INDICATE

Injection or Decompression in Carpal Tunnel Syndrome: A Feasibility Study

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BSSH
The British Society for Surgery of the Hand

SITU
SURGICAL INTERVENTION TRIALS UNIT

UNIVERSITY OF OXFORD

Gloucestershire Hospitals NHS
NHS Foundation Trust

AIMS

Aim of the proposed trial:

- To assess whether surgical decompression or a single steroid injection is the better treatment for patients with moderate carpal tunnel syndrome

Aims of the Feasibility trial:

- To assess the study design in terms of:
  - study protocol
  - methods of identification
  - recruitment and retention success
  - possibility of NCS in all participants

Patient Selection

Clinical diagnosis of CTS in adult:

- intermittent parasthesiae in median nerve distribution
- Nocturnal symptoms
- Positive provocation test

Moderate severity:

- > 3 months duration
- Failed 2 weeks of night splints
- Disturbed sleep or difficulty performing activities of daily living

Exclusion criteria:

- clinically severe CTS
- secondary CTS,
- previous injection
- other peripheral neuropathy
- concomitant hand disorder
- cognitive difficulties

Recruitment

- 5 sites for *identification*
  - Gloucestershire
    - Primary care – from databases of 20 GP practices
    - Secondary care – referrals to one hand surgeon
  - Canterbury – dedicated neurophysiology CTS service
  - Plymouth – referrals to two hand surgeons
  - Somerset - 2 physiotherapy interface services
- 40 patients recruited

Interventions & outcomes

Randomly allocated to either:

- Single steroid injection

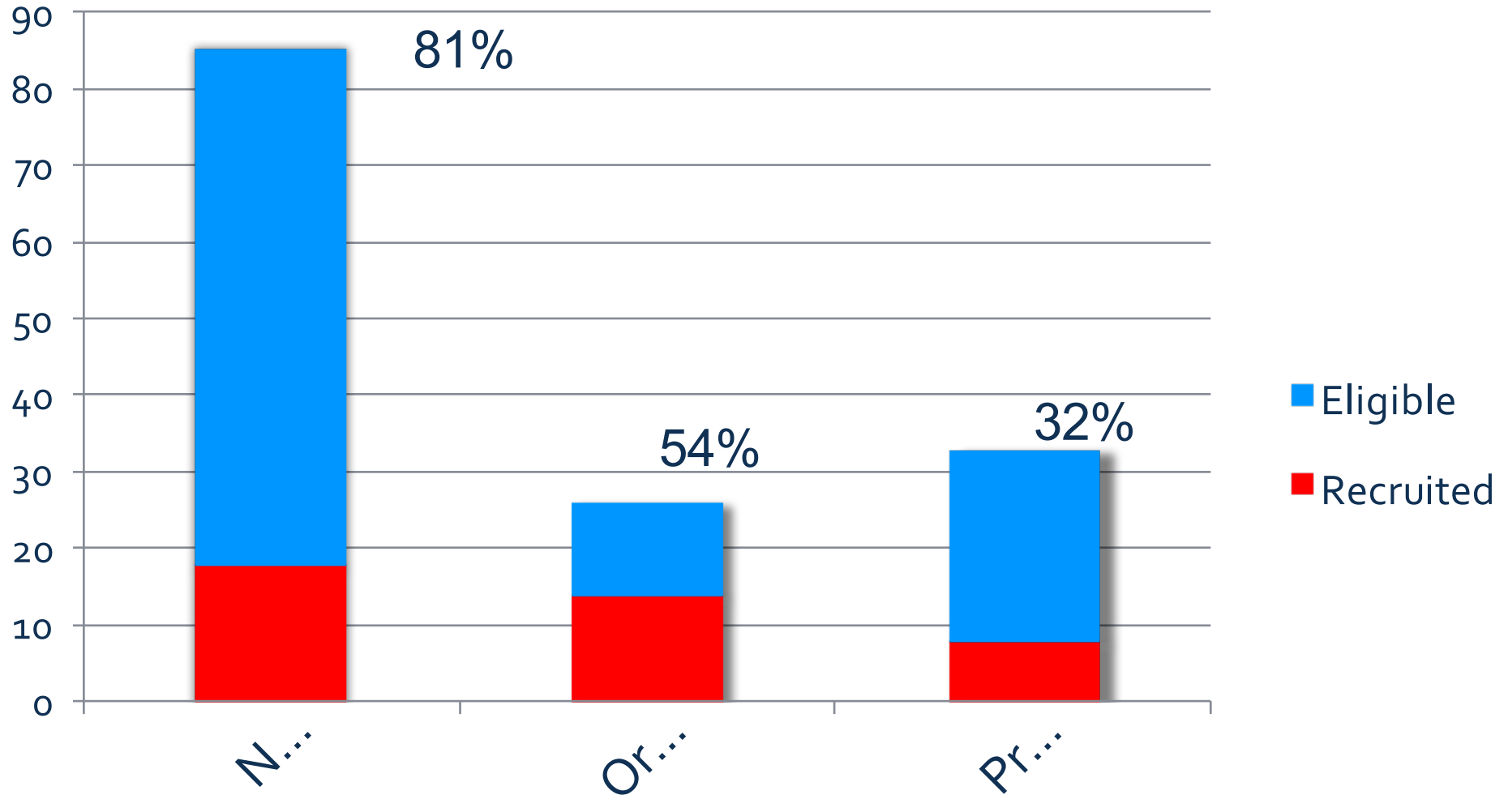
  or

- Carpal tunnel decompression (surgeon's usual technique)

- Patients offered further treatment if symptoms persist/recur
- Postal follow up – 1, 3, 6 and 12 months
- **1° Outcome – Change in Symptom Severity Score at 1 year**

Recruitment
Total Rectuitment Target
Monthly Rectuitment Target
40
35
30
25
20
15
10
5
0
8
7
6
5
4
3
2
1
0
November 2015
December 2015
January 2016
February 2016
March 2016
April 2016
May 2016
June 2016
July 2016
August 2016
Recruitment Period in Months
Monthly Total Target
Monthly Recruitment
Monthly Total Target
Total Recruitment

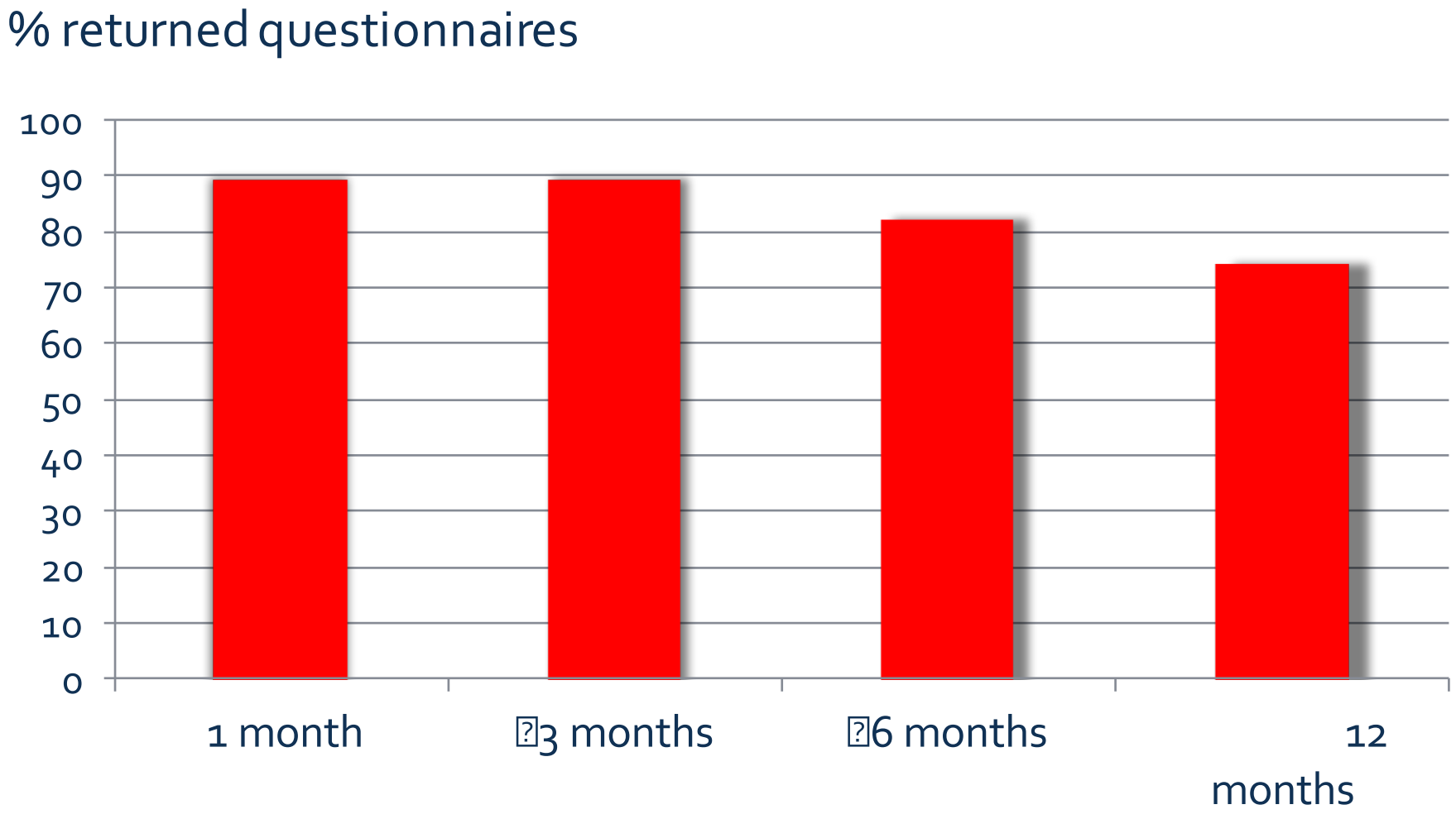
Recruitment



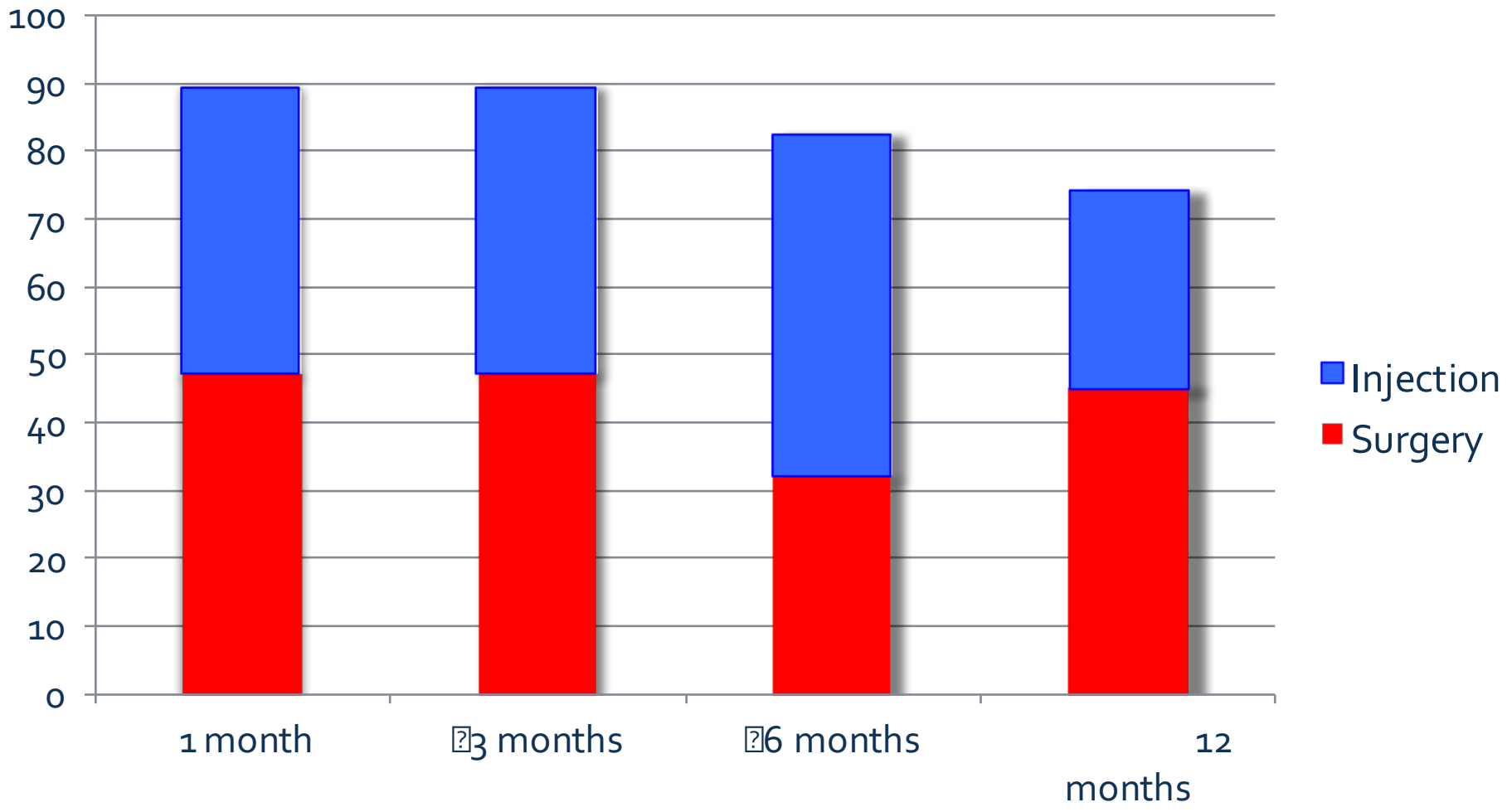
Change of status

- 2 patients changed treatment allocation after recruitment:
  - 1 randomised for surgery but declined and had injection
  - 1 randomised to surgery but symptoms improved before operation - had no treatment
- N = 38

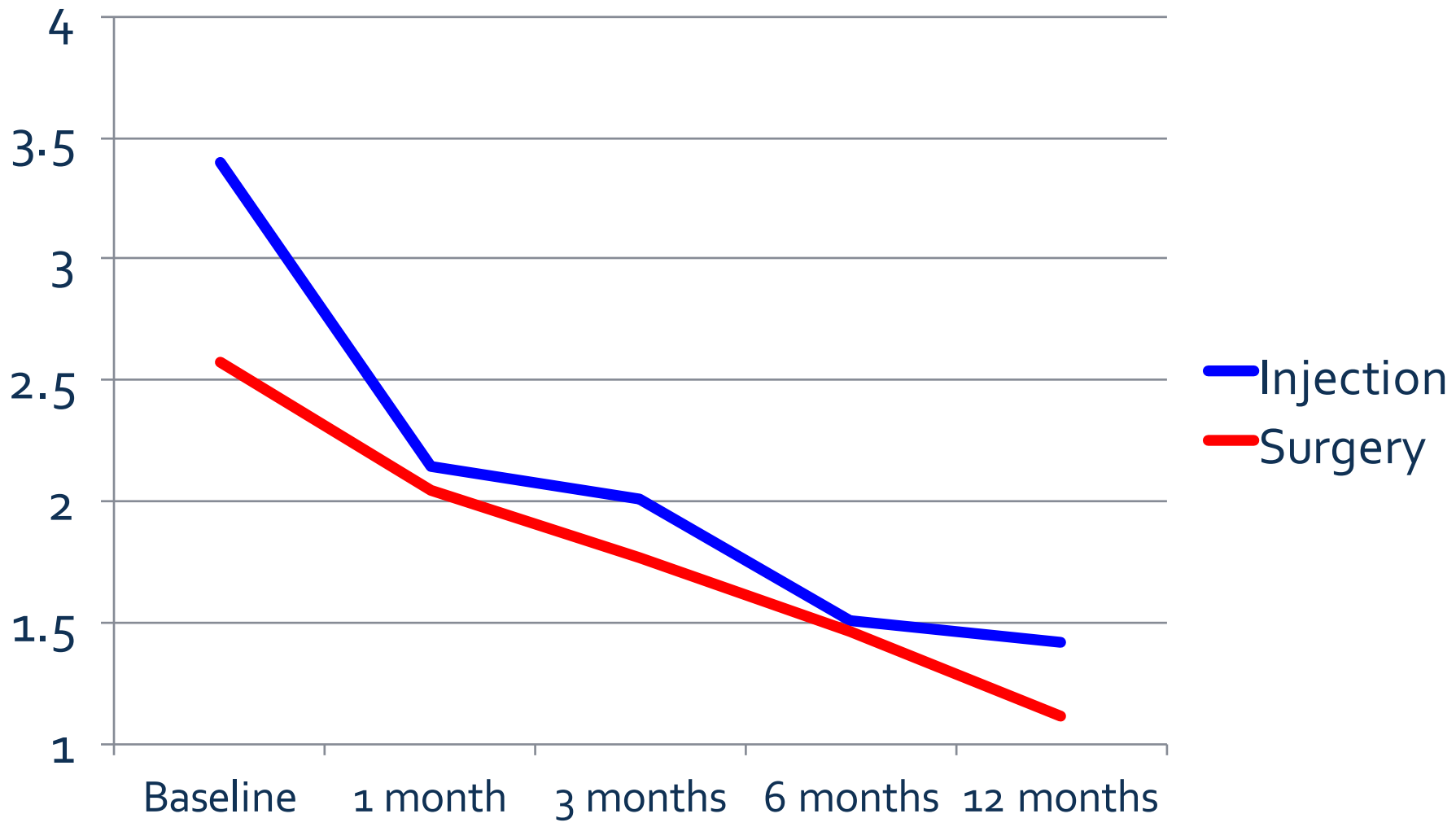
Participant retention



Participant retention

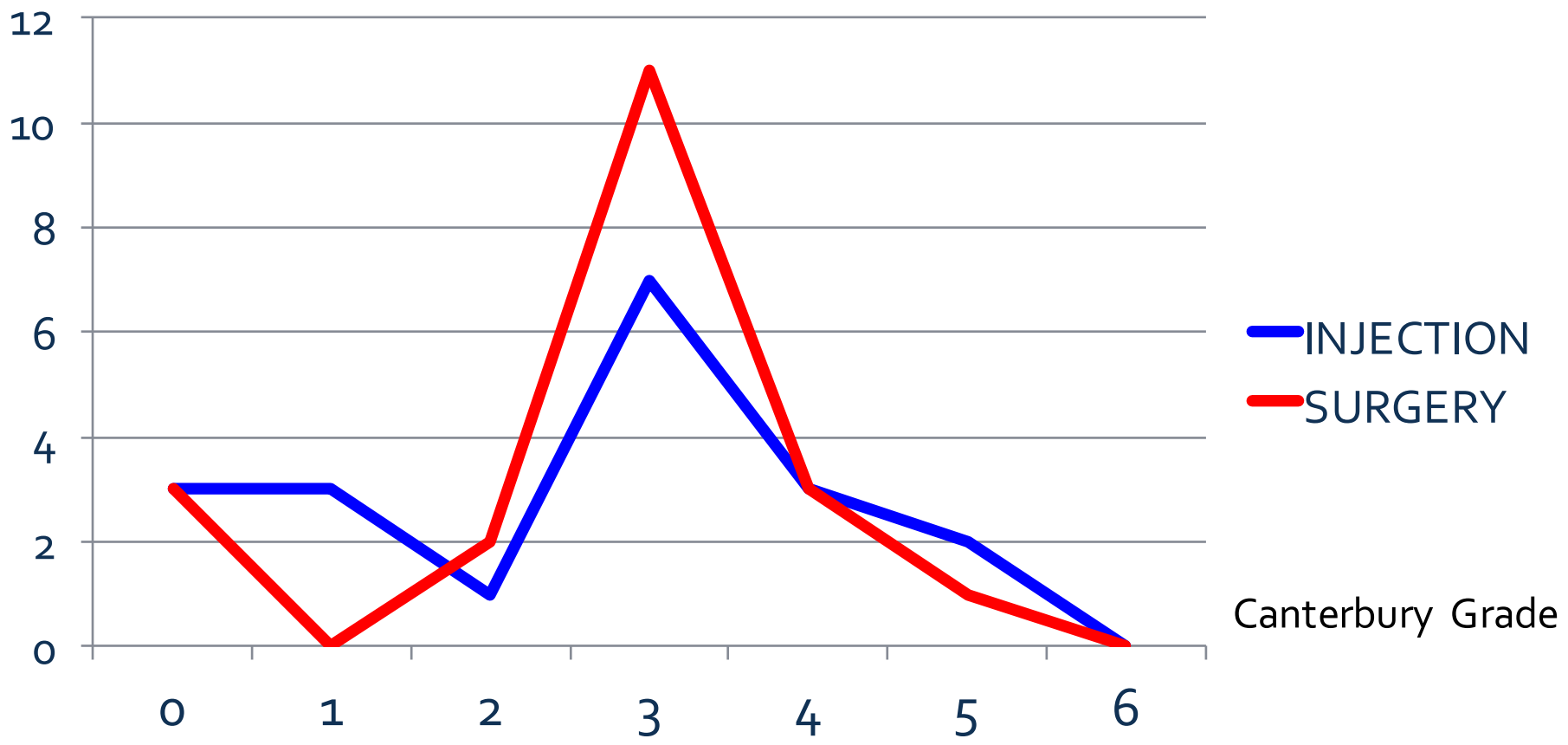


Primary Outcome - Symptom Severity Score



Nerve Conduction Studies

- 39 patients underwent NCS



Expected Adverse Events

- Infection (CDC definition of superficial incisional SSI)
- Nerve injury (permanently reduced sensibility or power)
- Vessel injury (sup palmar arch injury/haematoma drainage)
- CRPS (Budapest criteria)

- None reported

Additional Treatment

- Surgical group:
  - 1 patient had early recurrence of symptoms and required revision CTR 1 year later (also ulnar nerve release)
- Injection group:
  - 8/21 patients required surgery within 1 year of injection
  - 1 patient had no change in symptoms and was dissatisfied

  (received 2nd injection, also no effect. Normal NCS)

Conclusions

- Recruitment of patients with moderate primary CTS with no previous injection is possible
- Identification through primary care does work, but requires more effort and expense
- Retention is adequate - 74% at 1 year
- NCS no problem in these 2 sites

The Future

- A trial is possible – current trial protocol is functional
- Careful site selection is required. Increasingly difficult with CCG stance towards surgery – aim for 20 nationwide
- Retention could be improved
  - by omitting 1 and 3 month follow up
  - by offering online
- Similar trial submitted for NIHR funding – awaiting decision.

Acknowledgements

- Will Mason – Chief Investigator
- Jeremy Bland – Principle Investigator
- James Berwin, Danny Ryan, Asif Khan, Hui-Ling Kerr
  Specialist Trainees T&O, Severn Deanery
- David Beard, Jonathan Cook, Ines Rombach, Cushla Cooper, Rachel Dorman
  Surgical Intervention Trials Unit, NDORMS, Oxford

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