

## **2009-013426-16 - Summary**

Title: Management of Irritable Bowel Syndrome in Primary Care: Feasibility randomised controlled trial of mebeverine, methylcellulose, placebo and a patient self-management cognitive behavioural therapy website

Objectives: Is it appropriate to test a fibre-based bulking agent in all groups of IBS patient?

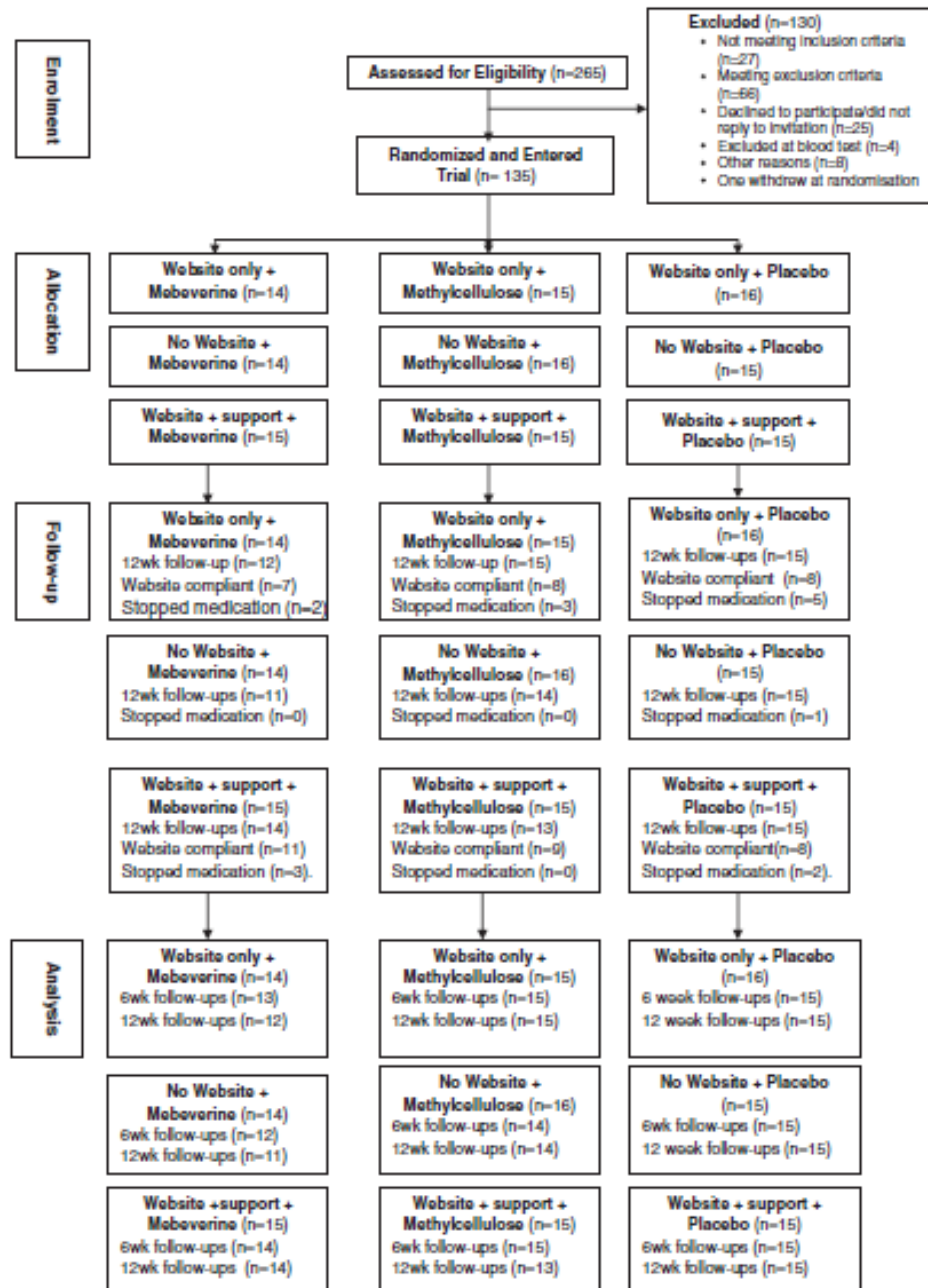
Should the full trial test the website with minimal email support on request or with the scheduled telephone nurse consultation after session two plus the minimal email support?

Methods: Feasibility Randomised Controlled trial of mebeverine, methylcellulose, placebo and a patient self-management cognitive behavioural therapy website (MIBS trial).

3 levels of the website condition, Regul8 with a nurse telephone session and email support, Regul8 with minimal email support, or no website, thus creating 9 groups.

ClinicalTrials.gov: NCT00934973

## 1. Participants flow



## 2. Baseline Characteristic

Variable	Website only N = 45	Website with support N = 45	No website N = 45	Test
Age (years), mean (SD)	45.76 (9.21)	45.13 (10.13)	42.18 (11.48)	F(2,132) = 1.524, p = 0.222
Length of symptoms (years), mean (SD)	10.51 (8.19)	12.87 (9.47)	9.00 (8.14)	KW, ap = 0.129
Median (IQR)	10.00 (12.00)	12.00 (15.00)	7.50 (8.75)	
IBS-SSS total, mean (SD)	237.33 (85.36)	237.30 (100.78)	251.36 (75.92)	F(2,132) = 0.377, p = 0.687
IBS-QOL score, mean (SD)	67.32 (17.89)	60.00 (3.13)	64.86 (19.39)	F(2,132) = 1.65, p = 0.20
HADS score for anxiety, mean (SD)	8.73 (3.40)	9.46 (3.91)	10.00 (4.12)	F(2,132) = 1.23, p = 0.30
HADS score for depression, mean (SD)	4.20 (2.87)	5.26 (3.68)	5.32 (3.56)	KW, ap = 0.263
Median (IQR)	4 (4)	5 (6)	5 (5)	
Deprivation score, mean (SD)	12.27 (9.07)	8.65 (5.54)	12.81 (9.40)	KW, ap = 0.026*
Median (IQR)	10.06 (9.79)	6.57 (7.63)	9.79 (9.21)	
Gender n (%)				
Male	14 (46.7)	12 (40.0)	4 (13.3)	$\chi^2(2) = 6.844, p = 0.034^*$
Female	31 (95.5)	34 (32.4)	40 (38.1)	
Type of IBS n (%)				$\chi^2(4) = 0.70, p = 0.953$
Constipation	5 (38.5)	5 (38.5)	3 (23.1)	
Diarrhoea	14 (34.1)	13 (31.7)	14 (34.1)	
Mixed	26 (32.1)	28 (34.6)	27 (33.3)	
Severity IBS on IBS SSS n (%)				
Mild	10 (33.3)	12 (40.0)	8 (26.7)	$\chi^2(4) = 1.37, p = 0.85$
Moderate	24 (32.4)	23 (31.1)	27 (36.5)	
Severe	11 (35.5)	11 (35.5)	9 (29.0)	
Education n (%)				$\chi^2(10) = 3.65, p = 0.97$
No formal	2 (25.0)	4 (50.0)	2 (25.0)	
GCSE/O	11 (31.4)	11 (31.4)	13 (37.1)	
A level	11 (32.4)	10 (29.4)	13 (38.2)	
Degree	12 (38.7)	10 (32.3)	9 (29.0)	
Postgraduate	5 (33.3)	7 (46.7)	3 (20.0)	
Other	4 (33.3)	4 (33.3)	4 (33.3)	

### 3. Outcomes: Analysis of the 6 week follow-up scores

Variable	Website	Website + support	No website group	Significance
<i>IBS-SSS total mean (n = 123)</i>	197.0 (172.4 - 221.7)	208.0 (188.1 - 233.0)	162.8 (137.4 -188.3)	p = 0.037*
<i>IBS-QOL score (n = 123)</i>	71.6 (67.9-75.2)	67.6 (63.9-71.3)	69.4 (65.7-73.1)	p = 0.315
<i>HADS score for anxiety (n = 114)</i>	8.9 (7.9-9.8)	9.7 (8.8-10.6)	8.3 (7.3-9.2)	p = 0.109
<i>HADS score for depression (n = 114) (%)</i>				p = 0.122
<i>Normal (0-7)</i>	35 (89.7)	28 (71.8)	31 (79.5)	
<i>Mild (8-10)</i>	2 (5.1)	8 (20.5)	8 (20.5)	
<i>Moderate or Severe (11-21)</i>	2 (5.1)	3 (7.7)	0 (0)	
<i>Enablement score (n = 113) (%)</i>				p = 0.000**
<i>0</i>	7 (18.4)	4 (10.5)	21 (56.8)	
<i>1-2</i>	7 (18.4)	5 (13.2)	4 (10.8)	
<i>3-5</i>	13 (34.2)	15 (39.5)	7 (18.9)	
<i>6-12</i>	11 (28.9)	14 (36.8)	5 (13.5)	

ANCOVA for IBS SSS, IBS-QOL and HADs Anxiety, Mean (95% CI). Ordinal Regression for HADs Depression and Enablement (n (%)).

### 4. Adverse events

There was no evidence of increased dropouts or reported adverse events.

### 5. Publication

Everitt H, Moss-Morris R, Sibelli A, Tapp L, Coleman N, Yardley L, Smith P, Little P. Management of irritable bowel syndrome in primary care: the results of an exploratory randomised controlled trial of mebeverine, methylcellulose, placebo and a self-management website. BMC Gastroenterol. 2013 Apr 21;13:68. doi: 10.1186/1471-230X-13-68.

Everitt HA, Moss-Morris RE, Sibelli A, Tapp L, Coleman NS, Yardley L, Smith PW, Little PS. Management of irritable bowel syndrome in primary care: feasibility randomised controlled trial of mebeverine, methylcellulose, placebo and a patient self-management cognitive behavioural therapy website. (MIBS trial). BMC Gastroenterol. 2010 Nov 18;10:136. doi: 10.1186/1471-230X-10-136.