Factors influencing baseline and change over 6 weeks in WEB-based IBS-SSS and IBS-QOL:

Results based on 108 subjects in a controlled clinical trial

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Table1: distribution of IBS-SSS and IBS_QOL at baseline, week 6 and the difference. 108 patients.

	SSS1			*SSS2*			*Dif SSS*		
	N	*Mean*	*Std*	*N*	*Mean*	*Std*	*N*	*Mean*	*Std*
All	108	307.7	88.5	108	230.8	121.9	108	**-76.9**	114.4
Age 40									
<=40	66	334.8	77.7	66	251.2	121.6	66	-83.7	116.1
> 40	42	265.1	88.3	42	198.7	116.7	42	-66.4	112.4
Gender									
Male	24	271.5	91.4	24	206.6	130.0	24	-64.9	90.5
female	84	318.1	85.4	84	237.7	119.4	84	-80.4	120.7
Abdominal surgery before start of the study									
No	88	304.2	87.3	88	229.0	114.8	88	-75.1	116.5
Yes	20	323.3	94.2	20	238.4	152.4	20	-84.9	107.2
Medicin at baseline									
No	61	303.6	76.0	61	213.3	108.9	61	-90.3	110.1
Yes	47	313.0	103.1	47	253.4	134.8	47	-59.6	118.8
Smoking									
.	2	370.0	14.1	2	139.5	13.4	2	-231	0.7
never	65	309.3	92.2	65	209.1	116.1	65	-100	124.4
former smoker	27	309.7	84.9	27	262.9	120.1	27	-46.8	70.0
currently	14	287.8	84.5	14	282.4	135.5	14	-5.4	90.1
IBS type, D diareal, C constipation, A, mixtured									
IBS-D	45	313.0	100.3	45	208.3	124.8	45	-105	109.1
IBS-C	19	305.9	73.0	19	255.7	123.3	19	-50.2	119.2
IBS-A	44	303.1	83.1	44	243.0	117.1	44	-60.1	114.3
Treatment group FODMAP Dicoflor Kontrol									
fodmap	34	326.9	93.7	34	193.7	123.2	34	**-133**	121.7
dicoflor	37	279.1	83.5	37	211.1	118.6	37	**-68.0**	106.9
kontrol	37	318.8	83.3	37	284.5	107.2	37	**-34.2**	94.8

NOTE: IData are expressed in Mean (SD)BS-SSS results on 0-500 scale (0-75 remission, 75-175 mild, 175-300 moderate, 300-500 severe)
NOTE: Signed rank test for change (from zero) in IBS-SSS: **p<0.0001**
NOTE: Wilcoxon rank test for TREATMENT influence on ΔIBS-SSS: **p=0.006**
NOTE: Wilcoxon rank test for TREATMENT allocation on IBS-SSS1: p=0.032

	QOL1			QOL2			Dif QOL		
	N	Mean	Std	N	Mean	Std	N	Mean	Std
All	108	59.0	19.5	108	63.8	22.1	108	**4.8**	17.0
Age 40									
<=40	66	56.9	19.2	66	61.1	22.8	66	4.3	16.3
> 40	42	62.4	19.7	42	68.0	20.6	42	5.6	18.3
Gender									
Male	24	61.9	22.2	24	66.0	24.0	24	4.1	16.1
Female	84	58.2	18.7	84	63.2	21.6	84	5.0	17.4
Abdominal surgery before start of the study									
No	88	59.9	19.5	88	65.3	20.8	88	5.4	16.0
Yes	20	55.3	19.3	20	57.3	26.7	20	2.0	21.3
Medicin at baseline									
No	61	59.8	20.0	61	67.2	20.2	61	7.3	15.1
Yes	47	58.0	18.9	47	59.5	23.9	47	1.5	18.8
Smoking									
.	2	52.9	8.3	2	71.3	11.4	2	18.4	19.8
Never	65	59.5	19.7	65	67.0	21.9	65	7.5	16.5
former smoker	27	58.9	20.1	27	60.1	23.1	27	1.2	13.5
Currently	14	57.7	19.9	14	55.1	20.4	14	-2.5	22.4
IBS type, D diareal, C constipation, A, mixtured									
IBS-D	45	59.5	19.1	45	67.4	20.7	45	7.8	18.5
IBS-C	19	59.2	13.1	19	61.5	19.1	19	2.4	14.7
IBS-A	44	58.4	22.3	44	61.2	24.6	44	2.8	16.3
Treatment group FODMAP Dicoflor Kontrol									
Fodmap	34	55.8	20.6	34	63.8	23.3	34	**8.0**	18.3
Dicoflor	37	64.0	15.2	37	70.7	17.1	37	**6.6**	17.2
Control	37	56.9	21.6	37	57.0	23.8	37	**0.1**	14.9

NOTE: All IBS-QOL results on 0-100 scale (0 worst, 100 best)
NOTE: Signed rank test for change (from zero) in IBS-QOL: **p=0.001**
NOTE: Wilcoxon rank test for TREATMENT influence on ΔIBS-QOL: **p=0.130**
NOTE: Wilcoxon rank test for TREATMENT allocation on IBS-QOL1: p=0.239

Table2: distribution of IBS_QOL DOMAIN scores at baseline and the difference. 108 patients.

Baseline *domain-QOLs*	*All*		
	N	*Mean*	*Std*
QOL1	108	59.0	19.5
Dysphoria1	108	56.3	25.3
Interference_activity1	108	58.8	24.1
Body_image1	108	52.9	21.0
Health_worry1	108	61.2	22.7
Food_avoidance1	108	40.4	27.5
Social_reaction1	108	67.5	25.4
Sexual1	108	69.6	30.1
Relationship1	108	72.8	23.8

NOTE: All IBS-QOL results and DOMAIN scores on 0-100 scale (0 worst, 100 best)

Change *in domain-QOLs*	*All*			*Treatment*									*Treatment difference*
				fodmap			*dicoflor*			*kontrol*			*p value*
	N	*Mean*	*Std*	*N*	*Mean*	*Std*	*N*	*Mean*	*Std*	*N*	*Mean*	*Std*	
Dif QOL	108	4.8	17.0	34	8.0	18.3	37	6.6	17.2	37	0.1	14.9	*0.130*
Dif Dysphoria	108	6.1	22.2	34	10.1	23.7	37	6.9	23.8	37	1.5	18.7	0.357
Dif interference	108	6.1	20.6	34	8.5	19.8	37	8.6	20.2	37	1.4	21.5	0.335
Dif body image	108	6.6	20.3	34	11.0	24.7	37	9.8	19.1	37	-0.7	14.7	0.027
Dif health worry	108	2.1	18.7	34	5.1	19.6	37	3.6	18.4	37	-2.3	17.7	0.398
Dif food avoidance	108	4.8	21.4	34	7.8	20.9	37	5.9	22.9	37	0.9	20.2	0.354
Dif social	108	3.2	20.7	34	6.8	23.4	37	4.1	19.2	37	-0.8	19.4	0.110
Dif sexual	108	4.7	27.0	34	7.0	29.9	37	7.8	23.6	37	-0.3	27.4	0.110
Dif relationship	108	0.8	20.6	34	2.0	22.5	37	3.6	21.5	37	-3.2	17.6	0.251

NOTE: All change in IBS-QOL results and DOMAIN scores on -100 to +100 scale (-100 worst, 100 best)
NOTE: Kruskal-Wallis rank test used for test for TREATMENT differences in Dif_domain_QOLs

Table3: IBS-SSS categories at baseline versus at week 6 (remission/mild/moderate/severe=4)

IBS-SSS categories at baseline and week 6	*IBS-SSS week 6*			
	1	*2*	*3*	*4*
IBS-SSS baseline *1*	0	0	0	0
2	5	4	0	1
3	4	11	16	7
4	4	9	24	23

NOTE: Generalized McNemar test for change in IBS-SSS ranking: $p < 0.001$

Figure1: IBS-SSS and IBS-QOL cumulative distributions

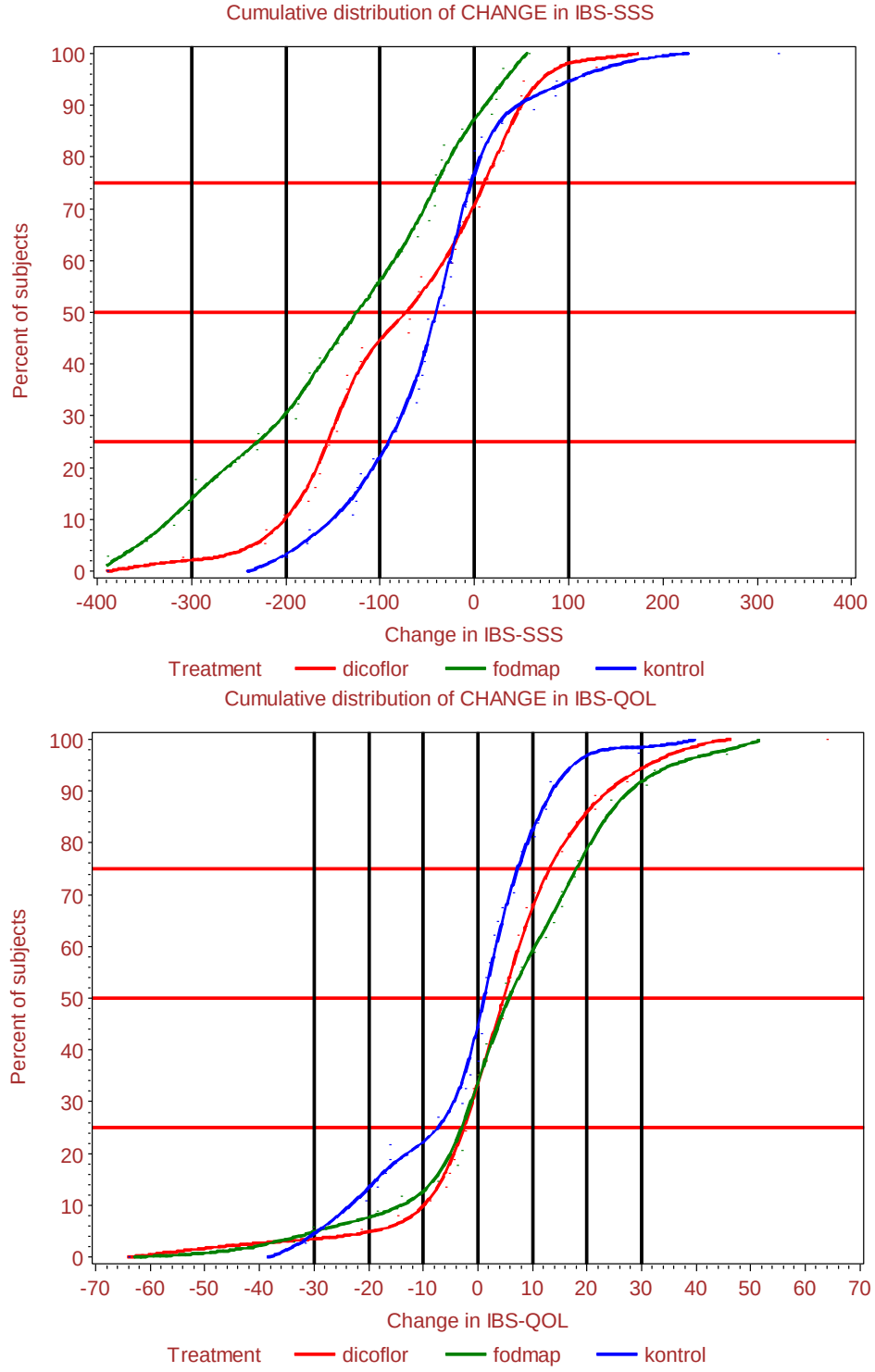
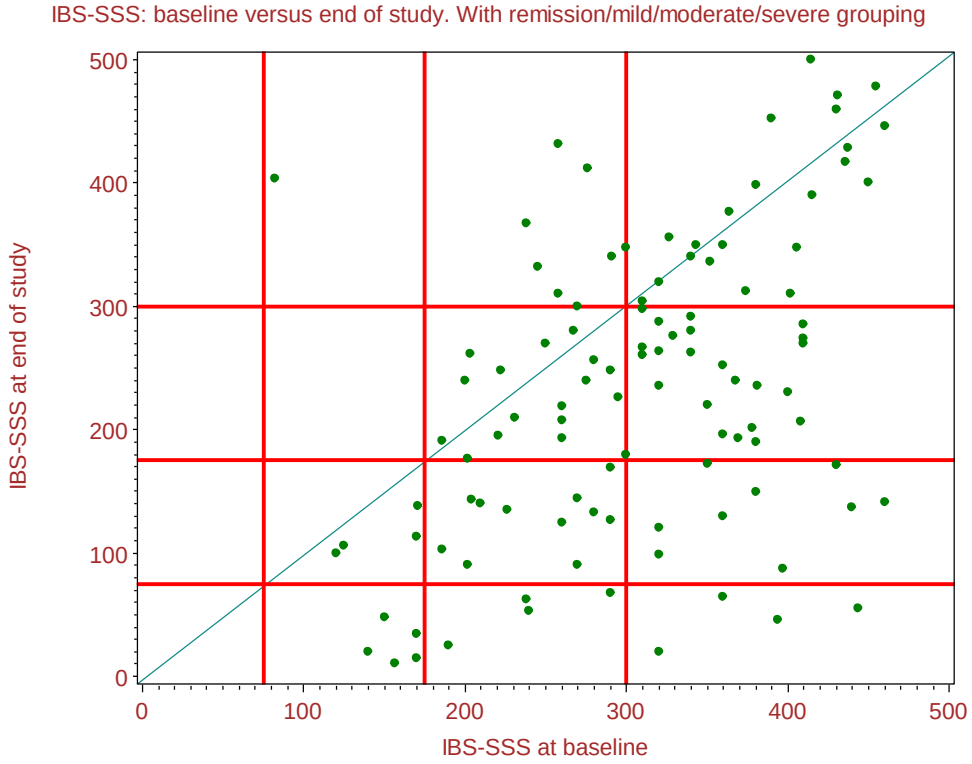
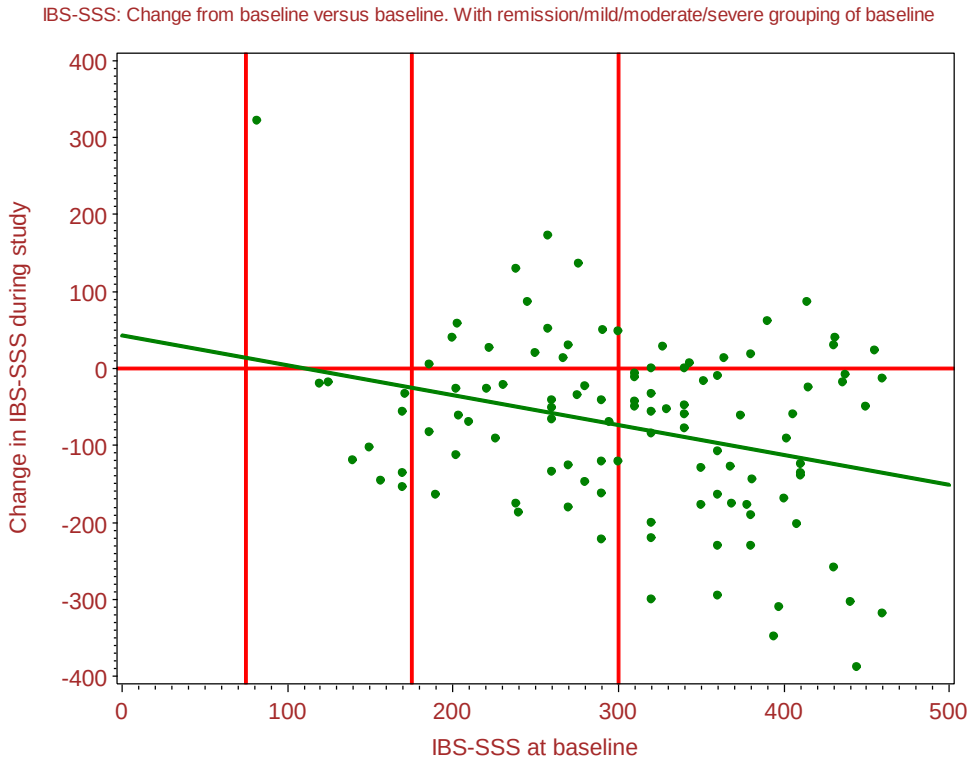


Figure2: change in IBS-SSS





IBS-SSS: Change from baseline versus baseline, according to TREATMENT

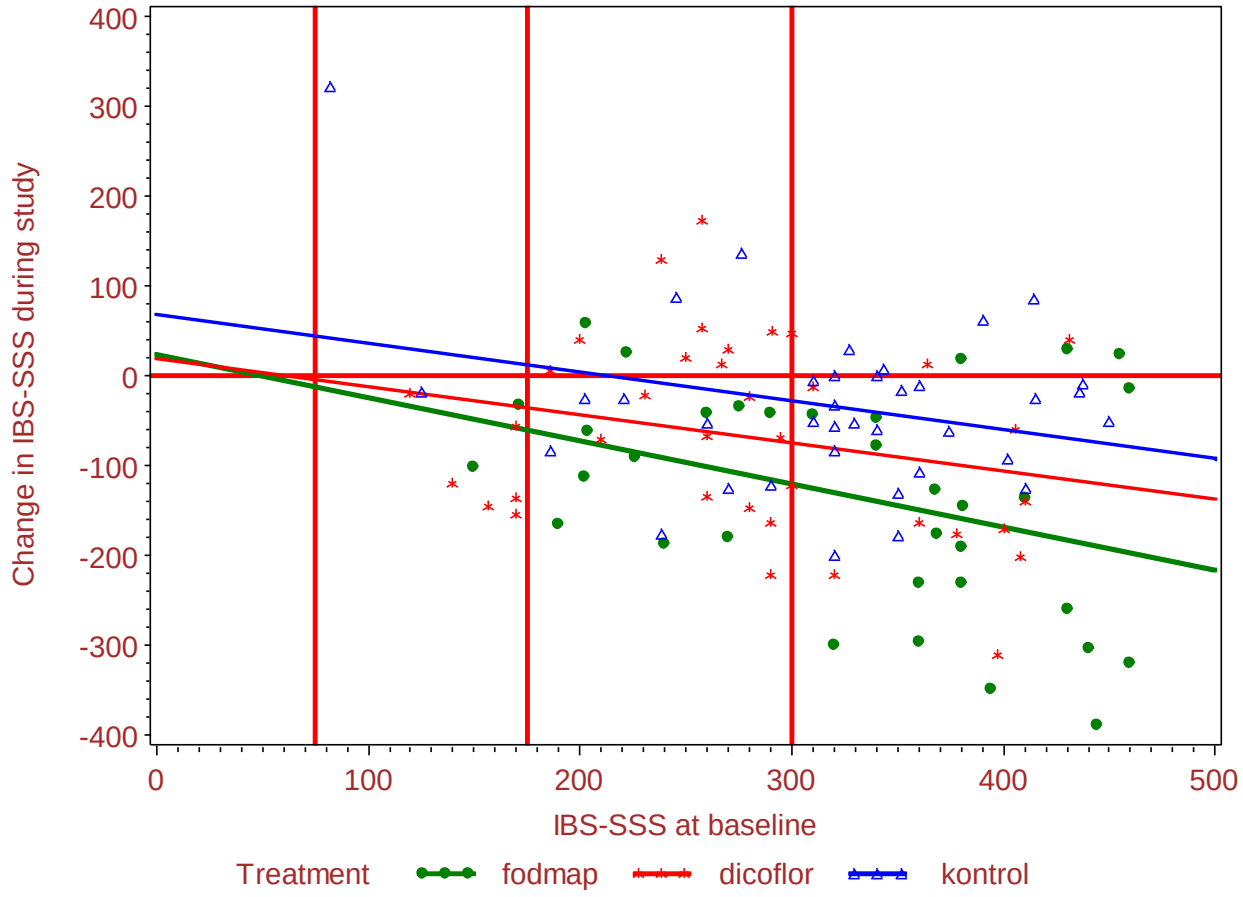
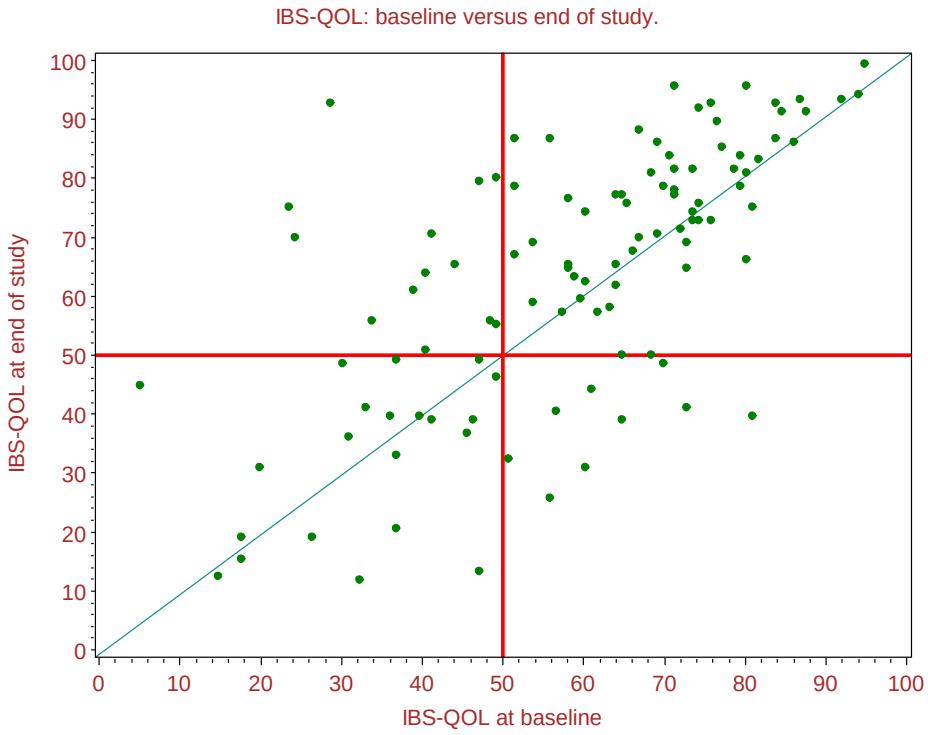
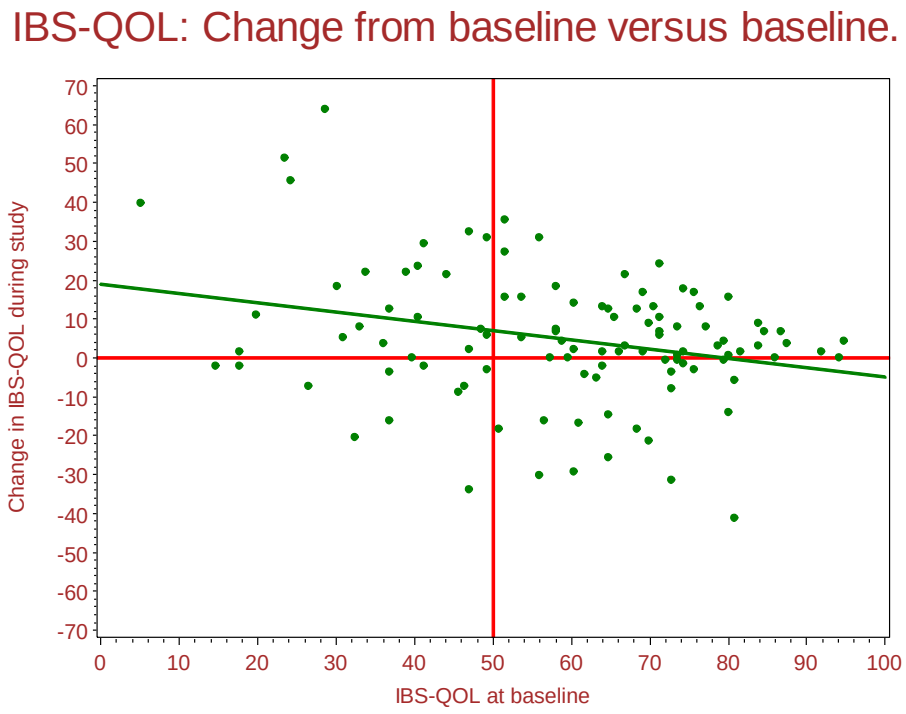


Figure3: change in IBS-QOL





IBS-QOL: Change from baseline versus baseline, according to TREATMENT

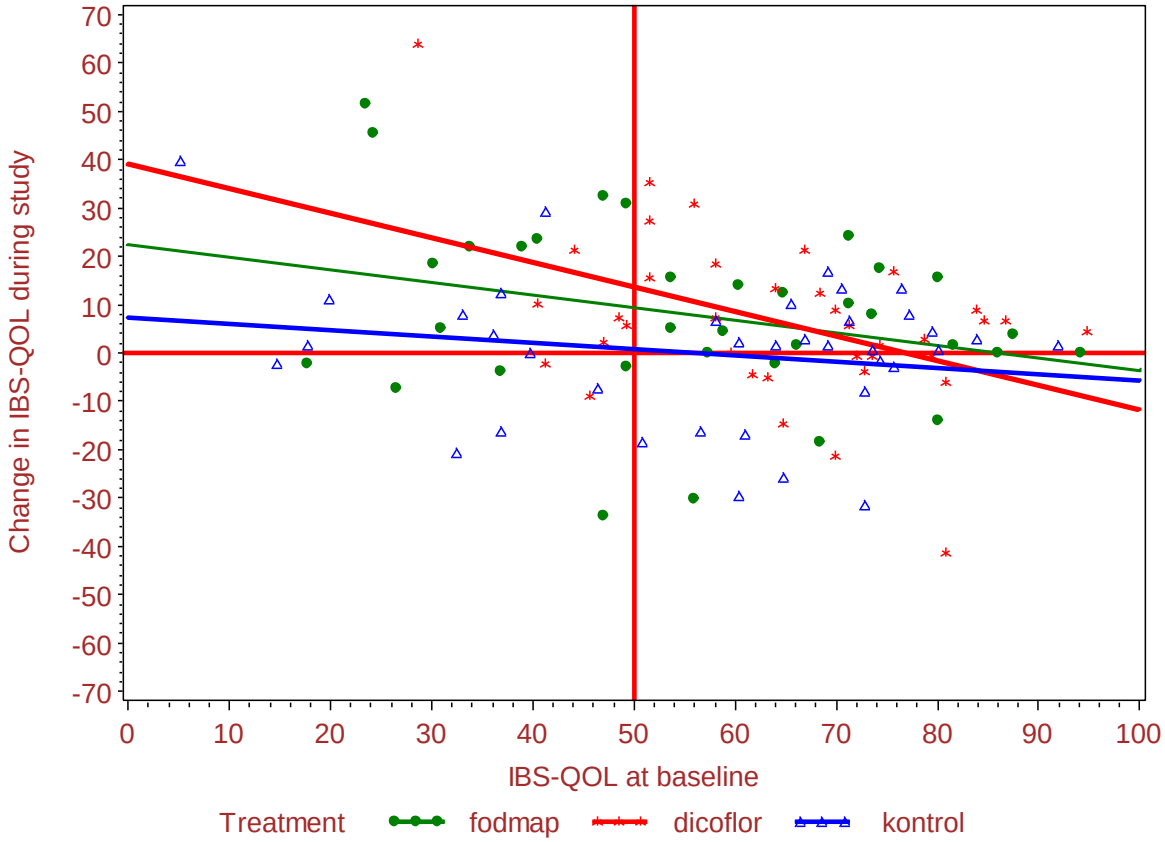


Figure4: change in IBS-QOL versus change in IBS-SSS

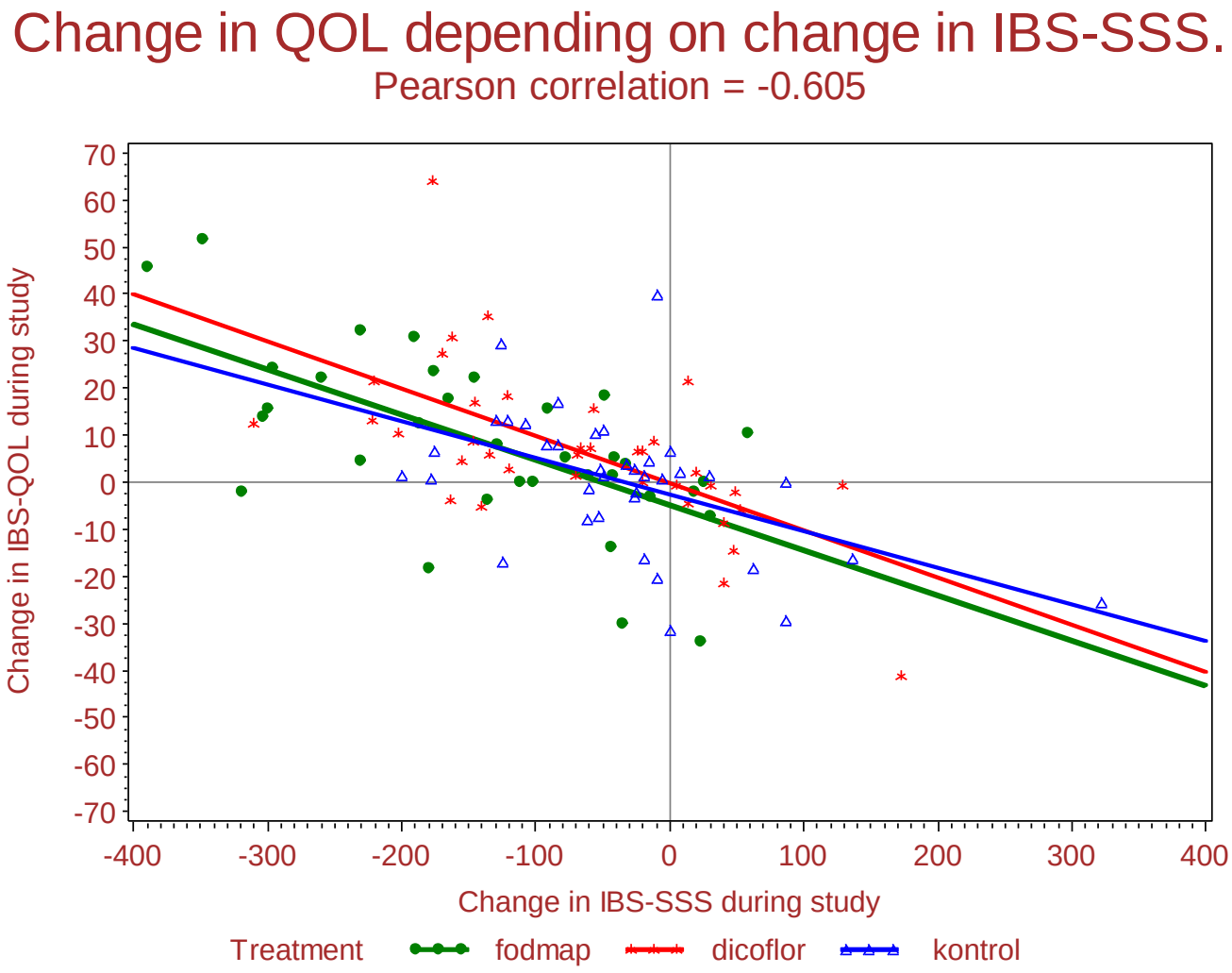


Table4: IBS-SSS at baseline: analysis of COVARIANCE:

Effect	*Contrast*	*Base_SSS*	*Lower*	*Upper*	*p_value*
AGE40	Below 40 years vs. above	63.9387	24.8189	103.06	0.0017
No Surgery		-23.9860	-68.4268	20.4548	0.2862
No Medicine		-12.4651	-50.7111	25.7809	0.5186
Smoking	Current vs. never	5.6834	-51.5396	62.9063	0.8439
Smoking	Former vs. never	8.5610	-33.5296	50.6517	0.6869
Time from diagnosis	Per year	2.8665	-3.9735	9.7066	0.4069
BMI	Per kg/m2	1.7768	-2.8762	6.4297	0.4497
Gender	Females versus males	26.9021	-19.2129	73.0170	0.2493
IBS_type	IBS-A vs. IBS-D	5.1998	-35.0217	45.4212	0.7977
IBS_type	IBS-C vs. IBS-D	-9.5847	-60.2198	41.0505	0.7075

The baseline IBS-SSS is considered a continuous dependent variable and is treated using a linear normal analysis of covariance (ANCOVA) with covariates: Gender, Age40, Smoking status, IBS type, Surgery before baseline, Medicines at baseline, years since IBS diagnosis and BMI. Note that BMI and years since diagnosis are used as regression variables.

Table5: IBS-SSS CHANGE from baseline to week 6: analysis of COVARIANCE:

Effect	*Contrast*	*DIFF_SSS*	*Lower*	*Upper*	*p_value*
AGE40	Below 40 years vs. abo	38.0246	-9.4334	85.4826	0.1148
BMI	Per kg/m2	0.1812	-5.1063	5.4687	0.9458
Gender	Females versus males	8.4693	-45.6473	62.5859	0.7563
IBS_type	IBS-A vs. IBS-D	46.1096	0.6579	91.5613	0.0469
IBS_type	IBS-C vs. IBS-D	50.3197	-7.1618	107.80	0.0853
No Medicine		-54.8795	-98.4657	-11.2933	0.0143
No Surgery		-11.6029	-62.1065	38.9007	0.6488
SSS1	Per baseline SSS point	-0.4082	-0.6566	-0.1598	0.0016
Smoking	Current vs. never	66.0478	1.0815	131.01	0.0464
Smoking	Former vs. never	51.6542	3.8682	99.4401	0.0345
Time from diagnosis	Per year	4.7145	-3.0897	12.5188	0.2328
Treat_group	Dicoflor vs. control	-31.5190	-80.7763	17.7384	0.2066
Treat_group	FODMAP vs. control	-75.3656	-126.81	-23.9216	0.0046
Treat_group	Dicoflor vs FODMAP	43.8466	-8.0787	95.7720	0.0968

The change in IBS-SSS is analyzed using the same model, EXCEPT for the inclusion of the baseline IBS-SSS value as regression variable and finally the Treatment effect..

Table6: IBS-QOL at baseline: analysis of COVARIANCE

Effect	*Contrast*	*Base_QOL*	*Lower*	*Upper*	*p_value*
AGE40	Below 40 years vs. above	-5.4342	-14.1743	3.3059	0.2197
No Surgery		7.2874	-2.6416	17.2163	0.1481
No Medicine		3.0284	-5.5164	11.5733	0.4828
Smoking	Current vs. never	-7.7973	-20.5819	4.9874	0.2286
Smoking	Former vs. never	-4.4765	-13.8803	4.9274	0.3465
Time from diagnosis	Per year	0.2691	-1.2591	1.7973	0.7270
BMI	Per kg/m2	0.002884	-1.0367	1.0424	0.9956
Gender	Females versus males	-4.1648	-14.4678	6.1381	0.4237
IBS_type	IBS-A vs. IBS-D	-1.9926	-10.9789	6.9936	0.6603
IBS_type	IBS-C vs. IBS-D	1.9307	-9.3821	13.2436	0.7351

The baseline IBS-QOL is considered a continuous dependent variable and is treated using a linear normal analysis of covariance with covariates: Gender, Age40, Smoking status, IBS type, Surgery before baseline, Medicines at baseline, years since IBS diagnosis and BMI. Note that BMI and years since diagnosis are used as regression variables.

Table7: IBS-QOL CHANGE from baseline to week 6: analysis of COVARIANCE:

Effect	*Contrast*	*DIFF_QOL*	*Lower*	*Upper*	*p_value*
AGE40	Below 40 years vs. abo	-6.3823	-13.6223	0.8577	0.0832
BMI	Per kg/m2	-0.2785	-1.1185	0.5615	0.5113
Gender	Females versus males	2.2012	-6.3816	10.7840	0.6112
IBS_type	IBS-A vs. IBS-D	-6.4508	-13.7027	0.8012	0.0805
IBS_type	IBS-C vs. IBS-D	-4.3839	-13.5478	4.7800	0.3440
No Medicine		7.9708	1.0208	14.9209	0.0251
No Surgery		6.1371	-1.9592	14.2335	0.1354
QOL1	Per baseline QOL point	-0.2972	-0.4739	-0.1205	0.0012
Smoking	Current vs. never	-6.2665	-16.7074	4.1743	0.2358
Smoking	Former vs. never	-6.9729	-14.6297	0.6839	0.0737
Time from diagnosis	Per year	-0.1678	-1.4072	1.0716	0.7883
Treat_group	Dicoflor vs. control	7.2158	-0.5844	15.0160	0.0693
Treat_group	FODMAP vs. control	3.7883	-4.4003	11.9769	0.3600
Treat_group	Dicoflor vs FODMAP	3.4275	-4.8844	11.7395	0.4143

The change in IBS-QOL is analyzed using the same model, EXCEPT for the inclusion of the baseline IBS-QOL value as regression variable and finally the Treatment effect..