

By-Band-Sleeve: results of a pragmatic randomised controlled trial

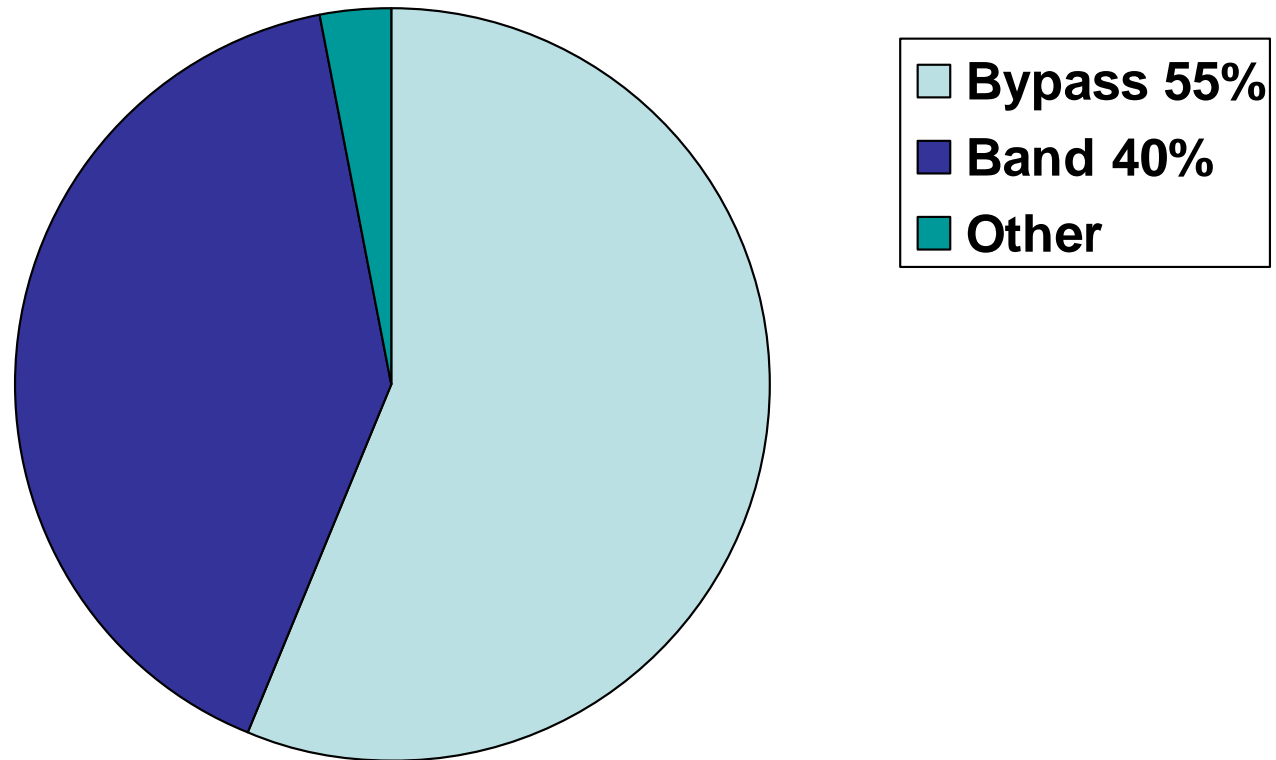
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On behalf of the By-Band-Sleeve Collaborating group

Declaration

- I have no conflicts of interest to declare
- My research is funded by the National Institute of Healthcare Research (NIHR), the Medical Research Council (MRC) and the Royal College of Surgeons on England.
- The views' expressed are not necessarily those of the funding bodies.

US Bariatric Centres of Excellence 2007-2009



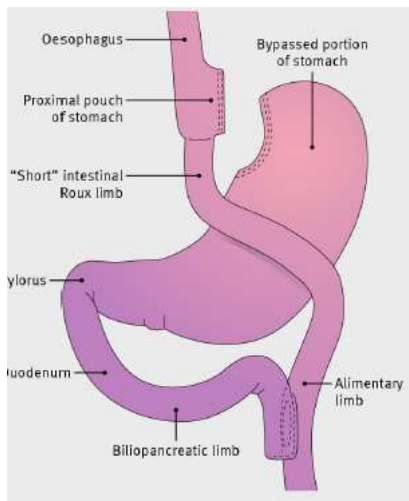
De Maria E. www.surgicalreview.org accessed May 10; SOARD 2010; 6: 347-355 July

2011

Eligible patients

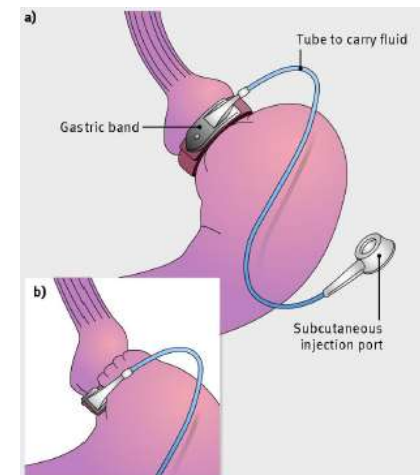
Bypass

N=362



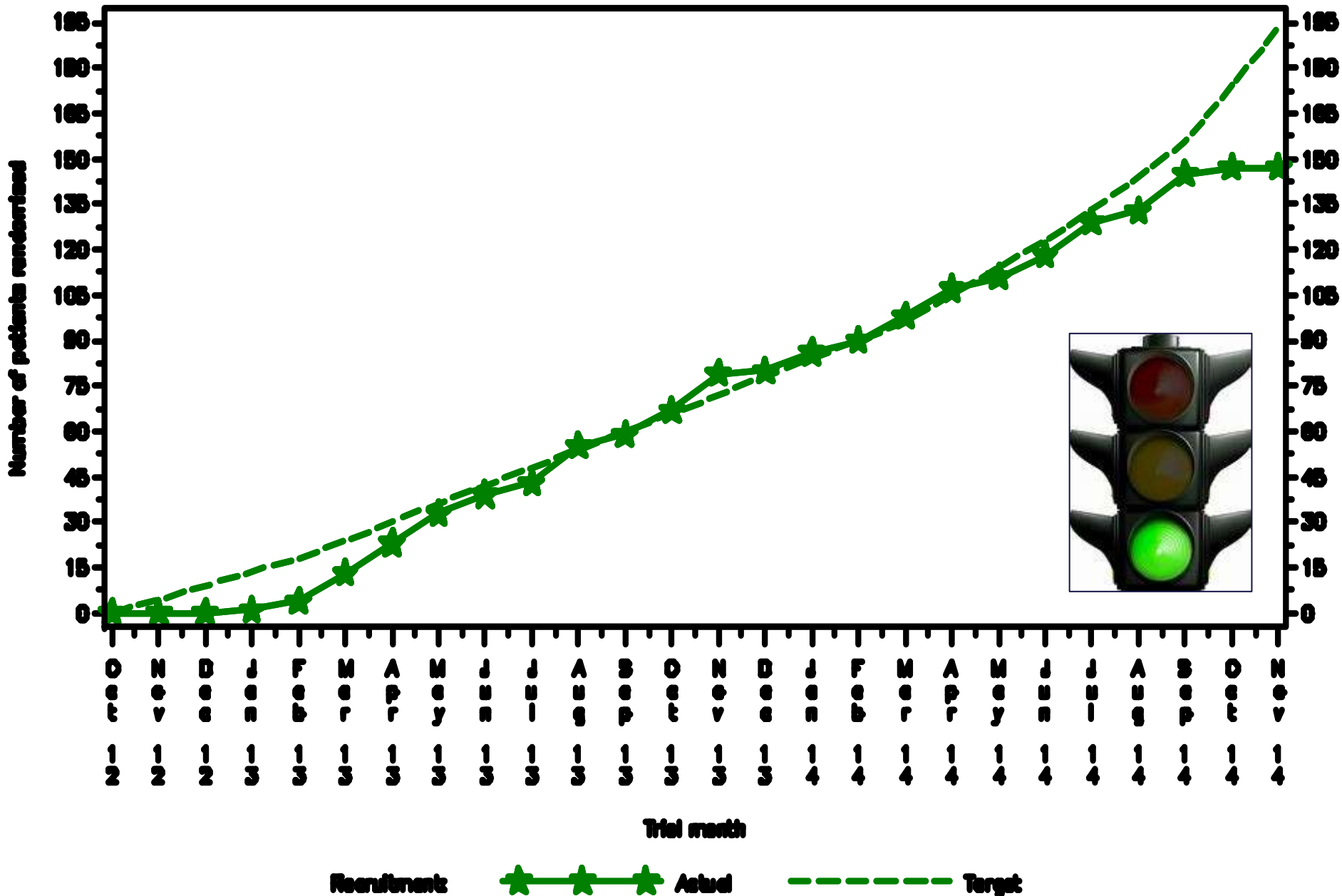
Band

N=362

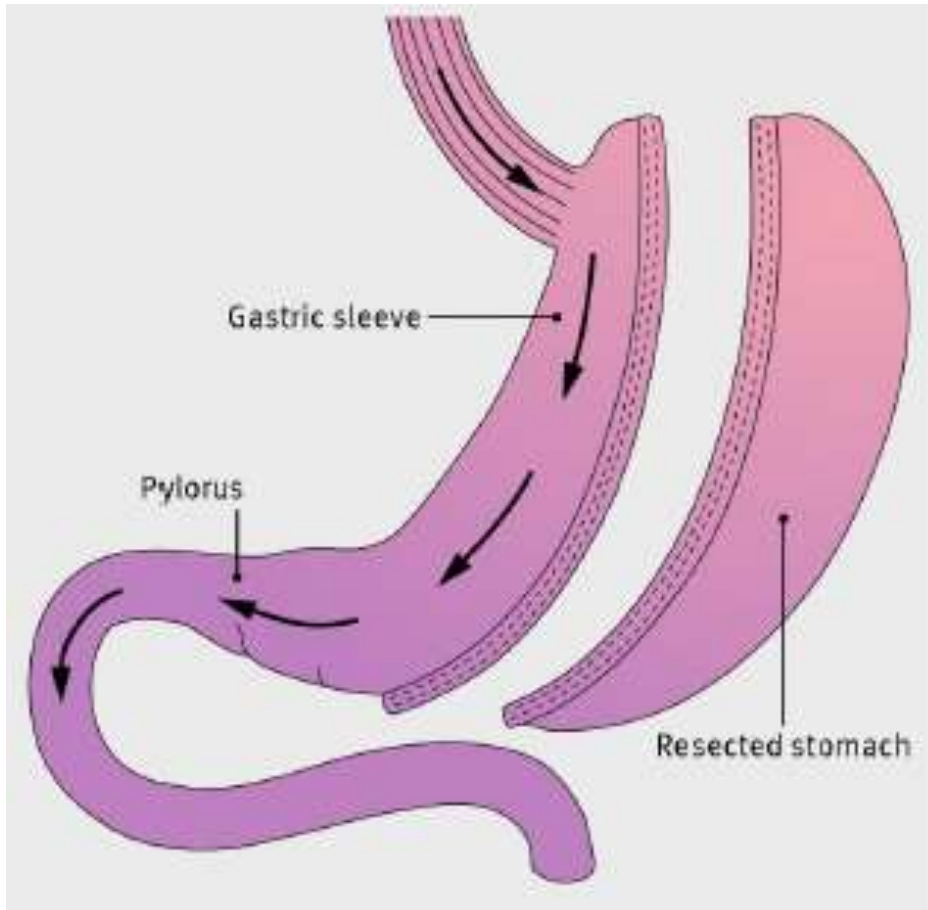


By-Band
BUILDING EVIDENCE TOGETHER

Pilot in Taunton & Southampton possible to recruit



Sleeve gastrectomy



**2011 to 2014
Popularity grew**

Comparative data limited



Is new better?

Randomised data

Continue Band

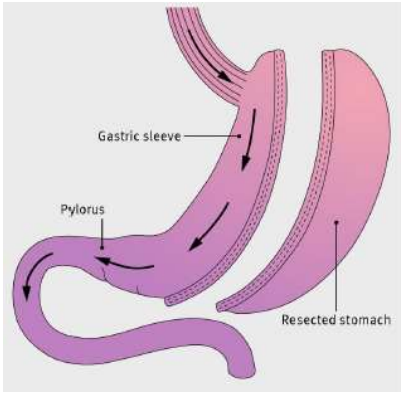
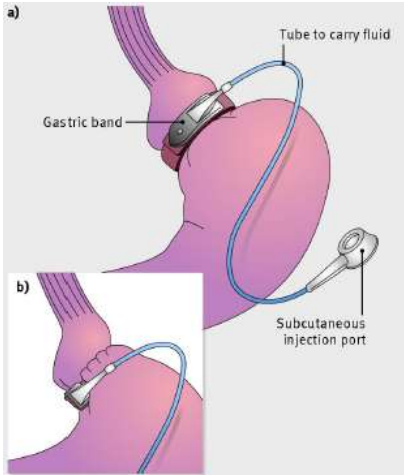
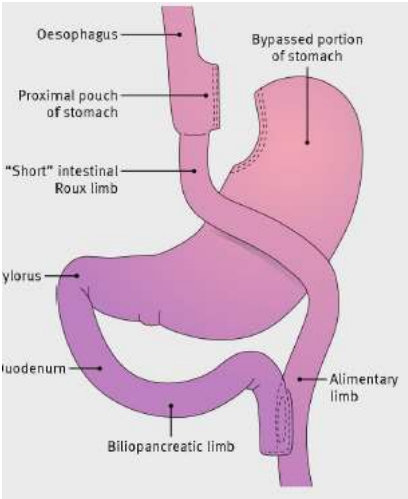
**Revised sample size
n=1351 participants**

Design (primary endpoint @ 3 yrs)
 Non-inferiority weight loss hypothesis
 Superiority hypothesis for QoL
 Sleeve > QoL than Bypass & Band
 Bypass > QoL than Band

Bypass

Band

Sleeve



12 centres

NHS
Musgrove Park Hospital

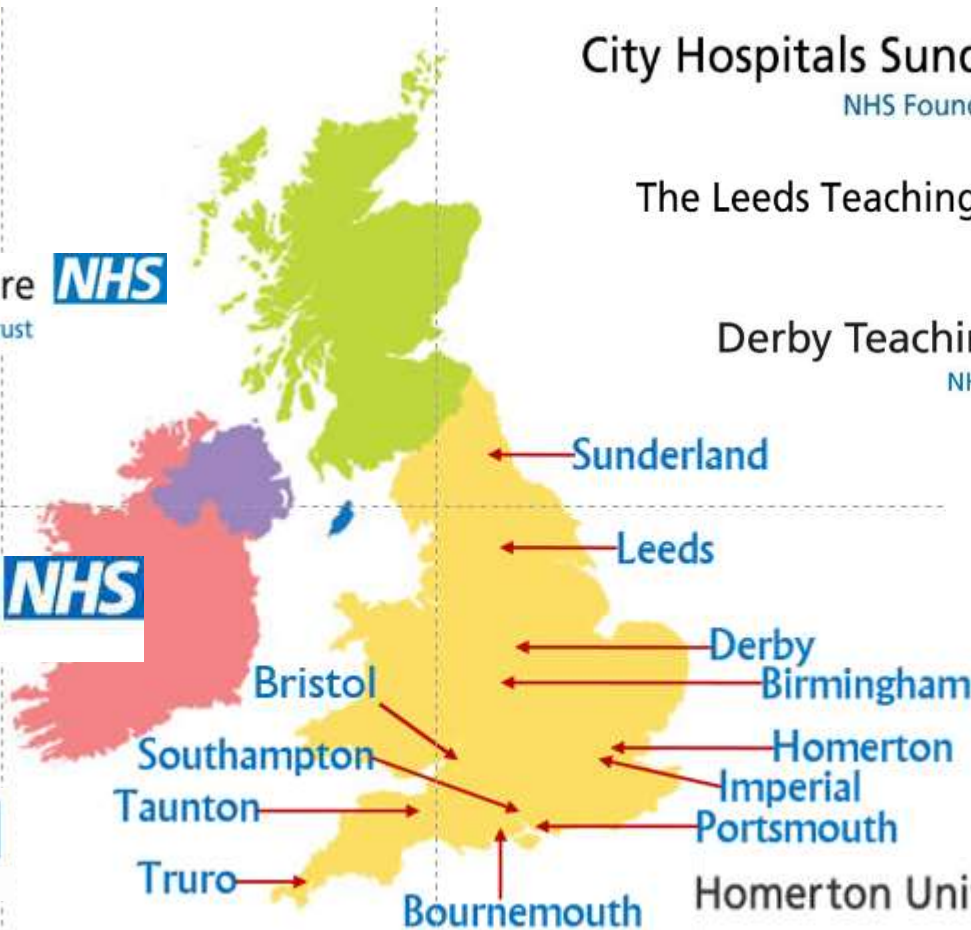
Imperial College Healthcare **NHS**
NHS Trust

NHS
North Bristol
NHS Trust

Portsmouth Hospitals **NHS**
NHS Trust

Royal Cornwall Hospitals **NHS**
NHS Trust

University Hospital Southampton **NHS**
NHS Foundation Trust



City Hospitals Sunderland **NHS**
NHS Foundation Trust

The Leeds Teaching Hospitals **NHS**
NHS Trust

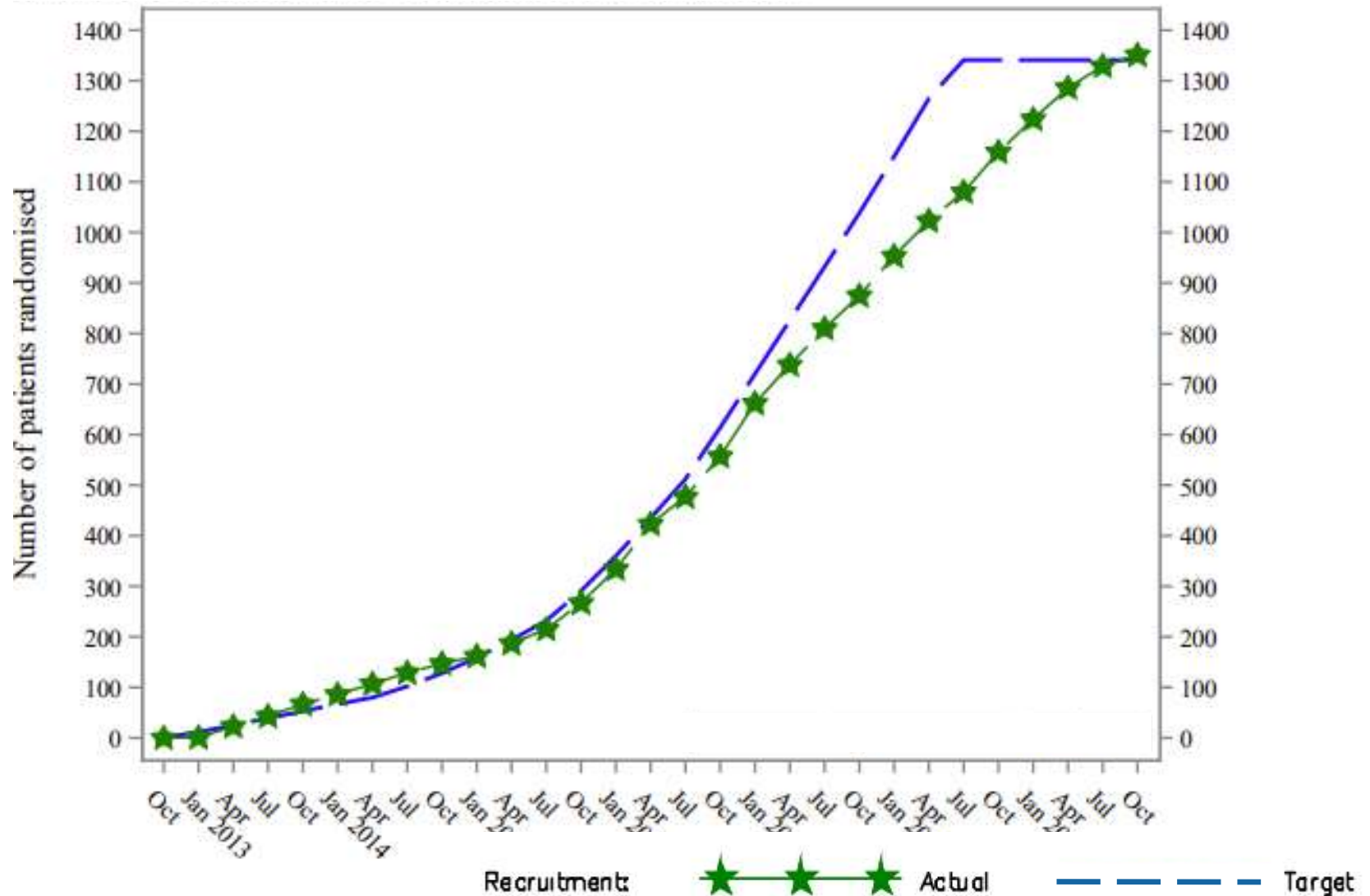
Derby Teaching Hospitals **NHS**
NHS Foundation Trust

HEART of ENGLAND
NHS Foundation Trust

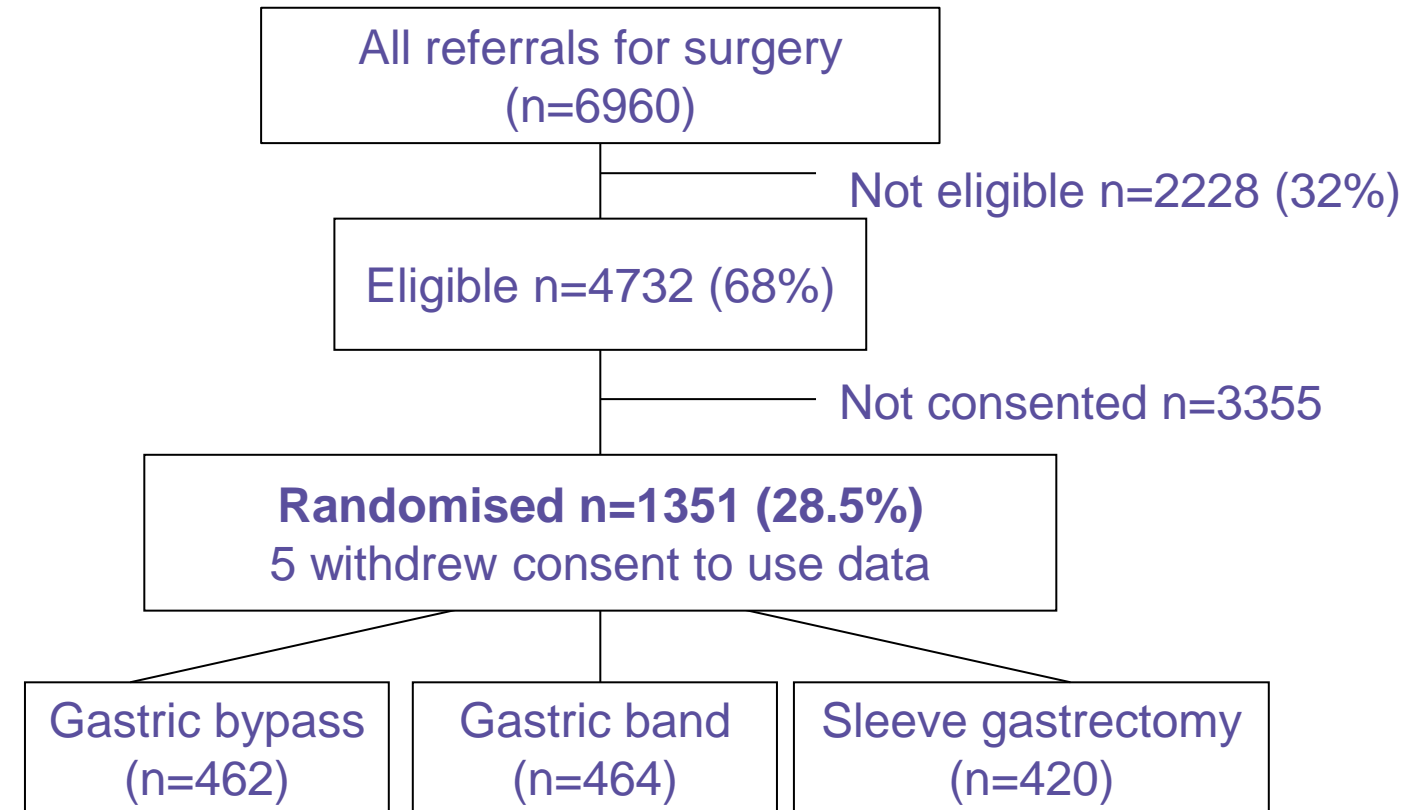
Homerton University Hospital **NHS**
NHS Foundation Trust

The Royal Bournemouth & Christchurch Hospitals **NHS**
NHS Foundation Trust

Recruitment over 6 years n=1351



Flow diagram



Primary endpoint: Data completion @3yrs
QoL n=995 (73.9%), Weight n= 1130 (83.4%)

115 (9.7%) did not receive randomised allocation

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ORIGINAL ARTICLE

Clinical Trials and Investigations



Roux-en-Y gastric bypass, gastric banding, or sleeve gastrectomy for severe obesity: Baseline data from the By-Band-Sleeve randomized controlled trial

By-Band-Sleeve Collaborative Group 

Trial participants have similar characteristics to UK patients being offered bariatric surgery

Results will be generalisable

3 year data

Co-primary endpoints

Proportion loosing 50% excess weight (BMI)

Quality of life: generic measure (EQ-5D)

Secondary endpoints

% total weight loss

Quality of life: disease specific measure (IWQOL-Lite)

Safety

(Health economic outcomes)

Comparisons made between

- i) Bypass and band
- ii) Sleeve and band
- iii) Sleeve and bypass

Treatment differences & confidence intervals

Baseline is time of randomisation

Intention to treat analyses

Weight loss

Weight loss @ 3 years

Proportion achieving 50% excess weight loss

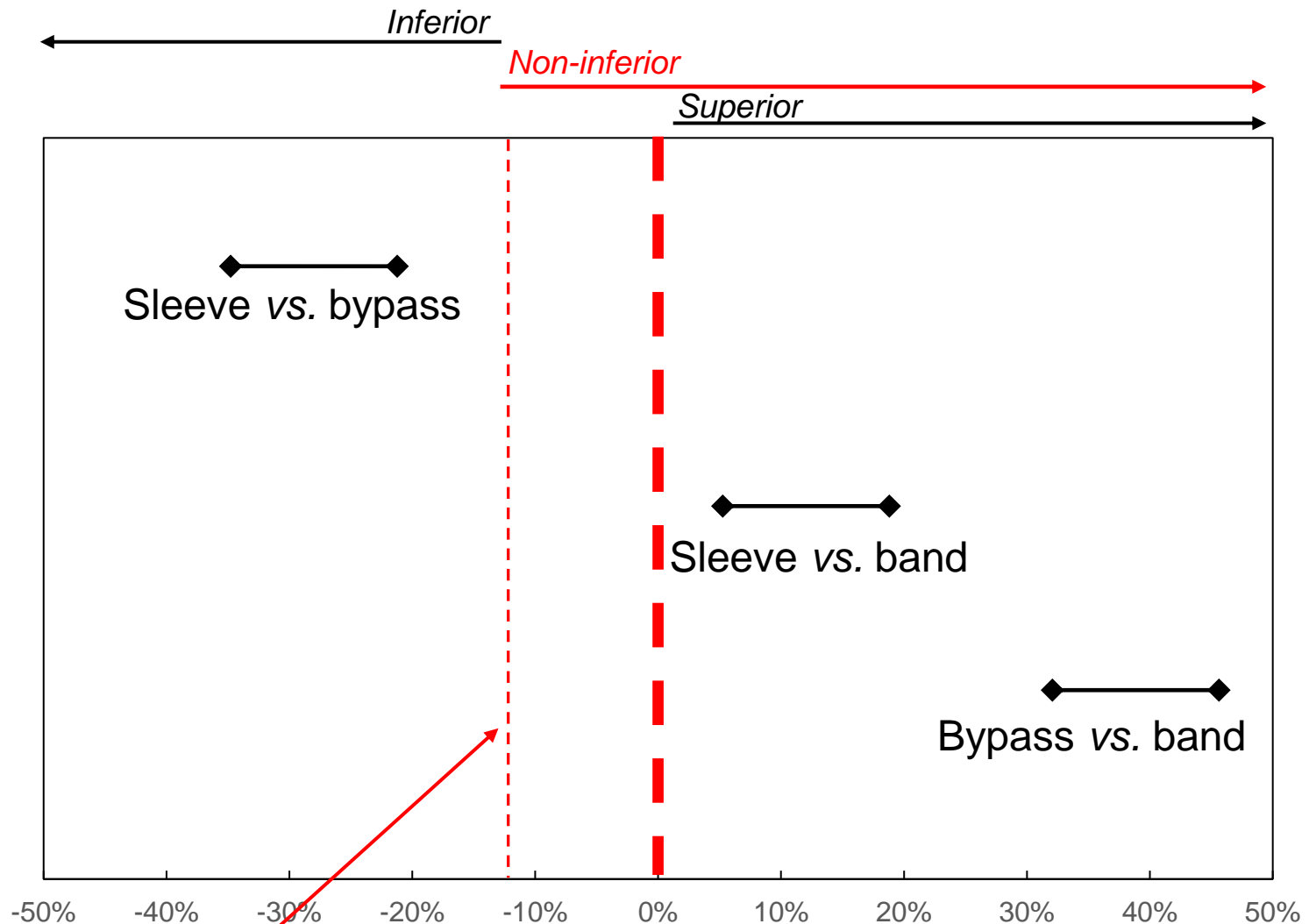
	Bypass	Band	Sleeve
50% excess weight loss	66%	26%	40%

Non-inferiority margin was pre-agreed at 12%

	Comparison	Difference in proportions	98% confidence intervals
50% excess weight loss	Bypass vs. band	41%	34 to 48*
50% excess weight loss	Sleeve vs. band	15%	7 to 22*
50% excess weight loss	Sleeve vs. bypass	-26%	-34 to -18*

* Statistically significant

Interpretation: difference in proportions



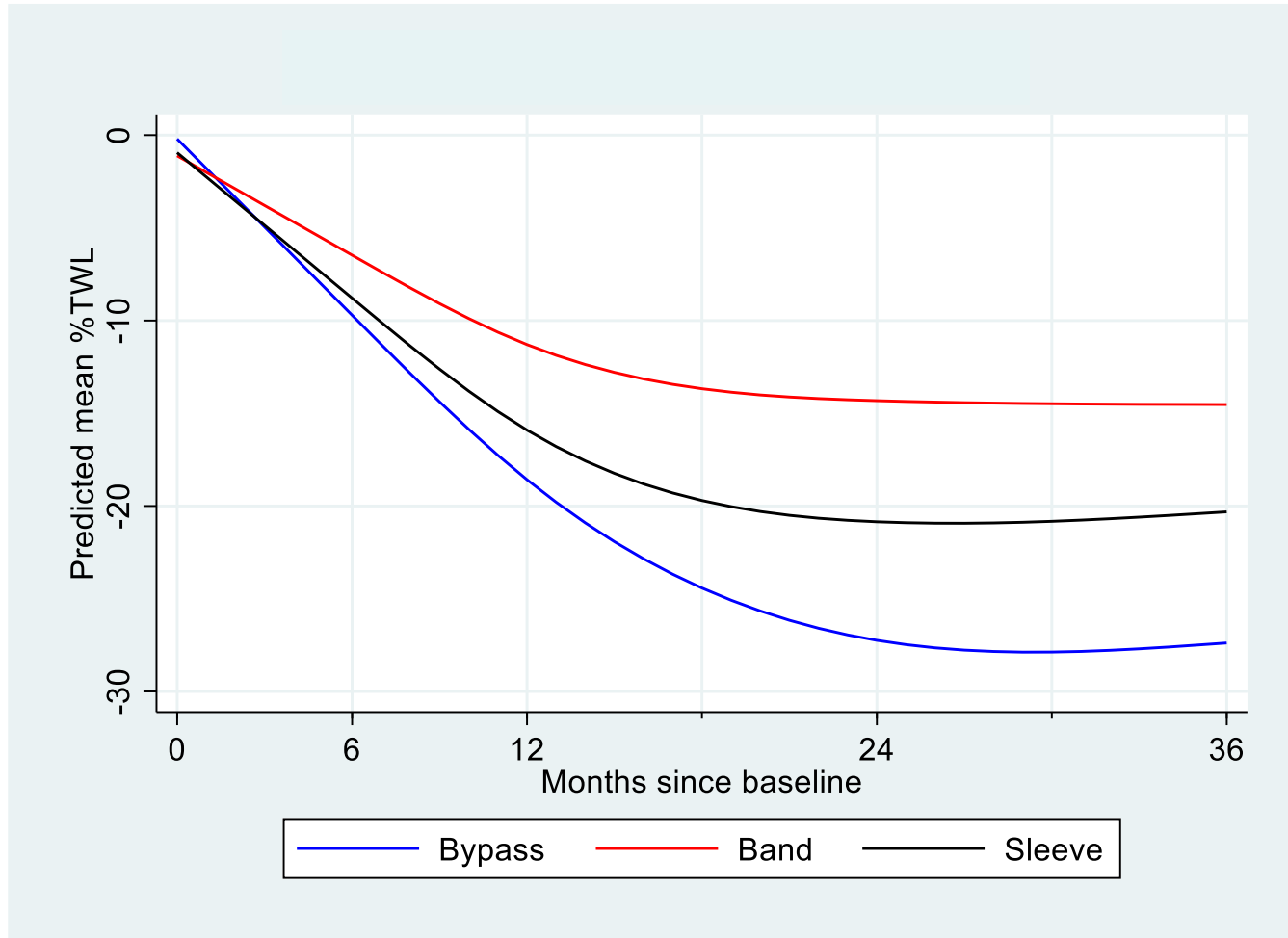
-12% lower margin for non-inferiority

% total weight loss

	Randomised to Bypass	Randomised to Band	Randomised to Sleeve
Mean weight at baseline (kg)	131.4 kg	129.0 kg	128.8 kg
Mean weight at 3 years (kg)	95.4 kg	110.9 kg	102.8 kg
Mean change from baseline	-35.3 kg	-18.3 kg	-25.3 kg
Mean % change from baseline	-26.8%	-14.0%	-20.2%
Adjusted mean % change from baseline *	-27.4%	-14.5%	-20.3%

*Predicted from the regression model

%Total weight loss (TWL)



%TWL @ 3 years

	Mean difference	98% confidence interval
Bypass vs. band	-12.9	-15.3 to -10.4*
Sleeve vs. band	-5.79	-7.70 to -3.87*
Sleeve vs. bypass	7.07	4.27 to 9.87*

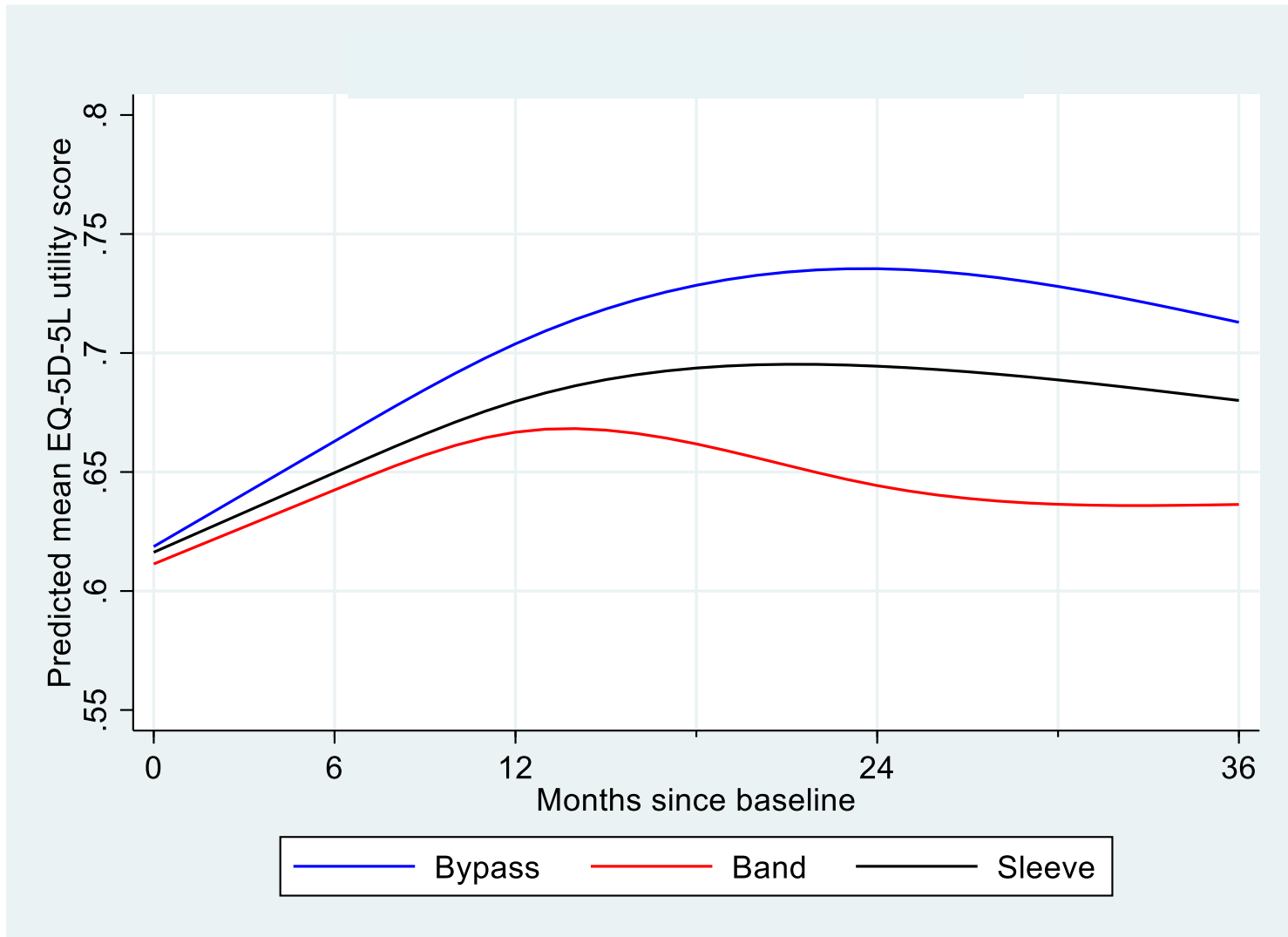
Mean %TWL is 13% greater with bypass compared to band

Mean %TWL is 6% greater with sleeve compared to band

Mean %TWL is 7% less with sleeve compared to bypass

*Statistically significant

QoL (EQ-5D) over time by group



Higher score = better quality of life

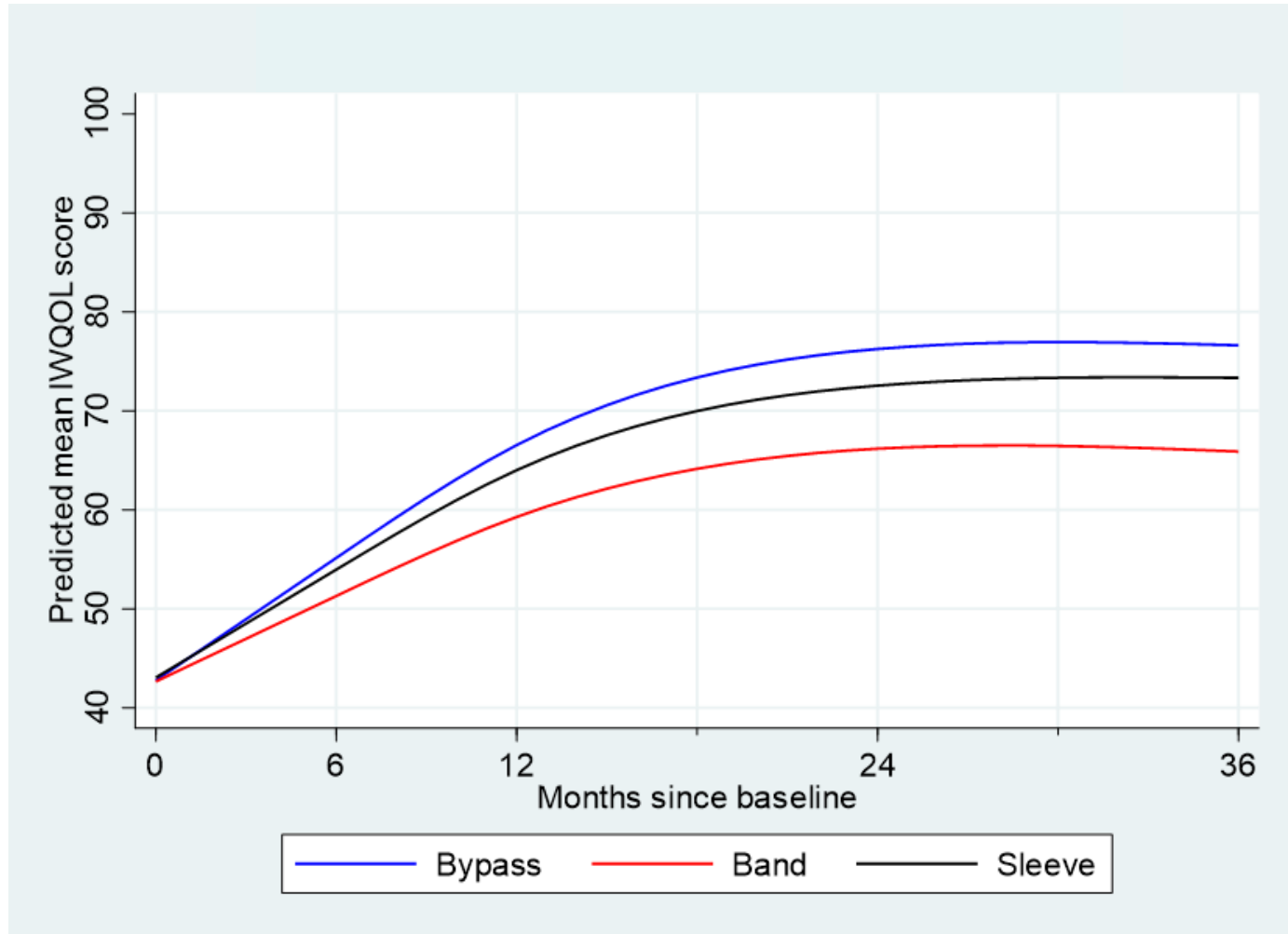
EQ-5D scores at 3 years

	Mean difference	98% confidence interval
Bypass vs. band	0.077*	0.033 to 0.120
Sleeve vs. band	0.044*	0.001 to 0.086
Sleeve vs. bypass	-0.033	-0.073 to 0.007

*Statistically significant

Analyses use data from all time points

Impact of weight on quality of life (IWQoL-Lite)



High score = better quality of life

IWQOL-Lite – overall score

	Mean difference	98% confidence interval
Bypass vs. band	10.73	6.88 to 14.6*
Sleeve vs. band	7.45	3.78 to 11.12*
Sleeve vs. bypass	-3.28	-6.01 to -0.56*

All comparisons are significantly significant

Analysis uses data from all time points

Count of all complications regardless of severity

1. Surgery to 30 days

- Participants who had surgery
- Grouped by surgery received

2. 30 days post surgery to 3 years post randomisation

- Only with participants who had surgery
- Grouped by surgery received

1. Surgery to 30 days

Surgery received	Number of events
Bypass	176
Band	120
Sleeve	181

Surgery received	Adjusted rate ratio	98% confidence interval
Bypass vs. band	1.39	0.91 to 2.12
Sleeve vs. band	1.28	0.82 to 1.97
Sleeve vs. bypass	0.92	0.57 to 1.47

None of the comparisons are statistically significant

2. Surgery to 3 years post randomisation

Surgery received	Number of events
Bypass	406
Band	445
Sleeve	325

Surgery received	Incidence rate ratio	98% confidence interval
Bypass vs. band	0.84	0.59 to 1.18
Sleeve vs. band	0.64	0.46 to 0.88*
Sleeve vs. bypass	0.76	0.58 to 0.99*

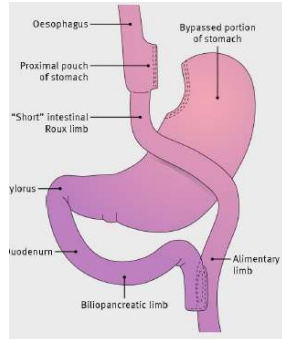
*Sleeve significantly lower number of events than band and bypass

Complications requiring surgery/drain

	Bypass n=393	Band n = 363	Sleeve n=434
Intra-abdominal haematoma	1	0	3
Internal hernia	15	0	0
Small bowel obstruction	4	0	0
Re-do J-J anastomosis	1	0	0
Re-do G-J anastomosis	3	0	0
Sleeve fistula	0	0	3
Leak from Band sutures	0	1	0
Corrective surgery for Band	0	16	0
Band removal (not revised)	0	21	0
Revision: Band to bypass	0	10	0
Revision: Band to Sleeve	0	1	0
Revision: Sleeve to bypass	0	4	4
Death < 3 years (by allocation)	2	4	1

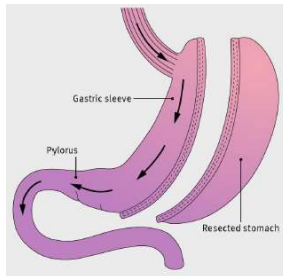
Headlines

1.



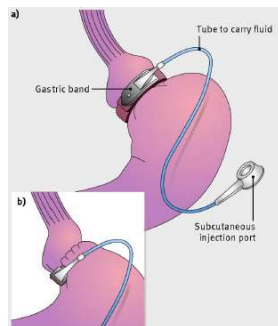
Gastric bypass more clinically effective than sleeve gastrectomy and gastric band

2.



Sleeve gastrectomy more clinically effective than gastric band

3.



Implications

1. High quality evidence can be built by working together.



2. BBS evidence will dominate over data from other RCTs
3. New procedures need RCT evaluation before widespread uptake
4. What is the future of sleeve gastrectomy?

More results **JOINT IFSO-EC and YOUNG IFSO WEBINAR 28 September 2023.**

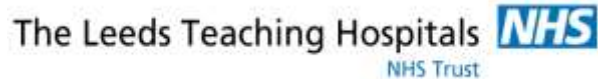
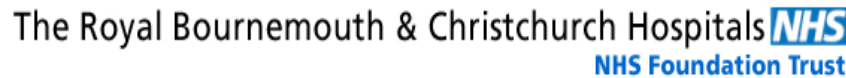
Long term follow up

A photograph of a dirt path leading through a dense forest of green trees. The path is in the center, leading away from the viewer into the distance. The trees are lush and green, creating a canopy overhead. The ground is covered in grass and some small yellow flowers.

Are differences maintained

Complications

Patient experience



By-Band-Sleeve is funded by the UK NIHR HTA programme (09/127/53). The opinions expressed are those of the authors & do not necessarily reflect those of the HTA programme, the NIHR, the UK NHS or the Department of Health & Social care