

UK BRAVE consortium (initial)

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** St. Mary's Hospital
Imperial College London UK

**** Radcliffe Dept Medicine
Oxford University UK

3 centres actively interested so far

UK BRAVE consortium

Funding strategy:

Application to UK NIHR

Typically 2 years from application to opening

- Likely need for feasibility study to teach equipoise / recruiting skills in perhaps 3 initial centres before get major grant
- Rollout to other centres once ability to recruit demonstrated to funder's satisfaction
- Inclusion criteria a 'copy and paste' of typical cardiology clinics eg 20 patients per month per centre
- Recruitment target?
- Time to primary endpoints?

Challenges to recruitment to RCTs

Patient bias
Peer pressure
Internet influence

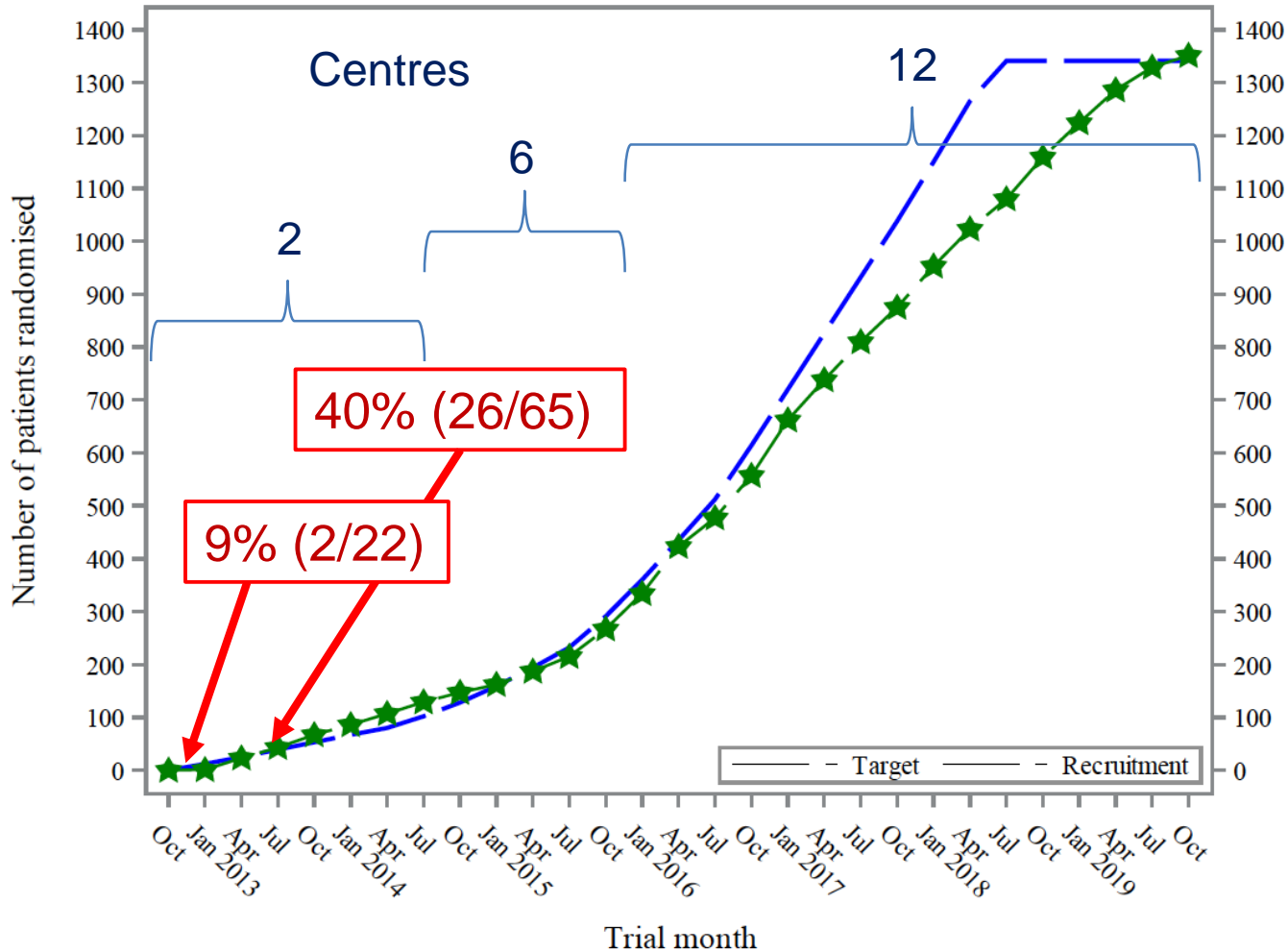


Team preference
Surgeon expertise
Surgeon bias



Recruitment to By-Band-Sleeve RCT

Figure 1. Recruitment to the randomised trial against target



18 months feasibility study

1,351 recruited, target = 1,341

Recruitment rate = 29% of eligible patients

Welbourn R et al. Obesity (In Press) Roux-en-Y gastric bypass, gastric banding or sleeve gastrectomy for severe obesity: baseline data from the By-Band-Sleeve RCT

Social Sciences and
Health 

Medical Anthropology

**Qualitative Research Integrated
within Trials (QuinteT)**

↳ People

↳ Publications

↳ The Integrated QRI (for RCTs
that anticipate recruitment
challenges)↳ The QRI-Two (for RCTs
underway with enrolment
shortfalls)

↳ QRI-informed Recruiter Training

↳ Collaborations

Qualitative Research Integrated within Trials (QuinteT)

<https://www.bristol.ac.uk/population-health-sciences/research/groups/social-sciences-health/quinte/>



The QuinteT team of researchers pioneer qualitative approaches to optimise recruitment and informed consent to randomised controlled trials (RCTs).

QuinteT Recruitment Intervention in practice

QuinteT = Qualitative research integrated in Trials

QRI = Quintet Recruitment Intervention

By-Band-Sleeve example recruitment:

Before Quintet = 9% (2/22) in first 2 months

After Quintet = 40% (26/65) in next 4 months

Methodology = assess and recommend:

Audio recordings of recruitment interviews: ‘targeted conversation analysis’ / clinics reorganised / surgeons taught how to deliver equipoise / remove bias / undo prejudice / learn to clear obstacles and remove hidden challenges

ORIGINAL ARTICLE

Enabling recruitment success in bariatric surgical trials: pilot phase of the By-Band-Sleeve study

S Paramasivan¹, CA Rogers², R Welbourn³, JP Byrne⁴, N Salter³, D Mahon³, H Noble³, J Kelly⁴, G Mazza², P Whybrow¹, RC Andrews³, C Wilson¹, JM Blazeby¹ and JL Donovan^{1,5} on behalf of the By-Band-Sleeve TMG⁶

Conclusion:

“The QRI identified issues that enabled the clinical integration of the trial. This contributed to successful recruitment and offers opportunities to optimize recruitment in other trials in bariatrics.”

“I’m a genuine believer in the principle that [intervention 1] might be as good as [intervention 2] and therefore I’m a strong supporter of the basis of this trial ... But it’s been a nightmare, frankly ... I love this trial. I think it’s beautifully designed, I think it is extremely clever, which fits [name of CI] who is extremely clever ... But, I honestly have never had as many problems with recruiting to a trial in all my born days.”

Donovan et al. *Trials* 2014, 15:5

<http://www.trialsjournal.com/content/15/1/5>

Top recruiting tips:

- a) Don't apologize for doing the trial! eg
 - “Well we're doing this trial and if you'd like to take part, well that's up to you”
- b) Learn and use phrases that put the patient into equipoise eg
 - “Keep an open mind”
 - “We don't know which is the best treatment”
 - “It sounds like you'll do very well with any of the procedures”
- c) Call it a 'study' not a 'trial'!
- d) Do mention the study early in the consultation
- e) Don't pressurize “keep an open mind, our research nurse will chat through it all with you next time”

'Difficult to recruit to' RCTs:

RESEARCH

Open Access



Optimising recruitment and informed consent in randomised controlled trials: the development and implementation of the Quintet Recruitment Intervention (QRI)

Jenny L. Donovan^{1,2*}, Leila Rooshenas¹, Marcus Jepson¹, Daisy Elliott¹, Julia Wade¹, Kerry Avery¹, Nicola Mills¹, Caroline Wilson¹, Sangeetha Paramasivan¹ and Jane M. Blazeby¹

“QRI provides a flexible way of understanding recruitment difficulties... can facilitate recruitment to controversial RCTs... are likely to be of interest [both] for ‘difficult’ RCTs with lower than expected recruitment and to the funding bodies”

Donovan et al. *Trials* (2016) 17:283
DOI 10.1186/s13063-016-1391-4