

# The success of blinding in surgical trials

Dr Caroline Boulind



An NIHR Research for Patient  
Benefit funded Programme



Avery K; Savovic J; Metcalfe C; Francis NK; Blazeby JM

# Blinding



## Aim

To explore a method for testing the success of blinding in a feasibility RCT in surgery

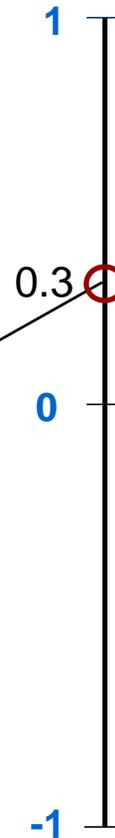


# 🌟 The Bang Blinding Index

## Responses:

Arm A  
Arm B  
Don't Know

0.3 = 30% more than  
expected guess correctly



Unblinded  
100% correct

Null – fully blinded

? Unblinded  
100% incorrect

# The Bang Blinding Index

Which sort of pain relief do you think you received?

Epidural

Wound infusion

Don't know

Why do you think this?

.....

.....

.....

**If you answered don't know;**

Please guess which one you think you received

Epidural

Wound infusion

Thank you for your help



# 🌿 Qualitative Interviews

- Blinded Interviewer
- Semi-structured schedule
- Reasons for guess
- Views about blinding
- Reliability of blinding index

*Savage Chickens*

by Doug Savage



[www.savagechickens.com](http://www.savagechickens.com)

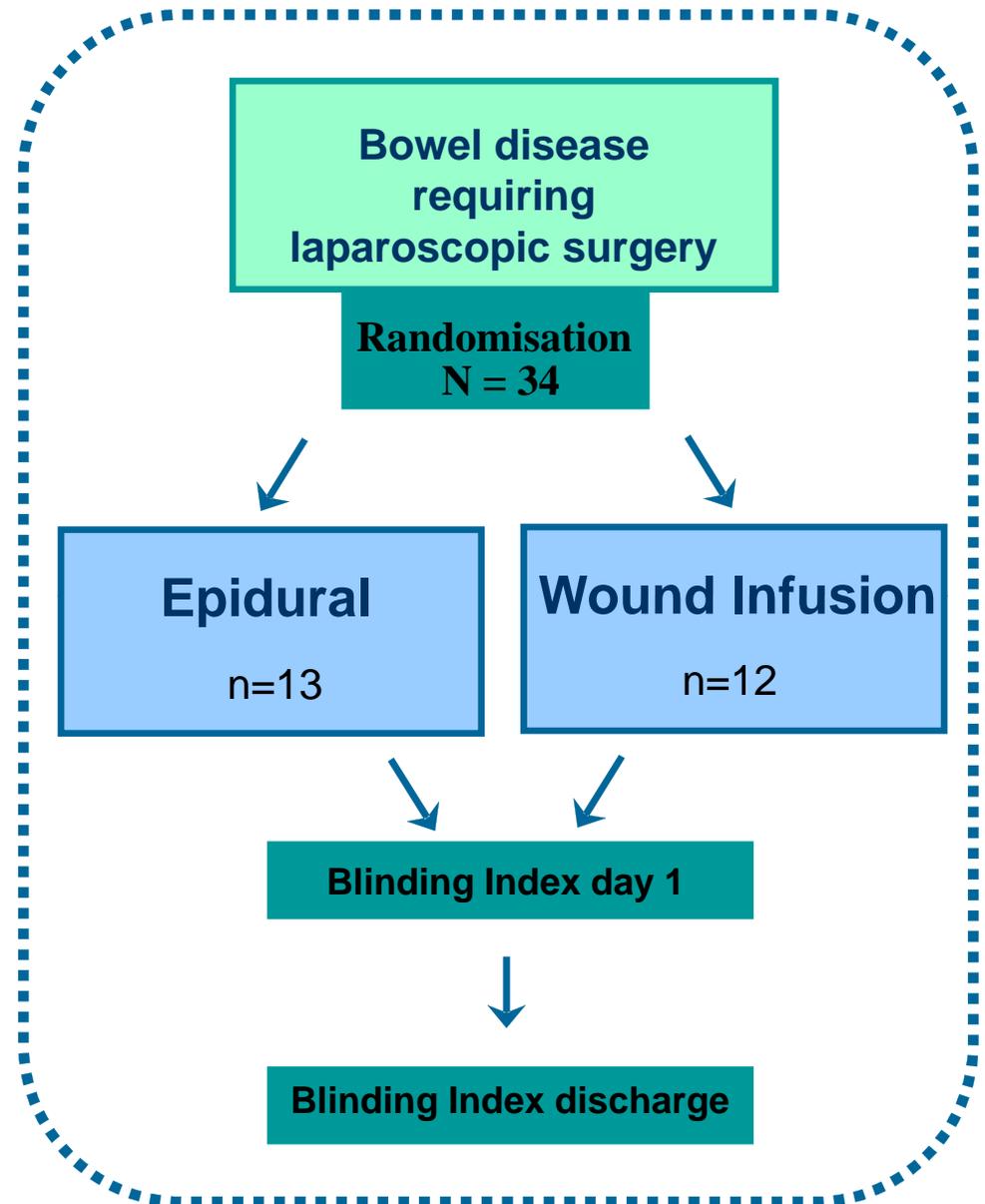
# 🌿 Methods

- **Responses:**

Epidural  
Wound infusion  
Don't Know

- **Endpoints:**

- Recruitment rate
- Blinding methods
- Outcome measures
- **1° outcome:** patient reported pain



# 🌿 Results - Quantitative

## Original Data

Allocation	Response			
	Epidural	WIC	DK	Total
Epidural	5	3	5	13
WIC	3	6	3	12
Total	8	9	8	25

### Blinding Index

**Epidural: 0.15**

**WIC: 0.25**

**P=0.41**

## 'Forced' guesses

Allocation	Response		
	Epidural	WIC	Total
Epidural	9	4	13
WIC	6	6	12
Total	14	11	25

### Blinding Index

**Epidural: 0.38**

**WIC: 0**

**P=0.43**

# Results - Qualitative

**Wife** I think I know which one you had.

**YE19** You do?

**Wife** Yes, because your legs were dead.

**YE19** Were they?

**Wife** Yes. You don't remember much after the operation.

**YE19** No.

**Wife** But you couldn't move your legs. I think you might have had an epidural.



**YE22** The reason I thought it was [in my tummy], coz when I had a pain, and then all of a sudden something hit in and took the pain away, and that's why I thought it was there like.



## Results - qualitative



**YE20** ...on a few occasions you've asked on one of your sheets to say what I thought I had an because I was getting a bit of numbness in my leg I presumed I was having the epidural. But that doesn't mean to say it was that.

**YE23** I thought it was from my back because I didn't have any aches and pains in my back, but as for anything else, I don't know which was which.



## 🌟 Results – Qualitative



**CB** Were you happy with the idea of not knowing [which treatment you received]?

**YE17** Yes, completely yeah, because then I could guess, coz I could have the thing here and I could guess, you know?

**YE18** I was happy with that. Yes, I was happy with that. I, if something like this eventually results in, you know, things being easier for people, I'm all for that. You know, it's all important.



# 🌿 Results - Qualitative



**YE21** They might have thought I would have worried about it. It didn't worry me.

**YE22** Not really, but erm, I took it from what [the research nurse] was saying and just carried on as she wanted to do it, you know. I was there, for your trial, and that's how it was.

**YE20** ...it was explained to me it was a valid way of doing the trial because you may have a biased view if I knew what pain relief I was getting...



# 🌿 Results - Comparison

## YE23

“I thought it was from my back because I didn’t have any aches and pains in my back, but as for anything else, I don’t know which was which.”

## YE17

“Because I had a little erm, a little [ball at the side of me here, and I felt nothing in my back.”



## From form

No pain in back, but some in tummy (day 1)

Because I felt no pain in my back (discharge)

## From Form

Didn’t feel anything in my back, but had some feeling in tummy (discharge)



# Summary

## Bang Blinding Index

- Simple and reliable
- A simple question is a reliable way to collect data



A test for blinding success is particularly important in surgical trials with a patient reported outcome as the primary endpoint.

# Thank you

This report presents independent research commissioned by the National Institute of Health Research. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health



Funded by the National  
Institute for Health Research



[caroline.boulind@ydh.nhs.uk](mailto:caroline.boulind@ydh.nhs.uk)