The Royal College of Surgeons of England

British Orthopaedic Association
Caring for Patients; Supporting Surgeons

Orthopaedic Surgical Trials

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THE UNIVERSITY of York

The problem with T&O research

- Most published papers in T&O have methodological flaws
  - Small sample size
  - Large treatment effect
  - Small number of outcome events
- Single centre studies may not recruit to target, with smaller sample size
- Poor impact on clinical practice

Pibouleau L et al BMJ 2009; 339: 4538

BMJ 2014;350:g7835 doi: 10.1136/bmj.g7835 (Published 2 January 2015)

EDITORIALS

The evidence base for orthopaedics and sports medicine

Scandalously poor in parts

L Stefan Lohmander *professor*[1], Ewa M Roos *professor*[2]

T&O paradigm shift - UK strategy

- New BOA research strategy
- Focus on muti-centre clinical trials
  - Generate high quality primary evidence
  - Answer key research questions in T&O
- Commission support for study development
- Collaboration rather than competition
- Link with RCSE Clinical Trials Initiative

Address four main areas:

- Culture
- Infrastructure
- Research Priorities
- Engagement with stakeholders

Infrastructure

- Clinical research networks
  - Specialist Societies
  - **Trainee research networks**
  - Link with NIHR CRN

NHS
National Institute for Health Research
Clinical Research Network
North East and North Cumbria

- BOSRC at York

Levels of research competence

- **Level 1** – Understanding of regulatory framework and conduct of clinical research
- **Level 2** – Formal certification of competence in clinical research methods
- **Level 3** – Higher degrees, training of future CIs and research leaders

JCST
Joint Committee on Surgical Training

Research - evidence of an understanding of, and participation in, research as defined by the specialty	Trainees should undertake research during training and provide evidence recorded on the ISCP of a minimum of: **Either** • Author of two peer reviewed publications from research (or instructional notes or literature review) performed during training (ST3 onwards) in print or accepted for publication at the time of award of CCT**. **Or** • Evidence of the screening/recruitment of 5 patients to an REC approved study. **And:** • Completion of a Good Clinical Practice course in Research Governance within 3 years of award of CCT. • Evidence of critical analysis of publications (i.e. journal club activity). • Author of two presentations (podium or poster) at national meetings from research performed during the period of training (ST3 onwards)**. ** Authorship should be according to "Guidelines on authorship: International Committee of Medical Journal Editors" BMJ p722 Vol 291 Sept 1985.

Result - Increasing number of portfolio trials

UK Rotator Cuff Surgery Trial
UKUFF

UK Heel Fracture Trial

PROFHER

UK FROST
Frozen Shoulder Trial

TARVA
RANDOMISED CLINICAL TRIAL

aim Ankle Injury Management

DRAFFT
Distal Radius Acute Fracture Fixation Trial

CSAW
CAN SHOULDER ARTHROSCOPY WORK?

FixDT
UK Fixation of Distal Tibia Fractures

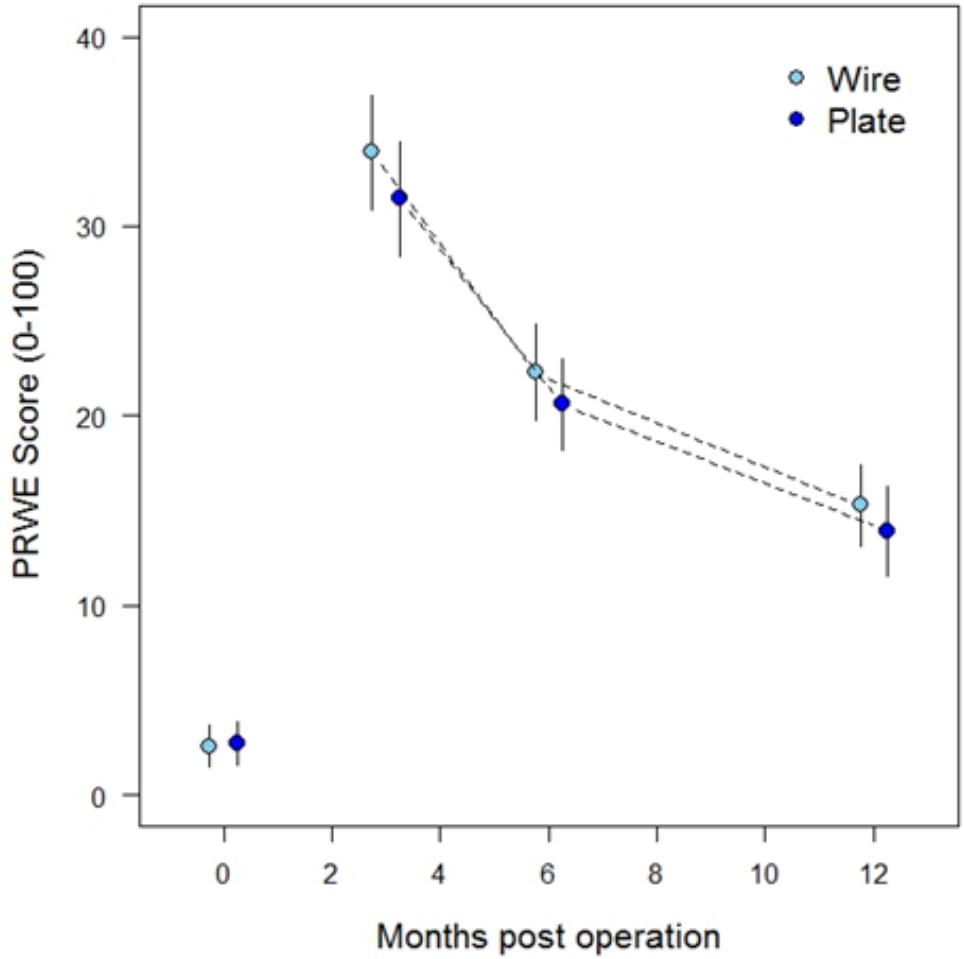
SWIFFT
Scaphoid Waist Internal Fixation for Fractures Trial

The trial....

DRAFFT
Distal Radius Acute Fracture Fixation Trial

VS

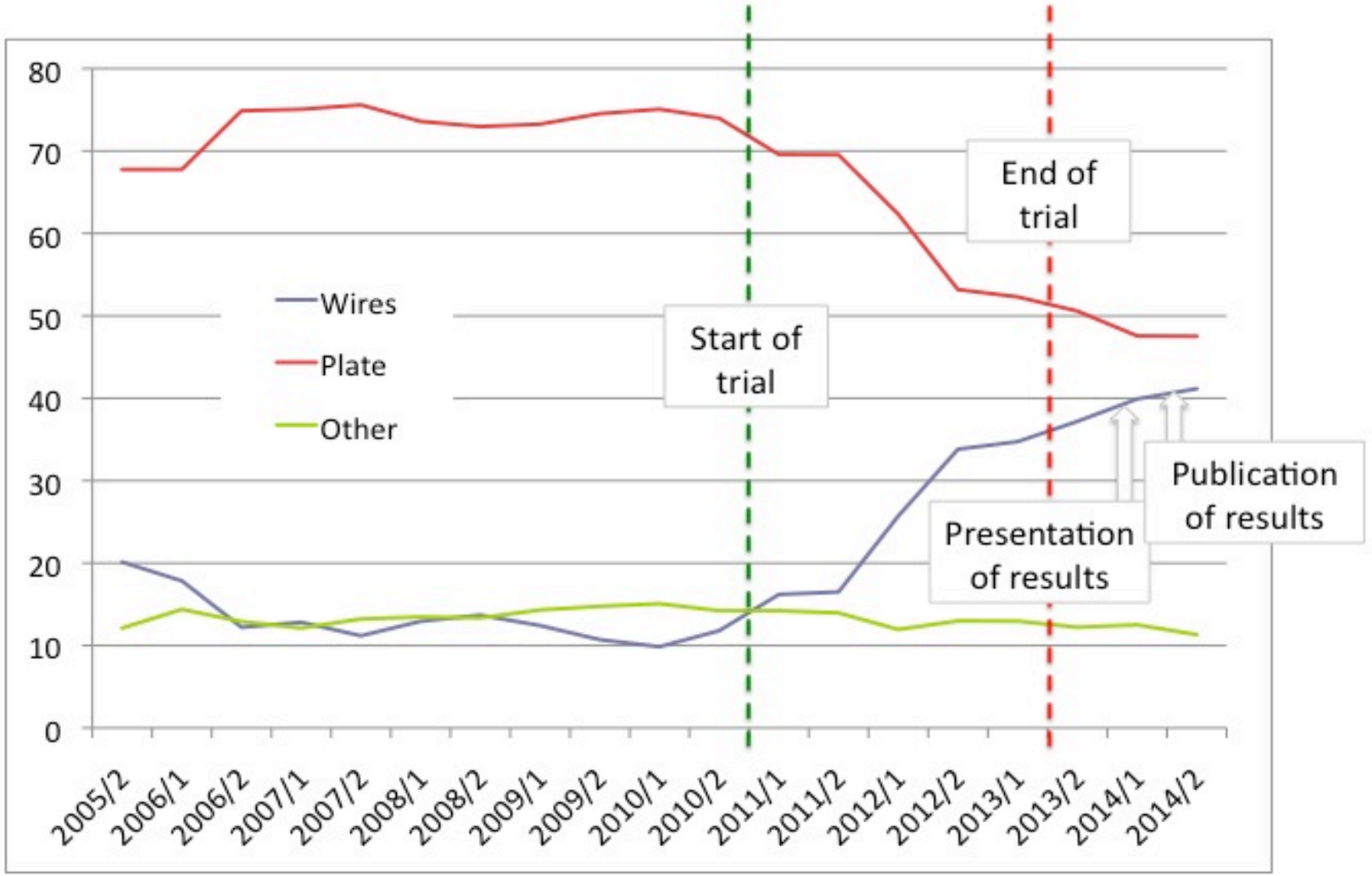
Patient-rated wrist evaluation



DRAFFT: “Percutaneous fixation with Kirschner wires versus volar locking plate fixation in adults with dorsally displaced fracture of distal radius: randomised controlled trial”

– Matt Costa, Juul Achten, ….Amar Rangan.. et al

DRAFFT
Distal Radius Acute Fracture Fixation Trial


80
70
60
50
40
30
20
10
0
Wires
Plate
Other
Start of trial
End of trial
Presentation of results
Publication of results
2005/2
2006/1
2006/2
2007/1
2007/2
2008/1
2008/2
2009/1
2009/2
2010/1
2010/2
2011/1
2011/2
2012/1
2012/2
2013/1
2013/2
2014/1
2014/2

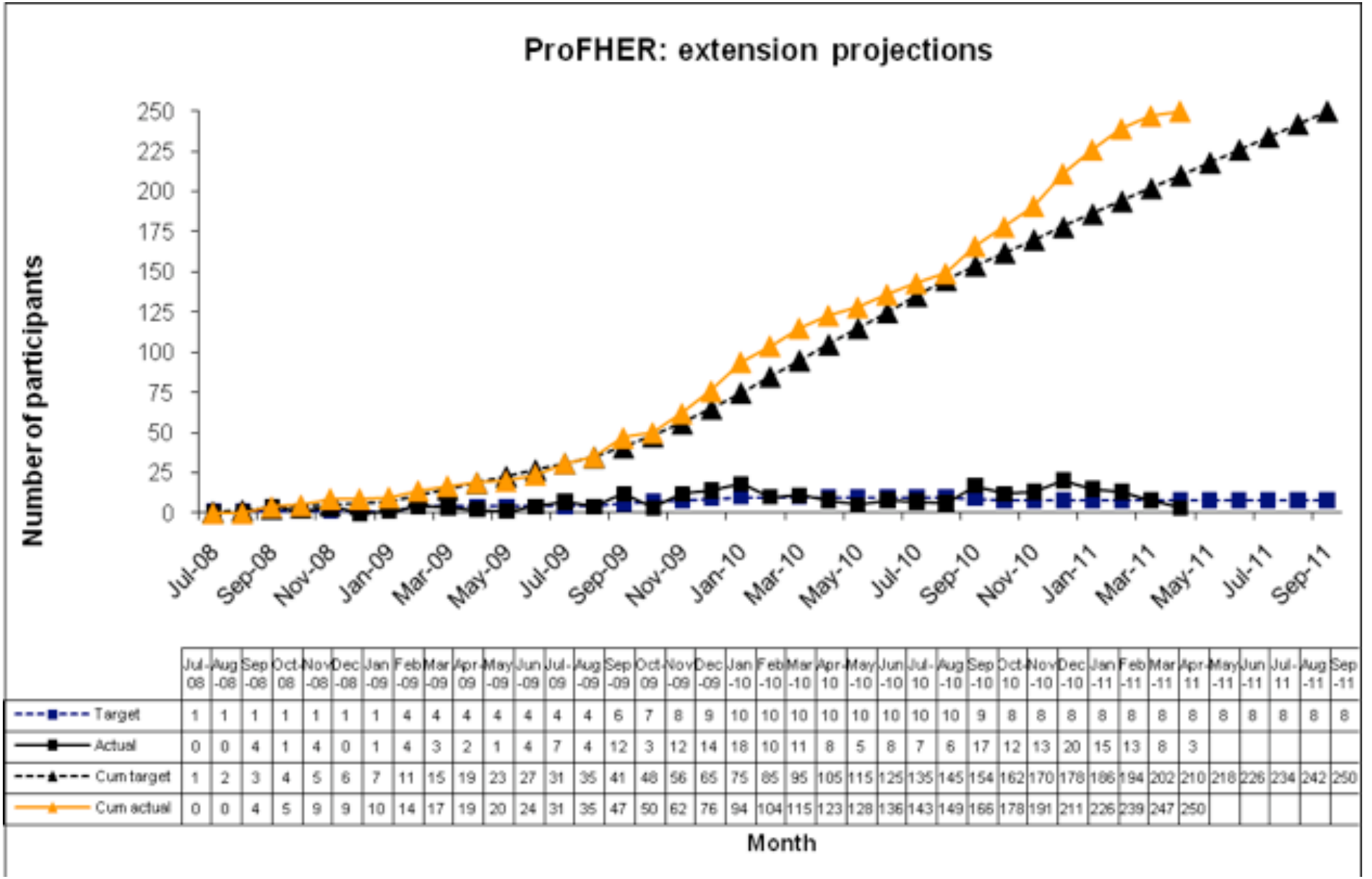
JAMA®
The Journal of the American Medical Association

Surgical vs Nonsurgical Treatment of Adults with Displaced Fractures of the Proximal Humerus

The PROFHER Randomized Clinical Trial

Amar Rangan, Helen Handoll, Stephen Brealey, Laura Jefferson, Ada Keding, Belen Corbacho Martin, Lorna Goodchild, Ling-Hsiang Chuang, Catherine Hewitt, David Torgerson,
for the PROFHER Trial Collaborators

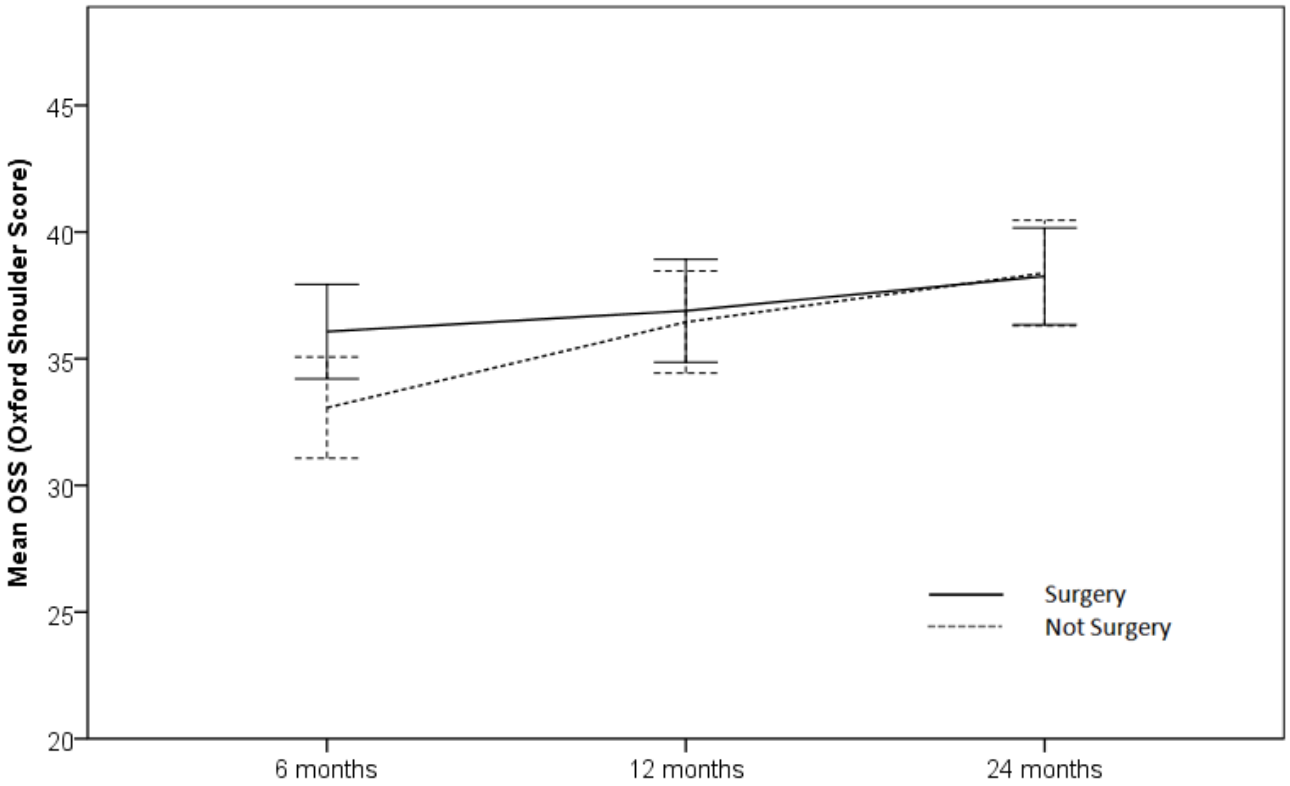
JAMA March 10, 2015 Volume 313, Number 10: pages 1037-1047



	Jul-08	Aug-08	Sep-08	Oct-08	Nov-08	Dec-08	Jan-09	Feb-09	Mar-09	Apr-09	May-09	Jun-09	Jul-09	Aug-09	Sep-09	Oct-09	Nov-09	Dec-09	Jan-10	Feb-10	Mar-10	Apr-10	May-10	Jun-10	Jul-10	Aug-10	Sep-10	Oct-10	Nov-10	Dec-10	Jan-11	Feb-11	Mar-11	Apr-11	May-11	Jun-11	Jul-11	Aug-11	Sep-11
Target	1	1	1	1	1	1	1	4	4	4	4	4	4	4	6	7	8	9	10	10	10	10	10	10	10	10	9	8	8	8	8	8	8	8	8	8	8	8	8
Actual	0	0	4	1	4	0	1	4	3	2	1	4	7	4	12	3	12	14	18	10	11	8	5	8	7	6	17	12	13	20	15	13	8	3					
Cum target	1	2	3	4	5	6	7	11	15	19	23	27	31	35	41	48	56	65	75	85	95	105	115	125	135	145	154	162	170	178	186	194	202	210	218	226	234	242	250
Cum actual	0	0	4	5	9	9	10	14	17	19	20	24	31	35	47	50	62	76	94	104	115	123	128	136	143	149	166	178	191	211	226	239	247	250					

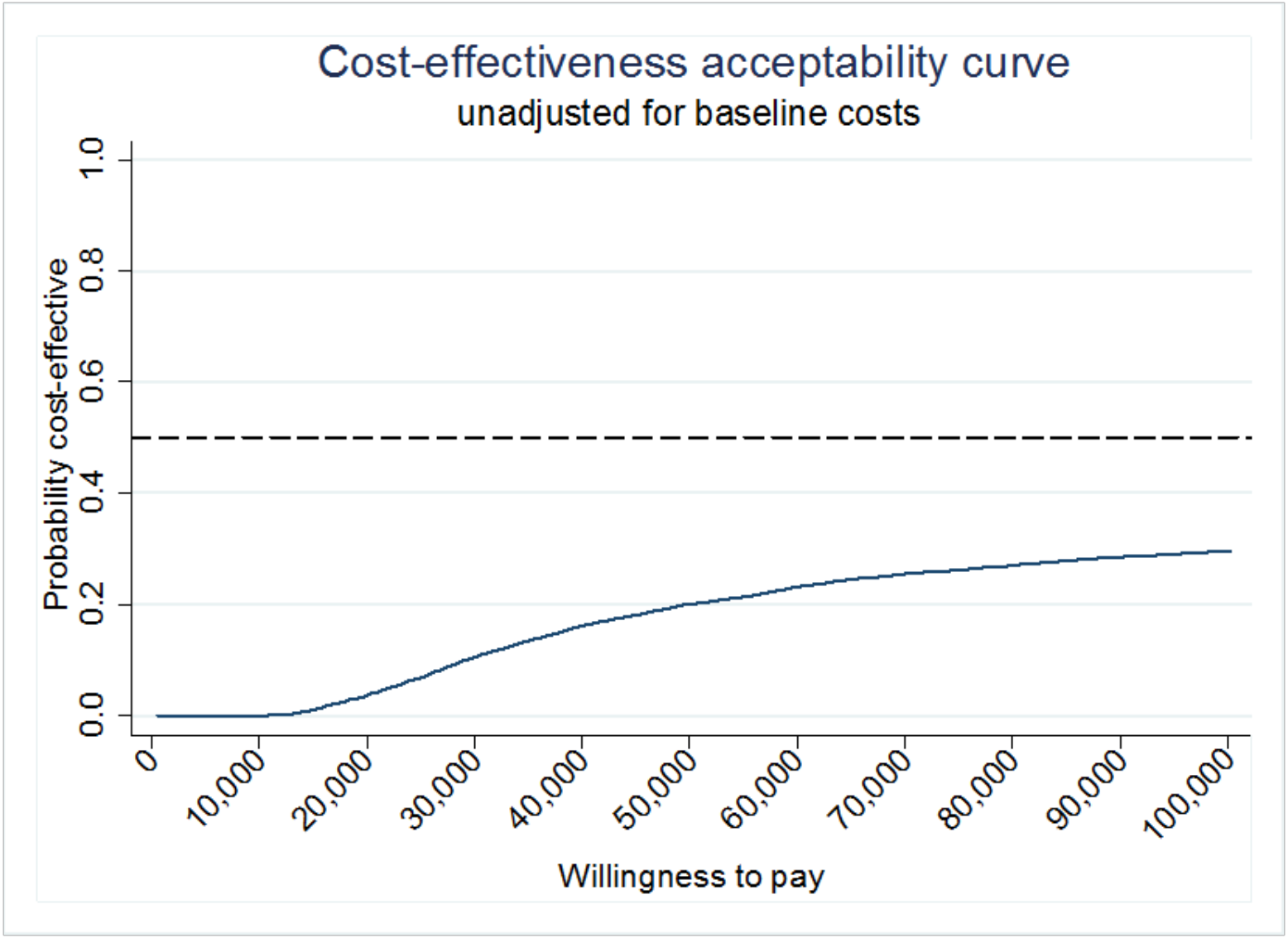
Primary outcome

There was no significant difference in the OSS over the two-year period: 0·75 points in favour of surgery, 95% CI -1·33 to 2·84; p = 0·479.



None reach the magnitude of the pre-specified difference of 5 OSS points judged to be of 'clinical significance'.

CEACs


Cost-effectiveness acceptability curve
unadjusted for baseline costs
Probability cost-effective
0.0
0.2
0.4
0.6
0.8
1.0
0
10,000
20,000
30,000
40,000
50,000
60,000
70,000
80,000
90,000
100,000
Willingness to pay

Impact

- NICE guidance on fracture management published Feb 2016:
  - Recommendations based on PROFHER Trial for proximal humeral fracture management
  - Recommendations based on DRAFFT for distal radial fracture fixation

Trainee Research Collaborative

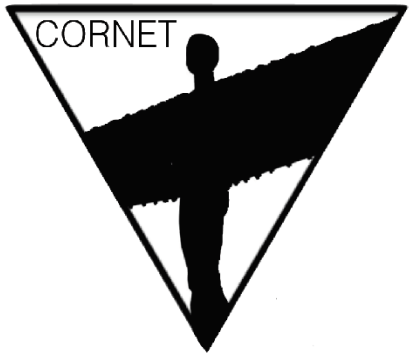
- Regional – CORNET
- National – BONE

- Vehicle to achieve CCT research requirements
  - Audit loops
  - Practical clinical research training
  - GCP
- Develop future PIs and CIs

How can a Trainee Research Network become effective?

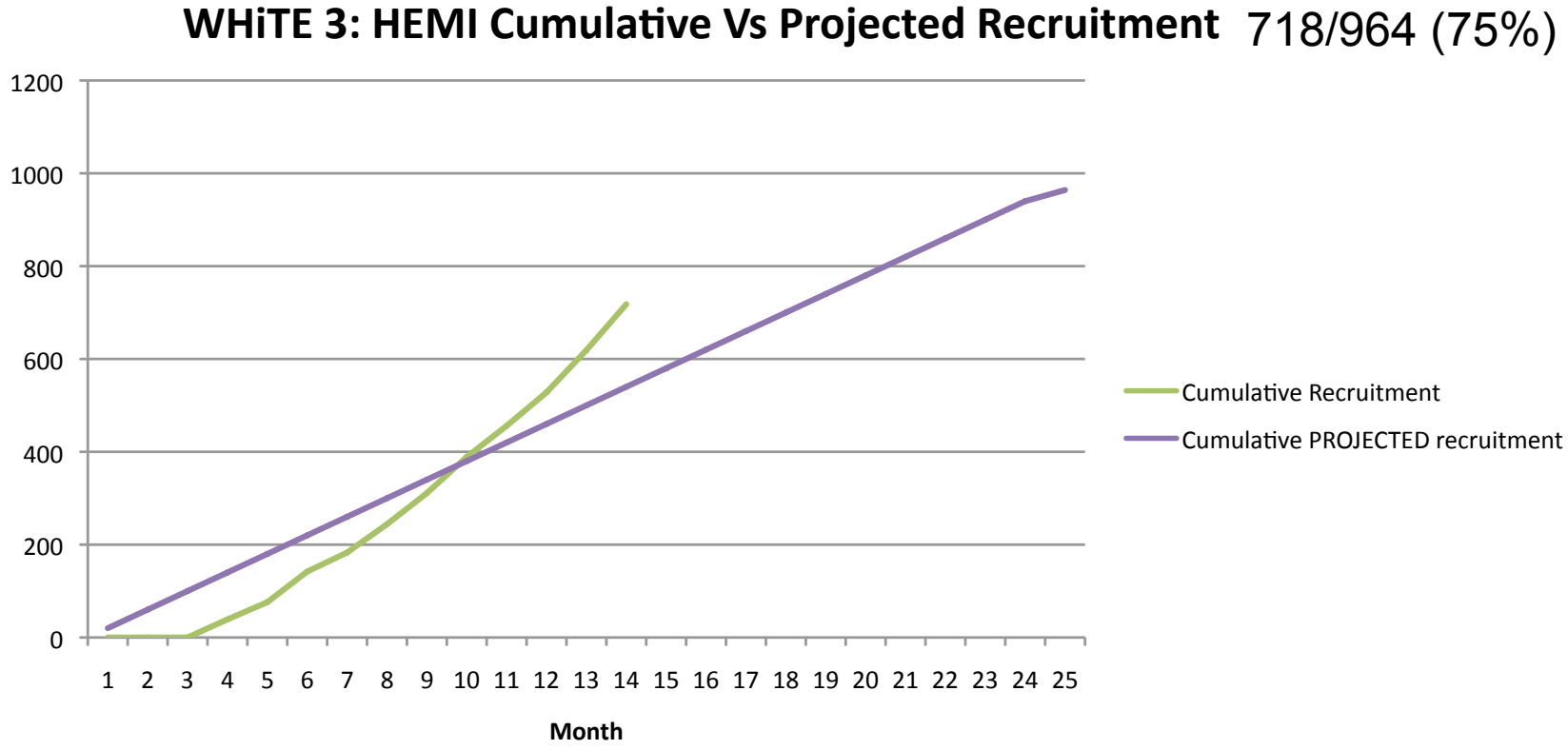
- Structure for managing activities
- Full trainee engagement
- Recruit effectively to on going trials
- Engage with RDS & CTU
- Get involved in study development early

RCS Orthopaedic Trials Day



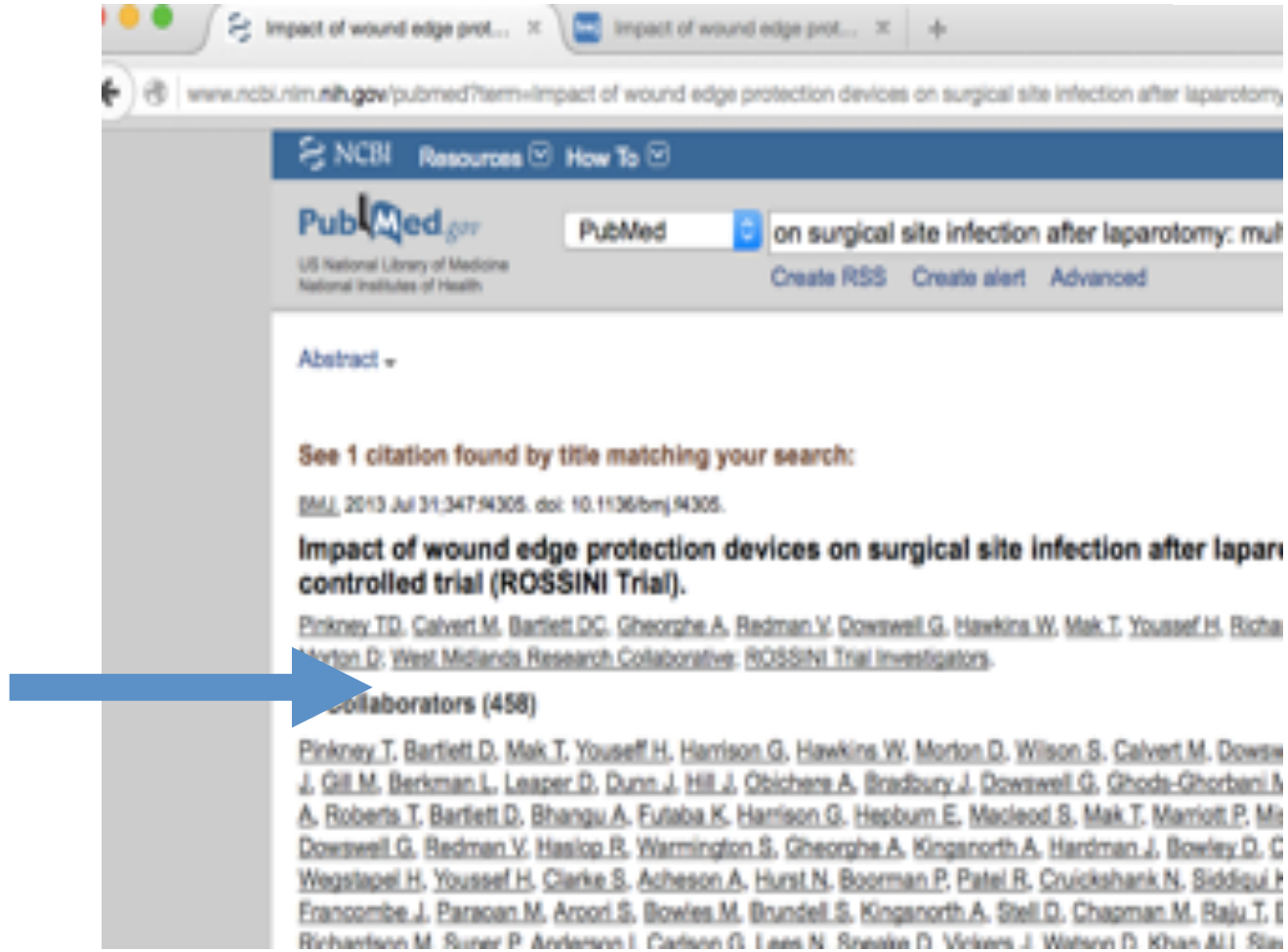
CORNET – The Collaborative Orthopaedic Research Network

WHiTE 3: HEMI (NIHR funded RCT with industry backing)



Publication Details

- Share the credit



Identify research priorities

- Hip & Knee OA
- Shoulder surgery
- Fragility fractures

James Lind Alliance

Priority Setting Partnerships

BMJ Open

Research priorities for shoulder surgery: results of the 2015 James Lind Alliance patient and clinician priority setting partnership

Amar Rangan,[1] Sheela Upadhaya,[2] Sandra Regan,[3] Francine Toye,[4] Jonathan L Rees[5]

Summary – T&O Research

- Growing number of multi-centre clinical trials
- Collaborate – Principal Investigators
- Lead – Chief Investigators

- BOSRC
- RCS STCs
- Collaboration NOT competition