Standardising surgical interventions in large scale RCTs: The By-Band-Sleeve Study

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on behalf of the By-Band-Sleeve (BBS) Trial Management Group.

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Background

Surgical practice for severe obesity is predominantly informed by surgeon experience and single centre case series. There is a need for more and better randomised controlled trials to provide comparative data to inform decision-making. Surgical trials, however, are challenging. It is difficult to standardise and quality assure the interventions because of widespread variation in practice. The aim of this poster is to describe how surgical procedures in this trial were standardised within certain boundaries and how we monitored adherence to the study protocols with on-going results.

The By-Band-Sleeve Study

This study is funded by the UK National Institute of Health Research and run by a registered clinical trials unit.

It aims to compare adjustable gastric Band with Roux-en-Y gastric Bypass and Sleeve gastrectomy; sample size 1341.

Regular independent oversight committees monitor adverse events and outcomes.

Protocols for the trial interventions have been developed from the literature, 'real-time' observation of procedures in theatre, and consensus discussions with the trial team. The study uses key surgical parameters including flexible, mandated and prohibited components of each procedure. Adherence to surgical protocols is monitored and deviations investigated. Intervention protocols are discussed with the trial team before modification in line with emerging high-quality evidence.

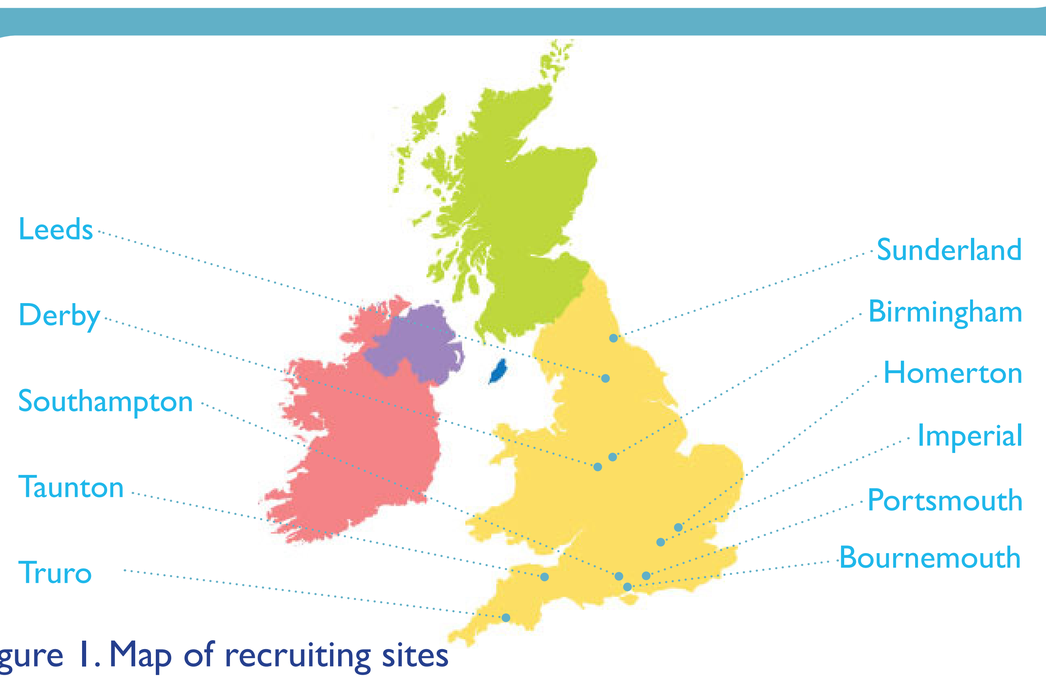

Figure 1. Map of recruiting sites

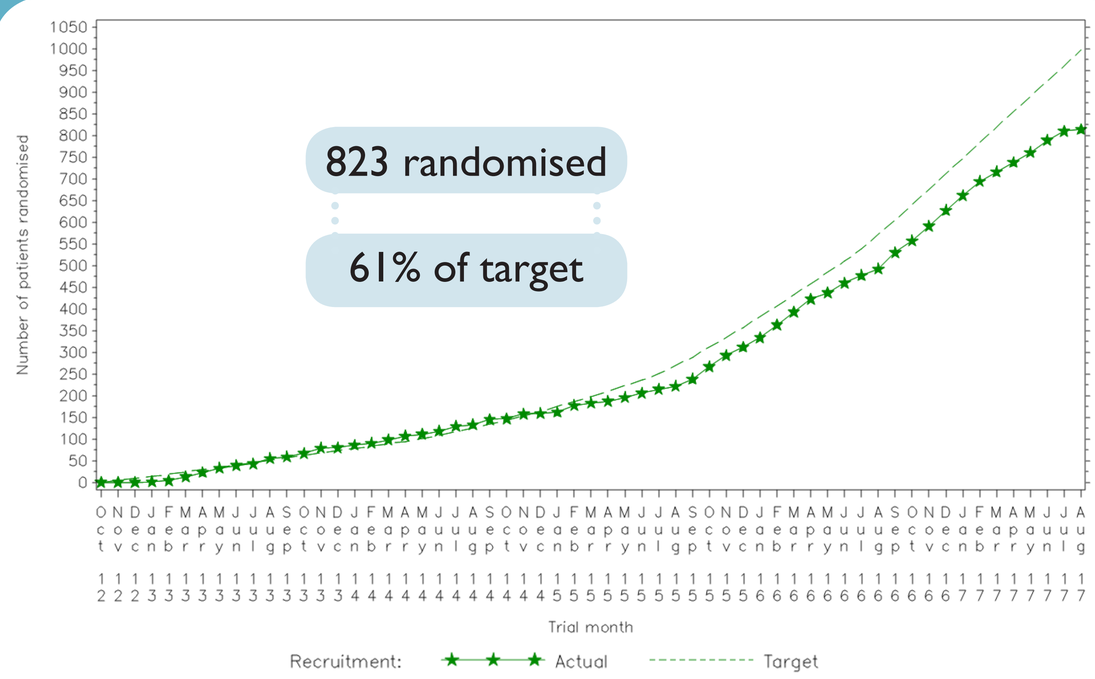

Figure 2. By-Band-Sleeve recruitment graph

Results

Eleven centres have randomised 823 patients and 573 procedures are complete to date (Figures 1 & 2). There have been 41(7.2%) patients who have not received their allocated treatment. Table 1 shows procedures allocated and numbers of crossovers. Reasons for the crossover included: patient preference (28), medical reason (1), error (1), other (1).

Adherence to surgical standards for each procedure is high; 13 procedure related deviations for Band, none for Bypass and Sleeve (Table 2). Recent evidence for the inclusion of mesenteric defect closure in the trial is being considered and a protocol amendment may be made.

Centre	Had surgery	Randomised to BYPASS	Randomised to BAND	Randomised to SLEEVE	Non-compliance with allocation*
Taunton	162	64	73	25	9
Southampton	93	35	38	20	6
Bournemouth	31	13	9	9	0
Leeds	30	11	9	10	1
Sunderland	38	14	12	12	2
Truro	26	9	8	9	2
Birmingham	51	18	16	17	3
Derby	27	5	10	12	5
Portsmouth	46	17	15	14	1
Homerton	19	7	5	7	0
Imperial	50	18	14	18	12
Overall	573	211	209	153	**41 (7.2%)**

** Crossovers consist of: 7 Bypass to Band, 10 Bypass to Sleeve, 11 Band to Bypass, 10 Band to Sleeve, 1 Sleeve to Bypass , 2 Sleeve to Band.*

Table 1. Allocation and crossovers.

Protocol Deviations	Number / % Patients	
General		
Procedure abandoned midway	0	0%
Surgery not carried out laparoscopically	0	0%
Inadequate anti DVT prophylaxis*	0	0%
No prophylactic antibiotics	2	0%
Apronectomy performed	0	0%
Bypass specific		
Vertical lesser curve pouch not used	0	0%
Band specific		
Pars flaccida dissection not used	0	0%
Gastro-gastric tunnelling sutures not used	1	1%
Fat pad not reflected to ensure band approximated directly to serosa	11	6%
Method of fixing point = not done	1	1%
Sleeve specific		
No visualisation of left crus after dissection of fundus	0	0%

Table 2. Protocol deviations

Conclusion

It is possible to establish and monitor standards of surgery within a multi-centre RCT. Detailed recording of adherence will inform how trial results are implemented in practice.

This project was funded by the NIHR Health Technology Assessment programme (ref 09/127/53). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Funded by NHS National Institute for Health Research