

The Bluebelle study: designing trials of relevance to patients, clinicians and the NHS

Jane M Blazeby on behalf of the Bluebelle Study Management Group

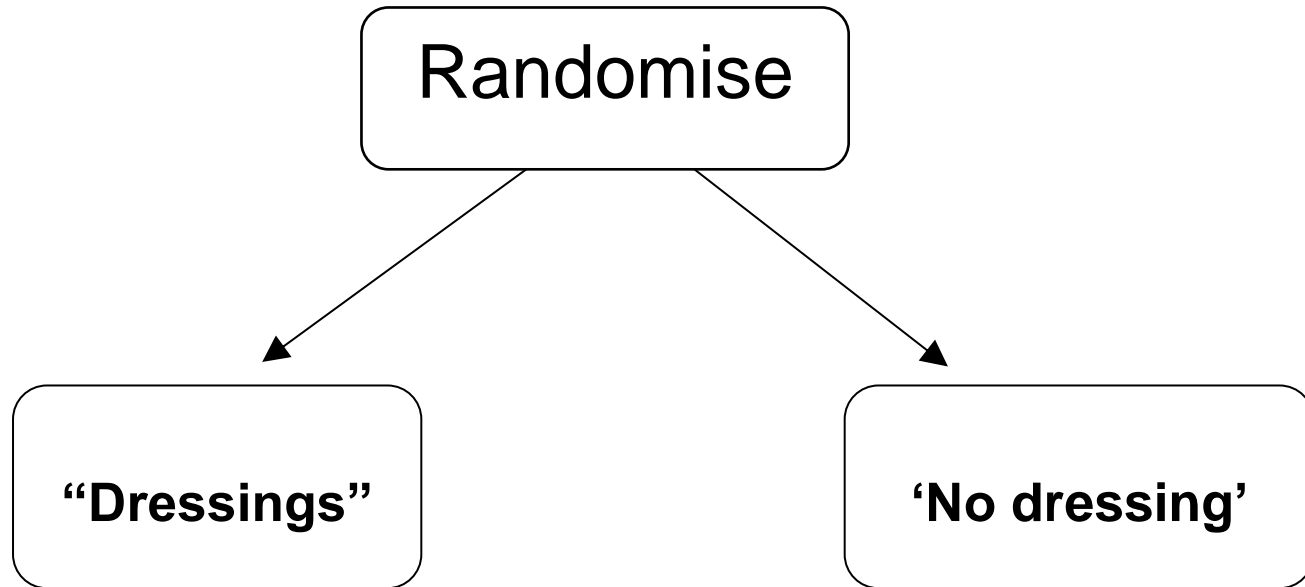


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Winning trial design



Needs loads of feasibility work!



NIHR HTA commissioned call

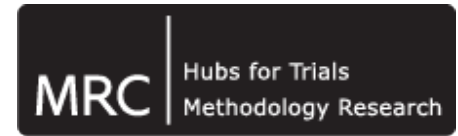
A feasibility study to establish whether a main trial of *'complex'*, *'simple'* or *'absent'* wound dressings is possible



BRISTOL ROYAL HOSPITAL
FOR CHILDREN
Paul O'Gorman Building



University Hospitals Birmingham **NHS**
NHS Foundation Trust



ConDuCT-II Hub

University Hospitals Bristol **NHS**
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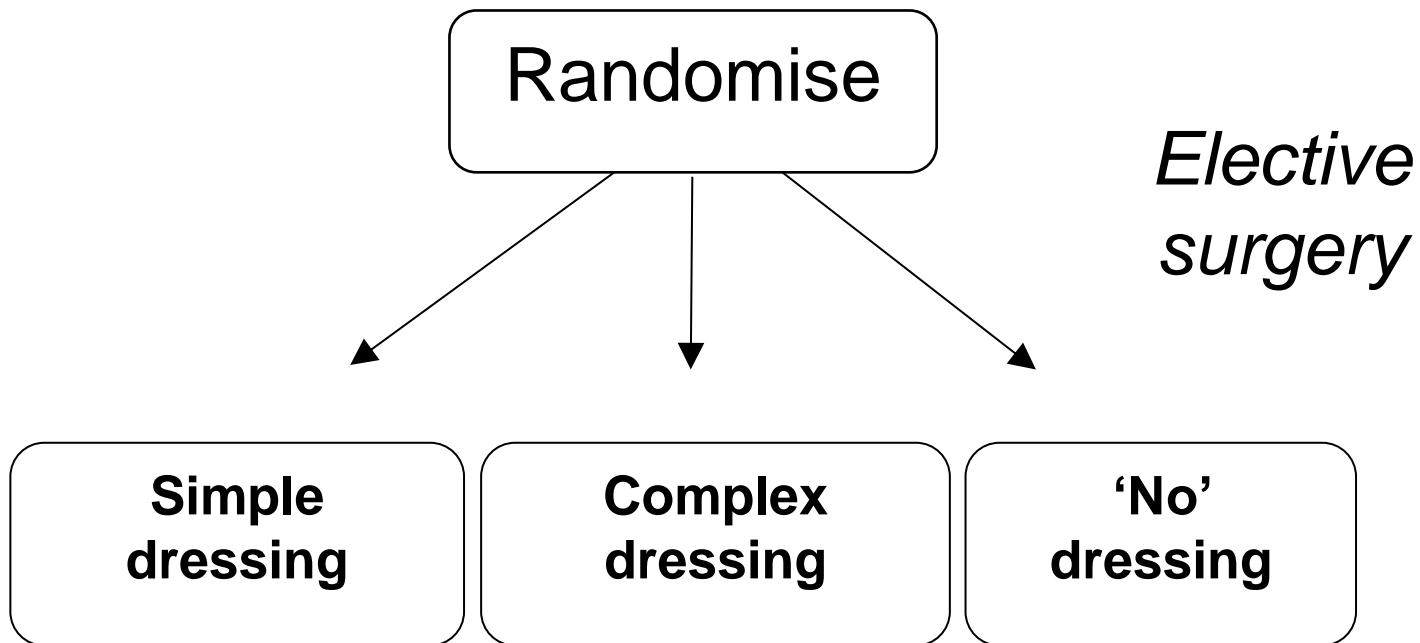


Surgical research nurses

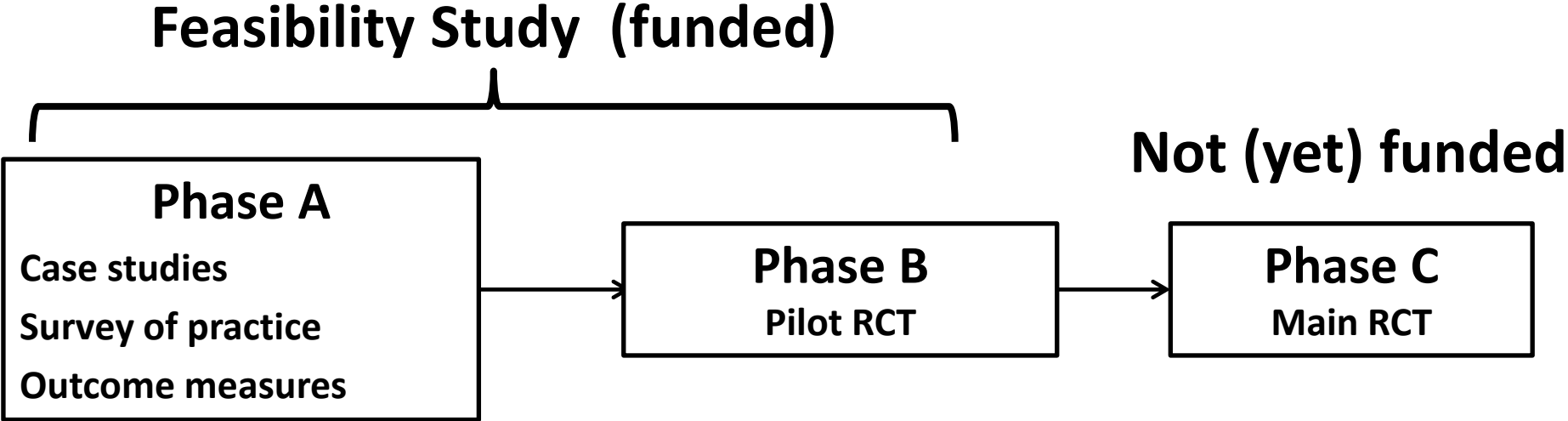
Trainee research collaboratives

Aim of Bluebelle Phases A & B

Is a main RCT possible?



Feasibility study: Phase A & B



Phase A – preliminary work

- Qualitative case studies
- Surveys & literature work
- Development of outcome measures

Qualitative work

A large, solid black silhouette of a person's head in profile, facing left. A hand is shown holding a magnifying glass over the eye area, symbolizing close examination or research.

Case studies to:

Understand current practice

Explore views of stakeholders

Methods/data collection

- 91 interviews - clinicians and patients
- Abdominal, obstetric, paediatric surgery
- University and district hospitals

What is a 'dressing'?

- Inconsistencies in what considered as a 'dressing'



Relevance of 'simple & complex'

Surgeon 1016

I've never heard of the terms [simple and complex] in terms of dressings.



The vast majorityhave got a simple covering over the wound.

Nurse 1002

Type of trial design & 'no dressing'

- ***They did*** engage with 'no dressing' comparison

Because we don't use very many different types of dressings then probably 'dressings' vs. 'no dressings' is simpler and more useful.

Surgeon 2014

The purpose of wound dressings

Dressings used
for practical
reasons

Solutions for
'leaky'
wounds?



Need to consider: If no dressing applied, does this change the quality of surgical skin closure?



Phase A – preliminary work

- Qualitative case studies
- **Surveys & literature work**
- **Development of outcome measures**



Survey of current practice



Newcastle Surgical Research Collaborative

Yorkshire Surgical Research Collaborative



EMSAN



Survey details

- Prospective, in theatre
- 14 days
- Emergency/elective
- Upper/lower GI

21 centres

727 patients

1794 wounds



Survey results

		Patients n = 727 (%)
Sex	Female	375 (52)
Age	<30	118 (16)
	30-50	193 (26)
	51-70	253 (35)
	71+	158 (22)
Diabetes		62 (9)
BMI	<20	50 (7)
	20-25	275 (39)
	26-30	238 (34)
	30+	141 (20)

Survey of dressings: surgery

		Patients n = 727 (%)
Upper gastrointestinal	Oesophagogastric resection	8 (1)
	Pancreaticobiliary resection	11 (2)
	Anti-reflux surgery	10 (1)
	Bariatric surgery	11 (2)
	Cholecystectomy	153 (21)
Lower gastrointestinal		82 (11)
		10 (1)
		40 (6)
	Wound debridement/closure	48 (6)
General	Hernia repair (groin/abdominal wall)	128 (17)
	Appendicectomy	109 (15)
	Diagnostic laparoscopy	20 (3)
	Small bowel procedure	17 (2)
	Other	76 (10)

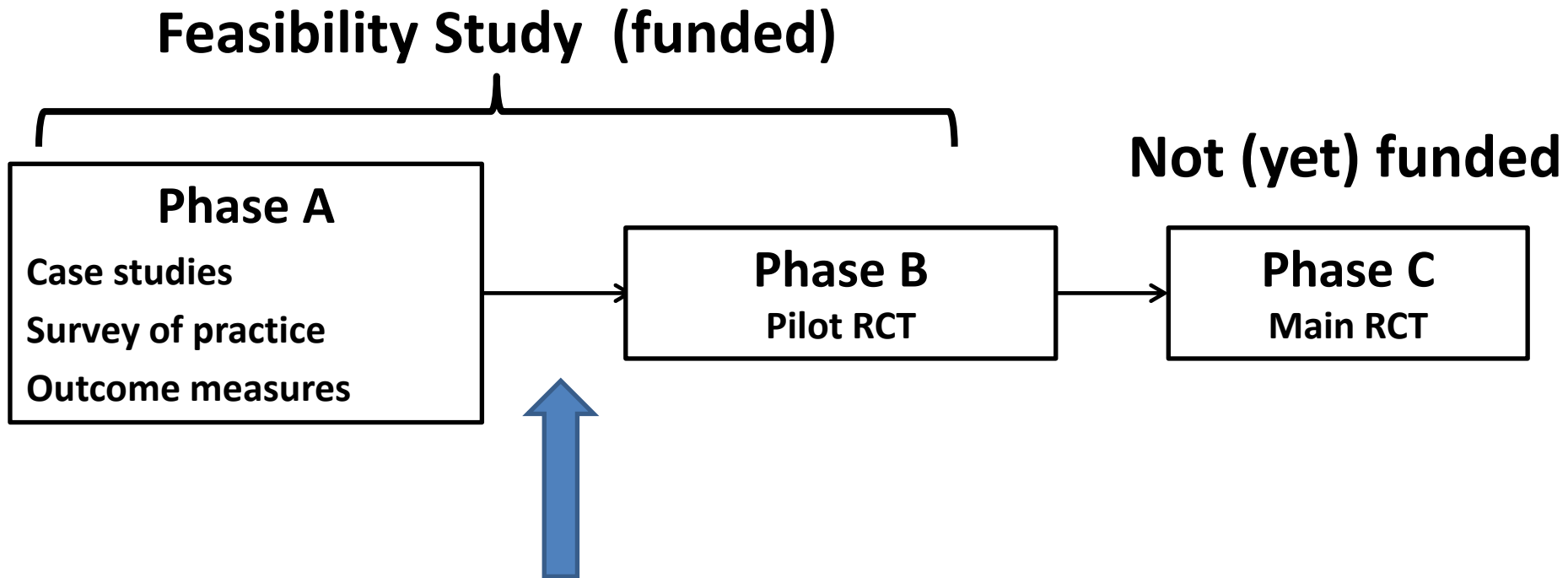
**Elective (70%)
Emergency (30%)**

Survey of dressings: types used

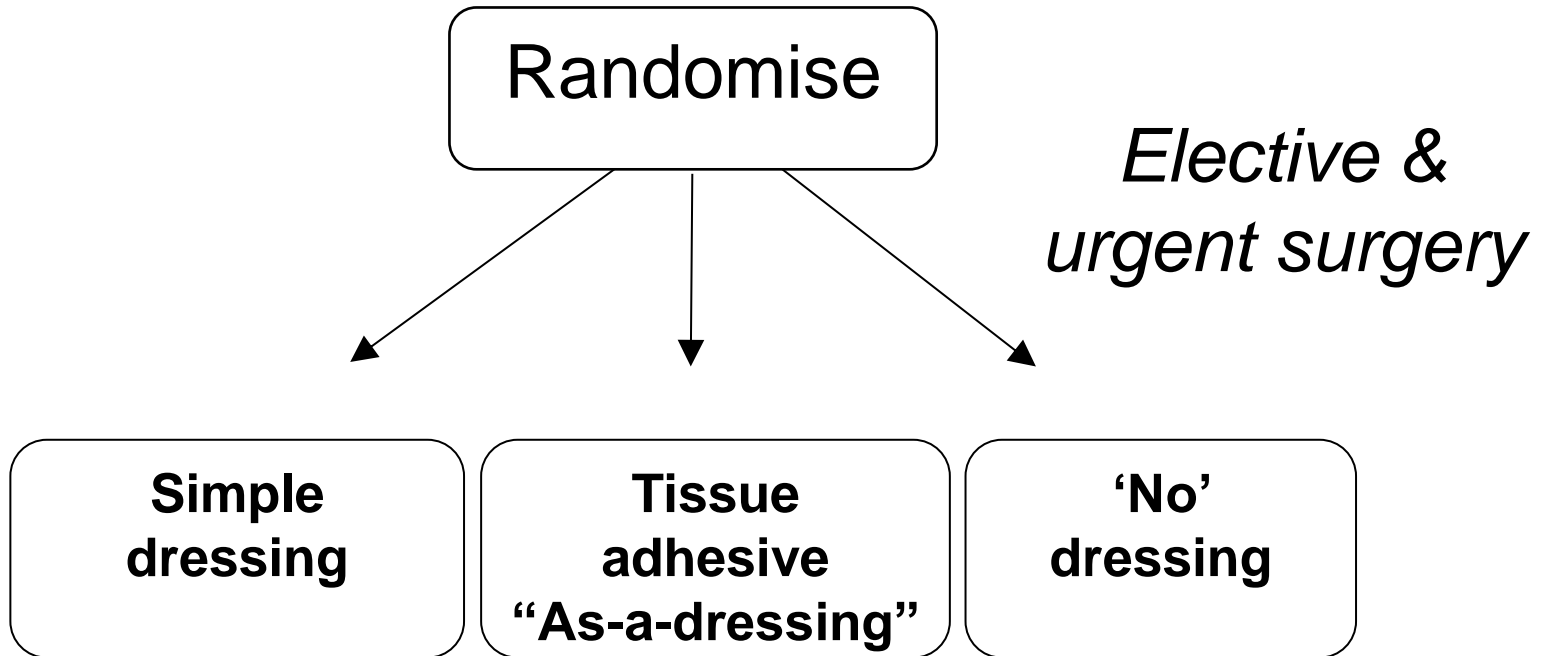
	n = 1794 (%)
Simple	1200 (67)
Advanced/complex	594 (33)
T:	
N	63 (4)

Type of dressing did not vary according to patient or surgical factors

Feasibility study: Phase A & B



New design of Phase B



Where next?

- ❖ Under take the pilot RCT
- ❖ Design main trial
- ❖ Surgical Trials Showcase Day (March 18th)



Bristol Surgical Trials Centre: Surgical Showcase

18 March 2016, 10.00 AM - 18 March 2016, 4.00 PM

Eventbrite



REGISTER

Discover how to get involved in RCTs in surgery. Hear inspirational stories from leading surgeons. Learn to explain clinical equipoise.

The Bristol Surgical Trials Centre Showcase day is for surgeons, allied health professionals and methodologists of all grades and types.

Key note speakers will include [Professor Gianni Angelini](#), [Professor Dion Morton](#), [Miss Adele Francis](#) and more.

