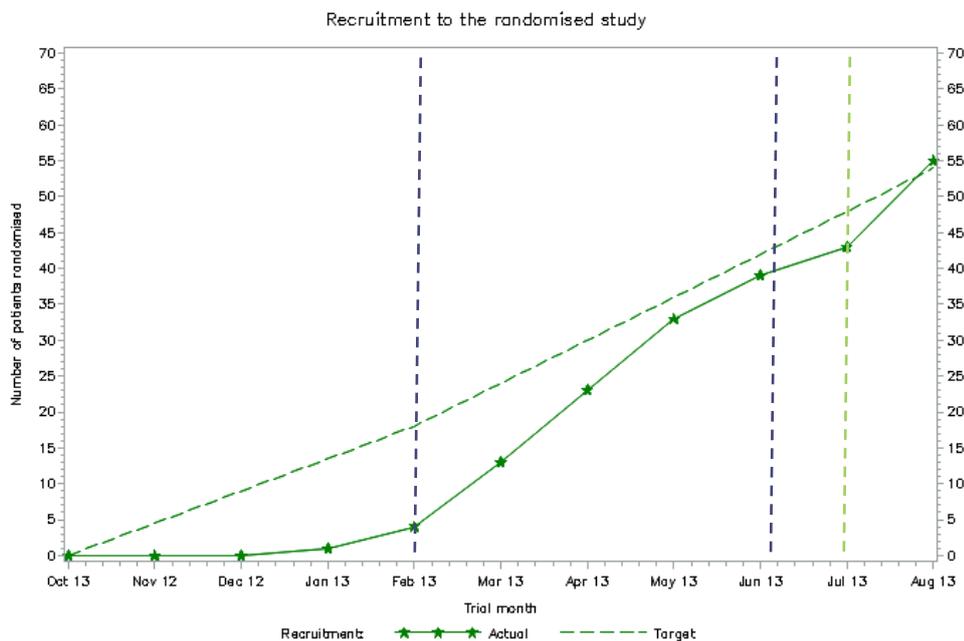


Recruitment to the By-Band study is underway!

The By-Band study, which will compare the effectiveness, cost-effectiveness and acceptability of Band versus Bypass surgery for the treatment of complex obesity, has now recruited 55 patients. The figure below shows the target recruitment (dashed line) and thanks to the fantastic efforts from staff at Musgrove Park Hospital (Taunton), Southampton General Hospital and the Southampton Spire we are almost meeting our targets for the number of patients randomised! The timing of feedback meetings from the qualitative research team are shown by the vertical lines for Taunton (purple) and Southampton (green).



- * 55 patients randomised
- * 19 patients have had surgery

The key to successful recruitment

Recruitment at Taunton took a significant upturn after the first feedback session from the qualitative research team led by Professor Jenny Donovan. All consultations between surgeons and patients were audio-recorded and the feedback was based on analyses of the consultation data. There was



individual confidential and supportive feedback and group feedback. Regular feedback sessions are planned throughout the whole study, which we are hoping will help us to keep recruitment levels high!



“ We really do need to know where we should be spending our money, what we should be doing. ”

By-Band surgeon

A core benefit and adverse event set for bariatric surgery - the Bariact sub-study



Background

Evaluation of benefits and adverse events after bariatric surgery requires outcomes that are consistently reported to improve cross-study comparisons, data synthesis and clinical decision-making. We are aiming to develop a core outcome set (set of endpoints reported as a minimum in all studies) for this purpose.

A systematic literature review and an evaluation of the National Bariatric Surgery Register (NBSR) identified all verbatim outcomes and outcome definitions. The individual verbatim outcomes were classified into outcome domains (broad aspects of health measured to assess the effects of an intervention) by independent reviewers. A detailed analysis of adverse event reporting, further classified definitions.

Initial results

Sixty-six studies (18 randomised, 48 non-randomised) identified 1073 verbatim outcomes and a further 21 were in the NBSR. Some 912 verbatim outcomes were reported only once. Outcomes were categorised into domains:

- ❖ surgical adverse events (n=357)
- ❖ obesity-related disease (n=267)
- ❖ anthropometry (n=117)
- ❖ mortality (n=30)
- ❖ haematological or biochemical markers (n=80)
- ❖ treatment pathway outcomes (n=75)
- ❖ observer assessment of symptoms & function (n=65)
- ❖ peri-operative clinical outcomes (n=45)

The next step is to use this information to survey bariatric surgeons to gain opinions about which outcomes reported should be part of the core outcome set – watch this space, we will be in touch.

Phase 2 of By-Band

By-Band is designed in two parts; Phase 1 is being undertaken in two centres to optimise methods for trial recruitment. The second part (Phase 2) will expand the study into more centres. We envisage this beginning in 2014 and therefore we are keen to hear from centres willing to participate. New centres will join the By-Band team and receive funding to support and optimise trial recruitment and conduct. Participating in By-Band will also provide the opportunity to learn more about clinical effectiveness research, core outcome sets and experience multi-disciplinary collaborative research—something not to be missed! Please contact Jane Blazeby if you are interested (j.m.blazeby@bristol.ac.uk)



By-Band Trial Steering Committee, June 2013
 From left to right: Miss Sally Norton, Prof. Joanna Coast, Prof. Jane Blazeby, Dr. Chris Rogers, Prof. John Dixon, Mr. Richard Welbourn, Prof. Michel Suter, Dr. Graziella Mazza, Dr. Charlotte McCaie.

The Bristol Clinical Trials and Evaluation Unit (CTEU) is responsible for the overall management of the study (coordinator Dr Graziella Mazza, by-band@bristol.ac.uk). Chief investigator is Jane Blazeby, Professor of Surgery at the University of Bristol. The study is funded by the NIHR Health Technology Assessment programme.

Word Search

- ❖ Eligible
- ❖ Surgery
- ❖ Obesity
- ❖ Research
- ❖ Band
- ❖ Bypass
- ❖ Weight
- ❖ Bariatric
- ❖ Gastric
- ❖ Data

B	T	D	N	A	B	I	E	O	T
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I	N	O	E	G	H	P	T	T	R
C	S	U	R	G	E	R	Y	Y	L
H	C	R	A	E	S	E	R	R	O

@ByBandStudy

Email: by-band@bristol.ac.uk