

## The impossible is possible.

Thanks to the tremendous work and dedication of the 12 sites we have completed recruitment with 1351 participants. This achievement reflects true team working between bariatric centres, the Quintet Recruitment Intervention and the trials unit. We are now fully immersed in follow up. Our focus is to retain all patients to 36 months (primary end point) and achieve at least 85% data completion.

### Recruitment summary

Centre	Randomised
Taunton	244
Southampton	160
Bournemouth	52
Leeds	71
Sunderland	75
Truro	76
Birmingham	219
Derby	97
Portsmouth	113
Homerton	49
Imperial	169
North Bristol	26
<b>Total</b>	<b>1351</b>

### Cross-overs (non compliance)

Allocation	Received	N	Total
Band	Bypass	22	48
	Sleeve	26	
Bypass	Band	9	33
	Sleeve	23	
Sleeve	Bypass	2	7
	Band	2	
<b>Total</b>		<b>88*</b>	<b>88</b>

\*Reasons: patient preference (n=57), clinical reason (n=21), unclear/unknown (n=7) and errors (n=3).

### Optimising data completeness

With input from patient representatives and recruiting centres we have devised strategies to improve data collection and quality, for example:

- ◆ We phone patients who have not returned/completed questionnaires
- ◆ We offer different options for questionnaire completion (by mail on paper, online or at follow up clinics) according to patient preference
- ◆ Patients receive 'incentives' with shopping vouchers. They get these after we have received and entered their 12 and 36 months questionnaires

**The primary end point of BBS is a combination  
of weight loss and quality of life**



Tweet us!  
@ByBandSleeve

Study  
progress

Screened  
n = 6949

Eligible  
n = 4703

Approached  
n = 4113

Consented  
n = 1379

Randomised  
n = 1351

Surgery  
complete  
n = 1107

Reached  
6 months  
n = 1265

Reached  
12 months  
n = 1131

Reached  
24 months  
n = 842

Reached  
36 months  
n = 534

Timepoint	Bypass		Band		Sleeve	
	Weight	EQ5D	Weight	EQ5D	Weight	EQ5D
Baseline	100%	100%	100%	99%	100%	100%
4 weeks	96%	86%	95%	77%	96%	80%
6 months	92%	81%	89%	77%	91%	81%
12 months	89%	81%	89%	73%	88%	76%
24 months	82%	74%	80%	65%	76%	70%
36 months	81%	72%	75%	74%	68%	70%



### Planned publication

We are currently working with the twelve sites to finalise all the baseline data. We plan to publish this in 2020. This will mean that the descriptive clinical data, sociodemographic information and baseline quality of life data will be available. It is important to understand how the participants in By-Band-Sleeve compare and contrast to patients generally undergoing bariatric surgery (thus supporting the generalisability of the study results).

### Metabolomics sub-study

In a ‘bolt-on’ study of By-Band-Sleeve, led by **Prof. Nic Timpson** (funded by the Wellcome Trust) samples from up to **1,000 patients**, collected at baseline (pre-surgery) and three years post-randomisation will be sent for metabolomics analysis. **Metabolites** are the small molecule substrates, intermediates and products of metabolism. By measuring many metabolites at once we can assess the **complex systemic effects** of bariatric surgery. By-Band-Sleeve is an incredible opportunity for this type of research. The combined expertise of Nic Timpson and the multi-centre collaboration with bariatric surgeons and the trial team will help to refine our understanding of the **impact of weight loss** after surgery on the body and crucially how this relates to future risk of disease. The aims are to:

- Compare patient metabolomes from before and after surgery
- Compare the effects of different surgical procedures
- Explore the differences we see in patient response to surgery

This work will provide a greater understanding of the **metabolic adaptations** to weight loss which, when combined with the results from the trial itself, should significantly enhance the evidence base available to clinicians faced with the challenge of treating obesity.

**Note from Jane Blazeby.** So far, we have collected **over 200 paired samples** within the RCT and recruited an additional 90 patients to the prospective cohort of non-randomised patients. Thank you to the centres participating in this sub-study and to the clinical trials unit for making it possible. It’s great to work with Nic and his team and be educated in this exciting area.

4							
	8					4	
	3		2		8	1	5
3			9	1		2	
6	4				5	9	
7			3	8		4	
	7		6		1	3	4
	1						2
5							

Are you good at Sudoku?

### Contacts

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