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SABRTooth: a randomised controlled feasibility study of stereotactic ablative radiotherapy (SABR) with surgery in patients with peripheral stage I nonsmall cell lung cancer considered to be at higher risk of complications from surgical resection

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Despite recruiting at a higher rate than previous studies, SABRTooth showed that a large UK RCT was not feasible. Patients found it challenging to accept randomisation between surgery and SABR due to their preferences. Alternative study designs are needed. https://bit.ly/2XtlVo6

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ABSTRACT
Objectives: Stereotactic ablative radiotherapy (SABR) is a well-established treatment for medically inoperable peripheral stage I nonsmall cell lung cancer (NSCLC). Previous nonrandomised evidence supports SABR as an alternative to surgery, but high-quality randomised controlled trial (RCT) evidence is lacking. The SABRTooth study aimed to establish whether a UK phase III RCT was feasible.
Design and methods: SABRTooth was a UK multicentre randomised controlled feasibility study targeting patients with peripheral stage I NSCLC considered to be at higher risk of surgical complications. 54

patients were planned to be randomised 1:1 to SABR or surgery. The primary outcome was monthly average recruitment rates.

Results: Between July 2015 and January 2017, 318 patients were considered for the study and 205 (64.5%) were deemed ineligible. Out of 106 (33.3%) assessed as eligible, 24 (22.6%) patients were randomised to SABR (n=14) or surgery (n=10). A key theme for nonparticipation was treatment preference, with 43 (41%) preferring nonsurgical treatment and 19 (18%) preferring surgery. The average monthly recruitment rate was 1.7 patients against a target of three. 15 patients underwent their allocated treatment: SABR n=12, surgery n=3.

Conclusions: We conclude that a phase III RCT randomising higher risk patients between SABR and surgery is not feasible in the National Health Service. Patients have pre-existing treatment preferences, which was a barrier to recruitment. A significant proportion of patients randomised to the surgical group declined and chose SABR. SABR remains an alternative to surgery and novel study approaches are needed to define which patients benefit from a nonsurgical approach.