

Oral Anti-Obesity Medication after Bariatric Surgery: a RCT on naltrexone/bupropion for recurrent weight gain after MBS

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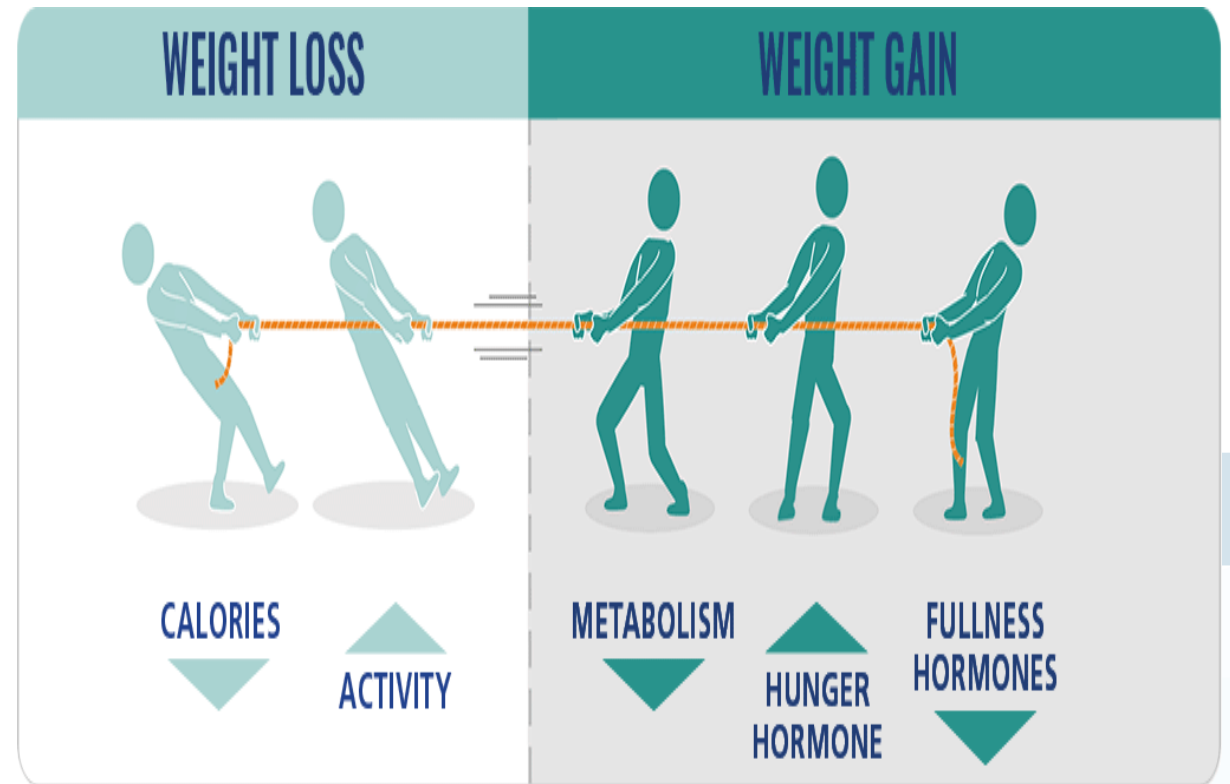
Conflicts of interest statement

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Study medication was sponsored by: GoodLife Pharma

Background

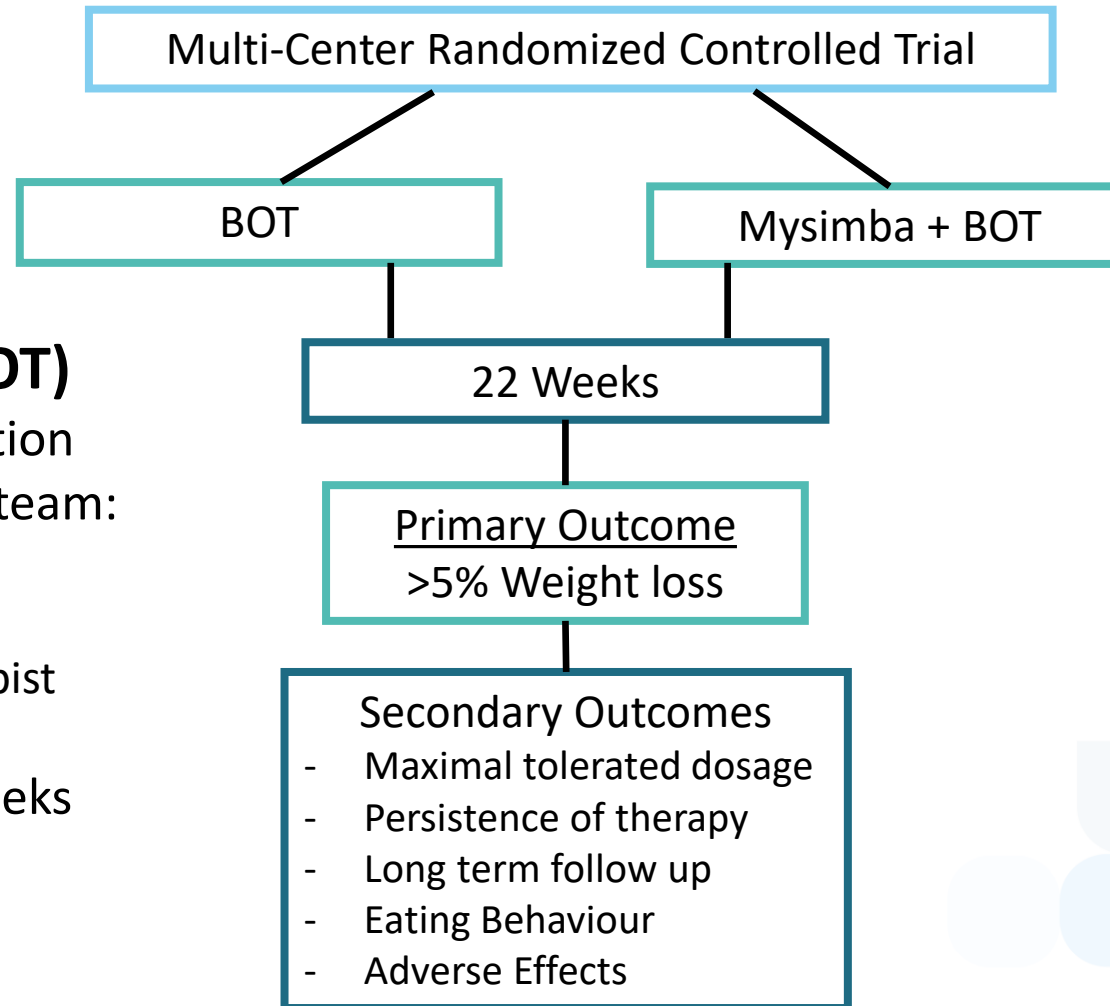
- Recurrent weight gain after MBS 10-40%
- Different causes
- How to solve this problem?
 - Lifestyle modifications?
 - Surgery?
 - Obesity management medications
 - Naltrexone/bupropion: Mysimba



Study design



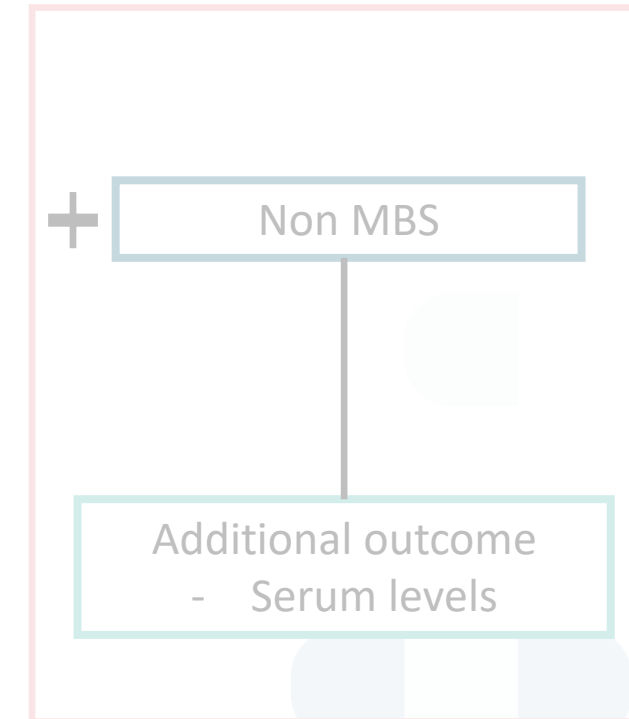
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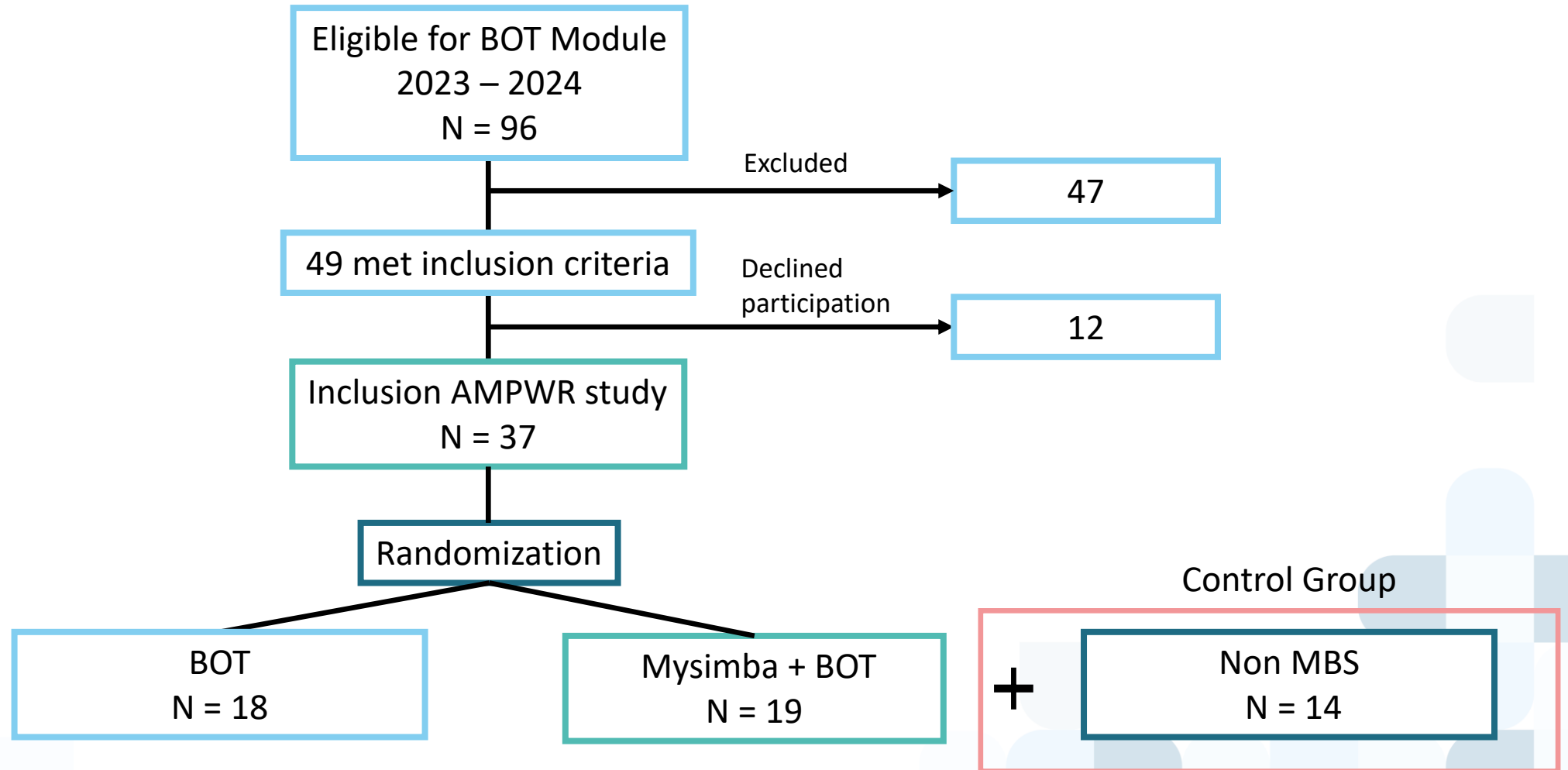
Back on Track (BOT)

- Lifestyle intervention
- Mult disciplinary team:
 - Psychologist
 - Dietitian
 - Exercise therapist
 - MD
- Program of 22 weeks

Control Group



Methods



Baseline Characteristic

Characteristic	Mysimba + BOT N = 19	Back on Track N = 18	P-value
Age, years	48.2 ±11.5	47.4 ±11.9	0.854
Sex			
Male (%)	3 (16)	2 (11)	1.000
Female (%)	16 (84)	16 (89)	
BMI Primary Surgery	42.24 [39.5 – 43.2]	42.04 [39.4 – 46.9]	0.499
BMI at Start Study	31.5 [27.8 – 33.3]	30.3[29.6 – 37.8]	0.518
<u>Comorbidities</u>			
Hypertension	4 (21)	5 (28)	0.714
OSAS	2 (11)	2 (11)	1.000
Dyslipidemia	0 (0)	1 (6)	0.486
Lower Joint Pain	12 (63)	6 (33)	0.070
Diabetes type 2	0 (0)	1 (6)	0.486
<u>Type of Surgery</u>			
RYGB	16 (84)	15 (83)	1.000
Sleeve Gastrectomy	3 (16)	3 (17)	

Results

Characteristic	Mysimba + BOT N = 19	Back on Track N = 18	P-value
	N = 15	N = 9	
Intention to treat*			
Successful weight loss (>5% TWL)	7 (47)	0 (0)	0.022
	N = 7	N = 9	
Per protocol*			
Successful weight loss	5 (71)	0 (0)	0.005
Total weight loss, percentage	6.3 [4.0 – 7.8]	1.5 [-1.0 – 3.7]	0.041

*Weight was measured at $\pm T=22$



Results Naltrexone Bupropion

Adverse Events	N = 19	Stopped treatment
None	9 (47)	
Adverse Event*	10 (53)	4 (40)

*Minor adverse events reported: nausea, dizziness, headache, constipation, abdominal bloating, malaise.

Dosage

No. of pills	No. of patients
1	1 (7)
2	3 (20)
3	2 (13)
4	9 (60)
Total	15

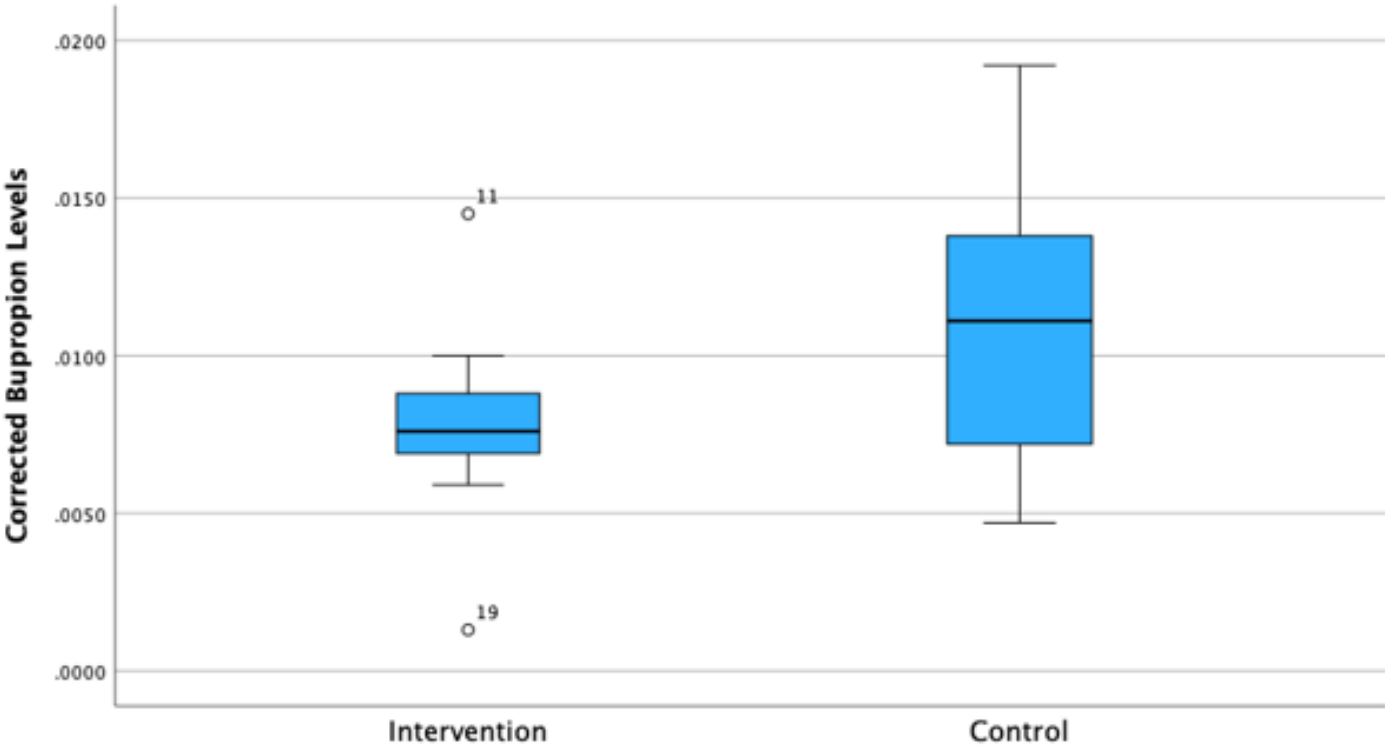


Additional Results



Characteristic	Control Group N = 13	Mysimba + BOT N = 14	P-value
Intention to treat*			
Corrected Bupropion	0.011 [0.007 – 0.015]	0.007 [0.006 – 0.009]	0.014

*Serum Bupropion was measured for 13 patients in control group and 13 patients in intervention group.

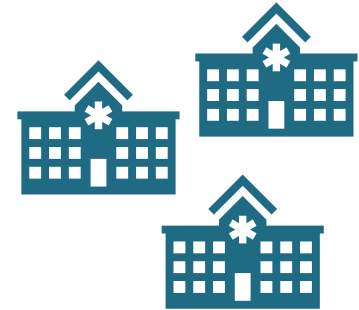


Conclusion

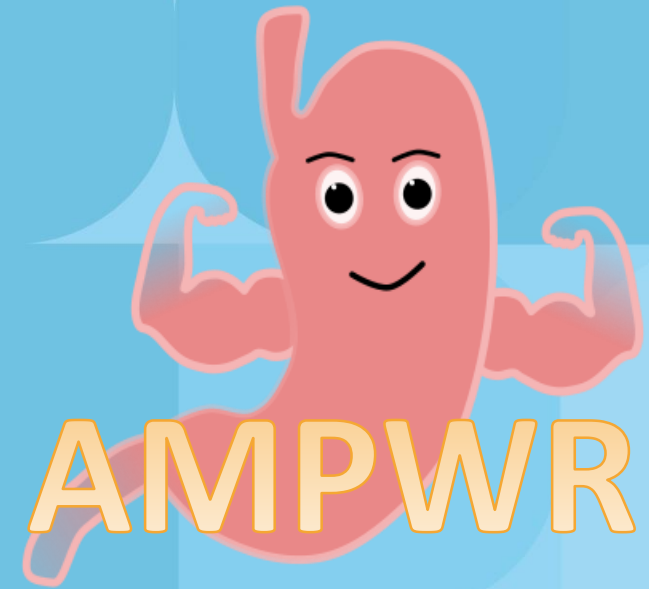


Patients receiving **Mysimba + Back on Track (BOT)** on an adequate dosage showed a **statistically significant increase** in successful weight loss ($\geq 5\%$ TWL) at 22 weeks **compared to BOT**

As 40% of patients discontinued the medication **due to side effects** **careful patient selection** and **expectation management** is of great importance



Patients in the **surgery group** experience **similar side effects** as described in patients using Mysimba without surgery. Blood **plasma levels do however show a difference**, with a lower level in MBS patients.



Questions?

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Additional Results

- Yale Food Addiction Scale 2.0 (YFAS)

Characteristic	Complete cohort N= 37	Mysimba + BOT N = 19	Back on Track N = 18	P-value
Classification at baseline				
No FA	16 (59)	10 (63)	6 (55)	0.625
Mild	3 (11)	1 (6.3)	2 (18)	
Moderate	0 (0.0)	0 (0.0)	0 (0.0)	
Severe	8 (30)	5 (32)	3 (27)	
Missing	10 (N/A)	3 (N/A)	7 (N/A)	
Classification at T=22	Complete cohort			
No FA	11 (85)	7 (78)	4 (100)	0.591
Mild	0 (0.0)	0 (0.0)	0 (0.0)	
Moderate	1 (7.7)	1 (11)	0 (0.0)	
Severe	1 (7.7)	1 (11)	0 (0.0)	
Missing	24 (N/A)	10 (N/A)	14 (N/A)	