

## Participant Flow

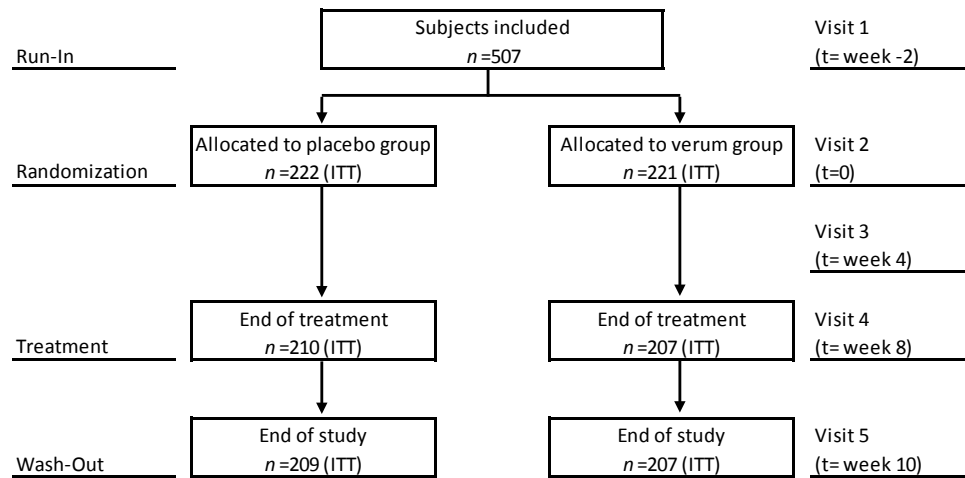


Figure 1: Flowchart of the patients through the study. Verum=B. bifidum SYN-HI-001

## Baseline Characteristics

**Table 1:** Demographic characteristics of the ITT population

	<i>B. bifidum</i> SYN-HI-001 (N=221)	Placebo (N=222)
	N(%) or mean $\pm$ s.d.	N(%) or mean $\pm$ s.d.
Age	40.1 $\pm$ 12.8	42.6 $\pm$ 13.8
Female sex	155 (70.1)	152 (68.5)
Height (cm)	172.4 $\pm$ 8.9	171.3 $\pm$ 9.1
Weight (kg)	73.2 $\pm$ 17.7	72.8 $\pm$ 16.6
BMI	24.5 $\pm$ 5.3	24.7 $\pm$ 5.0
<i>IBS type</i>		
IBS-C	54 (24.4)	53 (23.9)
IBS-D	95 (43.0)	82 (36.9)
IBS-M	14 (6.3)	20 (9.0)
IBS-U	58 (26.2)	67 (30.2)
Abdominal pain in 2 <sup>nd</sup> week of Run-In*	4.1 $\pm$ 2.0	4.0 $\pm$ 1.9

\*weekly means of abdominal pain

## Outcome Measures:

**Table 2:** Basic Results

	<i>B. bifidum</i> SYN- HI-001 (N=221)	Placebo (N=222)	
	N(%) or mean	N(%) or mean	p-value
<b>Primary Outcome Measure</b>			
Combined Response Rate*	33.5	19.4	0.00071
<b>Secondary Outcome Measures</b>			
Adequate Relief Response Rate	60.2	44.1	0.0009
Change in Mental Health Sum**	+3.3	1.7	0.0309

\*Adequate Relief of IBS symptoms in combination with an improvement in abdominal pain at the end of treatment

\*\*Assessed via SF-12 health survey; change from baseline to the end of treatment

## Adverse Events:

**Table 3:** Incidence of Adverse Events with suspected relationship by preferred term (according to MedDRA ).

	B. bifidum HI-MIMBb75		Placebo		Total		P
	N	(%)	N	(%)	N	(%)	
Abdominal distension	1	0.45	1	0.45	2	0.45	1.0000
Abdominal pain	2	0.90	1	0.45	3	0.68	0.6233
Abdominal pain upper	0	0.00	1	0.45	1	0.23	1.0000
Constipation	0	0.00	1	0.45	1	0.23	1.0000
Diarrhoea	0	0.00	2	0.90	2	0.45	0.4989
Gastroenteritis	1	0.45	0	0.00	1	0.23	0.4989
Irritable bowel syndrome aggravated	1	0.45	0	0.00	1	0.23	0.4989
Liver function test	0	0.00	2	0.90	2	0.45	0.4989
Nausea	1	0.45	0	0.00	1	0.23	0.4989
Urinary incontinence	1	0.45	0	0.00	1	0.23	0.4989

**Table 4:** List of Serious Adverse Events

Treatment Group	Low Level Term	Relationship to study treatment*
Placebo	Femoral neck fracture	Unlikely
Placebo	Acute myocardial infarction of anterior wall	Unlikely

\*classified by the investigator