Objectives: Randomised controlled trials involving interventions in an emergency setting are notoriously difficult. Successful recruitment and retention of participants into research studies is critical for optimising internal and external validity. Balancing service pressures and the administrative burden necessary for robust trial methodology creates challenges that must be reconciled to maintain recruitment targets.

Methods: The CoNNECT study is a randomised controlled interventional trial with three arms evaluating the role of tension in a digital nerve repair model (Figure 1). The study centre is a tertiary referral hand trauma service with approximately 600 new attendances resulting in approximately 350 hand trauma cases each month. Recruitment is through a 2-stage eligibility screening process with final confirmation of eligibility after surgical exploration of the wound. At this stage the nerve to be repaired is randomised with stratification for age. Repair is then completed with microsurgical suture, Neurolac protection of a suture repair or with a Neurolac-assisted tension free co-aptation with remote sutures. The complexity of the trial design requires co-ordination between several different clinical areas and co-operation between junior medical staff, hand co-ordinators and research nurses. Interim recruitment audit in the early phase of the trial identified missed recruitment opportunities. This has been achieved through continuing audit trail of all screened and recruited patients into the CoNNECT trial, in order to identify any issues or difficulties in recruitment of patients. A bespoke electronic patient record for hand trauma has been re-engineered to provide automated prompts during initial assessment of all patients with potential nerve injuries (Figure 2). Intra-operatively, surgeons will be provided with a poster to aid in the data collection for the purposes of the trial (Figure 3).

Results: The E-hand system was designed at the Birmingham Hand Centre for the assessment and management of hand injuries. Referral, assessment, surgery and therapy data is compiled in a single system that generates workload data for co-ordination of the patient pathway. Activity reports provide accurate data on trial recruitment and missed potential trial patients. Redesign of the assessment tool to create an automated alert regarding trial eligibility and confirmation of inclusion criteria has resulted in optimisation of trial recruitment. Patients can be provided with trial information that they can review in advance of a planned day surgery admission for surgery and the research team are alerted to the date and time of attendance for surgery.

Conclusion: Randomised controlled trials in trauma surgery are complex and there are challenges created by the short time available between presentation and surgery. Rotating junior staff are the first point of contact for new trauma patients and clinical pressures may limit trial recruitment. Redesign of the E-hands management system has ensured trial recruitment is optimised and that there is compliance with Good Clinical Practice guidelines.

References: