: Events at Target Visit												
Occurrence of discussion[e]	215/98	.382	.752	1.036	**< 0.001**	180/82	0.248	0.732	1.396	**< 0.001**	−0.339	0.276
Aim 2: Concordance at 3 Months[f]	157/84	0.565	0.693	0.331	0.172	124/75	0.570	0.711	0.400	0.140	−0.057	0.869
Aim 3: Depression and Anxiety												
Standard PHQ-8 score, 3 months[g]	201/93	4.262	5.963	0.340	0.497	158/83	5.501	5.855	0.195	0.759	0.082	0.915
Standard GAD-7 score, 3 months[h]	208/96	2.454	3.118	0.453	0.517	158/82	3.588	3.508	−0.235	0.747	0.538	0.611
Standard PHQ-8 score, 6 months[g]	186/92	4.587	5.421	−0.322	0.547	128/72	5.125	6.907	1.583	0.052	−2.125	**0.029**
Standard GAD-7 score, 6 months[h]	190/93	2.349	3.371	0.666	0.376	137/73	3.902	3.382	−1.108	0.128	1.853	0.070

a Results were based on complex regression models with patients clustered under clinicians. All models included automatic adjustment for patient age, gender, and racial/ethnic minority status.

b Number of patients/number of clinician clusters.

c For binary outcomes, the descriptives show the proportion of the group with the outcome. For composite scores, the descriptives represent the mean value of the score at follow-up.

d Test for stratification group as an effect modifier of the association between the randomization group and the outcome. This statistic was based on a model using data from both disease groups, and with the randomization group indicator, the binary disease group indicator, and the product of the 2 indicators as predictors, along with the adjustments used in the stratified models. The coefficient and P value are for the product term.

e   Binary outcome modeled with probit regression, estimated with weighted least squares estimator with mean and variance adjustment.

f   Binary outcome (1 = treatment preference and actual treatment at 3 months were both life extension or comfort care; 0 = treatment preference at 3 months was life extension and actual treatment was comfort care, or the reverse; or patient wasn't sure about preference or actual treatment). In addition to the adjustments for patient gender, age, and racial/ethnic minority status, adjustment was automatically made for treatment preference at 3 months (life extension or comfort care); patients with other values on this adjustment variable were excluded.

g   Robust linear regression model, estimated with restricted maximum likelihood. In addition to the adjustments for patient gender, age, and racial/ethnic minority status, automatic adjustment was made for the scale score at baseline.

h   Tobit regression model (scale score defined as censored from below), estimated with WLSMV. In addition to the adjustments for patient gender, age, and racial/ethnic minority status, automatic adjustment was made for the scale score at baseline.