

V10

The role of surgical trainees in recruiting to multicentre RCTs: an example from the Sunflower Study

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Background: The Sunflower Study aims to compare the effectiveness of expectant management and MRCP prior to laparoscopic cholecystectomy (LC) in patients at low or moderate risk of common bile duct stones. This is the largest surgical randomised controlled trial (RCT) in the UK and a secondary aim is to describe trainees' contributions.

Methods: Participants are randomised to receive expectant management or MRCP in a 2:1 ratio. Over 13,500 patients from more than 50 UK

hospitals are required over five years. Trainees' contributions are documented as follows: total number signed up to the study; number enrolled in the NIHR associate PI scheme; and the number of patients approached and recruited. The proportion of 'emergency' and 'elective' patients recruited was also recorded.

Results: Sunflower has been open since February 2019 and 48 centres are currently participating. A total of 104 trainees have been actively involved and 34 are/have been enrolled in the associate PI scheme. To date, 3992 patients have been screened, by trainees ($n = 719, 18\%$), consultants ($n = 439, 11\%$) and research nurses ($n = 2214, 71\%$). 1996 patients have been recruited, 359(18%) of which by trainees, 319(16%) consultants and 1318(66%) research nurses. Of the recruited patients, 423 (21%) presented as emergencies, recruited by trainees ($n = 169, 40\%$), consultants ($n = 59, 14\%$) and research nurses ($n = 195, 46\%$).

Conclusions: Trainees have an important role to play in recruiting patients to multicentre surgical RCTs, in particular in emergency settings, which can help improve studies' generalisability. The associate PI scheme seems to provide an extra incentive for trainees to be involved in an RCT.